Briefing Series on Trilateral Cooperation

World Health Organization

WORLD TRADE ORGANIZATION

WIPO WORLD INTELLECTUAL PROPERTY ORGANIZATION

WHO, WIPO, WTO Joint Technical Symposium on Sustainable Development Goals: Innovative technologies to promote healthy lives and well-being

Key issues

- Innovation, including in medical technologies, based on an economically sustainable basis, will expedite the realization of the health-related United Nations Sustainable Development Goals (SDGs).
- Countries are entitled to make full use of available policy options under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in line with the Doha Declaration.
- Access to health technologies is a key pillar of universal health coverage.
- Lack of access to medical technologies is rarely due to a single determinant. Important factors include: needs-based research, development and innovation; intellectual property and trade policies; manufacturing processes and systems; regulatory environment; price transparency, pricing policies and health system infrastructure; integrity and efficiency in procurement and supply chain management; and appropriate selection, prescribing and use.
- Availability of, and access to, appropriate and affordable health technologies, including off-patent medicines, are still insufficient in low- and middle-income countries where up to 90% of the population purchase medicines through out-of-pocket payments. However, affordable access is no longer only an issue for low- and middle-income countries.
- Medicines on the WHO Model List of Essential Medicines should be available in low- and middle-income countries at affordable prices. A transparent list of minimum drug prices would facilitate government price negotiations.
- Well-conceived and applied trade agreements and policies can foster innovation of, and access to, medical technologies and should avoid creating access barriers for affordable medicines and innovative health technologies for those who need them most.
- New incentives are needed for attracting investment in innovative activities to address certain health problems, particularly those affecting the poorest countries.
- Making affordable and effective innovative medicines available is a shared responsibility and requires the cooperation of all key stakeholders.

The World Health Organization (WHO), the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) Joint Technical Symposia provide a platform for participants to exchange information and experiences and to discuss current issues. The seventh Joint Technical Symposium, held in Geneva on February 26, 2018, reviewed issues related to innovative technologies to promote healthy lives and well-being. Access to, and innovation in, health technologies is a requisite element for ensuring progress toward universal health coverage and achievement of the Sustainable Development Goals (SDGs), namely SDG 3 to ensure healthy lives and promote well-being for all at all ages.

Introductory remarks

WHO Director-General Dr. Tedros Adhanom Ghebreyesus emphasized the strong commitment of the heads of the three organizations to further strengthening the ongoing cooperation in order to more effectively deal with matters at the crossroads of public health, trade and intellectual property.

Dr. Tedros noted that access to innovative technologies is a key pillar of universal health coverage at a time when non-communicable diseases and the financial burden of paying for long-term treatment are rising globally. Dr. Tedros said that access to off-patent medicines remains unaffordable for many, including in low- and middle-income countries, and called for greater transparency on how prices are set in order to strike a balance between fair profits and public health priorities.

Dr. Tedros underlined that good trade policies can help increase access to health technologies by streamlining customs procedures, abolishing tariffs and fostering good procurement practices. He warned against trade agreements that extend patent monopolies and delay the availability of lower-priced generics, putting new and innovative health technologies out of reach for those who need them the most. He said that while WHO supports the use of TRIPS flexibilities, it was also exploring cooperation with the private sector to constructively address pressing public health needs.

WIPO Director General Francis Gurry stressed that health, innovation and trade are inextricably interlinked. He emphasized that it will not be possible to enjoy relative health security unless efforts were continued to innovate and to bring on new technologies to improve health outcomes. Innovations exist to improve the quality of life and these innovations need to flow freely across borders, through a market-based system, to reach populations in need. Mr. Gurry underlined the need for partnerships to support innovative activities as well as the complexity of the policy considerations regarding access to innovative medical technologies and the architecture for their implementation.

Mr. Gurry pointed to the extreme complexity and increasing costs related to health systems. The necessary innovation requires an economically sustainable basis for which historically there have been only two sources: the public purse and the market system. The burden of disease as well as fiscal demands and competition for scarce resources throughout the world have led to new stresses, tensions and changes in the world trading system. In each system, there are major transformations on the way, e.g. non-state actors that have assumed a prominence that was unimaginable 20 years ago. In this regard, he pointed to two WIPO initiatives. The first, the WIPO Re:Search public-private consortium, mobilizes intellectual property for research and development (R&D) in neglected tropical diseases. The second, the Pat-INFORMED public-private partnership, promotes accessibility of patent information for health agencies tasked with procurement of medicines.

WTO Director-General Roberto Azevêdo noted the WTO is deeply invested in work on the SDGs, recognizing the linkage between trade, economic growth and development more generally. Trade was very important in achieving Millennium Development Goal (MDG) 1 – reduction of poverty – early on, but WTO work now is cross-cutting in nature and, therefore, trade contributions to the SDGs have a bearing on a number of specific targets on which WTO has started delivering, including zero hunger, agricultural export subsidies and, most recently, subsidies linked to overfishing, he said.

Reaffirming the WTO commitment to the trilateral cooperation with WHO and WIPO, DG Azevêdo stressed that WTO plays an important role in ensuring innovative technologies are developed and new medicines are brought to patients, thus, promoting healthy lives and well-being in line with SDG 3. This requires a balanced intellectual property regime that recognizes the entitlement of countries to make full use of available policy options and flexibilities under the TRIPS Agreement in line with the Doha Declaration. To get there, WTO members have, among others, agreed to give least developed countries (LDCs) maximum possible flexibility under the WTO TRIPS Agreement in the area of pharmaceuticals until at least 2033.

Members also secured, in early 2017, the entry into force of the public health amendment to the TRIPS Agreement. This was the first multilateral amendment to WTO law and gave legal certainty to an additional pathway for access to affordable medicines for developing countries that lack the capacity to produce those medicines. The WTO Secretariat is now actively working with members to ensure that the mechanism functions as a practical procurement tool that enhances access to innovative medicines for patients in need, DG Azevêdo said.

He also underlined the importance of the WTO Trade Facilitation Agreement in tackling red tape and cumbersome border procedures and of the WTO Government Procurement Agreement in providing useful guidance about the type of provisions needed in order to put a well-functioning procurement regime in place. He highlighted the need to help micro, small- and medium-sized enterprises (MSMEs) find the necessary support for their innovative R&D activities in the international

trading system, and manage the related IP effectively, bearing in mind ultimately that the public interest in the effective availability of their innovative technologies is the main goal.

Participants from governments, international agencies, the private sector, civil society and academia underlined the need to engage all stakeholders in fostering innovative medical technologies to reach universal health coverage.

Panel 1 – Global health data, disease burden and the challenges ahead

In a panel on global health data, disease burden and the challenges ahead, Mariângela Simão, WHO Assistant Director-General, stressed that the international community has a moral imperative to make innovative medicines available for all on a low-cost or no-cost basis.

Andrew Hill, Senior Visiting Research Fellow of the University of Liverpool presented his research on discrepancies between drug manufacturing costs and selling prices. He said that in some cases, medicines are sold for 100 to 1,000 times more than cost of production. He called for a transparent list of minimum drug prices so countries can see what prices to aim for when negotiating with pharmaceutical companies. He also noted that all essential medicines should be available in low- and middle-income countries at prices close to the cost of production.

Sarah Rickwood, Vice-president of IQVIA, a company providing data and services to the life sciences industry, said that global sales of prescription medicines are expected to decelerate during the next five years. She noted that prices reported by IQVIA did not take into account the considerable value of private and confidential discounts, nor wholesaler and retailer margins. Costs of orphan drugs remain a challenge even for high-income markets, but orphan drug development has experienced a growth in innovation in Europe as a result of enabling legislation. Antibiotic drug development, however, has stalled and efforts to incentivize innovation growth in this area are yet to be seen.

Sherine Helmy, CEO of Pharco Pharmaceuticals of Egypt, stressed that political will is the first and most important factor in addressing these complex issues, and showcased Egypt's success in transforming its position from the country with the highest worldwide prevalence of infection with Hepatitis C, a disease killing one person every 80 seconds, to the first country to treat all patients on the waiting list. Pharco is working in partnership with the Drugs for Neglected Diseases *initiative* (DND*i*) to conduct a pan-genotopic study on sofosbuvir and ravidasvir.

Panel 2 – Technology as a driver of medical progress and access

In a panel on technology as a driver of medical progress and access, Julio Raffo, Head of the WIPO Innovation Economics Section, presented work done by the organization on the history of breakthrough innovation, such as antibiotics, since the early 1920s. Mr. Raffo stressed that "this disruptive health-related innovation contributed to the way the regulatory system was designed" and to the structure of the pharmaceutical industry, and vice versa.

Luiza Pinheiro, representative of the Universities Allied for Essential Medicines (UAEM) of Brazil, spoke about how universities can take advantage of their unique position to share medical and research breakthroughs under open, non-collusive licenses, or licenses that promote access in all countries. She also referred to the UAEM Global Transparency Campaign regarding clinical trials, R&D and pricing, on the basis of transparency metrics.

John Brennan, Secretary General of EuropaBio, the European Association for Bioindustries representing over 1,800 SMEs, explained the essential role biotechnology plays to promote sustainable health innovation and, hence, achievement of the SDGs. He presented recent examples of biomedical innovation and noted the development of biologic medicines is time-consuming, costly and subject to many uncertainties during the research and clinical trial stages.

Panel 3 – How policy choices impact on access to innovative technologies

A third panel discussion addressed how policy choices impact access to innovative technologies. Antony Taubman, Director of the Intellectual Property Division at the WTO, highlighted that the amount of information and evidence-based data is far greater than 20 years ago in two broad areas – patent activities and the wide range of public actions implemented.

Margaret Kyle, Professor of Economics from the Center for Industrial Economics (CERNA) of France, set out existing policy choices in science and innovation as well as in trade and health. She provided empirical evidence illustrating that patents are only one among many factors impacting on access to medicines; other important dimensions include regulatory, health insurance and price control mechanisms. Regarding the criteria to regulate prices for medicines, she noted that profits should be associated with the social value of the innovation in order to promote the "right" innovation.

Kenneth Shadlen, Professor of the London School of Economics and Political Science, compared developing countries' strategies to limit the granting of secondary pharmaceutical patents, finding that these have minimal effects and that grant rates seem to be driven by other aspects of the patent system, including backlogs that encourage patent applicants to withdraw less important applications.

Daniel López Salcedo, Advisor to the Director-General of the Ecuadorian National Service on Public Procurement (SERCOP), explained the experience of his country in bringing down significantly the prices of medicines as a result of the introduction of a transparent and effective e-procurement

system to purchase pharmaceuticals. This has helped to bring essential medicines to 95% of the population and responds to Ecuador's constitutional right to health.

Closing

Assistant Director General Mariângela Simão from WHO emphasized that health is a fundamental human right and that no one should get sick and die just because they are poor or because they cannot access the health services they need. In framing access to medicines, vaccines and health technologies as a human rights-based issue, all stakeholders have a collective responsibility to ensure that international agreements, national policies, laws and regulations are health-sensitive and are implemented to ensure the protection of public health.

Further information

Symposium webpage with links to the DG speeches, event presentations and programs: *www.who.int/phi/sustainable_development_goals_February2018/en/*

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This summary of key issues was prepared by the Secretariats of the three organizations for information purposes. It does neither represent the positions nor the opinions of WHO, WIPO, WTO, nor their respective memberships.

WHO, Department of Essential Medicines and Health Products, iauinfo@who.int

WIPO, Global Challenges Division, global.challenges@wipo.int

WTO, Intellectual Property, Government Procurement and Competition Division, ipd@wto.org