RECENT INTERNATIONAL INITIATIVES ON FACILITATING ACCESS TO VACCINES AGAINST COVID-19

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Since the beginning of the COVID-19 pandemic in January 2020, several initiatives and negotiating proposals have been launched by the international community to improve access to vaccines and other treatments. The results of mechanisms such as COVAX have not been as expected and negotiations at the World Trade Organization (WTO) on a waiver for intellectual property obligations are not moving as quickly as needed. A new proposal on a 'pandemic treaty' will be discussed at the next Extraordinary World Health Assembly (WHA) in November 2021, but whatever the outcomes of the negotiations are, they will not allow to address the urgent issues raised by the limitations of supply and sharp inequalities in access to vaccines. This article examines some of the initiatives and proposals mentioned above and explores solutions to correct the shortcomings identified.

PANDEMIC PREPAREDNESS AND RESPONSE

The COVID-19 pandemic is demonstrating that no country can tackle the threat of this and future pandemics alone. However, many World Health Organization (WHO) Member States have acted individually according to their own interests, whether political, commercial or health-related.

In August 2021, for example, the WHO has spoken out against a third dose of vaccines to boost immunity, so that the poorest countries could increase the percentage of their population vaccinated, but countries such as Israel have already started injecting it into their population over 60 years of age, and Germany, France and the United Kingdom have decided to follow suit and plan to offer a booster dose to older people from September 2021 (El Publico 2021). These doses of vaccines will not reach developing countries, despite that "the global rollout of COVID-19 vaccines is progressing at two alarmingly different speeds. Less than 2 % of adults are fully vaccinated in most low-income countries compared to almost 50 % in high income countries. These countries, the majority of which are in Africa, simply cannot access sufficient vaccine to meet even the global goals of 10 % coverage in all countries by September and 40 % by end 2021, let alone the African Union's goal of 70 % in 2022" (WHO 2021a). As a result, as noted by the WHO Director General Tedros Adhanom Ghebreyesus, "Increasingly, we see a two-track pandemic" (Miller et al. 2021).

It is frustrating indeed that despite declarations about solidarity and cooperation by many bodies and agencies (see e.g. Syam 2020), the situation of unequal access to vaccines has not changed since the start of the pandemic. However, as noted by the Emergency Committee regarding the coronavirus disease (COVID-19) pandemic convened by the WHO Director-General, "… the world will not exit the pandemic unless, and until, all countries have access to appropriate supplies of diagnostics, treatments and vaccines, irrespective of their ability to pay and the capacity and financial resources to rapidly and effectively vaccinate their populations. Inequities within and among all countries is slowing the return to normal social and economic life" (WHO 2021b).

The inequality in access to vaccines and other needed products is the result of limitations in the manufacturing capacity of active ingredients and other components and the reluctance of technology holders to share the needed technologies to expand such a capacity (Correa 2021a). But it is also due to the absence of a multilateral mechanism adequate to ensure a global distribution of such products on the basis of public health needs and equality.

The main normative instrument the WHO has for responding to health emergencies are the International Health Regulations (IHR), adopted by the WHA in 1969 and revised in 2005. The purpose and scope of the IHR is "to prevent, protect against and control the international spread of disease..." (WHO 2005). The 2005 revision of the IHR was made with the aim of overcoming the original limitation to three notifiable diseases: yellow fever, plague and cholera. While the current version of the IHR is not limited to specific diseases, it imposes a

limitation on measures that may be adopted in relation to international traffic and trade. This limitation seems to be ill-suited to situations such as the one experienced with COVID-19 since January 2020.

The IHR spell out the minimum core capacities that States Parties must put in place to detect, assess, report and respond to potential Public Health Emergencies of International Concern (PHEIC) (Gostin/Katz 2016). However, concerns about the adverse socio-economic impact on a country following an IHR declaration of a PHEIC (in the form of possible temporary travel or trade restrictions) may deter States Parties from rapidly sharing information on a potential PHEIC (ibid.). While it is true that in the context of the COVID-19 health emergency, genome sequence information was shared immediately (WHO 2020: 31), many countries have acted unilaterally and without coordination with regard to the movement of people and traffic in goods (Habibi et al. 2020). The non-binding global recommendations issued by the WHO have not been followed by all the IHR State Parties, although it is clear that global, coordinated and effective responses are needed in the face of a global emergency.

In this context, WHO Member States should address the systemic deficiencies that allow many governments to ignore WHO's advice on the collective actions required to respond to the pandemic and to mitigate the inequities in the global distribution of vaccines and other needed products. As noted in a recent analysis of a proposed pandemic treaty (see below), "the pandemic has been a telling reminder of the fragility of the mechanisms at WHO's disposal and shows that the Organisation does not have the means to enforce its standards and guidelines" (Duff et al. 2021).

THE COVAX MECHANISM

The COVAX mechanism is the vaccine pillar of the WHO's Accelerator for Access to COVID-19 Tools (ACT Accelerator), officially known as "the Global Access to COVID-19 Vaccines mechanism". It was established in April 2020 and is co-led by Gavi-The Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations (CEPI) and WHO. This mechanism has no binding character and the funding and capacity to act is outside the WHO.

Médecins Sans Frontières (MSF) analyses of the operation of COVAX have shown a long delay in achieving its objectives (Algar González 2021). It was expected to deliver 2 billion doses by the end of 2021, but so far (August 2021) it has only distributed 229 million doses[1], a very small proportion of the doses needed to address the need of the countries participating in the COVAX mechanism. COVAX is falling short of its target, and the global gap between the vaccine haves and have-nots is widening.

A key weakness of COVAX is that it has had to compete with rich-country governments desperately trying to make purchase arrangements with the vaccines producers in response to their own needs. This competition for a scarce good has been one of the crudest manifestations of what has been rightly termed 'vaccine nationalism' (see e.g. Abbas 2020). At the onset of the pandemic in the early 2020s, there were repeated calls for a shift away from the business-as-usual approach. Pharmaceutical corporations developing vaccines received unprecedented levels of public money support with no strings attached, and sold at whatever price they wanted to the highest bidder. Predictably, this led the same governments that had trumpeted the importance of equity at the launch of the ACT-Accelerator to buy bilaterally to secure their national needs.

In accordance with MSF, "COVAX was not set up to succeed"; it was rather "designed to operate within the current parameters of the pharmaceutical market...". COVAX fell behind, as rich country governments secured their doses through bilateral agreements with an industry that acted as expected: selling the doses first to the buyers who could pay the most' (Algar González 2021).

Today, instead of trying to correct the structural deficiencies of the COVAX mechanism, industrialized countries are announcing charitable measures to donate leftover vaccines, or those vaccines, such as Astra Zeneca's, that some countries do not want to use (e.g. Le Saint 2021). But donations, though welcome, are not the solution to the current situation nor for future pandemics. In this regard, it is encouraging that the African Union has launched the Partnership for African Vaccine Manufacturing with the aim of overcoming the African overdependence on vaccines produced outside the continent.[2]

Notwithstanding its unquestionably valid objectives, the governance of COVAX has not allowed it to perform its expected role. COVAX is not a true multilateral institution as its operation is not subject to multilateral rules. This is one of the key factors explaining why the efforts by the WHO to ensure an equal global access to vaccines have

failed so dramatically. Any future model of pandemic response must aim at improving the governance of COVAX (or any alternative mechanism) to permit it to intervene more effectively. An assessment of such a governance should be associated with a reconsideration of the current pharmaceutical model of innovation and production (e.g. Velásquez 2020) including how Research & Development (R&D) is conducted and its outcomes appropriated, the conditions to be attached to public funding, and the transparency around costs and prices. Ultimately, pharmaceutical products should be generated and distributed as global public goods, particularly in the context of a pandemic (Thomas et al. 2020).

UTILIZING WHO LEGAL INSTRUMENTS

There seems to be a wide recognition today of the gaps in the current global health governance system to address the multifaceted health and socio-economic implications of a pandemic. The COVID-19 pandemic has highlighted the need for a strong and independent global health governing body capable of managing an international health crisis. As Gostin, Moon and Mason Meier recently noted, "the world faces an unprecedented threat to global health, and the response has highlighted the structural limitations of international organisations' ability to coordinate with nation states" (Gostin et al. 2020).

WHO's competence, however, includes adopting conventions and regulations with respect to international health matters; normative activity is considered part of its work in directing international health. The WHA has the authority to adopt international conventions or treaties under article 19 of its Constitution (see box). However, this competence has been exercised only once for the adoption of the WHO Framework Convention on Tobacco Control (FCTC).

Article 19 of the WHO Constitution

Article 19 of the WHO Constitution states: „The Health Assembly shall have authority to adopt conventions or agreements with respect to any matter within the competence of the Organization. The adoption of conventions and agreements shall require a two-thirds vote of approval by the Health Assembly; conventions and agreements shall come into force for each Member upon acceptance by it in accordance with its constitutional processes".

In the current international context brought about by COVID-19 and in the face of uncoordinated intervention by multiple health actors, WHO could regain its identity and leadership through the use of Article 19 of its Constitution in the negotiation and adoption of international instruments that help States Members to comply with their human rights obligations in promoting the right to health.

Not surprisingly, the health, economic and social crisis provoked by COVID-19 has led to different initiatives including a call for an international treaty on pandemic preparedness and response. The limitations of current global health governance have become evident. Is the recent call by 25 heads of the State to negotiate a treaty against pandemics going in this direction?[3] Before starting negotiations for a pandemic treaty, the first step should be to assess how to build on existing instruments, especially the IHR, and identify the aspects of pandemic preparedness and response that the current crisis has shown are not working adequately.

The COVID-19 health crisis has revealed the need for new approaches and actions in many areas to ensure a rapid and coordinated response to the spread of the disease in countries and regions, such as[4]:

- Increasing laboratory and surveillance capacity in order to identify diseases of zoonotic origin in all countries.
- Improve independent, reliable and accurate scientific communication and alerts.
- Develop mechanisms for rapid sharing of pathogens, including biological samples and genomic data, without prejudice to the equitable sharing of benefits arising from their use.
- Expand the use of digital technologies for data collection and sharing while respecting the sovereign rights of States over their health data and its use.
- Prioritize R&D efforts and develop collaborative mechanisms for funding and conducting translational and scientific research, as well as transparent and independent clinical trials.
- Ensure transparency of R&D costs and prices.
- Make pandemic-related health supplies available as global public goods (without limitations imposed by the enforcement of intellectual property rights).
- Establish mechanisms to allow open access to technologies, including know-how, to expand local manufacturing of pandemic-related health supplies.

- Coordinate the supply of vaccines and other health products to all countries, including developing and least developed countries, on the basis of equity and health needs.
- Remove unnecessary regulatory barriers to market entry for generic manufacturers by establishing shortened regulatory approval pathways for faster marketing approvals and promoting inter-agency cooperation.
- Take measures to ensure the continued availability and affordability of vital medical supplies and equipment and other essential goods and services to meet basic needs, in accordance with national requirements. Regulate the scope of legal immunities and liability insurance for negligence, failure of manufacturing practices or adverse events associated with vaccines.

Many of these measures cannot be implemented solely on the basis of solidarity or voluntary cooperation. The use of binding instruments and enforcement tools to implement them are necessary in order to promote and protect health in the context of pandemics.

INCREASING MANUFACTURING CAPACITY

Given the shortage of supply of vaccines, expanding the manufacturing capacity around the world should have been one of the main targets of a concerted international action to fight the COVID-19 pandemic (see Correa 2021b). Vaccine shortages are not a new phenomenon in an industry characterized by a high level of concentration and the market dominance of a few large producers (Lobo 2021). The problem has become more visible and serious in the face of a pandemic that has already produced 4,5 million deaths and affected the health and life (economically, socially and culturally) of the world population. Although the production of vaccines is more complex than that of pharmaceutical products of chemical synthesis, there are many manufacturers in developed and developing countries[5] that may have produced COVID-19 vaccines, in some cases by repurposing plants used for the production of other biologicals. Access to know-how and data would have allowed them to move fast, but acquiring the needed skills would not be otherwise impossible if scientific and industrial support were available for the different phases of manufacturing (active ingredient, formulation, fill and finish). While many developing countries have the skills to produce vaccines with conventional technologies, some, such as Thailand[6] and China[7], have also engaged in the development of vaccines based on the most recent mRNA technology utilized by Moderna and Pfizer/Biontech.

Technology transfer would be critical to rapidly increase manufacturing capacity. The COVID-19 Technology Access Pool (C-TAP) established under the auspices of the WHO – upon an initiative of the President of Costa Rica – was intended to compile, in one place, pledges of commitments made to voluntarily share technologies needed to address the pandemic.[8] However, the C-TAP has failed, after more than one year, to show any concrete results in terms of receiving and disseminating needed manufacturing technologies. The current producers of vaccine technologies have ostensibly not responded to this call. While some of them (e.g. Bharat Biotech, Gamaleya Research Institue, Astra Zeneca, Centre for Genetic Engineering and Biotechnology) have entered into agreements for the transfer of technology, the main Western producers have only engaged in manufacturing contracts[9] that allow them to retain control over the technology and its outputs.

While the C-TAP did not generate the expected interest from potential technology contributors, another initiative by the WHO and its COVAX partners has focused on the creation of a COVID mRNA vaccine technology transfer hub worked with a South African consortium comprising Biovac, Afrigen Biologics and Vaccines, a network of universities and the Africa Centres for Disease Control and Prevention (CDC) to establish its first COVID mRNA vaccine technology transfer hub.[10] Apparently, the main producers of mRNA vaccines for COVID-19, Moderna and Pfizer, have again shown no desire to support this initiative.

TEMPORARY WAIVER FROM TRIPS OBLIGATIONS

Since October 2020, WTO member countries have been discussing a proposal to waive obligations under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) with respect to technologies needed to respond to the COVID-19 crisis (WTO 2020), which is being led by India and South Africa and supported by more than 100 countries in the WTO. Suspension of such obligations in times of pandemic should certainly be a component of any framework that promotes the expansion of production and equitable access to products needed for diagnosis, prevention or treatment (De Menezes 2021).

If this is a global emergency, why not start by adopting a temporary waiver of TRIPS obligations during the current pandemic?

In May 2021, the United States announced its readiness to negotiate the waiver proposed by India and South Africa at the WTO. It is certainly a step forward for a country that champions the global protection of intellectual property under high standards and uses unilateral measures to threaten countries that do not (legitimately) meet such standards (see e.g. Correa 2020). The US announcement contains five points that raise concerns regarding the rhythm and possible outcomes of the negotiations (Velasquez 2021).

The WTO negotiations on an intellectual property rights (IP) exemption for COVID-19 vaccines could last months, provided that opposition from some member countries can be overcome. The talks are likely to focus on a much narrower scope and shorter duration exemption than the one initially proposed by India and South Africa in October 2020. Some optimistic experts expect a deal to be agreed by the next WTO ministerial conference, scheduled for 30 November to 3 December 2021 (Lawder 2021).

The initial IP exemption proposal submitted by India and South Africa (ibid.) included vaccines, treatments, diagnostic kits, ventilators, protective equipment and other products needed to combat the COVID-19 pandemic. The US is likely to pursue a reduction of the scope of the possible suspension of obligations, by limiting it to vaccines. US companies are trying hard to influence the United States Trade Representative (USTR) position, and have mobilized to try and get the WTO talks to result in as limited a waiver as possible: "This is a mitigation effort. Our goal is to make it less bad than it would be," is reported to have been said by one industry source (ibid.). Republican lawmakers are arguing that the decision will hand over US technology to China: "What this decision will do, if it goes forward, is benefit countries like China, which are aggressively trying to obtain US technology to bolster their own national champions" (ibid.). This claim, however, looks as an attempt to raise the phantom of China appropriating US technology, while China has developed its own vaccines and has in development a vaccine based on the mRNA platform which is in Phase III testing in Indonesia and Mexico.[11]

The European Union (EU) is one of the main opponents to the proposed waiver. It has tabled an alternative proposal for a declaration on TRIPS and public health in the context of a pandemic [12] which aims at adopting some interpretations or clarifications with regard to article 31bis of the TRIPS Agreement. The legal nature of such a declaration is unclear, as it has not been submitted as an authoritative interpretation as provided for under article IX.2 of the Agreement Establishing the WTO.[13] The EU proposal aims at facilitating the use of the compulsory licensing system set out by article 31bis. However, this article imposes cumbersome requirements and procedures that may explain why it has only been used in one case after the adoption (in 2003) of the waiver on which that article is based (see e.g. Correa 2019).

The EU proposed clarification that the circumstances of a pandemic fulfil the requirement of a national emergency does not add anything significant, as such a possibility already exists (albeit it may be understood as applicable in relation to the importing country only). Similarly, governments granting a compulsory license can determine how the remuneration is to be calculated taking into account the economic value of the authorization. They may also indicate in a single notification a list of all countries to which the products are to be supplied under the compulsory license.

While the proposed clarifications would contribute little to make compulsory licenses an effective tool in the context of the pandemic, they miss to address the hurdles created by the conditions in the referred-to system that have discouraged governments and generic manufacturers to use it. In fact, the report of the UN Secretary-Generals' High Level Panel on Access to Medicines in 2016 had specifically recommended that "WTO Members should revise the paragraph 6 decision in order to find a solution that enables a swift and expedient export of pharmaceutical products produced under compulsory license. WTO Members should, as necessary, adopt a waiver and permanent revision of the TRIPS Agreement to enable this reform." (UN Secretary General's High Panel on Access to Medicine 2016: 27).

CONCLUDING REMARKS

The mismanagement of the COVID-19 pandemic at the global level is likely to remain as one of the major failures of the international community in the XXI century. Cooperation and true solidarity may have saved many lives. Producing and distributing vaccines and other products as global public goods was not an impossible objective if governments had agreed to act collectively. A clear les-

son from this crisis is that the WHO, despite its efforts and good intentions, lacked the instruments to adopt and enforce the required measures.

The control over the technology and the reluctance to share it to expand production have been critical determinants of the insufficient supply. The adoption of a waiver regarding the TRIPS obligations can contribute to solve this problem, but the decision thereon cannot be further delayed. It is an open question whether a new pandemic treaty can address the gaps and provide the WHO with the necessary tools to act, having in view the needs of countries at different levels of development and, consequently, with different capacities to meet the obligations that may be imposed.

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9 See https://www.unicef.org/supply/covid-19-vaccine-market-dashboard (03.11.2021).

10 See https://www.who.int/news/item/21-06-2021-who-supporting-south-african-consortium-to-establish-first-covid-mrna-vaccine-technology-transfer-hub (03.11.2021)

11 See https://www.bloomberg.com/news/articles/2021-09-02/china-s-own-mrna-covid-shot-expects-efficacy-data-by-year-end (03.11.2021).

12 The following analysis is based on Syam (2021).

13 In accordance to this article 'The Ministerial Conference and the General Council shall have the exclusive authority to adopt interpretations of this Agreement and of the Multilateral Trade Agreements' (article IX.2 of the Agreement Establishing the WTO).