



**Thematic Budget for
Science, Technology
and Innovation in
Medicines (OTMED ST&I)**
Technical Note

Brasilia, May 2021



Thematic Budget for Science, Technology and Innovation in Medicines (OTMED ST&I) – Technical Note

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Acronyms

ANVISA – Brazilian National Health Surveillance Agency
API - Active Pharmaceutical Ingredient
BNDES - Brazilian National Bank for Economic and Social Development
BRICS – Brazil, Russia, India, China and South Africa
CEFET - Federal Technological Education Centers
CNS - National Health Counsel
CIS - Industrial Health Complex
CITEC - Commission for Technology Incorporation
CONITEC - National Commission for Technology Incorporation at SUS
CNEN - Nuclear Power National Commission
ST&I - Science, Technology and Innovation
FINEP - Funding Authority for Studies and Projects
FIOCRUZ - Oswaldo Cruz Foundation
FNDCT - National Fund for Scientific and Technological Development
FNS - National Health Fund
GECIS - Executive Group of the Industrial Health Complex
ICT - Scientific and Technological Institution
INESC – Institute of Socioeconomic Studies
INPI - Brazilian National Institute of Industrial Property
IS - Innovation System
LOA - Annual Budget Law
MCTI - Ministry of Science, Technology and Innovations
MS - Ministry of Health
OT - Thematic Budget
OTMED - Access to Medicines Thematic Budget
OTMED ST&I - Thematic Budget for Science, Technology and Innovation in Medicines
PAC - Growth Acceleration Program
PD&I - Research, Development and Innovation
PDP - Productive Development Partnership
PIS - Pharmaceutical Innovation System
PITCE - Industrial, Technological and Foreign Trade Policy
PNAF - National Pharmaceutical Assistance Policy
PNM - National Medicines Policy
PROFARMA - Support Program for the Development of the Pharmaceutical Productive Chain
SNCTAF - National Symposium on Science, Technology and Pharmaceutical Assistance
SUS - Brazilian Public Unified Health System
TRIPS - *Agreement on Trade-Related Aspects of Intellectual Property Rights*
USA - United States of America
WTO - World Trade Organization

Presentation

Thematic budgets (OT) were developed by the Institute for Socioeconomic Studies (Inesc) to analyze a specific topic in depth. They are built by groupings of expenses, using official open data platforms in order to integrate the items that allocate resources to the promotion of the right that is intended to be researched. This allows for monitoring of historical series, and following trends within the same topic without being limited to a specific policy or program. OTs are composed of the set of budgetary actions related to a certain topic. The choice for this object of analysis is because such actions are established in the Brazilian Annual Budget Law (LOA) and are the unit that organizes the entire budget of the Federal Government, enabling independent analysis by the executing agency.

The Thematic Budget for Science, Technology and Innovation in Medicines (OTMED ST&I) aims to investigate the Federal Government's expenditures on science, technology and innovation in medicines. The definition of the National Pharmaceutical Assistance Policy was taken into account¹, which says that it involves the research, development and production of medicines and supplies. Thus, the entire innovation cycle was considered, from budgetary actions aimed at research to those of production, by official pharmaceutical laboratories.

Unlike the [Access to Medicines Thematic Budget \(OTMED\)](#), which has a consolidated methodology and several editions, this is the first production of the methodology to investigate federal investments in ST&I in medicines. Therefore, it has a few limitations. The main limitation is that the chosen perspective (budgetary actions by the Ministry of Health and the Ministry of Science and Technology) only captures part of the activities, especially those of research and production in public institutions. The resources allocated to innovation in companies are fundamental for the analysis of this area of public investment. However, due to its mostly transversal nature, the analysis of budgetary actions is not able to segregate sectorial investments for the pharmaceutical area.

Thus, we launch this study as a Technical Note, to start the debate on its construction and receive external contributions. Even so, we believe that this first effort brings relevant data to light, and we hope that it will contribute to analyzes and the fight for the human right of access to medicines.

The methodology is described in the methodological annex. Contributions can be sent to the *email*: <inesc@inesc.org.br>.

¹MS Resolution 388/2004. Available at: <https://bvsms.saude.gov.br/bvs/saudelegis/cns/2004/res0338_06_05_2004.html>.

Introduction

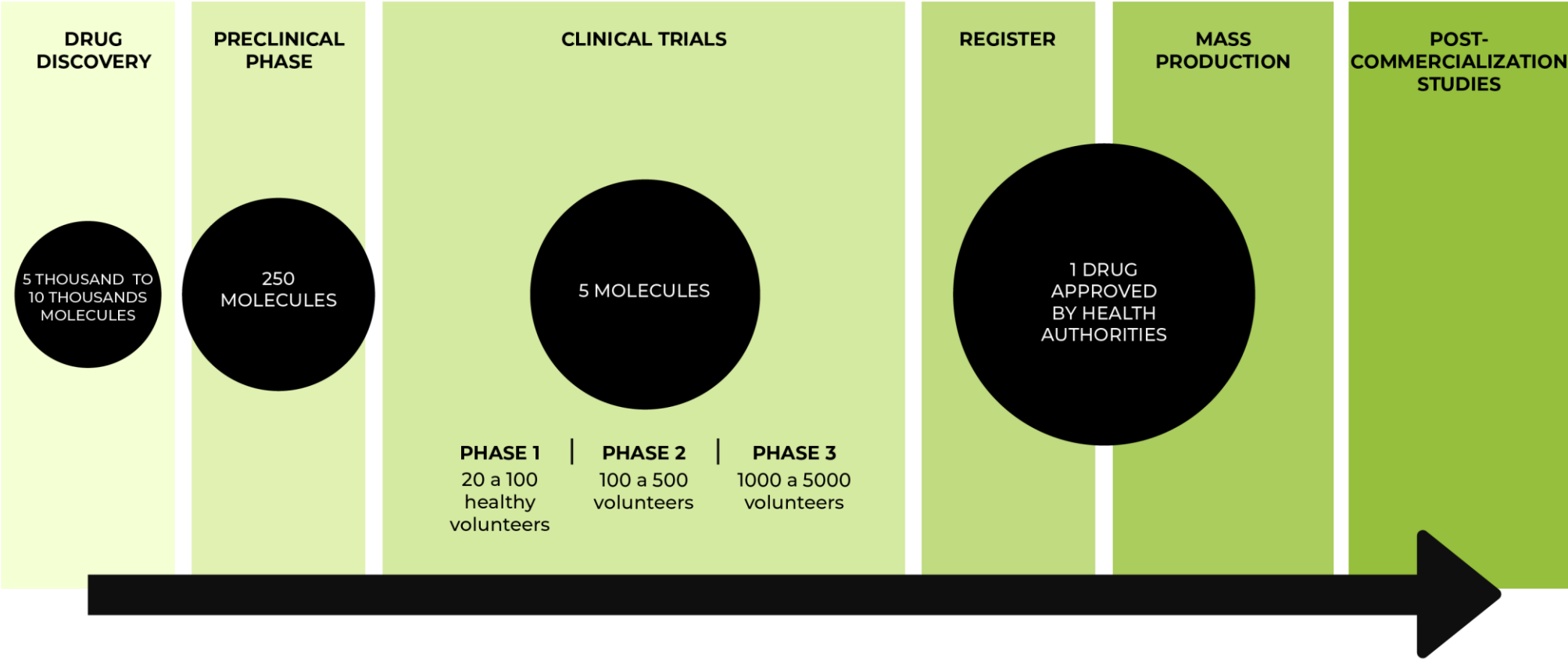
In general, innovation is the successful employment of new ideas in the market. Specifically in Brazil, innovation is defined as the introduction of novelty or improvement in the productive and social environment that results in new products, services or processes, or that includes the addition of new features or characteristics to an existing product, service or process that can result in improvements and an effective gain in quality or performance.² In other words, both unprecedented novelties and improvements in existing products are considered, as well as several types: products, processes, services and others.

Today, innovation has become a central element for economic and social development. It has a transversal nature, that is, crossing different areas of knowledge and often being multidisciplinary. In addition, innovation is a complex process, involving several public and private stakeholders. Finally, to reach innovation, it is necessary to accumulate knowledge over several stages of scientific and technological research.

The Pharmaceutical sector has one of the most complex development processes, a wide knowledge base, involving also highly technological and specialized resources. Figure 1 illustrates the process of developing innovation in this sector. It is a time-consuming process, which requires extremely high volumes of resources and with great associated uncertainty, since a new product can fail in any of the stages. Thus, it is a sector that often relies on public investments for innovation to happen.

²Law No. 10,973, of December 2nd, 2004, as amended by Law No. 13,243, 2016.

FIGURE 1 | Medication Development Process



Source: figure adapted from Pharma, 2012.

In general, the process begins with knowledge accumulation in several areas, such as molecular chemistry, cytology, physiology, pharmacology, among others. This phase is called the pre-discovery stage. The drug discovery phase refers to the identification of an active ingredient and how it works, using laboratory models. Next is the preclinical stage, which involves carrying out laboratory tests with animals, to understand how that molecule behaves or works within a living organism, but not yet human.

Having shown results that allow the application in humans with certain safety, clinical trials are started. Three clinical phases must be carried out so that the product can be approved by the regulatory agency, in the Brazilian case, the National Health Surveillance Agency (Anvisa). Phase 1 takes place with a few healthy volunteers, to test safety and adjust the dosage. Phase 2, which can be undertaken by hundreds of people with the target disease, tests the effectiveness and the presence of adverse effects. Finally, Phase 3 expands the analysis, reaching thousands of participants, to prove the effectiveness and safety on a larger scale. Each of these phases lasts several months, and can last for years.

The pharmaceutical area - and health as a whole - is one in which innovation is evidently related to the realization of human rights. The Covid-19 health crisis is a good example. Product innovations (in this case, vaccines, and treatments against the new coronavirus) were key elements not only for the protection of health, but also for the possibility of resolving the economic crisis, after the population's immunization, resume of normal activities, and end of quarantine measures. In a short period, process and service innovations were needed to adapt factories, businesses, and health services, among other sectors to meet the new context required by the pandemic. And this was only possible due to the accumulation of previous knowledge and the presence of a framework and resources for science, technology, and innovation (ST&I).

The Covid-19 pandemic also showed that countries that have built capacity for science, technology and innovation in the health area were able to create their own solutions and be more independent in the international context - which was marked by the interruption in the circulation of goods, due to isolation measures and consequent scarcity of products and technologies. A country's scientific, technological and innovation capacity is crucial to its independence and to ensure the right to health for the population.

Problems related to innovation are configured as barriers to the realization of the right to health, especially considering that innovation, as expected in a capitalist system, is oriented mainly by the market. In the case of medicines, two extreme situations are well documented in the literature. On the one hand, there are neglected diseases, for which there are no innovative treatments, as they especially affect impoverished populations. They are neglected populations, for which the industry is not interested in developing

products with low expectations of profits. On the other hand, we have diseases for which the price of new drugs is so abusive, that neither high-income patients nor the public health systems of the wealthiest countries are able to afford it. Cancer medication is an example of this development. The cost of treating one patient per year can reach tens of thousands of dollars. The growth rate of spending on cancer medication is much higher than the number of identified new cases, and one of the main reasons refers to prices, which is also a barrier to equitable access to these drugs.³

Thus, a policy of access to medicines must also encompass innovation. Scientific and technological development is included in the scope of the Unified Health System (SUS).⁴ Brazil has research institutions that are world references in the area, as well as public pharmaceutical laboratories. Two examples are the Oswaldo Cruz Foundation (Fiocruz) and the Butantã Institute, public laboratories that have signed contracts for technology transfer and production of two vaccines against the new coronavirus. In addition, the country has a robust private pharmaceutical industry, which also contributes to access policies, such as generic medicines.

Public policies are carried out through the public budget, which expresses a government's programs and priorities. Even if the public budget is not sufficient in itself to make a complete assessment of a policy, its analysis contains important elements. Thematic budgets are the tools adopted by the Institute for Socioeconomic Studies (Inesc) to analyze specific topics.

Each OT contains a methodology to fit specificities of the analyzed area. In the case of the Thematic Budget for Science, Technology and Innovation in Medicines (OTMED ST&I), it is not possible to consider just one ministry or program, because - as innovation is a transversal action - the activities related to it (and, consequently, its expenditure) are distributed among different bodies. For the construction of the OTMED ST&I at Federal level, the actions started at the Ministry of Health (MS) and the Ministry of Science, Technology and Innovation (MCTI). In addition, budgetary actions related to the topic were selected, totaling 56. The methodology is detailed in the methodological annex, at the end of this study.

The study is organized in three parts, in addition to the present introduction. The first describes stakeholders that generate innovation in this field, the so-called *innovation system*, as well as a brief background of public policies for the sector. The second provides budget information for the Health and ST&I Budgets, as well as the OTMED ST&I. Final considerations comprise an analysis in the light of Inesc's Budget & Rights methodology, in addition to some recommendations.

³WHO, 2018. Technical Report: Pricing of cancer medicines and its impacts. Available at: <<https://apps.who.int/iris/handle/10665/277190>>.

⁴Law No. 8,080/1990.

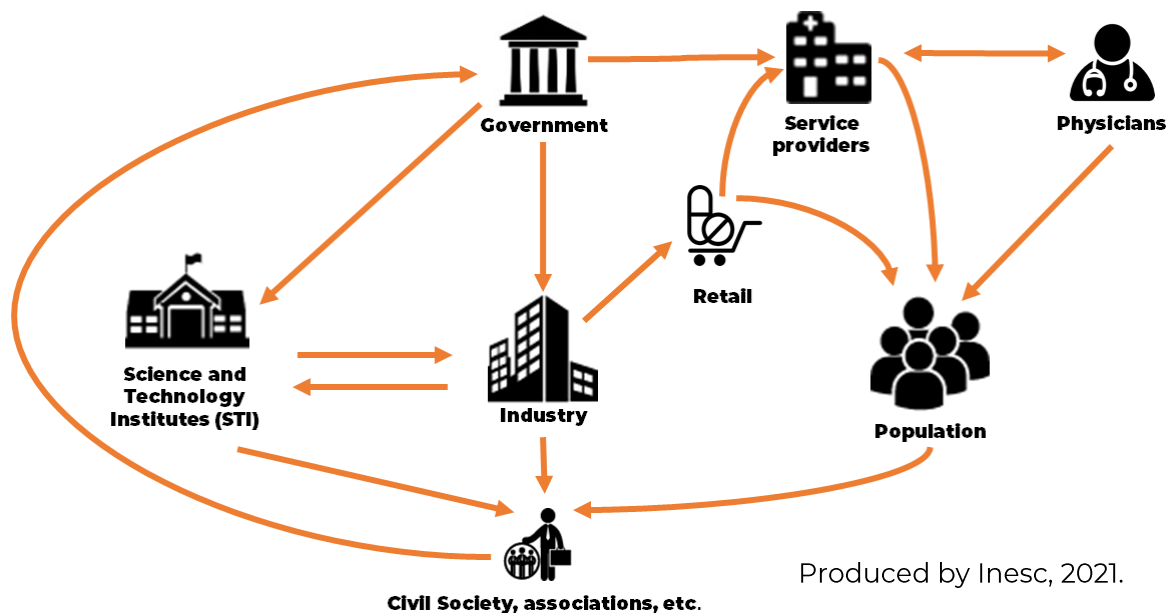
The Brazilian innovation system

An innovation system (IS) is the set of institutions or stakeholders that interact during the innovative process. In addition to all stakeholders, the way they interact with each other has direct influence in the generation of innovations in companies⁵⁶. A public policy for innovation tries to influence this system according to the objectives of those who formulate it, which may have different focuses, such as: a) stimulate the growth, productivity and profitability of companies; b) guarantee the supply of strategic or essential products for SUS; c) to seek independence from other countries and to reduce spending on imports of high-tech products; or d) a combination of the above.

It is possible to analyze an innovation system from a sectorial perspective. This way, it considers the distinctive characteristics and the specific actors in each sector. The Pharmaceutical Innovation System (PIS) is an example of these cases. It is highly complex, due to specific characteristics in the development process and plurality of actors. Figure 2 illustrates this system in a simplified way.

The main actors in an innovation system are academia, industry, and government, the so-called triple helix of technological development⁷. But in practice, there are many more stakeholders, especially in an innovation system that is just as important for the economy as it is for social welfare.

FIGURE 2 | Pharmaceutical Innovation System



⁵Available at: <<https://via.ufsc.br/o-que-sao-sistemas-de-inovacao/>>.

⁶PARANHOS, J. et al., 2018. Regional Innovation Systems in the Brazilian Pharmaceutical Sector: Comparative Study. Available at: <<https://www.e-publicacoes.uerj.br/index.php/cdf/article/view/47678>>.

⁷Available at: <<https://pesquisas.face.ufmg.br/time/2017/01/27/voce-ja-ouviu-falar-do-modelo-de-tripla-helice-para-inovacao/>>.

Industry ⁸

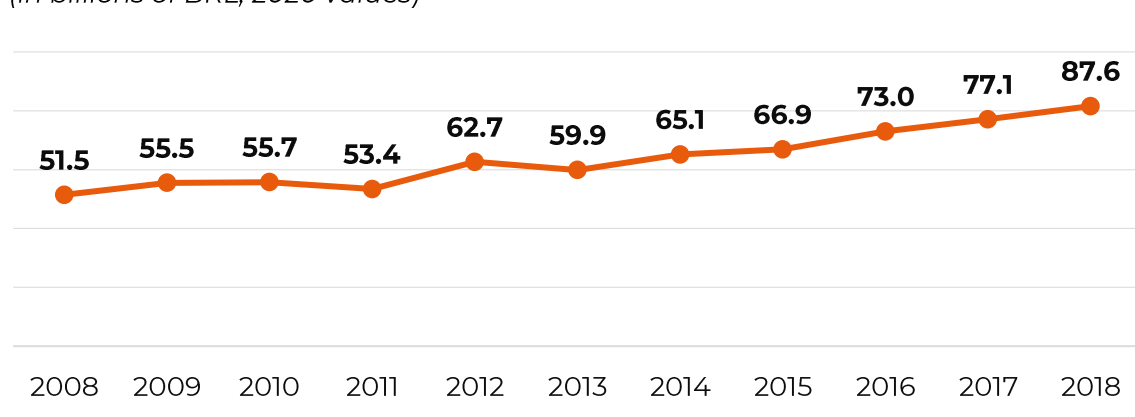
Industry is the sector responsible for distributing pharmaceutical innovations into the market. In Brazil, it is composed of national and multinational companies, along with public laboratories. In 2017, there were more than 200 companies, and half of them were large enterprises. It is a market with low competition, highly concentrated. In the last decades, nationally-owned companies have gained market share. Among the 20 largest companies, seven were national and two of these were public laboratories: Fundação Oswaldo Cruz and Instituto Butantã. One of the engines for the projection of national industries was the Generic Drugs Law (Law No. 9,787 /1999), which opened this market. Anvisa was created that same year and established standards for good manufacturing practices, which forced companies to modernize to meet new regulatory requirements as they evolved. Brazil is the seventh largest pharmaceutical market in the world. The country has been rising in the international *ranking*, and it is estimated that Brazil will be the 5th by 2023. Between 2008 and 2018, the market grew 58%, as shown in Graph 1.

Official public laboratories are a particular feature, since many countries do not have public manufacturers. They are aimed at meeting SUS demand, especially for drugs of low interest to the private industry, such as those indicated for neglected diseases, as mentioned. And recently, based on the policy of Productive Development Partnerships (PDP), they also started to have the function of expanding local production of high-cost drugs, to reduce technological dependence and the vulnerability of SUS to the market. Currently, there are 21 official laboratories in operation, which produce 30% of the medicines used in SUS.

GRAPH 1

Revenue from the Brazilian pharmaceutical market | 2008-2018

(in billions of BRL, 2020 values)



Source: CMED/ANVISA, apud Interfarma.⁹

⁸ PARANHOS, J. et al., 2021. Articulation of Policies and Instruments of Production and Innovation for the Industrial Health Complex in Brazil, 2003-2017: The cases of Inova Saúde and Profarma. Available at: <<https://sites.google.com/ie.ufrj.br/juliaparanhos/publica%C3%A7%C3%B5es>>

⁹Available at: <<https://www.interfarma.org.br/public/files/biblioteca/guia-interfarma-2019-interfarma2.pdf>>.

The Brazilian pharmaceutical industry, as a whole, is very dependent on the import of raw materials, mainly active pharmaceutical ingredients (API). On the other hand, Brazil does not export as much. Also, the value of imported medicines is much higher than the price of those produced in Brazil, which leads to a deficit in the commercial balance of medicines and pharminochemical products. In 2019, that deficit was more than USD 5.7 billion. The national industry innovates, particularly, in incremental innovations, that is, they are not new to the national or world market. The number of companies in the sector that innovate has been declining in recent years. This may be due to the political and economic crisis. The uncertain environment leads to unwillingness of companies to take the risk of innovation. Thus, only the largest and most robust companies maintain their innovative activities. The number of innovations for the national or global market has gone up. This is a positive result, because - although fewer companies are innovating - the types of innovation are more significant.

Retail/distributors

The industry sells most of its medicines through distributors (58%), pharmacies and drugstores (19%).¹⁰ The pharmaceutical retailer is one of the stakeholders that has been standing out in this innovation system. It is a sector that presents expressive growth, despite the low performance of the economy in general. Only the chains of pharmacies and drugstores in Brazil achieved record sales of BRL 58.2 billion in 2020, with an increase of 8.8% compared to 2019.¹¹

Academia

Academia encompasses both universities and research institutions, both of which are called scientific and technological institutions (ICT). In both cases, research and teaching activities are carried out concurrently.

In 2019, Brazil had 108 public universities (including federal, state and municipal) and 90 private universities. In addition, there were about 2,200 university centers and colleges, mostly private (93%), in addition to 40 federal institutes and Federal Technological Education Centers (Cefet), all public.¹²

Almost half (49%) of public universities are Federal. Graph 2 shows the Federal Government's spending on them over the past 10 years.

¹⁰Anvisa. Anuário Estatístico do Mercado Farmacêutico 2018.

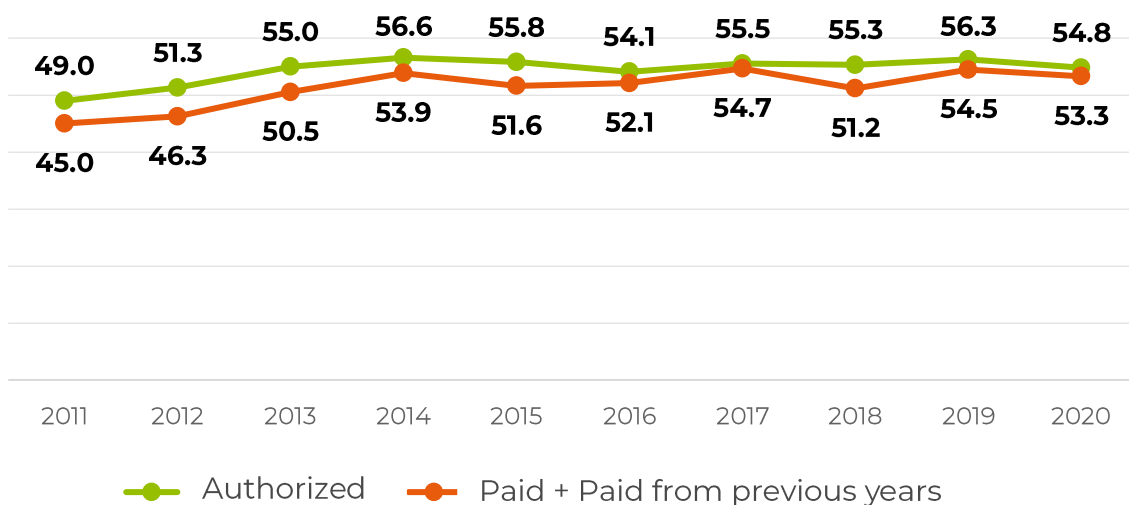
¹¹Available at: <<https://www.istoedinheiro.com.br/varejo-farmacautico-alcanca-recorde-de-r-582-bi-de-receita/>>.

¹²Inep - Higher Education Census 2019. Available at: <<https://www.gov.br/inep/pt-br/areas-de-atuacao/pesquisas-estatisticas-e-indicadores/censo-da-educacao-superior/resultados>>.

GRAPH 2

Financial execution of the Federal Government with universities | 2011-2020

(in billions of BRL, 2020 values)



Source: elaboration by INESC, based on data from SIGA Brasil

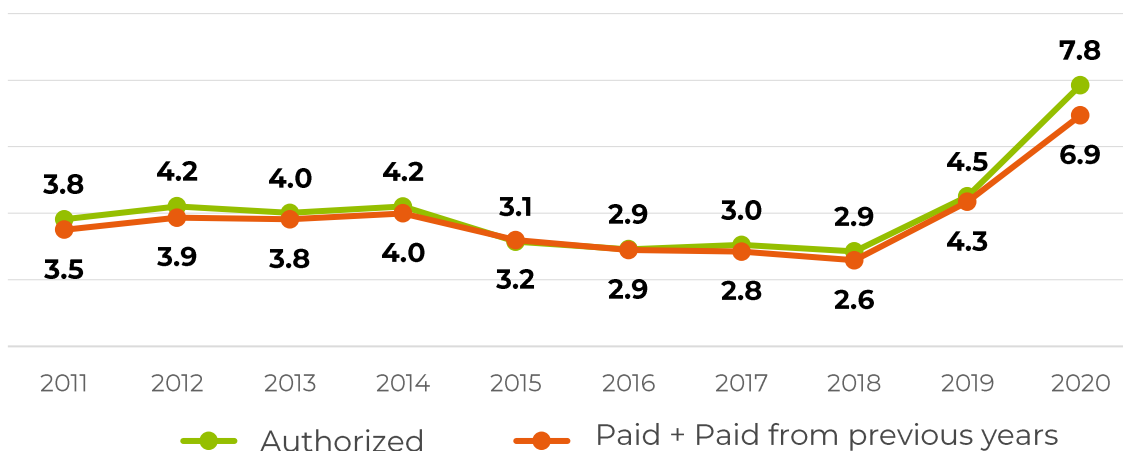
Federal spending on public universities grew, in real terms, by 26% between 2010 and 2014. Thereafter, it remained relatively constant, with slight up and down variations. Meanwhile, the number of students attended and teaching, research and extension activities carried out during this period increased significantly. For example, enrollment in undergraduate courses alone increased by 42% between 2010 and 2019.

Graph 3 shows the Federal Government's spending on Fiocruz, which - in addition to being a producer of medicines and vaccines - is also the most important health research institute in Brazil. The budget grew, in real terms, by 38% between 2010 and 2014. But, from 2014 and until 2018, spending dropped 32%, essentially due to the fiscal austerity measures adopted by the Federal Government. It increases in 2019 and even more in 2020, when Fiocruz carried out several initiatives to fight Covid-19.

GRAPH 3

Federal financial execution with Fiocruz | 2011- 2020

(in billions of BRL, 2020 values)



Source: elaboration by INESC, based on data from SIGA Brasil.

Government

The government has several functions in the pharmaceutical innovation system (PIS). As already mentioned, in Brazil, it has an important role in the academy, since most of the research is carried out by public institutions. In addition, it also plays the role of policy maker, regulator and financier. Finally, because of SUS, it plays the role of medicine buyer.

As policy maker,¹³ as well as a regulator, the government operates in several areas: economic, fiscal, social, among others. Our focus will be in the areas of innovation and health. Several regulatory initiatives have been implemented over the years, but we will consider the most recent ones, of the 21st century. In 2003, the Industrial, Technological and Foreign Trade Policy (PITCE) was established, which aimed to resume the country's industrial policy, with a systemic view on innovation. Among its four priority sectors, was that of drugs and medicines. From this context, the Support Program for the Development of the Pharmaceutical Productive Chain (Profarma) was born. Executed by the National Bank for Economic and Social Development (BNDES), it was an important public policy for the sector, as it supported the expansion of production and the strengthening of national companies, especially in relation to Research, Development & Innovation (RD&I) activities. Other important instruments that emerged at that time are the financial grants from the Funding Authority for Studies and Projects (FINEP). Despite being a cross-sector measure, generally the areas covered included pharmaceuticals.

¹³PARANHOS, J. et al., 2021. Articulation of Policies and Instruments of Production and Innovation for the Industrial Health Complex in Brazil, 2003-2017: The cases of Inova Saúde and Profarma.

In 2008, PITCE was replaced by the Productive Development Policy. It expanded the number of sectors targeted and, among them, included the health area for its entire industrial health complex (CIS),¹⁴ which contains: a) chemical and biotechnology-based industries; b) mechanical, electronic and material based industries; and c) service providers.¹⁵ In this context, an inter-ministerial mechanism called the CIS Executive Group (GECIS) was created to coordinate actions for this sector. In 2009, policies were resumed to strengthen official public laboratories, mentioning Productive Development Partnerships (PDP). They consisted of partnerships between public and private producers, aiming at the transfer of strategic technologies to SUS, in exchange for guaranteeing a market share. The PDPs aimed to strengthen public laboratories and expand their role in regulating the market, stimulating local production of high-cost and/or high-impact products for public health and promoting the development of productive capacity for the national pharmaceutical industry. In 2012, a new regulatory framework for PDP was launched (MS Ordinance n° 837/2012), which was again revised in 2014 (MS Ordinance n° 2.531/2014) and, more recently, in 2021 (MS Ordinance n°184/2021).

¹⁴Available at: <https://www.paho.org/bra/index.php?option=com_content&view=article&id=550:complexo-industrial-e-inovacao-em-saude&Itemid=558>.

¹⁵Chemical and biotechnology-based industries - sector covering the pharmaceutical, vaccine, hemoderivative, and diagnostic reagents industries. Mechanical, electronic and materials-based industries - sectors that encompasses the industries of mechanical and electronic equipment and instruments, orthoses, prostheses and consumables. Service providers - sector that involves sectors that develop activities to provide hospital, outpatient, diagnostic and therapeutic services. These sectors organize the supply chain for industrial health products, articulating consumption by citizens in the public and private space.

BOX 1 | Productive Development Partnerships (PDP)¹⁶

PDPs are part of a program aimed at expanding access to medicines and health products considered strategic for the Unified Health System (SUS), by strengthening the country's industrial complex. The main objective is to promote national development to reduce the costs of purchasing medicines and health products from foreign countries or that represent a high cost for SUS.

They are carried out between two or more public institutions or between public institutions and private companies, seeking to promote national public production. The technology is transferred to public laboratories in exchange for a purchase guarantee from the Ministry of Health.

PDPs go through four phases:

1. **Evaluation and decision:** institutions submit PDP projects for products found in the Strategic Product List published by the Ministry of Health. They are evaluated according to their feasibility and, in case of approval, an agreement is signed between the Ministry of Health and the public institution.
2. **Absorption and technology transfer:** corresponds to the implementation of the PDP, involving, for example, the drafting of contracts between partners, training, framework development and qualification of work processes.
3. **Absorption and transfer of technology with acquisition:** execution of product development, effective transfer, and absorption of technology. At this stage, the Ministry of Health starts to buy the product from the public institution.
4. **Technology Internalization:** in the last phase, transfer of technology to the public institution is completed.

They were instituted in 2009 and, over the years, the program has undergone several modifications, with PDP reassessed and suspended or extinguished. Currently, more than 60 are in force.¹⁷ Half of them are in phase III or IV, which means that the products are already being purchased by the Ministry of Health. The last data made available by the Ministry of Health on the savings generated by the program is from 2017, and estimated BRL 4.7 billion at the time.¹⁸

The program had an important effect on the pharmaceutical innovation system (PIS): for example, by orienting decisions about public financing to the sector, which prioritized projects included in the program's scope, in addition to increasing value of national public laboratories. However, it has also received criticism by civil society - aiming at its improvement and to focus on the right to health - especially about lack of transparency and social control, as well as abuse by large multinational companies and inadequate technology transfer.¹⁹

¹⁶Available at: <<http://antigo.saude.gov.br/saude-de-a-z/parcerias-para-o-desenvolvimento-produtivo-pdp>>.

¹⁷Considers spreadsheet updated until 9/21/2020.

¹⁸Available at: <<https://portalarquivos2.saude.gov.br/images/pdf/2017/maio/11/Economia-e-Faturamento-PDP-09-05-2017.pdf>>.

¹⁹Available at: <<http://deolhonaspateentes.org/nota-decisao-suspender-19-contratos-de-producao-de-medicamentos-precisa-ser-revista/>>.

Between 2007 and 2010, the Growth Acceleration Program (PAC) was launched, which contained specific ramifications, such as the Science, Technology & Innovation PAC and "Mais Saúde", the More Health Program. The ST&I PAC was an attempt by the Ministry of Science, Technology and Innovations (MCTI) to articulate five policies: 1) Growth and Infrastructure Acceleration Plan; 2) Industrial, Technological and Foreign Trade Policy (PITCE); 3) Agricultural Development Policy; 4) Health Development Plan; and 5) Education Development Plan. The Mais Saúde Program aimed to reduce the vulnerability to the Brazilian health policy market, by strengthening the Industrial Health Complex (CIS), connecting the deepening of SUS objectives with the necessary transformation of the country's productive and innovation structure.

The Profarma program was continued and started to include public laboratories among its target audience, in order to strengthen them for the establishment of PDP, as well as activities aimed at export. It continued to be reformulated and, after the establishment of Plano Brasil Maior (Bigger Brazil Plan) between 2011 and 2014, it began to focus on the biotechnology sector, in addition to production and innovation. During this period, FINEP also refocused its operating strategy and launched mixed calls for proposals with various types of financing, economic subsidies and others, for different areas, including health again.

Since 2014, there have been no verticalized industrial and innovation policies, that is, with focus on specific sectors. This discontinuity of policies can be harmful. Without it, considering the sector's long development time, important and more challenging projects may have been abandoned before going through all stages of development, in addition to losing the assembled infrastructure and specialized human resources. These projects are generally aimed precisely at the public health needs of less interest to the private industry, or those who contribute to reduce the dependence on other countries.

With regard to drug-related policies, in 1998 the Ministry of Health published Ordinance No. 3,916, which instituted the National Medicines Policy (PNM). It aimed to guarantee the necessary safety, efficacy and quality of medicines, the promotion of rational use and the population's access to those considered essential. It also represented an attempt by the Ministry to coordinate pharmaceutical SI, pointing out that, for its implementation, it would be necessary to define or redefine specific plans, programs and activities of the related agencies at federal, state and municipal levels.

In 2004, the Pharmaceutical Assistance Policy (PNAF) was approved by the Minister of Health. Originated in the National Health Council (CNS), it defines pharmaceutical assistance as a set of actions aimed at the promotion, protection and recovery of health, both individual and collective, with

medication as an essential input, aiming at fair access and rational use. The set of actions involves research, development and manufacture of medicines and supplies. It also involves a systemic vision, stating that it should be understood as a guiding public policy for the formulation of sectorial policies, among which the policies of medicines, science and technology, industrial development and training of human resources stand out, guaranteeing the *intersectoriality* inherent to the country's Health System (SUS) and whose implementation involves both the public and private health care sectors. Both the PNM and the PNAF are an integral part of the National Health Policy.

One of the great problems of the government, as a policy maker, is that policies are designed, many implemented, but few have their outcomes and objectives evaluated. Without auditing, it is impossible to improve or abandon inefficient public policies, which generates a loss of financial and economic resources and prevents progress towards resolving social issues.

The legal framework for innovation in Brazil is the Innovation Law (Law No. 10,973/2004). It established the regulatory framework for these activities, brought several important definitions to the field, in addition to defining instruments, such as the allocation of nonreimbursable public resources to companies. It aimed to promote interaction and knowledge transfer between academia and companies, in addition to strengthening innovation in the private business sector. Another important legislation was "*Lei do Bem*" (Law No. 11,196/2005), which established tax incentives for innovation, such as, for example, income tax deduction for investments in R&D. The legal framework for science, technology and innovation in Brazil was updated by Law No. 13,243/2016, in order to reduce legal insecurities associated with the Innovation Law.

Brazilian health regulation goes back to Empire times. But the recent major milestone was the institution of SUS. It was defined in the Federal Constitution of 1988 that health is the right of all and a duty of the State. The public health system was regulated by Law No. 8,080/1990. Several other relevant mechanisms have been implemented, especially in the area of medicines. First, the Generics Law (Law No. 9,787/1999), which was a public health achievement and for SUS budgetary sustainability, as it regulated these effective, safe and inexpensive drugs. It was also important to boost the national pharmaceutical industry. The creation of Anvisa (Law No. 9,782), also in 1999, was essential to increase the quality and safety of medicines sold in the country.

Another milestone that deserves mention was the insertion of the activity of evaluating technologies to be incorporated into SUS. In order to rationalize spending on medicines and care, this step defines which products or services will be made available by the health system. Several countries have agencies responsible for carrying out this activity, but in Brazil it was initiated in 2006,

with the creation of the Commission for the Incorporation of Technologies (Citec). In 2011, the process was improved and the National Commission for the Incorporation of Technology at SUS (Conitec) was created and continues to exercise this function until today.

Another important role relates to intellectual property. Patents granted by the State confer a temporary monopoly for the developers of a medicine, so that they can recover from investments made in the innovation process. However, in the pharmaceutical sector, what is seen in practice is that patent holders, mainly multinational companies, abuse this power, practicing abusive prices and extending this monopoly, in order to maximize their profit. This restricts access to medicines and other health technologies, leading to the death of several people, especially in the poorest countries.

The TRIPS Agreement defines the rules of the industrial property system. It was established in 1994, together with the World Trade Organization (WTO), which is responsible for its implementation. It defines rules common to all countries, such as the possibility of patenting technologies in all areas of knowledge and their duration for a period of 20 years.

Countries had different deadlines to adapt to the new common rules, as they had their own internal structures. Thus, developed countries had up to one year (until 1996) to reform their legislation, while developing and less developed countries had, respectively, five years (until 2000) and 11 years (until 2006). However, Brazil, under the strong influence of the USA and at the time implementing several measures to liberalize the economy, did not take advantage of this transition time and instituted its industrial property law in 1996 (Law No. 9,279/1996). In return, India took advantage of the transition period and, with that, developed a robust pharmaceutical industry, capable not only of exporting generic medicines, but also active pharmaceutical ingredients (API), which are the main components of a medicine.²⁰ In 2001, the Ministerial Declaration on the TRIPS Agreement and Public Health 19, known as the Doha Declaration, established flexibility measures to protect public health, such as compulsory licensing²¹. It was recognized that the agreement should not and does not prevent members from taking measures to protect public health.²²

²⁰Available at <https://www.scielo.br/scielo.php?script=sci_arttext&pid=S0102-311X2007000200002#:~:text=Per%C3%A7%C3%A3o,%20d%20deesenvolvim%20entoada%20c%20pa%3%ADs>.

²¹Compulsory licensing is a flexibility provided for in Article 31 of the TRIPS Agreement that allows the country to use the patented product, even if the holder does not authorize, in very specific cases, for example, when public interest prevails. <http://www.abiaids.org.br/_img/media/EFAVIRENZ.pdf>

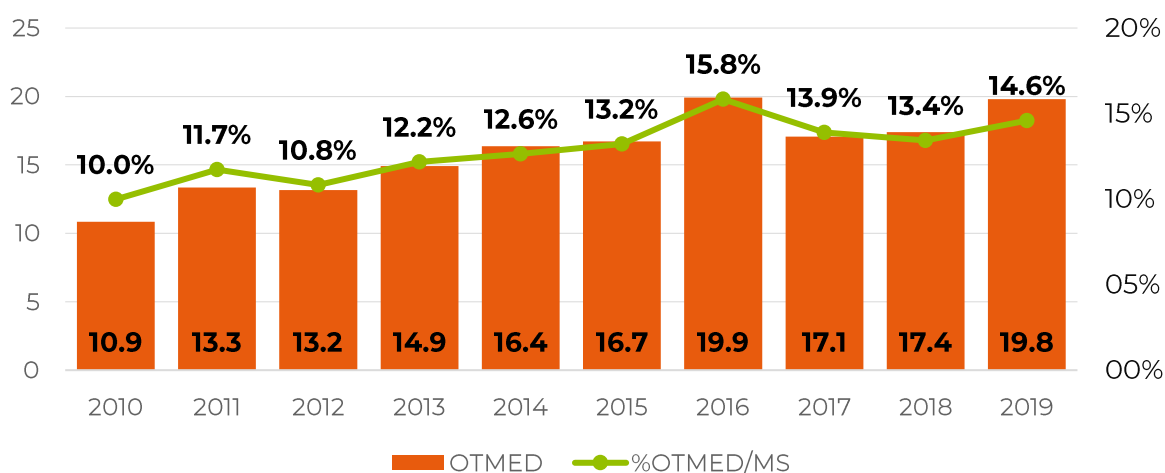
²²Available at <http://delbrasomc.itamaraty.gov.br/pt-br/acordo_trips.xml#:~:text=%20sAolu%C3%A7%C3%A3o%20acordada%20pelos%20Membros,%20s%20eincidentesobreexporta%C3%A7%C3%B5ese%20d%20produtos>.

The body responsible for the management of industrial property in Brazil is the National Institute of Industrial Property (INPI). Given the importance of patents, it plays a key role in the national pharmaceutical innovation system.

One of the main roles of the government in the Brazilian PSI is that of medicine consumer through SUS. Federal spending on medicines has increased over the past decade. In 2019, it reached a figure that corresponds to more than double the amount observed for 2010 (Graph 4). It also consumes an increasing share of the health budget, which is enduring an increase in demands on the one hand, and de-financing caused by the fiscal austerity measures implemented by the Federal Government on the other. The Access to Medicines Thematic Budget (OTMED)²³ assesses the allocation of federal resources with pharmaceutical assistance in promoting access to medicines in Brazil, and the impacts of financial execution. It also aims to discuss this issue with an in-depth analysis of the components of pharmaceutical assistance, judicialization and tax expenditures with the sector, among other topics.

GRAPH 4
Financial execution of the Access to Medicines Thematic Budget (OTMED) from 2008 to 2019 and corresponding percentage of the Ministry of Health budget (MS) | 2008 - 2019

(in billions of BRL, 2020 values)



Source: elaboration by INESC, based on data from SIGA Brasil.

Public research funding can take two forms. One happens through a continuous investment for the maintenance of the installed infrastructure, the payment of personnel, and daily operation activities. Another way is to invest in projects, usually through calls for tender or public calls, which select specific sectors for the allocation of resources, which can be used for research as well

²³Available at: <https://www.inesc.org.br/orcamento-tematico-de-acesso-a-medicamentos-2019/>.

as the modernization or expansion of infrastructure. The role of the State as a financier of the pharmaceutical innovation system will be discussed further in the next chapter.

BOX 2 | The Covid-19 pandemic and Brazilian vulnerabilities

The Covid-19 pandemic dramatically and urgently showed the importance of investments in ST&I and national production. At first, there was a need to innovate to develop therapeutic options against the new virus. When they were identified or developed, countries with productive and innovative capacity stood out, as they were able to guarantee access to their population, as well as export medicines to other countries.

Brazil was able to develop several initiatives that contributed to the fight against Sars-Cov-2. The main examples are the Oswaldo Cruz Foundation (Fiocruz) and the Butantã Institute, public institutions that have established partnerships for the production of vaccines. As the production process of an immunobiological product is highly complex, these projects are carried out in several stages. At first, they involve manufacturing from an imported active pharmaceutical ingredient (API). Even for finalization operations, such as bottling and quality assurance, they require highly specialized knowledge, as well as state-of-the-art facilities. A transfer of technology is expected so that, in the future, the production of the API can be viable in Brazil. When that happens, Brazil will be able to produce vaccines on a large scale, which can guarantee the fastest vaccination of its population.

It is important to note that BRICS countries, such as India, Russia and China, are in a leading position in the development and production of vaccines against Covid-19. Brazil could have followed the same path. However, political decisions, such as not using the TRIPS transition period and not investing in ST&I activities, as shown in this thematic budget, led the country to miss this opportunity.

In addition, under the Bolsonaro government, Brazil was no longer seen by the world as an advocate and leader in the matter of access to medicines. Formerly the leader of initiatives in this direction, such as the approval of the TRIPS flexibilities, Brazil abandoned the emerging countries to align with the interests of the richest countries. For example, when the government rejected adherence to a proposal from India and South Africa for suspension of all patents on drugs, vaccines and anti-Covid-19 products, Brazil was the only developing country to explicitly do so.²⁴

²⁴Available at: <<https://noticias.uol.com.br/colunas/jamil-chade/2020/10/16/brasil-se-distancia-de-emergentes-e-rejeita-suspender-patentes-na-covid-19.htm?cmpid=copiaecola>>.

Analysis of federal financial execution with drug innovation

ST&I and Health Budget

The resources of OTMED ST&I come mainly from the health and science and technology functions. So, initially, we will consider the total budget with these two areas, as shown in the Graph 5 (health function) and Graph 6 (science and technology function) from 2010 to 2020.

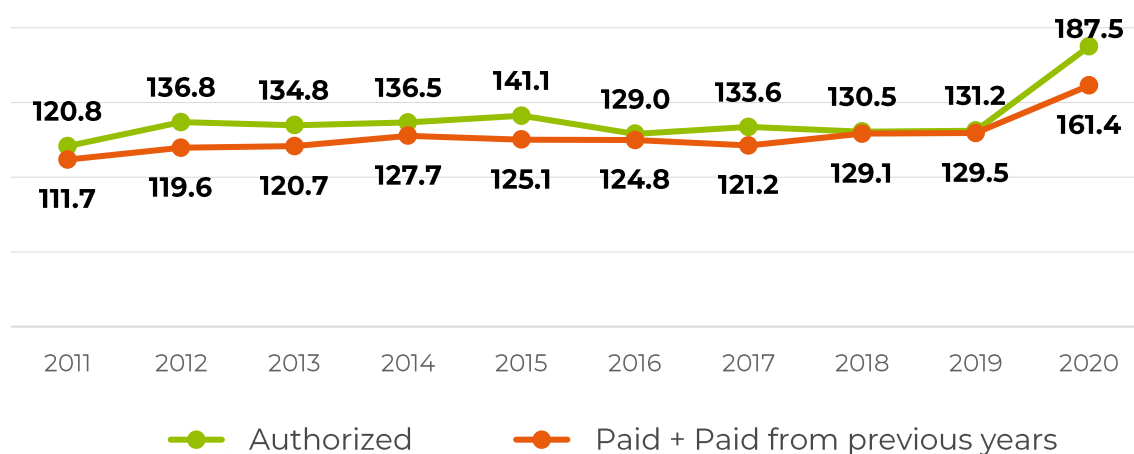
The budget for health is significantly larger than for S&T, which is understandable, given the centrality of the area and the breadth of the Brazilian public health system. The health budget is more stable than that of science and technology, experiencing relatively small variations, except in 2020, due to the coronavirus pandemic. In addition, there is little difference between the authorized and paid amounts for health, that is, the amounts approved in the Annual Budget Law (LOA) are, for the most part, fulfilled. This is due to the constitutional obligation of a minimum investment in health.

The budget for S&T, on the other hand, varies greatly over the years. In addition, it has a clear downward trend from 2014, reaching 2020 with an authorized value corresponding to half of that of 2010. Moreover, the amount effectively paid is a third less. Furthermore, until 2015, the amount actually paid was less than authorized. In 2012 and 2013, with the largest difference among the analyzed years, only 68% of the authorized resources were actually spent.

GRAPH 5

Financial execution with the health function | 2011 - 2020

(in billions of BRL, 2020 values)



Source: elaboration by INESC, based on data from SIGA Brasil.

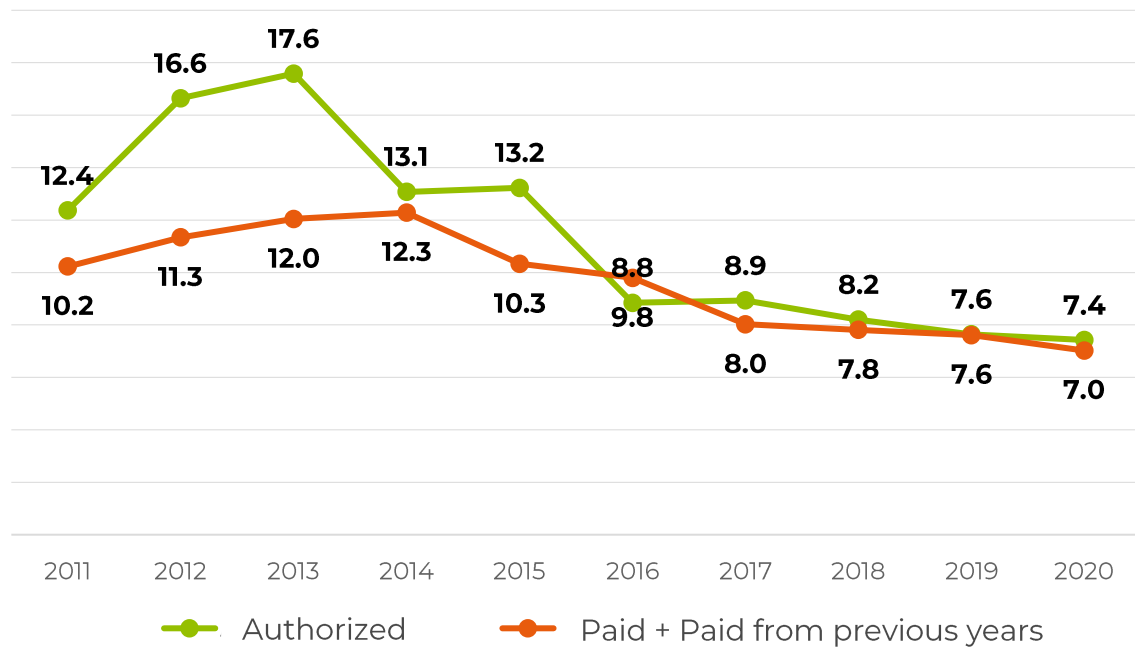
The significant increase in health spending is due to the extraordinary situation caused by the Covid-19 pandemic. It led to the issuing of several measures, starting with the national emergency declaration, such as Constitutional Amendment No. 106, better known as the war budget. The [General Balance of the Union Budget 2020](#) provides a general analysis of that year's budget.

GRAPH 6

Financial execution with the science and technology function | 2010 - 2020

2020

(in billions of BRL, 2020 values)



Source: elaboration by INESC, based on data from SIGA Brasil.

The National Fund for Scientific and Technological Development (FNDCT), created in 1969, is an accounting fund that aims to finance innovation and scientific and technological development in Brazil. It is one of the main sources of budgetary and financial resources to support the scientific and technological infrastructure of public institutions, such as universities and research institutes, and to support technological innovation in companies with nonreimbursable resources. It is managed by the Funding Authority for Studies and Projects (Finep).

Its budget can be divided into three main groups: vertical and transversal actions and special operations. Vertical and transversal actions are aimed at supporting research and technological development and innovation projects from scientific and technological institutions developed individually, cooperatively with companies, or in the form of networks with the participation of other ICT. The resources of vertical actions are applied in a

specific sector, as opposed to transversal actions. Special operations, on the other hand, are those directed at companies and are subdivided into equalization of interest rates, economic subsidies, investment in innovative companies, and incentives for investment through the implementation of liquidity guarantee instruments.²⁵

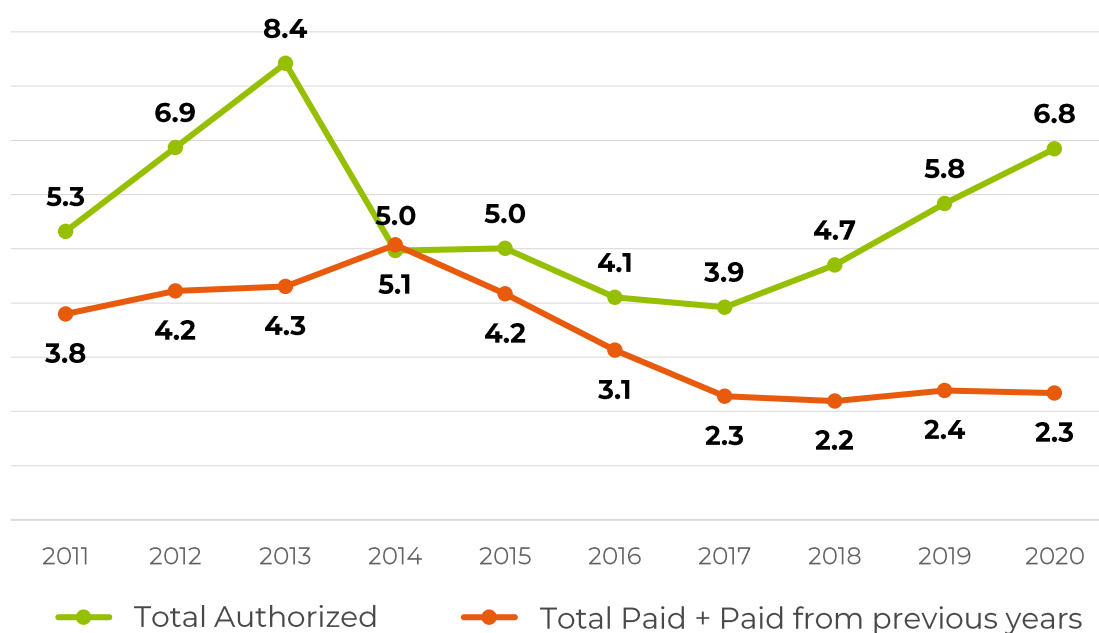
The amounts actually spent on the FNDCT have historically been lower than authorized. However, in 2014, the amount paid was similar to that authorized, due to a sharp decrease in the latter. Since then, the values have fallen sharply. Although the authorized resources rose from 2017, they were subject to repeated contingencies, used by the Federal Government to achieve the primary result's fiscal targets. In addition, Source: elaboration by INESC, based on data from SIGA Brasil.

shows that credit operations have become the main form of application of the resource, unlike other so-called “non-refundable” funds, such as nonreimbursable resources to support ICT and economic subsidy to companies, as well as investments and others.

GRAPH 7

Financial execution with the FNDCT | 2010 - 2020

(in billions of BRL, 2020 values)



Source: elaboration by INESC, based on data from SIGA Brasil.

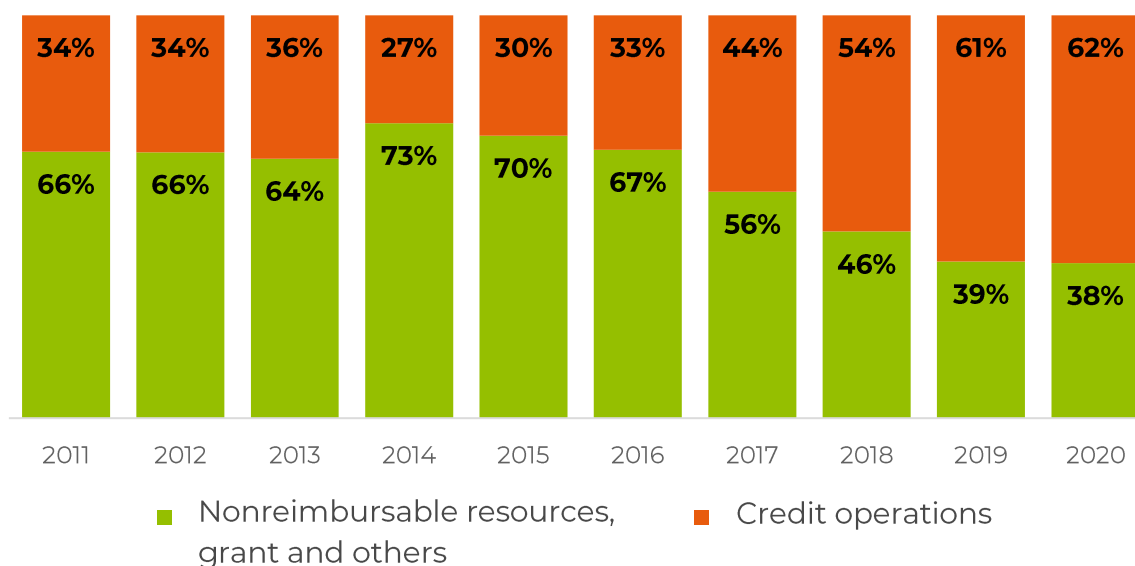
²⁵Available at: <<http://www.finep.gov.br/a-finep-externo/fndct/estrutura-orcamentaria/composicao-do-fndct>>.

GRAPH 8

Financial execution of the FNDCT by budgetary unit.

Credit operations x nonreimbursable resources, grant and others | 2010 - 2020

(in percentage)



Source: elaboration by INESC, based on data from SIGA Brasil.

In 2021, a complementary law was passed that prevents the contingency of FNDCT resources and transforms it into a fund of a financial nature, which can count on income from investments, and profits from shares of innovative companies, in addition to being able to use the financial balances of the previous year, instead of having a purely accounting nature.^{26,27}

The vertical actions of the FNDCT include the Sectorial Funds for Science and Technology, which are instruments for financing research, development and innovation projects in specific sectors, created since 1999. One of these sectoral funds is CT-Saúde, or CT-Health. The fund's expenses shown in Graph 9, fully illustrate the dramatic dismantling of the Brazilian science and technology policy for health.

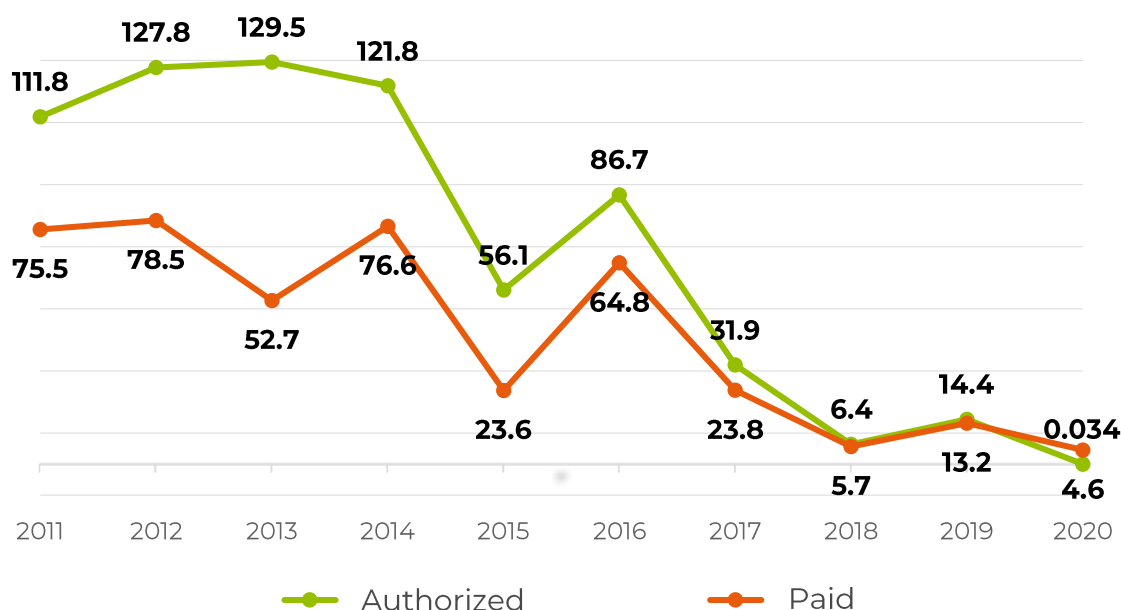
²⁶Complementary Law No. 177, of January 12, 2021. Available at: <http://www.planalto.gov.br/ccivil_03/LEIS/LCP/Lcp177.htm>.

²⁷Available at: <<https://www12.senado.leg.br/noticias/materias/2021/01/13/lei-que-proibe-contingenciamientos-do-fndct-e-sancionada-com-dois-vetos>>.

GRAPH 9

Financial execution of CT-Health | 2010 - 2020

(in billions of BRL, 2020 values)



Source: elaboration by INESC, based on data from SIGA Brasil.

Budget for innovation in medicines (OTMED ST&I)

This thematic budget is an unprecedented effort to compile federal spending on drug innovation. Budgetary data complement the analysis of public policies that placed the pharmaceutical sector as a priority for economic development and for the sustainability of SUS. The Covid-19 pandemic demonstrated the critical importance of this investment, as shown in Box 2.

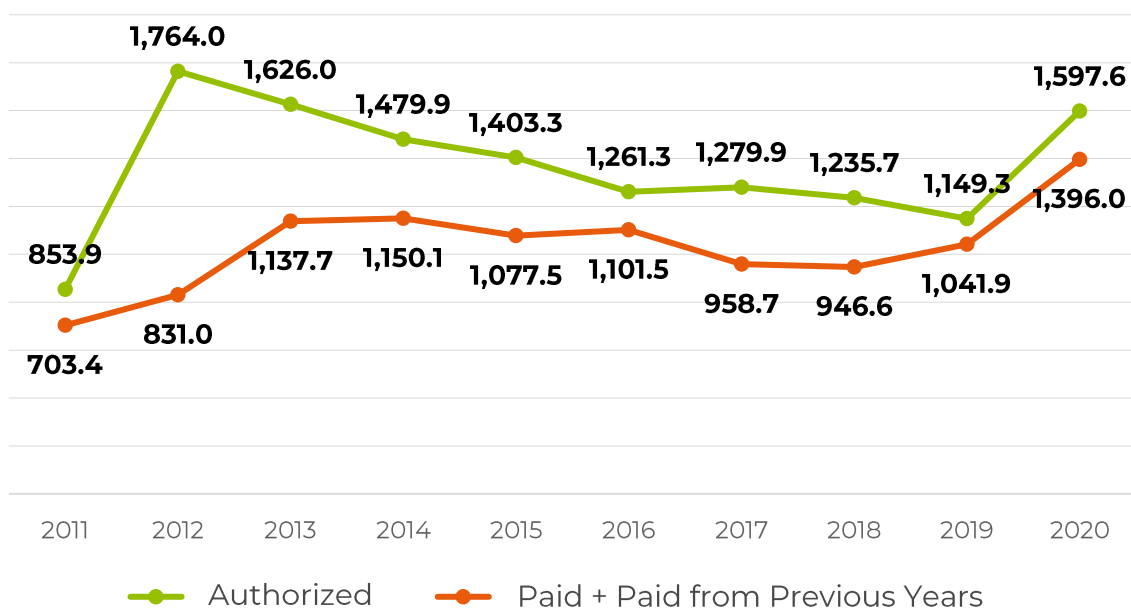
It consists of budgetary actions related to the topic. They are executed, for the most part, by the MS and the MCTI. However, there is also allocation by the Ministry of Education (MEC) (due to universities), by the former Ministry of Development, Industry and Foreign Trade (MDIC) - which, in 2019, was incorporated into the Ministry of Economy, responsible for industrial policy in general - and by the Ministry of Defense (to which the Military public pharmaceutical laboratories are attached, which explains the innovation system and the need for interaction between multiple actors).

It is important to say that the expenses incurred in transversal actions, that is, without a specific sector, but which may also include medicines for human use, were not identified, nor the expenses allocated by multidisciplinary entities, such as universities and research centers that do not work only in the health area. The methodology is explained in detail in the Methodological Annex.

In the last 10 years, BRL 11.1 billion were invested in real terms in drug innovation, as can be seen in Graph 10.

Between 2011 and 2014, there was an increase in spending, which can be explained by the strengthening of PDP policies. Between 2014 and 2018, there is a real 18% drop in resources. In 2019 there is a slight recovery, and in 2020 there is a significant increase in spending driven by actions to combat Covid-19.

GRAPH 10
Authorized amount and financial execution of the Thematic Budget for Innovation in Medicines | 2010 - 2020
(in billions of BRL, 2020 values)



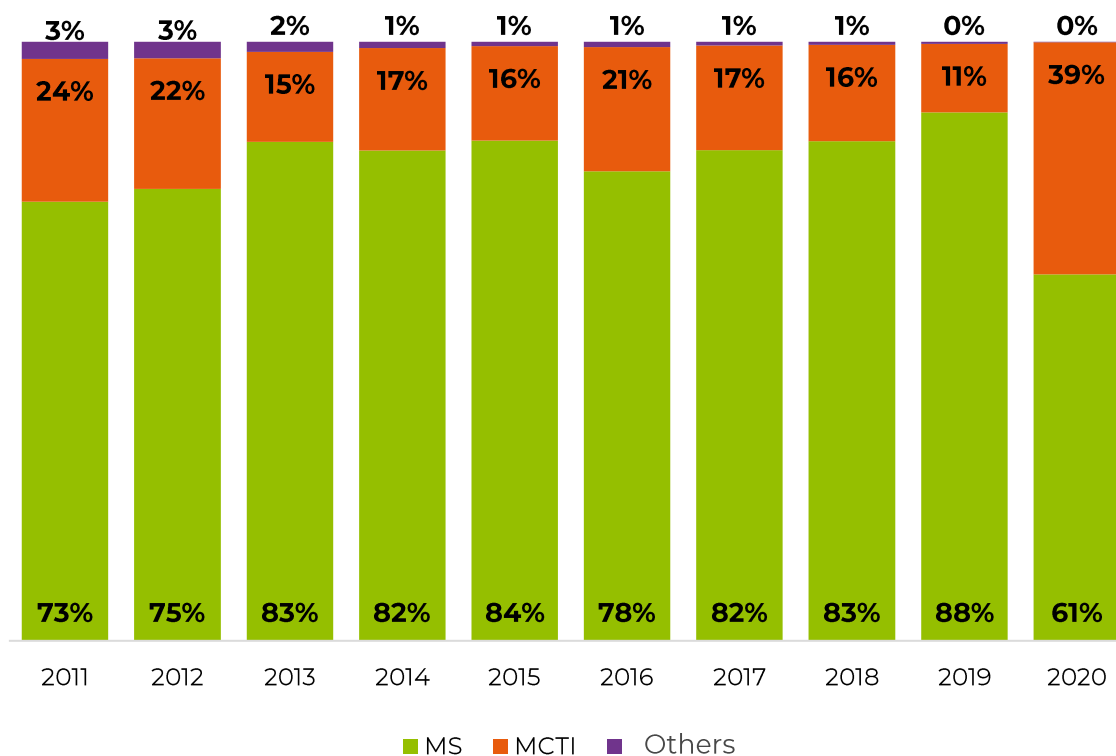
Source: elaboration by INESC, based on data from SIGA Brasil.

In all years, most of the expenses have their origin in the Ministry of Health, as shown in Graph 11. This is expected, as MCTIC resources are generally allocated in cross-cutting programs, with no specific area, such as, for example, economic grants or scholarship. MCTIC's investments grew in 2020 due to the implementation of the action aimed at facing Covid-19 (21C0). But, from the graph, it is clear that the MS is the main investor in innovation in medicines in the Federal Government and was the body that sustained the investment in the area during the period. The other Ministries are: the Ministry of Education (MEC), the Ministry of Development, Industry and Foreign Trade, now part of the Ministry of Economy (ME), and the Ministry of Defense (MD).

GRAPH 11

Financial execution of the Innovation in Medicines Thematic Budget, from 2010 to 2020, by Ministry | 2010 - 2020

(in percentage)

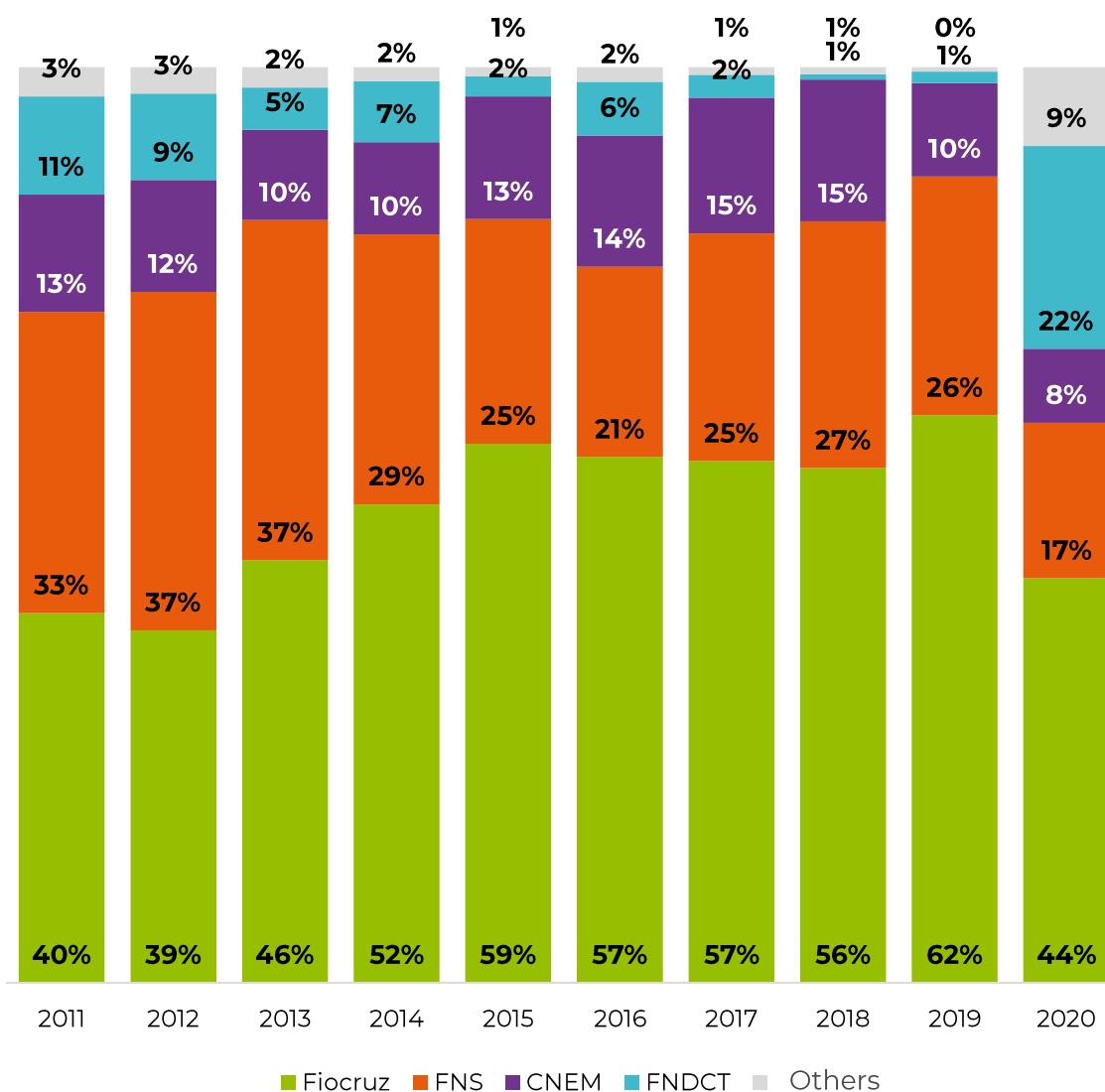


Source: elaboration by INESC, based on data from SIGA Brasil.

The largest budgetary unit is Fiocruz, which is the main federal institution in the sector and has representations spread across the country. There is an expressive participation of the National Nuclear Energy Commission (CNEM), linked to the MCTI, as there are several investment actions in radiopharmaceuticals. In addition to them, the National Health Fund (FNS) and the FNDCT also stand out.

GRAPH 12

Financial execution by budgetary unit, considering the total | 2010 - 2020
(in percentage)



Source: elaboration by INESC, based on data from SIGA Brasil.

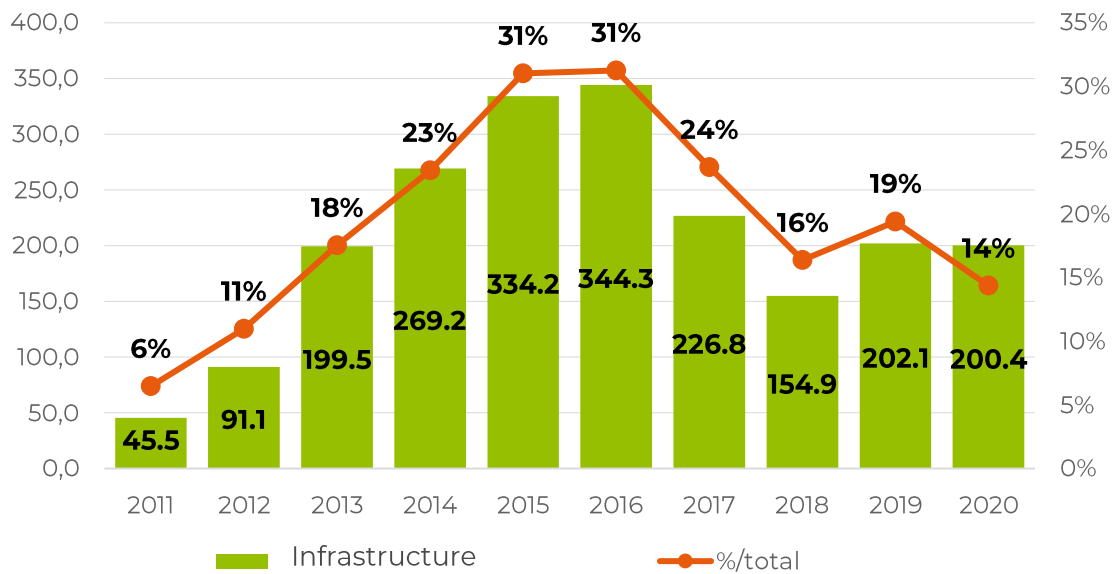
Note: the “Others” category includes the direct administration of the MCTI, the National Health Foundation, the Army Command, the Aeronautical Fund, the Army Fund, the Naval Fund, the Federal University of Rio Grande do Norte, the Superintendency of Manaus Free Trade Zone and the National Health Surveillance Agency.

Part of this expenditure was invested in physical infrastructure, such as the construction or modernization of facilities for public research institutions. There was a peak in investment in 2015 and 2016, reaching up to one-third of the OTMED ST&I. In total, over the 10 years, 19% was invested in infrastructure, which corresponds to BRL 2.1 billion.

GRAPH 13

Investment in infrastructure and its corresponding percentage of OTMED ST&I | 2011 - 2020

(in billions of BRL, 2020 values)



Source: elaboration by INESC, based on data from SIGA Brasil.

Final considerations

The analysis of the financial execution of resources for ST&I in the area of medicines clearly shows the lack of funding for this sector in Brazil. The lack of scientific and technological development weakens Brazil's economy (which is increasingly based on products with low added value) and increases dependence on other countries. The Covid-19 pandemic exposed the risks of said approach to global proportions since countries without the capacity to produce medical equipment, medicines and other products with higher technological content had no one to turn to, given the scarcity of these products and considering protectionism of the richest countries. The lack of resources not only prevents progress but also compromises the installed innovative capacity, as the necessary specialized equipment gets more and more obsolete without maintenance and modernization. In addition, the specific infrastructure required for ST&I gets outdated.

The impact in the health area could've been much worse if it wasn't considered a strategic area. The Ministry of Health has sustained investments in ST&I in recent years, despite its budget being in a state of disinvestment. Covid-19 made it urgent and boosted investments in this area. However, the fiscal austerity imposed by the Spending Cap of Amendment No. 95/2016, which the Bolsonaro government has said will continue to be the major fiscal anchor of the budget, calls into question the continuity of said boost.

The pandemic has demonstrated in practice the importance of investments in ST&I and in the national productive capacity of drugs and medicines, in addition to the importance of their maintenance in the long run. If we had sustained investments in the area, added to a policy strongly oriented towards national autonomy and meeting the needs of SUS, we would probably not be hostages from other countries for the import of API for the production of vaccines against Covid-19. We could be producing in order to guarantee timely access for the entire Brazilian population. In addition, we could be establishing partnerships with other BRICS countries (Russia, India, and China) that have developed effective and safe vaccines and are exporting them to other countries, in particular to Latin America and Africa.

Despite having been the target of several policies in recent years, the Industrial Health Complex does not have a State policy, with well-defined principles, objectives, priorities and governance, among others. The lack of a coordinated and continuous drug innovation policy hinders the maturation of the pharmaceutical IS dynamics. It creates an obstacle to the achievement of objectives to promote economic development and guarantee the right to health, through an industrial health complex independent of other countries and focused on the needs of a universal, equitable, comprehensive, and free public health system.

For this, it is necessary that the Ministry of Health assume a leadership position in the design and implementation of this policy and the defense of these principles, instead of promoting the dismantling of SUS or leaving it for ministries with purely economic and industrial interests. It is also essential that the education policy be strengthened, as its actors - universities, development agencies, among others - are an indispensable part of any innovation system.

Finally, it is important to reiterate the exploratory nature of this study, whose methodology will be improved for the next editions. The methodology and its limitations are described in the Methodological Annex.

Analysis in the light of budget pillars

Inesc's Budget & Rights methodology proposes five pillars to analyze public policies from the perspective of human rights promotion: financing with fiscal justice, maximum mobilization of available resources, progressive realization of rights, non-discrimination, and social participation.

In general, public policies in Brazil are **not financed fairly**. This is because our tax system is extremely regressive, taxing proportionately more from those who have less.

It fails to allocate the maximum of available resources, as this OTMED ST&I shows setbacks since spending has decreased in recent years. This is one of the main factors that led the country to a brittle state facing the Covid-19 pandemic. To the extent that SUS needs are not met and its vulnerability in relation to the market is not diminished, **the progressive realization of rights is also not achieved**. In addition, Brazil - with its high rate of inequality and poverty - is affected by several conditions for which there is no innovation, since there is no interest on the part of the private pharmaceutical industry. Examples that make this clear are the neglected tropical diseases ²⁸, considering that Brazil concentrates a large proportion of population affected in Latin America.²⁹

The maximum allocation of available resources for investment in public policies that promote social development is urgent and impossible to achieve with fiscal austerity measures. Investments in ST&I policies - for areas such as health, food, education, housing, etc. - contribute to the progressive realization of human rights.

²⁸For example: Malaria, Chagas disease, visceral leishmaniasis, dengue, schistosomiasis, among many others.

²⁹Available at: <http://saudeamanha.fiocruz.br/wp-content/uploads/2019/10/PJSSaudeAmanha_Texto0035_V03.pdf>.

Pharmaceutical innovation should also contribute to **reducing gender and race inequalities**. Among the 150 million users who depend exclusively on SUS, 67% are black.³⁰ In turn, 69.9% of adults who sought primary care services in 2019 were women.³¹ The drug innovation policy should be geared to meet the needs of these populations, as well as others, such as indigenous people and the LGBTQIA + community.

Another possible application of the non-discrimination pillar is in relation to Brazil's **regional disparities**. Resources for ST&I can be allocated to help overcome inequalities between regions and to take advantage of the potential of the country's different biomes and cultures. They can also serve to add value to the knowledge of traditional Brazilian peoples and communities.

Finally, **social participation** in this field is extremely necessary. A first step is to make society aware of the relationship between innovation and access to medicines and the guarantee of the right to health. It is also important to promote more spaces for social participation within the scope of governmental actors involved in the innovation system, not only those related to health. The National Health Council (CNS), which has an Intersectoral Commission on Science, Technology and Pharmaceutical Assistance (CICTAF), addresses the issue, should be increasingly involved and its decisions must be timely followed by these actors.

Recommendations

1. Revoke the spending cap imposed by Amendment No. 95/2016, in order to allow the expansion of investments in health, science, technology and innovation.
2. Build and implement, in a participatory manner, a National Policy for Innovation in Medicines, with short, medium and long-term goals, for all relevant actors of the Brazilian Innovation System.
3. Grant the Ministry of Health a central role in coordinating the National Policy for Innovation in Medicines, guiding public investments for research, development and production of strategic products for the SUS, aiming at independence from other countries and meeting the health needs of the Brazilian population.
4. Promote transparency by building an online panel that shows the results of investments in innovation in medicines, with information about the projects, beneficiaries, deadlines and results, among others.

³⁰Available at: <<https://www.geledes.org.br/quase-80-da-populacao-brasileira-que-depender-do-sus-se-autodeclara-negra/>>.

³¹Available at: <<https://agenciadenoticias.ibge.gov.br/agencia-sala-de-imprensa/2013-agencia-de-noticias/releases/29203-pns-2019-quem-mais-utiliza-o-sus-avaliou-mais-positivamente-a-qualidade-dos-servicos-de-atencao-primaria-a-saude>>.

- 5.** Evaluate and disseminate the results of public policies and programs directed to the sector and implemented in the last 20 years, such as Profarma, which was extinguished in 2016, with economic and public health indicators.
- 6.** Assess the impacts of the tax benefits for innovation, specifically in the pharmaceutical sector and link the granting of the tax benefits to measures that favor SUS priorities and access to medicines.
- 7.** Homologate and implement the decisions of the National Health Council in a timely manner.
- 8.** Train the staff at SUS Council Networks and other social control spaces related to innovation and access to medicines.
- 9.** Expand social participation in all spaces and bodies related to the Pharmaceutical Innovation System.
- 10.** Support and promote valorization and systematization of the communities and traditional peoples' knowledge, guaranteeing adequate access, as well as remuneration from commercial use by third parties.
- 11.** Establish the temporary suspension of patents on any and all health technology that can be used against Covid-19, in accordance with Bill No. 1,462 / 2020.³²

We also reiterate the recommendations of the Rio de Janeiro Letter, presented by the participants of the 8th National Symposium on Science, Technology and Pharmaceutical Assistance (8th SNCTAF), with the following highlights:

- 1.** Guarantee a seat for social control in advisory councils of the governmental agencies of the Pharmaceutical Innovation System (PIS), such as Anvisa and INPI, as well as in similar spaces, such as working groups.
- 2.** Guarantee the financing and expansion of the PIS official laboratories and public research centers according to the needs of SUS.
- 3.** Expand the participation of social control in the National Commission for Technology Incorporation at SUS (Conitec), so that users play an active role in establishing priorities in the incorporation of new technologies.
- 4.** Ensure investments in research, technology development, incorporation of appropriate technologies and pharmaceutical assistance, guaranteeing resources to territories according to their peculiarities and their epidemiological profile, such as, for example, the Amazonian factor for transport, packaging, and purchase of medicines.

³²Available at: <<http://abiaids.org.br/projeto-de-lei-para-quebrar-patentes-propoe-aco-es-para-ampliar-o-acesso-a-tecnologias-de-saude-usadas-no-enfrentamento-da-covid-19/33911>>.

Methodological annex

INESC consolidated its experience of more than decades monitoring public policies and analyzing financial aspects with the Budget & Rights methodology, which analyzes the public budget from the perspective of realizing human rights. It is based on five pillars: 1) state financing with fiscal justice; 2) maximum use of resources; 3) progressive realization of human rights; 4) non-discrimination; and 5) popular participation. Its latest version was published in 2017 and is available for free access on the INESC website.³³

Thematic Budgets (OT) are the tools used to analyze a topic in depth. They are built by groupings of expenses, using official open data platforms in order to integrate the items that allocate resources to the promotion of the right that is intended to be researched. This allows for monitoring of historical series, and following trends within the same topic without being limited to a specific policy or program. OTs are composed of the set of budgetary actions related to a certain topic. The choice for this object of analysis is because such actions are established in the Brazilian Annual Budget Law (LOA) and are the unit that organizes the entire budget of the Federal Government, enabling independent analysis by the executing agency.

The Thematic Budget for Science, Technology and Innovation in Medicines (OTMED ST&I) aims to investigate the Federal Government's expenditures on science, technology and innovation in medicines. Thus, the entire innovation cycle was considered, from budgetary actions aimed at research to those of production, by official pharmaceutical laboratories. Ancillary activities, such as maintaining collections and libraries, were considered, as they are important elements of biomedical research. Infrastructure construction actions for federal institutes dedicated to the health area were also considered.

The definition of the National Pharmaceutical Assistance Policy was taken into account.³⁴ Pharmaceutical Assistance deals with a set of actions aimed at the promotion, protection and recovery of health, both individual and collective, with medicines as essential inputs and aiming at fair access and rational use. This set of actions involves research, development and production of medicines and supplies, as well as their selection, programming, acquisition, distribution, dispensing, guaranteeing the quality of products and services, monitoring and evaluating their use, from the perspective of obtaining concrete results and improving the population's quality of life.

³³Available at: <<https://www.inesc.org.br/en/orcamento-direitos-2018-2/>>. Access on: November, 27, 2020.

³⁴MS Resolution 388/2004. Available at: <https://bvsmms.saude.gov.br/bvs/saudelegis/cns/2004/res0338_06_05_2004.html>.

The actions were selected based on their name and description, consulted in the Integrated Planning and Budgeting System (SIOP) action record.³⁵ The search focused on the higher bodies of the Ministry of Science, Technology, Innovations and Communications (MCTIC, code 24000) and the Ministry of Health (MS, code 36000). Actions that fell within the scope of the study, but had no budget allocation, authorized or paid resources, were not included. In total, 56 actions were included.

Action 21C0 includes a large part of the resources allocated to fight Covid-19, including health spending and emergency aid. For this study, only the resources allocated by the MCTIC for this action were considered. To identify infrastructure expenditures among these actions, a classification was made based on the title and description of each action.

Some identified actions have their budgetary execution carried out by more than one higher body. This is the case of Action 2092 ("Development of products and processes at the Amazon Biotechnology Center - CBA"), carried out by MCTIC, the Ministry of Development, Industry and Foreign Trade (MDIC, code 28000) and the Ministry of the Environment (MMA, code 44000). However, there were only resources authorized to MMA, but not paid or with accrued liability. Because of this, it is not shown in the budget execution charts. Another example is Action 2522 ("Production of drugs, medicines and herbal medicines"), carried out by the Ministry of Health, the Ministry of Education (MEC, code 26000) and the Ministry of Defense (MD, code 52000). In this case, the MD appears due to the public pharmaceutical laboratories linked to departments of the Brazilian Military.

The budgetary data of the actions were taken from the Expert Panel of Siga Brasil. All amounts are extracted using the filter that disregards spending on refinancing the public debt. And they were deflated to average 2020 prices by the National Extended Consumer Price Index (IPCA), calculated by the Brazilian Institute of Geography and Statistics (IBGE), except when explained in the text.

³⁵Available at: <<https://www1.siop.planejamento.gov.br/acessopublico/?pp=acessopublico&ex=0&fp=inicio>>.

TABLE 1**Details of the budgetary actions considered in the OTMED ST&I**

UO	Action	Description
MCTIC	20UU	Research, development and innovation in biotechnology, drugs and medicines
MCTIC	21C0	Coping with the public health emergency of international importance due to the coronavirus
MCTIC, MDIC and MMA	2092	Development of products and processes at the Amazon Biotechnology Center - CBA
MCTIC	2478	Production and supply of radiopharmaceuticals in the country
MCTIC	2997	Promotion of institutional projects for research in the health sector (CT-Health)
MCTIC	8480	Research, development and innovation in drugs and medicines
MS	00QB	Voluntary contribution to the International Agency for Research on Cancer (IARC)
MS	1M36	Construction of the headquarters of the Regional Directorate of the Oswaldo Cruz Foundation in Brasília
MS	2B40	Preservation of the scientific, cultural and historical heritage of health in Brazil
MS	2B42	National and international technical cooperation in health science and technology
MS	2E47	Structuring of official public laboratory and production of medicines, serums, vaccines, and strategic inputs
MS	10LE	Construction of the new headquarters of the Leonidas and Maria Deanne Research Center, in Manaus/AM
MS	10LF	Construction of the new administrative headquarters of the René Rachou Research Center, in Belo Horizonte/MG
MS	11PE	Adequacy of the industrial drug plant in Jacarepaguá
MS	11PJ	Structuring biomedical research laboratories
MS	12BH	Construction of the official laboratory for analysis and research of tobacco products
MS	13DT	Construction of the new administrative unit of Fiocruz
MS	13DU	Construction of the research and development complex in health and production of immunobiologicals at Fiocruz in Ceará

MS	13DV	Construction of the Technological Research and Development Center in Belo Horizonte/MG
MS	13DW	Construction of the Center for Final Processing of Immunobiologicals
MS	13DX	Construction of the Fiocruz Research Center in Teresina/PI
MS	13DY	Construction of the Biological Resources Center
MS	13DZ	Construction of the Biotechnology Pole at Fiocruz in Porto Velho/RO
MS	13E0	Construction of the Fiocruz Research Center in Campo Grande/MS
MS	14KA	Expansion of the Biotechnology Pole at Fiocruz Paraná
MS	14UO	Implementation of centers for technological development and production of inputs for SUS
MS	15EG	Implementation of the new headquarters of the National Institute of Cardiology - INC
MS	15UH	Modernization and adaptation of the Farmanguinhos industrial park
MS	20AJ	Support for research and technological innovations in diseases of the tropics - IPEPATRO
MS	20AQ	Maintenance of biological collections of science and health in Brazil
MS	20K0	Technological development and innovation for the prevention and surveillance of infectious diseases and in the response to emergencies
MS	20K1	Adequacy of platforms for technological development in health
MS	20K2	Fostering research and development of regionalized alternative technologies, with a view to the sustainability of environmental health services and actions
MS	20K4	Support for human research ethics system
MS	20K7	Support for the modernization of the industrial health production park
MS	20Q7	Preservation of the historical and cultural heritage of science and health at Fiocruz
MS	20QF	Research, teaching and biomedical technological innovations and in tropical medicine and the environment
MS	21BF	Research, technological development and innovation in health

MS	147J	Construction of the Women and Children's Health Institute and Infectious Diseases Institute
MS, MEC, MD	2522	Production of drugs, medicines and herbal medicines
MS	4360	Biomedical research at the National Primate Center
MS	4363	Research and technological innovations in tuberculosis and other lung-related diseases at the Hélio Fraga Reference Center
MS	4365	Production of vaccines, diagnostic reagents and biopharmaceuticals
MS	4386	Research and technological innovations in tropical medicine and the environment at the Evandro Chagas Institute
MS	6145	Promotion of pharmaceutical production and strategic inputs
MS	6146	Promotion of research and development of strategic inputs in the Health Productive Complex
MS	6189	Health libraries network
MS	7670	Implementation of the Oswaldo Cruz Foundation Campus in Jacarepaguá
MS	7674	Modernization of Oswaldo Cruz Foundation units
MS	7676	Construction of the Center for Technological Development in Health
MS	7680	Construction of the Integrated Center for Prototypes, Biopharmaceuticals and Diagnostic Reagents (CIPBR)
MS	8305	Reference care and clinical research in highly complex pathologies of women, children and adolescents, and infectious diseases
MS	8315	Research and technological development in health
MS	8317	Clinical, epidemiological and biological, human and social sciences research applied to health at the Oswaldo Cruz Foundation
MS	8636	Innovation and production of strategic health supplies
MS	8701	National System of Public Health Laboratories

Source: elaboration by INESC, based on data from SIGA Brasil.

For the analysis of general data, the functions health (code 10) and science and technology (code 19) were considered.

The resources of the FNDCT are executed through two budgetary units (UO): 1) "74910 - Resources under Supervision of the FNDCT", whose budget is part of the Union's Official Credit Operations, where the resources for application in the action of financing companies (n° 0A37) can be found, through a loan to Finep; And 2) "24901 - FNDCT", which includes discretionary expenses: nonreimbursable actions to support ICT and special operations (economic subsidy to companies, investment, equalization of resources and liquidity guarantee), in addition to the contingency reserve. The resources corresponding to CT-Health are in Budget Action 2997.

Each university corresponds to a budgetary unit; thus, it is possible to identify them in the budget. In the analysis of their financial execution, UOs destined to university hospitals, related foundations, and resources under their supervision were also considered.

This methodology has several limitations. When looking at the budget of MCTI and MS, it is clear that it is unable to raise funds that have been invested by other ministries, such as the Ministry of Economy (ME). Thus, this OT mainly captures resources invested in research institutions, and not the public resource transferred to companies, which are considered the locus of innovation, since the concept of innovation assumes market introduction. In addition, it also considers actions for the production and construction of infrastructure, activities that are not traditionally considered an investment in innovation.

Other limitations are the parameters and search units made available by budget platforms, such as Siga Brasil. Some budgetary actions related to investment in innovation are transversal, that is, they do not have sectorial direction at the action level. Thus, in order to identify health expenditures, it is necessary to request data from the responsible higher bodies, for example, via the Access to Information Law (LAI), which was not done in this edition of this OT.

Considering this, this first edition was launched in a technical note format, in order to start the debate on the topic and receive feedback and considerations for improvement.

Suggestions, feedback and comments can be sent to the following email: <inesc@inesc.org.br>.

Get to know INESC

In the world we live in, nothing is more urgent than guaranteeing human rights for everyone. For that to happen, we need to improve democratic processes, strengthen citizens and popular movements and fight all forms of oppression, inequality and prejudice. We have been working towards this goal since 1979.

We are a non-governmental, non-profit, non-partisan organization with headquarters in Brasília (DF). For over 40 years, we have acted politically with partner organizations from civil society and social movements to have a voice in national and international spaces to discuss public policies and human rights, always keeping an eye on the public budget. We believe that understanding and interpreting the public budget is a fundamental part of promoting and strengthening citizenship and guaranteeing the rights of all citizens.

Other INESC publications:



[Access to Medicines Thematic Budget 2019](#) Last edition of the Access to Medicines Thematic Budget.



[A country suffocated - Review of the Union's General Budget 2020](#). Analysis of the budget expenditures of the Union of the previous year and comments regarding the forecasts for the current year for the different areas in which it operates. With this, we hope to contribute to the public debate, making information on budget and rights more accessible.



[Budget & Rights Methodology](#). This booklet looks at the public budget in terms of both revenue and expenditure, through the lens of human rights. It represents the systematization of Inesc's methodology translated into a popular education language. This is the main material for Inesc's training initiatives.



[Booklet: "Public Budget and the Right to Indigenous Health"](#). Guided by popular education principles, the booklet takes up the history of struggles that culminated in the National Policy for the Health of Indigenous Peoples (PNASPI) and bet on the strengthening of social control for policy improvement.