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Towards an industrial policy for expanding access to health

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Abstract *The text presents and discusses a new direction of the Unified Health System (SUS) policy geared toward the Health Industrial Complex. A policy aimed at the technological and productive development of public and private companies in the health field flourished from 2007 to 2016 and has been weakened and deformed since then. Despite its success, the so-called Productive Development Policy (PDP) evidenced some weaknesses that must be tackled during its resumption. Besides suggesting this resumption, the text proposes to expand the policy by articulating the primary PDP tool – Public-Private Partnerships – with other related policies that involve the health industry operated by the Ministry of Health.*

Key words *Health Industrial Complex, Public-Private Partnerships*

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Introduction

In particular, based on the line of research by Carlos Gadelha and José Temporão, the relationship between health and development has been enriched in recent years with the category of the Health Economic-Industrial Complex (CEIS)[1]. These authors argue that studying the relationship between health, development, industrial production, and services had several designations depending on the desired angle of analysis, until it resulted in the CEIS concept[2] more recently. In an even more recent paper, the author presents this concept as an object of research and development[3].

On the other hand, from my viewpoint, this vital development should not eclipse the Health Industrial Complex concept, firstly because it is part of the CEIS, but also because it must stand in a privileged place in the more concrete terrain of policy construction and management. After all, it guided the Ministry of Health in building relevant public policies in the first two decades of this century.

This text does not intend to discuss a research program or even look at the global outlook, although a debate on these broader dimensions is more than relevant. I aim to discuss the organization of public health policy management in its relationship with the industry producing goods of interest to this policy in approaching the Brazilian situation. Here, the theme is to resume the debate on the Health Industrial Complex, the policy that thematized it, and its primary operational tool – Productive Development Partnerships.

However, instead of just taking stock of experience, I believe we should look ahead and approach the issue of Policy and Partnerships in a broader framework, which will be to outline a possible (in my view, necessary) backdrop for the relationship between the Ministry of Health (MS) and the industrial products. I understand that this very successful policy must be reconfigured within management. In other words, I understand that it must exceed "productive development partnerships" in this broader framework, which was its primary operational tool. I also believe that several other policies underpinned by the Health Industrial Complex component and aiming to put technology and industrial production at the service of expanding access to industrial products by the population as a common denominator should take part in this reconfiguration. It could be called an "industrial policy with increased access". In this new configuration, we should emphasize that the policy will feed and also be fed in several aspects by the low-, medium-, and high-complexity care policies, health surveillance, and the very close pharmaceutical care policy.

The Productive Development Policy stemmed from the 2002 and 2006 elections, which reoriented Brazilian political life. In the new situation, the SUS and the MS held a central place, valuing that they were the destination of an essential share of the Brazilian market for industrial products and, from 2007, using the power conferred by this demand as an instrument of public policy.

In my opinion, the axis of the new configuration of the productive development policy lies in its expanded scope and greater integration of its executing agents. I understand that a public policy with this scope should include activities whose governance is not in the Ministry, the SUS, and not even exclusively in the health sector.

From this perspective, without prejudice to others, I would highlight the following policies:

- The Productive Development Policy in its original configuration;
- The Brazilian Industrial Policy;
- The Policy on scientific and technological research in health;
- The SUS technology assessment and incorporation policy (ATS);
- The Drug Price Control Policy;
- The Health Surveillance Policy;
- The Intellectual Property Policy.

These seven policies played a crucial role in the work of the MS focused on industrial products. In my viewpoint, in what I am calling reconfiguration, they should continue to fulfill this role, but in a much more pronounced synergy and coordination relationship.

One of the measures that contributed to the success of the PDP was an Executive Board called GECIS (the Health Industrial Complex Executive Group). It consisted of government bodies and was complemented by another collegiate body in which business representatives from the health complex participated. GECIS was extinguished in 2017. For this new proposal, it is essential to create an executive (albeit nonorganizational) body that gathers representatives from these seven policies: a reconfiguration of GECIS.

Next, I will comment on each of the programs and policies involved in this reconfiguration, with suggestions about their actions and some residual challenges from their participation in the relationships between the MS and the Health Industrial Complex between 2008 and 2016.

The Productive Development Policy

The primary guiding principle of this policy was that it should include strengthening the Industrial Complex in its entirety – research, development, and production – in harmony and articulation with SUS priorities.

Alongside its successes, the PDP left some crucial challenges, among which I highlight its exclusive focus on mature technologies and its detachment from fundamental research activity and, as it is known today, from translational research. Moreover, some weaknesses were identified in some official laboratories regarding their ability to absorb more complex technologies, in particular, those involved in drugs produced by biological routes. Finally, there may have been failures in selecting "strategic" products, where almost always only cost was used as a criterion for selecting products for potential partnerships.

The Brazilian Industrial Policy

The central institution for building this policy is the BNDES. It was established in 1952 and was responsible for promoting industrial activity, despite the different ways of conceiving this policy over time and even the very concept of industrial policy. These variations included replacing imports, trade liberalization in the 1990s, the three versions of industrial policy from the first decade of this century, and the current phase in which the BNDES drastically reduced industrial development, emphasizing, from 2017 onwards, its institutional downsizing, service and agriculture financing, and the modeling of the privatization process. Building a policy for industrial products geared to health must count on the active participation of the Bank, in particular, its Industrial Complex and Health Services Department. This department inherited the department that launched, in 2004, the Pharmaceutical Chain Support Program (PROFARMA), which had a significant presence in the PDP from 2008 to 2016. The health services component was only incorporated into the department in 2017, and there is room for debate about the opportunity of this merging of objects. Besides the BNDES, the role of a revived FINEP will be essential in building mechanisms to foster health innovation. Finally, a debate on the role of the Brazilian Industrial Research and Innovation Company (EMBRAPII) should be included in industrial policy, inspired by the German *Fraunhofer-Gesellschaft* model. Alongside essential contributions in bringing research groups and industrial companies together, EMBRAPII has had an isolated performance vis-à-vis other technological and industrial policy tools and a negligible presence in the Health Industrial Complex. It would be necessary, for example, to discuss its complementarity/competition relationship with FINEP.

The Policy on scientific and technological research in health

I believe that a health research policy within the SUS must encompass it entirely, including health-disease transitions, health systems and policies, research on the Health Economic-Industrial Complex, and the relationships between health and society. This approach avoids limiting the efforts of the scientific and technological creation of the SUS to the immediate operational needs of its managers, despite the importance of these needs. The health research agenda for the SUS must be broad, particularly when a spatial and temporal approximation between research results and the solution of health problems is observed globally. The Ministry of Health has extensive and quality research structures, including the Oswaldo Cruz Foundation, with units throughout the country, the National Cancer Institute in Rio de Janeiro, and the Evandro Chagas Institute in Belém. These three institutions underpin what could be called the SUS intramural research capacity and should continue to receive special attention from the Ministry. However, most of the country's scientific and technological research activities in health are disseminated by universities and research institutes not directly linked to it. A health research policy operated by the Ministry of Health should embrace this large installed capacity, responsible for the most significant number of researchers and graduate programs in the Brazilian research sectors. To this end, the MS policy must be closely articulated with the Ministry of Science, Technology, and Innovation (MCTI) and its agencies (CNPq and FINEP), besides CAPES, linked to the Ministry of Education. The primary institutional environment of this articulation is the management committees of the Sectorial Funds, where the presence of the Ministry of Health must be strengthened.

The SUS technology assessment and incorporation policy (ATS)

In 2007, Congress started to discuss a legal norm to regulate the constitutional provision of

comprehensiveness that Law 8.080/1990 failed to do, which resulted in the enactment of Law 12.401/2011[4]. In a nutshell, it prescribes which and under what circumstances goods and services can be provided by the SUS and duties for the MS, and the most important is establishing the National Committee for the Incorporation of Technologies in the SUS (CONITEC). As we know, CONITEC comprises members of the Ministry of Health, including ANVISA and ANS, CONASS, CONASSEMS, the National Health Council, and the Federal Council of Medicine. The committee decides with the technical collaboration of an extensive network of research groups in universities and institutes inaugurated in 2008, which I will discuss next.

CONITEC has two major threats, both involving potential conflicts of interest. One of them is the presence of representatives of the pharmaceutical industry among its members. The other concerns conflicts of interest by research groups that analyze items that could potentially be incorporated into the SUS and linked to the industry. A more recent threat to CONITEC emerged during the Temer and Bolsonaro governments. It consisted of modifying the mechanism for incorporating technologies into the SUS, with the establishment of a body external to the Ministry of Health that would absorb CONITEC's duties and would also include decisions on incorporating items in the supplementary health list. As far as I know, this proposal was unsuccessful, but it is necessary to be attentive to it.

The Drug Price Control Policy

In Brazil, this policy began in 1999/2000 with the Parliamentary Commission of Inquiry (CPI) on medicines, followed by the enactment of the Generics Law and the creation of the Drug Market Regulation Chamber (CMED) in 2003, which is still active today. Compared to most countries, this has been a distinctly counter-cyclical trajectory. Despite measures that may improve its performance, CMED's action was the primary tool for this journey, along with implementing the generic policy, whose price management is incumbent on the Chamber. Among the positive aspects of CMED's work, perhaps the most important is the concept that price control should be predominantly located in the sphere of health interests, overdetermining the economic and industrial interests involved in pricing. CMED's Executive Secretariat at ANVISA and the presidency of the council of ministers involved in the final deliberation on prices chaired by the Minister of Health were fundamental for this option's sustainability. A public consultation (2021) that proposes very unclear changes in the pricing methodology and, above all, shifts drug price control from the health sphere to the economic sphere was recently published by the Ministry of Economy (public consultation SEAE nº 02/2021[5]), which is a severe mistake and should cause disproportionate drug price increases.

The Health Surveillance Policy

ANVISA's relevance, repeatedly demonstrated throughout its history, became even more evident in its performance during the COVID-19 pandemic, when it resisted the denialism of the leaders of the Ministry of Health and the President of the Republic. Regarding the Health Industrial Complex policy, strengthening ANVISA implies rebuilding its staff, paying particular attention to its components that have been neglected in recent times (such as CMED's Executive Secretariat), establishing the Agency's cooperative relationships with CONITEC and improving its operational practices.

The Intellectual Property Policy

This is, perhaps, the most complex component to be addressed in the implementation of a policy for industrial products in the SUS, because it is anchored in rigorous international standards and advocates for the interests of patent-holding oligopolies (TRIPS-1994), complemented by local lobbies in the National Congress and other forums for the benefit of the interests of the international pharmaceutical industry (TRIPS-PLUS devices). These lobbies played a significant role in drafting the 1996 Intellectual Property Law and currently have an essential trench in large specialized law firms. In all significant national intellectual property agencies worldwide, besides upholding high-quality technical standards, there is permanent attention to the strategic industrial policy guidelines in the country to which they belong. The example of India in this regard is quite eloquent. In the Brazilian case and the field of human health, this means that the National Institute for Intellectual Property (INPI) should include in its technical repertoire a closer perspective of an industrial policy that values the local development and production of industrial products in the field of health to expanding access.

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Conclusion

Finally, I reiterate that this draft proposal addresses the reconfiguration of a successful experience, albeit with weaknesses, which was the policy inaugurated in 2008, expanded in 2012, disfigured in 2017, and extinct in 2019 – the Productive Development Policy. This reconfiguration proposes an increasing synergy and articulation of several policies previously conducted without these characteristics and I believe this will require aligning strategic objectives built with much dialogue and exchanging experiences and viewpoints. However, such construction will demand a profound change in the country's general policy, including in the health field and the relationship between this field and industrial, scientific, technological, and innovation policies.

The Ministry will have a greater degree of governance in some of the dimensions mentioned in this proposed reconfiguration, while this will not happen in others. Hence, it will be as crucial as enunciating its components, building, in the Ministry, the corporate bodies that will make this proposal happen. It is not a matter of detailing this structure. However, I believe that, with regard specifically to the Productive Development Policy, the Ministry of Health's Secretariat of Science, Technology, and Strategic Supplies should once again have a specific department to manage it. One possibility would be reactivating the Industrial Complex and Innovation in Health Department, created in 2007 and extinguished in 2019. The decision to extinguish this department, whose attributions were transferred to a new department, was motivated by a misunderstanding of the relationships between the components of productive development and the evaluation and incorporation of technologies. In the current situation, the evaluation and incorporation of technologies encompass and subordinates the MS policy for the Health Industrial Complex, which is a notorious mistake.

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