

# Pharmaceutical Services and global health governance in times of COVID-19

*Assistência Farmacêutica e governança global da saúde em tempos de Covid-19*

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DOI: 10.1590/0103-11042022133181

**ABSTRACT** This essay addresses how and at what levels Pharmaceutical Services is affected by the dynamics of global health governance, and how it correlates with geopolitical and socioeconomic aspects. It attempts to go beyond access to medicines and health products, as well as to address the rational use of medicines, the impact in antimicrobial resistance and in people's health. Furthermore, it debates how Pharmaceutical Services can be seen in this context.

**KEYWORDS** Pharmaceutical Services. Global health. COVID-19.

**RESUMO** *Este ensaio aborda como e em que níveis a Assistência Farmacêutica é atravessada pela dinâmica da governança global da saúde, e como se relaciona com aspectos geopolíticos e socioeconômicos. Tenta-se ir além do acesso a medicamentos e produtos para saúde, abordando também o uso racional de medicamentos, seu impacto na resistência aos antimicrobianos e na saúde dos povos. Além disso, discute como a Assistência Farmacêutica pode ser vista nesse contexto.*

**PALAVRAS-CHAVE** Assistência Farmacêutica. Saúde global. Covid-19.

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## Introduction

Global health governance can act through different types of regulatory instruments. The hard law, with legally binding instruments, restricts the practices of countries and transnational corporations through treaties, conventions, sanctions, among others. One of the examples of hard law in the health area, at a global level, is the Framework Convention on Tobacco Control of the World Health Organization (WHO), which has 182 countries and a series of binding commitments<sup>1</sup>. Soft law is more flexible, does not have a mandatory character and is implemented through resolutions, directives, intergovernmental policies, among other things. The WHO List of Essential Medicines<sup>2</sup> is an example of soft law.

In addition, global health governance also takes place in other ways, strongly influenced by the economic and political powers of non-state actors, who often ignore the multilateral system and place forums such as the WHO on the sidelines of the process. These actors include large transnational biopharmaceutical corporations, which are able to influence, directly or indirectly, the definition of global research priorities, the configuration of standards and the establishment of rules for their activities in the global market. As examples, there are the rules on trade of products and Intellectual Property (IP) – in particular, within the scope of the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO) –, ISO certifications and the standardization of nomenclatures. Additionally, increasingly, public-private partnerships, large philanthropic institutions and United Nations (UN) donors are driving global policy through funding organizations, governments, projects and studies that gain strategic political influence in the health area<sup>3,4</sup>.

The focus of this essay's analysis is on the asymmetries between transnational

biopharmaceutical corporations, governments and civil society. The first section deals with recent documents related to policy formulation, normative guiding principles and WHO guidance documents that interface with Pharmaceutical Services (PS) actions. Then, a cut is made on the initiatives of multiple actors linked to the COVID-19 pandemic scenario, such as COVID-19 Technology Access Pool (C-TAP), Access to COVID-19 Tools (ACT) Accelerator, COVID-19 Vaccines Global Access (Covax Facility) and the proposal filed by India and South Africa at the WTO with the aim of temporarily exempting certain obligations of the Agreement on Trade-Related Aspects of IP Rights (TRIPS Agreement) in relation to prevention, containment or treatment of COVID-19 (TRIPS Waiver).

Subsequently, the limits and possibilities of the initiatives are discussed in the light of barriers and facilitators of global governance, analyzing the predominance of these initiatives within the cases and contexts analyzed. The text is supported by institutional information and data and scientific literature. It is hypothesized that changes in the dynamics of global health governance related to corporate capture deepen the asymmetry of PS offer and people's health status.

## Aspects of Pharmaceutical Services in Global Health Governance

The PS crosses aspects related to integrated care, guarantee of access and rational use of medicines. An important challenge for PS policies is the inequity of access to medicines, especially due to high prices and the lack of research into therapeutic options for certain diseases. This challenge has increased since the advent of the TRIPS Agreement, signed in 1994 within the scope of the WTO,

guaranteeing, among others, patent protection for pharmaceutical products for a minimum period of 20 years. Under the justification of contributing to the promotion of technological innovation, the transfer and diffusion of technology, the implementation of the TRIPS Agreement resulted in an increase in costs and dependence on the purchase of inputs from transnational laboratories holding patents, creating barriers to access and favoring the marketing of counterfeit and substandard products as a result of inaccessibility<sup>5</sup>.

However, the first WHO Resolution specifically focused on ‘Intellectual Property Rights, Innovation and Public Health’ was only adopted in 2003<sup>6</sup>, many years after the TRIPS Agreement. From that point onwards, the WHO became yet another forum for discussion and analysis of the issue of the impact of IP on public health, under a different prism from that practiced within the scope of the WTO until then<sup>5</sup>. In this sense, in 2006, the Resolution ‘Public health, innovation, essential

health research and intellectual property rights: towards a global strategy and plan of action’<sup>7</sup> was adopted; and, in 2008, the Resolution<sup>8</sup> that culminated in the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA)<sup>9</sup>, with the objective of promoting innovation in health and access to medicines. However, the GSPA has not yet been fully implemented, especially due to vehement opposition from high-income countries, which could be interpreted as a way of protecting the interests of the biopharmaceutical industry.

Convened by the UN Secretary-General in 2015, a High Level Panel on Access to Medicines was launched and clarified the discussion on the requirement for clear information on how much it costs to innovate and bring a certain health technology to market<sup>10</sup>. This analysis may also have influenced WHO instruments that are strategic for access to medicines and other technologies, such as the documents presented in *table 1*.

Table 1. Recent United Nations documents in interface with Pharmaceutical Services. 2021

Theme	Document
Intellectual property, innovation and public health rights	WHO. World Health Assembly. WHA 56.27. Intellectual property rights, innovation and public health Resolution. WHA 28 May 2003.
	WHO. World Health Assembly. WHA61.21. Global strategy and plan of action on public health, innovation and intellectual property. 2008. <a href="http://mobile.wpro.who.int/health_research/policy_documents/global_strategy_may2008.pdf">http://mobile.wpro.who.int/health_research/policy_documents/global_strategy_may2008.pdf</a>
	WHO. Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. 2011. <a href="https://www.who.int/phi/publications/Global_Strategy_Plan_Action.pdf">https://www.who.int/phi/publications/Global_Strategy_Plan_Action.pdf</a>
	WHO. World Health Assembly. WHA68.18: Global strategy and plan of action on public health, innovation and intellectual property. 2015.
	WHO. World Health Assembly. WHA69.23: Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination. 2016.
	WHO. World Health Assembly. WHA71.9: Global strategy and plan of action on public health, innovation and intellectual property: overall programme review. 2017.
	WHO. World Health Assembly. WHA71.13: Global strategy and plan of action on public health, innovation and intellectual property: overall programme review. 2018.
	WHO. World Health Assembly. Resolution WHA73.1: COVID-19 response. 2020. <a href="https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_R1-en.pdf">https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_R1-en.pdf</a>

Table 1. (cont.)

Theme	Document
Expanding access to medicines and other technologies	<p>UN. United Nations General Assembly. Resolution UN A/RES/74/274. Resolution adopted by the General Assembly on 20 April 2020. International cooperation to ensure global access to medicines, vaccines and medical equipment to face COVID-19. 2020. <a href="https://undocs.org/en/A/RES/74/274">https://undocs.org/en/A/RES/74/274</a></p> <p>UN. United Nations General Assembly. Resolution UN S/RES/2565 (2021). Resolution adopted by the General Assembly on 26 February 2021. 2021. <a href="https://undocs.org/en/S/RES/2565(2021)">https://undocs.org/en/S/RES/2565(2021)</a></p> <p>WHO. World Health Assembly. WHA70.12: Cancer prevention and control in the context of an integrated approach. 2017.</p> <p>WHO. World Health Assembly. WHA71.8: Addressing the global shortage of, and access to, medicines and vaccines. 2018.</p> <p>WHO. World Health Organization. Roadmap for access to medicines, vaccines and health products 2019-2023: comprehensive support for access to medicines, vaccines and other health products. 2019a. ISBN 9789241517034. <a href="https://apps.who.int/iris/handle/10665/330145">https://apps.who.int/iris/handle/10665/330145</a></p> <p>WHO. Executive Board. Report EB 148/9. Expanding access to effective treatments for cancer and rare and orphan diseases, including medicines, vaccines, medical devices, diagnostics, assistive products, cell- and gene-based therapies and other health technologies; and improving the transparency of markets for medicines, vaccines, and other health products. 2020. <a href="https://apps.who.int/gb/ebwha/pdf_files/EB148/B148_9-en.pdf">https://apps.who.int/gb/ebwha/pdf_files/EB148/B148_9-en.pdf</a></p> <p>WHO. World Health Organization. Resolution WHA73.1: COVID-19 response. 2020. <a href="https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_R1-en.pdf">https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_R1-en.pdf</a></p> <p>OEA. CP/doc. 5673/21 rev. 2. Organización de los Estados Americanos. Draft Resolution - The Equitable Distribution of Covid-19 Vaccines. <a href="http://www.oas.org/es/council/CP/documentation/var_documents/cpdoc/">http://www.oas.org/es/council/CP/documentation/var_documents/cpdoc/</a></p>
Drug prices	<p>WHO. World Health Organization. Technical report: pricing of cancer medicines and its impacts: a comprehensive technical report for the World Health Assembly. 2018. <a href="https://apps.who.int/iris/handle/10665/277190?show=full">https://apps.who.int/iris/handle/10665/277190?show=full</a></p> <p>WHO. World Health Organization. WHO guideline on country pharmaceutical pricing policies. 2020. ISBN: 9789240011878 <a href="https://www.who.int/publications-detail-redirect/9789240011878">https://www.who.int/publications-detail-redirect/9789240011878</a></p> <p>WHO. World Health Organization. Fair pricing of medicines. 2021. <a href="https://www.who.int/medicines/access/fair_pricing/en/">https://www.who.int/medicines/access/fair_pricing/en/</a></p>
Strengthening local production of medicines and other health technologies	<p>WHO. World Health Organization. Resolution WHA 74.6. Strengthening local production of medicines and other health technologies to improve access Draft resolution proposed by China, Eswatini, Ethiopia, Ghana, Kenya, Namibia, Rwanda, South Africa, Sudan, Togo and Zimbabwe. 2021. <a href="https://apps.who.int/gb/ebwha/pdf_files/EB148/B148_CONF9-en.pdf">https://apps.who.int/gb/ebwha/pdf_files/EB148/B148_CONF9-en.pdf</a></p>
Strengthening the transparency of the pharmaceutical and other healthcare technologies market	<p>WHO. World Health Organization. Resolution WHA 72.8. Improving the transparency of markets for medicines, vaccines, and other health products. 2019. <a href="https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf">https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf</a></p> <p>WHO. Executive Board. Report EB 148/9. Expanding access to effective treatments for cancer and rare and orphan diseases, including medicines, vaccines, medical devices, diagnostics, assistive products, cell- and gene-based therapies and other health technologies; and improving the transparency of markets for medicines, vaccines, and other health products. 2020. <a href="https://apps.who.int/gb/ebwha/pdf_files/EB148/B148_9-en.pdf">https://apps.who.int/gb/ebwha/pdf_files/EB148/B148_9-en.pdf</a></p>

Source: Self elaborated.

Subsequently, the 41st session of the United Nations Human Rights Council approved the Resolution on access to medicines and vaccines in the context of the right to the highest possible standard of physical and mental health, of which Brazil was one of the proponent countries<sup>11</sup>. In the same field, the signatories of the political declaration adopted during the High Level meeting on universal health coverage, within the scope of the UN General Assembly, commit to making efforts to promote a range of incentive mechanisms that separate the cost from

the investment in Research and Development (R&D) of price and sales volume, facilitating equitable and affordable access to new tools and other results to be obtained through R&D. However, in the following paragraph, it only supports the role played by the private sector in R&D of innovative medicines, leaving aside the important role of universities and other public institutions in R&D<sup>12</sup>.

The topic of access to health technologies returned to the agenda at the 148th meeting of the WHO Executive Board, a forum for discussion and negotiation in preparation for

the 2021 World Health Assembly. A report presented on the topic of social determinants of health states that

advances in technology, increasing urbanization and the risks of climate change consolidate existing inequalities and further increase gaps in health outcomes<sup>13(1)</sup>.

Furthermore, the report reaffirms the uneven distribution of gains in health status over the past century, within and across countries. However, the document does not address the need to enable a health care and wellness economy and to redistribute power and resources, currently concentrated in unfair trade agreements, privatizations, environmental racism stemming from extractive capitalism and other forms of exploitation and spoliation of life.

Themes related to PS – such as integrated care, antimicrobial resistance, guarantee of access, rational use of medicines and patient safety in medication – have been recurrent in global health governance forums, receiving special attention in the context of coping with the COVID-19 pandemic, as barriers and inequities in access to health technologies have been highlighted, pointing out that private interests have suffocated public health interests in decision-making.

## Initiatives linked to COVID-19

In May 2020, the WHO, in partnership with several Member States, launched the C-TAP, aimed at encouraging the global community to voluntarily share knowledge, data and IP, with a view to accelerating the development of products necessary to combat the disease pandemic. Unfortunately, Member States seem reluctant to require the sharing of knowledge and IPs as a condition for companies to receive public funding mobilized to support relevant research. In January 2021, the

People's Vaccine Alliance and Health Action International (HAI) sent an open letter to the WHO Director-General expressing concern regarding the progress of C-TAP, as well as making recommendations regarding the publication of periodic monitoring reports, data transparency and information on technology transfer agreements<sup>14</sup>.

On the other hand, the Covax Facility initiative, which is restricted to funding large pharmaceutical companies in exchange for providing limited doses of COVID-19 vaccine to previously identified countries, has received greater support from countries, organizations and companies. However, the initiative does not anticipate agreements for the transfer of technology, maintaining the knowledge gap of technological development, as well as it does not provide for the sharing of IP or transparency in agreements with other countries.

Considering that emerging patent disputes may affect the manufacturing and supply of medical products, and in light of the need for a rapid and truly global response to COVID-19, in October 2020, India and South Africa made joint submission to the WTO TRIPS Agreement Council, which became known as the 'TRIPS Waiver'<sup>15</sup>. The proposal sought to obtain a temporary exemption from the implementation, application and compliance of provisions of the TRIPS Agreement related to copyright, industrial design, patents and protection of undisclosed information, in order to ensure the prevention, containment and treatment of COVID-19. It should be noted that, in the presentation of the proposal, while most low and middle-income countries (including China) supported or abstained, some high and upper-middle-income countries (including Brazil) were opposed. In a statement on the TRIPS Waiver proposal, the European Union (EU) stated that "there is no indication that IP rights issues are a genuine barrier to COVID-19 related technologies"<sup>16</sup>.

On the other hand, the representative of South Africa stated in a formal meeting of the TRIPS Council in February 2021 that:

Regardless of how much money any donor country can throw at the problem, the philanthropic donation and convenience model cannot resolve the fundamental disconnect between the monopoly model it underwrites, and the problem with philanthropy is that it cannot buy equality<sup>17</sup>.

If the exemption was granted, important barriers that exist today for better access to essential products related to COVID-19 would be eliminated, making it possible to diversify production through technology transfer, stimulating innovation and lowering product prices. It should be noted that countries that have used TRIPS flexibilities, such as compulsory licensing, are under intense intimidation and persuasion by high-income countries in international trade and diplomacy<sup>18,19</sup>. The argument that IP rights are necessary to finance innovation is not consistent and loses even more strength when one sees the dependence on donor funding and early purchase agreements in R&D for COVID-19.

Countries such as the United States of America (USA) and EU members have managed to create financial conditions for the rapid development of vaccines, not with the objective of collective or even individual well-being, but with the priority of putting their economies back on track, reproducing the objectification of life and placing the disease in the center of attention.

The annual meeting of the World Economic Forum (WEF), held in June 2020, entitled ‘Great Reset’, pointed to COVID-19 as an opportunity that created conditions for a new ‘green’ deal and a ‘reset’ of the system. For this Forum, terms such as sustainability, fourth industrial revolution, climate change, biotechnology and artificial intelligence are considered catalysts for the capitalization of life and recovery factors from yet another cyclical crisis of capital<sup>20</sup>. These terms are in the public interest, however, they are not designed to achieve the structural changes needed to transform everyone’s health. It’s no wonder

that major biopharmaceutical corporations, major health philanthropists, and even the UN are partners with the WEF.

With the pandemic, the need for sufficient production of equipment and inputs, supply and affordable prices in all regions is even more evident. Trade statistics show that only a small fraction of the world’s additional production of COVID-19-related supplies reached low-income countries<sup>21</sup>. The WHO Director-General, during the 148th meeting of the Executive Committee, warned the world that, on the “border of catastrophic moral failure, the price of this failure will be paid with lives and livelihoods in the world’s poorest countries”<sup>22(1)</sup>.

For Sunyoto et al.<sup>23(27)</sup>, “the COVID-19 pandemic is likely to have profound impacts on national and global approaches to R&D in biosafety”, such as the US national strategy for responding to COVID-19 through operation ‘Warp Speed’ and the priorities listed by the ‘NIH-Wide Strategic Plan for COVID-19 Research’<sup>24</sup>. This situation can also be influenced by the political effects of the use of war narratives against COVID-19 by countries and the WHO, which reinforces the discourse of “guilty countries”, that is, “external sources of guilt” or “enemies”<sup>25(3)</sup>. For Wright<sup>25(4)</sup>, COVID-19 securitization policies “increase tensions and insecurities within and between states, increasing inequalities and hampering a coordinated global response”. The author also points out that

designating the virus as a security issue is a political move that frames global health debates in ways that do not help with the ultimate goal of international health cooperation<sup>25(4)</sup>.

We emphasize the need to recognize that COVID-19 deepens individual, community and structural vulnerabilities of our time, and reveals the effects of the health-environment relationship, in addition to the precariousness of health systems.

## Are these global health governance initiatives serving all countries?

Global health diplomacy can be understood as a set of practices through which various actors try to coordinate and orchestrate global policy solutions with the argument of global health<sup>26</sup>, through negotiation of strategies and alliances, management of donors and stakeholders, acting in the relations between countries<sup>27</sup>. On the other hand, for Basile<sup>28(16)</sup>, this global health is understood as “the path between globalization, neoliberal hegemony and global commodification of life”. Thus, it is necessary to analyze in its entirety how diplomacy in global health affects the landscape of policies and the global biopharmaceutical market and its implications for the health of people from the local to the global level.

Strategies for accessing medicines and other health products need to be aligned with the quest to reduce the profound asymmetries in the production and access to these technologies among the people of central and peripheral countries<sup>29,30</sup>. However, in these times of a pandemic, national protectionism in the acquisition of vaccines, masks, respirators, reagent tests and workforce stood out, to the detriment of diplomacy of comprehensive care and global health, with an emergency routine that can put even more at the end of the queue other relevant health issues<sup>31</sup>.

To Almeida<sup>32(273)</sup>,

The central premise that guides the WTO system is that human well-being will increase with economic growth based on trade liberalization in a context of non-discriminatory and transparent rules.

In this context, the author argues that there is no link between the benefits of global trade and sound social policies, nor in the

application of public health principles and methods in the formulation and implementation of trade policies. Biopharmaceutical technologies, in addition to being under IP rights of several patents on the same product, may also be under the rights of supplementary protection certificates, trade secrets, and numerous evergreening strategies as a way to postpone the patent, among other mechanisms.

Commercial decision-making has a direct impact on health and takes place within the framework of the WTO, in which the WHO has a superficial role and influence, and low and middle-income countries have little voice and influence in decisions. The IP system has reproduced artificial scarcity and deprivation, in which price and production capacity are manipulated as sources of wealth for the few and deprivation for the many, reinforcing structural inequality. For Thambisetty<sup>33(2)</sup>, the patents:

They rely on self-interested behavior to drive innovation, and in doing so, undermine altruism, collaboration, and any notion of intellectual work to advance the common good.

Compulsory licenses, despite the importance of their use, have proved to be insufficient to minimize these asymmetries, as, among other weaknesses, the terms and conditions that limit competition and the absence of a legal obligation of broad transparency make R&D difficult and compose a restrictive geographic scope. Another example of the overlap between the right to health and commercial rights is the growing financialization of the biopharmaceutical sector, mergers and acquisitions of startups that, over time, gain market value, which influences the lack of detailing of the R&D costs of the product. This lack of transparency gives biopharmaceutical companies an advantage in price and competitiveness negotiations, especially those with monopoly technologies<sup>34</sup>.

As reported by Sarpatwari et al.<sup>35(2303)</sup>,

Broader knowledge of the cost of drug development can lead to better incentives to drive innovation in areas of high public health importance.

In this context, transparency is a core value for access to medicines, as a human rights issue<sup>36,37</sup> and must be aligned with the principles of open science, such as Open data, Open access, Open methods, Open peer review, Open source and Open resources<sup>38</sup>.

Such a scenario of opacity implies barriers for R&D and public production in peripheral countries. For Ido<sup>39(3)</sup>,

Even if the transparency of the pharmaceutical sector increases, and governments take steps to do so [...]. In this sense, it is also necessary that this agenda allows a broader reflection on the persistence of conflict of interests in the health field, especially in the undue lobby of certain private actors in the determination of public policies and international negotiations.

Furthermore, transparency must also ensure that investors' contributions and their risks are detailed<sup>40</sup>.

In central countries, there is a concentration of biotechnology and IP, while in peripheral countries, dependence and technological vulnerability are reproduced, deepened by the loss in international purchases due to the devaluation of other currencies in relation to the dollar and the euro. In this sense, measures of restrictions or temporary liberalization of trade in health products that took place during the pandemic may have different reflexes in northern and southern countries<sup>41</sup>. For Velasquez<sup>42(3)</sup>:

A binding global treaty or convention, negotiated at the WHO, could allow sustainable funding of research and development of useful and safe medicines at affordable prices for the population and public social security systems.

The adoption of such a convention within the WHO, based on article 19 of its constitution, could also make it possible to review the way in which the WHO acts in a broader sense.

For this to happen, it is necessary to require political and technical involvement on the part of Member States and civil society for the proper consideration of regulatory or fiscal strategies that subsidize gradual limits and targets to be agreed with private sector entities, as occurred, for example, in the Framework Convention on Tobacco Control. Furthermore, issues such as real-world evidence, drug pricing, new curative therapies, value-based alternative payment models, price transparency, digital technologies, precision medicine, population aging, and universal health care need to be discussed critically, in particular, regarding the link with the logic of financialization and the need to be guided by the public health perspective.

The initiatives pointed out in the previous section have limitations in that they still privilege the cosmopolitanism of the hegemonic health of the contemporary world system. Among the constraints are: a) flight of human talent from the south to the global north; b) IP rights regime for corporate profit, not global access; c) trade policies that sanction the reduction of tariff protection and export taxes in peripheral countries; d) disconnection from the social determinations of local health; e) fragmented and commodified health systems<sup>43</sup>.

The WHO has taken timid actions on the components of the rational use of medicines. Meanwhile, the standardization of nomenclature for biological and biosimilar medicines has advanced and is a topic of great business interest, as it impacts competition between these products<sup>44</sup>. This situation is aggravated by the actions of corporations and influential countries in the maintenance of structural asymmetries in the international system, such as the supremacy of economic power in influencing multilateral arenas, both in terms of final decisions and in the construction of

rules and guidelines, as well as in emptying out initiatives that are not of their interest. The ongoing international cooperation initiatives and their stakeholders have not minimized these asymmetries.

## Importance of rebuilding multilateral forums

Multilateralism is defined as arrangements involving more than two states, while multilateral institutions are understood as multilateral arrangements with a set of rules<sup>45</sup>. Ruggie<sup>46</sup> goes further, pointing out that these arrangements between three or more States are coordinated by certain general principles and conduct, in a more qualitative approach.

Furthermore, Ruggie<sup>46(571)</sup> considers that, unlike multilateralism, “imperialism is another way of coordinating relations between three or more States, however, denying the sovereignty of the subject States”. This internationalization of States is articulated with the so-called ‘American informal empire’, in which it coordinates the other powers of the global North in an integrated way and even China does not pose major challenges to this mechanism<sup>47</sup>, even with the current competition between the USA and China. This context can be elucidated by the criticism that the WTO has received for allegedly not incorporating and addressing the concerns and notes of developing countries regarding the TRIPS Waiver, placing these countries on the sidelines of decision-making<sup>48,49</sup>.

For Lima and Albuquerque<sup>50</sup>, international organizations promise to guarantee coordination between unequals, through mechanisms such as reciprocity, transparency, plurality of opinions and identities, and legitimacy. However, the transformational incapacity of these mechanisms is verified, which is reflected in a crisis of legitimacy of multilateralism and its institutions. The authors suggest “increasing cultural diversity and national representation”<sup>50(10)</sup> as an anti-status quo

strategy of power asymmetry in multilateral arenas, but there are limits to this strategy.

On the other hand, the so-called ‘multi-stakeholderism’ is defined by Raymond and DeNardis<sup>51(573)</sup> as the engagement between two or more categories of actors, such as the State, intergovernmental organizations, companies and civil society, involved in issues involving important values and public interest and by “polyarchic relations of authority constituted by procedural rules” and that spend some effort to influence the management of public affairs.

In the field of health, despite the harmful permeability of the WHO, it is still important to insist on governance based on principles of cooperation and solidarity and on the constitutional role of the WHO as a leading and coordinating authority on global health, defining public health rules and concrete solutions in global level and with co-responsibility at the local level, not only in emergencies. For this, it is necessary: social participation and participatory governance with transparency and without conflict of interest or corporate capture; incorporation of actors that have been left out of the negotiations, such as specialists and non-governmental institutions from peripheral countries<sup>52</sup>; and support for the WHO, disputing it in common collective interests and truly feasible cooperation.

In addition, its Member States need to act beyond the colonial mentality, moral rhetoric, fragile negotiations, self-promotion and permeability to corporations<sup>53</sup>, despite such a challenging situation. The WHO cannot be just a symbolic figure for the elaboration of fragile technical documents and resolutions. At the same time, a new global health architecture<sup>54</sup> or binding arrangements<sup>55</sup> alone are not enough to change the power structure, which is still favorable to corporate interests and restricted to the biomedical model<sup>56</sup>.

The Civil Society Declaration in 2017, presented during the election of the new WHO Director-General, among other issues, called for a WHO with

Leading voice for Health for All among international and multilateral actors, taking a courageous stand in favor of public health in relation to potentially harmful actions carried out by other entities, such as in the field of Access to Essential Medicines and IP Rights<sup>57(1)</sup>.

This declaration remains current, because, in the midst of the financial vulnerability of donor dependence with their own interests, as well as the possible failure in the coordination of some collaborative research initiatives to face COVID-19, it is urgent to progressively recover the character multilateral and normative of the WHO, ahead of the mission to promote, preserve and regulate global public health, despite fragile legal and binding obligations<sup>58,59</sup>.

Nay et al.<sup>60(1819)</sup> point out that

WHO will not regain its full authority if Member States do not relinquish some of their national prerogatives for the benefit of global public health.

If in a pandemic everyone is affected, even if unequally, governance spaces should address access to health technologies as a common and solidarity right. Donations from high-income countries and other actors should not override the isonomy of bargaining power or make the implementation of resolutions and plans unfeasible. The Civil Society Declaration supporting the WHO states that:

The time has come for all WHO Member States to recognize and support the organization's immense value in comprehensively addressing the health challenges that lie ahead due to climate change and other threats, rather than using their own mistakes as an excuse to further weaken the organization's leadership and role in protecting global health<sup>61(1)</sup>.

Engagement with private sector entities in implementing WHO actions highlights conflicts of interest, especially given the lack of

independent WHO funding. Consequently, the organization is insufficiently protected from undue influence from industry lobbies. In multistakeholderism, despite the anticipated participation of multiple actors – including international organizations, the private sector, philanthropic foundations, global public-private partnerships and civil society – there is no standardized definition of stakeholders, nor accountability, governance or representative mandates. Thus, multistakeholderism allows transnational corporations to expand their interests and image, through the involvement of actors that address ethical and social issues, but with deep private interests.

Multistakeholder governance disregards standards for preventing conflicts of interest, transparency of members' finances or financial transactions, and fundamental democratic safeguards. On the other hand, there is corporate self-interest, often with profit-oriented decision-making contrary to the public interest. A report by the Transnational Institute<sup>62</sup> exemplifies some side effects of multistakeholderism, as in the case of the GAVI Alliance, which does not address the strengthening of public and universal health systems as a strategic axis for immunization.

As for 'multistakeholderism', it is necessary to combat all forms of for-profit stakeholders that weaken the decision-making of Member States, that present conflicts of interest, that are harmful to the balance of power, that are undemocratic and that leave countries and populations at the mercy of private interests. For Dowbor<sup>63(1)</sup>:

In this era in which the planetary concentration of social wealth in a few hands is becoming unsustainable, understanding the mechanism of generation and appropriation of this wealth is fundamental.

The aforementioned 'Great Reset', organized by the World Economic Forum, which includes environmental aspects and access to vaccines, is a sample of how 'multistakeholderism' is

trying to make multilateralism obsolete in addressing complex global issues. Organized civil society organizations have called the ‘Great Reset’ the ‘Great Take Over’, that is, the great capture of global governance<sup>64</sup>. In addition, the World Economic Forum’s partnership with the UN has led to multistakeholder governance that drains public money and leverages UN legitimacy for initiatives by transnational corporations<sup>65</sup>. In this sense, the Covax Facility initiative can be mentioned as an example, which brought several decisions outside the WHO. Other alternative multilateral articulations, such as the Paris Peace Forum<sup>66</sup>, where funds were raised and strategies aligned, and the European Health Union<sup>67</sup>, took place outside the multilateral governance framework, included dominant corporate voices, and are likely to have lasting ramifications for the future of global health governance.

The UN has made several multistakeholder partnerships, such as the Global Action Plan for Healthy Lives and Well-being for All<sup>68</sup>. In addition, a Strategic Partnership Agreement was signed for the implementation of the 2030 Agenda for Sustainable Development, which institutionalized the corporate capture of the UN, providing preferential access to the formulation of initiatives to transnational companies<sup>69</sup>. Among these transnationals is the ‘big pharma’, which operates in the privatization of public investments and in the maintenance of the market monopoly, and not for equitable and universal access. A situation that did not differ from the receipt of large sums of public money for R&D of health supplies related to COVID-19.

Gleckman<sup>70(xv)</sup> questions if

The current unique responsibilities and obligations of nation-states will change when powerful non-state actors play a formal or semi-formal decision-making role in international relations.

Added to this is the concern about how these changes influence the participation of

civil society and the general public and how this directly affects our daily lives. The political rise (and increase in wealth) of the transnational elite, including through supposed strategies of ‘benevolence’<sup>71</sup>, and a loss of trust in governments can contribute to the lack of perspective on health as a right and a common and accessible good to all.

Reports from 2017 to 2020 prepared by the UN Conference on Trade and Development recommend inducing inclusive growth in the age of digitization, ending austerity and fiscal gaps, and counterbalancing corporate power<sup>72</sup>. However, these recommendations can be rhetorical, without really breaking the circuit that feeds dependency and without having human dignity and nature as pillars in initiatives that recognize the contradictions of ‘inclusion’ and ‘developmentalism’, crossed by the new geography of domination subsidized by disruptive technological changes and growing inequity.

Multilateralism needs to be rebuilt through strategies that make power relations less unequal and initiatives less fragmented. Unequal relations of political power condition public policies – and how we live (or survive), get sick and die – and favor a neoliberal vision of health. For this, funding and allocation of resources need to be ensured, issues need to be addressed in an integrated manner and articulated with human, natural and intergenerational needs, enabling the participation of people and subordinate populations in the formulation of strategic global issues for the global agenda and in decision-making.

## Final considerations

The economic discourse of pharmaceutical corporations has perpetuated the situation of scarcity and colonial exploitation, even if disguised as ‘pro life’ capitalist companies. To effectively promote PS for all peoples, it is necessary to recognize biopharmaceuticals as public goods and based on a comprehensive, participatory and inclusive public health

approach that integrates rights, social dimensions, progressive taxation to reduce inequality and debt cancellation of the poorest countries. Furthermore, there is the importance of remodeling the R&D and IP ecosystem, with greater technical-scientific, financial and political independence, greater authority and transparency of the WHO; and that the different forms of knowledge and innovation have equity and universality as objectives.

Subsidizing PS that are integrated, efficient and oriented for the scaling up and rational use of medicines requires interventions and structural reforms at all stages of the value chain, including research, IP, production, pricing, regulation, health systems and services, procurement, analysis of the health situation and approach to the social determinants of health. It is necessary to consider that low and lower-middle-income countries cannot participate in pre-purchase agreements; they lack financing, have tax and fiscal injustice, deficit in purchasing power (especially with low quantity demand) to negotiate prices of pharmaceutical products and implement services that promote their rational and appropriate use. In general, they have fragile regulatory systems and may not have the necessary technical infrastructure for the proper and safe use of pharmaceuticals.

The question is whether we will be able and willing to face the pharmaceutical industry, the private and health insurance systems and the professional categories that are traversed by subordination in its various layers and strata. More critical and transdisciplinary analyzes are suggested, focusing on the intersections between policies related to pharmaceuticals, public health, and economic constraints that determine the chances of health and good living everywhere.

## Collaborators

Ribeiro AA (0000-0003-0233-9465)\* contributed to the design, planning, analysis and interpretation of data; review of the article text and approval of the final version of the manuscript. Ricardi LM (0000-0002-7500-0465)\* contributed to the analysis and interpretation of data and review of the article's text. Pontes MA (0000-0002-0726-7475)\* contributed to the analysis and interpretation of data and revision of the article's text. Leite SN (0000-0002-5258-9684)\* contributed to the planning, review of the article's text and approval of the final version of the manuscript. ■

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Received on 08/13/2021

Approved on 12/23/2021

Conflict of interests: non-existent

Financial support: non-existent