

Access to medicines: a dead-lock between health and trade!

Acesso a medicamentos: impasse entre a saúde e o comércio!

Acceso a los medicamentos: ¡el estancamiento entre la salud y el comercio!

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doi: 10.1590/0102-311X00123117

The importance of medicines for access to health has drawn growing attention since the Conference held by the World Health Organization in 1985, consolidating the notion of access to medicines as a central component of primary care ¹. Thirty years later, a Commission was established to assess the impact of essential medicines on universal healthcare coverage, discussed in the sphere of the World Health Organization ².

And we repeat familiar questions: what has changed in these three decades, and why do we continue to face the same issues and engage in the same struggle? Year after year, access to medicines and the clash between health and trade are repeated in all the global health forums. The World Health Assembly has discussed the issue every year for the last two decades. The World Trade Organization (WTO) TRIPS Agreement (*Trade-Related Aspects of Intellectual Property Rights*) signed by all the member states in 1995, the *Millennium Declaration* with the *Millennium Development Goals* in the year 2000, and the *Doha Declaration* on the TRIPS Agreement and Public Health, also in 2000, assigned even greater importance to this confrontation ^{2,3}.

Facing heavy resistance, the 70th World Health Assembly in May 2017 indirectly included on its agenda the discussion on access to medicines and proved particularly reluctant to discuss the Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines ³. The issue was only addressed timidly on the agenda of the World Health Assembly (http://www.who.int/gb/e/e_who70.html, accessed on 18/Jul/2017), avoiding the approval of resolutions or decisions that implicitly mentioned the High-Level Panel, only including it in more general discussions.

From the global health perspective, we feel it is essential to discuss the reasons for this resistance by a United Nations agency responsible for coordinating activities in the field of public health. The resistance, displayed by a large share of the WHO Secretariat, responds to pressure by large countries and donors, who have repeatedly attempted to prevent the WHO from addressing sensitive issues, especially those related to intellectual property and the clash between health and trade. The current innovation and intellectual property system clearly assigns privilege to individual rights over collective rights and fails to prioritize access to health as a fundamental human right ^{4,5,6,7}. Such denial by the WHO runs counter to the other United Nations agencies, where all the recent forums have featured this issue on their agendas and in their events.

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Meanwhile, in the transition from the *Millennium Development Goals* to the *Sustainable Development Goals*, the issue of health and thus the issue of access to medicines occupy an outstanding place in ensuring health as a priority in all age groups. The Secretary-General's report for the post-2015 agenda explicitly mentions guaranteeing the availability of essential medicines⁸.

We contend that it is necessary to discuss the lessons learned, the progress made, and what remains to be implemented with the recent High-Level Panel mentioned above³. The report, published in September 2016, sparked a whole series of manifestations, the vast majority of which praised its content and admitted that the process carried out from November 2015 to September 2016 was a huge step forward on the issue of considering health and access to medicines as a fundamental human right. Clearly there were also voices against the report, due to the emphasis of discussions of intellectual property as a barrier to access to medicines.

The main progress we see in the report is that it takes note of the fact that access to medicines is no longer viewed as a problem only for low and middle-income countries, but constitutes a worldwide problem. Even in high-income countries, direct-acting antivirals for the treatment of hepatitis C, new cancer drugs, and other new products now show the inability of the respective health systems to cover the high monopoly prices charged for these products on the market^{9,10}. At the population level, this lack of access to medicines had already been detected by the WHO, but oriented to low or middle-income countries. The report shows clearly that the problem affects rich and poor countries alike and provides a set of 24 recommendations to overcome the gap in access to medicines³.

The recommendations address controversial issues like the flexibilities of the WTO TRIPS Agreement and the TRIPS-plus provisions found in free trade agreements that countries of the North implement bilaterally or regionally with countries of the South. The recommendations emphasize that all WTO member countries should commit, at the highest political level, to respect the letter and spirit of the *Doha Declaration* on the TRIPS Agreement and Public Health. They also explicitly state that governments should enact legislation to facilitate compulsory licensing to meet grounds of legitimate public health needs. The text also discusses public financing of research and development, frequently leading to patent registration. Other featured points are the obligations of governments, multilateral agencies, and the private sector.

One of the most widely discussed issues during the process was the need for discipline in investments in innovation, proceeding with the discussions already under way in the WHO on the establishment of global agreements for the coordination, financing, and development of health technologies. This includes negotiations on drafting a binding research and development (R&D) convention, capable of dissociating research costs from the products' final prices, thereby promoting access to these products. Very timidly, it was proposed that this convention begin its discussions with neglected tropical diseases and antimicrobial resistance, complementing existing mechanisms.

Comments were added separately to the report, specifying the need to go beyond the recommendations, including a list of off-patent essential medicines that could additionally lead different countries to recognize their own lists of medicines that would be left off the respective country's patent protection. This proposal was based on the analysis of the contributions received by the Panel during the discussion process and will still be the object of discussion and further elaboration on our part.

The clash between health and trade is not new, but it has become more evident and polarized^{4,5,6}. Based on Brazil's *1988 Federal Constitution*, the country has endeavored to implement policies for universal access that have been cited as an international example. However, the current underfinancing of the Brazilian Unified National Health System (SUS) and the recessive policies and loss of social rights denounced daily have given way to government policies prioritizing the private sector and backsliding on historical gains.

The issue of access to medicines is not limited to low-income countries or to a narrow range of diseases, so that when we address all diseases, we should adopt a change of terminology from "neglected diseases" to "neglected populations"^{7,11}. Respect for human rights and access to health as a fundamental human right are thus central components for improving the health conditions of the most vulnerable populations. If investment in innovation leads to the production of new medicines that are not affordable, it favors commerce with unbridled and sometimes even extortionist profits, to the detriment of health and the underlying principles of the right to life with dignity.

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Submitted on 18/Jul/2017

Approved on 24/Jul/2017