

Development policy for the Brazilian health industry and qualification of national public laboratories

A política de desenvolvimento produtivo da saúde e a capacitação dos laboratórios públicos nacionais

La política de desarrollo productivo en salud en Brasil y la cualificación de los laboratorios públicos nacionales

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Abstract

Technological innovations play a decisive role in societies' development by contributing to economic growth and the population's welfare. The state has a key role in this process by inducing innovative behavior, strategies, and decisions. This study addresses Brazil's current policy for development of the health industry and its effects on qualification of national public laboratories by contextualizing different cycles of interaction between health policy and the industrial base, discussing the government's development strategy and the transfer and absorption of health technology (through Industrial Development Partnerships), and presenting two current partnerships involving public laboratories in the production of medicines and vaccines.

Innovation and Development Policy; Official Laboratory; Unified Health System; Sustainable Development; Innovation

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Introduction

Technological innovations that generate new products, new production processes, and new organizational formats¹ play a decisive role in the development of societies, contributing to economic growth and the population's welfare^{2,3}. Their importance has achieved wide consensus among governments, public policymakers, companies, and the scientific community in developed countries, where innovation policies have developed as an amalgam of science and technology policies and with the agreement that innovation is a complex, systemic phenomenon⁴.

The systemic nature of innovation processes refers to the influence exerted by factors that are external to the organizations, such as institutions (laws, regulations, rules, etc.), the political process, public research infrastructure (universities, research institutes, funding agencies, etc.), financial institutions, and professional training, among others⁵. These are the systems' principal components for the creation and commercialization of knowledge. Innovations thus emerge in such innovation systems, combining economic, political, social, organizational, and institutional factors that influence their development, diffusion, and use⁶. These aspects tend to act as incentives and/or obstacles to the innovative process.

Innovations generally occur in companies, but the state can strongly induce company behavior, strategies, and decisions pertaining to innovation⁷. Furthermore, recognition of the collective and social nature of innovation fosters the adoption of public policies focused on the public sector's specific role in this process, so as to contribute to the materialization of research and development (R&D) activities that would not have happened otherwise^{8,9}. Various policy instruments are used for this purpose, including public financing for teaching and research institutions, infrastructure for innovation, technology transfer mechanisms, public demand, government purchases, etc.¹⁰. These instruments allow managing the risks associated with the innovative process (high costs, long timeframes, and uncertainties). They also have short and long-term direct and indirect impacts on the scientific, economic, and social fields¹¹.

In the health field, the state can orient and fund specific R&D projects and favor the appropriate use of technologies by adopting a coherent set of public policies¹²: trade policies (which influence the creation of companies and their activities), R&D policies (which promote the development of technologies that can transform health services), and health policies (with a direct

impact on healthcare supply, including regulation of the entry of new technologies in health systems). Various examples show the state's centrality in generating innovations in the health field. For example, 75% of all molecules approved by the U.S. Food and Drug Administration from 1993 and 2004 had received public funding⁹.

According to article 200 of Brazil's 1988 *Federal Constitution*, the Brazilian Unified National Health System (SUS) is responsible for promoting scientific and technological development in its area. However, several signs point to a mismatch between Brazil's health and innovation systems in recent years^{13,14}: (a) the lack of organic relations between the services provision network and companies in the health industrial complex; (b) health policy centered on expanding the supply of services, with no major concern for the industry's capacity for innovation or thus the state's purchasing power in a development policy targeting domestic companies and laboratories; (c) a science and technology policy focused on the science system, overlooking links with an industrial policy for innovation and the health system's needs; and (d) absence of convergent regulatory policies for intellectual property and health surveillance.

Trade balance problems and the strong presence of non-resident patents are two indicators of the dissociation characterizing the Brazilian health sector's innovation system. There is a heavy external technological dependency in accessing new health technologies, as illustrated by the trade balance for these products: the cumulative deficit increased from some US\$ 3 billion in 2003 to more than US\$ 10 billion in 2012¹⁵. Meanwhile, 87% of the 2,972 patents obtained by Brazil in 2013 belonged to non-residents (foreigners)¹⁶, demonstrating domestic industry's weak performance in generating new technologies and the persistent immaturity of the Brazilian innovation system¹⁷.

The article analyzes the Brazilian health sector's current industrial development policy and its effects on the qualification of national public laboratories. It contextualizes the different cycles of interaction between health policy and its industrial base; discusses the Brazilian government's strategy for the development, transfer, and absorption of technology in the health sector (industrial development partnerships); and presents two current partnerships involving public laboratories for the production of antiretroviral drugs and influenza vaccines, respectively.

Cycles of interaction between health policy and its industrial base

Capitalist development and health policy have interacted in such a way as to construct different formats in the organization of services, combined with the establishment of health's own industrial base, consisting of industries that have produced different technologies (sera, vaccines, medicines, equipment, materials, etc.) at each stage in history^{13,18}. The degree of external dependency in this industrial base accompanies the historical patterns of capitalist development, in which countries with original (England) or delayed industrialization (Western Europe and the United States) predominated – and still predominate – in production and technological development in a major portion of this industrial segment¹⁹. In the peripheral countries, or those with late industrialization²⁰, e.g. Brazil, this industrial base has been very incipient and dependent on the development of the model adopted by the country.

Brazil's recent history has witnessed three emblematic models or arrangements between health policy and industrial production²¹: (i) the age of sanitation, during the First Republic (1889-1930), when the country developed a public industrial base devoted to the production of sera and vaccines by public institutes (Oswaldo Cruz Foundation and Butantan Institute); (ii) the age of individual or collective social security, in 1930-1988, when the policy's industrial base was supplied by the importation of nearly all the necessary inputs, along with the domestic production of medicines and equipment with low technological density; and (iii) the age of the SUS, post-1988, with the combined expansion of the public industrial base based on government laboratories and a model of public-private partnership in health, developing a synergy between expanded access and technological and industrial capacity-building in public and private institutions.

The main characteristics of the first model (age of sanitation) was the fact that it was public and national, since it consisted of public institutions and services, received government funding, and displayed a low degree of external dependency^{22,23,24}. The model also opened the way for a genuinely national scientific development in biotechnology (sera and vaccines)^{25,26}. This first arrangement focused on combatting major endemics and epidemics. It was launched and initially developed during the First Republic (1889-1930). The protagonists were government agencies engaged in the formulation and coordination of actions in the health field (at the federal

and state levels) and public institutes of science and technology, created in the late 19th and early 20th centuries.

The second model (social security) was developed together with the social security health model, beginning in the 1930s^{27,28,29}. Unlike the previous model, this arrangement was essentially private and international. Its financing was mixed (public and private), with a predominant supply of private services (hospitals and laboratories) and an internationalized chain of producers and suppliers of medical inputs, medicines and equipment. All this produced a scenario of major external dependency and growing trade balance deficits with these health products.

The third model (SUS) experienced major growth in the last decade, with the consolidation of a new model of interaction between state and market, centered on national development³⁰. Various public policies were created, aimed at a new investment cycle in infrastructure and some industrial sectors, with subsidized credit and financing to foment innovation and scientific and technological development in specific areas, notably health³¹.

In the history of health policy, the first two models existed side by side during the developmentalist period (1930-1980). However, the predominant public and national model was gradually replaced by the private international arrangement, due to various factors: technological change (biotechnological products for fine chemistry and synthesis of molecules in the pharmaceutical sector); creation of private laboratories producing sera and vaccines (e.g., the Pinheiros Laboratory in São Paulo); the leading role of heavy industry and infrastructure investments on the development agenda; and internationalization of capital with the arrival of multinational industries in Brazil.

The two models coexisted during the 1980s and 90s, when neoliberal policies were adopted. On the one hand there were initiatives to foment the public model via public policies like the expansion of immunization (National Immunization Program – PNI), incentives for public production of inputs (e.g., the National Program for Self-Sufficiency in Immunobiologicals), and stimulus for healthcare based on primary care (the Family Health Program). On the other hand, private insurance and health plan companies were strengthened, which helped consolidate the characteristics of the social security model³²; the supply of private beds and tests based on a strong increment in the importation of medicines and medical and hospital equipment, with private financing and government subsidies for expanding the supply and purchasing healthcare services.

In the current period, the first model (public and national) gained a new centrality on the government agenda. This period is illustrated by specific policies for promoting science and technology (S&T) activities and supporting domestic companies in the health industrial complex, alongside expansion of the public hospital and outpatient capacity, especially in the Northeast and Central regions of the country. However, there has also been a major expansion of the second model (privately oriented and internationalized) via an increase in the coverage of private health plans, favoring and encouraging the expansion and capitalization of health insurance and health plan companies.

The two healthcare production arrangements illustrate the historical tensions between health and development in Brasil²¹. While these arrangements contributed to the de-commodification of access to health services through the development of the SUS, they also allowed denser commodification of supply (salaried staff, incorporation of group medicine companies, etc.) and the development of health as a field of capital accumulation of capital accumulation¹⁸. These arrangements were not established or combined during the same historical period, but they coexist today in a complex way within the Brazilian health system (Table 1).

Partnerships for industrial development in health: a brief institutional overview

In March 2004, the Brazilian government launched its Industrial, Technological, and Foreign Trade Policy (PITCE), establishing a framework for the resumption of policies to induce production and technological development in the country. The health field was basically contemplated in the pharmaceuticals and medicines sector. However, the structuring and implementation of the PITCE was embryonic and contained significant institutional gaps, in addition to dissociation from the prevailing macroeconomic policy, unfavorable to sustained growth³³. In the subsequent years, with the creation of the Executive Group for the Health Industrial Complex (GECIS) and the Department of the Health Industrial Complex and Innovation in Health (DECIIS) under the Brazilian Ministry of Health, interaction between health policy and industrial policy gained institutional force, which allowed including on the government's agenda the importance of the health industrial complex and public production of strategic technologies for the SUS.

Table 1

Characteristics of arrangements for the production of health services in Brazil.

Characteristics	Type of arrangement	
	Public-National	Private-International
Historical origins	1st Republic (1889-1930)	1920s-1930s
Areas	Public health	Social security-based medicine
	Control of endemics and epidemics	Individual care
Supply of services	Predominantly public	Predominantly private
Financing	Public	Mixed
Scientific development	National	International
	Public laboratories	Foreign companies
	Mainly sera and vaccines	Medicines, vaccines, equipment, etc.
External dependency	Low	High

The PITCE was succeeded by the Industrial Development Policy, launched in May 2008, which proposed to overcome the preceding policy's limitations and expand the scope of action to include a broader range of sectors. Health was included as one of the strategic areas, with explicit goals related to the local production of strategic products for the SUS and reduction of the trade deficit in sectors comprising the health industrial complex. Despite progress in the governance model proposed in the policy area, with a clear definition of roles and responsibilities, the policy's implementation was jeopardized by the deepening international economic crisis, reversing the favorable conditions that had based its formulation and limiting the capacity to meet its goals³⁴.

Based on recognition of an unfavorable conjuncture for Brazilian industry, the "Plan for a Greater Brazil" (PBM) was launched in August 2011, replacing the previous policy. With the overall objective of sustained economic growth (even in an adverse economic context), the PBM defined ten major program goals and adopted instruments to reduce the labor and capital costs (tax unbundening) and support innovation and defense of the domestic market (regulatory framework, credit lines, and government purchases). The plan contemplated the health industrial complex as one of the 19 strategic sector agendas, setting priority goals and measures for implementation. Although the majority of the system and sector measures were implemented^{35,36}, preliminary assessments suggests that the PBM failed to achieve the expected results^{37,38}.

Linked to these economic development policies, some measures were adopted by the Brazilian Ministry of Health to stimulate domestic production of strategic and priority items for the SUS. Examples of these measures include the creation of the Program for Investment in the Health Industrial Complex (Procis); the use of the state's purchasing power, with the application of a 25% preference margin in federal public bids for medical products; and the formation of Industrial Development Partnerships (PDP) between public institutions and private corporations for the production of strategic products to meet the demands of the SUS, with expected technology transfer and absorption.

The institutionalization of these measures involved a broad set of standards adopted in the last decade (Table 2). This regulatory framework was not built all at once, but by layers, reflecting the issue's centrality on the government's agenda in recent years.

Data presented by the Brazilian Ministry of Health in December 2014 point to 103 PDP under

way, with 33 products registered with Anvisa (the Brazilian National Health Surveillance Agency) and 26 products acquired by the Brazilian Ministry of Health through these partnerships³⁹. Also according to the Brazilian Ministry of Health, 74 institutions were involved, including 19 public laboratories and 55 private companies. This scenario provided a turnover of 3.8 billion BRL for the public institutions and a savings of 1.6 billion BRL in 2011-2014. By the end of the projects in the PDP phase, estimates points to a savings of some 5.3 billion BRL.

Despite the progress provided by the PDP, studies have identified limits and areas for improvement^{40,41,42}: the Brazilian Ministry of Health's limited budget capacity to stimulate the market using its own purchasing power; the need to extend beyond the mere regulatory issues and sustain the state's active role in the promotion of development; the need to maximize the success rate of the established partnerships in terms of delivering products and actual technology transfer to domestic producers; the need to verticalize the industrial process for pharminochemical and pharmaceutical components involved in the partnerships; the need to guarantee the quality of the products involved in the partnerships; and the need to interrupt partnerships that are failing to meet the agreed-upon goals. Gadelha & Costa⁴³ identified other obstacles to the effectiveness of the PDP: lack of expertise in the processes of technology transfer from the private sector to the public sector and limitation of public producers in relation to technical competency, laboratories' management capacity, and good manufacturing practices of Anvisa.

Gaps and imperfections have also been identified in the new legislation on PDP⁴⁴: unclear rules on choice of the private partner; lack of transparency in information on established PDP; and legal insecurity as to protection of intellectual property rights. Other equally controversial issues involve the direct hiring of partnerships (without the need for public bids); the possibility that partnerships may merely disguise the purchase of medicines as technology transfer agreements; and the fact that some of the products covered by the PDP are in a mature stage of development, with their patents already expired or about to expire, which would guarantee markets for transnational pharmaceutical companies involved in the agreements until domestic production is effectively implemented.

Despite these weaknesses, various representative organizations from the health industrial complex (Brazilian Association of the Fine Chemicals Industry, Biotechnology and its Specialties – ABIFINA, Brazilian Association of the Industry

Table 2

Health policy and industrial production: principal legislation.

Date	Legislation	Subject
December 2, 2004	Law 10,973	Rules on incentives for innovation and scientific and technological research in production, among others
February 28, 2008	Ruling 374/GM/MS	Establishes the National Program to Foment Public Production and Innovation in the Health Industrial Complex. According to article 2, "the Program's objective is to promote the strengthening and modernization of the public laboratories in charge of producing strategically important medicines and immunobiologicals for the Brazilian Unified National Health System, through the expansion of participation in the Health Industrial Complex, increased innovative capacity, and change in competitiveness, contributing to the reduction of the existing technological gap and to the country's economic, scientific, and technological development"
February 28, 2008	Ruling 375/GM/MS	Establishes the National Program for Qualification, Production, and Innovation in Equipment and Materials for Use in Health in the Health Industrial Complex, whose attributions include stimulating productive efficiency according to the "Guidelines for Industrial, Technological, and Foreign Trade Policy". Article 3 presents the following objectives: "set priorities based on the technological demands of the Brazilian Unified National Health System, the target markets of the industrial sector, and the country's installed capacity; stimulate interaction between companies, universities, and science and technology institutes and the industry and encourage technological exchange among the industrial sectors; provide linkage to guarantee regulatory stability with Anvisa (National Health Surveillance Agency) and INMETRO (the National Metrology Institute); stimulate certification of products as an instrument to promote the sector's innovation and development; stimulate expansion of public and private investments in R,D&I.; stimulate the private sector to use the existing support instruments to expand technological development in the public and private sectors; stimulate training and capacity-building of human resources in biomedical areas; expand and modernize the infrastructure for Basic Industrial Technology in the sector; and propose the adoption of government bidding and procurement policies based on the inputs' quality and technology transfer"
May 12, 2008	Decree DNN 11,578	Creates, in the Ministry of Health, the Executive Group of the Health Industrial Complex (GECIS)
May 16, 2008	Ruling 978/GM/MS	Defines a list of strategic products in the Brazilian Unified National Health System (SUS) in accordance with the development of the health industrial complex. Relevant provision on its key role with PITCE and PROFARMA (BNDES), especially as it specifies the Ministry of Health as the institution to back these two policies
May 30, 2008	Inter-Ministerial Ruling 128/MPOG/MS/MCT/MDIC	Establish guidelines for government purchases of medicines and drugs by the Brazilian Unified National Health System (SUS)
September 17, 2008	Ruling GM/MS 1,942	Approves the bylaws of the Executive Group of the Health Industrial Complex (GECIS) and establishes the Standing Forum for Linkage with Civil Society
December 16, 2008	Ruling 3,031/GM/MS	Rules on criteria for Government Laboratories in the production of medicines, for bidding procedures for purchase of raw materials.
May 26, 2010	Ruling 1,284/GM/MS	Amends Ruling 978 of May 16, 2008, by establishing a list of priority products for the Brazilian Ministry of Health
December 15, 2010	Law 12,349	Amends Laws 8,666 of June 21, 1993, 8,958 of December 20, 1994, and 10,973 of December 2, 2004, and repeals paragraph 1, article 2 of Law 11,273 of February 6, 2006. According to Law 12,349, the bidding process should promote national development and give preference to domestically developed products or services and their cost may exceed by 25% the price of foreign manufactured products and services

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Table 2 (continued)

Date	Legislation	Subject
February 2, 2011	Resolution of the Collegiate Board (RDC) 2/Anvisa	Rules on the procedures in the National Health Surveillance Agency (ANVISA) for monitoring, instructing, and analyzing the registration and post-registration processes in Brazil for medicines produced through public-public or public-private partnerships and technology transfer in the interest of the Brazilian Unified National Health System (SUS)
April 4, 2011	Ruling 649/GM/MS	Amends paragraph 1 of article 2 of Ruling GM/MS n. 1,942 concerning the definition of membership of the Standing Forum for Linkage with Civil Society
April 28, 2011	Law 12,401	Amends Law n. 8,080 of 1990, rules on technological incorporation in the Brazilian Unified National Health System (SUS), and provides in Article 19-Q that "the incorporation, exclusion, or alteration of new medicines, products, and procedures by the SUS as well as the establishment or alteration of clinical protocols or treatment guidelines are attributions of the Ministry of Health, advised by the National Commission on the Incorporation of Technologies in the SUS"
June 28, 2011	Decree 7,508	Regulates Law n. 8,080 of 1990 on the organization of the Brazilian Unified National Health System (SUS), health planning, healthcare, and linkage between states and municipalities, and Section II rules on the National List of Essential Medicines (RENAME), which is provided by the Ministry of Health and includes the selection and standardization of recommended medicines for treatment of diseases or conditions within the SUS
September 28, 2011	Resolution 001/GEPBM	Refers to the decision by the Executive Group of the Plan for a Greater Brazil (Brasil Maior) on the creation of the Executive Committees, Sectorial Competitiveness Councils, and Systemic Coordination Bodies
September 28, 2011	Resolution 002/GEPBM	Refers to the decision by the Executive Group of the Plan for a Greater Brazil (Brasil Maior) on the bylaws of the Executives Committees, Sectorial Competitiveness Councils, and Systemic Coordination Bodies
December 21, 2011	Decree 7,646	Deals with the membership, competencies, and functioning of the National Commission for the Incorporation of Technologies in the Brazilian Unified National Health System (CONITEC) and further addresses the administrative process for the incorporation, exclusion, and alteration of health technologies by the Brazilian Unified National Health System (Article 1)
January 18, 2012	Law 12,593	Establishes the National Health Plan (2012-2015) in keeping with the Multiannual Plan (PPA) and establishes as one of its 16 guidelines the strengthening of the health industrial complex and science, technology, and innovation in health as a structuring vector in the national agenda for economic, social, and sustainable development with reduction of vulnerability in access to health
September 17, 2012	Law 12,715	Amends Article 24 of Law on Public Bidding (Law 8,666 of June 21, 1993), raising the possibility of exemption from public tenders in hiring that involves technology transfer for strategic products for the Brazilian Unified National Health System (SUS), in accordance with Law 8,080 of September 19, 1990, as listed in the minutes of the national board of the SUS, including acquisition of such products during the technology absorption stage
February 7, 2012	Ruling 204/GM/MS	Designates full members and alternates for the Plenary of the National Commission on the Incorporation of Technologies in the Brazilian Unified National Health System (CONITEC)
March 21, 2012	Ruling 506/GM/MS	Establishes the Program for the Development of the Health Industrial Complex (PROCIS) and its Management Board. PROCIS aims to strengthen public manufacturers (of drugs, biologicals, medicines, immunobiologicals, medical products, equipment, and materials for use in health and diagnostic kits for "in vitro" use) through investment in qualification of personnel and infrastructure. The central strategy of PROCIS is the expansion of Industrial Development Partnerships (PDP)
April 18, 2012	Ruling 837/GM/MS	Defines guidelines and criteria for the establishment of Industrial Development Partnerships (PDP)
September 13, 2012	Resolution of the Collegiate Board (RDC) 50/Anvisa	On Anvisa procedures for registration of pipeline products or technology transfers subject to public-public or public-private Industrial Development Partnerships of interest to the Brazilian Unified National Health System (SUS)

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Table 2 (continued)

Date	Legislation	Subject
September 17, 2012	Decree 7,807	On definition of strategic products for the SUS, in accordance with section XXXII of the heading and paragraph 2 of Article 24 of Law 8,666 of 1993, ruling that the national board of the SUS will define the strategic products for the SUS in keeping with the recommendations issued by the Executive Group of the Health Industrial Complex (GECIS)
July 30, 2013	Ruling 1,554/GM/MS	Provides rules on the financing and execution of the Specialized Component of Pharmaceutical Care in the SUS
December 11, 2013	Ruling 3.089/GM/MS	Redefines the list of strategic products for the Brazilian Unified National Health System (SUS) and the respective rules and criteria for such definition
May 29, 2014	Resolution of the Collegiate Board (RDC) 31/Anvisa	Rules on the simplified procedures for applications for registration, post-registration, and renewal of registration of generic drugs, similar drugs, specific drugs, dynamized drugs, herbal drugs, and biologicals, among other provisions
September 19, 2014	Resolution of the Collegiate Board (RDC) 43/Anvisa	Rules on the unlinking of registrations granted by means of the simplified procedure established by RDC 31/2014 for medicines resulting from Industrial Development Partnerships or technology transfer aimed at internalization of the production of strategic medicines as defined by the Brazilian Ministry of Health, among other provisions
November 12, 2014	Ruling 2,531/GM/MS	Redefines the guidelines and criteria for definition of the list of strategic products for the Brazilian Unified National Health System (SUS) and the establishment of Industrial Development Partnerships (PDP) and rules on the respective processes for submission, instruction, decision, transfer, and absorption of technology, acquisition of strategic products for the SUS within the PDP and respective monitoring and evaluation
December 30, 2014	Ruling 2,888/GM/MS	Defines the list of strategic products for the Brazilian Unified National Health System (SUS)

of the Medical, Dental, Hospital and Laboratory Equipment – ABIMO, Brazilian National Association of Pharmaceutical Laboratories – Alanac, Pró-Genéricos) and the public health field (Brazilian Public Health Association – ABRASCO and Brazilian Center of Health Studies – Cebes) have recently come out publicly in favor of the Federal government's industrial development policy implemented by the Brazilian Ministry of Health ⁴⁵.

The role of public laboratories in industrial development partnerships

An important issue for PDP is qualification of public laboratories, involving various previously outlined aspects for innovation and self-sufficiency in the health sector. According to the Brazilian Ministry of Health ⁴⁶, there are 21 government laboratories in the country which jointly produce 80% of the vaccines and 30% of the drugs used in the SUS ⁴⁷. These laboratories play relevant roles in price regulation; support in emergency situations; supply to strategic public health programs such as STD/AIDS and the PNI; and as partners in the development of new products and pharmaceutical formulations ^{48,49}.

Despite the importance of public laboratories in meeting the needs of the SUS, some studies ^{50,51} have identified political, administrative,

and operational problems, along with low technological capability and lack of qualified human resources. The low utilization rate of the installed capacity and lack of agility in meeting the SUS demand, due to the requirement of complying with the public sector's rules for bidding and purchases, especially for purchasing imported raw materials, also hinder the work by public laboratories ⁵².

In order to discuss the influence of PDP on qualification of public laboratories, two partnerships were selected, one related to the National HIV/AIDS Program (antiretroviral drugs) and the other to the PNI (influenza vaccines). The criteria for selecting these partnerships were the products' relationship to strategic programs, participation by different public laboratories in their execution, and two recent studies that allow a more critical view of this process ^{49,53}. In the case of antiretroviral drugs, the existence of visible short-term effects such as the growth of financial turnover, greater availability of locally produced active pharmaceutical ingredients (APIs), and savings for public purchases and foreign reserves. The second case highlights the range of changes involved: construction of new installations; purchase and adaptation of equipment; and large-scale manufacturing processes, with strong participation by the government agency in all the phases.

PDP linked to the HIV/AIDS Program

Brazil is a world reference in the fight against HIV/AIDS. For 16 years the SUS has guaranteed universal access to medicines for treating HIV/AIDS, in addition to tests and medical follow-up, benefiting 217 thousand persons, or 97% of all Brazilians diagnosed with AIDS. The production of antiretroviral drugs (ARV) in Brazil has reached important milestones, for example with Efavirenz, where the country declared compulsory licensing for the first time, guaranteeing more affordable prices based on domestic production of this drug⁵⁴.

The Brazilian Ministry of Health currently invests 850 million BRL in the purchase of 21 ARV. Of the 21 products, eight were the object of PDP between 2009 and 2012. The following public laboratories are involved in ARV production: Ezequiel Dias Foundation – Funed (Tenofovir 300mg, Entecavir), Pernambuco State Pharmaceutical Laboratory – LAFEPE (Tenofovir, heat-stable Ritonavir, Raltegravir), and Institute of Technology on Drugs – Farmanguinhos in partnerships with Funed, Popular Drugs Foundation – FURP, and LAPEDE [Atazanavir sulfate, Lopinavir + Ritonavir, Tenofovir + Lamivudine (2 in 1), and Tenofovir + Lamivudine + Efavirenz (3 in 1)]. Two public laboratories (Funed and LAFEPE) participated in a foreign (Blanver/Nortec) and national partnership (Cristália) for production of Tenofovir.

As for the potential impact of PDP on qualification of public laboratories, some issues were identified that corroborate the results presented by Rezende⁴⁹:

- a) Annual turnover: all the partners showed a two- to threefold increase in turnover after implementing the PDP;
- b) Innovative impacts: increased production or services provision capacity; opening of new markets and expansion of market share; and quality improvement in goods or services;
- c) In-house R&D activities: compares the number of persons occupied in R&D, showing relatively less growth in public as compared to private laboratories, but with a significantly greater share in fulltime R&D staff;
- d) Organizational innovations: adoption of new management techniques (revision of business processes, knowledge, total quality control, and training systems), marketing concepts and strategies, pharmacovigilance programs;
- e) Product innovations: the majority of the laboratories that innovated their products attributed such innovations primarily to the partnerships;
- f) Process innovation: better performance of public laboratories compared to private.

Many of the problems and obstacles that were identified relate to historically constructed situations with important cultural and organizational issues: difficulty adjusting to standards, norms, and regulations; organizational rigidity; lack of qualified personnel; high costs of innovation; and lack of sufficient funding sources. Added to this are difficulties related to lack of an entrepreneurial culture (establishing a new vision of their role in national S&T policy) and positioning in terms of agility of processes and networking with other companies and research institutes⁵¹.

PDP with the PNI

Brazil has a long history of success in immunizations. The Brazilian Ministry of Health launched two important strategies in the 1970s and 80s: the creation of the PNI in 1973 and the National Self-Sufficiency Program (PASNI) in 1985. These strategies, especially the PNI, played a key role in consolidating the national health system, mainly in the following areas⁵⁵: public health planning; methodology for operationalization of large-scale mobilizations; detailed training methodology for public health professionals; progress in science and technology; promotion of quality of life and longevity; targeted approach to groups with increased vulnerability; and guarantee of citizenship.

Introduction of the influenza vaccine produced an important redefinition in the vaccination schedule. The decision was made in 1999, with two epidemiological approaches, namely benefiting the country's growing elderly population and including technology transfer from a foreign laboratory (Sanofi) to a Brazilian public laboratory, the Butantan Institute.

The technical assistance contract for the technology transfer was signed on October 1st, 1999. The contract was scheduled to end in February 2004 but had to be extended due to delays in the factory's construction, which was only finished in May 2007 because of problems with the bidding process⁵⁵. Considering the process development and external and internal contexts, three different periods can be identified in implementation of the partnership: (i) 1994-2004: beginning of the transfer process and construction of the factory; (ii) 2005-2008: conclusion of the installations and beginning of the transfer per se; and (iii) 2009-2011: certification of the transfer, especially with formal creation of a PDP in 2010.

The partnership had the following positive effects on qualification of the Butantan Institute: expanded institutional capacity for technology transfer; qualification for large-scale influenza vaccine production; improvement

in good manufacturing practices; command of new technologies; and possibility of developing innovations (in this case, the introduction of an adjuvant tested at the institute and institutional development capable of influencing the production of other vaccines).

Institutionally, the study shows the possibility of proceeding with this process backed by the preconditions that were identified, but also weaknesses related to prevailing science and technology policy strategies to support public institutions and the structure of these same institutions (the Butantan Institute in this case) and the limits imposed by serious structural obstacles to their development.

Nearly all of the institutions' administrative structures are heavily based on rules for direct government administration, insufficiently agile to meet the demands of technology transfers (ranging from purchase of inputs to retrofitting installations). Human resource policy in this area adopts job definitions and career paths that are inconsistent with vaccine production activities (where the commands and technical structure need to be clearly defined, with flexible management and development).

Conclusions

Brazil was hindered for a long time by the lack of public policies to develop a national innovation system in health, strengthen public laboratories, and expand the installed capacity of companies belonging to strategic sectors of the health industrial complex. The result is heavy international technological dependency, making the country an example of a non-virtuous model of the association between health and development⁵⁶. However, the more recent adoption of policies and programs to induce national development, with specific initiatives for the health field, sug-

gest the emergence of a new model. The PDP are a prime example, since their design prioritizes a combination of positive forces to overcome the health system's external dependency and expand the population's access to priority products.

Despite the progress provided by PDP for interaction between health policy and production, it is necessary to identify the historical challenges faced by the public laboratories, which have been relegated to a secondary role during the long predominance of the private international model. The technology transfer process encouraged by PDP thus represents a potentially dynamic element for incremental innovations to be developed more effectively in the public laboratories, as demonstrated by two examples of partnerships discussed in this study.

Major challenges include the adoption of more transparent decision-making, investments in infrastructure and staff qualification in the public laboratories, adoption of mechanisms to monitor and evaluate results, and guaranteed continuity in the health policy's focus and dialogue with the industrial base, even during changes in government administration. Given the diversity of institutions involved in the management of public laboratories, an additional challenge is to establish a special support policy, considering the different realities and defining proportional targets for the respective stages, besides an on-going incentives policy.

A pressing issue is to guarantee the capacity of the current healthcare production arrangement to reconcile the public logic of collective welfare and social inclusion with the private and individual market logic. The answer necessarily involves recognition of the state's responsibility in defining and linking public policies for integration of the multiple dimensions of development in order to help combine the market's interests with public health concerns and needs.

Contributors

A. L. d'A. Viana participated on the conception and project of the article, writing, critical revision and approval of the final version for publication H. P. Silva, N. Ibañez and F. L. Iozzi contributed on the data analysis and interpretation, writing of the article and approval of the final version.

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Resumo

As inovações tecnológicas jogam papel decisivo no processo de desenvolvimento das sociedades, pois contribuem para gerar crescimento econômico e bem-estar da população. O Estado possui grande importância e centralidade nesse processo, pois pode induzir fortemente o comportamento, as estratégias e as decisões relativas à inovação. O presente artigo tem por objetivo investigar a atual política de desenvolvimento produtivo em saúde no Brasil e seus reflexos sobre a capacitação dos laboratórios públicos nacionais. Para essa finalidade, contextualiza os diferentes ciclos de interação entre a política de saúde e a sua base produtiva, discute a estratégia do governo brasileiro para o desenvolvimento, a transferência e a absorção de tecnologia na área da saúde (as parcerias para o desenvolvimento produtivo) e apresenta duas parcerias vigentes envolvendo laboratórios públicos para a produção de medicamentos e vacinas.

*Política de Inovação e Desenvolvimento;
Laboratório Oficial; Sistema Único de Saúde;
Desenvolvimento Sustentável; Inovação*

Resumen

El Las innovaciones tecnológicas juegan un papel decisivo en el proceso de desarrollo de las sociedades, pues contribuyen a generar crecimiento económico y bienestar de la población. El Estado tiene una gran importancia y centralidad en este proceso, pues puede inducir fuertemente el comportamiento, las estrategias y las decisiones relativas a la innovación. El presente artículo tiene por objetivo investigar la actual política de desarrollo produtivo en salud en Brasil y sus reflejos sobre la capacitación de los laboratorios públicos nacionales. Con este fin, contextualiza los diferentes ciclos de interacción entre la política de salud y su base productiva, discute la estrategia del gobierno brasileño para el desarrollo, la transferencia y absorción de tecnología en el área de salud (las colaboraciones para el desarrollo produtivo) y presenta dos modelos de colaboración vigentes, involucrando laboratorios públicos para la producción de medicamentos y vacunas.

*Política de Innovación y Desarrollo;
Laboratorio Oficial; Sistema Único de Salud;
Desarrollo Sostenible; Innovación*

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