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REVIEW

Brazilian legislation on innovation policy: a brief history

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ABSTRACT

Innovation is essential for socio-economic progress, particularly in today's fiercely competitive global environment. This article's primary focus is to review the evolution of Brazilian regulations on innovation policy, a subject of intense debate by the government and academic and business institutions. The goal is to review this evolution and dissect the key regulatory frameworks, policies, and initiatives shaping the current scenario. Qualitative research is carried out in three stages: searching and selecting documents, reading and categorizing sources and records, and reviewing relevant information. Since the 2000s, Brazil has promoted legislative reforms to modernize the mechanisms to encourage research and development, such as the Legal Framework for Innovation (2004), the inclusion of the term innovation in the Federal Constitution (2015), the new Legal Framework for Innovation (2016) and the National Policy for Technological Innovation in Health (2017). These changes enhance legal certainty and tax benefits for collaborations between companies and Science, Technology, and Innovation Institutions. Despite the progress, it is still crucial for Brazilian institutions to adopt more robust innovation

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policies and more effectively align them with national development policies. Recently, the country intensified its innovation efforts by summarizing the Health Economic-Industrial Complex, integrated with the New Industrialization Policy, focused on economic, social, and sustainable development, highlighting public health. Brazil's evolution in innovation policy is a testament to the nation's steadfast commitment to technological and economic progress. While significant strides have been made, greater integration between institutions is imperative to maximize the benefits of innovation.

Key Words: innovation; innovation policy; innovation regulations; public health; normative evolution; Brazilian regulations.

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Introduction

This review aims to present the Brazilian regulatory history related to Innovation in the last twenty years and its main progress, especially in health. Understanding history is crucial for all stakeholders, as they provide a comprehensive view of the evolution of the regulatory system and the key milestones that have shaped the current scenario. Technological Innovation in healthcare has been a major catalyst, driving significant improvement that transcends borders and transforms how we care for health, preventing, diagnosing, and treating different health problems. At the heart of this innovation is the relentless search for more effective, accessible, and personalized care solutions. This includes increasing the efficiency of health systems, reducing costs, optimizing workflows, improving clinical outcomes, and seeking new or better technologies for use in medicine. The Brazilian federal government recognizes that Innovation is the key to sustainable development and that this development is only feasible with effective and coordinated public policies. Different government actions have been carried out since the early 2000s, including the sanctioning of laws and other normative documents related to Innovation. Also, it includes the recent resumption of the Health Industrial Economic Complex (in Portuguese: Complexo Econômico-Industrial da Saúde, CEIS), in 2023, and the industrial policy agenda (New Brazilian Industrialization Policy), in 2024.

Therefore, it is crucial that health professionals are well-versed in the evolution of Brazilian innovation policy regulations. This knowledge equips them to play a significant role in scientific research and healthcare, acting broadly, consciously, and collaboratively.

Objective

This paper aims to present the Brazilian regulatory history related to Innovation in the last twenty years and the main advances, especially in Health. Covering all content and knowledge related to innovation is not the aim of this review article, as the study of the conceptual and theoretical basis of innovation can be considered an established science. However, it is expected to contribute to science, knowledge and dissemination of the topics brought, both in theory and in its application, aiming to cooperate with the training of the contributors involved in the innovation

ecosystem, especially those in the health area. This paper has the potential to significantly impact the training and development of health professionals, providing them with the necessary knowledge and understanding of the Brazilian regulatory system to contribute to Innovation in the health sector effectively.

Research Method

This is qualitative research, in which bibliographic research was carried out as a data source from June 2023 to June 2024. For data analysis, the 'content analysis' technique was used according to Bardin's proposition [1]. In stage 1 (pre-analysis), the search and selection of documents and articles were conducted. The data sources were documents and scientific articles available in journal databases, website searches, and the federal government, where central themes were explored, with the following entries: “innovation”, “innovation in health”, “innovation policy”, “company-institution partnerships”, “resumption of the CEIS”, and “New Brazilian Industrialization Policy”. In stage 2 (exploration of the material), the reading, selection of information sources, and systematization of ideas and categories to be reviewed were carried out. In stage 3 (information processing), the relevant information of the identified categories was reviewed and highlighted.

Results

Innovation: Concepts and Typology

Although it is unanimous that the idea that technological Innovation is essential for scientific development, it was only with Schumpeter, one of the most influential economists of the first half of the twentieth century, that technological Innovation began to be considered a fundamental element for economic development and a driving factor of capitalist economies. Schumpeter used the word 'innovation' to describe a series of novelties that can be introduced into the economic system and that considerably modify the relations between producers and consumers. Since then, new development theories related to innovation and schools of thought have emerged, such as the neoclassical theory with Solow (1957) and the evolutionary theory with Nelson and Winter (1974) as precursors[1].

Currently, the concept and typology of Innovation considered by most organizations around the world are those described in the Oslo Manual of the Organization for Economic Cooperation and Development (OECD). The general definition of Innovation described in the 4th edition of the Oslo Manual[2], the latest version, is: "New or improved product or process (or combination thereof) that differs significantly from the unit's previous products or processes and that has been made available (product) to potential users or put into use by the unit (process). This definition uses the generic term "unit" to describe the actor responsible for innovations. It refers to any institutional unit in any sector”.

Regarding the typology of Innovation, the third and fourth editions of the Oslo Manual differ. According to the 3rd edition of the Oslo Manual[3], Innovation can be classified into four types:

[1] Varella SRD, de Medeiros JBS, Junior MTS. O desenvolvimento da teoria da inovação Schumpeteriana. XXXII Encontro Nacional de Engenharia de Produção; Bento Gonçalves, RS, Brasil; 2012. 10 p. (In Portuguese). Accessed 07.02.2025. https://abepro.org.br/biblioteca/enegep2012_tn_sto_164_954_21021.pdf.

[2] OECD & Eurostat. Oslo Manual: Guidelines for Collecting, Reporting and Using Data on Innovation. 4th Edition. Luxembourg: OECD & Eurostat; 2018. 258 p. Accessed 07.02.2025. https://www.oecd-ilibrary.org/science-and-technology/oslo-manual-2018_9789264304604-en.

[3] OECD & Eurostat. Oslo Manual: Guidelines for Collecting and Interpreting Innovation Data. 3rd Edition. Paris, France: OECD & Eurostat; 2005. 166 p. Accessed on 07.02.2025. https://www.oecd-ilibrary.org/science-and-technology/measurement-of-scientific-and-technological-activities_9789264065581-en.

A) Product Innovation: the introduction of a new or significantly improved good or service with respect to its characteristics or intended uses. Significant improvements in technical specifications, components and materials, embedded software, ease of use, or other functional features are included.
B) Process Innovation: The implementation of a new or significantly improved production or distribution method. Significant changes in techniques, equipment, and/or software are included.
C) Marketing Innovation: It is the implementation of a new marketing method with significant changes in the design of the product or its packaging, in the positioning of the product, in its promotion or in the setting of prices.
D) Organizational Innovation: This involves implementation of a new organizational method in the company's business practices, in the organization of its workplace, or in its external relations.

The fourth edition of the Oslo Manual reduces the complexity of the "types of innovation" from four types presented in the third edition of the Oslo Manual to only two main types: "product innovations" and "business process innovations". Product innovation is a new or improved good or service that differs significantly from the company's previous goods or services and has been introduced to the market. Product innovations can use new knowledge or technologies or be based on new uses or combinations of existing ones. They are characterized by the improvement of one or all the functions or performance specifications, the improvement or addition of a new function combined with the loss of other functions, or a decline in some performance specifications. Business process innovation is a new or improved process for one or more business functions that differ significantly from the company's previous business, and that have been put into use. In this sense, business process innovations concern six different functions of a company: production of goods or services; distribution and logistics, Marketing and Sales, Information and Communication Systems, Administration and Management of products, and Business Process Development.

Within the context of the innovation system, two models of interaction between the internal research department of an organization and the external environment have recently been addressed: closed innovation and open innovation. Closed innovation is a model in which the internal research departments of organizations do not communicate with external agents (such as other companies, stakeholders, partners, consumers, or other market actors). That is to say, all innovation efforts are internal to the very borders of organizations, which are the ones that keep all intellectual property. On the other hand, in open innovation there are inputs and outputs of knowledge to accelerate the Innovation of a company or organization and expand markets[4], bringing a participatory and decentralized innovation approach [2]. Open innovation can be categorized into three types: (a) Inbound Open Innovation occurs when a company acquires and absorbs knowledge from external sources in its external innovation activities to improve its internal processes and technologies; (b) Outbound Open Innovation occurs when a company intentionally allows other companies or organizations to use, combine, or further develop its technologies, tools, or ideas for its own innovation activities and for the purpose of commercializing it. An example is when a company licenses its technol-

[4] Chesbrough HW. Open Innovation: Researching a New Paradigm. Berkeley, CA: Oxford University Press; 2005. Chapter 1, Open Innovation: A New Paradigm for Understanding Industrial Innovation; p. 1-27. Accessed 07.02.2025. https://www.academia.edu/2008513/Open_innovation_a_new_paradigm_for_understanding_industrial_innovation?auto=download.

ogy, patents, or prototypes to another company; (c) Coupled Open Innovation (or Mixed Open Innovation) is the combination of open Innovation inbound and Outbound by the same company, in which the company works in partnership with other companies/organizations to develop or commercialize innovations. Consequently, the company proactively offers to collaborate on other projects and also seeks new ideas and partnerships for its own processes[4,5].

Evolution of the Brazilian RD&I Normative System

Historically, Brazil occupies a low position in the Global Innovation Index (GII) for a nation of its territorial size and economic potential. In 2011, Brazil achieved its best global position in the annually GII published by the World Intellectual Property Organization (WIPO), occupying the 47th position. However, in the following years, there was a decline, reaching the 70th position in 2015. Brazil's position improved in 2019, rising four places to 66th in the GII. With the goal of changing this scenario, Brazil has been promoting political discussions and structural reforms in its legislation since the early 2000s. These efforts aim to modernize the legal mechanisms to encourage innovation and the intellectual property system, thereby strengthening the innovation system and increasing the effectiveness of investments and activities in Research, Development, and Innovation (RD&I)[6]. Since then, the country has shown a progressive recovery. The recent GII (2023) revealed that Brazil rose from 54th (GII in 2022) to 49th position in 2023, thus occupying the leadership of the economies of Latin America and the Caribbean, a position previously held by Chile[7,8].

The Brazilian normative system in RD&I underwent significant changes at the end of 2004 when Law 10.973/2004 was sanctioned[9], known as the Federal Innovation Act and the Technological Innovation Act. Through this legal framework, public institutions were able to begin to participate effectively and legally in the innovation process, based on the regulation of technology transfer, the interaction between companies and Institutes of Science, Technology, and Innovation (ISTI), and guidance on incentives for Innovation and scientific and technological research in the productive environment. This law was initially regulated by Decree 5.563/2005, later revoked by Decree 9.283/2018, which is the current regulation in force of this law.

Subsequently, at the end of 2005, Law 11.196/2005 was sanctioned, known as the "Good Law", which creates the granting of tax incentives to legal entities that carry out research and development of technological Innovation. In other words, it is indirect financial support from the federal government, which abdicates part of the tax collection from private companies that prove to have invested in technological RD&I. These legal initiatives were driven by the considerable expansion of national programs to foster Innovation, with an increase in calls for technological innovation

[4] Chesbrough HW. Open Innovation: Researching a New Paradigm. Berkeley, CA: Oxford University Press; 2005. Chapter 1, Open Innovation: A New Paradigm for Understanding Industrial Innovation; p. 1-27. Accessed 07.02.2025. https://www.academia.edu/2008513/Open_innovation_a_new_paradigm_for_understanding_industrial_innovation?auto=download.

[5] Nerone MA, Canciglieri Junior O, Liao Y. Classification of the Open Innovation Practices: the Creativity Level. Open Access by IOS Press; 2014. Volume 1: Moving Integrated Product Development to Service Clouds in the Global Economy; p. 871–9. Accessed 07.02.2025. https://ebooks.iospress.nl/publication/37940.

[6] Lozouet L, Fonseca JC, Mazzonetto N. Guia de Melhores Práticas nas colaborações ICT-Empresas. Brasil: Brasil International Chamber of Commerce; 2020. 29 p. (In Portuguese). Accessed 07.02.2025. https://www.iccbrasil.org/wp-content/uploads/2021/09/icc_guia-de-melhores-praticas-ict-empresa_2020.pdf.

[7] Dutta S, Lanvin B, León LR, Wunsch-Vincent, S. Global Innovation Index 2023: Innovation in the face of uncertainty. Switzerland: World Intellectual Property Organization; 2023. 250 p. Accessed 07.02.2025. https://tind.wipo.int/record/48220.

[8] Dino. Brasil é 1o em inovação entre 19 países da América Latina. Valor Econômico; 20/October/2023. (In Portuguese). Accessed 07.02.2025. https://valor.globo.com/patrocinado/dino/noticia/2023/10/20/brasil-e-1o-em-inovacao-entre-19-paises-da-america-latina.ghtml.

[9] Brazil. Law 10.973, December 2, 2004. (In Portuguese). Accessed 07.02.2025. https://www.wipo.int/wipolex/en/legislation/details/19033.

projects considering ISTI-business partnerships. This innovation scenario in Brazil demanded a change in culture and adaptation of the structures and work processes of companies and ISTI to leverage successful interactions and partnerships capable of integrating knowledge in various fields of research for the generation of Innovation.

It is essential to highlight that the Federal Constitution of 1988 and Law 8.080 of 19.09.1990, did not mention "innovation" in their original texts. The introduction of the word "innovation" in the Federal Constitution of 1988 took place in 2015, through Constitutional Amendment 85 of 2015, Article 200, item V, as follows: “to increase scientific and technological development and innovation in its area of activity”. Constitutional Amendment 85 of 2015, therefore, introduced mechanisms that facilitate action in RD&I, such as allowing budget changes between capital and funding within the scope of scientific and technological projects, and assigned a more explicit role to the State in issues related to Innovation, such as encouraging the formation of partnerships between different spheres of the State, the academic sector (universities and research institutions) and the private sector.

In 2016, the new legal framework for science, technology, and Innovation was granted through Law 13.243/2016. This law, in addition to bringing its own provisions, amended nine other laws:

- Innovation Law – Law 10.973/2014
- Foreigner Statute – Law 6.815/1980 (later repealed by Law 13.445/2017)
- Bidding Law – Law 8.666/1993
- Differentiated Regime of Public Procurement Law – Law 12.462/2011
- Law of Temporary Hiring of Exceptional Public Interest – Law 8.745/1993
- Law of Support Foundations – Law 8.958/1994
- Law on the Import of Goods and Inputs for Research – Law 8.010/1990
- Law of Exemption or Reduction of Import Tax and Additional Freight for the Renewal of the Merchant Marine – Law 8.032/1990
- Law of the Career Plan of Higher Education – Law 12.772/2012

The strategic objective, at the time, was to allow more significant economic and social progress in Brazil through better use of the skills accumulated by ISTI and companies, facilitating synergistic efforts capable of making Brazil more innovative and competitive, either independently or through joint efforts with other countries[10].

In line with Law 13.243/2016, the Ministry of Science, Technology, Innovation and Communications (MSTIC) launches the "Guidance Guide for the elaboration of innovation policy in ISTI" in 201910. Built jointly by the National Forum of Innovation and Technology Transfer Managers (FORTEC) and the MSTIC, this guide aims to help ISTI managers to adapt their internal rules to the Legal Framework of Science, Technology, and Innovation. The institution of the Innovation Policy in ISTI has certainly provided greater agility and legal certainty so that the knowledge generated in academia, ISTI, and research and teaching institutions can be used by the business sector and society so that Brazil can take better advantage of this knowledge. The following year, in 2017, the National Health Innovation System received another stimulus in public policy, the institution of the "National Policy for Technological Innovation in Health" through Decree 9.245/2017. In 2020, Decree 10.534 was promulgated, which established the National Innovation Policy and provided for its governance.

[10] Martin AR et al. Guia de orientação para elaboração da política de inovação nas ICTs. Brasil: Ministério da Ciência, Tecnologia, Inovações e Comunicações/Secretaria de Empreendedorismo e Inovação; 2019. 55 p. (In Portuguese). Accessed 07.02.2025. https://repositorio.mcti.gov.br/handle/mctic/5129

Table. Key international and national documents related to R&DI in the health area.	
1992	Oslo Manual – 1st Edition.
1996	Law 9.279 of 14.05.1996. Regulates rights and obligations related to industrial property.
1997	Oslo Manual – 2nd Edition.
1998	Decree 2.553 of 16.04.1998. Regulates articles 75 and 88 to 93 of Law 9.279 of 14.05.1996, which regulates rights and obligations related to industrial property.
2001	Law 10.196 of 14.02.2001. Amends and adds provisions to Law 9.279 of 14.05.1996, which regulates rights and obligations related to industrial property, and provides for other provisions.
2004	(Innovation Law) Law 10.973 of 02.12.2004. Provides for incentives for innovation and scientific and technological research in the productive environment and provides for other measures.
2004	Law 11.079 of 30.12.2004. Establishes general rules for bidding and contracting public-private partnerships within the scope of public administration.
2005	(Law of Good) Law 11.196 of 21.09.2005. Establishes the special tax regime for the Information Technology Services Export Platform – REPES, the Special Regime for the Acquisition of Capital Goods for Exporting Companies – RECAP and the Digital Inclusion Program; provides for tax incentives for technological innovation; amends other decrees and laws.
2005	Decree 5.563 of 11.10.2005. Regulates Law 10.973 of 02.12.2004, which provides for incentives for innovation and scientific and technological research in the productive environment, and provides for other provisions.
2005	Oslo Manual – 3rd Edition.
2006	Decree 5.798 of 07.06.2006. Regulates tax incentives for technological research and development of technological innovation activities, as provided for in articles 17 to 26 of Law 11,196 of 21.11.2005 (regulates Chapter III of the Good Law).
2006	Complementary Law 123 of 14.12.2006. Establishes the National Statute of Micro and Small Enterprises; amends provisions of Laws 8.212 and 8.213, both of 24.07.1991 of the Consolidation of Labor Laws – CLT, approved by Decree 5.452 of 01.05.1943 of Law 10.189 of 14.02.2001 of Complementary Law 63 of 11.01.1990; and repeals Laws 9.317 of 05.12.1996, and 9.841 of 05.10.1999.
2007	Decree 6.041 of 08.02.2007. Establishes the Biotechnology Development Policy, creates the National Biotechnology Committee and provides other measures.
2007	(MEC Law) Law 11.487 of 15.06.2007. Amends Law 11.196 of 21.11.2005, to include a new incentive for technological innovation and to modify the rules related to accelerated amortization for investments linked to research and development (adds article 19-A to the Good Law to include a new incentive for technological innovation in ISTI financed by companies).
2007	(FNDCT Law) Law 11.540 of 12.11.2007. Provides for the National Fund for Scientific and Technological Development – FNDCT; amends Decree 719 of 31.07.1969, and Law 9.478 of 06.08.1997; and makes other arrangements.
2011	Normative Instruction 1,187 of 29.08.2011. Regulates the tax incentives for technological research and development of technological innovation activities referred to in articles 17 to 26 of Law 11.196 of 21.11.2005 (regulates Chapter III of the Good Law).
2012	Ordinance 837 of 18.04.2012. Defines the guidelines and criteria for the establishment of Partnerships for Productive Development (PDP).
2014	Ordinance 2.531 of 12.11.2014. Redefines the guidelines and criteria for the definition of the list of strategic products for the Unified Health System (SUS) and the establishment of Partnerships for Productive Development (PDP) and regulates the respective processes of submission, instruction, decision, transfer and absorption of technology, acquisition of strategic products for the SUS within the scope of the PDP and the respective monitoring and evaluation.
2015	Constitutional Amendment 85 of 26.02.2015. Amends and adds provisions in the Federal Constitution to update the treatment of science, technology and innovation activities.
2016	Law 13.243 of 11.01.2016. Provides for incentives for scientific development, research, scientific and technological training and innovation and amends other decrees and laws (update of the Innovation Law).
2017	Law 13.529 of 20.12.2017. Provides for the participation ofthe Federal Government in a fund to support the structuring and development of concession projects and public-private partnerships; amends other decrees and laws.
2017	Decree 9.245 of December 20th, 2017. Establishes the National Policy for Technological Innovation in Health
2018	Decree 9.283 of 07.02.2018. Regulates Law 10.973 of 02.12.2004, Law 13.243 of 11.01.2016, Law 8.666 of 21.06.1993, Law 8.010 of 29.03.1990, 1990, Law 8.032, of12.04.1990; Decree 6.759 of 05.02.2009.
2018	Oslo Manual – 4th Edition.
2019	Biotechnology Roadmap 2031 for Paraná is launched at FIEP event.
2019	Publication of the Term of Reference of the National Program to Support Innovative Environments (PNI).
2019	Guidance for the elaboration of innovation policy in ISTI. Ministry of Science, Technology, Innovation and Communications (MSTIC). Secretariat of Entrepreneurship and Innovation.
2019	MSTIC Ordinance 6.762 of 17.12.2019. Establishes the National Program to Support Innovative Environments – PNI, aiming to foster the emergence and consolidation of innovation ecosystems and mechanisms for the generation of innovative enterprises in the country.

Table. Key international and national documents related to R&DI in the health area.

2020	Decree 10.534 of 28.10.2020. Establishes the National Innovation Policy and provides for its governance.
2021	Ordinance 4.488 of 23.02.2021. Establishes, within the scope of the MSTIC, the Brazil-Biotec Initiative and creates the Steering Committee responsible for its supervision and implementation of its objectives.
2021	Law 14.133 of 01.04.2021. Bidding and Administrative Contracts Law.
2021	CI Resolution 1 of 23.07.2021. Approves the National Innovation Strategy and the Action Plans for the Axes of Development, Technological Base, Culture of Innovation, Market for Innovative Products and Services and Educational Systems.
2021	Law 14.195 of 26.08.2021. Amends Patent Law 9279 of 1996.
2021	Law 14.200 of 02.09.2021. Amends Law 9.279 of 14.05.1996 (Industrial Property Law), to provide for the compulsory licensing of patents or patent applications in cases of declaration of national or international emergency or public interest, or recognition of a state of public calamity of national scope.
2021	SGI Resolution 001 of 23.11.2021 – Establishes the Qualifica Mais Program, within the scope of the Digital Entrepreneurship Support Plan established by Decree 5.672 of 14.09.2020.
2021	Launch of the Theoretical Appendix of the National Innovation Strategy.
2023	Ordinance 1.100 of 28.09.2023. Establishes the Innovation Policy of the National Health Surveillance Agency (Anvisa).
2023	Ordinance OM/MoH (Office of the Minister/Ministry of Health) 2.259 of 08.12.2023 – Establishes the Production and Technological Development Program for Neglected Populations and Diseases – PPDN.
2023	Ordinance OM/MoH 2.260 of 08.12.2023 – Establishes the Program for Preparation in Vaccines, Serums and Blood Products – PPVACSH.
2024	Ordinance OM/MoH 4.472 of 20.06.2024 – Amends Consolidation Ordinance OM/MoH 5 of 28.09.2017, to provide for the Partnership Program for Productive Development – PDP.
2024	Ordinance OM/MoH 4.473 of 20.06.2024 – Amends Consolidation Ordinance of Ministry of Health (MoH) of 28.09.2017 and establishes the Local Development and Innovation Program – PDIL.
2024	Ordinance OM/MoH 3.089 of 15.01.2024 – Amends OM/MoH Ordinance 2.262 of 08.12.2023, which establishes the Program for the Expansion and Modernization of Infrastructure of the Economic-Industrial Health Complex – CEIS.

In Table, a timeline is provided and outlines the history of Brazilian regulations (laws, decrees, resolutions, and others) related to RD&I, the documents that encourage Innovation in Brazil, and the primary international documents.

Among the laws to encourage Innovation in Brazil, Law 11.079/2004 stands out, and Ordinance 837 of 18.04.2012, which made the Public-Private Partnership (PPP) and the Partnerships for Productive Development (PDP) possible respectively. In Brazil, the adoption of partnerships between the public and private sectors is identified, primarily through the concession regimes of public services, especially in the areas of Health, transportation, education, and housing. In Health, partnerships focus on the works, provision of services, and management of hospital units and have shown growth in recent years; in the Unified Health System (In Portuguese: Sistema Único de Saúde, SUS), there are examples of the Suburb Hospital in Salvador/Bahia, the Barreiro Metropolitan Region Hospital in Belo Horizonte/Minas Gerais and the Modernization of the Hospital Network in São Paulo/Brazil[11]. PPP are agreements between the public and private sectors for the joint performance of a particular service or work of interest to the population. It is signed by a contract of at least five years with a value of not less than 10 million reais and in which the private company is usually responsible for the project, as well as its financing, execution, and operation. PDP are collaborations between public institutions that produce strategic health and science, technologies and innovation products and private companies, in which the Ministry of Health (MoH) guarantees partners a particular share of the public market for a

[11] CONASS. Parceria Público Privada – Guia de Apoio à Gestão Estadual do SUS. Guia de Apoio à Gestão Estadual do SUS. (In Portuguese). Accessed 07.02.2025. https://www.conass.org.br/guiainformacao/parceria-publico-privada/.

specific drug, vaccine, or health product for a certain period. On the other hand, the technology is fully transferred to the public institution. These collaborations, therefore, are intended to meet the specific demands of the SUS and to give the Brazilian State sufficient bargaining power to reduce national technological dependence[12]. Ordinance 2.531, of 12.11.2014, of the MoH determines the establishment of PDP by repealing Ordinance 837 of 18.04.2012, 2012, and consolidates the guidelines and criteria for defining the list of strategic products for acquisition by SUS. The PDP are cited as strategic instruments of the National Policy for Technological Innovation in Health in Federal Decree 9.245/2017, Subsection II. The laws that made PPP and PDP feasible were essential initiatives to promote the results of R&D efforts and foster innovation through cooperation between companies and ISTI – public and private.

Resumption of the CEIS and the New Industrialization Policy in Brazil

The concept of CEIS emerged in the 2000s, highlighting health as a strategic area for the country's development. Its implementation began with Minister José Gomes Temporão in 2008, with its apogee in 2011. After 2011, this experience was stagnant and resumed in 2023 as a state policy. On 26.09.2023, the "National Strategy for the Development of the Health Economic and Industrial Complex" was officially launched by the Federal Government with an investment forecast of 42.1 billion by 2026. The strategy launched has six structuring programs and aims to expand the national production of priority items for SUS and to reduce Brazil's dependence on foreign inputs, medicines, vaccines, and other health products. This seeks to give the country greater autonomy in order to reduce the vulnerability of the health sector, strengthen the local production of goods and services, reduce judicialization in Health, and stimulate job creation in the sector[13]. One of the priorities is to support the production of inputs for the prevention, diagnosis, and treatment of socially determined diseases, such as tuberculosis, Chagas disease, viral hepatitis, and HIV. Another priority is addressing diseases relevant to public health, including chronic diseases (cancer, cardiovascular, diabetes, and immunological), dengue, health emergencies, and orthopedic trauma. In 2023, the health sector accounted for 10% of the Gross Domestic Product (GDP) and accounted for a third of scientific research in the country. However, Brazil's dependence on health inputs makes SUS vulnerable to the foreign market; namely, more than 90% of the raw material used in Brazil to produce vaccine and medicine inputs is imported. In the area of medical equipment, the national production is at 50%; in medicines, it is about 60%, and in vaccines, it is higher. The goal, with the investment foreseen in the strategy launched, is to reach an average of 70% of national production in the health sector[13].

The National Strategy for the Development of the CEIS is integrated into the effort to implement the New Policy for the Development of the Brazilian Industrial Sector, presented by the federal government in January 2024, whose guidelines are aimed at the economic, social, and sustainable development of Brazil. The new policy has the following measures: creation of memorable credit lines, grants, regulatory actions, intel-

[12] Gadelha C. Dinâmica global, impasses do SUS e o CEIS como saída estruturante da crise. Resgate. 16/novembro/2021 [Atualizado 15/02/2022]. (In Portuguese). Accessed 07.02.2025. https://outraspalavras.net/resgate/2021/11/16/dinamica-global-impasses-do-sus-e-o-ceis-como-saida-estruturante-da-crise/.

[13] Ministério da Saúde, Brasil. Governo Federal lança Estratégia Nacional para o Desenvolvimento do Complexo Econômico-Industrial da Saúde com investimento de R$ 42 bilhões até 2026. Brasil: Portal do Governo Federal – Ministério da Saúde; 26/setembro/2023 [Atualizado em 27/setembro/2023]. (In Portuguese). Accessed 07.02.2025. https://www.gov.br/saude/pt-br/assuntos/noticias/2023/setembro/governo-federal-lanca-estrategia-nacional-para-o-desenvolvimento-do-complexo-economico-industrial-da-saude-com-investimento-de-r-42-bilhoes-ate-2026.

lectual property actions, and policy of public works and purchases (with incentives for local content) to stimulate the productive sector. The goals are grouped into six missions that guide efforts until 2033, in which Mission 2 stands out referring to the CEIS[14]. Along with the policy, the National Council for Industrial Development delivered the action plan for the period 2024-2026, indicating the priority strategic areas for the application of resources.

The current New Brazilian Industrialization Policy and government actions to encourage Innovation in Brazil predicts the country's rise in the GII in the coming years. These actions include revisions to the current RD&I regulations and public policies to encourage partnerships between companies and ISTI, such as: Public Consultation 53/2023 DECEIIS/SECTICS – Local Development and Innovation Program – PDIL (extended by CP 55, of 12.22.2023, Official Gazette of 01.02.2024, Section 1, page 156); Public Consultation 54/2023 DECEIIS/SECTICS/MoH – Partnership Program for Productive Development – PDP (extended by CP 56, of 12.26.2023, Official Gazette of 12.28.2023, Section 1, p. 174).

Final considerations / conclusions

In the current techno-productive paradigm, innovating is a matter of survival and, at the same time, sovereignty in the market. "Not innovating" incurs a high risk of deterioration in the competitive performance of the company or institution. Since the early 2000s, Brazil has been increasing policy actions and promoting structural reforms in its legislation to modernize the legal mechanisms to encourage RD&I, including the intellectual property system. Noteworthy is the establishment of the Legal Framework for Innovation in 2004, the inclusion of the term innovation in the Federal Constitution in 2015, the new Legal Framework for Innovation in 2016, and the National Policy for Technological Innovation in Health in 2017, which offer greater legal certainty and tax incentives for the establishment of partnerships between companies and ISTIs. Despite all these efforts, it is still urgent and necessary for Brazilian institutions to adopt an innovation policy as a reflection of the consensus that the efforts to boost Innovation in Brazil depend on the participation of ISTI and their more incredible insertion in national and local development policies. Brazil has recently intensified the innovation movement with the resumption of the CEIS (2023) integrated with the New Brazilian Industrialization Policy (2024), whose guidelines focus on the economic, social, and sustainable development of Brazil, with particular attention to the area of public Health.

References

1. Bardin L. Análise de Conteúdo. 1st Edition. São Paulo, Brasil: *Edições 70*. 2015; 288 p.
2. Chesbrough HW. Open Innovation: The New Imperative for Creating and Profiting from Technology. Boston, Massachusetts: *Harvard Business School Press*. 2003; 227 p.

[14] Ministério do Desenvolvimento, Indústria, Comércio e Serviços, Brasil. Brasil ganha nova política industrial com metas e ações para o desenvolvimento até 2033. Brasil: Portal do Governo Federal – Ministério do Desenvolvimento, Indústria, Comércio e Serviços; 22/janeiro/2024 [Atualizado em 23/janeiro/2024]. (In Portuguese). Accessed on 07.02.2025. https://www.gov.br/mdic/pt-br/assuntos/noticias/2024/janeiro/brasil-ganha-nova-politica-industrial-com-metas-e-acoes-para-o-desenvolvimento-ate-2033.