## Policy coherence for improved medical innovation and access

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Public policy-making is an increasingly complex undertaking in a globalizing world, especially as policy domains formerly viewed in isolation become more intertwined. This complexity marks the interplay between health, intellectual property and trade policies. Can such interplay be managed so as to enhance the discovery, development and delivery of medical technologies for better health services and outcomes? This question is at the heart of a joint study on promoting access to medical technologies and innovation recently launched by the World Health Organization (WHO), the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO).1

The study, conceived as a coherent, systematic and transparent information base for the capacity-building programmes run by the three agencies, is a practical compendium of useful policy information that showcases the value of multilateral interagency cooperation.

This collaboration flows from a shared understanding that the protection of human health is the foundational rationale for international cooperation, and it provides a focus for analysing the interplay between intellectual property, trade and health policies. At the global political level, this focus is underpinned by WTO's Doha Declaration on the TRIPS Agreement and public health,2 WHO's global strategy and plan of action on public health, innovation and intellectual property3 and WIPO's development agenda.4 This trilateral study maps the complex policy landscape affecting medical innovation and access and helps readers to navigate this territory through empirical data, practical examples and descriptions of current and emerging challenges. Although intellectual property and trade policy settings feature prominently in this landscape, their role and impact can only be assessed holistically, within a wider cluster of interacting policy domains that together determine health outcomes.

Medical innovation and access to its products are mutually dependent. Universal health coverage cannot be achieved without continued needsbased medical innovation, alongside expanded access to essential technologies, now recognized as integral to the human right to health.<sup>5</sup> Policies surrounding universal health coverage require the careful integration of linked measures: prioritization of medical technologies, quality assurance through effective regulation, efficient procurement, reliable supply and product affordability through appropriate pricing policies.

Innovation, research and development, and technology diffusion are costly and risky and falter without appropriate incentives. Policy on intellectual property aims to incentivize innovation in the public interest, and the patent system has spurred much medical product development. However, business models built entirely on commercial incentives and strong markets may not deliver when purchasing power is weak. The study reviews new innovation and incentive models, including the concept of de-linkage of product price from research costs, and the emergence of new players and partnerships (e.g. product development partnerships) and of new collaborations (e.g. WIPO Re:Search),6 especially to address evident market failures.

All countries rely heavily on international trade in health-related products and services, which has grown in recent years - from 92 000 million United States dollars (US\$) in 1995 to US\$ 500 000 million in 2010. This trade and the resultant access to medical products are enhanced provided import tariffs do not make medical products more costly. Developed countries have largely eliminated tariffs on health-related products, in line with a WTO agreement on pharmaceutical trade;7 other countries have lowered tariffs, but the picture is still mixed.

A complex web of multilateral, plurilateral, regional and bilateral trade agreements governs this trade, which makes legal and policy analysis challenging, particularly as these agreements touch on regulatory and commercial policy settings. Positive public health considerations, such as the policy options and flexibilities available under the WTO's TRIPS Agreement, are generally built into multilateral trade agreements. The study explains the use of flexibilities to leverage access to medicines, notably antiretrovirals, yet effective promotion of medical innovation and sustained access to medical technologies require the coherent, mutually supportive functioning of a much wider mix of trade policy measures. The study considers the health implications of trade agreements covering policy domains such as competition, tariffs and non-tariff measures, trade in services, technical barriers to trade and government procurement. It contrasts rules set under the trade agreements with a growing trend towards bilateral standardsetting in these areas outside the WTO.

The analysis conducted in the study helps policy-makers from different backgrounds grapple with these interlocking issues when formulating policy. The trilateral cooperation brings home the vital need for policy coherence across diverse policy areas, founded on clear vision and a willingness to cooperate at the national and multilateral levels. National health, trade and intellectual property policy-makers need to learn from each other and to respect each other's perspectives. The trilateral cooperation between WHO, WIPO and WTO pursues the same goal on the international plane: supporting their members coherently and effectively to improve health policy.

## References

Available at: http://www.who.int/bulletin/ volumes/91/5/13-122705

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## References

- Promoting access to medical technologies and innovation: intersections between public health, intellectual property and trade. Geneva: World Health Organization, World Intellectual Property Organization & World Trade Organization; 2012. Available from: http://www.wto.org/english/res\_e/ publications\_e/who-wipo-wto\_2013\_e.htm [accessed 3 April 2013]
- World Trade Organization. Declaration on the TRIPS Agreement and public health, adopted 14 November 2001. Geneva: WTO; 2013. Available from: http://www.wto.org/english/thewto\_e/minist\_e/min01\_e/mindecl\_ trips\_e.htm [accessed 3 April 2013]
- Global strategy and plan of action on public health, innovation and intellectual property. Geneva: World Health Organization; 2011. Available from: http://www. who.int/phi/publications/gspa-phi/en/index.html [accessed 3 April 2013]
- World Intellectual Property Organization [Internet]. Development agenda for WIPO. Geneva: WIPO; 2013. Available from: http://www.wipo.int/ ip-development/en/agenda/ [accessed 3 April 2013]
- 5. Hogerzeil HV, Mirza Z. The world medicines situation 2011: access to essential medicines as part of the right to health. Geneva: World Health Organization; 2011. Available from: http://apps.who.int/medicinedocs/en/m/abstract/ Js18772en/ [accessed 3 April 2013]
- World Intellectual Property Organization [Internet]. Guiding principles of WIPO Re:Search. Geneva: WIPO; 2013. Available from: http://www.wipo.int/ research/en/about/guiding\_principles.html [accessed 3 April 2013]
- World Trade Organization [Internet]. General Agreement on Tariffs and Trade: trade in pharmaceutical products. Geneva: WTO; 1994. Available from: http://www.wto.org/gatt\_docs/English/SULPDF/91770009.pdf [accessed 4 April 2013].