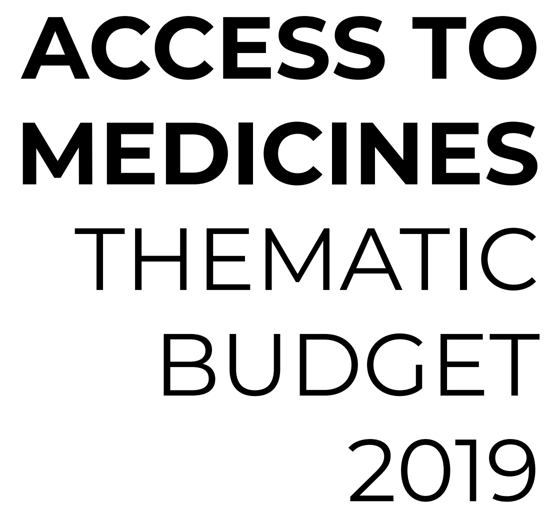

ACCESS TO MEDICINES

THEMATIC BUDGET 2019

ACCESS TO MEDICINES - THEMATIC BUDGET 2019

DECEMBER, 2020

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ACCESS TO MEDICINES - THEMATIC BUDGET 2019

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Brasília - DF - Brazil, 2020.

Acronyms

ANVISA – Brazilian National Health Surveillance Agency
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 Comission
CT&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
IFA - Active Pharmaceutical Ingredient
INESC – Institute of Socioeconomic Studies
INPI - Brazilian National Institute of Industrial Property
LOA - Annual Budget Law
MCTI - Ministry of Science, Technology and Innovations
MS - Ministry of Health
OGU - General Budget of the Union
OT - Thematic Budget
OTMED - Access to Medicines Thematic Budget
OTMED CT&I - Thematic Budget for Science, Technology and Innovation in Medicines
PAC - Growth Acceleration Program
PD&I - Research, Development and Innovation
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
PDP - Productive Development Partnership
IS - Innovation System
PIS - Pharmaceutical Innovation System
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
WTO - World Trade Organization

OTMED 2019 - Summary of key data

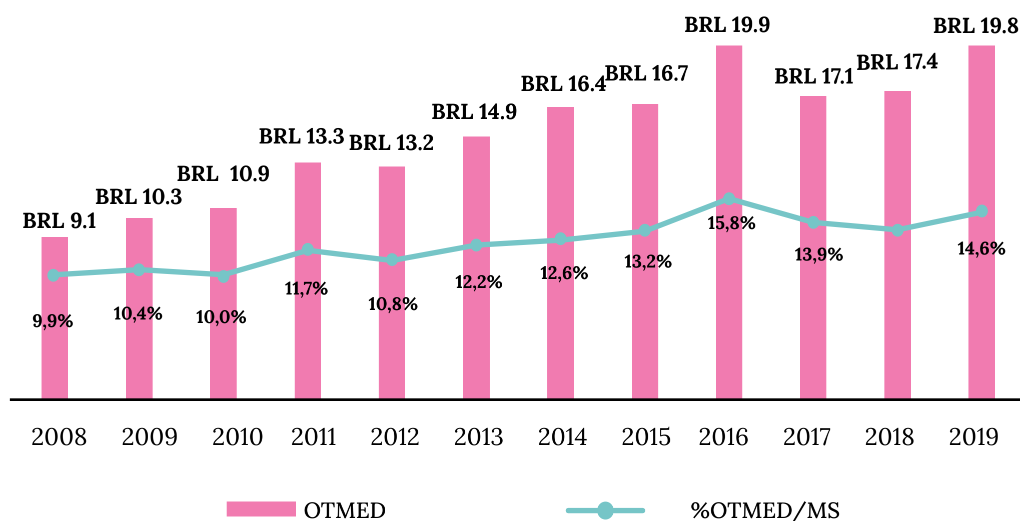
Evaluation of the Ministry of Health's financial execution with medicines from 2008 to 2019

The amounts paid and accrued liability, extracted from the Federal Senate's portal SIGA Brasil, are considered. Values are deflated to 2019 average prices.
Graphics elaboration: Inesc

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

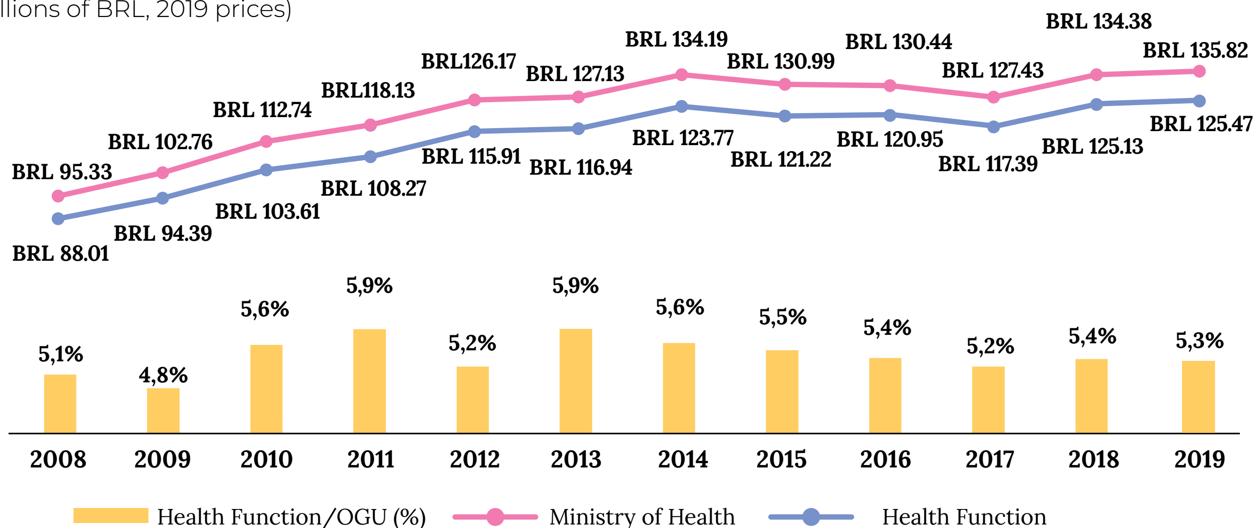
(billions of BRL, 2019 prices)

The financial execution of the MS with drugs rose again in 2019, reaching R$ 19.8 billion after being stable in previous years and is similar to the peak of 2016. This expense more than doubled when compared to 2008, while that of the Ministry grew about 42% in real terms. Thus, it consumes an increasing share of the health's budget.



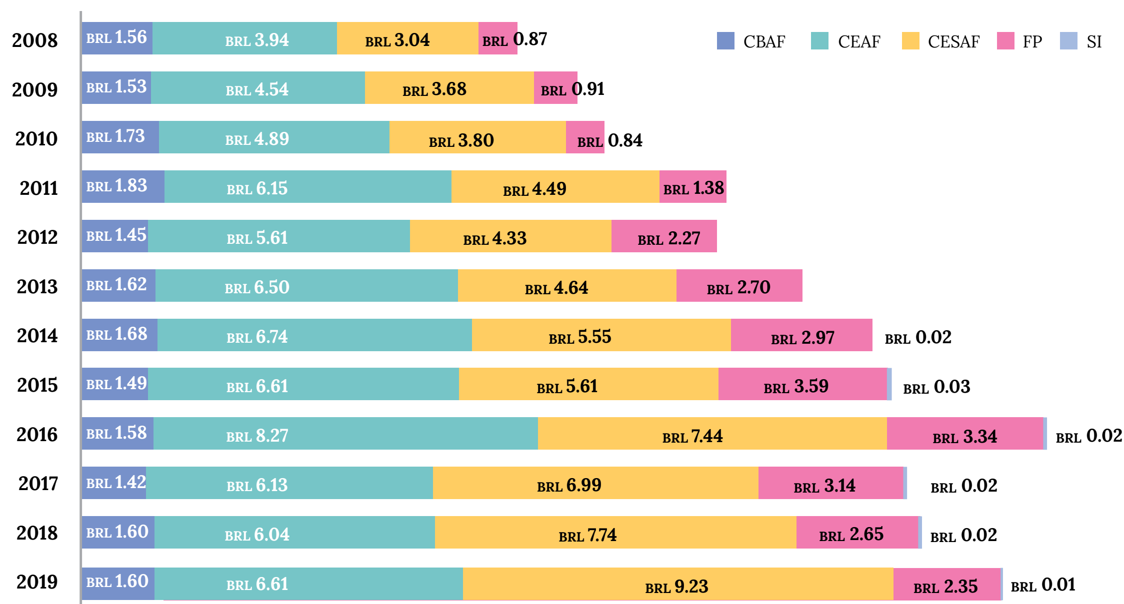
Financial execution of the Ministry of Health and the Health Function and percentage share of the Health Function in the General Budget of the Union, 2008–2019

(billions of BRL, 2019 prices)



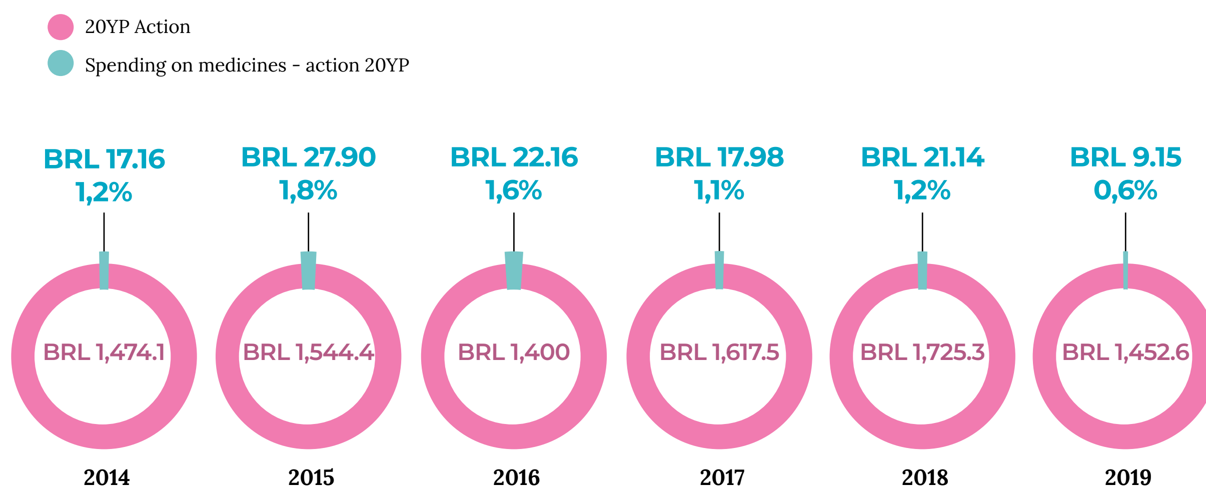
In 2019, as expected due to the Spending Cap, the MS budget remained at the same level as in 2018, which is comparable to 2014, while the Brazilian population increased by 7 million people in the same period, leaving the Brazil with low immunity to cope with the coronavirus in 2020.

OTMED by pharmaceutical assistance component
(billions of BRL, 2019 prices)



In the breakdown by component, expenditure on CESAF continues to be the most significant, corresponding to 46.6% of OTMED. In 2019, spending on this component grew 19.3% due to greater purchase of the MMR vaccine and the incorporation of the meningococcal vaccine. CEAF also grew (almost 10%). Spending on CBAF remained the same. The Popular Pharmacy program had a reduction of 11%.

Spending on indigenous health and medicines
(billions of BRL, 2019 prices)



The Health Care Subsystem for Indigenous Peoples receives an average of R$ 1.4 billion per year. Of this total, just over 1% is spent on medicines. The amount invested is insufficient to adequately serve the 34 Indigenous Health Districts spread throughout the national territory, the specific characteristics of these populations and their access.

1. Introduction

Since 2015, the Institute for Socioeconomic Studies (INESC) has been preparing the Access to Medicines Thematic Budget (OTMED), which aims to assess the allocation of federal resources in promoting access to medicines in Brazil and their impacts to guarantee this fundamental part of the right to health. This edition continues this series of publications and contemplates spending up to 2019.

The OTMED is the sum of the amount paid, and the accrued liability, for budgetary actions related to Pharmaceutical Assistance per year, which is equivalent to the financial execution for this activity. In summary, the value of the OTMED represents the expenditure of the Ministry of Health (MS) with medication and services of Pharmaceutical Assistance. The methodology is described in the item 4 of the present study.

It is important to emphasize that the analysis restricted to the values does not demonstrate the quality of the pharmaceutical assistance provided or the access to medicines. Thus, it is necessary to combine data analysis with the context surrounding said data. This is what we propose to do in this study, explain or deepen our understanding of how the management of Pharmaceutical Assistance is related to the realization of human rights - more specifically the right to health, of which access to medicines is a fundamental part. This discussion is based on academic articles and other sources, reports and the website of the Ministry of Health including its different agencies, public databases, requests for the Access to Information Law (LAI), among other sources with free access.

Considering federal spending on medicines is fundamental to reflect on the direction of the National Pharmaceutical Assistance Policy, and to understand the budget and health policy as a whole. First, because this activity has a significant weight and is transversal to others, and second, because the Union has a central role in these policies.

It is responsible for most health spending (42.4%, in 2019),[1] while municipalities account for 31.3%, and states for 26.3%, in addition to being the one most capable of creating revenue. The average health spending per capita in Brazil is about BRL 1,400, which corresponds to BRL 3.83 per day per inhabitant. It's not much, considering the challenge of having a universal and free healthcare system in a country as large as Brazil. A significant portion of these expenditures is private. Countries with similar health models and dimensions, such as the United Kingdom and Canada, spend almost ten times more and have a greater share of public

1 Available at: <https://portal.cfm.org.br/index.php?option=com_content&view=article&id=28827:2020-10-08-13-00-09&catid=3>. Access on: November 27, 2020.

spending. Even so, the Brazilian Unified Health System (SUS) presents impressive and crucial results for the realization of other rights, such as: high vaccination coverage, reduction of infant and maternal mortality, carrying out transplants and overly complex procedures, among others. In addition, this universal, free and comprehensive public health system has been crucial in the fight against Covid-19. Even with the catastrophic management of the current Ministry of Health, it was the structure and organization of SUS that prevented the situation from being even worse.

And, regarding medicines, according to the agreement between the managers of the different levels, the Federal Government is responsible for the acquisition of high-cost medication. They conduct this process in a centralized way, in order to concentrate the demand and, thus, create bargaining power and generate economies of scale. Pharmaceutical products have been putting pressure on health spending in all countries, including high-income countries. This happens, among several factors, due to their increasing price. Especially with newer drugs, which are under the monopoly of manufacturers, who abuse prices based on their patent rights. On the other hand, health budgets are limited by measures of fiscal austerity or lack of priority, which is given to economic measures.

BOX 1 | What is pharmaceutical assistance?

Pharmaceutical assistance is the set of actions aimed at the promotion, protection and recovery of health, both individual and collective, with medication as an essential input, aiming at its access and rational use (National Health Council - Resolution nº 338/2004).

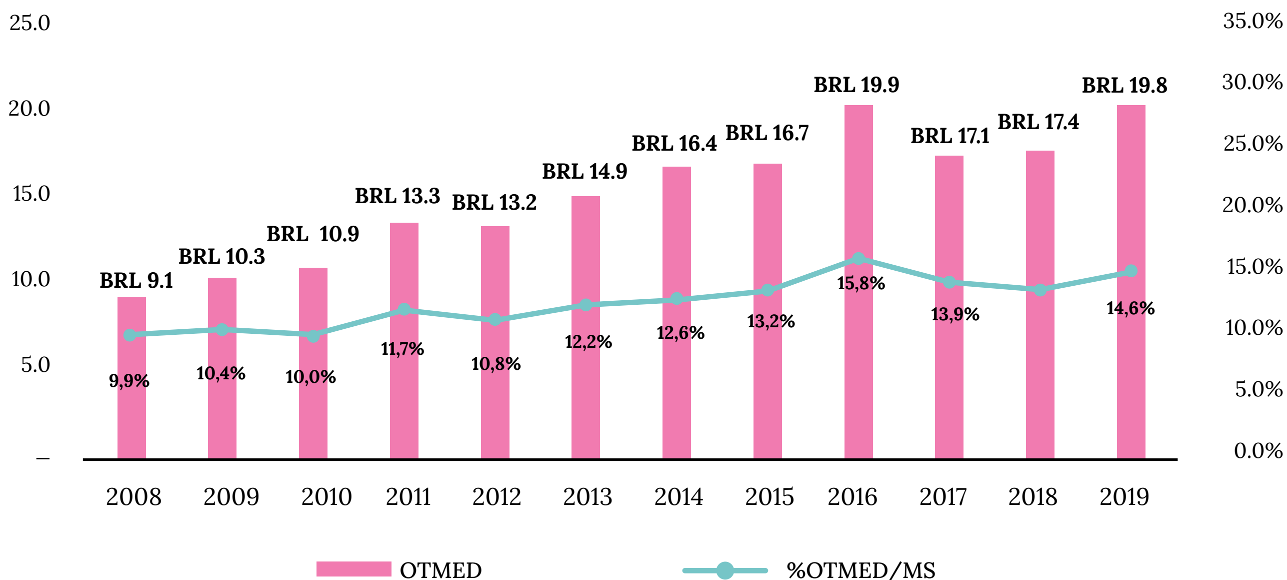
It happens at different levels of care and in different places where health services are provided (in hospitals, clinics and emergency units, in pharmacies at health centers, in vaccination units, in specialized pharmacies, among other places), either by dispensing or delivering medicines for the patient to use at home or in the hospital environment.

2. ACCESS TO MEDICINES THEMATIC BUDGET (OTMED) 2019

2.1 Overview

In 2019, federal spending on medicines was BRL 19.8 billion, an increase of almost 10% compared to 2018, in real terms. This spending follows an upward trend in relation to previous years and more than doubled when compared to 2008, the first year of the series. It consumes an increasing share of the Ministry of Health's budget, which corresponded to 14.6% in 2019 (see graph 1).

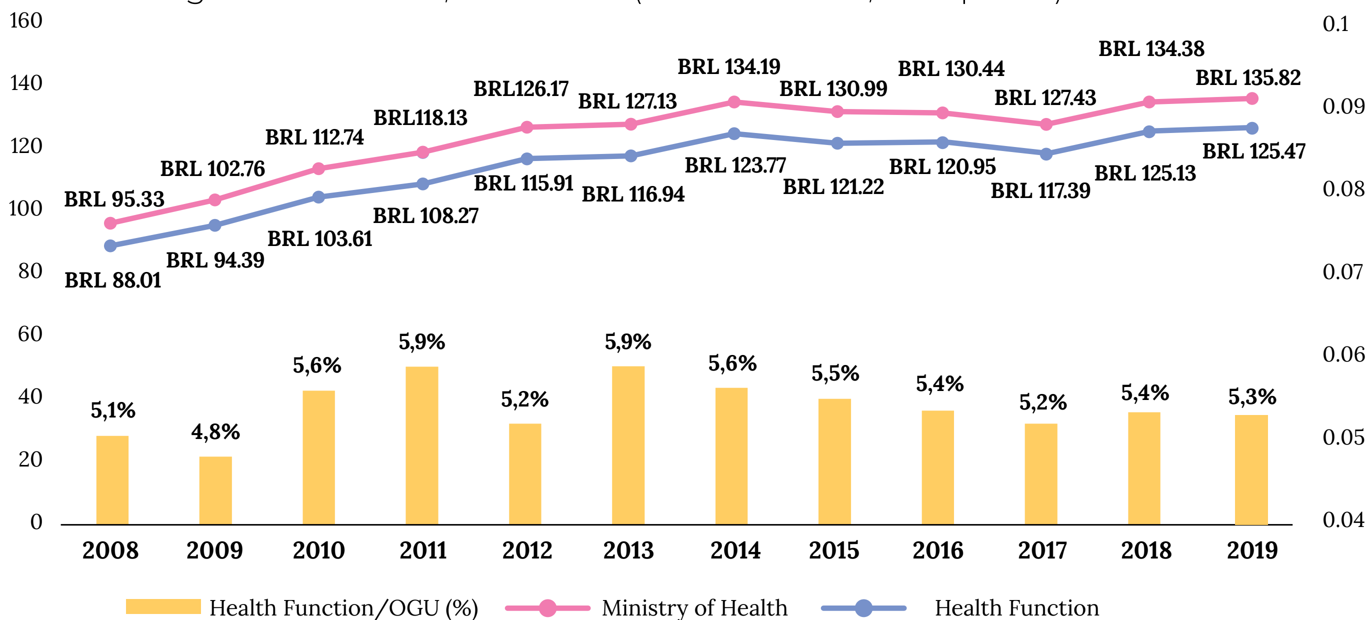
GRAPH 1. Financial execution of the Access to Medicines Thematic Budget (OTMED) from 2008 to 2019 and corresponding percentage of the Ministry of Health (MS) budget (in billions of BRL in 2019 prices)



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

The budget of the Ministry of Health in 2019 was BRL 135.82 billion, in real terms, a value similar to the previous year. And more: it is a value very close to that of 2014, while in that period the population increased by more than 7 million people. The same happened with the Health function budget, whose BRL 125.47 billion spent in 2019 correspond to 5.3% of the General Budget of the Union (OGU) for the same year. In the last five years, from 2014 to 2019, OGU grew 41%, from BRL 1.66 trillion to BRL 2.35 trillion (see graph 2).

GRAPH 2. Financial execution of the Ministry of Health and the Health Function and percentage share of the Health Function in the General Budget of the Union, 2008–2019 (billions of BRL, 2019 prices)



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

2.2 Spending by component

Regarding the components of pharmaceutical assistance, the Strategic Component of Pharmaceutical Assistance (CESAF) remains the most important, corresponding to 46.6% of the financial execution, as can be seen in Graph 3. Spending on this component grew 19.3% this year and occurred in action 20YE: "Acquisition and Distribution of Immunobiologicals and Disease Prevention and Control Supplies", whose resources are allocated for the acquisition of vaccines, serums, diagnostic supplies, larvicides, insecticides, male and female condoms, lubricating gel and the acquisition of refrigerated chambers to serve the cold chain of the National Immunization Program. In consultation with the Ministry of Health,[2] it was found that the increase was due to a greater demand for the MMR (measles, mumps, and rubella) and MR (measles and rubella) vaccines, caused by the measles outbreaks that occurred in the year and the incorporation of the ACWY Meningococcal vaccine.

Then, comes the Specialized Component of Pharmaceutical Assistance (CEAF), which corresponded to 33.4% of expenses and grew by almost 10%. Spending on the Basic Component of Pharmaceutical Assistance (CBAF) remained practically the same, corresponding to 8.1% of total expenses.

BOX 2 | The components of pharmaceutical assistance

The supply of medicines in the Unified Health System (SUS) is organized into three components: the Basic Component of Pharmaceutical Assistance (CBAF), the Strategic Component of Pharmaceutical Assistance (CESAF) and the Specialized Component of Pharmaceutical Assistance (CEAF), in addition to the Popular Pharmacy (FP) program. Except for Popular Pharmacy, the choice of which drugs will be part of which component is "tripartite", that is, shared between the Union, States and Municipalities.

This definition is described in the National List of Essential Medicines (Rename). In addition to the national list, which serves as a guideline, states and municipalities should develop their own lists, which should be made available to users according to local needs.

The CBAF guarantees the cost and distribution of medicines and essential supplies for Primary Care. The responsibility for the acquisition, selection, storage, distribution and dispensing of these drugs rests with the states, the Federal District and the municipalities. However, some medicines are purchased centrally, to rationalize spending or ensure supply. They are: insulins and contraceptives. Also included in the CBAF are actions for the qualification of Pharmaceutical Assistance, assistance to persons deprived of liberty, and in case of natural disasters.

The CBAF budget also includes the National Pharmaceutical Assistance Qualification Program (Qualifar-SUS). Divided into four axes, this program operates in: I) the physical structuring of pharmaceutical services (Structure Axis); II) the promotion of permanent education and training of professionals on Health Care Networks (Education Axis); III) the provision of information on the actions and services of Pharmaceutical Assistance practiced within the scope of SUS (Information Axis); and IV) the elaboration of proposals for the insertion of

2 Response obtained via the Access to Information Law (LAI).

Pharmaceutical Assistance (Care Axis) in clinical practices.

CEAF finances drug treatment for outpatient care, for clinical conditions that have higher or more complex treatment costs. In addition, it includes most spending on judicialization of medicines. CEAF medications and their respective lines of care are defined in the Clinical Protocols and Therapeutic Guidelines (PCDT).

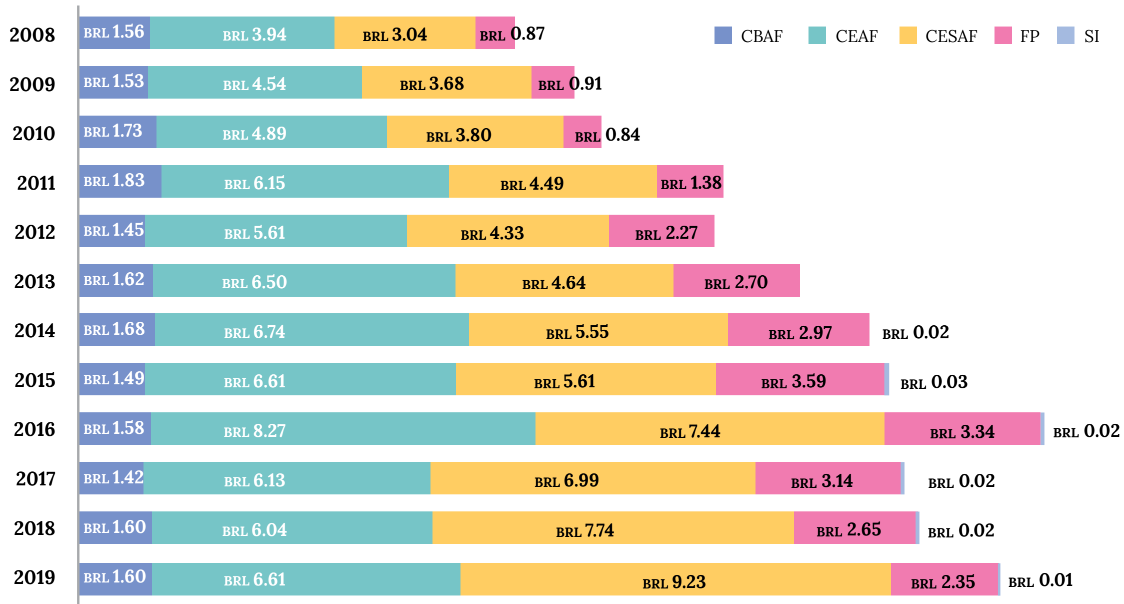
This component is organized into groups according to the responsibility for financing and purchasing. For group 1, financing is an exclusive duty of the Union. For group 1A, the Union is also responsible for the acquisition, while for group 1B, it transfers the funds to the State Health Departments. Group 2 funding is an exclusive duty of these State Departments. And, for group 3, the responsibility is tripartite, that is, it is shared by the three levels of government.

CESAF finances medicines and supplies included in SUS strategic health programs that target diseases of endemic profile, with epidemiological importance, socioeconomic impact or that affect vulnerable populations. They are medicines for the treatment of neglected diseases, such as tuberculosis, leprosy, Chagas disease, for focal endemic diseases (e.g.: malaria, leishmaniasis, dengue, among others), coagulopathies, STD/AIDS, anti-smoking policies, and food and nutrition. These drugs are purchased centrally by the Ministry of Health and distributed to states and municipalities according to the schedule informed by them.

Popular Pharmacy (FP) is a federal program to promote access by subsidizing the prices of medicines in the country purchased from private pharmacies registered with the program. Through FP, the Health Ministry subsidizes asthma, diabetes, and hypertension medication free of charge, and dyslipidemia, osteoporosis, rhinitis, Parkinson's disease and glaucoma medication, as well as contraceptives and geriatric diapers, in the form of co-payment with discount for the user.

There is an overlap between CBAF and the Popular Pharmacy program. The FP was created with the objective of offering an alternative for people to access medicines, through purchase subsidies, initially through its own network and later through private drugstores, a modality that remains active until today.

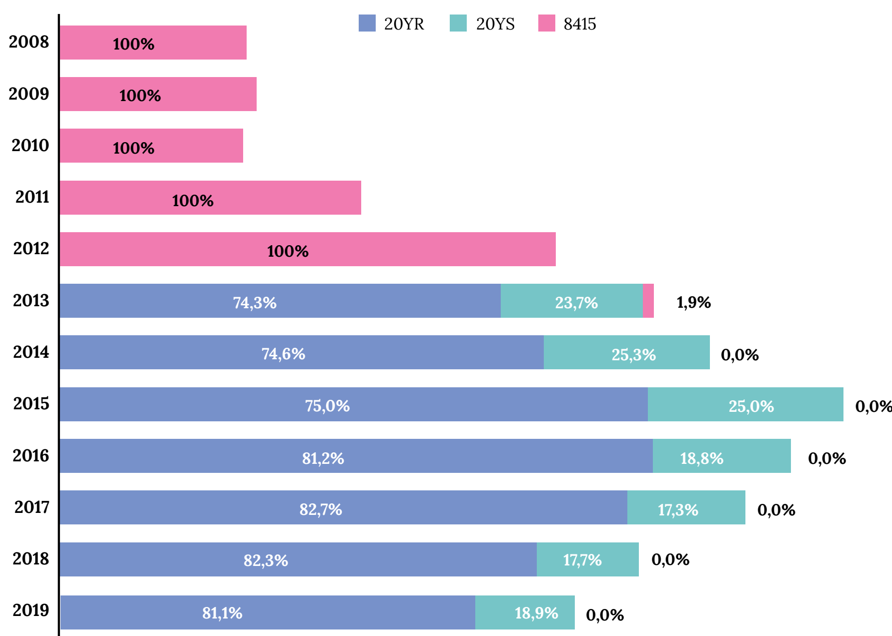
GRAPH 3. OTMED by pharmaceutical assistance component, 2008–2019 (in billion BRL, 2019 prices)



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

Spending on the Farmácia Popular, or Popular Pharmacy program decreased by 11%, corresponding to 11.9% of OTMED 2019. This may reflect the interruption of new accreditations in 2014 and revisions to the program's price list. The action aimed at free mediation, for which the government subsidizes the total value of the medicine, remains the one with the highest budgetary expenditure, in contrast to the co-payment action, for which the buyer pays for a percentage of the value (see the graph 4).

GRAPH 4. Details of the budgetary actions of the Popular Pharmacy program, percentage and total value, 2008–2019 (in billion BRL, 2019 prices)



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

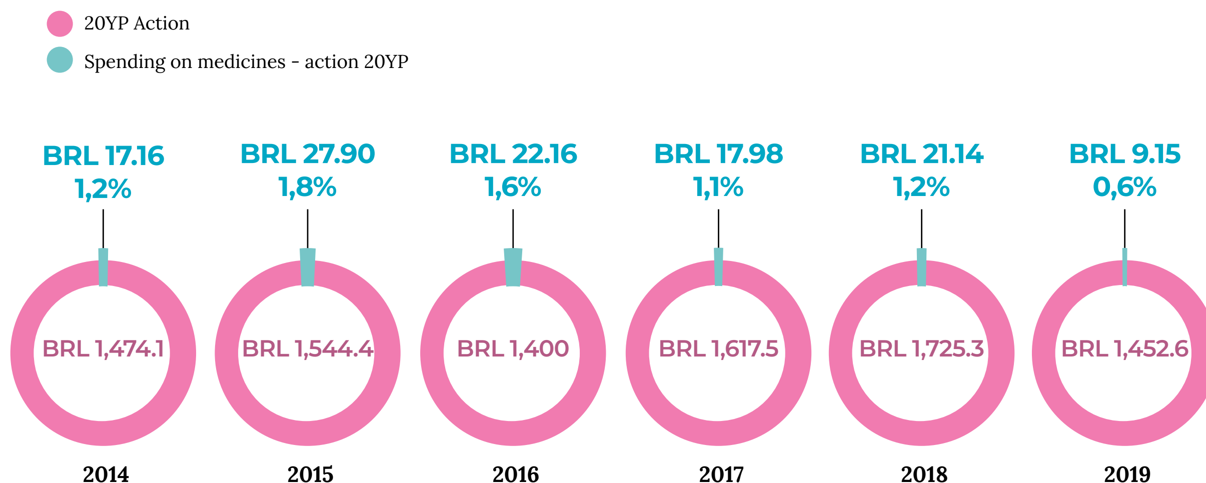
20YR: Maintenance and Functioning of Popular Pharmacy program of Brazil through the Gratuitousness System;
20YS: Maintenance and Functioning of the Popular Pharmacy program of Brazil through the Copayment System;
8415: Maintenance and Functioning of Popular Pharmacies.

2.3 Medicines for indigenous health

Spending on indigenous peoples health lost, in real terms, almost BRL 270 million in 2019, which further undermines adequate care for this population, which is distributed throughout the entire Brazilian territory (see box 1 and box 3).[3]

With regard to expenses with medicines for indigenous health, there was also a significant reduction in 2019, to less than half. However, it can be attributed to changes in the data extraction methodology in response to the request for access to information. The 2018 request was answered by the Special Secretariat for Indigenous Health, while the 2019 request was answered by the General Coordination of Planning and Budget. This variation reflects the importance of correctly identifying such spendings in budget monitoring systems, due to the importance of ensuring health for this population and monitoring the special indigenous health subsystem - in which a good part of the actions and resources are carried out by outsourced organizations.

FIGURE 1. Spending on indigenous health and medicines, 2014–2019 (in millions BRL corrected, 2019 prices)



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

3 Available at: <https://www.inesc.org.br/cartilha-orcamento-publico-e-direito-a-saude-indigena-2/>. Access on: November 27, 2020.

BOX 3 | The special subsystem of indigenous peoples care

Indigenous populations are served through the Indigenous Peoples Health Care Subsystem (SasiSUS), articulated with SUS but decentralized, with administrative, budgetary and financial autonomy. It is organized in 34 Special Indigenous Health Districts (DSEI), distributed throughout the national territory. A DSEI is a health union under federal responsibility. It is a delimited social, cultural and geographical space, in which there is a network of health resources and services, where people habit, live and coexist.

The Districts are responsible for providing specific health care to the indigenous populations who live in the Indigenous Lands within that territory. SasiSUS is responsible for primary health care for the indigenous population, settled in villages or not. When people need other types of assistance, such as surgeries, exams or other procedures, the District needs to articulate with the regional SUS to guarantee the assistance of indigenous people in all their needs BRAZILIAN HEALTH MINISTRY, 2016.

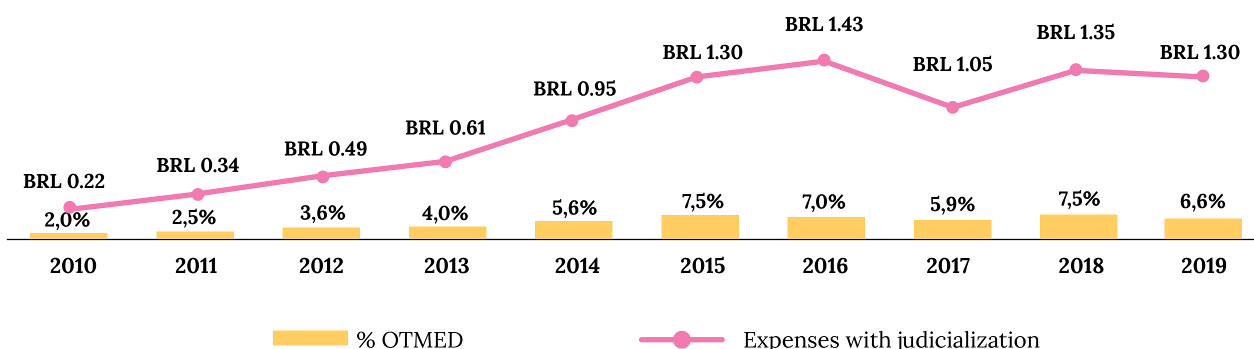
DSEI should function as interlocutors between communities and government bodies, taking into account particularities of the territories, demands and the peoples way of life. SasiSUS is a health model designed particularly for indigenous peoples and was an achievement after much struggle. When we talk about indigenous health, we are actually talking about a wide variety of elements. The way health happens varies a lot within communities, villages and settlements. One of the important points for indigenous health is that diversity is respected - including all the possible ways of being indigenous. In addition, indigenous health does not necessarily have to do with the health offered by the state. It is also composed of what communities consider important to live well.

2.4 Judicialization of medicines

Spending on medicine granted through court (see box 4)[4] fell 4.1%, in real terms, in 2019, totaling BRL 1.3 billion, which may mean that the measures to contain it have been successful. The majority of expenses with judicialization are allocated in budgetary action 4705, referring to CEAF. However, about BRL 250 thousand were computed in action 4370, referring to HIV/AIDS and other sexually transmitted infections (STI) medicines, from CESAF (see graph 5).

4 ANDIA and LAMPREA, 2019. Is the judicialization of health care bad for equity? A scoping review. International Journal for Equity in Health, v. 18, n. 61. Available at: <https://equityhealthj.biomedcentral.com/articles/10.1186/s12939-019-0961-y>. Access on: November 11, 2019. LOPES et al., 2019. (Un)Equitable distribution of health resources and the judicialization of healthcare: 10 years of experience in Brazil. International Journal for Equity in Health, v. 18, n. 10. Available at: <https://equityhealthj.biomedcentral.com/track/pdf/10.1186/s12939-019-0914-5>. Access on: November 11, 2019.

GRAPH 5. Ministry of Health expenses with judicialization of medicines and corresponding percentage of OTMED, 2010–2019 (in billions of BRL, 2019 prices)



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

BOX 4 | Judicialization of medicines

The judicialization of health is when citizens seek access to health services and products, such as medicines, through judicial demands, based on the right to health, guaranteed by the Federal Constitution. However, despite being a strategy that guarantees access to health goods and services, it has implications for public health. One of them is its high budgetary impact, which has grown exponentially in the last two decades, being an important pressure factor in public budgets and health management, since they are outside the schedule for purchase and dispensation of public services. In addition, the purchase to meet these demands is made on an emergency basis, which prevents the use of mechanisms such as pricing, which is aggravated with medication getting more expensive overtime and high prices to import some of it. This development has impacts on equity, as there is a redirection of resources to meet specific demands, despite the population's health priorities, considering that only a small portion of the population can access the Judiciary and be successful in a judicial process.

One of the measures adopted to rationalize distribution of medicines by SUS was the creation of the National Commission for Technology Incorporation at SUS (Conitec), determining which technologies will be made available free of charge by SUS, based on scientific evidence. Through the assessment of health technologies, Conitec not only assesses the effectiveness and safety of therapeutic options compared to the others available, but also their budgetary impact.

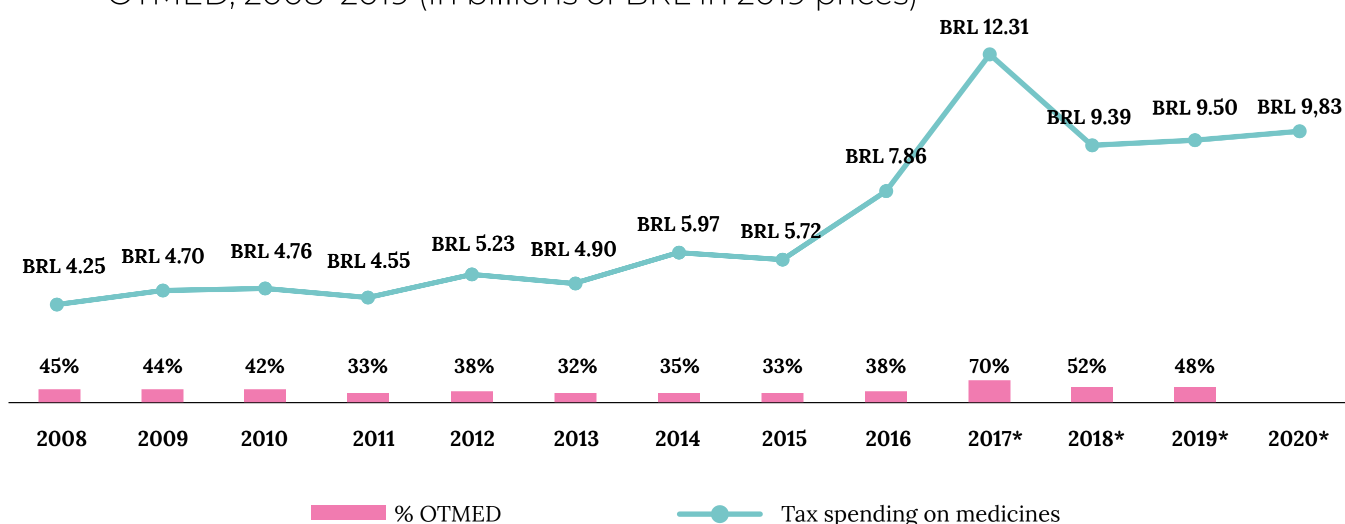
Judicialization is a means for patients to have guaranteed their right of access to health and medicines. However, it is a process that reflects asymmetries when it comes to access to rights, such as differences based on income and race/color. An increasing number of studies show the inequalities in the judicialization process, conducted mainly by people with high-income, or living in municipalities with a high development rate. This shows that judicialization does not reach municipalities most in need of public policies and intervention via the Judiciary, but those whose population with easier access to justice. The distribution of health resources is decisive for establishing an equitable public policy, but judicialization has a negative effect on the redistribution of resources.

2.5 Tax spending on medicines

Tax spending on medicines in 2017, the last year for which we have the effective bases and not projections, grew by almost 60%, reaching BRL 12.31 billion. In other words, the tax waiver corresponded to almost 70% of the spending on medicines that year.

In comparison to the pharmaceutical market, this amount corresponded to 18% of its sales for the same year. In 2018, the Brazilian industrial pharmaceutical market grew 9.8%, reaching BRL 76.3 billion in revenues.

GRAPH 6. Tax spending on medicines and corresponding percentage of OTMED, 2008–2019 (in billions of BRL in 2019 prices)



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

3. 3. Final considerations

In 2019, spending on medicines from the Federal Government increased (10%), putting even more pressure on the Ministry of Health's budget, limited by the spending cap. It is important to guarantee quality pharmaceutical care for the population, but it must be in balance with SUS's budgetary sustainability. Thus, issues such as the excessive profit of the pharmaceutical market (which includes both the manufacturing and retail industries), the commodification of health and excessive medicalization must be addressed.

Ensuring enough resources for SUS is essential, but impossible in the context of fiscal austerity. The "Balance of the General Budget of the Union 2019 - Brazil with low immunity",[5] launched by INESC in 2020, shows that these measures and the approval of Constitutional Amendment 95, known as the Expense Cap, has reduced social policies, leaving the population to the mercy of the coronavirus pandemic, especially the most vulnerable. The report shows that, from 2014 to last year, the Union's constant fiscal effort resulted in cuts of 28.9% in the discretionary expenses of the country's social programs. Between 2018 and 2019 alone, the decrease in social spending reached 8.6%.

The Strategic Component of Pharmaceutical Assistance (CESAF) is gaining more and more expression in the budget, which, on the one hand, can be positive, since a good part of it is destined to vaccines for disease prevention. On the other hand, the incorporation of new products, with increasingly higher prices and extra expenses to correct supply problems, is a point of attention in relation to this component.

The stagnation of Federal Government spending on primary care drugs is also worrying, because, although the responsibility for purchasing these medicines lies mainly with the municipalities, they are the entity with the lowest collection capacity and already have their health expenses pushed to the limit during the pandemic. In addition, it was demonstrated that the Popular Pharmacy program, despite questions regarding its arrangement linked to retail (and, thus, to market logic), contributes to expanding access to medicines in the areas that have the program. Therefore, any budget reduction must be analyzed with caution, as well as the decision to end the program.[6] In addition, in 2019, the Federal Government changed the form of financing primary care, which no longer considers the entire population of the municipalities to focus only on registered users, which can impact actions aimed at the collective (such as community actions, territorial planning and public health surveillance) and put even more pressure on the municipalities' budget.[7]

Regarding indigenous health, it is important to consider medicines within the scope of the Indigenous Peoples Health Care Subsystem (SasiSUS), the traditional knowledge of each people and the medicine derived from them. Considering such complex variables, it is important to keep track (for example, with a budget plan) of the budgetary actions aimed at indigenous health, to allow the adequate identification (replicable, yearly) of the expenses with medicines for this population. In any case, the deterioration of the budget for indigenous health puts this population even more at risk.

Spending on judicialization of medicines, despite a slight drop in 2019, must continue to be rationed. For example: in 2020, the drug Zolgensma (onasemnogene abeparvoveque) was

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5 Available at: <https://bit.ly/3fLIe08>. Access on: November 28, 2020.

6 Available in: <https://economia.uol.com.br/noticias/estadao-conteudo/2020/08/25/na-mira-de-guedes-farmacia-popular-atende-21-milhoes-de-pessoas.htm>. Access on: November 27, 2020.

7 Available at: <https://www.inesc.org.br/o-que-muda-com-o-novo-financiamento-da-atencao-basica-a-saude/>. Access on: November 27, 2020.

incorporated for the treatment of spinal muscular atrophy, which has a treatment cost in the order of USD 2 million, which is equivalent to more than BRL 10 million. The point here is not to limit patients' access to this treatment, but rather to question the price charged by the industry, which abusez its market power to achieve maximum profit, to the detriment of people's health.

Along the same lines, tax spending on tax exemptions for medicines must be carefully assessed, in order to gauge whether it is, in fact, facilitating the population's access or just guaranteeing the industry's profit. Only in 2017, the Union failed to collect an amount corresponding to 70% of OTMED with tax exemptions.

3.1 Analysis in the light of budget pillars

The INESC's Budget & Rights methodology presents five pillars that public policies for the promotion of human rights and their respective budgets must meet: financing with fiscal justice, maximum mobilization of available resources, progressive realization of rights, non--discrimination and social participation.

Brazil's Public Health System suffers from a chronic problem of underfunding, and now, with the Expense Cap, the reality is one of definancing, since an amount that was not enough to begin with, will be reduced. Thus, the pillar of maximum resource mobilization was not met, as well as that of progressive realization of rights, as it is not possible to expand the coverage of SUS care or health actions and services in a context of scarcity of resources and austerity. On the other hand, the lack of transparency regarding tax spending calls into question state compliance with the pillar of tax justice, given that it is not clear whether the tax exemption favors the users or the pharmaceutical industry and distributors, which have a high market power.

The existence of the Indigenous Peoples Health Care Subsystem is a good start for meeting the non-discrimination pillar, as it contributes to fight inequality and structural segregation, that have been causing struggles for historically discriminated groups and populations to access their rights. However, the lack of adequate investments and problems in the implementation of this policy prevent it from fulfilling its function. In addition, it is necessary to have and properly implement effective health care policies for other groups, such as quilombolas, black communities, women, LGBTQIA +, among others.

Regarding the social participation pillar, fortunately, as it was established by federal law, the SUS Council Network was preserved, despite the extinction of several social participation councils and instances, through Presidential Decree No. 9,759/2019. Municipal, State, District and National Councils are spaces of resistance against fiscal austerity measures and other attacks that the public health system has been suffering. In 2019, the 16th National Health Conference was followed by a series of Municipal and State Conferences, which constitutes the most important instance of social participation and defines the guidelines for the health policies of the coming years. In total, more than 20 thousand people participated in the local conferences, and the national stage had almost 3 thousand participants. However, it is necessary that the recommendations of the 16th Conference, and others to come, are effectively implemented by health executive bodies.

3.2 Recomendations

Below, we have compiled some recommendations for guaranteeing the right to health and compliance with the pillars.[8] And, in box 5,[9] we present initial comments on the year 2020.

- Revoke the spending cap imposed by EC No. 95/2016.

- Rebuild the budget with the amounts withdrawn by EC No. 95/2016 and allocate at least 10% of the Union's gross current revenue to SUS.

- Establish, for 2021, an emergency budget floor for health of BRL 168.7 billion.

- Adopt more measures of active transparency in relation to medicines and pharmaceutical assistance spending, due to the significant volume and its importance, especially in the context of Covid-19 (for example, through the annual breakdown of these expenses).

- Homologate and implement the decisions of the National Health Council in a timely manner.

- Evaluate, with civil society participation and wide publicity of the results, the impacts of the new primary care financing model and revise it accordingly.

- Evaluate tax spending on medicines, with participation of civil society and wide publicity of the results, and review them, so that they promote the realization of the right to health.

- Make a transparent financial assessment on the fight against Covid-19, explaining the details of budget execution for each area.

- Reject PEC (Proposed Amendment to the Constitution) No. 188/2019, to maintain fiscal solidarity between the entities of the Federation and the provision of public services, since it aims, among other factors, to relativize social rights enshrined in the Federal Constitution - especially in the areas of health and education - with effective breaking of the constitutional bond, and subordination of these rights to fiscal rules and precarization of public service, including health professionals and other social areas.

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8 Available at <https://www.inesc.org.br/obrasilcombaixaimunidade/> e <https://direitosvalemmais.org.br/2020/09/30/orcamento-2021-e-pandemia-sociedade-civil-apresenta-ao-congresso-propostas-para-a-lei-orcamentaria-2021-e-denuncia-efeitos-da-pec-18/3>.Access on: November 27, 2020.

9 Available in: <https://www.inesc.org.br/orcamento-de-2021-mantem-equilibrio-fiscal-acima-das-necessidades-da-populacao/>. Access on: November 27, 2020.

BOX 5 | What about 2020?

The year 2020 was overthrown by the Covid-19 pandemic. Coping with it and the exceptionalities it has caused require several emergency and atypical measures, with great budgetary impact and on the organization of the health system. Several extraordinary credits were approved for different ministries, especially the Ministry of Health - but the delay in budgetary execution and the targeting of them by non-technical criteria hindered the country's response capacity. The Federal Government left the task of containing the new coronavirus in the hands of the governors, despite its greater collection capacity and the responsibility to articulate and coordinate SUS. To make matters worse, the Federal Government's budget proposal for 2021 is based on the assumption that the pandemic and its effects will end with the turn of the year. Thus, the Spending Cap is the priority for this year, despite the continuity of Covid-19, its chronic effects, the high unmet demand for elective postponed procedures, the higher spending on medicines and vaccines, and the economic crisis, which led several people to lose even private health care.

Budget execution for 2020 should be carefully analyzed, as well as budget allocation for 2021.

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.[10]

Thematic Budgets (OT, from Orçamentos Temáticos) are the tools used to analyze a topic in depth. They are built by groupings of expenses, using official open data platforms and requests via the Access to Information Law (LAI), the Brazilian Freedom Of Information Act, 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, 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 Access to Medicines Thematic Budget (OTMED) aims to assess the allocation of pharmaceutical assistance federal resources for the promotion of access to medicines in Brazil, and the impacts behind the financial execution of such access, which is fundamental for the realization of the right to health. Three OTMED publications were launched: one in 2016, covering the period from 2008 to 2015; another in early 2018, which focuses on the years 2016 and 2017; and the last, which includes data from 2018 and revisits the entire series since 2008.

The methodology described below has been consolidated over the years of construction of OTMED. The budgetary actions that comprise it include mainly the purchase of medication, but also other important pharmaceutical assistance activities. Actions that do not cover only these activities are partially included. In these cases, only the expense related to medicines is taken into account, and this information is requested via the Brazilian Freedom of Information Act (acronym in Portuguese LAI).

The following actions are not considered: promoting the use of medicinal plants and herbal medicines within SUS (20K5), donations to international organizations for the purchase of medicines (00NJ, 00NK), research and teaching actions, and drug production (for example, 2522, 7835, 11PJ, 20QF, 211V, 20UU, 2478, 13DW). There are also other budgetary actions that are related to medication policies and were not part of this OTMED, as they did not execute resources in this period, such as action 4383 (vaccination of the population), action 0804 (support for structuring pharmaceutical care services) and action 8415 (maintenance and operation of popular pharmacies).

Each budgetary action is classified according to the definition of the pharmaceutical assistance components and does not depend on the secretariat or department responsible in the internal organization chart of the Ministry of Health.

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

TABLE 1. Details of the budgetary actions considered in the OTMED

#	Names	Component	Years
4368	Promotion of pharmaceutical assistance through the purchase of medicines from the Strategic Component	CESAF	2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018 and 2019 (full in all years)
20AE	Promotion of pharmaceutical assistance and strategic inputs in Primary Health Care	CBAF	2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018 and 2019 (full in all years)
4705	Financial support for the purchase and distribution of medicines from the Specialized Component of Pharmaceutical Care	CEAF	2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018 and 2019 (full in all years)
4370	Assistance to the population with medicines for the treatment of HIV/ AIDS and other sexually transmitted diseases	CESAF	2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018 and 2019 (full in all years)
4295	Transfusion safety and quality of blood and hemoderivatives	CESAF	2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018 and 2019 (full in all years)
20YE	Acquisition and distribution of immunobiologicals and supplies for disease prevention and control	CESAF	2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018 and 2019 (full in all years)
20YR	Maintenance and operation of the Brazilian Popular Pharmacy program through a free system	FP	2012, 2013, 2014, 2015, 2016, 2017, 2018 and 2019 (full in all years)
20YS	Maintenance and operation of the Brazilian Popular Pharmacy program through a co-pay system	FP	2012, 2013, 2014, 2015, 2016, 2017, 2018 and 2019 (full in all years)
20AH	Organization of pharmaceutical assistance services in SUS	CBAF	2012, 2013, 2014, 2015, 2016, 2017, 2018 and 2019 (full in all years)
20YP	Promotion, protection and recovery of indigenous peoples health	SI	2012, 2013, 2014, 2015, 2016, 2017, 2018 and 2019 (partial in all years)
8735	Implementation of actions aimed at food and nutrition for health	CESAF	2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017 and 2018 (partial in all years)

2E88	Financial support for the purchase and distribution of medicines for the treatment of rare diseases (so called orphan-drugs)	CEAF	2018 (full)
6031	Immunobiologicals for disease prevention and control	CESAF	2008, 2009 (full in all years)
20BA	Prevention, preparedness and coping with the influenza pandemic	CESAF	2008, 2009 (full in all years)
8415	Maintenance and operation of popular pharmacies	FP	2008, 2009, 2010, 2011 (full in all years)

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

Caption: SI = Indigenous Health; FP = Popular Pharmacy; CBAF = Basic Component of Pharmaceutical Assistance; CEAF = Specialized Component; CESAF = Strategic Component.

Except for data obtained through LAI, the values were extracted from the Siga Brasil portal, maintained by the Federal Senate. The financial execution of these actions was accounted for, that is, the amounts paid and the accrued liability. Accrued liability relates to amounts pledged in previous years but paid in that year. Accordingly, we accounted for the entire amount disbursed during the year through that action, and not just the payments related to commitments entered in the current year. In order to work with Health data as a whole, we extracted the financial executions of the Health Function and the Ministry of Health, in addition to the total expenses of the General Budget of the Union (Fiscal Budget and Social Security Budget).

All amounts are extracted using the filter that disregards spending on refinancing the public debt. And they were deflated to average prices in 2019 by the National Extended Consumer Price Index (IPCA), calculated by the Brazilian Institute of Geography and Statistics (IBGE), except when explained in the text.

It was requested, via the LAI, the breakdown of the expenses of the 20YP action and the Management Report of the Secretariat of Science, Technology and Strategic Inputs of the Ministry of Health (SCTIE/MS), as it was not found on the Ministry's website. In response, the Ministry of Health forwarded a link to the Ministry's Management Report and not the one specific to SCTIE. In addition, clarifications were requested about the increase in CESAF spending and tax expenditures.

There is a problem with requesting data via LAI. As requests are submitted for each update of the OTMED, there is a variation in the methodology of data extraction according to the respondent on each occasion. Therefore, the values may differ for each response received.

In order to avoid this fluctuation, methodological changes have occurred in relation to previous years, to consider information that is open and available to the public, which can be verified. In the case of data on judicialization, it was decided to consider the information provided by the Ministry of Health, through the 2016 SCTIE Management Report and the 2018 and 2019 Ministry of Health Management Report. It is important to note that the reports do not specify which stage of the budget cycle is considered and whether the amounts are in pledge, settled or paid.

About 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 for discussing 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 (2008–2018). In the last edition of OTMED, the analyzed historical series completed 10 years and assessed that period.

- Brazil with low immunity - Balance of the General Federal Budget 2019. 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 spending, 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.

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