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Strategies for drug production and procurement in a context of technological dependency

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In 1899, an epidemic of the bubonic plague struck the port city of Santos, São Paulo State, Brazil, a strategic hub for Brazil's exports. The event was at the heart of the Butantan Institute's subsequent creation. The Pasteur Institute in Paris (France) was the sole producer of anti-plague serum, which created difficulties for its rapid importation. The director of the São Paulo Health Service at the time, Emílio Ribas, thus proposed a solution to the provincial government to decrease foreign dependency: the founding of a lab to produce antisera in Brazil [1].

This story is an example of Brazil's efforts to free itself of foreign dependency in the production and purchase of essential goods such as drugs, antisera, and vaccines. Unfortunately, this dependency has become more acute over time. The pharmachemical industry, among others, suffered a process of accelerated deindustrialization. In the last 40 years, the production of active pharmaceutical ingredients (API) dropped from 55% to 5%, according to the Brazilian Pharmachemical Industry Association (Associação Brasileira da Indústria de Insumos Farmacêuticos – Abiquifi) [2].

The issue has come under discussion again in recent months, due to the need to import active ingredients for production of the two vaccines approved for emergency COVID-19 use in Brazil. This dependency has become more evident, since in November 2020 some 50% of the volume of vaccines in advanced stages of development had been reserved by European Union countries, Canada, United States, United Kingdom, Australia, and Japan [3], leaving middle- and low-income countries uncovered and prompting World Health Organization (WHO) Director-General Tedros Adhanom Ghebreyesus to condemn "vaccine nationalism" [4].

Beginning in the 2000s, various industrial policy proposals aimed to reverse the situation of deindustrialization, including Brazil's domestic pharmaceutical industry among their targets. Dependency on imports of APIs and medicines, reflected in a trade balance deficit for the sector, sustained the argument of vulnerability of the Brazilian Unified National Health System (SUS) in the face of high prices and health technologies supply. This argument allowed the adoption of a series of instruments to promote domestic production of active ingredients and medicines. These have included the so-called Productive Development Partnerships (PDP), which use temporary exclusive reserve of the public market

through the procurement of medicines used by the SUS to seek technology transfers' between private companies and government laboratories and encourage domestic production of API.

One of the milestones in the use of government procurement as an incentive for domestic drug production was a change in Brazil's legislation in 2012. The provision introduced the possibility of government agencies making direct purchases of strategic health inputs produced by government laboratories and products established through PDP, either still in the technology transfer process or as products that have already been fully nationalized (paragraphs XXXII and XXXIV, *Law 8,666/1993* [5]). Still, the Law requires the prices offered by government laboratories to be consistent with market prices.

This provision guarantees a public market for government laboratories to serve the demands from the SUS. In practice, however, servicing this demand has met challenges, such as questions concerning transparency of information in the purchase agreements and stimulus for an environment of competitive "disadvantage" for other products already available on the domestic market, and even difficulty in comparing prices, thereby hindering their adoption by local purchases managers.

Despite advances in price transparency in Brazil's domestic public market through initiatives like the government Price Panel, for purposes of comparability, public administrators do not enjoy sufficient backing to make purchases, especially in the decision to dispense with public bidding to purchase medicines directly from the government laboratories. The prices contained in the Panel must be based on strict parameters such as regionalization of the purchase site, due to distortions in tax legislation, purchase volumes, and time between orders, thus preventing comparisons of the products' unit values.

This scenario helps explain the Brazilian Ministry of Health's historically central importance in direct purchases, in both practical and operational terms. The situation thus reinforces the key role of the Ministry's purchasing power at the national level, by effectively promoting and maintaining any initiative backed by guarantees of the public procurement market in public health.

Notwithstanding the promise that such initiatives would favor Brazil's autonomy, reduce the vulnerabilities of policies for pharmaceutical services in the SUS, and strengthen the country´s capacities for innovation, the data show that the trade balance in the pharmaceutical sector still records a huge deficit [6]. The monopoly situation generated by patent protection contributes to the high prices of new imported technologies; as demonstrated by the current scenario, the monopoly can affect production capacity in different countries.

Even though the lessons learned from technology transfers might allow technological capacity-building to innovate in the future, and although transfers have been backed by greater flexibility in acquisitions of this type of product by the government, they have not been accompanied in a coordinated way by investments in research and development and education, which are essential for technological accumulation. Thus, the use of the State's purchasing power to stimulate technology transfers (already existing), as an isolated strategy, is a government option that maintains Brazil in a situation of technological dependency.

In this sense, the article *Assessment of the Economic Savings and Advantages of Productive Development Partnerships*, by Alexandra Albareda & Ricardo Lobato Torres [7] (both from the Federal Technological University of Paraná), illustrates the critical importance of assessing new strategies for innovation and supply from the point of view of the public administration. The results show the relative efficiency of PDP in economicity – lower prices, larger

volumes purchased – but not their success in aspects related to quality, represented by lack of the technology's quality or doubts as to its essentialness, thus compromising its advantageousness. The study's results show that PDPs have still not achieved their expected effectiveness as a public policy initiative.

However, even though government pharmaceutical laboratories represent a small fraction of Brazil's domestic pharmaceutical industry, their strategic place in health policy has changed over the years and according to context; the laboratories are often hostage to circumstances in which certain public policies include (or exclude) them when meeting the SUS's needs. From this perspective, PDPs were relevant in the recognition of government laboratories, guaranteeing their presence in purchases by the SUS. And the COVID-19 pandemic has underlined the importance of installed production capacity for preparedness and timely response to crisis situations and shortages of technologies.

Brazil is still far short of autonomy in the production of active ingredients, medicines, and vaccines. Even so, the country's domestic production, including government production, is still essential for the health system and for the health of the Brazilian population. The analysis of recent efforts to promote domestic production provides valuable sources for learning and documenting experiences for the present and future, allowing the improvement and defense of an industrial policy to tackle the vulnerabilities of pharmaceutical services in the SUS, which often requires confronting and breaking with the rules set by the international pharmaceutical industry.

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All the authors participated in the editorial's planning, writing, and revision.

Additional informations

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