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Council for Trade-Related Aspects of Intellectual Property Rights

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ANNUAL REVIEW OF THE DECISION ON THE IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Report to the General Council

1. Paragraph 8 of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health of 30 August 2003 (the "2003 Decision") provides that the Council for TRIPS shall review annually the functioning of the System set out in the Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council. This review is deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

2. The Council for TRIPS undertook the eighth annual review in October 2011. The General Council took note of the report of the Council for TRIPS (IP/C/61) at its meeting on 30 November 2011 (WT/GC/M/134, paragraph 278). The present report covers the period since October 2011.

3. At its meeting of 6-7 November 2012, the Council undertook the ninth annual review. Annex 1 to this report records the statements made in the review. The paragraphs below set out factual information regarding the implementation and use of the 2003 Decision and the acceptance of the Protocol Amending the TRIPS Agreement.

1. Information on implementation and use of the System established under the Decision

4. Since the last annual review, no new implementing legislation has been notified to the Council for TRIPS. An overview of the notified implementing laws and regulations, including hyperlinks to the legal texts, is available on a dedicated page on the WTO website at http://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm.

5. During the period covered by the present report, no notifications by importing or exporting Members pursuant to paragraphs 1(b), 2(a) and 2(c) of the 2003 Decision have been made to the Council for TRIPS. As foreseen in the 2003 Decision, the Secretariat regularly updates a page on the WTO website dedicated to this Decision, notably to ensure the public availability of notifications made pursuant to it (http://www.wto.org/english/tratop_e/trips_e/public_health_e.htm).

2. Decision on the Amendment to the TRIPS Agreement

6. As called for in paragraph 11 of the 2003 Decision, the General Council adopted a Protocol Amending the TRIPS Agreement, by a Decision of 6 December 2005 (WT/L/641). The Protocol is open for acceptance by Members until 31 December 2013 or such later date as may be decided by the Ministerial Conference (WT/L/829). In accordance with Article X:3 of the WTO Agreement, the Protocol will enter into force upon acceptance by two thirds of the WTO Members.

7. As of 30 September 2012, the following Members have notified their acceptance:

- United States, 17 December 2005, WT/Let/506;
- Switzerland, 13 September 2006, WT/Let/547;
- El Salvador, 19 September 2006, WT/Let/548;
- Republic of Korea, 24 January 2007, WT/Let/558;
- Norway, 5 February 2007, WT/Let/563;
- India, 26 March 2007, WT/Let/572;
- Philippines, 30 March 2007, WT/Let/573;
- Israel, 10 August 2007, WT/Let/582;
- Japan, 31 August 2007, WT/Let/592;
- Australia, 12 September 2007, WT/Let/593;
- Singapore, 28 September 2007, WT/Let/594;
- Hong Kong, China, 27 November 2007, WT/Let/606;
- China, People's Republic of, 28 November 2007, WT/Let/607;
- European Communities[1], 30 November 2007, WT/Let/608;
- Mauritius, 16 April 2008, WT/Let/619;
- Egypt, 18 April 2008, WT/Let/617;
- Mexico, 23 May 2008, WT/Let/620;

[1] The text of the instrument of acceptance reads as follows:

"THE PRESIDENT OF THE COUNCIL OF THE EUROPEAN UNION,

HAVING regard to the Treaty establishing the European Community, and in particular Article 133(5) in conjunction with the first sentence of the first subparagraph of Article 300(2) and the second subparagraph of Article 300(3) thereof,

NOTIFIES by these presents the acceptance, by the European Community, of the Protocol amending the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), done at Geneva on 6 December 2005,

CONFIRMS, in accordance with Article 300(7) of the Treaty establishing the European Community, that the Protocol will be binding on the Member States of the European Union.

The Secretary-General/High Representative — The President of the Council of the European Union"

- Jordan, 6 August 2008,WT/Let/630;
- Brazil, 13 November 2008, WT/Let/636;
- Morocco, 2 December 2008, WT/Let/638;
- Albania, 28 January 2009, WT/Let/639;
- Macao, China, 16 June 2009, WT/Let/645;
- Canada, 16 June 2009, WT/Let/646;
- Bahrain, 4 August 2009, WT/Let/652;
- Colombia, 7 August 2009, WT/Let/650;
- Zambia, 10 August 2009, WT/Let/651;
- Nicaragua, 25 January 2010, WT/Let/663;
- Pakistan, 8 February 2010, WT/Let/664;
- Former Yugoslav Republic of Macedonia, 16 March 2010, WT/Let/671;
- Uganda, 12 July 2010, WT/Let/678;
- Mongolia, 17 September 2010, WT/Let/684;
- Croatia, 6 December 2010, WT/Let/747;
- Senegal, 18 January 2011, WT/Let/753;
- Bangladesh, 15 March 2011, WT/Let/758;
- Argentina, 20 October 2011, WT/Let/830;
- Indonesia, 20 October 2011, WT/Let/831;
- New Zealand, 21 October 2011, WT/Let/832;
- Cambodia, 1 November 2011,WT/Let/833;
- Panama, 24 November 2011, WT/Let/837;
- Costa Rica, 8 December 2011; WT/Let/838;
- Rwanda, 12 December 2011, WT/Let/839;
- Honduras, 16 December 2011, WT/Let/843;
- Togo, 13 March 2012, WT/Let/848;

- Saudi Arabia, 29 May 2012, WT/Let/855; and
- Chinese Taipei, 31 July 2012, WT/Let/870.

8. At the Council's meeting on 5 June 2012, the delegation of Viet Nam informed the Council that it was in the process of preparing its acceptance of the Protocol and expected the domestic procedures to be soon completed.

9. Information on the status of acceptances of the Protocol is periodically updated in revisions of document IP/C/W/490.

10. At the Council's meeting on 5 June, the Chairman also reported that the WTO Director General, at the General Council meeting of 1 May 2012, had drawn Members' attention to the importance of accepting the Protocol and urged those Members who had not yet accepted it to consult with their governments so that domestic procedures could be completed in due course. That was needed to give legal certainty to this additional pro-health flexibility for the more vulnerable Members. The Director-General had also recalled that by accepting the Protocol, a Member needed not implement domestic legislation to use the flexibilities; the acceptance simply confirmed the existing political agreement that the new flexibilities should be open to other Members to make use of, if they chose to do so.

11. The Chairman also recalled that the Secretariat had made available on the WTO website information regarding the procedural requirements of acceptance together with a model instrument of acceptance[2], which could be accessed through the dedicated gateway page on "TRIPS and Public Health".[3] The purpose of that information was to assist Members in drawing up their instruments of acceptance.

[2] http://www.wto.org/english/tratop_e/trips_e/accept_e.htm
[3] http://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm

ANNEX 1

Excerpt from the Minutes of the Council's meeting of 6-7 November 2012
to be circulated as IP/C/M/71

F. REVIEW UNDER PARAGRAPH 8 OF THE DECISION ON THE IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

1. The Chairman recalled that, as he had indicated in a fax sent to Members on 17 October in preparation for this review, the feedback in his consultations had been that this year's review should follow the standard format. Accordingly, after the introduction of the item and an update on any relevant recent developments, the floor would be open to delegates for comments. As he had also indicated in the fax, in these consultations it had been suggested that Members, in preparing themselves for the meeting, could refer to the records of the discussions that had taken place in October 2010 (IP/C/57 and Corr.1), March 2011 (IP/C/M/65, paras.118-198) and October 2011 (IP/C/61). He also drew attention to the fax that his predecessor had sent out in preparation for the October 2011 review with a list of topics and issues for discussion prepared in the light of earlier discussions and consultations with Members.

2. He said that Members had stressed the importance and value of a substantive review of the system under the Decision (the System) and of Members' experience with it and with alternatives. The records of the past reviews, including the exchange of questions and responses, provided a unique and valuable avenue for greater understanding of this important measure. He therefore encouraged Members to pose further questions and to respond to those questions that had already been posed, to promote this greater understanding.

3. The Chairman said that, during his consultations, some delegations had also reiterated their proposal for an open-ended workshop involving all the key stakeholders. However, views continued to diverge on this proposal.

4. As regards the purpose of the review, he recalled that paragraph 8 of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (the 2003 Decision) provided that the Council for TRIPS shall annually review the functioning of the System with a view to ensuring its effective operation and report on its operation to the General Council. Furthermore, the paragraph provided that this review shall be deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

5. The Secretariat had circulated a draft cover note for the Council's report modelled on previous years' reports (JOB/IP/6). This draft cover page contained factual information on the implementation and use of the System and on the acceptance of the Protocol Amending the TRIPS Agreement (the Protocol). In accordance with the way that the Council had prepared its past reports, the part of the minutes of the meeting that reflected the discussions held under this agenda item might be attached to the cover note.

6. Paragraph 7 of the cover note contained a list of Members that had notified their acceptance of the Protocol. Since the Council's meeting in June 2012, Chinese Taipei had also accepted the Protocol (WT/Let/870). Paragraph 7 would need to be updated accordingly.

7. The Chair recalled that the Protocol shall enter into force for the Members that had accepted it upon acceptance of the Protocol by two thirds of the Members. It was open for acceptance by Members until 31 December 2013 or such later date as might be decided by the Ministerial Conference. He encouraged delegations to ensure that necessary measures were taken in their capitals to allow the consideration of the acceptance in a timely fashion.

8. The representative of Chile said that his Government had forwarded draft legislation to enable approval of the Protocol to the National Congress in August 2012. Rapid progress was made in completing the legislative steps prescribed by domestic legislation. The draft had been approved by the Chamber of Deputies in the National Congress and was being reviewed by the Senate. It should therefore be finalized soon. The approval of the Protocol emphasized the importance that his delegation attached to providing flexibility in relation to public health. Such flexibility could and had to be part of the multilateral trading system as it was an essential tool for building balanced IP systems.

9. The representative of China recalled that the adoption of the 2003 Decision by the General Council had been a historical moment. The 2003 Decision was the first result that had been achieved by WTO Members through consensus under the Doha mandate. Her delegation continued to feel very encouraged by this achievement in the field of public health, especially considering the fact that the Doha Round negotiations on other topics were currently stalled. By waiving Members' obligations under Article 31(f) of the TRIPS Agreement, the System allowed poorer countries to make full use of TRIPS flexibilities in order to deal with diseases that ravaged their people. Whether it had completely achieved its objectives was not easy to assess. Many Members were facing public health challenges from time to time, but the System had been used only once so far. Its review was therefore necessary in order to improve it. During the past annual reviews, Members had also discussed the broader issues related to innovation of and access to medicines, including those on the list of topics and issues that had been circulated by the Chair in 2011. However, the difficulties in using the System and possible improvements had not been clearly identified. Her delegation therefore agreed with the approach suggested by the Chair, of encouraging Members to pose more questions for the purposes of conducting future annual reviews. She reiterated her delegation's support for the organization of a dedicated workshop that would allow to gather information from all relevant stakeholders so that answers could be found to some of the open issues

10. The representative of Canada welcomed the opportunity to discuss the implementation of the System and to share some thoughts on the issue of access to medicines. In response to the questions and views that had been exchanged at the review in October 2011, he updated Members on relevant legislative developments related to Canada's Access to Medicines Regime (CAMR). At the last review, Canada had advised Members that Bill C-393, which had sought to amend CAMR, had died on the Order Paper when Parliament had been dissolved. In February 2012, a similar bill, Bill C-398 had been introduced in Parliament. It had been the object of a second reading in October 2012. As was the case with Bill C-393, Bill C-398 had been introduced by a private member and not by the Government. Up-to-date information on Bill C-398, including transcripts of all debates, was available on the website of the Parliament of Canada. He recalled that his delegation had also asked a number of questions at the review in October 2010, mainly whether potential importing Members had availed themselves of pooled procurement schemes, whether Members had increased their domestic manufacturing capacities since the adoption of the 2003 Decision, and whether potential importing Members still imposed tariffs or duties on the products concerned by the 2003 Decision, as well as on other products, such as anti-malarial commodities.

11. The representative of Turkey said that the implementation of the System was very important for his delegation. He informed Members that domestic procedures to ratify the Protocol were at the final stage and would hopefully be completed by end 2012.

12. Concurring with the delegation of China that the adoption of the 2003 Decision had been a historical achievement, the representative of Cuba recognized the important progress that had been made in this area. In particular, past annual reviews had helped to clarify some of the issues raised with respect to the first use of the System to export medicines from Canada to Rwanda. She also acknowledged the existence of alternative solutions that could support Members with insufficient manufacturing capacities in the pharmaceutical sector to ensure access to medicines at reasonable

prices. However, before the amendment to the TRIPS Agreement could be accepted and legislation to implement the System into national law be put in place, the practical aspects related to the use of the System had to be looked at. Those included the restrictions that potential exporting Members had introduced in their domestic legislation, which were not required by the System but which made it difficult to use it. She supported the proposal by China that an open-ended workshop be held to gather information and share experiences that would make it possible to assess the functioning of the System.

13. The representative of India said that a dedicated workshop on the functioning of the System involving all stakeholders was needed in order to move beyond the annual ritualistic review of the System and related issues, which did not add any value to the debate. In his view, the System had been sub-optimally used so far as it had been used only once by a single country for a single drug and for a single supplier. Since the issue was of fundamental interest to most WTO Members, including developed country Members, it was important to hold such a dedicated workshop. It would provide an opportunity for a substantive discussion with the participation of all relevant stakeholders, including capital-based officials. Genuine efforts were being made by several countries to implement the System in their domestic legislation. His delegation had implemented it by incorporating Section 92-A in the Indian Patent Act. Canada, as the only country that had used the System once to supply HIV/AIDS medicines to Rwanda, had implemented it through CAMR. However, the Canadian generic companies had soon realised the complexities in the System and had publicly stated that they were unable to supply affordable generic medicines to the needy countries in Africa. He welcomed the information provided by the delegation of Canada on Bill C-398.

14. The representative of India asked how developed countries who had opted out of using the System would deal with a situation of shortage of affordable medicines in their countries in case of influenza pandemic or any other public health emergency. He sought clarity as to what steps were available to import medicines or vaccines to address such a shortage when patents or other IPRs presented a barrier. In particular, he referred to media reports according to which a German pharmaceutical company had stopped supplying life-saving cancer medicines to Greece on account of its inability to settle pending bills. He asked whether Greece as an opt-out country could issue a compulsory licence to manufacture the medicine locally to meet the domestic demand at an affordable price or, in case of insufficient manufacturing capacity, whether it could import the needed medicines from a generic manufacturer at an affordable price.

15. He also asked whether the provision of test data exclusivity in national legislation could act as a major hurdle in using the System. This question was particularly directed towards Members like the US and the EU, who were spear-heading the inclusion of such and other TRIPS plus provisions in free trade agreements and plurilateral agreements. It was his understanding that countries acceding to the WTO had also been obliged to provide for TRIPS plus provisions, including test data exclusivity.

16. The representative of Brazil agreed with the delegations of China and Cuba that the adoption of the System was a milestone in the history of the implementation of the TRIPS Agreement. Normative act advancement always faced the challenge of implementation and the System was no exception to this rule. Years after its adoption it had yet to fulfil its ultimate objective. Regarding the annual review, different approaches had been used over the past few years. One of the most positive experiences had been the review that the Council had undertaken in 2010. It had been well prepared, including through the establishment of a list of pre-selected topics and questions. The result had been a very dynamic debate which had engaged most Members, some of them actively facilitating the debate. He supported the suggestion made by the delegation of China that this approach be revisited for future reviews. His delegation also supported the proposal that an open-ended workshop be held by the Council in order to understand the challenges that different countries and international agencies were facing in implementing the System.

17. The representative of the United States said that his delegation strongly supported the System as established under the 2003 Decision and the Protocol. He encouraged other Members to notify their acceptance of the amendment so that it could enter into force.

18. As noted previously (IP/C/M/67, paras.202-203), his delegation viewed the System as one of many tools to address the issue of access to medicines. Among others, tariffs were applied to medicines, to the components of those medicines, such as active ingredients, and medical products. Tariffs imposed by governments were, however, borne by patients. During the Uruguay Round negotiations, his delegation had therefore joined several other Members (Canada; the EU; Japan; Norway; Switzerland; and Macao, China) in an agreement to eliminate tariffs on medicines and active ingredients in order to liberalize trade, lower costs, and increase access to these essential products. Since then, the participants in the pharmaceutical zero-for-zero agreement had updated it four times in order to include additional inputs for medicines, thereby further reducing the costs of production for medicines.

19. According to a paper by the WTO Economic Research and Statistics Division entitled "More Trade for Better Health, International Trade and Tariffs on Health Products", which had been released on 18 October 2012, several countries continued to maintain relatively high tariff rates on medicines, active ingredients and medical products, despite a general trend toward tariff reduction on these goods. The report concluded that "the question to ask is why countries even maintain tariffs on health products. Imposing tariffs typically translates into higher product prices, especially in the presence of long supply changes. Maintaining tariffs ultimately means taxing the sick and creating additional costs for the health system." To exemplify this point, the representative of the United States drew attention to a report by the Assistant Minister for Public Health and Sanitation of Kenya in 2011, according to which the removal of taxes and tariffs for malaria products had led to a 44% decline in the rate of infant mortality and disease, and a 50% reduction on infant mortality in one region. He said that, as demonstrated by a 2005 WHO study, the impact of tariffs on medicines extended beyond consumers, as tariffs also adversely affected local industries that often relied on the import of active ingredients.

20. He noted that voluntary licensing and policies that promote such licensing also provided important tools to promote access to medicines. A good example was the US National Institute of Health (NIH). It was the first contributor to the Medicines Patent Pool (MPP) in the voluntary licensing of US government-owned patents related to the use of ARV protease inhibitor drugs. The MPP promised to enhance access to ARV treatment for people living with HIV/AIDS in developing countries and facilitated the development of new combinations of ARVs and adapted formulations for developing countries. While the NIH was only one owner of intellectual property in the area of public health, the actions undertaken demonstrated the partnerships that were occurring internationally, as well as the trend towards voluntary licensing. These practices were helping to enhance access to medicines. He urged other Members to consider participating in this effort.

21. In response to the questions raised by the delegation of India regarding the situation in Greece, the representative of the European Union said that, while he agreed that Greece was going through difficult economic times, he failed to see the link with the annual review of the System. The System was designed for countries with no or limited manufacturing capacities in the pharmaceutical sector in order to ensure that they could make effective use of compulsory licences to import medicines from other countries. In the European Union, public health systems provided universal coverage for all patients. Those systems were expensive and represented an important part of public expenditure. This explained why economies had to be made and delays in payments sometimes occurred. It was, however, simplistic to blame IP for this, as it was simplistic to think that all the problems in the public health sector could be solved by systematic recourse to compulsory licences. Recent studies in Europe had shown that the cost incurred by purchasing the most innovative patent-protected medicines represented only a relatively small fraction of the overall costs of national

health systems. The studies had also illustrated that the money to buy those medicines was well spent because it helped to avoid higher costs, for instance, for long-term treatments or treatment in hospitals. He was of the view that it was possible to keep an IP system in place that supported the development and production of innovative medicines. There was no debate in the European Union to change the status as an opt-out Member that was not allowed to use the System as an importer.

22. The representative of Japan said that, in his view, IP protection was conducive to the development of medical technology. He emphasized that the debate on access to medicines should not be limited to the functioning of the System, but also needed to take into account other important elements, such as procurement and tariffs. The very objective of the System was to contribute to increasing access to medicines for WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector. Compulsory licences were just one tool to promote this objective. The System should therefore not be considered as the only solution in an isolated manner, but as an optional measure next to other efforts to address this critical problem.

23. He said that knowing about the specific concerns of potential importing countries that wanted to use the System was indispensable for the review. He therefore invited those Members to share their experiences, including any difficulties they were facing. It would be beneficial for the Council to listen to such observations by potential importing Members, based on the list of topics and questions for discussion prepared for the annual reviews in 2010 and 2011. Because some topics in the list had not yet been fully discussed, he maintained that the organization of an open-ended workshop was premature.

24. Reverting to the response provided by the delegation of the European Union, the representative of India clarified that he was trying to relate the situation in Greece to that in developing countries. Difficulties in accessing medicines caused by the IP system were normal for them, but the example of Greece showed that even a developed country could face access problems because of IP. If Greece had an option to import generic medicines from another manufacturer, it could solve the problem.

25. Drawing on the details that were set out in the overall report on technical cooperation in the area of TRIPS provided by the Secretariat (IP/C/W/577), the representative of the Secretariat said that the focus in technical cooperation on TRIPS and public health continued to rest on assisting Members to understand the rights and obligations, including the available options which flew from the TRIPS Agreement and subsequent decisions of the WTO bodies in the light of the Doha Declaration on the TRIPS Agreement and Public Health. A key aspect was the cooperation with other intergovernmental organizations, in particular the WHO and WIPO. There was a continuing emphasis on strengthening coordination both on the provision of technical cooperation and the provision of background information in support of that activity. Complementarity and cooperation meant that the scope of policy tools considered and the scope of information had broadened to encompass the overall context of public health, innovation and access issues.

26. As an example of the work that was undertaken, he referred to the Workshop on Intellectual Property and Public Health, the eighth in the series that had been held in Geneva in October 2012. Organized in close collaboration with the WHO and WIPO, and with the involvement of other international organizations such as UNCTAD, the workshop had been held principally for the benefit of developing country Members and LDCs, but some developed country participants had also attended. It had provided an overview of the key issues involving both the innovation of new medicines and medical technologies, as well as the strategies for an effective access and the dissemination of the fruits of innovation in the field of public health. It had addressed the key concepts and measures under the TRIPS Agreement and other international instruments, focusing on the public health-related provisions of the TRIPS Agreement and flexibilities that enabled Members to adapt their systems to meet public health objectives. A key feature of the Workshop had been to take

advantage of the policy ecosystem in Geneva which allowed to draw on experts with a wide range of expertise, experience and background, including non-governmental organizations such as Medicines for Malaria Venture, the Global Fund, IFPMA and Médecins San Frontières. Some of the themes beyond the TRIPS Agreement that were covered included the role of competition rules; pricing and procurement policies and strategies; the use of patent landscaping as a guide to policy makers; the impact of provisions in bilateral and regional trade agreements; the economics of health technologies; the operational aspects of the international patent system, including the use of information on patents and on their legal status for freedom to operate; data on access to medicines and medicine prices; current issues, such as the challenges regarding prevention and control of non-communicable diseases as well as the essential elements of medicines policy; the regulatory process, quality control and effectiveness of medicines, including counterfeit, falsified and sub-standard medicines; licensing practices; and a wide range of country reports and national policy perspectives by a number of participants and delegates from Nepal, South Africa, Botswana, Oman, Ghana, Honduras, Colombia, the EU, the US, Brazil, India and Switzerland. Participants from developing countries had reported on the domestic implementation and use of the System and the implementation of other TRIPS flexibilities in their national law, experiences in reforming domestic legislation to enhance the synergy between health and trade objectives, and experiences in negotiating bilateral and regional trade agreements with bearing on intellectual property and public health. As part of a side event, the German Federal Ministry for Economic Co-operation and Development had briefed participants in cooperation with UNCTAD and the South Centre on technical cooperation activities relating to fostering pharmaceutical production by using TRIPS flexibilities.

27. IP and public health had also been a key thematic focus of a range of other activities, in particular three regional workshops in Kuwait for Arab and Middle Eastern countries, in Malaysia for Asia and the Pacific Region, and in Croatia for the Central Eastern European, Central Asia and Caucasian Region. At the request of a number of Members, TRIPS and public health had also been specifically addressed in national workshops.

28. The representative of the Secretariat informed the Council about the forthcoming trilateral study on "Promoting Access and Medical Innovation - Intersections between Public Health, Intellectual Property and Trade" that was being prepared together with the WHO and WIPO. The publication tracked closely the content and themes of technical cooperation activities and consolidated the material used in such activities, notably the series of trilateral symposia that the three Organizations had convened, as well as the series of workshops on IP and public health. It was intended to serve as a factual and comprehensive platform for continued technical cooperation and capacity building in this area. An outline had been presented in 2011 at a high-level symposium of the Global health programme of the Graduate Institute, chaired by Madame Ruth Dreifuss, in which the Directors-General of the three cooperating Organizations had taken part.

29. The representative of WIPO informed the Council about legislative and policy advice on patents, referring to or including considerations regarding the System, that had been provided from June 2011 to June 2012. Among others, the WIPO Secretariat had drafted laws and had provided comments on draft laws at the request of 10 Member States. In the framework of legislative assistance on patents, matters related to health policies had also been addressed in the context of eight short term missions to capitals and four consultations in WIPO headquarters in Geneva. Legislative implementation of patent law matters related to health policies had been addressed in a number of events, including a Regional Seminar for Certain Latin American and Caribbean Countries on the Implementation and Use of several Patent-Related Flexibilities, held in Bogota, Colombia from 6 to 8 February 2012 and the Second Meeting of Intellectual Property Experts from the Common Market for Eastern and Southern Africa (COMESA), held in Lusaka, Zambia from 23 to 25 November 2011. WIPO's assistance was consistently based on the multilateral legal framework. A number of authorities in charge of drafting laws had been seeking advice from WIPO regarding how to use the available multilateral flexibilities so as to accommodate particular national

interests that were specific to their countries. The System, being a part of those flexibilities which are considered by several countries as part of their access-to-medicine policies, was regularly covered WIPO's legislative and policy assistance.

30. The representative of WIPO recalled that, at the annual review in 2011, his delegation had provided information on a new consortium called "WIPO Re:Search – Sharing Innovation in the Fight Against Neglected Tropical Diseases". WIPO Re:Search had been launched on 26 October 2011, with about 30 members, including pharmaceutical companies, research institutions and a range of public and private entities as members. One year after its launch, WIPO Re:Search had doubled its membership to 62, including a growing number of members from African-based organizations. It had resulted in 11 research collaborations or agreements. A number of additional agreements were in advanced stages of discussion between members with more collaboration ideas and agreements in early development. WIPO Re:Search was a consortium of which members categorized as providers, users and supporters. It was led by WIPO in partnership with BIO Ventures for Global Health (BVGH), a non-profit organization based in San Francisco, whose role was to facilitate research agreements between members. Each member had endorsed the guiding principles when joining the consortium. The commitment to the guiding principles had achieved a common understanding about how WIPO Re:Search operated and the way in which it achieved its goals. The WHO was supporting this initiative by providing technical advice to WIPO.

31. WIPO Re:Search was founded on the belief that IP and knowledge could be used creatively and positively to stimulate more investment in research and development for new health solutions. It was grounded on voluntary agreement and operated on the basis of voluntary licenses. While the guiding principles provided partners with all the flexibility needed to achieve appropriate licensing agreements, they set some minimum terms for licensing. In particular, providers had agreed to grant royalty-free licences to qualified researchers anywhere in the world for the purpose of R&D for neglected tropical diseases (NTDs), malaria, and tuberculosis (TB). Any researchers anywhere in the world would thus be able to carry out their research free from royalties, provided the research is focused on NTDs, malaria, and TB. There was no royalty requirement for carrying out research under a WIPO Re:Search licence. Any products resulting from this research would also be royalty-free for sales in least developed countries. Royalties for sales of products in other countries would have to be negotiated on a case-by-case basis between the partners.

32. The basic structure of WIPO Re:Search contained three components. First, there was the platform in the form of a database operated by WIPO (www.wiporesearch.org), where Providers made their assets available for research free from royalties. Second, the partnership hub administrator, BVGH, engaged with members to facilitate research collaborations. BVGH was available for members who had identified assets of interest in the database to provide more detailed information, to connect potential partners and to help making a deal. Third, support was provided under the responsibility of WIPO, which included training and a range of activities that aimed at capacity building, sometimes carried out in cooperation with others. For example, on 1 and 2 November 2012, a training on Successful Technology Licensing had been organized at the WIPO headquarters for a group of invited representatives of research organizations in cooperation with the African Network for Drugs and Diagnostics Innovation (ANDI), the Medical Research Council (MRC), South Africa, and with the support of the Japan Patent Office (JPO).

33. The Chairman proposed that the Council agree to the cover note to the report as contained in JOB/IP/6, with Chinese Taipei to be added to the list of Members having accepted the Protocol, and also that the Council minutes containing the record of the discussion be attached thereto.

34. The Council took note of the statements made and so agreed.