

# **LEVERAGING WTO RULES TO COMBAT ILLICIT TRADE IN MEDICAL PRODUCTS**

**WORKING PAPER  
(AS OF 27 JULY 2022)**

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## EXECUTIVE SUMMARY

- **Illicit trade in medical products is a complex, global problem that poses a serious threat.** Measuring illicit trade is challenging but WTO estimates indicate that illicit trade in medical products constitutes between 1.3 per cent and 4.2 per cent of global trade in the sector. Available evidence suggests that such activity may have expanded during the COVID-19 pandemic, with a 5 per cent increase in seizures reported in 2020 compared with 2019. More generally, illicit trade in medical products presents a number of health, social and economic impacts, complicating the achievement of the United Nations Sustainable Development Goals (SDGs), particularly those relating to poverty and health outcomes.
- **WTO rules and trade policy activities should be part of a global, multifaceted strategy.** Key WTO rules include those that improve customs procedures, promote coherent regulatory frameworks and protect and enforce intellectual property rights (IPRs). Complemented by the work of WTO councils and committees, these measures support the fight against illicit trade by promoting transparency and setting the foundation for strengthened border and regulatory controls. They also aid in curbing discretionary or sub-optimal practices that give rise to inefficiencies and corruption.
- **The WTO offers a strong framework to help members establish mutually reinforcing layers of oversight.** Reforms to strengthen border controls associated with trade facilitation measures go hand in hand with efforts to improve the conformity of medical products with quality, health and safety regulations and the protection and enforcement of IPRs. These rules can be mutually supportive by providing multiple layers of border and regulatory oversight that offer enhanced prospects for the detection of illicitly traded medical goods. In addition, the collection of transparency provisions across WTO agreements promotes cooperation between customs authorities and national regulators and the exchange of information needed to detect and stop illicit trade in medical products.
- **Developing country and least-developed country (LDC) members need improved capacity.** The WTO Secretariat provides technical assistance to support border reforms, the infrastructure that underpins standardization, such as national quality infrastructure (NQI), and IPR enforcement. Other means are also available. The WTO's Trade Facilitation Agreement has a built-in mechanism of assistance to implement reforms, including those most needed in addressing illicit trade concerns. Developing country members can also make greater use of existing mechanisms to request advice and technical assistance from other members on matters relevant to illicit trade, such as strengthening NQI or effectively using IPR-related tools, and a dedicated mechanism for NQI capacity building could also be developed.
- **Greater coordination within and between members, as well as among international organizations, is required.** Existing WTO mechanisms can serve to combat illicit trade in medical products by promoting greater interaction between customs authorities and regulators within countries as well as across borders. As national bodies mandated to implement trade facilitation reforms, National Trade Facilitation Committees offer great potential for domestic coordination by involving broad stakeholder representation, including all relevant border and regulatory agencies and the private sector. Some developing members have joined resources to establish regional committees which offer the potential to further integrate sound border practices both domestically and regionally. Improved international cooperation, with the support of international organizations, can also build on WTO rules that require or promote transparency, information exchanges and the designation of contact points, or urge reliance on international standards in harmonizing good governance practices. WTO committees also have untapped potential as a venue for the exchange of information and best practices.
- **The rise of e-commerce poses challenges and opportunities.** WTO rules and activities offer tools for members to adapt to the emergence of the digital economy. Members can optimize the use of reforms, such as implementing risk management systems, which improve the ability of customs to target suspect imports, even small consignments sold through digital platforms, while also addressing border and regulatory concerns related to illicit trade in medical products. This can be combined with the development of new e-commerce rules, and efforts to adopt advanced technologies like blockchain and AI to secure and improve border and regulatory controls.
- **Supply chain disruptions create uncertainty that can be exploited.** WTO rules and activities assist members in managing supply chain disruptions. Strengthening border and regulatory practices also helps members safeguard supply chain integrity by helping them manage disruptions in the trade and distribution of key medical products that have generated illicit trading opportunities during the pandemic. These measures can be combined with the use of advanced technologies to promote automation and improve data quality so that information can be shared and used to bolster supply chains and combat illicit trade.

## **1 THE PERILS OF ILLICIT TRADE DURING THE COVID-19 PANDEMIC**

1.1. The international community is still reeling from a once-in-a-century pandemic. In a little over two years, millions have died from the COVID-19 virus, and surviving communities continue to endure its health, economic, and social consequences. One of the abiding challenges during this period has been the ramping up of production and distribution of needed medical resources – in particular, vaccines, diagnostics, therapeutics, face masks and other personal protective equipment (PPE) – to diagnose, treat, and protect populations from the ravages of the virus. These developments have focused particular attention on the medical product sector, with much of that attention focused on the causes and consequences of the disruptions, shortfalls, and uneven distribution of critical resources. In this context, the perils associated with illicit trade have faced fresh scrutiny.

1.2. Illicit trade poses a persistent and evolving threat to people, economies and governments everywhere. It threatens human welfare, endangering the health and safety of people and denying them and communities of critical resources. It undermines legitimate economic activity and leads to revenue and reputational losses for businesses that stifle product development and innovation. And it deprives governments of revenue for public investment and the resources needed to ensure good governance and freedom from corruption.

1.3. Illicit trade is a complex, global problem that undermines the world trading system and leaves no country, developed or developing, untouched. Accordingly, the effort to combat illicit trade requires a coordinated and multilateral response. The WTO has an important role to play in assisting WTO Members in their fight against illicit trade. Fundamentally, licit and illicit trade are two sides of the same coin and thus the rules with regard to legal trade also define the contours of the movement of illegal products and other unlawful trading activity. When governments rely on WTO disciplines to deepen cooperation with public and private stakeholders and boost border and regulatory capacity, they can achieve a dual benefit by strengthening their ability to fight illegal trade while creating new and expanded opportunities for legal trade.

1.4. This working paper focuses on the issue of illicit trade as it relates to a sector that has garnered particular attention during the COVID-19 pandemic – the medical product sector. This paper is divided into three sections. This section will look at definitions, data and recent developments to explore what is known about the problem of illicit trade and any consequences for the medical product sector during the pandemic. Section 2 then turns to survey the disciplines and trade policy activities of the WTO by focusing on specific areas that can assist Members in addressing the illicit trade threat with regard to medical products – in particular, improving border controls through trade facilitation and other customs measures; strengthening regulatory frameworks for product quality and safety standards; and enhancing domestic enforcement and international cooperation regarding intellectual property rights. It also highlights good governance requirements and practices relating to government procurement. This is followed by a summary in Section 3 that also seeks to identify some of the potential synergies and next-level guidance that can inform WTO Members and stakeholders in developing and strengthening policy responses to illicit trade.

### **1.1 DEFINING "ILLICIT TRADE" AND "MEDICAL PRODUCTS"**

1.5. Although there is no universally accepted definition for illicit trade, it is understood for purposes of this paper as the selling of goods to the public in violation of national and/or international laws. This is meant to cover trade in goods that are illegal due to their characteristics, as well as those that contravene laws by virtue of how they are produced, distributed, marketed, labelled, identified, certified, or sold. Such an understanding allows for the inclusion of the more obvious forms of illicit trade, for example, in illegal drugs, endangered wildlife, or goods that fail safety or quality protocols or infringe IPRs, while at the same time capturing trade in goods that may have been legally produced but which are, for instance, smuggled, stolen and then traded, or intentionally mis-declared upon import or export.

1.6. Regarding the sectoral focus of this paper, the terms "medical products" and "medical goods" are used interchangeably and are understood to include pharmaceutical products, medical equipment, orthopaedic equipment, personal protective equipment (PPE), and other medical supplies, including all products that have been of particular interest during the COVID-19 pandemic (e.g., vaccines, diagnostics, therapeutics, face masks and other pandemic-specific PPE).<sup>1</sup>

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<sup>1</sup> Although the terms medical products or medical goods are used, different terminology has been used in other collaborative projects involving the WTO. The 2020 edition of the publication 'Promoting Access to Medical Technologies and Innovation' – jointly published by the WTO, WIPO and WHO – employs, as its title suggests, the term "medical technologies". As the authors explain, medical technologies are associated with the concept of medical intervention,

## BOX 1: DEFINITIONAL CHALLENGES FOR ILLICIT TRADE IN MEDICAL PRODUCTS

As noted, the use of different terminology to describe illicit trade in medical goods may influence any findings regarding such trade. For many years, the response to this important threat to public health was embroiled in a discussion of definitions that meant different things to different people. Based on extensive deliberations, the World Health Assembly, which governs WHO, adopted the following definitions:<sup>2</sup>

- Substandard medical products – also called "out of specification", these are authorized medical products that fail to meet either their quality standards or their specifications, or both.
- Unregistered/unlicensed medical products – medical products that have not undergone evaluation and/or approval by the national or regional regulatory authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.
- Falsified medical products – medical products that deliberately/fraudulently misrepresent their identity, composition or source.

There are also specific terminological challenges that arise when discussing IP-infringement. First, while terms like "fake" are often used to denote violations of various international or national norms and standards, care should be taken to distinguish the violation of IP rights (such as trademarks and patents) from violations of provisions designed to ensure the quality and safety of medical products. While these violations often occur together, and each will lead to trade in such products being characterized as "illicit", the root causes for such trade, the potential health impact, and other consequences may differ, and thus require different policy responses.

Second, specific terminology with regard to IP infringement may be used in different ways. While the term "counterfeit" is sometimes used to describe IP-infringing goods more broadly, including those infringing, for example, patents or geographical indications, the TRIPS Agreement contains a precise definition of the term "counterfeit trademark goods", thus confining it to certain instances of trademark infringement.<sup>3</sup> Therefore, the magnitude of illicit trade linked to counterfeit goods may vary considerably, depending on the way the term "counterfeit" is understood.

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which can be preventive (e.g. vaccine), diagnostic (e.g. in vitro diagnostic kit, stethoscope, thermometer), therapeutic (e.g. medicine, surgical instrument, surgical procedure, implant) or rehabilitative (e.g. physiotherapy equipment, assistive device such as a crutch). [Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade, 2nd edition \(wto.org\)](#), Box 1.3, p. 39.

<sup>2</sup> World Health Organization (WHO) (2017) *A study on the public health and socioeconomic impact of substandard and falsified medical products*, Geneva: WHO; World Health Assembly document A70/23, 2017, Appendix 3 to Annex.

<sup>3</sup> For purposes of the TRIPS Agreement, "counterfeit trademark goods" means any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation. In other words, counterfeit trademark goods as defined in the TRIPS Agreement are goods involving slavish copying of trademarks. A counterfeit good gives the impression of being the genuine product originating from the genuine manufacturer or trader. It can usually be characterized as fraud since confusion between the genuine product and the substantially identical copy is intended. This is distinct from "ordinary" trademark infringement: in such cases, the issue may be whether an alleged infringer's mark is sufficiently close to a registered mark for there to be a likelihood of confusion between the marks. [WTO | Intellectual Property \(TRIPS\) – Agreement text – Enforcement](#), footnote 14 to Article 51; WTO, Guide to the TRIPS Agreement, Enforcement Module 8, available at [modules8\\_e.pdf \(wto.org\)](#).

## 1.2 THE SCOPE OF THE ILLICIT TRADE PROBLEM

*While there is some evidence that illicit trade in the medical product sector has increased since the outbreak of the COVID-19 pandemic, efforts to yield precise estimates remain difficult since the methodologies developed to measure the phenomenon are limited in their ability to capture the full scope of the problem. Nonetheless, illicit trade in medical products continues to pose a number of health, social, and economic impacts, making the achievement of various development goals, including those relating to poverty and health outcomes, more difficult.*

### 1.2.1 Understanding the illicit trade problem

1.7. In order to understand the causes and consequences of illicit trade, it is first necessary to be able to measure it. Since illicit trade is an inherently clandestine activity, however, this has proven quite difficult. Various methodologies have been advanced to quantify the nature and magnitude of illicit trade. In general, two broad approaches have been developed: (i) tracking cross-border transactions in counterfeit or mislabelled products;<sup>4</sup> and (ii) tracking various forms of customs mis-invoicing, such as the mis-classification of products, the under-reporting of unit prices, or the under-declaration of product quantities.<sup>5</sup> Due to the nature and quality of the data used, these approaches can capture only certain aspects of illicit trade.<sup>6</sup>

1.8. Based on the first methodology described above, OECD and EUIPO (2021) estimate that trade in counterfeit and pirated goods amounted to up to USD 464 billion globally in 2019, representing 2.4% of total world trade in goods in that year.<sup>7</sup> Based on the second methodology described above, in analysis of 135 developing countries' bilateral trade with 36 advanced economies, Global Financial Integrity (GFI) (2020) finds that the sum of all trade gaps amounted to USD 817.6 billion in 2017, representing 5.2% of total world trade in that year.<sup>8</sup> According to WTO estimations, the overall amount of illicit trade related to mis-invoicing was USD 535 billion in 2019, representing 2.8% of total world trade in goods in that year.<sup>9</sup>

1.9. The economic literature has identified potential underlying causes of illicit trade. First, higher levels of trade restrictions at the border have been found to increase illicit trade in the form of mis-invoiced or mis-

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<sup>4</sup> With this approach, mostly using data on customs seizures together with interviews with customs officials, it is possible to obtain estimates of the size of trade where some infringement of IPRs has been detected by customs. The Organisation for Economic Co-operation and Development (OECD) and European Union Intellectual Property Office (EUIPO) have developed a methodology (General Trade-Related Index of Counterfeiting, or GTRIC) that assigns the relative likelihood of there being counterfeit products in each product category and from each provenance economy and allows for the estimate of a ceiling for the international trade in counterfeit and pirated goods.

<sup>5</sup> With this approach, trade mis-invoicing is identified by comparing the reported value of a trade transaction in a country with the corresponding entry in the mirror statistics of the partner country, under the assumption that traders have an incentive to mis-declare on only one side of a transaction, while the data entry on the opposite side of the transaction is correct. While there are several potential measurement issues – most prominently, unrecorded flows cannot be captured, and mis-invoicing practices are best identified using transaction-level data, while the use of more aggregate data flows can introduce errors due to cancelling out of mis-invoiced trade transactions – the methodology based on mirror trade statistics has been used in the economic literature to uncover evidence of illicit trade in antiques, cultural property, natural resources, and livestock.

<sup>6</sup> A third approach relies on identifying "abnormal" prices in trade transactions, using transaction-level data from individual customs declarations. This approach is relatively data-intensive, and can only be used for case study analysis, but is particularly informative when considering homogeneous products with known reference prices. Chalendar, Raballand and Rakotoarisoa, (2019), for instance, find considerable mis-invoicing in the price of Madagascar's imports, noting that the declared import unit value is close to the top world price of rice, despite the fact that the country is likely to import price of poor quality. Chalendar, C., Raballand, G. and Rakotoarisoa, A. (2019), 'The use of detailed statistical data in customs reforms: The case of Madagascar', *Development Policy Review* 37(4):546-563.

<sup>7</sup> Organisation for Economic Co-operation and Development (OECD) and European Union Intellectual Property Office (EUIPO) (2021) *Global Trade in Fakes*, OECD and EUIPO. This report estimates a higher ceiling for trade in counterfeit and pirated goods in 2017 (more than USD 500 million), corresponding to almost 3% of total world trade in that year.

<sup>8</sup> Global Financial Integrity (GFI) (2020) *Trade-Related Illicit Financial Flows in 135 Developing Countries: 2008-2017*, Washington, DC: Global Financial Integrity.

<sup>9</sup> To compute this figure, the formula  $\frac{\sum(M+X)}{\sum(\tilde{m}+\tilde{x})}$  is used. In this formula,  $\tilde{m}$  and  $\tilde{x}$  respectively denote imports and exports for which both importer- and exporter-reported trade values are available at the HS 6-digit level.  $M$  and  $X$ , in turn, denote all available imports and exports, irrespective of the availability of mirror trade flows (i.e. they include both "lost exports", where  $X$  are reported but  $M$  are unreported, and "orphan imports", where  $M$  are reported but  $X$  are unreported). The missing world trade is then estimated based on two components: first, the difference between imports and exports is summed over all country-pairs and products:  $\sum(\tilde{m} - \tilde{x})$ . Second, this difference is adjusted for the fact that  $\tilde{m}$  and  $\tilde{x}$  are under-inclusive. The scaling factor  $\frac{\sum(M+X)}{\sum(\tilde{m}+\tilde{x})}$  is the inverse of the proportion of world trade covered by  $\tilde{m}$  and  $\tilde{x}$ .

reported imports.<sup>10</sup> Second, corruption is well-established as a determinant of illicit trade as evidenced by correlations found between reported trade gaps and smuggling activities.<sup>11</sup> Third, the importance of country characteristics other than tariffs in explaining illicit trade is further highlighted in recent work by Kellenberg and Levinson, (2019).<sup>12</sup> Using aggregated bilateral trade data, they find that low auditing and accounting standards and high domestic tax rates are also found to increase the mis-reporting of imports.

1.10. One well-known motivation for illicit trade is the aim of avoiding import duties and value added taxes on imports. Braml and Felbermayr, (2021) observe that tax fraud is a prominent phenomenon even in high income countries with relatively good state capacity.<sup>13</sup> Indeed, fiscal revenue shortfalls can be substantial. Global Financial Integrity (GFI), (2019) estimates that tax revenues lost to the Indian Government in 2016 due to trade mis-invoicing amounted to USD 13 billion, which was equal to about 5.5% of total tax revenue collections in India in that year.<sup>14</sup> According to WTO estimations, at the global level, the tariff revenue losses from illicit trade related to mis-invoicing amounted to USD 87 billion in 2019.<sup>15</sup>

1.11. Perhaps the most important dimension of this problem, however, but also the most difficult to measure, is the impact illicit trade has for the well-being of people around the world, especially in developing countries. TRACIT, (2019) provides a qualitative mapping of the impact of illicit trade on the 17 Sustainable Development Goals (SDGs), arguing that "the socio-economic impacts of illicit trade are all quantifiably negative and present significant deterrence to achieving all 17 of the SDGs".<sup>16</sup> In particular, TRACIT maintains that various forms of illicit trade collectively undermine achievement of the economic goals for poverty reduction, decent jobs and economic growth; rob governments of taxable income that could be invested in public services; undermine goals for peace and stability when generating revenues for organized criminal and terrorist groups; plunder natural resources; abuse supply chains; and expose consumers to potentially harmful products.<sup>17</sup>

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<sup>10</sup> Fisman and Wei, (2004) estimate that the "evasion gap" between China's imports and Hong Kong's exports is highly correlated with tax rates (tariff plus value-added tax rates) in China. Fisman, R. and Wei, S.-j. (2004), 'Tax Rates and Tax Evasion: Evidence from "Missing Imports" in China', *Journal of Political Economy* 112(2):471-496. Various other studies corroborate this pattern of positive correlation between "missing" trade (evasion gap) and tariff rates for other countries. See Javorcik, B. S. and Narciso, G. (2008), 'Differentiated products and evasion of import tariffs', *Journal of International Economics* 76(2):208-222; Mishra, P., Subramanian, A. and Topalova, P. (2008), 'Tariffs, enforcement, and customs evasion: Evidence from India', *Journal of Public Economics* 92(10-11):1907-1925; and Rotunno, L. and Vézina, P.-L. (2012), 'Chinese Networks and Tariff Evasion', *The World Economy* 35(12):1772-1794. Vézina, (2015) provides evidence that minerals, metals, or wood products are more likely to be missing from exporter's statistics if they face export barriers such as taxes or prohibition. Vézina, P.-L. (2015), 'Illegal trade in natural resources: Evidence from missing exports', *International Economics* 142(August):152-160.

<sup>11</sup> Exploiting the stark difference in legality of shipments between importing and exporting countries, Fisman and Wei, (2009) document that under-recording of exports of cultural property and antiques to the United States is highly correlated to the exporting country's level of corruption. Fisman, R. and Wei, S.-J. (2009), 'The Smuggling of Art, and the Art of Smuggling: Uncovering the Illicit Trade in Cultural Property and Antiques', *American Economic Journal: Applied Economics* 1(3):82-96. In his analysis of illicit trade in natural resources, Vézina, (2015) provides evidence that the presence of export barriers leads to more under-reporting of exports in countries with a high level of corruption. More generally, Nitsch and Berger, (2008) find that the reporting gaps are highly correlated with the level of corruption in both partner countries. Nitsch, V. and Berger, H. (2008), 'Gotcha! A Profile of Smuggling in International Trade', CESifo Working Paper No. 2475.

<sup>12</sup> Kellenberg, D. and Levinson, A. (2019), 'Misreporting trade: Tariff evasion, corruption, and auditing standards', *Review of International Economics* 27(1):106-129.

<sup>13</sup> Braml, M. T. and Felbermayr, G. J. (2021), 'The EU self-surplus puzzle: an indication of VAT fraud?', *International Tax and Public Finance*.

<sup>14</sup> Global Financial Integrity (GFI) (2019) *India: Potential Revenue Losses Associated with Trade Misinvoicing*, Washington, DC: Global Financial Integrity.

<sup>15</sup> This figure only takes into account tariff revenue losses. The overall fiscal revenue losses would also include lost VAT or sales taxes and corporate profit taxes. The figure is calculated based on all trade flows for which both importer- and exporter-reported trade values are available at the HS 6-digit level, and where reported exports exceed reported imports. The differences between exports and imports are multiplied with the importer's most-favoured nation duty rate or, if available for a given importer-exporter-product combination, the lowest applicable preferential duty rate. The estimated values of the tariff revenues losses are equal to the overall sum of these values.

<sup>16</sup> TRACIT (2019), Mapping the Impact of Illicit Trade on the Sustainable Development Goals, Geneva, available at [tracit\\_sdg\\_july2019\\_highres.pdf](https://tracit.org/2019/07/tracit_sdg_july2019_highres.pdf).

<sup>17</sup> TRACIT, (2019) considers illicit trade in the following 12 sectors/activities: agri-food industry, agrochemicals and pesticides, alcohol, counterfeit and pirated goods, forestry products, illegal, unreported, and unregulated fishing, petroleum products, pharmaceuticals, precious metals and gemstones, tobacco products, trafficking in persons, and wildlife trafficking.

## 1.2.2 The problem of illicit trade in medical products

1.12. The medical products sector has been the focus of particular scrutiny during the COVID-19 pandemic due to surging demand for medical products and their inputs both to diagnose and treat the disease, and to prevent its spread. Even as the pandemic severely disrupted trade and global supply chains, the value of trade in medical goods rose by 16% in 2020, and by 12% in the first half of 2021, with global imports of products such as ventilators, test kits and diagnostic equipment, face masks and other protective equipment all achieving double-digit growth.<sup>18</sup>

1.13. Global estimates of illicit trade in the medical products sector are scarce, remain sensitive to how such trade is defined, and rely on data that mostly pre-date the current pandemic. The WHO uses information from its substandard and falsified medical products surveillance database from 2013 to 2017 to show an increasing trend in the number of suspect products reported, but does not provide further statistics on the number of incidents. WHO observes that "[t]he WHO GSMS [(Global Surveillance and Monitoring System)] provides some insights into the size and scope of the trade in medical products that are falsified, poorly made or degraded, but it is impossible to determine exactly how many are in the market".<sup>19</sup> OECD and EUIPO report a value of global trade in counterfeit pharmaceuticals of up to USD 4.4 billion in 2016.<sup>20</sup> This represented 0.84% of total world-wide imports in pharmaceutical products in the same year, and 0.86% of (the ceiling of) global trade of fake goods, estimated at USD 509 billion for 2016.<sup>21</sup> (See Box 2 below for additional anecdotal evidence relating to illicit trade in COVID-19 medical products).

1.14. A proxy for the amount of illicit trade in medical products can also be constructed from discrepancies in trade data. Observing imports that exceed the respective export is not particularly surprising: import values often include trade costs, denoted as CIF figures (costs, insurance, freight), whereas exports are reported FOB (free on board). However, large discrepancies are likely to reflect trade mis-invoicing beyond the trade costs differential. Based on discrepancies between reported imports and reported exports, the WTO estimates a range of illicit trade in pharmaceutical products due to mis-invoicing between USD 9 and USD 28 billion in 2019.<sup>22</sup> These two bounds respectively correspond to 1.3% and 4.2% of the total value of trade of pharmaceutical products in 2019.

1.15. Many have argued that illicit trade in medical products has substantially increased during the COVID-19 pandemic. According to the United Nations Office on Drugs and Crime, with very high demand for medical products during the COVID-19 pandemic, "criminal groups quickly adapted by providing substandard and falsified medical products, including PPE, and offering non-existent supplies of products to defraud individuals and procurement agencies".<sup>23</sup> Various organizations have accordingly increased their surveillance and enforcement activities. Interpol<sup>24</sup>, for instance, coordinated Operation Pangea XIII in March 2020,

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<sup>18</sup> World Trade Organization (WTO) *Trade in medical goods in the context of tackling COVID-19: Developments in 2020* (30 June 2021), and *Trade in medical goods in the context of tackling COVID-19: Developments in the first half of 2021* (16 December 2021), Geneva: WTO. See [WTO | WTO reports on COVID-19 and world trade](#).

<sup>19</sup> World Health Organization (WHO) (2017) *WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products Report*, Geneva: WHO, p. 22.

<sup>20</sup> Organisation for Economic Co-operation and Development (OECD) and European Union Intellectual Property Office (EUIPO) (2019) *Trends in Trade in Counterfeit and Pirated Goods*, OECD and EUIPO, Table 4.4.

<sup>21</sup> Ibid., and Organisation for Economic Co-operation and Development (OECD) and European Union Intellectual Property Office (EUIPO) (2020) *Trade in Counterfeit Pharmaceutical Products*, OECD and EUIPO, p. 29.

<sup>22</sup> The definition of pharmaceutical products from the WTO Agreement on Trade in Pharmaceutical Products was used for these calculations. Pharmaceutical products thus include all HS-6 subheadings of HS chapter 30, as well as all HS-6 subheadings of HS headings 2936, 2937, 2939, and 2941. The upper bound estimate (USD 28 billion) is obtained using the following steps. First, discrepancies (in percentage terms) are calculated from HS6-level reported imports ( $M$ ) and reported exports ( $X$ ) using the following formula from Braml and Felbermayr, (2021) (see footnote 13):  $disc = 100 * \frac{2(M-X)}{M+X}$ . The data show that  $disc$  was equal to 6.3% on average in 2019. Second, we assume that trade costs are equal to 2.1%, the lower bound of  $disc$ . Therefore, one third (2.1/6.3) of  $disc$  is attributed to trade costs, and two thirds (1 - 2.1/6.3) to mis-invoicing. Third, we calculate a value of USD 38.4 billion for total value of all the differences between reported imports and reported exports in the data in 2019. Two thirds of this value, i.e. USD 25.6 billion, is therefore attributed to mis-invoicing. Fourth, and finally, we note that both imports and exports are reported on 93% of global trade in pharmaceutical products. We attribute the same mis-invoicing probability to the 7% of trade with "lost exports" ( $X$  reported,  $M$  unreported) or "orphan imports" ( $M$  reported,  $X$  unreported), and therefore we calculate an amount of illicit trade due to mis-invoicing in 2019 equal to  $25.6/0.93 \approx USD\ 28\ billion$ . The lower bound estimate (USD 9 billion) is obtained following the same methodology, assuming that trade costs are higher, and equal to 5%, in step two.

<sup>23</sup> United Nations Office on Drugs and Crime (UNODC) (2020) *COVID-19-related Trafficking of Medical Products as a Threat to Public Health*, Vienna: UNODC, p. 9.

<sup>24</sup> International Criminal Police Organization: <https://www.interpol.int/en>.

reporting increased seizures of COVID-19-related medical products relative to previous similar operations.<sup>25</sup> The WCO<sup>26</sup> ran two emergency operations against illegal trafficking linked to COVID-19. Operation STOP, which took place between May and July 2020, involved 99 WCO members, and led to 1,683 seizures.<sup>27</sup> The second iteration of Operation STOP, which took place between April and September 2021, involved 146 WCO members, and generated twice as many seizures.<sup>28</sup> EUROPOL's<sup>29</sup> Operation Shield, conducted between March and September 2020, highlighted how emerging pharma crime is linked to the pandemic and resulted in seizures of almost 33 million pharmaceutical devices, 8 tonnes of raw materials, chemicals, and antivirals and 70 000 litres of hygienic sanitizers.<sup>30</sup> Based on interviews with industry experts, OECD and EUIPO report that the average seizure value of pharmaceuticals increased by 5% in 2020 compared with 2019, and conclude that, "[c]onsidering the overall drop in enforcement, this suggests that the trade in illicit medicines has grown by 25% from 2019. Of these 45% are counterfeits and 55% are stolen."<sup>31</sup>

1.16. These data, while pointing to an increase in illicit trade in medical products during the COVID-19 pandemic, may need to be interpreted with caution. First, since the COVID-19 pandemic is still ongoing, the data are still preliminary in nature and may not illustrate broader trends. Second, the number of seizures clearly depends on the intensity of enforcement operations, since, as the WHO puts it, "the more one looks, the more one finds".<sup>32</sup> Third, since detailed information on the underlying reasons for a seizure (e.g. lack of accompanying documentation, lack of regulatory approval in the importing country, IPR infringement, tax evasion) is generally unavailable, it remains unclear how to interpret aggregate seizure numbers or how to establish a correlation with health outcomes. Fourth, and related to the previous point, the data remain sensitive to uncertainties regarding definitions as to what constitutes "fake", "substandard", "falsified", or "counterfeit" medical products.<sup>33</sup>

1.17. Nonetheless, assuming that such an increase in illicit medical product trade is indeed evident, this may have been caused by the number of export restrictions imposed by countries. Since the outbreak of the pandemic, export restrictions accounted for 85% of all restrictive measures recorded, and 45 export restrictions (out of 117 recorded) were still in place as of mid-October 2021, covering products such as medicines, other medical supplies, and personal protective equipment.<sup>34</sup> Empirical evidence shows that products are more likely to be missing from exporter's statistics if they face export barriers such as taxes or prohibition<sup>35</sup>, and that in the presence of export restrictions smuggling activities will increase.<sup>36</sup> Therefore, a positive impact of export restrictions in medical products on illicit trade in these products during the COVID-19 pandemic is very plausible.

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<sup>25</sup> See <https://www.interpol.int/News-and-Events/News/2020/Global-operation-sees-a-rise-in-fake-medical-products-related-to-COVID-19>. Compared to the 2018 edition of Operation Pangea, Pangea XIII reported an increase of about 18% in seizures of unauthorized antiviral medication, and an increase of more than 100% in seizures of unauthorized chloroquine (an antimalarial medication that may be connected to the COVID-19 pandemic). Interpol reports a large increase in international shipments of small parcels (by about 40%), probably due to the coronavirus outbreak. During the week of action (3-10 March 2020), 48,000 packages, out of 326,000 packages inspected, were seized by customs and regulatory authorities in participating Interpol countries. Furthermore, as of March 2020 the operation had closed down more than 2,500 web links (websites, social media pages, online marketplaces, and online adverts for illicit pharmaceuticals).

<sup>26</sup> World Customs Organization: <http://www.wcoomd.org/>.

<sup>27</sup> These seizures amounted to over 300 million units of medicines, more than 47 million units of medical supplies (masks, gloves, COVID-19 test kits, thermometers and gowns), and approximately 2.8 million litres of hand sanitizer gel. See <http://www.wcoomd.org/en/media/newsroom/2020/october/operation-stop--the-wco-operation-hits-hard-the-illegal-trafficking-linked-to-covid19.aspx>.

<sup>28</sup> Under STOP II, a total of 2,769 cases of trafficking were reported by 90 Members and some 4,034 cases of seizures recorded. Of the 501.5 million units seized, 273.6 million were medicines related to COVID-19 (ivermectin, doxycycline, pregabalin, etc.), 214.4 million were medical devices (COVID-19 test kits, face masks, used gloves, sanitizer gel, oxygen cylinders, etc.), and around 13.5 million were doses of COVID-19 vaccines. See <http://www.wcoomd.org/en/media/newsroom/2022/july/the-stop-ii-project-ends-on-a-high-note-with-outstanding-results.aspx>.

<sup>29</sup> The EU Agency for Law Enforcement Cooperation: [www.europol.europa.eu](http://www.europol.europa.eu).

<sup>30</sup> EUIPO/EUROPOL (2022), Intellectual Property Crime Threat Assessment 2022, available at: <http://www.europa.eu>, p 22.

<sup>31</sup> OECD and EUIPO, (2021), *Global Trade in Fakes*, p. 61.

<sup>32</sup> World Health Organization (WHO) (2017) *WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products Report*, Geneva: WHO, p. 10.

<sup>33</sup> See Box 1 above for more information on some of these definitional challenges.

<sup>34</sup> World Trade Organization (WTO) *Overview of Developments in the International Trading Environment: Annual Report by the Director-General (Mid-October 2020 to Mid-October 2021) (WT/TPR/OV/24)*, Geneva: WTO.

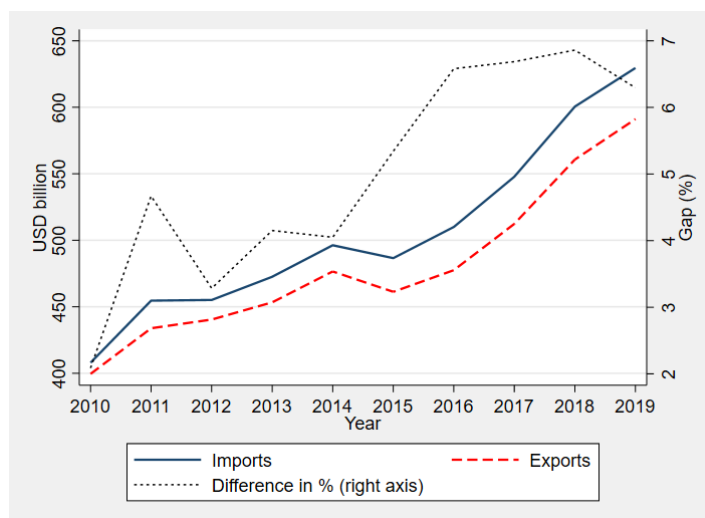
<sup>35</sup> Vézina, P.-L. (2015), 'Illegal trade in natural resources: Evidence from missing exports', *International Economics* 142(August):152-160.

<sup>36</sup> Chimeli, A. B. and Soares, R. R. (2017), 'The Use of Violence in Illegal Markets: Evidence from Mahogany Trade in the Brazilian Amazon', *American Economic Journal: Applied Economics* 9(4):30-57.



1.18. It may also be noted that any upward trend in illicit trade in medical products could have, in fact, predated the pandemic. Figure 1 depicts the evolution of the global discrepancies, summing up all imports and all exports recorded globally. Total imports increased from USD 408 billion to USD 630 billion between 2010 and 2019; at the same time, exports rose from USD 400 billion to USD 591 billion. Thus, the absolute discrepancy ( $M - X$ ) has surged almost fivefold from USD 8 billion to USD 38 billion between 2010 and 2019. Put into relative terms using the formula by Braml and Felbermayr, (2021) (see footnotes 13 and 22), the discrepancy tripled from 2.1% to 6.3%, as shown by the dotted line and right axis in Figure 1.<sup>37</sup>

**Figure 1: Evolution of imports, exports, and trade discrepancies in pharmaceutical products, global, 2010-2019**



Notes: WTO Secretariat calculations based on WTO trade statistics. Pharmaceutical products, as defined in the WTO Agreement on Trade in Pharmaceutical Products, include all HS-6 subheadings of HS chapter 30, as well as all HS-6 subheadings of HS headings 2936, 2937, 2939, and 2941.

1.19. Duty rates on pharmaceutical products are, on average, relatively low. According to WTO tariff data, the average rate amounts to 1.7%, and the trade-weighted figure stands even below that at 1.2%. Thus, tariff revenue shortfalls are limited. Based on the same calculation method as above (see paragraph 1.9), the WTO estimates that tariff revenue losses from illicit trade in pharmaceutical products due to mis-invoicing amounted to USD 293 million in 2019.

1.20. Despite relatively limited impact on tariff revenue, illicit trade in medical products, and the trafficking of substandard, un-registered, or falsified products, can have serious public health, economic, and socio-economic consequences. According to the WHO, the *public health* impact is measured in terms of (i) adverse effects (for example toxicity or lack of efficacy) from incorrect active ingredients; (ii) failure to cure or prevent future disease, increasing mortality, morbidity and the prevalence of disease; (iii) progression of antimicrobial resistance and drug-resistant infections; and (iv) loss of confidence in health care professionals, health programmes and health systems.<sup>38</sup> The *economic* impact is measured in terms of (i) increased out-of-pocket and health system spending on health care; (ii) economic loss for patients, their families, health systems and firms operating in quality medical products supply chains; (iii) waste of human effort and financial outlay across the health system; and (iv) increased burden for health care professionals, national medicine regulatory authorities, law enforcement and criminal justice systems. Finally, the *socio-*

<sup>37</sup> As noted above, because of CIF-FOB differentials, imports exceeding their mirror exports appear plausible. Such a drastic change is however likely to reflect increasing illicit trade in pharmaceutical products, as measured by mis-invoicing.

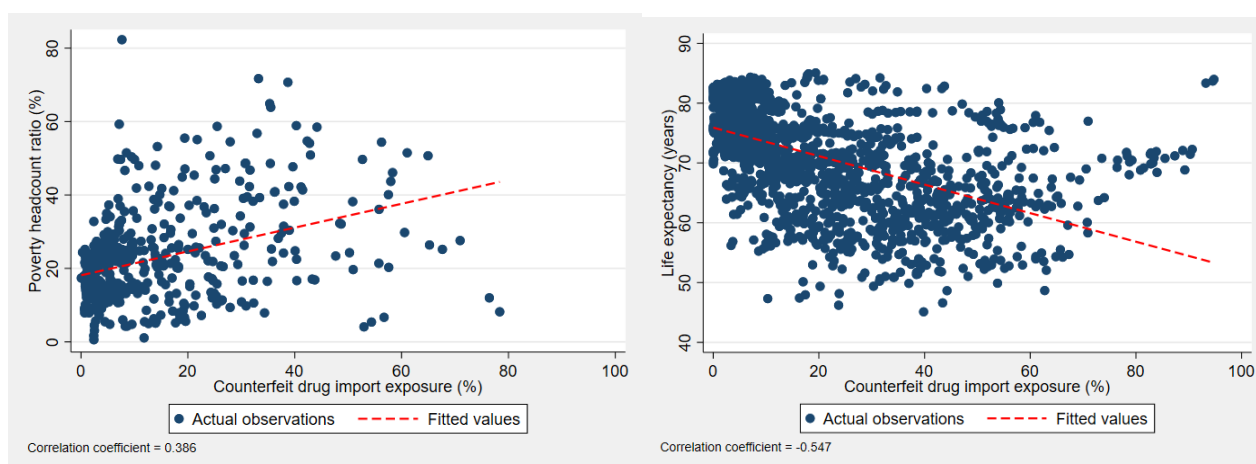
<sup>38</sup> World Health Organization (WHO) (2017) *A study on the public health and socioeconomic impact of substandard and falsified medical products*, Geneva: WHO. Two studies commissioned by the WHO and conducted by academic researchers report respectively on the impact of substandard and falsified antibiotics in the treatment of childhood pneumonia, and on the health cost of substandard and falsified medical products for malaria in sub-Saharan Africa. The former study estimates that, in the most likely scenario of two-fold increase in the case fatality rate, the number of childhood pneumonia deaths that can be attributed to the use of substandard and falsified antibiotics ranges from 8,668 if the prevalence of substandard and falsified products is equal to 1%, to 72,430 if the prevalence of substandard and falsified products is equal to 10%. The latter study estimates that incremental deaths in sub-Saharan Africa due to substandard and falsified antimalarials comprise approximately 2.1% to 4.9% of total malaria deaths, or approximately 3.8% to 8.9% of malaria deaths relating to cases seeking treatment.

*economic* impact is measured in terms of (i) lost productivity and income due to prolonged illness or death; and (ii) lack of social mobility and increased poverty.

1.21. Similar insights are provided by TRACIT, (2019), which argues that illicit trade in pharmaceuticals negatively impacts achievement of the seven following SDGs: SDG 1 (no poverty); SDG 3 (good health and well-being); SDG 5 (gender equality); SDG 8 (decent work and economic growth); SDG 9 (industry, innovation and infrastructure); SDG 12 (responsible consumption and production); and SDG 16 (Peace, justice and strong institutions).<sup>39</sup> While the theoretical channels through which illicit trade in pharmaceuticals can push the achievement of these SDGs further away are relatively clear, there is to date very little evidence on the relationship between illicit trade in pharmaceuticals and SDGs, let alone on any causal impact that such trade may have on SDGs.

1.22. In a preliminary attempt to address this gap, Figure 2 provides scatterplots of the relation between exposure to imports of counterfeit pharmaceuticals (horizontal axis) and poverty (left panel) or life expectancy (right panel).<sup>40</sup> Exposure to imports of counterfeit pharmaceuticals positively correlates with poverty headcount as percentage of population (a proxy for SDG 1), and negatively correlates with life expectancy (a proxy for SDG 3).<sup>41</sup> These correlations should be interpreted only as a suggestion that countries that are highly exposed to the risk of importing counterfeit pharmaceuticals also tend to be poorer and to have worse health outcomes. A causal interpretation is prevented due to potential omitted variables and reverse causality.<sup>42</sup> As a tentative conclusion, however, it can be argued that the presence of a vicious circle of poverty, poor health outcomes and the consumption of counterfeit pharmaceuticals appears plausible, as these variables are interdependent and determine each other.

**Figure 2: Correlations between exposure to illicit pharmaceutical imports and selected SDG indicators**



Notes: WTO Secretariat calculations based on World Bank World Development Indicators, Trade Data Monitor and GTRIC-e (General Trade-Related Index of Counterfeiting for economies) data from Table 4.1 in OECD and EUIPO (2020) (see footnote 21). The above panels are based on available data from 140 countries in the period from 2010-2019. In the left panel, the poverty headcount ratio is expressed at national poverty lines, as per cent of the population.

<sup>39</sup> TRACIT (2019), Mapping the Impact of Illicit Trade on the Sustainable Development Goals, Geneva, available at [tracit\\_sdg\\_july2019\\_highres.pdf](https://tracit.org/wp-content/uploads/2019/07/tracit_sdg_july2019_highres.pdf).

<sup>40</sup> Counterfeit drug import exposure is measured as the cumulative share of pharmaceutical imports sourced from the top five economies most likely to be a provenance of counterfeit pharmaceutical products (see Table 4.1 in OECD and EUIPO (2020)) in total pharmaceutical imports.

<sup>41</sup> Correlations between exposure to imports of counterfeit pharmaceuticals and proxies for other SDGs (SDG 5, 8, 9, 12, and 16) are not displayed because they do not show any interesting pattern.

<sup>42</sup> Do less healthy people demand more counterfeit drugs, or are they less healthy because they consume counterfeit drugs? If they are less healthy because they consume counterfeit drugs, they are also likely to become poorer. Being poor, however, is likely to increase demand for counterfeit drugs. Identifying the causal impact of illicit trade on individual outcomes such as poverty or health status would require data at individual household level over time.

## BOX 2: ANECDOTAL EVIDENCE OF ILLICIT TRADE IN COVID-19 MEDICAL PRODUCTS

The following are some examples of falsified COVID-19 medical products identified in WHO medical product alerts<sup>43</sup> and other public sources:

- [Falsified COVID-19 VACCINE AstraZeneca](#) (ChAdOx1-S [recombinant]) and [falsified Pfizer-BioNTech COVID-19 Vaccine](#) were identified in the Islamic Republic of Iran and reported to WHO in October 2021. The falsified products were reported at the patient level outside authorized and regulated supply chains and authorized immunization programmes in the Islamic Republic of Iran.
- Falsified [COVISHIELD \(ChAdOx1 nCoV-19 Corona Virus Vaccines \(Recombinant\)\)](#) were identified in the WHO African Region, and the WHO South-East Asia Region. The falsified products were reported to WHO in July and August 2021. These falsified products have been reported at the patient level in Uganda, India and Myanmar.
- Two batches of [falsified remdesivir injection 100mg/20ml \(5mg/ml\)](#) were identified in the WHO Region of the Americas and reported to WHO in July 2021. These falsified products have been reported at the patient level (including at a hospital) in Mexico and were illicitly supplied on the internet.
- Falsified COVID-19 Vaccines identified as "[BNT162b2](#)" were detected in Mexico in February 2021 and confirmed as falsified to the WHO. The falsified product was supplied and administered to patients outside authorized vaccination programs.
- Significant volumes of substandard or falsified PPE (e.g. protective masks and hand sanitizers) were found to be circulating in the United States<sup>44</sup>; the United Kingdom<sup>45</sup>; the European Union<sup>46</sup>; Turkey<sup>47</sup>; and Argentina.<sup>48</sup> There were also significant imports of non-compliant COVID-19 test kits reported into the European Union and the United States.<sup>49</sup>

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<sup>43</sup> WHO website, [Substandard and falsified medical products \(who.int\)](#). The WHO has also issued a [Statement for healthcare professionals: How COVID-19 vaccines are regulated for safety and effectiveness](#).

<sup>44</sup> Andrew Jacobs, "Counterfeit Covid Masks Are Still Sold Everywhere, Despite Misleading Claim" (The New York Times, 2021).

<sup>45</sup> ["Falsified: Test Reports & Certificates - Identification and Impact of Counterfeit Test Reports and Certificates in the Global Marketplace"](#) (TIC Council, Anti-Counterfeiting Committee).

<sup>46</sup> [Chair's note "Illicit Trade in a time of crisis"](#), (OECD, 23 April 2020).

<sup>47</sup> [The factories pumping out dangerous fake masks](#), (The Independent, 2020).

<sup>48</sup> United Nations Office on Drugs and Crime (UNODC) (2020) *COVID-19-related Trafficking of Medical Products as a Threat to Public Health*, Vienna: UNODC.

<sup>49</sup> [Chair's note "Illicit Trade in a time of crisis"](#), (OECD, 23 April 2020); Chair's note "Trade in fake medicines at the time of the COVID-19 pandemic", available at [oecd-fake-medicines-webinar-june-10-summary-note.pdf](#).

## **2 WTO RULES AND ACTIVITIES ARE KEY ALLIES IN THE FIGHT AGAINST ILLICIT TRADE**

2.1. This section highlights the role WTO disciplines and trade policy activities can play in assisting governments to address illicit trade in three substantive policy areas: (i) improving border controls through trade facilitation and other measures; (ii) strengthening regulatory coherence in product quality and safety controls; and (iii) fighting illicit trade through domestic IPR enforcement and international cooperation. It also sets out some of the good governance requirements and practices relating to government procurement. In each of the following sections, the particular context and challenges relating to each policy area are set out, followed by a description of relevant WTO disciplines and activities in each area to identify how WTO Members may use WTO tools to tackle illicit trade, particularly with respect to medical products.

### **2.1 IMPROVING BORDER CONTROLS THROUGH TRADE FACILITATION AND OTHER MEASURES**

*Trade facilitation measures strengthen the ability of WTO Members to tackle illicit trade. Provisions of the Trade Facilitation Agreement bolster border controls by requiring greater transparency of customs rules, improved risk management and pre- and post-clearance processes, and increased domestic coordination and international customs cooperation. The Trade Facilitation Committee also encourages the sharing of experiences that enhance customs processes. In addition, rules on customs valuation further buttress the aims of transparency and predictability by setting out rules to address possible mis-invoicing at the border. When Members supplement reforms with increased automation and data sharing, WTO Members augment their ability to operate in an increasingly digital economy and to confront the challenges of illicit trade. Greater customs functioning and transparency both enhance the ability of governments to address the threat of illicit trade while curbing discretionary practices that can give rise to inefficiencies and corruption.*

2.2. Customs administration plays an essential role in overseeing the conduct of international trade by ensuring the movement of goods across borders in a manner that is efficient, safe, and secure. Adequate customs controls should thus enable smooth trade operations while safeguarding a government's interest in appropriately addressing other policy concerns such as the fight against illicit trade. Those engaged in illicit trade are keen to take advantage of the gaps and uncertainty in regulatory regimes to market their illegal products or engage in otherwise illegal trading practices. And as noted in the previous section, the medical product sector is equally if not more prone to such illicit products and practices. Amidst the challenges governments face in combating illicit trade, including with respect to medical products, the recent pandemic experience has intensified key structural and supply chain shifts that have had the potential to exacerbate illicit trade activity. Two such recent developments are of particular relevance for the medical product sector.

2.3. First, there has been a marked increase in the use of electronic means to conduct trade, and this phenomenon has only accelerated during the course of the COVID-19 pandemic. In 2020, retail e-commerce sales worldwide amounted to USD 4.3 trillion.<sup>50</sup> Social distancing, lockdowns and other measures adopted to combat the pandemic led consumers to ramp up online shopping, with e-retail revenues projected to grow to USD 5.4 trillion in 2022. This has generated immense benefits by allowing customers to access a broad range of goods while enabling businesses, especially micro, small, and medium enterprises (MSMEs), to access new markets. As the OECD has observed, however, this has also created opportunities for illicit traders in the medical product sector.<sup>51</sup> Sales of substandard or falsified masks on e-commerce platforms grew significantly during the pandemic, which was especially problematic during periods of peak demand.<sup>52</sup> Misleading online marketing has also been identified as a related challenge.<sup>53</sup> Moreover, customs and regulatory authorities have encountered new challenges in regulating such trade, including the difficulties of monitoring higher volumes of small parcels traded through international delivery service companies. These

<sup>50</sup> See <https://www.statista.com/statistics/534123/e-commerce-share-of-retail-sales-worldwide/>.

<sup>51</sup> According to the OECD, "[e]-commerce is becoming the main platform for illicit products, including fake and substandard medicines, test kits and other COVID-19-related goods. Enforcement officials also highlight that fake medical products related to COVID-19 are often bought online and shipped by air cargo in small parcels" ([Chair's note "Trade in fake medicines at the time of the COVID-19 pandemic"](#) (OECD, 10 June 2020)).

<sup>52</sup> Andrew Jacobs, "Counterfeit Covid Masks Are Still Sold Everywhere, Despite Misleading Claim" (The New York Times, 2021).

<sup>53</sup> An EU trade association reports that at any one time there are between 30,000-35,000 online pharmacies, and that 95% of websites do not comply with jurisdictional law or regulation. "Charting the True Costs of Illicit Trade", Alliance for Safe Online Pharmacies, Launch of OECD-EUIPO Report "Dangerous Fakes", 16-17 March 2022. As part of an operation against illegal online sale of medicines and medical devices, the UK Medicines and Healthcare Products Regulatory Agency found 871,616 doses of unlicensed medicines with a value of £2.6m, while 294 websites were taken down and 1031 social media adverts removed selling medicines illegally. Press release (2020), available at [Coronavirus: global crackdown sees a rise in unlicensed medical products related to COVID-19 - GOV.UK \(www.gov.uk\)](#).

developments have heightened the risks for customs authorities of failing to establish and update proper border controls, and for regulators to effectively implement post-market controls.

2.4. Second, supply chain disruptions caused by the COVID-19 pandemic have generated considerable uncertainty in product markets. In particular, surges in demand and the imposition of various restrictions have led to uneven trade and distribution of key medical products. In a study on trade-related bottlenecks during the COVID-19 pandemic, the WTO noted the particular challenges associated with a lack of transparency in import and export restrictions and applicable customs controls, lengthy and unpredictable processing times, and uncertainties and delays associated with sourcing inputs.<sup>54</sup> Such disruptions to the functioning of supply chains provide criminal groups with new opportunities to ply their illicit goods and activities.

2.5. Trade facilitating measures can strengthen the customs controls that assist governments in addressing the illicit trade threat, including in the medical product sector. The Trade Facilitation Agreement (TFA) entered into force in 2017 and has, since then, become a major driver for the simplification, modernization, and harmonization of customs procedures. In embracing TFA commitments, WTO Members have sought to improve customs procedures and processing times to facilitate and expedite the movement of goods across borders. This has had the benefit of lowering costs for producers and consumers, which is vital in enhancing economic growth, particularly for MSMEs and those living in developing countries.

2.6. At the same time, many of the improvements in border processing also have the capacity to enhance controls that safeguard the ability of customs and other agencies to address illicit trade concerns. The TFA contains a number of provisions that bolster the capacity of customs to maintain such controls, by requiring greater transparency of customs rules and procedures, the advent of risk management systems and greater reliance on pre- and post-clearance processes, and a focus on increased domestic coordination and international customs cooperation. In addition, disciplines in the Customs Valuation Agreement further stabilize the customs environment with regard to the valuation of goods at the border. Greater customs functioning and transparency both enhance the ability of governments to address the threat of illicit trade while at the same time curbing discretionary practices that can give rise to inefficiencies and corruption. (See Box 3 below on how improved customs controls can mitigate risks of corrupt practices.)

### **BOX 3: TACKLING CORRUPTION VIA IMPROVED CUSTOMS CONTROLS**

Corruption corrodes the moral and economic fabric of society. It undermines values and value systems and erodes trust in public institutions and the notion of a fair social contract. It represents a misallocation of finite resources away from public services, infrastructure, and other investments that can help poor and vulnerable people improve their lives. It raises costs for businesses. And in the long-term it is a roadblock to lasting economic growth and development, leaving societies poorer and more unequal than they otherwise would have been.

– WTO Director-General Ngozi Okonjo-Iweala<sup>55</sup>

Corruption at the border amplifies the threat and incidence of illicit trade. When illicit traders seek to move illegal goods across borders or otherwise engage in illegal trading practices even in respect of legal goods, collusion with government officials can pave the way for their unlawful conduct. The implications of such extend beyond particular transactions, and can involve both public and private actors, and developing as well as developed countries. If a customs official is paid off to allow the importation of fake or stolen medical products, this certainly implicates illegal conduct on the part of the customs official and trader involved, but it also carries consequences for the producers and consumers of these goods wherever they are located, and may even involve collusion by financial and other systems situated elsewhere in the world that have played a role in facilitating that corrupt transaction. Indeed, corruption linked to illicit medical products may potentially include any actor in the supply chain and this underscores the need for governments to focus on a coordinated approach to border management.

<sup>54</sup> Indicative List of Trade-Related Bottlenecks and Trade-Facilitating Measures on Critical Products to Combat COVID-19, 8 October 2021. See [bottlenecks\\_update\\_oct21\\_e.pdf \(wto.org\)](#)

<sup>55</sup> Dr Ngozi Okonjo-Iweala, Transparency International United Kingdom Annual Anti-Corruption Lecture, December 2021. See [WTO | News - Speech - DG Ngozi Okonjo-Iweala - DG Okonjo-Iweala: WTO rules can support fight against corruption, illicit trade and enhance transparency.](#)

The WCO has outlined a number of factors that make customs authorities particularly susceptible to corruption, including control and discretion over border transactions; low levels of supervision and accountability; and the volume and complexity of regulatory frameworks.<sup>56</sup> More recently, the OECD has examined the extent to which trade facilitation policies help in reducing corruption.<sup>57</sup> Although it was noted that countries with more efficient border processes generally had higher levels of border integrity, it has been difficult to establish causality due to data challenges and limitations. The OECD found, however, that specific trade facilitation policies – in particular, measures focusing on transparency and predictability in customs rules, the streamlining of formalities, and coordinated border management – were powerful tools in reducing both the incentives and opportunities for corruption, and thus in supporting border integrity. Such effects are further confirmed by research by Beverelli and Ticku, (2022) showing that trade facilitation improvements contribute to reducing tariff evasion in countries with low control of corruption at the border.<sup>58</sup>

### 2.1.1 Enhancing transparency and streamlining customs procedures

2.7. The TFA contains a host of provisions requiring WTO Members to publish a wide range of trading information and to do so in an easily accessible way. This includes essential information on relevant import, export and transit procedures and any required forms and documents, most of which must also be made available on the internet.<sup>59</sup> In addition, Members must publish all of their domestic rules in connection with customs valuation, rules of origin, and any import, export or transit restrictions or prohibitions, as well as those relating to duties and taxes imposed on inbound or outbound trade and any related fees and charges. The TFA also increases transparency by requiring Members to designate and publish contact information for a national enquiry point to field the inquiries of governments, traders and other interested parties.<sup>60</sup>

2.8. TFA provisions also encourage the streamlining and digitalization of customs procedures which can both facilitate cross-border transactions and minimize the opportunities for illegal conduct and corruption. The TFA requires Members, for example, to establish a single-entry point (or "single window") through which traders can submit documents supporting their transactions.<sup>61</sup> They must also notify the details of operation of the single window and, where possible, support the single window through the use of information technology. This is complemented by other provisions that encourage digitalization, such as allowing for the option of electronic payment.<sup>62</sup> This sort of streamlining and automation not only simplifies the process for traders but also reduces the frequency of interactions that could give rise to instances of corruption at the border. Implementation issues, however, remain for developing and least developed countries, with two-thirds indicating that they need technical assistance to implement the single window provisions.

2.9. Through the publication of this wide-ranging customs information and the streamlining of customs procedures, traders are alerted to the rules and procedures governing their transactions, which has the effect of both facilitating and securing their supply chains and trading activities. In this manner, while the clarification of procedures, requirements and costs of trading clearly facilitates the movement of goods, it also constrains the opportunities for private or public actors to exploit uncertainty in the trading system in order to engage in illicit or corrupt trading practices. Moreover, the benefits of these developments are further enhanced whenever customs rules and processes can be digitalized, and this is an area where current e-commerce negotiations, for instance on establishing a paperless trading environment, could make a difference. (See Box 4 below on WTO negotiations currently addressing rules on e-commerce.) In this respect, the WCO has also contributed to this field by developing and periodically updating standards and relevant principles in the context of its Framework of Standards on Cross-Border E-Commerce.<sup>63</sup>

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<sup>56</sup> WCO Integrity Development Guide, 2021.

<sup>57</sup> Exploring the Role of Trade Facilitation in Supporting Integrity in Trade, OECD Working Party of the Trade Committee, TAD/TC/WP(2019)1/FINAL, 15 April 2019.

<sup>58</sup> Beverelli, C. and Ticku, R. (2022), 'Reducing tariff evasion: The role of trade facilitation', *Journal of Comparative Economics*. <https://doi.org/10.1016/j.jce.2021.12.004>.

<sup>59</sup> TFA, Article 1.1.

<sup>60</sup> TFA, Articles 1.2 and 1.3.

<sup>61</sup> TFA, Article 10.4.

<sup>62</sup> TFA, Article 7.2.

<sup>63</sup> See [World Customs Organization \(wcoomd.org\)](http://www.wcoomd.org).

## BOX 4: WTO NEGOTIATIONS ON RULES RELATING TO ELECTRONIC COMMERCE

Current e-commerce negotiations under the WTO Joint Statement Initiative on Electronic Commerce<sup>64</sup> could offer additional support to the efforts of WTO Members in combating illicit trade. By the end of 2021, good convergence had been achieved on several sets of rules, and the co-convenors noted that outcomes achieved in these areas would deliver important benefits including boosting consumer confidence and supporting businesses trading online.<sup>65</sup> The negotiations are open to all Members; currently 86 Members are participating in the negotiations, representing over 90 per cent of global trade.

These e-commerce negotiations aim to create a more secure and predictable environment for digital and online commerce that could, among other benefits, reduce opportunities for illicit traders. Negotiations on paperless trading, for instance, reinforce provisions in the TFA by extending transparency provisions to the digital trading environment. Increased transparency is helpful in ensuring predictability and in clarifying and supporting the further strengthening of rules and practices that discourage illicit practices. In addition, such rules facilitate increased reliance on automation and technology that can reduce opportunities for corruption and illicit behaviour at the border.

Other rules being developed pertain to efforts to shield consumers from fraudulent practices by seeking to establish certain online consumer protections and protections against unsolicited commercial electronic messages. In addition, these discussions aim not only to facilitate digital trade but also to ensure the accuracy and reliability of information exchanges. Enhanced rules in the areas of electronic signatures and authentication, electronic contracts, and electronic invoicing would also have a dampening effect on the incentives and opportunities to engage in illicit trade.

### 2.1.2 Managing risk through pre- and post-import activities

2.10. The TFA also sets out obligations relating to activities conducted prior to or following the arrival of goods that both streamline and strengthen oversight by customs authorities. Prior to import, for instance, WTO Members are under a general obligation to adopt procedures allowing for the submission of import documentation to begin processing goods prior to their arrival.<sup>66</sup> They are also required to issue advance rulings to requesting traders setting forth what treatment will be provided regarding a good's tariff classification or origin, and advance rulings are encouraged on other matters including customs valuation, duty exemptions and quota administration.<sup>67</sup> Customs authorities must issue such advance rulings in a reasonable, time-bound manner, and must publish information relating to relevant requirements, deadlines and the duration of such rulings. WTO Members also endeavour to make publicly available any information on advance rulings which they consider to be of significant interest to other interested parties. This reinforces the transparency and visibility of a WTO Member's advance ruling regime. In addition, of particular relevance in respect of illicit trade is the fact that customs authorities are also permitted to revoke, modify, or invalidate advance rulings with retroactive effect when they are based on incomplete, incorrect, false, or misleading information.

2.11. After a good is imported, the TFA also requires WTO Members to provide for post-clearance audits to ensure compliance with customs and other related laws and regulations.<sup>68</sup> Selection of a person or consignment for post-clearance audit must be conducted in a risk-based manner according to appropriate selectivity criteria. This allows for expedited release of goods while maintaining proper oversight and control by customs authorities. Reliance on post-clearance audits also generates information that can strengthen risk management systems. (See Box 5 below on how risk management systems can assist governments in more accurately detecting transactions that may be illicit in nature.)

2.12. A further feature in the TFA toolbox is a system for the approval of authorized operators which requires WTO Members to extend additional trade facilitation measures to operators who meet specified criteria.<sup>69</sup> These provisions allow for the screening of such operators on the basis of whether they have a record of compliance with customs and other related laws and regulations, whether they retain a system of managing records to allow for necessary internal controls, and whether they provide for supply chain security. These sorts of criteria support a risk-based assessment and a trading environment that reduces the incidence of

<sup>64</sup> See [WTO | Electronic commerce](#).

<sup>65</sup> WTO Joint Statement Initiative on E-Commerce, Statement by Ministers of Australia, Japan and Singapore, 14 December 2021.

<sup>66</sup> TFA, Article 7.1.

<sup>67</sup> TFA, Article 3.

<sup>68</sup> TFA, Article 7.5.

<sup>69</sup> TFA, Article 7.7.

illicit trade activities. The provisions further enhance regulatory coherence and international cooperation by also encouraging WTO Members to develop authorized operator schemes on the basis of international standards and to engage in mutual recognition schemes with other Members.

#### **BOX 5: IMPROVING RISK MANAGEMENT TO TACKLE ILLICIT TRADE**

Customs administrations and regulatory authorities across the world face the ongoing challenge of processing an increasing volume of import, export and transit transactions while ensuring adequate controls to detect customs fraud, including the movement of illicit products or other illicit trading activity. One of the key approaches to achieving that balance is the advent of risk management systems which use more targeted criteria in order to determine which goods ought to be subject to further checks. As the WCO has noted, the aim of a risk management system is to identify reliable operators and low-risk consignments and transactions that may benefit from greater facilitation, while also ensuring the ability to target consignments and transactions that require higher levels of control.<sup>70</sup>

The TFA requires WTO Members, to the extent possible, to adopt or maintain a risk management system for customs control.<sup>71</sup> While requiring a focus on high-risk consignments and the expedited release of low-risk consignments, customs authorities retain the authority to conduct random checks as part of their risk management regime. The provision offers further guidance in establishing appropriate selectivity by specifying the following possible criteria: the Harmonized System (HS) code; the nature and description of goods; the country of origin; the country from which goods are shipped; the value of the goods; the compliance record of traders; and the type of means of transport. In the same vein, in adopting conformity assessment procedures in accordance with the TBT Agreement, Members have discussed the need to select controls and their stringency in accordance with factors like the level of risk associated with the regulated products or sectors.<sup>72</sup> These practices equip customs and regulatory authorities with improved analytics to identify potential illicit trade transactions.

Despite these developments, setting up risk-based systems poses a number of implementation challenges for WTO Members. Indeed, the risk management provision of the TFA ranks first among measures with the lowest rate of implementation commitments by WTO Members.<sup>73</sup> Moreover, around half of developing Members have indicated the need for technical assistance to implement TFA risk management requirements, and LDC Members in particular have identified risk management as one of the provisions requiring the greatest level of technical assistance in order to implement.<sup>74</sup> Added to these implementation challenges are the difficulties developing Members face in implementing technologies and data analytics needed to effectively monitor and control cross-border transactions. As noted in a recent WTO/WCO report on the role of advanced technologies in trade, the greatest hurdles to implementing the use of technologies like blockchain to achieve greater efficiency and reliability in risk management is overcoming a lack of expertise and good practices, and the associated costs of implementation.<sup>75</sup>

2.13. The foregoing illustrates how the TFA empowers customs authorities to modernize and harmonize their processes in a manner that improves their ability to identify and thwart illicit trade activities at the border while at the same time ensuring the benefits of reduced trading times and costs for legal traders. The TFA accomplishes this by adopting a risk-based approach to customs management, whether through advance rulings prior to import, the authorization of operators who can evidence a reduced risk profile, or the reliance on post-import audits to manage such risks. All of these elements are informed by, and feed

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<sup>70</sup> WCO Customs Risk Management Compendium, Executive Summary, p. vi. See [risk-management-compendium-common-part.pdf \(wcoomd.org\)](#)

<sup>71</sup> TFA, Article 7.4.

<sup>72</sup> "Decisions and recommendations adopted by the WTO Committee on Technical Barriers to Trade since 1 January 1995", 24 September 2019, G/TBT/1/Rev.14, Section 4.1, pp. 12-17. In the TBT Committee, Members have discussed different risk assessment and management tools, such as the US Food and Drug Administration (FDA) "PREDICT" tool which electronically screens and assigns scores to consignments of regulated products, identifying higher risk shipments subject to further examination and testing. "Ninth Triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade under Article 15.4", 17 November 2021, G/TBT/46, para. 4.4.

<sup>73</sup> G/TFA/2, para. 3.10. Developing Members may self-determine when they will comply with particular provisions of the TFA. Accordingly, the rate of implementation commitments signals the willingness on the part of WTO Members to undertake certain commitments by a given date. The other provisions with the lowest rate of implementation commitments include those relating to border agency cooperation (Article 8), test procedures (Article 5.3), authorized operators (Article 7.7), and single window (Article 10.4).

<sup>74</sup> G/TFA/2, para. 6.16.

<sup>75</sup> See [WTO | The role of advanced technologies in cross-border trade: A customs perspective](#).



into, risk management systems that can more accurately target potentially illicit transactions for further scrutiny. As noted, however, more remains to be done to ensure that Members implement the sort of risk management systems that generate the dual benefits of smoother and more secure trade.

### **2.1.3 National coordination and enforcement at the border**

2.14. Illicit trade poses a threat that can implicate various dimensions of cross-border trade. The fight against illicit trade thus requires a multifaceted approach that relies on coordination among the different agencies and actors that have responsibility for overseeing import, export and transit activities. Such coordination not only serves to harmonize and streamline border processes, but can lead to the use of clear, accountable and systematized practices by customs authorities that are effective in dealing with fraudulent and other illegal practices.

2.15. The TFA promotes customs coordination among domestic constituencies in several ways. First, the TFA calls on each WTO Member to ensure that its authorities and agencies responsible for border controls and procedures cooperate with one another and coordinate their activities in order to facilitate trade.<sup>76</sup> This provision thus establishes a baseline obligation of governments to coordinate internally among their relevant border agencies. The TFA builds on this coordination by also requiring that Members provide for consultations where appropriate between border agencies and private traders and stakeholders.<sup>77</sup>

2.16. It is expected that much of this coordinating activity would occur within a Member's National Trade Facilitation Committee (NTFC), which each Member is required to set up to direct implementation of the TFA.<sup>78</sup> NTFCs offer an invaluable opportunity for governments to improve communication and coordination among relevant border agencies and to liaise with the private sector to enhance the ability to address a host of trading challenges including those relating to illicit trade. Improved coordination and integration of border processes can also reduce redundancy in border processes, which assists in limiting opportunities for bad actors to engage in illicit or corrupt trading practices.<sup>79</sup> Establishing fully functioning NTFCs, however, remains a challenge for developing Members. In some instances, neighbouring developing Members have sought to join resources in establishing regional committees which offers the potential to further integrate sound border practices both domestically and regionally.

### **2.1.4 International customs cooperation**

2.17. Similarly, the fact that illicit trade is a multi-dimensional problem requiring a coordinated and multifaceted response highlights the importance of also supporting opportunities for cooperation at the multilateral level. The TFA contains a couple of mechanisms to accomplish this. First, just as it did in relation to internal customs administration, the TFA also calls on WTO Members where possible to cooperate on mutually agreed terms with neighbouring Members in an effort to coordinate procedures at border crossings to facilitate cross-border trade.<sup>80</sup> Such cooperation may include, for instance, efforts at establishing joint controls and aligning border procedures and formalities.<sup>81</sup>

2.18. In addition, the TFA contains provisions regarding international cooperation between customs authorities.<sup>82</sup> The TFA signals the importance of promoting compliance and cooperation between customs authorities and encourages WTO Members to share information on best practices in managing customs compliance, including through the Trade Facilitation Committee. The TFA thus contains a number of provisions that oblige WTO Members, upon request, to share information that enhances coordination of customs controls. Specifically, such information may be requested for the purpose of verifying an import or export declaration in cases where there are reasonable grounds to doubt the truth or accuracy of that declaration. International cooperation on such enforcement matters is of invaluable assistance to Members seeking to halt illicit trade practices.

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<sup>76</sup> TFA, Article 8.1.

<sup>77</sup> TFA, Article 2.2.

<sup>78</sup> TFA, Article 23.2. WTO Members may also designate an existing mechanism for this purpose.

<sup>79</sup> In furtherance of the goal of limiting opportunities for corruption, the TFA also places certain constraints on penalty disciplines to ensure that Members avoid conflicts of interest or creating incentives for the collection of penalties that are not commensurate with the nature of the breach. TFA, Article 6.3.

<sup>80</sup> TFA, Article 8.2.

<sup>81</sup> Other possible areas of cooperation including the alignment of working days and hours, development and sharing of common facilities, and the establishment of one stop border post control.

<sup>82</sup> TFA, Article 12.

### 2.1.5 Work of the Trade Facilitation Committee

2.19. The WTO Committee on Trade Facilitation also serves a critical function by serving as a forum to exchange views on matters that might implicate illicit trade concerns or as it relates to the implementation of certain provisions that could be most useful in addressing such concerns. Chief among the activities of the TF Committee is the monitoring of notifications from WTO Members that contain certain information that can be especially helpful in addressing illicit trade concerns. In furtherance of the transparency objectives highlighted above, Members are required to notify where they have published their import, export and transit procedures, including relevant websites. Similarly, they are required to furnish their measures on the use of customs brokers and the details of operation of their single window. Each of these elements is helpful in clarifying the rules applicable to traders and ensuring the sort of transparency and predictability that can help to reduce illicit trade. And as noted, implementation of a single window is of particular significance in streamlining and automating processes that reduce the opportunities and incentives to engage in illicit trade. WTO Members must also provide contact points for the exchange of customs information which promotes international coordination on enforcement matters.

2.20. In addition, the TF Committee oversees a range of technical assistance activities to assist developing WTO Members in implementing measures that are crucial to strengthening their customs operations. Developing WTO Members self-determine when they will apply specific provisions of the TFA as follows: Category A commitments are those undertaken upon entry into force of the TFA (or a year after that, in the case of LDCs); Category B commitments are undertaken following a transition period; and Category C commitments are also undertaken following a transition period but for which the Member further requires the acquisition of implementation capacity through the provision of assistance and support for capacity building.<sup>83</sup> Given the particular challenges developing Members face in ensuring robust customs controls, the provision of technical assistance and capacity building is of crucial significance. In addition, the Trade Facilitation Agreement Facility was launched at the conclusion of the TFA negotiations to, among other things, support developing Members to assess their specific needs and to identify possible development partners to help them meet those needs.<sup>84</sup>

2.21. At the end of 2021, WTO Members concluded their first review of the TFA and developed several recommendations of particular significance in improving and strengthening customs controls.<sup>85</sup> First, developing Members that had designated Category C commitments were encouraged to organize meetings with donors to review the state of assistance and potential future needs, and then invited to share the outcomes of these meetings with the TF Committee. Category C commitments are most frequently undertaken in respect of many of the obligations described above and which tend to be the most critical in addressing matters of illicit trade.<sup>86</sup> Second, it was recommended that Members whose implementation dates have passed share on a voluntary basis their implementation experiences. These recommendations may be critical for Members, in particular those facing the greatest implementation challenges, to get the assistance they need to ensure compliance and improve their customs control systems.

### 2.1.6 Ensuring the accurate valuation of goods for customs purposes

2.22. Similar to how certain provisions of the TFA can assist Members in addressing aspects of illicit trade, the Customs Valuation Agreement (CVA) and related instruments also contain disciplines – in this case, relating to the valuation of goods for customs purposes – that clarify certain rules and promote greater transparency and predictability. CVA rules are particularly useful in addressing instances where products may be under- or over-invoiced for illicit reasons, such as for money laundering or tax evasion purposes.

2.23. The CVA sets out guidance for WTO Members so that they can develop fair, uniform and neutral systems for the valuation of goods for customs purposes while guarding against the use of arbitrary or fictitious customs values.<sup>87</sup> The CVA thus provides for certain valuation methodologies that are to be applied in a sequential order to value goods. It prescribes transaction value (the price actually paid or payable for the goods when sold for export) as the primary methodology but also specifies alternative methods that may be used when transaction value cannot be established.<sup>88</sup>

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<sup>83</sup> See also TFA, Article 21.

<sup>84</sup> [www.tfafacility.org](http://www.tfafacility.org).

<sup>85</sup> G/TFA/2.

<sup>86</sup> For instance, the two TFA provisions most often designated as Category C commitments are the provisions relating to single window (Article 10.4) and risk management (Article 7.4).

<sup>87</sup> CVA, preamble.

<sup>88</sup> CVA, Articles 1-7.

2.24. Importantly, customs authorities may question a declared value when they have reasons to doubt its truth or accuracy. The CVA expressly states that nothing in the agreement shall be construed as restricting or calling into question the rights of customs administrations to satisfy themselves as to the truth or accuracy of any statement, document or declaration presented for customs valuation purposes.<sup>89</sup> WTO Members also agreed to certain procedural steps whereby customs authorities that have reason to doubt the truth or accuracy of the declared value may seek additional information from the importer before concluding that such reasonable doubts warrant the rejection of that value.<sup>90</sup>

2.25. Finally, it bears noting that the WTO Committee on Customs Valuation oversees notifications by WTO Members of their national customs legislation which assists in clarifying the valuation rules applicable to all traders. Transparency with respect to national legal obligations thus clarifies the relevant customs valuation rules and promotes adherence to, and dialogue between and coordination among, such national regimes.

## 2.2 STRENGTHENING REGULATORY COHERENCE IN PRODUCT QUALITY AND SAFETY CONTROLS

*Ensuring appropriate verification that products comply with quality, health and safety regulations and standards is vital in the fight against illicit trade, and the TBT Agreement and the work of the TBT Committee are essential to that fight. Adequate regulatory measures to safeguard product quality and safety are particularly relevant when non-compliance results in health and safety risks; when global health challenges arise in the context of a pandemic; or when managing risks from disruptive technologies such as digital products and e-commerce. In order to minimize the risks of substandard/non-compliant products entering the market – a matter of particular concern for medical products during the COVID-19 pandemic – WTO Members may focus on designing and enforcing effective conformity assessment procedures (CAPs) in line with the TBT Agreement disciplines such as transparency, cooperation, implementation and improvement of national quality infrastructure (NQI), and the use of international standards.*

2.26. Illicit trade also poses a considerable challenge to government efforts to ensure product quality and safety. The COVID-19 pandemic forced governments to develop new solutions to ensure regulations facilitate access to essential health products. To meet surging demand for products like personal protective equipment (PPE), governments introduced a range of emergency regulatory measures to accelerate approval and access to medical goods during the COVID-19 pandemic. These included streamlining conformity assessment procedures (CAPs) (e.g., emergency use authorization pathways which reduced the level of controls applied by governments), simplifying product labelling, or deepening reliance on decisions of other regulators.<sup>91</sup>

2.27. While these measures allowed governments to overcome acute shortages and approve medical goods more quickly, the pandemic also exposed pre-existing weaknesses in national systems and may have created new opportunities for illicit trade in medical goods. This may have been due to gaps in novel regulations that were adopted during the pandemic, as well as in the ability of regulators to effectively control through CAPs the quality and safety of medical goods in an emergency context. Anecdotal evidence indicates that bad actors engaging in this illicit trade used techniques such as deceptive labelling, falsified or adulterated tests results and certificates in an attempt to pass the products off as legitimate.<sup>92</sup> When there is an intentional effort to falsify testing documentation and/or "certification marks"<sup>93</sup>, especially with respect to medical goods, this may place the safety and welfare of people at serious risk.<sup>94</sup>

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<sup>89</sup> CVA, Article 17.

<sup>90</sup> Decision Regarding Cases Where Customs Administrations Have Reasons to Doubt the Truth or Accuracy of the Declared Value, adopted by the WTO Customs Valuation Committee on 12 May 1995.

<sup>91</sup> Information notes ["Standards, Regulations and COVID-19 – what actions taken by WTO Members?"](#) (WTO Secretariat, December 2020).

<sup>92</sup> See Box 1 above.

<sup>93</sup> Certification marks are covered by the TBT Agreement (see e.g., Article 5.1.1). A certification mark is also known as a mark of conformity, which in turn is defined as a "protected mark, applied or issued under the rules of a certification system, indicating that adequate confidence is provided that the relevant product, process or service is in conformity with a specific standard or other normative document." (ISO/IEC Guide 2:1991 *General Terms and Their Definitions Concerning Standardization and Related Activities*, para. 14.9). Certain terms and definitions of the ISO/IEC Guide 2:1991 have been adopted, subject to certain modifications and conditions, by the TBT Agreement (see opening paragraph of Annex 1 to the TBT Agreement). The TRIPS Agreement addresses intellectual property aspects by setting out principles for categories of distinctive signs used in national legal systems to protect certification marks (although national practice differs, it may include trademarks, geographical indications and hallmarks or official signs).

<sup>94</sup> ["Falsified: Test Reports & Certificates - Identification and Impact of Counterfeit Test Reports and Certificates in the Global Marketplace"](#) (TIC Council, Anti-Counterfeiting Committee). See also more generally [Misuse of Third-Party Marks of Conformity](#) (ISO).

2.28. Further, in response to the pandemic, both developed and developing Members introduced new technical requirements and specifications for certain medical goods that were not previously regulated (e.g., community face masks), or for which domestic production was initiated to avoid disruptions in supply. These included certain safety, quality, and efficacy criteria (e.g., mandatory laboratory verification specifically tailored for all COVID-19 test kits; new packaging and labelling technical specifications for hand-sanitizing solutions; or clearer information and additional marketing requirements for hygiene masks), the conformity assessment and enforcement of which can help curb substandard or falsified products. In the absence of standards, regulations and CAPs, there is fertile ground to engage in illicit trade since there are no clear means to identify substandard, unlicensed, or falsified medical products.

2.29. Two additional challenges bear mentioning. First, as noted in the previous section, the efforts of regulators during the COVID-19 pandemic were further complicated by the dramatic rise of e-commerce, including with respect to medical goods. Generally speaking, regulatory and law enforcement officials have limited capacity to control access by bad actors to e-commerce platforms, and e-commerce is therefore challenging traditional regulatory approaches and demanding new solutions, including in terms of applying and enforcing standards and technical regulations via CAPs.

2.30. Second, while all countries are affected by illicit trade, the challenges are more pronounced for developing and least developed countries in stemming the flow of substandard, unlicensed, or falsified medicines. The special vulnerability of developing countries to illicit trade is in part related to gaps and resource constraints faced by their National Quality Infrastructure (NQI), more broadly, and their national regulatory authorities (NRAs), in particular. Such constraints hamper their ability to conduct market surveillance in order to ensure products conform with safety and quality standards and regulations on a permanent basis, that is, not only before and when (*ex ante*) they are certified and can thus enter a market, but also thereafter (*ex post*). These difficulties are then compounded by various other complicating factors such as difficult access to medicines for populations due to cost and the lack of pharmacies in rural areas. (See Box 6 below for more information on improving NQI and NRA capacities.)

## BOX 6: IMPROVING NQI AND NRA CAPACITIES

Estimates suggest that many developing countries in Africa, parts of Asia, and parts of Latin America have markets where 30% of the medicines on sale could have been falsified and substandard, while in other developing markets this number is closer to 10%.<sup>95</sup> Weak NQIs and NRAs can provide an opening for illicit trade. The WHO estimates that less than 30% of the NRAs worldwide have the "capacity to perform the functions required to ensure medicines, vaccines and other health products actually work and do not harm patients."<sup>96</sup> In an assessment of the regulatory capacity of 26 countries in Africa published in 2010, the WHO concluded that these countries did not generally have the capacity to control the quality, safety or efficacy of the medicines circulating on their markets or passing through their territories.<sup>97</sup> The huge disparity in resources available to regulators in different countries is striking: while the US FDA has over 14,000 staff, including more than 3,000 in its Center for Drug Evaluation and Research, the Food and Drug Department of the Lao People's Democratic Republic has approximately 20 staff.<sup>98</sup> Moreover, many developing, and especially least developed countries, face various gaps in their NQI.<sup>99</sup> For instance, a 2020 assessment of NQI in Africa found that, despite improvements since 2014, the majority of African countries were still classified as having partially developed, limited or very little to no NQI.<sup>100</sup> This hinders their ability to develop and enforce standards and technical regulations through CAPs.

The WTO, in cooperation with other organizations, has an important role to play in strengthening NQI and NRAs. The TBT Agreement provides an overall structure for efficient and effective regulatory activity backed by the NQI, facilitating trade and access to medical goods. Capacity building delivered by the WTO can help improve cooperation and coordination between NRAs, trade officials, and the NQI (e.g.,

<sup>95</sup> [FIP combats falsified and substandard medicines](#) (last update 5 May 2021). In the WCO's Operation STOP I, more than 300 million items of miscellaneous medicines were intercepted by Members, and region-by-region analysis of seizures/detentions of medicines revealed that 99.45% came from the West and Central Africa region. During Operation Stop II, more than 80% of seizures were from the West and Central Africa region.

<sup>96</sup> See, e.g., [Tanzania is first African country to reach an important milestone in the regulation of medicines | WHO | Regional Office for Africa](#), [Singapore medicines regulator world's first to achieve highest maturity level in WHO classification](#).

<sup>97</sup> ["Assessment of medicines regulatory systems in sub-Saharan African countries"](#) (WHO, 2010).

<sup>98</sup> Douglas Ball, Susann Roth, Jane Parry, "Better regulation of medicines means stronger regional health security: strengthening and convergence of national regulatory agencies has benefits beyond country borders" (2016) ADB BRIEFS No. 54.

<sup>99</sup> World Bank, 2019, Ensuring Quality to Gain Access to Global Markets.

<sup>100</sup> Pan-African Quality Infrastructure, July 2020, Stocktaking Document – 2020 Edition.

standardization bodies, accreditation bodies, national metrology institutes, certification bodies and testing laboratories) for a stronger regulatory system that better addresses the risk of illicit trade. In the area of Sanitary and Phyto-Sanitary Measures (SPS), the WTO participates with other international organisations in the Standards and Trade Development Facility (STDF), which supports increased capacity of developing countries to implement international SPS standards, guidelines and recommendations. However, the WTO lacks a similar coordination mechanism in the area of TBT.<sup>101</sup> Such a structure could be further explored, as it may amongst other benefits, allow the WTO to make a greater contribution to fighting illicit trade.

2.31. The TBT Agreement, supported by the work of the TBT Committee, was designed to help governments, regulators and policymakers strike a balance between, on the one hand, their aim of ensuring products are safe and of quality, while, on the other hand, avoiding such interventions are not misused for protectionist purposes and do not restrict trade beyond what would be necessary to attain those policy objectives.<sup>102</sup> The TBT Agreement can thus assist WTO Members in ensuring that only compliant (i.e. safe) products reach consumers. As will be explored below, the TBT Agreement sets out a framework for the adoption of effective CAPs. It also establishes the TBT Committee, a forum for WTO Members to exchange regulatory experiences and, eventually, adopt principles, guidance and shared understandings on how best to implement the Agreement. Finally, the Agreement also supports developing countries' efforts to strengthening their NQIs and improving transparency. In sum, effective implementation of the TBT Agreement supports better, more efficient regulatory systems, an essential tool to combat illicit trade.

### 2.2.1 Designing and enforcing effective CAPs

2.32. The TBT Agreement covers three types of regulatory interventions affecting trade in all products (both industrial and agricultural): technical regulations, standards, and CAPs.<sup>103</sup> Technical regulations and standards set out specifications and requirements on the production, importation and sale of products in order to achieve policy objectives such as health and quality.<sup>104</sup> However, laying down safety and quality specifications, cannot, alone, necessarily guarantee actual compliance.

2.33. To ensure that these policy goals are fully attained in practice, governments normally adopt and apply CAPs in the form of various procedures (inspection, testing and certification etc.) for verifying that safety or quality specifications have been really fulfilled. These CAPs are particularly relevant when non-compliance can result in high health and safety risks, which is normally the case for medical products. Frequently, a CAP can be a combination of different procedures, and vary in their levels of stringency, ranging from self-certification (i.e., "supplier's declaration of conformity") to third-party certification. The choice of which specific type of CAP is used depends, among other factors, on the extent and nature of the risk addressed by the underlying standard or technical regulation against which conformity is being assessed. CAPs can, and normally are, applied before, during, and after products are manufactured, imported and sold. This is especially true for medical goods in general, and COVID-19-essential goods in particular.<sup>105</sup>

2.34. Given their nature and purpose, CAPs play a key role for a well-functioning regulatory framework. This is particularly important for medical goods, which are normally subject to a plethora of regulations addressing safety, efficacy, and quality. This means that ill-designed and ill-enforced CAPs can have serious consequences for consumers' safety and health: the weaker a CAP, the higher the risk that more non-compliant products will enter the market. As one commentator has put it: "a weak regulatory environment that does not act as an effective barrier promotes the manufacture and sale of low quality, potentially ineffective and unsafe medicines."<sup>106</sup> This, in turn, can open pathways for illicit trade in non-compliant or

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<sup>101</sup> G/TBT/41, para. 7.12.b.

<sup>102</sup> For an overview of the TBT Agreement and the work of the TBT Committee, see [Handbook on the TBT Agreement](#) (WTO Secretariat, 3<sup>rd</sup> Ed. 2021).

<sup>103</sup> TBT Agreement, Article 1.3.

<sup>104</sup> Such specifications and requirements can address various aspects of a product, ranging from their intrinsic characteristics (composition, size, shape, colour etc.) to way they are manufactured (e.g., good manufacturing practices for pharmaceuticals), or how they are labelled and packaged.

<sup>105</sup> Vaccines, for instance, are highly regulated throughout the entirety of their trade value chain: "*upstream to the raw materials and components needed for vaccine production and downstream to post-market surveillance. Quality assurance and testing of vaccines starts before, and continues well after, the factory gate.*" According to some estimates, around 70% of vaccines' manufacturing time "*is consumed by control testing*" ("[Developing and delivering COVID-19 vaccines around the world: an information note about issues with trade impact](#)" (WTO Secretariat, 22 December 2020), p. 19.

<sup>106</sup> Douglas Ball, Susann Roth, Jane Parry (ADB Briefs, No. 54, April 2016), "Better Regulation of Medicines Means Stronger Regional Health Security", available at [Better Regulation of Medicines Means Stronger Regional Health Security \(adb.org\)](#).

substandard products.<sup>107</sup> Conversely, well-designed and well-enforced CAPs are a crucial element of a country's NQI,<sup>108</sup> including for stemming the flow of illicit trade.

## 2.2.2 The work of the TBT Committee on regulatory cooperation and guidance

2.35. As indicated above, well-designed CAPs can reduce the risks and incentives of illicit trade. The TBT Committee is currently undertaking developing non-prescriptive practical guidelines aimed at supporting regulators in the choice and design of appropriate and proportionate CAPs.<sup>109</sup> Such guidance could contribute to better targeted and more effective CAPs, while avoiding unnecessary red tape.<sup>110</sup> Members also use the Committee as a platform for exchanging regulatory experiences and challenges. For example, as mentioned above, e-commerce is challenging traditional regulatory approaches, in particular the effective application of CAPs for ensuring product safety and quality. As a result, the TBT Committee has recently agreed to discuss challenges posed by e-commerce as part of its 2022-2024 work plan. Another challenge, as highlighted above, is that streamlined and simplified CAPs (that were frequently used in the context of the COVID-19 pandemic) not only allowed governments to overcome acute shortages of essential medical products, but also created opportunities for illicit trade. Reflecting on such side effects of streamlining CAPs during the COVID-19 pandemic could be part of the work TBT Committee Members have decided to initiate by examining and compiling best regulatory practices for future pandemic preparedness.<sup>111</sup> (See Box 7 below on the important role market surveillance plays in respect of vaccine quality and safety.)

### BOX 7: COVID-19 VACCINES AND THE IMPORTANCE OF MARKET SURVEILLANCE

Market surveillance and control plays a crucial role in assuring consumer safety of medical products in general, and vaccines in particular.<sup>112</sup> According to a WHO global benchmarking tool published in 2018, such activities cover control of import activities, prevention and detection of and responses to substandard and falsified medical products, market surveillance programmes (e.g., spot checks) for monitoring the quality of medical products throughout the supply chain, and control of promotional, marketing, labelling/packaging and advertising activities. Quality infrastructure and metrology systems underpin market surveillance and enforcement. Vigilance activities should be established in countries based on a risk management approach. A vigilance system, in general, monitors all kinds of patient harm potentially related to medical products, vaccines in special, whether due to inadequate product quality, inappropriate use (e.g., medication errors) or intrinsic adverse effects. It is important to establish such a system because serious effects can erode confidence in these products. A further consideration is national laboratory testing capacity and calibration. Collaboration with other regulatory authorities on lot release and cooperation in laboratory testing for quality assurance are options recognized by WHO laboratory testing benchmarking. Quality infrastructure, including metrology systems, is also indispensable for the integrity of vaccines' "cold chain". Reliable storage and temperature monitoring equipment is necessary to protect vaccine potency from exposure to improper conditions. The use of "smart labels" (e.g., vaccine vial monitors, designed to measure heat exposure) monitor vaccines that must be maintained in low temperatures.

## 2.2.3 Implementing and improving NQI

2.36. NQI is a multifaceted system encompassing the technical institutions responsible for standardization, metrology, accreditation, and conformity assessment and ability to conduct market surveillance. NQI is essential for the efficient and effective preparation, adoption and application of technical regulations, standards and CAPs. As such, the NQI plays a vital supporting role for regulators and underpins the ability

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<sup>107</sup> Of course, not all substandard medical products are a result of illicit activities or intentional acts to circumvent regulations. For instance, according to a recent WTO Secretariat publication, "poor transportation and storage, including breaks in cold chain integrity, can lead to patients receiving substandard, unsafe or impotent vaccines". See "[Developing and delivering COVID-19 vaccines around the world: an information note about issues with trade impact](#)" (WTO Secretariat, 22 December 2020), p 25.

<sup>108</sup> The technical institutions responsible for standardization, metrology, accreditation, and conformity assessment.

<sup>109</sup> G/TBT/46, para. 4.18.a.

<sup>110</sup> Note by Secretariat "Elements Paper" (Committee on Technical Barriers to Trade), JOB/TBT/438, (31 January 2022); Note by Secretariat "Overview of the TBT Committee's Work on Conformity Assessment Procedures (Revision)" (Committee on Technical Barriers to Trade), JOB/TBT/224/Rev.1, (16 July 2020).

<sup>111</sup> G/TBT/46 (17 November 2021), paras. 4.18 and 8.4.

<sup>112</sup> [Developing and Delivering COVID-19 Vaccines around the World: An Information Note About Issues With Trade Impact](#) (WTO Secretariat, 22 December 2020), p. 32.

to effectively control products on the market (through testing, measurement, standards, etc.) and, therefore, creating effective barriers against illicit trade.

2.37. The TBT Agreement can play a role in helping countries develop internationally aligned and recognized NQI systems. For instance, the Agreement contains provisions requiring Members to provide advice and technical assistance to other Members, especially developing and least developed countries, including on implementing and improving NQI.<sup>113</sup> This type of assistance supports effective enforcement of regulatory requirements and minimizes incidents of illicit trade and substandard products reaching the market. WTO Members that are successful in addressing illicit trade through the functioning of effective NQI could support the strengthening of capacities of those Members that have gaps in their regulatory systems. Further work by the TBT Committee, including the consideration of a coordinating mechanism in the TBT area, modelled on the STDF, could be considered.<sup>114</sup> This type of additional support could allow developing and least developed Members to benefit from the strengthening of their capacity to fight illegal trade, while at the same time also creating new and expanded opportunities for legal trade.

#### 2.2.4 Using TBT transparency tools

2.38. The TBT Agreement contains multiple transparency provisions, such as notification obligations, the establishment of enquiry points and a notification authority, and publication requirements.<sup>115</sup> Those obligations aim to promote information exchange, regulatory cooperation and predictability and reduce potential trade frictions.

2.39. In the context of illicit trade, notifications could shed light on proposed measures by WTO Members that are aimed at addressing trade in substandard products. This can be useful source for Members wishing to gain some experience in developing TBT-related policies for addressing trade in substandard products. By promoting early and better access to standards and regulations at an early stage, when they are still being drafted, TBT transparency procedures also give Members an opportunity to provide better comments either bilaterally or at the TBT Committee with respect to the proposed TBT measures that can eventually improve the quality of mechanisms aimed at fighting illicit trade. An important transparency tool, in this respect, is the [ePing SPS & TBT Platform](#) – a publicly available website that includes an email alert service on such notifications covering products and markets of interest. It also allows stakeholders to discuss and share information on these notifications at the national and international level.

2.40. Transparency obligations under the TBT Agreement are also closely linked to the work of the TBT Committee that serves as a forum for discussing any issues related to the implementation of the TBT Agreement. In this respect, Members can raise "specific trade concerns" (STCs) before the Committee with respect to measures aimed at combatting illicit trade. Discussing such STCs can contribute to an improved understanding by WTO Members of the rationale underlying other Members' regulations that relate to illicit trade and present an opportunity to question, among other, the appropriateness or effectiveness of TBT measures aimed at combatting illicit trade. (See Box 8 below on recent developments before the TBT Committee relating to illicit trade.)

#### BOX 8: RECENT DEVELOPMENTS BEFORE THE TBT COMMITTEE RELATING TO ILLICIT TRADE

Notifications have been submitted by Members to the TBT Committee with respect to measures aimed at combatting illicit trade<sup>116</sup>, including in the medical health sector.<sup>117</sup> For instance, in 2021, the United Kingdom notified a regulation for validation of all COVID-19 detection tests for private sale to prevent retailers from selling tests that were not validated to meet minimum quality standards for specificity and sensitivity.<sup>118</sup>

There have also been many notifications and STCs regarding TBT measures against "illegal logging"; "illicit trade in cement"; "illegal imports of wastes"; trafficking of "narcotics" or regulating trade in

<sup>113</sup> See Articles 11.2, 11.4, 11.5, 11.6, 11.7 and 11.8 of the TBT Agreement.

<sup>114</sup> See Box 6, above.

<sup>115</sup> See Articles 2.9, 2.9.1, 2.10, 2.11, 3.2, 5.6, 5.6.1, 5.7, 5.8 7.2, 10.1, 10.3, 10.10, 15.2 and Annex 3 (paragraphs J and O) of the TBT Agreement.

<sup>116</sup> See, e.g., notifications to the TBT Committee concerning the measures combatting illegal logging (G/TBT/N/AUS/96); illicit trade in food products (G/TBT/N/CHN/1401); electrical appliances and industrial products (G/TBT/N/KOR/674; G/TBT/N/KOR/544), coffee and cocoa (G/TBT/N/LBR/1).

<sup>117</sup> See, e.g., notifications to the TBT Committee concerning the measures combatting illicit trade in tobacco products: G/TBT/N/LTU/41; G/TBT/N/DOM/232; G/TBT/N/ARE/439.

<sup>118</sup> G/TBT/N/GBR/39.

products that could be used in "terrorist attacks" or other criminal activities (chemicals, bioterrorism, military weapons etc.). Labelling and packaging requirements are a common type of regulatory intervention in this area, and can be imposed on wide variety of products, such as alcoholic beverages, cosmetics, tobacco, pharmaceuticals, clothing, etc.

In the context of some STCs against TBT measures not themselves about combating illicit trade, the argument has been made that the regulation's compliance costs and burdens to legal products were so high that this created unintended incentives for illegal or illicit trade of the products concerned (e.g., various STCs against tobacco plain packaging measures; STC against a new certification measure on cosmetics).

## 2.2.5 Using international standards

2.41. The TBT Agreement strongly encourages the use, when possible, of international standards as a basis for technical regulations, standards and CAPs. International standards, by ensuring compatibility across countries, can generate economies of scale and production efficiencies, reduce transaction costs and facilitate international trade. International standards can also be seen as "evidence-based" documents codifying scientific and technical knowledge developed at the global level. Their development and use can thus be an important means of disseminating knowledge and fostering innovation.<sup>119</sup>

2.42. By creating a common benchmark between countries, the use of international standards can help make it easier to identify illicit trade. For example, internationally aligned testing protocols based on international standards, guides or recommendations can help countries work together to trace the sources of substandard, unlicensed, or falsified medical goods. Regulatory cooperation, based on alignment to international standards, can also support multi-jurisdictional market surveillance and enforcement efforts. (See Box 9 below on the particular issue of supply chain traceability of medical products.)

2.43. For example, certain standard-setting bodies develop standards that could directly assist NRAs in preventing substandard products entering the market or detecting those substandard products that have already penetrated the market. For example, ISO works on developing standards that help to spot fake medicines,<sup>120</sup> test for authenticity,<sup>121</sup> provide guidelines to measure the competency of testing laboratories and provide quality and minimum safety guidelines.<sup>122</sup>

### BOX 9: IMPROVING SUPPLY CHAIN TRACEABILITY OF MEDICAL PRODUCTS

The introduction of illicit health products was a concern for many lower-and-middle-income countries before the COVID-19 pandemic, and challenges with supply chain integrity and transparency during the crisis made matters worse. That no single country in all of sub-Saharan Africa has a functioning system to trace medicines may have caused many non-COVID deaths indirectly attributable to the pandemic.<sup>123</sup> Because the safety of medical products crucially depends on supply chain integrity and transparency, measures that ensure traceability along value chains are critical in addressing some of the harmful consequences of illicit trade. Developed economies increasingly rely on product serialization to help track and trace medicines and other health commodities from the manufacturer to the patient. These national, and, in the case of the EU, regional traceability programs make it much harder for illicit products to enter legitimate supply chains.<sup>124</sup> Theft and diversion also become easier to spot. Conversely, in the absence of stringent regulation and modern global traceability standards, many less developed countries face severe supply chain uncertainties for COVID and non-COVID

<sup>119</sup> For more info see, e.g., [Handbook on the TBT Agreement](#) (WTO Secretariat, 3<sup>rd</sup> Ed. 2021), pp. 31-36.

<sup>120</sup> E.g., ISO/TS 16791, Health informatics – Requirements for international machine-readable coding of medicinal product package identifiers, provides guidance for machine-readable coding based on globally harmonized and interoperable standards, which can be used internationally on a wide scale, thus providing essential support to the industry in preventing counterfeit products; ISO 28000, Specification for security management systems for the supply chain, specifies the requirements for a security management system, including those aspects critical to security assurance of the supply chain and all activities controlled or influenced by organizations that impact on supply chain security

<sup>121</sup> E.g., ISO 12931, Performance criteria for authentication solutions used to combat counterfeiting of material goods; ISO 16678, Guidelines for interoperable object identification and related authentication systems to deter counterfeiting and illicit trade; ISO 28000, Specification for security management systems for the supply chain.

<sup>122</sup> [Tackling counterfeit with ISO and IEC standards](#).

<sup>123</sup> See AK Heuschen et al., "Public health-relevant consequences of the COVID-19 pandemic on malaria in sub-Saharan Africa", 2021.

<sup>124</sup> "GS1 Standards in the Pharmaceutical Supply Chain". GS1 US. Available at [https://www.gs1us.org/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core\\_Download&EntryId=614](https://www.gs1us.org/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core_Download&EntryId=614).



related health products alike. The Global Steering Committee (GSC) for Quality Assurance, hosted by the World Bank, recently launched broad-based public and private collaboration to help countries initiate global standards for medicines traceability.<sup>125</sup> A recent WTO/WCO report on the role of advanced technologies in trade highlighted the benefits of blockchain, AI and other technologies in ensuring secure and quality transaction data that can be more easily shared.<sup>126</sup> Customs authorities have been adopting these technologies to secure supply chains, but more work remains to be done.

### 2.3 FIGHTING ILLICIT TRADE THROUGH DOMESTIC ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS AND INTERNATIONAL COOPERATION

*Intellectual property rights and their enforcement are instrumental in preventing illicit trade. The TRIPS Agreement sets minimum standards for the protection and enforcement of IPRs that are directly linked to the fight against illicit trade in IPR-infringing goods, including as it relates to counterfeit medical goods. Enforcement tools mandated by the TRIPS Agreement respond to certain challenges connected to illicit trade of medical products in that they task WTO Members with (i) putting in place effective border measures; (ii) promoting the exchange of information and cooperation between customs authorities; and (iii) allowing for the exchange of information with right holders. There is a need for policy makers to clarify the application of enforcement tools to free trade zones and to consider policy options as to the application of IPR-based border measures to goods in transit and to the increasing number of small parcels shipped as a result of the rise of e-commerce.*

[NB: WTO LDC Members currently benefit from extended transition periods and are not obligated to implement TRIPS provisions or apply existing IP laws.<sup>127</sup> Some regional trade agreements contain stricter enforcement standards than those established by the TRIPS Agreement in this and other regards.<sup>128</sup>]

2.44. The infringement of IPRs poses a significant challenge to governments in the fight against illicit trade, which arises both in terms of its economic impact and magnitude, and potential health and safety concerns. According to TRACIT, (2019), the global trade in counterfeit and pirated goods<sup>129</sup> accounts for the largest economic value of all forms of illicit trade, depriving the legitimate economy of jobs and economic growth.<sup>130</sup> EUIPO and OECD, in their latest report, found that global trade in counterfeits amounted to EUR 412 billion in 2019, corresponding to 2.5% of world trade.<sup>131</sup> With regard to illicit trade in medical products, OECD and EUIPO report that:

These challenges have become even greater with the COVID-19 pandemic, which has created new opportunities for profits for criminal networks. Supply chains broken by border closures, a strong demand for medicines, protective equipment and tests, and the limited capacity of law enforcement officials all shape the illicit trade in fake pharmaceuticals. Criminals are clearly taking advantage of the global pandemic, and enforcement authorities are reporting a sharp increase in seizures of fake and substandard medicines, test kits and personal protective equipment (PPE), as well as other medical products.<sup>132</sup>

[...] Interviews with industry experts point to an overall growth of 5% in the average seizure value in 2020 compared with 2019. Considering the overall drop in enforcement, this suggests

<sup>125</sup> "GS1 Global Forum 2020". GS1. Available at <https://www.gs1.org/events/2020/g1-global-forum-2020>.

<sup>126</sup> See [WTO | The role of advanced technologies in cross-border trade: A customs perspective](#).

<sup>127</sup> See [IP/C/73](#) and [IP/C/88](#) and [WTO | intellectual property \(TRIPS\) - Responding to least developed countries' special needs in intellectual property](#).

<sup>128</sup> For a database of RTAs notified to the WTO, and provisions on IP enforcement contained therein, see [WTO | Regional trade agreements](#).

<sup>129</sup> For further information on the definition of the term "counterfeit" under the TRIPS Agreement, see Box 1 above. The TRIPS Agreement defines pirated copyright goods as "any goods which are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation." TRIPS Agreement, footnote 14 to Article 51.

<sup>130</sup> TRACIT (2019), Mapping the Impact of Illicit Trade on the Sustainable Development Goals, Geneva, available at [tracit\\_sdg\\_july2019\\_highres.pdf](#).

<sup>131</sup> OECD/EUIPO (2021), Global Trade in Fakes: A Worrying Threat, available at: [Global Trade in Fakes \(europa.eu\)](#).

<sup>132</sup> Ibid., Chapter 3.

that the trade in illicit medicines has grown by 25% from 2019. Of these 45% are counterfeits and 55% are stolen. These findings are confirmed by the results of enforcement operations.<sup>133</sup>

2.45. Illicit trade in medical goods includes trade in medical technology that is IPR-infringing, and certain infringing goods, such as counterfeit medical products, may at the same time also fall within the definitions of the WHO pertaining to falsified medicines. Substandard, unregistered and falsified medicines as defined by the WHO (see Box 1 above) present significant health risks because they may: (i) contain the wrong level of active ingredient – too little, none at all or even too much; (ii) contain an active but harmful ingredient intended for a different purpose; (iii) fail to meet quality standards or regulatory specifications; or (iv) have not undergone evaluation or approval by regulatory authorities.<sup>134</sup>

2.46. Therefore, while IP enforcement is an important tool to fight the substantial economic damage caused by IP infringement as such, the fact that IP-infringing medicines are often also falsified medicines means that in the area of illicit trade in medical goods, IP enforcement can usefully complement health regulatory tools to fight the significant health risks associated with substandard medical products. According to some recent studies, IP-infringing products are also "often substandard".<sup>135</sup> Importantly, consumers can be at serious health and safety risks by products which are otherwise highly regulated, such as pharmaceuticals, when these simultaneously infringe IPRs and are at the same time considered substandard in the sense that they do not comply with safety, health and quality regulations.<sup>136</sup>

2.47. The fact that detecting IP infringements, such as counterfeit trademark goods, requires comparatively fewer resources than establishing a product's failure to meet pharmacological standards, further adds to the synergy of this association, and may inadvertently promote the conflation of "falsified" and "counterfeit" medicines in public discourse. Although data is limited in this regard, the significant involvement of organized crime in the trade in counterfeit medicines<sup>137</sup>, and the anecdotal evidence available<sup>138</sup>, suggest that the underlying assumption of co-occurrence of both types of violations is often correct, although they are conceptually distinct. This fact highlights the need for coordinated efforts in establishing both adequate IPR enforcement tools and the NQI/NRA capabilities fostered through implementation of the TBT Agreement.

2.48. In light of this relationship between IPR protection and the safety and quality of goods, including medical products, TRACIT concludes that effective IPR enforcement is crucial in safeguarding the health of consumers, maximizing the value of human creativity and innovation, promoting economic development and deploying modern technologies.<sup>139</sup>

2.49. Another important link exists between trade in IPR-infringing/counterfeit goods and corruption. A 2019 OECD/EUIPO report found that:

gaps in governance, especially high levels of corruption and gaps in intellectual property rights enforcement, are the crucial factor for trade in fakes, multiplying the effects of FTZs, logistic facilities or trade facilitation policies. [...] While all the factors identified above matter, it is important to note that none of these factors alone can explain the intensity of exports of fakes from a given economy – it is the combination of numerous factors that allows important nodes in counterfeit trade to emerge.<sup>140</sup>

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<sup>133</sup> Ibid., Chapter 6.

<sup>134</sup> TRACIT (2019), Mapping the Impact of Illicit Trade on the Sustainable Development Goals, Geneva, available at [tracit\\_sdg\\_july2019\\_highres.pdf](https://tracit.org/publications/tracit_sdg_july2019_highres.pdf), p. 84.

<sup>135</sup> See e.g., OECD/EUIPO (2022), Dangerous Fakes: Trade in Counterfeit Goods that Pose Health, Safety and Environmental Risks, Illicit Trade, OECD Publishing, Paris, <https://doi.org/10.1787/117e352b-en>, e.g., pp. 11, 13-14.

<sup>136</sup> Ibid., p. 11, observing that:

"... for some products, counterfeits are often of low quality, which creates significant risks for consumers. These include health risks (e.g. fake pharmaceuticals, toys or food products), safety risks (e.g. fake automotive spare parts, fake batteries) and environmental risks (e.g. fake chemicals or pesticides). For all these products, legitimate suppliers must comply with health, safety or environmental regulations to make sure their products will cause no harm or damage. Counterfeiters are not bound by these regulations and consequently, the fake goods that they offer can pose significant health, safety and environmental risks."

<sup>137</sup> See UNICRI (2012), Counterfeit Medicines and Organized Crime, available at [Microsoft Word - Cmf medicines and oc advance unedited2013.doc \(unicri.eu\)](https://www.unicri.org/publications/microsoft-word-cmf-medicines-and-oc-advance-unedited2013.doc)

<sup>138</sup> TAXUD (2009), Report on EU Customs Enforcement of Intellectual Property Rights. Results at the European Border 2008, pp. 12-13, points out that in a customs action leading to the stopping of 32 million medicinal products and 25 million items containing drug precursors, "[m]ore than 93 per cent of all articles were intercepted on the suspicion of a trademark infringement and 6 per cent on the suspicion of a patent infringement ...".

<sup>139</sup> Ibid, p. 43.

<sup>140</sup> OECD/EUIPO (2019), [Trends in Trade in Counterfeit and Pirated Goods \(europa.eu\)](https://www.oecd.org/euiipo/trends-in-trade-in-counterfeit-and-pirated-goods/).

2.50. In regard to the COVID-19 pandemic, the OECD recommends measures to ensure good governance and co-operation, working hand-in-hand with the pharmaceutical industry, to ensure adequate distribution e.g. of COVID-19 vaccines. Furthermore, good international co-operation is needed to monitor trends and to detect bottlenecks as early as possible.<sup>141</sup> This is due to the fact that preserving the integrity of global trade in legitimate goods that satisfy applicable standards (including generic medicines) is critical to ensure equal access to needed health technologies and to support countries in recovering from the crisis and building health systems that foster greater resilience against future pandemics.<sup>142</sup> Overall, therefore, it is crucial for WTO Members to be able to use the tools provided by different instruments, such as the TFA and the TBT Agreements discussed above, together with the IPR enforcement mechanisms established in line with the TRIPS Agreement, in order to counter illicit trade and foster legitimate trade in optimal ways. This becomes even more relevant in responding to a global crisis situation such as the COVID-19 pandemic.

2.51. Concerns about adequate enforcement of IP rights in the multilateral trading system have a long history that predates the entry into force of the TRIPS Agreement upon the establishment of the WTO.<sup>143</sup> It is therefore unsurprising that the TRIPS Agreement, as the only multilateral international agreement setting minimum standards with regard to the protection and enforcement of IPRs, inherently recognizes and addresses illicit trade in its preamble. It contains a general obligation for WTO Members to make the necessary tools available to right holders to take effective action against IPR infringement while not impeding legitimate trade – thus addressing both the need to fight illicit trade, and to facilitate trade that is not illicit. In its 2nd recital, the preamble of the TRIPS Agreement recognizes the need for effective and appropriate means for the enforcement of trade-related IPRs. It also explicitly addresses (3rd recital) the need for a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods. At the same time, it provides flexibility in that Article 1.1 stipulates clearly that Members are free to determine appropriate methods of implementation.

2.52. The most efficient enforcement action against IPR-infringing goods is generally at the point of production. The TRIPS Agreement therefore establishes minimum standards for IPR protection, whose enforcement can help in the fight against the production in addition to the distribution, sale, import and export of illicit goods. However, as will be elaborated further below, the TRIPS Agreement also takes account of the fact that enforcement at the point of production may not be possible where imported goods are involved and therefore incorporates special procedures regarding enforcement of IPRs at the border – typically at the request of private sector right holders. It furthermore mandates international cooperation to improve information flows with regard to IPR enforcement and the TRIPS Council serves as an important forum for discussion in this regard. The WTO Secretariat provides technical assistance on the implementation of the TRIPS Agreement, including its enforcement provisions. These mechanisms, set out in more detail below, provide effective tools to fight illicit trade in IPR-infringing goods which governments must make available to IPR owners.<sup>144</sup>

### 2.3.1 Protecting consumers from goods that are misleading

2.53. One of the most important aspects of the fight against trade in illicit Covid-19 medical products is the need to protect consumers from harm resulting from products that are misleading as to their true origin. The TRIPS Agreement is designed to support Members in those efforts. The provisions of the Paris Convention and Berne Convention, which predate the TRIPS Agreement, are incorporated by reference into the Agreement (see Articles 2.1 and 9.1) and thus form part of the obligations to be respected by Members. Several provisions in those conventions relate to enforcement, for instance the provisions on seizure on importation of goods unlawfully bearing a trademark or trade name (Article 9 of the Paris Convention). Those provisions also apply to seizure on importation of goods unlawfully bearing a false indication of source or

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<sup>141</sup> OECD (2020), COVID-19 vaccines and the threat of illicit trade, available at: [summary-note-covid-19-vaccine-and-the-threat-of-illicit-trade.pdf \(oecd.org\)](#).

<sup>142</sup> See WTO, WIPO, WHO (2021), Updated extract: integrated health, trade and IP approach to respond to the COVID-19 pandemic – Insert to Promoting Access to Medical Technologies and Innovation SECOND EDITION, available at: [PAMTI\\_2E\\_BROCHURE.indd \(wto.org\)](#).

<sup>143</sup> A proposal on trade in counterfeit goods was developed in the General Agreement on Tariffs and Trade (GATT) in 1978 as part of the Tokyo Round of trade negotiations but no agreement was reached at that time. Subsequent work led to the inclusion of the Uruguay Round negotiating mandate on IP rights, which included the development of disciplines dealing with international trade in counterfeit goods, and ultimately resulted in the conclusion of the TRIPS Agreement. See Jayashree Watal and Antony Taubman (eds.) (2015), The Making of the TRIPS Agreement Personal insights from the Uruguay Round negotiations, available at: [WTO | The Making of the TRIPS Agreement Personal Insights from the Uruguay Round Negotiations](#).

<sup>144</sup> See also WTO, Guide to the TRIPS Agreement, Module 8: Enforcement, available at: [modules8\\_e.pdf \(wto.org\)](#).

the identity of the producer (Article 10 of the Paris Convention).<sup>145</sup> They thus establish a clear link to the need to protect consumers from trade in goods that are misleading as to their origin.

### 2.3.2 Enforcing intellectual property rights

2.54. The most practical tools in addressing illicit trade in IPR infringing goods are set out in the TRIPS provisions on enforcement. TRIPS provisions specify the civil and administrative procedures and remedies, including provisional measures, which must be available in respect of acts of infringement of any covered IPR.<sup>146</sup> Importantly, IPRs covered by the TRIPS Agreement include, among others, certification marks as envisaged by the TBT Agreement as means to ensure the quality and safety of medical products. Indeed, the possibility that IP-infringing products may also pose serious health and safety risks, and therefore be considered substandard, highlights that efforts to promote effective IP enforcement and better regulatory surveillance frameworks (e.g., NQIs) can be mutually supportive.<sup>147</sup>

2.55. Members need to ensure that enforcement procedures as specified in the relevant part of the Agreement are available under their law so as to permit effective action against any act of infringement of IPRs covered by the Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements.<sup>148</sup> Safeguards built into the Agreement make sure that the procedures permit effective action against any infringement of IPRs while ensuring that basic principles of due process are met, avoiding the creation of barriers to legitimate trade, and providing safeguards against abuse of the procedures.

2.56. With a view to creating an effective deterrent to infringement, the TRIPS Agreement mandates that the judicial authorities (while respecting the proportionality principle) have the authority to order, without compensation: (i) removal of the infringing goods from the channels of commerce; or (ii) their destruction (unless not permitted under the member's constitution). The enforcement requirements are more stringent for trademark counterfeiting and copyright piracy. In the case of counterfeit trademark goods, the simple removal of the trademark unlawfully affixed shall normally not be sufficient for the goods to be released into the channels of commerce, and criminal sanctions also need to be put in place.

2.57. These fundamental enforcement tools are most effective when used to fight illicit trade at its origin: the country of production. The TRIPS Agreement also takes into account that enforcement at that point may not be possible where imported goods are involved and therefore incorporates special procedures regarding enforcement of IPRs at the border.<sup>149</sup>

### 2.3.3 Border measures

2.58. IPR holders can obtain the cooperation of customs administrations to intercept infringing goods at the border and to prevent the release of these goods into circulation. This is termed "suspension of release" of the goods by the customs authorities; it is not the same as a full infringement action, and to be ultimately effective must be followed by legal proceedings leading to a decision on the merits of the case. As a general rule, right holders must request customs authorities to take action. Members need to have procedures in place that enable a right holder, who has valid grounds for suspecting that the importation of counterfeit trademark or pirated copyright goods may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation of such goods. Members also may provide competent authorities with the power to act ex officio (i.e. out of their own initiative without a request from the right holder) subject to certain conditions.<sup>150</sup>

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<sup>145</sup> The Berne Convention establishes liability to seizure of infringing copies of a work enjoying copyright protection, including when they are imported (Article 16 of the Berne Convention).

<sup>146</sup> The general obligations of members concerning enforcement are found in Article 41 of the TRIPS Agreement.

<sup>147</sup> Such a link was recently identified by a WTO Member in a notification to the TBT Committee. See e.g., Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (notified to the TBT Committee in G/TBT/N/EU/542 and G/TBT/N/EU/542/Add.1), stating in its 17<sup>th</sup> recital that:

"While this Regulation does not deal with the protection of intellectual property rights, it should nevertheless be borne in mind that often counterfeit products do not comply with the requirements set out in the Union harmonisation legislation, present risks to health and safety of end users, distort competition, endanger public interests and support other illegal activities. Therefore, Member States should continue taking effective measures to prevent counterfeit products from entering the Union market pursuant to Regulation (EU) No 608/2013 of the European Parliament and of the Council".

<sup>148</sup> TRIPS Agreement, Article 41.1.

<sup>149</sup> TRIPS Agreement, Articles 51 to 60.

<sup>150</sup> TRIPS Agreement, Article 58. For examples of internationally coordinated ex officio enforcement operations, see Box 12 below.

Competent authorities must also have the power to order the destruction or disposal outside the channels of commerce of infringing goods in such a manner as to avoid any harm to the right holder. In practice, the border measures envisaged under the TRIPS Agreement are mostly carried out by officials acting in accordance with their mandate as customs authorities. This provides a clear link between enforcement tools available under the TRIPS Agreement and improvements in border controls implemented under the TFA. Border measures are, however, optional for goods which involve other infringements of IPRs (i.e. those that do not meet the definition of counterfeit trademark or pirated copyright goods), and goods destined for export or in transit.

2.59. These flexibilities account for the challenges customs authorities face in screening and inspecting large volumes of goods to determine whether or not these are IPR infringing. While this may be obvious in some cases of counterfeit trademark or counterfeit copyright goods, or coincide with a lack of documentation or other suspicious signs, detailed knowledge of the genuine product and regular trade patterns may be required in other cases.<sup>151</sup> This is why it is particularly important for customs authorities to have access to information on products, including through communication with right holders, and to be aware of risk indicators, for example, through exchanges of information with other customs authorities. In this regard, the tools provided by the TFA can provide important mechanisms to improve the capacity of customs authorities to fight illicit trade in IPR-infringing goods. For example, a systematic review of data collected through pre- and post-import activities and international customs cooperation can help customs authorities establish patterns of legitimate trade, and identify higher-risk shipments that fall outside such patterns, thus allowing them to concentrate their enforcement efforts more efficiently. Similarly, national coordination with health regulatory and other authorities may be helpful and needed in order to establish whether or not a product is falsified/counterfeit and/or substandard.

2.60. In most cases, the right holder is best placed to assist enforcement authorities in the identification of infringing goods.<sup>152</sup> The authorities may therefore give the right holder, and also the importer, sufficient opportunity to inspect any goods detained by the customs authorities. This is meant to allow the right holder to substantiate his or her claims, and the importer to prepare the defence. Where goods have been found infringing as a result of a decision on the merits, the TRIPS Agreement leaves it to members to decide whether the right holder should be enabled to be informed of other persons in the distribution channel so that appropriate action could also be taken against them.<sup>153</sup> Both the right of inspection and information are subject to the protection of confidential information.<sup>154</sup> (See Box 10 below for a description of tools developed by the WCO to aid the dissemination and exchange of information regarding border practices.)

#### **BOX 10: WCO TOOLS TO FIGHT ILLICIT TRADE AT THE BORDER DURING THE PANDEMIC**

The WCO has set up its IPR, Health and Safety Programme in order to fight illicit trade in IPR infringing goods and to prevent related threats to consumer health and safety.<sup>155</sup> In 2021, the WCO Secretariat also developed two new IPR-related tools: the Training Handbook on Legal and Practical Measures Against Offences Relating to Intellectual Property Rights and the IPR Self-Assessment Tool.<sup>156</sup> They supplement the Model Legislation, the IPR Diagnostic Tool, and the Handbook for Customs Officers on Risk Indicators: Factors for Intellectual Property Infringement.

Recognizing the importance of permanent and real-time exchange of relevant information to fight fraudulent activities, particularly trafficking counterfeit medical supplies such as face masks and medical gloves during the COVID-19 pandemic, the World Customs Organization (WCO) launched the Intellectual Property Rights (IPR) CENcomm Group on the newly modernized CENcomm 3.0 platform.<sup>157</sup> This tool is a web-based communication system and will allow a closed user group of customs officers to exchange intelligence information, messages and alerts via secure channels. This information exchange empowers

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<sup>151</sup> TRIPS Agreement, Article 46.

<sup>152</sup> See also Marius Schneider, Nora Ho Tu Nam (2021), [How pharmaceutical companies can prevent falsified medicine and vaccines from entering African markets | 16 Journal of Intellectual Property Law & Practice 9 | Oxford Academic \(oup.com\)](#).

<sup>153</sup> As noted above, some RTAs contain stricter enforcement standards than those established by the TRIPS Agreement. For a database of RTAs notified to the WTO, and provisions on IP enforcement contained therein, see [WTO | Regional trade agreements](#).

<sup>154</sup> TRIPS Agreement, Article 57.

<sup>155</sup> WCO's IPR, Health and Safety Programme, available at: [World Customs Organization \(wcoomd.org\)](#).

<sup>156</sup> See [WCO launches new IPR-related tools – WCO \(wcoomd.org\)](#).

<sup>157</sup> COVID-19: WCO launches an IPR CENcomm Group for data exchange on counterfeit medical supplies and fake medicines, 25 March 2020, available at: [World Customs Organization \(wcoomd.org\)](#).

and enhances participating administrations' risk management and enforcement operations in the areas of countering IPR infringements and consumer safety. It was used effectively during Operation STOP II.<sup>158</sup>

Since April 2021, and in the framework of STOP II Operation, IPR CENcomm has featured a COVID-19 pre-arrival information template aimed at facilitating the Customs-to-Customs exchange of non-nominal data and at supporting Members in tackling the challenges associated with the requirement for a proper legal basis for the exchange of information. IPR CENcomm was originally intended for law enforcement officers only. However, to strengthen cooperation with the private sector, a dedicated "Rights Holders' Corner" has been created for inputting essential information that can help in the fight against counterfeiting and piracy. The Rights Holders' Corner was also developed to ensure a smooth exchange of information between rights holders and Customs. To facilitate rapid reporting of seizures, even in the field, an IPR CENcomm mobile shortcut has also been developed.<sup>159</sup>

### 2.3.4 Taking account of challenges in IPR enforcement

2.61. As IPRs are generally conferred by implementing legislation with effect only in the jurisdiction concerned, a good or service may be legal in one jurisdiction, and at the same time IPR-infringing (and thus "illicit") in another. This can pose challenges in regard to goods in transit, which may be IPR-infringing in the transit country, even if no IPRs apply in the country of production and/or final destination. Under the TRIPS Agreement, border measures are optional with regard to goods in transit.<sup>160</sup> The detention of generic medicines transiting EU territory and subsequent developments in multilateral organizations, as well as in EU law and jurisprudence, represent an interesting case study and have been the object of consultations under the WTO DS mechanism.<sup>161</sup>

2.62. Restrictions may need to be put in place to prevent diversion of products, in particular for medical goods which are produced under a special compulsory licence<sup>162</sup> for export to Members who have notified their needs to the WTO. Under such a licence, a government could authorize a government entity or a third party to manufacture pharmaceutical products exclusively for Members relying on imports without the authorization of the patent owner. Medical goods produced in the context of such compulsory licenses are subject to anti-diversion measures to ensure that the goods reach the Member that relies on importation,<sup>163</sup> as diversion of products which are legal as such to higher income countries could be considered a form of illicit trade. IPRs therefore may have a role to play in supporting the intended distribution of goods across different economies, and thus ensure equity of access. That said, some reports on illicit trade use the term "diversion" more loosely, and therefore may include other instances of diversion. (See Box 11 below for further detail on diversion and theft as it relates to pharmaceuticals.)

#### BOX 11: DIVERSION AND THEFT OF PHARMACEUTICAL PRODUCTS

According to the Pharmaceutical Security Institute (PSI, 2019),<sup>164</sup> illegal diversion occurs when a genuine pharmaceutical product is approved and intended for sale in one country but is then illegally intercepted and sold in another country. This is usually accomplished through the use of false statements or declarations. Drug regulators in the second country may not have approved the use of the diverted drug.

Pharmaceutical theft is defined as the illegal taking of medicines (PSI, 2019). Thefts include burglary, robbery or the embezzlement of goods. The theft may occur anywhere in the distribution chain such as at the site of manufacture, freight forwarder, distribution centres, warehouses, pharmacies, or hospitals.

<sup>158</sup> Operation STOP II – Executive Summary, available at: [wco\\_operation-stop-ii\\_executive-summary.pdf \(wcoomd.org\)](https://www.wcoomd.org/publications/operation-stop-ii-executive-summary.pdf).

<sup>159</sup> The WCO Secretariat has also developed an e-learning module on "Combatting illicit medicines and counterfeit or substandard medical supplies related to COVID-19 and other pandemics", which is available on the Organization's CLiKC! Platform (May 2022). The aim of this online training material is to give frontline Customs officers greater tactical insight, through training in risk profiling and targeting, when carrying out focused controls on suspicious consignments and/or searching for counterfeit/illicit medicines and COVID-19-related goods.

<sup>160</sup> Article 51 of the TRIPS Agreement.

<sup>161</sup> For details, see WTO, WIPO, WTO (2020) Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade (second edition): [WTO | Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade \(second edition\)](https://www.wto.org/publications/default.aspx?lang=en&docid=4462) and [WTO | dispute settlement - the disputes - DS408](https://www.wto.org/publications/default.aspx?lang=en&docid=4462) and [DS409](https://www.wto.org/publications/default.aspx?lang=en&docid=4462)

<sup>162</sup> See Article 31bis of the TRIPS Agreement.

<sup>163</sup> TRIPS Agreement, Article 31bis.1 in conjunction with Annex to the TRIPS Agreement, paras. 3 and 4.

<sup>164</sup> Trade in Counterfeit Pharmaceutical Products, OECD/EUIPO 2020, available at [Trade in counterfeit pharmaceutical products \(europa.eu\)](https://www.oecd.org/euiipo/trade-in-counterfeit-pharmaceutical-products). p. 18, Box 2.1.

Importantly, as with cases of counterfeiting, diversion and theft escape the control of the IP right owner. In addition, diverted and stolen medicines are often stored and transported in poor conditions, which might have negative effects on their active ingredients. Moreover, these medicines can be unlawfully supplied to the public without observing prescription conditions. Consequently, diverted and stolen drugs can be potentially damaging to consumers' health and "blur" product identification in the marketplace.

2.63. Finally, the TRIPS Agreement makes the application of border measures optional with regard to de minimis imports, that is the importation of small quantities of goods of a non-commercial nature, typically contained in travellers' personal luggage or sent in small consignments. This reflects the reality that customs authorities often find it difficult to control such imports as systematic checks of small parcels put a strain on resources and personnel available to customs authorities, and that the right holder may be less disposed to bear the costs of enforcement, including the destruction of such goods. Historically, small consignment shipments were considered as below the threshold for systematic enforcement by customs authorities. Today, however, the rise of e-commerce transactions and related increase in such shipment arguably poses a challenge with regard to illicit trade in IPR infringing goods. According to some sources, the COVID-19 pandemic has increased both the volumes of e-commerce and the potential for its misuse.<sup>165</sup> Cyber law enforcement reported increasing volumes of various e-crimes, including offerings of illicit goods, among them fake and substandard medicines, test kits and other COVID-19-related goods. With regard to pharmaceuticals, EUIPO/EUROPOL found that the distribution of counterfeit pharmaceuticals had shifted to online markets, relying both on dedicated platforms, such as online pharmacies, as well as social media platforms.<sup>166</sup> Thus, the question as how to best tackle de minimis imports remains a challenge in an e-commerce environment.

2.64. Free trade zones are designed to facilitate trade and reduce administrative hurdles for importers and exporters. In that regard, it is important to avoid any unintended effects with regard to illicit trade in COVID-19 medical goods. According to an OECD/EUIPO 2020 report, the use of free trade zones has facilitated trade in counterfeit pharmaceuticals, providing a venue for packaging and repackaging products in ways that effectively disguise their true origin.<sup>167</sup> The TRIPS and other WTO Agreements described above can help Members in determining what disciplines should be applied in fighting illicit trade also in such areas.<sup>168</sup>

### 2.3.5 Criminal sanctions

2.65. Members also need to put in place criminal procedures and penalties in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale (this is again optional for other IP-infringements).<sup>169</sup> Such penalties can act both as sanction and as deterrent, and are warranted where IP violations, such as in the form of counterfeiting, affect the interests of the general public, calling for the application of criminal law to ensure stringent IP protection.<sup>170</sup> As criminal law is usually enforced by relevant authorities ex officio, government action in that regard is not reliant on the right holder. Experience from the COVID-19 pandemic suggests that international cooperation between relevant authorities is particularly relevant in using criminal sanctions in times of global crisis.<sup>171</sup> (See Box 12 below for examples of arrests by international criminal enforcement organizations related to seizures of illicit medical products during the COVID-19 pandemic.)

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<sup>165</sup> See also [Chapter 6. The trade in counterfeits during the pandemic | Global Trade in Fakes : A Worrying Threat | OECD iLibrary \(oecd-ilibrary.org\)](#)

<sup>166</sup> EUIPO/EUROPOL (2022). According to the report, medicines were the seventh most seized products at the EU's external border and the Covid-19 pandemic presented new opportunities for criminals attempting to capitalize on the high demand for certain goods.

<sup>167</sup> OECD/EUIPO (2020), Trade in Counterfeit Pharmaceutical Products, Illicit Trade, OECD Publishing, Paris, <https://doi.org/10.1787/a7c7e054-en>.

<sup>168</sup> While not addressing FTZs as such, the obligation to "give effect" to the provisions of the TRIPS Agreement extends to the entire territory of a WTO Member, arguably including any zones with special regimes for export activities. Article 1.1 of the TRIPS Agreement. See also OECD (2018), [Trade in Counterfeit Goods and Free Trade Zones: Evidence from Recent Trends | READ online \(oecd-ilibrary.org\)](#).

<sup>169</sup> Article 61 of the TRIPS Agreement.

<sup>170</sup> For a discussion see Ajay K Sharma (2021), "The Relevance of Criminal Law in Intellectual Property Law Research," in Irene Calboli and Maria Lilla Montagnani (2021), Handbook of Intellectual Property Research: Lenses, Methods, and Perspectives, available at: DOI:10.1093/oso/9780198826743.003.0014.

<sup>171</sup> See e.g. [\(English\) Exchange of experiences on the trafficking of vaccines and other COVID medicines Exchange of experiences on the trafficking of vaccines and other COVID medicines \(elpaccto.eu\)](#).

## BOX 12: ARRESTS LINKED TO ILLICIT TRADE IN MEDICAL PRODUCTS DURING THE PANDEMIC

When IP-infringing goods are seized, this can mean the arrest of those who are criminally involved. Interpol reports that a fake COVID vaccine distribution network was dismantled by South African and Chinese authorities after an INTERPOL alert.<sup>172</sup> Some 400 ampoules - equivalent to around 2,400 doses - containing the fake vaccine were found at a warehouse in Germiston, Gauteng, where officers also recovered a large quantity of fake 3M masks. In China, police successfully identified a network selling counterfeit COVID-19 vaccines, raided the manufacturing premises, resulting in the arrest of some 80 suspects, and seized more than 3,000 fake vaccines on the scene. The investigation was supported and facilitated by INTERPOL's Illicit Goods and Global Health (IGGH) Programme and an alert warning law enforcement of risks related to the pandemic. The alert also included details and images of genuine vaccines and authorized shipping methods provided by pharmaceutical companies to assist in the identification of fake vials. EUIPO and Europol have reported that Europol's Operation Shield, conducted between March and September 2020 to target the trafficking of counterfeit and misused medicines and doping substances, resulted in nearly 700 arrests and highlighted how emerging pharma crime is linked to the pandemic.

### 2.3.6 International cooperation and the role of the TRIPS Council

2.66. The TRIPS Agreement mandates international cooperation to support the fight against illicit trade.<sup>173</sup> As a concrete measure to promote this goal, members are required to establish contact points in their administrations and be ready to exchange information on trade in IPR-infringing goods. There is a particular obligation to promote the exchange of information and cooperation between customs authorities with respect to two categories of IPR infringement: trade in counterfeit trademark goods and pirated copyright goods. The TRIPS Council receives notifications and updates of these contact points from its Members, and these can be accessed through the e-TRIPS Gateway.<sup>174</sup> A total of 147 out of the 164 WTO Members have notified their respective contact points. The WTO's Council on Trade-Related Aspects of Intellectual Property Rights (TRIPS) also serves as important forum for discussion on Members' implementing legislation and related developments.<sup>175</sup>

### 2.3.7 Technical assistance

2.67. The TRIPS Agreement requires developed countries to provide technical and financial cooperation on mutually agreeable terms when requested by developing countries and LDCs.<sup>176</sup> This obligation also covers technical assistance on enforcement and other measures that can help fight illicit trade in IP-infringing goods. In addition, WTO capacity building activities covering the TRIPS Agreement and IP issues regularly feature a component on intellectual property enforcement.<sup>177</sup> Technical assistance activities regarding intellectual property enforcement under the TRIPS Agreement may also be delivered to WTO technical assistance beneficiaries on request. WTO training materials also address intellectual property enforcement under TRIPS, such as the WTO webpage on [enforcement of intellectual property rights](#) and the [Guide to the TRIPS Agreement](#). Further, the joint WHO-WIPO-WTO Trilateral Study "[Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade \(second edition\)](#)" includes sections on intellectual property enforcement.

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<sup>172</sup> INTERPOL News item "Fake COVID vaccine distribution network dismantled after INTERPOL alert", 3 March 2021, available at: [Fake COVID vaccine distribution network dismantled after INTERPOL alert](#).

<sup>173</sup> Article 69 of the TRIPS Agreement.

<sup>174</sup> [Trade-Related Aspects of Intellectual Property Rights - Welcome to the e-TRIPS Gateway \(wto.org\)](#).

<sup>175</sup> The e-TRIPS Gateway offers full-text and subject-matter search functions to follow past discussions on issues such as the discussion of the Anti-Counterfeiting Trade Agreement (ACTA) or the transit of generic pharmaceuticals, or of a EUIPO report on the impact of counterfeiting and piracy on creative industries. See <https://e-trips.wto.org/En/Search/CouncilMinutes>.

<sup>176</sup> Article 67 of the TRIPS Agreement. Descriptions of such TRIPS and IP-related technical and financial cooperation programmes must be reported to the TRIPS Council. Reports can be accessed through the [e-TRIPS Gateway](#).

<sup>177</sup> Including, for example, the WIPO-WTO IP Advanced Course for Government Officials and the WIPO-WTO Colloquium for IP Professors, two flagship technical assistance activities jointly held by the WTO and WIPO Secretariats, in addition to courses held by the WTO Secretariat including Regional Trade Policy Courses, Advanced Trade Policy Courses and WTO eLearning courses related to the TRIPS Agreement. For the latest reports of the Secretariat on its technical cooperation activities, see WTO document [IP/CRTC/WTO](#). Other reports are available through the [e-TRIPS Gateway](#).



## 2.4 STRENGTHENING SYSTEMS FOR GOVERNMENT PROCUREMENT

*The WTO Agreement on Government Procurement 2012 serves the dual purpose of enabling signatory governments to take full advantage of the benefits of international trade, including by providing access to high-quality medical goods, while equipping them to design and run government procurement procedures in a way that mitigates the risk of government procurement becoming an inadvertent conduit for the entry of counterfeit, fake or substandard medical goods into domestic healthcare sectors.*

2.68. Good governance in government procurement systems has an important role to play in countering illicit trade. Governments spend around 9% of their GDPs to procure health-related goods and services, making healthcare the second largest sector attracting government procurement spending.<sup>178</sup> Government procurement of high-quality medical supplies is vital for saving lives and supporting the health of the population. Procuring entities have a duty to make sure that even during emergency situations counterfeit medical goods detrimental to human health and presenting a risk for human life do not get into supply chains. The risk of entry of illicit goods is real. To cite just one example, in Panama, the government purchased and distributed cough syrups containing toxic substances that killed 116 people.<sup>179</sup>

2.69. The COVID-19 pandemic created an unprecedented situation of scarcity of supply of essential medical goods. Faced with urgency, governments in some cases compromised on, and temporarily relaxed, procedural or transparency safeguards in government procurement.<sup>180</sup> This, in turn, created a fertile ground for possible fraud and the consequent procurement by governments of counterfeit or substandard medical goods.<sup>181</sup>

2.70. Government procurement is commonly defined as the purchase by governments of goods that are not for commercial (re)sale or for use in the production or supply of goods for commercial sale.<sup>182</sup> Thus, leaving aside the scourge of corrupt practices, governments themselves do not have a commercial interest in engaging in illicit trade in the context of government procurement, as they do not look to resell procured medical supplies with a profit. Rather, illicit trade is a risk for procuring entities that they must manage, especially in the domestic healthcare sector, to protect their citizens' health.

2.71. The WTO Agreement on Government Procurement 2012 (GPA 2012) is a plurilateral agreement opening government procurement markets among its signatory WTO Members (GPA Parties) and strengthening good governance in their procurement systems.<sup>183</sup> Government procurement by GPA Parties above specified contract value thresholds is subject to GPA 2012 requirements, unless otherwise excluded.<sup>184</sup> By partially opening their procurement markets to competition from suppliers from other GPA Parties, procuring entities can purchase and access high-quality medical products while optimizing value for money.

2.72. The opportunity to trade, i.e. to source health-related goods internationally, presents great benefits, including in public health emergencies. But it also exposes procuring entities to the phenomenon of illicit trade. As further explained below, however, the GPA 2012 enables its Parties to engage in trade and at the same time prevent the wilful or inadvertent introduction of counterfeit, fake or substandard goods into the domestic healthcare sector. The usefulness of the GPA 2012 as a tool to fight illicit trade, including in the healthcare sector, was highlighted also by the Director-General of the WTO, Dr Ngozi Okonjo-Iweala.<sup>185</sup>

2.73. While the GPA 2012 generally seeks to discipline the conduct of procuring entities subject to its rules, it also provides for the flexibility that governments need to procure goods in sufficient quantities and quality

<sup>178</sup> See OECD, Health and Public Procurement, viewed at: [Health and Public Procurement - OECD](#).

<sup>179</sup> See Thomas T. Kubic, "Counterfeit drug aftermath still plagues Panama", viewed at: [Counterfeit Drug Aftermath Still Plagues Panama – Partnership for Safe Medicines](#)

<sup>180</sup> See OECD, "Stocktaking report on immediate public procurement and infrastructure responses to COVID-19", viewed at: [Stocktaking report on immediate public procurement and infrastructure responses to COVID-19 \(oecd.org\)](#).

<sup>181</sup> See OECD, "Public integrity for an effective COVID-19 response and recovery", viewed at: [Public integrity for an effective COVID-19 response and recovery \(oecd.org\)](#).

<sup>182</sup> See Articles II:2(a)(ii) and III:8 of the GATT 1994.

<sup>183</sup> Currently, the GPA 2012 has 21 Parties covering 48 WTO Members. For more about the GPA 2012, see [WTO | Government procurement - The plurilateral Agreement on Government Procurement \(GPA\)](#).

<sup>184</sup> For more details on the coverage of medical goods and services under the GPA 2012, see Robert D Anderson and Anna Caroline Müller, "Keeping markets open while ensuring due flexibility for governments in a time of economic and public health crisis: the role of the WTO Agreement on Government Procurement (GPA)", 29 PPLR, Issue 4 (2020).

<sup>185</sup> See Transparency International United Kingdom Annual Anti-Corruption Lecture, viewed at: [WTO | News - Speech - DG Ngozi Okonjo-Iweala - DG Okonjo-Iweala: WTO rules can support fight against corruption, illicit trade and enhance transparency](#).

in public health emergencies (emergency procurement). As noted, such situations of urgency can, however, present heightened dangers of corruption and mismanagement of public funds. That is why the GPA 2012 requires minimum transparency even in situations of urgency.<sup>186</sup>

#### 2.4.1 Countering illicit trade through anti-corruption measures

2.74. Corruption constitutes a major risk when it comes to the entry of illicit goods into legitimate government procurement channels, including in the healthcare area. One third of OECD citizens consider the healthcare sector to be corrupt or extremely corrupt.<sup>187</sup> It is therefore a central task and responsibility of governments to prevent or fight corruption in government procurement so that counterfeit medical goods do not enter healthcare systems. Specifically, the UNODC recommends that governments "identify and manage corruption risks within authorities mandated with procuring ... medicine and medical supplies".<sup>188</sup>

2.75. As concerns identification of corruption risks, the transparency of the government procurement system as a whole is key to identifying corruption risks.<sup>189</sup> Electronic procurement systems in particular can make an important contribution.<sup>190</sup> The GPA 2012 provides for extensive transparency obligations, including the obligation to give reasons to unsuccessful suppliers, and encourages GPA Parties to use electronic procurement systems.<sup>191</sup>

2.76. Regarding the management of corruption risks, the GPA 2012 requires that GPA Parties conduct GPA-covered procurement procedures in a manner that prevents corrupt practices, in keeping with such international standards as the United Nations Convention Against Corruption (UNCAC).<sup>192</sup> It notably prescribes that GPA Parties conduct their GPA-covered procurement in a fair and impartial<sup>193</sup> and non-discriminatory manner.<sup>194</sup> GPA Parties must also establish effective and non-discriminatory domestic review procedures involving independent administrative or judicial review bodies, which creates accountability and deters corruption.<sup>195</sup> These good governance features of the GPA 2012 help governments to manage corruption risks, including in the healthcare area, by making it more difficult for procuring entities and suppliers to engage in corrupt practices or making it easier to detect such practices.

#### 2.4.2 Countering illicit trade through supplier selection

2.77. Even with anti-corruption measures in place, the risk of unintended entry of illicit goods into legitimate government procurement channels persists. An effective way to mitigate this risk is to intervene early in a government procurement procedure when procuring entities evaluate the eligibility of interested suppliers (supplier selection). Specifically, procuring entities may be able to exclude from a particular health-related procurement any suppliers that raise justifiable concerns with regard to the delivery of counterfeit, fake or substandard goods. Another possibility is to impose requirements that suppliers must satisfy. For instance, procuring entities can establish non-discriminatory eligibility criteria that relate to compliance with good manufacturing practices (GMPs).<sup>196</sup>

2.78. The GPA 2012 specifically permits governments to exclude from participation in GPA-covered government procurement procedures any potential suppliers that have provided false declarations, have been significantly deficient in performing prior contracts or were convicted for serious crimes or other serious

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<sup>186</sup> For instance, GPA Parties may have recourse to limited tendering in situations of extreme urgency (e.g. a pandemic). However, they must publish a report justifying the use of this method and informing interested parties about the value and kind of goods or services procured. See Article XIII:1(d) and XIII:2 of the GPA 2012.

<sup>187</sup> See OECD, Health and Public Procurement, viewed at: [Health and Public Procurement - OECD](#).

<sup>188</sup> See UNODC, (2020), "COVID-19-related trafficking of medical products as a threat to public health", viewed at: [FINAL COVID-19 BRIEF 06-07-2020.indd \(unodc.org\)](#).

<sup>189</sup> For a detailed discussion on the importance of transparency for procurement of medical goods, see Jillian Clarke Kohler and Tom Wright, "The urgent need for transparent and accountable procurement of medicine and medical supplies in times of COVID-19 pandemic", *Journal of Pharmaceutical Policy and Practice*, N13 (2020).

<sup>190</sup> See, for example, the Technical Guide to the United Nations Convention against Corruption, viewed at: [Microsoft Word - V0984395.doc \(unodc.org\)](#).

<sup>191</sup> See Articles VI, XVI and XVI, and the preamble, of the GPA 2012

<sup>192</sup> See Article IV:4 of the GPA 2012.

<sup>193</sup> See, for example, Article XV:1 of the GPA 2012.

<sup>194</sup> See Article IV:1-2 of the GPA 2012

<sup>195</sup> See Article XVIII:1 of the GPA 2012.

<sup>196</sup> See Andreas Seiter, "A practical approach to pharmaceutical policy", The World Bank, 2010. Can be viewed at: [World Bank Document](#).

offences in a final judgement.<sup>197</sup> These grounds for exclusion might extend to suppliers for which there is supporting evidence that they have previously introduced counterfeit or substandard medical supplies into the supply chain through government procurement, e.g. because they made false declarations about their medical supplies, failed to deliver supplies of the requisite quality, or were convicted for fraud, etc.

### 2.4.3 Countering illicit trade through contract award criteria

2.79. A further option open to procuring entities wishing to mitigate risks of unintended entry of illicit goods relates to the choice of appropriate contract award criteria and their relative importance. It is useful to recall in this connection that "counterfeit drugs are manufactured without any thoughts to quality, efficacy or even safety of the intended patient".<sup>198</sup> Therefore, an exclusive or predominant focus by procuring entities on the price of healthcare-related goods that is to be procured might provide an unintended incentive for some suppliers to keep their price low by delivering counterfeit, fake or substandard supplies. Procuring entities can to some extent counter that risk by placing weight on other award criteria in addition to the price, like the quality of medical products (e.g. face masks). This could reduce the likelihood of suppliers of counterfeit, fake or substandard supplies winning government contracts.

2.80. The GPA 2012 allows governments to step away from an exclusive focus on the lowest price as an award criterion and include additional criteria such as product quality.<sup>199</sup> The lowest price criterion may attract relatively more offers from suppliers of counterfeit products. Such products can be offered at a lower price as they are not produced using the same materials and processes as medical products of good quality.<sup>200</sup>

### 2.4.4 International cooperation in the WTO Committee on Government Procurement

2.81. Besides playing an important role as a good governance tool, the GPA 2012 also facilitates the cooperation of GPA Parties and observers at an international level. The body administering the GPA 2012 at the WTO level, the Committee on Government Procurement (the CGP), is an important forum for discussion and exchange about the implementation of the GPA 2012 and international best practices in the area of government procurement, including the conduct of transparent, fair, impartial procedures that prevent corrupt practices.

## 3 SUMMARY AND NEXT STEPS IN THE FIGHT AGAINST ILLICIT TRADE

*This section summarizes key points from this working paper and sets out some broader, cross-cutting observations about how WTO disciplines and trade policy activities can further boost border and regulatory capacity and deepen cooperation with public and private stakeholders in the fight against illicit trade.*

**3.1. Illicit trade in medical products is a complex, global problem that poses a threat to people, economies and governments everywhere.** Often clandestine in nature, illicit trade is difficult to measure. WTO estimates indicate that illicit trade in medical products constitutes between 1.3 per cent and 4.2 per cent of global trade in the sector. Anecdotal evidence indicates that such activity has not abated, and may even have expanded during the COVID-19 pandemic, with a 5% increase in seizures reported in 2020 versus 2019. More generally, illicit trade in medical products presents a number of health, social and economic impacts, complicating the achievement of the United Nations Sustainable Development Goals (SDGs), particularly those relating to poverty and health outcomes.

**3.2. More and stronger evidence is needed to discern any clear trend in illicit trade in medical products since the outbreak of the pandemic.** Greater efforts can be made to coordinate efforts with the public and private sectors to improve the quality and analysis of data on trade in medical products.

<sup>197</sup> See Article VIII:4(b), (c) and (d) of the GPA 2012. See also UNODC, "Combating falsified medical product-related crime: A guide to good legislative practices", Vienna 2019. Can be viewed at: [\\*COMBATING FALSIFIED MEDICAL PRODUCT-RELATED CRIME: A GUIDE TO GOOD LEGISLATIVE PRACTICES \(unodc.org\)](https://www.unodc.org/en/publications-and-reports/combating-falsified-medical-product-related-crime-a-guide-to-good-legislative-practices)

<sup>198</sup> See David Elder, "The cost of drug counterfeiting", European Pharmaceutical Review, viewed at: [The cost of drug counterfeiting \(europeanpharmaceuticalreview.com\)](https://www.europeanpharmaceuticalreview.com/news/2019/07/11/the-cost-of-drug-counterfeiting/).

<sup>199</sup> See Articles X:9 and XV:5 of the GPA 2012.

<sup>200</sup> According to the WHO, "there are no good quality counterfeit medicines", viewed at: [Does quality of medicines matter \(who.int\)](https://www.who.int/news/2019/07/11/does-quality-of-medicines-matter).

## WTO rules equip Members with critical tools needed in the fight against illicit trade

3.3. **The WTO rulebook is an important ally in the fight against illicit trade.** WTO disciplines support the efforts of WTO Members to address the threat of illicit trade by promoting transparency and laying the foundation for strengthened border and regulatory controls. Many of these disciplines also reinforce good governance by curbing discretionary practices that can give rise to inefficiencies and corruption.

- a. The **Trade Facilitation Agreement (TFA)** contains a host of measures that strengthen the border controls needed to tackle illicit trade by requiring transparency of customs rules and procedures, risk management systems, and pre- and post-clearance processes. These rules foster predictability and security in the trading environment, narrow the opportunities for illicit traders, and favour the simplification and automation of processes that reduce corruption.
- b. The **Customs Valuation Agreement (CVA)** further buttresses the aims of transparency and predictability by setting out rules with regard to the proper valuation of goods at the border that can help in guarding against illicit mis-invoicing.
- c. The **Technical Barriers to Trade (TBT) Agreement** provides for the adoption of CAPs that aid in fighting illicit trade by verifying that products comply with quality and safety standards and regulations (before, during, and after they are placed on the market). It also contains important provisions regarding transparency and the use of international standards. The TBT Committee reinforces the importance of NQI to support implementation of the Agreement and the need for additional support for developing countries to strengthen their NQIs.
- d. The **Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement** sets minimum standards for the protection and enforcement of IPRs that are directly linked to the fight against illicit trade in IPR-infringing goods. It also mandates critical enforcement tools by tasking Members with installing effective border measures, promoting the exchange of information and cross-border customs cooperation, and allowing for the exchange of information with IP right holders that aids in the targeting of trade in IP-infringing goods.
- e. The **Government Procurement Agreement (GPA 2012)** prescribes good governance features that assist signatories in alleviating the risk of corruption and specify rules and procedures (for instance, those relating to supplier selection and contract criteria) that serve to mitigate the incidence of illicit trade in the public sourcing of goods.

3.4. **WTO disciplines as they relate to illicit trade in goods can be mutually reinforcing.** Although the rules identified above have a potential bearing on the ability of WTO Members to effectively control and regulate the incidence of illicit trade, it is equally important to recognize the ways in which discrete requirements arising under different WTO Agreements may be mutually supportive in this regard. Identifying these linkages, and exploring the potential to benefit from such synergies, will be especially important in addressing the multifaceted threat posed by illicit trade.

- a. **Improvements in border controls go hand in hand with regulating product safety and enforcing IPRs.** Improving border controls is essential to addressing illicit trade, and the TFA, CVA, TBT Agreement, and TRIPS Agreement all contain provisions that strengthen efficient and secure borders. These rules and practices are also mutually reinforcing in that, for example, a particular trade facilitation improvement – implementing a robust risk management system – will also improve the ability of customs to target suspect imports due to concerns that such products do not meet quality or safety standards and/or infringe IPRs. Similarly, mechanisms to exchange information between customs and other authorities, or with authorities in trading partners, can help leverage resources in countering illicit trade through national and international cooperation. The WTO can serve as an important forum in this regard.
- b. **The linkages between conformity with IPRs and TBT standards means that border and regulatory enforcement in these areas are especially complementary.** Highly regulated products that infringe IPRs can often also be substandard when they fail to comply with safety, health, and quality standards. Furthermore, counterfeiting or falsification of "certification marks" affixed on regulated products can also implicate both IP and TBT regimes. This indicates that efforts to promote effective IP enforcement and better regulatory surveillance frameworks through NQIs can be mutually supportive, especially where enforcement of one set of disciplines

leads to better enforcement of the other. It also suggests prospects for increased detection of the same illicitly traded goods in instances where both TBT and IP controls are implicated.

- c. **Transparency rules are important tools in the fight against illicit trade.** Each of these WTO Agreements contain disciplines that seek to foster greater transparency in national laws and practices. This has the benefit of creating greater predictability by alerting legitimate traders to the rules of the game while reducing the opportunities for illicit trade that come with border and regulatory uncertainty. Enhanced transparency also provides the foundation for information exchange and cooperation among customs authorities and national regulators.

### The WTO can help Members facing illicit trade challenges caused by the rise of e-commerce

**3.5. WTO rules can assist Members in seizing new trade opportunities arising from the emergence of the digital economy while limiting avenues for illicit trade.** During the course of the COVID-19 pandemic, the use of e-commerce platforms to conduct trade accelerated significantly, which has both exacerbated and mitigated the challenges posed by illicit trade. While the rise of e-commerce has generated immense benefits for customers and businesses (particularly MSMEs) wishing to access new markets, it has also allowed illicit traders to exploit new vulnerabilities. In particular, high volumes of small consignments have posed significant challenges to customs authorities at the border and regulators seeking to implement effective border or post-market controls. These developments have been documented with regard to medical products during the pandemic period, particularly as it relates to fake and substandard medicines, test kits, masks, and other COVID-19 related goods.

- a. **Making effective use of existing frameworks.** As noted, improving border controls is essential to addressing illicit trade, and several provisions of the WTO Agreements are mutually reinforcing in strengthening efficient and secure borders. The example identified with regard to implementing a risk management system is also especially pertinent in dealing with digital trade since, even with respect to small consignments sold through digital platforms, improving the ability of customs to target suspect imports may also address border and regulatory concerns relating to substandard and IPR-infringing products.
- b. **Developing new e-commerce rules and practices.** Certain WTO developments may also require increased attention in the digital age. Negotiations among a large group of WTO Members on e-commerce aim to create a more secure and predictable environment for digital and online commerce, including by promoting reliance on paperless processes that could reduce opportunities for illicit traders by reducing the frequency of interactions that can give rise to corruption and other illicit activity at the border. At the same time, certain areas – such as in the case of small quantities of goods that may not be subject to IP enforcement under de minimis rules – may pose new challenges in regulating illicit trade in a digital trading environment.
- c. **Utilizing innovations in advanced technologies and data management.** Customs authorities have increasingly relied on advanced technologies such as the use of blockchain and AI to establish more accurate and secure transaction records and to achieve greater efficiency and reliability in risk management systems. These innovations not only ensure better quality data with regard to legitimate trade, but also strengthen customs and regulatory compliance in a manner that narrows opportunities for illicit traders. Although half of customs authorities currently use some form of data analytics, for example, the clear benefits of using these systems, including in detecting illicit trade, indicates that more work remains to be done. Efforts must focus on collecting and digitalizing better quality data so that it can be shared, used to trace products across the supply chain, and then feed back into risk management systems.

### The WTO can help Members facing challenges caused by supply chain disruptions in goods

**3.6. WTO rules may also guide Members who have been tested by the demand surges and supply chain disruptions that have generated new opportunities for illicit traders.** Over the course of the COVID-19 pandemic, surges in demand and the imposition of lockdowns, border closures, and other restrictions have led to uneven trade and distribution of key medical products. Such disruptions to the functioning of supply chains have provided criminal groups with new opportunities to pursue illicit activities.

- a. **Strengthening customs controls can safeguard supply chain integrity.** At times when unmet demand and new restrictions hand illicit traders new vulnerabilities to exploit, it is

particularly critical to maintain and strengthen existing enforcement mechanisms. In particular, the tools available to right holders and governments to guard against trade in IP-infringing goods remain especially pertinent, as does securing strong NQI systems and border processes. Even more fundamentally, all of the obligations pertaining to transparency and border and regulatory controls stabilize the trading environment to minimize supply chain disruptions.

- b. **Adapting new approaches to supply chain management can thwart the efforts of illicit traders.** The innovations in customs processes due to automation and technology that aid Members in addressing illicit risks in digital trade also help in securing supply chains, and trade facilitating measures that prioritize digitalization (e.g. online processes and single window requirements) are especially important in that regard. As noted, customs authorities have begun to adopt blockchain, AI and other technologies to ensure secure and quality transaction data that can be more easily shared, but more work remains to be done. In addition, WTO rules recognize the importance of allowing for checks that can occur prior to (e.g. authorized operator provisions) or following (e.g. post-market surveillance) importation, and this allows for more targeted controls that minimize supply disruptions. Initiatives to undertake product traceability could also be critical in dealing with the illicit trade consequences of unmonitored medicines.

### Effectively tackling illicit trade requires greater coordination within and among Members

**3.7. Tackling a multifaceted problem like illicit trade requires approaches that build on opportunities for domestic coordination and international cooperation, and that involve both public and private sector actors.** Each of the outlined WTO Agreements contain provisions that require or encourage interaction between customs authorities and regulators that can occur not only among domestic agencies and stakeholders within WTO Members but also between WTO Members themselves. This is an area where greater dialogue and exchange of information can generate potential synergies that will improve the functioning of customs and regulatory processes and mitigate the harms of illicit trade.

- a. **National Trade Facilitation Committees (NTFCs) can play a critical role in addressing concerns relating to illicit trade.** WTO Members have been setting up their NTFCs, as required under the TFA, to facilitate domestic coordination and implementation of trade facilitating laws and policies. This has tremendous potential to improve domestic border and regulatory controls because it allows for the sharing of information within and among NTFCs and involves broad representation by stakeholders, including all relevant border and regulatory agencies and the private sector. In some regions, developing Members have joined resources to establish regional committees which offers the potential to further integrate sound border practices both domestically and regionally.
- b. **WTO rules create multiple avenues for international cooperation and the exchange of information that can assist Members in the fight against illicit trade.** Several WTO Agreements provide for international cooperation between customs and regulatory authorities. The TFA contains mechanisms to share information on best practices, to coordinate procedures at border crossings, and to cooperate in instances where customs authorities question import or export declarations. The TRIPS Agreement requires the exchange of information and cooperation between customs authorities regarding counterfeit and pirated goods. The TBT Agreement does not have explicit rules on cooperation but promotes regulatory cooperation, including with respect to CAPs, and information exchanges through its transparency provisions and the requirement of a TBT Enquiry Point. These agreement also have provisions requiring the designation of contact points for purposes of all international cooperation matters.
- c. **Reliance on international standards also helps Members tackle illicit trade.** The TFA, TBT Agreement, and TRIPS Agreement all urge recourse to international standards in certain contexts, although the extent to which such reliance is deemed mandatory or voluntary varies. The aim of these measures is to encourage cooperation on potentially common practices used to address various policy challenges, including those relating to illicit trade concerns. Aligning international practices, for example, can help countries work together to trace the sources of substandard, unlicensed, or falsified medical goods, and customs and regulatory cooperation can be used to further support multi-jurisdictional market surveillance and enforcement efforts.
- d. **WTO bodies provide useful fora to address illicit trade concerns and to share information on domestic practices.** WTO Members can utilize their involvement with various WTO councils, committees, and other bodies to share experiences and strengthen implementation and cooperation. The TF Committee allows for the monitoring of customs

reforms with a clear nexus to illicit trade; the TRIPS Council has served as an important forum for discussion on the impact of IPR legislation and enforcement on goods in transit; and the TBT Committee has already witnessed discussion on specific trade concerns relating to illicit trade.

### **Equipping developing WTO Members to combat illicit trade through capacity building**

**3.8. The WTO is well placed to assist developing Members in strengthening their capacity to face the challenges posed by illicit trade.** There are various formats available to provide developing Members, and in particular LDCs, with the information, training and development assistance that can solidify implementation efforts and promote the development of sound institutions and processes that will reduce the incentives for corrupt or illicit trading behaviour.

- a. **Developing Members may request technical assistance and capacity building to implement TFA commitments that are crucial in the fight against illicit trade.** Developing and LDC Members have the right to self-determine when they will apply specific provisions of the TFA, and to designate those commitments for which they are requesting a transition period together with assistance and support for capacity building. This is of crucial significance, particularly as it relates to some of the TFA commitments that are most helpful in addressing illicit trade concerns, such as the implementation of risk management and a single window. Around half of developing and LDC Members have indicated the need for technical assistance to implement risk management requirements, and two-thirds have done so for the implementation of a single window. In addition, developing and LDC Members may also have recourse to the Trade Facilitation Agreement Facility which can support them in assessing their specific needs and in identifying possible development partners to help them meet those needs.
- b. **Developing and LDC Members may also request advice and technical assistance from other Members on matters particularly relevant to fighting illicit trade, such as those relating to implementing and improving NQI or enforcement of IPRs.** Thus, WTO Members that are successful in addressing illicit trade through effective NQI or IP enforcement could support the strengthening of capacities of those Members that have gaps in their customs or regulatory systems. This type of assistance supports the closing of those gaps and the narrowing of opportunities for illicit trade in the form of substandard or IP-infringing goods. LDC Members not yet under an obligation to implement the TRIPS Agreement may still benefit from advice and assistance where they have undertaken to use such enforcement tools.
- c. **A dedicated TBT coordination mechanism for capacity building on the NQI could allow the WTO to make a greater contribution to fighting illicit trade.** As contemplated by the TBT Committee, the model of the STDF could be used to develop a TBT coordination mechanism for NQI-related capacity building in cooperation with other organizations. Material support for the NQI, especially in least developed Members, would strengthen regulatory authorities and their ability to enforce quality, safety, or environmental regulations.
- d. **The WTO also provides technical assistance to developing and LDC Members on all of the border and regulatory disciplines of interest in addressing illicit trade challenges.** As part of its ongoing technical assistance programmes, the WTO Secretariat provides training to government officials on all matters relevant to its disciplines and trade policy activities, including as it relates to, for example, improving border controls, designing and improving Member NQIs, and enforcing IPRs. The WTO Secretariat also participates in other more broad-based conferences and information sharing sessions, which may also involve the participation of other international organizations and private sector representatives.