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## Promoting global health: utilizing WHO to integrate public health, innovation and intellectual property

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The appropriate role of innovation and intellectual property (IP) in global public health is a controversial issue. Discussion is one-sided, with potential benefits advocated by industry in stark contrast to condemnation by certain civil society players. WHO's Public Health, Innovation and Intellectual Property Department (PHI) was established to address healthcare resource need for developing countries, assess impact of innovation and IP on access to medicines, explore innovative funding mechanisms for R&D and provide evidence-based policy-making recommendations in response to the changing global health landscape. Importantly, PHI could represent a potential forum to bridge shared, yet often diverse, interests and opportunities between various public and private stakeholders, a crucial issue for ensuring the future viability of WHO.

### Introduction

As global health encompasses concerns and considerations beyond geopolitical borders, stakeholders are concomitantly expanding and engaging as they never have before. However, the resulting arsenal of overlapping, conflicting and misaligned incentives are well illustrated in key global health challenges such as global drug supply safety, where continued conflict regarding the appropriate 'definition' of counterfeit medicines, within the context of commercial rights and access, has stymied needed action [1].

One key area is the rapidly expanding interface of intellectual property (IP), innovation and access to medicines. The global health environment has created an urgent need to find areas of consensus to balance public health goals and innovation incentives. Building upon existing infrastructures, and adapting WHO's potential to

bridge communication and assessments among stakeholders, can help identify opportunities to promote global health interests now and provide needed innovation incentives for the future.

### The environment for innovation, IP and global health

The appropriate role of innovation and IP in global health is a controversial yet crucial topic [2,3]. This discussion includes international treaties with public health implications, such as the World Trade Organization (WTO) Trade-Related Aspects of Intellectual Property Agreement (TRIPS) establishing minimum global IP standards and the Doha Declaration that reaffirmed the importance of public health considerations under TRIPS. In addition, this also includes various regional and bilateral trade arrangements with IP provisions impacting

public health, technology transfer efforts to resource-poor countries, data-exclusivity provisions and patent linkage requirements in drug registration systems, and new and innovative forms of IP management (such as the Medicines Patent Pool) [2,4–6].

Current global health challenges require careful bridging of innovation and IP with public health goals. This includes assessing the potential impact of emerging markets and least-developed countries (LDCs) that have recently transitioned, or are in the process of transitioning, to TRIPS requirements on access to medicines and drug development [7,8]. As an example, in 2005, emerging markets such as India represented an estimated 22% of all generic drug production globally and 80% of the global market share for antiretrovirals, and implemented TRIPS along with other large-scale

generics producing countries such as Brazil and China [9–11]. Countries that meet the criteria of an LDC have until 2016 to come into compliance with TRIPS [11]. Commentators have argued that recent and future TRIPS implementation will impact access to new and future drugs and restrict past unauthorized production of generics, leading to reduced competition, higher prices and reduction in supply that could have a detrimental impact, especially for LDCs with limited manufacturing capacity [9–12].

However, the importance of research and investment in this space is not limited to public sector concerns. From a private industry perspective, the high cost of drug discovery and impending patent expiration of many current blockbuster drugs presents significant hurdles for future commercial viability [13–15]. Hence, the private sector must also respond to a changing global health landscape through more-effective drug development, IP management, and equitable technology transfer and pricing of medicines meeting the diverse needs and socioeconomic status of different patient populations. Proper incentivizing of R&D (e.g. such as advanced market commitments, prize funds, tax credits, public–private partnership models) for development of medicines that treat neglected tropical diseases is one example where current efforts target leveraging public and private sector collaboration and development of innovative funding and business models to address unmet public health needs [16–18].

### WHO role in innovation, IP and global health

WHO, as the world's preeminent public health entity, has a well-established role in promoting global health. Through a wide array of programs and policies, it has addressed key global health concerns including pandemics and infectious disease control, as well as recently focusing on non-communicable diseases and identifying underlining social determinants of health.

### The WHO Secretariat on Public Health, Innovation and Intellectual Property

Less well known are WHO's important efforts to assess and promote policy that maintains incentives and develops funding mechanisms for innovation that is core to global health. WHO Secretariat on Public Health, Innovation and Intellectual Property (PHI) was established in 2006 to explore potential links between public health, innovation and various forms of IP to improve access to healthcare resources and medicines [19].

The initial formation of the Intergovernmental Working Group and subsequent adoption by the

World Health Assembly (WHA) of a global strategy and plan of action on public health, innovation and intellectual property (GSPOA) established a central and strategic role for WHO in assessing and providing technical assistance in this area [20].

PHI was formed to facilitate implementation of this mandate and the core elements of GSPOA which focused upon promoting innovation, capacity building and access to and mobilizing of health-related resources [21]. This includes promoting innovative R&D funding mechanisms, assisting in evidence-based policymaking and rendering technical assistance to member states (including providing guidance on obligations and rights of member states under international treaties). In addition, PHI supports analyses of trade and health issues, engaging in training and education with other agencies and sector-wide coordination through mobilization of resources [21]. Although still a relatively new program with limited funding, PHI has begun efforts with the potential to make a lasting imprint on global public health policy.

Highlighting these efforts was PHI's coordination of the Consultative Expert Working Group on Research and Development (CEWG) established by the WHA in 2010; its mandate was to assess and recommend innovative forms of financing and coordination for development of health products and technologies [22,23]. This included assessing proposals for use of new patent pools, open source R&D platforms, innovation prize funds, purchase or procurement agreements, taxation mechanisms and incentives, direct grants to small and medium-sized enterprises and a biomedical R&D treaty [24]. CEWG issued its final report in May 2012 which included recommendations that all countries should commit at least 0.01% of GDP to R&D devoted to meeting health needs of developing countries and beginning intergovernmental negotiations on a Global R&D treaty: an international binding instrument long advocated by several civil society organizations [24]. Recently, the 65th WHA adopted a resolution to hold open-ended member state meetings to assess the feasibility of CEWG's recommendations [25].

A key role of PHI is also providing ongoing technical support to member states and guidance on TRIPS flexibilities (i.e. public health measures member states can take under TRIPS), including guidelines for the 'Paragraph 6' system that allows the export of pharmaceutical products manufactured under compulsory licenses [26]. Navigating the complex web of global, regional, local laws, regulations and agreements with trade and IP implications can be extremely

challenging for LDCs. This necessitates direct country support and broader technical capacity-building by PHI through targeted research, technical briefing papers and in-country training [26].

A further strength of PHI is its ability to coordinate actions among intergovernmental UN agencies to address shared linkages between public health, IP and trade. This has culminated in the WHO–WTO–World Intellectual Property Organization Trilateral Cooperation arrangement that includes regular meetings, information exchange, coordination of research, budget discussions and an in-progress trilateral study on promoting access to medical innovations [27]. Through this framework, PHI has become a major stakeholder in promoting cooperation and coordination of shared interests in IP and public health.

### WHO PHI reform

There are, however, several areas where the PHI has failed to take advantage of opportunities for consensus building. This includes the need for even greater policy coherence within this emerging global health policy framework.

One important area that has been neglected is active promotion of the WHO Research for Health Strategy, a common framework for prioritizing research in WHO and establishing WHO's role in global health research. This framework could act as a potential model for effective global health research governance with WHO acting as the central authority and coordinating body for prioritizing health research and standard setting [28]. Within the scope of this relatively unknown strategy are opportunities to consolidate and more-effectively mobilize various resources of global health players into a prioritized global health research agenda.

Using this platform would eliminate existing redundancies in global health funding and the multiplicity of monitoring and evaluation requirements currently hampering delivery of health interventions in LDCs with limited resources [29]. Although the department originally tasked with implementing the WHO Research for Health Strategy was shut down owing to lack of funding, this task it is now within the scope of PHI. CEWG also highlighted the need to reinvigorate this strategy through its recommendations for global coordination in health R&D for developing country needs as part of the current WHO reform process [24]. It advocates that WHO should have a central role by collecting and analyzing R&D data and coordinating advisory mechanisms [24].

In addition, PHI has not adequately engaged with non-member state stakeholders in collaborative exercises, despite the fact it represents an appropriate forum for these activities. PHI can expand its efforts from primarily providing technical assistance to member states in assessing and funding innovative technology products to more-actively facilitating partnerships with the public sector, private foundations and industry [30]. This should include establishing joint programs for funding of innovation activities by LDCs with other agencies such as the World Bank, and developing public-private partnerships to align IP management tools and mutually beneficial drug discovery practices, including shared investment in local manufacturing of medicines and equitable technology transfer to improve access [31–33]. Examples of past joint programs include the Joint Funding Platform of the GAVI Alliance, the Global Fund and the World Bank facilitated by WHO for health system strengthening [34]. In this context, PHI could extend its own technical expertise to strengthen drug regulatory delivery systems and policies, prioritize R&D funding aligned with local country priorities, coordinate multi-sector funding and strengthen health systems and technical capacity through training.

Indeed, this need for common ground comes at a time when continued efforts in this area are crucial. On one hand, TRIPS transition for LDCs occurs in 2016, whereas, by contrast, there is growing pressure on industry to develop innovative business models to improve drug access to needy populations. Further, concerns of possible declines in generic medicine production (highlighted by attempts by Novartis to gain patent protection for Gleevec<sup>®</sup> in India following TRIPS adoption), the need for more data regarding patents and medicines and broad impact of trade and IP issues for public health emergencies creates greater urgency for collaboration [11,35,36].

Recognition of the need for broader stakeholder involvement within WHO governance and the current pragmatic needs for external funding create opportunities for PHI to engage in broader consensus building and policymaking across the global health governance spectrum [37]. Indeed, WHO was previously taking steps toward greater participation of non-state players by exploring the establishment of the World Health Forum which is no longer being contemplated [37]. PHI could act as an effective agent to bring these stakeholders together in such a similar future forum.

Because WHO PHI occupies a unique operational and policy space in global health that

cannot be easily replicated by another organization, it can transform IP from a potential barrier to a coordinated component to promote global health objectives. Bridging the current gap between divergent perceptions and interests regarding public health and IP and facilitating implementation of TRIPS obligations, as well as available flexibilities, requires a respected forum for study and broader stakeholder inclusion. PHI, as an engaged WHO actor, can provide the substantial expertise and leadership needed to address these complex issues of health, innovation, trade and IP by coordinating public and private sector partnership. Adapting this current structure to engage a future vision of global governance inclusion that not only transcends geopolitical lines but also public-private divisions can promote innovation and drug development for all parties concerned.

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