Trade and Health: The Contentious Issue of Counterfeit Medicines

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Introduction

Article 2(u) of the Constitution of the World Health Organization (WHO) defines the development of norms, standards and guidelines for quality control of pharmaceuticals as one of the Organization's main functions. This mandate has been endorsed by many resolutions of the World Health Assembly (WHA), particularly resolutions 41/16 of 1988 and resolution 47/13 of 1994, which called on the Organization to initiate a program for the "prevention and detection of export, import and smuggling of falsely labeled, spurious, counterfeited or substandard pharmaceutical preparations" and to assist member states in this endeavor.

The recognition of WHO's mandate in this area derives from the consensual acknowledgement that the counterfeiting of medicines represents a clear threat to human life and health, as well as to the credibility of health systems; hence, constituting a public health issue of important concern for all. Accordingly, the topic of "counterfeit drugs" is not at all new and, indeed, has been addressed at different levels since the 1980s without raising major controversies, for instance during the International Conferences of Drug Regulatory Authorities (ICDRA), and most specifically in the 1985 Nairobi Conference of Experts on the Rational Use of Drugs.

From 2006 onwards, nevertheless, the topic grew bigger to become one of the main contentious items of the global health agenda. The reason to that lies behind the often-evoked tension between public health goals and commercial interests. Such a controversial scenario is also revealing of the fact that, when it comes to global health governance, no issue is completely free from conflict of interests; and no matter how technical the WHO is, or claims to be, it is an Organization undeniably embedded in politics.

Developments

The controversy about counterfeit medicines has one of its starting points in the fact that, whereas in the world of intellectual property law, i.e.: in the World Trade Organization (WTO) and within the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), counterfeiting has a very precise meaning related to trademarks infringements; in the field of public health law, on the other hand, there is no agreed definition and a range of terms have been used interchangeably and indiscriminately to describe the problem of "fraudulent", "spurious", "fake", "falsified" or "substandard" medicines. Additionally, counterfeit is defined differently among countries, whose definitions may or may not include intellectual property (IP) rights' aspects. Consequently, since many countries do not have legal instruments specifically designed to combat those kinds of drugs from a strict public health perspective, particularly less developed countries, authorities have tended to use or rely on non-specific instruments related to the protection of trademarks as a way to combat the problem.

As a result of this situation, in 2006, there was a call out of the 11th ICDRA for legal regulation, that is, for an International Convention on the topic. However, what came into being instead was an International Conference on Combating Counterfeits Drugs,[2] which adopted the Declaration of Rome that launched the International Medical Products Anti-Counterfeiting Taskforce, or so-called IMPACT initiative; a multi-stakeholder partnership hosted, at the

time, by WHO Secretariat. This was the moment when all confusion around the topic crystalized in a huge battle at the WHA.

IMPACT is in the hart of the controversy because it led some WHO member states to question the legitimacy and accountability of the global response to counterfeits. Countries like Brazil, Indonesia, Thailand and India accused IMPACT of not being endorsed by the WHA, nor by the WHO's Executive Board (EB), and being comprised of mainly developed countries and big pharmaceutical companies, lacking representation of developing countries. Among other issues, there was also a big concern related to the lack of reliable statistics and empirical data on the extent and nature of the problem, what could potentially lead to manipulation.

The main accusation was that under the guise of helping to address dangerous and ineffective medicines, OCDE countries and businesses were pushing to strengthen an IP-enforcement agenda with reliance on police – rather than health regulatory – action. Those countries raised concerns, which were also supported by non-governmental organizations (NGOs) like the Third World Network and Oxfam, about how such policy was posing serious threats to the legitimate trade in generic drugs. This point became particularly contentious after the incident in 2008 of the detention by EU custom authorities of shipments of generic medicines in transit from India to Brazil.[3]

The issue, nevertheless, was not a simple question of North-South divide. The group of developing countries fell short of being homogenous or coherent. Moreover, arguments advanced by countries like Brazil and India differed from the ones raised by Least Developed Countries, which could potentially benefit from technical support and transfer of expertise from the initiative.

The year of 2010 was the peak of intense political discussions and consequent legal developments. It was by then that some WTO members adopted its Anti-Counterfeiting Trade Agreement (ACTA), and the Council of Europe adopted the Convention against Counterfeiting of Medical Products and similar Crimes involving threats to Public Health (MEDICRIME, not yet in force). In this same year, the issue was also raised within the World Intellectual Property Organization (WIPO) and dealt with at the United Nations, by its Office on Drugs and Crime (UNODC), as well as by the Commission on Crime Prevention and Criminal Justice, which adopted a resolution on the subject in 2011 (Resolution 20/6).

In 2010 the topic raised such a level of controversy that even WHO credibility was put into question. A good illustration of the heated debate is provided by the pronouncement made by Kenya during a WHA session, expressing that IMPACT had talked its government into adopting anti-generic trade laws. In this regard, an interesting development from April 2012 is the landmark judgment delivered by the Kenyan High Court in the case of *Patricia Asero Ochieng and Others v. the Attorney General & Another* , which held that three sections of the Kenya Anti-Counterfeit Act of 2008 were unconstitutional because they represented a threat to the right to life, dignity and health.[4]

The extent to which WHO's credibility was questioned ultimately motivated the Secretariat's decision to disengage and suspend its involvement with IMPACT. A Working Group (WG) of member states was hence set up to discuss the way forward. The final result of this "WG on substandard/spurious/falsely-labelled/falsified and counterfeit medical products" was released in May 2011 as a typical decided-not-to-decide-decision: they agreed not to discuss definitions, but that substandard is a different category of drugs; they recognized the role of WHO in the area excluding IP questions; and, finally, suggested the creation of a mechanism comprised of all WHO member states, i.e.: an intergovernmental commission with transparent advisory functions that would report directly to the WHA and the EB – instead of an expert commission under the umbrella of a the WHO Expert Committee on Specifications for Pharmaceutical Preparations, which was another proposal.

Since then, the topic has to a certain extent downgraded its relevance as debates cooled down, but it certainly remained in the agenda for the forthcoming sessions of the WHA. Next outcomes and developments yet remain to be seen.

Final Remarks

As a matter of conclusion, it is important to point out that counterfeits medicines thrive mainly where environments allow, meaning that certain conditions may favor its existence. As such, those must be taken as a crucial part of the equation on how to solve the problem. Those factors include, among others, the unwillingness or unawareness of public authorities, inadequate legal frameworks, lack of sanctions, ineffective control, investigation and persecution, and finally, perhaps most importantly, socio-economic factors like inadequate access to health services, fragmented and unreliable supply channels and the high costs of medicines. An appropriate answer to the question can only be found if states start to tackle seriously those underlying reasons to why counterfeits medicines are still an unfortunate reality.

The trade of medicines is of a different nature than the trade of other goods, because in principle the purchase of drugs does not depend on a purely individual decision; in fact, it follows a medical prescription and it is primarily driven by strict necessity. Against this background, access to safe and reliable medicines for all becomes the crucial element in the fight against counterfeiting. In this regard, tackling ways to reduce the extremely high prices of drugs available, as well as finding alternatives for the promotion of research and development (R&D) for neglected diseases, must be taken as important elements in the negotiation table.

The tension revolving around "how to ensure universal access to essential medicines, how to realize the right to health for all, and at the same time guarantee quality and safety standards" will possibly not disappear as quickly as one might wish. But a positive way forward seems to be possible only if WHO is allowed by its members to perform its full governance potential in this regard; that is, by strengthening the enactment of global norms and standards to help shaping the demand, ensuring technical assistance to national regulatory systems, and guaranteeing an effective global monitoring system and reliable database. Leadership, governance and cooperation are urgently required in this field.

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[2] Attended by only 57 states, together with 7 International Organizations and 12 Associations.

[3] Those detentions have even give rise to a dispute before a WTO panel:

http://ictsd.org/i/news/bridgesweekly/75730/

[4] Available at: http://www.iqsensato.org/blog/2012/04/23/kenya-anti-counterfeiting-act-struck-down/print/

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