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Public Health and “Counterfeit” Medicines: The Role of the World Health Organization

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Introduction

The normative and policy-setting functions of the World Health Organization (“WHO”) have been substantially influenced by the differences of opinion within WHO’s membership about the impact of trade and intellectual property (“IP”) rules on public health. In particular, WHO members differ as to the organization’s role in addressing the perceived failure of the pharmaceutical market to generate safe and affordable medicines for diseases predominantly affecting developing countries.

A number of ongoing developments in the WHO demonstrate the difficult interface between trade, health, IP, and medicines. This *Insight* will provide a short overview of one that has recently progressed to the implementation stage, namely the role of a public health agency such as the WHO in the fight against “counterfeit” medical products.

Background

Fraudulent, falsified, and substandard medicines pose a considerable threat to health as they can fail to cure, promote antimicrobial resistance, and even kill patients. This problem has been exacerbated by weak national regulatory systems and supply chains, and the explosion of largely unregulated internet trade. Fraudulent activities concern both patented and cheap generic medicines, and the diffused nature of such a global problem makes it difficult to obtain reliable data on its extent. What is clear is that preventing and fighting substandard or falsified medicines is a complex global issue requiring technical and regulatory capacities at the national level, law enforcement, international cooperation, and interaction with international legal instruments on IP protection and illicit drug trafficking.

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Given the growing public health impact of counterfeit medicines, the World Health Assembly (“WHA”) has requested the Secretariat since the late 1980s to develop programs on “falsely labeled, spurious, counterfeited or substandard” medicines^[1] within the general framework of the WHO’s normative activities on the quality and safety of medicines. The WHO’s involvement in this difficult area has recently been challenged on the ground that the organization is veering towards the protection of trademarked and patented medicines and inadvertently promoting a “TRIPS-plus agenda” to the detriment of legitimate high-quality generics, rather than focusing on the impact on health and health systems of substandard and fraudulent medical products.

Health and Intellectual Property Perspectives of Counterfeit Medicines

Two events that precipitated the rather acrimonious debate in the WHO’s governing bodies since 2009 were the WHO’s leadership in establishing and coordinating the “International Medical Products Anti-Counterfeiting Taskforce” (“IMPACT”), and the seizure in 2008 and 2009 by Dutch and German customs authorities of several shipments of generic medicines in transit—mostly from India and destined for Latin American countries—on the ground of patent infringement.

IMPACT is an alliance of national medicines regulatory authorities and international organizations (including the European Union, World Trade Organization (“WTO”), Organization for Economic Co-operation and Development (“OECD”), and INTERPOL), as well as international associations representing pharmaceutical manufacturers, among others. IMPACT’s establishment in 2006 reflected the need for broad collaboration among the different sectors addressing medical “counterfeit” and constituted a reaction to the lack of consensus towards negotiating within the WHO an international agreement on “counterfeit medicines.” IMPACT’s main objectives are creating awareness, promoting intersectoral coordination, developing technical competencies, and promoting investigation and enforcement capabilities with regard to “counterfeit” medicines.^[2] The Secretariat of IMPACT was provided by the WHO until 2011 and then transferred to Italy’s medicine agency.

The main challenges to the WHO’s involvement were the lack of legitimacy as the policy initiative had not been approved by the WHA, the use of concepts and approaches linked to IP rather than public health protection, and the involvement of international agencies working on the enforcement of IP rights, including with regard to “counterfeit medicines.” The discussions in the WHO’s governing bodies revealed the conceptual and political difficulty of agreeing on the kind of products that should be prevented and controlled, and in particular the differences between “counterfeit” from an IP versus public health perspective.

From an IP perspective, counterfeiting, as defined in the WTO’s Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”), essentially entails unlawfully bearing a registered trademark, and the victims of counterfeiting are the trademark owners, who can seek private enforcement of their trademark rights.^[3] In some cases, references to counterfeit have been linked to the breach of any IP, including patents and industrial design.^[4] Such a broad approach to IP protection under the framework of anti-counterfeit enforcement was further exemplified by the conclusion in October 2011 by a number or largely OECD countries of the “Anti-Counterfeiting Trade Agreement,” which aimed to establish international standards for IP enforcement.^[5] The secretive negotiations towards this treaty, the draft text of which was disclosed only at a late stage, fostered more suspicions about the real agenda of the OECD countries in terms of the expansion and enforcement of IP rights, including in the public health arena.

In contrast, from a public health perspective, the greatest concern about counterfeit

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medicines is the risk to public health created by unsafe and unregulated products; in this respect, the victims are the consumers of those products and the national health systems burdened by the consequences. The fact that a product willfully breaches third parties' trademark rights is not a central consideration from a public health perspective. Enforcement and control therefore take on a different dimension and are unconnected to IP concerns.

Defining Counterfeit Medicines

The operational definitions of counterfeit medicines adopted by the WHO Secretariat in 1992 and subsequently revised by IMPACT in 2008 were criticized for not focusing exclusively on the safety, quality, and efficacy of medicines, and for incorporating IP language and considerations. The definition adopted by the WHO Secretariat in 1992 jointly with the International Federation of Pharmaceutical Manufacturers and Associations read:

A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredient or with fake packaging.[6]

“Counterfeit” as defined here is not used in the same way as in international IP rules but does combine various concepts.

The 2008 IMPACT definition more clearly explains the concern that references to counterfeit medicines could inject IP enforcement into public health matters. The definition developed by IMPACT read:

A medical product is counterfeit when there is a false representation in relation to its identity and/or source Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct components . . . or with the wrong components, without active ingredients, with incorrect amounts of active ingredi- ents or with fake packaging Substandard batches or quality defects or non-compliance with good manufacturing practices/good distribution practices (GMP/GDP) in legitimate medical products must not be confused with counterfeiting.[7]

Neither definition was endorsed by the WHO's governance but public health stakeholders relied on them as a generally accepted concept until they became controversial as a result of the recent debate. As a result, since 2011, the WHO has been using the expression “Substandard/Spurious/Falsely-labelled/Falsified/Counterfeit medical products” (“SSFFC”) to designate the range of products that may raise public health concerns and require international cooperation for the purpose of their prevention and control.

Recent Developments in the WHO

The controversy over the definition of counterfeit medicines and related tensions about the relationship between health and IP led the WHO Director-General to reaffirm at the 63rd WHA in 2010 that the WHO would focus on its mandate and address the public health aspects of counterfeit medicines. The Director-General indicated that the WHO “had no role and no competency in the enforcement of intellectual property rights” and that the

complexity of the problem required a multisectoral approach and presented the challenge of “knowing how to collaborate with other agencies and stakeholders without becoming part of their agenda.”^[8]

The WHA decided in May 2011 to establish an intergovernmental working group to examine the WHO’s role in ensuring the availability of quality, safe, efficacious, and affordable medical products; its relationship with IMPACT; and its role in prevention and control of SSFFC medical products “from a public health perspective, excluding trade and intellectual property considerations.”^[9]

The Working Group met twice in 2011. It failed to make progress on a definition that could replace “counterfeit” and was deadlocked concerning the continuation or suspension of the WHO’s participation in IMPACT. Nevertheless, the Working Group reaffirmed that the WHO’s main functions as a public health agency should be information sharing, elaboration of norms and standards, national policy development, and capacity building. It also agreed that substandard medical products—which could be legitimate products not meeting required quality standards—should be kept conceptually separate from falsified products for the purpose of international cooperation.

On the recommendation of the Working Group, the 65th WHA in 2011 established a new “Member State mechanism” (“MSM”) open to all WHO Member States and the European Union to promote collaboration from a purely public health perspective regarding SSFFC medical products. The MSM is a novel body in the WHO’s practice: it is not a negotiating committee with a time line and a defined outcome but rather a long-term platform for collaboration, policy formulation, and capacity building on the prevention and control of SSFFC medical products as a tool to promote access to medicines. As such, the MSM is an action-oriented body that will not limit itself to meeting annually, as required in its terms of reference, but is expected to conduct or oversee work on an almost permanent basis and to rely to that end on the WHO’s Secretariat and expert resources. The WHA, at the same time, requested the MSM to “collaborate with and contribute to the work of other areas of WHO that address access to . . . medical products . . . which should complement measures for the prevention and control of” SSFFC medical products.^[10] This distinction between a specific focus on SSFFC medical products and the broader issue of access to medicines could be seen as a way to avoid subjecting the crucial area of the WHO’s normative work on medicines—including promoting access to generic medical products and promoting safety and quality standards—to the oversight of a potentially politicized intergovernmental mechanism.

The MSM held its first session in Buenos Aires, Argentina, in November 2012. The MSM could not reach agreement on its workplan, and negotiations will have to continue at its next session in late 2013. As anticipated, differences of opinion persisted, especially with regard to the linkage between control of SSFFC medical products and access to medicines, in particular generics. This issue remains controversial, reflecting lingering debates about the impact of IP rules on access to medicines.

In a significant shift that could narrow the differences around an agreed definition of SSFFC medical products, the MSM accepted a proposal by Brazil to establish a working group to identify activities and behaviors that result in SSFFC medical products from a public health perspective.^[11] Shifting the discussion from trying to define the characteristics and legal status of products to focus on a set of activities could facilitate an agreement on the exact scope of international cooperation and the WHO’s role therein.

The MSM also decided to establish an enlarged bureau—described as a Steering Committee—comprising a chairperson and twelve vice-chairpersons (two for each of the six regions of the WHO’s membership). The terms of reference of the Steering Committee are

unusual, as they are not only substantive but also aim at closer intergovernmental oversight of the WHO Secretariat's activities than is normally the case in WHO practice. Although that approach may ensure ownership by WHO Member States, it may also lead to micromanagement and politicization of technical activities usually carried out by the Secretariat without such operational scrutiny.

Conclusion

The impression generated by the first session of the MSM confirms the trend of the last few years with regard to the discussion over the proper role of the WHO in the fight against SSFFC medical products. In particular, WHO Member States do not challenge the normative functions of the Organization or the importance of its technical cooperation role in strengthening national regulatory activities. Controversies, however, immediately arise as soon as Member States approach the interface between purely technical activities and issues of trade and IP policy. As long as this mistrust persists, an integrated and coordinated international effort to fight SSFFC medical products with the full participation of the WHO will be hampered. In view of the crowded institutional landscape, with numerous organizations playing a role in this area, the WHO faces a difficult policy and governance challenge.^[12]

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Endnotes:

[1] World Health Assembly [WHA], Res. 41.16 (1988).

[2] A description of the history, mandate, and activities of IMPACT can be found in World Health Organization [WHO], WHO's Relationship With the International Medical Products Anti-Counterfeiting Taskforce, Doc. A/SSFFC/WG/4, *available at* http://apps.who.int/gb/ssffc/e/ssffc_wg1.html (last visited Dec. 20, 2012).

[3] Agreement on Trade-Related Aspects of Intellectual Property Rights [TRIPS Agreement] art. 51, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), *available at* http://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

[4] Charles Clift, Combating Counterfeit, Falsified and Substandard Medicines: Defining the Way Forward? 7 (Chatham House Briefing Paper GH BP 2010/01 2010), *available at* http://www.accesstomedicineindex.org/sites/www.accesstomedicineindex.org/files/charles_clift_-_combating_counterfeit.pdf.

[5] European Commission, Anti-Counterfeiting Trade Agreement, Aug. 23, 2011, *available at* <http://ec.europa.eu/trade/tackling-unfair-trade/acta/>.

[6] World Health Organization [WHO], Report by the Secretariat, Counterfeit Medical Products, Doc. A62/13, ¶ 10 (Apr. 30, 2009).

[7] Clift, *supra* note 4, at 11.

[8] WHA Doc. A63/A/SR/6, at 14-15.

[9] Decision WHA 63(10) (May 21, 2010), *available at* http://apps.who.int/gb/or/e/e_wha63r1.html.

[10] WHA, Substandard/Spurious/Falsely-labelled/Falsified/Counterfeit Medical Products, Res. WHA 65.19 (May 26, 2012), *available at* http://apps.who.int/gb/e/e_wha65.html.

[11] WHO, Report of the First Meeting of the Member State Mechanism on Substandard/Spurious/Falsely-labelled/Falsified/Counterfeit/Medical Products, Doc. A/MSM/1/4 (Dec. 14, 2012).

[12] Jonathan Liberman, *Combating Counterfeit Medicines and Illicit Trade in Tobacco Products: Minefields in Global Health Governance*, 40 (2) J.L. Med. & Ethics 326, 334-37 (2012).