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**Council for Trade-Related Aspects of  
Intellectual Property Rights**

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## **TECHNICAL COOPERATION ACTIVITIES: INFORMATION FROM OTHER INTERGOVERNMENTAL ORGANIZATIONS**

### WORLD HEALTH ORGANIZATION (WHO)

#### *Addendum*

At its meeting of 11 June 2014, the Council for TRIPS agreed to invite intergovernmental organization observers to the Council to update the information on their technical and financial cooperation programmes relating to the implementation of the TRIPS Agreement.

The present document reproduces the information which has been received from the World Health Organization (WHO) by means of a communication dated 7 October 2014.

## **1 INTRODUCTION**

1.1. This communication summarizes the technical cooperation activities of the World Health Organization (WHO) in the area of public health, innovation and intellectual property that took place since the submission of the last report in September 2013.<sup>1</sup> These are part of the implementation of the *Global strategy and plan of action on public health, innovation and intellectual property* (Resolution WHA61.21). The overall objective of WHO's technical cooperation is to strengthen the capacity of developing countries in the areas of health innovation, access to medicines and management of intellectual property. Public health interests should be prioritized in the formulation of national policies and legislation on trade and intellectual property.

1.2. WHO's technical cooperation is based on its mandate derived from the *Global strategy and plan of action* as well as from relevant resolutions of the World Health Assembly. For example, Resolution WHA67.6 on the prevention, diagnosis and treatment of viral hepatitis requested the Director-General "to work with national authorities, upon their request, to promote comprehensive, equitable access to prevention, diagnosis and treatment for viral hepatitis" and "to assist Member States to ensure equitable access to quality, effective, affordable and safe hepatitis B and HCV treatments and diagnostics, in particular in developing countries". In 2014, contributing to the implementation of this resolution was one of the main activities in the area of public health and intellectual property.

## **2 FOCUS ON HEPATITIS C**

2.1. The WHO's 2014 Guidelines for the screening, care and treatment of persons with hepatitis C infection state that more than 185 million people are infected with the hepatitis C virus (HCV) worldwide. Of these people, 350 000 to 500 000 die each year. An estimated one third of those who become chronically infected develop liver cirrhosis or hepatocellular carcinoma. HCV infection can be cured, but most people infected with the virus are unaware of their infection and do not seek timely treatment. Several medicines are available to treat HCV, but treatment duration is long, involves weekly injections, and side effects are considerable. With the development of new

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<sup>1</sup> Communications of previous years can be found on the website of WHO:  
[http://www.who.int/phi/wto\\_communications/en/index.html](http://www.who.int/phi/wto_communications/en/index.html).

direct-acting antiviral medicines, the treatment landscape is rapidly changing. These new antivirals are expected to reach cure rates of more than 90% in persons with HCV infection across different genotypes, with fewer side effects and a shorter duration of treatment. Two new compounds, simeprevir and sofosbuvir, have recently been approved in the United States and Europe and are recommended by the new WHO treatment guidelines. Many others are in various stages of development. However, the new treatments are currently out of reach for many of those in need. In the framework of developing national hepatitis programmes, WHO has thus advised a number of Member States through their national hepatitis task forces on their available options with respect to accessing the new treatments at affordable prices. WHO also presented on how to improve access to hepatitis C treatment in various fora, including the WHO Global Partners' Meeting on Hepatitis and the UNITAID/WHO 2014 HIV Market Forum in spring 2014. WHO Regional Office for South-East Asia (SEARO) made a presentation on "Access to Antivirals and Treatment" covering intellectual property aspects on the occasion of World Hepatitis Day, 28 July 2014, at the Institute of Liver and Biliary Sciences in New Dehli, India. A round table consultation on "Viral Hepatitis: Gaps, Challenges and Priorities" brought together stakeholders from the government, academia, clinics, public health, civil society, research institutions and partner agencies to deliberate on the issue.

2.2. In April 2014, the Pan American Health Organization/WHO Regional Office for the Americas (PAHO), the Ministry of Health of Brazil, Fundação Oswaldo Cruz (Fiocruz) and the Open Society Foundation co-organized a two day meeting to review options to facilitate access to high cost medicines, in particular for the new hepatitis C treatments. Participants, that included non-governmental organizations and researchers, analyzed different paths to maintain balance between public health interests and intellectual property protection and what could be the trade-off between research and development, innovation and access to essential medicines. In this context, participants assessed current progress to reform the Brazilian patent law and draw parallels to the dramatic price decrease for HIV treatment. Experts presented the main outcomes to the Brazilian Congress (Commission for Health and Social Affairs).<sup>2</sup>

2.3. For countries to identify ways of increasing access to and affordability of new HCV medicines, they need clarity about patent status. To assess whether a medicine is patent protected in a certain country requires expert knowledge and access to specialized databases that are not easily available. Therefore, WHO Secretariat published an analysis of the patent situation of seven new hepatitis treatments. This also corresponds to the mandate provided by the WHO *Global strategy and plan of action on public health, innovation and intellectual property* that requests WHO to support efforts to determine the patent status of health products (element 5.1c). The patent working papers identify the most relevant patents with respect to the seven medicines and list the countries in which these patents have been filed and granted.<sup>3</sup>

### 3 POLICY AND TECHNICAL GUIDANCE

3.1. Market failures in the discovery and development of new antibiotics are well-documented, underscoring the need for innovative approaches and models to sustainably encourage research and development in this area. Hence, WHO organized a technical consultation on innovative models for new antibiotics' development and preservation in Geneva, Switzerland, 13 May 2014.<sup>4</sup> The meeting focused on innovative models fostering discovery and development of new antibiotics as part of the tool-kit to address challenges related to antimicrobial resistance.

3.2. The new WHO Technical Report on *Access to antiretroviral drugs in low and middle-income countries* examines global trends in prices of antiretroviral treatment and assesses how WHO treatment guidelines have influenced the uptake of different formulations. It describes the current constraints limiting the use of second-line, third-line and pediatric treatment, and explores how the quality of antiretroviral treatment can be secured and in-country distribution can be improved.

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<sup>2</sup> [http://www.paho.org/bra.../index.php?option=com\\_content&view=article&id=4618:fundacao-oswaldocruz-fiocruz-open-society-foundation-osf-organizam-oficina-sobre-direitos-humanos-saude-ao-acesso-medicamentos-no-rio-janeiro&catid=844:bra-02-c-noticias&Itemid=455](http://www.paho.org/bra.../index.php?option=com_content&view=article&id=4618:fundacao-oswaldocruz-fiocruz-open-society-foundation-osf-organizam-oficina-sobre-direitos-humanos-saude-ao-acesso-medicamentos-no-rio-janeiro&catid=844:bra-02-c-noticias&Itemid=455)

<sup>3</sup> The working papers can be found on:  
[http://www.who.int/phi/implementation/ip\\_trade/ip\\_patent\\_landscapes/en/](http://www.who.int/phi/implementation/ip_trade/ip_patent_landscapes/en/)

<sup>4</sup> [http://www.who.int/phi/implementation/consultation\\_imnadb/en](http://www.who.int/phi/implementation/consultation_imnadb/en)

The report includes chapters on the role of intellectual property in access to treatment, on prices, quality assurance, increasing global demand as well as on supply chain management.<sup>5</sup>

3.3. Developed from the consultation on access to HIV medicines in middle-income countries held from 10 to 12 June 2013 in Brasilia, Brazil, WHO published the report *Increasing access to HIV treatment in middle-income countries: Key data on prices, regulatory status, tariffs and the intellectual property situation*<sup>6</sup> in June 2014. The paper provides information on the prices paid by 20 middle-income countries for adult and pediatric formulations of antiretroviral treatments recommended by WHO. It links pricing information with an analysis of the intellectual property situation of the selected medicines taking into account existing license agreements as well as compulsory licenses. It also includes data and general information on a number of other determinants of prices and availability of ARVs, including tariffs, markups and taxes as well as the regulatory status.<sup>7</sup> The data shows that middle-income countries are a heterogeneous group and that procurement prices vary widely. Middle-income countries supported by the Global Fund to Fight AIDS, Tuberculosis and Malaria pay low prices for first-line and many second-line treatment regimens, comparable to those paid by low-income countries. Other middle-income countries pay higher prices, especially for newer second line and third line treatments sourced from originator producers.

3.4. WHO launched the Global Platform for Innovation and Access (GPIA)<sup>8</sup> in May 2014. The Platform hosts initial data from two key sources, the PAHO Regional Platform on Access and Innovation for Health Technologies and the WHO Pharmaceutical Country Profiles. It provides information on national research and development infrastructure, policies, human resources, local production of medical technologies, intellectual property, regulation of and access to health technologies. The finalization of the development of the GPIA is expected in early 2015.

#### 4 TRANSFER OF TECHNOLOGY AND LOCAL PRODUCTION

4.1. Within the context of the implementation of the *Global strategy and plan of action*, WHO is leading a European Union supported project on local production to increase access to medical products in developing countries.<sup>9</sup> The first phase aimed at identifying the main challenges of local production and technology transfer in developing countries regarding medicines, vaccines, blood and blood products, and medical devices. The second phase is a country-based policy analysis. It assesses policy coherence across industrial and health policies, the degree of promotion of local production, and compares prices of locally produced medicines with those of imported medicines. It also includes training and capacity-building for manufacturers and national regulatory authorities to support quality production across a range of medical products. In the framework of the project, WHO identifies essential medicines that are most suitable for local production, determines the feasibility of local production of blood products, assesses selected medical devices on their potential for local production and analyses the patent situation for a number of medicines.

4.2. In the framework of the Global Pandemic Influenza Action Plan (GAP), WHO facilitated the transfer of influenza vaccine production technology to fourteen vaccine manufacturers in developing countries. So far five countries have established local production of approved influenza vaccines, amounting to a combined capacity of 330 million pandemic doses. WHO continues to help manufacturers through technical support and clinical trial implementation. With three clinical trials ongoing in 2014 and others planned for 2015, the goal is to exceed 500 million dose capacity by 2016.

#### 5 TRAINING AND ENHANCING CAPACITY

5.1. Training and capacity building, carried out in collaboration with other competent organizations, are among the core activities of WHO, with regard to public health and intellectual property.

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<sup>5</sup> <http://www.who.int/hiv/pub/amds/access-arv-2014/en/>

<sup>6</sup> [http://www.who.int/phi/publications/hiv\\_increase\\_access/en/](http://www.who.int/phi/publications/hiv_increase_access/en/)

<sup>7</sup> [http://www.who.int/phi/publications/WHO\\_Increasing\\_access\\_to\\_HIV\\_treatment.pdf](http://www.who.int/phi/publications/WHO_Increasing_access_to_HIV_treatment.pdf)

<sup>8</sup> <http://69.90.223.32:9090/oms>

<sup>9</sup> [http://www.who.int/phi/publications/local\\_production/en/](http://www.who.int/phi/publications/local_production/en/)

5.2. In this context, the WHO made a substantial contribution to the Workshop on Intellectual Property and Public Health that was organised by the WTO in close collaboration with the WHO and WIPO in Geneva, from 10 to 13 December 2013. This workshop provided a comprehensive overview of the key issues related to the promotion of innovation, access to medicines and the protection of intellectual property. It included presentations on the impact of intellectual property on prices and access to medicines, regulatory questions, license agreements and other related issues.

5.3. WHO also presented at the Conference on Intellectual Property and Health Innovation - Challenges for the Future organized by WIPO and the Hellenic Industrial Property Organization, 28 April 2014 in Athens, Greece, focusing on the trilateral cooperation and the challenges of facilitating access to the new hepatitis C treatments.

5.4. WHO participated in a two-days' workshop on the WTO TRIPS Agreement and public health organized jointly by the European Commission and the Ministry of Health of Belarus, on 11-12 August 2014. Presentations and discussions aimed at familiarizing participants with selected issues at the crossroad between intellectual property and public health, focusing on Belarus' continuing negotiations on accession to the World Trade Organization.

5.5. WHO contributed to a WTO national workshop on intellectual property and public health in Bandung, Indonesia, 11 to 12 November 2013. This workshop provided a comprehensive overview of the key issues related to the promotion of innovation, access to medicines and the protection of intellectual property rights. It included presentations on the implementation of TRIPS flexibilities and on special compulsory licenses for the export of medicines.

5.6. For the 23<sup>rd</sup> Meeting of the WHO South East Asia Region National AIDS Programme Managers, held in New Delhi from 1 to 4 July 2014, SEARO prepared a technical paper and made a presentation on "Access to medicines for HIV/AIDS and hepatitis: the intellectual property rights context". The meeting brought together partners UNAIDS and UNICEF as well as the US Center for Disease Control and The Global Fund to Fight AIDS, Tuberculosis and Malaria.

5.7. The World Health Organization Regional Office for the Western Pacific co-sponsored a consultation on overweight, obesity, diabetes and law held in Manila, Philippines, from 9 to 11 April 2014 and provided among other contributions a presentation on intellectual property rights and trade issues titled "Access to Medicines for Non-Communicable Diseases". The consultation introduced some central concepts of public health law, besides outlining the role that law can play in creating healthy environments and supporting healthy behaviours. It highlighted the role that legislation and regulation have played in all major public health successes.

5.8. WHO contributed lectures on trade, intellectual property and public health to the annual Executive Course on Intellectual Property, Diplomacy and Global Public Health as well as to the Executive Course on Global Health Diplomacy organized by the Global Health Programme of the Graduate Institute in Geneva in February and June 2014. WHO also presented the findings of its trilateral study with WIPO and WTO, *Promoting access to medical innovation: Intersection between public health, intellectual property and trade*, at the Meeting of Experts of Biological Weapons Convention from 12 to 16 August 2013 in Geneva.<sup>10</sup> Furthermore, WHO contributed to the seminar on the right to enjoy the benefits of scientific progress and its applications hosted by the United Nations Human Right Council, from 3 to 4 October 2013.<sup>11</sup> The meeting aimed at providing further clarification on the normative content of the right to enjoy the benefits of scientific progress and its applications as well as to clarify its relationship with other human rights.

5.9. As every year, WHO also contributed to the 11<sup>th</sup> WTO-WIPO Colloquium for teachers of intellectual property from developing countries and countries with economies in transition, which took place in Geneva from 16 to 27 June 2014, as well as to the sixth WIPO-WTO Advanced course on intellectual property for government officials in Geneva, from 10 to 21 March 2014.

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<sup>10</sup> [http://www.unog.ch/80256EE600585943/\(httpPages\)/EED3E63397C2144BC1257BF80054FE12?OpenDocument](http://www.unog.ch/80256EE600585943/(httpPages)/EED3E63397C2144BC1257BF80054FE12?OpenDocument)

<sup>11</sup> <http://www.ohchr.org/EN/Issues/CulturalRights/Pages/Seminarbenefitsofscientificprogress.aspx>

## 6 DIRECT COUNTRY SUPPORT

6.1. In collaboration with relevant international organizations, through its Headquarter, Regional and Country Offices, WHO provides technical and policy support in framing national policies, laws and regulations to favour application and management of intellectual property in a manner that maximizes health-related innovation and promotes access to health products. Provided upon request, such support is directed to assisting Member States in devising ways to safeguard public health interests, while adhering to their obligations under international trade agreements.

6.2. On request of the Egyptian Ministry of Health and Population, WHO in collaboration with WTO and WIPO organized a joint training workshop on intellectual property and public health in Cairo, Egypt from 3 to 5 June 2014. The workshop focused on the granting process for patents in the pharmaceutical field and the involvement of health authorities in this process as well as on the relationship between the intellectual property system and the regulatory system. Participants and speakers came from the Ministry of Health and Population, the Egyptian Patent Office and the Ministry of Foreign Affairs.<sup>12</sup>

6.3. WHO Country Office for India and the Ministry of Health & Family Welfare, Government of India jointly organized a number of events, including a colloquium on intellectual property rights for high-level policymakers from 17 to 20 September 2013 in New Delhi, India.<sup>13</sup> The forum provided a platform for cross exchange between high-level policymakers from several key union ministries and the states on these issues. Representatives from WTO, WIPO and WHO and national experts contributed as resource persons. The colloquium aimed at enhancing knowledge of policymakers on the relationship between public health and intellectual property, including how to optimally apply the flexibilities contained in the WTO TRIPS Agreement. On 2 July 2014, a follow up symposium on public health and intellectual property rights in India was organized in New Delhi.<sup>14</sup> The objective was to further familiarize participants with current developments relating to intellectual property and access to medicines, and biologicals as well as bilateral investment treaties. The symposium was attended by senior government officials, policymakers, international organizations, academics, non-governmental organizations, and intellectual property experts. From 7 to 9 August 2014, WHO Country Office for India in collaboration with Ministry of Health & Family Welfare, Government of India and the Centre for Technology and Policy organized a national consultation in Chennai, India on improving access and promoting innovation in the context of universal health coverage. The workshop brought together government officials, representatives from WHO, WTO, civil society and industry as well as other key organizations with the mandate to ensure universal access to drugs.<sup>15</sup> The consultation focused on access to medicines and innovation in the context of universal health coverage, voluntary and compulsory licensing and finally the importance of global health diplomacy in relation to international trade agreements.

6.4. The WHO Framework Convention on Tobacco Control (FCTC) Secretariat convened a workshop at the WHO headquarters on 31 March 2014 for health and trade representatives of Permanent Missions in Geneva, focusing on international trade and investment issues relevant to implementation of the WHO FCTC, and to facilitate sharing of the national experiences that continue to accumulate in this area. Representatives of WHO, WTO, UNCTAD and WIPO participated in the workshop and provided presentations. A background paper to the workshop summarizes the developments that have taken place in this area since the first similar workshop was convened in 2012. It provides an overview of relevant laws and legal concepts with reference to the law of the World Trade Organization, and International Investment Agreements respectively, as they are relevant to implementation of the WHO FCTC.<sup>16</sup>

6.5. SEARO made a technical presentation on "Trade and Health, Intellectual Property Rights in Medicines and Medical products related R&D" for the Global Conference on Community Health, Sustaining Change in Community Health held from 19 to 21 March 2014 in Dhaka, Bangladesh. This conference focused on the need to address community health for realizing national and global

<sup>12</sup> <http://www.emro.who.int/egy/egypt-infocus/workshop-on-intellectual-property.html>

<sup>13</sup> [http://www.unog.ch/80256EE600585943/\(httpPages\)/EED3E63397C2144BC1257BF80054FE12?OpenDocument](http://www.unog.ch/80256EE600585943/(httpPages)/EED3E63397C2144BC1257BF80054FE12?OpenDocument)

<sup>14</sup> [http://www.searo.who.int/india/mediacentre/events/2014/ipr\\_symposium/en/](http://www.searo.who.int/india/mediacentre/events/2014/ipr_symposium/en/)

<sup>15</sup> [http://www.searo.who.int/india/mediacentre/releases/2014/national\\_consultation/en/](http://www.searo.who.int/india/mediacentre/releases/2014/national_consultation/en/)

<sup>16</sup> [http://www.who.int/fctc/workshop\\_trade\\_2014/en/](http://www.who.int/fctc/workshop_trade_2014/en/)

development goals, and was organized together by the Bangladeshi government and Eminence and Partners for World Health, and supported by WHO.

6.6. SEARO assisted the Ministry of Health in Thailand in the design of the International Trade and Health Conference that took place in Bangkok, Thailand, from 10 to 11 March 2014. It delivered presentations on international case studies at the interface of public health, innovation, intellectual property and trade as well as on the *Global strategy and plan of action on public health, innovation and intellectual property* (GSPA-PHI) and on intellectual property related aspects of the Pandemic Influenza Preparedness Framework.

6.7. SEARO also provided technical support for the Regional Workshop on Strengthening Quantification and Procurement of Essential Medicines in New Delhi, from 10 to 12 June 2013, where countries of the region met to increase the availability of essential medicines through efficient procurement of medicines.

6.8. SEARO organized workshops and provided technical support for Sri Lanka in the framework of the implementation of the *Global strategy and plan of action for public health, innovation and intellectual property*, from 29 to 30 April 2014. Sri Lanka is the first country in the SEARO region to undertake this assessment, which will facilitate development of a national roadmap for innovation, R&D and access to health technologies.

6.9. SEARO also provided training support on the WTO TRIPS Agreement and public health for Indian Foreign Service Officers and Indian Trade Service Officers at the Indian Institute of Foreign Trade for Capacity Building Programme on Contemporary Issues in International Trade. It also provided training for the Certificate Course on Arbitration and Intellectual Property Rights in the context of public health for participants of the Institute of Chartered Accountants of India.

6.10. As in the past years, SEARO provided support for the Indian Ministry of Micro, Small and Medium Enterprises under the scheme "Building Awareness of Intellectual Property Rights" relating to micro, small and medium pharmaceutical enterprises. This included evaluation of proposals from these enterprises to facilitate access to intellectual property management practices.

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