



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

WORLD HEALTH ORGANIZATION (WHO)

Addendum

At its meeting of 6 June 2019, 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 20 September 2019.

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 last report in October 2018 (IP/C/W/644/Rev.1/Add.2). 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 (GSPoA) as well as other relevant resolutions of the World Health Assembly, including WHA72.8 on "Improving the transparency of markets for medicines, vaccines, and other health products."¹ Following discussions at its 142nd session (2018), the WHO Executive Board recommended to the Seventy-first World Health Assembly implementation of the recommendations from an overall programme review of the GSPoA. The Seventy-first World Health Assembly decided to urge Member States to implement GSPoA-consistent recommendations of the review panel addressed to Member States while urging further discussion on recommendations not emanating from the GSPoA.² An implementation plan is currently under development. As requested by the Seventy-first World Health Assembly³, the Director-General presented a road map report to the Seventy-second World Health Assembly, outlining the programming of WHO's work on access to medicines and vaccines, including activities, actions and deliverables for the period 2019–2023.⁴

2 UPDATE OF THE WHO ESSENTIAL MEDICINES LIST

2. WHO's Essential Medicines List (WHO EML) and List of Essential Diagnostics (WHO EDL) are core guidance documents that help countries prioritize critical health products that should be widely available and affordable throughout health systems.

¹ WHA72.8 https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf

² WHA71(9) [http://apps.who.int/gb/ebwha/pdf_files/WHA71/A71\(9\)-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA71/A71(9)-en.pdf)

³ WHA71(8) [http://apps.who.int/gb/ebwha/pdf_files/WHA71/A71\(8\)-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA71/A71(8)-en.pdf)

⁴ A72/17. https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_17-en.pdf

3. In April 2019, the meeting of the 22nd WHO Expert Committee on the Selection and Use of Essential Medicines met to revise and update the WHO Model List of Essential Medicines (EML) and Model List of Essential Medicines for Children (EMLc). The Committee considered 65 applications, including proposals to add 53 new medicines and new formulations of 19 existing medicines, extend the indications for 34 listed medicines, and to remove ten medicines or formulations from the lists. The Expert Committee also considered reports and recommendations from the EML Antibiotics and Cancer Medicines Working Groups. In accordance with applicable procedures, the Expert Committee evaluated the scientific evidence for the comparative effectiveness, safety and cost-effectiveness of the medicines in question. In summary, the Expert Committee: recommended the addition of 28 new medicines to the EML (12 to the core list and 16 to the complementary list); recommended the addition of 23 new medicines to the EMLc (six to the core list and 17 to the complementary list); recommended the addition of new formulations of 16 currently listed medicines; recommended adding additional indications for 26 currently listed medicines; recommended the deletion of nine medicines and of specific formulations of a further four medicines; and; rejected 21 applications for inclusion, change or deletion of 31 medicines.⁵ Based on current data from MedsPal 11% of medicines in the new EML are under patent protection, either primary and/or secondary patents.⁶

3 FAIR PRICING FORUM

4. In August 2019, the second Fair Pricing Forum was convened in Johannesburg, South Africa. The Forum was hosted by the South African National Department of Health together with WHO, and attended by representatives from Member States, non-governmental and patient organizations, and the innovator and generic pharmaceutical industry. The event addressed the following objectives: 1) to share experiences in employing regulatory and non-regulatory measures for achieving 'fair' prices for pharmaceutical products that are affordable to patients and healthcare systems while incentivizing enterprise, efficiency and innovation; 2) to explore tools, approaches and system factors that could facilitate affordable and sustainable pricing of pharmaceutical products; 3) to identify areas of actions that would support countries in achieving fairer pricing of pharmaceutical. The Forum consisted of a series of participatory workshops, followed by plenary and parallel panel discussions on key issues of current interest, and concluded by a plenary discussion on key learnings and commitments for further action. Participants acknowledged difficulties in defining a price that is truly fair, but also that it is most important to think practically about what fairness means in practice and how all stakeholders can work together to achieve it. To that end, a set of technical working groups will focus on specific areas of pricing to determine what is achievable in the short- and medium-term, reporting to the next Fair Pricing Forum in 2021, in line with WHA72.8, which requests the Director-General "to continue WHO's efforts to biennially convene the Fair Pricing Forum with Member States and all relevant stakeholders to discuss the affordability and transparency of prices and costs relating to health products." ⁷

4 TECHNICAL REPORT: PRICING OF CANCER MEDICINES AND ITS IMPACTS

5. In December 2018, WHO published a "Technical Report on Pricing of Cancer Medicines and its Impacts."⁸ The comprehensive report examines pricing approaches adopted by the pharmaceutical industry and authorities responsible for the pricing of medicines, with a specific focus on medicines for the prevention and treatment of cancer. It reviews pricing approaches applied throughout the "value chain" (i.e., activities required to bring medicines to patients, from R&D to service delivery), and at different time points of product life cycle from market launch to the entry of clinically substitutable medicines. The report presents evidence relating to the impacts of pricing approaches (or lack thereof) on the price, availability and affordability of cancer medicines. It examines the possible relationship between pricing approaches and (a) R&D of cancer medicines, including incentives for investment in R&D on cancer and in innovation of these measures, as well as possible gaps in undertaking research and development (that is, a possible shortfall in funding or activities

⁵ Executive Summary: The Selection and Use of Essential Medicines 2019: <https://apps.who.int/iris/bitstream/handle/10665/325773/WHO-MVP-EMP-IAU-2019.05-eng.pdf?sequence=1&isAllowed=y>

⁶ MedsPal: The Medicines Patents and Licences Database, www.medsPal.org

⁷ Fair Pricing Forum Johannesburg: <https://apps.who.int/iris/bitstream/handle/10665/326407/WHO-MVP-EMP-IAU-2019.09-eng.pdf?ua=1>

⁸ Technical Report: Pricing of cancer medicines and its impacts <https://apps.who.int/iris/bitstream/handle/10665/277190/9789241515115-eng.pdf?ua=1>

in certain areas of cancer research); (b) transparency in price and governance; and (c) benefits and unintended negative consequences that would deviate from the original policy intent.

5 TRAINING AND ENHANCING CAPACITY

6. The WHO, WIPO and WTO are currently collaborating on an update to the joint study on "Promoting access to medical technologies and innovation: Intersections between public health, intellectual property and trade." The publication updates the first edition, published in 2013. Several trilateral workshops were conducted with the aim of discussing the latest information and evidence on the relationships between intellectual property, trade and the dynamics of access to and innovation in medical technologies. The study update will inform ongoing technical cooperation activities undertaken by the three organizations and support policy discussions.

7. In July 2019, the WTO Secretariat, in close collaboration with the Secretariats of WIPO and WHO and the UEMOA Commission, organized a regional workshop in Dakar, Senegal. The workshop discussed the WTO TRIPS Agreement, including the use of public health flexibilities and how countries in the UEMOA region can implement certain provisions. Another main topic was pricing issues and best practices for government procurement of pharmaceutical products. In addition to two case studies and a roundtable discussion, WHO presentations addressed the following topics: "Introductory session on public health, the trade, intellectual property and markets public," "Public health in UEMOA: state of the art situation and challenges," and "The regulatory dimension: Quality, safety and effectiveness of drugs, including substandard, falsified and counterfeit."

8. In June 2019, the 16th WIPO-WTO Colloquium for Teachers of Intellectual Property was held in Geneva, Switzerland. During Theme 5 on "Intellectual Property and Public Health" WHO participated in a "Panel Discussion on the Intersections of Public Health, Intellectual Property and Trade," and presented "WHO Perspective: Public Health and the Intellectual Property System."

9. In June 2019, during the Thirtieth Session of WIPO's Standing Committee on the Law of Patents in Geneva, WHO was invited to present its "Current Work on IP and Access to Achieve UHC Licensing and Access Provisions for Medicines and Health Technologies" during the "Sharing Session on Patents and Health."

10. In April 2019, during the WIPO Global Challenges Seminar on Urgent Innovation: Policies and Practices for Effective Response to Global Health Crises WHO Chief Scientist, Soumya Swaminathan, provided the keynote address and the WHO Health Emergencies Programme participated in the event, including moderating Panel 1 on "Science & Innovation – IP and R&D models to accelerate innovation in response to public health crises." The seminar brought together experts in R&D, policy and delivery from a range of public and private sector organizations involved in facilitating innovation in response to health crises. It provided the opportunity to explore critical questions such as: How are urgency and innovation defined in these contexts? What are the priorities and targets, and how can they be achieved? What lessons can be drawn from past experiences?

11. In November 2018, WHO-WIPO-WTO in collaboration with the IMF-Middle East Center for Economics and Finance, hosted the "Regional Workshop on Public Health, Intellectual Property, and Trade" to provide technical support and guidance to Arab and Middle Eastern countries on issues at the intersection of public health, intellectual property and trade. WHO participated in several sessions, including: "Roundtable Discussion: Mapping the Interface between Health, Trade and Intellectual Property," "The Intellectual Property System as Determinant for Innovation in the Medical Technologies Sector," "The Public Health Context: Overview and Determinants for Access," "Using the IP System and its Policy Options to Support Access to Medical Technologies," "Health-Related Provisions in Bilateral and Regional Trade Agreements," "Competition Policy and Rules," "Pooled Procurement," "Approval, Quality Control and Effectiveness of Medicines, including Falsified and Substandard, as well as Counterfeit Medicines," and "Protection of Clinical Trial Data – Policy, Legal and Economic Aspects."

12. In October 2018, WTO, in close collaboration with WHO and WIPO, hosted the 14th Annual WTO Workshop on Trade and Public Health. Key features of the programme included: public health determinants; the intellectual property system; pricing and procurement policies; competition policy and rules; tariffs, quotas and licensing; health services; and regulatory issues. Under regulatory issues, participants looked at approval, quality control and effectiveness of medicines, the protection

of clinical trial data under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and health-related measures in the Committee on Technical Barriers to Trade (TBT) and the Committee on Sanitary and Phytosanitary Measures (SPS). WHO led or participated in the following sessions: Roundtable Discussion: Mapping the Interface between Health, Trade and Intellectual Property; The Intellectual Property System as Determinant for Innovation in the Pharmaceutical Sector: Implementing and Managing IPRs; Breakout Session on Anti-Microbial Resistance: How to Foster Innovation, Access and Appropriate Use of Antibiotics; The Public Health Context: Overview of Determinants Related to Access; Using the IP System and its Policy Options to Further Global Access to Health Technologies; Procurement Rules and Practices; Breakout Session on Non-Communicable Diseases: Tobacco Plain Packaging; Approval, Quality Control and Effectiveness of Medicines, including Falsified and Substandard, as well as Counterfeit Medicines.

6 COUNTRY SUPPORT

13. In collaboration with relevant international organizations, through its Headquarters, 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. In July 2019, WHO, jointly with the World Intellectual Property Organization and the World Trade Organization, participated in a panel discussion on "Public health, trade, intellectual property and public procurement in Senegal." The national workshop responded to a demand of Ministry of Trade of Senegal and the intellectual property office, focusing on access to medicines and other medical technologies. WHO, jointly with the World Intellectual Property Organization and the World Trade Organization, participated in a panel discussion on "Public health, trade, intellectual property and public procurement in Senegal." The national workshop responded to a demand of Ministry of Trade of Senegal and the intellectual property office, focusing on access to medicines and other medical technologies.

15. In November 2018, the National Intellectual Property Office of Kyrgyz Republic (KyrgyzPatent) and WIPO organized a national seminar, in close collaboration with WHO and WIPO. The seminar provided trilateral technical support on issues at the intersections of public health, intellectual property and trade with a focus on access to and innovation of medicines and other medical technologies and especially to the Kyrgyz Republic on the implementation of their amended patent law. Participants came from various government agencies, including the Ministry of Economy, the Ministry of Health, and KyrgyzPatent, as well as from agencies such as UNDP, local representatives supporting the country on public procurement of medicines and civil society representatives. WHO presented on "Promoting Access to Medical Technologies: Public Health Perspective."

ANNEX¹

Activity	Date	Location	Brief Description	Link to further details (if available)
Fair Pricing Forum	11-13 August 2019	Johannesburg, South Africa	The Forum was hosted by the South African National Department of Health together with WHO, and attended by representatives from Member States, non-governmental and patient organizations, and the innovator and generic pharmaceutical industry. The event addressed the following objectives: 1) to share experiences in employing regulatory and non-regulatory measures for achieving 'fair' prices for pharmaceutical products that are affordable to patients and healthcare systems while incentivizing enterprise, efficiency and innovation; 2) to explore tools, approaches and system factors that could facilitate affordable and sustainable pricing of pharmaceutical products; 3) to identify areas of actions that would support countries in achieving fairer pricing of pharmaceutical.	https://apps.who.int/iris/bitstream/handle/10665/326407/WHO-MVP-EMP-IAU-2019.09-eng.pdf?ua=1
National Workshop on Public Health and Intellectual property	5 July 2019	Dakar, Senegal	WHO, jointly with the World Intellectual Property Organization and the World Trade Organization, participated in a panel discussion on "Public health, trade, intellectual property and public procurement in Senegal." The national workshop responded to a demand of Ministry of Trade of Senegal and the intellectual property office, focusing on access to medicines and other medical technologies.	http://tamis.wto.org/sites/default/files/SE_N19-103.05.2019%20SENEGAL%20atelier%20national%20version%20provisoire.docx
Workshop on Public Health, Intellectual Property and Public Procurement for UEMOA Members	2-4 July 2019	Dakar, Senegal	Organized by the WTO Secretariat in close collaboration with the Secretariats of WIPO and WHO and the UEMOA Commission, the regional workshop discussed the WTO TRIPS Agreement, including the use of public health flexibilities and how countries in the UEMOA region can implement certain provisions. Another main topic was pricing issues and best practices for government procurement of pharmaceutical products.	https://www.wto.org/french/news_f/news19_f/tra_04jul19_f.pdf

¹ In English only.

Activity	Date	Location	Brief Description	Link to further details (if available)
Delivering on the sustainable access of antibiotics: moving from principles to practice	1-2 July 2019	Geneva, Switzerland	Organized by GARDP in partnership with the Medicines Patent Pool and WHO, a two-day interactive workshop convened a multi-disciplinary group of technical experts and stakeholders (public health organizations/non-governmental organizations/industry/government representatives from low- and middle-income countries and high-incomes countries) to consider and shape future access and stewardship interventions and understand how to make them successful. The outcome resulted in defining a roadmap of activities pre- and post- registration of a new antibiotic that promotes both access and stewardship and identified practical ways to implement the roadmap, including the key steps, potential funding mechanisms and critical success factors.	
Standing Committee on the Law of Patents-Agenda Item 8: Patents and Health	24-27 June 2019	Geneva, Switzerland	During the Thirtieth Session of the Standing Committee on the Law of Patents, WHO was invited to present its "Current Work on IP and Access to Achieve UHC Licensing and Access Provisions for Medicines and Health Technologies" during the "Sharing Session on Patents and Health."	https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=440257
16 th WIPO-WTO Colloquium for Teachers of Intellectual Property	19 June 2019	Geneva, Switzerland	Since 2004, the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) have jointly organized annual two-week colloquiums for teachers of intellectual property from developing countries and countries with economies in transition. During Theme 5 on "Intellectual Property and Public Health" WHO participated in a "Panel Discussion on the Intersections of Public Health, Intellectual Property and Trade," and presented "WHO Perspective: Public Health and the Intellectual Property System."	https://www.wto.org/english/tratop_e/trips_e/collquium_prog19_e.pdf
Congress on Intellectual Property and Access to Medicines	3-5 June 2019	Kyiv, Ukraine	The Ministry of Health of Ukraine requested WHO's participation in a "Congress on Intellectual Property and Access to Medicines." The national-level technical meeting united government and civil society representatives with professionals in public health, intellectual property, trade and competition and served as a capacity building intervention which consisted of two parts: 1) operationalization of National Medicines Strategy (Day 1); 2) regional consultation (Ukraine, Moldova, Georgia) on	

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WIPO Global Challenges Seminar on Urgent Innovation: Policies and Practices for Effective Response to Global Health Crises	16 April 2019	Geneva, Switzerland	opportunities to increase access to essential medicines (Days 2 and Day 3). The seminar brought together experts in R&D, policy and delivery from a range of public and private sector organizations involved in facilitating innovation in response to health crises. WHO Chief Scientist, Soumya Swaminathan, provided the keynote address and the WHO Health Emergencies Programme participated in the event, including moderating Panel 1 on "Science & Innovation – IP and R&D models to accelerate innovation in response to public health crises."	https://www.wipo.int/meetings/en/details.jsp?meeting_id=51766
UN Inter-Agency Meeting on Intellectual Property & Health	29 November 2018	Geneva, Switzerland	Hosted by WHO with participants from OHCHR, UNAIDS, UNCTAD, UNDP, Unitaid, WIPO, and WTO, the inter-agency meeting facilitated information sharing about major ongoing and planned activities and publications. The meeting also served as a venue to explore future areas of work and collaboration towards improved transparency and data/evidence gathering.	
WHO-WIPO-WTO Regional Workshop on Public Health, Intellectual Property, and Trade	18-21 November 2018	Kuwait City, Kuwait	The trilateral regional workshop, in collaboration with the IMF-Middle East Center for Economics and Finance, provided technical support and guidance to Arab and Middle Eastern countries on issues at the intersection of public health, intellectual property and trade.	
National Seminar on Exceptions and Limitations to Patent Rights Relating to Inventions in the Pharmaceutical Field	15-16 November 2018	Bishkek, Kyrgyzstan	The seminar was organized by the National Intellectual Property Office of Kyrgyz Republic (KyrgyzPatent) and WIPO, in close collaboration with WHO and WIPO. The seminar provided trilateral technical support on issues at the intersections of public health, intellectual property and trade with a focus on access to and innovation of medicines and other medical technologies and especially to the Kyrgyz Republic on the implementation of their amended patent law. Participants came from various government agencies, including the Ministry of Economy, the Ministry of Health, and KyrgyzPatent, as well as from agencies such as UNDP, local representatives supporting the country on public procurement of medicines and civil society representatives.	

Activity	Date	Location	Brief Description	Link to further details (if available)
Working Group on Intellectual Property at the Expert Meeting on Access to Hepatitis B&C Treatment	22-24 October 2018	Casablanca, Morocco	The overall objective of the meeting was to improve access to quality and affordable hepatitis B and C medicines and diagnostics. The specific objectives were to: 1) review the situation in the region with respect to the availability of hepatitis antiviral medicines and their prices; 2) identify bottlenecks to price reduction and to share experiences on price reduction strategies; and to 3) address intellectual property rights issues related to those products; and develop strategies for price reduction for countries in different economic and epidemic situations. The meeting was attended by participants representing hepatitis programme focal points and experts in registration, pricing and procurement of hepatitis B and C from 6 Member States of the region, namely Egypt, Iran, Morocco, Pakistan, Sudan, and Saudi Arabia. Additional participants from civil society organizations representing the most affected groups in the region and organizations with expertise in advocacy and actions for improving access to treatment.	
14 th Annual WTO Workshop on Trade and Public Health, Geneva, Switzerland	8-12 October 2018	Geneva, Switzerland	The 2018 workshop built on similar training activities held since 2014 as well as on earlier workshops on intellectual property and public health that had been convened by the WTO Secretariat since 2005. The workshop followed the approach of the WHO-WIPO-WTO Trilateral Study on "Promoting Access to Medical Technologies and Innovation: Intersections Between Public health, Intellectual Property and Trade." ² The programme of the workshop has evolved to cover the link between trade and public health in a comprehensive and multidisciplinary manner in order to build the capacity of governments in developing countries and LDCs to take effective and coherent policy decisions.	https://www.wto.org/english/news_e/news_18_e/tra_15oct18_e.htm

² https://www.who.int/phi/promoting_access_medical_innovation/en/