Between regional convergence, and locally rooted technological and cultural aspects: lessons from the case of COVID-19 vaccines in Latin America

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Abstract

The COVID-19 pandemic challenged the capacity of all States to ensure the health of their citizens, especially in developing countries where the pandemic bursted in contexts of limited resources and inequalities. While developed countries showed a concentration of COVID-19 vaccine development and production, coupled with the jurisdictional expansion of intellectual property and pharmaceutical companies' power at the global level, several middle-income countries undertook initiatives to try to reduce the center-periphery dependency in terms of vaccine access. In particular, Argentina and Brazil, leading countries in biopharmaceutical manufacturing in Latin America, became nodes for testing foreign vaccines and signed agreements for the local production of vaccine components, in addition to venturing into the development of their own vaccines. Thus, the pandemic marked a repositioning of the role of the State, the Scientific and Technological (S&T) system (mostly public) and its forms of intervention in society, thanks to strategic and oriented policies deployed by the State, greater institutional integration, and a change in the R&D and production dynamics of biopharmaceutical laboratories (both public and private). Departing from the lessons learned from both countries, we developed a series of public policy recommendations based on the locally situated context and health urgency. In particular, we focused on vaccine access in geopolitical terms (as semi-peripheral countries), on regulatory convergence and empowerment of regional vaccine value chains, on the promotion of complementary capacities in innovation, and on the importance of taking into account local culturally rooted aspects embedded in S&T developments.

The COVID-19 pandemic strained the capacity of all States (in their various levels of action) to fulfill their role in ensuring the health of their citizens. In developing countries, where the pandemic struck in contexts of limited resources and inequalities, this challenge was even more critical (Perrota 2021; Lancet 2021). In Latin America the performance of the State was the focus of scrutiny and public debate. From diagnostic reagents, masks and, especially, vaccines, these artifacts acquired a political status: both as political technologies, embedding visions of the Nation (Winner 1987), as well as a representative emblem of State policies (Joerges 1999) in the face of COVID-19.

From the beginning of the pandemic, vaccines became the focus of Research and Development (R&D) efforts. Globally, big pharma in developed countries joined the race to develop a vaccine against COVID-19 (Balawejder et al. 2021; Zhang 2021), accentuating the center/semi-periphery dependency (Blinder, Zubeldía and Surtayeva 2021). These asymmetries gave rise to mechanisms such as COVAX, with mixed results and many low-income countries with reduced access to vaccines (Gemünden and Thiel 2021; Usher 2021). In this global context of concentration of vaccine development and manufacturing, and the jurisdictional expansion of intellectual property (IP), several middle-income countries ventured into different initiatives to increase their access to vaccines. On the one hand, some of them requested temporary exemption of any type of IP on medical products and their associated technologies related to the prevention, diagnosis, and treatment of COVID-19 (Chattu et al, 2021). On the other hand, some developing countries opted for their own vaccine production (Sharma 2021; Medeiros et al. 2022).

In particular, Argentina and Brazil became nodes for testing vaccines developed and produced abroad, signing agreements for their the local manufacturing (Cuello 2021). Together with Cuba and Mexico, they lead the vaccine manufacturing capacities in the region (Cortes et al. 2012). However, these countries exert scarce articulation between institutions and a discontinuity of promotion policies to the sector, with important consequences in the loss of national capacities in this area (Di Bello 2018; Corvalán 2017; Homma 2020). The adopted strategy of transferring vaccine technologies for local production allowed Brazil and Argentina to produce about 200 million and 80 million doses of COVID-19 vaccines, respectively, for their immunization programs.

Some facts about pandemic responses in the region

The pandemic marked a repositioning of the role of the State and the Scientific and Technological (S&T) sector (mostly public). The latter was summoned as a key actor and authoritative voice, hoping to contribute to the resolution of social problems. In a context of historical disconnection between S&T capacities and socio-productive needs, the health emergency gave rise to a flexible articulation between the State, the S&T and the private sectors in Latin America that enabled to obtain useful knowledge and technologies to respond to the pandemic at an unprecedented speed (Bortz and Gázquez 2020). This was possible due to strategic and oriented policies deployed by the States to address economic, financial, technological, regulatory and IP issues; to greater institutional integration (in terms of S&T planning and financing, and regulatory aspects); and to a change in the R&D and production dynamics of biopharmaceutical laboratories (both public and private).

In the Argentinean case, the State focused initially on the acquisition of foreign vaccines, both through its own negotiations and the COVAX mechanism (October 2020-February 2021), and then focused on the local production of vaccines designed and developed abroad (August 2020-July 2021). Simultaneously, both the public S&T sector and private biopharmaceutical laboratories endeavoured the design and development of national COVID-19 vaccines (April 2020-present).

In the case of Brazil, amidst a lack of a coordinated health response at the national level, the country opted for acquiring foreign vaccines, through signing clinical trials agreements to be held in Brazilian territory, and the purchase through the COVAX mechanism (da Fonseca et al, 2021). In a second phase, the government of Sao Paulo and the Ministry of Health signed agreements with foreign pharmaceutical companies to transfer vaccine technologies for domestic manufacturing, although initially still importing the vaccines' active ingredients. Given its track record in vaccine development and production in public S&T institutes, Brazil also opted for developing a national vaccine (ButanVac) by combining local and foreign R&D (da Fonseca et al, 2021).

Policy recommendations: lessons learned from the State-S&T sector dynamics in the face of the pandemic in Latin America

COVID-19 presented an emergency context of extreme uncertainty where the aforementioned particularities regarding center-periphery inequalities came into play. In this scenario, public policies oriented to promote access to vaccines required taking into account these factors, including particular institutional dynamics, forms of governance, and coalitions between key actors. We propose five recommendations for the design and implementation of S&T public policies by the States in the region, based on the extensive analysis of regional experiences:

Focus on local specificities. The design and manufacturing of COVID-19 vaccines were concentrated in developed countries, with South America/Africa, Asia, and Australia together accounting for 30% (Thanh Le et al., 2020). With the exception of the Oxford-AstraZeneca case, the large pharmaceutical companies from the global North were responsible for developing the vaccines. In Latin America, including the emblematic case of Cuba and its successful track record in promoting biotechnology (Natzik & Ban, 2022), the initiative to develop national COVID-19 vaccines was in the hands of the public S&T sector. However, funding is not enough. There is also a need for public policies that encourage promoting the sector in the long term, with convergence between different areas (regulatory, health, S&T), a key aspect for large-scale biopharmaceutical projects. These policies must take into account local and regional economic, political, social, and cultural specificities in order to aspire to intra-regional collaboration.

Regional convergence. Regional collaboration in the development and production of vaccines is another viable strategy to facilitate vaccine access, materialized in the coordination and integration of regional value chains (RVC) (Scholvin et al, 2021). This is facilitated by the fact that regional firms know the regulations, standards and policies of their own region, favoring the organization of RVC. Moreover, in the case of countries such as Chile, which have research groups of excellence but lack infrastructure for the production of biologics under GMP standards (Cortes et al, 2012), intra-regional collaboration could contribute to making up for these deficiencies. This regional dynamic requires the implementation and coordination of national public policies that promote RVCs, for example, through protectionist policies in the face of foreign competition, and convergence in terms of IP. Regulatory

harmonization would not only allow a fluid exchange at the regional level but would also contribute to international competitiveness.

Regulatory issues. The strong demand for vaccine access in pursuit of the "public interest" in an emergency context conflicted with the traditional approval processes for biologics deployed by regulatory agencies, which require rigorous scientific evidence of safety and efficacy (Bortz et al. 2019). The pandemic put the spotlight on the State's construction of "citizenship" (and how it should behave), relying on State decisions based on scientific evidence. However, society judges public behavior through complex and heterogeneous criteria, including imaginaries, past memories of State failures, and power abuses (Jasanoff and Kim 2019), which must be taken into account when formulating public policies. In fact, in Brazil, vaccines originating from China (Sinovac) or Russia (Sputnik V) were less accepted by the population, even though in the case of Sinovac it was produced in Brazilian territory (Bernardeau-Serra et al, 2021).

Role of the S&T sector. The development of local vaccines such as the "ARVAC-Cecilia Grierson" in Argentina and ButanVac in Brazil, showed a change in public-private interaction dynamics. In the Argentinean case, the design of the vaccine took into account the available private manufacturing capacities and the fact that it would be administered in booster vaccination campaigns. As a local development, the researchers imprinted into the technology design imaginaries of "technology and health sovereignty", as well as they took into account the future conditions of distribution of the vaccine when selecting the vaccine technology. In the Brazilian case, previous public sector capacities acquired in the local production of influenza vaccine were mobilized in order to speed up the production and approval process of the ButanVac vaccine. It should be noted that in the case of vaccine production, inter-institutional and interdisciplinary collaboration through articulated partnerships, as well as the formulation of public policies that promote these dynamics, represent a critical factor in favoring competitiveness and innovation.

Developing complementary capabilities. As defined by Teece (1986), complementary assets are of vital importance for capturing value through innovations. Moreover, their management and control determine the results of the value chain: the lack of a key input can disrupt the entire chain. In both the Argentine and Brazilian cases, critical bottlenecks were identified in the local production of foreign vaccines, due to the lack of supply of key inputs (such as vials for packaging) (Simões Pazelli et al, 2022. Thus, the implementation of public policies at the regional level on complementary capacity building would allow for greater autonomy with respect to key biopharmaceutical inputs, as well as a critical step towards the consolidation of regional hubs and value chains.

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