

**ACCESS TO MEDICINES  
THEMATIC BUDGET:  
ANALYSIS OF FEDERAL  
RESOURCES ALLOCATED  
TO PHARMACEUTICAL  
ASSISTANCE OVER 10 YEARS**

ASSESSMENT OF MINISTRY OF  
HEALTH MEDICINES BUDGET  
EXECUTION FROM 2008 TO 2018

LUIZA PINHEIRO ALVES DA SILVA





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**Access to medicines Thematic Budget: Analysis of federal resources allocated to Pharmaceutical Assistance over 10 years**

*Assessment of Ministry of Health medicines budget execution from 2008 to 2018*

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## LIST OF ACRONYMS

**ANVISA** – National Sanitary Surveillance Agency  
**CAF** – Pharmaceutical Distribution Center  
**CASAI** – Indigenous Health Houses  
**CBAF** –Basic Pharmaceutical Assistance Component  
**CEAF** –Specialized Pharmaceutical Assistance  
**Component CESAF** – Strategic Pharmaceutical Assistance Component  
**CIT** – Tripartite Inter-Management Commission  
**CMED** – Drug Market Regulation Chamber  
**CNJ** – National Council of Justice  
**COFINS** – Contribution for the Financing of Social Security  
**CONITEC** – National Commission for the Incorporation of Technologies to the Unified Health System  
**DF** – Federal District  
**DSEI** – Indigenous Special Sanitary District  
**CA** – Constitutional Amendment  
**EMSI** – Indigenous Health Multidisciplinary Teams  
**USA** – United States of America  
**IBGE** – Brazilian Institute of Geography and Statistics  
**INESC** – Institute for Socioeconomic Studies  
**IPCA** – Broad Consumer Price Index  
**IR** – Income Tax  
**LAI** – Access to Information Law  
**LOA** – Annual Budget Law  
**MS** – Ministry of Health  
**OECD** – Organisation for Economic Co-operation and Development  
**WHO** – World Health Organization  
**OTMED** – Access to medicines Thematic Budget  
**TB** –Thematic Budget  
**PCDT** – Clinical Protocols and Therapeutic Guidelines  
**GDP** – Gross Domestic Product  
**PIS** – Social Integration and Civil Servants Fund Programs  
**PNAF** – National Pharmaceutical Assistance Policy  
**PNM** – National Drug Policy  
**QUALIFAR-SUS** – National Pharmaceutical Assistance Improvement Program  
**SASISUS** – Indigenous Peoples Healthcare Subsystem  
**SAGE/SUS** – SUS Strategic Management Support Room  
**SAMMED** –Drug Market Tracking System  
**SCTIE** – Secretariat of Science, Technology and Strategic Inputs of the Ministry of Health  
**SESAI** – Special Secretariat for Indigenous Health  
**SNTP** – Health is Priceless program  
**SUS** – Unified Health System  
**UBSI** – Indigenous health care centers



# 1. INTRODUCTION

Since 2015, Inesc has been preparing the Access to medicines Thematic Budget (OTMED, from the Portuguese acronym), whose goal is to assess allocation of federal resources to promote access to medicines in Brazil and how federal resources impact the guarantee to this fundamental aspect of the right to health. The novelty in this study is the presentation of the Ministry of Health's budget execution historical series for the 2008/2018 period. The new data enables us to assess and reflect upon the paths taken by the National Pharmaceutical Assistance Policy over the last decade.

This study is also relevant for its contribution to analysis of the realization of the right to health, as medicines are costlier for those who earn less. According to the 2017-2018 Consumer Expenditure Survey, the share of private expenditure on health care was similar for lower- and higher-income households (5.9% and 5.6%), even though absolute figures vary widely, on average from US\$ 30.42 to US\$ 360.97 per month. However, the composition of these expenditures varies. For the poorest, medicines account for 71.2% of health expenditure, but for the wealthiest, for only 25.0%. (IBGE, 2019).

In order to analyze the budget through the lens of human rights, Inesc created the Budget & Rights methodology, resting on five pillars: I) State financing with tax justice; II) maximum use of resources available; III) progressive realization of human rights; IV) nondiscrimination; V) popular participation.

Applying them to the thematic budget and health-related specificities, we see that the Unified Health System (SUS) is consistent with the idea of tax justice, since it is a public policy financed by all the citizens that delivers universal services to every person on the Brazilian territory with no discrimination.

It should be noted that tax expenditures undermine this pillar insofar as they compromise tax collection for this system, for the benefit of groups earning higher incomes or posting above-average profits.

Observing OTMED quantitative growth alone, it is fair to consider that the maximum use of available resources and the progressive realization of the right to access to medicines are being met. Still, a careful look is needed to see if inequalities are being fought against too, ensuring access to the poorest and to blacks, women, LGBTQI+, and historically excluded and disenfranchised populations. This would be the application of the nondiscrimination pillar.

Regarding social participation, it is traditionally strong in this area. The SUS itself is the outcome of popular mobilization, which it holds as one of its principles and is replicated in a network of SUS councils from the national level all the way to the municipal. Yet many important decisions are still taken without due popular participation, while a lack of transparency of information also undermines this pillar.

OTMED is the sum of the amount paid and of previous year's payables paid for Pharmaceutical Assistance every year, which is equivalent to the budget execution with this activity. In short, OTMED amounts to the Ministry of Health's expenditure on medicines and Pharmaceutical Assistance services, though these services account for a very small share of expenditure. The methodology is described in the Annex to the present study.

It is worth stressing that analyses that are restricted only to amounts do not prove the quality of the pharmaceutical assistance provided or of access to medicines. So, we have to combine the critique of the data with that of the context they are embedded in. This is what this study proposes to do in order to clarify or deepen how management of Pharmaceutical Assistance is related with the realization of rights, more specifically the right to health, of which access to medicines is a key component. This discussion is based on academic and nonacademic articles, reports, the website of the Ministry of Health and its multiple bodies, public databases, requests through Access to Information Law (LAI), among other free-access sources.

## 2. CONTEXTUALIZATION

Globally, according to 2018 data by the World Health Organization (WHO), total expenditure on health is growing faster than the Gross Domestic Product (GDP) of countries, in particular of low- and middle-income countries. Health care is increasingly more dependent on public funding and less on the individuals' own expenses, even in the context of developed nations. Public spending on health increases as a country's income grows, yet low-income individuals lag behind. The same path is bound to be followed by Brazil, given the expenditure cap imposed by Constitutional Amendment (CA) 95/2016,<sup>1</sup> which came into effect in 2017.

It is worth noting that high-income countries have increased health allocations even after the 2008-2009 economic crisis, as they, with their countercyclical policies, prioritized health-related per capita public spending, which rose by 66% from 2000 to 2016.

With this increase, social sectors tend to be elected as priorities for public spending, but this is not always the case. Higher incomes or more government revenues do not necessarily lead to a higher priority to health. Setting priorities is mostly a collective choice made by societies, generally expressed by politicians elected by their citizens. (WHO, 2018).

According to Organisation for Economic Co-operation and Development (OECD) data, health care spending in Brazil accounted for 9.2% of GDP in 2016, 43.5% of which was public. For the sake of comparison, considering 2018 data of other countries with free, universal health care systems, like the United Kingdom and Canada, those two countries spend, respectively, 9.8% and 10.7% of GDP, while the public share is 76.5% and 70.1% of total expenditure. However, in the United States, whose health care system is overwhelmingly private, 16.9% of GDP is spent on health and, even so the country does not ensure universal, full, equitable access,<sup>2</sup>

1 CA 95/2016 limited primary expense increases to the inflation rate and changed the way minimum allocations in health are calculated. Prior to that, primary expenses were 15% of the Union Net Current Revenue and since then started to be adjusted by inflation, with 2017 expenditure as the baseline. Thus, the systematic fall of the Health budget over the last years has reduced the baseline for calculating the area's following budgets. CA 95/2016 became effective in 2017.

2 The following are the SUS principles. Universalization: health is a right of all persons, and it is incumbent upon the State to ensure it. Access to health actions and services must be guaranteed to all persons, regardless of their social or personal characteristics. Equity: inequalities reduction. People have different needs, and equity means treating those who are unequal unequally, investing more where investment is most needed. Integrality: considering people as a whole, tending to all their needs. This involves integrating health promotion actions, disease prevention, treatment, and rehabilitation. This principle also presupposes coordinating health with other public policies to ensure intersectoral action by every area that may bear on the individual's health and quality of life. Further information available at: <<http://www.saude.gov.br/sistema-unico-de-saude/principios-do-sus>>. Accessed on November 14, 2019.

while 84.6% of this spending is private or provided by health private insurances. Annual expenditure per capita in Brazil is USD 1,282, whereas in the United Kingdom and in Canada, it is USD 4,070 and USD 4,974, and USD 10,586 in the U.S.

What is striking is that, even though Brazil has a free public health care system for all citizens and comprehensive coverage of (low-, medium-, and high-complexity) medical procedures, private spending on health in Brazil is higher than public spending. This reality differs from the pattern seen in developed countries, whose public spending outweighs private spending (except in the United States), regardless of the way they organize their health care systems, a situation that is likely to be related to the Brazilian public system's funding, management, and effectiveness problems. (TESOURO NACIONAL, 2018).

The Brazilian public health care system is universal, that is, it is available for everyone regardless of social and economic conditions and position in the labor market. It is characterized by a high level of decentralization both from the point of view of its functioning and of its funding. Federal government participation, as health care policy implementer, is limited insofar as most of its expenses are based on transfers to states and municipalities, participation that has been on the wane over the last years. Thus, the Union's direct health care expenditure is limited and concentrated mainly in Pharmaceutical Assistance activities.<sup>3</sup> (TESOURO NACIONAL, 2018).

Conversely, federal sphere participation in Pharmaceutical Assistance has become increasingly more significant, as states and municipalities have reduced their share sharply over the last years, a reflection of the financial crisis affecting state and municipal entities. The states' and municipalities' reduced share deepened in 2016, year-on-year, with a 49-percent drop for states and the Federal District, while the municipal share fell by 43%. The federal government's greater participation can be accounted to direct procurement, since decentralization in the purchase of medicines is being reversed particularly because of the Specialized Pharmaceutical Assistance Component (CEAF),<sup>4</sup> which includes high-cost drugs, thus justifying centralized procurement on the grounds of economy of scale. (VIEIRA, 2018).

Graph 1 shows that the Ministry's and the Health function budgets<sup>5</sup> trended upwards until 2014, when they started to shrink. In spite of the spending cap imposed by CA 95/2016, which came into effect in 2017, these budgets once again grew in 2018. A possible reason for that is that, despite the cap, the amendment moved forward the 15-percent freeze on Health expenditure to 2018, which, by the previous amendment, CA 86/2015, would only happen in 2020, and in a gradual way. Therefore, even though CA 95/2016 established a freeze on health and education spending, in real terms, the freeze on both areas was postponed by one year. (PIOLA, 2019). Nevertheless, the health care budget is likely to stabilize, while health care demand will grow in size and complexity. Some effects, namely rising infant and maternal mortality, can already be attributed to this austerity measure. (DONIEC et al., 2018; SOUZA et al., 2019).

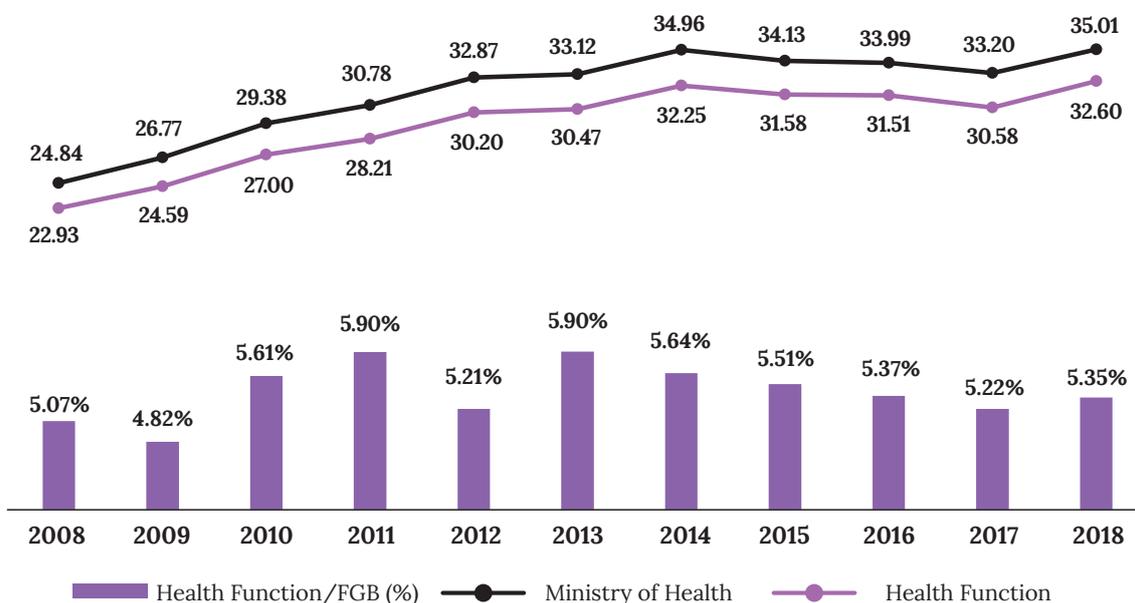
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3 Pharmaceutical Assistance is a set of actions designed to promote, protect, and restore health, both an individual's and collective health, with medication as a key input whose access and rational use is to be ensured. (National Health Council- Resolution n. 338/2004).

4 See Item 3 in this paper.

5 The Health function aggregates expenses on health policies regardless of the ministry implementing them. However, this is not to be confused with Ministry of Health expenditure, since the ministry also incurs other types of expenses such as retirement/pensions.

**GRAPH 1** – Ministry of Health and Health function budget execution (in US\$ billion at 2018 prices) and Health function share in the Federal Government Budget (FGB) from 2008 to 2018



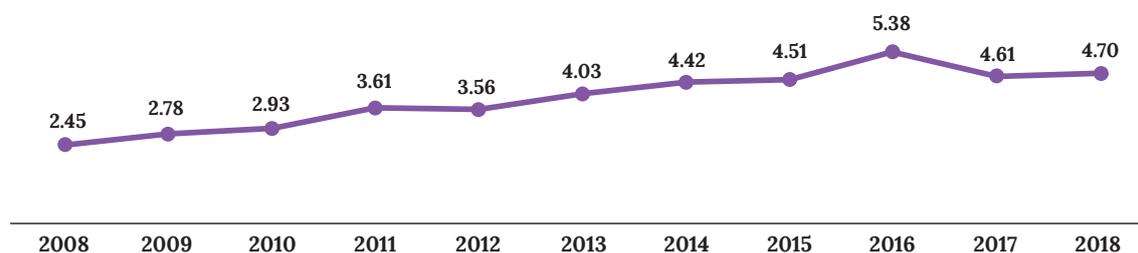
Items that most contributed to push up federal health spending were Pharmaceutical Assistance and Health Surveillance, mostly on account of procurement of specialized prescription drugs (largely due to ‘judicialization’ of access to medicines) and the acquisition of immunobiological drugs (scaling up of influenza, HPV, and other diseases vaccination campaigns). (TESOURO NACIONAL, 2018).

Therefore, we must keep tracking health expenditure trends attentively over the coming years, because of the freeze imposed by the cap and the adoption of austerity measures. According to the Brazilian Treasury, the future dynamic of health expenditure, however difficult that is in itself (due, for example, to the ageing of the population), becomes even more challenging in a context of limitation of public spending growth and of fiscal adjustment. Besides, as other social programs have been affected by the cuts, demand for public health services is bound to grow, since the population’s shrinking income and their increasing vulnerability result in more health-related problems. By the same token, with high unemployment levels, many lose their private health plans, further worsening the country’s huge social gap. Thus, it is of fundamental importance to discuss ways to increase health spending coverage and equity. Funding is one of the area’s main challenges. (SECRETARIA DO TESOURO NACIONAL, 2018; SOUZA et al., 2019; DONIEC et al., 2018).

### 3. ACCESS TO MEDICINES THEMATIC BUDGET (OTMED)

From 2008 to 2018, federal government spending on pharmaceutical assistance increased nearly twofold – by 91.8% (Graph 2). OTMED exhibits a clear growth trend until 2016. In 2017, spending drops dramatically, yet rebounds slightly in 2018.

**GRAPH 2** – Budget execution of Access to medicines Thematic Budget from 2008 to 2018 (US\$ billions at 2018 prices)



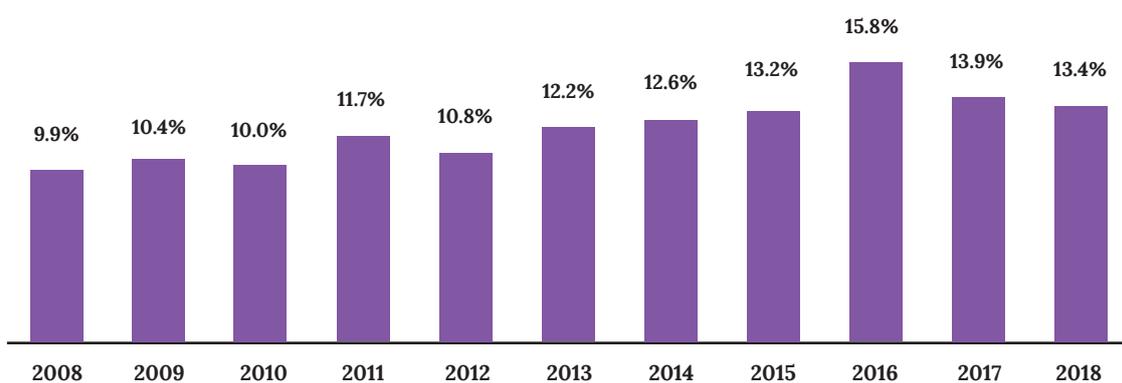
Source: Prepared by Inesc, based on Siga Brasil.

An exploratory analysis of the Ministry of Health's management reports failed to provide any explanation for the 2016 spike. In formulating a hypothesis, we considered for each year amounts disbursed for the payment of previous years' payables, the number of Productive Development Partnerships (PDPs)<sup>6</sup> signed, variations in quantities and prices of the pharmaceutical assistance components purchased, and budget variations. None of these factors in itself indicated a satisfactory answer. What we verified was that, in 2016, expenditure spiked on account of 'judicialization' of access to medicines and PDP-brokered acquisitions. It is worth noting that the Brazilian pharmaceutical market grew by 17.8% from 2015 to 2016, but only 9.3% in the following year.<sup>7</sup> (CMED, 2018). Still, these behaviors offer no explanation for a 19% increase, in real terms, of OTMED in 2016 in relation to 2015. Further analysis is needed to better understand this phenomenon, which seems rather more of a 2016 outlier than an inflection in the graph.

As can be seen in Graph 3, OTMED's budget grows faster than that of the Ministry of Health, committing every year an increasingly higher share of Health Care funds, which have always suffered from chronic underfunding, aggravated by the spending freeze set forth by CA 95/16. Graph 3 shows OTMED expenditure peaking in 2016, with a 20-percent increase.

Moreover, it is worth verifying if the increased Ministry of Health expenditure on medicines means prioritizing drug treatments over other forms of health care, such as promotion and prevention.

**GRAPH 3** –OTMED share of Ministry of Health budget from 2008 to 2018 (%)



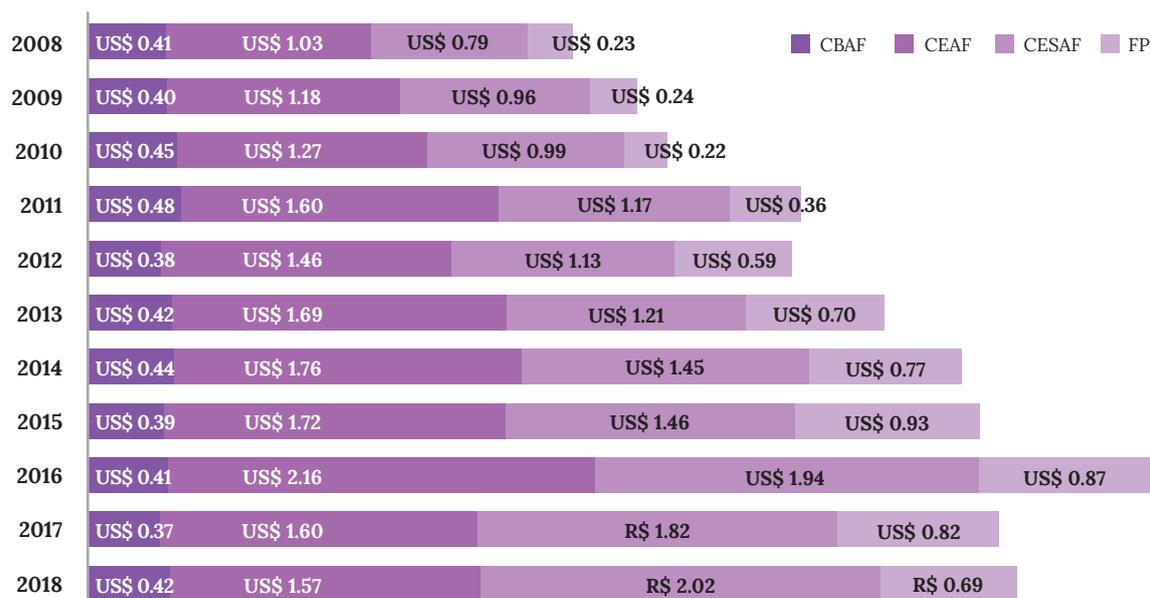
Source: Prepared by Inesc, based on Siga Brasil.

<sup>6</sup> PDPs are a public policy tool used by the Ministry of Health that is designed to build technological capability and reduce foreign dependence by transferring technology from private pharmaceutical laboratories to public laboratories in exchange for assured purchases over a previously agreed upon period.

<sup>7</sup> CMED has been providing Pharmaceutical Market Statistical Yearbooks only since 2015, thus not allowing for a long historical series.

Graph 4 breaks down OTMED by component. Strategic Pharmaceutical Assistance Component (CESAF) exhibited the highest growth over the period in real terms, amounting to, in 2018, two and a half times more than in 2008. Specialized Pharmaceutical Assistance Component (CEAF) rose by 53%, while Basic Pharmaceutical Assistance Component (CBAF) remained almost constant, with a mere 3% growth. However, the category that expanded the most over the period was the Popular Pharmacy program (FP), whose resources grew threefold, in real terms, in 10 years.

**GRAPH 4** – OTMED by pharmaceutical assistance component from 2008 to 2018 (US\$ billions at 2018 prices)



Source: Prepared by Inesc, based on Siga Brasil.

CBAF<sup>8</sup> ensures funding and distribution of primary care essential drugs and inputs. Acquisition, selection, storage, distribution, and dispensing of these primary care drugs is incumbent upon the states, the Federal District, and the municipalities. Funds are transferred from the federal government to the states and municipalities according to demographic estimates made by the Brazilian Institute of Geography and Statistics (IBGE). However, some drugs are purchased centrally with a view to rationalizing expenses or ensuring supply – insulins and contraceptives. The CBAF also includes funding for improving the quality of the Pharmaceutical Assistance, caring for people deprived of liberty, and affected by natural disasters.<sup>9</sup>

There is an overlap between CBAF and the Popular Pharmacy (FP) program. Popular Pharmacy was created for the purpose of offering the population an alternative access to medicines by means of a subsidy for the purchase of drugs, initially through Popular Pharmacy’s public chain of pharmacies and later on through private pharmacies, the latter still in place today. The sharp budget increase of Popular Pharmacy over the period may point to a preference for that option, which was meant to be complementary, to the detriment of basic care CBAF.

8 Descriptions of basic, specialized, and strategic drugs were based on information made available by the Ministry of Health on its website (<http://www.saude.gov.br/assistencia-farmaceutica/sobre-a-assistencia-farmaceutica>) and on the book “Assistência Farmacêutica no SUS: 20 anos de políticas e propostas para desenvolvimento e qualificação: Relatório com análise e recomendações de gestores, especialistas e representantes da sociedade civil organizada”, published by the Ministry of Health in 2018.

9 CBAF also includes funds for the SUS National Program for Medicinal Plants and ‘Phytotherapeutic’ Drugs, but for methodological reasons they have not been considered in the OTMED.

This issue is controversial, because distribution of medicines through private pharmacies presents different characteristics when compared to public distribution, as discussed in Item 4, which details the Popular Pharmacy program. The disparity between CBAF and FP raises discussions as to an existing competition for the capture of funds and users, instead of complementarity. (RONDINELLI, 2018).

The federal government's large share in the funding of drugs used in Primary Care – notably, through the Popular Pharmacy program – and of the specialized drug CEAF program may account for the fact that state and municipal medicines spending fell while Ministry of Health spending rose over the 2014–2016 period. (VIEIRA, 2018).

CBAF budget includes the National Pharmaceutical Assistance Improvement Program (QUALIFAR-SUS). Divided into four axes, this program is focused on: I) the physical structure of pharmaceutical services (Structure Axis); II) the promotion of permanent education and capacity building of professional staff regarding the rationale of Health Care Networks (RASs, from the Portuguese *Redes de Atenção à Saúde*) (Education Axis); III) the dissemination of information on Pharmaceutical Assistance actions and services provided within the SUS framework (Information Axis); and IV) the drafting of proposals to embed the Pharmaceutical Assistance program (Care Axis) in clinical practices.

CEAF, in turn, funds drug treatments for inpatients whose clinical conditions entail higher treatment costs and complexity. Additionally, it incurs costs with 'judicialization' of access to medicines.

As specialized drug program CEAF has considerable impact on the Pharmaceutical Assistance budget, decision-making based on evidence and the adoption of strategies leading to greater cost-efficiency and the effectiveness of the medicines procurement process are vital mechanisms in maintaining the system. Accordingly, CEAF medicines and respective care protocols are established in the Clinical Protocols and Therapeutic Guidelines (PCDT) published by the Ministry of Health.

Furthermore, CEAF is organized in groups according to funding and procurement responsibilities. For group 1, funding is the sole responsibility of the federal government. For group 1A, the federal government is also responsible for procurement, while for group 1B, it transfers funds to State Health Departments. Funding of group 2 is the responsibility of these departments. And for group 3, responsibility is tripartite, that is, shared by the three levels of government.

In 2017, after conducting economic studies, the Ministry of Health decided to centralize the procurement of some prescription drugs previously funded by transfers to the states and the Federal District. Among the drugs selected were products whose difficulty in acquiring resulted in shortages, and others whose bulk orders delivered cost savings for the public system. Actually, CEAF budget has been falling since 2016. The streamlining of the procurement process, as well as the 'judicialization' process, may have contributed to the CEAF budget fall in recent times.

CESAF funds drugs and inputs for SUS strategic health care programs focusing on endemic diseases, of epidemiological importance, socioeconomic impact, or afflicting vulnerable populations. These are drugs for the treatment of neglected diseases like tuberculosis, Hansen's disease, Chagas disease, for focal endemic diseases (e.g. malaria, leishmaniasis, dengue, among others), blood clotting disorders, STD/Aids, the fight against tobacco, and food and nutrition. These drugs are procured centrally by the Ministry of Health and distributed to states and/or municipalities in accordance with their requests.

Four strategies are adopted in managing CESAF. The first one is the monitoring the access to medicines for neglected diseases or diseases of little commercial interest, given the known difficulties municipalities/states face in acquiring these drugs and production discontinuation. In these cases, the Ministry of Health adopts measures to regularize supply, as happened with penicillin for the treatment of syphilis. The second one is procurement centralization when there is an undersupply or access-related problems. Production by official laboratories is also a strategy, its main goal to meet CESAF needs, particularly with regard to diseases on the verge of being eradicated. This strategy was most important in the Brazilian anti-Aids program, internationally recognized as one of the first to guarantee free access to retroviral drugs. The fourth is international procurement,

in cooperation with multilateral bodies. The official laboratories are the main suppliers of drugs designed to treat poverty-related diseases<sup>10</sup> (62%), followed by international procurement (24%). For this group of diseases, private laboratories only have a 14% share.

CEAF and CESAF weigh more heavily on the OTMED budget. It is worth noting that, over the last years, their positions as a share of the budget changed, with CESAF taking most of the budget, initially a CEAF characteristic.

## 4. POPULAR PHARMACY PROGRAM

The Popular Pharmacy Program (in Portuguese, Farmácia Popular (FP)) aims to promote access to medicines by subsidizing the price of prescription drugs in the country. It can be divided into two fronts: public network and partner network.

The FP public network, created in 2004, was the program's first initiative. It comprised public pharmacies strategically located for the lower-income population. It partnered up with state and city governments and public institutions to set up and maintain these units, under the responsibility of Oswaldo Cruz Foundation (Fiocruz). Public FP units supplied and dispensed medicines at cost value, which meant a reduction of up to 90% in their market cost.

The public network coexisted with the partner network until 2017, when the Tripartite Inter-Management Commission (CIT)<sup>11</sup> resolved to stop transferring maintenance funds to these units, with the Ministry of Health agreeing to fully transfer the units' maintenance funds to finance the Basic Pharmaceutical Assistance Component program in the Brazilian municipalities. Due to that decision, gradually public FP network units were discontinued, until they finally closed down in late 2017. (SAGE/SUS, 2019).

In 2006, the partner network, named "There's a Popular Pharmacy in Here" (in Portuguese, "Aqui tem Farmácia Popular (ATFP)"), was started in partnership with private pharmacies, under the argument of broader geographic distribution. In 2011, the Ministry of Health, with pharmaceutical industry manufacturers and distributors, launched the campaign Your Health is Priceless (SNTP, from the Portuguese *Saúde não tem Preço*) with the aim of ensuring the gratuitousness of the hypertension and diabetes drugs available at the Popular Pharmacy program. In 2012, drugs for asthma with a greater variety of active principles and presentations were made available at the partner network rather than at the public network.

Through the Popular Pharmacy program, the Ministry of Health subsidizes drugs for asthma, diabetes, and hypertension freely, and drugs for dyslipidemia, osteoporosis, rhinitis, Parkinson's disease, and glaucoma, as well as contraceptives and adult diapers in copayment at a discount for the user. In copayment, discounts may vary and, as the Ministry of Health established the price of reference for each product, when the sales price is the same or lower than the reference price,

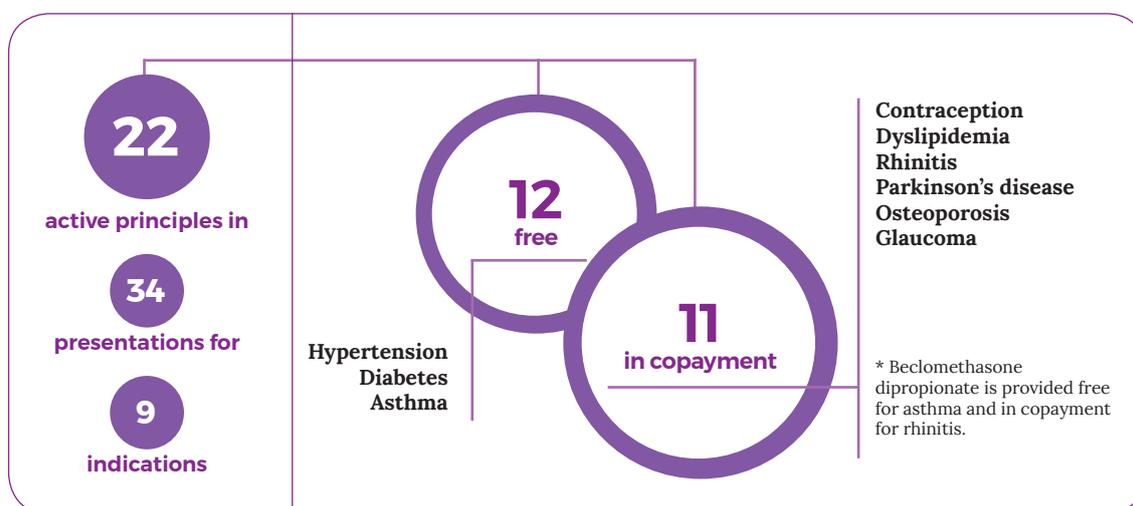
<sup>10</sup> Also often called "tropical, transmitted, neglected, emerging, and reemerging diseases", there seems to be a conceptual convergence toward calling them "poverty-related diseases" or simply "diseases of poverty". This concept allows the expansion of care to non-communicable diseases such as undernourishment-related diseases and many forms of deficiency anemia, caused by food deficit or blood loss (due to worms, hemorrhage, or alcoholism), and underscore the increasingly more evident relation of these diseases with the population's socioeconomic conditions. (SANTANA, 2017).

<sup>11</sup> The Tripartite Inter-Management Commission (CIT) was established as a permanent forum for negotiation, coordination, and decision-making between managers in operational matters and for building national, state, and regional agreements within the SUS. As such, it strengthens governance in these spaces and prioritizes accountability so that decision-making is transparent, ultimately aiming at full access to health care. Available at: <<http://www.saude.gov.br/gestao-do-sus/articulacao-interfederativa/comissao-intergestores-tripartite>>. Accessed on November 11, 2019.

the Ministry of Health pays 90% of the cost and the citizen, 10%. But when the establishment's sales price is higher than the price of reference, the citizen pays the difference. Therefore, the bigger the discount offered by the establishment to the user, as regards the final sales price, the less the citizen pays. Medicines are dispensed on a monthly basis and follows the recommended dosage and limits set by the disease treatment consensus to which it is indicated.<sup>12</sup>

In 2018,<sup>13</sup> drug prices were adjusted to eliminate distortions between prices paid by the federal government for drugs in the program. Some products were priced 200% above market prices. The measure is the result of a study based on the Drug Market Tracking System (Sammed), which shows that prices paid by the Ministry on 22 drugs were either outdated or above market price. At the time, the Ministry of Health estimated savings of up to US\$ 216 million.<sup>14</sup> That may have been one of the factors for the program's lower spending that year (Graph 4). According to the Ministry, in 2018 there were 31,008 pharmacies accredited by the Popular Pharmacy program in 4,383 municipalities (78.7% of Brazilian cities). (MINISTÉRIO DA SAÚDE, 2019). Most of the resources are spent on arterial hypertension treatment drugs (about 60% of expenditure), followed by diabetes and dyslipidemia (less than 20% each). (RONDINELLI, 2018).

**CHART 1** – Information on the Popular Pharmacy program in 2018



Source: List of prescription drugs made available by “There’s a Popular Pharmacy in Here”, posted on the Ministry of Health website.<sup>15</sup>

Graph 5, shows that, until 2012, the Popular Pharmacy program had been included in only one budget action, n. 8415, whose description is “Maintenance and Functioning of Popular Pharmacies”. As of 2013, it was entered in two actions, 20YR, on the gratuitousness system, and 20YS, on the copayment system, both by the name of “Maintenance and Functioning of the Popular Pharmacy Program of Brazil”. It can be seen that the act allocating funds for the gratuitousness system had its budget increased over the years, accounting for 82.3% of the program's total budget in 2018.

Between 2008 and 2010, Ministry of Health payments stagnated due to a number of administrative adjustments such as changes in the rules for filling medical prescriptions, storage of information, and informational support. After that, the prevailing growth trend in the number of

12 Further information available at: <<http://www.saude.gov.br/aco-es-e-programas/farmacia-popular/sobre-o-programa>>. Accessed on November 11, 2019.

13 Directive n. 739/2018.

14 Available at: <<http://www.saude.gov.br/noticias/agencia-saude/42878-farmacia-popular-garante-mais-acesso-e-nao-muda-para-usuario>>. Accessed on November 11, 2019.

15 Available at: <<https://portalquivos2.saude.gov.br/images/pdf/2018/maio/17/Lista-de-Medicamentos.pdf>>. Accessed on November 11, 2019.

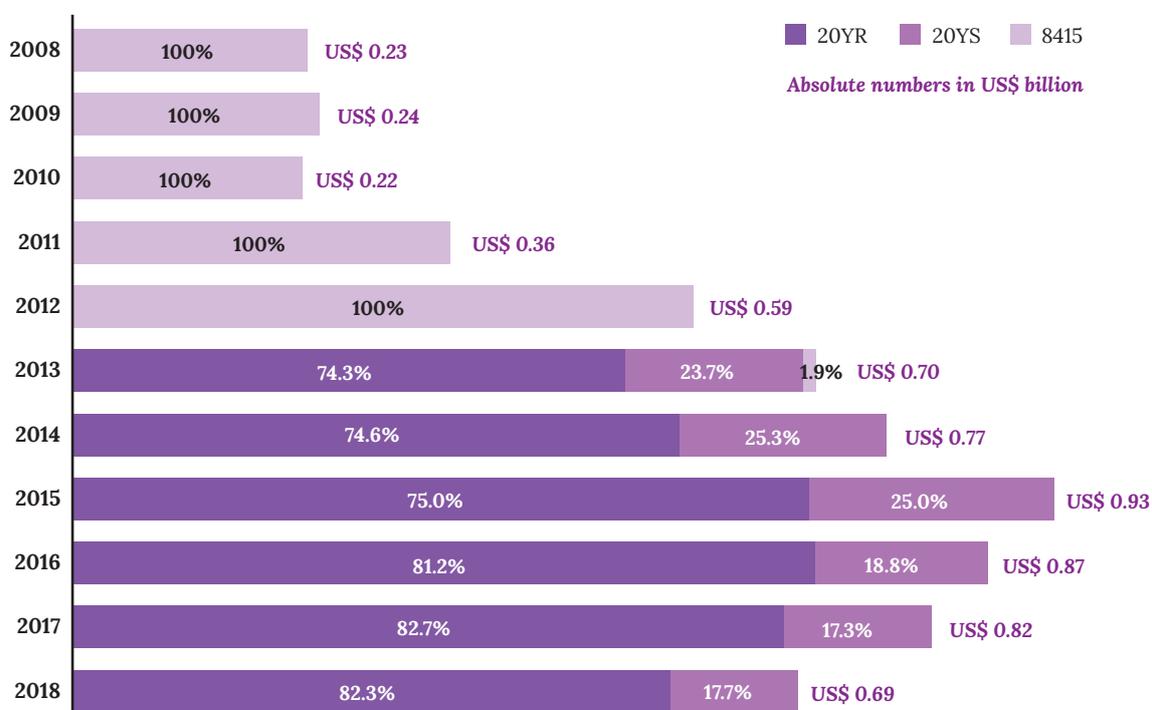
patients and newly accredited establishments was restored, remaining over most of the period analyzed. (RONDINELLI, 2018).

The Ministry of Health, via Access to Information Law, informed that, starting in 2014, accreditation of new establishments was interrupted in consideration of, among other factors, the established target and budget. Since that year, besides to new accreditations, some establishments may have been excluded due to control and monitoring actions.

The Ministry clarified, furthermore, that the decision to discontinue its public network took into account the fact that 80% of the funds allocated to it were spent on unit maintenance, in addition to the fact that these units were present only in 410 municipalities, out of a total of over 5,000. In compensation, fund allocation was scaled up for the Basic Pharmaceutical Assistance Component program in August 2017, with a per capita increase from US\$ 1.39 per inhabitant/year to US\$ 1.51 per inhabitant/year. This increase, according to the Ministry of Health, resulted in an increase in federal government funding to Pharmaceutical Assistance and the optimization of the federal appropriations allotted to Pharmaceutical Assistance. Graph 4 shows that the basic health care CBAF budget did indeed grow in 2018. And for 12 months, the Ministry set out to enlarge the partner network in those northern and northeastern municipalities that only relied on federal government pharmacies. This was important because the public network provided services to high social vulnerability municipalities, most of them located in those two regions. Since these municipalities are not attractive to retailers, given their low market potential, the public network ensured access to medicines to the poorest population.

Increasing the number of medical conditions covered, thus leading to an increase of the prescription drugs portfolio offered, and geographic distribution, by adding new points of sale, contributed to an increase in the program’s budget over time.

**GRAPH 5** – Popular Pharmacy program budget allocation (%) from 2008 to 2018



Source: Prepared by Inesc, based on Siga Brasil.

**Key:** **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.

The scaling up of the partner network budget to the detriment of the government's own network, and to CBAF, draws one's attention to a pharmaceutical market actor that is often overlooked. Economic power and the subsequent influence of the pharmaceutical industry on public policies is often a matter of debate; yet, the pharmaceutical retail industry is also an important actor, one deserving of analysis. Pharmaceutical retail is one of the few sectors in Brazil that are growing in spite of the unfavorable economic situation: more than 10%, much above GDP growth. In 2018, drugstore sales rose by 11.76% year-on-year, nearly reaching US\$ 32 billion.<sup>16</sup> The pharmaceutical retail industry is characterized by high profit margins and by other similarities with the pharmaceutical industry, such as mergers and acquisitions.

Even though CBAF and the Popular Pharmacy program rely on a similar number of points of dispensation, the number of municipalities covered by the former is bigger (over 90%, against 77% in 2014), as is their use as source for hypertension and diabetes drugs (45-60% in CBAF and 13-19% in Popular Pharmacy, the rest obtained from the private sector). For other drugs, the private sector remains as the main source of supply. Despite CBAF's greater coverage and number of users, Popular Pharmacy funding grew sharply, especially with the adoption of the *Your Health is Priceless* (SNTP) program, exceeding CBAF allocations. (MATOS, 2015). Moreover, Popular Pharmacy's presence is bigger in the south and the southeast, in line with these two regions greater population concentration and market potential. (RONDINELLI, 2018).

It is worth mentioning that recent studies have shown the positive effects of greater access to medicines afforded by the Popular Pharmacy program. For hypertension and diabetes, this meant a striking and statistically significant reduction in the number of inpatients and deaths caused by these illnesses. (ALMEIDA et al., 2019; FERREIRA, 2017). The study also shows that access to medicines in Basic Care prevents economic and health costs of higher complexity cases.

Their management models differ, though. On one side, CBAF-related Pharmaceutical Assistance is guided by the State's direct management rules and by SUS principles. Additionally, it has structural and human resources problems, as well as deficiencies in the programming, acquisition, and logistics stages. On the other, as Popular Pharmacy is a public-private partnership, the State is exempt from any responsibilities associated with public execution. However, the evidence available shows that the Popular Pharmacy model, which involves outsourcing functions, is less cost-effective. Availability of medicines in the Popular Pharmacy program is much higher, which may prompt user migration from CBAF to FP, albeit intermittently. Both policies are focused on acquisition and distribution, but not on patient care. This points to an essentially financial prioritization of Popular Pharmacy as a public policy to the detriment of CBAF, which, in turn, still exhibits some precariousness. (MATTOS, 2015).

An association with the retail sector is warranted in face of the National Medicines Policy (PNM) and the National Pharmaceutical Assistance Policy (PNAF) guidelines, as well as in face of the State's difficulties in providing medicines through its own network, and the presence of a consolidated and barely regulated network of private pharmacies, thus prompting the pharmaceutical retail sector to gain ground in pharmaceutical assistance public policies, with the Popular Pharmacy program, more specifically with its expansion, called "There's a Popular Pharmacy in Here" (ATFP). Commercial pharmacies, with their own logistic system, find it easier to carry out the medicines acquisition, distribution, and storage stages – stages with which municipal administrations have had many problems. However, the existence of two public policies – CBAF and Popular Pharmacy – with similar target audience and goals, yet with different characteristics, raises the likelihood of overlapping and even competition. (MATTOS, 2015).

The good results obtained by the program are important; however, as there are studies indicating that the costs of providing medicines to SUS pharmacies can be more effective than to the Popular Pharmacy program, constant assessments must be made to make sure that the resources invested are maximized and that access to medicines by the most vulnerable groups is broadened.

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16 Available at: <<https://www.febrafar.com.br/varejo-farmaceutico-cresce-1176/>>. Accessed on November 11, 2019.

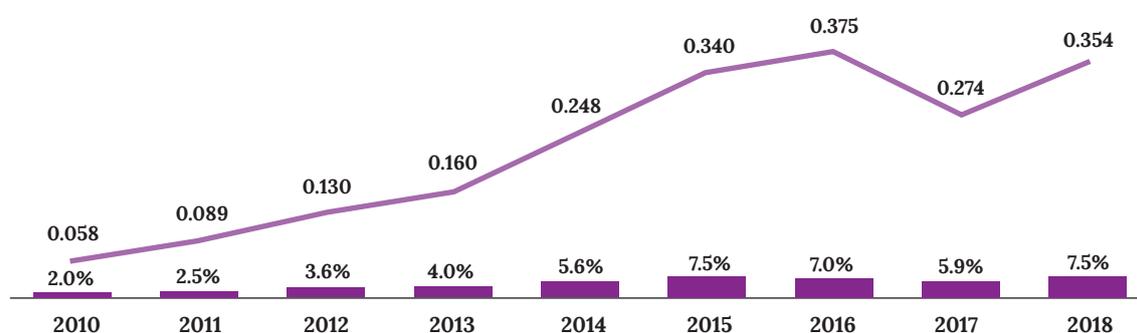
## 5. 'JUDICIALIZATION'

After a sharp drop in 2017, SUS expenses with the 'judicialization' of access to medicines rose again in 2018, to US\$ 354 million, though not reaching the same level as 2016 inflation-adjusted expenditure (Graph 6). There was no variation in the number of lawsuits to account for the higher expenses, as petitions filed had been falling since 2016 (2,639 new lawsuits in 2016 and 1,240 new lawsuits in 2018). One of the reasons for that may be a significant increase in the volume of acquisitions of imported medicines, mostly to meet court orders. Most of the lawsuits involve rare prescription drugs and inputs that are not made in the country; thus, imports have a significant financial impact on the Ministry of Health. (MINISTÉRIO DA SAÚDE, 2019).

In its justification, sent via LAI, the Ministry of Health explained that, from August 2017 to June 2018, problems arose with the bidding processes for the acquisition of judicialized medicines, which led to a failure in meeting court orders. An attempt was made to obey the orders through judicial deposits, yet this procedure failed to include all the cases and was insufficient to fund all the payments. This explains the decrease seen in 2017. In 2018, the purchasing process and payment of court-mandated decisions was regularized, which accounts for the increased expenditure. According to the Ministry of Health, there was also an increase in the number of lawsuits demanding very high-cost prescription drugs to be provided, as was the case with Spinraza (active principle: nusinersen), a drug used in the treatment of spinal muscular atrophy. In 2017, there were only 21 Spinraza-related petitions filed; in 2018, this number rose to 122; and in 2019, the Ministry of Health was facing 210 lawsuits. The cost for importing this drug is very high, US\$ 58,700 a vial, which amounts to a total cost of US\$ 351,000 for a one-year treatment, which requires six vials of the medication. The Spinraza case exemplifies the impact of imports, as mentioned earlier.

In short, increased expenditure derived from 'judicialization' of access to medicines over the last two years is largely related to the acquisition of high-cost prescription drugs. Compounding this is the State's obligation to immediately comply with court rulings. This is made worse with the states' financial crisis, forcing the federal government to meet court-mandated subnational state obligations, they are held jointly liable.

**GRAPH 7** -Ministry of Health expenses with the 'judicialization' of access to medicines from 2010 to 2018 (US\$ billions at 2018 prices) and OTMED corresponding shares (in %)



Source: Prepared by Inesc, based on the 2016 SCTIE Management Annual Report and on the 2018 Management Report of the Ministry of Health.

Table 1<sup>17</sup> puts together the ten judicialized medicines with the greatest weight on the federal government's health budget in 2018, out of more than 200 items. The data reveal that these prescription drugs accounted for more than 90% of total expenditure on 'judicialization' in that year. It is also worth noting that the Ministry of Health spent nearly US\$ 1.35 billion on these drugs just over the last five years.

**TABLE 1** – The ten 'judicialized' medicines accounting for the Ministry of Health biggest expenses in 2018<sup>14</sup>

Medicines (active principles and brand names)	Incorporated?	Amounts in 2018 in US\$ millions (nominal value)	Total amounts over last 5 years (2014 – 2018) in US\$ millions (nominal value)	Variation over last 5 years (2014 – 2018)
<b>Ecuzumabe (Soliris)</b>	In December 2018	120.85	521.51	52.2%
<b>Galsufase (Naglazyme)</b>	In December 2018	41.41	209.17	-9.4%
<b>Idursulfase (Elaprase)</b>	Incorporated in 2017	73.79	152.09	73.4%
<b>Alfagalsidase (Replagal)</b>	Decision against incorporation	26.63	106.31	34.6%
<b>Elosulfase (Vimizim)</b>	In December 2018	28.35	105.46	71.4%
<b>Atalureno (Translarna)</b>	No, registered in April 2019	42.37	99.67	82.9%
<b>Betagalsidase (Fabrazyme)</b>	Decision against incorporation	13.59	59.72	17.0%
<b>Alfaglicosidase (Myozyme)</b>	Under analysis after public hearing	11.50	35.46	53.6%
<b>Nusinersen (Spinraza)</b>	In April 2019	31.31	31.31	0.0%
<b>Metreleptina (Myalept)</b>	Unregistered	4.74	20.30	-59.0%
<b>Total</b>	-	394.54	1,341.02	87.7%

Source: Prepared by Inesc, based on the Federal Government Procurement Portal.

<sup>17</sup> It is worth underscoring that some of the amounts posted on the Federal Government Procurement Portal and mentioned in an answer received via access to information law (LAI) differ from those presented in the Ministry of Health 2018 Management Report. In the answer sent via LAI, the Ministry pointed out that not every purchase was concluded, as some appropriations may have been cancelled, thus causing some discrepancies in amounts effectively spent by the federal government. Furthermore, the sources do not clarify to which phase a given incurred expense belongs, if it refers to appropriated, settled, or paid funds.

All these medicines are indicated for rare diseases. The number of patients with these diseases in Brazil is estimated at 11 million.<sup>18</sup> For the sake of comparison, the SUS has nearly 200 million users. It is mandatory that they have access to SUS treatment, as set forth in the National Comprehensive Care Policy for Persons with Rare Diseases.<sup>19</sup> However, it is also important to consider the budgetary impact of medicines prescribed to rare disease patients. Generally, these are new drugs, often patent protected, with high prices. As purchases under judicial order do not follow the Ministry's regular procurement process, this makes it even more difficult to reduce prices through bargaining or rationalization of purchases.

Additionally, suppliers abuse their position of monopoly by using practices to force or uphold the 'judicialization' of access to medicines. One of them is to postpone registration in Brazil. Registration is the first step for marketing a drug in the country. One of the final steps in the registration process is analysis by the Drug Market Regulation Chamber (CMED), which establishes a sales price cap on a given drug. Filing for registration with the National Sanitary Surveillance Agency (Anvisa), obtaining the registration (most often making use of priority status analysis, as these are orphan medicines), and thereafter not requesting a price with CMED and not placing the product on the Brazilian market has been an artifice used by some companies to flout Brazilian regulations and deceive prescribers. As soon as a product's registration is published by Anvisa, marketing campaigns are set in motion, doctors and patients associations are misinformed that the product "is in Brazil" and 'judicialization' starts. Registration is also a condition for analysis of technology by the National Commission for the Incorporation of Technologies into the Unified Health System (Conitec), which establishes which technologies will be made available free of charge by the public health system, on the basis of scientific evidence. Not submitting a drug to Conitec's evaluation is another strategy to keep 'judicialization' on, since many medicines are not approved by a thorough process to establish the benefits of incorporating a given technology. (CONITEC, 2016).

There are examples of all of these problems among the medicines included in Table 1. Myalept has no registration in Brazil, and Translarna was registered in 2019. Replagal and Fabrazyme were not recommended by Conitec for inclusion in the SUS. The remaining medicines were incorporated recently or are in public hearing process. It is worth stressing that the inclusion of Soliris, Naglazyme, and Vimizim was recommended by Conitec, provided their prices were significantly reduced. One must acknowledge and congratulate the Ministry of Health on its efforts to mitigate the impacts of 'judicialization'. Other public bodies are also involved in solving this issue, as pointed out in the Ministry of Health Management Report: such is the case of the creation of circuit courts specializing in the "right to health" by the National Council of Justice (CNJ), as well as the strengthening and capacity-building of Judiciary Branch technical support units and improvement of judicial decisions by means of initiatives for the integration with Justice Courts and the Council itself.

Table 2 presents the suppliers of the most judicialized medicines over the last five years. Out of the list of 17, seven supplied for the first time in 2018, which may point to a movement toward diversification, thus favoring competition and ultimately resulting in a decrease in expenditure. Also striking is the presence of foreign suppliers on the list, who received 88% of the amount spent. Moreover, purchases are made mostly from retailers (84%), rather than from manufacturing companies, almost all of them foreign companies.

Import of medicines is troublesome, for foreign manufacturers are not held responsible for their products used in Brazil, such as occurrence of adverse events and agreements for the exchange of expired products. Besides, stability tests of products imported from cold countries are no guarantee that the expiry date will be the same in Brazil, a warm and humid country. (CONITEC, 2016) This underscores the importance of discussing the pharmaceutical retail sector and the impact of its practices on access to medicines .

In conclusion, 'judicialization' is a way for patients to guarantee their right of access to health and medicines. However, this process reflects all the country's other asymmetries of access

18 Available at: <<http://conitec.gov.br/doencas-raras-governo-especialistas-e-pacientes-juntos-por-um-sistema-de-saude-publico-inclusivo>>. Accessed on November 11, 2019.

19 Directive n.199, January 30, 2014.

to rights, such as to income and as regards color and race. A growing number of studies show the inequalities of the 'judicialization' process, conducted by urban elites and private interests, in addition to being used to access high-cost medicines that have not been standardized by governments in their incorporation lists, which are based on scientific evidence. Most of those filing access to medicines petitions are high-income people. (ANDIA, 2019).

Analysis of a decade of lawsuits in Minas Gerais state concluded that the main beneficiaries are the residents of municipalities ranking high on the Human Development Index and low on the Social Vulnerability Index. Therefore, those lawsuits do not benefit those municipalities more in need of public policies and intervention via the Judiciary, but rather those whose population has easier access to Justice. Allocation of health-related resources is of the utmost importance to establish an equitable public policy, but 'judicialization' interferes in the redistribution of resources in this area. Hence the importance of the matter when discussing the budget. (LOPES, 2019).

**TABLE 2** – Suppliers of the most judicialized medicines in 2018<sup>14</sup>

Suppliers	Amounts in 2018 in millions (nominal value)	Total amounts over last 5 years (2014 - 2018) in millions (nominal value)	Foreign/national	Retail/pharmaceutical industry
<b>Multicare</b>	99.60	546.14	Foreign	Retail
<b>Uno Healthcare</b>	74.18	482.66	Foreign	Retail
<b>Genzyme</b>	-	65.25	National	Pharma company
<b>M3 Pharma</b>	42.37	52.18	Foreign	Retail
<b>Shire Brazil</b>	41.59	50.25	National	Pharma company
<b>Shire Ireland</b>	38.51	38.51	Foreign	Pharma company
<b>Biogen</b>	30.34	30.34	Foreign	Pharma company
<b>Sanofi-Aventis</b>	24.72	24.72	National	Pharma company
<b>Tuttopharma</b>	21.63	23.10	Foreign	Retail
<b>Global</b>	10.33	14.84	National	Retail
<b>Green Cross</b>	3.96	5.24	Foreign	Pharma company
<b>Hosp - Log</b>	4.73	4.73	National	Retail
<b>Alium</b>	1.34	1.34	Foreign	Retail
<b>Sens Farma</b>	0.66	0.66	Foreign	Retail
<b>Paragonsmeds</b>	0.58	0.58	Foreign	Pharma company
<b>Hospfar</b>	-	0.35	National	Retail
<b>Diprophar</b>	-	0.13	Foreign	Retail
<b>Total</b>	394.54	1,341.02	-	-

Source: Prepared by Inesc, based on the Federal Government Procurement Portal

Considering its budgetary impact, particularly on the Pharmaceutical Assistance budget, it is imperative to streamline the process, for example by means of technical support to the Judiciary, apart from improving management by seeking to include judicialized medicines in the Ministry of Health's regular procurement process. And also discuss and mitigate the inequality of the 'judicialization' process.

## 6. INDIGENOUS HEALTH

Indigenous health is covered by the Indigenous Peoples Healthcare Subsystem (SasiSUS), which is coordinated with SUS, decentralized, and administratively, budgetarily, and financially autonomous. The SasiSUS is organized in 34 Special Indigenous Sanitary Districts (DSEI), distributed across the national territory. A Special Indigenous Sanitary District is a unit under federal sanitary responsibility. It is a delimited social, cultural, and geographical space in which there is a network of resources and health services, where the people live and relate with each other.

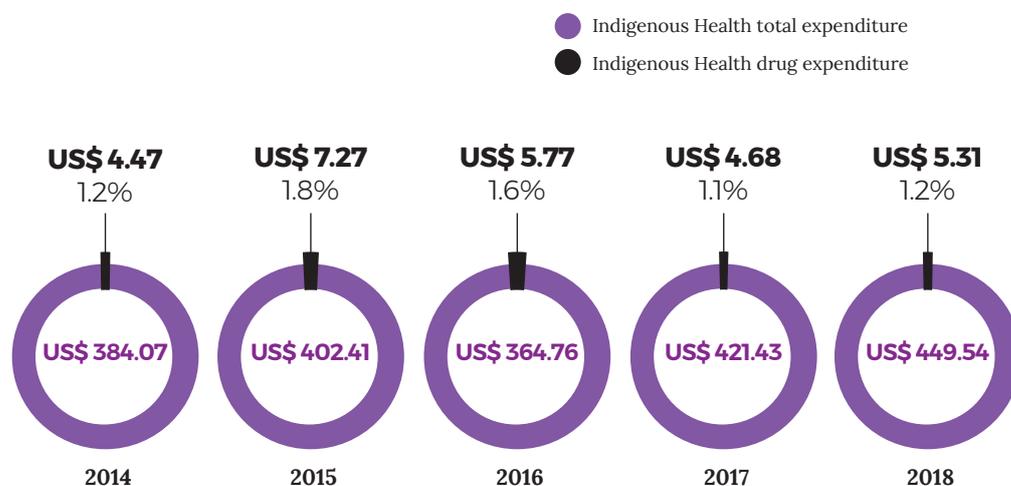
The Districts are responsible for providing targeted health care to peoples living in the Indigenous Lands located within this territory. The SasiSUS is responsible for the primary health care of the indigenous populations living in villages. When there is need for another type of health service, such as surgeries, exams, or other procedures, the District coordinates with the regional SUS to make sure that health care needs are fully met. (MINISTÉRIO DA SAÚDE, 2016).

The Indigenous Peoples Healthcare Subsystem receives, on average, US\$ 404 million billion a year. Out of this total amount, about 1.4% is spent on medicines. The amount invested in Indigenous health is insufficient to adequately fund all the DSEI districts. Proof of this is that Indigenous health indicators are worse than those of the rest of the population. (MINISTÉRIO DA SAÚDE, 2019). Consideration must be given to the specific characteristics of this population group, often in situations of great vulnerability and lacking basic services, such as quality water and sanitation. Moreover, their access to health care is precarious, since they inhabit distant areas, at times only accessible by water or air.

What's more, according to its 2018 Management Report, the Ministry of Health does not even meet its own goals, such as those targeting: I) health coverage of pregnancy with nutritional follow-up and four prenatal care visits; II) coverage of indigenous population for first dental appointment; and III) upgrade in distribution of infectious disease rapid tests. For some of them, percentages have risen in comparison with previous years, yet not enough to meet the targets set. On the other hand, targets related to maternal and infant death investigations were met, as well as the goal of providing children with full vaccination coverage. An alarming finding associated with Indigenous health is suicide. The indigenous suicide death rate is three times higher than the national average. Infectious diseases, like tuberculosis and malaria, also have greater incidence among indigenous populations.

In the same report, the Ministry of Health informs that indigenous health care will be reformulated. Yet, the postponement, by the Indigenous Health Care Secretariat, of the National Indigenous Health Conference, which should have been held in May, indicates that social participation in this reformulation process is compromised.

**CHART 2** – Indigenous health care total expenditure, including medicines, from 2014 to 2018 (US\$ million at 2018 prices)



Source: Prepared by Inesc, based on Siga Brasil.

Regarding the medicines budget, firstly it is important to underscore that it does not have a clear scope, as for example the three components of the Pharmaceutical Assistance; nor does it have any specific budgetary action or plan that may facilitate its analysis. Furthermore, only part of the prescription drugs is bought centrally by the Ministry of Health secretariat in charge of SasiSUS, the Special Secretariat for Indigenous Health (SESAI). The rest is bought separately by DSEI districts managing organizations. The drugs acquired by SESAI/MS are stored in a Ministry of Health warehouse in Guarulhos (SP), and are distributed to the Districts, which are responsible for making them reach the final patient.

Distribution programming is based on the monitoring of monthly consumption and, as soon as the medicine arrives at the DSEI, it is stored in the Pharmaceutical Distribution Center (CAF). After that, the medicines are distributed to Primary Centers (Polos-Base), Indigenous Health Houses (CASAI), and Indigenous Health Care Basic Units (UBSI), where they are dispensed or transported by the Indigenous Health Multidisciplinary Teams (EMSI) during their health care routines.

It is important to consider, too, that indigenous peoples have their own traditional practices which include, for example, treatment with medicinal plants, which must be respected; as a matter of fact, the SasiSUS was proposed and premised on respect for and preservation of indigenous medicinal knowledge. Thus, pharmaceutical assistance, in this context, must be carried out in complementarity with this knowledge, but not lead to excessive medicalization of the indigenous population, as already happens with the rest of the population.

Lastly, there is a lack of information that may allow more in-depth analysis of pharmaceutical assistance to indigenous peoples and their access to medicines.

## 7. TAX SPENDING ON PHARMACEUTICAL SECTOR

Tax spending is indirect government spending through renunciation of tax revenue and benefits. They are indirect expenses because the government gives up collecting these amounts, that is, does not receive them, and with that renounces using them to invest in public policies. The justification for tax expenditure is that it aims to promote economic or social development that, in this case, is not paid for by the budget, but rather through the tax system. Tax spending includes reliefs that aim to: I) compensate taxpayers for expenses incurred by them on services the government fails to provide; II) compensate for actions that are complementary to the typical functions of the State that are carried out by civil society entities; III) promote income equalization across regions; and IV) incentivize a particular sector of the economy. (RECEITA FEDERAL DO BRASIL, 2018).

The problem with this type of expenditure is its opacity: nothing is known about who benefits from it, the amounts involved, and if it actually delivered the development promised. In practice, most of the tax expenditures go to companies (multinational companies included). Moreover, most of the tax incentives are granted to and maintained on the basis of the economic and political power of the interested groups, which negotiate them without any transparency with the public powers, which pass bills authorizing tax expenditures in order to keep their privileges.

This volume of non-collected revenue is even more critical in the present context of fiscal crisis, budgetary deficits, and public expenditure cuts that penalize the population, especially the poorest. Compounding this setting, tax spending is barely redistributive and its effectiveness very poor from the perspective of the Brazilian population. A study conducted by Inesc is revealing: the data proved that the granting of fiscal benefits is mostly geared toward big corporations carrying out activities that cause high socioenvironmental impact, in addition to maintaining promiscuous relations with the public power.<sup>20</sup>

In 2016, the most recent year with estimates based on effective data and not on projections, tax expenditure was estimated at US\$ 71.5 billion, which is equivalent to more than 20% of tax collection, just for the federal sphere. For 2020, tax expenditure is estimated at US\$ 88,1 billion. In comparison, the incumbent government is planning to save US\$ 236,8 billion over the next ten years with the Pension Reform, which corresponds to three years of tax expenditures. Tax spending was concentrated in five budgetary functions: commerce and services (28.57%); labor (16.13%); health (14.14%); manufacturing industry (9.83%); and agriculture (8.89%). (RECEITA FEDERAL DO BRASIL, 2019).

Tax expenses on health accounted for more than 30% of the Ministry of Health's budget, reaching US\$ 10.1 billion. Among them stand out deductions of expenses in the personal and corporate income tax returns, amounting to nearly half of total collection. Personal income tax deductions are highly regressive because they benefit higher-income taxpayers. For example, deductions with medical expenses are the highest among the existing income tax deductions; In addition to their high value, they are distributed rather unequally: almost half of the deductions with medical expenses refer to taxpayers earning more than ten minimum wages. Unlike education expenses, also deductible from the income tax, there is no cap on medical expense deductions. This is even more serious when we verify that the cost of private health services has systematically increased above consumer price index IPCA. This causes tax losses derived from this benefit to grow in real terms every year, further hindering the restrictive fiscal context the country is going through.

20 Available at: <[https://www.inesc.org.br/wp-content/uploads/2018/12/Estudo\\_Gastos\\_trIBUTARIOS\\_empresas.pdf](https://www.inesc.org.br/wp-content/uploads/2018/12/Estudo_Gastos_trIBUTARIOS_empresas.pdf)>. Accessed on November 11, 2019.

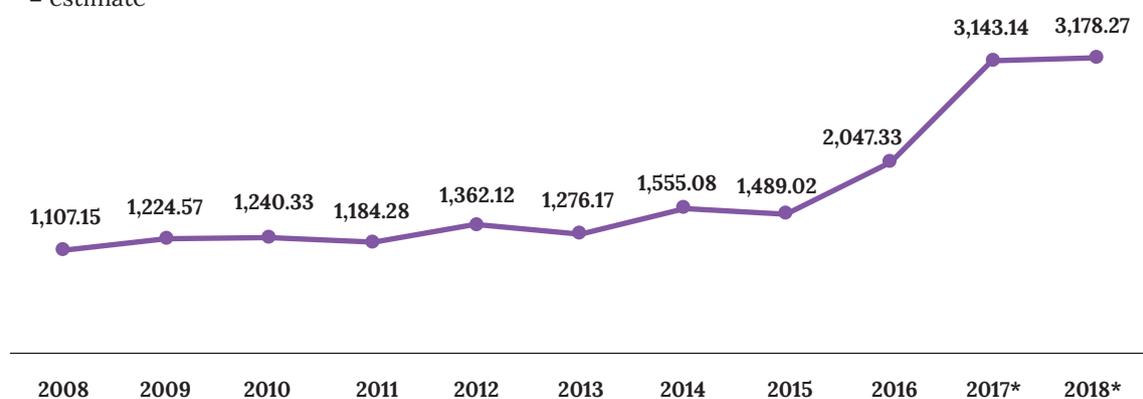
(TESOURO NACIONAL, 2018; RECEITA FEDERAL DO BRASIL, 2019). It is worth recalling that the absolute majority of the Brazilian population lives on less than one minimum wage, and that most of the SUS users who depend entirely on federal government health care are low-income users.

Tax expenditures on pharmaceutical products grew dramatically over the period analyzed (Graph 8).<sup>21</sup> Tax spending on these products is based on presumed PIS/Cofins tax credits for companies manufacturing or importing drugs. It is worth noting that the Cofins tax is the main source of revenue of the Ministry of Health. (RECEITA FEDERAL DO BRASIL, 2019). In 2016, the last year with effective data available, tax spending accounted for 38% of OTMED.

According to the Drug Market Regulation Chamber (CMED), 65% of the products sold and 70% of their revenue are exempt from PIS/Cofins, thus making it clear that most medicines sold in the country are sold with an exemption of nearly every federal tax.

**GRAPH 6** – Tax spending on pharmaceutical products from 2008 to 2018 (US\$ million at 2018 prices)

\* = estimate



Source: Statement of Tax Expenditures – Effective Bases.<sup>22</sup>

On the other hand, the Brazilian pharmaceutical market had earnings of US\$ 18.8 billion in 2017. The pharmaceutical sector's growth has exceeded GDP growth over the last years, one of the few sectors not to have been affected by the 2008 crisis. New medicines have the largest market share, with 38.2% of revenue, even as they have been losing market share over the last three years. Generic drugs account for 13.5% of the market, and similar drugs (generic drugs being marketed with a brand name) for 20.4%. Generic drugs have been increasing their market share and rank first in sales in the country. Biological drugs account for 22.2% of the market, and most of them are sold to the government. The unit price of these drugs is very high, as they only correspond to 3.8% of total units sold. The Brazilian pharmaceutical market is characterized by large companies, overwhelmingly concentrated in the state of São Paulo. (CMED, 2018).

Considering the sector's performance and the difficulties in securing sustainable financing for health actions, which benefit hundreds of millions of Brazilians, it is necessary to assess tax spending carefully. Tax exemptions can make access to medicines easier for the population. However, given the huge amount tax exemption accounts for and the economic power of the pharmaceutical industry and pharmaceutical retailers, it is imperative to verify if such renunciation of tax revenue is translating into benefits to the population and not merely into huge corporate profits.

21 Chemical and pharmaceutical products excluded.

22 Available at: <<http://receita.economia.gov.br/dados/receitadata/renuncia-fiscal/demonstrativos-dos-gastos-tributarios/dgt-bases-efetivas>>. Accessed on November 11, 2019.

## 8. FINAL CONSIDERATIONS

In ten years, Ministry of Health expenditure on medicines nearly doubled in real terms, from US\$ 2.5 billion in 2008 para US\$ 4.7 billion in 2018. The increase was proportionally bigger than that of the Health budget: in 2008, medicines expenditure accounted for 10% of health-related federal expenses; in 2018, this percentage rose to 13%. Tax expenditures targeting the sector also presented substantial growth, increasing from US\$ 1.1 billion in 2008 to US\$ 2.0 billion in 2016, last effective data available.

Increased public spending on medicines is positive, given the lack of health-related resources afflicting large part of the Brazilian population and the key role played by drugs in today's health care. However, a good part of these resources is retained by the pharmaceutical industry and the retailers, mostly large multinational companies, which have been posting rising profits even in the context of an economic crisis.

Additionally, the proportionately bigger OTMED budget in comparison with the ministry's budget puts pressure on the already scarce resources allocated to the sector, including those channeled for promotion and prevention, rather than being allocated to more complex procedures and medical attention. Thus, there remains the unpleasant feeling that public funds are being drained to the private sector instead of being invested to improve the population's quality of life.

In order to guarantee the right to health, huge investments are needed to tackle a growing and increasingly more complex demand, in addition to the sector's intrinsic characteristics, such as higher-than-inflation price raises and the incorporation of technological innovations whose cost is increasingly higher. In a context of budget cuts, analyzing and examining data beyond the numbers and from the lens of human rights is essential, since fiscal matters should not be a justification for cutting social policies.

Social inequalities are perceptible in practice. According to the Special Health Surveillance Bulletin, in Brazil registered causes of death according to race/color of skin in 2017 were: I) homicides, among blacks; II) cerebrovascular diseases, among whites and Asians; and III) ill-defined causes, followed by pneumonias and homicides, among indigenous people. (MINISTÉRIO DA SAÚDE, 2019). Socioeconomic and health inequalities among people of different races/colors and ethnic origins are striking: while whites and Asians die more of chronic diseases, blacks and indigenous persons die of conditions associated with violence and infectious diseases or do not even have their cause of death identified. These findings make it plain to see that health inequality is intrinsically related to other social issues, thus requiring broad and multidisciplinary public policies.

Lastly, the main objective of any economic and financial policy must be the broadening of rights and the reduction of inequalities. Austerity measures as constitutional amendment CA 95/2016 reversed this logic. Therefore, it is of the utmost importance to keep tracking government investment trends over the next years. Medicines contribute strongly to pressure health budgets worldwide; therefore, they are a key analytical point.

With this study, we expect to contribute not only to this debate, but also to the broadening of access to quality medicines, as well as to the reduction of inequalities in fulfilling the right to health in Brazil. Thus, we leave a few recommendations:

- I. Promote information transparency: data transparency and coherence are important. Throughout the study, some inconsistencies were observed between the various

sources analyzed, which included Siga Brazil, the Federal Government Procurement Portal, and the Ministry of Health Management Report. Those inconsistencies occur either for a lack of detailed categories allowing for extraction of data that is consistent across categories or for a lack of detailed categorization and organization of the data used. Therefore, we suggest that consultation tools be enhanced, with the creation of markers or budgetary plans that itemize pharmaceutical assistance expenses so as to permit monitoring and social control, as recommended by the SUS.

- II. Conduct pharmaceutical assistance policy assessments: analysis is needed to determine if they actually promote access to medicines, in particular for those who need them most. Examples of that are studies for the assessment of the effects of the Popular Pharmacy program on health outcomes. Consideration must be given to the different steps of the process (acquisition, distribution, and dispensation), but also to health outcomes, that is, the practical results for the population and for inequality reduction. It is vital to discuss the effectiveness of the different management models, for example whether pharmaceutical assistance should be public (via CBAF) or private (via Popular Pharmacy), including the influence of different actors, such as that of the pharmaceutical industry and retailers.
- III. Create mechanisms for the promotion of equity via pharmaceutical assistance: policies must be devised that fight against gender, race/ethnicity, and income inequalities in accessing medicines, and that foster the rational use of medicines. Seeking to understand specificities and enhancing pharmaceutical assistance to such groups as women, blacks, and indigenous people is essential.
- IV. Debate the effectiveness of tax spending: beneficiaries of tax expenditures must be disclosed in detailed form, thus enabling their monitoring. It is indispensable to assess whether renunciation of tax revenue does indeed prompt economic and social development for the population.
- V. Foster popular participation: engaging civil society in matters related to Pharmaceutical Assistance is necessary, from budget allocation to the rational use of medicines. It is also extremely important to build the skills of health council members and other actors interested in the budget and human rights theme and in pharmaceutical assistance.

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# ANNEX

## METHODOLOGY

Inesc has consolidated its decades-long experience in public policy tracking and budget analysis in the Budget & Rights methodology, which looks at the public budget from the prism of realization of human rights. It is based on five pillars: 1) State financing with tax justice; 2) maximum resource use; 3) progressive realization of human rights; 4) nondiscrimination; and 5) popular engagement. Its most recent version was published in 2017, and free access to it is available at the Inesc website.<sup>23</sup>

Thematic Budgets (In Portuguese, “Orçamentos Temáticos (OTs)”) are tools used for in-depth analysis of a specific theme. Thematic Budgets are built by grouping expenses, making use of official open data platforms and requests via Access to Information Law (LAI), so as to integrate budget lines channeling resources to the promotion of the right being researched. This allows us to monitor historical series and track trends within the same theme without limiting ourselves to a specific policy or program. OTs are comprised of the whole set of budgetary actions related to a given theme. The choice for this object of analysis stems from that fact that budgetary actions are established in the Annual Budget Law (acronym in Portuguese LOA) and are the only unit that organizing the whole federal budget, thus enabling independent analysis of the executing agency.

The Access to medicines Thematic Budget (OTMED) aims to assess federal budget allocation to pharmaceutical assistance in driving access to medicines in Brazil and the impacts of financial execution in ensuring it, indispensable for the realization of the right to health. The OTMED was released in two publications, one in 2016, spanning the period from 2008 to 2015, and another one, in early 2018, focused on the years of 2016 and 2017.

The methodology described next was consolidated for years as OTMED was being built. The budgetary actions it is made up of include mainly the acquisition of medicines, but also other important steps of pharmaceutical assistance, such as distribution and dispensation. Table 1 shows budgetary actions by year and component.

Also included, though partially, are budgetary actions whose scope transcends pharmaceutical assistance activities per se. In such cases, only drug-related expenditure is considered, information of which is requested via Access to Information Law (LAI).

Actions concerning the following topics are not considered: stimulation of the use of medicinal plants and ‘phytotherapeutic’ drugs in SUS (20K5); donations to international bodies for the purchase of medicines (00NJ, 00NK); and pharmaceutical product research, teaching, and production (for example, actions 2522, 7835, 11PJ, 20QF, 211V, 20UU, 2478, 13DW). Other budgetary actions, however related to drug prescription policies, were not included in OTMED because they incurred no expense over this period, such as 4383 (vaccination of the population), 0804 (support to organization of pharmaceutical assistance services), and 8415 (maintenance and functioning of popular pharmacies).

<sup>23</sup> Available at: <<https://www.inesc.org.br/en/orcamento-direitos-2018-2/>>. Accessed on November 11, 2019.

Each budgetary action is classified in accordance with the pharmaceutical assistance components regardless of the secretariat or department in charge, as per the Ministry of Health organizational chart.

**TABLE 1** – Detailing of budgetary actions considered in OTMED

#	Names	Components	Years
4368	Promotion of pharmaceutical assistance through the acquisition of Strategic Component drugs	CESAF	2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018 (full for every year)
20AE	Promotion of pharmaceutical assistance and strategic inputs in Primary Health Care (Atenção Básica em Saúde)	CBAF	2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018 (full for every year)
4705	Financial support for the acquisition and distribution of Specialized Pharmaceutical Assistance Component	CEAF	2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018 (full for every year)
4370	Health care of population with drugs for the treatment of patients with HIV/Aids and other sexually transmitted diseases	CESAF	2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018 (full for every year)
4295	Blood transfusion safety and quality of blood and blood products	CESAF	2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018 (full for every year)
20YE	Acquisition and distribution of immunobiological drugs and inputs for preventing and controlling diseases	CESAF	2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018 (full for every year)
20YR	Maintenance and functioning of Popular Pharmacy program of Brazil by gratuitousness system	FP	2012, 2013, 2014, 2015, 2016, 2017, 2018 (full for every year)
20YS	Maintenance and functioning of Popular Pharmacy program of Brazil by copayment	FP	2012, 2013, 2014, 2015, 2016, 2017, 2018 (full for every year)
20AH	Organization of pharmaceutical assistance in SUS	CBAF	2012, 2013, 2014, 2015, 2016, 2017, 2018 (full for every year)
20YP	Promotion, protection, and recuperation of Indigenous health	SI	2012, 2013, 2014, 2015, 2016, 2017, 2018 (partial for every year)

To be continued

Table 1

#	Names	Components	Years
8735	Implementation of actions targeting food and nutrition for health	CESAF	2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018 (partial for every year)
2E88	Financial support for the acquisition and distribution of drugs for the treatment of rare diseases (orphan drugs)	CEAF	2018 (integral)
6031	Immunobiological drugs for the prevention and control of diseases	CESAF	2008, 2009 (full for every year)
20BA	Influenza pandemic prevention, preparation, and	CESAF	2008, 2009 (full for every year)
8415	Maintenance and functioning of popular pharmacies	FP	2008, 2009, 2010, 2011 (full for every year)

Source: Prepared by Inesc.

**Key to acronyms:** SI = Indigenous Health; FP = Popular Pharmacy; CBAF = Basic Pharmaceutical Assistance Component ; CEAF = Specialized Pharmaceutical Assistance Component ; CSAF = Strategic Pharmaceutical Assistance Component

With the exception of the data obtained via Access to Information Law, amounts were extracted from the Siga Brazil portal, of the Brazilian Federal Senate. Financial execution of these actions was accounted for, that is, amounts paid and payables from previous year(s) paid. Prior year payables are amounts appropriated in previous years, but paid in a given following year. Therefore, we accounted for all the disbursements made as the result of a particular budgetary action, and not just the payments made with regard to appropriations of a current year. To work on Health data as a whole, financial executions of the function and Ministry of Health were extracted, in addition to Federal Government Budget (Fiscal Budget and Social Security Budget) total expenditure.

All amounts were extracted using a filter that disregards expenses with public debt refinancing. Amounts were deflated to 2018 median prices by the Broad Consumer Price Index (IPCA), calculated by the Brazilian Institute of Geography and Statistics (IBGE), except when otherwise stated in the text. Values in Real were converted to US dollars using a exchange rate of R\$3.70/US\$.

Requests were made, via Access to Information Law, as to the itemization of budgetary actions 20YP and 8735 and a detailed statement of Ministry of Health purchases derived from 'judicialization' of access to medicines and total purchases. A request was also filed regarding the Management Report of the Secretariat of Science, Technology and Strategic Inputs of the Ministry of Health (SCTIE/MS), as the report could not be found on the Ministry of Health website. In answer, the Ministry of Health provided a link to the Management Report of the Ministry of Health rather than a specific link to the Secretariat. Clarification was also requested concerning the Popular Pharmacy program and pharmaceutical assistance at the DSEI indigenous health districts.

There is a problem in requesting data via LAI. As requests are filed with every OTMED update, a variation can be perceived in the methodology for the extraction of data depending on the respondent at a given moment, which causes the amounts not to be continuous. Therefore, the amounts can be different for each answer received.

In order to avoid this fluctuation, methodological changes were introduced with regard to previous years, only considering information that is open and available to the public, that can be verified. In the case of 'judicialization'-related data, the decision made was to consider the data informed by the Ministry of Health, through the 2016 SCTIE Management Report and the Ministry of Health's 2018 Management Report. It is worth noting that these reports do not specify what stage of the budgetary cycle is considered, and if the amounts are appropriated, settled, or paid. Additionally, purchase-related data were extracted directly from the Federal Government Procurement Portal.<sup>24</sup> Data used also included data from the Ministry of Health's SUS Strategic Management Support Room (SAGE/SUS), chiefly data on the Popular Pharmacy program.

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24 Available at: <<http://painelcompras.planejamento.gov.br>>. Accessed on: November 11, 2019.









