

Promoting Medical Innovation and Access, Together

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1 minute read: key messages

- Improving access to, and promoting innovation in, health technologies are interconnected issues that touch the mandates of WHO, WIPO and WTO, which are deepening their cooperation in these areas to assist policymakers.
- Main joint activities include assembling fact-based information and empirical data to inform the policymaking process, publishing studies and reports on key issues, organizing symposia, and providing capacity building and training activities.
- Future work will include the launch of distancelearning courses to improve understanding among policymakers, researchers and NGOs of the policy options that exist in the fields of public health, intellectual property and trade.

Why is Trilateral Cooperation Needed?

Improving access to, and promoting innovation in, health technologies are crucial to improving public health. These twin global challenges must involve stakeholders from all sectors: private, public, intergovernmental organizations (IGOs) and nongovernmental organizations (NGOs).

This paper addresses the trilateral partnership between the World Health Organization (WHO), the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO). Each has distinct, but complementary, mandates to work on issues relating to public health, innovation, intellectual property (IP), and trade. As such, these organizations share a responsibility to strengthen dialogue among themselves and their partners to fulfil their mandates more effectively, to ensure efficient and coherent use of resources for technical cooperation.

Of the three organizations, WHO's work is the most directly relevant to public health, as it is the directing and coordinating authority for global health. But the process of achieving public health is complex and takes place within a broader policy environment that raises a range of issues relating to, for example, innovation, access, IP, and trade. This underlines the need for cooperation to assist countries in implementing policies that cut across the complex and interconnected areas of public health, IP and trade.

When implementing policies relating to public health, IP and trade, governments work within the framework of agreed international standards. Under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) for example, governments give effect to agreed standards but have some latitude or "policy space" to interpret and implement those standards in line with national needs and priorities when crafting domestic legislation.

Identifying the right mix of policy options to best advance their national objectives, however, is a huge challenge. Coherent, comprehensive and accessible information can help inform their decision-making. The complementary and coordinated expertise of the WHO, WIPO and WTO can offer real benefits to national policymakers.

What Each Organization Brings to the Table

- WHO brings vast expertise in all areas of public health, including medicine and vaccine policies, medical devices, regulatory issues, pricing and procurement, research, development and innovation, in addition to other factors affecting access to medicines.
- WIPO is uniquely positioned to promote a truly global understanding of the value of the IP system and the importance of the right policy mix to encourage innovation by providing information on patents, including the patent status of key medicines and vaccines in developing countries, and lending its expertise on patent law and its interplay with public policy.
- WTO works on several aspects of trade policy that have direct relevance to public health, including

international IP rules, regulations and flexibilities, and commitments on tariffs and easing trade barriers. These aspects of trade policy can affect both the innovation of and access to medicines.

Trilateral cooperation between WHO, WIPO and WTO traces its origins to the Doha Declaration on the TRIPS Agreement and Public Health of 2001, which promotes TRIPS as part of the wider action to address public health challenges, and clarifies a number of public health-related flexibilities. In conjunction with making public health issues a central focus of WTO's work on IP and international trade, the Doha Declaration has been taken up by others, such as by various World Health Assembly (WHA) resolutions on ensuring innovation of, and accessibility to essential medicines. It was notably a point of reference in negotiations on the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.

Similarly, the WIPO Development Agenda adopted in 2007, reflects, in part, broad interest in flexibilities in international IP law, including the health-related flexibilities specifically identified in the Doha Declaration. Since 2009, collaboration among WHO, WIPO and WTO has intensified with a marked increase in the sharing of knowledge to promote better understanding of the policy options surrounding public health, IP and trade (see Box 1).

Box 1: Steps towards increased coherence on public health, intellectual property and trade policy

2000	United Nations Committee on Economic, Social and Cultural Rights General Comment on the Right to the Highest Standard of Health
2001	WTO Doha Declaration on the TRIPS Agreement and Public Health
2002	WHO-WTO joint study: WTO Agreements and Public Health
2003/2005	WTO creates new TRIPS flexibility for access to medicines in countries lacking manufacturing capacity
2006	WHO commissions report on Public Health, Innovation and Intellectual Property
2007	WIPO Development Agenda formally adopted by WIPO Member States
2008	Adoption of WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property
2009	Director Generals of WHO, WIPO and WTO commit to reinforce Trilateral Cooperation
2010	Inaugural Trilateral Symposium on Access to Medicines, Pricing and Procurement Practices¹
2011	Trilateral Symposium on Access to Medicines, Patent Information and Freedom to Operate ²
2013	Trilateral Symposium on Medical Innovation – Changing Business Models ³
2013	Trilateral Study: <i>Promoting Access to Medical technologies and Innovation:</i> Intersections between public health, intellectual property and trade published⁴
2014	Trilateral Symposium on Innovation and Access to Medical Technologies: Challenges and Opportunities for Middle-income Countries ⁵
2015	Trilateral Symposium on Public Health, Intellectual Property and TRIPS at 20: Innovation and Access to Medicines; Learning from the Past, Illuminating the Future ⁶

Trilateral Activities

Policymakers dealing with the challenges of public health, IP and trade work in a complex environment that is affected by a host of national, regional and international policy, legal and administrative structures. In this potentially confusing environment, policymakers need access to factual data and empirical evidence upon which they can base their decisions. In response to this need, the WHO, WIPO and WTO have taken steps to provide policymakers with reliable and accessible information that can assist and guide the process throughout.

The flagship "**Trilateral Study**", published in 2013, is available in Arabic, Chinese, English, French, Spanish, and Russian. The study was prepared to serve the needs of policymakers, lawmakers, government officials, NGOs and researchers who seek a comprehensive overview of the full range of issues. The result of the close collaboration of dozens of experts from across the partnership, the study presents an accessible and comprehensive analysis of the interrelated issues associated with promoting innovation in medical and health technologies.

- On health, it explores new trends in the global disease burden, the importance of regulation and local production for innovation and access to quality medical products, and the innovation challenges associated with addressing neglected diseases.
- On intellectual property, it discusses issues of access to, and innovation of, medical technologies.
 It also takes and in-depth look at a range of technical issues around IP.
- On trade, it examines relevant WTO agreements, the role, inter alia, of competition policy, government procurement, trade flows of medical technology, and analyses relevant provisions of selected Free Trade Agreements.

In the framework of the negotiations for the sharing of influenza viruses and benefits, WIPO has, on request of WHO, contributed **patent search reports** on H1N1 and H5N1.8 WIPO has also published a comprehensive report on freedom-to-operate and global access related to dengue vaccines.9 In 2014, WIPO's Standing Committee on Patents requested that the WIPO Secretariat prepare a "Feasibility Study on the Disclosure of International Non-proprietary Names (INN) in Patent Applications and/or Patents".10 This report was prepared in close collaboration with WHO and WTO. WIPO also contributed its IP expertise to WHO's Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property11 as well as broader policy goals.

A series of **Joint Symposia** have been co-organized in Geneva by the trilateral partners since 2010 (see also Box 1). These events are designed to improve the flow of practical information and to guide and support

technical cooperation. The symposia achieve this by bringing together experts from all over the world to discuss current developments and trends in access to, and innovation of, medicines and other medical technologies. In addition to broadening public understanding of the issues, the symposia help the partner organizations to identify areas for further cooperation.

When implementing international standards at the country level, policymakers working on public health, IP and trade look to international organizations for guidance and training. WHO, WIPO and WTO cooperate and coordinate their **capacity in building and training activities** in order to make best use of their respective areas of expertise. These activities include a comprehensive IP and health component, which the three organizations design and implement in close collaboration (see Box 2).

The Response of Member States

The Member States of WHO, WIPO and WTO have welcomed the increased cooperation between the agencies and in particular, the information and insights generated in support of more effective policymaking and implementation. TRIPS Council delegates from China, 12 the EU, 13 India, 14 and the US, for example, have drawn on the Trilateral Study and related studies on tariffs on medicines, the burden of disease 15 and innovation. 16 Information from the study has also fed into the deliberations of WIPO's Standing Committee on Patents, in particular its study on the role of patent

Box 2: Examples of trilateral cooperation in capacity building and training

- National Workshops on Issues at the Intersection between Intellectual Property and Public Health.
- WIPO Seminars on Flexibilities in IP Law in South Africa and Kazakhstan (2013).
- WTO Workshops on Trade and Public Health (annual).¹⁷
- WTO-WIPO Colloquium for Teachers of Intellectual Property (annual). 18
- WIPO-WTO Advanced Course on Intellectual Property for Government Officials (annual). 19
- WHO/WIPO/WTO Joint Workshop on Patent Searches and Freedom to Operate (2011).
- WHO/Government of India Colloquium on IPRs for High-Level Policymakers in New Delhi (2014).

Key Implications & Considerations for Policy & Policymakers

The following implications and considerations for policy and policymakers are intended as starting points for reflection, to be adapted to specific needs and circumstances:

- Public health has been a priority for global action for many years. The right to the enjoyment of the highest attainable standard of physical and mental health is a universal human right, just as the burden of disease is shared by all humanity.
 In the age of globalization, progress made in public health in one country has an impact on the international community as a whole. Consequently, a compelling case can be made for effective international cooperation in public health, and such cooperation is an essential foundation for sustainable development.
- Public health and medical technologies are an important focus of the international system, including in the system-wide work of the United Nations most notably in the Millennium Development Goals (MDGs) and now the Sustainable Development Goals. The founding objective of WHO is the attainment by all peoples of the highest possible level of health. In addition, WIPO and WTO in line with the mandates given to them by governments and their respective areas of expertise have increasingly stepped up their efforts to support global endeavors to improve health outcomes.
- The complementary expertise of the three organizations, applied in coordination, can offer real benefits to policymakers at the national level. Given the "policy space" under the TRIPS Agreement, national policymakers and government officials are faced with the challenging task of identifying the right mix of policy options to best advance their national objectives. Coherent, comprehensive and accessible information can help inform their decision-making.
- There is today a richer, more diverse and more inclusive body of empirical data and practical experience available to guide technical cooperation. The technical cooperation offered by the three organizations has been characterized by active dialogue, coordination and partnership, leading to more effective and tailored capacity-building activities, all based on a better-informed factual background. The three agencies will continue to work, together with other international partners, towards the shared objective of better health outcomes for all.

systems in promoting innovative medicines, and in fostering the technology transfer necessary to make generic and patented medicines available in developing and least developed countries.²⁰

Future Plans

WHO, WIPO and WTO will continue to host annual trilateral symposia on topical issues. They will also continue to collaborate, within their respective mandates and budgets, to ensure the exchange of data, experiences and other information of benefit to policymakers.

A major activity underway is the development of distance-learning courses based on the Trilateral Study, facilitated by the WIPO Academy, to be launched in 2016. An introductory program provides an overview of the factors that shape access to, and influence innovation of medical technologies. The course describes the many overlapping factors that span the policy fields of public health, IP and international trade. A more advanced course will examine the subjects covered in the Trilateral Study in greater depth in far greater detail.

- 1 www.ow.ly/SMEhg
- 2 www.ow.ly/SMMvf
- 3 www.ow.ly/SMR0e
- 4 www.ow.ly/STWab

- 5 www.ow.ly/SMRbk
- 6 The 2015 symposium took advantage of the 20th anniversary of the establishment of the WTO and the TRIPs Agreement, and reviewed the information base on access and innovation in medical technologies. It also identified possibilities and limitations for better integrating data in support of policymakers' future work (see www.ow.ly/SMT5X).
- www.ow.ly/SMRDV
- 8 www.ow.ly/SMSG5
- 9 www.ow.ly/TdfY8
- 10 www.ow.ly/TdgfB
- 11 www.ow.ly/TfuZy
- 12 IP/C/M/74/Add.1, para 79 and IP/C/M/77/Add.1, para 162
- 13 IP/C/M/74/Add.1, para 100
- $14\ IP/C/M/74/Add.1, para 101, IP/C/M/77/Add.1, paras 153-155, and IP/C/M/79/Add.1, paras 201, 209-210$
- 15 www.ow.ly/SMTT0
- 16 www.ow.ly/SMTT0
- 17 www.ow.ly/SMTgf
- 18 www.ow.ly/SMT1T
- 19 www.ow.ly/SMTs4
- 20 www.ow.ly/SMU2i

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WIPO Global Challenges Briefs provide overviews of issues relevant to debates about solutions to global challenges, such as climate change, public health and food security.

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