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**TURKEY – CERTAIN MEASURES CONCERNING THE PRODUCTION,
IMPORTATION AND MARKETING OF PHARMACEUTICAL PRODUCTS**

**NOTIFICATION OF AN APPEAL BY TURKEY UNDER ARTICLE 25 OF THE UNDERSTANDING ON
RULES AND PROCEDURES GOVERNING THE SETTLEMENT OF DISPUTES (DSU),
UNDER PARAGRAPH 5 OF THE AGREED PROCEDURES FOR ARBITRATION
UNDER ARTICLE 25 OF THE DSU (ARBITRATION AGREEMENT),
AND UNDER RULE 20 OF THE WORKING PROCEDURES FOR APPELLATE REVIEW**

The following communication, dated 25 April 2022, from the delegation of Turkey, is being circulated to Members.

Notification of an Appeal by Turkey under Article 25 of the Understanding on Rules and Procedures Governing the Settlement of Disputes ("DSU"), under paragraph 5 of the Agreed Procedures for Arbitration under Article 25 of the DSU ("Arbitration Agreement"),¹ and under Rule 20 of the Working Procedures for Appellate Review²

Pursuant to paragraph 5 of the Arbitration Agreement, Turkey hereby notifies the Dispute Settlement Body of its decision to initiate an arbitration under Article 25 of the DSU to decide an appeal with regard to certain issues of law and legal interpretation covered in the Panel Report in the dispute *Turkey – Certain Measures concerning the Production, Importation and Marketing of Pharmaceutical Products*.

Pursuant to paragraph 5 of the Arbitration Agreement and Rule 20 of the Working Procedures for Appellate Review, Turkey simultaneously files this Notice of Appeal and its Appellant Submission with the European Union and the third parties in the panel proceedings and with the WTO Secretariat. The Notice of Appeal includes the final report of the Panel in the working languages of the WTO.

For the reasons further elaborated in its Appellant Submission to the Arbitrators, Turkey appeals and requests the Arbitrators to reverse the findings, conclusions and recommendations of the Panel, with respect to the following errors of law and legal interpretation contained in the Panel Report:³

1. The Panel erred in the interpretation and application of Article III:8(a) of the GATT 1994 when finding that the localisation measure does not involve a "purchase" within the meaning of Article III:8(a), is thus not covered by the government procurement derogation and is therefore subject to the national treatment obligation in Article III:4 of the GATT 1994 and Article 2.1 of the TRIMs Agreement.⁴ In particular, the Panel erred in interpreting Article III:8(a) as requiring that the purchase of products procured for governmental

¹ WT/DS583/10.

² Rule 20 of the *Working Procedures for Appellate Review* applies pursuant to paragraph 11 of the *Arbitration Agreement*.

³ Pursuant to Rule 20(2)(d)(iii) of the *Working Procedures for Appellate Review*, which apply *mutatis mutandis* pursuant to paragraph 11 of the *Arbitration Agreement*, this Notice of Appeal includes an indicative list of the paragraphs of the Panel Report containing the alleged errors, without prejudice to the ability of Turkey to refer to other paragraphs of the Panel Report in the context of the arbitration proceedings.

⁴ Panel Report, paras. 7.104, 7.107 and 8.1(b)(ii).

purposes must be made by a governmental agency⁵ and in interpreting the term "purchased" as requiring the transfer of ownership from the seller to the entity purchasing the product concerned.⁶ Because of these interpretive errors, the Panel erred in its application of Article III:8(a) of the GATT 1994. First, the Panel erred in finding that Article III:8(a) does not apply because there is no purchase of medicines included in Annex 4/A by the Turkish Social Security Institution ("SSI"). Second, the Panel also erred in finding that there is no purchase by the SSI because the SSI does not acquire the ownership of medicines included in Annex 4/A. Furthermore, even if the Panel's interpretation of the term "products purchased" was found to be correct (*quod non*), the Panel erred in concluding that the SSI does not acquire the ownership of medicines included in Annex 4/A.⁷ The Panel also failed to consider that, alternatively, retail pharmacies that purchase medicines that are dispensed to patients covered by the public healthcare system act on behalf of the SSI and to that extent act as "governmental agencies", within the meaning of Article III:8(a).⁸ In light of the foregoing, Turkey requests the Arbitrators to reverse the relevant Panel's findings in paragraphs 7.61-7.107 and 8.1(b)(ii) of the Panel Report, including the Panel's conclusion that the localisation measure is not covered by the government procurement derogation in Article III:8(a) of the GATT 1994 and is therefore subject to the national treatment obligation in Article III:4 of the GATT 1994 and Article 2.1 of the TRIMs Agreement.

Turkey requests that consequently the Arbitrators find the Panel's conclusion that the localisation requirement is inconsistent with the national treatment obligation in Article III:4 of the GATT 1994 to be moot and of no legal effect.⁹ If not, Turkey requests the Arbitrators to complete the analysis under Article III:8(a) of the GATT 1994 and find that the localisation measure falls within the scope of the government procurement derogation provided by that provision. In that case, Turkey further requests the Arbitrators to reverse the Panel's findings that the localisation measure is inconsistent with Article III:4 of the GATT 1994 in paragraphs 7.121-7.127 and 8.1(b)(iii) of the Panel Report.

2. The Panel erred in the interpretation and application of Article XX(b) of the GATT 1994 when finding that the localisation measure is not "designed to" protect human, animal, or plant life or health.¹⁰ The Panel erred in defining the legal standard applicable for determining the design of the measure by requiring that a measure must address a health risk that has "a substantial degree of probability" of materialising for the measure to be "designed to" protect human, animal, or plant life or health".¹¹ The Panel also erred by confusing the "design" and "necessity" steps of the legal test under subparagraph (b), and by relying on the legal tests under subparagraphs (a) and (j) of Article XX of the GATT 1994 and Article XIV(a) of the GATS, as interpreted by previous panels.¹² The Panel also erred in applying Article XX(b) of the GATT 1994 by concluding that the evidence submitted by Turkey does not indicate that the localisation measure is "designed to" protect human life or health.¹³ In addition, the Panel failed to make an objective assessment of the matter before it pursuant to Article 11 of the DSU when addressing Turkey's claim that the localisation measure is justified under Article XX(b) of the GATT 1994. The Panel wilfully disregarded part of the evidence and failed to make a holistic assessment of the evidence presented by Turkey.¹⁴ These errors were material and affected the Panel's finding that the localisation measure is not "designed to" protect human life or health and therefore not justified under Article XX(b) of the GATT 1994. Thus, Turkey requests the Arbitrators to reverse the Panel's findings in paragraphs 7.157-7.214, 7.219 and 8.1(b)(iv) of the Panel Report and requests the Arbitrators to complete the legal analysis and to find that the localisation measure is justified under Article XX(b) of the GATT 1994.

⁵ Panel Report, para. 7.65.

⁶ Panel Report, paras. 7.74 and 7.81.

⁷ Panel Report, paras. 7.85-7.88 and 7.90.

⁸ Panel Report, paras. 7.98 and 7.103.

⁹ Panel Report, paras. 7.121-7.127 and 8.1(b)(iii).

¹⁰ Panel Report, paras. 7.211, 7.219 and 8.1(b)(iv).

¹¹ Panel Report, para. 7.171.

¹² Panel Report, paras. 7.167-7.170.

¹³ See, for example, Panel Report, paras. 7.173, 7.180, 7.199, 7.207, 7.210.

¹⁴ See, for example, Panel Report, paras. 7.186-7.200 and 7.210.

3. The Panel erred in the interpretation and application of Article XX(d) of the GATT 1994 when finding that the localisation measure is not taken to secure compliance with laws requiring Turkey to ensure accessible, effective and financially sustainable healthcare.¹⁵ By considering that its analysis of Turkey's defence under Article XX(b) of the GATT 1994 applies *mutatis mutandis* to the analysis of Turkey's defence under Article XX(d), the Panel applied the wrong legal standard and erroneously rejected Turkey's defence under Article XX(d) of the GATT 1994. Thus, Turkey requests the Arbitrators to reverse the Panel's findings under Article XX(d) of the GATT 1994 set out in paragraphs 7.217-7.219 and 8.1(b)(iv) of the Panel Report. If the Arbitrators reverse the Panel's findings under Article XX(d) of the GATT 1994, Turkey requests the Arbitrators to complete the analysis and find that the localisation measure is justified under that provision.

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¹⁵ Panel Report, para. 7.218.

**TURKEY – CERTAIN MEASURES CONCERNING THE PRODUCTION,
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CASES CITED IN THIS REPORT

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<i>Argentina – Financial Services</i>	Appellate Body Report, <i>Argentina – Measures Relating to Trade in Goods and Services</i> , WT/DS453/AB/R and Add.1, adopted 9 May 2016, DSR 2016:II, p. 431
<i>Argentina – Import Measures</i>	Appellate Body Reports, <i>Argentina – Measures Affecting the Importation of Goods</i> , WT/DS438/AB/R / WT/DS444/AB/R / WT/DS445/AB/R , adopted 26 January 2015, DSR 2015:II, p. 579
<i>Argentina – Textiles and Apparel</i>	Appellate Body Report, <i>Argentina – Measures Affecting Imports of Footwear, Textiles, Apparel and Other Items</i> , WT/DS56/AB/R and Corr.1, adopted 22 April 1998, DSR 1998:III, p. 1003
<i>Brazil – Retreaded Tyres</i>	Appellate Body Report, <i>Brazil – Measures Affecting Imports of Retreaded Tyres</i> , WT/DS332/AB/R , adopted 17 December 2007, DSR 2007:IV, p. 1527
<i>Brazil – Retreaded Tyres</i>	Panel Report, <i>Brazil – Measures Affecting Imports of Retreaded Tyres</i> , WT/DS332/R , adopted 17 December 2007, as modified by Appellate Body Report WT/DS332/AB/R, DSR 2007:V, p. 1649
<i>Canada – Aircraft</i>	Panel Report, <i>Canada – Measures Affecting the Export of Civilian Aircraft</i> , WT/DS70/R , adopted 20 August 1999, upheld by Appellate Body Report WT/DS70/AB/R, DSR 1999:IV, p. 1443
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<i>Canada – Renewable Energy / Canada – Feed-in Tariff Program</i>	Panel Reports, <i>Canada – Certain Measures Affecting the Renewable Energy Generation Sector / Canada – Measures Relating to the Feed-in Tariff Program</i> , WT/DS412/R and Add.1 / WT/DS426/R and Add.1, adopted 24 May 2013, as modified by Appellate Body Reports WT/DS412/AB/R / WT/DS426/AB/R, DSR 2013:I, p. 237
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<i>China – Auto Parts</i>	Appellate Body Reports, <i>China – Measures Affecting Imports of Automobile Parts</i> , WT/DS339/AB/R / WT/DS340/AB/R / WT/DS342/AB/R , adopted 12 January 2009, DSR 2009:I, p. 3
<i>China – Auto Parts</i>	Panel Reports, <i>China – Measures Affecting Imports of Automobile Parts</i> , WT/DS339/R , Add.1 and Add.2 / WT/DS340/R , Add.1 and Add.2 / WT/DS342/R , Add.1 and Add.2, adopted 12 January 2009, upheld (WT/DS339/R) and as modified (WT/DS340/R / WT/DS342/R) by Appellate Body Reports WT/DS339/AB/R / WT/DS340/AB/R / WT/DS342/AB/R, DSR 2009:I, p. 119
<i>China – Publications and Audiovisual Products</i>	Appellate Body Report, <i>China – Measures Affecting Trading Rights and Distribution Services for Certain Publications and Audiovisual Entertainment Products</i> , WT/DS363/AB/R , adopted 19 January 2010, DSR 2010:I, p. 3
<i>China – Publications and Audiovisual Products</i>	Panel Report, <i>China – Measures Affecting Trading Rights and Distribution Services for Certain Publications and Audiovisual Entertainment Products</i> , WT/DS363/R and Corr.1, adopted 19 January 2010, as modified by Appellate Body Report WT/DS363/AB/R, DSR 2010:II, p. 261
<i>China – Rare Earths</i>	Panel Reports, <i>China – Measures Related to the Exportation of Rare Earths, Tungsten, and Molybdenum</i> , WT/DS431/R and Add.1 / WT/DS432/R and Add.1 / WT/DS433/R and Add.1, adopted 29 August 2014, upheld by Appellate Body Reports WT/DS431/AB/R / WT/DS432/AB/R / WT/DS433/AB/R, DSR 2014:IV, p. 1127

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<i>Colombia – Ports of Entry</i>	Panel Report, <i>Colombia – Indicative Prices and Restrictions on Ports of Entry</i> , WT/DS366/R and Corr.1, adopted 20 May 2009, DSR 2009:VI, p. 2535
<i>Colombia – Textiles</i>	Appellate Body Report, <i>Colombia – Measures Relating to the Importation of Textiles, Apparel and Footwear</i> , WT/DS461/AB/R and Add.1, adopted 22 June 2016, DSR 2016:III, p. 1131
<i>Colombia – Textiles</i>	Panel Report, <i>Colombia – Measures Relating to the Importation of Textiles, Apparel and Footwear</i> , WT/DS461/R and Add.1, adopted 22 June 2016, as modified by Appellate Body Report WT/DS461/AB/R, DSR 2016:III, p. 1227
<i>Dominican Republic – Import and Sale of Cigarettes</i>	Panel Report, <i>Dominican Republic – Measures Affecting the Importation and Internal Sale of Cigarettes</i> , WT/DS302/R , adopted 19 May 2005, as modified by Appellate Body Report WT/DS302/AB/R, DSR 2005:XV, p. 7425
<i>EC – Asbestos</i>	Appellate Body Report, <i>European Communities – Measures Affecting Asbestos and Asbestos-Containing Products</i> , WT/DS135/AB/R , adopted 5 April 2001, DSR 2001:VII, p. 3243
<i>EC – Asbestos</i>	Panel Report, <i>European Communities – Measures Affecting Asbestos and Asbestos-Containing Products</i> , WT/DS135/R and Add.1, adopted 5 April 2001, as modified by Appellate Body Report WT/DS135/AB/R, DSR 2001:VIII, p. 3305
<i>EC – Bananas III</i>	Appellate Body Report, <i>European Communities – Regime for the Importation, Sale and Distribution of Bananas</i> , WT/DS27/AB/R , adopted 25 September 1997, DSR 1997:II, p. 591
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<i>EC – Poultry</i>	Appellate Body Report, <i>European Communities – Measures Affecting the Importation of Certain Poultry Products</i> , WT/DS69/AB/R , adopted 23 July 1998, DSR 1998:V, p. 2031
<i>EC – Seal Products</i>	Appellate Body Reports, <i>European Communities – Measures Prohibiting the Importation and Marketing of Seal Products</i> , WT/DS400/AB/R / WT/DS401/AB/R , adopted 18 June 2014, DSR 2014:I, p. 7
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<i>EC – Tariff Preferences</i>	Panel Report, <i>European Communities – Conditions for the Granting of Tariff Preferences to Developing Countries</i> , WT/DS246/R , adopted 20 April 2004, as modified by Appellate Body Report WT/DS246/AB/R, DSR 2004:III, p. 1009
<i>EC and certain member States – Large Civil Aircraft</i>	Appellate Body Report, <i>European Communities and Certain Member States – Measures Affecting Trade in Large Civil Aircraft</i> , WT/DS316/AB/R , adopted 1 June 2011, DSR 2011:I, p. 7
<i>EU – Biodiesel (Argentina)</i>	Appellate Body Report, <i>European Union – Anti-Dumping Measures on Biodiesel from Argentina</i> , WT/DS473/AB/R and Add.1, adopted 26 October 2016, DSR 2016:VI, p. 2871

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<i>EU – Energy Package</i>	Panel Report, <i>European Union and its member States – Certain Measures Relating to the Energy Sector</i> , WT/DS476/R and Add.1, circulated to WTO Members 10 August 2018 [appeal/adoption pending]
<i>Guatemala – Cement I</i>	Appellate Body Report, <i>Guatemala – Anti-Dumping Investigation Regarding Portland Cement from Mexico</i> , WT/DS60/AB/R , adopted 25 November 1998, DSR 1998:IX, p. 3767
<i>India – Solar Cells</i>	Panel Report, <i>India – Certain Measures Relating to Solar Cells and Solar Modules</i> , WT/DS456/R and Add.1, adopted 14 October 2016, as modified by Appellate Body Report WT/DS456/AB/R , DSR 2016:IV, p. 1941
<i>Indonesia – Autos</i>	Panel Report, <i>Indonesia – Certain Measures Affecting the Automobile Industry</i> , WT/DS54/R , WT/DS55/R , WT/DS59/R , WT/DS64/R , Corr.1 and Corr.2, adopted 23 July 1998, and Corr.3 and Corr.4, DSR 1998:VI, p. 2201
<i>Indonesia – Chicken</i>	Panel Report, <i>Indonesia – Measures Concerning the Importation of Chicken Meat and Chicken Products</i> , WT/DS484/R and Add.1, adopted 22 November 2017, DSR 2017:VIII, p. 3769
<i>Indonesia – Chicken (Article 21.5 – Brazil)</i>	Panel Report, <i>Indonesia – Measures Concerning the Importation of Chicken Meat and Chicken Products – Recourse to Article 21.5 of the DSU by Brazil</i> , WT/DS484/RW and Add.1, circulated to WTO Members 10 November 2020 [adoption/appeal pending]
<i>Indonesia – Import Licensing Regimes</i>	Panel Report, <i>Indonesia – Importation of Horticultural Products, Animals and Animal Products</i> , WT/DS477/R , WT/DS478/R , Add.1 and Corr.1, adopted 22 November 2017, as modified by Appellate Body Report WT/DS477/AB/R , WT/DS478/AB/R , DSR 2017:VII, p. 3131
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<i>Korea – Various Measures on Beef</i>	Appellate Body Report, <i>Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef</i> , WT/DS161/AB/R , WT/DS169/AB/R , adopted 10 January 2001, DSR 2001:I, p. 5
<i>Mexico – Taxes on Soft Drinks</i>	Appellate Body Report, <i>Mexico – Tax Measures on Soft Drinks and Other Beverages</i> , WT/DS308/AB/R , adopted 24 March 2006, DSR 2006:I, p. 3
<i>Peru – Agricultural Products</i>	Panel Report, <i>Peru – Additional Duty on Imports of Certain Agricultural Products</i> , WT/DS457/R and Add.1, adopted 31 July 2015, as modified by Appellate Body Report WT/DS457/AB/R , DSR 2015:VII, p. 3567
<i>Russia – Railway Equipment</i>	Appellate Body Report, <i>Russia – Measures Affecting the Importation of Railway Equipment and Parts Thereof</i> , WT/DS499/AB/R and Add.1, adopted 5 March 2020
<i>Russia – Traffic in Transit</i>	Panel Report, <i>Russia – Measures Concerning Traffic in Transit</i> , WT/DS512/R and Add.1, adopted 26 April 2019
<i>Thailand – Cigarettes (Philippines)</i>	Appellate Body Report, <i>Thailand – Customs and Fiscal Measures on Cigarettes from the Philippines</i> , WT/DS371/AB/R , adopted 15 July 2011, DSR 2011:IV, p. 2203
<i>Turkey – Rice</i>	Panel Report, <i>Turkey – Measures Affecting the Importation of Rice</i> , WT/DS334/R , adopted 22 October 2007, DSR 2007:VI, p. 2151
<i>US – Anti-Dumping Methodologies (China)</i>	Appellate Body Report, <i>United States – Certain Methodologies and Their Application to Anti-Dumping Proceedings Involving China</i> , WT/DS471/AB/R and Add.1, adopted 22 May 2017, DSR 2017:III, p. 1423
<i>US – Carbon Steel</i>	Appellate Body Report, <i>United States – Countervailing Duties on Certain Corrosion-Resistant Carbon Steel Flat Products from Germany</i> , WT/DS213/AB/R and Corr.1, adopted 19 December 2002, DSR 2002:IX, p. 3779

Short title	Full case title and citation
US – COOL	Appellate Body Reports, <i>United States – Certain Country of Origin Labelling (COOL) Requirements</i> , WT/DS384/AB/R / WT/DS386/AB/R , adopted 23 July 2012, DSR 2012:V, p. 2449
US – COOL	Panel Reports, <i>United States – Certain Country of Origin Labelling (COOL) Requirements</i> , WT/DS384/R / WT/DS386/R , adopted 23 July 2012, as modified by Appellate Body Reports WT/DS384/AB/R / WT/DS386/AB/R , DSR 2012:VI, p. 2745
US – Corrosion-Resistant Steel Sunset Review	Appellate Body Report, <i>United States – Sunset Review of Anti-Dumping Duties on Corrosion-Resistant Carbon Steel Flat Products from Japan</i> , WT/DS244/AB/R , adopted 9 January 2004, DSR 2004:I, p. 3
US – Export Restraints	Panel Report, <i>United States – Measures Treating Exports Restraints as Subsidies</i> , WT/DS194/R and Corr.2, adopted 23 August 2001, DSR 2001:XI, p. 5767
US – FSC	Appellate Body Report, <i>United States – Tax Treatment for "Foreign Sales Corporations"</i> , WT/DS108/AB/R , adopted 20 March 2000, DSR 2000:III, p. 1619
US – FSC (Article 21.5 – EC)	Appellate Body Report, <i>United States – Tax Treatment for "Foreign Sales Corporations" – Recourse to Article 21.5 of the DSU by the European Communities</i> , WT/DS108/AB/RW , adopted 29 January 2002, DSR 2002:I, p. 55
US – Gambling	Appellate Body Report, <i>United States – Measures Affecting the Cross-Border Supply of Gambling and Betting Services</i> , WT/DS285/AB/R , adopted 20 April 2005, DSR 2005:XII, p. 5663 (and Corr.1, DSR 2006:XII, p. 5475)
US – Gasoline	Appellate Body Report, <i>United States – Standards for Reformulated and Conventional Gasoline</i> , WT/DS2/AB/R , adopted 20 May 1996, DSR 1996:I, p. 3
US – Lead and Bismuth II	Appellate Body Report, <i>United States – Imposition of Countervailing Duties on Certain Hot-Rolled Lead and Bismuth Carbon Steel Products Originating in the United Kingdom</i> , WT/DS138/AB/R , adopted 7 June 2000, DSR 2000:V, p. 2595
US – Renewable Energy	Panel Report, <i>United States – Certain Measures Relating to the Renewable Energy Sector</i> , WT/DS510/R and Add.1, circulated to WTO Members 27 June 2019 [appeal/adoption pending]
US – Shrimp	Appellate Body Report, <i>United States – Import Prohibition of Certain Shrimp and Shrimp Products</i> , WT/DS58/AB/R , adopted 6 November 1998, DSR 1998:VII, p. 2755
US – Shrimp (Ecuador)	Panel Report, <i>United States – Anti-Dumping Measure on Shrimp from Ecuador</i> , WT/DS335/R , adopted on 20 February 2007, DSR 2007:II, p. 425
US – Supercalendered Paper	Appellate Body Report, <i>United States – Countervailing Measures on Supercalendered Paper from Canada</i> , WT/DS505/AB/R and Add.1, adopted 5 March 2020
US – Tariff Measures (China)	Panel Report, <i>United States – Tariff Measures on Certain Goods from China</i> , WT/DS543/R and Add.1, circulated to WTO Members 15 September 2020 [appeal/adoption pending]
US – Tuna II (Mexico) (Article 21.5 – Mexico)	Appellate Body Report, <i>United States – Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products – Recourse to Article 21.5 of the DSU by Mexico</i> , WT/DS381/AB/RW and Add.1, adopted 3 December 2015, DSR 2015:X, p. 5133
US – Underwear	Appellate Body Report, <i>United States – Restrictions on Imports of Cotton and Man-made Fibre Underwear</i> , WT/DS24/AB/R , adopted 25 February 1997, DSR 1997:I, p. 11

Short title	Full case title and citation
<i>US – Wheat Gluten</i>	Appellate Body Report, <i>United States – Definitive Safeguard Measures on Imports of Wheat Gluten from the European Communities</i> , WT/DS166/AB/R , adopted 19 January 2001, DSR 2001:II, p. 717
<i>US – Zeroing (EC)</i>	Appellate Body Report, <i>United States – Laws, Regulations and Methodology for Calculating Dumping Margins ("Zeroing")</i> , WT/DS294/AB/R , adopted 9 May 2006, and Corr.1, DSR 2006:II, p. 417

EXHIBITS CITED IN THIS REPORT

Exhibit	Description/Title
EU-1, TUR-2	Social Insurance and Universal Health Insurance Law No.5510 (31 May 2006), Official Gazette No. 26200 of 16 June 2006 ("Social Insurance and UHI Law")
EU-2	Social Security Institution, "Universal Health Insurance"
EU-3	M. Tatar, "Short PPRI Pharma Profile, Turkey 2017", WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policy ("Short PPRI Pharma Profile Turkey")
EU-4, TUR-3	Social Security Institution Law No 5502 (16 May 2006), Official Gazette No. 26173 of 20 May 2006 ("Social Security Institution Law")
EU-5	G. Oner and M. Kecik, "Turkish Medicines and Medical Devices Agency", presentation at 2014 WHO Technical Briefing Seminar
EU-8, TUR-11	Social Security Institution Regulation on Medicine Reimbursement, Official Gazette No. 29620 of 10 February 2016 ("Drug Reimbursement Regulation")
EU-11, EU-95, EU-102, TUR-10, TUR-10a	Excerpts from the Health Implementation Notification/Communiqué (SUT - Sağlık Uygulama Tebliği), 11 February 2019 ("HIC/SUT")
EU-12	Republic of Turkey, Ministry of Development, Tenth Development Plan 2014-2018 (2014), approved by Decision No. 1041 of the Grand National Assembly of Turkey of 2 July 2013 ("Tenth Development Plan 2014-2018")
EU-14, TUR-37	Ministry of Health and Ministry of Development, Structural Transformation Program for Healthcare Industries Action Plan, November 2014 ("Structural Transformation Program for Healthcare Industries Action Plan")
EU-15	Republic of Turkey, Office of the Prime Minister, 2016 Action Plan of the 64th Government (Implementation and Reforms), 10 December 2015 ("2016 Action Plan of the 64 th Government")
EU-16	65th Government Programme, 24 May 2016 ("65 th Government Programme")
EU-19	A. Yücel, "Foreign investments will be [like] medicine!", Dünya, 30 July 2019
EU-21	Social Security Institution, Rejoinder in court proceedings raised by the Association of Research-Based Pharmaceutical Companies (AIFD) before the Turkish State Council, Case 2017/1308, 21 September 2017 ("SSI Rejoinder")
EU-23	TMMDA, "Pharmaceutical Localisation Project Work Conducted by the Ministry of Health", presentation of December 2017
EU-28	EU Commissioner for Trade, Letter to the Turkish Minister of Economy, 5 April 2017
EU-29	Turkish Minister of Economy, Letter to the EU Commissioner for Trade, 19 June 2017
EU-30	Social Security Institution, Defense in court proceedings raised by the Association of Research-Based Pharmaceutical Companies (AIFD) before the Turkish State Council, Case 2017/1308, 29 June 2017 ("SSI Defense")
EU-34	H. Gursoz, President of the TMMDA, "Pharmaceutical Localisation Project: Transition from Importation to Manufacturing", presentation of 6 March 2017
EU-35	HSPC Decision regarding the Localization Process, October 2016 ("HSPC Decision")
EU-38, TUR-12	Social Security Institution Regulation on Alternative Reimbursement for Universal Health Insurance, published in the Official Gazette 29620 on 10 February 2016 ("Alternative Reimbursement Regulation")

Exhibit	Description/Title
EU-40	H. Eroğlu, Vice President of the TMMDA, "Local Production", presentation at the Symposium on Rational Approach to Current Issues concerning Medicines, Ankara, 7-9 October 2016
EU-45, TUR-60	Roadmap for the process of localization, setting forth of the principles for the negotiation, 14 March 2016 ("Localisation roadmap")
EU-46	SSI and TMMDA, Communication, "Local production"
EU-51	Excerpts from Annex 4/A to the HIC/SUT, December 2018
EU-52, TUR-20	Protocol on the procurement of medicines from pharmacies which are members of the Turkish Pharmacists' Association (TEB) by persons covered by the Social Security Institution ("TPA Protocol")
EU-53	Regulation on the procedures and principles governing checking of invoices of healthcare providers and reimbursement of their fees, Official Gazette No. 30001 of 8 March 2017
EU-62, TUR-58	Social Security Institution, Public Announcement on the Localisation Process, 19 January 2018
EU-84	Republic of Turkey Ministry of development, Eleventh Development Plan (2019-2023), Transformation in healthcare industries, Specialised Committee Report of July 2018 ("Ministry of development, Eleventh Development Plan 2019-2023")
EU-87, TUR-35	Ministry of Health, Strategic Plan of TMMDA for 2019-2023, 31 December 2018
EU-88	Government of Turkey, 11th Development Plan for the period 2019-2023 ("Government of Turkey, Eleventh Development Plan 2019-2023")
EU-89	Regulation on the Marketing Authorization of Medicinal Products for Human Use, Official Gazette No. 25705 of 19 January 2005 ("Marketing Authorization Regulation")
EU-91, TUR-33	Ministry of Trade, Implementing Regulation on Import Control of certain products inspected by the Ministry of Health, Official Gazette No. 30991 of 27 December 2019 ("Implementing Regulation on Import Control")
EU-92	TMMDA, Announcement on import applications for medical products, 31 December 2019
EU-93	Regulation regarding the Variations on Medicinal Products for Human Use with Marketing Authorization or Pending Registration, Official Gazette No. 25823 of 23 May 2005
EU-95, EU-11, EU-102, TUR-10, TUR-10a	Implementing Regulation for Healthcare ("HIC/SUT")
EU-96	Annex 4/C to the HIC/SUT
EU-97	TMMDA, Guideline for Working Principles and Procedures of Human Medicinal Products Priority Assessment Commission ("Prioritization Guideline")
EU-99, TUR-36	Ministry of Health, TMMDA, Administrative Activity Report 2016, February 2017 ("2016 TMMDA Activity Report")
EU-100	R. Yeter, "Watch out with the localization trap", Yeni Şafak, 24 February 2018
EU-102, EU-11, EU-95, TUR-10, TUR-10a	Excerpts from the Health Implementation Notification/Communiqué (SUT - Sağlık Uygulama Tebliği), 5 May 2020 ("HIC/SUT")
EU-109, TUR-7	Social Security Institution, Activity Report 2018 ("SSI Activity Report 2018")
EU-111, TUR-78	TMMDA Administrative Operation Report 2019
EU-117	IQVIA, Report on the Turkish healthcare market, September 2020

Exhibit	Description/Title
EU-118	Comparison between applications for priority granted for imported and domestic products
TUR-17	Communiqué on the Pricing of Medicinal Products for Human Use, Official Gazette No. 30195 of 29 September 2017 ("Pricing Communiqué")
TUR-18	Decree on Pricing of Human Medicinal Products No. 2017/9901, Official Gazette No. 29989 of 24 February 2017 ("Pricing Decree")
TUR-19	Article 26, Regulation on the Marketing Authorization of Medicinal Products for Human Use, Official Gazette No. 25705 of 19 January 2005, amended on 14 November 2013
TUR-21	Annex 4/A of the HIC/SUT
TUR-27	Law on Turkish Pharmacists Association No. 6643 (25 January 1956), Official Gazette No. 9223 of 2 February 1956
TUR-30	"Commission aims to bring back medicine production to Europe", <i>Euractiv</i> , 22 April 2020
TUR-31	Rym Momtaz, "Macron urges massive increase in local production of medical equipment", <i>Politico</i> , 31 March 2020
TUR-34	Ministry of Health, Strategic Plan 2019-2023
TUR-38	Ministry of Health, Strategic Plan of TMMDA for 2018-2022
TUR-43	Healthcare Industries Steering Committee, Minutes of the 56th meeting, 13 December 2017
TUR-45	Social Security Institution Decision No. 2015/3 of 1 April 2015 \$
TUR-57	Social Security Institution, Public Announcement on the Localisation Process, 25 April 2017
TUR-64	Table, Reimbursement applications for inclusion in Annex 4/A of Drug Reimbursement Regulation
TUR-72	UN Human Rights Council, Resolution A/HRC/RES/12/24, 12 October 2009
TUR-77	Ministry of Health, Strategic Plan of TMMDA for 2013-2017, 12 December 2013
TUR-79	Ministry of Health, TMMDA Administrative Operation Report 2018, February 2019 ("2018 TMMDA Activity Report")
TUR-80	TMMDA Administrative Operation Report 2017, February 2018 ("2017 TMMDA Activity Report")
TUR-95	Jakob Hanke Vela, "Germany wants to reshore pharma production from Asia", <i>Politico</i> , 13 March 2020
TUR-96	Jim Brunnsden and Michael Peel, "Covid-19 exposes EU's reliance on drug imports", <i>Financial Times</i> , 20 April 2020
TUR-97	European Commission, Health and Food Safety Directorate-General, Pharmaceutical Committee, <i>Dependency of the EU pharmaceutical industry on active pharmaceutical ingredients and chemical raw materials imported from third countries</i> , 12 March 2020
TUR-98	H. Biskin, "Shortage of supply in medicine to cure breast cancer", <i>Duvar</i> , 22 September 2017; "Local solution for imported medicine used in intestinal diseases", <i>Anadolu</i> , 16 January 2017
TUR-99	"Shortage of supply in this medicine", <i>Sağlık Aktüel</i> , 23 August 2012
TUR-100	"Citizens are victims, that drug is still not on the market", <i>Yeniakit</i> , 29 November 2018
TUR-101	Antalya Provincial Health Directorate, Letter to the Ministry of Health regarding oxytocine ampoule, 7 March 2016; Yaşam Hastanesi Life Hospital Antaliya, Letter to the Pharmacies Branch of the Provincial Health Directorate, 26 February 2016; Private Vitale Gynecology and Obstetrics Hospital, Letter to the Provincial Health Directorate Pharmacies Branch, 25 February 2016;

Exhibit	Description/Title
	Medical Park Özel Antalya Hastane Kompleksi, Letter to the Provincial Health Directorate Pharmacies Branch, 24 February 2016; Private Akdeniz Şifa Hospital, Letter to the Provincial Health Directorate Pharmaceuticals and Pharmacies Branch, 22 February 2016; Özel/Private Anadolu Hastanesi Antalya, Letter to the Provincial Health Directorate Pharmaceuticals and Pharmacies Branch, 1 March 2016
TUR-102	Ministry of Family and Social Policies, Directorate General for Disabled and Elderly, Letter to the Ministry of Health, 25 March 2016
TUR-106	Table, Applications for priority under the Prioritization Guideline
TUR-112	Social Security Institution, Directorate General for Provision of Services Healthcare Software Department, "Medula Project" presentation 2019
TUR-117	Documents relating to a purchase by the SSI from a pharmacy of the pharmaceutical products dispensed to patients in December 2020
TUR-130	"Pharmacy chambers blame medical firms for drug shortages", Daily News (Istanbul, 23 January 2017); C. Caglayan and E. Erkoyun, "Pharmacy stocks run low as Turkey's drug price policy hits supplies", Reuters (Istanbul, 6 February 2019); M. Xuequan, "Spotlight: Turkey faces shortages of medicine due to currency fluctuations", Xinhuanet (21 February 2019)
TUR-131	"The rise in the exchange rate also hit the pharmaceutical industry: alleged supply problems in 'more than 500 medicines'", Medimagazin (10 October 2018)

ABBREVIATIONS USED IN THIS REPORT

Abbreviation	Description
ARC	Alternative Reimbursement Commission
BCI	Business confidential information
DCR	Domestic content requirement
DRC	Drug Reimbursement Commission
DSB	Dispute Settlement Body
DSU	Understanding on Rules and Procedures Governing the Settlement of Disputes
GATS	General Agreement on Trade in Services
GATT 1994	General Agreement on Tariffs and Trade 1994
GMP	good manufacturing practices
GPA	Agreement on Government Procurement
HISC	Healthcare Industries Steering Committee
HSPC	Healthcare Services Pricing Commission
LAC	Localisation Assessment Commission
PPAs	Power purchase agreements
SCM Agreement	Agreement on Subsidies and Countervailing Measures
SPDs	Solar power developers
SSI	Social Security Institution
TBT Agreement	Agreement on Technical Barriers to Trade
TMMDA	Turkish Medicines and medical Devices Agency
TPA	Turkish Pharmacists' Association
TRIMs Agreement	Agreement on Trade Related Investment Measures
TRIPS Agreement	Agreement on Trade-Related Aspects of Intellectual Property Rights
TRRs	Trade-related requirements
UHS	Universal Health Insurance Scheme
UNCTAD	United Nations Conference on Trade and Development
UNIDO	United Nations Industrial Development Organization
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

1 INTRODUCTION

1.1 Complaint by the European Union

1.1. On 2 April 2019, the European Union requested consultations with Turkey pursuant to Articles 1 and 4 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU) and Article XXII:1 of the General Agreement on Tariffs and Trade 1994 (GATT 1994), Article 8 of the Agreement on Trade Related Investment Measures (TRIMs Agreement), Article 64 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), and Article 4.1 of the Agreement on Subsidies and Countervailing Measures (SCM Agreement) with respect to the measures and claims set out below.¹

1.2. Consultations were held on 9 and 10 May 2019.

1.2 Panel establishment and composition

1.3. On 2 August 2019, the European Union requested the establishment of a panel pursuant to Articles 4 and 6 of the DSU, Article XXIII of GATT 1994, Article 8 of the TRIMs Agreement, and Article 4.4 of the SCM Agreement with standard terms of reference.² At its meeting on 30 September 2019, the Dispute Settlement Body (DSB) established a panel pursuant to the request of the European Union in document WT/DS583/3, in accordance with Article 6 of the DSU.³

1.4. The Panel's terms of reference are the following:

To examine, in the light of the relevant provisions of the covered agreements cited by the parties to the dispute, the matter referred to the DSB by the European Union in document WT/DS583/3 and to make such findings as will assist the DSB in making the recommendations or in giving the rulings provided for in those agreements.⁴

1.5. On 4 March 2020, the European Union requested that the Director-General determine the composition of the panel, pursuant to Article 8.7 of the DSU. On 17 March 2020, the Director-General accordingly composed the Panel as follows⁵:

Chairperson: Mr Gudmundur HELGASON

Members: Ms Beverley PEREIRA
Ms Paulyne WAIRIMU

1.6. Brazil, Canada, China, India, Indonesia, Japan, the Russian Federation, Switzerland, Ukraine, and the United States notified their interest in participating in the Panel proceedings as third parties.

1.3 Panel proceedings

1.3.1 General

1.7. After consultation with the parties, the Panel adopted its initial Working Procedures and initial timetable on 15 April 2020. Both were modified in the course of the proceedings, as elaborated further below, for reasons related to the COVID-19 pandemic.⁶

¹ See Request for consultations by the European Union, WT/DS583/1, G/L/1305, G/TRIMs/D/44, IP/D/41 G/SCM/D126/1.

² Request for the establishment of a panel by the European Union, WT/DS583/3 (European Union's panel request).

³ See WT/DSB/M/434.

⁴ WT/DS583/4.

⁵ WT/DS583/4.

⁶ See the Panel's Working Procedures in Annex A-1 to this Report. On 15 April 2020, after consultation with the parties, the Panel also adopted Additional Working Procedures concerning Protection of Business Confidential Information (BCI) (see Annex A-2 to this Report). Neither party submitted BCI to the Panel in these proceedings.

1.8. The European Union and Turkey submitted their first written submissions on 19 May 2020 and 20 July 2020, respectively, and their second written submissions on 30 October 2020 and 29 January 2021, respectively. The Panel sent a first set of questions to the parties and third parties for written responses by 29 March 2021. The Panel held a substantive meeting with the parties during the period 20-23 April 2021. A session with the third parties took place on 21 April 2021. Following the meeting, the Panel sent a second set of questions to the parties for written responses by 28 May 2021 and the parties provided comments on one another's responses by 18 June 2021. On 29 June 2021, the Panel issued the descriptive part of its Report to the parties. The Panel issued its Interim Report to the parties on 30 September 2021 and its Final Report to the parties on 11 November 2021.

1.3.2 Preliminary ruling under Article 6.2 of the DSU

1.9. On 15 May 2020, Turkey requested a preliminary ruling by the Panel that the European Union's panel request fails to identify the specific measures at issue and, with respect to certain claims, fails to provide a brief summary of the legal basis of the complaint sufficient to present the problem clearly.⁷ Turkey requested that the Panel issue the preliminary ruling before the date on which Turkey's first written submission was due (22 June 2020).

1.10. On 25 May 2020, the Panel invited the European Union and the third parties to comment on Turkey's preliminary ruling request. On the same date, the Panel informed the parties and third parties that it intended to issue its decision on the preliminary ruling request by 6 July 2020. The Panel then extended the deadline for the submission of Turkey's first written submission, and of the third parties' written submissions, until after the issuance of its preliminary ruling.

1.11. On 5 June 2020, the Panel received the European Union's comments on Turkey's request for a preliminary ruling. On 12 June 2020, the Panel received comments from Canada, Ukraine, and the United States. On 19 June 2020, the Panel received Turkey's comments on the European Union's comments. On 26 June 2020, the Panel received further comments from the European Union. On 3 July 2020, the Panel informed the parties that to fully consider the issues arising from Turkey's preliminary ruling request, it would issue its preliminary ruling on 10 July 2020.

1.12. The Panel issued its preliminary ruling on 10 July 2020 and indicated that it would become an integral part of the Panel's Final Report, subject to any changes that may be necessary in the light of comments received from the parties at the interim review stage. The Panel's preliminary ruling is included in Annex A-3.

1.4 Impact of the COVID-19 pandemic on the proceedings

1.13. For reasons relating to the COVID-19 pandemic, and as elaborated further below, the Panel modified its initial Working Procedures and timetable as follows: (i) when it became clear that it would be impossible to proceed with an in-person first substantive meeting with the parties in September 2020, and both parties expressed a preference for the Panel to postpone the meeting while avoiding undue delay in the proceedings, the Panel proposed that the parties file their first and second written submissions, and respond to a first set of written questions from the Panel, prior to the date of the postponed substantive meeting; (ii) when it subsequently became clear that it would still not be possible to hold an in-person meeting during the March/April 2021 window that the Panel had envisaged, the Panel decided to hold the meeting in virtual format; and (iii) following further consultation with the parties at that meeting, the Panel decided that an additional substantive meeting with the parties was not warranted in the circumstances of this dispute. The Panel's decisions, which are interrelated, are reflected in a series of communications to the parties annexed to this Report (in Annex B) and summarized below.

1.14. At the time that it adopted the initial Working Procedures for this dispute, the Panel indicated that, if any change to the proceedings were to become necessary because of the COVID-19 pandemic, the Panel would amend the Working Procedures following consultation with the parties. In a 10 July 2020 communication to the parties, the Panel noted that the travel restrictions in place at that time would restrict travel to Geneva by some participants in the proceedings. The Panel stated that it would continue to monitor developments with respect to travel restrictions with a view

⁷ Turkey's request for a preliminary ruling, para. 2.

to consulting further with the parties on or confirming, by the middle of August, the timing of the first substantive meeting initially scheduled for 22-24 September 2020. The Panel invited the parties to provide their views on how the Panel should proceed if the current restrictions were to remain in place, and they did so on 17 July 2020.

1.15. In their comments, both parties proposed that if an in-person meeting was impossible in September, the first substantive meeting should be postponed to a later date. At the same time, both parties agreed that the Panel should conduct the proceedings in a manner that avoided undue delay. The European Union proposed that the Panel should amend its Working Procedures to have just one substantive meeting with the parties in person, and have the parties file their second written submissions (and possibly have an exchange of written questions and answers) prior to that meeting. The European Union suggested that the postponed first substantive meeting could be held on the dates when the second substantive meeting with the parties had initially been scheduled, i.e. 12-13 January 2021.

1.16. In a 12 August 2020 communication (Annex B-1), the Panel informed the parties that, based on the information available at that time, it would not be possible to hold an in-person first substantive meeting in September 2020, as initially scheduled. The Panel proposed to modify its Working Procedures to provide that the parties would file their second written submissions prior to the first substantive meeting, and to provide that the Panel may hold a second substantive meeting with the parties if so requested by either party. In their comments, neither party objected to the proposed procedure, but both requested a longer time period to prepare their second written submissions. Accordingly, in a communication to the parties and third parties on 25 August 2020 (Annex B-2), the Panel adopted and transmitted to the parties and third parties revised Working Procedures and a new partial timetable, setting out the dates for the parties' second written submissions and a provisional window for the timing of the first substantive meeting (March/April 2021). Pursuant to the revised partial timetable, the European Union submitted its second written submission on 30 October 2020. Turkey submitted its second written submission on 29 January 2021.

1.17. In a 3 February 2021 communication (Annex B-3), the Panel informed the parties that, based on the information available at that time, it would not be possible for the participants in the proceedings to plan to hold an in-person first substantive meeting within the March/April 2021 provisional window for the timing of the rescheduled first substantive meeting. The Panel proposed holding a first substantive meeting with the parties (including the third-party session) in virtual format. The European Union and Turkey provided their comments on the possibility of holding the first substantive meeting in virtual format on 8 February and 10 February 2021, respectively. In a 17 February 2021 communication (Annex B-4), the Panel informed the parties that it had decided to proceed by holding a first substantive meeting with the parties in virtual format (including a third-party session) during the week of 19-23 April 2021. In a 25 February 2021 communication to the parties (Annex B-5), the Panel set out its proposed approach for conducting the first substantive meeting, reflected in proposed revisions to the partial timetable, revisions to the Working Procedures, and a Protocol for logistical aspects of the virtual meeting. On 3 March 2021, the parties provided their comments on the Panel's proposed approach as reflected in these proposed procedures and timetable. In a communication on 5 March 2021 (Annex B-6), the Panel transmitted to the parties the adopted revised partial timetable, revised Working Procedures and a Protocol for logistical aspects of the virtual meeting.

1.18. The Panel held a substantive meeting with the parties from 20 to 23 April 2021. At the substantive meeting, the parties presented their views on the necessity of holding a second substantive meeting, on the timing of such a meeting, on the format of such a meeting (i.e. in-person or virtual again), and on any alternatives to holding a second substantive meeting. Turkey argued that a second substantive meeting was the usual practice and necessary in this case. The European Union argued that a second substantive meeting was not required and was unnecessary in this case. In a 3 May 2021 communication to the parties, the Panel informed the parties that it considered that an additional substantive meeting was not warranted for the reasons set out in that communication (Annex B-7). Instead of holding an additional substantive meeting, the Panel invited the parties to provide written comments on one another's responses to the second set of questions from the Panel, sent to the parties following the first substantive meeting.

1.5 Translation issues

1.19. With its first written submission, the European Union provided, as exhibits, its English translations of various Turkish legal instruments and documents. In its first written submission, Turkey stated that "with regard to the content of a number of exhibits, the European Union has provided an erroneous or misleading translation with a view to skew the Panel's opinion."⁸ Turkey referred, in particular, to Exhibits EU-1, EU-4, EU-8, EU-11, EU-38, EU-45, EU-51, EU-52, EU-62, EU-95 and EU-102.⁹ Turkey stated that, in its own submission, it "will identify the errors of translation provided by the European Union and will re-submit new exhibits, as appropriate".¹⁰ Accordingly, Turkey submitted Exhibits TUR-2, TUR-3, TUR-10, TUR-10a, TUR-11, TUR-12, TUR-20, TUR-21, TUR-33, TUR-37, TUR-57, TUR-58 and TUR-60.

1.20. In its second written submission, the European Union stated that "[w]hile mistakes are always possible, nothing in the EU's translations supports Turkey's allegation that the EU was attempting to mislead the Panel."¹¹ The European Union responded to some of the translation issues raised by Turkey.¹² The European Union also submitted that "Turkey agrees with the main factual elements of the Localisation Requirement and Turkey's reimbursement system for outpatient pharmaceuticals, as described by the EU."¹³ In its second written submission, Turkey addressed some of the European Union's responses and reiterated its position with respect to the translation of certain terms.¹⁴

1.21. Neither party directed any request to the Panel to take any decision on any of the disputed translation issues, and the Panel did not consider it necessary to take any further steps in relation to them. The Panel has taken note of the parties' disagreement, and of the different translations provided by the parties. Where relevant, the Panel addresses the differences in translation with respect to certain exhibits when referring to these exhibits.¹⁵

2 FACTUAL ASPECTS

2.1. This section provides an overview of the wider factual and regulatory context in which the measures at issue in this dispute operate, drawing upon common elements from the parties' submissions. It then identifies the measures at issue, as set out in the European Union's request for the establishment of a panel (European Union's panel request) and describes the factual aspects of each of these measures. A more detailed review of the facts, and the Panel's findings on any disputed factual issues, will be set out as necessary in the Panel's findings in section 7 of this Report.

2.1 Factual background

2.1.1 Turkey's Universal Health Insurance Scheme and relevant governmental entities

2.2. In 2006, Turkey introduced the Universal Health Insurance Scheme (UHS)¹⁶, which covers approximately 99% of its population¹⁷ and provides "comprehensive, fair and equitable access to healthcare services"¹⁸, including access to pharmaceutical products, to virtually anyone residing in Turkey.¹⁹ The system is mainly financed by social security premiums based on employer and employee contributions. Any deficit is covered from public funds.²⁰

⁸ Turkey's first written submission, para. 17.

⁹ Turkey's first written submission, fn 8 to para. 17.

¹⁰ Turkey's first written submission, para. 17.

¹¹ European Union's second written submission, para. 15.

¹² European Union's second written submission, paras. 16-25.

¹³ European Union's second written submission, para. 33.

¹⁴ Turkey's second written submission, paras. 9-15.

¹⁵ See footnotes 26, 39, 41, 45, 51, 52, 56, 92, 637, 644, and paragraph 7.91.

¹⁶ Social Insurance and Universal Health Insurance Law, Law No. 5510 (31 May 2006), Official Gazette No. 26200 of 16 June 2006 (Social Insurance and UHI Law) (Exhibits EU-1, TUR-2).

¹⁷ M. Tatar, "Short PPRI Pharma Profile, Turkey 2017", WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policy (Short PPRI Pharma Profile Turkey) (Exhibit EU-3), p. 7. See also Social Security Institution Activity Report 2018 (SSI Activity Report 2018) (Exhibits EU-109, TUR-7), p. 1.

¹⁸ Social Security Institution, "Universal Health Insurance" (Exhibit EU-2).

¹⁹ Turkey's first written submission, para. 28.

²⁰ Short PPRI Pharma Profile Turkey (Exhibit EU-3), p. 7.

2.3. The Ministry of Health is the main regulatory body in respect of matters concerning the market authorisation, pricing, legal classification and inspection of pharmaceutical products.²¹ Within the Ministry of Health, the Turkish Medicines and Medical Devices Agency (TMMDA) is responsible for the registration, marketing approval and authorization, pricing, legal classification and inspection of all human medicinal products.²²

2.4. The Social Security Institution (SSI), currently affiliated with the Ministry of Family, Labour and Social Services, is in charge of implementing social security policies.²³ It is responsible, *inter alia*, for paying for all healthcare goods and services, including pharmaceuticals.²⁴ It also leads several commissions, consisting of members from various governmental entities. These include, in particular, the Healthcare Services Pricing Commission (HSPC)²⁵, which decides on the prices of healthcare services and determines the reimbursement amounts, and its sub-commissions: the Drug Reimbursement Commission (DRC)²⁶ and the Alternative Reimbursement Commission (ARC).²⁷

2.1.2 Placing of pharmaceutical products on the Turkish market

2.5. To be placed on the Turkish market, a pharmaceutical product must obtain:

- a. a "good manufacturing practices" (GMP) certification²⁸;
- b. a marketing authorization²⁹;

²¹ Short PPRI Pharma Profile Turkey (Exhibit EU-3), p. 13. See also Turkey's first written submission, para. 39.

²² G. Oner and M. Kecik, "Turkish Medicines and Medical Devices Agency", presentation at 2014 WHO Technical Briefing Seminar (Exhibit EU-5); Turkey's first written submission, para. 40.

²³ Law on Social Security Institution, Law No. 5502 (16 May 2006), Official Gazette No. 26173 of 20 May 2006 (Social Security Institution Law) (Exhibits EU-4, TUR-3), Article 3.

²⁴ Turkey's first written submission, para. 39; second written submission, para. 19.

²⁵ The European Union, in its first written submission, refers to this entity as the "Healthcare Services Pricing Commission". Turkey, in its first written submission, refers interchangeably to the "Healthcare Services Pricing Commission" and "Healthcare Services Pricing Committee". The Panel notes this difference and refers to this entity as the "Healthcare Services Pricing Commission" (HSPC).

²⁶ The Drug Reimbursement Commission (DRC) is mainly responsible for deciding which new pharmaceutical products are included in and excluded from the list of pharmaceuticals reimbursed by the SSI. (Social Security Institution Regulation on Medicine Reimbursement, Official Gazette No. 29620 of 10 February 2016 (Drug Reimbursement Regulation) (Exhibits EU-8, TUR-11), Article 5(1)(a), (b) and (d).) The Drug Reimbursement Regulation refers to this entity as the "Medicine Reimbursement Commission" (in the translation provided by Turkey, Exhibit TUR-11) or the "Drug Reimbursement Committee" (in the translation provided by the European Union, Exhibit EU-8). The European Union refers in its first written submission interchangeably to the "Drug Reimbursement Committee" and "Drug Reimbursement Commission". Turkey uses in its first written submission the term "Drug Reimbursement Commission". The Panel notes this difference in translation and refers to this entity as the "Drug Reimbursement Commission".

²⁷ The Alternative Reimbursement Commission (ARC) is in charge of drawing up and establishing alternative reimbursement models for pharmaceutical products reimbursed by the SSI based on their financial or medical benefits in areas of specific need. (Social Security Institution Regulation on Alternative Reimbursement for Universal Health Insurance, Official Gazette No. 29620 of 10 February 2016 (Alternative Reimbursement Regulation) (Exhibits EU-38, TUR-12), Article 6.) Some legal instruments provided by the parties, as well as the European Union in its first written submission, refer to the ARC as the "Alternative Reimbursement Committee". The title page of Exhibit TUR-12 explains that the Alternative Reimbursement Committee and Alternative Reimbursement Commission are the same actor. The Panel refers to this entity as the "Alternative Reimbursement Commission".

²⁸ A good manufacturing practices (GMP) certification is conducted by the Turkish Medicines and Medical Devices Agency (TMMDA) on a facility-basis for domestically produced pharmaceutical products and on a product-basis for imported pharmaceutical products. It is a prerequisite for obtaining a marketing authorization. (Turkey's first written submission, paras. 42-43.)

²⁹ A marketing authorization is granted by the TMMDA if a product meets all quality standards, and efficacy and safety conditions. (Regulation on the Marketing Authorization of Medicinal Products for Human Use, Official Gazette No.25705 of 19 January 2005 (Marketing Authorization Regulation) (Exhibit EU-89), Article 16).

- c. a fixed price, proposed to the TMMDA³⁰ by the holder of a marketing authorization and calculated according to specific rules³¹; and
- d. a sales permit.³²

2.6. To import some pharmaceutical products into Turkey, the importer is required to also submit an inspection certificate (or "control certificate"³³) when making a customs declaration at customs offices. Inspection certificates are delivered by the Ministry of Health upon application by the pharmaceutical companies importing the products and on the basis of the relevant marketing authorization.³⁴ They certify the products' "suitability for human health and safety"³⁵ and are valid for twelve months.

2.1.3 Reimbursement³⁶ of pharmaceutical products

2.1.3.1 The Annex 4/A list

2.7. Pharmaceutical products are distributed to outpatients³⁷ by retail pharmacies, which are private entities. The amounts charged by pharmacies for pharmaceutical products covered by the social security system are met from payments made by the SSI and out-of-pocket payments by outpatients. The SSI makes payments to pharmacies based on monthly invoices submitted by the pharmacies. Regarding inpatient treatment, inpatients receive medicines directly from the hospitals, through a process different from the system at issue in this dispute.³⁸

2.8. To be reimbursable, a pharmaceutical product must be included in the list in Annex 4/A to the Health Implementation Communiqué (HIC/SUT).³⁹ The SSI determines which pharmaceutical

³⁰ Decree on Pricing of Human Medicinal Products No. 2017/9901, Official Gazette No. 29989 of 24 February 2017 (Pricing Decree) (Exhibit TUR 18), Article 4.

³¹ Communiqué on the Pricing of Medicinal Products for Human Use, Official Gazette No. 30195 of 29 September 2017 (Pricing Communiqué) (Exhibit TUR-17) and Pricing Decree (Exhibit TUR-18).

³² Sales permits are issued by the Ministry of Health on the basis of the marketing authorization and a price copy of the products, and after evaluation of the accuracy of the information on the patient leaflet, package and label, as well as price adequacy. (Article 26, Regulation on the Marketing Authorization of Medicinal Products for Human Use, Official Gazette No. 25705 of 19 January 2005, amended on 14 November 2013 (Exhibit TUR-19).)

³³ Turkey's first written submission, para. 586.

³⁴ Turkey's responses to the second set of questions, para. 95. See also Turkey's responses to the first set of questions, para. 106.

³⁵ Ministry of Trade, Implementing Regulation on Import Control of certain products inspected by the Ministry of Health, Official Gazette No. 30991 of 27 December 2019 (Implementing Regulation on Import Control) (Exhibits EU-91, TUR-33), Article 4(1).

³⁶ The parties disagree on the use of the terms "reimbursement" and "reimbursement list". The European Union uses these terms to describe the process through which the Turkish authorities (in particular the SSI) cover the costs for pharmaceutical products provided to patients. (See European Union's first written submission, Section 2.2.1.) Turkey maintains that the term "reimbursement", though occasionally used by Turkish authorities, does not accurately reflect the SSI's practice concerning payment of medicines (Turkey's second written submission, para. 12), and that Turkey's healthcare system is implemented through "direct payments" by the SSI to hospitals and retail pharmacies. (Turkey's first written submission, para. 65.) Instead of "reimburse" and "reimbursement list", Turkey uses the terms "pay for" and "list of medicines to be paid for". (Turkey's first written submission, para. 66; second written submission, paras. 11-13.) The European Union disagrees and presents arguments as to why the facts support its description of the system for outpatient pharmaceuticals in Turkey as one that involves "reimbursement" rather than "direct provision". (European Union's second written submission, paras. 42-67.) The Panel takes note of the parties' disagreement concerning the terms "reimbursement", "reimbursement list", "pay for" or "list of medicines to be paid for". To the extent that the Panel uses these terms in the descriptive part of the Report, such use does not prejudice any disputed issue about the proper characterization of the measure before the Panel.

³⁷ Turkey and the European Union both refer to consumers who obtain prescribed pharmaceutical products from retail pharmacies as "outpatients", as distinguished from "inpatients" who receive pharmaceutical products in hospitals (Turkey's first written submission, para. 64; European Union's first written submission, para. 12). The Panel uses the term "outpatients" in the same way in this Report.

³⁸ Turkey's first written submission, paras. 111-114; European Union's second written submission, para. 33.

³⁹ Social Security Institution Health Implementation Communiqué, Official Gazette No. 28597 of 24 March 2013 (HIC/SUT) (Exhibits EU-11, EU-95, EU-102, TUR-10, TUR-10a). The Panel notes the parties' disagreement with respect to the translation of the title of this document. The European Union refers to this document in various ways (Implementing Regulation for Healthcare (IRH), Health Implementation Notification /

products are included in the Annex 4/A list. According to Turkey, close to 90% of the pharmaceutical products that are actively sold and prescribed in Turkey are included in the Annex 4/A list.⁴⁰ The Annex 4/A list is revised regularly to reflect the inclusion or exclusion of certain pharmaceutical products. Any updates to the list are then published on the SSI's website and in the Official Gazette.

2.9. Products in the Annex 4/A list are put in equivalent groups. Products containing the same active ingredient (substance) that can be used for the same indication are included in the same group of equivalent pharmaceuticals on the basis of price comparison between similar dosage forms.⁴¹ The rationale behind this grouping is related to the use of a reference pricing system (or "equivalent band practice"⁴²), whereby a single reimbursement price is set for each equivalent group (the lowest price in the equivalent group increased by 10%).⁴³

2.10. To request the inclusion of products in the Annex 4/A list, pharmaceutical companies apply to the SSI following one of two pathways: the "regular reimbursement pathway" or the "alternative reimbursement pathway".

2.11. Following the "regular reimbursement pathway", pharmaceutical companies submit an application for inclusion in the Annex 4/A list. This application is reviewed by the Scientific and Academic Consultation Council (SACC)⁴⁴, which issues an opinion that is then discussed by the Medical and Economic Evaluation Commission (MEEC).⁴⁵ The DRC takes the final decision on the inclusion of a product in the Annex 4/A list.

2.12. Following the "alternative reimbursement pathway", pharmaceutical companies submit an alternative reimbursement application to the ARC (which, as noted above, is a sub-commission of the SSI). The ARC evaluates the application based on the literature and data provided and takes the final decision about the inclusion of the product in the Annex 4/A list. The "alternative reimbursement pathway" concerns medicines otherwise unavailable on the Turkish market, i.e. "innovative and high-tech medicines customized for individual patients"⁴⁶, and certain groups of medicines which are

Communiqué, HIN or in Turkish, *Sağlık Uygulama Tebliği* (SUT). (See European Union's first written submission, para. 26.) Turkey disagrees with the use of the term "regulation" and maintains that the document is correctly translated as "Social Security Institution Health Implementation Communiqué" (cover page of Exhibit TUR-10). The Panel refers to this document as HIC/SUT. The Panel also notes that this document has been submitted by the EU in full (Exhibit EU-95) and as excerpts updated at different points in time (Exhibits EU-11 and EU-102). The Panel will cite this document as HIC/SUT (Exhibits EU-95, TUR-10) as they contain the full text of the document, unless otherwise specified.

⁴⁰ Turkey's responses to the second set of questions, para. 4.

⁴¹ HIC/SUT (Exhibits EU-95, TUR-10), Article 4.4.2(1). This provision continues with a reference to situations where the products are included in different groups. The Panel notes that the translations provided by the parties differ on this point. According to the translation provided by the European Union (Exhibits EU-11 and EU-95), "products containing an identical active substance that can be used for the same indication are put in the same group of equivalent medicines on the basis of a price comparison between similar dosage forms or on the basis of the same price comparison but in separate groups of equivalent medicines when being substituted in pharmacies" (emphasis added). According to the translation provided by Turkey (Exhibit TUR-10), "products containing the same active ingredient that can be used for the same indication are included in the same equivalent groups on the basis of price comparison between similar dosage forms, or in separate equivalent groups on the basis of the same price comparison but in terms of pharmacy substitution." (emphasis added).

⁴² Turkey's first written submission, para. 86.

⁴³ See Turkey's first written submission, para. 87; European Union's first written submission, para. 19.

⁴⁴ The Scientific and Academic Consultation Council (SACC) consists of academics and experts. It is in charge of evaluating the applications for inclusion of new pharmaceutical products on the Annex 4/A list (Article 3(m) of the Drug Reimbursement Regulation (Exhibits EU-8, TUR-11)). The SACC considers "the status of the product, its therapeutic benefits and alternative therapeutic methods, as well as the 'gold standard' in the treatment of the disease targeted by the product, the potential patients, the cost/benefit analysis and the size of the product's packaging". (Turkey's first written submission, para. 74.)

⁴⁵ The Medical and Economic Evaluation Commission (MEEC) evaluates the literature and data presented with the application file. (Drug Reimbursement Regulation (Exhibits EU-8, TUR-11), Article 9(a).) Turkey refers to this entity as the Medical and Economic Evaluation Commission. (Turkey's first written submission, paras. 74-75.) The European Union refers to this entity as the Medical and Economic Assessment Committee (MEAC). (European Union's first written submission, para. 21.) The Drug Reimbursement Regulation, in its translations provided by both parties, also uses the abbreviation "TEDK". (Drug Reimbursement Regulation (Exhibits EU-8, TUR-11), Article 8.) The Panel notes this difference in translation and refers to the entity as the "Medical and Economic Evaluation Commission".

⁴⁶ Turkey's first written submission, para. 92.

not manufactured or not available in Turkey.⁴⁷ It is an "exceptional mechanism"⁴⁸ that allows the inclusion (through "alternative reimbursement models") of pharmaceutical products in the Annex 4/A list on the basis of "their financial or medical benefits"⁴⁹ in areas of specific need.

2.13. Regardless of whether the regular or alternative reimbursement pathway is used, once approved, the pharmaceutical products are included in the same Annex 4/A list.⁵⁰ Once included in the Annex 4/A list, products may subsequently be "passivized" (their status in the list changes from "active" to "passive")⁵¹, or excluded from the list.⁵² Products are no longer reimbursed if they are excluded or "passivized".⁵³ In other words, to be reimbursed, products must be both included and listed as "active" in the Annex 4/A list.⁵⁴

2.1.3.2 Reimbursement of pharmaceutical products that are active on the Annex 4/A list

2.14. Pharmaceutical products are prescribed to patients by medical doctors and then provided to outpatients by retail pharmacies. All retail pharmacies are members of the Turkish Pharmacists' Association (TPA).⁵⁵ According to a Protocol concluded between the SSI and the TPA⁵⁶, individual

⁴⁷ Turkey's first written submission, para. 93.

⁴⁸ Turkey's first written submission, para. 96.

⁴⁹ Alternative Reimbursement Regulation (Exhibits EU-18, TUR-12), Article 1.

⁵⁰ European Union's first written submission, para. 24.

⁵¹ "Passivization" occurs when: (i) a pharmaceutical company does not submit its distribution certificate within five months after the product's inclusion in the Annex 4/A list (Drug Reimbursement Regulation (Exhibits EU-8, TUR-11), Article 12(5)(b)); (ii) the product has not been sold on the Turkish market for a year (ibid. Article 12(5)(c)); (iii) the price of the product is removed from or indicated as "0" in the list published by the Ministry of Health (ibid. Article 12(5)(d)); and (iv) according to Turkey, the market share of the product falls below 1% (Turkey's first written submission, para. 80, referring to Article 12(5)). The parties also appear to agree that pharmaceutical products may be passivized as a result of the localisation requirement. (Turkey's first written submission, para. 82; European Union's second written submission, para. 33.) Passivized products may be "re-activated" upon request of the pharmaceutical company if the conditions for passivization are no longer valid. (Turkey's first written submission, para. 81; responses to the second set of questions, para. 10; and European Union's first written submission, para. 34.) The Panel notes that while Turkey uses the term "passivize", the European Union indicates that the term "de-activate" better conveys the meaning of the Turkish word in this context but notes that "there does not seem to be a substantive disagreement here." (European Union's second written submission, para. 24.) The Panel uses the terms "passivize" and "passivization".

⁵² Exclusion occurs when: (i) a pharmaceutical company does not submit its distribution certificate within 10 months (Drug Reimbursement Regulation (Exhibits EU-8, TUR-11), Article 12(5)(b)); (ii) there has not been a request for re-activation of a passivized product for 10 months (ibid. Article 12(5)(c)); or (iii) the price of the product has been removed from or indicated as "0" in the list published by the Ministry of Health (ibid. Article 12(5)(d)). Excluded products may be "re-included" in the Annex 4/A list only after a period of six months following the date of their exclusion and are subject to a new application for inclusion in the Annex 4/A list. (Turkey's first written submission, para. 81; responses to the second set of questions, para. 11; and European Union's first written submission, para. 34.) The Panel notes that the European Union uses the term "excluded" interchangeably with the terms "delisted" and "removed". The Drug Reimbursement Regulation uses the term "remove" (in the translation provided by Turkey, Exhibit TUR-11) or "delist" (in the translation provided by the European Union, Exhibit EU-8). The Panel uses the terms "exclude" and "exclusion".

⁵³ While both "passivized" products and "excluded" products are no longer reimbursed, the "re-activation" of a product that has been passivized appears to be a less cumbersome process than its "re-inclusion" on the list after it has been excluded. If a passivized or an excluded product is prescribed, a pharmacist may dispense another pharmaceutically equivalent product which is included and active on the Annex 4/A list. (Protocol on the Provision of Medicines to the Persons Covered by the Social Security Institution by the Pharmacies which are Members of the Turkish Pharmacists' Association (TPA Protocol) (Exhibit TUR-20), para. 3.2.12.) "Passivized" and "excluded" products may still be prescribed by doctors and dispensed by pharmacies, without being reimbursed (Turkey's responses to the first set of questions, para. 4).

⁵⁴ See Turkey's responses to the second set of questions, para. 40.

⁵⁵ Law on Turkish Pharmacists Association No. 6643 (25 January 1956), Official Gazette No. 9223 of 2 February 1956 (Exhibit TUR-27), Article 1. The TPA is a public institution under Turkish law, established "to meet the common needs of pharmacists, to facilitate their professional activities and to ensure the development of pharmacy in accordance with general interests" (ibid, Article 1). Its Central Committee has the tasks, *inter alia*, to "take measures to facilitate the procedures related to professional activities between private and public institutions and organizations and members" and to "make agreements with all public and private institutions and organizations that will purchase health services from pharmacies" (ibid., Article 39(g) and Article 39(j)).

⁵⁶ TPA Protocol (Exhibit TUR-20); Protocol on the procurement of medicines from pharmacies which are members of the Turkish Pharmacists' Association (TEB) by persons covered by the Social Security Institution (TPA Protocol) (Exhibit EU-52). The parties disagree on the translation of the title of this document. The

retail pharmacies sign (and annually renew) standard contracts with the SSI.⁵⁷ On the basis of these contracts, pharmacies periodically send to the SSI invoices for all pharmaceutical products included in the Annex 4/A list that they have provided to outpatients during the relevant period.⁵⁸ The SSI reviews these invoices⁵⁹, and reimburses the "reimbursement price" as described below.

2.15. The reimbursement price of medicines⁶⁰ is lower than their retail price.⁶¹ Pharmaceutical products included in the Annex 4/A list are assigned a "public price" which results from the application of "public discounts" at each stage of the supply chain. If the product does not have an equivalent group in the Annex 4/A list, the SSI pays 100% of its public price. If a product has an equivalent group, the SSI pays a reimbursement price determined according to the "internal reference pricing mechanism".⁶² A single reimbursement price is set for each equivalent group.⁶³ It is calculated on the basis of the price of the product having the cheapest unit price in the group (and at least a 1% market share), increased by 10%.

2.16. If the public price of a pharmaceutical product is greater than the maximum reimbursement price set by the SSI for the relevant equivalent group, outpatients must pay the difference, unless they decide to opt for an equivalent product the public price of which is not greater than the maximum reimbursement price set by the SSI for the relevant equivalent group.⁶⁴ In addition, outpatients generally also pay two types of fees collected by pharmacies⁶⁵: (i) a fee calculated as a

European Union refers to it as "Protocol on the procurement of medicines from pharmacies which are members of the Turkish Pharmacists' Association (TEB) by persons covered by the Social Security Institution". (Exhibit EU-52, as referenced in European Union's first written submission, para. 17 and fns 10, 13, 34, and 35.) Turkey considers that the accurate translation of the title should be "Protocol on the Provision of Medicines to the Persons Covered by the Social Security Institution by the Pharmacies which are Members of the Turkish Pharmacists' Association". (Exhibit TUR-20, as referenced in Turkey's first written submission, paras. 65 and 107, and fns 54 and 85.) The Panel notes the parties' disagreement on this point and refers forthwith to this document as "TPA Protocol" (Exhibits EU-52, TUR-20).

⁵⁷ The legal basis for the TPA Protocol and the individual contracts between the pharmacies and the SSI is Article 73 of the Social Insurance and UHI Law (Exhibits EU-1, TUR-2). Of the 26,600 retail pharmacies in Turkey, 25,300 are under contract with the SSI. (Turkey's first written submission, para. 109.) The remaining 1,300 retail pharmacies that have not signed contracts with the SSI, as well as pharmacies whose contract with the SSI have not been renewed, can still dispense medicines included in the Annex 4/A list but cannot invoice these medicines to the SSI. (Turkey's responses to the second set of questions, paras. 14 and 19.) Those pharmacies may be (and, according to the European Union, typically are) bound by contracts with private insurers, and their sales of medicines included in the Annex 4/A list are covered by reimbursement by private insurers. (European Union's comments on responses to the second set of questions, para. 11.)

⁵⁸ TPA Protocol (Exhibits EU-52, TUR-20), paras. 4.1-4.3. See also Turkey's first written submission, para. 108; European Union's second written submission, para. 33.

⁵⁹ The SSI usually reviews invoices and their accompanying documents using a sampling method (Regulation on the procedures and principles governing checking of invoices of healthcare providers and reimbursement of their fees, Official Gazette No. 30001 of 8 March 2017 (Exhibit EU-53), Article 6). According to Turkey, the SSI can refuse to make a payment when the medicines were approved in the Medula system on the basis of incorrect information and dispensed to patients in breach of the specific medical rules that exist for those medicines (Turkey's opening statement, para. 32).

⁶⁰ While the European Union occasionally refers to the term "reimbursement price" (European Union's first written submission, para. 25), it appears to use interchangeably the terms "reimbursement level", "reference price" or "reference price for reimbursement". (European Union's first written submission, paras. 19 and 27.) Turkey uses the term "reference price" to reflect the price a product is given (in Euro (EUR)) in the reference countries. (Turkey's first written submission, para. 53.) The Panel uses the term "reimbursement price" to refer to the price paid by the SSI to a retail pharmacy for the pharmaceutical product provided to an outpatient. To the extent that the Panel uses the term "reimbursement price", such use does not prejudice any disputed issue between the parties. The reimbursement price is determined and paid in Turkish lira. (European Union's responses to the second set of questions, para. 35.)

⁶¹ A "retail price" is the price for pharmaceutical products that are not included in Annex 4/A list, and for products sold by pharmacies to patients without a prescription or with a prescription provided by a medical doctor "non contracted" with the SSI. (Turkey's first written submission, para. 59.)

⁶² Turkey's first written submission, para. 86.

⁶³ See HIC/SUT (Exhibits EU-95, TUR-10), Article 4.4.2.

⁶⁴ European Union's first written submission, para. 19; Turkey's first written submission, para. 87.

⁶⁵ Social Insurance and UHI Law (Exhibits EU-1, TUR-2), Article 68; HIC/SUT (Exhibits EUR-95, TUR-10), Article 1.8.2. The European Union uses the term "co-payments" to refer to these fees (European Union's first written submission, para. 15). Turkey takes issue with the use of this term. (Turkey's first written submission, fn 90). To the extent that there appears to be no factual disagreement between the parties with respect to the existence and operation of these fees (Turkey's first written submission, para. 110; European Union's second written submission, para. 33), the Panel will use the terms "contribution fee" and "prescription fee" (collectively "fees").

percentage of the price after public discount of the pharmaceutical product (contribution fee), being 10% for persons who receive income or a pension from the SSI, and also for their dependants, or 20% for all others⁶⁶; and (ii) a fee of 3 Turkish lira for up to three boxes/items in the prescription and 1 Turkish lira for each additional box/item (prescription fee).⁶⁷

2.17. Retail pharmacies and the SSI use an electronic information system (the Medula system) which "enables the registration, tracking and invoicing of medicines that are obtained from pharmacies through a single application".⁶⁸ Turkey explains that "[a]ll transactions between the SSI and the healthcare service providers, including the purchase of pharmaceutical products, are carried out through the Medula system."⁶⁹

2.2 The measures at issue

2.18. According to the European Union, the measures at issue in these proceedings are:

- a. a "localisation requirement" whereby "Turkey requires foreign producers to commit to localise in Turkey their production of certain pharmaceutical products"⁷⁰, and "[i]f such commitments are not given, are not accepted by Turkish authorities, or are not fulfilled, the pharmaceutical products concerned are excluded from the scheme for the reimbursement of the pharmaceutical products sold by pharmacies to patients operated by Turkey's social security system (the 'reimbursement scheme')"⁷¹;
- b. an "import ban on localised products" which the European Union describes as follows: "[w]here the production of a pharmaceutical product has been localised in Turkey in accordance with the localisation requirement, applied in conjunction with the Turkish rules for approving the importation and marketing of pharmaceutical products, the importation of that pharmaceutical product is no longer permitted"⁷²; and
- c. a "prioritization measure" whereby "even in certain cases where imported products are not excluded from the reimbursement scheme by virtue of the localisation requirement, Turkey gives priority to the review of applications for inclusion of domestic pharmaceutical products in the list of products covered by the reimbursement scheme, as well as with respect to any pricing and licensing policies and processes, over the review of the applications of like imported products."⁷³

2.19. According to the European Union, these measures at issue are "put in place and evidenced by, and are implemented and administered through" 28 different legal instruments or other types of documents, "considered alone and in any combination".⁷⁴

⁶⁶ HIC/SUT (Exhibits EU-95, TUR-10), Article 1.8.2(1). A contribution fee refers to the amount to be paid by the universal health insurance holder or the dependents in order to benefit from healthcare services (ibid, Article 1.8.1). Outpatients do not pay contribution fees for certain pharmaceutical products included in the List of Drugs Exempt from Patient Contribution Fee (Annex 4/D) (ibid. Article 1.8.2(3)). Turkey explains that these include products "necessary for the treatment of critical diseases such as cancer or long-standing chronic diseases" and products that are "used in the treatment of inpatients in both public and private hospitals" (Turkey's first written submission, fn 90). According to Turkey, in 2019, 34.7% of the total SSI's expenditure for medicines was exempt from the payment of the contribution fee (Turkey's first written submission, fn 90).

⁶⁷ HIC/SUT (Exhibits EU-95, TUR-10), Article 1.8.2(2).

⁶⁸ Social Security Institution, Directorate General for Provision of Services Healthcare Software Department, "Medula Project" presentation, 2019 (Exhibit TUR-112), p. 17.

⁶⁹ Turkey's second written submission, para. 52.

⁷⁰ European Union's panel request, p. 5.

⁷¹ European Union's panel request, p. 5. Turkey refers to the localisation requirement as the "localisation measure", because "Turkey understands that the measure that is challenged by the European Union is not only the 'requirement' allegedly imposed by Turkey on foreign producers to localise their production of certain pharmaceutical products in Turkey, but also the consequences following from the commitment or lack of commitment of localisation. In light thereof, Turkey will refer to this measure as the 'localisation measure' rather than as the 'localisation requirement'." (Turkey's first written submission, para. 117.)

⁷² European Union's panel request, p. 6.

⁷³ European Union's panel request, p. 6.

⁷⁴ European Union's panel request, p. 1.

2.2.1 The localisation requirement

2.2.1.1 Overview

2.20. The localisation requirement relates to Turkey's policy objective of achieving the gradual transition from imports to domestic manufacturing of pharmaceuticals.⁷⁵ To achieve this policy objective, Turkey requires foreign producers to commit to localise in Turkey their production of certain pharmaceutical products.⁷⁶ If a foreign producer does not make a commitment for a pharmaceutical product subject to localisation, if the Turkish authorities reject the commitment, or if the commitment made is not fulfilled, the pharmaceutical product concerned is no longer reimbursed by the SSI.

2.21. The main authorities within or affiliated with the Ministry of Health and the Ministry of Family, Labour and Social Services in charge of implementing the localisation requirement are⁷⁷: the SSI, its commissions⁷⁸ and sub-commissions⁷⁹; the TMMDA⁸⁰; the Healthcare Industries Steering Committee (HISC)⁸¹, and the Localisation Assessment Commission (LAC).⁸²

2.22. The parties disagree on whether the European Union has established the existence and precise content of the "localisation requirement" as a "single and cohesive measure". The Panel addresses this issue in its findings in section 7 of this Report.

⁷⁵ The objective is to meet 60% (by value) of domestic pharmaceutical demand through domestic production. (Republic of Turkey, Ministry of Development, Tenth Development Plan 2014-2018 (2014), approved by Decision No. 1041 of the Grand National Assembly of Turkey of 2 July 2013 (Tenth Development Plan 2014-2018) (Exhibit EU-12), point 1.16.) This 60% figure relates to the share of locally produced medicines in terms of sales value of the total domestic demand for medicines. (Turkey's responses to the second set of questions, para. 72.)

⁷⁶ Turkey explains that this does not mean that the entire production process needs to take place in Turkey, but rather that "the bulk production, i.e. the establishment of a finished pharmaceutical form (granular, tablet, solution) from raw materials (active substances) and excipients (inactive substances), takes place in Turkey." (Turkey's first written submission, para. 137.)

⁷⁷ The European Union also refers to the Commission on the Transition from Import to Manufactured Products (European Union's first written submission, para. 69) and the Localisation Executive Board (European Union's first written submission, para. 75). Turkey however asserts that neither of these bodies is operational. (Turkey's first written submission, paras. 143 and 147.)

⁷⁸ The SSI's HSPC sets out detailed steps and rules for the implementation of the localisation requirement. In particular, in October 2016, the HSPC adopted a Decision regarding the Localisation Process, which sets out the process and criteria for implementing the localisation requirement. (HSPC, Decision regarding the Localisation Process, October 2016 (HSPC Decision) (Exhibit EU-35.) Both the DRC and the ARC are sub-commissions of the HSPC.

⁷⁹ The SSI and its sub-commissions update the status of pharmaceutical products included in the Annex 4/A list and notify pharmaceutical companies about changes in the status of their products. The ARC plays an important role, in particular with respect to approving the passivization, re-activation and exclusion of pharmaceutical products from the Annex 4/A list. Turkey explains that the ARC has the authority to set the status of pharmaceutical products for which no localisation commitment has been offered or for which the localisation commitments have not been accepted to "passive". (Turkey's first written submission, para. 146.) According to the European Union it is not clear on which legal basis the ARC assumes this role. (European Union's first written submission, para. 33.) Turkey refers to Social Security Institution Decision No.2015/3 of 1 April 2015 (Exhibit TUR-45), transferring some of the powers of the HSPC to the ARC. (Turkey's first written submission, para. 146.)

⁸⁰ The TMMDA (i) determines which pharmaceutical products will be subject to localisation in each phase; (ii) examines the pharmaceutical companies' commitments and variation applications; and (iii) communicates the decisions regarding proposed commitments.

⁸¹ The Healthcare Industries Steering Committee (HISC) discusses the overall implementation of the localisation requirement, assigns relevant tasks to the specific authorities. (Turkey's first written submission, para. 144.) The HISC also "had an important role in designing the several phases of localisation." (European Union's first written submission, para. 68.)

⁸² The Localisation Assessment Commission (LAC) is a working group under the TMMDA created by the HISC, which reviews requests for exemption (i.e. offers to localise alternative pharmaceutical products) and for additional time. Based on this assessment, the LAC decides which products should be passivized by the SSI and which products should be re-assessed. (Turkey's first written submission, para. 145, (referring to Healthcare Industries Steering Committee, Minutes of the 56th meeting, 13 December 2017 (Exhibit TUR-43))).

2.2.1.2 Phases of implementation of the localisation requirement

2.23. The localisation requirement by design has five phases, which progressively target different products depending on their market share and the existence of equivalent products in the domestic market.⁸³ The phases are divided as follows:

- Phase 1 covers pharmaceutical products for which the overall market share of domestic production in the equivalent group is above 50% and there are three or more different local companies producing locally three or more generic pharmaceutical products. In January 2018, the SSI announced that a list of 45 pharmaceutical products included in the scope of Phase 1 would no longer be reimbursed as of 8 February 2018.⁸⁴
- Phase 2 covers pharmaceutical products for which the overall market share of domestic production in the equivalent group is between 10% and 50% and there are two or more different local companies producing locally two or more generic pharmaceutical products. In January 2017, the TMMDA held meetings with pharmaceutical companies producing Phase 2 products and later assessed the proposed commitments. The authorities subsequently announced that certain products would no longer be reimbursed as a result of the implementation of Phase 2.⁸⁵
- Phase 3 covers pharmaceutical products for which the overall market share of domestic production in the equivalent group is below 10% and there is one local company producing locally one generic pharmaceutical product.
- Phase 4 covers pharmaceutical products for which there is no domestic production in the equivalent group.
- Phase 5 covers pharmaceutical products with no equivalent groups.

2.24. The implementation of the localisation requirement is a dynamic process⁸⁶: some phases are operational in parallel⁸⁷, and the Turkish authorities regularly check to see if there are new products, or products that have to be moved from one phase to another.⁸⁸ As indicated above, the authorities have already identified products that, in the absence of localisation commitments being made by the producers and accepted by the authorities, will no longer be reimbursed by the SSI as a result of the implementation of Phases 1 and 2.⁸⁹ Meetings have been organized with pharmaceutical companies producing medicines that fall within the scope of the remaining phases inviting them to

⁸³ See H. Gursoz, President of the TMMDA, "Pharmaceutical Localisation Project: Transition from Importation to Manufacturing", presentation of 6 March 2017 (Exhibit EU-34), slide 3; TMMDA, "Pharmaceutical Localisation Project Work Conducted by the Ministry of Health", presentation of December 2017 (Exhibit EU-23), slide 9.

⁸⁴ Social Security Institution, Public Announcement on the Localisation Process, 19 January 2018 (Exhibits EU-62, TUR-58). See also European Union's first written submission, para. 125; Turkey's first written submission, para. 157.

⁸⁵ TMMDA, "Pharmaceutical Localisation Project Work Conducted by the Ministry of Health", presentation of December 2017 (Exhibit EU-23), slide 10.

⁸⁶ Turkey's first written submission, para. 140; European Union's first written submission, para. 82.

⁸⁷ European Union's first written submission, para. 95.

⁸⁸ Turkey explains that products are shifted from one phase to another because of changes in their market situations. (Turkey's second written submission, para. 17.) Turkey gives the example of a pharmaceutical product initially covered by Phase 3, which could become subject to Phase 2 if its market share exceeds 10%. (Ibid. para. 17.)

⁸⁹ The parties appear to agree that the implementation of Phases 1 and 2 has already resulted in the identification of products that will no longer be reimbursed by the SSI. Turkey asserts that "[o]nly Phase 1 and Phase 2 have been implemented so far." (Turkey's first written submission, para. 140.) The European Union submits that "so far, products have been deactivated within the framework of the first and second phase." (European Union's first written submission, para. 99.) See also Republic of Turkey, Ministry of Development, Eleventh Development Plan (2019-2023) Transformation in Healthcare Industries, Specialised Committee Report of July 2018 (Ministry of development, Eleventh Development Plan 2019-2023) (Exhibit EU-84), section 2.3.5: "[t]he first and second phases of this project, which is of key importance for the sector, have been successfully completed and are continually being updated. Work on the third phase is also under way. Preparatory work on the fourth and fifth phases has started."

present their views and to offer preliminary commitments, but as of the time of the Panel's establishment all products currently in the scope of Phases 3, 4 and 5 remain reimbursable.⁹⁰

2.2.1.3 Localisation process

2.25. The localisation process starts with the identification of the relevant products by the Turkish authorities (in particular, the TMMDA).⁹¹ The pharmaceutical companies producing these products are informed, through periodically published announcements or an individual communication, that their products are to be included in the scope of the localisation requirement, and are invited to a meeting at the Ministry of Health.⁹² The pharmaceutical companies then enter into discussions with the competent authorities with a view to preparing a "transition plan"⁹³ and submitting commitments to produce locally.⁹⁴ The time schedule for implementing any commitments typically must not surpass 18 months.⁹⁵ Pharmaceutical companies may also submit various requests to the TMMDA, including requests for additional time or for the localisation of an alternative product.⁹⁶

2.26. Any commitments made by pharmaceutical companies that have been accepted are followed up through regular progress reports presented by the pharmaceutical companies to the TMMDA. If a company does not submit a localisation commitment, the relevant products are no longer reimbursed

⁹⁰ Turkey's first written submission, paras. 161-162; European Union's first written submission, para. 132. Preliminary commitments have been submitted for some Phase 3 products, resulting in the amendment of the scope of Phase 2 to also cover Phase 3 products for which preliminary commitments were submitted. (Turkey's first written submission, para. 160.) The European Union asserts that the Turkish authorities have taken steps to implement Phases 3 and 4. (European Union's first written submission, para. 132.) Turkey disagrees and asserts that "[n]o further steps have been taken to implement either Phase 3 or Phase 4" (Turkey's first written submission, para. 162) and that Turkey "may decide not to proceed with [their] implementation." (Turkey's comments on responses to the second set of questions, para. 2.) The Panel notes the parties' disagreement on this point. The Panel also notes the European Union's argument that "[t]here is no doubt that phrases 3-5 exist, because they are part of and are provided for by the Localisation Requirement, even if they have not been applied yet." (European Union's responses to the second set of questions, para. 5.)

⁹¹ All products that hold a valid marketing authorization and sales permit in Turkey and that are included in the Annex 4/A list are initially considered within the scope of the localisation requirement. (Turkey's first written submission, para. 138; European Union's second written submission, para. 33, and comments on responses to the second set of questions, para. 3.)

⁹² Turkey uses the terms "meeting" and "consultation meeting" (Turkey's first written submission, paras. 148-149), while the European Union observes that the parties may disagree on whether the Turkish term "*görüşme*" should be translated as "meeting", "discussion" or "negotiation". (European Union's second written submission, para. 25.) The European Union notes, however, that it is unclear to what extent this is relevant. (European Union's second written submission, para. 25.)

⁹³ European Union's first written submission, para. 77 (referring to H. Eroğlu, Vice President of the TMMDA, "Local Production", presentation at the Symposium on Rational Approach to Current Issues concerning Medicines, Ankara, 7-9 October 2016 (Exhibit EU-40)).

⁹⁴ As Turkey explains, such commitments "in essence, amount to a declaration whether or not a pharmaceutical company will relocate within a specified period of time the production of the relevant pharmaceutical products to Turkey." (Turkey's first written submission, para. 149.)

⁹⁵ European Union's first written submission, paras. 105 and 114. See Roadmap for the process of localisation, setting forth of the principles for the negotiation, 14 March 2016 (Localisation roadmap) (Exhibits EU-45, TUR-60).

⁹⁶ Turkey's first written submission, para. 151; European Union's second written submission, para. 33.

by the SSI.⁹⁷ This is also the case if a company submits a localisation commitment, but this commitment is considered not to be "appropriate"⁹⁸, or if a company does not fulfil its commitment.

2.2.2 The import ban on localised products

2.27. When a pharmaceutical company commits to localise the production of a product and this commitment is accepted, the company has to submit, within a year, a variation application. This is a request to modify the marketing authorization for the relevant product from "import" to "local".⁹⁹

2.28. Pursuant to Article 20(2) of the Marketing Authorization Regulation:

A second local or import marketing authorization shall not be granted for any product with the same formulation and pharmaceutical form, already authorized by the Ministry, to the same real person or legal entity, even if the product has a different commercial name.¹⁰⁰

2.29. The alleged "import ban on localised products", as described by the European Union, arises from the combined operation of the localisation requirement and the Turkish rules for approving the importation and marketing of pharmaceutical products, and in particular Article 20(2) of the Marketing Authorization Regulation (Single Authorization rule).¹⁰¹ The parties hold diverging positions on the nature, scope, and significance of the restrictions arising from the Single Authorization rule. They also disagree on whether the localisation requirement and Single Authorization rule operate together as part of a "single measure" that exists distinct from its components. The Panel will address these issues, insofar as necessary, in its findings in section 7 of this Report.

⁹⁷ The parties disagree as to whether the products are "passivized" or "excluded" from the Annex 4/A list. The European Union asserts that "the pharmaceutical products concerned are *excluded* from the scheme for the reimbursement of the pharmaceutical products sold by pharmacies to patients operated by Turkey's social security system." (European Union's first written submission, para. 6 (emphasis added); see also European Union's first written submission para. 141; comments on responses to the second set of questions, paras. 8 and 9.) Turkey asserts that "imported pharmaceutical products may be 'passivized' if they do not comply with the localisation measure" (Turkey's first written submission, para. 82 (emphasis added)), that such products are never "excluded" from the Annex 4/A list, and that they may be re-activated "at any time should the pharmaceutical company decide to localise their production". (Turkey's comments on responses to the second set of questions, para. 4.) Turkey also asserts that, unlike in all other circumstances in which products are "passivized", pharmaceutical products which are passivized as a result of the localisation measure are not excluded from the Annex 4/A list after 10 months, but instead retain a "passivized" status. (Turkey's first written submission, para. 82; responses to the second set of questions, para. 12; and comments on responses to the second set of questions, para. 5.) The European Union considers that Turkey points to no evidence to substantiate this distinction. (European Union's second written submission, para. 69.) Finally, Turkey asserts that, before being passivized, these products remain "active" (and, therefore, reimbursable) for a period of one year, thereby providing the pharmaceutical company with an opportunity for "reconsidering its position". (Turkey's first written submission, para. 152; responses to the second set of questions, para. 7; and European Union's second written submission, para. 33.) The European Union notes that in this case, the products would eventually be localised or passivized. (European Union's comments on responses to the second set of questions, para. 7.)

⁹⁸ In this case, the SSI and TMMDA jointly notify the company that the relevant products "shall be excluded from the reimbursement list one year after the decision for exclusion from the reimbursement list is taken." (SSI and TMMDA, Communication, "Local Production" (Exhibit EU-46); HSPC Decision (Exhibit EU-35), para. 4.) Turkey argues that in this situation, the products are passivized and not "removed" from the list (Turkey's first written submission, para. 153), whereas the European Union asserts that the refusal of commitments "leads to an exclusion from reimbursement." (European Union's first written submission, para. 141.)

⁹⁹ Turkey's first written submission, para. 150; European Union's second written submission, para. 33. This is mandated by the Regulation regarding the Variations on Medicinal Products for Human Use with Marketing Authorisation or Pending Registration, Official Gazette No. 25823 of 23 May 2005 (Exhibit EU-93). The TMMDA delivers, or rejects the delivery of, marketing authorizations for both imported and locally produced pharmaceutical products.

¹⁰⁰ Marketing Authorization Regulation (Exhibit EU-89), Article 20(2).

¹⁰¹ European Union's panel request, p. 6.

2.2.3 The prioritization measure

2.30. The TMMDA's Guideline for Working Principles and Procedures of Human Medicinal Products Priority Assessment Commission (Prioritization Guideline)¹⁰² provides for the possibility to request priority assessment, in particular, of applications for GMP certification and marketing authorization, and of certain requirements relating to pharmaceutical products in specific cases. The Prioritization Guideline sets out the criteria that determine whether a particular product is eligible for priority assessment, as well as the procedure that must be followed to obtain priority assessment and treatment. The Prioritization Guideline also establishes a Prioritization Commission which is in charge of examining applications.¹⁰³

2.31. "Prioritization" can be requested for ten categories of applications, including applications relating to transferring the production of imported medicines to Turkey¹⁰⁴, applications for locally manufactured products for exportation purposes¹⁰⁵, and applications relating to products that have strategic importance in terms of the country's policies.¹⁰⁶

2.32. In addition, the Drug Reimbursement Regulation provides for the possibility of according priority to the applications for inclusion in the Annex 4/A list of some pharmaceutical products.¹⁰⁷

2.33. The parties disagree on whether the "prioritization measure", as characterized in the European Union's panel request and subsequent submissions, is challenged "as such", or concerns ongoing conduct. The Panel will address that issue, insofar as necessary, in its findings in section 7 of this Report.

3 PARTIES' REQUESTS FOR FINDINGS AND RECOMMENDATIONS

3.1. The European Union identifies three measures at issue in this dispute, which it refers to as "the localisation requirement", "the import ban on localised products", and "the prioritization measure". The European Union makes multiple claims in respect of these three measures, and Turkey presents multiple grounds on which it requests that the Panel reject all of these claims. Certain of the claims and defences are made in the alternative. To facilitate an understanding of the specific legal claims and defences and how they relate to one another, this section presents a breakdown of the claims and defences on a measure-by-measure basis, drawing on the European Union's panel request and the parties' submissions.

3.2. Regarding the localisation requirement, the European Union's panel request and submissions set out the following claims:

- a. the localisation requirement is inconsistent with Article III:4 of the GATT 1994, because, by excluding from the reimbursement scheme imported pharmaceutical products for which localisation commitments have not been given, have not been accepted or have not been fulfilled Turkey accords to imported pharmaceutical products treatment less favourable than that accorded to like products of national origin covered by that scheme;
- b. the localisation requirement is inconsistent with Article 2.1 of the TRIMs Agreement, because the localisation requirement is an investment measure related to trade in goods that is inconsistent with Article III:4 of the GATT 1994;
- c. in the alternative to the claims under Article III:4 of the GATT 1994 and Article 2.1 of the TRIMs Agreement¹⁰⁸, the localisation requirement is inconsistent with Article 3.1(b) of the

¹⁰² TMMDA, Guideline for Working Principles and Procedures of Human Medicinal Products Priority Assessment Commission (Prioritization Guideline) (Exhibit EU-97).

¹⁰³ The Prioritization Commission may put some products on its agenda without application if deemed necessary (Prioritization Guideline (Exhibit EU-97), Article 8(1)).

¹⁰⁴ Prioritization Guideline (Exhibit EU-97), Article 2(c).

¹⁰⁵ Prioritization Guideline (Exhibit EU-97), Article 2(d).

¹⁰⁶ Prioritization Guideline (Exhibit EU-97), Article 2(h).

¹⁰⁷ Drug Reimbursement Regulation (Exhibits TUR-11, EU-8), Articles 5(1)(g) and 5(1)(ğ).

¹⁰⁸ The European Union states that it "submits this claim in the alternative to its claim against the Localisation Requirement under Article III:4 of the GATT set forth in section 2.3. In other words, the European Union requests the Panel to rule on this claim only in the event that the Panel were to conclude that the

SCM Agreement, because the reimbursement scheme operated by the Turkish social security system involves the granting of a subsidy within the meaning of Article 1.1 of the SCM Agreement, and the localisation requirement makes the granting of that subsidy contingent upon the use of domestic over imported goods; and

- d. the localisation requirement is inconsistent with Article X:1 of the GATT 1994, because Turkey failed to publish certain elements, terms and conditions of general application of the localisation requirement promptly in such a manner as to enable governments and traders to become acquainted with them.

3.3. In its submissions, Turkey requests that the Panel reject all the European Union's claims regarding the localisation requirement on the grounds that:

- a. while the European Union characterizes the localisation requirement as a "single and cohesive measure", it fails to precisely identify the legal instruments forming part of or giving effect to the measure, and *a fortiori* provide evidence of how these components operate together as part of a single measure, and thereby fails to demonstrate the existence and precise content of the localisation requirement as a "single and cohesive measure";
- b. there is no inconsistency with Article III:4 of the GATT 1994 or Article 2.1 of the TRIMs Agreement as:
 - i. the procurement of pharmaceutical products included in the Annex 4/A list by the SSI constitutes government procurement within the meaning of Article III:8(a) of the GATT 1994 and thus the localisation requirement falls outside the scope of the national treatment obligation under Article III:4 of the GATT 1994 and Article 2.1 of the TRIMs Agreement;
 - ii. the localisation requirement is justified under Article XX(b) of the GATT 1994 because it is necessary to ensure uninterrupted access to safe, effective and affordable medicines in Turkey;
 - iii. in the alternative¹⁰⁹, the localisation requirement is justified under Article XX(d) of the GATT 1994 because it is necessary to secure compliance with laws requiring Turkey to ensure accessible, effective and financially sustainable healthcare;
- c. there is no inconsistency with Article 3.1(b) of the SCM Agreement because:
 - i. there is no subsidy within the meaning of the SCM Agreement since there is no financial contribution in the form of direct transfer of funds and no benefit is conferred. More specifically, any direct benefit to outpatients conferred by Turkey's reimbursement scheme falls outside the scope of Article 1.1 of the SCM Agreement, and the European Union has not established that any indirect benefit is conferred upon producers of the pharmaceutical products listed in Annex 4/A; and
 - ii. any alleged subsidy is not contingent upon the use of domestic over imported products within the meaning of Article 3.1(b) of the SCM Agreement; and
- d. the claim under Article X:1 of the GATT 1994 should be dismissed because:
 - i. the European Union has changed the scope of its claim in a way that raises serious due process concerns and/or falls outside the Panel's terms of reference; and
 - ii. the European Union has failed to demonstrate that the relevant measure(s), whether understood as a single cohesive measure, individual instruments/documents, or

Localisation Requirement is not in breach of Article III:4 of the GATT 1994, or that such breach is justified under any other provision of the GATT 1994." (European Union's first written submission, para. 382.)

¹⁰⁹ Turkey's first written submission, para. 504.

certain terms and conditions, fall within the scope of the obligation in Article X:1, and/or were not published promptly and adequately.

3.4. Concerning the "import ban on localised products" which, according to the European Union, arises from the localisation requirement "applied in conjunction with" the Turkish rules for approving the importation and marketing of pharmaceutical products, and in particular the Single Authorization rule, the European Union requests that the Panel find that this measure is inconsistent with Article XI:1 of the GATT 1994.

3.5. Turkey requests that the Panel reject the European Union's claim under Article XI:1 of the GATT 1994, on the grounds that:

- a. while the European Union characterizes the "import ban measure" as a "single measure", it fails to show how the different components operate together as part of a "single measure" distinct from its components, and thereby fails to establish the existence and precise content of the import ban measure as a "single measure";
- b. the measure causing the alleged restriction, i.e. the Single Authorization rule, does not fall within the scope of Article XI:1 and is an internal measure within the meaning of Article III:4 of the GATT 1994, and even if Article XI:1 applies there is no "ban" or "prohibition" on the importation of localised products. This is because, *inter alia*, the very same product, in a different form or different dosage, can receive a marketing authorization with a production site abroad. Turkey draws two conclusions from the fact that there is no "ban" on pharmaceutical products: (i) the measure which is characterized by the European Union as an "import ban" does not exist; and (ii) there is no violation of Article XI:1 of the GATT 1994 insofar as it applies to the measure at issue¹¹⁰;
- c. the import ban is justified under Article XX(d) of the GATT 1994 because it is necessary to secure compliance with the localisation requirement.

3.6. As to the prioritization measure, the European Union requests that the Panel find that this measure is inconsistent with Turkey's obligations under Article III:4 of the GATT 1994, because Turkey accords priority to the review of applications for inclusion in the reimbursement scheme, as well as with respect to any pricing and licensing policies and processes, to pharmaceutical products of national origin.

3.7. In its submissions, Turkey requests that the Panel reject the European Union's claim under Article III:4 of the GATT 1994 regarding the prioritization measure, on the grounds that:

- a. the European Union characterizes the measure as an overarching measure whereby Turkey "gives priority" to domestic pharmaceutical products, but fails to demonstrate the existence of ongoing conduct consisting in Turkish authorities granting priority to domestically produced pharmaceutical products, and thereby fails to demonstrate the existence of the challenged measure;
- b. the European Union has failed to demonstrate that the prioritization measure, understood as an overarching measure, is a law, regulation or requirement within the scope of Article III:4 of the GATT 1994, or that the prioritization measure accords "treatment less favourable" to imported products, given the discretion of the authorities when assessing priority applications.

3.8. The European Union requests, pursuant to Article 19.1 of the DSU, that the Panel recommend that Turkey bring its measures into conformity with its WTO obligations.

3.9. Turkey requests that the Panel reject all of the European Union's claims and confirm that Turkey's measures are not inconsistent with its WTO obligations under the covered agreements.

¹¹⁰ Turkey's first written submission, paras. 587-593, and 617.

4 ARGUMENTS OF THE PARTIES

4.1. The arguments of the parties are reflected in their executive summaries, provided to the Panel in accordance with paragraph 23 of the Working Procedures adopted by the Panel (see Annexes C-1 and C-2).

5 ARGUMENTS OF THE THIRD PARTIES

5.1. The arguments of Canada, Japan, Switzerland, Ukraine, and the United States are reflected in their executive summaries, provided in accordance with paragraph 26 of the Working Procedures adopted by the Panel (see Annexes D-1, D-2, D-3, D-4 and D-5). Brazil, China, India, Indonesia, and the Russian Federation did not submit written or oral arguments to the Panel.

6 INTERIM REVIEW

6.1 Introduction

6.1. On 30 September 2021, the Panel issued its Interim Report to the parties. On 14 October 2021, the European Union and Turkey each submitted written requests for the Panel to review precise aspects of the Interim Report. On 28 October 2021, the European Union and Turkey submitted comments on each other's requests for review. Neither party requested an interim review meeting.

6.2. In accordance with Article 15.3 of the DSU, this section of the Report sets out the Panel's response to the parties' requests made at the interim review stage. The Panel generally addresses the parties' requests individually and in sequence according to the paragraphs to which such requests pertain. The Panel addresses related requests together to avoid repetition. To provide context, the Panel structures its discussion using the subheadings of the Report where the relevant paragraphs are found.

6.3. In addition to the requests for substantive modifications discussed below, various corrections or improvements of a typographical or minor editorial nature were made to the Report, including but not limited to those suggested by the parties.

6.4. The numbering of some of the paragraphs and footnotes in the Final Report has changed from the numbering in the Interim Report. Except where otherwise indicated, references to footnote numbering in the discussion below correspond to the numbering in the Final Report.

6.2 General issue

6.5. As a general issue, Turkey states that it regrets that despite its earlier comments on the draft descriptive part of the Report¹¹¹, the Panel decided to use the incorrect and misleading terminology suggested by the European Union and throughout the Report used terms such as "reimbursement" (to describe the Turkish system of the provision of medicines included in Annex 4/A) and "consumers" (to describe patients). Turkey states that it does not agree with the use of these terms and requests the Panel to accurately reflect that in the Final Report. Turkey also requests the Panel to provide an explanation as to why it decided to use the terminology suggested by the European Union given that this terminology has been consistently contested by Turkey throughout the proceedings.

6.6. The European Union does not comment.

6.7. The Panel first notes that, contrary to what is suggested by Turkey's request, the Panel has not used the terminology suggested by the European Union throughout the Report: the Panel has sought to use neutral formulations.¹¹² The Panel further notes that, contrary to what is implied by

¹¹¹ Turkey's comments on the draft descriptive part of the Panel Report, para. 28.

¹¹² For example, instead of referring to the Annex 4/A list as the "reimbursement list" or the "list of medicines to be paid for", the Panel simply refers to it as the Annex 4/A list. In various other instances, the Panel uses the terms "reimburses" and "pays for" interchangeably, depending on the context. While the Panel in several instances refers to Turkey's "pharmaceutical reimbursement system", such terminology is mostly used as a generic shorthand expression. The Panel's analysis under Article III:8(a) of the GATT 1994 is generally cast in Turkey's own terminology, including the entirety of the Panel's assessment of Turkey's

Turkey's request, the Panel acknowledges and has already fully reflected, in the Report, that Turkey does not agree with the European Union's use of terms such as "reimbursement" and "consumer".¹¹³ Finally, and again contrary to what might be suggested by Turkey's request, the Panel has already provided thorough explanations of its approach to disputed terminology.¹¹⁴ For these reasons, the Panel rejects the premise underlying Turkey's request that the Panel provide an explanation "as to why it decided to use the terminology suggested by the European Union given that this terminology has been consistently contested by Turkey throughout the proceedings".

6.3 Descriptive part of the Report

6.3.1 Translation issues

6.8. Turkey observes that **paragraph 1.20** describes its position regarding the translation of certain terms included in Turkish legal instruments and documents. Turkey requests two changes. First, Turkey notes that the final two sentences suggest that whereas Turkey addressed "some" of the European Union's comments, it acquiesced to the European Union's broader statement that Turkey agreed with the European Union's factual description of the "Localisation Requirement and Turkey's reimbursement system for outpatient pharmaceuticals". Turkey considers that this characterization is misleading as it does not reflect Turkey's detailed response to the European Union's factual description at paragraphs 16-33 of Turkey's second written submission. Second, Turkey notes that despite its request for modification in the context of its comments on the draft descriptive part of the Report¹¹⁵, the Panel did not amend that paragraph as suggested by Turkey. Turkey reiterates its request to add additional explanation at the end of that paragraph in order to better reflect Turkey's arguments.¹¹⁶

6.9. The European Union disagrees with Turkey's request to have the Panel reflect that its second written submission "corrected the errors made by the European Union..." as it would create the impression of a finding, by the Panel, that the European Union made errors. The remaining

argument that the SSI "purchases" pharmaceutical products by paying for them. Furthermore, contrary to Turkey's statement that the Panel decided to use the incorrect and misleading terminology suggested by the European Union and throughout the report used the term "consumers" to describe patients, the Panel has consistently used the neutral expression "final consumers (i.e. outpatients)".

¹¹³ The Panel did so first in the descriptive part of the Report (see footnotes 36 and 56), and then again in the context of its findings (see in particular paragraph 7.91). The Panel observes that the present discussion now serves as an additional reflection that Turkey does not agree with the European Union's use of terms such as "reimbursement" and "consumer".

¹¹⁴ The Panel made clear in the descriptive part that the terminology used in certain instances would not prejudice any disputed issue about the proper characterization of the measure before the Panel (footnote 36). The Panel has also made clear in the relevant section of its findings that its conclusions and reasoning are not based on semantic considerations (see paragraph 7.91). More specifically, the Panel recalled the parties' disagreement over the correct translation of certain terms used in Turkish instruments and documents, and their wider disagreements over terminology, and clarified that its conclusion and reasoning are not based on such semantic considerations and are instead grounded in an objective legal standard arising from its understanding of the term "product purchased" in the context of Article III:8(a) of the GATT 1994.

¹¹⁵ Turkey's comments on the draft descriptive part of the Panel Report, para. 5.

¹¹⁶ In particular, Turkey requests the Panel to amend paragraph 1.20 as follows:

1.20. In its second written submission, the European Union stated that "[w]hile mistakes are always possible, nothing in the EU's translations supports Turkey's allegation that the EU was attempting to mislead the Panel." The European Union responded to some of the translation issues raised by Turkey. The European Union also submitted that "Turkey agrees with the main factual elements of the Localisation Requirement and Turkey's reimbursement system for outpatient pharmaceuticals, as described by the EU." In its second written submission, Turkey addressed ~~some of~~ the European Union's responses, **corrected the errors made by the European Union with respect to the factual elements** and reiterated its position with respect to the translation of certain terms. **In particular, Turkey explained that the SSI does not "reimburse" an already paid amount, but directly pays the prices of the dispensed medicines to retail pharmacies instead of the patients. Furthermore, Turkey explained that the word "temin" in the context of the Protocol concluded between the SSI and the Turkish Pharmacists' Association corresponds to "the provision" of medicines by retail pharmacies to patients, rather than "the procurement" of medicines by patients.**

suggestions by Turkey seem unnecessary, and even if considered, should state, for example, "Turkey argued", instead of "explained", which similarly creates the impression of a Panel finding.

6.10. The Panel observes that section 1.5 of the Report, which is entitled "Translation issues" and consists of three paragraphs, is meant to serve the limited purpose of recording the fact that disputed issues of translation arose in the course of the proceedings. Paragraph 1.20 does not aim to comprehensively set out the parties' positions on those issues. Bearing in mind the context and limited purpose of paragraph 1.20, the Panel does not consider the changes requested by Turkey to be necessary and appropriate. First, the Panel does not consider that the current text, read in its context, implies that Turkey acquiesced to the European Union's broader statement that Turkey agreed with the entirety of European Union's factual description of the "Localisation Requirement and Turkey's reimbursement system for outpatient pharmaceuticals". Nor does the Panel consider it appropriate to add two additional sentences setting out in further detail Turkey's arguments on the correct translation of particular terms. Among other things, Turkey's arguments on both of these points (the term "reimbursement" and the title of the Protocol) are reflected elsewhere in both the descriptive part of the Report and in the Panel's findings.

6.3.2 Factual aspects

6.3.2.1 Turkey's Universal Health Insurance Scheme and relevant governmental entities

6.11. Turkey notes that the second sentence of **paragraph 2.4** paraphrases Turkey's description of the SSI's responsibilities, providing that "[i]t is responsible for paying for all healthcare goods and services, including pharmaceuticals". However, the part of paragraph 39 of Turkey's first written submission, which the Panel has paraphrased, lists an additional responsibility of the SSI, namely, that "[i]t is also the SSI who oversees the distribution of pharmaceutical products to patients". Turkey notes that this description was included in the draft descriptive part shared by the Panel with the parties but was deleted from the Interim Report. Turkey considers that the current wording does not reflect its description of the responsibilities of the SSI and requests that the second sentence of paragraph 2.4 be modified to reflect the additional responsibility.¹¹⁷

6.12. The European Union disagrees with Turkey's suggestion to the extent that it substitutes Turkey's own views of the SSI's role for Panel findings. The European Union would not object if the Panel expanded on its findings on the role of the SSI but disagrees that the SSI "oversees the distribution of pharmaceutical products to patients". According to the European Union, such a finding is not borne out by the record.

6.13. The Panel recalls that, in its comments on the draft descriptive part of the Report, the European Union requested that the Panel amend the second sentence, as initially drafted, to include the qualification that the SSI "... oversees the distribution of pharmaceutical products to patients **in certain cases**." Anticipating a lack of agreement between the parties on how to formulate the SSI's "oversight" responsibility, the Panel elected to delete this reference in paragraph 1.20 because it was not necessary to the focus of this paragraph. However, in the light of Turkey's request to reintroduce a reference to this responsibility, while taking into account the European Union's subsequent objection, the Panel has revised paragraph 2.4 to neutrally state that "[i]t is responsible, ***inter alia***, for paying for all healthcare goods and services, including pharmaceuticals".

6.3.2.2 Reimbursement of pharmaceutical products

6.14. Turkey observes that **paragraph 2.7** sets out the process by which pharmaceutical products included in the Annex 4/A list are provided to patients and describes the role of retail pharmacies in that process. Turkey notes that the Panel did not amend that paragraph as requested by Turkey in the context of its comments on the draft descriptive part of the Report.¹¹⁸ Turkey reiterates its request to redraft this paragraph in order to accurately explain the system of dispensing pharmaceutical products to patients in Turkey. In particular, Turkey notes that the first sentence provides, at the end, that retail pharmacies "are private entities", but this statement ignores the "public role" of retail pharmacies as "primary healthcare service providers" under Turkish law. Turkey

¹¹⁷ In particular, Turkey requests the following revision: "It is responsible for paying for all healthcare goods and services, including pharmaceuticals, **and overseeing the distribution of pharmaceutical products to patients**".

¹¹⁸ Turkey's comments on the draft descriptive part of the Panel Report, para. 10.

states that this "public role" of the retail pharmacies has been described in detail in paragraphs 104-107 of Turkey's first written submission and paragraphs 27, 30, 48-49 and 82-85 of Turkey's second written submission. In addition, Turkey considers that the juxtaposition offered in the second sentence of paragraph 2.7 between the "main" amounts charged by pharmacies met by the SSI and out-of-pocket payments understates the share of the amounts covered by the SSI. Turkey proposes the addition of several additional sentences and revisions to paragraph 2.7 to reflect these points.¹¹⁹

6.15. The European Union disagrees with Turkey's suggestion to the extent that it substitutes Turkey's own views of the SSI's role for Panel findings. The European Union considers that the proposed additions are either unnecessary (for example, the discussion of the rules in place pre-2003) or factually incorrect and not borne out by the record (for example, the references to the "public" nature of retail pharmacies, their "acting on behalf" of the SSI, or Turkey's understatement of patients' out-of-pocket payments, which typically range up to 20%).

6.16. The Panel has addressed Turkey's multi-faceted request and proposed textual changes to paragraph 2.7 as follows:

- a. The Panel sees no reason to revise paragraph 2.7 with Turkey's proposed text regarding the healthcare system as it existed prior to 2003, in part because this is already fully reflected at paragraph 7.78 of the Panel Report.
- b. The Panel also sees no reason to revise paragraph 2.7 with Turkey's proposed additional description of pharmacies as "primary healthcare providers under Turkish law". The factual characterization of pharmacies as "private entities" relates to the fact that pharmacies in Turkey are privately owned, as opposed to being publicly owned, entities. The Panel observes that at paragraph 104 of Turkey's first written submission, Turkey itself refers to pharmacies as "private entities". While it is not contested that pharmacies are referred to as "primary healthcare providers under Turkish law", this does not negate the fact that pharmacies are privately owned entities.
- c. The Panel has also made some additional changes to paragraph 2.14, discussed further below, to accommodate the aspect of Turkey's requests pertaining to the role of the TPA.
- d. The Panel has revised the second sentence to refer to "[t]he amounts charged by pharmacies for pharmaceutical products **covered by the social security system**".
- e. With respect to the remaining part of Turkey's request related to this sentence, the Panel observes that the use of the word "mainly" is not intended to reflect a juxtaposition between the "main" amounts charged by pharmacies met by the SSI and out-of-pocket payments, but rather to refer to the two main sources that cover the

¹¹⁹ Turkey therefore requests the Panel to modify paragraph 2.7 as follows (with citations to Turkey's second written submission, para. 65):

2.7. Prior to the introduction of the Transformation in Health Program (THP) launched in 2003, pharmaceutical products were distributed by SSK, the predecessor of the SSI, which obtained physical control over the medicines, stored them in its own pharmacies and distributed directly to out-patients. As this system proved to be ineffective in reaching the entire population, Turkey implemented a different model for dispensing medicines to out-patients through retail pharmacies. Following that change, pharmaceutical products are distributed to outpatients by retail pharmacies. Although retail pharmacies, which are private entities, they are considered primary healthcare providers under Turkish law and have a legal duty to assist in the supply of pharmaceutical products. The Turkish Pharmacists' Association, which is mandated to represent retail pharmacies, is a public institution under Turkish law and may act on behalf of retail pharmacies in its relationship with other public institutions, such as the SSI. Almost the entire The amounts charged by pharmacies for pharmaceutical products, covered by the social security system, is are met mainly from payments made by the SSI and, while the remaining share is met by out-of-pocket payments by outpatients. The SSI makes payments to pharmacies based on monthly invoices submitted by the pharmacies. Regarding inpatient treatment, inpatients receive medicines directly from the hospitals, through a process different from the system at issue in this dispute.

amounts charged by pharmacies. However, to address Turkey's concern with the formulation of the second sentence, the Panel has deleted the word "**mainly**".

6.17. Turkey observes that **paragraph 2.8** describes which pharmaceutical products used by Turkish patients are included in the Annex 4/A list and indicates in its first sentence that "[n]ot all pharmaceutical products distributed to outpatients are reimbursed by the SSI". In a footnote to the third sentence of paragraph 2.8, the Panel indicates that "[a]ccording to Turkey, close to 90% of the medicines that are actively sold and prescribed in Turkey are included in the Annex 4/A list." Turkey considers that the wording of the body text, i.e., "[n]ot all", does not adequately reflect the uncontested figure provided by Turkey, which indicates that nearly all products distributed to outpatients are paid for by the SSI. Turkey therefore requests modifying the first sentence of paragraph 2.8 as follows: "**Not all Close to 90% of** pharmaceutical products distributed to outpatients by pharmacies are reimbursed by the SSI."

6.18. The European Union disagrees with Turkey's suggestion to the extent that it substitutes Turkey's own factual assertions for Panel findings.

6.19. The Panel has adjusted paragraph 2.8 to place more emphasis on the fact that approximately 90% of the pharmaceutical products that are actively sold and prescribed in Turkey are included in the Annex 4/A list.

6.20. Turkey observes that **paragraph 2.13** explains the process of "passivizing" products included in the Annex 4/A list. Turkey notes that footnotes 51, 52 and 53 to that paragraph explain the difference between excluded and passivized products, and the process of reactivation or re-inclusion. Because this distinction is important to Turkey's position on the trade-restrictiveness of the localisation measure, Turkey asks the Panel to move the explanation included in those footnotes to the body text.¹²⁰ Turkey refers in that regard to its comments on the draft descriptive part of the Report.¹²¹

6.21. The European Union does not object but would request that the remaining text currently in footnotes 52-54 be preserved.

6.22. The Panel declines Turkey's request. The Panel understands that Turkey's request only concerns the place where the factual information regarding the passivization and the exclusion of pharmaceutical products is provided (i.e. in the main body of the text rather than in footnotes 51, 52 and 53). The Panel notes that paragraph 2.13 is included in section 2.1.3.1 of the Report, titled "The Annex 4/A list". Previous paragraphs in this section explain that the SSI pays to pharmacies the price of certain pharmaceutical products (paragraph 2.7); clarify that to be reimbursable, pharmaceutical products must be included in the Annex 4/A list (paragraphs 2.8-2.9); and outline the pathways through which products are included in this list (paragraphs 2.10-2.12). Therefore, section 2.1.3.1 of the Report provides a description of the conditions under which a pharmaceutical product would be reimbursed by the SSI. This description follows chronologically the process that leads to a product being reimbursed by the SSI, i.e. its inclusion in the Annex 4/A list and its status in the list as "active". It is within this framework that paragraph 2.13 refers to the possibilities that a product be "passivized" or "excluded", which both result in the product not being reimbursed. In this context, the difference between excluded and passivized products with respect to the possibilities of re-activation or re-inclusion is of a secondary nature. While the Panel understands

¹²⁰ In particular, Turkey requests that the text be modified as follows:

2.13. Regardless of whether the regular or alternative reimbursement pathway is used, once approved, the pharmaceutical products are included in the same Annex 4/A list. Once included in the Annex 4/A list, products may subsequently be "passivized" (their status in the list changes from "active" to "passive"), or excluded from the list. Products **may still be prescribed by doctors and dispensed by the pharmacies, but** are no longer reimbursed if they are excluded or "passivized". In other words, to be reimbursed, products must be both included and listed as "active" in the Annex 4/A list. **Pharmaceutical products that have been "passivized" may be re-activated upon request of the pharmaceutical company if the conditions for setting the product's status to "passive" are no longer valid. Pharmaceutical products that have been "excluded" from the Annex 4/A list may be re-included after a period of 6 months following the date of their exclusion and are subject to a new application for inclusion in the Annex 4/A list.**

¹²¹ Turkey's comments on the draft descriptive part of the Panel Report, para. 11.

Turkey's comment that this distinction is important to Turkey's position on the trade-restrictiveness of the localisation measure, the Panel considers that the distinction is sufficiently clearly outlined in footnotes 51, 52 and 53 (as evidenced by Turkey's request to merely move these descriptions to the main body of the text without modifying the information provided). The Panel also notes that the fact that "passivized" and "excluded" products may still be prescribed by doctors and dispensed by pharmacies, without being reimbursed, is already reflected in the last sentence of footnote 53.

6.23. Turkey observes that **paragraph 2.14** explains how pharmaceutical products are provided to patients and the role of the retail pharmacies and the SSI in that process. Turkey notes that the Panel did not make all the changes suggested to that paragraph by Turkey in its comments on the draft descriptive part of the Report.¹²² Turkey reiterates its request to further redraft this paragraph in order to provide a more accurate description of the process of providing medicines to patients. In particular, Turkey states, the payment for medicines invoiced to the SSI is not optional (and refers to Turkey's opening statement, paragraph 32). Turkey states that while the SSI checks the invoices it receives from the retail pharmacies, mostly based on sampling, it can only refuse to make the payment in exceptional circumstances when the medicines were approved in the Medula system on the basis of incorrect information and dispensed to patients in breach of the specific medical rules that exist for those medicines. Turkey suggests adding that explanation to footnote 59. Turkey also suggests the following change to the last sentence of that paragraph: "The SSI reviews these invoices, and **pays reimburses** the 'reimbursement price' **based on the public price of the relevant medicines. (i.e. the balance of the amount remaining after the out-of-pocket payments by the patients).**"

6.24. The European Union disagrees with Turkey's suggestion because it substitutes Turkey's own views of the SSI's role for Panel findings, and because it is not borne out by the record.

6.25. The Panel has addressed Turkey's multi-faceted request and proposed textual changes to paragraph 2.14 as follows:

- a. With respect to Turkey's request to add certain explanations to footnote 59, the Panel recalls that, to accommodate certain of Turkey's requests presented in its comments on the draft descriptive part of the Report, the Panel added footnote 59 which explains that the SSI usually reviews invoices and their accompanying documents using a sampling method and refers to Article 6 of the Regulation on the procedures and principles governing checking of invoices of healthcare providers and reimbursement of their fees (Exhibit EU-53). The Panel considered this addition, including the specific reference to the relevant legal instrument, to accurately reflect a broader description which Turkey suggested without providing any reference to the evidence on record.¹²³ In its comments on the Interim Report, Turkey reiterates its request for the addition of a similarly broad explanation that "the payment for medicines invoiced to the SSI is not optional" and refers to its opening statement without providing further support for its statement based on the evidence on record.¹²⁴ The Panel observes that this is an issue of some contention between the parties. The parties appear to agree that, in some circumstances, the SSI can refuse to make a payment for a product even when the provision of the medicine to the patient was approved in the Medula system.¹²⁵ They disagree, however, as to the relevance, frequency or significance of this possibility – while Turkey states that the SSI can only refuse to make a payment "in exceptional circumstances"¹²⁶, the European Union highlights the "significant risk" that receiving "approval" in Medula system at the time of the transaction does not necessarily mean that the product will be reimbursed by the SSI.¹²⁷ For these reasons, to accommodate Turkey's request, the Panel has made an addition to footnote 59 to reflect that, according to Turkey, the SSI can refuse to make a payment when the medicines were

¹²² Turkey's comments on the draft descriptive part of the Panel Report, para. 13.

¹²³ Turkey's comments on the draft descriptive part of the Panel Report, para. 13, referring to Turkey's opening statement, para. 32.

¹²⁴ Turkey's comments on the Interim Report, para. 11. Turkey refers to para. 32 of its opening statement which does not include any reference to the evidence on record.

¹²⁵ Turkey's comments on the Interim Report, para. 11 and European Union's responses to the first set of questions, para. 11.

¹²⁶ Turkey's comments on the Interim Report, para. 11.

¹²⁷ European Union's responses to the first set of questions, para. 11.

approved in the Medula system on the basis of incorrect information and dispensed to patients in breach of the specific medical rules that exist for those medicines.

- b. With respect to Turkey's suggested change in the last sentence of the paragraph, the Panel notes that paragraph 2.16 includes a detailed description of the "reimbursement price" covered by the SSI. To avoid confusion and to partially accommodate Turkey's request, the Panel has made a revision to the last sentence of paragraph 2.14.
- c. Finally, to reflect Turkey's explanation of the status of the TPA in the context of its comments on paragraph 2.7, the Panel has added additional text to footnote 55 (footnote 55 in the Interim Report).

6.26. **Paragraph 2.15:** Turkey observes that this paragraph talks about the Medula system. Turkey suggests moving this paragraph to the end of section 2.1 (i.e., after paragraph 2.17) to improve the flow of the explanation relating to the price of the pharmaceutical products in Turkey, including the price paid by the SSI.

6.27. The European Union does not comment.

6.28. The Panel has made the change suggested by Turkey.

6.29. Turkey notes that **paragraph 2.16** (paragraph 2.17 in the Interim Report) illustrates what happens if the application of the reference pricing system results in a reimbursable amount which is lower than the public price of a pharmaceutical product included in the Annex 4/A list. It provides that "[i]f the public price of a pharmaceutical product is greater than the maximum reimbursement price set by the SSI for the relevant equivalent group, outpatients must pay the difference". Turkey states that it has explained at paragraph 1 of its responses to the Panel's first set of questions that this depiction is incomplete because a patient may opt for an equivalent medicine that is less costly than that which was prescribed by the medical doctor and is therefore not required to pay the difference. In addition, Turkey reiterates its previous comments on the draft descriptive part of the Report¹²⁸ given that the Panel did not make all the requested changes. In particular, Turkey considers that it is important to clarify that the fees paid by patients constitute contributions to the social security system and that in many instances patients do not pay any contribution fee. Accordingly, Turkey invites the Panel to add additional text to paragraph 2.16 to reflect these points.¹²⁹

6.30. The European Union responds that the first proposed addition is illogical, as the sentence only speaks of a scenario in which the public price is greater than the maximum reimbursement price. The second should be rejected because it substitutes Turkey's own views of the SSI's role for Panel findings, and because it is not borne out by the record. As for the third, the European Union does not object to a reference to some, or certain, instances where patients are exempt from a contribution fee, but it should not be qualified by the adjective "many" (which would require a factual

¹²⁸ Turkey's comments on the draft descriptive part of the Panel Report, para. 16.

¹²⁹ In particular, Turkey requests that paragraph 2.17 be amended as follows:

2.17. If the public price of a pharmaceutical product is greater than the maximum reimbursement price set by the SSI for the relevant equivalent group, outpatients must pay the difference **or are provided another equivalent product with a lower public price**. In addition, outpatients generally also pay two types of fees collected by pharmacies, **as contribution to the social security system**: (i) a fee calculated as a percentage of the price after public discount of the pharmaceutical product (contribution fee), being 10% for persons who receive income or a pension from the SSI, and also for their dependants, or 20% for all others; and (ii) a fee of 3 Turkish lira for up to three boxes/items in the prescription and 1 Turkish lira for each additional box/item (prescription fee). **In many instances, patients do not pay any contribution fee.[FN]**

[FN] Turkey's first written submission, para. 110. Among others, the contribution fee is waived for pharmaceutical products necessary for the treatment of critical diseases such as cancer or long-standing chronic diseases. In 2019, 34.7% of the total SSI's expenditure for medicines was exempt from the payment of the contribution fee.

assessment never undertaken by the Panel). The last sentence of the proposed footnote should also be rejected, as it would constitute a new factual finding.

6.31. The Panel has addressed Turkey's multi-faceted request and proposed textual changes to paragraph 2.16 as follows:

- a. With respect to Turkey's request to modify the first sentence of the paragraph, the Panel understands Turkey's explanation to mean that an outpatient may decide to opt either for the pharmaceutical product indicated on a prescription (and pay the difference between the public price of this product and the maximum reimbursement price set by the SSI for the relevant equivalent group), or for a cheaper equivalent product (thus paying a smaller difference between the public price of the selected product and the maximum reimbursement price set by the SSI for the relevant equivalent group, or paying no such difference if the public price of the product is not greater than the maximum reimbursement price set by the SSI for the relevant equivalent group). However, the Panel is of the view that the revision, as suggested by Turkey, and in particular the use of the conjunction "or", might lead to an erroneous conclusion that if an outpatient opts for a cheaper equivalent product with a lower price, this necessarily means that the outpatient will not pay the potential difference between the public price of this equivalent product and the maximum reimbursement price set by the SSI for the relevant equivalent group. This statement would only be correct if such difference does not exist, i.e. if the public price of the equivalent product is not greater than the maximum reimbursement price set by the SSI for the relevant equivalent group. For that reason, the Panel has revised the first sentence of the paragraph to include a clarification that outpatients must pay the difference, unless they decide to opt for an equivalent product the public price of which is not greater than the maximum reimbursement price set by the SSI for the relevant equivalent group.
- b. With respect to Turkey's request to clarify that the fees paid by patients constitute "contributions to the social security system", the Panel observes that the European Union does not disagree with this clarification but considers it "irrelevant because it concerns, at best, the ultimate use to which the money is put".¹³⁰ The Panel notes, however, that the legal instrument to which Turkey refers in its first written submission in support of the argument that the contribution fee forms part of patients' contribution to the social security system explains, more narrowly, that the contribution fee "refers to the amount to be paid by the universal health insurance holder or the dependents in order to benefit from healthcare services".¹³¹ To accommodate Turkey's request and precisely reflect the text of the relevant legal instrument, the Panel has added a sentence in footnote 66 (footnote 68 in the Interim Report) stating that a contribution fee refers to the amount to be paid by the universal health insurance holder or the dependents in order to benefit from healthcare services, along with a reference to the relevant legal instrument.
- c. With respect to Turkey's request to clarify that in many instances patients do not pay any contribution fee, the Panel observes that, following Turkey's request in its comments on the draft descriptive part of the Report, the Panel revised footnote 66 to include this factual information. To further accommodate Turkey's request, the Panel has added a sentence at the end of footnote 66 reflecting that, according to Turkey, in 2019, 34.7% of the total SSI's expenditure for medicines was exempt from the payment of the contribution fee. The Panel has added a reference to footnote 90 of Turkey's first written submission, where this information was initially provided.

¹³⁰ European Union's second written submission, para. 107.

¹³¹ HIC/SUT (Exhibits EU-95, TUR-10), Article 1.8.1. In the translation provided by the European Union of this document, Article 1.8.1 reads as follows: "Contribution means the amount payable by persons covered by universal health insurance and their dependents to be entitled to healthcare."

6.3.3 The measures at issue

6.3.3.1 The localisation requirement

6.32. Turkey strongly disagrees with the description, in **paragraph 2.20**, of the localisation requirement as having the "policy objective of achieving the gradual transition from imports to domestic manufacturing of pharmaceuticals". While Turkey does not deny the target of meeting 60% of domestic pharmaceutical demand through domestic production, mentioned in footnote 75, it reiterates that the *policy objective* behind that target relates to social security and public health. Turkey therefore suggests amending the first sentence of this paragraph.¹³²

6.33. The European Union rejects Turkey's attempt to completely re-qualify its measure, in a way that goes far beyond the scope of interim review. On the other hand, the European Union notes that the Panel extensively discusses Turkey's alleged policy objectives in the section dealing with Article XX of the GATT 1994 and would not object to a cross-reference to that discussion in this paragraph.

6.34. The Panel declines to make Turkey's proposed changes to paragraph 2.20, for the same reasons that the Panel declined to revise paragraph 2.20 in the light of Turkey's comments on the draft descriptive part of the Report. In the first sentence of paragraph 2.20, the Panel is simply indicating that it is not disputed that the challenged measure (i.e. the localisation requirement) is related to Turkey's wider objective of achieving the gradual transition from imports to domestic manufacturing of pharmaceuticals. The Panel refers to that objective as "Turkey's policy objective" in the context of paragraph 2.20 simply to distinguish it from the challenged measure (i.e. the localisation requirement). In referring to "Turkey's policy objective" in the first and second sentences of paragraph 2.20, the Panel is clearly not prejudging the heavily contested issue of whether and if so how that objective is related to Turkey's social security and public health objectives of securing uninterrupted access to medicines for all patients in Turkey and guaranteeing the financial sustainability of the social security system. The parties' respective positions and arguments on that issue are set out in detail in the section of the Report addressing the general exceptions under Article XX (see e.g. paragraph 7.165) and do not need to be reiterated in the context of paragraph 2.20.

6.35. In addition, Turkey, recalling its comments on the draft descriptive part of the Report¹³³, states that the reference to "foreign producer(s)" in **paragraph 2.20** is incorrect, given that the European Union's challenge of the measure is not directed at the nationality of producers but rather the origin of the products themselves. Turkey therefore respectfully suggests amending paragraph 2.20 so as to replace the words "~~foreign producers~~" with "producers of pharmaceutical products".

6.36. The European Union does not comment.

6.37. The Panel understands that the European Union's challenge of the localisation requirement is not directed at the nationality of producers but rather at the origin of the products themselves. However, when the Panel refers to a "foreign producer" (or conversely, "local producer"), the Panel is referring to the location of production, and not to the nationality of the producer. By way of illustration, an EU-owned enterprise producing pharmaceutical products in Turkey would be referred to as a "local producer", and a Turkish-owned enterprise producing pharmaceutical products in the European Union, and importing those products into Turkey, would be referred to as a "foreign producer". Accordingly, the Panel declines to make the revision suggested by Turkey for the same reason that the Panel declined to change references to "foreign" and "local" producers after receiving Turkey's comments on the draft descriptive part of the Report.¹³⁴

¹³² In particular, Turkey requests that the first sentence be amended as follows:

2.20. The localisation requirement ~~seeks to relate to Turkey's policy objective of achieving~~ the gradual transition from imports to domestic manufacturing of pharmaceuticals **which, according to Turkey, relates to social security and public health objectives of ensuring uninterrupted access to medicines for all patients in Turkey and guaranteeing financial sustainability of the social security system.**

¹³³ Turkey's comments on the draft descriptive part of the Panel Report, para. 18.

¹³⁴ Turkey's comments on the draft descriptive part of the Panel Report, paras. 18 and 21.

6.3.3.2 The prioritization measure

6.38. Turkey reiterates the request made in its comments on the descriptive part of the Report¹³⁵ to complete **paragraph 2.31** with additional examples in order to more accurately explain the circumstances when application may receive priority.¹³⁶

6.39. The European Union does not comment.

6.40. The Panel notes that the Prioritization Guideline provides for the possibility to request priority assessment of ten different types of applications.¹³⁷ To avoid including a list of all the circumstances when applications may receive priority, and noting that the European Union took issue with only some of these circumstances¹³⁸, the Panel opted for describing only those circumstances that pertained to the European Union's challenge and that were relevant for the potential distinction between domestically produced pharmaceutical products and pharmaceutical products produced abroad. The Panel flagged the existence of other circumstances by use of the words "*inter alia*". In the Panel's view, the addition suggested by Turkey of only one additional example ("applications relating to biosimilar and innovative products") would only partially serve the purpose of "more accurately explain[ing] the circumstances when application may receive priority". For that reason, to accommodate Turkey's request to the extent possible, the Panel has revised the paragraph to reflect that prioritization can be requested for ten categories of applications, including those specifically mentioned in paragraph 2.31.

6.3.4 Parties' requests for findings and recommendations

6.41. Turkey reiterates the request made in its comments on the draft descriptive part of the Report¹³⁹ to modify **paragraph 3.5 (a)** in order to accurately reflect Turkey's arguments.¹⁴⁰ In a related request on **paragraph 7.261** (paragraph 7.259 in the Interim Report), Turkey reiterates that its claim that the European Union has failed to establish the existence and precise content of the "import ban measure" is based, in the first place, on the argument that the European Union failed to demonstrate the existence of a "ban". Turkey notes that reference is made to that point in the accompanying footnote but considers that it should be part of point (i) of paragraph 7.261 to more precisely and accurately reflect the structure of its arguments as included, *inter alia*, in paragraphs 590-593 of Turkey's first written submission.¹⁴¹

¹³⁵ Turkey's comments on the draft descriptive part of the Panel Report, para. 25.

¹³⁶ In particular, Turkey suggests the following change (with a reference to the Prioritization Guideline (Exhibit EU-97), Article 2(b) and (c)):

2.31. "Prioritization" can be requested, *inter alia*, for applications relating to **biosimilar and innovative products, applications relating to** transferring the production of imported medicines to Turkey, applications for locally manufactured products for exportation purpose, and applications relating to products that have strategic importance in terms of the country's policies.

¹³⁷ Prioritization Guideline (Exhibit EU-97), Article 2.

¹³⁸ European Union's first written submission, paras. 339-341.

¹³⁹ Turkey's comments on the draft descriptive part of the Panel Report, para. 27.

¹⁴⁰ In particular, Turkey invites the Panel to make the following changes:

a. **the European Union has failed to establish the existence and precise content of the "import ban measure". In particular, the European Union has failed to demonstrate the existence of a "ban". while t** The European Union **also characterizes the "import ban measure" as a "single measure", it failed** to show how the different components operate together as part of a "single measure" distinct from its components, ~~and thereby fails to establish the existence and precise content of the import ban measure as a "single measure";~~

¹⁴¹ In particular, Turkey requests the following modification:

7.259. Turkey requests that the Panel reject the European Union's claim under Article XI:1 of the GATT 1994 on multiple separate grounds. The grounds invoked by Turkey are that: (i) **the European Union fails to establish the existence and precise content of that measure, first because it failed to demonstrate the existence of a "ban", i.e. a formal prohibition on the importation of localised pharmaceutical products and second, because** while the European Union characterizes the "import ban measure" as a "single measure", it fails to show how the different components operate together as part of a "single measure" distinct from its

6.42. The European Union does not comment.

6.43. The Panel considers that these paragraphs and their accompanying footnotes clearly and accurately reflect the structure of Turkey's layered arguments, and it was for that reason that the Panel did not modify the wording of these paragraphs following Turkey's comments on the draft descriptive part. It now appears from Turkey's comments on the Interim Report that Turkey's concern arises from the fact that reference is made to the argument in question using a footnote, rather than being reflected in main body text. The Panel notes that it presented the structure of Turkey's arguments through a combination of main body text and footnotes to reflect that there are several layers to Turkey's arguments, and not in any way to imply that both of the arguments referenced in the footnote are secondary. Insofar as that is Turkey's concern, the Panel has sought to accommodate it by reflecting all of Turkey's arguments in the main body text of these paragraphs.

6.4 The existence and precise content of the localisation requirement as a "single and cohesive measure"

6.44. Turkey observes that **paragraph 7.11** summarizes Turkey's arguments developed in its first written submission regarding the European Union's identification of the content and existence of the localisation measure. Turkey requests that the following sentence in that paragraph be modified in order to reflect the due process dimension of its arguments, with reference in that regard to paragraph 39 of its second written submission and paragraph 15 of its responses to the first set of questions: "According to Turkey, such identification and explanation are essential to establish the 'precise content' of the measure and have important consequences for **its ability to develop its defence against** some of the claims."

6.45. The European Union does not object to a more extensive description of Turkey's arguments, but would ask the Panel to limit this to direct citations of Turkey's submissions, and not to add any new language or modify the existing language summarising or qualifying those submissions.

6.46. The Panel declines to modify paragraph 7.11 to reflect these subsequent submissions: as Turkey itself recognizes, paragraph 7.11 has the purpose of summarizing Turkey's arguments developed in its first written submission. Furthermore, the above-quoted sentence in paragraph 7.11 as currently drafted corresponds to the cited sentence from Turkey's first written submission, which does not include the words "its ability to develop its defence against". However, with a view to accommodating Turkey's desire to have the due process dimension of its arguments reflected more explicitly in the main body text of the Report, the Panel has revised the first sentence of paragraph 7.30 to read "[f]inally, the Panel observes that Turkey's argument regarding the European Union's alleged failure to precisely identify the components of the localisation requirement **and resulting impact on Turkey's ability to develop its defence**, while presented as a general argument relevant to all of the European Union's claims, seems to be primarily, if not exclusively, relevant to the European Union's claim under Article X:1 of the GATT 1994." The Panel notes that the existing footnote to this sentence already refers to paragraph 39 of Turkey's second written submission and paragraph 15 of its responses to the first set of questions.

6.5 Article III:8(a) of the GATT 1994

6.47. Turkey observes that **paragraph 7.44** describes the European Union's arguments concerning the burden of proof under Article III:8(a) of the GATT 1994. Although the Panel did not make any findings on that issue, for the sake of completeness, Turkey suggests that the Panel also refer to Turkey's arguments on that point as reflected in paragraphs 31-37 of its responses to the second set of questions.

6.48. The European Union does not object to a more extensive description of Turkey's arguments, but would ask the Panel to limit this to direct citations of Turkey's submissions, and not to add any new language or modify the existing language summarising or qualifying those submissions.

6.49. The Panel has added the reference as requested by Turkey in footnote 257 (footnote 217 in the Interim Report).

6.50. Turkey observes that **paragraph 7.46** summarizes Turkey's argument in its first written submission on the first element of the legal test under Article III:8(a) of the GATT 1994, namely, that the localisation requirement is a "law, regulation or requirement governing procurement". Turkey requests that the Panel reflect Turkey's references to the Protocol between the TPA and the SSI and the contracts between individual pharmacies and the SSI. In a related request, Turkey also suggests modifying the third sentence of **paragraph 7.60** to add a reference to the Protocol between the TPA and the SSI and the contracts between individual pharmacies and the SSI.¹⁴²

6.51. The European Union does not object to a more extensive description of Turkey's arguments, but would ask the Panel to limit this to direct citations of Turkey's submissions, and not to add any new language or modify the existing language summarising or qualifying those submissions.

6.52. The Panel has made the additions requested by Turkey to paragraphs 7.46 and 7.60.

6.53. Turkey requests that the sentence in **paragraph 7.60** starting with "Turkey also points to several facts that, in its opinion, indicate that there is no commercial transaction between the patients and retail pharmacies" be corrected to indicate that these points were made to rebut the European Union's arguments.¹⁴³

6.54. The European Union does not object to a more extensive description of Turkey's arguments, but would ask the Panel to limit this to direct citations of Turkey's submissions, and not to add any new language or modify the existing language summarising or qualifying those submissions

¹⁴² In particular, Turkey requests the following changes:

7.46. Turkey submits that the localisation measure is a "law, regulation, or requirement governing procurement". According to Turkey, the SSI "acquires" the medicines that are prescribed to patients in Turkey "since it pays for their costs". Turkey explains that the pharmaceutical products included in the Annex 4/A list "are acquired by the SSI through retail pharmacies which are members of the TPA", and the "procurement process is governed by the Protocol concluded between the SSI and the TPA **as well as contracts concluded between the SSI and individual retail pharmacies**". Turkey submits that, contrary to what the European Union argues, the very title of that document, **i.e. Protocol on the Provision of Medicines to the Persons Covered by the Social Security Institution by the Pharmacies which are Members of the Turkish Pharmacists' Association**, makes it clear that it regulates the "provision" of pharmaceutical products by retail pharmacies, on behalf of the SSI, to patients.

7.60. [...] First, pharmacies do not resell the pharmaceutical products because they rather dispense them to outpatients on behalf of the SSI, **on the basis of the Protocol signed between the TPA and the SSI and the contracts signed between individual pharmacies and the SSI**.

¹⁴³ In particular, Turkey suggests the following changes:

7.60. [...] Turkey also points **out that contrary to what the European Union argues to several facts that, in its opinion, indicate that there is no commercial transaction between the patients and retail pharmacies, namely** (i) the fact that patients may replace the brand product from the prescription with an equivalent generic product (or *vice versa*); (ii) the fact that patients may decide "whether, when or where" to use their prescription; or (iii) the fact a patient may choose the pharmacy or even decide not to take his/her prescribed medicine, **do not indicate that there are any commercial transactions between the patients and retail pharmacies as far as the pharmaceutical products included in Annex 4/A are concerned**. Turkey further maintains that the prescription fee and the contribution fee paid by patients are not part of the price of the pharmaceutical products but rather "form part of the patients' contribution to the social security system and aim at preventing abuses of the healthcare system, including overconsumption of medicines, as well as ensuring its financial sustainability". Turkey also observes that in many instances, patients are exempted from the payment of the contribution fee.

6.55. The Panel has reformulated the wording of paragraph 7.60 in the manner requested by Turkey, to reflect that the argument being summarized is in the nature of a rebuttal argument.

6.56. Turkey notes that the statement in **paragraph 7.62** that the panel in *India – Solar Cells* did not make any findings on the remaining elements of Article III:8(a) of the GATT 1994, other than the issue of the nature of "products purchased", is incorrect. Turkey notes that the Panel appears to recognize this elsewhere in the Interim Report (and refers to paragraph 7.105). Turkey notes that the panel in that case considered it "useful to proceed with a limited analysis and review" (at paragraph 7.137) of the remaining elements of Article III:8(a) and examined (i) whether the measures at issue were "laws, regulations, or requirements governing procurement", (ii) whether the procurement was made "by governmental agencies", (iii) whether the procurement was of products purchased "for governmental purposes", and (iv) whether the procurement and purchase of products was "not with a view to commercial resale" (at paragraphs 7.139-7.186). Turkey therefore suggests adding a sentence to paragraph 7.62 to reflect this.¹⁴⁴

6.57. The European Union does not comment.

6.58. The Panel has revised the wording of the third sentence of paragraph 7.62, and elaborated the text of its accompanying footnote, to express more clearly that while the panel in *India – Solar Cells* observed that it was unnecessary to make findings on the remaining elements of Article III:8(a) given that "the threshold legal element" under this provision was not satisfied, it nonetheless considered it useful to proceed with a limited analysis and review of certain issues relating to the remaining elements of Article III:8(a).

6.59. In a related request, Turkey further requests the Panel to follow the same approach as did the panel in *India – Solar Cells* and thus to include in its final report limited analysis and review of the other elements of Article III:8(a) of the GATT 1994 as well as its factual findings related to those elements. Turkey notes that this would require redrafting section 7.2.4.5 in the Interim Report. In that regard, Turkey disagrees with the Panel's statement, in **paragraph 7.106**, that in the circumstances of this dispute there are "no compelling reasons to make additional findings or observations beyond those necessary to resolve the claims and defences at issue". Leaving aside the fact that the Panel did not further explain its decision not to address the remaining issues under Article III:8(a), Turkey submits that, as in *India – Solar Cells* (referring to paragraph 7.137 of the panel report in that dispute), the additional factual findings of the Panel are necessary in order to allow a review of the Panel's findings and the completion of the legal analysis under Article III:8(a) in case of appeal.

6.60. The European Union does not comment.

6.61. The Panel declines Turkey's request that the Panel redraft section 7.2.4.5 of the Report to include further analysis and review of the other elements of Article III:8(a) of the GATT 1994 as well as its factual findings related to those elements. The Panel is not persuaded by Turkey's argument that additional factual findings of the Panel are necessary in order to allow a review of the Panel's findings and the completion of the legal analysis under Article III:8(a) in case of appeal. The Panel notes that the work of the Appellate Body has been suspended for nearly two years and that Members remain unable to reach consensus on any selection process to fill the vacancies that are required for the Appellate Body to function. Moreover, the Panel's approach here is in line with the economical approach taken by the Panel elsewhere in the Report, including the scope of the Panel's findings on Turkey's defences under Article XX(b) and (d), and the European Union's claims under Article 3.1(b) of the SCM Agreement, Article 2.1 of the TRIMs Agreement, Article X:1 of the GATT 1994, and Article XI:1 of the GATT 1994.

6.62. The Panel recalls that, as reflected in paragraph 7.64 and the subsections that follow, Turkey advances three lines of argument in support of its contention that the localisation requirement

¹⁴⁴ In particular, Turkey suggests the following change:

7.62. [...] That panel ultimately found it unnecessary to make findings on the remaining elements of Article III:8(a) given that "the threshold legal element" under this provision was not satisfied. **That panel nevertheless decided to proceed with a limited analysis and review of the remaining elements of Article III:8(a) in order to provide sufficient factual findings that could be required in case of an appeal.**

involves the "purchase" of pharmaceutical products included in the Annex 4/A list by governmental agencies. As reflected in paragraph 7.64, the Panel's view is that these arguments are properly characterized as alternative arguments. In the light of the foregoing, the Panel considers it appropriate to address the following comments together:

- a. The European Union suggests that the Panel remove the word "alternative" from the first sentence of **paragraph 7.64**. It is not the European Union's understanding that Turkey necessarily frames all of the three lines of argument as alternative, i.e. mutually exclusive. For the same reasons, the European Union requests that the words "made in the alternative" be removed from **paragraph 7.82**. By contrast, the European Union states that the argument assessed in section 7.2.4.4 ("Pharmacies' purchases of pharmaceuticals from wholesalers") can more clearly be described as alternative in nature. In its comments on the European Union's request, Turkey asks the Panel to revise paragraph 7.64 to present the first two lines of argument as a single argument.¹⁴⁵ Turkey also requests that the Panel delete the words "second line of argument, made in the alternative" from paragraph 7.82.
- b. Turkey proposes to also refer to paragraphs 71-73 of its second written submission in **footnote 375** (footnote 335 in the Interim Report) to paragraph 7.64, because those paragraphs also contain elements of Turkey's position relating to the SSI gaining an entitlement over pharmaceutical products dispensed on its behalf by retail pharmacies. The European Union does not object to a more extensive description of Turkey's arguments, but would ask the Panel to limit this to direct citations of Turkey's submissions, and not to add any new language or modify the existing language summarising or qualifying those submissions
- c. Turkey comments on **paragraph 7.75**, which refers to Turkey's position on the interpretation of the terms "products purchased" as being that "the SSI must be deemed to 'purchase' pharmaceutical products because it pays for their cost, even if it does not acquire ownership of those products". Turkey is of the view that the Panel's summary oversimplifies Turkey's position and therefore asks the Panel to modify the first sentence

¹⁴⁵ In particular, in the context of its comments on the European Union's request that the Panel remove the word "alternative" from the first sentence of paragraph 7.64, Turkey requests the Panel to modify paragraph 7.64 as follows (with reference to Turkey's response to Panel question No. 33(b), para. 44; Turkey's first written submission, para. 206; Turkey's first written submission, para. 207; Turkey's first written submission, para. 209; Turkey's second written submission, paras. 71-76; Turkey's responses to Panel questions No. 5(a), paras. 25-26 and No. 6(c), para. 34; Turkey's response to Panel question No. 33(b), para. 44):

7.64. Turkey's ~~advances three alternative lines of~~ argument in support of its contention that the localisation requirement involves the "purchase" of pharmaceutical products included in the Annex 4/A list by governmental agencies **is two-fold**. First, Turkey argues that **the SSI purchases those medicines from the retail pharmacies which are charged with dispensing those medicines to patients. In that regard Turkey argues that** the concept of a "purchase" under Article III:8(a) should not be interpreted narrowly **as requiring the acquisition of property rights. Relying on the ordinary meaning of the verb "to purchase" which means "the action or an act of obtaining something in exchange for payment in money or an equivalent", Turkey argues that the notion of a "purchase" involves some kind of payment (usually monetary) in exchange for a good, and that the SSI "purchases" pharmaceutical products by paying for them, even if it does not acquire an entitlement to (or property rights over) the products.** Turkey argues that the SSI's reimbursement of the cost of outpatients' pharmaceuticals involves a "purchase" because it is "the SSI that pays for the pharmaceutical products and thus is the ultimate buyer (or the purchaser)".³³⁵ **Turkey explains that the SSI obtains the pharmaceutical products with the involvement of retail pharmacies. Second,** Turkey **further** argues that, even under an "extremely narrow"³³⁶ definition of what constitutes a "purchase" requiring the transfer of legal title over a product, which is an interpretation that Turkey disagrees with³³⁷, there is still a "purchase" by the SSI. This is because, as a matter of fact, the SSI does acquire title to the pharmaceutical products at the moment a retail pharmacy scans a prescription's QR code and the Medula system approves the provision of that pharmaceutical product to the patient. **Second Third,** Turkey argues that, even if that is incorrect, Article III:8(a) still applies because the purchase of pharmaceutical products included in the Annex 4/A list by the retail pharmacies from the wholesalers is made on behalf of the SSI and this means that the retail pharmacies are themselves "governmental agencies" that "purchase" pharmaceuticals for purpose of Article III:8(a). The European Union disputes all of Turkey's arguments.

of this paragraph. Indeed, Turkey argues, the fact that the SSI pays for the cost of pharmaceutical products included in Annex 4/A and dispensed by retail pharmacies to patients is only one of the elements invoked by Turkey. Turkey suggests that paragraph 7.75 begin with two new sentences to capture Turkey's position more fully.¹⁴⁶ The European Union considers that Turkey's proposed addition does not fit with the specific issue discussed by the Panel in that paragraph. It appears that Turkey is attempting to artificially create a contradiction between the current text and the text Turkey would wish to add, such that it could invoke that contradiction in a possible appeal. This should be rejected.

6.63. As set forth in paragraph 7.64, the Panel understands the first two of these three lines of argument, which are the subject of the European Union's request on paragraph 7.64 (and Turkey's related comment on paragraph 7.64), to be that (i) the SSI "purchases" pharmaceutical products by paying for them, even if it does not acquire an entitlement to (or property rights over) the products; (ii) even under that narrow definition of what constitutes a "purchase", with which Turkey disagrees, there is still a "purchase" by the SSI because the SSI does acquire title to the pharmaceutical products. These arguments rest on mutually exclusive interpretations of the term "purchase" in Article III:8(a). As reflected in paragraph 7.64, the Panel's view is that these arguments are properly characterized as alternative arguments, and the Panel remains of the view that characterizing them as such contributes to analytical clarity in the subsections that follow. Accordingly, the Panel does not make any change to the current wording of paragraph 7.64. However, the Panel has reformulated paragraph 7.82 to clarify that Turkey's second line of argument rests on an alternative interpretation of the term "products purchased" in Article III:8(a), rather than indicating that it was "made in the alternative". The Panel recognizes that the formulation "made in the alternative" would be misleading insofar as it was taken to mean that Turkey itself characterized its argument in this way. The Panel considers the reformulation of this element of paragraph 7.82 to more clearly convey that the Panel is referring to the logical relationship between the premises underlying Turkey's arguments, and not to Turkey's own framing of its position and arguments.

6.64. The Panel has sought to accommodate Turkey's request to add a citation to paragraphs 71-73 of its second written submission, but it appears that Turkey's request relates to the wrong footnote. Footnote 375 is a footnote accompanying the text referencing the first of the two lines of argument referred to in paragraph 7.64. However, Turkey's description of the content of the paragraphs 71-73 of its second written submission confirms that it relates the second line of argument referred to in paragraph 7.64 (i.e. relating to the SSI gaining an "entitlement" over pharmaceutical products dispensed on its behalf by retail pharmacies). The Panel has added a reference to Turkey's second written submission, paragraphs 71-73, to the pertinent sentence of paragraph 7.64.

6.65. The Panel declines Turkey's request to revise the opening sentence of paragraph 7.75. For the sake of analytical clarity, the Panel has addressed the three alternative lines of argument presented by Turkey separately and sequentially, in three different subsections. This paragraph is found in the subsection of the Panel's reasoning that addresses the first line of argument advanced by Turkey, which, as summarized in paragraph 7.64, is that the SSI "purchases" pharmaceutical products by paying for them, even if it does not acquire an entitlement to (or property rights over) the products. It is in this context that the Panel refers to Turkey's position as being that "the SSI must be deemed to 'purchase' pharmaceutical products because it pays for their cost". For the purposes of recalling the essence of Turkey's first line of argument, this is not an oversimplification. It is in the next subsection of the Panel's reasoning that the Panel addresses Turkey's second line of argument, i.e. that even under the narrow definition of what constitutes a "purchase", with which

¹⁴⁶ In particular, Turkey requests the Panel to modify paragraph 7.75 as follows (with a reference to Turkey's response to Panel question No. 33(a), para. 43):

According to Turkey, the concept of "purchase" is not limited to situations where a governmental agency obtains legal title or entitlement to a product, meaning property rights, but covers situations where the governmental agency obtains the right to dispose of a product according to its own choices. This does not necessarily imply the existence of a standard sales transaction between a seller and a public purchaser. The Panel considers that Turkey's interpretation of the term "products purchased", i.e. the SSI must be deemed to "purchase" pharmaceutical products because it pays for their cost, even if it does not acquire ownership of those products, is also inconsistent with the two prior disputes in which Article III:8(a) was interpreted and applied. More specifically, [...]

Turkey disagrees, there is still a "purchase" by the SSI because the SSI does acquire title to the pharmaceutical products.

6.66. Turkey observes that **paragraph 7.73** contains the Panel's analysis of the terms "products purchased" in light of the object and purpose of the GATT 1994. Turkey notes that the last sentence of this paragraph provides that "Turkey has not specified on what other basis, if not the acquisition of ownership, the concept of a 'purchase' by a government could be distinguished from mere financing of private purchases in circumstances where the relevant products are provided to, and consumed by, non-governmental recipients." First, Turkey notes that this comment appears to relate to an issue that has never been raised by the Panel. Indeed, the Panel never inquired as to what could distinguish the concept of a "purchase" by a government from a mere financing. Second, Turkey notes that it has extensively explained why the transactions between the SSI and the retail pharmacies cannot be considered as "mere financing". In particular, Turkey refers the Panel to paragraphs 23 and 51-53 of its second written submission as well as to its response to Panel Questions Nos. 4 and 6 and paragraph 55 of its response to Panel Question No. 35. Turkey therefore requests the Panel to modify paragraph 7.73 to reflect Turkey's arguments on this point.¹⁴⁷

6.67. While the European Union does not object to more extensive citations of Turkey's submissions (as long as they do not go beyond the content of the cited parts of Turkey's submissions), the European Union disagrees with Turkey's specific suggestion because it substitutes Turkey's own views of the SSI's role for Panel findings.

6.68. The Panel wishes to clarify that when it states in paragraph 7.73 that Turkey "has not specified on what other basis, if not the acquisition of ownership, the concept of a 'purchase' by a government could be distinguished from mere financing of private purchases in circumstances where the relevant products are provided to, and consumed by, non-governmental recipients", the Panel does not mean to suggest that Turkey's submissions reflect a deficit of argumentation about why, in Turkey's view, the Turkish system and others that are similar to it fall within the scope of Article III:8(a). The Panel understands that Turkey has identified a series of elements (reflected in its proposed text to add to paragraph 7.73) that, in Turkey's view, support that conclusion. The point being made by the Panel in this paragraph is that although Turkey has identified a series of factual elements that in its view support the conclusion that the Turkish system falls within the scope of Article III:8(a), these elements do not specify an objective legal standard for distinguishing the concept of a "purchase" by a government from mere financing of private purchases in circumstances where the relevant products are provided to, and consumed by, non-governmental recipients. The Panel has revised the text of paragraph 7.73 to make this clearer and has included a new accompanying footnote reflecting the summary of Turkey's arguments that Turkey asks the Panel to reflect in paragraph 7.73.

¹⁴⁷ In particular, Turkey suggests the following changes (with reference to Turkey's second written submission, para. 52, and Turkey's response to Panel question No. 4(a), para. 18):

7.73. [...] The Panel understands that Turkey's position is that the SSI does more than merely engage in "financing", and that Turkey takes issue with the European Union's attempt to "reduce the role of the SSI to the mere financing of the purchases of pharmaceutical products by outpatients". **~~However, even assuming that Turkey is correct in asserting that the SSI does more than merely engage in financing, Turkey has not specified on what other basis, if not the acquisition of ownership, the concept of a "purchase" by a government could be distinguished from mere financing of private purchases in circumstances where the relevant products are provided to, and consumed by, non-governmental recipients. Turkey explained that the SSI ensures the provision of medicines to outpatients and makes all the necessary arrangements for this purpose: it decides which medicines are listed in Annex 4/A; it sets public prices of those medicines; it signs contracts with pharmacies for ensuring the availability and distribution of those medicines throughout the country; it approves the provision of the medicines to be dispensed to outpatients through the Medula system and pays the invoice it receives for those medicines from the pharmacies. It is the combination of all the above elements that makes the Turkish system fall within the scope of Article III:8(a). Turkey further explained that a universal healthcare system in which public authorities control all aspects of the purchase and provision of prescribed medicines to outpatients would generally fall within the scope of Article III:8(a), while this would not be the case for a system which is voluntary, does not have universal coverage and is financed through the contributions of the participants.~~**

6.69. Turkey observes that **paragraph 7.80** describes arguments made by India before the panel in *India – Solar Cells*, which the Panel describes as analogous to the arguments presented by Turkey. Turkey strongly disagrees with that comparison and refers the Panel to paragraphs 52-53 of its response to Panel Question No. 35, where it addressed India's arguments and distinguished the facts in *India – Solar Cells* from the facts in this case. Turkey therefore requests the Panel to reconsider the content of this paragraph and at the very least to reflect Turkey's arguments differentiating the present case from *India – Solar Cells*.

6.70. The European Union does not comment.

6.71. The Panel declines Turkey's request. The Panel's findings under Article III:8(a) recall at the outset that this provision was interpreted and applied in *Canada – Renewable Energy / Canada – Feed-in Tariff Program* and *India – Solar Cells*. At the very beginning of its reasoning, the Panel notes in paragraph 7.63 that this dispute is distinguishable from *Canada – Renewable Energy / Canada – Feed-in Tariff Program* and *India – Solar Cells* to the extent that, unlike the two prior disputes, the products that are allegedly "purchased" for purposes of Article III:8(a) and the products that are allegedly being discriminated against for purposes of Article III:4 are the same, i.e. pharmaceutical products included in the Annex 4/A list. In connection with this point, the Panel includes a citation to Turkey's responses to the first set of questions, paragraph 29, and also to Turkey's responses to the second set of questions, paragraphs 51-53. The Panel sees no reason to repeat this in the context of paragraph 7.80. Moreover, the Panel fails to see the relevance of this point to the analogy being drawn by the Panel in paragraph 7.80 between Turkey's argument and an argument raised by the responding party in *India – Solar Cells*.

6.72. Turkey observes that the last sentence of **paragraph 7.84** provides that "it is undisputed between the parties that pharmacies acquire ownership of medicines when obtaining them from wholesalers, and that the final consumers (i.e. outpatients) subsequently acquire ownership of pharmaceutical products when obtaining them from retail pharmacies". Turkey submits that to the extent that the Panel equates the notion of ownership with the concept of a "purchase", this sentence needs to be modified. Indeed, throughout the Panel proceedings Turkey repeatedly explained that there is no purchase of medicines included in Annex 4/A by patients. Turkey refers in that regard in particular to paragraphs 202, 210, 236 of its first written submission and paragraphs 77-79 of its second written submission.

6.73. The European Union does not comment.

6.74. The Panel understands that Turkey has been consistent in arguing that there is no "purchase" by patients of pharmaceutical products included in the Annex 4/A list. The Panel does not consider that paragraph 7.84, as currently drafted, implies that Turkey agrees there is a "purchase" by patients of pharmaceutical products included in the Annex 4/A list. Turkey's concern appears to be that, insofar as the Panel equates the notion of ownership with the concept of a "purchase", it follows that when the Panel states that it is undisputed by Turkey that the final consumers (i.e. outpatients) acquire ownership of pharmaceutical products when obtaining them from retail pharmacies, this is tantamount to saying that it is undisputed by Turkey that the final consumers (i.e. outpatients) "purchase" pharmaceutical products when obtaining them from retail pharmacies. In the Panel's view, that is a simple *non sequitur*. Accordingly, the Panel sees no reason to modify paragraph 7.84.

6.75. Turkey observes that in **paragraph 7.86** the Panel states that the absence of a right to take physical possession of the goods is a strong indicator that the entity paying for these goods has not acquired any right of ownership over them. The Panel adds that "[t]his is especially so when the goods in question are in the nature of goods that can freely be transported and stored, such as pharmaceutical products". Turkey requests the Panel to add a footnote, at the end of that sentence, explaining Turkey's arguments with respect to the nature of the goods. Turkey refers in that regard to paragraph 208 of its first written submission and paragraphs 5 and 63-64 of its second written submission.

6.76. While the European Union does not object to more extensive citations of Turkey's submissions (as long as they do not go beyond the content of the cited parts of Turkey's submissions), the European Union disagrees with Turkey's specific suggestion because it substitutes Turkey's own views of the SSI's role for Panel findings.

6.77. The Panel understands Turkey's concern with paragraph 7.86 to be the statement that pharmaceutical products "can freely be transported and stored". However, the point of this sentence is that pharmaceutical goods are in the nature of goods that can freely be transported and stored in the sense that there are no physical, logistical or practical limitations on their transportation and storage of the type that may be encountered in the case of certain other types of goods – for instance, electricity. The Panel does not mean to suggest that pharmaceutical products are unregulated products that can be freely bought and sold by anyone, and/or that there are no legal and regulatory limitations on how they are transported and stored. To avoid any misunderstanding as to the Panel's intended meaning on this point, the Panel has added a footnote for clarifying the point being made and quoting from paragraph 5 of Turkey's second written submission.

6.78. The European Union proposes to add the word "government" before the word "ownership" in the last sentence of **paragraph 7.96**.

6.79. Turkey does not object to that change.

6.80. The Panel has made the revision requested by the European Union.

6.81. Turkey observes that **paragraph 7.99** addresses the relevance of the degree of control which the SSI exercises over retail pharmacies in the dispensing of pharmaceutical products included in the Annex 4/A list. Turkey considers that the second sentence of this paragraph, which characterizes Turkey's argument on this issue, unduly restricts the scope of its argument because Turkey has not only argued that the SSI "instructs" and "directs" what pharmacies must do. Turkey has also pointed out, in paragraphs 104-107 of its first written submission and paragraphs 27, 30, 48-49 and 82-85 of its second written submission, that retail pharmacies are primary healthcare service providers under Turkish law and have duties relating to the provision of pharmaceutical products. Turkey therefore requests the Panel to reflect this by adding an additional sentence at the end of paragraph 7.99 indicating that Turkey has stressed that retail pharmacies are primary healthcare service providers under Turkish law and have duties relating to the provision of pharmaceutical products.¹⁴⁸

6.82. The European Union does not object to more extensive citations of Turkey's submissions (as long as they do not go beyond the content of the cited parts of Turkey's submissions). Any addition should, however, be made to the first part of the paragraph, addressing Turkey's arguments, and include a reference to the corresponding arguments of the European Union.

6.83. The Panel considers that paragraphs 7.92-7.103 of its Report comprehensively address Turkey's argument that even if the SSI does not itself "purchase" pharmaceutical products included in the Annex 4/A list, there is still a "purchase" covered by Article III:8(a) because private retail pharmacies "act on behalf" of the SSI, and are, to that extent, themselves "governmental agencies" for purposes of Article III:8(a). In the Panel's view, Turkey has not adequately explained what purpose is served by adding the sentence in question to paragraph 7.99. As the Panel understands it, Turkey's concern with paragraph 7.99, as reflected in its comment, is that paragraph 7.99 erroneously reduces the argument that private retail pharmacies "act on behalf" of the SSI with the proposition that the SSI "instructs" and "directs" what pharmacies must do. In the Panel's view, this

¹⁴⁸ In particular, Turkey requests that paragraph 7.99 be amended as follows (with references to Turkey's first written submission, paras. 104-107; Turkey's second written submission, paras. 27, 30, 48-49 and 82-85):

7.99. The parties have engaged in extensive arguments about the extent to which the SSI controls the actions of the retail pharmacies. Turkey essentially argues that the SSI controls all the elements concerning the acquisition and distribution of pharmaceutical products included in the Annex 4/A list, starting with deciding which pharmaceutical products are listed in the Annex 4/A list, the price of those products at each stage of the supply chain, including the "public price" charged to the SSI, and how they are dispensed to patients. The European Union disagrees, arguing that retail pharmacies freely order and purchase their pharmaceutical products from wholesalers (also private entities) through a private sales contract, hold and manage their inventory on their own (including holding property rights over it), and bear the risks associated with their stock, with no SSI involvement. The parties engage in these arguments in relation to the question whether it is correct to say that the pharmacies "act on behalf" of the SSI. **Turkey also stressed that retail pharmacies are primary healthcare service providers under Turkish law and have duties relating to the provision of pharmaceutical products.**

involves a misreading of paragraphs 7.99 and 7.100, taken in the context of the reasoning developed in this section. Accordingly, the Panel declines to make the requested revision.

6.6 Article III:4 of the GATT 1994

6.84. Turkey requests that, in order to accurately reflect Turkey's position with respect to the European Union's claim that the localisation measure is inconsistent with Article III:4 of the GATT 1994, the Panel add additional text at the end of **paragraph 7.120** elaborating on Turkey's position.¹⁴⁹

6.85. The European Union does not object to more extensive citations of Turkey's submissions (as long as they do not go beyond the content of the cited parts of Turkey's submissions). However, the proposed addition is essentially already covered by paragraph 7.119, and, if needed, it should rather be that paragraph, or footnote 467 (footnote 422 in the Interim Report), that should be amended.

6.86. The Panel has added Turkey's proposed text to the end of paragraph 7.110, in the context of providing a global overview of the parties' respective positions. In the Panel's view, this elaboration of Turkey's position is more appropriately presented there, given that paragraph 7.120 (and the paragraphs immediately preceding it) are limited to summarizing the parties' arguments as set forth in their written submissions (with additional arguments or elaborations from the parties' oral statements and responses to questions reflected elsewhere).

6.87. Turkey requests the Panel to make the following change in **paragraph 7.124**: "The Panel notes that Turkey agrees that the localisation requirement is a 'requirement' for purposes of Article ~~III:4 and~~ III:8(a)." Turkey observes that in paragraph 187 of its first written submission, mentioned in the footnote to that sentence, Turkey only stated that the localisation measure constitutes a requirement for the purpose of Article III:8(a).

6.88. The European Union does not comment.

6.89. The Panel has qualified the fourth sentence of paragraph 7.124 to state that Turkey "**seems to agree**" that the localisation requirement is a "requirement" for purposes of both Article III:4 and III:8(a) and expanded on the accompanying footnote to elaborate on the Panel's basis for that assessment. The Panel notes that the accompanying footnote refers to paragraph 187 and accompanying footnote 199 of Turkey's first written submission. Turkey rightly notes that paragraph 187 states only that the localisation measure constitutes a requirement for the purpose of Article III:8(a), and the Panel agrees with Turkey that such a statement, taken alone, would not support the conclusion that Turkey agrees that the localisation requirement is a "requirement" for purposes of both Article III:4 and Article III:8(a). However, footnote 199 states that "[t]he European Union appears to agree that the localisation measure constitutes a 'requirement'. See European Union's first written submission, paragraph 160." The Panel notes that paragraph 160 of the European Union's first written submission is directed at the term "requirement" in the context of Article III:4. Thus, Turkey's reliance on paragraph 160 of the European Union's submission (arguing that the localisation requirement is a "requirement" for the purpose of Article III:4) to establish that the European Union agrees with Turkey that the localisation requirement is likewise a "requirement" for purposes of Article III:8(a) necessarily implies that Turkey accepts that, if the localisation requirement is a "requirement" for purposes of either of those provisions, it follows that it is also a

¹⁴⁹ In particular, Turkey requests that the Panel amend paragraph 7.120. as follows (with a reference to paragraph 46 of Turkey's response to Panel Question No. 9):

7.120. In its second written submission, the European Union observes that apart from Turkey's arguments on Article III:8(a) of the GATT 1994, Turkey "does not dispute that the Localisation Requirement is inconsistent with Article III:4 of the GATT 1994" and "[t]hus, there is no disagreement on the main elements of that provision: the domestic and imported products at issue are like, the Localisation Requirement is a law, regulation or requirement affecting the internal sale, offering for sale, purchase, transportation, distribution, or use of products, and it accords less favourable treatment to imported like products." **Turkey explains that given that the obligation set out in Article III:4 does not apply to that measure, there is no need to examine the different elements of Article III:4, including whether the measure constitutes 'laws, regulations and requirements affecting internal sale, offering for sale, purchase, transportation, distribution or use' or whether that measure accords 'less favourable treatment' to imported like products.**

"requirement" for purposes of the other. It is for this reason that the Panel understood Turkey to agree that the localisation requirement is a "requirement" for purposes of both Article III:4 and III:8(a). In the light of Turkey's comment at the interim review stage, the Panel has adjusted the wording of paragraph 7.124 to be more qualified in this respect.

6.7 Turkey's alternative defence under Article XX(d) of the GATT 1994

6.90. **Section 7.4.3:** Turkey observes that this section, which addresses Turkey's alternative defence under Article XX(d) of the GATT 1994, is limited to three paragraphs in which the Panel states, without any underlying analysis, that the arguments presented by Turkey overlap with those presented under Article XX(b) and thus that the Panel's assessment "under Article XX(b) extends *mutatis mutandis* to the analysis of the defence under Article XX(d)". While Turkey disagrees with the Panel's conclusion, Turkey understands that the interim review stage does not serve the purpose of rearguing the case. Turkey considers, however, that it would be appropriate for the Panel to at least summarize the arguments presented by the parties with respect to Article XX(d) as it did for the claim under Article XX(b) (paragraphs 7.139-7.156 in the Interim Report).

6.91. The European Union does not comment.

6.92. The Panel rejects Turkey's assertion that section 7.4.3 merely states, without any underlying analysis, that the arguments presented by Turkey overlap with those presented under Article XX(b) and thus that the Panel's assessment "under Article XX(b) extends *mutatis mutandis* to the analysis of the defence under Article XX(d)". As elaborated in greater detail in paragraphs 7.216-7.218 (paragraphs 7.215-7.217 in the Interim Report), the Panel explains that Turkey's argument under Article XX(d) "is substantially the same" as its argument under Article XX(b), in particular with respect to what the measure is "designed to" do; and further that, in responding to this argument, the European Union "reiterates the same arguments" that it makes in the context of the "designed to" step in Article XX(b) (paragraph 7.217). The brevity of the Panel's analysis in paragraphs 7.216-7.218 does not reflect a refusal to engage with Turkey's arguments under Article XX(d). Rather, it reflects the Panel's assessment that the overlap, as explained in paragraphs 7.216-7.218, makes it self-evident that the Panel's assessment under Article XX(b) logically extends *mutatis mutandis* to Turkey's defence under Article XX(d). In these circumstances, the Panel sees no reason to summarize the arguments presented by the parties with respect to Article XX(d) in the same manner as it did for the claim under Article XX(b).

6.8 Article 3.1(b) of the SCM Agreement

6.93. Turkey states that it does not see the relevance of the reference in **footnote 692** (footnote 647 in the Interim Report) to paragraph 7.226 to Turkey's responses to the first set of questions, paragraph 79, and therefore asks the Panel to delete that reference.

6.94. The European Union does not comment.

6.95. The Panel notes that the footnote in question states, in relevant part, that "Turkey does not dispute that the SSI 'entrusts' or 'directs' pharmacies to perform the function of 'providing goods', i.e. pharmaceutical products, to outpatients on the terms and conditions set by the SSI" and provides a reference to Turkey's first written submission, para. 370 and to Turkey's responses to the first set of questions, para. 79. The Panel recalls that the cited paragraph of Turkey's first written submission stated, in relevant part, that "it can be considered that pharmacies have been 'entrusted' or 'directed' by the SSI to dispense pharmaceutical products to out-patients". The Panel recalls that the first set of questions included a question, directed to Turkey, setting out the Panel's understanding that "Turkey does not appear to disagree with the European Union's argument that the SSI 'entrusts' or 'directs' pharmacies within the meaning of Article 1.1(a)(1)(iv), to perform the function of 'providing goods' (i.e. medicines), to out-patients on the terms and conditions set by the SSI." Paragraph 79 of Turkey's responses to the first set of questions sets out Turkey's response to that question. While Turkey's response does not directly address that aspect of the question, the Panel considered it sufficiently relevant to include as a citation. The Panel is not persuaded that the footnote should be deleted.

6.9 Article X:1 of the GATT 1994

6.96. Turkey observes that **paragraph 7.250** (paragraph 7.249 in the Interim Report) summarizes the parties' positions regarding the question whether it would be appropriate for the Panel to make additional findings under Article X:1 of the GATT 1994 if the Article III:4 claim were to be rejected. In the final sentence of this paragraph, the Panel characterizes Turkey's position relating to the European Union's claim that the present case differs from preceding cases in which panels exercised judicial economy over an Article X:1 claim in similar circumstances. Turkey suggests that it would be more accurate to include the name of the case which the European Union sought to distinguish in the body text.

6.97. The European Union does not comment.

6.98. The Panel agrees that the readability of paragraph 7.250 would be improved by the inclusion of the names of the relevant disputes in its main body text and has revised this paragraph accordingly.

6.10 Article XI:1 of the GATT 1994

6.99. Turkey observes that **paragraph 7.260** (paragraph 7.258 in the Interim Report) introduces the parties' positions regarding the alleged import ban challenged by the European Union. Turkey notes that, given that the existence of that measure is disputed by Turkey, the Panel uses the phrase "alleged import ban" in paragraph 7.266 (paragraph 7.264 in the Interim Report). Turkey asks the Panel to consistently use the phrase "alleged import ban" when referring to the measure challenged by the European Union under Article XI:1 of the GATT 1994 throughout the Report.

6.100. The European Union does not comment.

6.101. The Panel does not consider it necessary or appropriate to insert the word "alleged" before every reference to the "import ban" measure in the Report to signify that the existence of that measure is disputed by Turkey. Apart from the fact that this would entail adding the word "alleged" up to 50 times in relation to the "import ban", it would necessitate adding the word "alleged" several hundred times for every reference to the "localisation requirement" and "prioritization measure" – given that the existence and precise content of these measures are also disputed by Turkey.

6.11 The prioritization measure

6.102. Turkey observes that **footnote 766** (footnote 722 in the Interim Report) to the last sentence of paragraph 7.285 (paragraph 7.283 in the Interim Report) includes a comment suggesting that Turkey accepts certain elements of the European Union's position without disputing, as a threshold issue, whether the European Union has identified the existence and precise content of the measure it seeks to challenge. In order to accurately reflect Turkey's position, Turkey asks the Panel to add certain qualifying language to the first sentence of footnote 766.¹⁵⁰

6.103. The European Union does not comment.

6.104. The Panel understands the qualification requested by Turkey to already be implicit in the text as currently drafted. However, to avoid any possible misunderstanding of Turkey's position, the Panel has revised the text in the manner requested by Turkey.

¹⁵⁰ In particular, Turkey requests the Panel amend the footnote to read as follows:

Insofar as the European Union has demonstrated the existence and precise content of the measure, Turkey does not dispute the European Union's arguments that there can or will be domestic and imported products that are "like products" affected by the origin-based distinction in the prioritization measure (European Union's first written submission, paras. 366-369), and that the measure is one "affecting the internal sale, offering for sale, purchase, transportation, distribution, or use of products" (European Union's first written submission, paras. 372-375).

7 FINDINGS

7.1 The existence and precise content of the localisation requirement as a "single and cohesive measure"

7.1.1 Introduction

7.1. The Panel will begin by assessing whether the European Union has established the existence and precise content of the localisation requirement, based on the European Union's description and characterization of it as a "single and cohesive measure".

7.2. The European Union challenges a measure it refers to as the "localisation requirement", whereby Turkey requires foreign producers to commit to localise in Turkey their production of certain pharmaceutical products¹⁵¹, which are otherwise "excluded" from Turkey's reimbursement scheme if commitments are not given, accepted or fulfilled.¹⁵² The European Union argues that the localisation requirement is a "single and cohesive measure", "[d]espite the diversity of instruments used" in its implementation, because the individual steps pertaining to the localisation requirement are taken within the framework of a "single" measure.¹⁵³ The European Union submits that the "existence and precise content" of the localisation requirement are "undisputed"; the Turkish authorities themselves refer to these individual steps as part of a single localisation requirement, and Turkey agrees with the "main factual elements" of the localisation requirement as described by the European Union.¹⁵⁴ Moreover, the European Union considers that it has "explained [the localisation requirement] in great detail, based on extensive evidence".¹⁵⁵

7.3. Turkey submits that the Panel should reject all of the European Union's claims concerning the "localisation measure"¹⁵⁶ because the European Union has failed to establish the "precise content" and/or "existence" of this measure.¹⁵⁷ Turkey argues that the European Union, having characterized the measure as a "single and cohesive measure", "based on... 'plans'... and on 'various instruments and tools'" implementing a localisation policy in the pharmaceutical sector, challenges a "single measure which is composed of several different instruments". For that reason, Turkey asserts that the European Union was required to identify and explain which instruments and tools are components of the localisation measure and how they operate together. Having failed to do so, Turkey considers that the European Union consequently failed to establish the "existence" and "precise content" of the localisation measure.¹⁵⁸ Turkey also submits that it remains "unclear" from the European Union's

¹⁵¹ The parties' submissions refer variously to "pharmaceutical products", "pharmaceuticals", "medicines", and "drugs". So do the relevant Turkish documents and instruments cited throughout this Report. While the scope of the "pharmaceutical products" at issue in this dispute is not strictly limited to medicines and drugs, the Panel sees no issue with respect to the varying terminology and, like the parties, uses these terms interchangeably. Likewise, the Panel sees no issue with respect to the varying terminology used by the parties when referring to pharmaceutical products being "locally manufactured", "locally produced", "domestically manufactured", or "domestically produced".

¹⁵² European Union's first written submission, paras. 6-7; European Union's panel request, p. 5.

¹⁵³ European Union's first written submission, para. 60.

¹⁵⁴ European Union's first written submission, paras. 60-66; second written submission, paras. 31-34; and opening statement, paras. 6 and 8.

¹⁵⁵ European Union's second written submission, paras. 27-30 (referring to Appellate Body Reports, *Argentina – Import Measures*, para. 5.108); opening statement, paras. 6 and 8.

¹⁵⁶ As noted above in the descriptive part of the Report, Turkey refers to the localisation requirement as the "localisation measure" (see fn 71). The Panel shares Turkey's understanding that "the measure that is challenged by the European Union is not only the 'requirement' allegedly imposed by Turkey on foreign producers to localise their production of certain pharmaceutical products in Turkey, but also the consequences following from the commitment or lack of commitment of localisation." (Turkey's first written submission, para. 117). There is no issue between the parties in this regard. The Panel also agrees with Turkey that the measure challenged by the European Union could equally have been referred to as the "localisation measure". However, the Panel does not consider that referring to the challenged measure as the "localisation requirement" implies a more restrictive understanding of what the challenged measure is or entails, and therefore sees no reason to deviate from the terminology used by the European Union.

¹⁵⁷ Turkey's first written submission, paras. 116-121.

¹⁵⁸ Turkey's first written submission, paras. 119-121; second written submission, paras. 38-39; responses to the first set of questions, paras. 11 and 14; and responses to the second set of questions, paras. 26 and 29.

description of the localisation measure "what the components which 'form part of' the localisation measure are".¹⁵⁹

7.1.2 Relevant provisions

7.4. While the DSU does not define the concept of a "measure"¹⁶⁰, it is well established that in principle, any act or omission attributable to a WTO Member can be a "measure" for the purposes of dispute settlement proceedings.¹⁶¹ Therefore, a broad range of measures can be challenged in WTO dispute settlement.¹⁶²

7.5. In every WTO dispute, complainants are required to prove the existence of the measures at issue. How a measure is described, characterized, and challenged by a complainant will inform the kind of evidence a complainant is required to submit and the elements that it must prove in order to establish the existence of the measure challenged.¹⁶³ For every measure, a complainant must establish that the measure is attributable to the respondent, as well as the precise content of the challenged measure, to the extent that such content is the object of the claims raised.¹⁶⁴ A complainant may be required to demonstrate other elements, depending on the particular characteristics or nature of the measure being challenged.¹⁶⁵

7.6. In numerous disputes, complainants have challenged "single" measures comprised of multiple components, elements, or instruments.¹⁶⁶ In some of those disputes, panels and the Appellate Body had to consider whether the challenged measure constituted a "single" measure distinct from its constituent parts. Aside from being relevant to the question of whether the complainant has established the existence of the challenged measure, a proper characterization of the measure(s) at issue (as "single" or distinct measures, or otherwise) enables panels to make findings that assist the DSB in making "sufficiently precise recommendations and rulings" to ensure the effective resolution of WTO disputes.¹⁶⁷

¹⁵⁹ Turkey's responses to the second set of questions, para. 27.

¹⁶⁰ Article 3.3 of the DSU refers to the impairment of benefits by "measures" taken by another Member. Article 6.2 of the DSU requires that a panel request identify the "specific measures at issue". Such identification is one of two components of the "matter referred to the DSB", which in turn forms the basis for a panel's terms of reference under Article 7.1 of the DSU. (Appellate Body Report, *US – Carbon Steel*, para. 125 (referring to Appellate Body Report, *Guatemala – Cement I*, paras. 69-76).)

¹⁶¹ Appellate Body Reports, *US – Anti-Dumping Methodologies (China)*, para. 5.122 (referring to Appellate Body Report, *US – Corrosion-Resistant Steel Sunset Review*, para. 81); *Argentina – Import Measures*, para. 5.100.

¹⁶² Appellate Body Reports, *US – Anti-Dumping Methodologies (China)*, para. 5.122; *Guatemala – Cement I*, fn 47 to para. 69; *EC and certain member States – Large Civil Aircraft*, para. 794; and *Argentina – Import Measures*, paras. 5.108 and 5.110. In this vein, the Appellate Body has referred to the "comprehensive nature of the right of Members" in Article 3.2 of the DSU, to resort to dispute settlement to preserve their rights and obligations. (Appellate Body Report, *EU – Biodiesel (Argentina)*, para. 6.228 (referring to Appellate Body Report, *US – Corrosion-Resistant Steel Sunset Review*, para. 89).)

¹⁶³ Appellate Body Reports, *US – Anti-Dumping Methodologies (China)*, para. 5.123; *Argentina – Import Measures*, paras. 5.108-5.110.

¹⁶⁴ Appellate Body Reports, *Argentina – Import Measures*, para. 5.104. As to the requirement to establish the precise content of the challenged measure, a panel's examination is informed by the complainant's description of the alleged measure, including its "constituent elements" and "defining characteristics", substantiated through arguments and evidence. (Appellate Body Reports, *Argentina – Import Measures*, paras. 5.117-5.118, and 5.124; *Russia – Railway Equipment*, paras. 5.234 and 5.236.)

¹⁶⁵ Appellate Body Reports, *Argentina – Import Measures*, paras. 5.104 and 5.108; *US – Supercalendered Paper*, para. 5.17.

¹⁶⁶ See e.g. Panel Reports, *US – Export Restraints*, paras. 8.82-8.87 and 8.130-8.131; *Turkey – Rice*, paras. 7.273 and 7.280-7.281; *US – COOL*, paras. 7.35 and 7.44-7.61; *EC – Seal Products*, paras. 7.25-7.27; *Argentina – Import Measures*, paras. 6.221-6.231; *Indonesia – Chicken*, paras. 7.618-7.619, 7.624, and 7.664-7.688; *Colombia – Textiles*, paras. 7.270-7.274 and 7.343-7.344; *Russia – Railway Equipment*, paras. 5.229, 5.243, and 5.249; and *India – Solar Cells*, paras. 7.24-7.28. See also Appellate Body Reports, *EC – Seal Products*, para. 1.3; *US – Tuna II (Mexico) (Article 21.5 – Mexico)*, paras. 7.1 and 7.13-7.21; and *Argentina – Import Measures*, paras. 5.124 and 5.130-5.131.

¹⁶⁷ Panel Report, *US – COOL*, paras. 7.47-7.48. See also Panel Reports, *China – Raw Materials*, paras. 7.59-7.63 and 7.68; *China – Rare Earths*, paras. 7.41, 7.235, 8.1.a, 8.6.a, and 8.11.a for instances where panels have considered challenged measures as "single measures" despite that term not being used, in order to make such findings.

7.7. In cases involving challenges to a "single" measure comprised of multiple components¹⁶⁸, panels and the Appellate Body have generally considered three main factors¹⁶⁹: (i) the complainant's presentation of its claim(s) in respect of the constituent components¹⁷⁰; (ii) the respondent's position¹⁷¹; and (iii) the operation of and relationship between the components to determine whether they are "autonomous or independent", or more "interdependent" and integrated.¹⁷²

7.8. In examining the relationship between the various components of a "single" measure, panels and the Appellate Body have also considered the legal status of these components, the impact their relationship has on their functioning, any substantive legal links (e.g. implementing legislation, interpretive guidance or certain practices), and any relationship with or contribution to an overarching policy or framework where such policy is alleged.¹⁷³ Indeed, when referring to the three main factors above, the Appellate Body indicated that "a complainant challenging a single measure composed of several different instruments will normally need to provide evidence of how the different components operate together as part of a single measure and how a single measure exists as distinct from its components".¹⁷⁴

7.9. When analysing "single" measures, some panels have considered whether certain instruments are separate measures, or merely evidence of measures and their components. For example, in *India – Solar Cells*, the panel addressed certain domestic content requirement (DCR) measures requiring solar power developers to purchase or use solar cells or modules of domestic (Indian) origin in order to enter into and maintain certain power purchase agreements. These DCR measures were set forth, reproduced or otherwise reflected in a series of documents. The panel therefore had to decide whether the documents reflecting the DCR measures were themselves distinct measures.¹⁷⁵ In its analysis, the panel referred to the wording of the United States' panel request, the parties' submissions throughout the proceedings and the interconnectedness of the documents underlying each DCR measure. These factors all favoured treating the DCR measure for each of three "batches" as a measure, reflected or incorporated in the various documents. The underlying documents and instruments were not treated as distinct measures.¹⁷⁶

¹⁶⁸ The Panel uses the term "components" to refer to the constituent elements of a "single" measure, that make up the content of that measure. Some previous panels have used the terms "instruments", "requirements" or "measures" when referring to the constituent elements of a single measure.

¹⁶⁹ See Panel Reports, *US – COOL*, para. 7.50; *Argentina – Import Measures*, para. 6.222; Appellate Body Report, *Argentina – Import Measures*, fn 541 to para. 5.108.

¹⁷⁰ A complainant's characterization of the challenged measure as a "single measure" is usually but not necessarily the starting point for a panel's analysis. See Panel Reports, *China – Rare Earths*, paras. 7.41, 7.235, 8.1.a, 8.6.a, and 8.11.a; *China – Raw Materials*, paras. 7.59-7.63 and 7.68.

¹⁷¹ In some cases, it is undisputed between the parties that multiple components may be analysed as a "single" measure. For example, in *EC – Seal Products*, both parties agreed that the "EU Seal Regime" at issue should be treated as a single measure. (Panel Reports, *EC – Seal Products*, para. 7.26.)

¹⁷² Past panels and the Appellate Body have examined whether components operate in their "own right", have their own "functional life", do something "independently" to "independently give rise to a WTO violation" or have "autonomous status". In *Indonesia – Chicken*, that panel considered that "co-existence in the same legal instrument" or a "connection between different legal instruments" is not enough to assume that components operate as a single measure, "particularly" where they "operate in their own right". Rather, a panel must look at whether components are "inter-dependent in respect of the overall impact assessed". (Panel Report, *Indonesia – Chicken*, paras. 7.664-7.688.)

¹⁷³ For example, in *EC – Seal Products*, the panel and Appellate Body treated the EU Seal Regime (a Basic Regulation and an Implementing Regulation implementing the Basic Regulation) as a single measure. The regulations operated "in conjunction with each other in governing the importation and the placing of seal products on the EU market". Further, the Implementing Regulation did not "operate on its own", having been adopted to implement the Basic Regulation. (Panel Reports, *EC – Seal Products*, para. 7.26.) In *Indonesia – Chicken*, the lack of structural interdependence between the component measures, which could each be terminated without affecting other component measures, was fatal to there being a "single" measure. (Panel Report, *Indonesia – Chicken*, paras. 7.664-7.688.) On the relationship between components and policies, see e.g. Appellate Body Reports, *Argentina – Import Measures*, paras. 5.126, and 5.129-5.132; *US – Tuna II (Mexico) (Article 21.5 – Mexico)*, para. 7.16; and Panel Report, *Indonesia – Chicken*, paras. 7.664-7.688.

¹⁷⁴ Appellate Body Reports, *Argentina – Import Measures*, para. 5.108 and fn 451 to para. 5.108 (referring to Panel Reports, *Argentina – Import Measures*, para. 6.144; *US – COOL*, para. 7.50).

¹⁷⁵ Panel Report, *India – Solar Cells*, paras. 7.24-7.28.

¹⁷⁶ Panel Report, *India – Solar Cells*, para. 7.28.

7.1.3 Main arguments of the parties

7.10. In its first written submission, the European Union explains the localisation requirement by reference to: (i) its general features and objectives; (ii) why it constitutes a "single and cohesive measure"; (iii) the institutional set-up; (iv) the process and "phases" of localisation; (v) its implementation in general; (vi) its implementation through various "phases"; and (vii) its application to individual companies and their products.¹⁷⁷ According to the European Union, the localisation requirement is "a single and cohesive measure" because "[d]espite the diversity of instruments used, and despite the fact that much of the detailed implementation of the Localisation Requirement takes place in bilateral communications between Turkish authorities and individual pharmaceutical companies, there is no doubt that all of these steps are taken within the framework of a single Localisation Requirement, in order to achieve the objectives described above."¹⁷⁸ The European Union adds that "many of the relevant legal instruments and documents expressly refer, for example, to the Tenth Development Plan 2014-2018 or to the Action Plan of the 64th Government", and states that Turkish authorities "have repeatedly emphasized that the Localisation Requirement is a single, cohesive measure, and that individual steps such as the announcements on the removal of certain products from the Reimbursement List are taken within the framework of that measure".¹⁷⁹

7.11. Turkey responds that the European Union has failed "to precisely identify the components of the measure and *a fortiori* to provide evidence of how those components operate together as part of a single measure".¹⁸⁰ According to Turkey, the European Union claims that the localisation policy is "based on... 'various instruments and tools'" and therefore challenges a single measure "composed of several different instruments, including plans and other instruments"¹⁸¹, without, however, identifying those instruments and tools precisely or explaining which "instruments and tools" properly constitute the components of the localisation requirement and how those components operate together.¹⁸² According to Turkey, such identification and explanation are essential to establish the "precise content" of the measure and have important consequences for some of the claims.¹⁸³ Turkey submits that it is not for Turkey, as the responding party, to second-guess which of the elements referred to by the European Union in its first written submission, constitute the "legal instruments that form part of, or give effect to" the localisation measure and, thereby, constitute components of the measure; rather, it is for the complainant to establish the existence and precise content of the measure it challenges and therefore for that party to precisely identify the legal instruments forming part or giving effect to the measure.¹⁸⁴ Turkey submits that "by failing to do so the European Union has failed to demonstrate the existence and precise content of the measure".¹⁸⁵

7.12. In its second written submission, the European Union states that it "has explained in great detail, based on extensive evidence, what the components of the measure are and how they interrelate", and that it "is unclear from Turkey's submission what sort of explanation Turkey would like, or what it considers to be lacking".¹⁸⁶ As to the applicable legal standard, the European Union submits that there "is no requirement for a complainant to separately list or qualify each of the 'components' of a measure, or explain how each of them relates to all of the others", and that Turkey errs insofar as it reads the Appellate Body report in *Argentina – Import Measures* as supporting such a requirement.¹⁸⁷ According to the European Union, the issue in that case was whether or not several "components" are sufficiently related, or operate together, such that they can be described as a single measure as opposed to several *different* measures. By contrast, "the issue of explaining how different components of a measure operate together does not present itself in this case, because ... it is undisputed that the Localisation Requirement exists as a measure in its own right, and that the

¹⁷⁷ European Union's first written submission, section 2.2.2.

¹⁷⁸ European Union's first written submission, para. 60.

¹⁷⁹ European Union's first written submission, para. 60. See also European Union's first written submission, para. 62.

¹⁸⁰ Turkey's first written submission, para. 120. See also Turkey's first written submission, para. 119 (citing Appellate Body Reports, *Argentina – Import Measures*, para. 5.108).

¹⁸¹ Turkey's first written submission, para. 119 (referring to Appellate Body Reports, *Argentina – Import Measures*, para. 5.108).

¹⁸² Turkey's first written submission, para. 120.

¹⁸³ Turkey's first written submission, para. 120.

¹⁸⁴ Turkey's first written submission, para. 121.

¹⁸⁵ Turkey's first written submission, para. 121.

¹⁸⁶ European Union's second written submission, para. 27.

¹⁸⁷ European Union's second written submission, para. 28.

various elements cited by the EU form part of it or of its implementation."¹⁸⁸ According to the European Union, while the parties disagree on a number of factual aspects as well as on the legal characterization of the measure, "the existence and precise content of the Localisation Requirement are in fact undisputed".¹⁸⁹

7.13. In its second written submission, Turkey reiterates that it "takes issue with the fact that the European Union referred to the localisation measure as a single and cohesive measure which is based on a number of plans, instruments or tools but that the European Union failed to identify those instruments and tools precisely".¹⁹⁰ Turkey states that it is not for it to guess "which instruments constitute the components of the measure that the European Union challenges", and that by failing to identify them precisely, "the challenged measure becomes a moving target."¹⁹¹ According to Turkey, "this is particularly relevant in the context of the European Union's claim under Article X:1 of the GATT 1994 where the European Union has submitted that not all legal instruments that form part, or give effect to the localisation requirement have been published promptly".¹⁹² Turkey states that the European Union "should have identified the specific instruments and tools which, according to the European Union, form part or give effect to the localisation measure", and that, by failing to do so, "the European Union failed to identify the precise content and scope of the measure it challenges."¹⁹³

7.1.4 Assessment by the Panel

7.14. The Panel recalls that how the localisation requirement is described, characterized and challenged by the European Union informs the kind of evidence the European Union is required to submit and the elements that it must prove to establish the existence of the localisation requirement.¹⁹⁴ In assessing whether the localisation requirement is a "single" measure, the Panel will refer to the European Union's presentation of its claims (including what the content of the measure is), Turkey's position on the issue, and the operation of and relationship between the various components, including, where relevant, their relationship with an overarching policy or framework.¹⁹⁵ The Panel adopts a holistic approach in analysing these elements, and in addressing whether the European Union has established the existence and/or precise content of the localisation requirement as a "single measure".¹⁹⁶

7.15. Beginning with how the European Union has characterized and described the content of the measure that it is challenging, the Panel recalls that the European Union's panel request identifies the three measures at issue in this dispute as (i) the localisation requirement; (ii) the import ban on localised products; and (iii) the prioritization measure. The panel request then lists 28 different legal instruments or other types of documents, with the preface that the three measures "are put in place and evidenced by, and are implemented and administered through, *inter alia*, the following legal and other instruments, considered alone and in any combination".¹⁹⁷ The panel request is then divided into three sections, each devoted to one of the measures. These sections in turn contain a sub-section headed "identification of the specific measure at issue" containing a narrative description of the relevant challenged measure.¹⁹⁸

¹⁸⁸ European Union's second written submission, para. 29.

¹⁸⁹ European Union's second written submission, para. 31. The European Union lists examples of how it considers that Turkey explains that the localisation requirement is based on Turkish law, and the main factual elements of the localisation requirement with which it considers Turkey agrees. (European Union's second written submission, paras. 32-33.)

¹⁹⁰ Turkey's second written submission, para. 38.

¹⁹¹ Turkey's second written submission, para. 39.

¹⁹² Turkey's second written submission, para. 39.

¹⁹³ Turkey's second written submission, para. 39.

¹⁹⁴ Appellate Body Reports, *US – Anti-Dumping Methodologies (China)*, para. 5.123; *Argentina – Import Measures*, paras. 5.108-5.110.

¹⁹⁵ See Panel Reports, *US – COOL*, para. 7.50; *Argentina – Import Measures*, para. 6.222.

¹⁹⁶ See also the holistic approach taken by the panel and upheld by the Appellate Body concerning the precise content of the TRRs measure and its operation as a single measure in *Argentina – Import Measures*. (Appellate Body Reports, *Argentina – Import Measures*, paras. 5.133, 5.164 (quoting Panel Reports, *Argentina – Import Measures*, para. 6.119.)

¹⁹⁷ European Union's panel request, p. 1.

¹⁹⁸ See also preliminary ruling by the Panel, para. 3.8.

7.16. The narrative description of the localisation requirement in the panel request refers to the measure in the singular, and describes the challenged measure as follows:

Turkey requires foreign producers to commit to localise in Turkey their production of certain pharmaceutical products. If such commitments are not given, are not accepted by Turkish authorities, or are not fulfilled, the pharmaceutical products concerned are excluded from the scheme for the reimbursement of the pharmaceutical products sold by pharmacies to patients operated by Turkey's social security system (the "reimbursement scheme").¹⁹⁹

7.17. Based on the foregoing, the Panel understands the European Union to define the localisation requirement as a composite measure, comprising two elements, whereby (i) Turkey requires foreign producers to commit to localise in Turkey their production of certain pharmaceutical products, and (ii) where commitments are not given, not accepted or not fulfilled relevant products are no longer reimbursed by the SSI.²⁰⁰ This, in the Panel's view, serves as the description and characterization of the measure, which identifies the precise content of the measure that must be sufficiently established through evidence. The European Union's statement that this measure is "put in place and evidenced by, and [is] implemented and administered through" a variety of legal instruments and documents confirms that the legal instruments and documents are being referred to for the purpose of evidencing the existence of the measure (as described above) and explaining the means through which it is put in place. In the Panel's view, this statement, and others like it, do not have the effect of equating the listed instruments and documents with the content of the measure itself. Rather, they serve an evidentiary and explanatory purpose. Thus, the description of the content of the localisation requirement is entirely independent from the instruments through which that measure is evidenced and implemented.

7.18. This conclusion is buttressed by the fact that the European Union does not actually refer to any legal instruments or documents in the narrative description of the localisation requirement in its panel request. It is further reinforced by how the European Union refers to the measure, and related instruments, in its submissions. The European Union, in its first written submission, describes the localisation requirement in the same or similar terms as in its panel request.²⁰¹ While the European Union makes several references to "instruments", none of these references blur the distinction between what the measure at issue is, on the one hand, and how that measure is evidenced, implemented and/or administered (i.e. through various instruments), on the other hand. To the contrary, such references reinforce that distinction. For example, the European Union refers to instruments "implementing" a "localisation policy"²⁰², "outlining" processes and phases of the localisation requirement²⁰³, "governing" the reimbursement system²⁰⁴, "imposing" the localisation requirement²⁰⁵, and "giving effect to"²⁰⁶ the localisation requirement. Such statements serve to distinguish what the measure is, on the one hand, and the legal instruments and documents through which that measure is evidenced and implemented, on the other hand.

7.19. The Panel now turns more specifically to the question of how the European Union has presented its arguments on whether the localisation requirement (as described above) can be examined as a "single measure" for purposes of the Panel's findings. The Panel recalls that in its first written submission, the European Union refers to the localisation requirement as a "single and cohesive measure" which is implemented "through various instruments and tools".²⁰⁷ The European Union repeats its description of the localisation requirement in the same or similar terms as in its panel request²⁰⁸ before describing in greater detail the localisation requirement's general features and objectives, institutional set-up, and the process and phases of its implementation in practice.²⁰⁹ The European Union also explains why, "[d]espite the diversity of instruments used ... there is no

¹⁹⁹ European Union's panel request, p. 5.

²⁰⁰ European Union's panel request, p. 5.

²⁰¹ European Union's first written submission, paras. 1 and 6-7.

²⁰² European Union's first written submission, paras. 39, 58, 60, and 256.

²⁰³ European Union's first written submission, para. 76.

²⁰⁴ European Union's first written submission, para. 192.

²⁰⁵ European Union's first written submission, para. 231.

²⁰⁶ European Union's first written submission, para. 249.

²⁰⁷ European Union's first written submission, section 2.2.2.2, and in particular para. 58.

²⁰⁸ European Union's first written submission, paras. 1, and 6-7.

²⁰⁹ European Union's first written submission, section 2.2.2.2.

doubt that all of these steps are taken within the framework of a single Localisation Requirement".²¹⁰ The Panel notes that the European Union also presents the localisation requirement as a "single" measure in its second written submission and opening statement at the substantive meeting.²¹¹

7.20. The European Union submits that the localisation requirement and its individual "steps", such as the passivization of certain pharmaceutical products in the Annex 4/A list, pursue a localisation policy, which itself is anchored in broader policies such as the Tenth Development Plan 2014-2018 or the Action Plan of the 64th Government.²¹² The European Union further argues that various evidence, including statements by Turkish ministers and institutions like the SSI, situates local production, commitments from pharmaceutical companies and treatment of products in the Annex 4/A list within the framework of the "localisation requirement". According to the European Union, such evidence includes²¹³:

- a. public and private communications, issued jointly or separately by the TMMDA and the SSI to pharmaceutical companies importing pharmaceutical products to Turkey, to commit to localise production of certain products and, failing that, announcing "the removal of certain products from the Reimbursement List"²¹⁴;
- b. documentation indicating that where the relevant pharmaceutical company does not submit a commitment, or where a commitment is refused or not fulfilled on time, the relevant products are "deactivated, and later potentially delisted" from the Annex 4/A list²¹⁵;
- c. express references in many relevant legal instruments and documents to the Tenth Development Plan 2014-2018 or the Action Plan of the 64th Government²¹⁶;
- d. statements by Turkish authorities concerning a "localisation policy" carried out as part of the Tenth Development Plan 2014-2018 and 64th Government Action Plan, including by the Turkish Minister of Economy and the SSI²¹⁷; and
- e. reference to a "process of localisation of imported drugs" as "[o]ne of the most important steps of indigenization in healthcare" in a policy document titled "Structural Transformation Program in Healthcare Industries".²¹⁸

7.21. The Panel considers that the European Union's description of these elements and the evidence it relies on, would *prima facie* support the conclusion that there exists a localisation policy, enacted

²¹⁰ European Union's first written submission, paras. 60 and 62.

²¹¹ Similarly, in its second written submission, the European Union responds to Turkey's arguments as to why the European Union has failed to establish the existence and precise content of the localisation requirement as a single and cohesive measure. (European Union's second written submission, section 2.2.3.) The European Union's opening statement argues along similar lines, also treating the localisation requirement as a single and cohesive measure. (European Union's opening statement, paras. 5-9.)

²¹² European Union's first written submission, para. 60.

²¹³ See for example European Union's first written submission, paras. 59-66 (referring to Social Security Institution, Rejoinder in court proceedings raised by the Association of Research-Based Pharmaceutical Companies (AIFD) before the Turkish State Council, Case 2017/1308, 21 September 2017 (SSI Rejoinder) (Exhibit EU-21); EU Commissioner for Trade, Letter to the Turkish Minister of Economy, 5 April 2017 (Exhibit EU-28); Turkish Minister of Economy, Letter to the EU Commissioner for Trade, 19 June 2017 (Exhibit EU-29); Social Security Institution, Defense in court proceedings raised by the Association of Research-Based Pharmaceutical Companies (AIFD) before the Turkish State Council, Case 2017/1308, 29 June 2017 (SSI Defense) (Exhibit EU-30); and H. Eroğlu, Vice President of the TMMDA, "Local Production", presentation at the Symposium on Rational Approach to Current Issues concerning Medicines, Ankara, 7-9 October 2016 (Exhibit EU-40)).

²¹⁴ European Union's first written submission, paras. 59-60.

²¹⁵ European Union's first written submission, para. 59 (referring to H. Eroğlu, Vice President of the TMMDA, "Local Production", presentation at the Symposium on Rational Approach to Current Issues concerning Medicines, Ankara, 7-9 October 2016 (Exhibit EU-40)).

²¹⁶ European Union's first written submission, paras. 60 and 66 (referring to SSI Rejoinder (Exhibit EU-21); EU Commissioner for Trade, Letter to the Turkish Minister of Economy, 5 April 2017 (Exhibit EU-28); Turkish Minister of Economy, Letter to the EU Commissioner for Trade, 19 June 2017 (Exhibit EU-29); and SSI Defense (Exhibit EU-30)).

²¹⁷ Ibid.

²¹⁸ European Union's first written submission, paras. 64-66.

as part of a broader governmental programme, with its own policy documentation such as the Structural Transformation Program in Healthcare Industries. The Panel also considers that, in practice, much of this measure is evidenced by and implemented through individual bilateral communications between Turkish authorities (especially the TMMDA and SSI) and foreign pharmaceutical companies announcing whether certain products fall within the scope of the localisation requirement, the treatment of relevant commitments and any "passivization" or removal from the reimbursement scheme through the Annex 4/A list. The Panel considers that, in the absence of any rebuttal arguments from Turkey, the nature of the explanation provided by the European Union in its first written submission would suffice to establish, *prima facie*, that the localisation requirement may be examined as a single measure for the purposes of this dispute.

7.22. While Turkey presents its arguments in terms of the European Union's failure to establish the "existence" and "precise content" of the localisation requirement²¹⁹, the Panel understands that Turkey does not deny that there is, in fact, one or more measures in place through which foreign producers of pharmaceutical products are required to submit to Turkish authorities commitments to localise in Turkey their production of certain products as a condition for those products to remain included and active in the Annex 4/A list.²²⁰ In this connection, the Panel notes that the European Union lists²²¹ the following points of agreement between the parties:

- products may be de-activated or "passivized", including as "a result of the localisation measure";
- pharmacies invoice the SSI for the price of the medicines they supplied to patients as well as other fees;
- on top of the reimbursed price, patients must pay a "contribution fee" and a "prescription fee" to pharmacies in order to receive the medicines;
- medicines are provided to inpatients directly, through a system that differs from the one at issue in this dispute;
- the localisation requirement "derives from" several high-level instruments adopted by the Turkish government, corresponding to those cited by the European Union;
- the localisation requirement "entails production activities in Turkey";
- the TMMDA selects which imported products will be subject to localisation;
- the measure is implemented in five phases without a set timeline, two of which have already been implemented, as described by the European Union;
- various Turkish authorities including the TMMDA, the HISC, the LAC and the SSI are "involved in the implementation of the localisation measure";
- all reimbursable medicines (i.e. all pharmaceutical products with a valid marketing authorization and sales permit included in the Annex 4/A list) are "subject to localisation";
- the TMMDA identifies the companies whose products are subject to localisation, informs them of possible de-activation, invites them to submit commitments (i.e. "a declaration whether or not a pharmaceutical company will relocate within a specified period of time the production of the relevant pharmaceutical products to Turkey";)
- if those commitments are accepted, variation applications must be submitted;
- companies must submit progress reports, and may request additional time, or the localisation of an alternative product;
- if there is no localisation commitment, a period of one year is accorded to the company to "reconsider its position"; if it does not, or if its commitment has not been accepted or fulfilled, the products will be "passivized" or de-activated;
- the status of a product as activated or de-activated may be updated;

²¹⁹ Turkey's first written submission, section VI.A; second written submission, section III.A.

²²⁰ See European Union's second written submission, paras. 32-34 (referring to Turkey's first written submission, paras. 6, 79, 82, 108, 111-114, 128-142, and 148-163).

²²¹ European Union's second written submission, para. 33.

- the different phases have been implemented according to a timeline, which by and large corresponds to the evidence set out by the European Union. Turkey disagrees that all phases should be considered as ongoing, pointing out that Phases 3 and 4 have so far not been implemented, however, it does accept that there is no set timeline, that products have been shifted from Phases 3, 4 or 5 to Phases 1 or 2, and presumably also that Phases 3 and onwards have not been cancelled, such that they continue to exist as parts of the measure.

7.23. Accordingly, the Panel understands Turkey's position to be that there is in fact a localisation requirement, i.e. one or more measures in place through which foreign producers of pharmaceutical goods are required to submit to Turkish authorities commitments to localise production if those products are to be included in the Annex 4/A list.²²² The Panel understands Turkey's argument regarding the European Union's failure to establish the "existence" and "precise content" of the measure to be limited to its contention that the European Union was required to specifically and exhaustively identify the "various instruments and tools" implementing the localisation requirement and how they interrelate, because they are component parts of the "single" challenged measure.²²³ The Panel therefore understands Turkey's argument to be limited to the question of whether a precise identification of all of the instruments that in Turkey's view are "components" of the localisation requirement is a prerequisite for making findings on the European Union's claims against the localisation requirement as a "single and cohesive measure". This appears to be Turkey's position throughout its written submissions, responses to Panel questions and statements at the substantive meeting.²²⁴

7.24. For the reasons given above, the Panel does not agree with the premise of Turkey's argument, namely, that the European Union has characterized and described the content of the measure at issue by reference to legal instruments and documents. In the Panel's view, Turkey's argument conflates the content of the localisation requirement with the instruments through which that measure is evidenced and implemented. In some cases, a complaining party may describe and define the content of the challenged measure by reference to certain legal instruments and documents, and in such a way as to equate the content of the measure to one or more legal instruments or documents, and make them constitutive components of the measure itself. In such cases, it may well follow that a complaining party is required to specifically and exhaustively identify all such legal instruments and documents to properly identify the content of the challenged measure. In this case, however, the European Union has not defined the content of the measure by reference to, or in terms of, legal instruments or documents. As already explained above, the precise content of the localisation requirement, as described and characterized by the European Union in its panel request, is that Turkey requires foreign producers to commit to localise in Turkey their production of certain pharmaceutical products, and where commitments are not given, not accepted or not fulfilled relevant products are no longer reimbursed by the SSI.

7.25. Consequently, the Panel disagrees with Turkey's argument that the European Union fails "to precisely identify the components of the measure and *a fortiori* to provide evidence of how those components operate together as part of a single measure".²²⁵ The Panel also rejects Turkey's argument that the European Union was required "to precisely identify the legal instruments forming part or giving effect to the measure"²²⁶, and that "by failing to do so the European Union has failed to demonstrate the existence and precise content of the measure."²²⁷

7.26. The Panel is also compelled to note that Turkey's argument is, to some extent, a reformulation of the same argument that the Panel has already considered in the context of assessing whether the European Union's panel request complies with the requirement, in Article 6.2 of the DSU, to identify the "specific measures at issue". The Panel recalls that in a request for a preliminary ruling, Turkey

²²² In this vein, the European Union points to examples whereby Turkey seemingly acknowledges the localisation requirement. See European Union's second written submission, paras. 32-34 (referring to Turkey's first written submission, paras. 6, 79, 82, 108, 111-114, 128-142, and 148-163).

²²³ See Turkey's responses to the first set of questions, paras. 13-14; responses to the second set of questions, paras. 23-24, 26 and 29.

²²⁴ See Turkey's first written submission, paras. 119-121; second written submission, paras. 38-39; responses to the first set of questions, paras. 11, 14; and responses to the second set of questions, paras. 23, 24, 26, and 29.

²²⁵ Turkey's first written submission, para. 120.

²²⁶ Turkey's first written submission, para. 121. See also Turkey's second written submission, paras. 38-39.

²²⁷ Turkey's first written submission, para. 121. See also Turkey's second written submission, para. 39.

argued that the European Union failed to identify "the specific measures at issue" pursuant to Article 6.2 of the DSU. Turkey argued that for each of the three measures, the European Union was required to specify individually and cumulatively (i) the nature of the measures at issue as written or unwritten; (ii) the content of the measures, including the products that are the subject of the measures and the requirement(s) concerned; and (iii) the legal instruments underpinning each of the measures at issue in its panel request.²²⁸

7.27. In its preliminary ruling of 10 July 2020, the Panel found that the panel request satisfies the requirement, in Article 6.2 of the DSU, to identify the "specific measures at issue".²²⁹ The Panel found that the European Union adequately identified the "content" of the measures "in terms of the requirements it was challenging in the narrative descriptions of the measures in the panel request".²³⁰ The Panel did not agree with Turkey's view that the European Union was required to specify the legal instruments underpinning each of the measures at issue in its panel request. The Panel instead concluded that "the narrative descriptions of the measures in the European Union's panel request are sufficient for purposes of compliance with Article 6.2 of the DSU, particularly in light of the fact that the European Union provided an illustrative list of relevant legal instruments that it contends put in place, evidence, implement, and administer the challenged measures".²³¹ Similarly, the Panel now concludes that the evidence and arguments before it are sufficient to establish the precise content of the localisation requirement as outlined in the narrative of the European Union's panel request.

7.28. Moreover, the Panel does not consider that Turkey's argument finds support in the Appellate Body's statement, in *Argentina – Import Measures*, that when dealing with a "single measure composed of several different instruments", a complainant will normally need to provide evidence of "how the different components operate together as part of a single measure and how a single measure exists as distinct from its components".²³² In that case, the complainants established that Argentina required importers and other economic operators to undertake one or more of five trade-related requirements (TRRs), as a condition to import goods or to obtain certain benefits, and that Argentina had imposed one or more of the five TRRs in different combinations.²³³ The panel agreed with the complainants that the five TRRs together constituted a "single" measure, and that a separate conclusion on each TRR would "go against the nature of the measure" and not reflect the measure's operation in practice or capture some of its main features.²³⁴ The Appellate Body upheld the panel's findings about the operation of the TRRs measure, and that the "components" of the measure (referenced by the Appellate Body in the above-cited statement) were the five TRRs that, according to the complainants' own characterization, constituted the content of the measure at issue.

7.29. In this case, Turkey's reliance on the Appellate Body's statement in *Argentina – Import Measures*, concerning the need for a complaining party to provide evidence of how the different "components" of a single measure operate together, seems to treat the legal and other instruments, referenced by the European Union as evidence of the existence of the localisation requirement, as "components" of that measure.²³⁵ However, as elaborated further above, the Panel does not consider that the European Union has characterized the localisation requirement by reference to any legal instruments or documents in a way that would make such instruments and documents "components" of the challenged measure in the same way that the five TRRs were "components" or "the constitutive elements"²³⁶ of the single TRRs measure in *Argentina – Import Measures*.

7.30. Finally, the Panel observes that Turkey's argument regarding the European Union's alleged failure to precisely identify the components of the localisation requirement and resulting impact on

²²⁸ Preliminary ruling by the Panel, paras. 1.3 and 3.10.

²²⁹ See Annex A-3.

²³⁰ Preliminary ruling by the Panel, para. 3.13.

²³¹ Preliminary ruling by the Panel, para. 3.14.

²³² Appellate Body Reports, *Argentina – Import Measures*, paras. 5.108 and 5.124.

²³³ Panel Reports, *Argentina – Import Measures*, para. 6.221.

²³⁴ Panel Reports, *Argentina – Import Measures*, para. 6.228.

²³⁵ For example, Turkey argues that "European Union did not precisely identify the components of the measure and failed to explain how they interrelate. In particular, taking into account that the European Union described the 'localisation measure' as being implemented through 'various legal instruments and tools' and 'embodied through [...] specific laws and decrees' and that it relied on those instruments to develop its claims, the European Union should have precisely identified those legal and other instruments." (Turkey's responses to the second set of questions, para. 26.)

²³⁶ Appellate Body Reports, *Argentina – Import Measures*, para. 5.108.

Turkey's ability to develop its defence, while presented as a general argument relevant to all of the European Union's claims, seems to be primarily, if not exclusively, relevant to the European Union's claim under Article X:1 of the GATT 1994.²³⁷ However, for reasons given later in this Report, the Panel exercises judicial economy over the European Union's claim under Article X:1.²³⁸ Insofar as Turkey's argument is related to the European Union's claim under Article X:1 of the GATT 1994, it has been rendered moot.

7.1.5 Conclusion

7.31. The Panel finds that the European Union has established the existence of the localisation requirement as a single measure, whereby (i) Turkey requires foreign producers to commit to localise in Turkey their production of certain pharmaceutical products; and (ii) where commitments are not given, not accepted or not fulfilled, affected products are no longer reimbursed by the SSI.

7.2 Article III:8(a) of the GATT 1994

7.2.1 Introduction

7.32. The Panel has found that the European Union has established the existence and precise content of the localisation requirement as a "single measure". The Panel now addresses Turkey's assertion that the localisation requirement falls within the scope of the government procurement derogation in Article III:8(a) of the GATT 1994 and is, for that reason, not subject to the national treatment obligation of Article III:4 of the GATT 1994.²³⁹

7.33. Turkey submits that the localisation requirement falls within the scope of Article III:8(a), arguing that it is a "law, regulation or requirement governing procurement" of pharmaceutical products, that the procurement of pharmaceutical products is done by a "governmental agency" and entails the "purchase" of those products "for governmental purposes", and is not done "with a view to commercial resale".²⁴⁰

7.34. The European Union argues that the localisation requirement is not protected by Article III:8(a), because it is not a "law, regulation or requirement governing procurement", does not involve the "purchase" of products by "governmental agencies", does not involve any

²³⁷ According to Turkey, the European Union's failure to precisely identify the components of the localisation requirement as a "single and cohesive measure" is "particularly relevant" in the context of the European Union's claim under Article X:1 of the GATT 1994, where the European Union has submitted that not all legal instruments that form part of, or give effect to the localisation requirement have been published promptly. (Turkey's second written submission, para. 39.) In its first set of questions to the parties, the Panel asked Turkey whether the alleged failure to precisely identify the components of the localisation requirement is exclusively relevant to the claim under Article X:1 and, if not, to please elaborate on how this alleged failure has affected Turkey's ability to develop its arguments under Articles III:8(a), XX(b) and/or XX(d) of the GATT 1994, and/or under Article 3.1(b) of the SCM Agreement. In its response, Turkey reiterated that "such failure has important consequences, for instance with regard to the European Union's claim under Article X:1 of the GATT 1994", and reiterated that "the lack of appropriate identification of the precise content of the measure affected Turkey's ability to develop its arguments under the Article X:1 GATT claim." Turkey offered no indication how this alleged failure has affected Turkey's ability to develop its arguments under the other referenced provisions. (Turkey's responses to the first set of questions, para. 15.)

²³⁸ See section 7.5.4.

²³⁹ The Panel addresses the government procurement derogation in Article III:8(a) before making any findings under Article III:4 of the GATT 1994 or Article 2.1 of the TRIMS Agreement, bearing in mind that measures satisfying the requirements of Article III:8(a) are not subject to the national treatment obligations set out in other paragraphs of Article III. The Panel does not consider that the nature of Article III:8(a) as a derogation from the obligations in Article III necessarily mandates this order of analysis in all cases, and notes that the panel in *India – Solar Cells* addressed the claims under Article III:4 and Article 2.1 before addressing the applicability of the Article III:8(a). (Panel Report, *India – Solar Cells*, para. 7.42.)

²⁴⁰ Turkey's first written submission, paras. 175-241; second written submission, paras. 40-95; responses to the first set of questions, paras. 16-43; opening statement, paras. 10-70; closing statement, paras. 9-23; responses to the second set of questions, paras. 31-55; and comments on responses to the second set of questions, paras. 6-16.

procurement or purchase "for governmental purposes", and any such procurement and purchase would be "with a view to commercial resale".²⁴¹

7.2.2 Relevant provisions

7.35. Article III:8(a) of the GATT 1994 provides:

The provisions of this Article shall not apply to laws, regulations or requirements governing the procurement by governmental agencies of products purchased for governmental purposes and not with a view to commercial resale or with a view to use in the production of goods for commercial sale.

7.36. By its terms, Article III:8(a) is a "derogation limiting the scope of the national treatment obligation" in Article III of the GATT 1994.²⁴² This means that measures satisfying the requirements of Article III:8(a) are not subject to the national treatment obligation set out in Article III:4.

7.37. It is clear from the text of Article III:8(a) that a series of elements must be satisfied for a measure to fall within the scope of the government procurement derogation:

- a. the challenged measure must fall within the scope of "laws, regulations, or requirements governing ... procurement";
- b. it must involve a "purchase" of products by a "governmental agency";
- c. the products must be purchased "for governmental purposes"; and
- d. the products must not be purchased "with a view to commercial resale or with a view to use in the production of goods for commercial sale".

7.38. Article III:8(a) has been interpreted and applied in two prior sets of WTO dispute settlement proceedings, *Canada – Renewable Energy / Canada – Feed-in Tariff Program* and *India – Solar Cells*, and the panel considers that the Appellate Body and panel reports (as modified on appeal) in those disputes provide useful guidance on each of these elements.

7.39. With respect to the first element above, the Appellate Body clarified that "the word 'procurement' [in Article III:8(a)] refers to the process pursuant to which a government acquires products."²⁴³ The Appellate Body observed that the ordinary meaning of the word "governing" is "constitut[ing] a law or rule for"²⁴⁴, and considered that Article III:8(a) thus requires an "articulated connection" between "the laws, regulations, or requirements" and the "procurement", in the sense that the act of "procurement" is undertaken "within a binding structure of laws, regulations, or requirements".²⁴⁵

7.40. With respect to the second element, the Appellate Body distinguished the concepts of "procurement" and "purchase". It clarified that they should not be equated as "[n]ot every procurement needs to be effectuated by way of a purchase, and not every purchase is part of a process of government procurement."²⁴⁶ According to the Appellate Body, "procurement" is the operative word in Article III:8(a) "describing the process and conduct of the governmental agency",

²⁴¹ European Union's first written submission, paras. 177-227; second written submission, paras. 83-116; responses to the first set of questions, paras. 5-33; opening statement, paras. 13-32; closing statement, paras. 5-14; responses to the second set of questions, paras. 8-17; comments on responses to the second set of questions, paras. 28-45.

²⁴² Appellate Body Report, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 5.56.

²⁴³ Appellate Body Report, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 5.59.

²⁴⁴ Appellate Body Report, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 5.58 (referring to Oxford English Dictionary online, <<http://www.oed.com/view/Entry/80304>>).

²⁴⁵ Appellate Body Report, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 5.58. The panel in *India – Solar Cells* considered that the domestic content requirement at issue "govern[ed] the procurement" of electricity, because it "operate[d] to impose compulsory conditions for bidding eligibility and participation under each of the relevant Batches of the National Solar Mission, and further mandate the use of domestically manufactured solar cells and modules through enforceable contractual obligations of [solar power developers]". (Panel Report, *India – Solar Cells*, para. 7.145.)

²⁴⁶ Appellate Body Report, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 5.59.

and the word "purchased" is used "to describe the type of transaction used to put into effect that procurement".²⁴⁷ In *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, the Appellate Body stated that "[t]he precise range of contractual arrangements that are encompassed by the concept of "purchase" is not a matter we need to decide in this case".²⁴⁸ Regarding the entity making the purchase, the Appellate Body clarified that the term "governmental agencies" in Article III:8(a) "refers to those entities acting for or on behalf of government in the public realm within the competences that have been conferred on them to discharge governmental functions".²⁴⁹ According to the Appellate Body, whether an entity is a "governmental agency" within the meaning of Article III:8(a) is "determined by the competences conferred on the entity concerned and by whether that entity acts for or on behalf of government".²⁵⁰

7.41. With respect to the third element, the Appellate Body stated that the term "governmental purposes" in Article III:8(a) refers to "purchases of products directed at the government or purchased for the needs of the government in the discharge of its functions".²⁵¹ The Appellate Body further clarified that the phrase "products purchased for governmental purposes" in Article III:8(a) "refers to what is consumed by the government or what is provided by government to recipients in the discharge of its public functions", with the scope of such functions determined on a case by case basis.²⁵²

7.42. With respect to the fourth element, the Appellate Body explained that the word "commercial resale" refers to "a resale of a product at arm's length between a willing seller and a willing buyer".²⁵³ Whether a transaction constitutes a "commercial resale" must be assessed having regard to the entire transaction and looking at the transaction from the perspective of both the seller and the buyer. In terms of the seller's perspective, the Appellate Body noted that a profit-orientation is generally an indication that a resale is made at arm's length.²⁵⁴ The last clause "not ... with a view to use in the production of goods for commercial sale" signifies that Article III:8(a) does not cover purchases made by governmental agencies with a view to using the product purchased in the production of other goods for sale at arm's length.²⁵⁵

7.2.3 Main arguments of the parties

7.2.3.1 Introduction

7.43. Both parties present their arguments by parsing the text of Article III:8(a) into a series of elements, and then presenting their arguments under headings in relation to those elements. The parties parse the elements of Article III:8(a) in a similar (if not always identical) manner: (i) as the first element, whether the localisation requirement falls within the scope of "laws, regulations or requirements governing ... procurement"; (ii) as the second element, whether the localisation requirement involves a "purchase" by "governmental agencies"²⁵⁶; (iii) as the third element, whether the procurement/purchase is "for governmental purposes"; and (iv) as the fourth element whether the procurement/purchase is done "with a view to commercial resale". As elaborated below, there are one or more points of contention between the parties in relation to each of these elements.

²⁴⁷ Appellate Body Report, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 5.59.

²⁴⁸ Appellate Body Report, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 5.59.

The panel in *India – Solar Cells* recalled the Appellate Body's findings above and stated that "this conceptual distinction" between the concepts of procurement and purchase "informs the cumulative and separate elements of Article III:8(a)." (Panel Report, *India – Solar Cells*, para. 7.133.)

²⁴⁹ Appellate Body Report, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 5.61.

²⁵⁰ Appellate Body Report, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 5.60.

²⁵¹ Appellate Body Reports, *Canada – Renewable Energy / Feed-In Tariff Program*, para. 5.67.

²⁵² Appellate Body Reports, *Canada – Renewable Energy / Feed-In Tariff Program*, para. 5.68.

²⁵³ Appellate Body Report, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 5.70.

²⁵⁴ Appellate Body Report, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 5.71.

²⁵⁵ Appellate Body Report, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, paras. 5.72-5.74.

²⁵⁶ In its first written submission, Turkey addresses the "purchase" element in the context of presenting its arguments on the first element, which it formulates in terms of whether the localisation measure is a "law, regulation or requirement governing ... procurement". However, in its second written submission Turkey addresses, as a second element, whether the alleged procurement of pharmaceutical products is "done by a governmental agency and entails the purchase of those products".

7.44. While the European Union maintains that Turkey has the burden of establishing that the challenged measure is covered by the government procurement derogation in Article III:8(a)²⁵⁷, the European Union addressed the applicability of Article III:8(a) to the localisation requirement in its first written submission. In that submission, the European Union, noting Turkey's earlier assertion that the localisation requirement falls within the scope of Article III:8(a)²⁵⁸, engaged in this discussion "in an attempt to be helpful to the Panel and address all possibly relevant legal issues as early as possible".²⁵⁹

7.2.3.2 "laws, regulations or requirements governing ... procurement"

7.45. The European Union submits that the localisation requirement is not a "law, regulation or requirement governing procurement".²⁶⁰ According to the European Union, that is "for the simple reason that no procurement is involved"²⁶¹ and it is impossible for a measure to "govern" procurement if no "procurement" is involved.²⁶² The European Union submits that, according to the ordinary meaning of the term "procurement" and the prior panel and Appellate Body reports under Article III:8(a), the derogation only applies where the government, and not another actor or set of actors, "acquires" or "obtains" products.²⁶³ Furthermore, this acquisition must be done on the basis of a particular legal process, specifically designed for that purpose and binding on governmental authorities.²⁶⁴ In this case, in the outpatient sector²⁶⁵, pharmaceutical products are never acquired or obtained, and thus never "procured", by any governmental agencies in Turkey, whether through the requisite type of legal process or otherwise; instead, they are acquired or obtained by consumers from pharmacies, and the Turkish government reimburses the pharmacies for (in most instances) a part of the cost.²⁶⁶ The European Union further argues that this is clear from the legal instruments governing the reimbursement system, including the very title of the "Protocol on the procurement of medicines from pharmacies which are members of the Turkish Pharmacists' Association (TEB) by persons covered by the Social Security Institution".²⁶⁷

7.46. Turkey submits that the localisation measure is a "law, regulation, or requirement governing procurement".²⁶⁸ According to Turkey, the SSI "acquires" the medicines that are prescribed to patients in Turkey "since it pays for their costs".²⁶⁹ Turkey explains that the pharmaceutical products included in the Annex 4/A list "are acquired by the SSI through retail pharmacies which are members of the TPA", and the "procurement process is governed by the Protocol concluded between the SSI and the TPA as well as contracts concluded between the SSI and individual retail pharmacies, which

²⁵⁷ European Union's responses to the second set of questions, paras. 8-12; European Union's comments on responses to the second set of questions, paras. 28-31. For Turkey's arguments on this point, see Turkey's responses to the first set of questions, paras. 31-37.

²⁵⁸ European Union's first written submission, para. 177 (referring to minutes of the meetings of the Committee on Trade-Related Investment Measures held on 6 November 2017, 1 June 2018, and 17 October 2018 (respectively G/TRIMS/M/43, G/TRIMS/M/44, and G/TRIMS/M/45)).

²⁵⁹ European Union's comments on responses to the second set of questions, para. 31.

²⁶⁰ European Union's first written submission, paras. 181-195.

²⁶¹ European Union's first written submission, para. 184.

²⁶² European Union's first written submission, para. 185.

²⁶³ European Union's first written submission, paras. 185-187. The European Union adds that this interpretation is supported by the use of the terms "*acquisition*" and "*adquisición*" in place of "procurement" in the French and Spanish versions of the GATT 1994, and notes that these terms are different, and narrower, than the terms used in the French and Spanish titles of the Agreement on Government Procurement (*Accord sur les Marchés Publics, Acuerdo sobre Contratación Pública*). (European Union's first written submission, para. 188.)

²⁶⁴ European Union's first written submission, para. 189.

²⁶⁵ According to the European Union, "it is useful to compare the reimbursement system which applies to out-patient pharmaceuticals with Turkey's treatment of in-patient pharmaceuticals. For in-patients, public entities – hospitals – procure medicines by acquiring or obtaining them. Furthermore, those entities provide those pharmaceutical products to patients directly. Moreover, when doing so, public hospitals acquire or obtain pharmaceuticals on the basis of a tendering process that applies to Turkish government entities more generally. Thus, the necessary elements of "procurement" seem to be present: the government (including public hospitals) acquires or obtains products, pursuant to a particular process designed for that purpose. By contrast, in the out-patient sector, no public entity or governmental agency ever acquires or obtains pharmaceutical products." (European Union's first written submission, paras. 193-194.)

²⁶⁶ European Union's first written submission, paras. 190-191.

²⁶⁷ European Union's first written submission, para. 192.

²⁶⁸ Turkey's first written submission, paras. 186-204.

²⁶⁹ Turkey's first written submission, para. 189.

essentially reproduce the text of the Protocol".²⁷⁰ Turkey submits that, contrary to what the European Union argues, the very title of that document, i.e. Protocol on the Provision of Medicines to the Persons Covered by the Social Security Institution by the Pharmacies which are Members of the Turkish Pharmacists' Association, makes it clear that it regulates the "provision" of pharmaceutical products by retail pharmacies, on behalf of the SSI, to patients.²⁷¹ Turkey explains that the text of that Protocol shows that pharmaceutical products "are procured, that is acquired, by the SSI" and distributed to patients through retail pharmacies under contract with the SSI.²⁷² According to Turkey, the fact that the provision of pharmaceutical products is organized differently in the outpatient and inpatient sectors does not mean, contrary to what the European Union argues, that in the outpatient sector "no public entity or governmental agency ever acquires or obtains pharmaceutical products".²⁷³ Furthermore, the localisation measure is a "law, regulation or requirement governing" procurement, as it constitutes a "requirement"²⁷⁴ and "the entire process pursuant to which the SSI acquires those pharmaceutical products", including the decision about which products are included in Annex 4/A, their prices and the modalities of their purchase, "is regulated and controlled by the relevant Turkish authorities".²⁷⁵

7.47. The European Union responds by recalling the Appellate Body's statement that the term "procurement" refers to "the process pursuant to which a government acquires products" and argues that, instead of loosening the test, as Turkey suggests, "the requirement of a 'process' pursuant to which products are acquired (meaning that the simple act or practice of acquiring a product is not enough) makes the legal test *stricter*".²⁷⁶ The European Union rejects Turkey's argument that the SSI acquires the medicines because it pays for their cost, and is therefore the "ultimate buyer" of those products, the pharmacies being just an "agent for the SSI" and the "distribution network of the SSI". The European Union asserts that, under Turkey's reading, whenever a government finances or pays for something, even partly, this would constitute public procurement and would therefore fall outside the scope of Article III of the GATT 1994 and that this is plainly wrong.²⁷⁷ Furthermore, none of the provisions of Turkish law or the Protocol between pharmacists and the SSI that Turkey cites in any way suggest that the SSI "acquires" any medicines.²⁷⁸ Finally, the European Union argues that the localisation requirement itself is not a law, regulation or requirement that governs *procurement* because through it, Turkey "actively seeks to obtain localisation commitments from foreign producers, rather than to simply apply an 'origin rule' for the 'procured products'".²⁷⁹ According to the European Union, "the Localisation Requirement is not a necessary and usual component of a procurement system, but rather an industrial policy and economic development measure that seeks, inter alia, to attract investments in Turkey".²⁸⁰

7.48. In its second written submission, Turkey maintains that the localisation requirement is a "law, regulation or requirement governing procurement" within the meaning of Article III:8(a) because it "governs the process through which the Turkish Government acquires pharmaceutical products included in Annex 4/A".²⁸¹ According to Turkey, the SSI's role "goes far beyond the mere financing of the pharmaceutical products included in Annex 4/A to outpatients."²⁸² Rather, the SSI purchases the pharmaceutical products included in Annex 4/A²⁸³, ensures the provision of these products to outpatients, and makes all the necessary arrangements for this purpose.²⁸⁴ To dispense these

²⁷⁰ Turkey's first written submission, para. 190. (fns omitted)

²⁷¹ Turkey's first written submission, para. 191.

²⁷² Turkey's first written submission, paras. 191-201.

²⁷³ Turkey's first written submission, para. 203. In its second written submission, Turkey explains that "in both outpatient and inpatient sectors, the medicines are acquired by public entities" and that "the differences between the provision of pharmaceutical products to inpatients and to outpatients have to do with the practical aspects of dispensing pharmaceutical products in the most effective way." (Turkey's second written submission, para. 33).

²⁷⁴ According to Turkey, it is a "requirement" in the sense that compliance with the localisation requirement determines whether a pharmaceutical product will be covered by the reimbursement scheme. (Turkey's first written submission, paras. 187, 204.)

²⁷⁵ Turkey's first written submission, para. 189.

²⁷⁶ European Union's second written submission, para. 86. (emphasis original)

²⁷⁷ European Union's second written submission, para. 88.

²⁷⁸ European Union's second written submission, paras. 89-94.

²⁷⁹ European Union's second written submission, para. 96.

²⁸⁰ European Union's second written submission, para. 97.

²⁸¹ Turkey's second written submission, para. 46.

²⁸² Turkey's second written submission, para. 51. See also *ibid.* para. 23.

²⁸³ Turkey's second written submission, para. 18.

²⁸⁴ Turkey's second written submission, para. 52.

products to outpatients, it acts through retail pharmacies.²⁸⁵ According to Turkey, retail pharmacies dispense pharmaceutical products to patients on behalf of the SSI²⁸⁶, acting "as service providers for the SSI."²⁸⁷ Turkey submits that this conclusion is supported by the following: (i) the Protocol and the individual contracts concluded between the SSI and retail pharmacies "establish that the latter act as a service provider of the SSI by dispensing pharmaceutical products included in Annex 4/A to outpatients"²⁸⁸; (ii) retail pharmacies receive a service fee from the SSI for the service they provide, "namely the provision of pharmaceutical products to the outpatients"²⁸⁹; (iii) retail pharmacies collect contribution fees from the outpatients on behalf of the SSI²⁹⁰; and (iv) retail pharmacies have the status of primary healthcare service providers which "also collect contribution fees on behalf of the SSI and provide other public health services".²⁹¹ Finally, Turkey also rejects the European Union's argument that the localisation requirement does not "govern procurement" because it goes beyond a simple preference for domestic products.²⁹² Turkey argues that the localisation requirement "governs the procurement" of pharmaceutical products by the SSI because compliance with this requirement is "a necessary prerequisite for the continued inclusion of a pharmaceutical product subject to localisation in Annex 4/A and thus for the procurement of that product by the SSI to take place".²⁹³

7.2.3.3 "by governmental agencies of products purchased"

7.49. The European Union submits that, even if the Panel finds that the measure at issue is somehow connected to "procurement", Article III:8(a) would still not apply because the relevant products are not being "purchased" by "governmental agencies".²⁹⁴ Recalling the prior panel and Appellate Body reports examining Article III:8(a), the European Union submits that it is clear that the concept of "purchase" covers only a sub-set of the various types of transactions that can be used to put into effect a procurement²⁹⁵, that the requirement that there must be a "purchase" is distinct and additional to the requirement that there must be a "procurement", and that to be covered by Article III:8(a), government procurement can only be effectuated by means of a purchase, and not by means of any other contractual arrangement.²⁹⁶ The European Union notes that the ordinary meaning of the term "purchase" is "[t]he acquisition of property (esp. land) by any legal means other than inheritance"²⁹⁷ and observes that this is how the term "purchase" is used in the Agreement on Government Procurement (GPA) as well.²⁹⁸ In the outpatient sector no Turkish "governmental agency" acquires the relevant pharmaceutical products, at any point, whether through purchase or otherwise; in this connection, the European Union submits that pharmacies, like individual consumers, are "private entities, not acting for or on behalf of the government".²⁹⁹

²⁸⁵ Turkey's second written submission, para. 48.

²⁸⁶ Turkey's second written submission, paras. 23, 29 and 49.

²⁸⁷ Turkey's second written submission, para. 18. In that sense, Turkey states that "there is a split between the government-purchaser (the SSI) and the private party provider (the retail pharmacies)", whereby the SSI is the purchaser of pharmaceutical products provided to outpatients such as to ensure their universal access, while retail pharmacies take on the role of service provider by dispensing those pharmaceutical products in a more efficient and timely manner. (Turkey's second written submission, para. 23.)

²⁸⁸ Turkey's second written submission, paras. 27 and 48-49. Turkey also explains that the TPA Protocol deals with the "provision" or "supply" of pharmaceutical products to patients by the retail pharmacies on behalf of the SSI, and does not relate to the procurement of pharmaceutical products by patients, because "patients do not procure pharmaceutical products included in Annex 4/A but are provided with those products." (Ibid. para. 15.)

²⁸⁹ Turkey's second written submission, para. 27.

²⁹⁰ Turkey's second written submission, para. 27.

²⁹¹ Turkey's second written submission, para. 30.

²⁹² European Union's second written submission, para. 96.

²⁹³ Turkey's second written submission, para. 56.

²⁹⁴ European Union's first written submission, paras. 196-206.

²⁹⁵ The European Union refers to the definition of "procurement" in the Agreement on Government Procurement (GPA) to explain that a "purchase" is merely one of a number of contractual arrangements typically used in procurement ("lease, rental or hire purchase, with or without an option to buy"), and that these other arrangements do not involve the acquisition of property rights over products. (European Union's first written submission, para. 202.)

²⁹⁶ European Union's first written submission, paras. 198-200.

²⁹⁷ European Union's first written submission, para. 201 (referring to Oxford English Dictionary online, <<https://www.oed.com/view/Entry/154831?rskey=07nKL5&result=1&isAdvanced=false#eid>>).

²⁹⁸ European Union's first written submission, para. 202.

²⁹⁹ European Union's first written submission, paras. 204-205.

7.50. Turkey argues that the localisation requirement involves the "purchase" of products "by governmental agencies".³⁰⁰ Turkey submits that even under a narrow interpretation of the term "purchase"³⁰¹, in the present case the procurement of pharmaceutical products is effectuated by means of a "purchase". In Turkey's view, the fact that this purchase is effectuated with the involvement of retail pharmacies acting on behalf of the SSI, and that the pharmaceutical products are not physically with the SSI, does not change the fact that it is the SSI that pays for the pharmaceutical products and thus is the ultimate buyer (or the purchaser).³⁰² Nothing in the text of Article III:8(a) suggests that the purchase must be necessarily made directly by the governmental agency itself (in contrast to the "*procurement by a governmental agency*"), rather than by other entities acting as an intermediary.³⁰³ Furthermore, patients themselves do not "purchase" pharmaceutical products included in the Annex 4/A list, as they "do not pay for those medicines which are provided to them free of charge, the costs being paid by the SSI".³⁰⁴ With regard to the second prong of this element of Article III:8(a), Turkey explains that it is the SSI, the governing authority of the Turkish social security system affiliated to the Ministry of Family, Labor and Social Services, that constitutes the relevant "governmental agency" within the meaning of Article III:8(a).³⁰⁵

7.51. In its second written submission, the European Union confirms that it does not dispute that the SSI is a "governmental agency", but that, in the context of the reimbursement system and the localisation requirement, neither the SSI nor any other governmental agency engages in the "procurement", let alone "purchase", of any products.³⁰⁶ The European Union reiterates that the term "purchase" should be interpreted to mean "acquiring property over" products.³⁰⁷ However, it argues that even under Turkey's broader reading of the term as covering "obtaining something in exchange of payment", the SSI does not "obtain" any products for the reasons already explained at length in its first written submission.³⁰⁸ The SSI "merely provides financing through reimbursement", and "[p]roviding financing is different from obtaining, acquiring or purchasing products".³⁰⁹ Finally, as for Turkey's alternative argument that the SSI could be said to engage in purchasing because retail pharmacies, allegedly acting "on behalf of" the SSI, purchase medicines from wholesalers, the European Union argues that there is no support whatsoever for these assertions: retail pharmacies are private entities, they freely order and purchase their medicines from wholesalers through a private sales contract, hold and manage their inventory on their own (including holding property rights over it), and bear the risks associated with their stock, with no SSI involvement. Thus, according to the European Union, Turkey's attempt to portray the retail pharmacies' purchase of medicines from wholesalers as a "purchase" by the SSI fails.³¹⁰ Finally, the European Union comments that it has already addressed Turkey's assertion that patients do not purchase

³⁰⁰ Turkey's first written submission, paras. 205-217. As noted earlier, the parties do not parse the terms of Article III:8(a) in the same way, with each addressing the "purchase" element under a different element. In its first written submission, the European Union addresses the issue of "purchase" as part of the second element, i.e. "purchased by governmental entities"; in contrast, Turkey addresses the "purchase" element in tandem with the first element, i.e. whether the localisation measure is a "law, regulation or requirement governing ... procurement".

³⁰¹ Turkey refers to the dictionary definition of "the action or an act of obtaining something in exchange for payment in money or an equivalent", which in its view "suggests that the notion of a 'purchase' involves some kind of payment (usually monetary) in exchange for a good." (Turkey's first written submission, para. 207.) Turkey also doubts the validity and probative value of the European Union's reliance on the GPA to interpret Article III:8(a) of the GATT 1994. (Turkey's first written submission, fn 219.)

³⁰² Turkey's first written submission, paras. 206-208. Turkey refers to the statement by the panel in *Canada – Renewable Energy / Canada – Feed-in Tariff Program* that a "purchase" does not require obtaining physical possession over the goods that are purchased. (Turkey's first written submission, para. 208, referring to Panel Report, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 7.228.)

³⁰³ Turkey's first written submission, para. 209.

³⁰⁴ Turkey's first written submission, para. 210. According to Turkey, "the contribution fee paid by patients forms part of the patients' contribution to the social security system in general and aims at preventing abuse of that system. The European Union therefore errs when it argues that part of the price of pharmaceutical products is borne by patients." (Ibid. para. 210)

³⁰⁵ Turkey's first written submission, paras. 212-217.

³⁰⁶ European Union's second written submission, paras. 98-99.

³⁰⁷ European Union's second written submission, para. 100.

³⁰⁸ European Union's second written submission, para. 101.

³⁰⁹ European Union's second written submission, para. 101.

³¹⁰ European Union's second written submission, paras. 105-106.

pharmaceutical products but even if it was shown that patients, for whatever reason, do not "purchase" pharmaceutical products, it would still not follow that the SSI does.³¹¹

7.52. In its second written submission, Turkey disagrees with the European Union's argument that the concept of "purchase" pertains to transactions that involve "physical possession and property" over a product.³¹² In this case, Turkey argues that because of the nature of the products at issue, and the specific features of the Turkish healthcare system, "it would make no economic or practical sense for the SSI to take physical possession of medicines that are ultimately provided to Turkish patients".³¹³ Turkey submits that the SSI does not merely finance pharmaceutical products, but purchases them "at the time they are dispensed to the patients"³¹⁴, because it acquires the title to them and instructs the retail pharmacies to dispense them immediately to the patients.³¹⁵ According to Turkey, the "purchase" by the SSI "occurs when a patient presents a prescription for a medicine included in Annex 4/A in a retail pharmacy and the provision of that medicine to the patient is approved through the Medula system".³¹⁶ The SSI then delegates to retail pharmacies the dispensing of the purchased products to outpatients.³¹⁷ According to Turkey, since it is the SSI that purchases the pharmaceutical products included in the Annex 4/A list, the SSI does not "reimburse" patients, nor retail pharmacies³¹⁸, because neither of them "purchases" these products. Retail pharmacies obtain the products from wholesalers and keep them at their premises until they are dispensed to patients upon the presentation of a medical prescription.³¹⁹ The SSI purchases from and makes direct payments for those medicines to the retail pharmacies³²⁰, which "receive a service fee in return for the service they perform on behalf of the SSI, namely, dispensing pharmaceutical products to patients".³²¹ Patients receive the products but do not purchase them.³²² They merely pay "a relatively small contribution fee which is, however, not part of the price of the pharmaceutical products but forms part of the patients' contribution to the social security system in general and aims at preventing abuse of that system."³²³

7.2.3.4 "for governmental purposes"

7.53. The European Union argues that the localisation requirement does not involve procurement of products purchased "for governmental purposes".³²⁴ The European Union accepts that "providing universal healthcare, ensuring access to medicines and protecting human health are legitimate governmental objectives."³²⁵ However, the European Union notes that it is obvious that the Turkish government neither uses nor consumes the relevant pharmaceutical products.³²⁶ While the prior panel and Appellate Body reports confirm that "products purchased for governmental purposes" in Article III:8(a) may cover not only "what is consumed by the government" but also "what is provided by government to recipients in the discharge of its public functions", there is no such "provision" in

³¹¹ European Union's second written submission, paras. 107-108.

³¹² Turkey's second written submission, paras. 62-63. Turkey refers to the example given by the panel in *Canada – Renewable Energy / Canada – Feed-in Tariff Program* of a book that is bought on the internet by an entity that directs the seller to deliver it to somebody else as a gift. (Ibid. para. 63 (referring to Panel Reports, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 7.228).

³¹³ Turkey's second written submission, para. 64. Turkey relates that prior to the 2003 reform of its healthcare system, the SSI did obtain physical control over the medicines it provided to patients and this system proved to be ineffective (Ibid. para. 65).

³¹⁴ Turkey's second written submission, para. 76.

³¹⁵ Turkey's second written submission, paras. 73 and 76. Turkey provides a series of documents attesting the details of this process in Exhibit TUR-117 (Documents relating to a purchase by the SSI from a pharmacy of the pharmaceutical products dispensed to patients in December 2020 (Exhibit TUR-117)).

³¹⁶ Turkey's second written submission, para. 71. See also Turkey's second written submission, para. 72.

³¹⁷ Turkey's second written submission, para. 66. The payment for the pharmaceutical products purchased by the SSI and dispensed by retail pharmacies to patients is made by the SSI on the basis of consolidated invoices sent by the retail pharmacies to the SSI at the end of each month (Ibid. para. 74). This invoice covers the public price of the medicines dispensed to patients and a service fee that the pharmacies receive "in return for the service they perform on behalf of the SSI, namely, dispensing pharmaceutical products to patients". (Ibid. para. 69).

³¹⁸ Turkey's second written submission, para. 18.

³¹⁹ Turkey's second written submission, para. 69.

³²⁰ Turkey's second written submission, para. 13.

³²¹ Turkey's second written submission, para. 69.

³²² Turkey's second written submission, paras. 13, 18, 70 and 72.

³²³ Turkey's second written submission, para. 77.

³²⁴ European Union's first written submission, paras. 207-216.

³²⁵ European Union's first written submission, para. 211.

³²⁶ European Union's first written submission, para. 213.

this case.³²⁷ According to the European Union, "it is clear that the Turkish government does not *provide* the relevant pharmaceutical products to recipients. It merely reimburses a part of the cost of those pharmaceuticals, which are provided to patients (as "recipients", in this context) by pharmacies."³²⁸ This should be contrasted with the scenario in which "a public hospital purchases pharmaceuticals and provides them to patients."³²⁹

7.54. Turkey asserts that the localisation measure involves procurement of products purchased for "governmental purposes".³³⁰ Specifically, the pharmaceutical products are procured to provide healthcare services to the Turkish population.³³¹ The fact that the provision of healthcare, including provision of pharmaceutical products, falls within the scope of a government's public functions is confirmed both by international instruments and Turkish legislation.³³² In response to the European Union's argument that there is no "direct provision" of pharmaceuticals by the government to outpatients, Turkey reiterates that the provision of pharmaceutical products in case of outpatient treatment is, for practical reasons, organized through retail pharmacies (which have the status of healthcare providers in the Turkish healthcare system and act on behalf of the SSI); and in that sense, as in the case of inpatient treatment, pharmaceutical products are "provided" by the government, i.e. the SSI, through retail pharmacies, to patients.³³³

7.55. In its second written submission, the European Union comments that Turkey is "preaching to the choir" when it explains, at length, the reasons why healthcare is an important governmental objective, and recalls that this is not in dispute.³³⁴ The European Union reiterates that being linked to a government objective is not enough, as the Appellate Body stated that it must be shown that products are "purchased for the use of government, consumed by government, or provided by government to recipients in the discharge of its public functions".³³⁵ Turkey does not claim that the products are "purchased for the use of government" or "consumed by government", and it "is clear that no Turkish governmental agency *provides* the pharmaceutical products to anyone – pharmacies do".³³⁶

7.56. In its second written submission, Turkey maintains that pharmaceutical products included in the Annex 4/A list are provided by the SSI to recipients (i.e. outpatients) "in the discharge of its public function, namely the provision of healthcare services".³³⁷ In this process, Turkey explains, the SSI uses retail pharmacies as a distribution network to dispense the products to patients on its behalf.³³⁸ Thus, according to Turkey, retail pharmacies provide (dispense) the pharmaceutical products included in the Annex 4/A list to outpatients "on behalf of the SSI".³³⁹ For this service, Turkey submits, the pharmacies receive a service fee from the SSI.³⁴⁰

7.2.3.5 "not with a view to the commercial resale"

7.57. The European Union contends that if the government "procures" and "purchases" pharmaceutical products when it reimburses a part of their cost to the pharmacies which ultimately sell them to consumers, it follows that the government purchases pharmaceutical products "with a view to the commercial resale" of pharmaceutical products by pharmacies to consumers.³⁴¹ The

³²⁷ European Union's first written submission, paras. 208, 212.

³²⁸ European Union's first written submission, para. 214. (emphasis original)

³²⁹ European Union's first written submission, para. 215 (referring to Appellate Body Report, *Canada – Renewable Energy/Feed-in Tariff Program*, fn 514.)

³³⁰ Turkey's first written submission, paras. 218-231.

³³¹ Turkey's first written submission, para. 219.

³³² Turkey's first written submission, paras. 220-229.

³³³ Turkey's first written submission, para. 231.

³³⁴ European Union's second written submission, para. 110.

³³⁵ European Union's second written submission, para. 112 (quoting Panel Report, *India – Solar Cells*, para. 7.156, summarizing the findings of the Appellate Body in *Canada – Renewable Energy / Feed-In Tariff Program*, paras. 5.66–5.68 and 5.74).

³³⁶ European Union's second written submission, paras. 112-113. (emphasis original)

³³⁷ Turkey's second written submission, para. 81.

³³⁸ Turkey's second written submission, para. 83. Turkey submits that "the European Union appears to agree that pharmacies act on behalf of the SSI when they dispense pharmaceutical products to patients in the context of its claim under Article 3.1(b) of the SCM Agreement." (Turkey's second written submission, para. 86.)

³³⁹ Turkey's second written submission, para. 82. (emphasis original)

³⁴⁰ Turkey's second written submission, paras. 85 and 13.

³⁴¹ European Union's first written submission, paras. 217-227.

European Union refers to the fact that pharmacies provide the product, in exchange for payment that is partly borne by the consumer, and asserts that this provision is made within the framework of a straightforward arms-length sales transaction: pharmacies are profit-seeking, and end-users are interest-maximizing.³⁴² The European Union submits that Article III:8(a) captures not only direct resale by the very agency purchasing the products, but also commercial resale³⁴³ through another actor, such as, in this case, a pharmacy.³⁴⁴

7.58. Turkey responds that the pharmaceutical products are not "resold" on the "commercial" market but are dispensed by retail pharmacies – on behalf of the SSI – to patients.³⁴⁵ According to Turkey, the patients – which it says are "curiously referred to" by the European Union as "consumers" or "end-users"³⁴⁶ – are not "buying" pharmaceutical products of their choice, as they cannot choose the products or their quantities or discuss their price, and they receive the specific medicine that was prescribed to them in a specific dose by a medical doctor based on those patients' specific health needs.³⁴⁷ There is thus no "commercial transaction" between the patient and the medical doctor or the pharmacy.³⁴⁸ All elements of the "exchange" between the patient and the retail pharmacy are decided by the Turkish government which determines which pharmaceutical products are paid for by the SSI, what their price is and how they will be dispensed to patients.³⁴⁹ Turkey also reiterates that the contribution fee and the prescription fee paid by patients in retail pharmacies are not the "resale price" of the pharmaceutical product, as the European Union seems to suggest, but form part of the patients' contribution to the social security system and aim at preventing abuse.³⁵⁰ Furthermore, contrary to what the European Union suggests, the retail pharmacy is also not acting as a regular, profit-seeking "willing seller": the price of a pharmaceutical product provided to patients and paid by the SSI, as well as the mark-up made by a retail pharmacy, are all set by law.³⁵¹ Finally, the SSI does not procure the pharmaceutical products with a view to using those products in the production of other goods for commercial sale.³⁵²

7.59. In its second written submission, the European Union responds that Turkey, in claiming that the European Union misrepresents its reimbursement system as a set of purely commercial transactions, fails to engage with the European Union's actual argument. The European Union reiterates that its argument is that if the Panel were to find that the government purchases pharmaceutical products when *reimbursing* their cost to the pharmacies, then it would logically follow that the government is purchasing those products with a view to their *commercial resale* by pharmacies.³⁵³ The European Union submits that Turkey provides no direct response to this argument.³⁵⁴ Furthermore, according to the European Union, Turkey makes a number of "startling remarks" that "must be corrected", including that patients cannot choose the products (even though Turkey itself describes a scenario in which they can choose between different products in equivalent groups); that all elements of the exchange are decided by the government (even though patients may decide, among other things, which product to purchase); and that pharmacies are not profit-seeking (even though they are private entities with a commercial interest and receive a mark-up as well as a service fee).³⁵⁵

7.60. In its second written submission, Turkey argues that the relationship between the retail pharmacies and patients does not fit the definition of "commercial resale" within the meaning of Article III:8(a) as "a resale of a product at arm's length between a willing seller and a willing

³⁴² European Union's first written submission, paras. 224-225.

³⁴³ The European Union notes that it is aware that this reading would mean that pharmacies are both *selling* the products to the government and *reselling* the same products to consumers. It argues that "this oddity ... is caused by accepting the argument that, when it engages in reimbursement, the Turkish government is procuring and purchasing products for governmental purposes." (European Union's first written submission, para. 227.)

³⁴⁴ European Union's first written submission, para. 226.

³⁴⁵ Turkey's first written submission, paras. 232-240.

³⁴⁶ Turkey's first written submission, para. 236.

³⁴⁷ Turkey's first written submission, para. 236.

³⁴⁸ Turkey's first written submission, para. 236.

³⁴⁹ Turkey's first written submission, para. 236.

³⁵⁰ Turkey's first written submission, para. 236.

³⁵¹ Turkey's first written submission, para. 237.

³⁵² Turkey's first written submission, para. 239.

³⁵³ European Union's second written submission, paras. 114-115.

³⁵⁴ European Union's second written submission, para. 116.

³⁵⁵ European Union's second written submission, para. 116.

buyer".³⁵⁶ According to Turkey, this relationship is not in the nature of a "transaction" because pharmacies do not "resell" medicines and outpatients do not "buy" them.³⁵⁷ First, pharmacies do not resell the pharmaceutical products because they rather dispense them to outpatients on behalf of the SSI, on the basis of the TPA Protocol and the contracts signed between individual pharmacies and the SSI.³⁵⁸ The elements of any "transaction" between retail pharmacies and patients are either set by the SSI or the medical doctor prescribing the pharmaceutical products, and thus "do not have a commercial character".³⁵⁹ Second, Turkey disagrees with the European Union's position that patients "purchase" pharmaceutical products which would then be reimbursed by the SSI. Turkey submits that patients "go to retail pharmacies with their prescription and get the prescribed medicines from the pharmacies, the medicines being paid for by the SSI."³⁶⁰ According to Turkey, "patients receive the medicines indicated on their prescription and the cost of those medicines is covered by the SSI who purchases them from the pharmacies".³⁶¹ Patients "cannot choose the pharmaceutical products but obtain the specific medicine prescribed to them in a specific form and dosage by a medical doctor."³⁶² If a patient prefers a more expensive product from the same equivalent group, he or she must pay the difference between the price of that product and the price paid by the SSI – but according to Turkey this does not mean that patients pay the retail price of those pharmaceutical products.³⁶³ Turkey also points out that, contrary to what the European Union argues, (i) the fact that patients may replace the brand product from the prescription with an equivalent generic product (or *vice versa*)³⁶⁴; (ii) the fact that patients may decide "whether, when or where" to use their prescription³⁶⁵; and (iii) the fact a patient may choose the pharmacy or even decide not to take his/her prescribed medicine, do not indicate that there are any commercial transactions between the patients and retail pharmacies as far as the pharmaceutical products included in the Annex 4/A list are concerned.³⁶⁶ Turkey further maintains that the prescription fee and the contribution fee paid by patients are not part of the price of the pharmaceutical products but rather "form part of the patients' contribution to the social security system and aim at preventing abuses of the healthcare system, including overconsumption of medicines, as well as ensuring its financial sustainability".³⁶⁷ Turkey also observes that in many instances, patients are exempted from the payment of the contribution fee.³⁶⁸

7.2.4 Assessment by the Panel

7.2.4.1 Introduction

7.61. The government procurement derogation in Article III:8(a) concerns "the procurement by governmental agencies of products purchased for governmental purposes". This provision was interpreted and applied in *Canada – Renewable Energy / Canada – Feed-in Tariff Program* and *India – Solar Cells*. In both disputes, the measures at issue required entities seeking to sell electricity to the government at preferential rates to satisfy certain domestic content requirements with respect to the equipment used to generate that electricity (e.g. solar cells). The conclusion ultimately

³⁵⁶ Turkey's second written submission, para. 89 (referring to Appellate Body Reports, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 5.70).

³⁵⁷ Turkey's second written submission, para. 88.

³⁵⁸ Turkey explains that retail pharmacies are "considered as primary healthcare service providers and act on behalf of the SSI to carry out its function to provide pharmaceutical products to outpatients in Turkey". (Turkey's second written submission, para. 92.)

³⁵⁹ Turkey's second written submission, para. 32. According to Turkey, the fact that retail pharmacies receive a mark-up, does not change this conclusion, because "the pharmacy mark-up forms part of the retail price of a pharmaceutical product and is set by law." (Ibid. para. 32.) See also Turkey's second written submission, para. 94.

³⁶⁰ Turkey's second written submission, para. 13.

³⁶¹ Turkey's second written submission, para. 88.

³⁶² Turkey's second written submission, para. 90.

³⁶³ Turkey's second written submission, para. 26.

³⁶⁴ Turkey's second written submission, para. 90.

³⁶⁵ Turkey's second written submission, para. 91.

³⁶⁶ Turkey's second written submission, para. 91. Turkey also submits that "the fact that the price of pharmaceutical products includes a pharmacy mark-up does not show that pharmacies are regular 'profit-seeking' sellers." (Turkey's second written submission, para. 94). Turkey explains that the mark-up is paid by the SSI when it purchases medicines included in Annex 4/A from the pharmacies and "covers, among others, the prefinancing of the medicines provided by the pharmacies during the period between the moment they pay the wholesalers and the moment they receive payment from the SSI." (Ibid. para. 94).

³⁶⁷ Turkey's second written submission, paras. 24 and 77.

³⁶⁸ Turkey's second written submission, paras. 24 and 78.

reached was that, for purposes of Article III:8(a), the "product purchased" by the governmental agencies through the relevant measures was electricity, and not also the electricity generation equipment subject to the challenged domestic content requirement. On that basis, Article III:8(a) was found to be inapplicable to the domestic content requirements at issue, because the electricity generation equipment subject to those requirements was not a "product purchased" within the meaning of Article III:8(a).

7.62. In both disputes, the examination of the applicability of Article III:8(a) to the measure at issue started, and ultimately ended, with an assessment of the nature of the "products purchased" within the meaning of Article III:8(a), without any adopted findings as to whether the measure qualified as a "law, regulation or requirement governing ... procurement".³⁶⁹ The panel in *India – Solar Cells* explained that the assessment of the nature of the "products purchased" was the "dispositive factor" of the Appellate Body's analysis in *Canada – Renewable Energy / Feed-In Tariff Program*³⁷⁰ and characterized this question in terms of a "threshold matter of the applicability of Article III:8(a) in respect of the 'products purchased'".³⁷¹ That panel observed that it was therefore unnecessary to make findings on the remaining elements of Article III:8(a) given that "the threshold legal element" under this provision was not satisfied.³⁷² The Appellate Body upheld the panel's interpretation and application of the term "products purchased" in Article III:8(a), and made no findings on what it termed "the remaining elements" of Article III:8(a) (including whether the challenged measure was a "law, regulation or requirement governing ... procurement").³⁷³

7.63. This dispute is distinguishable from *Canada – Renewable Energy / Canada – Feed-in Tariff Program* and *India – Solar Cells* to the extent that, unlike the two prior disputes, the products that are allegedly "purchased" for purposes of Article III:8(a) and the products that are allegedly being discriminated against for purposes of Article III:4 are the same, i.e. pharmaceutical products included in the Annex 4/A list.³⁷⁴ However, there are certain parallels between the arguments made in these disputes, and, like the panels in those two cases, the Panel will start its assessment by focusing on the "products purchased" (if any) through the challenged measure, and more specifically with the question whether the localisation requirement involves the "purchase" of pharmaceutical products included in the Annex 4/A list by governmental agencies.

7.64. Turkey advances three alternative lines of argument in support of its contention that the localisation requirement involves the "purchase" of pharmaceutical products included in the Annex 4/A list by governmental agencies. First, Turkey argues that the concept of a "purchase" under Article III:8(a) should not be interpreted narrowly, and that the SSI "purchases" pharmaceutical products by paying for them, even if it does not acquire an entitlement to (or property rights over) the products. Turkey argues that the SSI's reimbursement of the cost of outpatients' pharmaceuticals involves a "purchase" because it is "the SSI that pays for the pharmaceutical products and thus is the ultimate buyer (or the purchaser)".³⁷⁵ Second, Turkey argues that, even under an "extremely narrow"³⁷⁶ definition of what constitutes a "purchase" requiring the transfer of legal title over a product, which is an interpretation that Turkey disagrees with³⁷⁷, there is still a

³⁶⁹ The panel in *Canada – Renewable Energy / Feed-In Tariff Program* interpreted the terms "procurement" and "purchase" to mean the same thing, and addressed them together in the context of finding that the challenged measure qualified as a "law, regulation, or requirement governing the procurement by governmental agencies of electricity". The panel found that the procurement and purchase of electricity was undertaken "with a view to commercial resale" and found Article III:8(a) inapplicable on that basis. On appeal, the Appellate Body stated that the terms "procurement" and "purchase" should not be given the same meaning, and clarified that the relevant question was whether electricity generation equipment (as distinct from electricity) was a product being "procured" or "purchased". After finding that it was not, the Appellate Body ended its analysis at that point.

³⁷⁰ Panel Report, *India – Solar Cells*, para. 7.106.

³⁷¹ Panel Report, *India – Solar Cells*, para. 7.106.

³⁷² Panel Report, *India – Solar Cells*, para. 7.136. In *India – Solar Cells*, the panel nonetheless considered it useful to proceed with a limited analysis and review of certain issues relating to the remaining elements of Article III:8(a), so that the Appellate Body could have the benefit of its factual findings related to these issues in case the Appellate Body were to modify or reverse the Panel's interpretation and application of the nature of the "products purchased". (Panel Report, *India – Solar Cells*, paras. 7.136-7.138.)

³⁷³ Appellate Body Report, *India – Solar Cells*, paras. 5.42-5.44.

³⁷⁴ Turkey's responses to the first set of questions, para. 29; responses to the second set of questions, paras. 51-53.

³⁷⁵ Turkey's first written submission, paras. 206-208.

³⁷⁶ Turkey's first written submission, para. 205.

³⁷⁷ Turkey's first written submission, para. 206.

"purchase" by the SSI. This is because, as a matter of fact, the SSI does acquire title to the pharmaceutical products at the moment a retail pharmacy scans a prescription's QR code and the Medula system approves the provision of that pharmaceutical product to the patient.³⁷⁸ Third, Turkey argues that, even if that is incorrect, Article III:8(a) still applies because the purchase of pharmaceutical products included in the Annex 4/A list by the retail pharmacies from the wholesalers is made on behalf of the SSI and this means that the retail pharmacies are themselves "governmental agencies" that "purchase" pharmaceuticals for purpose of Article III:8(a). The European Union disputes all of Turkey's arguments.

7.65. In the light of the parties' arguments, the Panel will first set forth its interpretation of the term "purchased" in the context of the phrase "products purchased by governmental agencies". The Panel will then apply that legal standard to assess whether the localisation requirement involves a "purchase" by the SSI. The Panel will then assess Turkey's argument that, even if the SSI itself does not "purchase" pharmaceutical products included in the Annex 4/A list, there is still a "purchase" covered by Article III:8(a) because pharmacies act on behalf of the SSI, and to that extent, are themselves "governmental agencies" for purposes of Article III:8(a).

7.2.4.2 Interpretation of the term "products purchased" in Article III:8(a)

7.66. The Panel observes that most cases of governmental procurement involve situations in which a government obtains products for its own use or consumption, and do not give rise to any conceptual issues in terms of Article III:8(a). In the classical situation where a government obtains products for its own use or consumption, it will typically do so pursuant to tendering procedures prescribed by domestic laws and regulations governing procurement; the government's action of using or consuming the products itself will reflect rights of ownership of the product associated with a product "purchased" in the narrowest sense of the term; the purchase of a product by a government for its own use and consumption will fall within the narrowest concept of a product purchased "for a governmental purpose"; and when the government uses or consumes the product itself, it will by definition not be "with a view to commercial resale".

7.67. However, the scope of the government procurement derogation in Article III:8(a) is not limited to the classical situation in which a government acquires products for its own use or consumption. The Appellate Body interpreted the term "governmental purposes" in Article III:8(a) as referring more generally to products "purchased for the needs of the government in the discharge of its functions"³⁷⁹, and clarified that the phrase "products purchased for governmental purposes" in Article III:8(a) covers not only what is consumed by the government itself, but also "what is provided by government to recipients in the discharge of its public functions".³⁸⁰ In the present case, neither of the parties, nor any of the third parties, has disagreed with this understanding of what may constitute a "governmental purpose".

7.68. In those situations where a government pays for products that are ultimately used and consumed by non-governmental third parties, rather than by the government itself, the applicability of Article III:8(a) may become less straightforward. Among other things, it may become more difficult in such situations to differentiate a payment constituting a "purchase" of products, which in principle falls within the scope of the derogation in Article III:8(a), from other forms of payments which might be labelled as financing, reimbursement or funding, which in principle are not covered by Article III:8(a). The difficulty of conceptualizing what is meant by a "product purchased", and how to differentiate a purchase from other types of transactions, may be compounded where the end result of different types of arrangements is identical – i.e. the government pays for products that are ultimately used or consumed by third parties. In such situations, it becomes necessary to ensure that the application of Article III:8(a) is grounded in an objective legal standard and sound interpretation of the definition of the term "product purchased".

7.69. The Panel has been presented with opposing interpretations of the term "products purchased" in Article III:8(a). The European Union argues that the term "purchased" should be interpreted relatively narrowly, to mean a transaction which results in a government "acquiring property over"³⁸¹ products. Turkey does not agree with the European Union that government procurement effectuated

³⁷⁸ Turkey's second written submission, paras. 71-73.

³⁷⁹ Appellate Body Reports, *Canada – Renewable Energy / Feed-In Tariff Program*, para. 5.67.

³⁸⁰ Appellate Body Reports, *Canada – Renewable Energy / Feed-In Tariff Program*, para. 5.68.

³⁸¹ European Union's second written submission, para. 100.

through means of a purchase under Article III:8(a) necessarily requires acquiring an "entitlement" to or "obtaining property rights over" the products.³⁸² The Panel considers that, in accordance with Article 31(1) of the Vienna Convention on the Law of Treaties, it must resolve the meaning of the term "product purchased" in accordance with "the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose".

7.70. Beginning with the ordinary meaning of the term "product purchased", the Panel considers that in everyday usage a person or entity is said to purchase a product at the moment that the person or entity acquires ownership of a product through some kind of payment. Indeed, it is the acquisition of ownership over a product that constitutes the defining characteristic of what it means to purchase a product, and it is what distinguishes purchasing a product from renting/leasing that product. If the word "purchase" is defined in more general and abstract terms as "the action or an act of obtaining something in exchange for payment in money or an equivalent"³⁸³, then when what is being purchased is a product, the "something" that is obtained for purposes of that general and abstract definition is the ownership of (i.e. property rights over) the product.

7.71. Turning to the immediate context of the term "purchase" in Article III:8(a), the Panel recalls that the Appellate Body clarified that the word "procurement" refers to "the process pursuant to which a government *acquires* products"³⁸⁴, and that the word "purchased" in Article III:8(a) refers to "the type of transaction used to put into effect" that acquisition.³⁸⁵ Thus, the concept of "purchase" covers only a subset of the various types of transactions that can be used to put into effect a "procurement".³⁸⁶ Article I:2 of the GPA supports the Appellate Body's understanding, as it refers to "procurement by any contractual means, including through such methods as purchase or as lease, rental or hire purchase, with or without an option to buy". The Panel considers that interpreting the term "purchased" in accordance with its ordinary meaning, i.e. as covering only the type of transaction through which the government acquires ownership of the products, gives the term "purchase" a meaning that is distinct from the broader concept of "procurement" which may involve other types of transactions by which products might be procured (e.g. leasing). As the European Union observes, the common element of these other contractual arrangements is that, "while they may lead to the acquisition of *products* (for example, in the case of rental, the acquirer takes possession and has the right to use the product for a certain period of time), they do not lead to the acquisition of *property* over products."³⁸⁷

7.72. The Panel considers that the term "products purchased" must also be interpreted taking into account, as part of the immediate context, the additional requirement that, in order to fall within the scope of Article III:8(a), the products purchased must be "for a governmental purpose". The Appellate Body clarified that the phrase "products purchased for governmental purposes" in Article III:8(a) "refers to what is consumed by the government or what is provided by government to recipients in the discharge of its public functions".³⁸⁸ The Panel considers that both of those actions – i.e. a government consuming a product that it has acquired, or providing a product that it has

³⁸² Turkey's responses to the first set of questions, para. 31.

³⁸³ Oxford English Dictionary online,

<<https://www.oed.com/view/Entry/154831?rskey=07nKL5&result=1&isAdvanced=false#eid>>. The Panel notes that the parties have presented it with alternative dictionary definitions of the word "purchase" to support their opposing interpretations. Consistent with its view that the acquisition of property over products is a defining characteristic of a "purchase", the European Union considers that the relevant dictionary definition is "[t]he acquisition of property (esp. land) by any legal means other than inheritance" (European Union's first written submission, para. 201). In contrast, Turkey refers to a dictionary definition of the term "purchase" that does not make reference to property, and defines the term more broadly as "the action or an act of obtaining something in exchange for payment in money or an equivalent." (Turkey's first written submission, para. 207). Both parties draw their definitions from the same source, i.e. the Oxford English Dictionary Online.

³⁸⁴ Appellate Body Report, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 5.59. (emphasis added)

³⁸⁵ Appellate Body Report, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 5.59.

³⁸⁶ See para. 7.40 and fn 369 above.

³⁸⁷ European Union's first written submission, para. 202. (emphasis original). The Panel notes that the GATT panel in *US – Sonar Mapping* stated, in the context of a similar provision in a predecessor version of the GPA in force at the time, that "[w]hereas ownership is not a necessary element of government *procurement*, as is clear from *the various methods* of procurement mentioned in Article I:1(a), transfer of title to the Government is a strong indication that government procurement is involved." (GATT Panel Report, *US – Sonar Mapping*, para. 4.10.) (emphasis added)

³⁸⁸ Appellate Body Reports, *Canada – Renewable Energy / Feed-In Tariff Program*, para. 5.68.

acquired to other recipients to be consumed by them – presuppose that the government acquires ownership of the product being consumed.

7.73. Turning to the Panel's consideration of the object and purpose of the GATT 1994, the Panel notes that if situations in which a government pays for products used by non-governmental consumers are treated as "purchases" by the government even though the government never acquires ownership over those products, simply on the basis that it is the government that "pays for the pharmaceutical products and thus is the ultimate buyer (or the purchaser)"³⁸⁹, then this would result in Article III:8(a) covering an open-ended range of protectionist measures. As the European Union observes, the range of governmental financing measures that might be covered under Article III:8(a) as "purchases" by a government agency could, on the basis of Turkey's interpretation of the term, include coupons for food, subsidies for renovating real estate, and tax credits for environmentally friendly purchases.³⁹⁰ Recalling that Article III:8(a) is a limited derogation from the national treatment obligation in Article III, the Panel considers that such a result would undermine the object and purpose of the GATT 1994. The Panel understands that Turkey's position is that the SSI does more than merely engage in "financing", and that Turkey takes issue with the European Union's attempt to "reduce the role of the SSI to the mere financing of the purchases of pharmaceutical products by outpatients".³⁹¹ However, even assuming that Turkey is correct in asserting that the SSI does more than merely engage in financing, Turkey has not specified on what other basis, if not the acquisition of ownership, the concept of a "purchase" by a government could be distinguished from mere financing of private purchases in circumstances where the relevant products are provided to, and consumed by, non-governmental recipients. In other words, while Turkey has identified a series of factual elements that, in its view, support the conclusion that the Turkish system falls within the scope of Article III:8(a)³⁹², these elements do not specify an objective legal standard for distinguishing the concept of a "purchase" by a government from mere financing of private purchases in circumstances where the relevant products are provided to, and consumed by, non-governmental recipients.

7.74. The foregoing analysis leads the Panel to conclude that, in the context of the phrase "procurement by governmental agencies of products purchased for governmental purposes" in Article III:8(a), a product is "purchased" by a government only if the government acquires ownership of that product through some kind of payment. The fact that SSI pays for the products is not sufficient: for a purchase to occur by the SSI, it would have to be established that the SSI acquires ownership of the products. As elaborated in the next subsection, the Panel agrees with Turkey that the range of transactions through which a government may acquire ownership of products may vary, and the specific features of what constitutes ownership may vary depending on factors such as the nature of the good. However, the Panel considers that in all cases, if there is no acquisition of ownership of products by the government, then there is no "purchase" of products by the government and the measure at issue will not fall within the scope of the government procurement derogation in Article III:8(a). Thus, the Panel does not agree with Turkey's argument that the SSI "pays for the pharmaceutical products and thus is the ultimate buyer (or the purchaser)".³⁹³

7.75. The Panel considers that Turkey's interpretation of the term "products purchased", i.e. the SSI must be deemed to "purchase" pharmaceutical products because it pays for their cost, even if it does not acquire ownership of those products, is also inconsistent with the two prior disputes in which Article III:8(a) was interpreted and applied. More specifically, in *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, the panel interpreted government "purchases" of goods "to mean

³⁸⁹ Turkey's first written submission, paras. 206-208.

³⁹⁰ European Union's responses to the first set of questions, para. 8.

³⁹¹ Turkey's second written submission, para. 23.

³⁹² In the context of its comments on the Interim Report, Turkey reiterated that "the SSI ensures the provision of medicines to outpatients and makes all the necessary arrangements for this purpose: it decides which medicines are listed in Annex 4/A; it sets public prices of those medicines; it signs contracts with pharmacies for ensuring the availability and distribution of those medicines throughout the country; it approves the provision of the medicines to be dispensed to outpatients through the Medula system and pays the invoice it receives for those medicines from the pharmacies. It is the combination of all the above elements that makes the Turkish system fall within the scope of Article III:8(a). Turkey further explained that a universal healthcare system in which public authorities control all aspects of the purchase and provision of prescribed medicines to outpatients would generally fall within the scope of Article III:8(a), while this would not be the case for a system which is voluntary, does not have universal coverage and is financed through the contributions of the participants." (Turkey's comments on the Interim Report, para. 28.)

³⁹³ Turkey's first written submission, paras. 206-208.

the action by which a government obtains possession (including via obtaining an entitlement) over goods through some kind of payment (monetary or otherwise)".³⁹⁴ Although the panel referred to the concept of possession, which might be understood to mean physical possession³⁹⁵, it made clear that it did not use the term in this sense, reasoning that "nothing in the ordinary meanings we have reviewed suggests that a 'purchase' must involve obtaining *physical* possession over something".³⁹⁶ Instead, the panel used the expression "possession over goods" to refer to the rights acquired by the government in respect of electricity sold by the generators, namely the right to receive, distribute and charge for electricity passing through the transmission system. These appear to be rights of ownership associated with electricity, a product that cannot be stored and that is generated and consumed almost instantaneously. Indeed, the panel concluded that "given the specific characteristics of electricity, it is perhaps best to conceive of a purchase of electricity as involving the transfer of an *entitlement* to electricity, rather than the taking of physical possession over electricity".³⁹⁷

7.76. In *India – Solar Cells*, the governmental agencies in question purchased electricity from generators, and India accepted that those agencies did not "purchase" or "directly acquire" the solar cells and modules used to generate the electricity, which were the subject of the domestic content requirements at issue. India accepted that this was so because the agencies did not "take title or custody" of the electricity generation equipment.³⁹⁸ India nonetheless sought to argue that it was "effectively procuring" solar cells and modules for purposes of Article III:8(a), because the electricity generation equipment constituted "integral inputs for the generation system"³⁹⁹ and thus "cannot be treated as distinct from solar power"⁴⁰⁰, and because "the tariff for the power purchased under the [power purchase agreements] incorporated within it the cost for the solar cells and modules".⁴⁰¹ However, the panel and the Appellate Body in that dispute were not persuaded by those arguments and concluded that the only product being "purchased" was electricity.

7.77. Thus, in both of these disputes, the conclusion reached was that, for purposes of Article III:8(a), the "product purchased" by the governmental agencies through the relevant measures was only electricity, and not also the electricity generation equipment subject to the challenged domestic content requirement. This conclusion was reached even though, in both cases, the relevant governmental agencies paid the electricity generators a price that covered the cost of the equipment used in generating the electricity that the governments purchased. However, the governmental agencies involved in purchasing electricity acquired ownership of electricity, but did not acquire ownership of the electricity generation equipment (e.g. solar cells) that was the subject of the domestic content requirement at issue.

7.78. In this dispute, Turkey explains that in the past, the SSI itself obtained the pharmaceutical products from the wholesalers and dispensed them to patients through pharmacies run by the SSI.⁴⁰² Turkey explains that because that system was not very efficient, it was changed, with the

³⁹⁴ Panel Report, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 7.136.

³⁹⁵ The Panel notes that the term "possession" is susceptible to several different meanings and depending on the context may be used interchangeably with "ownership". For example, the Oxford English Dictionary Online defines "possess" as "[t]o own, to have or gain ownership of; to have (wealth or material objects) as one's own; to hold as property." In the *US – Sonar Mapping* case, the panel appeared to use the terms "possession" and "ownership" interchangeably. Specifically, the panel stated that while not intending to offer a definition of government procurement within the meaning of Article I:1(a), it enumerated several factors that should be considered on the facts of any case, including what it termed "government possession" (GATT Panel Report, *US – Sonar Mapping*, para. 4.7). In the context of elaborating on the facts of the case, the panel stated, apparently in relation to that enumerated factor, that the relevant governmental agency would "take title to the sonar mapping system as of the time of its delivery" and made the observation that "[w]hereas ownership is not a necessary element of government procurement, as is clear from the various methods of procurement mentioned in Article I:1(a), transfer of title to the Government is a strong indication that government procurement is involved" (para. 4.10). In summing up its assessment of the factors it had considered, the panel again referred to the government's "ownership" of the sonar mapping system. (Ibid. para. 4.13).

³⁹⁶ Panel Report, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 7.228. (emphasis original)

³⁹⁷ Panel Reports, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 7.229. (emphasis original)

³⁹⁸ Panel Report, *India – Solar Cells*, para. 7.114.

³⁹⁹ Panel Report, *India – Solar Cells*, paras. 7.109 and 7.114.

⁴⁰⁰ Panel Report, *India – Solar Cells*, para. 7.128.

⁴⁰¹ Panel Report, *India – Solar Cells*, para. 7.129.

⁴⁰² Turkey's second written submission, paras. 65-68.

introduction of the Transformation in Health Program in 2003, to a system whereby pharmaceutical products are dispensed through retail pharmacies. Turkey understands that the European Union would consider the practice before this reform as amounting to government procurement and in that sense would agree that the practice falls under Article III:8(a) just because the pharmaceutical products were dispensed by the state-owned pharmacies directly to patients. However, according to Turkey, "the essence of the system after the reform remains unchanged, the only difference being that part of the tasks previously carried out by the SSI has now been delegated to the retail pharmacies", and therefore Turkey submits that the European Union's interpretation of Article III:8(a) is "overly formalistic and puts form before substance".⁴⁰³

7.79. The Panel is not persuaded by Turkey's argument. First, the Panel notes that Turkey's argument is formulated in terms that imply that the European Union is arguing that Article III:8(a) only applies where a government acquires "physical possession" of the products purchased.⁴⁰⁴ However, the Panel does not understand the European Union's interpretation of Article III:8(a) to be that "physical possession" of goods is a constitutive element of a "purchase". Rather, the Panel understands the European Union's interpretation of Article III:8(a) to be essentially the same interpretation as the one elaborated by the Panel in its reasoning above, namely, that a product is "purchased" by a government only if the government acquires ownership of the product through some kind of payment. Thus, Turkey's argument appears to conflate the notion of acquisition of ownership over a good and the notion of having physical possession of that good. Second, insofar as Turkey's argument is that treating the acquisition of ownership over a good as a constitutive element of the concept of a "purchase" of that good is overly formalistic, then the Panel disagrees. The Panel does not consider it formalistic to interpret Article III:8(a) as being, in principle, applicable to situations in which a governmental agency (e.g. state-owned pharmacy and/or hospital) purchases pharmaceutical products and then provides them directly to patients, and as being, in principle, not applicable to other situations where the government pays for the cost of the pharmaceutical products consumed by patients without ever acquiring ownership over these products.⁴⁰⁵

7.80. The Panel observes that an analogous argument was made by the responding party in *India - Solar Cells*, and that it did not persuade the panel or the Appellate Body. In that case, India argued that under the relatively narrow interpretation of Article III:8(a) advocated by the complaining party, and ultimately adopted by the panel and the Appellate Body, there would be an arbitrary result. Specifically, the result would be that Article III:8(a) would in principle apply only if the government itself purchased solar cells and then provided them to private solar power developers (SPDs) (or the government itself generated the electricity from them without involving SPDs), but that Article III:8(a) would in principle not apply if the government paid for their cost (i.e. the tariff for the power purchased from SPDs incorporated within it the cost for the solar cells and modules they were required to use) without acquiring ownership. In India's view, both situations involved the relevant governmental agency "effectively procuring" solar cells and modules for purposes of Article III:8(a). India considered that it could not have been the intent of the drafters of Article III:8(a) to treat these situations differently. However, neither the panel nor the Appellate Body was persuaded by India's argument, and evidently did not consider the distinction drawn to be formalistic.⁴⁰⁶

7.81. Based on the foregoing, the Panel concludes that, in the context of the phrase "procurement by governmental agencies of products purchased for governmental purposes" in Article III:8(a), a product is "purchased" by a government if the government acquires ownership of that product through some kind of payment. The Panel considers that the broader interpretation of the term "products purchased" advanced by Turkey, i.e. that the SSI "pays for the pharmaceutical products and thus is the ultimate buyer (or the purchaser)"⁴⁰⁷ regardless of whether the SSI ever acquires ownership over those products, is difficult to reconcile with the ordinary meaning of the term "purchased", the immediate context afforded by the other cumulative elements of Article III:8(a),

⁴⁰³ Turkey's opening statement, para. 69.

⁴⁰⁴ See Turkey's second written submission, paras. 63-64.

⁴⁰⁵ See Turkey's second written submission, para. 42.

⁴⁰⁶ See Panel Report, *India - Solar Cells*, paras. 7.130-7.133; Appellate Body Report, *India - Solar Cells*, paras. 5.33-5.34.

⁴⁰⁷ Turkey's first written submission, paras. 206-208.

the object and purpose of the GATT 1994, and the Appellate Body's findings in *Canada – Renewable Energy / Canada – Feed-in Tariff Program* and *India – Solar Cells*.

7.2.4.3 Whether the SSI purchases pharmaceutical products from retail pharmacies

7.82. Having concluded that a product is a "product purchased" by a government only if the government acquires ownership of that product, the Panel will now apply this legal standard to assess whether Turkey's pharmaceutical reimbursement system involves a "purchase" by the SSI. The Panel recalls that Turkey's second argument which rests on an alternative interpretation of the term "products purchased" in Article III:8(a), is that even under the "extremely narrow"⁴⁰⁸ definition of what constitutes a "purchase" that it disagrees with⁴⁰⁹, i.e. a transaction requiring the transfer of legal title over a product, there is still a "purchase" by the SSI because, as a matter of fact, the SSI does acquire title to pharmaceutical products at the moment a retail pharmacy scans a prescription's QR code and the Medula system approves the provision of that pharmaceutical product to the patient. Thus, the Panel must assess whether the SSI acquires ownership of pharmaceutical products included in the Annex 4/A list, whether at the moment of approval in the Medula system or otherwise.

7.83. The Panel accepts that the range of transactions through which a government may acquire ownership of products may vary, and that the specific features of what constitutes ownership may vary depending on factors such as the nature of the good. As elaborated above in the context of interpreting the term "purchase", the Panel does not consider physical possession of goods to be a constitutive element of a purchase. In this connection, the Panel agrees with both parties that the *Canada – Renewable Energy / Canada – Feed-in Tariff Program* panel's approach to the example of electricity – a product that generally cannot be stored in large quantities, and which in the context of delivery by public utilities through the electricity grid is generated and consumed almost instantaneously – is instructive. That panel stated that "given the specific characteristics of electricity, it is perhaps best to conceive of a purchase of electricity as involving the transfer of an *entitlement* to electricity, rather than the taking of physical possession over electricity"⁴¹⁰ and found that there was such a transfer of an "entitlement" to electricity on the basis that the governmental agencies in question acquired certain legal rights in respect of the products, including the right to receive, distribute and charge for (i.e. resell) electricity passing through the transmission system.

7.84. Thus, in assessing whether the SSI acquires ownership of pharmaceutical products included in the Annex 4/A list, the Panel has sought to determine whether the SSI acquires any legal rights over the products of the type typically associated with ownership of goods. The Panel has also taken into account the kinds of legal rights over pharmaceutical products that are acquired by other entities that undisputedly acquire ownership over those products in the context of the Turkish system. These other entities include private pharmacies that acquire ownership of pharmaceutical products when they purchase them from wholesalers, and the final consumers (i.e. outpatients) that acquire ownership of pharmaceutical products when they obtain them from pharmacies. The Panel observes that it is undisputed between the parties that pharmacies acquire ownership of medicines when obtaining them from wholesalers, and that the final consumers (i.e. outpatients) subsequently acquire ownership of pharmaceutical products when obtaining them from retail pharmacies.⁴¹¹

7.85. The Panel is unable to discern any basis upon which it could conclude that the SSI acquires any legal rights over the pharmaceutical products it pays for, let alone that it acquires the types of legal rights that are typically associated with ownership of goods. Generally, there is nothing in the parties' description of Turkey's pharmaceutical reimbursement system to suggest that the SSI

⁴⁰⁸ Turkey's first written submission, para. 205.

⁴⁰⁹ Turkey's first written submission, para. 206.

⁴¹⁰ Panel Reports, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 7.229. (emphasis original)

⁴¹¹ The point of disagreement between the parties is whether the SSI acquires intervening ownership of the product. The European Union argues that the pharmacy retains ownership and control of their stock, once purchased from wholesalers, until they are sold to patients, and that when sold to patients, there is "no doubt that patients obtain those products (including property over them)". (European Union's second written submission, paras. 106-107.) Turkey argues that the pharmacy retains ownership and control of their stock, once purchased from wholesalers, and that the SSI acquires the title to medicines listed in Annex 4/A and prescribed to patients at the moment the provision of such medicines is registered and approved in the Medula system and that, at that moment, the SSI acquires the right to dispose of those medicines by dispensing them, through the retail pharmacies, to patients, and "the title to those medicines is then immediately transferred to patients because the patients have the legal right to those medicines." (Turkey's closing statement, para. 23.)

acquires any right of possession, any right of control, any right of exclusion, any right to derive income, or any right to freely dispose of the pharmaceutical products that it acquires.

7.86. As an example of the kinds of legal rights typically associated with ownership of goods that the SSI does not acquire, the Panel notes that it is undisputed that SSI does not ever acquire the right to take physical possession of the pharmaceutical products that it pays for. For reasons already given, the Panel does not consider taking physical possession of goods to be a constitutive element of a "purchase". However, while a purchaser need not necessarily exercise the right to take physical possession of the purchased goods for the transaction to be considered a purchase, the absence of any such right to take physical possession of the goods is a strong indicator that the entity paying for these goods has not acquired any right of ownership over them. This is especially so when the goods in question are in the nature of goods that can freely be transported and stored, such as pharmaceutical products.⁴¹² The absence of any right for the SSI to take physical possession of the products it pays for stands in marked contrast to the rights of ownership acquired by retail pharmacies when purchasing pharmaceutical products from warehouses, and the rights of ownership acquired by outpatients when receiving those products from the retail pharmacies. In both cases, these purchasing entities acquire, and exercise, the right to take physical possession of the products in question.

7.87. In addition, the Panel finds no basis to support Turkey's assertion that the SSI obtains the right to dispose of the pharmaceutical products that it pays for according to its own choices. Based on the parties' description of the process, it seems undisputed that, following approval in the Medula system, the pharmaceutical product in question must be provided to the individual consumer (i.e. outpatient) named in the prescription. According to the parties' description of the process, all relevant decisions and choices associated with the disposition of pharmaceutical products are made by the prescribing doctor, the pharmacy, and the ultimate consumer (i.e. the outpatient). The Panel is unable to discern any SSI involvement in choosing who receives and consumes any of the pharmaceutical products that the SSI pays for. Put differently, all of the pharmaceutical products paid for by the SSI would be disposed of in exactly the same manner in a counterfactual scenario in which the SSI did not pay for all or part of the cost of those products. Neither the SSI nor any other governmental agency plays any role in directing, or redirecting, pharmaceutical products to recipients of their choosing.

7.88. The Panel is not persuaded by Turkey's argument, in this connection, that the SSI can be deemed to acquire title to pharmaceutical products included in the Annex 4/A list and prescribed to patients at the moment the provision of such pharmaceutical products is registered and approved in the Medula system. Approval through the Medula system is essentially a confirmation that the patient is within SSI coverage and that the prescribed pharmaceutical products are on the Annex 4/A list. That approval confirms, among other things, that the pharmaceutical product may be invoiced by the pharmacy to the SSI at the previously set price.⁴¹³ In the Panel's view, it would require an artificial and strained construction of the facts to characterize this confirmation as a transaction through which "the SSI acquires the right to dispose of those medicines by dispensing them, through the retail pharmacies, to patients", and "the title to those medicines is then immediately transferred to patients because the patients have the legal right to those medicines."⁴¹⁴ If that characterization of the facts in this case were accepted, then almost any measure through which the government (provisionally) approves the payment of the cost of a product could also be so characterized. In addition, the Panel observes that Turkey has not directed the Panel to any reference to the SSI

⁴¹² The Panel considers that pharmaceutical products are in the nature of goods that can freely be transported and stored in the sense that there are no physical, logistical or practical limitations on their transportation and storage of the type that may be encountered in the case of certain other types of goods – for instance, electricity. Of course, pharmaceutical products cannot be freely transported and stored in the sense of being unregulated products that can be freely bought and sold by anyone, and there are a range of legal and regulatory limitations on how they are transported and stored. As Turkey observes "[t]heir production and placing on the market are strictly regulated and their consumption is subject to the prescription by medical doctors. Their provision requires specific conditions and must be carried out by trained professionals, i.e. pharmacists. Medicines cannot be freely bought by consumers and cannot be treated as such." (Turkey's second written submission, para. 5.)

⁴¹³ See Turkey's responses to the first set of questions, para. 26; European Union's responses to the first set of questions, paras. 10-22, opening statement para. 24.

⁴¹⁴ Turkey's second written submission, para. 73; responses to the first set of questions, paras. 32-34; closing statement, para. 23; and responses to the second set of questions, para. 43.

acquiring "title" to pharmaceutical products in the Protocol signed between the SSI and the Turkish Pharmacists Association or to any other evidence on record.⁴¹⁵

7.89. The Panel notes that none of the third parties that took a position on the applicability of Article III:8(a) to the localisation requirement consider that the SSI acquires ownership of pharmaceutical products. Canada notes that in the case of a pharmaceutical reimbursement system like the one in Turkey, the "governmental agency" does not "purchase" the pharmaceutical products because it does not "obtain any form of 'property rights' over the pharmaceutical products".⁴¹⁶ Japan, likewise, notes that the SSI "cannot be the purchaser for purposes of Article III:8(a) because it never gains an entitlement to the products", in contrast to the pharmacies that acquire an "entitlement to the products, including the authority to store, ship, or sell the product".⁴¹⁷ Switzerland observes that it would be difficult to consider that there is "procurement by governmental agencies" or "purchase of products" within the meaning of Article III:8(a) "where private entities have ownership of the products" and "control their disposition" (and, Switzerland continues, where they have the right to cancel contracts with wholesalers, bear the risks of unsold inventories and other commercial risks, do not go through tendering processes to acquire the products, or are not perceived to be government agencies by wholesalers).⁴¹⁸

7.90. Based on the foregoing, the Panel concludes that the SSI does not acquire ownership of pharmaceutical products included in the Annex 4/A list and therefore the SSI's reimbursement of part or all of the cost of those products does not qualify as a "purchase" by the SSI in the context of the phrase "procurement by governmental agencies of products purchased for governmental purposes" in Article III:8(a).

7.91. As indicated in the descriptive part of the Report⁴¹⁹, the parties use different terminology, at times supported by alternative translations of relevant Turkish instruments and documents, to characterize what happens in transactions between retail pharmacies, outpatients, and the SSI. For the European Union, the SSI "reimburses" retail pharmacies for medicines "sold to" "consumers", pursuant to the Protocol that, under its translation, refers to pharmaceutical products being "procured by" those consumers. For Turkey, the pharmaceutical products are "paid for" (not "reimbursed") by the SSI, the retail pharmacies "dispense" or "provide" (and do not "sell") those medicines to "outpatients" (not "consumers"), and the correct translation of the Protocol refers to medicines being "provided to", as opposed to being "procured by", outpatients. In the light of the parties' disagreement over the correct translation of certain terms used in Turkish instruments and documents, and their wider disagreements over terminology, the Panel wishes to clarify that its conclusion and reasoning above are not based on semantic considerations. The Panel's conclusion and reasoning are instead grounded in an objective legal standard.

7.2.4.4 Pharmacies' purchases of pharmaceuticals from wholesalers

7.92. The Panel has concluded that the SSI's payment of part or all of the cost of pharmaceutical products does not qualify as a "purchase" by the SSI. The Panel will now assess Turkey's alternative argument that, even if the SSI does not itself "purchase" pharmaceutical products included in the Annex 4/A list, there is still a "purchase" covered by Article III:8(a) because private retail pharmacies act on behalf of the SSI, and are, to that extent, themselves "governmental agencies" for purposes of Article III:8(a).

7.93. The Panel notes at the outset that this alternative argument, i.e. that Article III:8(a) applies to the localisation requirement because private retail pharmacies are themselves "governmental agencies", has been unfolded in the course of the proceedings in a manner that is less than clear and remains somewhat ambiguous. First, Turkey argues that "the procurement is done by a governmental agency, namely the SSI"⁴²⁰, and Turkey "confirms that the relevant governmental

⁴¹⁵ The Panel considers the lack of such a characterization to be a relevant supplementary consideration, bearing in mind that the label or characterization given to a transaction under domestic law cannot be dispositive of the proper characterization under Article III:8(a). (See Appellate Body Reports, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 5.127.)

⁴¹⁶ Canada's responses to the Panel's questions to third parties, para. 4.

⁴¹⁷ Japan's responses to the Panel's questions to third parties, para. 6.

⁴¹⁸ Switzerland's responses to the Panel's questions to third parties, para. 7.

⁴¹⁹ See section 1.5 and footnotes 36 and 56.

⁴²⁰ Turkey's opening statement, para. 28.

agency is the SSI".⁴²¹ In its written submissions, Turkey argued that the retail pharmacies "act on behalf" of the SSI in dispensing the pharmaceutical products approved and paid for by the SSI to outpatients. The Panel understood from Turkey's written submissions that Turkey was arguing that the SSI purchases pharmaceutical products from pharmacies, and that the pharmacies "act on behalf" of the SSI insofar as they perform the service of dispensing pharmaceutical products included in the Annex 4/A list to outpatients. The Panel has addressed this argument in the previous subsection.

7.94. However, in its responses to the first set of questions from the Panel, Turkey stated, in a footnote, that "[i]n any event, even if the transaction between the SSI and the retail pharmacies would not be qualified as a 'purchase' (*quod non*), it is clear that the retail pharmacies purchase medicines included in Annex 4/A from the wholesalers acting on behalf of the SSI."⁴²² In response to the Panel's second set of questions, Turkey clarified that its alternative argument in this connection is that private retail pharmacies are themselves "governmental agencies" for the purposes of Article III:8(a), because they act on behalf of the SSI when purchasing medicines from wholesalers.⁴²³ Turkey explained that its "argument relating to the purchase of medicines included in Annex 4/A and dispensed to patients by the SSI is two-fold. In the first place, Turkey argues that the SSI purchases those pharmaceutical products from the retail pharmacies which are charged with dispensing those medicines to patients. Should the Panel find that the SSI does not purchase medicines from the retail pharmacies, Turkey submits that Article III:8(a) applies in the present case also because the purchase of medicines included in Annex 4/A by the retail pharmacies from the wholesalers is made on behalf of the SSI."⁴²⁴

7.95. In its comments on Turkey's response, the European Union states that Turkey "seems to propose a novel theory of why Article III:8(a) should apply", and observes that "[u]nder that theory, it would be wholesale purchases of pharmaceutical products, and not their government-financed supply to out-patients, that would constitute 'government procurement' protected by Article III:8(a)."⁴²⁵

7.96. The Panel agrees with Turkey that the terms of Article III:8(a) do not necessarily preclude a governmental agency from purchasing products through an "intermediary".⁴²⁶ However, the Panel considers that, to fall within the scope of Article III:8(a), a governmental purchase effected through an intermediary, and/or through the combined actions of several entities⁴²⁷, must be conducted in a way that leads to the government acquiring ownership of the product purchased. In a situation in which a purchasing entity is an organ of the State (whether legislative, executive, or judicial), its acquisition of ownership over products entails that the government has acquired ownership over those products. Likewise, in the case of purchases made by a publicly owned and controlled entity,

⁴²¹ Turkey's responses to the second set of questions, para. 46.

⁴²² Turkey's responses to the first set of questions, fn 36.

⁴²³ Turkey's responses to the second set of questions, paras. 47-49.

⁴²⁴ Turkey's responses to the second set of questions, para. 44.

⁴²⁵ European Union's comments on responses to the second set of questions, para. 39.

⁴²⁶ Turkey's first written submission, para. 209.

⁴²⁷ The Panel considers that where a government acts through several entities that are each/all "governmental agencies", then responsibilities may be allocated in a manner that necessitates an assessment of whether their "combined actions" establish the requisite elements of a governmental purchase. In *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, one government entity (the OPA) made the payments for electricity, while a different government entity (Hydro One) received and transmitted electricity delivered by suppliers. This led Japan to argue that the OPA served as a mere financing entity, not a purchasing entity, because the OPA itself never took possession of electricity. However, neither the panel nor the Appellate Body considered that the allocation of responsibilities between different *governmental* entities undermined the conclusion that the Government of Ontario "purchased" electricity, because all of the entities involved were *governmental* entities. More specifically, the Appellate Body reasoned that "[s]ince in the present case all the entities involved are public bodies and thus their activities are attributable to the government, it is not relevant whether the Government of Ontario acts through one or several of these entities." Consequently, the Appellate Body considered that the fact that "the OPA itself does not take possession over electricity does not undermine the Panel's finding that the Government of Ontario purchases electricity through the FIT Programme and Contracts ... because Hydro One, which is the entity transmitting electricity, was also found to be a public body, and the Panel found that the "combined actions" of the OPA, Hydro One, and the IESO demonstrate that the Government of Ontario purchases electricity." (Appellate Body Reports, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 5.124.) The panel and the Appellate Body's analysis of that issue was made in the context of interpreting and applying Article 1.1(a)(1)(iii) of the SCM Agreement, but the panel considered that its findings under Article 1.1(a)(1)(iii) applied equally to Article III:8(a). (See Panel Reports, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 7.136.)

the government's ownership of the purchasing entity may entail the government also acquiring ownership over any products purchased by that publicly owned and controlled entity. A government may also enter into transactions through a private, arms-length third party entity that involve purchasing products and, insofar as the relevant transactions are structured and organized in a manner that results in the government acquiring ownership, that entity may well qualify as a "governmental agency" for purposes of Article III:8(a). What is relevant in each of these cases is that the entity's purchases entail, or result in, government ownership over the products in question.

7.97. To find otherwise would lead to the conclusion that Article III:8(a) would apply to purchases made by non-governmental, private entities despite the government never acquiring ownership over the products. This would entirely negate the limitation in Article III:8(a) that a product is "purchased" by a government if the government acquires ownership of it. For the reasons already given, this limitation is grounded in the provision's ordinary meaning and context, and in the object and purpose of the GATT 1994. The concept of a "governmental agency" cannot be interpreted in a manner that is divorced from the fact that Article III:8(a) is limited to the acquisition of products, through procurement and "purchase" by the government.

7.98. It is not necessary for the Panel to elaborate further in the abstract on the types of entities that may constitute "governmental agencies" in the context of Article III:8(a), because in the circumstances of this case, it is clear that the pharmacies' purchases of pharmaceutical products from wholesalers do not entail, or result in, the acquisition of ownership over those products by the SSI. In this case, the Panel has concluded that the SSI does not acquire ownership of pharmaceutical products included in the Annex 4/A list and therefore, the SSI's reimbursements of part or all of the cost of those products do not qualify as a "purchase" by the SSI. Rather, the private pharmacies acquire ownership of pharmaceutical products from wholesalers and retain ownership until it is transferred to the final consumers (i.e. outpatients). Accordingly, this suffices to establish that private pharmacies do not qualify as "governmental agencies" under Article III:8(a).

7.99. The parties have engaged in extensive arguments about the extent to which the SSI controls the actions of the retail pharmacies. Turkey essentially argues that the SSI controls all the elements concerning the acquisition and distribution of pharmaceutical products included in the Annex 4/A list, starting with deciding which pharmaceutical products are listed in the Annex 4/A list, the price of those products at each stage of the supply chain, including the "public price" charged to the SSI, and how they are dispensed to patients. The European Union disagrees, arguing that retail pharmacies freely order and purchase their pharmaceutical products from wholesalers (also private entities) through a private sales contract, hold and manage their inventory on their own (including holding property rights over it), and bear the risks associated with their stock, with no SSI involvement. The parties engage in these arguments in relation to the question whether it is correct to say that the pharmacies "act on behalf" of the SSI.

7.100. In the Panel's view, these disputed issues do not relate to the question whether the pharmacies' purchases from wholesalers entail or result in the SSI acquiring ownership over those products, and therefore are not directly relevant. Even if the Panel were to accept Turkey's assertion that the SSI controls all the elements concerning the acquisition of pharmaceutical products included in the Annex 4/A list, to such an extent that it could be said that the SSI instructs and directs pharmacies what to do, this would not make pharmacies "governmental agencies" for the purposes of Article III:8(a), or transform their purchases into purchases by the government, so long as the pharmacies acquire ownership over pharmaceutical products independently of the government.

7.101. To find otherwise would imply that if private parties are instructed or directed by a government to purchase certain products, the act of instruction or direction would make those private parties "governmental agencies" with the result that their purchases would then be covered by Article III:8(a). If that were correct, then it would follow that all domestic content requirements imposed by governments on private entities would fall within the scope of Article III:8(a) because the measure imposing the requirement – be it a general law, regulation or requirement, or an individual contractual arrangement – would have the effect of turning those entities into "governmental agencies" for purposes of Article III:8(a).

7.102. Indeed, if it were correct to reason that a private entity should be deemed to be a "governmental agency" whenever it is instructed or directed by the government to purchase certain products, then it would follow, by way of illustrative example, that private electricity generators subjected to certain domestic content requirements on generation equipment were themselves

"governmental agencies" acting on behalf of the government. This would, of course, stand in direct contradiction to what the panels and Appellate Body found in previous cases under Article III:8(a). In *India – Solar Cells*, the measures expressly stipulated the origin of the goods that were to be used by SPDs wishing to bid to sell electricity to the government⁴²⁸; the measures were then implemented by means of power purchase agreements (PPAs) and the "specific plan" that SPDs had to submit within 180 days after entering into the PPA, specifying how they would meet the domestic content requirements⁴²⁹; SPDs entering into a PPA thus became legally bound, by contract, to fulfil the obligation of using certain solar cells and modules manufactured in India⁴³⁰; and the tariff for the power purchased under the PPAs incorporated within it the cost for the solar cells and modules.⁴³¹ This did not make SPDs governmental agencies.

7.103. Based on the foregoing, and recalling the Panel's conclusion that the SSI never acquires ownership over the pharmaceutical products that it pays for, the Panel concludes that the private retail pharmacies that do acquire and retain ownership over those pharmaceutical products until they are dispensed to the final consumer (i.e. outpatients), do not qualify as "governmental agencies" in the context of the phrase "procurement by governmental agencies of products purchased for governmental purposes" in Article III:8(a).

7.2.4.5 Remaining elements under Article III:8(a)

7.104. The Panel has found that the localisation requirement does not involve the "purchase" of pharmaceutical products included in the Annex 4/A list by governmental agencies. Accordingly, the localisation requirement is not covered by the government procurement derogation of Article III:8(a). This is a threshold legal element that must be satisfied for a measure to be covered by the derogation in Article III:8(a), and the localisation requirement fails to meet this threshold. Accordingly, it is not necessary for the Panel to conduct any further assessment of the remaining legal elements of Article III:8(a) to determine the applicability of this derogation.

7.105. In *India – Solar Cells*, the panel considered it useful to proceed with a limited analysis and review of certain issues relating to the remaining elements of Article III:8(a), including the requirements that: (i) the measures in question are "laws, regulations or requirements governing ... procurement"; (ii) the procurement is "by governmental agencies"; (iii) the procurement is of products purchased "for governmental purposes"; and (iv) the products purchased are not procured "with a view to commercial resale or with a view to use in the production of goods for commercial sale".⁴³² That panel's reason for doing so was to ensure that the Appellate Body could have the benefit of its factual findings related to these issues in case the Appellate Body were to modify or reverse the Panel's interpretation and application of the nature of the "products purchased".⁴³³ The panel followed a similar approach in respect of certain other issues in that dispute, and made certain additional findings beyond those strictly necessary to resolve the claims under Article 2.1 of the TRIMs Agreement and Article III:4 of the GATT 1994⁴³⁴, and to resolve the defences under Articles XX(j) and (d) of the GATT 1994.⁴³⁵

7.106. In the circumstances of this dispute⁴³⁶, the Panel sees no compelling reason to make additional findings or observations beyond those necessary to resolve the claims and defences at issue. Accordingly, the Panel makes no findings on the disputed issues that arise in respect of the remaining elements under Article III:8(a).

⁴²⁸ Panel Report, *India – Solar Cells*, para. 7.63.

⁴²⁹ Panel Report, *India – Solar Cells*, para. 7.27.

⁴³⁰ Panel Report, *India – Solar Cells*, paras 7.85 and 7.88.

⁴³¹ Panel Report, *India – Solar Cells*, para. 7.129.

⁴³² Panel Report, *India – Solar Cells*, paras. 7.136-7.186.

⁴³³ Panel Report, *India – Solar Cells*, paras. 7.136-7.138.

⁴³⁴ Panel Report, *India – Solar Cells*, paras. 7.74-7.98.

⁴³⁵ Panel Report, *India – Solar Cells*, paras. 7.334-7.382.

⁴³⁶ The Panel notes that the work of the Appellate Body has been suspended for nearly two years and that Members remain unable to reach consensus on any selection process to fill the vacancies that are required for the Appellate Body to function.

7.2.5 Conclusion

7.107. The Panel concludes that the localisation requirement is not covered by the government procurement derogation in Article III:8(a) of the GATT 1994, and is therefore subject to the national treatment obligation in Article III:4 of the GATT 1994 and Article 2.1 of the TRIMs Agreement.

7.3 Article III:4 of the GATT 1994

7.3.1 Introduction

7.108. The Panel, having rejected Turkey's assertion that the localisation requirement is covered by the government procurement derogation in Article III:8(a) of the GATT 1994, now proceeds to address the European Union's claim that the localisation requirement is inconsistent with the national treatment obligation in Article III:4 of the GATT 1994.

7.109. The European Union claims that the localisation requirement is inconsistent with Article III:4 because, by excluding imported pharmaceutical products from the reimbursement scheme, Turkey accords imported pharmaceutical products treatment less favourable than that accorded to like products of national origin that are covered by the reimbursement scheme.⁴³⁷

7.110. Turkey limits its response to the European Union's claim under Article III:4 to arguing that this provision is inapplicable to the localisation requirement by virtue of the government procurement derogation in Article III:8(a) of the GATT 1994, and that any inconsistency with Article III:4 would be justified by Article XX(b) or XX(d) of the GATT 1994.⁴³⁸ Turkey explains that, given that the obligation set out in Article III:4 does not apply to that measure, by virtue of Article III:8(a), there is no need to examine the different elements of Article III:4, including whether the measure constitutes 'laws, regulations and requirements affecting internal sale, offering for sale, purchase, transportation, distribution or use' or whether that measure accords 'less favourable treatment' to imported like products.⁴³⁹

7.3.2 Relevant provisions

7.111. Article III:4 of the GATT 1994 provides:

The products of the territory of any Member imported into the territory of any other Member shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use.

7.112. Thus, the complaining party has the burden of establishing the following three elements⁴⁴⁰: (i) the imported and domestic products at issue are "like products"; (ii) the measure at issue is a "law, regulation, or requirement affecting their internal sale, offering for sale, purchase, transportation, distribution, or use"; and (iii) the imported products are accorded "less favourable" treatment than that accorded to like domestic products.

7.113. With respect to the first element, the Appellate Body clarified that a determination of "likeness" is "fundamentally, a determination about the nature and extent of a competitive relationship between and among products".⁴⁴¹ Likeness must be considered from both a qualitative and quantitative aspect and necessitates a case-by-case analysis considering the evidence as a

⁴³⁷ European Union's first written submission, paras. 149-176; second written submission, paras. 81-82; and opening statement, paras. 10-12.

⁴³⁸ Turkey's first written submission, paras. 6, 123, 174, 242, 243-244, and 414; second written submission, paras. 95 and 158; and responses to the first set of questions, paras. 44-46.

⁴³⁹ Turkey's responses to the first set of questions, para. 46.

⁴⁴⁰ Appellate Body Report, *Korea – Various Measures on Beef*, para. 133.

⁴⁴¹ Appellate Body Report, *EC – Asbestos*, para. 99.

whole.⁴⁴² When origin is the sole criterion for a regulatory distinction between products, the likeness of the products that are distinguished in this way can be presumed.⁴⁴³

7.114. With respect to the second element, a broad range of governmental actions is covered by "laws, regulations, or requirements" affecting the internal sale, offering for sale, purchase, transportation, distribution, or use of like products. Panels have found that where measures are "embodied, wholly or at least partly, in formal legal instruments such as codes, rules, acts and statutes", they may qualify as laws or regulations under Article III:4.⁴⁴⁴ Likewise, where a measure contains a "statutory" and "regulatory" element, it may be qualified as a law or regulation by virtue of its "legal form". A "requirement" within the meaning of Article III:4 is not limited to requirements reflected in "laws" or "regulations", and may encompass both obligations that an enterprise is legally obliged to carry out, as well as voluntary action in order to obtain an advantage from a government.⁴⁴⁵ To fall within the scope of Article III:4, a measure need only "affect", as opposed to directly govern (or be primarily aimed at regulating), the conditions of sale, purchase, transportation, distribution, or use of products.⁴⁴⁶

7.115. Lastly, a complaining party must establish that imported products are treated less favourably than like domestic products. Treatment no less favourable means "according conditions of competition" no less favourable to the imported product than the like domestic product.⁴⁴⁷ Notably, examination of less favourable treatment need not be based on the actual effects of the measure in the market place; the "potential effects" of the measure may suffice.⁴⁴⁸ In assessing the effects of a measure, the Appellate Body indicated that panels should carefully scrutinize the measure, including its design, structure and expected operation. This could, but need not, involve assessing the measure in light of evidence regarding its actual effects.⁴⁴⁹ A measure may accord imported products "less favourable treatment" in various ways, including through the imposition of additional processes and costs⁴⁵⁰, presentation of imported products to final consumers in a less appealing manner⁴⁵¹, or additional administrative burdens for imported products.⁴⁵² Even where a measure may not legally require certain treatment of imported products, it may be found to accord less favourable treatment insofar as it creates incentives for market participants to behave in certain ways, with the "practical effect" of treating imported products less favourably.⁴⁵³

7.3.3 Main arguments of the parties

7.116. Regarding the first element under Article III:4, the European Union submits that the domestic and imported products at issue are like.⁴⁵⁴ The European Union recalls that it is well established in prior panel and Appellate Body reports that measures distinguishing between goods solely on the basis of national origin satisfy the "like product" requirement.⁴⁵⁵ In this case, the only

⁴⁴² Appellate Body Report, *EC – Asbestos*, paras. 101 and 103. Relevant factors can include: the properties, nature and quality of the products, end uses of the products, consumers' tastes and habits, and tariff classification. (Appellate Body Report, *EC – Asbestos*, para. 101.)

⁴⁴³ See Appellate Body Report, *Argentina – Financial Services*, para. 6.38; and Panel Reports, *Argentina – Import Measures*, para. 6.274; *China – Publications and Audiovisual Products*, para. 7.1447; and *Canada – Wheat Exports and Grain Imports*, para. 6.164.

⁴⁴⁴ Panel Report, *US – Renewable Energy*, para. 7.152.

⁴⁴⁵ Panel Reports, *China – Auto Parts*, para. 7.240; *China – Publications and Audiovisual Products*, para. 7.1448.

⁴⁴⁶ Appellate Body Reports, *EC – Bananas III*, para. 220 (referring to Panel Report, *Italy – Agricultural Machinery*, para. 12); *US – FSC (Article 21.5 – EC)*, para. 210; *China – Auto Parts*, para. 194.

⁴⁴⁷ Appellate Body Report, *Korea – Various Measures on Beef*, para. 135.

⁴⁴⁸ Appellate Body Reports, *US – FSC (Article 21.5 – EC)*, para. 215; *Thailand – Cigarettes (Philippines)*, para. 135.

⁴⁴⁹ Panel Report, *Dominican Republic – Import and Sale of Cigarettes*, para. 7.196; Appellate Body Report, *Thailand – Cigarettes (Philippines)*, para. 134.

⁴⁵⁰ Panel Report, *Dominican Republic – Import and Sale of Cigarettes*, para. 7.196.

⁴⁵¹ Panel Report, *Dominican Republic – Import and Sale of Cigarettes*, para. 7.196.

⁴⁵² Appellate Body Report, *Thailand – Cigarettes (Philippines)*, para. 130.

⁴⁵³ See Appellate Body Reports, *Korea – Various Measures on Beef*, paras. 144-145; *China – Auto Parts*, paras. 195-196; and *US – COOL*, para. 288.

⁴⁵⁴ European Union's first written submission, paras. 151-154.

⁴⁵⁵ European Union's first written submission, paras. 151-153. Thus, where a Member draws an origin-based distinction, a comparison of specific products is not required and it is not necessary to examine the traditional likeness criteria – such as, their physical properties, end-uses and consumers' tastes and habits. It is sufficient for the purpose of satisfying the "like product" test for a complaining party to demonstrate that there can or will be domestic and imported products that are "like". (Ibid.)

"factor of distinction" on which the localisation requirement is premised is the country of production.⁴⁵⁶ The reimbursement of the products to which the localisation requirement applies is explicitly conditioned on their production in Turkey, and not on any other characteristics of the products.⁴⁵⁷

7.117. Regarding the second element under Article III:4, the European Union submits that the localisation requirement is a "law, regulation, or requirement affecting the internal sale, offering for sale, purchase, transportation, distribution, or use of products".⁴⁵⁸ In the European Union's view, as the localisation requirement is to a significant extent "embodied" through various "specific laws or decrees" or "formal legal instruments", it should, as a whole, be described as a "law or regulation".⁴⁵⁹ Alternatively, the European Union submits that it should be characterized as a "requirement"⁴⁶⁰ because "it is clear that the measure imposes a requirement (localisation) as a condition for obtaining an advantage (reimbursement)".⁴⁶¹ Furthermore, the European Union submits that "when the purpose of complying with certain requirements is to obtain an advantage, or when they create an incentive to buy certain products over others, it is clear that those requirements affect the sale, offering for sale or purchase of products".⁴⁶² According to the European Union, the localisation requirement is "designed to confer an advantage on locally produced pharmaceutical products by encouraging their sale, purchase and use, to the detriment of like imported products", and it "is clearly capable of influencing the choice between like imported and domestic products".⁴⁶³

7.118. Regarding the third element under Article III:4, the European Union submits that the localisation requirement accords "less favourable treatment" to imported products.⁴⁶⁴ According to the European Union, this is so because it "expressly reserves a major advantage – reimbursement, which covers approximately 90% of the entire Turkish pharmaceuticals market – to domestic like products to the exclusion of imported like products".⁴⁶⁵ The European Union argues that while imported products caught by the localisation requirement can still be imported and sold, "their exclusion from reimbursement creates a clear disincentive on their sales in Turkey" and "[c]onsumers are unlikely to choose a non-reimbursed product over a like reimbursed product."⁴⁶⁶

7.119. In its first written submission, Turkey does not present arguments on any of the above elements of Article III:4 of the GATT 1994. Rather, Turkey limits its response to the European Union's claim to arguing that Article III:4 is not applicable to the localisation requirement by virtue of the government procurement derogation in Article III:8(a) of the GATT 1994, and that any inconsistency with Article III:4 would be justified by Article XX(b) or Article XX(d) of the GATT 1994.⁴⁶⁷

7.120. In its second written submission, the European Union observes that apart from Turkey's arguments on Article III:8(a) of the GATT 1994, Turkey "does not dispute that the Localisation Requirement is inconsistent with Article III:4 of the GATT 1994" and "[t]hus, there is no disagreement on the main elements of that provision: the domestic and imported products at issue are like, the Localisation Requirement is a law, regulation or requirement affecting the internal sale, offering for sale, purchase, transportation, distribution, or use of products, and it accords less favourable treatment to imported like products."⁴⁶⁸

7.3.4 Assessment by the Panel

7.121. The Panel considers that the fact that Turkey does not present any arguments on the elements of the claims under Article III:4 of the GATT 1994 is not in and of itself a sufficient basis for the Panel to summarily conclude that the European Union's claims are well founded. In line with the approach taken by other panels in similar circumstances, the Panel will consider whether the

⁴⁵⁶ European Union's first written submission, para. 154.

⁴⁵⁷ European Union's first written submission, para. 154.

⁴⁵⁸ European Union's first written submission, paras. 155-168.

⁴⁵⁹ European Union's first written submission, paras. 156-159.

⁴⁶⁰ European Union's first written submission, paras. 160-163.

⁴⁶¹ European Union's first written submission, para. 163.

⁴⁶² European Union's first written submission, para. 166.

⁴⁶³ European Union's first written submission, para. 168.

⁴⁶⁴ European Union's first written submission, paras. 169-176.

⁴⁶⁵ European Union's first written submission, para. 173.

⁴⁶⁶ European Union's first written submission, para. 173.

⁴⁶⁷ Turkey's first written submission, paras. 6, 123, 174, 242, 243-244, and 414.

⁴⁶⁸ European Union's second written submission, para. 81.

complainant has presented evidence and argument "sufficient to identify the challenged measure and its basic import, identify the relevant WTO provision and obligation contained therein, and explain the basis for the claimed inconsistency of the measure with that provision".⁴⁶⁹

7.122. In section 7.1 of this Report, the Panel concluded that the European Union has established the existence of the localisation requirement as a single measure, whereby (i) Turkey requires foreign producers to commit to localise in Turkey their production of certain pharmaceutical products; and (ii) where commitments are not given, not accepted, or not fulfilled, affected products are no longer reimbursed by the SSI. Thus, the Panel has found that the European Union has identified the challenged measure with sufficient clarity and precision for purposes of enabling the Panel to make an assessment of whether the elements of Article III:4 of the GATT 1994 are satisfied.

7.123. As regards the first element under Article III:4, the Panel considers that the European Union has made a *prima facie* case that domestic pharmaceutical products and imported pharmaceutical products affected by the localisation requirement are "like products".⁴⁷⁰ The Panel recalls that through the localisation requirement: (i) Turkey requires foreign producers to commit to localise in Turkey their production of certain pharmaceutical products; and (ii) where commitments are not given, not accepted, or not fulfilled, affected products are no longer reimbursed by the SSI. Thus, the only "factor of distinction" on which the localisation requirement is premised is the country of production for the pharmaceutical products affected by the measure. As has been indicated above, when the country of origin is the sole criterion for a regulatory distinction between products, the likeness of the products that are distinguished in this way can be presumed.⁴⁷¹

7.124. As for the second element under Article III:4, the Panel considers that the localisation requirement constitutes a "requirement" affecting the internal sale, offering for sale, purchase, transportation, distribution, or use of pharmaceutical products. The Panel recalls that a "requirement" within the meaning of Article III:4 is not limited to requirements reflected in "laws" or "regulations", and may encompass both obligations that an enterprise is legally obliged to carry out, as well as voluntary action in order to obtain an advantage from government.⁴⁷² Given the content of the localisation requirement, referred to above, it follows that the measure imposes a requirement (localisation) as a condition for obtaining an advantage (reimbursement/payment). The Panel notes that Turkey seems to agree that the localisation requirement is a "requirement" for purposes of Article III:4 and III:8(a).⁴⁷³ Recalling that a measure need only "affect" the conditions of sale, purchase, transportation, distribution, or use of products to fall within the scope of Article III:4⁴⁷⁴, the Panel considers that this aspect of the second element under Article III:4 is also satisfied. As the European Union observes, "when the purpose of complying with certain requirements is to obtain an advantage, or when they create an incentive to buy certain products over others, it is clear that those requirements affect the sale, offering for sale or purchase of products."⁴⁷⁵

7.125. Regarding the third element under Article III:4, the Panel recalls that treatment no less favourable means "according conditions of competition" to the imported product that are no less favourable than those accorded to the like domestic product.⁴⁷⁶ The Panel considers it to be axiomatic

⁴⁶⁹ Panel Report, *US – Shrimp (Ecuador)*, para. 7.11.

⁴⁷⁰ European Union's first written submission, paras. 151-154.

⁴⁷¹ See Appellate Body Report, *Argentina – Financial Services*, para. 6.38; and Panel Reports, *Argentina – Import Measures*, para. 6.274; *China – Publications and Audiovisual Products*, para. 7.1447; and *Canada – Wheat Exports and Grain Imports*, para. 6.164.

⁴⁷² Panel Reports, *China – Auto Parts*, para. 7.240; *China – Publications and Audiovisual Products*, para. 7.1448.

⁴⁷³ Turkey's first written submission, para. 187 and fn 199 (cross-referencing paragraph 160 of the European Union's first written submission in a manner that implies that Turkey considers the term "requirement" to have the same meaning in the context of Article III:4 and III:8(a) of the GATT 1994). The Panel notes that in the context of responding to the European Union's claim under Article X:1 of the GATT 1994 pertaining to the non-publication of certain terms and conditions of the measure, Turkey argues that the European Union has failed to demonstrate that the localisation requirement as a single measure constitutes a "law" or "regulation". (Turkey's first written submission, paras. 272-279.) The Panel considers it unnecessary to make a finding on whether the localisation requirement additionally constitutes a "law" or "regulation" within the meaning of Article III:4, given that it clearly constitutes a "requirement".

⁴⁷⁴ Appellate Body Reports, *EC – Bananas III*, para. 220; *US – FSC (Article 21.5 – EC)*, para. 210 (referring to Panel Report, *Italy – Agricultural Machinery*, para. 12); *China – Auto Parts*, para. 194.

⁴⁷⁵ European Union's first written submission, para. 166.

⁴⁷⁶ Appellate Body Report, *Korea – Various Measures on Beef*, para. 135.

that, if a measure is designed to create a financial incentive for consumers (i.e. outpatients in this case) to select domestically produced pharmaceutical products over imported pharmaceutical products, it accords "less favourable treatment" to those imported pharmaceutical products. While Turkey has stressed that outpatients cannot change the active substance, dosage or the duration of their treatment, it does not dispute that outpatients are free to select among equivalent medicines based on price.⁴⁷⁷ Accordingly, the Panel is of the view that the localisation requirement is "designed to confer an advantage on locally produced pharmaceutical products by encouraging their sale, purchase and use, to the detriment of like imported products", and it "is clearly capable of influencing the choice between like imported and domestic products".⁴⁷⁸

7.126. For the foregoing reasons, the Panel finds that domestic pharmaceutical products and imported pharmaceutical products affected by the localisation requirement are "like products"; the localisation requirement constitutes a "requirement" affecting the internal sale, offering for sale, purchase, transportation, distribution, or use of those pharmaceutical products; and by creating a price incentive for consumers (i.e. outpatients) to select domestically produced pharmaceutical products over imported pharmaceutical products, the localisation requirement accords "less favourable treatment" to those imported pharmaceutical products.

7.3.5 Conclusion

7.127. The Panel concludes that the localisation requirement is inconsistent with the national treatment obligation in Article III:4 of the GATT 1994.

7.4 Article XX of the GATT 1994

7.4.1 Introduction

7.128. The Panel has found that the localisation requirement is not covered by the government procurement derogation in Article III:8(a) of the GATT 1994, and that it is inconsistent with the national treatment obligation in Article III:4 of the GATT 1994. Accordingly, the Panel now proceeds to address Turkey's invocation of the general exceptions in Articles XX(b) and (d) of the GATT 1994.

7.129. Turkey submits that the localisation measure is covered by the general exception in Article XX(b) because it is designed to ensure an uninterrupted access to safe, effective and affordable medicines for all patients in Turkey, is "necessary" to achieve that objective, and satisfies the requirements of the chapeau of Article XX.⁴⁷⁹ Turkey submits that if the Panel finds that the localisation requirement is not justified under Article XX(b), then, in the alternative, it is justified under Article XX(d) of the GATT 1994 as a measure necessary to secure compliance with laws and regulations requiring Turkey to ensure "accessible, effective and financially sustainable healthcare".⁴⁸⁰

7.130. The European Union agrees that the declared objective of ensuring adequate access to medicines falls within the scope of Article XX(b) and is extremely vital and important, but submits that the localisation requirement is not designed to achieve the public health objective alleged by Turkey, and is not "necessary" to achieve that objective.⁴⁸¹ The European Union presents similar arguments under Article XX(d).

⁴⁷⁷ More specifically, Turkey confirms that if a prescribed product is not on the Annex 4/A list (i.e. for which the patient will have to pay), the pharmacist will typically inform the outpatient that there is an equivalent product that is on the list (i.e. for which the patient will not have to pay), and that the outpatient may decide to opt for the equivalent medicine, the cost of which will be paid by the SSI. (Turkey's responses to the first set of questions, paras. 1-4.)

⁴⁷⁸ European Union's first written submission, para. 168.

⁴⁷⁹ Turkey's first written submission, paras. 414-503; second written submission, paras. 158-224; responses to the first set of questions, paras. 47-68; opening statement, paras. 72-86; closing statement, paras. 36-47; responses to the second set of questions, paras. 56-72; and comments on responses to the second set of questions, paras. 20-32.

⁴⁸⁰ Turkey's first written submission, para. 504.

⁴⁸¹ European Union's second written submission, paras. 140-199; responses to the first set of questions, paras. 34-63; opening statement, paras. 33-73; closing statement, paras. 16-21; responses to the second set of questions, paras. 24-61; and comments on responses to the second set of questions, paras. 46-66.

7.4.2 Article XX(b)

7.4.2.1 Relevant provisions

7.131. Article XX(b) of the GATT 1994 provides:

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any Member of measures:

...

(b) necessary to protect human, animal or plant life or health;

7.132. Article XX of the GATT 1994 allows Members to justify measures that would otherwise be inconsistent with the GATT 1994. Article XX sets out a "two-tier test": (i) the measure must fall under one of the listed exceptions in Article XX such as Article XX(b) (it is then "provisionally justified"); and (ii) the measure must be applied in a manner that satisfies the requirements of the chapeau of Article XX.⁴⁸²

7.133. Measures may be provisionally justified under Article XX(b) if they (i) are taken to (i.e. are designed to) protect human, animal or plant life or health; and (ii) are "necessary" to protect human, animal or plant life or health.⁴⁸³

7.134. When assessing whether a measure is taken to protect human, animal or plant life or health, prior panels have often commenced their analysis by determining the existence of the risk to human, animal or plant life or health (health risk) that the challenged measure aims to reduce.⁴⁸⁴ Where there is no sufficient evidence as to the existence of a health risk, a challenged measure is not necessary to *protect* human, animal or plant life or health.⁴⁸⁵

7.135. Next, if the alleged health risk exists, panels will examine whether the measure at issue was taken for the purpose of protecting human, animal or plant life or health by reducing that risk⁴⁸⁶, or was instead taken for other reasons. To determine whether a challenged measure is "designed to" protect human, animal or plant life or health, a panel must examine all the evidence before it, including the text of the relevant legal instruments, the legislative history, and other evidence regarding the design, structure and expected operation of the challenged measure.⁴⁸⁷ Such an

⁴⁸² Appellate Body Reports, *US – Gasoline*, p. 22; *Brazil – Retreaded Tyres*, para. 139.

⁴⁸³ See Panel Reports, *Indonesia – Chicken*, para. 7.208; *Brazil – Taxation*, para. 7.858.

⁴⁸⁴ Panel Reports, *EC – Asbestos*, para. 8.170; *Brazil – Retreaded Tyres*, para. 7.42; *China – Rare Earths*, para. 7.156; *Brazil – Taxation*, para. 7.859; and *Indonesia – Chicken*, para. 7.209. For instance, in *EC – Asbestos*, the panel determined, as the first step in its analysis, whether chrysotile-asbestos posed a risk to human life or health. (Panel Report, *EC – Asbestos*, paras. 8.170, 8.182, and 8.185-8.194.) In *Brazil – Retreaded Tyres*, the panel assessed whether the accumulation of waste tyres posed risks to human, animal or plant life or health. (Panel Report, *Brazil – Retreaded Tyres*, paras. 7.42, and 7.53-7.93.) In *China – Rare Earths*, the panel found that the mining and production of rare earths, tungsten, and molybdenum have caused grave harm to the environment and to the life and health of humans, animals, and plants in China. (Panel Reports, *China – Rare Earths*, paras. 7.149-7.156.) In some other cases, including those where there was no dispute as to the existence of the risks that the measure allegedly aimed to address, prior panels have addressed this step of the analysis succinctly. (See Panel Reports, *US – Gasoline*, para. 6.21; *EC – Tariff Preferences*, paras. 7.180 and 7.200.)

⁴⁸⁵ As the panel in *EC – Asbestos* observed, "inasmuch as they include the notion of 'protection', the words 'policies designed to protect human life or health' imply the existence of a health risk." (Panel Report, *EC – Asbestos*, para. 8.170.) See also Appellate Body Reports, *EC – Seal Products*, para. 5.197.

⁴⁸⁶ See Panel Reports, *Indonesia – Chicken*, para. 7.216; *Brazil – Taxation*, para. 7.859.

⁴⁸⁷ See e.g., Panel Reports, *Indonesia – Import Licensing Regimes*, para. 7.620; *Brazil – Taxation*, para. 7.884; *China – Raw Materials*, para. 7.479; *China – Rare Earths*, para. 7.145; and *EC – Tariff Preferences*, para. 7.200 (referring to Appellate Body Reports, *Japan – Alcoholic Beverages II*, p. 29; *Argentina – Textiles and Apparel*, para. 55; and *US – Shrimp*, para. 137). See also Appellate Body Reports, *Colombia – Textiles*, para. 5.69 (referring to Appellate Body Reports, *US – Shrimp*, paras. 135-142; *EC – Seal Products*, para. 5.144) and *EC – Seal Products*, para. 5.144 (referring to Appellate Body Reports, *US – Tuna II (Mexico)*, para. 314 and *US – Gambling*, para. 304).

enquiry has led some panels to conclude that the challenged measures were not designed to protect human, animal or plant life or health, and instead pursued other objectives.⁴⁸⁸ If this threshold enquiry reveals that the challenged measure is incapable of meeting the stated objective, the analysis need not go further to determine whether this measure is necessary to protect this objective.

7.136. If a measure is "designed to" protect human, animal or plant life or health, panels must then examine whether that measure is "necessary" to protect human, animal or plant life or health. In doing so, panels will weigh and balance several factors, including the importance of the objective, the contribution of the measure to the achievement of that objective, and the trade-restrictiveness of the measure. Panels may then compare the challenged measure with possible alternative measures.⁴⁸⁹ In assessing the *first* of these factors, panels and the Appellate Body have focused on the relative importance of the interests or values furthered by the challenged measure.⁴⁹⁰ As to the *second* factor, a measure contributes to the objective when there is a "genuine relationship of ends and means between the objective pursued and the measure at issue".⁴⁹¹ In assessing the contribution of the measure to the achievement of the objective, panels may have regard to quantitative and qualitative evidence. Whether a contribution is established ultimately depends on the nature of the risk, the objective pursued, and the level of protection sought, as well as the nature, quantity and quality of evidence at the time such assessment is made.⁴⁹² The *third* factor relates to the trade-restrictiveness of the challenged measure, which can be assessed in a qualitative or quantitative manner.⁴⁹³ Finally, alternative measures must be more than "merely theoretical in nature"⁴⁹⁴, and should allow the responding Member to achieve the same level of protection while being less trade-restrictive.⁴⁹⁵ The burden lies on complaining Members to identify possible alternative measures.⁴⁹⁶

7.137. The process of weighing and balancing these factors is "a holistic operation that involves putting all the variables of the equation together and evaluating them in relation to each other after having examined them individually, in order to reach an overall judgement".⁴⁹⁷ The more vital or important the societal value pursued by a challenged measure⁴⁹⁸, the greater the contribution of this measure to the objective pursued⁴⁹⁹, and the less restrictive its effects⁵⁰⁰, the more readily the measure may be considered to be "necessary".

7.138. If a measure is provisionally justified under Article XX(b), it must also satisfy the requirements of the chapeau in Article XX. The chapeau requires that a provisionally justified measure be applied in a manner that does not constitute "arbitrary or unjustifiable discrimination between countries where the same conditions prevail" or a "disguised restriction on international trade".

⁴⁸⁸ See e.g., Panel Report, *EC – Tariff Preferences*, paras. 7.207 and 210; *China – Rare Earths*, paras. 7.169- 7.171.

⁴⁸⁹ Appellate Body Reports, *Colombia – Textiles*, para. 5.70; *India – Solar Cells*, para. 5.59; and *EC – Seal Products*, para. 5.214 (referring to Appellate Body Reports, *US – Gambling*, para. 307 and *Korea – Various Measures on Beef*, para. 166).

⁴⁹⁰ Appellate Body Report, *US – Gambling*, para. 306 (citing Appellate Body Report, *Korea – Various Measures on Beef*, para. 162) and Panel Reports, *Indonesia – Chicken*, para. 7.138; *Brazil – Taxation*, para. 7.525.

⁴⁹¹ Appellate Body Report, *Brazil – Retreaded Tyres*, para. 145.

⁴⁹² Appellate Body Report, *Brazil – Retreaded Tyres*, paras. 145-146.

⁴⁹³ Appellate Body Report, *Korea – Various Measures on Beef*, para. 163. See also Panel Reports, *Indonesia – Chicken*, para. 7.143.

⁴⁹⁴ The responding Member must be capable of taking the alternative measure, and it should not impose an undue burden on the responding Member. (Appellate Body Report, *Brazil – Retreaded Tyres*, paras. 156, and 172-175.)

⁴⁹⁵ Appellate Body Reports, *US – Gambling*, paras. 307-308; *Brazil – Retreaded Tyres*, para. 156. See also Panel Report, *EU – Energy Package*, para. 7.1209.

⁴⁹⁶ Appellate Body Report, *Brazil – Retreaded Tyres*, para. 156.

⁴⁹⁷ Appellate Body Report, *Brazil – Retreaded Tyres*, para. 182.

⁴⁹⁸ Appellate Body Reports, *EC – Asbestos*, para. 172 and *Korea – Various Measures on Beef*, para. 162; Panel Reports, *Brazil – Taxation*, para. 7.525.

⁴⁹⁹ Appellate Body Report, *Korea – Various Measures on Beef*, para. 162; Panel Reports, *Brazil – Taxation*, para. 7.528.

⁵⁰⁰ Appellate Body Report, *China – Publications and Audiovisual Products*, para. 310 (referring to Appellate Body Reports, *Korea – Various Measures on Beef*, para. 163; *Brazil – Retreaded Tyres*, para. 150).

7.4.2.2 Main arguments of the parties

7.4.2.2.1 The risk of a shortage of safe, effective and affordable medicines in Turkey

7.139. Turkey submits that the need for local production of pharmaceutical products has become evident in the context of the COVID-19 pandemic, and in that context the need for local production of pharmaceutical products has been officially endorsed by several countries, including some of the EU member States.⁵⁰¹ Turkey submits that even without a pandemic, there are situations when over-reliance on imported products can lead to dangerous shortage of supply, and provides examples from the Turkish context.⁵⁰²

7.140. The European Union argues that Turkey has not met its burden of proving that there is a risk of shortage of supply of the pharmaceutical products within the scope of the localisation requirement.⁵⁰³ In line with the guidance provided by the Appellate Body in the context of Article XX(j), the general exception governing products in "short supply", the European Union submits that Turkey has the burden of demonstrating, for each category of "equivalent products", that there is a risk that "the quantity of available supply from both domestic and international sources in the relevant geographical market may be insufficient to meet demand", having regard to all relevant factors affecting supply and demand.⁵⁰⁴ According to the European Union, Turkey has provided no relevant evidence of the existence of a risk of shortage of supply; to the contrary, it stresses that there is no risk of shortage of supply as regards the products covered by Phase 1 and Phase 2.⁵⁰⁵ The European Union submits that in practice, disruptions of supply of pharmaceutical products appear to be occasional and of short duration, and notes that Turkey has identified just five instances of alleged disruption of supply since 2012. The European Union comments that Turkey's allegations are based on anecdotal evidence in the form of press articles of limited probative value and official correspondence between Turkish authorities that provides scant information on the causes and extent of the disruption.⁵⁰⁶

7.141. In its second written submission, Turkey responds that it is undisputed that "the lack of access to medicines poses a very serious threat to human life or health".⁵⁰⁷ Turkey clarifies that it is not arguing that the pharmaceutical products covered by the localisation measure are "in short supply".⁵⁰⁸ Rather, Turkey has explained that the objective of the localisation measure is to ensure, in the long term, that all patients in Turkey have uninterrupted access to safe, effective and affordable medicines.⁵⁰⁹ Turkey maintains that WTO Members "are allowed to take preventive measures before any actual shortage of supply arises".⁵¹⁰ Based on these considerations, Turkey submits that it is not required to demonstrate the existence of a risk of shortage of supply and even less so the existence of such a risk separately for each category of pharmaceutical products subject to the localisation requirement.⁵¹¹ Turkey submits that, contrary to the arguments of the European Union, the press articles provided by Turkey provide ample evidence of disruptions in the supply of pharmaceutical products linked to the over-reliance on imports.⁵¹² Turkey adds that the risk of shortage of supply due to unilateral decisions of pharmaceutical companies can be also illustrated by recent decisions of Pfizer and AstraZeneca to cut the supply of the COVID-19 vaccines to certain EU member States.⁵¹³ In any event, Turkey reiterates that the localisation requirement "is not meant to remedy an *ad hoc* short-term shortage of supply but aims to ensure that in the long-term, all patients in Turkey are guaranteed stable access to safe, effective and affordable medicines".⁵¹⁴

⁵⁰¹ Turkey's first written submission, paras. 486-487.

⁵⁰² Turkey's first written submission, para. 488.

⁵⁰³ European Union's second written submission, paras. 159-173. The European Union observes that "the notion of 'protection' in Article XX(b) of the GATT 1994 implies the existence of a health risk" (European Union's second written submission, para. 159 (citing Panel Report, *EC – Asbestos*, para. 8.170). See also Appellate Body Reports, *EC – Seal Products*, para. 5.197.)

⁵⁰⁴ European Union's second written submission, paras. 162-165.

⁵⁰⁵ European Union's second written submission, para. 166.

⁵⁰⁶ European Union's second written submission, paras. 167-173.

⁵⁰⁷ Turkey's second written submission, para. 179.

⁵⁰⁸ Turkey's second written submission, para. 181.

⁵⁰⁹ Turkey's second written submission, para. 181.

⁵¹⁰ Turkey's second written submission, para. 181.

⁵¹¹ Turkey's second written submission, paras. 177-182.

⁵¹² Turkey's second written submission, paras. 183-188.

⁵¹³ Turkey's second written submission, fn 236.

⁵¹⁴ Turkey's second written submission, para. 189.

7.4.2.2.2 The localisation requirement's objective

7.142. Turkey submits that the localisation measure is designed to ensure "an uninterrupted access to safe, effective and affordable medicines for all patients in Turkey" which falls within the range of policies to protect human life and health covered by Article XX(b).⁵¹⁵ Turkey explains that by requiring that certain pharmaceutical products be produced domestically to be included in the Annex 4/A list, the localisation requirement seeks to ensure that those products are available to patients in Turkey.⁵¹⁶ Turkey submits that it is now widely agreed that the proximity of manufacturing to the point of use is of major relevance for ensuring an uninterrupted access to safe and effective medicines, for several reasons.⁵¹⁷ According to Turkey, the fact that the localisation requirement is concerned with ensuring adequate access to medicines and thus pursues an objective of protecting human life and health, is confirmed by the design and structure of that measure, by the authorities responsible for its implementation, and by several official documents.⁵¹⁸

7.143. The European Union does not dispute that the alleged objective to ensure adequate access to medicines falls within the scope of Article XX(b)⁵¹⁹, but submits that the localisation requirement is not designed to achieve the public health objective alleged by Turkey.⁵²⁰ Rather, the localisation requirement has been designed to promote the economic development and industrial policy objectives pursued by Turkey in the pharmaceutical sector.⁵²¹ Such objectives are confirmed by several official documents that evidence a preoccupation with the large size of Turkey's trade deficit in the pharmaceutical sector, together with a desire to promote the domestic production of higher value-added pharmaceutical products with a view to becoming competitive in global markets, thereby contributing to the development of Turkey's economy.⁵²² In the European's Union's view, these stated objectives are fully consistent with the "structure and design" of the localisation requirement, which cannot be reconciled with the stated public policy alleged by Turkey in this dispute. Specifically, and reiterating essentially the same arguments it presents on the "contribution" step in the "necessity" analysis, the European Union submits that "the Localisation Requirement does not, and indeed cannot, contribute to the alleged objective of ensuring access to medicines with regard to any pharmaceutical product within the scope of the Localisation Requirement".⁵²³ According to the European Union, Turkey cannot explain away the manifest inconsistencies between its alleged public health objective and the structure and design of the measure "simply by citing vague and rhetorical political statements included in documents of the Turkish government where an unsubstantiated link is asserted between access to medicines and the Localisation Requirement".⁵²⁴

7.144. In its second written submission, Turkey responds by pointing out that WTO dispute settlement practice recognizes that a measure may pursue multiple objectives, and such multiple objectives will often be intertwined and may be advanced in a mutually supportive manner.⁵²⁵ In the present case, the public health objective and the alleged industrial policy objective of the localisation requirement are both legitimate policy objectives, and they are interrelated, because a strong domestic pharmaceutical sector contributes to ensuring uninterrupted access to medicines.⁵²⁶ Turkey submits that numerous documents issued by the Turkish health authorities, referred to in its first written submission, demonstrate that the localisation requirement clearly pursues a public health objective. Turkey moreover considers that even the documents referred to by the European Union confirm that the localisation requirement has a public health objective.⁵²⁷ In response to the

⁵¹⁵ Turkey's first written submission, paras. 441-463.

⁵¹⁶ Turkey's first written submission, para. 443.

⁵¹⁷ Turkey's first written submission, para. 445. According to Turkey, this is so for three reasons. Local production of medicines: (i) shortens the supply chain thereby reducing the lead time and minimizing the risk of shortages; (ii) enables closer regulatory oversight by national regulatory authorities, as excessive reliance on imports from distant geographies can have a negative impact on the quality assurance of pharmaceutical products; and (iii) provides opportunities to ensure that pharmaceutical products meet local needs and are fit for local purposes. (Ibid.)

⁵¹⁸ Turkey's first written submission, paras. 451-463.

⁵¹⁹ European Union's second written submission, para. 142.

⁵²⁰ European Union's second written submission, paras. 144-157.

⁵²¹ European Union's second written submission, para. 144.

⁵²² European Union's second written submission, paras. 145-148.

⁵²³ European Union's second written submission, para. 156.

⁵²⁴ European Union's second written submission, para. 157.

⁵²⁵ Turkey's second written submission, para. 164.

⁵²⁶ Turkey's second written submission, paras. 166-169.

⁵²⁷ Turkey's second written submission, para. 170.

European Union's arguments regarding the structure and design of the localisation requirement, Turkey clarifies that this measure serves the "long-term objective" of guaranteeing more stable access to safe, effective and affordable medicines in Turkey and is "not a tool to remedy any potential short-term shortage of supply".⁵²⁸

7.4.2.2.3 Contribution to the declared objective

7.145. Turkey submits that the importance of local production for ensuring access to medicines and improving health security in developing countries has been widely recognized and endorsed by the World Health Organization (WHO) and other international organizations such as United Nations Conference on Trade and Development (UNCTAD), United Nations Industrial Development Organization (UNIDO), and the Office of the United Nations High Commissioner for Human Rights.⁵²⁹ Furthermore, while it is not necessary under Article XX(b) to demonstrate that the localisation requirement has already yielded concrete results, and given that only two of the five phases of the localisation requirement have been implemented such that any conclusion as to the effectiveness of that measure would appear premature, the localisation requirement so far has already helped to resolve problems concerning the availability of certain pharmaceutical products on the Turkish market.⁵³⁰

7.146. The European Union responds that Turkey's selective (often out-of-context) quotations from documents of various international organizations, that suggest that a policy of local production of pharmaceutical products contributes to improving access to medicines, do not meet Turkey's burden of proving that the localisation requirement contributes to the alleged public health objective.⁵³¹ The European Union accepts that in "specific contexts, and subject to certain conditions, local production may be a useful tool, alongside other policy tools, for improving access to medicines"⁵³², but that Turkey must demonstrate "how, in the specific context of the Turkish market for each of the categories of 'equivalent products' covered by the Localisation Requirement, local production would contribute to improve access to those products by the Turkish citizens, as compared to the situation preceding the introduction of that measure".⁵³³ According to the European Union, Turkey tellingly provides no evidence for its assertion that "the implementation of the localisation measure so far has helped to resolve problems related to the availability of certain pharmaceutical products on the Turkish market."⁵³⁴ The European Union argues that there should be quantifiable effects of the localisation requirement by now, given that the implementation of Phases 1 and 2 started in 2016 and 2017, respectively.⁵³⁵

7.147. In its second written submission, Turkey submits that the European Union fails to substantiate its allegation that Turkey's quotations from the cited documents are "selective" and "taken out of context", and that the European Union conveniently ignores the statements made by its own authorities and member States endorsing the need for local production of medicines.⁵³⁶ Turkey argues that although local production of medicines may have different effects in different countries, it is recognized by the WHO and other international organisations as an effective tool for improving access to medicines.⁵³⁷ Turkey submits that the European Union does not explain why local production should not be successful in the context of Turkey, and points out that: (i) other developing countries including Bangladesh, Ethiopia, and Nigeria, have realized the value of local production of medicines for improving access to health and have pursued or are currently pursuing similar policies⁵³⁸; (ii) the factors that may jeopardize the successful implementation of a localisation policy are not present in Turkey (prices of medicines are closely regulated by the relevant authorities, who ensure the enforcement of high-quality standards, and Turkey does not lack affordable,

⁵²⁸ Turkey's second written submission, paras. 171-174.

⁵²⁹ Turkey's first written submission, paras. 471-485.

⁵³⁰ Turkey's first written submission, paras. 489-491.

⁵³¹ European Union's second written submission, paras. 174-180.

⁵³² European Union's second written submission, para. 176.

⁵³³ European Union's second written submission, para. 178.

⁵³⁴ European Union's second written submission, para. 180.

⁵³⁵ European Union's second written submission, para. 180.

⁵³⁶ Turkey's second written submission, para. 191 (referring to Turkey's first written submission, paras. 484-487).

⁵³⁷ Turkey's second written submission, para. 193.

⁵³⁸ Turkey's second written submission, para. 193.

quality-assured materials or a skilled workforce)⁵³⁹; and (iii) several empirical case studies, by UNCTAD and others, found that locally produced medicines improved access to medicines for poor rural populations, and Turkey has a large rural population.⁵⁴⁰ Turkey further argues that several EU documents recognise the fact that local production is an effective tool for ensuring uninterrupted access to medicines and avoiding shortages.⁵⁴¹ In response to the European Union's argument that there should be quantifiable effects by now, Turkey submits that since the implementation of the measure is still ongoing, it is too early to accurately evaluate the effects of the measure.⁵⁴² The fact that an adequate assessment of the effectiveness of local production can only be made after a certain period of time is also confirmed by the WHO and other relevant organizations.⁵⁴³

7.4.2.2.4 Trade-restrictiveness

7.148. As regards trade-restrictiveness, Turkey argues that the localisation requirement "is not trade-restrictive since it does not relate to the conditions under which pharmaceutical products may be imported and placed on the Turkish market".⁵⁴⁴ Turkey adds that "the market data show that pharmaceutical products which did not comply with the localisation measure continue to be sold on the Turkish market. The data confirms that in 2018-2019, 139 imported medicines from 39 different pharmaceutical companies were placed on the Turkish market."⁵⁴⁵

7.149. The European Union responds that the localisation requirement is "extremely trade-restrictive because, in practice, it has the effect of excluding imports from a very large part of the Turkish market".⁵⁴⁶ The European Union explains that while imported products caught by the localisation requirement can still be legally imported and sold, imported products excluded from reimbursement are unable to compete with the reimbursable like domestic products (i.e. because consumers are "most unlikely to choose a non-reimbursed product over a like reimbursed product").⁵⁴⁷ The European Union states that the reimbursement scheme covers approximately 90% of all sales of pharmaceutical products in Turkey, hence imported products excluded from reimbursement are in practice effectively excluded from a very large part of the market.⁵⁴⁸

7.150. In its second written submission, Turkey reiterates that the localisation requirement does not affect the access of pharmaceutical products to the Turkish market because products that do not comply with the localisation requirement may continue to be imported and placed on the Turkish market without any restrictions.⁵⁴⁹ According to Turkey, the European Union's argument that the localisation requirement is trade-restrictive because "*consumers* are [...] most unlikely to choose [a] non-reimbursed product over a like reimbursed product" once again "ignores the fact that *patients* do not freely choose the pharmaceutical products which are prescribed to them by medical doctors on the basis of their specific health needs".⁵⁵⁰ Furthermore, any trade-restrictiveness entailed by the localisation requirement, "even though unintended", is outweighed by a material contribution which that measure makes to the achievement of the invoked public health objective, as explained above.⁵⁵¹ Turkey recalls that a measure that makes a material contribution to a public health

⁵³⁹ Turkey explains that it has a well-established regulatory framework for producing pharmaceutical products that is generally in line with European Union legislation. Turkey also has a highly qualified workforce and production facilities that meet all quality standards so as to ensure that no substandard or falsified medical product is placed on the market. As a result, Turkey has so far not experienced any of the negative effects that the European Union alludes to. The cost of medicines has not increased, nor has the quality of medicines decreased. (Turkey's second written submission, paras. 194-195.)

⁵⁴⁰ Turkey's second written submission, paras. 196-199.

⁵⁴¹ Turkey's second written submission, para. 200. Specifically, Turkey refers to the recent Pharmaceutical Strategy for Europe, which refers to "fostering production and investment in Europe" among the actions that will be taken by the European Union.

⁵⁴² Turkey's second written submission, para. 201.

⁵⁴³ Turkey's second written submission, para. 202.

⁵⁴⁴ Turkey's first written submission, para. 493.

⁵⁴⁵ Turkey's first written submission, para. 494.

⁵⁴⁶ European Union's second written submission, para. 181.

⁵⁴⁷ European Union's second written submission, paras. 182-183.

⁵⁴⁸ European Union's second written submission, para. 184.

⁵⁴⁹ Turkey's second written submission, para. 203.

⁵⁵⁰ Turkey's second written submission, para. 205.

⁵⁵¹ Turkey's second written submission, para. 206.

objective may be justified under Article XX(b), even when that measure is considered "trade-restrictive to the highest degree".⁵⁵²

7.4.2.2.5 Less trade-restrictive alternative measures

7.151. Turkey notes that it is for the European Union to identify "reasonably available alternative measures" to the localisation requirement, which are less trade restrictive but equally effective in achieving uninterrupted access to safe, effective and affordable medicines for all patients in Turkey.⁵⁵³

7.152. The European Union submits that given their multifaceted causes, there is no single response to medicine shortages. While recognizing that in "specific contexts, and subject to certain conditions, local production may be a useful tool for improving access to medicines", the European Union identifies several alternative measures for ensuring access to medicines that do not involve local production: (i) the creation of contingency reserves of medicines at risk of shortage, and in particular of those previously identified as essential; (ii) the diversification of sources of supply; (iii) the simplification of supply chains; (iv) the facilitation of imports; (v) the improvement of pricing mechanisms and procurement procedures; (vi) the harmonization and simplification of regulatory requirements; and (vii) increased international cooperation.⁵⁵⁴ The European Union lists several strategies recommended by the WHO for forecasting, averting or reducing shortages of medicines and vaccines, and stresses in particular that "the importance of monitoring medicine supply, demand, and availability and of alerting responsible departments to possible shortages cannot be overemphasised".⁵⁵⁵ Alternatively, "in those cases where local production can be an effective tool", there are less trade-restrictive alternative measures which the WHO has identified including (i) direct support to reduce the cost of manufacture (i.e. subsidies); and (ii) a wide range of other strategies to indirectly support local production.⁵⁵⁶ The European Union notes that the strategies listed by the WHO do "not include any measure resembling Turkey's Localisation Requirement"⁵⁵⁷, and considers the recommendation on developing appropriate investment policies and joint ventures to be of particular relevance.⁵⁵⁸

7.153. In its second written submission, Turkey responds with three arguments. It asserts first, that the European Union enumerates certain "general categories of measures" that it suggests may be "useful for improving access to medicines" but fails to explain how any of these "extremely vague" measures would contribute to its long-term objective⁵⁵⁹, achieve the same level of protection, or be less trade restrictive.⁵⁶⁰ Second, the European Union's proposed system of monitoring and import

⁵⁵² Turkey's second written submission, para. 207.

⁵⁵³ Turkey's first written submission, para. 496.

⁵⁵⁴ European Union's second written submission, para. 186.

⁵⁵⁵ European Union's second written submission, paras. 187-188. The strategies listed are: (i) the implementation of effective notification systems to identify potential shortages; (ii) ensuring best practices for procurement, distribution and contract management processes to mitigate the risk of shortages; (iii) developing/strengthening systems capable of monitoring supply, demand, and availability, alerting procurement departments to possible shortages; (iv) ensuring sound financial management of procurement systems, to prevent funding shortfalls for medicines; (v) prioritizing, in the case of shortages, the health needs of the most affected groups; and (vi) advancing regional and international cooperation in support of national notification systems.

⁵⁵⁶ European Union's second written submission, para. 190. The strategies listed are: (i) investment in strengthening regulation; (ii) developing national priority lists; (iii) improving the financing of health services for expanding the domestic market; (iv) facilitating access to foreign markets; (v) developing regional pooled procurement mechanisms; (vi) regulatory harmonization; (vii) appropriate pricing policies; (viii) relevant technology transfer; (ix) incremental innovation and production; (x) appropriate IP regimes; (xi) appropriate investment policies and joint ventures; and (xii) international cooperation.

⁵⁵⁷ European Union's second written submission, para. 191.

⁵⁵⁸ European Union's second written submission, para. 192.

⁵⁵⁹ Turkey reiterates here that the localisation requirement "serves the long-term objective of ensuring uninterrupted access to safe, effective and affordable medicines and thus any measures that may remedy an *ad hoc* short-term shortage of supply are not alternatives to the localisation measure". (Turkey's second written submission, para. 212.)

⁵⁶⁰ Turkey's second written submission, paras. 210-212. According to Turkey, this stands in stark contrast to the level of detail and explanation provided by complainants identifying alternative measures in other WTO cases. Turkey indicates that this argument is directed at the following general categories of alternative measures: contingency reserves of medicines at risk of shortage, diversifying sources of supply, simplifying supply chains, facilitating imports, improving pricing mechanisms and procurement procedures, harmonizing and simplifying regulatory requirements, and increasing international cooperation. (Ibid.)

licensing is already in place, and is thus "complementary" and not an alternative measure to the localisation requirement⁵⁶¹; additionally, a monitoring and licensing system does not address the localisation requirement's safety and affordability objectives, and would not address scenarios in which imports are simply shut off or become excessively expensive.⁵⁶² Third, in relation to the several recommendations included in the WHO report cited by the European Union, Turkey submits that (i) it is unclear whether all of these general recommendations are put forward by the European Union as alternative measures⁵⁶³; (ii) the suggestion that Turkey provide grants and subsidies is difficult to reconcile with the European Union's claim under Article 3.1(b) of the SCM Agreement⁵⁶⁴; and (iii) relying on possible "joint-ventures" with "efficiency-seeking foreign investors" is not a viable strategy for ensuring reliable access to medicines.⁵⁶⁵ Turkey also notes "the growing consensus that the COVID-19 pandemic has revealed a need to revise the measures that were, until recently, considered sufficient to guarantee access to medicines and medical products", and refers to a recent European Parliament report in support.⁵⁶⁶

7.4.2.2.6 Chapeau of Article XX

7.154. Turkey argues that the localisation requirement is applied in accordance with the requirements of the chapeau as it is not applied in a manner that would constitute "arbitrary or unjustifiable discrimination between countries where the same conditions prevail" or in a manner that constitutes "a concealed or unannounced restriction or discrimination in international trade".⁵⁶⁷ It applies "indistinctly to pharmaceutical products falling within the scope of localisation irrespective of the country of origin of the products"; the pharmaceutical products subject to localisation are selected on the basis of objective criteria which aim to avoid any shortage of supply and, ultimately, lead to better access to medicines in Turkey; and while based on objective criteria, it provides necessary flexibility for taking into account the circumstances of specific pharmaceutical companies.⁵⁶⁸

7.155. The European Union submits that the localisation requirement is applied in a manner that cannot be rationally reconciled with the public health objective alleged by Turkey and, as a result, leads to "arbitrary or unjustifiable discrimination" between domestic and imported products. The localisation requirement is not calibrated to reflect the difference in health risks that may arise in relation to different pharmaceutical products, and in principle "applies to all pharmaceutical products covered by the Reimbursement Scheme, regardless of how essential they are, and regardless of the degree of risk of shortage of supply of each group of equivalent products".⁵⁶⁹ To the extent that Turkey modulates the application of the localisation requirement, by dividing its implementation into five phases, "such modulation is at odds with the public health objective allegedly pursued by Turkey" because Phase 1 and Phase 2, the only ones implemented so far by Turkey, "cover pharmaceutical products where, by Turkey's own admission, there is no risk of shortage of supply and, hence, no health risk".⁵⁷⁰ In the absence of that risk, the European Union submits, it becomes clear, that the public health objective invoked by Turkey is an excuse for promoting the economic development and industrial policy objectives pursued by Turkey in the pharmaceutical sector.⁵⁷¹

7.156. In its second written submission, Turkey responds that the manner in which the localisation requirement is implemented has "a clear rational connection to its aim"⁵⁷² and therefore does not lead to arbitrary or unjustifiable discrimination under the chapeau of Article XX. First, the implementation of the localisation requirement through five phases follows a discernible logic: Turkey sought to minimize the risk of a short-term shortage of supply due to the implementation of the measure by including in the first and second phases only medicines that are already available in Turkey. This approach "balances long-term supply security with avoiding short-term shortages and

⁵⁶¹ Turkey's second written submission, para. 214.

⁵⁶² Turkey's second written submission, para. 215.

⁵⁶³ Turkey's second written submission, para. 216.

⁵⁶⁴ Turkey's second written submission, para. 216.

⁵⁶⁵ Turkey's second written submission, para. 217.

⁵⁶⁶ Turkey's second written submission, para. 218.

⁵⁶⁷ Turkey's first written submission, paras. 497-503.

⁵⁶⁸ Turkey's first written submission, para. 501.

⁵⁶⁹ European Union's second written submission, para. 197.

⁵⁷⁰ European Union's second written submission, para. 198.

⁵⁷¹ European Union's second written submission, para. 198.

⁵⁷² Turkey's second written submission, para. 224.

does not give rise to a contradiction"⁵⁷³, contrary to the European Union's suggestion. Second, in order to balance the localisation requirement's goals of ensuring long-term access to medicines with guaranteeing the sustainability of the Turkish healthcare system, "the scope of the measure cannot be limited to only medicines which are currently at a risk of shortage of supply."⁵⁷⁴ Access and sustainability must be ensured with regard to all pharmaceutical products included in the Annex 4/A list, "because inadequate access to those products would present a health risk for the patients and the availability of those medicines entails costs that are expected to rise".⁵⁷⁵

7.4.2.3 Assessment by the Panel

7.4.2.3.1 Introduction

7.157. The general exceptions in the GATT 1994 and certain other covered agreements provide that Members may take any measures necessary, *inter alia*, "to protect human life or health".⁵⁷⁶ Article 8.1 of the TRIPS Agreement recognizes that "Members may ... adopt measures necessary to protect public health and nutrition...", and the preamble to the TBT Agreement affirms that "no country should be prevented from taking measures necessary ... for the protection of human ... life or health". Panels and the Appellate Body have repeatedly emphasized that the preservation of human life and health, which extends to measures protecting people against life-threatening diseases, is "both vital and important in the highest degree".⁵⁷⁷

7.158. The more specific objective of ensuring access to pharmaceutical products is also recognized in the WTO covered agreements. Notably, the 1994 Agreement on Trade in Pharmaceutical Products, negotiated in the context of the Uruguay Round, committed the signatories to eliminating all tariffs and other duties and charges on most pharmaceutical products and the substances used to produce them, permanently binding them at duty-free levels in their Schedules.⁵⁷⁸ The 2001 Declaration on the TRIPS Agreement and Public Health reflects WTO Members' shared understanding that the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of the right of WTO Members to protect public health "and, in particular, to promote access to medicines for all".⁵⁷⁹ Article 31*bis* of the TRIPS Agreement and paragraph 1(b) of the Annex thereto, which entered into force in 2017, provide that the obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall not apply with respect to the grant by it of a compulsory licence "to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s)" in circumstances including times of "national emergency" or "extreme urgency".⁵⁸⁰

7.159. The more specific objective of ensuring access to pharmaceutical products is also recognized by various international authorities and through various instruments. For example, a 2009 Resolution of the UN Human Rights Council on "Access to medicine in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health" underscores that improving access to medicine could save millions of lives every year. It recognizes that access to medicine is one of the fundamental elements in achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. It also stresses the responsibility of States to ensure access to all, without discrimination, of medicines, in particular essential medicines, that are affordable, safe, effective and of good quality.⁵⁸¹

⁵⁷³ Turkey's second written submission, para. 222.

⁵⁷⁴ Turkey's second written submission, para. 223.

⁵⁷⁵ Turkey's second written submission, para. 223.

⁵⁷⁶ See also Article XIV(b) of the GATS and Article II:2(b) of the Agreement on Government Procurement.

⁵⁷⁷ See e.g. Appellate Body Reports, *EC – Asbestos*, para. 172; *Brazil – Retreaded Tyres*, para. 179; and Panel Reports, *Brazil – Retreaded Tyres*, para. 7.210; *Indonesia – Chicken*, para. 7.225.

⁵⁷⁸ See "Trade in Pharmaceutical Products", GATT Doc. L/7430, 25 March 1994.

⁵⁷⁹ Ministerial Conference, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, para. 4.

⁵⁸⁰ See protocol amending the TRIPS Agreement, adopted by the General Council, WT/L/641, 6 December 2005; Article 31*bis* of the TRIPS Agreement; and paragraph 1(b) of the Annex to the TRIPS Agreement. The amendment entered into force on 23 January 2017.

⁵⁸¹ UN Human Rights Council, Resolution A/HRC/RES/12/24, 12 October 2009 (Exhibit TUR-72), p. 2, paras. 1 and 2.

7.160. The importance of ensuring access to affordable medicines is also recognized through multiple initiatives and publications by various international organizations. For example, the WTO, the World Intellectual Property Organization (WIPO) and the World Health Organization (WHO) have cooperated as part of increasing international efforts to support innovation in health technologies and to ensure the availability of affordable, new and more effective medicines for patients in all countries. A recent joint publication, *Promoting Access to Medical Technologies and Innovation, 2nd edition: Intersections between public health, intellectual property and trade*, confirms that access to medicines and health services is an element of the fulfilment of the right of everyone to the enjoyment of the highest attainable standard of health; that furthering access to medicines is also part of the United Nations Sustainable Development Goals; and that affordable prices are a critical determinant of access to medicines.⁵⁸²

7.161. While it may go without saying that providing universal healthcare, ensuring access to pharmaceutical products and protecting human health are legitimate governmental objectives⁵⁸³, the Panel considers it useful to stress that this dispute does not involve any challenge to Turkey's declared objective of preventing a risk of long-term shortage of supply of safe, effective and affordable pharmaceutical products. The Panel understands there to be no disagreement between the disputing parties that the lack of access to pharmaceutical products poses a risk to human life and health⁵⁸⁴; that the objective of ensuring adequate access to pharmaceutical products is thus one that relates to the protection of "human life or health" under Article XX(b) of the GATT 1994, and is vital and important⁵⁸⁵; that WTO Members are free to decide how to organize their social security and healthcare systems⁵⁸⁶; and that governmental policies of covering all or part of the cost of pharmaceutical products are linked to the objective of providing universal healthcare, ensuring access to pharmaceutical products and protecting human health.⁵⁸⁷

7.162. Furthermore, the parties agree that Members may, in the context of Article XX(b), take measures to address the risk of future shortages of supplies before such shortages actually arise.⁵⁸⁸ All third parties that expressed a view on this issue agree as well.⁵⁸⁹ The Panel understands that while two prior panels ruled that the "short supply" exception in Article XX(j) of the GATT 1994⁵⁹⁰ does not cover measures taken to prevent a potential future shortage, both of those rulings were based on the particular wording of the "short supply" exception in Article XX(j).⁵⁹¹ Indeed, both panels accepted that measures taken to address the risk of future shortages could in principle fall within the scope of other sub-paragraphs of Article XX of the GATT 1994 or Article XIV of the GATS.⁵⁹²

⁵⁸² WTO, WIPO, and WHO, *Promoting Access to Medical Technologies and Innovation, 2nd edition: Intersections between public health, intellectual property and trade* (2020), p. 17. (available at https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm)

⁵⁸³ European Union's first written submission, para. 211.

⁵⁸⁴ Turkey's second written submission, para. 179; European Union's responses to the first set of questions, para. 45. As Turkey explains, "[m]edicines shortages pose risks for patient health due to undertreatment, medication errors, and adverse reactions from attempts to substitute unavailable medicines." (Turkey's first written submission, para. 488.)

⁵⁸⁵ Turkey's first written submission, para. 470; European Union's second written submission, para. 142.

⁵⁸⁶ Turkey's first written submission, para. 26; European Union's second written submission, para. 39.

⁵⁸⁷ European Union's first written submission, para. 211.

⁵⁸⁸ Turkey's second written submission, para. 181; European Union's responses to the first set of questions, para. 43.

⁵⁸⁹ Canada's responses to the Panel's questions to third parties, paras. 10-14; Japan's responses to the Panel's questions to third parties, paras. 9-13; Switzerland's responses to the Panel's questions to third parties, paras. 8-11; United States' responses to the Panel's questions to third parties, paras. 10-15.

⁵⁹⁰ Article XX(j) provides that that Members may take, under certain conditions, measures "essential to the acquisition or distribution of products in general or local short supply".

⁵⁹¹ See Panel Report, *India – Solar Cells*, para. 7.250. The panel in *EU – Energy Package* agreed that "the plain reading of the terms 'products in ... short supply' indicates that the products referred to in Article XX(j) of the GATT 1994 are those products that are presently in short supply". (Panel Report, *EU – Energy Package*, para. 7.1348.)

⁵⁹² The panel in *India – Solar Cells* found that Article XX(j) only applies to products presently in short supply, not products at risk of becoming in short supply, but reasoned that insofar as that was incorrect, it could only apply to products in respect of which there was an "imminent risk". However, it stated that it saw "no basis for applying the same standard of imminent risk, and therefore [did] not apply this same standard, in the context of assessing whether the DCR measures are designed to secure compliance with laws or regulations within the meaning of Article XX(d) of the GATT 1994, or are 'essential' or 'necessary' within the meaning of Articles XX(j) and XX(d)". (Panel Report, *India – Solar Cells*, footnote 618.) The panel in *EU – Energy Package* agreed that Article XX(j) only applies to products presently in short supply but did not read this limitation into Article XIV(a) of the GATS, which provides a general exception for measures "necessary to

Other panels have adopted a similar approach in the context of other sub-paragraphs of Article XX.⁵⁹³ Thus, the Panel agrees with Turkey that, in the context of Article XX(b), WTO Members "are allowed to take preventive measures before any actual shortage of supply arises".⁵⁹⁴

7.163. Based on the foregoing, the Panel emphasizes that what is in dispute in this case is *not* the legitimacy of Turkey's declared objective of preventing a risk of long-term shortage of supply of safe, effective and affordable medicines, or whether a measure taken to fulfil that objective would in principle qualify as a measure "to protect human life or health" within the meaning of Article XX(b). The question is whether Turkey has discharged its burden of demonstrating that the localisation requirement is a measure that was taken to prevent a risk of long-term shortage of supply of safe, effective and affordable medicines, and, if so, whether Turkey has discharged its burden of demonstrating that the localisation requirement is necessary to fulfil that objective. When Article XX(b) is invoked, the responding party carries the burden of proof in respect of the elements of that affirmative defence.⁵⁹⁵

7.164. Following the traditional analytical approach to the interpretation of Article XX(b)⁵⁹⁶, the Panel will first assess whether the localisation requirement is provisionally justified under Article XX(b). In this context, the Panel will address the threshold issue of whether the localisation requirement is a measure taken to protect human life or health. If the Panel finds that this is the case, it will then proceed to examine the remaining elements of the test under Article XX(b), namely whether the localisation requirement is necessary to protect human life or health, and thus provisionally justified under Article XX(b), and whether it has been applied consistently with the requirements of the chapeau of Article XX.

7.4.2.3.2 Whether the localisation requirement is a measure taken to protect human life or health

7.165. Turkey asserts that its over-reliance on imported pharmaceutical products creates a risk of long-term⁵⁹⁷ shortage of supply of safe, effective and affordable medicines, and argues that the localisation requirement, by localising the production of pharmaceutical products, is a measure designed to address this risk and thus to ensure an uninterrupted access to safe, effective and affordable pharmaceutical products for all patients in Turkey. The European Union argues that there is no relevant evidence of the existence of a risk of shortage of supply of safe, effective and affordable medicines in Turkey arising from an over-reliance on imported pharmaceutical products, and that the localisation requirement is designed only to promote Turkey's economic development and industrial policy objectives in the pharmaceutical sector.

7.166. This is not the first case in which a responding party has argued that a challenged measure was taken to prevent a risk of supply-side disruptions that could arise from its alleged over-reliance on imports of essential goods and/or services, to ensure a continuous and affordable supply of those goods or services. In prior cases, panels and the Appellate Body have consistently required the responding party to demonstrate, at a minimum, that the asserted risk arising from over-reliance on imports was more than a merely hypothetical possibility.

7.167. In *India – Solar Cells*, India argued that the challenged measures, which conditioned government purchases of electricity from SPDs on those SPDs sourcing certain types of equipment (e.g. solar cells) domestically, were justified under Articles XX(j) and (d) of the GATT 1994 because

protect public morals or to maintain public order". The footnote to Article XIV(a) of the GATS expressly indicates that it applies to situations involving a "genuine and sufficiently serious threat" to fundamental societal interests, and the panel found that "evidence of a threat already having materialized is not a prerequisite for demonstrating that this threat is genuine, i.e. has the character of a threat and is real and true." (Panel Report, *EU – Energy Package*, para. 7.1190.)

⁵⁹³ See e.g. Panel Report, *Brazil – Taxation*, fn 1001, noting that Brazil's argument regarding the risk of a shortage of digital TV equipment was based on an invocation of Article XX(a), and not Article XX(j), of the GATT 1994.

⁵⁹⁴ Turkey's second written submission, para. 181.

⁵⁹⁵ See e.g. Appellate Body Report, *US – Gasoline*, p. 22; Panel Report, *EC – Asbestos*, paras. 8.177-8.178.

⁵⁹⁶ See paras. 7.132 - 7.138 above.

⁵⁹⁷ In its submissions, Turkey emphasizes that the localisation requirement is "not a tool to remedy any potential short-term shortages of supply, but aims to ensure a guaranteed stable and long-term access to medicines". (Turkey's opening statement, para. 73.)

"dependence on imports of foreign solar cells and modules creates a risk of disruption in continuous and affordable supply of solar cells and modules [and] it is therefore necessary to ensure that there is an adequate reserve of domestic manufacturing capacity for solar cells and modules in case there is a disruption in supply of foreign solar cells and modules."⁵⁹⁸ The panel in that case examined the individual pieces of evidence provided by India to substantiate its concerns about the risk of shortage. The panel noted that "there is always some risk of a future shortage of any product."⁵⁹⁹ However, the panel ultimately found that India had failed to provide sufficient evidence of any imminent risk of a disruption in supply of foreign solar cells and modules to India SPDs.⁶⁰⁰

7.168. In *Brazil – Taxation*, Brazil argued that certain challenged tax exemptions and reductions on digital TV equipment produced domestically were justified under Article XX(a) of the GATT 1994 because to bridge the digital divide, it needed to ensure the supply of digital TV transmitting equipment and the capacity to develop and manufacture this equipment in Brazil, since there was no guarantee that there would be a sufficient quantity of imported products to adequately supply the market with transmitting equipment compliant with Brazil's standards.⁶⁰¹ The panel in that case examined whether Brazil had presented sufficient evidence in support of its assertions that domestic producers required protection and that it had taken into account the capacity of foreign producers to supply the Brazilian market in order to secure access to digital television equipment, and concluded that this was not the case.⁶⁰² The panel found that Brazil had provided no evidence to substantiate its assertion that there was a risk that it could not obtain all of the necessary transmitting equipment from foreign sources, stating that "Brazil has not provided any evidence to indicate that transmitting equipment would not be made available in the Brazilian market in the necessary scale"⁶⁰³ and that "Brazil has not undertaken any analysis, nor presented any evidence (quantitative or qualitative), in support of its contention that imported products could not supply the market."⁶⁰⁴

7.169. In *EU – Energy Package*, the European Union defended two of the challenged measures on the grounds that they were related to securing an uninterrupted and affordable supply of energy within the European Union. More specifically, the European Union argued that the third-country certification measure was justified under Article XIV(a) of the GATS because it was necessary to ensure the European Union's security of energy supply and hence to maintain public order⁶⁰⁵; and that the TEN-E measure was justified under Article XX(j) of the GATT because natural gas was a product "in general or local short supply" because of the existence of "genuine and serious risks of disruption of supply of gas."⁶⁰⁶ The panel in that case engaged in a review of the evidence and arguments and found that there was a sufficient factual basis to conclude that certain risks of natural gas disruptions were not merely hypothetical.⁶⁰⁷ The panel stated that the European Union made a "prima facie case that there is a real and true possibility, rather than a merely hypothetical one, of foreign governments requiring or inducing foreign controlled [transport service operators] to undermine the European Union's security of energy supply".⁶⁰⁸

7.170. Thus, in those cases, panels and the Appellate Body required the responding party to demonstrate, at a minimum, that the asserted risk arising from alleged over-reliance on imports was more than a merely hypothetical possibility. The Panel considers that in the context of Article XX(b), as in the context of the other sub-paragraphs of Article XX, a party invoking a general exception must identify some degree of probability that the alleged risk exists.⁶⁰⁹ In this case, Turkey

⁵⁹⁸ Panel Report, *India – Solar Cells*, para. 7.189. See also *ibid.* para. 7.237. India provided evidence on what the possible supply-side disruptions for solar cells and modules are, and why they could be reasonably expected. Such evidence included a World Bank study, certain market forecasts, and two press reports. (*Ibid.* paras. 7.251-7.254.)

⁵⁹⁹ Panel Report, *India – Solar Cells*, para. 7.245.

⁶⁰⁰ Panel Report, *India – Solar Cells*, paras. 7.261-7.264.

⁶⁰¹ Panel Reports, *Brazil – Taxation*, para. 7.572.

⁶⁰² Panel Reports, *Brazil – Taxation*, para. 7.582.

⁶⁰³ Panel Reports, *Brazil – Taxation*, para. 7.573.

⁶⁰⁴ Panel Reports, *Brazil – Taxation*, para. 7.600.

⁶⁰⁵ Panel Report, *EU – Energy Package*, para. 7.1135.

⁶⁰⁶ Panel Report, *EU – Energy Package*, para. 7.1326.

⁶⁰⁷ Panel Report, *EU – Energy Package*, paras. 7.1194 and 7.1346.

⁶⁰⁸ Panel Report, *EU – Energy Package*, paras. 7.1194 and 7.1346.

⁶⁰⁹ The Panel sees nothing in the text of Article XX(b) that would establish a materially different evidentiary standard, in this respect, than has been applied in previous cases in the context of Article XX(j) of the GATT 1994, Article XX(a) of the GATT 1994, and Article XIV(a) of the GATS. In the context of assessing whether a ban on certain products containing asbestos was taken to protect human life or health, the panel in

asserts that its over-reliance on imported pharmaceutical products creates a risk of long-term shortage of supply of safe, effective and affordable pharmaceutical products, and argues that the localisation requirement, by localising the production of pharmaceutical products, is a measure designed to address this risk. Contrary to what some of Turkey's arguments suggest⁶¹⁰, it therefore falls on Turkey to demonstrate the existence of a risk of shortage of supply arising from its over-reliance on imported pharmaceutical products.

7.171. The Panel does not consider that there is any rigid or pre-determined threshold or evidentiary standard that should be applied in this respect. Insofar as a responding party presents evidence and arguments demonstrating that there is a substantial degree of probability of a specified risk to human life or health materializing, it will be easier for the responding party to discharge its burden of proving that the challenged measure was taken to protect against that risk, thus qualifying as a measure taken to protect human life or health under Article XX(b). Conversely, insofar as a responding party asserts the existence of a risk without establishing any substantial degree of probability, such that the risk appears to be theoretical, abstract or otherwise hypothetical, it will be more difficult for the responding party to discharge its burden of proving that the challenged measure was taken to protect against that risk.

7.172. According to Turkey, its over-reliance on imported pharmaceutical products creates a risk of long-term shortage of supply of safe, effective and affordable pharmaceutical products risk because of several prevailing economic circumstances relating to the cost of imported pharmaceutical products in Turkey, including most notably that: (i) the low prices of pharmaceutical products on the Turkish market create the risk that foreign pharmaceutical producers might decide to supply other countries where they can receive a higher price for their products, instead of Turkey⁶¹¹; and (ii) imported pharmaceutical products may become unaffordable to the SSI if a foreign currency gains in value or the Turkish lira depreciates.⁶¹²

7.173. In the Panel's view, the nature of the risk identified by Turkey in this dispute involves the kind of hypothetical possibility that previous panels and the Appellate Body have regarded as insufficient to discharge a responding party's burden under Article XX. Significantly, Turkey has not identified any instance of shortage of supply of a specific product caused by foreign producers deciding to stop supplying medicines to Turkey to instead sell in other countries where they can receive a higher price for their products; or caused by a medicine becoming unaffordable to the SSI because of a foreign currency gaining in value or the Turkish lira depreciating.

7.174. The Panel has carefully reviewed the examples of shortages of certain pharmaceutical products offered by Turkey in support of its contention that this is "not merely a hypothetical situation".⁶¹³ The evidence provided by Turkey, which consists of press articles over the period 2017-2019 (and one from 2012), shows that shortages of pharmaceutical products have arisen on more than one occasion. While the evidence suggests that all such shortages were temporary in nature, it also shows that a range of different pharmaceutical products were affected. Thus, the Panel agrees with Turkey that the press articles submitted "provide ample evidence of disruptions in the supply

EC – Asbestos first assessed whether the product at issue (i.e. chrysotile-asbestos in that case) posed a risk to, in that case, human life or health. (Panel Report, *EC – Asbestos*, para. 8.170.) Likewise, in the context of assessing whether the ban on imported retreaded tyres was taken to protect human life or health, the panel in *Brazil – Retreaded Tyres* first assessed whether Brazil had demonstrated that risks posed by mosquito-borne diseases (such as dengue, yellow fever and malaria) to human health and life exist in Brazil in relation to the accumulation as well as transportation of waste tyres. (Panel Report, *Brazil – Retreaded Tyres*, para. 7.43.)

⁶¹⁰ Turkey's second written submission, paras. 177-182.

⁶¹¹ Turkey's first written submission, paras. 127, 488, and 547; responses to the first set of questions, para. 58.

⁶¹² Turkey's second written submission, para. 244. Turkey explains that, at a certain point, "the costs of imported medicines become so expensive that a decision must be made to either stop covering the costs of certain medicines, thereby risking limiting access, or continue paying for those medicines even if this is not supported by revenue, thereby risking the financial stability of the healthcare system." (Ibid. para. 245.)

⁶¹³ Turkey's second written submission, para. 245 (referring to "Pharmacy chambers blame medical firms for drug shortages", Daily News (Istanbul, 23 January 2017); C. Caglayan and E. Erkoyun, "Pharmacy stocks run low as Turkey's drug price policy hits supplies", Reuters (Istanbul, 6 February 2019); M. Xuequan, "Spotlight: Turkey faces shortages of medicine due to currency fluctuations", Xinhuanet (21 February 2019) (together Exhibit TUR-130); "The rise in the exchange rate also hit the pharmaceutical industry: alleged supply problems in 'more than 500 medicines'", Medimagazin (10 October 2018) (Exhibit TUR-131)).

of pharmaceutical products" in Turkey, and furthermore, that insofar as the products in question were imported, such shortages were "linked to" imports.⁶¹⁴

7.175. The Panel in no way questions the gravity of these situations or the legitimate concerns that they raise. However, the Panel's review of the articles does not reveal any instance of shortage of supply of a specific product caused by foreign producers deciding to stop supplying pharmaceutical products to Turkey to sell instead in other countries where they can receive a higher price for their products; or shortage of supply caused by a pharmaceutical product becoming unaffordable to the SSI because of a foreign currency gaining in value or the Turkish lira depreciating:

- a. Three press articles submitted by Turkey⁶¹⁵ refer to situations where pharmaceutical producers, warehouses and/or pharmacies temporarily "hoarded" pharmaceutical products pending, and to take advantage of, a previously announced increase of the exchange rate for imported medicines or hikes in prices. The Panel understands that these shortages arose from the Turkish government's announcement of price *increases* (operated through the adjustment of the fixed exchange rate for pharmaceutical products), and that the products concerned were made available on the market shortly after the prices increased⁶¹⁶, or following an authorization by the Ministry of Health for certain pharmaceutical products to be sold at prices higher than those set by the fixed exchange rate.⁶¹⁷
- b. Another press article submitted by Turkey⁶¹⁸ refers to supply problems concerning 521 pharmaceutical products, including some imported products (e.g. eye drops), but gives mostly examples of shortages of pharmaceutical products *produced in Turkey* using imported raw materials.
- c. Three other press articles provided by Turkey relate to temporary shortages of Tamoxifen (a breast cancer medicine)⁶¹⁹, Purinethol (a medicine used to treat leukaemia)⁶²⁰, and Salofalk (a medicine used to treat ulcerative colitis).⁶²¹ However, none indicates whether the supply disruptions are the result of reliance on imports, as opposed to other factors:
 - i. One of the articles on Tamoxifen quotes an official as saying that this pharmaceutical product is also produced locally. This raises the question of how the temporary shortage arose from an over-reliance on imports in the manner argued by Turkey.⁶²²

⁶¹⁴ Turkey's second written submission, paras. 183-188.

⁶¹⁵ "Pharmacy chambers blame medical firms for drug shortages", Daily News (Istanbul, 23 January 2017); C. Caglayan and E. Erkoyun, "Pharmacy stocks run low as Turkey's drug price policy hits supplies", Reuters (Istanbul, 6 February 2019); M. Xuequan, "Spotlight: Turkey faces shortages of medicine due to currency fluctuations", Xinhuanet (21 February 2019) (Exhibit TUR-130).

⁶¹⁶ "Pharmacy chambers blame medical firms for drug shortages", Daily News (Istanbul, 23 January 2017); C. Caglayan and E. Erkoyun, "Pharmacy stocks run low as Turkey's drug price policy hits supplies", Reuters (Istanbul, 6 February 2019); M. Xuequan, "Spotlight: Turkey faces shortages of medicine due to currency fluctuations", Xinhuanet (21 February 2019) (Exhibit TUR-130).

⁶¹⁷ C. Caglayan and E. Erkoyun, "Pharmacy stocks run low as Turkey's drug price policy hits supplies", Reuters (Istanbul, 6 February 2019) (Exhibit TUR-130).

⁶¹⁸ "The rise in the exchange rate also hit the pharmaceutical industry: alleged supply problems in 'more than 500 medicines'", *Medimagazin* (10 October 2018) (Exhibit TUR-131).

⁶¹⁹ H. Biskin, "Shortage of supply in medicine to cure breast cancer", *Duvar*, 22 September 2017; "Local solution for imported medicine used in intestinal diseases", *Anadolu*, 16 January 2017 (Exhibit TUR-98).

⁶²⁰ "Shortage of supply in this medicine", *Sağlık Aktüel*, 23 August 2012 (Exhibit TUR-99).

⁶²¹ "Citizens are victims, that drug is still not on the market", *Yeniakit*, 29 November 2018 (Exhibit TUR-100).

⁶²² "Local solution for imported medicine used in intestinal diseases", *Anadolu*, 16 January 2017 (Exhibit TUR-98). The other press article regarding Tamoxifen notes the following explanation provided by H. Gürsöz, President of the TMMDA: "There is no supply problem for cancer medicines that we have identified at the moment. Last year, the short-term problem experienced in breast cancer patients' medications was caused by the firm, which has the highest market share of the drug, [which] wants to close the production line abroad. We also produced this product locally. There is no procurement problem that reaches us about other cancer medicines. After this problem has been solved, the normal supply flow has continued." (H. Biskin, "Shortage of supply in medicine to cure breast cancer", *Duvar*, 22 September 2017 (Exhibit TUR-98).)

- ii. The article on Purinethol relates a statement by the SSI that appears to indicate that price was not an issue, in that "there is no demand from the importer company, especially for a price increase".⁶²³
- iii. The article on Salofalk contains statements suggesting that the shortage of supply may have been related to a decision by pharmaceutical companies to stop the sale of the product in Turkey "by claiming that the SSI did not offer desired prices for their products" but also states that "despite the fact that the Ministry of Health said that the price was eventually agreed with the pharmaceutical company and that the distribution would be made, it was noticed that the sale still is not made."⁶²⁴ It also contains statements relating the shortages to an unspecified "long" and "official procedure", and quotes an official's statement that "pharmaceutical companies have caused problems in access by turning the recent exchange rate fluctuations into an opportunity". However, it also quotes the official as referring to "alternative procurement ways, including quick licensing and mandatory license liberalization method, are put into use, and drugs are procured at an affordable price to our country".
- iv. In sum, none of these press articles provided by Turkey mentions a situation where the companies producing Tamoxifen, Purinethol, Salofalk, or any other pharmaceutical product decided to stop supplying pharmaceutical products to Turkey to sell instead in other countries where they could receive a higher price for their products; or where the pharmaceutical product became unaffordable to the SSI because of a foreign currency gaining in value or the Turkish lira depreciating.

7.176. Turkey also provides as evidence correspondence between Turkish authorities relaying shortages of medicines containing the active substance Oxytocin (used to treat antenatal contraction insufficiencies and postnatal atony)⁶²⁵ and medicines containing L-carnitine (used for carnitine insufficiencies).⁶²⁶ The Panel notes that this correspondence does not specify whether the pharmaceutical products containing these substances are produced in Turkey or imported. The correspondence also contains no indication whether or how the supply disruptions are related to reduced imports.

7.177. The Panel recalls that it is for Turkey, as the party invoking the general exception in Article XX(b), to substantiate its assertion that its alleged over-reliance on imported pharmaceutical products creates a risk of long-term shortage of supply of safe, effective and affordable medicines. As indicated above, the Panel agrees with Turkey that the press articles submitted "provide ample evidence of disruptions in the supply of pharmaceutical products" in Turkey and further that, insofar as the products in question were imported, such shortages were "linked to" imports. However, the Panel's review of these press articles does not reveal any instance of shortage of supply of a specific product caused by foreign producers deciding to stop supplying medicines to Turkey to sell instead in other countries where they can receive a higher price for their products; or caused by a medicine becoming unaffordable to the SSI because of a foreign currency gaining in value or the Turkish lira depreciating. Thus, the absence of evidence linking these past instances of shortages to Turkey's over-reliance on imports further confirms that the risk identified by Turkey – and more specifically, that the factors that give rise to a risk of future shortages in respect of any and all pharmaceutical products can only be characterized as hypothetical.

⁶²³ "Shortage of supply in this medicine", *Sağlık Aktüel*, 23 August 2012 (Exhibit TUR-99), p. 1.

⁶²⁴ "Citizens are victims, that drug is still not on the market", *Yeniakit*, 29 November 2018 (Exhibit TUR-100), pp. 1-2.

⁶²⁵ Antalya Provincial Health Directorate, Letter to the Ministry of Health regarding oxytocine ampoule, 7 March 2016; Yaşam Hastanesi Life Hospital Antaliya, Letter to the Pharmacies Branch of the Provincial Health Directorate, 26 February 2016; Private Vitale Gynecology and Obstetrics Hospital, Letter to the Provincial Health Directorate Pharmacies Branch, 25 February 2016; Medical Park Özel Antalya Hastane Kompleksi, Letter to the Provincial Health Directorate Pharmacies Branch, 24 February 2016; Private Akdeniz Şifa Hospital, Letter to the Provincial Health Directorate Pharmaceuticals and Pharmacies Branch, 22 February 2016; Özel/Private Anadolu Hastanesi Antalya, Letter to the Provincial Health Directorate Pharmaceuticals and Pharmacies Branch, 1 March 2016 (Exhibit TUR-101).

⁶²⁶ Ministry of Family and Social Policies, Directorate General for Disabled and Elderly, Letter to the Ministry of Health, 25 March 2016 (Exhibit TUR-102).

7.178. In addition to being merely hypothetical, the situation described by Turkey in this dispute is characterized by a level of temporal and sectoral generality that is at odds with the concept of risk under Article XX(b). The generality of Turkey's argument is in fact such that the risk identified by Turkey could be present in any sector and concern any market. Indeed, Turkey refers to general economic circumstances that are not specific to the pharmaceutical sector⁶²⁷, and not specific to Turkey (such as exchange rate fluctuations).⁶²⁸ The generality of Turkey's underlying argument would lead to the conclusion that there is a permanent risk of shortage of products concerning each and every sector of any WTO Member's economy. Following the logic of Turkey's argument, international trade liberalization in products and sectors that are necessary for the protection of human life or health creates a permanent risk to human life or health under Article XX(b).

7.179. The Panel is also not persuaded that the risk of a shortage of supply of pharmaceuticals, as described by Turkey, has been proven in the context of the COVID-19 pandemic.⁶²⁹ The Panel understands Turkey to argue that the COVID-19 pandemic demonstrates that the risk of shortage of supply of safe, effective and affordable pharmaceutical products is not merely theoretical, because an acute emergency such as the pandemic can lead to such shortages.⁶³⁰ The Panel considers that what the COVID-19 pandemic demonstrates is simply that an acute emergency in any sector could potentially trigger a risk of short-term shortage of any products. Any additional parallel between the COVID-19 pandemic and Turkey's alleged risk would be precluded by the specific nature of the shortages related to the COVID-19 pandemic, which involved a novel virus, a global pandemic, unprecedented global demand for newly developed vaccines, and insufficient worldwide production to meet that demand. In the Panel's view, the COVID-19 pandemic is relevant for Turkey's argument only to the extent that it provides a highly publicized example of worldwide short-term shortages of products (such as vaccines and other pharmaceutical products). The COVID-19 pandemic does not demonstrate, however, how over-reliance on imports of globally available pharmaceutical products can lead to long-term risks of shortage of these products, nor how occasional disruptions of supply of *some* pharmaceutical products can be indicative of a potential risk of disruption of supply of *all* pharmaceutical products.

7.180. In sum, Turkey asserts the existence of a risk without establishing any substantial degree of probability, such that the risk appears to be theoretical, abstract and hypothetical. In the Panel's view, the hypothetical and overly general nature of the alleged risk, as asserted by Turkey, casts serious doubt on Turkey's assertion that the localisation requirement was taken to protect against a future shortage of supply of safe, effective and affordable pharmaceutical products in Turkey.

7.181. The Panel recalls that to determine whether a challenged measure was taken to protect human, animal or plant life or health, a panel must examine all the evidence before it, which may include the text of the relevant legal instruments, the legislative history, and other evidence regarding the design, structure and expected operation of the challenged measure.⁶³¹ The Panel

⁶²⁷ The Panel notes that, in *India – Solar Cells*, the responding party likewise referred to currency fluctuations and the depreciation of the Indian rupee in the context of asserting possible risks of supply-side disruptions and related risks of overreliance on imported solar cells and modules. (Panel Report, *India – Solar Cells*, paras. 7.251-7.252.) In that case, the panel found it "significant that India has not identified any actual disruptions in imports of solar cells and modules to date, whether stemming from 'the unprecedented depreciation in [Indian rupee] in 2013' or otherwise". (Ibid. para. 7.262.)

⁶²⁸ As the European Union observes, "[e]xchange rate fluctuations are a common re-adjustment mechanism in responses to trade and capital imbalances. They affect all currencies, and not only the Turkish lira." (European Union's responses to the first set of questions, para. 56.)

⁶²⁹ Turkey's first written submission, paras. 486-487; second written submission, fn 236; responses to the first set of questions, para. 57; and opening statement, para. 76. According to Turkey, the COVID-19 pandemic "confirmed that an acute emergency such as a virus outbreak can quickly lead to dangerous medicine shortage" and "shows the risks of overreliance on imported pharmaceutical products". (Turkey's first written submission, para. 486.)

⁶³⁰ The parties appear to agree that the localisation requirement is not similar to the measures imposed by a number of countries in the context of the COVID-19 pandemic. (See European Union's responses to the second set of questions, paras. 24-33; Turkey's comments on responses to the second set of questions, para. 21.)

⁶³¹ See e.g., Panel Reports, *Indonesia – Import Licensing Regimes*, para. 7.620; *Brazil – Taxation*, para. 7.884; *China – Raw Materials*, para. 7.479; *China – Rare Earths*, para. 7.145; and *EC – Tariff Preferences*, para. 7.200 (referring to Appellate Body Reports, *Japan – Alcoholic Beverages II*, p. 29; *Argentina – Textiles and Apparel*, para. 55; and *US – Shrimp*, para. 137). See also Appellate Body Reports, *Colombia – Textiles*, para. 5.69 (referring to Appellate Body Reports, *US – Shrimp*, paras. 135-142; *EC – Seal Products*, para. 5.144) and *EC – Seal Products*, para. 5.144 (referring to Appellate Body Reports, *US – Tuna II (Mexico)*, para. 314 and *US – Gambling*, para. 304).

further recalls that such an enquiry has led some panels to conclude that the challenged measures were not designed to protect human, animal or plant life or health, and instead pursued other objectives.

7.182. For example, in *EC – Tariff Preferences*, the European Communities argued that certain tariff preferences given to 12 beneficiary countries were justified under Article XX(b) as measures necessary to protect human life or health, because the tariff preferences supported measures taken in those countries against the illicit production and trafficking of narcotic drugs, thereby reducing the supply of those drugs into its territory and protecting the life and health of EC citizens. The panel found that the tariff preferences were not designed to protect the life and health of EC citizens, based on, among other things, the fact that there was no mention of the asserted objective (protecting the life and health of EC citizens) in the text of the relevant instruments.⁶³²

7.183. In *China – Rare Earths*, China argued that its export duties on rare earths, tungsten, and molybdenum products were justified under Article XX(b), because they were "an integral part of a comprehensive policy that has the goal to reduce pollution and protect the health of China's population, its animals and plants".⁶³³ The panel found that the export duties were not taken to protect human, animal or plant life or health, based on, among other things, the fact that the Chinese instruments imposing the export duties made no link between the duties and any environmental or health objective.⁶³⁴

7.184. The Panel observes that most of the legal instruments putting into place the localisation requirement do not refer to a public health objective. To the extent that some of them do, such references are cast at a general level (as general policy objectives of the entire Turkish healthcare system) and are not linked with the localisation requirement or the declared objective of preventing a shortage of supply of safe, effective and affordable medicines arising from an over-reliance on imports.

7.185. The main legal instruments serving as a basis for the localisation requirement, as identified by the parties⁶³⁵, are the Tenth Development Plan 2014-2018⁶³⁶, the Structural Transformation Program for Healthcare Industries Action Plan⁶³⁷, and the 2016 Action Plan of the 64th Government.⁶³⁸

7.186. The Tenth Development Plan 2014-2018 does not relate the localisation requirement (or the main assessments and objectives from which the localisation requirement derives) to a public health objective. The Panel also notes that in the section describing "global trends and their impact on Turkey" in the Health and Social Security sector, the Tenth Development Plan 2014-2018 does not mention the existence of any risk of shortage of supply of safe, effective and affordable pharmaceuticals in Turkey, but only refers to an expected increase in health expenditures in Turkey "in parallel with the projected global rise".⁶³⁹

7.187. Among its objectives and policies, the Tenth Development Plan 2014-2018 identifies certain general "objectives and targets" related to the topic of "Health"⁶⁴⁰ (in Chapter 2.1, "Qualified People, Strong Society") and relates them to a series of policies (such as the implementation of a referral

⁶³² Panel Report, *EC – Tariff Preferences*, para. 7.201.

⁶³³ Panel Reports, *China – Rare Earths*, para. 7.157.

⁶³⁴ Panel Reports, *China – Rare Earths*, paras. 7.169-7.171.

⁶³⁵ See Turkey's first written submission, paras. 128 and 165; European Union's first written submission, paras. 37-42.

⁶³⁶ Tenth Development Plan 2014-2018 (Exhibit EU-12).

⁶³⁷ Ministry of Health and Ministry of Development, Structural Transformation Program for Healthcare Industries Action Plan, November 2014 (Structural Transformation Program for Healthcare Industries Action Plan) (Exhibits EU-14, TUR-37). Turkey submitted this document as a separate exhibit, arguing that "the translation provided by the European Union was inadequate". According to the exhibit provided by Turkey, the document is titled "Action Plan of Structural Transformation Program in Health Industry" (Exhibit TUR-37).

⁶³⁸ Republic of Turkey, Office of the Prime Minister, 2016 Action Plan of the 64th Government (Implementation and Reforms), 10 December 2015 (2016 Action Plan of the 64th Government) (Exhibit EU-15).

⁶³⁹ Tenth Development Plan 2014-2018 (Exhibit EU-12), para. 52.

⁶⁴⁰ Tenth Development Plan 2014-2018 (Exhibit EU-12), para. 172. These general objectives and targets do not refer specifically to a public health objective beyond the general description: "[i]ncreasing the quality of life and life span of the citizens and ensuring their participation to the economic, social and cultural life in a conscious, active and healthy manner is the main objective. For this purpose, accessible, qualified, cost-effective and sustainable health service delivery supported by data and evidence-based policies is essential."

system, increased awareness of health service providers and citizens, control of the quality and use of pharmaceuticals, clear defining of educational and research activities, determination of standards in the area of complementary medicine etc.).⁶⁴¹ The Panel finds it telling that none of these policies pertains to the localisation requirement. Rather, a reference to local production of pharmaceutical products appears in the description of policies related to the topic of "Transformation in the manufacturing industry" in a different Chapter of the Plan (Chapter 2.2, Innovative Production, High and Stable Growth).⁶⁴² This suggests that the premise of the localisation requirement is seen as part of an industrial policy objective and not as pursuing a public health objective.

7.188. The Tenth Development Plan 2014-2018 also contains a Healthcare Related Industries Structural Transformation Program (Section 1.16). In setting the "objective and scope of the program", it clarifies that "[b]y this program, the aim is transforming into a production structure which is capable to produce high value-added products, offer such products and services to global markets and meet a higher portion of domestic pharmaceutical and medical device demands."⁶⁴³ While the Plan thus relates the Healthcare Related Industries Structural Transformation Program to the objective of meeting a higher portion of domestic pharmaceutical demand through domestic production, it does not appear to relate this objective to concerns pertaining to public health, such as improving the safety or affordability of available medicines, or addressing a risk that domestic pharmaceutical demand may not be met by supply from the international market by imports. The Plan also identifies program targets, performance indicators and program components, none of which refer to an objective of ensuring access to safe, effective and affordable pharmaceutical products.

7.189. The Structural Transformation Program for Healthcare Industries Action Plan further develops the elements set out in the Tenth Development Plan 2014-2018. In particular, the program targets performance indicators and program components. The Panel finds it again telling that neither of these elements, nor the description of the Program, refer to the objective of ensuring access to safe, effective and affordable pharmaceutical products. Rather, the *Structural Transformation Program for Healthcare Industries Action Plan* appears to reproduce and build upon the industrial policy objective described in the *Tenth Development Plan*:

In the long haul, it is vital that Turkey becomes a global hub for R&D and production in medicines and that it reaches a competitive position in medicines and medical devices sector. The aim of this program is to switch to a production structure that is able to produce high added-value products; to place products and services to the global markets; and is capable of meeting a larger portion of domestic need for medicines and medical devices.⁶⁴⁴

7.190. The Action Plan of the 64th Government sets out a series of "reforms to be implemented within 3 months", including Action 46: "[t]o improve the reimbursement, pricing and licensing procedures for medical devices and strategic and domestic medicines" under the responsibility of the Ministry of Health.⁶⁴⁵ The description of Action 46 includes "speed[ing] up the evaluation process for including domestically manufactured healthcare products on the reimbursement list", the prompt licensing of "medicines for which an application has been lodged for production in Turkey", and the

⁶⁴¹ Tenth Development Plan 2014-2018 (Exhibit EU-12), paras. 173-182.

⁶⁴² Tenth Development Plan 2014-2018 (Exhibit EU-12), para. 669: "[p]harmaceuticals industry will attain a more competitive state in which; exports are higher, its internationally competent technology is integrated with R&D, necessary measures are taken to develop new molecules in the long run, and higher value added drugs, biotechnology and bio-similar products being the priority, are produced." See also *ibid.* para. 675: "[d]omestic capability in manufacturing and exporting will be improved in the medical devices and supplies industry."

⁶⁴³ Tenth Development Plan 2014-2018 (Exhibit EU-12), p. 180.

⁶⁴⁴ Structural Transformation Program for Healthcare Industries Action Plan (Exhibits EU-14, TUR-37), p. 1. In the translation provided by Turkey, this paragraph also does not make any reference to a public health objective: "[i]t is important for Turkey to be a global pharmaceutical R&D and production center in the field of pharmaceuticals and medical devices and to reach a competitive position in long term. With this program, it is aimed to introduce a production structure capable of producing high value-added products, providing products and services to global markets, and meeting a greater portion of the domestic pharmaceutical and medical device needs."

⁶⁴⁵ 2016 Action Plan of the 64th Government (Exhibit EU-15), Action 46.

exclusion of imported pharmaceutical products from the Annex 4/A list which "will be defined, provided that necessary assurance is obtained for provision of the treatment".⁶⁴⁶

7.191. Thus, the three main legal instruments serving as a basis for the localisation requirement strongly indicate that the localisation requirement was not conceived to pursue a public health objective (in particular, that of ensuring uninterrupted access to safe, effective and affordable medicines for all patients in Turkey) but rather appears to pursue an industrial policy objective. The few contemporaneous references to public health concerns that may be related to the objective of ensuring uninterrupted access to safe, effective and affordable medicines in Turkey, are made in the broader context of describing the general functions of Turkey's healthcare sector. By contrast, in those same documents, the premises and objectives of the localisation requirement appear in the context of industrial policy objectives.

7.192. Several Strategic Plans of the TMMDA were published at or around the time when the implementation of the localisation requirement began. The parties refer, in particular, to the Strategic Plans of the TMMDA for 2013-2017⁶⁴⁷, 2018-2022⁶⁴⁸, and 2019-2023.⁶⁴⁹ After a careful examination of each of these Strategic Plans of the TMMDA, the Panel notes that none of these provides any further indication that the localisation requirement pursues a public health objective by contemporaneously referring to the objective of ensuring uninterrupted access to safe, effective and affordable medicines for all patients in Turkey.

7.193. With respect to the Strategic Plan of the TMMDA for 2013-2017, the Panel takes note of Turkey's explanation that this plan links, through a correlation matrix, the localisation objectives included in the Tenth Development Plan 2014-2018 with the TMMDA's strategic actions. However, the Panel notes that: (i) each of the objectives included in the Tenth Development Plan (2014-2018) appearing in the excerpt provided by Turkey is generally related to one or more of three TMMDA objectives ("to provide access to quality, effective and safe products", "to take the necessary measures to minimize risks and raise awareness to ensure the correct use of products", and "to provide corporate excellence"); and (ii) the policies pertaining to the localisation requirement are linked to all three TMMDA objectives. If the correlation matrix were indicative of the objective pursued by each measure, this would lead to the conclusion that any measure, whose implementation involves the TMMDA or the SSI, would necessarily be characterized as a measure designed to protect human health within the meaning of Article XX(b) of the GATT 1994 merely because its implementation involves the TMMDA or the SSI.

7.194. The Strategic Plan of the TMMDA for 2018-2022 refers to the objective of "protecting public health" which "is possible with the presence of a strong pharmaceutical industry". This mention is followed by the statement that "[r]ather than making very important contributions in terms of economic development, the country should have a pharmaceutical sector capable of producing to meet the medicine needs of the country against factors such as war, epidemic diseases and a possible embargo."⁶⁵⁰ The Panel observes that this statement links the development of the domestic pharmaceutical industry to avoiding shortages, and is thus broadly consistent with Turkey's assertion that the localisation requirement was adopted to ensure an uninterrupted access to safe, effective and affordable pharmaceutical products for all patients in Turkey. However, the factors referred to ("war, epidemic diseases and a possible embargo") do not align to the specific factors that Turkey refers to as the basis for the asserted risk of over-reliance on imports⁶⁵¹, and are generic factors that could be invoked to support self-sufficiency arguments, and industrial policy measures, in virtually any sector of the economy. In addition, the Strategic Plan of the TMMDA for 2018-2022

⁶⁴⁶ 2016 Action Plan of the 64th Government (Exhibit EU-15), Action 46.

⁶⁴⁷ Ministry of Health, Strategic Plan of TMMDA for 2013-2017, 12 December 2013 (Exhibit TUR-77).

⁶⁴⁸ Ministry of Health, Strategic Plan of TMMDA for 2018-2022, 11 October 2018 (Exhibit TUR-38).

⁶⁴⁹ Ministry of Health, Strategic Plan of TMMDA for 2019-2023, 31 December 2018 (Exhibits EU-87, TUR-35).

⁶⁵⁰ Ministry of Health, Strategic Plan of TMMDA for 2018-2022, 11 October 2018 (Exhibit TUR-38), pp. 74-76.

⁶⁵¹ The Panel recalls that, according to Turkey, its over-reliance on imported pharmaceutical products creates that risk because of several prevailing economic circumstances relating to the cost of imported pharmaceutical products in Turkey, including most notably that: (i) the low prices of pharmaceutical products on the Turkish market create the risk that foreign pharmaceutical producers might decide to supply other countries where they can receive a higher price for their products, instead of Turkey; and (ii) imported pharmaceutical products may become unaffordable to the SSI if a foreign currency gains in value or the Turkish lira depreciates.

refers to the concept of public health in the context of describing a largely industrial policy objective: "[i]n long term, it is expected that Turkey will be a global pharmaceutical R&D and production center and reach a competitive position in the field of pharmaceuticals and medical devices."⁶⁵²

7.195. The Strategic Plan of the TMMDA for 2019-2023 lists three aims, each further elaborated upon with the addition of "goals" and "performance indicators". The goals and performance indicators for "Aim 1: providing access to quality, effective, and safe products" do not contain any mention of the localisation requirement. In fact, localisation appears as a separate component of "Aim 3: priority evaluation of applications for the public health and country economy, support of R & D *and domestic production in health*".⁶⁵³ The Panel considers that this further confirms that the localisation requirement does not pursue a public health objective but rather an industrial policy objective.

7.196. Turkey also refers to a Strategic Plan 2019-2023 of the Ministry of Health.⁶⁵⁴ The sixth aim identified in this plan is "[t]o contribute to the socioeconomic development of our country and global health; developing national technology and increasing domestic production in healthcare industries".⁶⁵⁵ The Panel disagrees with Turkey's explanation that two out of the four main components of that aim "explicitly refer to the connection between 'ensuring the accessibility, safety and rational use of medicines, biological products and medical devices' and the localisation measure".⁶⁵⁶ Rather, the Panel observes that the first of these components refers to a general objective of "ensuring the accessibility, safety and rational use of medicines, biological products and medical devices" without reference to localisation, and the second of these components is "[p]romoting R&D and innovation in health, ensuring nationalization and localization, increasing exports". Rather than a "connection", as suggested by Turkey, the coexistence of these two components implies – at most – that both form part of the overarching objective of contributing to the socioeconomic development of the country and global health. The Panel does not find that this conclusively shows that the localisation requirement has a "public health objective" as argued by Turkey.

7.197. In addition to the Strategic Plans of the Ministry of Health and the TMMDA, Turkey refers to several TMMDA Administrative Operation and Activity Reports. An analysis of these reports confirms the Panel's initial assessment that the documents pertaining to the implementation of the localisation requirement do not contain any indication of a public health objective underpinning the localisation requirement. For instance, the *2016 TMMDA Activity Report* refers to the goal of "increasing domestic production in the field of pharmaceuticals and medical devices with the sustainability of the quality we achieve in healthcare" and an engagement to "move to a production structure that can produce high value-added products in pharmaceuticals and medical devices, offer products and services to global markets, and meet a greater portion of the domestic pharmaceutical and medical device needs", without any connection to the objective of protecting public health.⁶⁵⁷ The Panel disagrees with Turkey's assessment that the 2018 TMMDA Activity Report⁶⁵⁸ and the 2019 TMMDA Activity Report⁶⁵⁹ "indicate that the objective of local production of pharmaceutical products lies in its

⁶⁵² Ministry of Health, Strategic Plan of TMMDA for 2018-2022, 11 October 2018 (Exhibit TUR-38), pp. 74-76.

⁶⁵³ Ministry of Health, Strategic Plan of TMMDA for 2019-2023, 31 December 2018 (Exhibits EU-87, TUR-35), Aim 3. (emphasis added)

⁶⁵⁴ Ministry of Health, Strategic Plan 2019-2023 (Exhibit TUR-34).

⁶⁵⁵ Ministry of Health, Strategic Plan 2019-2023 (Exhibit TUR-34), p. 15.

⁶⁵⁶ Turkey's first written submission, para. 457.

⁶⁵⁷ Ministry of Health, TMMDA, Administrative Activity Report 2016, February 2017 (2016 TMMDA Activity Report) (Exhibits EU-99, TUR-36), pp. 1, 86-87. The 2017 TMMDA Activity Report similarly describes the localisation requirement as follows: "In the Tenth Development Action Plan, it is envisaged to carry out actions that will encourage the pharmaceutical and medical device industry to domestic production. With these actions, domestic production will be encouraged in our country and the domestic producer will have a competitive structure. Thus, contribution will be made in the pharmaceutical and medical device sectors to bring the domestic production to a level that meets the country's needs. With the Tenth Development Plan 1.16 within the scope of the Structural Transformation Program in Health Industries, it is envisaged to increase the efficiency of global value chains by increasing the domestic production capacity in the mid-term, developing the R&D and enterprise ecosystem, developing a new molecule in the long term, producing higher value added medicines and medical devices." (Ministry of Health, TMMDA Administrative Operation Report 2017, February 2018 (2017 TMMDA Activity Report) (Exhibit TUR-80), p. 95).

⁶⁵⁸ Ministry of Health, TMMDA Administrative Operation Report 2018, February 2019 (2018 TMMDA Activity Report) (Exhibit TUR-79).

⁶⁵⁹ Ministry of Health, TMMDA Administrative Operation Report 2019, February 2020 (2019 TMMDA Activity Report) (Exhibit TUR-78).

contribution to public health and the country's economy".⁶⁶⁰ The Panel finds it hard to derive such a conclusion from the mere fact that, as described above, one of the aims pursued by the TMMDA is described as "priority evaluation of applications for the public health and country economy, support of R & D and domestic production in health".

7.198. Having analysed the evidence before it, the Panel concludes that the documents pertaining to the implementation of the localisation requirement do not contain any contemporaneous references to a public health objective that could support the argument that the localisation requirement is a measure taken to protect human health or life. The Panel notes, in particular, that: (i) some of these documents do not mention a public health objective at all; (ii) some of the documents that mention a public health objective do not relate this objective to the localisation requirement, but rather describe the localisation requirement within the context of industrial policy objectives; (iii) some of the documents that mention a public health objective, do so in relation to broader policy considerations (i.e. pertaining to the general functions of Turkey's healthcare system, or to health as an element of general societal values), and not in relation to the localisation requirement; and (iv) some of the documents that mention the potential effects of increased local production of pharmaceuticals on public health, appear to consider these effects not as an objective of the localisation requirement, but rather as a potential positive by-product, as a result of the improved performance of Turkey's domestic pharmaceutical industry.

7.199. In the Panel's view, this demonstrates the Turkish government's ongoing aim to improve the performance of Turkey's domestic pharmaceutical industry, in particular with respect to its meeting a higher share of domestic demand for pharmaceutical products. However, beyond the general assertion that such an improved performance of the domestic pharmaceutical industry could be beneficial for public health, the documents pertaining to the implementation of the localisation requirement do not seem to relate this objective to specific public health concerns such as improving the safety or affordability of available pharmaceutical products, or addressing a risk that domestic pharmaceutical demand may not be met by supply from the international market.

7.200. In the Panel's view, this casts further doubt on Turkey's assertion that the localisation requirement was taken to protect against a future shortage of supply of safe, effective and affordable pharmaceutical products in Turkey.

7.201. The Panel's view is further reinforced by the fact that the objective of the localisation requirement, as it appears in several documents, has no rational relationship to the invoked objective of ensuring a continuous supply of safe, effective and affordable pharmaceutical products.

7.202. The Tenth Development Plan (2014-2018) sets, as one of the two programme targets for the Healthcare Industries Structural Transformation Program (Section 1.16), the aim of "meeting 60 percent (by value) of domestic pharmaceutical demand by domestic production".⁶⁶¹ The Structural Transformation Program for Healthcare Industries Action Plan⁶⁶², as well as several other documents related to the implementation of the localisation requirement, reiterate this objective.⁶⁶³ The Panel considers it clear from these documents that the localisation requirement, as one of the measures put in place to implement the Tenth Development Plan (2014-2018), also pursues the objective of meeting 60% of domestic pharmaceutical demand by domestic production.⁶⁶⁴

⁶⁶⁰ Turkey's first written submission, para. 461.

⁶⁶¹ The other program target is "[m]eeting 20 percent of the domestic medical devices and supplies demand by domestic production". (Tenth Development Plan 2014-2018) (Exhibit EU-12), p. 180.) It appears that, as of 2018/2019, approximately 40% of domestic pharmaceutical demand was met by domestic production (see Ministry of Development, Eleventh Development Plan 2019-2023 (Exhibit EU-84), Section 2.3.5; A. Yücel, "Foreign investments will be [like] medicine!", *Dünya*, 30 July 2019 (Exhibit EU-19), p. 4).

⁶⁶² Structural Transformation Program for Healthcare Industries Action Plan (Exhibits EU-14, TUR-37), p. 1.

⁶⁶³ See, for instance, Ministry of Health, Strategic Plan of TMMDA for 2013-2017, 12 December 2013 (Exhibit TUR-77), pp. 91-93. For further reference, see also H. GURSOZ, President of the TMMDA, "Pharmaceutical Localisation Project: Transition from Importation to Manufacturing", presentation of 6 March 2017 (Exhibit EU-34), slide 1; TMMDA, "Pharmaceutical Localisation Project Work Conducted by the Ministry of Health", presentation of December 2017 (Exhibit EU-23), slide 1.

⁶⁶⁴ Turkey argues that the 60% target mentioned in the Tenth Development Plan (2014-2018) is "an overarching objective which does not exclusively relate to the localisation measure" (Turkey's responses to the second set of questions, para. 72). However, the Panel recalls that Turkey identified the Tenth Development

7.203. The Panel agrees with Turkey that "each WTO Member has the right to set its own objectives for developing its pharmaceutical sector in order to ensure access to safe, effective and affordable medicines in line with the sustainable development goals"⁶⁶⁵, and understands that Turkey has set its own objective of meeting 60% of domestic pharmaceutical demand through domestic production. However, the Panel disagrees with Turkey to the extent that Turkey appears to suggest that any objective set by a WTO Member for developing its pharmaceutical sector is automatically or necessarily set "in order to ensure access to safe, effective and affordable medicines in line with the sustainable development goals". To the contrary, in the Panel's view, a measure adopted in pursuit of developing a WTO Member's pharmaceutical sector could only be seen as having a public health objective if there is a rational relationship between the objective set by that WTO Member for developing its pharmaceutical sector and the specific public health objective invoked.

7.204. The Panel does not see such a rational relationship between the localisation requirement's stated objective of increasing domestic production from meeting 40% to covering 60% of domestic demand, and the declared objective of ensuring a continuous supply of safe, effective and affordable pharmaceutical products. This is because: (i) it remains unclear from Turkey's arguments and the evidence before the Panel how the target of meeting 60% of domestic demand by domestic production relates to ensuring continuous supply of safe, effective and affordable pharmaceutical products; (ii) this target is set simply in terms of the total sales value of the total domestic demand for medicines; and (iii) the performance indicators for this target do not appear to be related to the objective of ensuring a continuous supply of safe, effective and affordable pharmaceutical products.

7.205. Turkey has provided no explanation as to why and how the localisation requirement's stated objective of specifically meeting 60% of domestic demand through domestic production (rather than, for instance, maintaining the current figure of 40%, or setting a higher target of 100%) relates to ensuring a continuous supply of safe, effective and affordable pharmaceutical products.⁶⁶⁶ The various legal instruments related to the implementation of the localisation requirement do not provide further clarity. The Panel observes that the program targets for the Healthcare Industries Structural Transformation Program (Section 1.16) are set in terms of increasing the share of domestic production similar to those used for other programs that pursue an industrial policy objective⁶⁶⁷, whereas the program targets for other programmes are set in terms that have a much clearer relationship with the objective of improving public health.⁶⁶⁸

Plan (2014-2018) as one of the "high-level policy documents which paved the way for the localisation measure" and specified that the localisation requirement "encourages local production and implements the Tenth Development Plan" (Turkey's first written submission, paras. 165 and 555). The Tenth Development Plan (2014-2018) refers to the fact of meeting 60% of domestic pharmaceutical demand by domestic production as a "program target". (Tenth Development Plan 2014-2018 (Exhibit EU-12), p. 180.) Since the localisation requirement implements the Tenth Development Plan (2014-2018), the Panel finds it logical to conclude that the localisation requirement pursues the program targets set in the Tenth Development Plan (2014-2018). Turkey also explains that it has considered it sufficient for domestic production to account for 60% of the domestic pharmaceutical market, making domestic production a "safety cushion" without eliminating imports of medicines (i.e. having 100% domestic production). (Turkey's responses to the second set of questions, para. 65.) The European Union disagrees that the 60% target is a "safety cushion" and argues that it is "rather an objective of Turkey's industrial and economic development policy". (European Union's comments on responses to the second set of questions, para. 61.) Whether or not the 60% target is a "safety cushion", it is clear from the evidence, and undisputed by Turkey, that the 60% target is one of the program targets set by the Tenth Development Plan (2014-2018) and pursued by the localisation requirement.

⁶⁶⁵ Turkey's responses to the second set of questions, para. 68.

⁶⁶⁶ Turkey only explains that it has considered "that it is sufficient for the domestic production to account for 60% of the medicine market" and relates this choice to "a factual assessment of Turkey's chosen level of protection and the expected operation of the measure at issue". (Turkey's responses to the first set of questions, para. 65; responses to the second set of questions, para. 69.)

⁶⁶⁷ For instance, the program targets for "Domestic resource based energy production program" (Section 1.13), include "[i]ncreasing the share of domestic resources, including domestic and international oil and natural gas drillings, in primary energy production to 35 percent at the end of 2018 which was 28 percent at the end of 2011" and "[i]ncreasing electricity generation from domestic coal sources to 60 billion kWh in 2018 which was approximately 39 billion kWh in 2012" (Tenth Development Plan 2014-2018) (Exhibit EU-12), p. 174). The "Domestic resource based energy production program" clearly refers to industrial policy and economic development objectives such as "[t]o establish high and stable growth in Turkish economy, utilization of all possible domestic resources in energy production". (Ibid. p. 174.)

⁶⁶⁸ For instance, the program targets for "Healthy life and mobility program" (Section 1.21) include "[r]educing the rate of deaths from non-communicable diseases" or "[r]educing the ratio of obese people among 19+ population to 24 percent." (Tenth Development Plan 2014-2018) (Exhibit EU-12), p. 190.)

7.206. The Panel also finds it telling that the 60% figure relates to the share of locally produced pharmaceutical products in terms of sales value of the total domestic demand for medicines.⁶⁶⁹ This reference to sales value rather than to other metrics, such as the range of medicines produced domestically, or the geographic or demographic coverage of demand in Turkey, suggests that the localisation requirement's stated objective pertains exclusively to industrial policy and cannot be related to the invoked objective of ensuring access to safe, effective and affordable pharmaceutical products.⁶⁷⁰

7.207. The Panel's conclusion that the localisation requirement's stated objective of meeting 60% of domestic demand through domestic production has no rational relationship to Turkey's declared objective of ensuring access to safe, effective and affordable pharmaceutical products is further confirmed by the performance indicators set in the Tenth Development Plan (2014-2018) and the Structural Transformation Program for Healthcare Industries Action Plan. These include, among other things, indicators such as "ratio of exports to imports", "number of companies producing medical devices in Turkey", "number of employees in the pharmaceutical industry"⁶⁷¹ or "capacity utilization rate"⁶⁷², and do not include any indicators related to Turkey's invoked objective of ensuring a continuous supply of safe, effective and affordable pharmaceutical products. The inclusion of a performance indicator related to the "ratio of exports to imports" appears particularly at odds with the pursuit of an objective of ensuring a continuous supply of pharmaceutical products *in Turkey*.⁶⁷³ The Panel is not convinced by Turkey's explanation that "in order to guarantee uninterrupted access to medicines in Turkey, it is important for the domestic pharmaceutical industry to be also capable to export medicines to other countries".⁶⁷⁴ In the Panel's view, there is an inherent contradiction between the declared objective of ensuring a continuous supply of safe, effective and affordable products in a particular market and encouraging domestic producers in that market to increase their export performance.⁶⁷⁵

7.208. For these reasons, the Panel is of the view that the stated objective of the localisation requirement, i.e. meeting 60% (by value) of domestic pharmaceutical demand by domestic production, has no rational relationship to the objective invoked by Turkey in this dispute, i.e. ensuring a continuous supply of safe, effective and affordable pharmaceutical products. This is a further indication that the localisation requirement is not a measure taken to protect human life or health.

7.209. The Panel is aware that the COVID-19 pandemic has prompted many WTO Members to consider increasing their local production of certain pharmaceutical products to mitigate against risks of disruptions in global supply chains in respect of essential medicines (including the raw materials needed to produce them).⁶⁷⁶ The Panel is also cognizant of the growing consensus within the

⁶⁶⁹ Turkey's responses to the second set of questions, para. 72.

⁶⁷⁰ The Panel notes the European Union's argument that "the use of such metric is designed to promote the localization of relatively more expensive medicines, regardless of their therapeutic uses or availability" and that "[i]f the Localization Requirement was genuinely designed to secure access to medicines, its 'target' would rather be defined in other metrics related to the range of medicines produced domestically, and their relative importance in light of that objective, having regard to relevant factors such as their therapeutic uses, consumption needs, and their availability on the international markets." (European Union's comments on responses to the second set of questions, paras. 65-66.)

⁶⁷¹ Tenth Development Plan 2014-2018 (Exhibit EU-12), p. 180.

⁶⁷² Structural Transformation Program for Healthcare Industries Action Plan (Exhibits EU-14, TUR-37), p. 2.

⁶⁷³ The Panel appreciates Turkey's explanation that "this performance indicator is not designed to measure the effectiveness of the localization measure with respect to meeting its public health objective" (Turkey's responses to first set of questions, para. 66), i.e. Turkey's invoked objective in this dispute. However, this performance indicator is clearly designed to measure the effectiveness of the localisation requirement with respect to the program target of meeting 60% of domestic pharmaceutical demand by domestic production, i.e. the localisation requirement's *stated objective*. For that reason, the Panel finds the inclusion of this performance indicator indicative of the expected outcomes of the localisation requirement, and – indirectly – of the potential existence, or lack, of a rational relationship between the stated objective and the invoked objective.

⁶⁷⁴ Turkey's responses to the first set of questions, para. 67.

⁶⁷⁵ According to the Structural Transformation Program for Healthcare Industries Action Plan, the ratio of exports to imports was expected to increase from 18.2% in 2013 to 29.3% in 2018. (Structural Transformation Program for Healthcare Industries Action Plan) (Exhibits EU-14, TUR-37), p. 2.)

⁶⁷⁶ Turkey states that "the need for local production of pharmaceutical products has been officially endorsed by several countries, including some of the European Union Members States. French President Emanuel Macron stated that '[t]his crisis teaches us that on some goods, materials, the strategic character

international community that the local production of medicines can provide for greater sustainability of supply chains, especially in public health emergencies. This growing consensus finds reflection in, among other things, the May 2021 resolution adopted by the Member States of the WHO on "Strengthening local production of medicines and other health technologies to improve access".⁶⁷⁷ The Panel, taking into account the current context of the COVID-19 pandemic, does not question that various risks of disruptions in global pharmaceutical supply chains exist; that there is a range of measures that countries have been encouraged to take to mitigate such risks and, more generally, to promote the sustainability of supply chains; and that these may include measures to strengthen the local production of pharmaceuticals.

7.210. However, it does not logically follow from this that any measure taken by a WTO Member to increase its local production of pharmaceutical products must be deemed to have been taken for the purpose of protecting human life or health. In this case, the Panel's analysis of the evidence before it relating to Turkey's localisation requirement, implemented in 2016, leads it to conclude that Turkey has not discharged its burden of demonstrating that the localisation requirement is a measure taken to protect against a risk of long-term shortage of supply of safe, effective and affordable pharmaceutical products in Turkey. First, Turkey has not identified any instance of shortage of supply of a specific product caused by the factors that it asserts create the alleged risk, namely foreign producers deciding to stop supplying pharmaceutical products to Turkey and to instead sell in other countries where they can receive a higher price for their products, or a pharmaceutical product becoming unaffordable to the SSI because of a foreign currency gaining in value or the Turkish lira depreciating. Second, the documents pertaining to the implementation of the localisation requirement do not contain any contemporaneous references to the specific risk and objective invoked by Turkey. Third, there is no rational relationship between the localisation requirement's stated objective of meeting 60% (by value) of domestic pharmaceutical demand through domestic production and the objective of ensuring a continuous supply of safe, effective and affordable pharmaceutical products.

7.211. For these reasons, the Panel finds that Turkey has not demonstrated that the localisation requirement is a measure taken to protect human, animal or plant life or health within the meaning of Article XX(b).

7.4.2.3.3 Remaining elements under Article XX(b)

7.212. The Panel has found that the localisation requirement is not a measure taken to protect human, animal or plant life or health. This is a threshold legal element that must be satisfied for a measure to be covered by the exception of Article XX(b)⁶⁷⁸, because there can be no justification under Article XX(b) for a measure that is not "designed" to protect human, animal or plant life or

imposes having a European sovereignty, produce more on the national territory to reduce our dependence and equip us over the long run. [...] Our priority today is to produce more in France and to produce more in Europe'. Similarly, the German Economy Minister Peter Altmaier called for an EU-wide initiative to reshore pharmaceutical production. The same was recognised by the EU Health Commissioner Stella Kyriakides, according to whom, 'it has become abundantly clear that we need to work towards the need for increasing the production of medicines and innovation within the EU'. In a similar vein, the Pharmaceutical Committee of the European Commission's Health and Food Safety Directorate-General stated that it was 'concerned that [the EU's] dependency on imports of APIs and chemical raw materials will put increasingly at risk the supply of certain essential medicines and threaten the EU's strategic autonomy. The recent outbreak of COVID-19 shows that a disruption of supply from India and China in the pharmaceutical value chain could present a major health security issue'". (Turkey's first written submission, para. 487, referring to Rym Momtaz, "Macron urges massive increase in local production of medical equipment", *Politico*, 31 March 2020 (Exhibit TUR-31); Jakob Hanke Vela, "Germany wants to reshore pharma production from Asia", *Politico*, 13 March 2020 (Exhibit TUR-95); "Commission aims to bring back medicine production to Europe", *Euractiv*, 22 April 2020, (Exhibit TUR-30); Jim Brunnsden and Michael Peel, "Covid-19 exposes EU's reliance on drug imports", *Financial Times*, 20 April 2020 (Exhibit TUR-96); European Commission, Health and Food Safety Directorate-General, Pharmaceutical Committee, *Dependency of the EU pharmaceutical industry on active pharmaceutical ingredients and chemical raw materials imported from third countries*, 12 March 2020 (Exhibit TUR-97).

⁶⁷⁷ Seventy-Fourth World Health Assembly, 25 May 2021, A74/A/CONF./1. This resolution was initially proposed by Ethiopia (on behalf of the African Group) and co-sponsored by the US, EU member States and many other developing and developed countries.

⁶⁷⁸ See Appellate Body Report, *Colombia – Textiles*, para. 5.68.

health.⁶⁷⁹ The localisation requirement fails to meet this threshold. Accordingly, the Panel need not assess the remaining legal elements of Article XX(b) to determine the applicability of this exception.

7.213. Since the localisation requirement does not fall under Article XX(b) and is thus not provisionally justified under this subparagraph, it is also not necessary for the Panel to assess whether the localisation requirement has been applied consistently with the requirements of the chapeau of Article XX.⁶⁸⁰

7.214. In the circumstances of this dispute, the Panel also sees no compelling reason to make additional findings or observations beyond those necessary to resolve the claims and defences at issue. Accordingly, it is unnecessary to make findings on the disputed issues that arise in respect of the remaining elements under Article XX(b).

7.4.3 Turkey's alternative defence under Article XX(d) of the GATT 1994

7.215. Article XX(d) of the GATT 1994 provides:

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any Member of measures:

...

(d) necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those relating to customs enforcement, the enforcement of monopolies operated under paragraph 4 of Article II and Article XVII, the protection of patents, trade marks and copyrights, and the prevention of deceptive practices;

7.216. Turkey submits that if the Panel finds that the localisation requirement is not justified under Article XX(b), then, in the alternative, it is justified under Article XX(d) of the GATT 1994 as a measure necessary to secure compliance with laws and regulations that are not inconsistent with the GATT 1994. According to Turkey, the localisation requirement is necessary to secure compliance with the laws and regulations requiring Turkey to ensure "accessible, effective and financially sustainable healthcare".⁶⁸¹

7.217. The Panel notes that Turkey's argument under Article XX(d) is substantially the same as its argument under Article XX(b). More specifically, Turkey submits that the localisation measure is designed to secure compliance with the obligation to ensure accessible, effective, and financially sustainable healthcare.⁶⁸² Turkey states that to meet its obligation to provide adequate healthcare to its population, Turkey needs to ensure that its healthcare system is sustainable, and to maintain the broad coverage of that system, Turkey regulates the prices of medicines available on the market. This, in turn, "leads to a risk of a shortage of supply when the prices are considered by the pharmaceutical companies as too low".⁶⁸³ The localisation requirement "aims to address that risk by ensuring the continuous availability of the medicines without undermining the financial balance of

⁶⁷⁹ See Appellate Body Reports, *Colombia – Textiles*, para. 5.68; *Argentina – Financial Services*, para. 6.203, and *Mexico – Taxes on Soft Drinks*, para. 72.

⁶⁸⁰ Prior WTO adjudicators have traditionally refrained from assessing for conformity with the chapeau of Article XX measures that they have found not to be provisionally justified. See e.g. Panel Reports, *US – Tariff Measures (China)*, para. 7.242; *India – Solar Cells*, paras. 7.389-7.390; *China – Publications and Audiovisual Products*, para. 7.912; and *Colombia – Ports of Entry*, para. 7.620. See also Appellate Body Reports, *India – Solar Cells*, para. 5.155; and *China – Publications and Audiovisual Products*, fn 614.

⁶⁸¹ Turkey's first written submission, para. 504.

⁶⁸² Turkey's first written submission, paras. 540-548. In its first written submission, Turkey addresses the "designed to" element of the test as an element of whether the measure is "necessary", and not as a threshold analytical issue.

⁶⁸³ Turkey's first written submission, para. 547.

the healthcare system".⁶⁸⁴ In responding to this argument, the European Union reiterates the same arguments that it makes in the context of the "designed to" step in Article XX(b).⁶⁸⁵

7.218. While Turkey presents two separate defences for the localisation requirement under Articles XX(b) and (d) of the GATT 1994, the essence of Turkey's arguments is that the measure is justified under Article XX(b) because it is necessary to ensure uninterrupted access to safe, effective and affordable medicines in Turkey; and under Article XX(d) because it is necessary to secure compliance with laws requiring Turkey to ensure accessible, effective and financially sustainable healthcare. Given the overlap, the Panel considers that its assessment under Article XX(b) extends *mutatis mutandis* to the analysis of the defence under Article XX(d). Thus, even assuming, for the sake of argument, that Article XX(d) could be interpreted as covering measures taken by a government to secure its *own* compliance with its laws or regulations, which is an interpretative issue the Panel considers unnecessary to resolve⁶⁸⁶, it follows from the Panel's assessment of the evidence under Article XX(b) that Turkey has failed to demonstrate that the localisation requirement was taken to secure compliance with laws requiring Turkey to ensure "accessible, effective and financially sustainable healthcare" for its population.

7.4.4 Conclusion

7.219. The Panel concludes that Turkey has not established that the localisation requirement is justified under Article XX(b) or Article XX(d) of the GATT 1994.

7.5 Additional claims relating to the localisation requirement and the "import ban on localised products"

7.5.1 Introduction

7.220. The Panel has found that (i) the localisation requirement is not covered by the government procurement derogation in Article III:8(a) of the GATT 1994, (ii) it is inconsistent with the national treatment obligation in Article III:4 of the GATT 1994, and (iii) Turkey has not established that the measure is necessary for the protection of human life or health under Article XX(b) of the GATT 1994 or to secure compliance with laws and regulations under Article XX(d) of the GATT 1994. The Panel now turns to the European Union's additional claims relating to the localisation requirement and the "import ban on localised products". While these claims raise distinct issues of fact and legal interpretation, each claim is the subject of a request, by at least one of the parties, that the Panel not rule on it for reasons related to considerations of judicial economy.

7.221. First, the European Union claims that the reimbursement scheme operated by the Turkish social security system involves the granting of a subsidy within the meaning of Article 1.1 of the SCM Agreement, and that the localisation requirement makes the granting of that subsidy contingent upon the use of domestic over imported goods, thereby violating Article 3.1(b) of the SCM Agreement. The European Union presents this as an alternative and conditional claim, requesting the Panel to rule on this claim only if the Panel were to conclude that the localisation requirement is not in breach of Article III:4 of the GATT 1994, or that such breach is justified under any other provision of the GATT 1994.⁶⁸⁷ Turkey does not comment on the alternative and conditional nature of the European Union's claim under Article 3.1(b).

7.222. Second, the European Union claims that the localisation requirement, in addition to being inconsistent with Article III:4 of the GATT 1994, is inconsistent with Article 2.1 of the TRIMs Agreement because it constitutes an "investment measure related to trade in goods" that is inconsistent with Article III:4 of GATT 1994. Turkey submits that if the Panel were to uphold the

⁶⁸⁴ Turkey's first written submission, para. 547.

⁶⁸⁵ European Union's second written submission, paras. 203-206.

⁶⁸⁶ The responding party in *India – Solar Cells* adopted a similar interpretation of the exception in Article XX(d). The complaining party in that case argued that Article XX(d) does not apply to measures taken to secure a government's own compliance with its laws and regulations, on the basis that the wording of Article XX(d), including the terms "secure compliance" and "enforce", "strongly suggest that the actor doing the enforcing is distinct from the object(s) subject to enforcement". The panel considered it unnecessary to resolve that issue. (Panel Report, *India – Solar Cells*, paras. 7.324 and 7.329.)

⁶⁸⁷ European Union's first written submission, para. 279; second written submission, para. 232.

European Union's claim under Article III:4 of the GATT 1994, then it would not be necessary for the Panel to also rule on the claim under Article 2.1 of the TRIMs Agreement.⁶⁸⁸

7.223. Third, the European Union claims that Turkey has acted inconsistently with its obligations under Article X:1 of GATT 1994 by failing to publish certain elements, terms and conditions of general application of the localisation requirement promptly, in such a manner as to enable governments and traders to become acquainted with them. Turkey argues that if the Panel were to conclude that the localisation requirement is inconsistent with Article III:4 of the GATT 1994, it would not be necessary for the Panel to also rule on the European Union's claim under Article X:1 of the GATT 1994.⁶⁸⁹

7.224. Fourth, the European Union claims that the measure it refers to as "the import ban on localised products" is inconsistent with Turkey's obligations under Article XI:1 of GATT 1994. Turkey argues that if the Panel were to conclude that the localisation requirement is inconsistent with Article III:4 of the GATT 1994, then one of the components of the "import ban" as defined by the European Union would disappear, such that it would be unnecessary that the Panel additionally rule on that alleged measure.⁶⁹⁰

7.5.2 Article 3.1(b) of the SCM Agreement

7.225. Article 1 of the SCM Agreement, entitled "Definition of a Subsidy", provides that a subsidy shall be deemed to exist if there is a financial contribution by a government or any public body within the territory of a Member (Article 1.1(a)(1)), and a "benefit" is thereby conferred (Article 1.1(b)). Article 1 sets forth an exhaustive list of what constitutes a "financial contribution". This list provides that a financial contribution exists, inter alia, where a government practice involves a "direct transfer of funds" (Article 1.1(a)(1)(i)), where a government "provides goods" (Article 1.1(a)(1)(iii)), and where a government "entrusts or directs a private body to carry out" those or other functions listed in Articles 1.1(a)(1)(i), (ii), or (iii) (Article 1.1(a)(1)(iv)).

7.226. Article 3 of the SCM Agreement, entitled "Prohibited Subsidies", establishes two categories of subsidies that Members are prohibited from granting or maintaining. The first category is subsidies contingent on export performance (Article 3.1(a)), which is not at issue in this dispute. The second category is "subsidies contingent, whether solely or as one of several other conditions, upon the use of domestic over imported goods" (Article 3.1(b)).

7.227. The European Union claims that the reimbursement scheme operated by the Turkish social security system involves the granting of a subsidy within the meaning of Article 1.1 of the SCM Agreement, and that the localisation requirement makes the granting of that subsidy contingent upon the use of domestic over imported goods, thereby violating Article 3.1(b) of the SCM Agreement.⁶⁹¹ Specifically, the European Union argues that: (i) there is a financial contribution in the form of a "direct transfer of funds", from the SSI to the pharmacies, within the meaning of Article 1.1(a)(1)(i)⁶⁹²; (ii) this financial contribution confers a direct "benefit", within the meaning of Article 1.1(b) of the SCM Agreement to the outpatients who receive the pharmaceutical products covered by the reimbursement scheme and, as a result, also an indirect benefit to the Turkish

⁶⁸⁸ Turkey's comments on responses to the second set of questions, para. 17.

⁶⁸⁹ Turkey's responses to the second set of questions, para. 84.

⁶⁹⁰ Turkey's responses to the second set of questions, para. 86.

⁶⁹¹ European Union's first written submission, paras. 278-299; second written submission, paras. 231-269; responses to the first set of questions, paras. 64-71; responses to the second set of questions, paras. 62-82; comments on responses to the second set of questions, paras. 67-79.

⁶⁹² The Panel notes that the European Union makes an additional and conditional argument, in the alternative, regarding the existence of a financial contribution in the form of "entrustment" or "direction" under Article 1.1(a)(1)(iv) of the SCM Agreement. Specifically, the European Union argues that if the Panel were to agree with Turkey that the SSI does "procure" and "purchase" pharmaceutical products "for governmental purposes" within the meaning of Article III:8(a) of the GATT 1994, then the European Union submits that the subsequent provision of those goods by the pharmacies to the outpatients would constitute, by itself, a financial contribution in the form of an "entrustment" or "direction" of the provision of goods within the scope of Article 1.1(a)(1)(iv) of the SCM Agreement. Turkey does not dispute that the SSI "entrusts" or "directs" pharmacies to perform the function of "providing goods", i.e. pharmaceutical products, to outpatients on the terms and conditions set by the SSI. (Turkey's first written submission, para. 370; Turkey's responses to the first set of questions, para. 79.) At this juncture of its analysis, however, the Panel has already found that the SSI does not "purchase" pharmaceutical products within the meaning of Article III:8(a) of the GATT 1994, which renders moot the European Union's alternative and conditional argument under Article 1.1.(a)(1)(iv).

producers of those pharmaceutical products⁶⁹³; and (iii) this subsidy is effectively contingent upon the use by the outpatient of domestic pharmaceutical products over like imported pharmaceutical products.

7.228. Turkey disputes each of these points⁶⁹⁴, arguing that (i) the payments made by the SSI to pharmacies are not a "direct transfer of funds" within the meaning of Article 1.1(a)(1)(i); (ii) any direct benefit to outpatients conferred by Turkey's reimbursement scheme falls outside the scope of Article 1.1 of the SCM Agreement, and the European Union has not established that any indirect benefit is conferred upon producers of the pharmaceutical products listed in Annex 4/A; and (iii) any alleged subsidy is not contingent upon the use of domestic over imported products within the meaning of Article 3.1(b) of the SCM Agreement.

7.229. The Panel notes that the European Union's claim under Article 3.1(b) of the SCM Agreement is expressly conditioned on the Panel rejecting the European Union's claim under Article III:4 of the GATT 1994. Specifically, the European Union states that it makes its claim under Article 3.1(b) of the SCM Agreement "in the alternative"⁶⁹⁵ to its claim concerning the localisation requirement under Article III:4 of the GATT 1994, and "requests the Panel to rule on this claim only in the event that the Panel were to conclude that the Localisation Requirement is not in breach of Article III:4 of the GATT 1994, or that such breach is justified under any other provision of the GATT 1994".⁶⁹⁶ The Panel has concluded that the localisation requirement does not fall within the scope of the government procurement derogation in Article III:8(a) of the GATT 1994, that the localisation requirement is inconsistent with Article III:4 of the GATT 1994, and that Turkey has not established that the localisation requirement is justified under either of the general exceptions in Article XX(b) or (d) of the GATT 1994. Thus, the condition on which the European Union's claim under Article 3.1(b) is predicated has not been fulfilled.

7.230. The Panel considers that the alternative and conditional nature of the European Union's claim under Article 3.1(b) of the SCM Agreement constitutes a sufficient basis for the Panel to decline to rule on it, and that it is unnecessary to consider this claim further.

7.5.3 Article 2.1 of the TRIMs Agreement

7.231. Article 1 of the TRIMs Agreement states that it applies to "investment measures related to trade in goods" (i.e. "TRIMs").

7.232. Article 2 of the TRIMs Agreement provides:

1. Without prejudice to other rights and obligations under GATT 1994, no Member shall apply any TRIM that is inconsistent with the provisions of Article III or Article XI of GATT 1994.
2. An illustrative list of TRIMs that are inconsistent with the obligation of national treatment provided for in paragraph 4 of Article III of GATT 1994 and the obligation of general elimination of quantitative restrictions provided for in paragraph 1 of Article XI of GATT 1994 is contained in the Annex to this Agreement.

7.233. That Illustrative List provides in relevant part:

⁶⁹³ In response to Turkey's argument that the direct benefit to outpatients "falls outside the scope of the SCM Agreement", the European Union clarifies that Turkey is responding to an argument that the European Union has not made and that it does not argue that any direct benefit conferred to outpatients constitutes, in and of itself, a subsidy within the scope of the SCM Agreement; rather, the European Union argues that the financial contributions confer a direct benefit to the outpatients as part of its demonstration that, as a result, the same financial contributions also confer an indirect benefit to the Turkish producers of pharmaceutical products. (European Union's second written submission, para. 246; responses to the first set of questions, paras. 64-65.)

⁶⁹⁴ Turkey's first written submission, paras. 330-413; second written submission, paras. 118-157; responses to the first set of questions, paras. 76-97; opening statement, paras. 101-115; closing statement, paras. 24-35; responses to the second set of questions, paras. 73-81; comments on responses to the second set of questions, paras. 33-38.

⁶⁹⁵ European Union's first written submission, para. 279; second written submission, para. 232.

⁶⁹⁶ European Union's first written submission, para. 279; second written submission, para. 232.

1. TRIMs that are inconsistent with the obligation of national treatment provided for in paragraph 4 of Article III of GATT 1994 include those which are mandatory or enforceable under domestic law or under administrative rulings, or compliance with which is necessary to obtain an advantage, and which require:

(a) the purchase or use by an enterprise of products of domestic origin or from any domestic source, whether specified in terms of particular products, in terms of volume or value of products, or in terms of a proportion of volume or value of its local production; or

(b) that an enterprise's purchases or use of imported products be limited to an amount related to the volume or value of local products that it exports.

7.234. Thus, Article 2 prohibits the application of any TRIM that is inconsistent with Articles III or XI of the GATT 1994. If a TRIM is one of the two types of TRIMs covered by paragraph 1 of the Illustrative List annexed to the TRIMs Agreement, then the measure is deemed to be inconsistent with Article III:4 of the GATT 1994 (and, by extension, Article 2.1 of the TRIMs Agreement) which obviates the need for any further examination of the elements of Article III:4.⁶⁹⁷ If the TRIM at issue is not one of the two types of TRIMs covered by paragraph 1 of the Illustrative list, then a claim under Article 2.1 of the TRIMs Agreement necessarily entails an examination of whether the elements of Article III:4 are satisfied.

7.235. The European Union claims that the localisation requirement, in addition to being inconsistent with Article III:4 of the GATT 1994, is inconsistent with Article 2.1 of the TRIMs Agreement because it constitutes an "investment measure related to trade in goods" that is inconsistent with Article III:4 of GATT 1994.⁶⁹⁸

7.236. Turkey does not present arguments on any of the elements of Article III:4 of the GATT 1994 or Article 2.1 of the TRIMs Agreement, and limits its response to the European Union's claims under these provisions to arguing that these provisions are inapplicable to the localisation requirement by virtue of the government procurement derogation in Article III:8(a) of the GATT 1994, and that any inconsistency with Article III:4 and Article 2.1 would be justified by Article XX(b) or Article XX(d) of the GATT 1994.⁶⁹⁹

7.237. The parties have presented opposing views on whether the Panel should, if it finds that the localisation requirement is inconsistent with Article III:4 of the GATT 1994, make any additional finding under Article 2.1 of the TRIMs Agreement. In response to a question from the Panel, the European Union argues that several previous panels in similar cases have made findings under both provisions⁷⁰⁰ and states that there is little to gain from exercising judicial economy over the claim under Article 2.1 because the only remaining elements to consider (i.e. whether the localisation requirement is an "investment measure" "related to trade in goods") are uncontested by Turkey.⁷⁰¹ Turkey submits that, contrary to what the European Union argues, if the Panel were to uphold the European Union's claim under Article III:4 of the GATT 1994 then it would not be necessary for the Panel to also rule on the claim under Article 2.1 of the TRIMs Agreement.⁷⁰² Turkey notes that in several past cases panels have decided to exercise judicial economy on claims under the TRIMs Agreement after having found violations of Article III:4 of the GATT 1994.⁷⁰³

7.238. In approaching arguments relating to judicial economy, the Panel considers it useful to distinguish and consider two separate questions. The first is whether the Panel has the discretion to decline to rule on a given claim. This is a legal question, and it turns on whether such a ruling would be superfluous from the perspective of implementation. If the answer to the first question is yes, the second question is whether the Panel should exercise that discretion, given that a panel is not

⁶⁹⁷ Panel Report, *India – Solar Cells*, para. 7.54.

⁶⁹⁸ European Union's first written submission, paras. 262-277; second written submission, paras. 227-230; opening statement, paras. 10-12; responses to the second set of questions, paras. 18-23.

⁶⁹⁹ Turkey's first written submission, paras. 6, 123, 174, 242, 243-244, and 414.

⁷⁰⁰ The European Union refers to Panel Reports, *Indonesia – Autos*, para. 15.1; *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, paras. 8.2 and 8.6; and *India – Solar Cells*, para. 8.2.

⁷⁰¹ European Union's responses to the second set of questions, paras. 18-23.

⁷⁰² Turkey's comments on responses to the second set of questions, para. 17.

⁷⁰³ Turkey refers to Panel Reports, *EC – Bananas III*, para. 7.186; *Turkey – Rice*, para. 7.184; *India – Autos*, paras. 7.161, 7.324; *China – Auto Parts*, para. 7.368; *US – Renewable Energy*, paras. 7.348-7.353.

required to exercise judicial economy in circumstances where it is entitled to do so.⁷⁰⁴ That assessment is not as much a legal question as it is a discretionary authority, the exercise of which is guided by the Panel's judgement of the circumstances of the case.

7.239. It is clear from the terms of the TRIMs Agreement, and confirmed in past dispute settlement practice, that the relationship between Article 2.1 of the TRIMs Agreement and Article III:4 of the GATT 1994 is such that, in principle, compliance with a finding of inconsistency with Article III:4 would bring about compliance with the parallel obligation in Article 2.1 of the TRIMs Agreement.⁷⁰⁵ Therefore, where a panel has already found a violation of Article III:4 of the GATT 1994, it is in principle not necessary to make additional findings on the consistency of the same measure(s) under the parallel obligation in the TRIMs Agreement. The steps taken by the responding Member to bring the measures at issue into compliance with Article III:4 of the GATT 1994 will also, by definition, eliminate the alleged non-conformity of the same measures with obligations under Article 2 of the TRIMs Agreement (which, as explained above, prohibits TRIMs inconsistent with Article III:4 of the GATT 1994).

7.240. The foregoing explains why there is a "relatively consistent practice"⁷⁰⁶ of past panels exercising judicial economy over claims under the TRIMs Agreement when faced with claims under Article III:4 of the GATT 1994. As indicated by the panel in a recent case involving parallel claims under Article III:4 of the GATT 1994 and Article 2.1 of the TRIMs Agreement:

Like the above panels, we do not find it necessary to address India's claims under the TRIMs Agreement in order to provide a positive solution to this dispute. Bearing in mind that Article 2 of the TRIMs Agreement is only concerned with TRIMs that are inconsistent with Article III (or Article XI) of the GATT 1994 and also in light of the relatively consistent practice of past panels when faced with claims under Article III:4 of the GATT 1994 and Article 2 of the TRIMs Agreement, we consider that steps taken by the United States to bring the measures at issue into compliance with Article III:4 of the GATT 1994 will also eliminate the alleged non-conformity of the same measures with obligations under the TRIMs Agreement.⁷⁰⁷

7.241. The Panel put a question to the European Union asking whether, if the Panel were to uphold the European Union's claim under Article III:4 of the GATT 1994, it would still be necessary to rule on the claim under Article 2.1 of the TRIMs Agreement. In its response, the European Union appears to accept the premise that, if the claim under Article III:4 is upheld, the Panel would be legally entitled to exercise judicial economy over the claim under Article 2.1.⁷⁰⁸ The only reasons given by the European Union for a ruling on the claim under Article 2.1 are that some panels in previous cases have ruled on both provisions, and that doing so in this case would be uncomplicated. Even assuming, for the sake of argument, that these could be valid reasons for a panel to refrain from exercising judicial economy⁷⁰⁹, the European Union's response does not suggest that the Panel is legally precluded from exercising judicial economy over the claim under Article 2.1.

7.242. Based on the foregoing, the Panel considers that it is legally entitled to exercise judicial economy over the claim under Article 2.1 of the TRIMs Agreement given that the Panel has already found that the localisation requirement is inconsistent with Article III:4 of the GATT 1994, and the Panel does not understand the European Union to argue otherwise. The disputed question is whether the Panel should exercise that authority in the circumstances of this case.

7.243. The Panel recalls that it has already followed an economical approach when assessing the central issues in this dispute. In addressing Article III:8(a) and Articles XX(b) and (d), the Panel indicated that in the circumstances of this dispute, the Panel saw no compelling reason to make

⁷⁰⁴ Appellate Body Report, *US – Lead and Bismuth II*, paras. 71 and 73.

⁷⁰⁵ See e.g. Panel Report, *US – Renewable Energy*, para. 7.348.

⁷⁰⁶ Panel Report, *US – Renewable Energy*, para. 7.353.

⁷⁰⁷ Panel Report, *US – Renewable Energy*, para. 7.353.

⁷⁰⁸ European Union's responses to the second set of questions, paras. 18-23.

⁷⁰⁹ The Panel acknowledges that there is not a uniform practice, but notes that two of the three cases referred to by the European Union involved arguments relating to Article 2.2 and the Illustrative List of TRIMs, which necessarily entailed ruling in tandem on the claims under the GATT 1994 and the TRIMs Agreement. (See e.g. Panel Reports, *Canada – Renewable Energy / Canada – Feed-in Tariff Program*, para. 7.167; Panel Report, *India – Solar Cells*, para. 7.73.) In this case, the European Union has not presented any arguments under Article 2.2 and the Illustrative List of TRIMs.

additional findings or observations beyond those necessary to resolve the claims and defences before it. Thus, the Panel ended its assessment under Article III:8(a) after finding that the localisation requirement did not involve the "purchase" of pharmaceutical products included in the Annex 4/A list by governmental agencies. The Panel made no findings on the disputed issues under the three remaining elements of Article III:8(a), all of which are disputed.⁷¹⁰ The Panel similarly ended its assessment under Article XX(b) after finding that Turkey had not discharged its burden of demonstrating that the localisation requirement is a measure taken to prevent a long-term shortage of supply of safe, effective and affordable pharmaceutical products in Turkey. The Panel made no findings on the heavily contested issue of whether the localisation requirement was "necessary" to fulfill that objective.⁷¹¹ And having found that its assessment under Article XX(b) extended *mutatis mutandis* to the analysis of the defence under Article XX(d), the Panel disposed of Turkey's Article XX(d) defence without making findings on the disputed issues specific to that provision and without making findings on whether the instruments referenced by Turkey constituted "laws or regulations" within the meaning of Article XX(d) or the extent to which Article XX(d) covers measures taken by a government to secure its *own* compliance with its laws and regulations.⁷¹²

7.244. The Panel considers that the economical approach it has taken to these issues comports with the economical approach that the European Union has itself advocated for resolving its claim under Article 3.1(b) of the SCM Agreement. Notably, as explained in the previous section, the European Union requested that the Panel rule on its claim under Article 3.1(b) of the SCM Agreement only if the Panel were to conclude that the localisation requirement is not inconsistent with Article III:4 of the GATT 1994, or that such inconsistency was justified under any other provision of the GATT 1994.⁷¹³ In the light of its findings under the relevant provisions of the GATT 1994, the Panel has followed the economical approach requested by the European Union and accordingly declined to rule on the European Union's conditional claim under Article 3.1(b) of the SCM Agreement. As a result, the Panel has made no findings on the heavily contested issues that arise in the context of that claim.

7.245. In line with the approach taken by the Panel elsewhere in this Report, the Panel sees no compelling reason to make additional findings under Article 2.1 of the TRIMs Agreement. In the light of its findings under the relevant provisions of the GATT 1994, the Panel exercises judicial economy over this claim.

7.5.4 Article X:1 of the GATT 1994

7.246. Article X:1 of the GATT 1994 provides in relevant part:

Laws, regulations, judicial decisions and administrative rulings of general application, made effective by any Member, pertaining to the classification or the valuation of products for customs purposes, or to rates of duty, taxes or other charges, or to requirements, restrictions or prohibitions on imports or exports or on the transfer of payments therefore, or affecting their sale, distribution, transportation, insurance, warehousing inspection, exhibition, processing, mixing or other use, shall be published promptly in such a manner as to enable governments and traders to become acquainted with them.

7.247. Article X:1 applies where the instrument challenged (i) is a law, regulation, judicial decision or administrative ruling; (ii) of general application; (iii) made effective; and (iv) pertains to the range of listed matters affecting imports or exports. If these conditions are satisfied, Article X:1 of the GATT requires Members to publish such instruments "promptly" (*vis-à-vis* the time at which the instruments were made effective) and in such a "manner as to enable governments and traders to become acquainted with them".

7.248. The European Union claims that Turkey has acted inconsistently with its obligations under Article X:1 of GATT 1994 by failing to publish certain elements, terms and conditions of general application of this measure promptly in such a manner as to enable governments and traders to

⁷¹⁰ See section 7.2.4.5 (Remaining elements under Article III:8(a)).

⁷¹¹ See section 7.4.2.3.3 (Remaining elements under Article XX(b)).

⁷¹² See section 7.4.3 (Turkey's alternative defence under Article XX(d) of the GATT 1994).

⁷¹³ European Union's first written submission, para. 279; second written submission, para. 232.

become acquainted with them.⁷¹⁴ More specifically, the European Union argues that the terms and conditions that Turkey should have published in manner compliant with Article X:1 include the process and various steps that must be taken as part of localisation; the phases of localisation; the product categories to which those phases relate; various steps and deadlines for the submission of commitments, the information that should be included in the commitments or justifications on why commitments could not be made; the authorities' criteria for accepting or refusing commitments; the criteria, phases and deadlines for delisting or deactivating their products (as the case may be); instructions on the various steps to be followed (including follow up, possible updates or alternative commitments, variation applications); and instructions for submitting progress reports.⁷¹⁵

7.249. Turkey responds that the claim under Article X:1 of the GATT 1994 should be dismissed on multiple separate grounds.⁷¹⁶ The grounds invoked by Turkey can be broadly categorized as follows: (i) the European Union has changed the scope of its claim in a way that raises serious due process concerns and/or falls outside the Panel's terms of reference; and (ii) the European Union has failed to demonstrate that the relevant measure(s), whether understood as a single cohesive measure, individual instruments/documents, or certain terms and conditions, fall within the scope of the obligation in Article X:1, and/or were not published promptly and adequately.

7.250. The parties have presented opposing views on whether the Panel should, if it finds that the substantive content of the localisation requirement is inconsistent with Article III:4 of the GATT 1994 (or Article 3.1(b) of the SCM Agreement), make any additional finding under Article X:1 of the GATT 1994 relating to its publication. According to the European Union, the Panel should make additional findings under Article X:1 relating to the publication of the localisation requirement for the same reason that the Panel should rule on its claim under Article XI:1 (discussed in the next subsection), namely, that it is possible that the Appellate Body could reverse the Panel's other findings regarding the WTO-inconsistency of the localisation requirement.⁷¹⁷ Additionally, in responding to a question from the Panel asking the parties to comment on two prior cases (*Argentina – Import Measures* and *Russia – Traffic in Transit*) in which panels refrained from ruling on claims under Article X:1, the European Union argues that one of those cases (*Russia – Traffic in Transit*) is distinguishable.⁷¹⁸ Turkey considers that if the European Union's first argument were to be followed this would mean that panels could hardly ever exercise judicial economy⁷¹⁹, whereas several panels have done so in relation to claims under Article X:1.⁷²⁰ Furthermore, according to Turkey, the European Union's attempt to distinguish the present case from *Russia – Traffic in Transit* is inapposite and should be rejected.⁷²¹

7.251. Article X of the GATT 1994 is entitled "Publication and Administration of Trade Regulations". The obligations in Article X govern the publication and administration of measures, rather than the substantive content of measures.⁷²² Thus, where the substantive content of a measure is found to be inconsistent with one or more substantive obligations in the GATT 1994, additional findings relating to the publication and/or administration of that measure – a measure that will cease to exist (in its current form) insofar as the Member concerned withdraws or modifies it to comply with its substantive obligations – will in principle be superfluous. The reason is that a finding by a panel under Article X:1 of the GATT 1994 would not be directed towards any *new* measures taken by the

⁷¹⁴ European Union's first written submission, paras. 228-261; second written submission, paras. 117-139; responses to the first set of questions, paras. 72-78; opening statement, paras. 99-110; responses to the second set of questions, paras. 83-95.

⁷¹⁵ European Union's responses to the first set of questions, para. 78 (referring to European Union's second written submission, paras. 130-134).

⁷¹⁶ Turkey's first written submission, paras. 245-329; second written submission, paras. 96-117; responses to the first set of questions, paras. 15; opening statement, paras. 96-100; responses to the second set of questions, paras. 82-84; comments on responses to the second set of questions, paras. 39-49.

⁷¹⁷ European Union's responses to the second set of questions, paras. 83-84.

⁷¹⁸ European Union's responses to the second set of questions, paras. 85-87.

⁷¹⁹ Turkey's comments on responses to the second set of questions, para. 41. Turkey adds that, in any case, the Appellate Body has completed the legal analysis where the factual findings of the panel or undisputed facts on the panel record provided a sufficient factual foundation for doing so. In light of the foregoing, only factual findings relating to the parties' arguments with respect to Article X:1 of the GATT would be necessary. (Turkey's comments on responses to the second set of questions, para. 42.)

⁷²⁰ Turkey refers to Panel Report, *Argentina – Import Measures*, paras. 6.302-6.305; Appellate Body Report, *Argentina – Import Measures*, paras. 5.185-5.203; Panel Report, *Peru – Agricultural Products*, para. 7.501; Panel Report, *Russia – Railway Equipment*, para. 7.939.

⁷²¹ Turkey's comments on responses to the second set of questions, paras. 39-40.

⁷²² Appellate Body Report, *EC – Poultry*, para. 115.

responding Member; rather, a finding of inconsistency under Article X:1 would lead only to proper publication of the *existing* measure.⁷²³

7.252. The foregoing explains why several past panels have exercised judicial economy over claims under Article X:1 of the GATT 1994 after finding that the substantive content of the measure violated one or more substantive obligations. In some cases, panels exercised judicial economy over claims under Article X:1 in such circumstances without further explanation.⁷²⁴ In other cases, panels and the Appellate Body have been more explicit in their reasoning. Notably, in *Argentina – Import Measures* the Appellate Body upheld the panel's exercise of judicial economy over a claim under Article X:1, noting that as Argentina would have to modify or withdraw the measure to comply with the recommendations under Articles III:4 and XI:1 of the GATT 1994, that the existing measure would "cease to exist".⁷²⁵ The Appellate Body failed to understand "how the publication of this WTO-inconsistent measure would contribute to securing a positive solution to this dispute".⁷²⁶ The subsequent panel in *Russia – Traffic in Transit* likewise exercised judicial economy over the claim under Article X:1 and, referring to the Appellate Body's reasoning, stated that "where a measure is found to be WTO-inconsistent, findings relating to the publication or administration of the same measure are unlikely to be necessary or useful in resolving the matter."⁷²⁷

7.253. The Panel asked the parties if the Panel were to uphold the European Union's claim under Article III:4 of the GATT 1994, would it still be necessary to rule on the claim under Article X:1. In its response, the European Union appears to accept the premise that, if the claim under Article III:4 is upheld, the Panel would be legally entitled to exercise judicial economy over the claim under Article X:1 of the GATT 1994.⁷²⁸ The only reasons given by the European Union for a ruling on the claim under Article X:1 are, as already indicated above, that it is possible that the Appellate Body might reverse the Panel's other findings regarding the localisation requirement⁷²⁹ and that one of the cases mentioned above is in some respects distinguishable.⁷³⁰ Leaving aside the circumstance that the Appellate Body is not currently functioning⁷³¹, and assuming that the reason given by the European Union for the Panel to refrain from exercising judicial economy could in principle still be a valid one, the European Union's response does not suggest that the Panel is legally precluded from exercising judicial economy over the claim under Article X:1. To construe the European Union's argument otherwise would imply that panels are legally precluded from exercising judicial economy in respect of any claim rendered superfluous by its findings on one or more other claims, insofar as those other claims involve a question of law or legal interpretation that might be modified or reversed on appeal.

7.254. Based on the foregoing, the Panel considers that it is legally entitled to exercise judicial economy over the claim under Article X:1 given that the Panel has already found that the localisation requirement is inconsistent with Article III:4 of the GATT 1994, and the Panel does not understand the European Union to argue otherwise. The disputed question is whether the Panel should exercise that authority in the circumstances of this case.

7.255. The Panel understands that in some cases, findings on claims under Article X:1 were made in circumstances where it would have been possible to exercise judicial economy. Moreover, the Panel accepts that there may be a good reason to make findings on issues relating to the publication and administration of a measure instead of exercising judicial economy. Notably, a panel may opt to make findings where there is a genuine possibility that the Member concerned could modify or reintroduce the challenged measure in such a way that the substantive content of the measure is brought into conformity with substantive WTO obligations, but without any adjustment to the same

⁷²³ Appellate Body Report, *Argentina – Import Measures*, para. 5.198.

⁷²⁴ See e.g. Panel Report, *Indonesia – Autos*, para. 14.152, where the panel merely stated that "[w]e have already found that the measures adopted pursuant to the National Car programme violate the provisions of Articles I and/or III of GATT. Therefore, we consider that it is not necessary to examine Japan's claims under Article X of GATT."

⁷²⁵ Appellate Body Report, *Argentina – Import Measures*, para. 5.200.

⁷²⁶ Appellate Body Report, *Argentina – Import Measures*, para. 5.200.

⁷²⁷ Panel Report, *Russia – Traffic in Transit*, paras. 7.200-7.201, citing Panel Reports, *Peru – Agricultural Products*, para. 7.501; and *Russia – Railway Equipment*, para. 7.939.

⁷²⁸ European Union's responses to the second set of questions, paras. 83-87.

⁷²⁹ European Union's responses to the second set of questions, paras. 83-84.

⁷³⁰ European Union's responses to the second set of questions, paras. 85-87.

⁷³¹ The Panel notes that the work of the Appellate Body has been suspended for nearly two years and that Members remain unable to reach consensus on any selection process to fill the vacancies that are required for the Appellate Body to function.

alleged shortcomings with respect to the publication and administration of the measure such that they are repeated or otherwise carried over into the modified or reintroduced measure. For example, in *China – Raw Materials*, the panel recognized the scope for applying judicial economy over the claims under Article X⁷³², which included a claim under Article X:1, but considered that "in the event that China were in any instance to impose a quota that was justified pursuant to Article XX, it would be relevant for the parties to know whether the aspects of China's system of quota administration at issue in this dispute comply with the relevant provisions of GATT Article X."⁷³³

7.256. In this case, the Panel has found the localisation requirement to be inconsistent as such with Article III:4 of the GATT 1994. This inconsistency with Article III:4 is inherent to the basic constitutive elements of the measure. The terms and conditions that the European Union alleges were not properly published relate to aspects of the measure that are inseparable from the aspects of the measure that give rise to the violation under Article III:4. It is not the Panel's role to speculate on the ways in which Turkey might choose to implement the recommendations and rulings of the DSB.⁷³⁴ However, neither party has suggested that Turkey could modify the localisation requirement in such a way that the substantive content of the measure is brought into conformity with Turkey's substantive WTO obligations, with the same alleged shortcomings with respect to the publication of the measure being repeated or otherwise carried over into the modified measure.

7.257. The Panel recalls that it has already followed an economical approach in the context of assessing the central issues in this dispute. As elaborated above, in the context of addressing Article III:8(a) and Articles XX(b) and(d), the Panel indicated that in the circumstances of this dispute, the Panel sees no compelling reason to make additional findings or observations beyond those necessary to resolve the claims and defences at issue. The Panel recalls that the economical approach it has taken with respect to these issues comports with the economical approach that the European Union has itself advocated for resolving its claim under Article 3.1(b) of the SCM Agreement. Recalling the approach taken by the Panel elsewhere in this Report, the Panel has also exercised judicial economy over the claim under Article 2.1 of the TRIMs Agreement.

7.258. In line with the approach taken by the Panel elsewhere in this Report, the Panel sees no compelling reason to make additional findings under Article X:1 of the GATT 1994. In the light of its findings under the relevant provisions of the GATT 1994, the Panel exercises judicial economy over this claim.

7.5.5 Article XI:1 of the GATT 1994

7.259. Article XI:1 of the GATT 1994 provides:

No prohibitions or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or export licences or other measures, shall be instituted or maintained by any Member on the importation of any product of the territory of any other Member or on the exportation or sale for export of any product destined for the territory of any other Member.

7.260. The European Union claims that the measure it refers to as "the import ban on localised products" is inconsistent with Turkey's obligations under Article XI:1 of GATT 1994.⁷³⁵ According to the European Union, "[w]here the production of a pharmaceutical product has been localised in Turkey in accordance with the localisation requirement, applied in conjunction with the Turkish rules for approving the importation and marketing of pharmaceutical products, the importation of that pharmaceutical product is no longer permitted."⁷³⁶ This "import ban", as described by the European Union, arises from the combined operation of the localisation requirement and the Turkish rules for

⁷³² Panel Reports, *China – Raw Materials*, para. 7.635.

⁷³³ Panel Reports, *China – Raw Materials*, para. 7.636.

⁷³⁴ Appellate Body Reports, *US – FSC*, para. 175; and *US – Wheat Gluten*, para. 185.

⁷³⁵ European Union's first written submission, paras. 300-321 and 351-364; second written submission, paras. 270-300; responses to the first set of questions, paras. 79-97; opening statement, paras. 111-134; closing statement, paras. 23-28; responses to the second set of questions, paras. 96-111; and comments on responses to the second set of questions, paras. 80-90.

⁷³⁶ European Union's panel request, p. 6.

approving the importation and marketing of pharmaceutical products, and in particular the Single Authorization rule.

7.261. Turkey requests that the Panel reject the European Union's claim under Article XI:1 of the GATT 1994 on multiple separate grounds.⁷³⁷ First, Turkey argues that while the European Union characterizes the "import ban measure" as a "single measure", it fails to show how the different components operate together as part of a "single measure" distinct from its components, and thereby fails to establish the existence and precise content of the import ban measure as a "single measure". Second, Turkey argues that the measure causing the alleged restriction, i.e. the Single Authorization rule, does not fall within the scope of Article XI:1 and is an internal measure within the meaning of Article III:4. According to Turkey, even if Article XI:1 applies there is no "ban" or "prohibition" on the importation of localised products because, *inter alia*, the very same product, in a different form or different dosage, can receive a marketing authorization with a production site abroad. From the fact that there is no "ban" on pharmaceutical products, Turkey draws two conclusions: (i) the measure which is characterized by the European Union as an "import ban" does not exist; and (ii) there is no violation of Article XI:1 insofar as it applies to the measure at issue. Third, Turkey argues that the import ban is justified under Article XX(d) of the GATT 1994 because it is necessary to secure compliance with the localisation requirement.

7.262. The parties have presented opposing views on whether the Panel should, if it finds that the localisation requirement is inconsistent with Article III:4 of the GATT 1994, make any additional finding on "the import ban on localised products" under Article XI:1 of the GATT 1994. In response to a question from the Panel, the European Union requests that the Panel rule on this measure and claim.⁷³⁸ The European Union argues that if the Appellate Body were to disagree with the Panel's view that the localisation requirement is WTO-inconsistent, then the "import ban" measure, as a different measure, could still be found to violate Article XI:1.⁷³⁹ Turkey submits that contrary to what the European Union argues, if the Panel were to uphold the European Union's claim under Article III:4 of the GATT 1994, it would not be necessary for the Panel to also rule on the claim under Article XI:1 of the GATT 1994. In that regard Turkey argues that if the Panel were to conclude that the localisation requirement is inconsistent with Article III:4 of the GATT 1994, then one of the components of the "import ban" as defined by the European Union will disappear and it would be unnecessary that the Panel additionally rule on that alleged measure.⁷⁴⁰

7.263. The Panel observes that in cases where the same measure is challenged under Article III:4 and Article XI:1, the decision to exercise judicial economy over one or the other of those claims may be relatively straightforward. For example, in *India – Autos*, the Panel found the indigenization condition "in its entirety to be inconsistent with Article III:4", and stated that in these circumstances it did "not see any need to address in addition whether the same condition is also inconsistent with Article XI:1" and therefore exercised judicial economy over that claim.⁷⁴¹ In *Indonesia – Chicken (Article 21.5 – Brazil)* the panel found a violation under Article III:4, and reasoned that even if Brazil had developed a *prima facie* case in respect of its claim under Article XI:1, it would have followed the original panel's approach of applying judicial economy to the Article XI:1 claim after finding a violation under Article III:4. The panel recognized that the scope and content of the two provisions were different, but noted that Brazil was unable to point to any potential differences in implementation, such that Panel saw no reason not to exercise judicial economy.⁷⁴² Having exercised such judicial economy, the panel indicated that it would leave open the "systemically important question" regarding the relationship between Article III:4 and Article XI:1.⁷⁴³

7.264. The Panel recalls that it has found the localisation requirement to be inconsistent as such with Article III:4 of the GATT 1994. This inconsistency with Article III:4 is inherent to the basic constitutive elements of the measure. To that extent, it could be said that the localisation requirement has been found in its entirety to be inconsistent with Article III:4. Furthermore, in this

⁷³⁷ Turkey's first written submission, paras. 571-646; second written submission, paras. 257-302; responses to the first set of questions, paras. 98-107; opening statement, paras. 116-118; responses to the second set of questions, paras. 85-101; and comments on responses to the second set of questions, paras. 50-60.

⁷³⁸ European Union's responses to the second set of questions, paras. 96-99.

⁷³⁹ European Union's responses to the second set of questions, paras. 96-99.

⁷⁴⁰ Turkey's responses to the second set of questions, para. 86.

⁷⁴¹ Panel Report, *India – Autos*, para. 7.208.

⁷⁴² Panel Report, *Indonesia – Chicken (Article 21.5 – Brazil)*, para 7.192.

⁷⁴³ Panel Report, *Indonesia – Chicken (Article 21.5 – Brazil)*, para 7.193.

case the arguments of the parties and third parties address the relationship between Article III:4 and Article XI:1. According to Turkey, the measure causing the alleged restriction, i.e. the Single Authorization rule, does not fall within the scope of Article XI:1 and is an internal measure within the meaning of Article III:4.

7.265. The Panel notes that in this case the possible exercise of judicial economy over the claim under Article XI:1 by virtue of the finding that the localisation requirement violates Article III:4 is not necessarily as straightforward as in some previous cases involving parallel claims under these provisions, because the European Union identifies the localisation requirement and the import ban on localised products as two separate measures.⁷⁴⁴ The European Union challenges the former under Article III:4 of the GATT 1994 (and Article 3.1(b) of the SCM Agreement, Article 2.1 of the TRIMs Agreement, and Article X:1 of the GATT 1994) and the latter under Article XI:1 of the GATT 1994. Insofar as these measures were distinct from one another, then there would be little scope for the Panel to consider exercising judicial economy in respect of the claims relating to one measure based on the rulings on claims relating to the other, distinct measure. That is because in general, if there are two distinct measures at issue, then a finding concerning one of them would not be expected to lead to the modification or withdrawal of the other. In those circumstances, there would be no basis to assume that a finding concerning a claim relating to only one of the measures would make findings concerning the other measure superfluous from the perspective of implementation.

7.266. In this case, however, the measure that the European Union refers to as "the import ban on localised products" comprises two components, one of which is the localisation requirement itself. As noted further above, this alleged "import ban", as described by the European Union, arises from the combined operation of the localisation requirement and the Turkish rules for approving the importation and marketing of pharmaceutical products, and in particular the Single Authorization rule. In response to a question from the Panel, the European Union confirmed that the measure it refers to as "the import ban on localised products" *is* the localisation requirement as "applied in conjunction" with the rules for approving the importation and marketing of pharmaceutical products.⁷⁴⁵ The European Union further clarified that it "did not challenge the rules for the importation and marketing of pharmaceutical products on their own (*per se*), in the absence of the Localisation Requirement".⁷⁴⁶

7.267. Given that the measure that the European Union refers to as "the import ban on localised products" comprises two components, one of which is the localisation requirement itself (the other component being the Single Authorization rule), the Panel asked the parties if a finding that the localisation requirement is WTO-inconsistent would render moot or superfluous any further finding on "the import ban on localised products". While the parties presented opposing views on whether the Panel should make any further finding, both parties' responses appear to confirm that if the Panel finds that the localisation requirement is inconsistent with Article III:4 of the GATT 1994, then it could in principle refrain from making any additional finding on "the import ban on localised products" under Article XI:1 of the GATT 1994.

7.268. The Panel notes that Turkey's response to this question⁷⁴⁷ presents reasoning that essentially mirrors the reasoning adopted by the Panel above in the context of exercising judicial economy over the publication claim under Article X:1 of the GATT 1994. Turkey responded that in this case where the European Union has explained that the "import ban on localised products" *is* the localisation requirement "as applied in conjunction" with the rules for approving the importation and marketing of pharmaceutical products, it follows that if the localisation requirement is found to be WTO-inconsistent, then Turkey will "have to modify or withdraw that measure". It follows from this, Turkey argues, that "the localisation measure – in its current form and with its current content – will cease to exist, so that one of the components of the 'import ban' in its current form and with its current content will disappear". Therefore, Turkey concludes, addressing claims with regard to the "import ban" would not contribute to securing a positive solution to this dispute.

⁷⁴⁴ The Panel recalls that, as set forth in the descriptive part of this Report, the European Union identifies the three measures at issue in this dispute which it refers to as (i) the localisation requirement; (ii) the import ban on localised products; and (iii) the prioritization measure.

⁷⁴⁵ European Union's responses to the first set of questions, para. 79.

⁷⁴⁶ European Union's responses to the first set of questions, para. 81.

⁷⁴⁷ Turkey's responses to the second set of questions, para. 86; comments on responses to the second set of questions, para. 50.

7.269. The Panel further notes that the European Union's response to this question does not contradict Turkey's reasoning. The only reason given by the European Union for a ruling on "the import ban on localised products" is that if the Appellate Body were to disagree with the Panel's view that the localisation requirement is WTO-inconsistent, then the "import ban" measure, as a different measure, could still be found to violate Article XI:1.⁷⁴⁸ The European Union's argument therefore implies that, in the absence of the possibility of the Appellate Body reversing the Panel's findings on the localisation requirement, there would be no need to rule on its separate claim under Article XI:1 relating to "the import ban on localised products". Indeed, the European Union refrained from making any comment on Turkey's argument that it would be unnecessary for the Panel to additionally rule on whether the import ban is consistent with Article XI:1 of the GATT 1994 if the Panel upholds the claims against the localisation requirement because pursuant to the European Union's description of the measure at issue, such a measure is partly composed of the "localisation requirement".⁷⁴⁹

7.270. Based on the foregoing, the Panel considers that it is legally entitled to exercise judicial economy over the claim under Article XI:1 given that the Panel has already found that the localisation requirement is inconsistent with Article III:4 of the GATT 1994, and the Panel does not understand the European Union to argue otherwise. As elaborated above, the Panel's findings on the localisation requirement require Turkey to modify or withdraw that measure. It follows that not only the localisation requirement, but also the "import ban on localised products", will cease to exist in its current form. As already explained above, this is because the European Union has defined the "import ban on localised products" as the localisation requirement applied in conjunction with the Single Authorization rule. Thus, the only disputed question is whether the Panel should exercise judicial economy in the circumstances of this case.

7.271. The Panel is conscious of the possibility that Turkey could withdraw the localisation requirement, and to that extent the "import ban on localised products" as defined by the European Union would cease to exist, but that without any adjustment to the Single Authorization rule the problem could be repeated or otherwise carried over into the new legal framework governing the manufacture of pharmaceuticals in Turkey. The Single Authorization rule exists independently of (and predates) the localisation requirement and the European Union argues that it prohibits the importation of all pharmaceutical products that are manufactured domestically, not only of the products that are localised pursuant to the localisation requirement.⁷⁵⁰ The Panel understands the European Union's arguments concerning the Single Authorization rule to imply that, even without the localisation requirement, the Single Authorization rule would continue to have the kind of limiting effect on importation, for any pharmaceutical product that is manufactured domestically, that the European Union regards as a "prohibition" or "restriction" giving rise to a violation of Article XI:1.

7.272. However, the Panel can only recall that the European Union has clarified that it is not challenging the Single Authorization rule separately, on its own, or *per se*. In other words, the European Union has not challenged the Single Authorization rule "as such", and the European Union has made clear that it is not challenging the Single Authorization as a measure distinct from the localisation requirement. Thus, insofar as the Single Authorization rule and its alleged limiting effect on importation would remain in place in the absence of the localisation requirement, that would not be a consequence that would be attributable to the Panel exercising judicial economy in respect of the "import ban on localised products" measure. It would simply be a consequence of the manner in which the European Union has described and challenged the measures at issue in this dispute, and the resulting limitations on the Panel's terms of reference.

7.273. Having made these observations, it bears repeating that the European Union has not argued that the Panel should refrain from exercising judicial economy over the "import ban on localised products" on that basis. To the contrary, and as indicated above, the European Union's argument on the issue of judicial economy implies that, in the absence of the possibility of the Appellate Body reversing the Panel's findings on the localisation requirement, there would be no need to rule on its separate claim under Article XI:1 relating to "the import ban on localised products".

7.274. The Panel recalls that it has already followed an economical approach in the context of assessing the central issues in this dispute. As elaborated above, in the context of addressing

⁷⁴⁸ European Union's responses to the second set of questions, paras. 96-99.

⁷⁴⁹ See Turkey's responses to the second set of questions, para. 86; European Union's comments on responses to the second set of questions, at Question 48.

⁷⁵⁰ See e.g. European Union's second written submission, para. 290.

Article III:8(a) and Articles XX(b) and(d), the Panel indicated that in the circumstances of this dispute, the Panel also sees no compelling reason to make additional findings or observations beyond those necessary to resolve the claims and defences at issue. The Panel recalls that this economical approach it has taken to these issues comports with the economical approach that the European Union has itself advocated for resolving its claim under Article 3.1(b) of the SCM Agreement. Recalling the approach taken by the Panel elsewhere in this Report, the Panel has also exercised judicial economy over the claim under Article 2.1 of the TRIMs Agreement, and over the claim under Article X:1 of the GATT 1994.

7.275. In line with the approach taken by the Panel elsewhere in this Report, the Panel sees no compelling reason to make additional findings on "the import ban on localised products" under Article XI:1 of the GATT 1994. In the light of its findings under the relevant provisions of the GATT 1994, the Panel exercises judicial economy over this claim.

7.6 The prioritization measure

7.6.1 Introduction

7.276. Having addressed the parties' claims and defences relating to the localisation requirement and the so-called "import ban on localised products", the Panel now addresses the third measure at issue in this dispute, which the European Union refers to as the "prioritization measure".

7.277. The European Union submits that in certain cases, where imported products are not excluded from the Annex 4/A list by virtue of the localisation requirement, Turkey gives priority to the review of applications for inclusion of domestic pharmaceutical products in the list of products covered by the reimbursement scheme, as well as with respect to any pricing and licensing policies and processes (in particular, GMP and marketing authorization applications), over the review of the applications of like imported products (the "prioritization measure").⁷⁵¹ The European Union claims that the prioritization measure is inconsistent "as such" with Article III:4 of GATT 1994. Specifically, the European Union contends that the prioritization measure is a law, regulation or requirement, which *de jure* gives priority to pharmaceutical products of national origin in the review of applications for inclusion in the Annex 4/A list and under other pricing and licensing policies and processes. On that basis, the European Union considers that Turkey accords to imported pharmaceutical products treatment less favourable than that accorded to like products of national origin.⁷⁵²

7.278. Turkey responds that the European Union fails to establish the existence of the prioritization measure, because the European Union has not shown any ongoing conduct or practice by the Turkish authorities actually granting priority to domestically produced pharmaceutical products. Turkey further responds that the European Union has not shown that the prioritization measure as an "overarching" measure is a "law, regulation or requirement" under Article III:4 of the GATT 1994. Moreover, Turkey argues that European Union has not demonstrated that the prioritization measure accords less favourable treatment to imported products than to like domestic products given the discretion of the authorities when assessing priority applications, and presents figures showing no significant difference between the treatment of domestically *manufactured* and imported products.⁷⁵³

7.6.2 Relevant provisions

7.279. Article III:4 of the GATT 1994 provides:

The products of the territory of any Member imported into the territory of any other Member shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use.

⁷⁵¹ European Union's panel request, p. 6; first written submission, para. 322.

⁷⁵² European Union's panel request, p. 6; first written submission, paras. 322-350, and 365-381; second written submission, paras. 301-318; responses to the first set of questions, paras. 98-105; and responses to the second set of questions, paras. 112-123.

⁷⁵³ Turkey's first written submission, paras. 647-697; second written submission, paras. 303-320; opening statement, paras. 119-125; and comments on responses to the second set of questions, paras. 61-63.

7.280. The Panel has already elaborated on the applicable legal standard under Article III:4 in addressing the localisation requirement.⁷⁵⁴

7.281. The Panel recalls that a complainant is required to prove the existence of the measure at issue, and that it is the complainant's description and characterization of the measure that informs the kind of evidence it is required to submit and the elements that it must prove to establish the measure's existence.⁷⁵⁵ For every measure, a complainant must show the measure is attributable to the respondent, and establish the precise content of that measure, to the extent that such content is the object of the claims raised. A complainant may be required to demonstrate other elements, depending on the particular characteristics or nature of the measure being challenged.

7.282. Panels have frequently examined measures consisting not only of particular acts applied exclusively to a specific situation ("as applied" claims), but also of acts setting forth rules or norms that are intended to have general and prospective application ("as such" claims); in other words, an instrument of a Member containing a rule or norm may constitute the challenged measure, without evidence of how it is applied in a particular instance or in practice.⁷⁵⁶ When a complaining party challenges rules or norms set forth in laws, regulations, or other instruments "as such", it will typically be necessary to show that the terms of the relevant provision(s) mandate one or more acts or omissions inconsistent with WTO obligations.⁷⁵⁷ Thus, when a measure is challenged "as such", the starting point for an analysis must be the measure on its face. If the meaning and content of the measure are clear on its face, then the WTO-consistency of the measure as such can be assessed on that basis alone.⁷⁵⁸

7.283. When challenging a rule or norm of general and prospective application (i.e. making an "as such" challenge), a complainant must show that the measure has both general and prospective application.⁷⁵⁹ Challenges to measures "as such" typically have as their object (written) legislation, which "prescribes" such norms or rules.⁷⁶⁰ A rule or norm has "general application" to the extent that it affects an unidentified number of economic operators.⁷⁶¹ A rule or norm has "prospective application" to the extent that it applies in the future. A complainant is not required to show with "certainty" that a given measure will apply in future situations.⁷⁶² Rather, prospective application may be demonstrated through several factors, such as the existence of an underlying policy implemented by the measure; the measure's design, architecture, and structure; the extent to which the measure provides administrative guidance for future conduct; and the expectations the measure creates among economic operators that it will be applied in the future.⁷⁶³

7.284. When challenging specific instances of application (i.e. making an "as applied" challenge), a complainant will need to provide evidence of those instances of application that it challenges. When challenging "ongoing conduct", a complainant must establish that the conduct has been repeatedly applied, and that it is likely to continue to be applied in the future.⁷⁶⁴

⁷⁵⁴ See section 7.3.2 of this Report.

⁷⁵⁵ See paragraph 7.5 of this Report.

⁷⁵⁶ Appellate Body Report, *US – Corrosion-Resistant Steel Sunset Review*, para. 82.

⁷⁵⁷ The mere fact that the application of the rule could in some circumstances lead to WTO-inconsistency will typically not be sufficient to discharge the complaining party's burden to make a prima facie case that the rule is inconsistent "as such" with WTO obligations. (See e.g. Appellate Body Report, *EU – Biodiesel (Argentina)*, paras. 6.282; Panel Report, *Canada – Aircraft*, para. 9.124.)

⁷⁵⁸ Appellate Body Report, *US – Corrosion-Resistant Steel Sunset Review*, para. 168.

⁷⁵⁹ Appellate Body Reports, *US – Anti-Dumping Methodologies (China)*, para. 5.127; *US – Zeroing (EC)*, para. 198.

⁷⁶⁰ Appellate Body Report, *Argentina – Import Measures*, para. 5.103.

⁷⁶¹ Appellate Body Report, *US – Anti-Dumping Methodologies (China)*, paras. 5.130 (referring to Appellate Body Reports, *US – Underwear*; *EC – Poultry*), 5.152, and 5.155-5.156.

⁷⁶² Appellate Body Report, *US – Anti-Dumping Methodologies (China)*, para. 5.132.

⁷⁶³ Appellate Body Report, *US – Anti-Dumping Methodologies (China)*, paras. 5.132-5.133.

⁷⁶⁴ Appellate Body Reports, *Argentina – Import Measures*, para. 5.108; *US – Supercalendered Paper*, para. 5.17.

7.6.3 Main arguments of the parties

7.6.3.1 Introduction

7.285. The parties disagree on several issues, including: (i) the nature of the measure challenged by the European Union (an "as such" challenge or a challenge to "ongoing conduct/practice" of "general application"⁷⁶⁵); (ii) whether the prioritization measure, as characterized by the European Union, is a "law, regulation or requirement" under Article III:4 of the GATT 1994; and (iii) whether the prioritization measure gives rise to any "less favourable treatment" to imported pharmaceuticals under Article III:4 of the GATT 1994.⁷⁶⁶

7.6.3.2 Whether the prioritization measure is challenged "as such" or as "ongoing conduct"/practice

7.286. In its panel request, the European Union states that Turkey "gives priority to the review of applications for inclusion of domestic pharmaceutical products in the list of products covered by the reimbursement scheme, as well as with respect to any pricing and licensing policies and processes, over the review of the applications of like imported products", and refers to this as the "prioritization measure".⁷⁶⁷ The European Union also states that the three measures at issue in this dispute are "put in place and evidenced by, and are implemented and administered through, *inter alia*" a series of listed "legal and other instruments", "considered alone and in any combination".⁷⁶⁸

7.287. In its first written submission, the European Union states that "[b]y this measure", Turkey "gives priority to the review of applications for inclusion of domestic pharmaceutical products in the list of products covered by the reimbursement system, as well as with respect to some licensing policies and processes, over the review of the applications of like imported products".⁷⁶⁹ The European Union submits that several "action plans and programmes" "confirm the existence and content of an overarching Prioritization Measure with respect to locally manufactured pharmaceutical products".⁷⁷⁰ The European Union then reviews in detail these action plans and programmes, as well as the provisions of a series of legal instruments and other documents.⁷⁷¹ In the context of arguing that the measure is a "law" or "regulation" within the meaning of Article III:4 of the GATT 1994, the European Union states that the prioritization measure is "imposed through a number of legal instruments, namely the SSI Regulation on Drug Reimbursement ... and the Priority Assessment Guideline".⁷⁷²

7.288. Turkey submits that the European Union does not demonstrate the existence of the prioritization measure as it was described by the European Union.⁷⁷³ Specifically, Turkey argues that the European Union describes the measure in its panel request and first written submission as an "overarching measure" whereby Turkey "gives priority" to domestic pharmaceutical products, but fails to demonstrate the existence of "ongoing conduct" consisting of Turkish authorities granting priority to domestically produced pharmaceutical products as a measure of general application.⁷⁷⁴ In Turkey's view, by describing the measure as an "overarching measure" whereby Turkey "gives priority" to domestic pharmaceutical products with regard to review of applications for inclusion in the Annex 4/A list and with respect to some licensing policies and processes, the European Union must provide evidence "of that conduct/practice and prove its general character".⁷⁷⁵ Accordingly, Turkey submits that the European Union "must show that Turkey *effectively* gives priority to

⁷⁶⁵ The Panel notes that following the preliminary ruling stage of this dispute, Turkey no longer asserts that the European Union makes an "as applied" claim with respect to the prioritization measure.

⁷⁶⁶ Turkey does not dispute that, insofar as the European Union has demonstrated the existence and precise content of the measure, there can or will be domestic and imported products that are "like products" affected by the origin-based distinction in the prioritization measure (European Union's first written submission, paras. 366-369), and the measure is one "affecting the internal sale, offering for sale, purchase, transportation, distribution, or use of products" (European Union's first written submission, paras. 372-375).

⁷⁶⁷ European Union's panel request, p. 6.

⁷⁶⁸ European Union's panel request, p. 1.

⁷⁶⁹ European Union's first written submission, para. 322.

⁷⁷⁰ European Union's first written submission, para. 323.

⁷⁷¹ European Union's first written submission, paras. 324-350.

⁷⁷² European Union's first written submission, para. 371.

⁷⁷³ Turkey's first written submission, paras. 662-677.

⁷⁷⁴ Turkey's first written submission, paras. 667-668.

⁷⁷⁵ Turkey's first written submission, para. 669.

domestic pharmaceutical products over imported products", and that "merely claiming that the possibility exists in certain legal instruments is not enough" to demonstrate that Turkey "gives priority to domestic pharmaceutical products", in particular in light of the discretion granted to the relevant bodies involved.⁷⁷⁶ Turkey notes that figures show that there is no significant difference between the number of applications for priority and the number of grants of priority across domestically manufactured and imported products.⁷⁷⁷

7.289. The European Union responds that the relevant instruments mandate giving priority to locally manufactured products.⁷⁷⁸ According to the European Union, Turkey's action plans and programmes further confirm that domestically produced medicines are granted priority, and recent reports continue to refer to priority given to domestically manufactured products.⁷⁷⁹ With respect to Turkey's submission that while the action plan sets out the "objective" to evaluate with priority reimbursement applications filed for domestically produced products it does not prejudge whether priority will be granted in each case, the European Union argues that Turkey actually concedes that, in certain cases, applications filed for domestically produced products will be granted priority.⁷⁸⁰ The European Union notes that even if applications for prioritization are not granted in every case, a measure need not give rise to less favourable treatment in every case, for there to be "less favourable treatment" under Article III:4 of the GATT 1994.⁷⁸¹ In this vein, the European Union notes that Article III:4 "does not require proof of actual effects" because it seeks to protect equality of opportunities. Moreover, the fact that, overall, the number of imported and domestic products that were granted priority is similar does not inform how frequently domestic products get priority because they are manufactured domestically.⁷⁸² In this connection, the European Union recalls that prior panel and Appellate Body reports examining Article III have rejected offsetting "less favourable treatment" of some imported products with more favourable treatment of other imported products.⁷⁸³ On that basis, the European Union submits that Turkey's argument that the European Union must demonstrate that the authority "effectively gives priority" to domestic pharmaceutical products is unfounded.⁷⁸⁴

7.290. In its second written submission, Turkey notes that the European Union does not dispute Turkey's description of the prioritization measure as "an ongoing conduct or practice of general application", but still fails to provide any evidence that Turkey "effectively gives priority" to domestic pharmaceutical products over imported products.⁷⁸⁵ In Turkey's view, the fact that certain legal instruments or documents refer to the possibility for authorities to give priority does not establish that there is "conduct" or a "practice" of the Turkish authorities giving priority to domestic pharmaceutical products "and that such a practice is of general application".⁷⁸⁶ Concerning the Annex 4/A list, Turkey emphasizes that the chair of the DRC has discretion to call an extraordinary meeting to examine applications of domestically manufactured products and that decisions at such meetings are taken at the DRC's discretion.⁷⁸⁷ As to the Prioritization Guideline, Turkey emphasizes that scoring certain applications for priority review on the basis of criteria including whether a medicine is locally produced does not imply that granting priority to those medicines is mandatory; although such scores "inform" the decision of the Priority Assessment Commission members, those

⁷⁷⁶ Turkey's first written submission, para. 672.

⁷⁷⁷ Turkey's first written submission, para. 675.

⁷⁷⁸ European Union's second written submission, paras. 302-303. Concerning the Annex 4/A list, the European Union states that Turkish legislation "mandates" listing pharmaceutical products manufactured in Turkey on the agenda of the MEEC and DRC as "prioritized topics for review" to be included in the Annex 4/A list, and that extraordinary meetings are held for that purpose. With respect to GMP and marketing authorization applications, the European Union states that the Priority Assessment Guideline "enables giving priority... to applications regarding pharmaceutical products manufactured in Turkey", including through a coefficient score of 0.15 for priority applications where local production is involved. (Ibid.)

⁷⁷⁹ European Union's second written submission, para. 304 (referring to Government of Turkey, 11th Development Plan for the period 2019-2023 (Government of Turkey, Eleventh Development Plan 2019-2023) (Exhibit EU-88); SSI Activity Report 2018 (Exhibit EU-109, TUR-7); and IQVIA, Report on the Turkish healthcare market, September 2020 (Exhibit EU-117)).

⁷⁸⁰ European Union's second written submission, para. 305.

⁷⁸¹ European Union's second written submission, paras. 306-307.

⁷⁸² European Union's second written submission, para. 309 (referring to Table, Applications for priority under the Prioritization Guideline (Exhibit TUR-106)).

⁷⁸³ European Union's second written submission, para. 310.

⁷⁸⁴ European Union's second written submission, para. 308.

⁷⁸⁵ Turkey's second written submission, paras. 303-304.

⁷⁸⁶ Turkey's second written submission, paras. 304.

⁷⁸⁷ Turkey's second written submission, para. 306 (referring to Exhibit TUR-11).

members must still decide by absolute majority. On that basis, Turkey argues that the Prioritization Guideline does not "mandate" or "require" the giving of priority to applications regarding medicines manufactured in Turkey.⁷⁸⁸ Turkey next reiterates that references to an objective of prioritization "do[] not show that there is an ongoing practice or conduct of general application", and thus those documents "do not show that Turkey *effectively* gives priority to domestic pharmaceutical products over imported products".⁷⁸⁹ In response to the European Union's argument that Article III:4 of the GATT 1994 does not require the complainant to show that like imported products are accorded less favourable treatment in every case, Turkey submits that the European Union confuses the issue of demonstrating the "existence and precise content" of the measure it challenges with the legal standard under Article III:4.⁷⁹⁰

7.6.3.3 "law, regulation or requirement"

7.291. The European Union notes that "the terms 'all laws, regulations and requirements' have been interpreted as encompassing a broad range of governmental actions", and states that the "Prioritization Measure could be considered as a 'law' or 'regulation'", because it is imposed through a number of legal instruments, namely the Drug Reimbursement Regulation (with respect to priority applications for reimbursement) and the Prioritization Guideline (with respect to priority applications for GMP and marketing authorization).⁷⁹¹

7.292. Turkey responds that the European Union "fails to substantiate how or why the prioritization measure as an overarching measure is a "law" or "regulation" by merely referring to two legal instruments that are components of, or elements through which the measure is implemented, but do not constitute the measure at issue".⁷⁹² According to Turkey, the mere observation that "laws, regulations and requirements" covers a broad range of measures does not discharge a complainant from substantiating its claim that a given measure falls within the scope of the provision under which that measure is challenged.⁷⁹³

7.293. The European Union replies that "the Prioritization Measure is embodied, wholly or at least partly, as shown above and in the first written submission, in formal legal instruments such as laws and guidelines", and these instruments "clearly qualify as 'laws' or 'regulations' resulting from 'governmental action'" and set out "rules with which compliance is necessary to obtain an advantage from a government".⁷⁹⁴ The European Union submits that in any case, the legal instruments in this dispute qualify at least as "requirements" within the meaning of Article III:4 of the GATT 1994, because they set out the "conditions and procedures that need to be followed to benefit from the priority for reimbursement, pricing policies and licensing procedures and they are issued by public authorities responsible for these matters".⁷⁹⁵ The European Union further submits that the governmental action plans and programmes presenting the prioritization measure as a policy of the Turkish government also qualify as "requirements".⁷⁹⁶

7.294. In its second written submission, Turkey responds that the European Union does not show that the "prioritization measure" as a "single measure" constitutes a "law, regulation or requirement".⁷⁹⁷ Turkey states that the European Union once again mixes the measure at issue with the legal instruments allegedly embodying the measure, when stating that because some of those instruments "clearly qualify as 'laws' or 'regulations'", it follows that the prioritization measure is a law or regulation, or when stating that in any case those legal instruments qualify at least as "requirements".⁷⁹⁸ In Turkey's view, what the European Union needs to show is that "what it has described as the prioritization measure, i.e. the fact that Turkey gives priority to domestic

⁷⁸⁸ Turkey's second written submission, paras. 307-309 (referring to Prioritization Guideline (Exhibit EU-97)).

⁷⁸⁹ Turkey's second written submission, para. 311.

⁷⁹⁰ Turkey's second written submission, paras. 312-314.

⁷⁹¹ European Union's first written submission, paras. 370-371.

⁷⁹² Turkey's first written submission, para. 688.

⁷⁹³ Turkey's first written submission, para. 688.

⁷⁹⁴ European Union's second written submission, para. 312 (fn omitted).

⁷⁹⁵ European Union's second written submission, para. 313.

⁷⁹⁶ European Union's second written submission, para. 314 (referring to Panel Reports, *Argentina – Import Measures*).

⁷⁹⁷ Turkey's second written submission, para. 316.

⁷⁹⁸ Turkey's second written submission, para. 316.

pharmaceutical products", is a "law, regulation or requirement".⁷⁹⁹ Finally, Turkey disagrees with the European Union's argument that the prioritization measure constitutes a "requirement" because it lays down a "condition to obtain an advantage, i.e. priority". According to Turkey, even if the product fulfils the condition (domestic production), it is not necessarily granted priority; therefore, "the discretion left to the authorities prevents from qualifying the measure as a 'requirement'".⁸⁰⁰

7.6.3.4 "less favourable treatment"

7.295. The European Union argues that the prioritization measure accords imported pharmaceutical products "less favourable treatment".⁸⁰¹ According to the European Union, the implications of the prioritization measure for the equality of competitive conditions are discernible from its design, structure, and expected operation.⁸⁰² As a *de jure* discriminatory measure that by its nature accords less favourable treatment to imports, the European Union submits that there is no need to analyse the actual market impact or other consequences of the measure further.⁸⁰³ The European Union explains that the "priority review" granted by the Turkish authorities to products of domestic origin means that these products are likely to be placed on the market faster than imported products, thereby providing them with an advantage over the imported products, and thus takes away the ability of imported products to compete on the basis of an "effective equality of opportunities".⁸⁰⁴ The European Union notes that the fact that imported products are not entirely excluded from the marketplace is no defence; prior reports indicate that there may be "less favourable treatment" even where the measure "will not give rise to less favourable treatment for like imported products in each and every case", or "where the coverage of the measure is only partial".⁸⁰⁵

7.296. Turkey responds that the European Union does not show that the prioritization measure accords "treatment less favourable" to imported products than to domestic like products, as (i) the authorities have discretion when assessing priority applications; and (ii) figures show no significant difference between the treatment of domestically manufactured and imported products.⁸⁰⁶ Turkey points out that under the Drug Reimbursement Regulation and Prioritization Guideline, both domestically produced and imported pharmaceutical products may be "granted priority with respect to the procedures covered under those instruments and subject to the criteria stipulated therein".⁸⁰⁷ Turkey reiterates that the figures demonstrate no significant difference between the number of priority applications and grants of priority across domestically manufactured and imported products.⁸⁰⁸

7.297. In response to Turkey's assertion, the European Union argues that the legal instruments underpinning the prioritization measure do not confer unfettered discretion on the responsible bodies: the Drug Reimbursement Regulation and Prioritization Guideline "actually mandate as a favourable criterion in assessing priority the local manufacture of pharmaceutical products".⁸⁰⁹ The European Union further responds that the fact that imported products may be granted priority for other reasons is not sufficient to refute the existence of domestic manufacturing as a criterion for priority, and that without such a criterion, it is likely that fewer domestically manufactured products would get priority review and in turn, would not be placed on the market as fast.⁸¹⁰ Lastly, while Turkey provides a table showing the number of applications the DRC included in the Annex 4/A list with a breakdown between domestic and imported products, the European Union submits that the data actually shows that domestic products are included faster in the Annex 4/A list than imported products: 24% to 92% of domestic applications were already granted by the DRC within the first

⁷⁹⁹ Turkey's second written submission, para. 316.

⁸⁰⁰ Turkey's second written submission, para. 317.

⁸⁰¹ European Union's first written submission, paras. 376-381.

⁸⁰² European Union's first written submission, paras. 378.

⁸⁰³ European Union's first written submission, paras. 379.

⁸⁰⁴ European Union's first written submission, para. 378.

⁸⁰⁵ European Union's first written submission, para. 380 (referring to Appellate Body Report, *US – FSC (Article 21.5)*, para. 221; Panel Report, *India – Solar Cells*, para. 7.95). The European Union provides an example of partial coverage, noting that the prioritization measure does not cover imported pharmaceutical products listed on the "Foreign Price List of Medicinal Products" (*ibid.*).

⁸⁰⁶ Turkey's first written submission, paras. 690-697.

⁸⁰⁷ Turkey's first written submission, paras. 694-696.

⁸⁰⁸ Turkey's first written submission, para. 695.

⁸⁰⁹ European Union's second written submission, paras. 315-316.

⁸¹⁰ European Union's second written submission, para. 317.

year following application, while only 8% to 58% of import applications were granted within the same period of time.⁸¹¹

7.298. In its second written submission, Turkey reiterates that the authorities have discretion to assess applications for prioritization, such that the status of a pharmaceutical product as a "domestic product" does not guarantee that such product will be treated with priority.⁸¹² With respect to the European Union's argument that the data submitted by Turkey regarding the relative rate of priority review accorded to imported and locally manufactured medicines is not instructive because it does not show how frequently domestic products are accorded priority because they are manufactured domestically, Turkey responds that the data it submitted support the conclusion that the European Union fails to make a *prima facie* case that imported medicines are treated less favourably than domestically manufactured medicines.⁸¹³

7.6.4 Assessment by the Panel

7.6.4.1 Introduction

7.299. The Panel will first examine whether the European Union has established the existence of the prioritization measure and then address the substance of the European Union's claim under Article III:4 of the GATT 1994, in particular, whether the prioritization measure is a "law, regulation, or requirement" that accords "less favourable treatment" to imported pharmaceutical products.

7.6.4.2 The existence of the measure

7.300. The European Union is required to establish the existence of the prioritization measure. How the prioritization measure is described, characterized and challenged by the European Union informs the kind of evidence the European Union is required to submit and the elements that it must prove to establish the existence of the prioritization measure.⁸¹⁴ Before assessing whether the European Union has established the existence of the prioritization measure, in light of the points of contention between the parties, the Panel will examine *what* it is the European Union contends the prioritization measure to be, and the *nature* of its challenge (being "as such", or to "ongoing conduct" of "general application").

7.301. The European Union's panel request identifies the "prioritization measure", *inter alia*, through a narrative description, which reads:

Lastly, even in certain cases where imported products are not excluded from the reimbursement scheme by virtue of the localisation requirement, Turkey gives priority to the review of applications for inclusion of domestic pharmaceutical products in the list of products covered by the reimbursement scheme, as well as with respect to any pricing and licensing policies and processes, over the review of the applications of like imported products (the "prioritization measure").⁸¹⁵

7.302. In its first written submission, the European Union repeats this formulation of the measure, before referring to several "action plans and programmes", as well as the Drug Reimbursement Regulation and Prioritization Guideline as confirming the existence and content of an "overarching Prioritization Measure".⁸¹⁶

7.303. The Panel understands that the European Union's reference to the "reimbursement scheme" concerns inclusion in the Annex 4/A list pursuant to the Drug Reimbursement Regulation⁸¹⁷, whereas

⁸¹¹ European Union's second written submission, para. 318.

⁸¹² Turkey's second written submission, para. 318.

⁸¹³ Turkey's second written submission, para. 320.

⁸¹⁴ Appellate Body Reports, *US – Anti-Dumping Methodologies (China)*, para. 5.123; *Argentina – Import Measures*, paras. 5.108-5.110.

⁸¹⁵ European Union's panel request, p.6.

⁸¹⁶ European Union's first written submission, paras. 322-350, and 371.

⁸¹⁷ The panel request defines "reimbursement scheme" in the narrative description of the localisation requirement as "the scheme for the reimbursement of the pharmaceutical products sold by pharmacies to patients operated by Turkey's social security system". Pharmaceutical products subject to the localisation requirement are "excluded" from this scheme if their production is not localised in line with the localisation

"pricing and licensing policies and processes" refers to GMP and marketing authorization applications under the Prioritization Guideline.⁸¹⁸ The Panel understands that there is no disagreement between the parties that the relevant reimbursement scheme refers to the reimbursement scheme under the Annex 4/A list, and that "pricing and licensing policies and processes" refers to GMP and marketing authorization applications only. This is reflected by the fact the parties' submissions almost exclusively concern provisions under the Drug Reimbursement Regulation and Prioritization Guideline.⁸¹⁹

7.304. By "overarching", the Panel understands the European Union to locate the prioritization measure (i.e. giving priority to applications for inclusion in the Annex 4/A list and for GMP and marketing authorization under the Prioritization Guideline) within the broader Turkish policy context contained and evidenced in the cited action plans and programmes, as well as other reports from Turkish governmental authorities, namely:

- a. the Structural Transformation Program for Healthcare Industries Action Plan 2014 (implementing the Healthcare Related Industries Structural Transformation Program), which refers to an "objective of prioritizing medicines and medical devices produced in Turkey in reimbursement and pricing policies and licensing processes", "accelerat[ing] the evaluation process" for the inclusion of domestically manufactured products in the Annex 4/A list, and supporting research and development activities in Turkey through "pricing and reimbursement practices", through the SSI, MOH and TMMDA⁸²⁰;
- b. the 2016 Action Plan of the 64th Government, which talks of improving "reimbursement, pricing and licensing processes for... domestic medicines", whereby the SSI will "speed up the evaluation process for including domestically manufactured healthcare products" on the Annex 4/A list⁸²¹;
- c. the 65th Government Program of 2016, which states that "[w]hen it comes to reimbursement and pricing policies and licensing procedures, we will give priority to domestically produced medicines and medical devices"⁸²²;
- d. the Turkish healthcare market report from September 2020, which refers to MOH "initiatives to improve review times" and a "priority evaluation" "points-based" system whereby "products receive a priority review if they meet a number of conditions" including "[t]echnology transfer to Turkey"⁸²³;

requirement. (European Union's panel request, p.5.) See also Panel Report, section 2.1.3.1. The Panel notes that the Annex 4/A list concerns reimbursement by the regular reimbursement pathway (through the DRC) as distinct from reimbursement by the alternative reimbursement pathway (through the ARC); products under the latter path are "unavailable on the Turkish market" and therefore have no like domestic counterparts. (Panel Report, paras. 2.10-2.12.) This is in keeping with the European Union's first written submission, which explicitly excludes reimbursement under the "Foreign Price List of Medicinal Products" (also known as the Annex 4/C list), which concerns products not available in Turkey, from the scope of this measure, as there are no like domestic counterparts for these products. (European Union's first written submission, paras. 335 and 369.) Turkey also takes note of the European Union's statement that products under the Annex 4/C list fall outside the scope of the prioritization measure (Turkey's first written submission, fn 621 to para. 659).

⁸¹⁸ See e.g. European Union's first written submission, paras. 371, 374, 378, and 381. Each of these paragraphs refers to the reimbursement scheme (being the Annex 4/A list), and review of GMP and marketing authorization applications. They no longer mention "pricing and licensing policies and processes".

⁸¹⁹ See e.g. European Union's first written submission, paras. 330-349; second written submission, paras. 302-303; Turkey's first written submission, paras. 650-661; second written submission, paras. 306-308.

⁸²⁰ European Union's first written submission, paras. 324-326 (referring to Structural Transformation Program for Healthcare Industries Action Plan (Exhibit EU-14)); TMMDA, Announcement on import applications for medical products, 31 December 2019 (Exhibit EU-92). See in particular Structural Transformation Program for Healthcare Industries Action Plan (Exhibit EU-14), Component 1 Policy 5 Action 2, and Component 3 Policy 1 Action 2.

⁸²¹ European Union's first written submission, paras. 327-328 (referring to 2016 Action Plan of the 64th Government (Exhibit EU-15)). See in particular 2016 Action Plan of the 64th Government (Exhibit EU-15), Action 46.

⁸²² European Union's first written submission, para. 329 (referring to 65th Government Programme, 24 May 2016 (65th Government Programme) (Exhibit EU-16), p. 81.)

⁸²³ European Union's second written submission, para. 304 (referring to IQVIA, Report on the Turkish healthcare market, September 2020 (Exhibit EU-117), p. 76).

- e. the SSI's 2018 Report, indicating that "[i]n reimbursement and pricing policies and in licensing procedures, the requisite arrangements and applications are to be put in place for priority assessment of medicines and medical devices produced in Turkey"⁸²⁴; and
- f. the TMMDA's Administrative Operation Report 2019, which includes the objective to "prioritise assessment of applications" and to "support domestic [yerli, which can also mean local] production".⁸²⁵

7.305. The Panel notes that Turkey does not dispute the objective of prioritization that is exemplified in these instruments, but instead limits its arguments to stating that evidence of an objective is not equal to evidence of actual conduct.⁸²⁶

7.306. Next, the Panel recalls that the parties have different understandings of whether Turkish authorities "give priority" in circumstances where those authorities have discretion, e.g. to call for an extraordinary meeting or take certain decisions. At this stage, the Panel limits its analysis to the significance of these arguments for establishing the existence of the prioritization measure, i.e. with respect to *what* the measure is and the *nature* of the European Union's challenge (being "as such" or to "ongoing conduct/practice" of "general application").

7.307. In this regard, the Panel observes that "gives priority" is used in a sentence in the European Union's panel request which reads: "Turkey gives priority *to the review of applications* for inclusion of domestic pharmaceutical products in the [Annex 4/A list], as well as with respect to [GMP and marketing authorization applications]".⁸²⁷

7.308. In its first written submission, the European Union refers to action plans and programmes which talk of "prioritizing medicines", "accelerat[ing]" and "speed[ing] up" the evaluation process for inclusion in the Annex 4/A list, "facilitation" and "improve[ment]" of price and reimbursement practices, and states that it "will give priority" in reimbursement and pricing policies and licensing procedures.⁸²⁸

7.309. With respect to the Annex 4/A list, the European Union submits that domestically manufactured products are listed in the DRC and MEEC agendas as "prioritized topics for review", whereby the relevant commissions hold extraordinary meetings for that purpose.⁸²⁹ The European Union refers to several provisions of the Drug Reimbursement Regulation in support of its argument⁸³⁰:

- a. Article 5(1)(g), which states that the DRC's duties include "[h]olding extraordinary sessions, when necessary, to assess applications for locally-manufactured medicinal products requesting to be listed, without waiting for conclusion of other applications made during the same period";
- b. Article 6(1)(ç), which states that the DRC chair's duties include "[r]eviewing assessments by [MEEC] related to applications for locally-manufactured products, that a decision be

⁸²⁴ European Union's second written submission, para. 304 (referring to SSI Activity Report 2018 (Exhibits EU-109, TUR-7), p. 29).

⁸²⁵ European Union's second written submission, para. 304 (referring to TMMDA Administrative Operation Report 2019 (Exhibit EU-111), pp. 200-201.) As reflected in Exhibit EU-111, the Turkish word "*yerli*" can be translated as "domestic" or "local". Excerpts from this instrument are also found in Exhibit TUR-78.

⁸²⁶ See e.g. Turkey's first written submission, para. 675; second written submission, para. 311. The Panel notes that in Turkey's first written submission, it argues that Turkey did not retain its prioritization objectives, evidenced by the document, Government of Turkey, Eleventh Development Plan 2019-2023 (Exhibit EU-88) (Turkey's first written submission, para. 676). In response to this the European Union referred to further documentation in its second written submission which refers to Turkey's prioritization objectives and post-dates Government of Turkey, Eleventh Development Plan 2019-2023 (Exhibit EU-88). With respect to these more "recent" documents, Turkey makes its argument that the fact they "refer to an objective of prioritization" does not show there is "ongoing practice or conduct of general application" (Turkey's second written submission, paras. 310-311).

⁸²⁷ European Union's panel request, p. 6. (emphasis added)

⁸²⁸ European Union's first written submission, paras. 325-329.

⁸²⁹ European Union's first written submission, para. 337.

⁸³⁰ European Union's first written submission, paras. 331, 332, and 336.

taken at an extraordinary meeting of the [DRC], and calling an extraordinary meeting of the [DRC] if necessary"; and

- c. Article 9(1)(c), which states that the MEEC's duties include "[p]rioritizing the review of applications involving locally manufactured medicinal products requesting listing for reimbursement... and referring them to the [DRC] Chair for publication, without waiting for conclusion of the other applications that were submitted during the same period, issuing an opinion that these should be given consideration during an extraordinary meeting of the DRC".

7.310. Similarly, the European Union submits that, read as a whole, the Prioritization Guideline gives priority for review to applications concerning all locally manufactured products, in the context of GMP and marketing authorization applications.⁸³¹ The European Union refers to several provisions of the Prioritization Guideline in support of its arguments, including⁸³²:

- a. Articles 2(1)(ç) and (d), which indicate that the Prioritization Guideline covers the "analysis and finalization of the requests about prioritization" i.e. "[a]pplications relating to transferring the production of imported medicines to our country" and "[a]pplications for locally manufactured products for exportation purposes";
- b. Article 4(1)(ç), which indicates that the assessment process of applications for GMP and marketing authorization spans from "pre-assessment" to "placing on the market" affected pharmaceutical products;
- c. Article 4(1)(h), which defines "prioritization" as the "assessment of applications within the determined criteria" and putting them "forward" in the "assessment process" by giving them priority;
- d. Article 6(1), which indicates that the Priority Assessment Commission's duties include "[a]ssessing and finalizing prioritization requests"⁸³³;
- e. Annex 3, which contains assessment criteria and a scoring chart, that attribute a coefficient of 0.15 to applications concerning "local production" (as well as a coefficient of 0.15 to applications concerning a "local active substance" and a coefficient of 0.3 to applications involving "bioequivalence studies in Turkey").

7.311. The European Union then refers to further evidence that local manufacture is among the criteria governing assessment of the prioritization process for pharmaceutical products, and that where a product has "no priority" its "licensing period" is 210 days, if it has "priority" its licensing period is 180 days, and if it has "high priority" its licensing period is 150 days.⁸³⁴

7.312. In its second written submission, the European Union reiterates that Turkish legislation "mandates" listing domestic pharmaceutical products on the MEEC and DRC agendas as "prioritized topics for review" and that extraordinary meetings are held for that purpose.⁸³⁵ With respect to the Prioritization Guideline, the European Union reiterates that it "enables" giving priority to applications for domestic pharmaceutical products and that no such possibility exists for like imported products, and that the assessment criteria for priority actually "mandate[]" giving priority to locally

⁸³¹ European Union's first written submission, paras. 338 and 349.

⁸³² European Union's first written submission, paras. 338-339, and 343-349.

⁸³³ The European Union also notes that the Priority Assessment Commission was established to implement Policy 5 Component 1 Action 2 of the 2014 Action Plan, which is described above. (European Union's first written submission, para. 345 (referring to 2016 TMDA Activity Report (Exhibit EU-99)).

⁸³⁴ European Union's first written submission, para. 350 (referring to R. Yeter, "Watch out with the localization trap", *Yeni Şafak*, 24 February 2018 (Exhibit EU-100)). See also Turkey's first written submission, para. 656 (referring to Prioritization Guideline (Exhibit EU-97), Articles 11(2) and 11(3)). The Panel notes that Turkey refers to "the registration process" instead of a "licensing period". The Panel understands the parties to refer, by this terminology, to the time period it takes for the relevant application process to be completed (such that the product can be placed on the market).

⁸³⁵ European Union's second written submission, para. 302; responses to the second set of questions, paras. 119-120.

manufactured products by virtue of the coefficient for "local production".⁸³⁶ The European Union also points to the "priority matter of locally manufactured product applications relating to the transferring of production of imported medicines" in Article 10(2)(ğ) as evidence of local manufacture as a "mandatory criterion" in the priority assessment process.⁸³⁷ The European Union identifies documentation that refers to products receiving "priority review" under a "points-based system" if they meet conditions like "[t]echnology transfer to Turkey", "priority assessment of medicines and medical devices produced in Turkey" and "priorit[izing] assessment of applications ... and to support domestic [yerli, which can also mean local] production".⁸³⁸

7.313. In the light of the European Union's panel request and written submissions, the Panel understands the European Union to challenge a prioritization measure whereby:

- a. Turkish authorities "give priority" to applications for inclusion in the Annex 4/A list by placing those applications as a priority on the agenda for DRC and MEEC meetings including extraordinary meetings or in MEEC's case, priority consideration at its own meetings and referral for consideration at a DRC extraordinary meeting. The Panel also notes the wording in Article 5(1)(g) of the Drug Reimbursement Regulation, referred to by both parties, which essentially gives the DRC the green light to consider applications for locally manufactured products "without waiting" for other applications made during the same period to be "concluded". In other words, the Panel understands Article 5(1)(g) to provide both a forum and "queue-jumping" mechanism for applications for inclusion in the Annex 4/A list where the relevant products are locally produced. The Panel notes that this is significant, given that regular DRC meetings are held twice yearly and extraordinary meetings can be convened at any time.⁸³⁹ The Panel further notes that Article 9(1)(c) contains similar wording with respect to MEEC meetings.
- b. With respect to GMP and marketing authorization applications, the Panel understands the European Union's challenge to the prioritization measure to refer specifically to the scoring system used by the Priority Assessment Commission in determining whether an application should receive priority (and therefore a shorter licensing period before a product is able to be placed on the market), whereby points are attributed for local production.⁸⁴⁰

7.314. The Panel observes that the provisions of the Drug Reimbursement Regulation (as mentioned above) and Prioritization Guideline are in keeping with the underlying action plans, programmes and other documentation, which both refer to prioritization as a desired outcome and a process of decision-making.

7.315. On that basis, the Panel does not understand the European Union to be arguing that in each and every case domestic pharmaceutical goods are granted "priority" in the sense that applications concerning those products are always processed fastest, but rather that their *assessment* within these approval processes for reimbursement, GMP and marketing authorization is prioritized by virtue of criteria attaching to a product's status as a locally manufactured pharmaceutical product. The Panel understands the European Union's claim to be that it is the inclusion of assessment opportunities (e.g. being placed on the DRC or MEEC agenda, role of extraordinary meetings) and criteria (e.g. the "local production" coefficient) in these approval processes, rather than the outcome for applications *per se*, that gives rise to the inconsistency with Article III:4 of the GATT 1994, because they result in a higher chance of actual priority being granted, (i.e. faster inclusion in the Annex 4/A list or shorter processing times with respect to GMP and marketing authorization applications).⁸⁴¹

⁸³⁶ European Union's second written submission, paras. 302-303 (referring to Prioritization Guideline (Exhibit EU-97), Article 10(2)(d)); responses to the second set of questions, paras. 119, and 121-122.

⁸³⁷ European Union's second written submission, para. 303 (referring to Exhibit EU-97).

⁸³⁸ European Union's second written submission, para. 304. As reflected in Exhibit EU-111, the Turkish word "*yerli*" can be translated as "domestic" or "local". Excerpts from this instrument are also found in Exhibit TUR-78.

⁸³⁹ Turkey's first written submission, para 659 (referring to Exhibit TUR-11, Articles 5(1)(g) and (ğ)). The Panel notes that Exhibit TUR-11 is the Drug Reimbursement Regulation also found in Exhibit EU-8.

⁸⁴⁰ See e.g. European Union's first written submission, paras. 341, and 347-349; second written submission, para. 303.

⁸⁴¹ See European Union's responses to the second set of questions, paras. 119-123.

7.316. The Panel finds nothing in Turkey's arguments or evidence that contradicts the existence of such a measure. Indeed, Turkey (i) does not dispute the objective of prioritization outlined by the European Union, with respect to both the Annex 4/A list and GMP and marketing authorization; (ii) notes that both the Drug Reimbursement Regulation and Prioritization Guideline "create the possibility of granting priority" to locally manufactured products⁸⁴²; and (iii) provides the same evidence concerning the scoring of applications under the Prioritization Guideline.⁸⁴³

7.317. The Panel notes that Turkey's arguments about the non-existence of the prioritization measure instead focus on the fact that imported products may also receive priority assessment in certain instances, and that the local manufacture criterion does not determine the *outcome* of an application. For the reasons given above, the Panel does not agree with Turkey that these factors impact the existence of the prioritization measure as characterized by the European Union, which is concerned at a minimum with in-built opportunities for prioritization within the relevant application *processes*. The Panel also notes that, with respect to certain *other* opportunities for "prioritization" of imported products referred to by Turkey, these opportunities only cover products for which there will be, by definition, no "like" domestic product.⁸⁴⁴

7.318. In the light of the Panel's conclusion as to how the European Union has characterized and described the prioritization measure in its panel request and first written submission, in particular, what is meant by "giving priority" in the context of the decision-making processes concerning the Annex 4/A list and GMP and marketing authorization, the Panel also understands the European Union to be challenging the prioritization measure "as such".

7.319. The Panel does not share Turkey's understanding that the European Union is challenging what Turkey refers to as an "ongoing conduct/practice" of general application. Indeed, the Panel is compelled to recall that it already clarified its understanding of the panel request in the context of a preliminary ruling.⁸⁴⁵ The Panel ruled that this measure did not concern specific instances of application (which, the Panel observes, would necessarily form part of the definition of an "ongoing conduct" measure).⁸⁴⁶ The Panel also found that the European Union did not need to explicitly identify its challenge to the prioritization measure as being "as such" or "as applied", and that the reference to "certain cases" in the panel request covers "all instances where imported products are still eligible under the reimbursement scheme", as distinct from specific instances of application.⁸⁴⁷ Moreover, the European Union clarified in response to Turkey's preliminary ruling request, which pre-dates Turkey's first written submission, that it challenges this measure "as such". Following such clarification by the European Union and the Panel's own ruling, the Panel sees no basis to construe words such as "gives priority" to imply that the European Union is in fact challenging an "ongoing conduct" measure (and doing so without providing any evidence of the kind needed to substantiate that type of claim).

7.320. Having concluded that the European Union's panel request, as clarified through its subsequent submissions, identifies an "as such" challenge to the prioritization measure as defined further above, the Panel now turns to consider whether the European Union has established the

⁸⁴² See e.g. Turkey's first written submission, paras. 649-651.

⁸⁴³ Turkey's first written submission, paras. 655-656.

⁸⁴⁴ See e.g. European Union's first written submission, para. 369.

⁸⁴⁵ In its request for a preliminary ruling, Turkey argued that it was unclear whether this measure was challenged as a "measure of general application" or "specific instances of application", such that the European Union had failed to identify the specific measure at issue under Article 6.2 of the DSU. At that stage of proceedings, Turkey submitted that the reference to "certain cases" in the narrative description of the measure indicated that the European Union was challenging specific instances of application (Turkey's request for a preliminary ruling, paras. 39 and 46). In response, the European Union clarified that its panel request identifies an "as such" challenge and that the full wording of the narrative description indicated that "certain cases" did not refer to instances of application, but the scope of the prioritization measure, being imported products that still have the benefit of the reimbursement scheme (European Union's responses to Turkey's request for a preliminary ruling, paras. 68-73).

⁸⁴⁶ The Panel recalls that when establishing the existence of an ongoing conduct measure, a complainant is required to provide evidence of how that conduct has been repeatedly applied (i.e. several instances of application) and likelihood of its continued application (which may also be evidenced by instances of application). (Appellate Body Reports, *Argentina – Import Measures*, para. 5.108; *US – Supercalendered Paper*, para. 5.17).

⁸⁴⁷ Preliminary ruling, paras. 3.17-3.18.

existence of an overarching, mandatory prioritization measure as a rule or norm of general and prospective application.

7.321. The Panel finds that the European Union has established the existence of an "overarching" measure whereby Turkish authorities give priority to the review of applications for inclusion in the Annex 4/A list and to GMP and marketing authorization applications concerning domestic pharmaceutical products over like imported products. The Panel, moreover, notes its conclusion above, that the prioritization measure *mandates* giving priority to the review of applications based on criteria attaching to local production and recalls that rules or norms that mandate certain action may be challenged "as such" in WTO dispute settlement.⁸⁴⁸

7.322. Given that the prioritization measure is a rule or norm which is expressly set out in writing in the provisions of the Drug Reimbursement Regulation and Prioritization Guideline, it is not clear that there is any need for the Panel to further assess whether this measure exhibits general and prospective application, typically considered in the context of unwritten measures. Assuming, for the sake of argument, that such further consideration is necessary, the Panel considers that this measure has general application; it is not limited in application to specific economic operators but applies across the board to imported pharmaceutical products not yet subject to the localisation requirement. Moreover, the Panel considers that the prioritization measure has prospective application, on the basis that it is reflected in legal instruments with continuing and prospective effect (i.e. the Drug Reimbursement Regulation and Prioritization Guideline) and implements an underlying current policy of prioritization.

7.323. Having found that the European Union challenges the prioritization measure "as such", the European Union is not required to prove any specific instances of application of this measure, that would otherwise have had relevance for evidencing repeated application and likelihood of continued application in establishing an "ongoing conduct" measure. The Panel therefore disagrees with Turkey's argument that the European Union was required to show that Turkish authorities "effectively" give priority to applications concerning domestically manufactured pharmaceutical products by evidencing specific instances of application, for the purposes of establishing the existence of the prioritization measure.

7.6.4.3 Article III:4 of the GATT 1994

7.324. The Panel now considers whether the prioritization measure is consistent with Article III:4 of the GATT 1994. In this section, the Panel considers the requisite elements in turn.

7.325. Concerning the first element under Article III:4, the Panel considers the European Union has made a *prima facie* case that domestic pharmaceutical products and imported pharmaceutical products affected by the prioritization measure are "like products"⁸⁴⁹ and Turkey has not presented any counterarguments in relation to this element of Article III:4.

7.326. The European Union indicates in its first written submission that "domestic pharmaceutical products" refers to "all pharmaceutical products manufactured in Turkey", and "imported products" refers to "all imported pharmaceutical products with the same characteristics".⁸⁵⁰ The European Union further clarifies that the category of imported products excludes pharmaceutical products, such as those in the "Foreign Price List of Medicinal Products" (also known as the Annex 4/C List), which are not available on the Turkish market.⁸⁵¹ The Panel notes that Turkey is aware that the European Union does not contend that such products are caught by the prioritization measure.⁸⁵² The Panel therefore understands the European Union to exclude – *by definition* – from the prioritization measure, imported products for which there are no domestic counterparts.

7.327. The Panel also recalls that the European Union had indicated in its response to Turkey's request for a preliminary ruling, that "imported products" refers to those that "benefit from the reimbursement scheme (for example, because they fall outside of the localisation requirement or

⁸⁴⁸ See paragraph 7.282.

⁸⁴⁹ European Union's first written submission, paras. 366-369.

⁸⁵⁰ European Union's first written submission, para. 368.

⁸⁵¹ European Union's first written submission, para. 369.

⁸⁵² Turkey's first written submission, fn 621 to para. 659.

localisation commitments were offered)".⁸⁵³ This is in keeping with the Panel's finding in its preliminary ruling, that "imported products" covers "all instances where imported products are still eligible under the reimbursement scheme", i.e. may be included in the Annex 4/A list for reimbursement.⁸⁵⁴ The Panel therefore considers that the scope of the prioritization measure affects domestically manufactured products that are reimbursable under Annex 4/A and their imported counterparts.

7.328. When origin is the sole criterion for a regulatory distinction between products, the likeness of the products that are distinguished in this way can be presumed.⁸⁵⁵ The Panel agrees with the European Union that the country of production for the pharmaceutical products affected by this measure is the sole distinguishing criterion between relevant products falling within the scope of this measure.⁸⁵⁶

7.329. Regarding the second element under Article III:4, the Panel considers that the prioritization measure constitutes a "requirement" affecting the internal sale, offering for sale, purchase, transportation, distribution, or use of pharmaceutical products. The Panel recalls that a "requirement" within the meaning of Article III:4 is not limited to requirements reflected in "laws" or "regulations", and may encompass both obligations that an enterprise is legally obliged to carry out, as well as voluntary action in order to obtain an advantage from government.⁸⁵⁷ As the European Union observes, the measure imposes "at least" a "requirement" (i.e. local production) as a condition for obtaining an advantage (i.e. priority review for inclusion in the Annex 4/A list, and in the context of GMP and marketing authorization applications).⁸⁵⁸

7.330. In the light of the Panel's understanding of the prioritization measure as challenged by the European Union, the Panel does not accept Turkey's argument that the "discretion" left to Turkish authorities prevents this measure from qualifying it as a "requirement".⁸⁵⁹ As the Panel understands this measure, it is only domestically manufactured pharmaceutical products that can benefit from priority assessment (e.g. listing and review by the DRC and/or MEEC for inclusion in the Annex 4/A list) and criteria (e.g. the "local production" coefficient) attaching to a product's status as locally produced. Therefore, in the context of both the Annex 4/A list and GMP and marketing authorization procedures, the advantage attaches to a domestic production criterion.

7.331. Recalling that a measure need only "affect" the conditions of sale, purchase, transportation, distribution, or use of products⁸⁶⁰, the Panel considers that this aspect of the second element under Article III:4 is also satisfied. As the European Union observes, "this measure affects the internal sale or offering for sale because it affects the conditions of competition of the imported products on the domestic market as it covers the priority of applications for inclusion in the [Annex 4/A list] and the review of GMP and marketing authorisation applications" (without which a product cannot be placed on the Turkish market).⁸⁶¹

7.332. Regarding the third element under Article III:4, the Panel recalls that treatment no less favourable means "according conditions of competition" no less favourable to the imported product than to the like domestic product⁸⁶². In the Panel's view, as discussed in the context of the localisation requirement, access to reimbursement for the costs of a domestic product but not for the costs of an imported like product obviously grants a competitive advantage to the domestic product.⁸⁶³ Similarly, having faster access to inclusion on the Annex 4/A list (i.e. "reimbursable" status) grants a competitive advantage to those products with faster access, namely domestic

⁸⁵³ European Union's responses to Turkey's request for a preliminary ruling, para. 73.

⁸⁵⁴ Preliminary ruling of the Panel, para. 3.18.

⁸⁵⁵ See Appellate Body Report, *Argentina – Financial Services*, para. 6.38; and e.g. Panel Reports, *Argentina – Import Measures*, para. 6.274; *China – Publications and Audiovisual Products*, para. 7.1447; and *Canada – Wheat Exports and Grain Imports*, para. 6.164.

⁸⁵⁶ European Union's first written submission, paras. 366-369.

⁸⁵⁷ Panel Reports, *China – Auto Parts*, para. 7.240; *China – Publications and Audiovisual Products*, para. 7.1448.

⁸⁵⁸ European Union's second written submission, para. 313.

⁸⁵⁹ Turkey's second written submission, para. 317.

⁸⁶⁰ Appellate Body Reports, *EC – Bananas III*, para. 220; *US – FSC (Article 21.5 – EC)*, para. 210 (referring to Panel Report, *Italy – Agricultural Machinery*, para. 12); and *China – Auto Parts*, para. 194.

⁸⁶¹ European Union's first written submission, paras. 373-375.

⁸⁶² Appellate Body Report, *Korea – Various Measures on Beef*, para. 135.

⁸⁶³ See paragraph 7.125 of this Report.

products within the scope of the prioritization measure. With respect to GMP and marketing authorization applications, the Panel notes that increased likelihood of access to priority licensing process times by virtue of a local production criterion means that locally manufactured products are available on the Turkish market faster.⁸⁶⁴ The Panel considers that such products benefiting from the prioritization mechanisms that attach to local production status therefore also have a competitive advantage over their like imported counterparts. The Panel agrees with the European Union that the prioritization measure affects the equality of competitive conditions between domestic and like imported products that fall within the scope of this measure, and that this is discernible from the design, structure and expected operation of this measure.⁸⁶⁵

7.333. The Panel rejects Turkey's argument that elements of "discretion" within the relevant approval procedures precludes any "less favourable treatment" arising from the prioritization measure.⁸⁶⁶ In this regard, the Panel recalls its understanding of the prioritization measure, as defined by the European Union, as comprising the in-built "prioritization" opportunities (as distinct from automatic outcomes) for locally manufactured products vis-à-vis their like imported counterparts, with respect to the Annex 4/A list and GMP and marketing authorization applications. As the Panel has found above, like imported products cannot benefit from any equivalent opportunities. The Panel notes that this is sufficient for a finding of inconsistency with Article III:4 of the GATT 1994.⁸⁶⁷

7.6.5 Conclusion

7.334. The Panel finds that the European Union has established the existence of an overarching measure whereby Turkish authorities give priority to the review of applications for inclusion in the Annex 4/A list and to GMP and marketing authorization applications concerning domestic pharmaceutical products over like imported products. The Panel concludes that the prioritization measure is inconsistent with Article III:4 of the GATT 1994.

8 CONCLUSIONS AND RECOMMENDATION

8.1. For the reasons set forth in this Report, the Panel concludes as follows:

- a. With respect to Turkey's request for a preliminary ruling:
 - i. Turkey's request for a preliminary ruling was not untimely;
 - ii. the localisation requirement, the import ban on localised products, and the prioritization measure were identified with sufficient specificity to comply with Article 6.2 of the DSU when reading the panel request on its face, as a whole, and in light of the attendant circumstances; and
 - iii. the European Union provided a brief summary of the legal basis of the complaint sufficient to present the problem clearly with respect to its claims under Article X:1 of the GATT 1994 and Article 3.1(b) of the SCM Agreement. Both claims, therefore, are properly within the Panel's terms of reference.
- b. With respect to the localisation requirement:
 - i. the European Union has established the existence of the localisation requirement as a "single measure", whereby (i) Turkey requires foreign producers to commit to localise in Turkey their production of certain pharmaceutical products; and (ii) where

⁸⁶⁴ Furthermore, the Panel notes that with respect to both the Annex 4/A list and GMP and marketing authorization applications, other regulatory benefits may flow from priority access to a market, such as market history data, that may be used when submitting applications to another market.

⁸⁶⁵ European Union's first written submission, paras. 378-379; second written submission, paras. 316-317.

⁸⁶⁶ Turkey's first written submission, paras. 693-697; second written submission, paras. 317-319.

⁸⁶⁷ Appellate Body Report, *US – FSC (Article 21.5)*, para. 221; and Panel Reports, *India – Solar Cells*, para. 7.95; *Canada – Wheat Exports and Grain Imports*, para. 6.202.

commitments are not given, not accepted or not fulfilled, affected products are no longer reimbursed by the SSI;

- ii. the localisation requirement is not covered by the government procurement derogation in Article III:8(a) of the GATT 1994, and is therefore subject to the national treatment obligation in Article III:4 of the GATT 1994 and Article 2.1 of the TRIMs Agreement;
 - iii. the localisation requirement is inconsistent with the national treatment obligation in Article III:4 of the GATT 1994;
 - iv. Turkey has not established that the localisation requirement is justified under Article XX(b) or Article XX(d) of the GATT 1994; and
 - v. in the light of these findings, the Panel declines to rule on the European Union's alternative and conditional claim under Article 3.1(b) of the SCM Agreement and exercises judicial economy over the European Union's additional claims under Article 2.1 of the TRIMs Agreement and Article X:1 of the GATT 1994.
- c. In the light of these findings, the Panel exercises judicial economy over the European Union's claim that the localisation requirement applied in conjunction with the Turkish rules for approving the importation and marketing of pharmaceutical products (referred to by the European Union as the "import ban on localised products") is inconsistent with Article XI:1 of the GATT 1994.
- d. With respect to the prioritization measure:
- i. the European Union has established the existence of an overarching measure whereby Turkish authorities give priority to the review of applications for inclusion in the Annex 4/A list and to GMP and marketing authorization applications concerning domestic pharmaceutical products over like imported products; and
 - ii. the prioritization measure is inconsistent with Article III:4 of the GATT 1994.

8.2. Under Article 3.8 of the DSU, in cases where there is an infringement of the obligations assumed under a covered agreement, the action is considered *prima facie* to constitute a case of nullification or impairment. The Panel concludes that, to the extent that the measures at issue are inconsistent with the GATT 1994, they have nullified or impaired benefits accruing to the European Union under that agreement.

8.3. Pursuant to Article 19.1 of the DSU, the Panel recommends that Turkey bring its measures into conformity with its obligations under the GATT 1994.
