

Articulation of production and innovation policies and instruments for the HIC in Brazil, 2003-2017: the cases of Inova Saúde and Profarma

Executive Summary
2021

Research team:

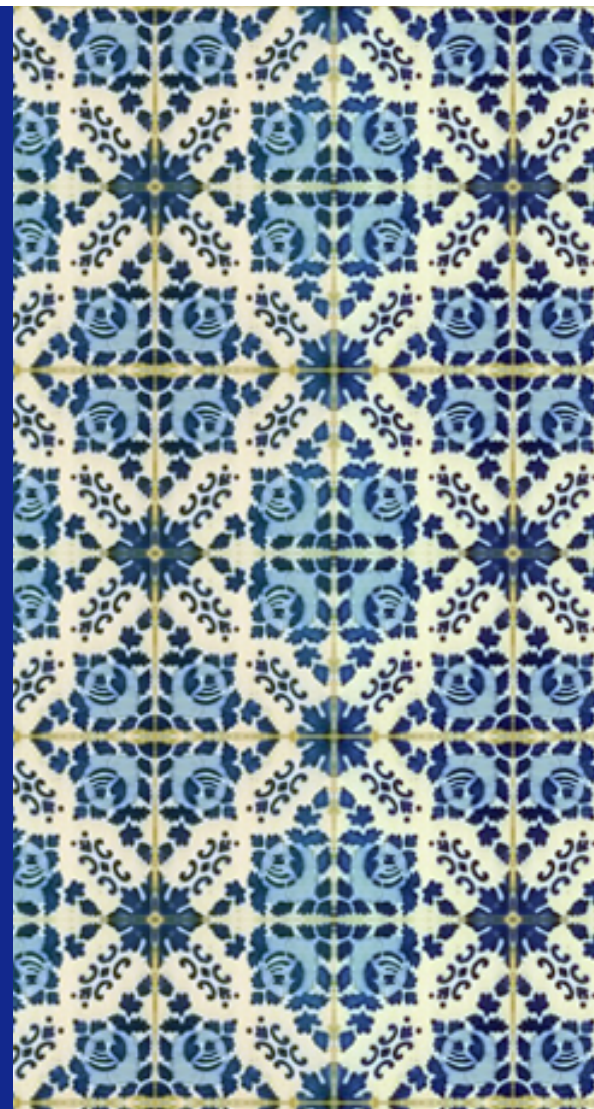
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FOREWORD

This Executive Summary presents the main findings of the research project “Innovation policies and instruments to the Health Industrial Complex in Brazil, 2003-2017”, funded by The Open Society Foundations and coordinated by Professor Dr Julia Paranhos. The project was carried out between 2018 and 2021 by the Economics of Innovation Research Group of the Institute of Economics at the Federal University of Rio de Janeiro (GEI/IE/UFRJ).

The purpose of the research is to contribute to the discussion on innovation and access to medicines in Brazil, seeking to bring scientific-based elements to demonstrate to policymakers the relevance of the connection and complementarity between health needs and support for production and innovation in the pharmaceutical industry. Furthermore, the aim is to collaborate to promote access to medicines and the sustainability of the Unified Health System (SUS).

The development of the research received contributions from a Steering Committee formed by members of the Associação Brasileira Interdisciplinar da Aids (ABIA), Instituto Brasileiro de Defesa do Consumidor (IDEC), Instituto de Estudos Socioeconômicos (INESC), Repórter Brasil, and three independent experts. The authors would like to thank the participation, collaboration and exchanges with all members of the Steering Committee and the four referees who gave their opinion on the preliminary version of the report.

The content presented in this publication is the author's responsibility.

THE PUBLIC HEALTH VALUE AS INNOVATION FINANCING-ORIENTED

Diagnosis

The Brazilian pharmaceutical industry is highly dependent on foreign production and technology, which affects the domestic access to medicines and the sustainability of the Unified Health System (SUS) due to the increase in health expenditures and pressure on the public budget.

Innovation policies and instruments focused on the unmet health needs of the Brazilian population are necessary to face these challenges.

Objectives

To present an ex-post analysis of the policies implemented in Brazil to strengthen the production and innovation of the Health Industrial Complex (CIS), mainly the local pharmaceutical industry, from 2003 to 2017, based on the perspective of the public health value.

To carry out an in-depth case study of the two main policy instruments that financially supported the pharmaceutical industry in the period.

Public Health Value

Driving health innovation through missions to pursue the public health value involves deciding which therapeutic areas

to prioritise and identifying unmet health needs (public and individual) that require new treatment options. The mission aims to expand the population's access to new medicines, financed with public and private resources.

Health Policies

- Plano Nacional de Saúde (2004-2007)
- Plano Nacional de Saúde (2008-2011)
- Plano Nacional de Saúde (2012-2015)
- Plano Nacional de Saúde (2016-2019)
- Pacto pela Saúde (2006-2011)
- Política Nacional de Ciência, Tecnologia e Inovação em Saúde (2008)
- Mais Saúde (2008-2011)
- Política Nacional de Inovação Tecnológica na Saúde (2017)

Industrial and STI Policies

- Política Industrial, Tecnológica e de Comércio Exterior (2003)
- Política de Desenvolvimento Produtivo (2008)
- Plano Brasil Maior (2011)
- Programa de Aceleração do Crescimento de Ciência e Tecnologia (2007)
- Estratégias Nacionais de Ciência, Tecnologia e Inovação (2012)
- Estratégias Nacionais de Ciência, Tecnologia e Inovação (2016)

WEAK HEALTH POLICIES IN SETTING PRIORITIES

The health policies were broad, generic and transitory concerning health demands.

A significant obstacle in defining health priorities was the implementation of different policies that addressed similar issues in overlapping periods and elaborated by various secretariats of the Ministry of Health (MoH), denoting a lack of coordination and articulation of proposals and actions.

They failed to set clear health priorities for industrial and science, technology, and innovation (STI) policies to create new industrial and technological capabilities.

Uncertainty about the demands and guidelines of the MoH reduces the interest of private investments, as it does not contribute to reducing the risks of investing in innovation.

The Strategic Products Lists were the policy documents that most clearly defined the MoH's priorities, indicating target diseases in line with the country's epidemiological profile. However, there were no transparency and disclosure to society about the selection criteria of the products.

In conclusion, the health policies could not provide a strategic orientation to meet society's current and future demands.

SHORT-TERM INDUSTRIAL AND STI POLICIES

The industrial policies defined priorities much more broadly than STI policies, and the latter was more aligned with health policies in determining target diseases and technologies.

The difficulty in coordinating policies stems from the divergence between the responsible bodies, i.e., industrial policies implemented by the Ministry of Development, Industry and Foreign Trade and the STI policies within the scope of the Ministry of STI.

The industrial and STI policies focused on local productive and technological capacity of CIS industries. The reduction of the SUS vulnerability appeared as a policies' objective only until 2008.

From 2016 onwards, a series of institutional breakdowns occurred, negatively affecting the continuity of policies.

FINEP AND BNDES: COMPETING INSTRUMENTS, NON-COMPLEMENTARY

Among the firms supported, 19 accessed instruments from both institutions, corresponding to 71.4% (BRL 5.9 billion) of the resources. More than BRL 4.1 billion (49.5%) were allocated to five firms, two of which received more than a quarter of the entire amount made available through the Innovation Agency (Finep) and the National Development Bank (BNDES) resources.

The Finep and BNDES programmes, especially the ones with reimbursable resources, were not aligned and were seen as competing rather than complementary instruments.

Among the 142 firms that accessed the policy instruments, 11 (8%) also had Productive Development Partnerships (PDPs) approved and accessed 36% of the resources (BRL 3 billion).

Finep	Subvenção Econômica (2006) Non-reimbursable resources Inova Saúde (2013) Reimbursable and non-reimbursable resources
BNDES	Profarma (2004) Reimbursable resources

The firms supported by the policy instruments and PDPs corresponded to 24% (11 firms) of the total firms with PDP approved. Among these, nine were national, and two were transnational firms.

The analysis of the three instruments shows a concentration in a few firms, which increases the importance of results evaluation processes in economic and social terms.

Finep & BNDES

- Resources made available: BRL 8.3 billion (USD 1.6 billion)
- Period: 2004-2018
- Funded projects/operations: 298
- Firms supported: 142

*Currency exchange BRL/USD = 5.04 (02 July 21).

LEARNINGS AND CHALLENGES

Positive remarks	Critical issues
POLICIES	
<ul style="list-style-type: none"> • Articulation between the demand for health and the supply of health goods and services • Creation of a concept to cover all actors participating in the health development process – CIS • Focus on strengthening SUS by expanding the productive and technological capacity of the CIS firms • Public procurement applied to encourage the strengthening of the firms' productive and technological capacity • Vital concern with the stimulus to local production and reduction of foreign technological dependence • Definition of a governance structure to coordinate and articulate policies and actors – GECIS (<i>Grupo Executivo do Complexo Industrial da Saúde</i>) 	<ul style="list-style-type: none"> • Lack of evaluation of policies in the three dimensions addressed: production, innovation, and health • Lack of clarity in the definition of MoH priorities and strong personification of actions, which were discontinued when the entry of new ministers and governments • Absence of actions aimed at small technology-based firms, especially in biotechnology • Low concern for the vulnerabilities of the pharmaceutical industry (i.e., Active Pharmaceutical Ingredient – API) • Increased focus on PDPs at the expense of the weakening of other policy instruments • Low civil society participation in debate forums, especially in GECIS
INSTRUMENTS	
<ul style="list-style-type: none"> • Availability of non-reimbursable resources for firms' innovation projects • Establishment of objectives and conditions for reimbursable resources following the evolution of firms, especially in BNDES' loans • Offer of different financing conditions for micro and small firms in the <i>Subvenção Econômica</i> and <i>Profarma</i> • Offer of financial support under special conditions for pharmaceutical and CIS firms for 13 years 	<ul style="list-style-type: none"> • Absence of external evaluation and monitoring of policy instruments focusing on productive and innovative development and their effects on public health • Lack of compensation for public health as a result of the public resources used • Loss of relevance of the <i>Subvenção Econômica</i> to support innovation projects at the expenses of the reimbursable resource • Constraint of the <i>Subvenção Econômica</i> resources • The intense concentration of resources to medium and large firms • Low articulation and complementarity during the elaboration of the policy instruments

LOOKING AHEAD

Policies recommendations

- Institutionalisation and continuity of actions, policies and instruments
- Rescue of the long-term policy proposal to strengthen CIS and ensure the sustainability of SUS and health promotion
- Recreation of the GECIS including civil society actors among its members
- Definition by GECIS of the health priorities to be pursued by joint industrial, STI, and health policies
- Coordination of explicit and implicit public policies for systemic action and construction of systemic policies
- Definition of missions for the adequate construction of the policy, instruments and its evaluation process
- Pursue the public resources transparency in government decisions, pharmaceutical companies' R&D costs and demand for public return on public investment
- Recognition of the contribution of public funds and publicly funded research institutions to the initial development of new drugs

Instruments recommendations

- Expanding access to medicine as an objective of public financing to CIS firms
- Coordination of policy instruments to provide complementary, non-rival support
- Implementation of monitoring and evaluation mechanisms in the productive, innovative and health dimensions
- Counterpart requirement from firms based on productive, innovative and health goals
- Reinforce and expand the public procurement through SUS, and create alternative forms linked to short- and long-term health demands
- Resumption of *Subvenção Econômica* from Finep
- Recreation of *Profarma* from BNDES

CONCLUSIONS

SUS as a driver of alignment between demand and supply instruments

The orientation of industrial and STI policies based on health needs was present in policy documents' rhetoric and design. However, there was no orientation in practice and the application of the policy instruments.

The *Subvenção Econômica*, *Inova Saúde* and *Profarma* were insufficient in articulating health needs and did not have the public health value as one of their goals. Moreover, this disarticulation took place within the scope of policies and ministries so that the responsibility is not solely of Finep and BNDES.

Brazil is the only country with a public health system (SUS) that cover an extensive population and geographic area. Therefore, in order to have a functioning system serving the entire population, it is necessary to think about the articulation between the demand for health and the supply of health goods and services. In this way, the existing opportunity must be used to implement demand and supply policy instruments to strengthen the local productive and innovative capacity.



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TRANSPARENCY

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