WORLD TRADE ORGANIZATION

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Page: 1/13

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 7-8 June 2016, 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 18 October 2016.

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1 INTRODUCTION

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 have taken place since the submission of the last report in October 2015 (IP/C/W/609/Add.5). 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. WHO's technical cooperation is based on its mandate derived from the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property as well as other relevant resolutions of the World Health Assembly.

2 THE GLOBAL ANTIBIOTIC RESEARCH AND DEVELOPMENT PARTNERSHIP

2. The Sixty-eighth World Health Assembly in 2015 adopted the Global Action Plan on Antimicrobial Resistance (GAP-AMR). This required the WHO to propose options for the establishment of new partnerships to identify priorities for new treatments, diagnostics, and vaccines to fight resistant pathogens. In response to this mandate the Global Antibiotic Research and Development Partnership (GARDP) was launched in May 2016, as a joint initiative by WHO and the Drugs for Neglected Diseases *initiative* (DND*i*). GARDP is aiming to develop new antibiotic treatments, promote their responsible use and ensure equitable access to these antibiotics. Over €2 million of the €3 million required for the incubation phase have been secured from the governments of Germany, the Netherlands, the United Kingdom, South Africa, Switzerland, as well as from Médecins Sans Frontières (MSF). GARDP will work closely with all global stakeholders in antibiotic R&D such as pharmaceutical and biotechnology companies, start-ups, academia, civil society and health authorities to develop new antibiotic treatments.

3. DND*i* will host the incubation phase. The GARDP team is responsible for developing the business plan, fundraising, building scientific strategy, setting up the scientific working group, preparing for the creation on an independent entity and building a product pipeline. WHO will support GARDP in priority setting, developing appropriate stewardship, and access policies, reporting back to its Member States, securing close collaboration with the AMR Secretariat and

relevant WHO departments, including the Essential Medicines List team, and the Global Health R&D Observatory.

4. In the first instance, GARDP in collaboration with WHO will identify R&D gaps that are currently not addressed. In response, GARDP will identify and launch R&D projects to develop needed new therapeutic solutions with the potential for short-term fruition, such as improving regimes of existing antibiotics, while also building more transversal approaches to antibiotic drug discovery, including the recovery of knowledge and assets of forgotten, withdrawn, or abandoned antibiotics. Ultimately, it will develop a broader portfolio of new antibiotics treatments. GARDP aims to have at least two projects that address urgent global health needs ready for implementation by the end of 2016 and two more by the end of 2017.

3 TRANSFER OF TECHNOLOGY AND LOCAL PRODUCTION

5. WHO collaborated closely with the Ethiopian Government in developing and launching a *National Strategy and Plan of Action for Pharmaceutical Manufacturing Development in Ethiopia* (2015-2025). The report was launched jointly by the Deputy-Prime Minister of Ethiopia and the Director-General of WHO in July 2015. Since the launch, WHO has been working with the Ethiopian Government in spearheading development partner support in the implementation phase. Under strategic objective 5, the strategy and plan of action emphasizes the support for the development of a local cluster for the production of new active pharmaceutical ingredients.[1] In line with the various strategic objectives of the national strategy and plan of action, WHO provided support in conducting assessments on the feasibility of local production of active pharmaceutical ingredients (API) in Ethiopia, as well as the prioritization of essential medicines for local production. The experience gained in Ethiopia in developing and implementation of the National Strategy and Plan of Action can be extended to other African countries.

6. In 2016 WHO, with support by the European Commission, published *The role of intellectual property in local production in developing countries: opportunities and challenges*[2] as part of a wider project covering different aspects and challenges of local production and the conditions under which local production may increase access to essential medicines.[3] The report focuses on the role of intellectual property in facilitating local production to ultimately improve access to medical products in low- and middle-income countries.

7. How a national intellectual property system is set up is important when considering options for local production of pharmaceuticals in developing countries. Using practical examples and patent landscapes, this report attempts to set out the various strategies and options available to facilitate local production. The report describes the options available to countries with a generic industry to design an intellectual property system that is favourable for local production and potentially for public health. The report highlights the importance of transparent and fair patent administration systems using the example of access to patent information. The report exemplifies how this can also support the use of certain pre-grant flexibilities to increase the space for local generic companies and facilitate local production.

8. The report contains patent landscapes identifying the most relevant patents and in which countries they have been filed or granted to showcase opportunities for local production in different product areas and countries. The products that were included in the landscape are:

- Atazanavir, a protease inhibitor antiviral medicine indicated for treatment of HIV infection;
- The human papillomavirus (HPV) vaccine Gardasil, a quadrivalent recombinant vaccine for the prevention of cervical cancer and genital warts caused by HPV types 6, 11, 16 and HPV vaccination;
- Imatinib, an essential medicine for the treatment of some cancers and tumours;

[1] http://www.who.int/phi/publications/Ethiopia_strategy_local_poduction.pdf?ua=1
[2] http://www.who.int/phi/publications/int_prop_role_local_prod_opportunities-challenges.pdf?ua=1
[3] http://www.who.int/phi/publications/local_production/en

- Pegylated interferon alfa-2a, an antiviral medicine indicated for treatment of chronic hepatitis C;

- Raltegravir, an antiviral medicine indicated in combination with other antiretroviral agents for the treatment of HIV infection;

- Sitagliptin, an antidiabetic drug indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus.

4 THE WHO R&D BLUEPRINT FOR ACTION TO PREVENT EPIDEMICS

9. WHO Member States welcomed the R&D Blueprint at the World Health Assembly in May 2016. The Blueprint is a global strategy and preparedness plan that fosters R&D activities to prevent epidemics. The aim of the Blueprint is to rapidly make available effective tests, vaccines and medicines to save lives, prevent large scale epidemics and minimise socio-economic disruption of an outbreak.

10. Despite the lack of preparedness of the global health community to cope with the Ebola outbreak in West Africa in 2014, the Ebola experience has also demonstrated the possibility of substantially expediting R&D timelines. The WHO, along with guided by an international scientific advisory group board, and partners engaged in global forums, are collaborating to create a novel R&D model for emerging pathogens for which few or no medical treatments exist. Progress that has been made so far includes identifying major bottlenecks to international collaboration, agreeing upon data sharing principles and exploring innovative approaches to conducting clinical trials.

11. There are three approaches currently being used to improve preparedness under the Blueprint. These are aligned with the lessons learned during the 2014-2016 Ebola epidemic and include: identifying priority infectious disease threats and gaps and priorities in research and development; improving collaboration between stakeholders; and promoting an enabling environment for the conduct of research and development during outbreaks. WHO efforts will help to maximize consistency, robustness and effectiveness of research efforts and interventions. These new approaches will significantly reduce the time between the identification of an outbreak and the deployment of new medical technologies to reach developing countries in a public health crisis to save lives and avoid full scale crisis.

5 WHO SUBMISSION TO THE UN SG HIGH LEVEL PANEL ON ACCESS TO MEDICINES

12. The 2016 WHO Submission to the UN SG High Level Panel on Access to Medicines summarized relevant WHO experience in access to medicines that relate to the current innovation system. In the submission, WHO argues for an expansion of the Medicines Patent Pool, calls for greater transparency of the patent status of essential medicines and encouraged the High-Level Panel to consider the question of how to draw the line between what advancements should be considered patentable and what is part of lifecycle management. The submission also presented a number of WHO-led projects for consideration by the Panel, including:

- the possibility of setting up a pooled fund for voluntary contributions toward pharmaceutical R&D for neglected diseases;
- the R&D Blueprint for pathogens likely to cause severe outbreaks in the near future, for example, being able to respond to emerging pathogens with limited to no medical countermeasures, such as the 2014-2015 outbreak of Ebola, see paragraphs 9-10;
- the joint WHO/DND*i* initiative on creating a Global Antibiotic R&D Partnership (GARDP), see paragraphs 2-4;
- organizing a Fair Pricing Forum to provide a global platform for relevant stakeholders to discuss and develop effective strategies towards universal health coverage. The underlying approach is to identify the most promising options and strategies to expand access to new medicines while ensuring that sufficient incentives remain for research and innovation, and that generic medicines also remain on the market.

6 DIRECT COUNTRY SUPPORT

13. 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 and services. Such support is provided upon request to assist Member States in devising ways to safeguard public health interests, while adhering to their obligations under international trade agreements.

14. WHO responded in particular to a request received by Colombia during the World Health Assembly in 2016 on ensuring access to Imatinib, a cancer treatment included in the WHO Essential Medicines List. PAHO/WHO supported some member countries on discussions around negotiations of new regional trade agreements and their potential impact on health policies. PAHO/WHO also provided support to countries in the implementation and use of TRIPS flexibilities to facilitate access for medicines.

15. Together with WTO, WIPO, and UNCTAD, WHO provided technical assistance to the South African Department of Trade and Industry on the development of an Intellectual Property Consultative Framework. A WHO expert attended a two-day working session with the Inter-Ministerial Committee on Intellectual Property providing input on the different elements of the Consultative Framework.[4] Jointly with UNCTAD, WHO provided technical assistance to Ethiopia on how to make use of their LDC status to foster local production.

[4] http://www.thedti.gov.za/news2016/IPConsultativeFramework.pdf

ANNEX[1]

Activity	Date	Location	Brief Description	Link to further details (if available)
Intellectual Property to Meet South Africa's Developmental Objectives National Workshop, WTO in collaboration with WHO, WIPO and UNCTAD	26-27 September 2016	Pretoria, South Africa	The Workshop aimed at the issues relating to the intersection between public health and intellectual property including patent examinations and review procedures and limitations to patent rights. It also considered the links between public health and policy dimensions including competition policy and rules and industrial polices.	
Pharmaceutical policies and rational use of medicines multi-country consultation, WHO	7-11 September 2016	Copenhagen, Denmark	The aim of the consultation is to bring together high-level academics, stakeholders and policy-makers to discuss current challenges and opportunities in pharmaceutical policies. The meeting focused on reviewing and sharing effective governance strategies for improving access to medicines, while implementing the World Health Assembly Resolution 67.22 and high-price medicines – affordability and sustainable access – and consulting on the next steps in providing health technologies and pharmaceuticals (HTP) country support.	http://www.euro.who.int/en/media-centre/events/events/2015/09/pharmaceutical-policies-and-rational-use-of-medicines-multicountry-consultation
Summer School on Pharmaceutical Pricing, the Austrian Health Institute in collaboration with WHO	29 August – 2 September 2016	Vienna, Austria	The summer school helped train high-level civil servants in the WHO European Region in shaping and implementing policies for pricing medicines. Participants learnt about medicine pricing across Europe, funding and reimbursement models, methods for comparing and analyzing prices, and the benefits and limitations of various policies.	http://www.euro.who.int/en/health-topics/Health-systems/health-technologies-and-medicines/news/news/2016/09/first-of-its-kind-training-targets-medicine-pricing-policies

[1] In English only.

Activity	Date	Location	Brief Description	Link to further details (if available)
Annual meeting of the interim network for promoting cooperation for regulation of medical products in the SEA Region, WHO	17–18 August 2016	Bangkok, Thailand	The meeting discussed the timely access to safe and efficacious medical products of assured quality to achieve Universal Health Coverage. This Network will support the development of efficient and effective medical products regulatory system and promote the strengthening of the role of National Regulatory Authorities of each country in the SEA region through fostering collaboration, building trust and sharing regulatory information.	
International Trade and Health Technical Conference (ITH), Ministry of Health Thailand, WHO-SEARO	7-11 August 2016	Bangkok, Thailand	The Ministry of Health Thailand organized the International Trade and Health Conference (ITH) that covered various areas where the Trans-Pacific Partnership Agreement (TPP) would impact health. These include traditional medicines, herbs and genetic resource; medicines, vaccines and biological products; medical devices; food; cosmetics; tobacco; alcoholic beverages; and health services. SEARO provided technical support in the area of traditional medicines and knowledge and genetic resources.	
13th WIPO-WTO Colloquium for Teachers of Intellectual Property from Developing Countries, with participation from WHO	13-24 June 2016	Geneva, Switzerland	The aim of the WIPO-WTO Colloquium is to help teachers of IP from developing countries become more aware of the Geneva institutions, negotiations and other activities dealing with intellectual property law and policy, and to strengthen their countries' independent research, policy analysis and teaching in international intellectual property law and economics with its diverse policy contexts.	

Activity	Date	Location	Brief Description	Link to further details (if available)
WTO Academic Support Programme – Lectures on TRIPS in Summer Academy at the Centre for WTO Studies, Indian Institute of Foreign Trade, with participation from WHO	30 May 2016	Delhi, India	This training course was sponsored by the Indian Government through the Indian Institute of Foreign Trade, New Delhi, in the form of a Summer Academy on trade law in cooperation with the World Trade Institute. It aimed at strengthening India's capacity on trade law.	
International Conference on IP and Counterfeit, Falsified and Substandard Drugs, WHO/Ministry of Health and Population/Institut Français Égypte	29-30 May 2016	Cairo, Egypt	The themes discussed at the Conference included IP and patent issues in Egypt, as well as the role of law and law enforcement in controlling counterfeit, falsified and substandard drugs. Presentations were made by representatives of the Government of Egypt, the WTO, French experts and private sector representatives. WHO contributed the public health perspective making a clear distinction between intellectual property and public health considerations.	
National consultation on Transitioning from MDGs to SDGs: Ensure healthy lives and promote well-being for all Indians at all ages, WHO, Indian Ministry of Health & Family Welfare	10-11 May 2016	New Delhi, India	The focus of the two-day consultation is to reflect on the successes and the lessons learnt from the Millennium Development Goals (MDG) era and the possible way forward for achieving the ambitious and inclusive agenda of SDGs in the health sector over the next 15 years. SEARO provided technical support on improving access to affordable medicines, vaccines and diagnostics.	http://www.searo.who.int/india/mediacentre/events/2016/consultation_MDG_SDG/en/

Activity	Date	Location	Brief Description	Link to further details (if available)
The Use of Intellectual Property Rights' Flexibilities to Promote Local Pharmaceutical Production in Ethiopia, UNCTAD in collaboration with WHO	3-4 May 2016	Addis Ababa, Ethiopia	The objective of the Workshop is to enhance the understanding of participants of the interface of intellectual property and local pharmaceutical production. The Workshop was organized in response to the invitation to contribute to the implementation of the National Strategy and Plan of Action for Pharmaceutical Manufacturing Development (2015-2025) in collaboration with the World Health Organization. Topics for discussion included pharmaceutical trademarks, unfair competition and anti-counterfeiting measures.	http://unctad.org/meetings/en/SessionalDocuments/tot_ip_2016_May_WorkshopReport_EthiopiaIPPharma.pdf
Regional Action plan for Hepatitis, WHO SEARO	26–28 April 2016	Jakarta, Indonesia	The presentations discussed the effective medicines and tools that have become available to prevent the development of advanced disease and reduce mortality in persons with chronic viral hepatitis B and C.	
Global Challenges Seminar on Patents and the WHO Model List of Essential Medicines: Clarifying the Debate on IP and Access, WIPO, with participation from WHO	12 April 2016	Geneva, Switzerland	The seminar covered topics including patent protection and access to essential medicines, identifying patent status of essential medicines, essential medicine patent transparency and interventions for patented products. WHO presented its work on patent transparency.	http://www.wipo.int/meetings/en/details.jsp?meeting_id=39383
Eighth WIPO-WTO Advanced Course on Intellectual Property for Government Officials, with participation from WHO	7-18 March 2016	Geneva, Switzerland	The main objective of the WIPO-WTO Advanced Course on Intellectual Property for Government Officials is to update government officials on the activities and instruments of WIPO and the WTO, and to provide a forum for them to exchange information and ideas with the two Secretariats and with a range of organizations based in Geneva.	

Activity	Date	Location	Brief Description	Link to further details (if available)
Regional Experts Consultation on Access to Affordable Medicines, Diagnostics and Vaccines, UNDP, ESCAP, UNAIDS, APN+, APCASO, WHO	15-17 March 2016	Bangkok, Thailand	The themes covered in the consultation included medicines, vaccines and diagnostics, policies for equitable access, balancing trade and health, country and civil society organizations approaches and developing a pro-health agenda for national consultations.	https://unaids-ap.org/2016/03/18/experts-call-for-renewed-urgency-to-ensure-access-to-affordable-medicines-in-asia
Workshop on Intellectual Property and Public Health, WTO in collaboration with WHO and WIPO	17-18 February 2016	Dubai, United Arab Emirates	The Workshop considered agreements relating to intellectual property and public health including TRIPS Agreement and the Doha Declaration. The different sessions considered patent roles for innovation and access in medical technologies, and perspectives on the interplay between intellectual property and public health.	
Information Session on Determination of Equivalence for Pesticide-based Vector Control Products, FAO/WHO	1-2 February 2016	Geneva, Switzerland	The objectives of the session was to discuss the current FAO/WHO definition and criteria used for determining equivalence of pesticide active ingredients and formulations under the International Code of Conduct on Pesticide Management and the WHO equivalent process for evaluation of medicines, to understand impact of equivalence on the availability of pesticide-based vector control products and perspectives of various stakeholders in vector control.	
Licensing Policies of Public Research Institutions: Optimising Health Benefits, Institut Pasteur, WHO	14-15 January 2016	Paris, France	The objective of the Workshop was to explore the role of licensing policies of academic research and public health institutions in assuring development, affordability and availability of new health products.	
WHO Essential Medicines and Health technologies English Technical Briefing Seminar (TBS)	23-27 November 2015	Geneva, Switzerland	Pharmaceutical Policies seminar aimed at people working on medicine issues in the pharmaceutical and health sector programmes in developing and transitional countries. The seminars provide an update on topics related to medicine quality, access, use, regulation, and innovation.	http://www.who.int/medicines/technical_briefing/tbs/tbs_en_programme_nov_2015/en/

Activity	Date	Location	Brief Description	Link to further details (if available)
WTO Regional Workshop on Intellectual Property, Public Health and Priority Needs in collaboration with WHO	3-6 November 2015	Abidjan, Ivory Coast	The Workshop aimed at providing participants with a better understanding of (i) the TRIPS Agreement; (ii) the linkages between the Intellectual Property regime and the access to the Public Health; and (iii) the WTO needs assessment process in the field of Intellectual Property.	
5th WHO-WIPO-WTO joint Trilateral Symposium on Innovation and Access to Medicines; Learning from the Past, Illuminating the Future	28 October 2015	Geneva, Switzerland	The Trilateral Symposium reviewed the information base on access and innovation in medical technologies and identified possibilities and limitations for better integrating data in support of policy makers' future work.	https://www.wto.org/english/news_e/news15_e/trip_31aug15_e.htm
WHO, WIPO and WTO Technical Workshop on "Patentability Criteria"	27 October 2015	Geneva, Switzerland	The Technical Workshop aimed at complementing the 28 October 2015 Symposium (see below) through providing participants with practical insights into how the main substantive patentability criteria are applied in practice at country level and how different interpretations can impact on public health.	https://www.wto.org/english/tratop_e/trips_e/trilat_workshop15_e.htm

Activity	Date	Location	Brief Description	Link to further details (if available)
WTO Workshop on Trade and Health for Capital-based officials from Developing Countries, in collaboration with WHO and WIPO	26-30 October 2015	Geneva, Switzerland	The Workshop laid emphasis on building capacity to analyse and undertake policy choices in the area of intersection between trade and public health. Presentations, discussions and practical exercises therefore looked at relevant trade agreements as part of the wider action to address needs specific to public health. In particular, the Workshop covered key factors that impact on innovation and access in the pharmaceutical sector, including: Public health determinants; intellectual property rights; pricing and procurement policies; competition policy and rules; tariffs, quotas and licensing; and health services. A separate section dealt with regulatory issues, including the approval, quality control and effectiveness of medicines, the protection of clinical test data under the TRIPS Agreement and health-related measures in the TBT and SPS Committees.	https://www.wto.org/english/news_e/news15_e/trip_12nov15_e.htm
Pharmaceutical Pricing and Reimbursement Policies: Challenges beyond the financial crisis, WHO	12-13 October 2015	Vienna, Austria	The conference aimed to present on-the-frontier academic analysis as well as foster discussion of challenges in pricing and reimbursement policies. Among other topics, sofosbuvir and the reimbursement of highly innovative drugs were discussed.	http://www.who.int/medicines/news/3rd_ppri_conf/en/
Trade and the Right to Health in the context of Non-Communicable Diseases, Ministry of Law and Human Rights in Indonesia, Indonesian Ministry of Law and Human Rights, WHO	6-9 October 2015	Batam, Indonesia	National Consultation was held to develop multisectoral coordination especially relating to the areas of trade and commerce to ensure the right to health of the citizens of Indonesia in line with international and national obligations.	

Activity	Date	Location	Brief Description	Link to further details (if available)
Regional Meeting for Promoting Cooperation for Regulation in Trade of Medical Products, WHO-SEARO	22-24 September 2015	New Delhi, India	Topics discussed included the need to develop a regulatory affairs network for cooperation, establishing a network to enhance information exchange and capacity building to adopt best practices and international standards and convening annual meeting on National Medicines Regulatory Authorities.	
The 2nd Meeting on Access to Medicines under Universal Health Coverage in the Asia Pacific Region, WHO	17-18 September 2015	Seoul, Republic of Korea	Presentation on hepatitis C and high-priced drugs. Specifically, the presentation focused on strategies to expand access to viral hepatitis treatment in Mongolia. Speaker details: Managing intellectual property for access to viral hepatitis Medications - Peter Beyer, Senior Advisor, Public Health, Innovation and Intellectual Property, WHO Headquarter (Skype presentation).	http://www.wpro.who.int/essential_medicines/documents/second_mtg_access_to_medicines_uhc/en/
WHO Essential Medicines and Health technologies French Technical Briefing Seminar (TBS)	14-18 September 2015	Geneva, Switzerland	Pharmaceutical Policies seminar aimed at people working on medicine issues in the pharmaceutical and health sector programmes in developing and transitional countries.	http://www.who.int/medicines/technical_briefing/tbs/fr/

Activity	Date	Location	Brief Description	Link to further details (if available)
Regional Meeting on High-Cost and Strategic Medicines, WHO, PAHO	2-3 September 2015	Santiago de Chile, Chile	The aim of the meeting was to analyze the impact of incorporating high-cost medicines into the health system; share experiences and lessons learned among different stakeholders and discuss strategies to improve access and decrease the financial impact of the incorporation of high-cost medicines; and, explore the adoption of common strategies that may improve access to high-cost and strategic medicines in countries in Latin America and the Caribbean. The gathering reached some important conclusions including suggesting (1) PAHO Member States should consider a Resolution to the Executive Council on the subject to ensure comprehensive technical cooperation and work to facilitate access to high-cost and strategic medicines and (2) countries should establish comprehensive health and pharmaceutical policies and strategies that provide long-term and sustainable solutions to ensure access to life-saving medicines.	http://www.paho.org/hq/index.php?option=com_content&view=article&id=11169%3Amedicamentoestrategicos-alto-costo&catid=4669%3Anews-hss&Itemid=39594&lang=en