GUIDE2019

INTERFARMA

Associação da Indústria Farmacêutica de Pesquisa

EXPEDIENT

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EDITORIAL PROJECT

Nebraska Composição Gráfica

ABOUT INTERFARMA

INTERFARMA is the Association of the Pharmaceutical Research Industry, a non-profit organization which brings together companies and researchers in this sector who seek to promote and encourage research, development, and innovation geared toward the production of pharmaceutical inputs, raw materials, medications, and products for human health. Members of the association are required to work in research, development, and innovation, and adhere to INTERFARMA's Code of Conduct.

COMPLIANCE NOTICE

In compliance with INTERFARMA's Code of Conduct (2016 edition), this publication:

- Provides historical and educational content on public health
- Is made available on the internet without restrictions on its use
- Has no commercial value
- Is distributed at no charge

Introduction

The INTERFARMA Guide is an annual publication which presents key data from the pharmaceutical and health sector, including some general indicators related to innovation, public health management, and the economy.

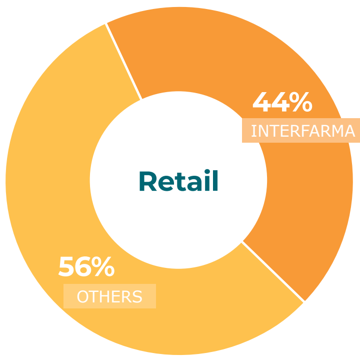
This content is meant to support discussions on the pharmaceutical and health sector, with a focus on **patient needs**. As stated in the Brazilian Constitution, which establishes the right to universal and comprehensive health care, the patient's right to access therapies must be respected, a right which includes new and modern treatments.

This has created major challenges for the country connected to management of public resources, models of care, and simplifying and hastening procedures. INTERFARMA hopes that it can contribute to progress in this sector through the data presented in this guide.

The INTERFARMA Team

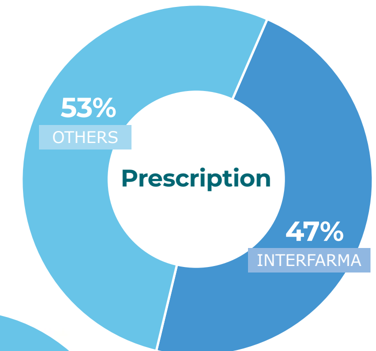
Industry data

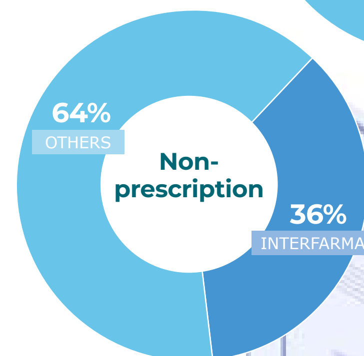
Representativity of INTERFARMA



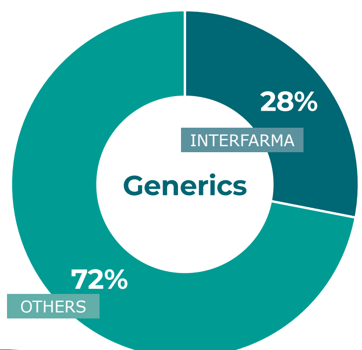
INTERFARMA currently represents 44% of all Brazilian pharmaceutical retail, encompassing drugstores and pharmacies.

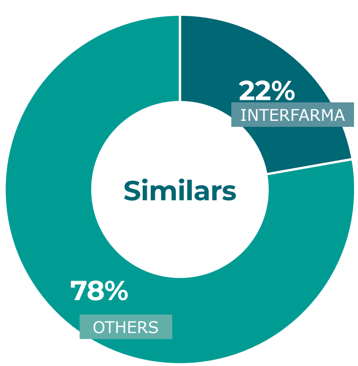
As for types of medications, associated companies also have a strong presence in prescription medications (regular prescription as well as controlled substances) and in non-prescription drugs.

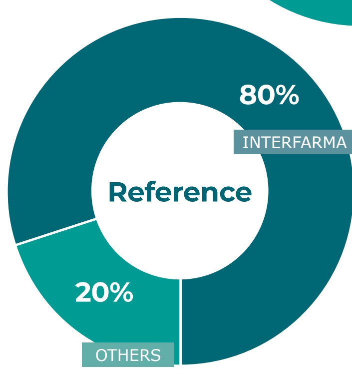




By segments, the **laboratories associated with INTERFARMA** account for 80% of the innovative treatments known as branded medications in the Brazilian retail market. But there is also a significant presence in other segments.







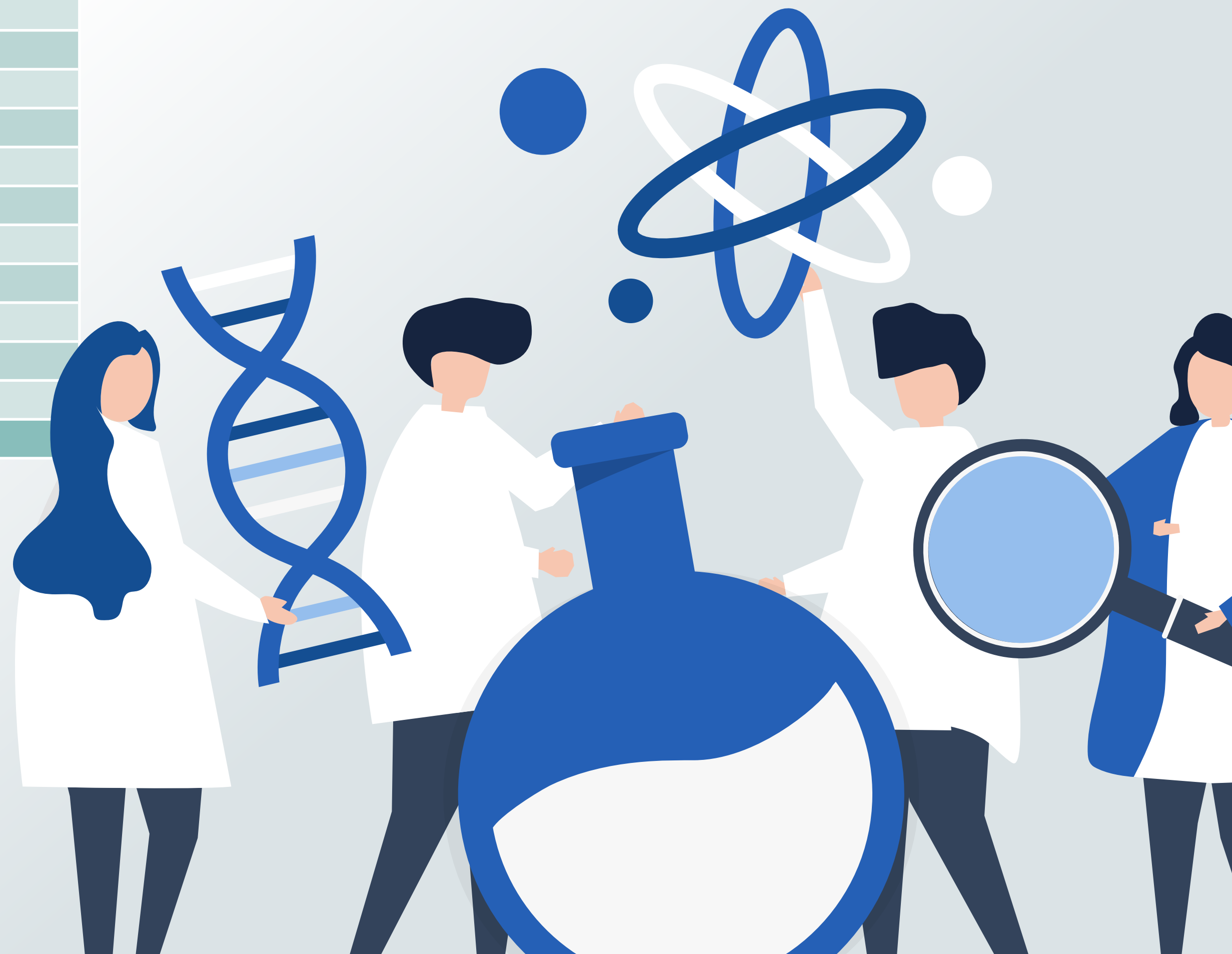
Revenues in the Brazilian pharmaceutical market (2005–2018)

CMED Revenues (R$ billion)

Year	Total	INTERFARMA	INTERFARMA share
2005	21.89	11.18	51%
2006	24.06	12.21	51%
2007	25.02	13.31	53%
2008	27.03	14.46	53%
2009	30.59	16.63	54%
2010	32.26	17.82	55%
2011	32.94	17.60	53%
2012	40.76	22.94	56%
2013	41.36	23.16	56%
2014	47.85	25.09	52%
2015	53.58	28.35	53%
2016	63.55	31.95	50%
2017	69.49	35.68	51%
2018	76.20	40.70	53%
Total 2005-2018	586.57	311.08	53%

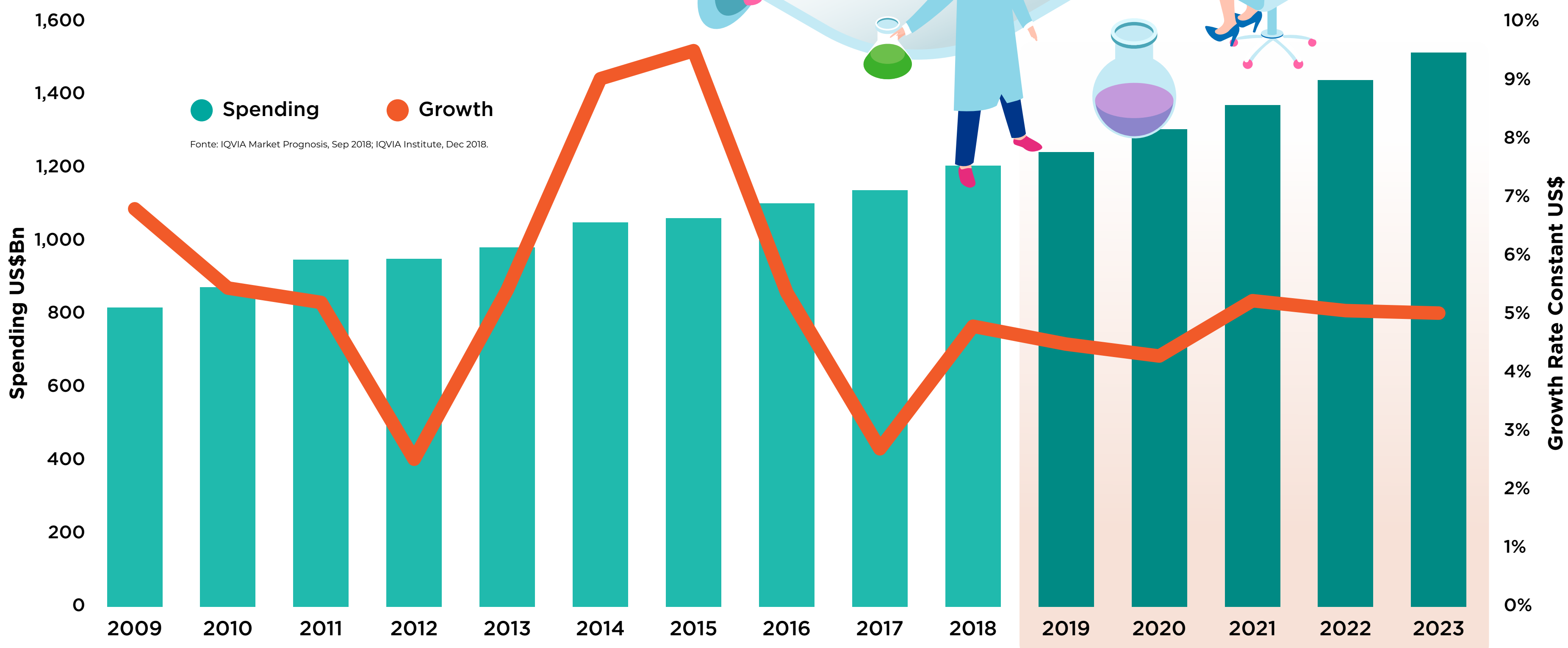
INTERFARMA associates have accounted for at least 50% of the Brazilian market for more than a decade. These companies currently represent 53% of the market, according to the revenues measured in the price reports sent to the Brazilian Medication Market Regulating Chamber (CMED).

This representation is directly linked to the fact that these companies are innovative and are constantly bringing new therapies to the country.



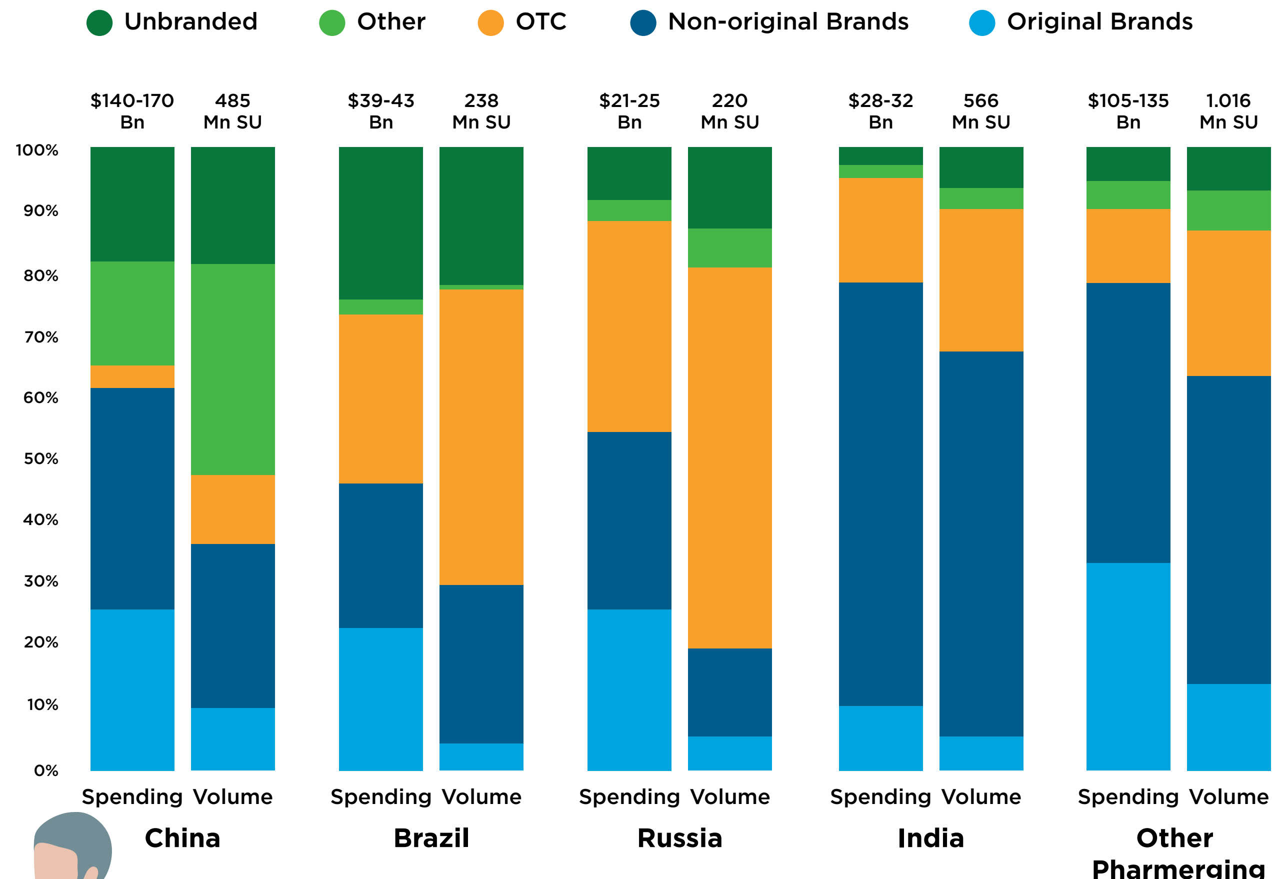
Worldwide spending on medications

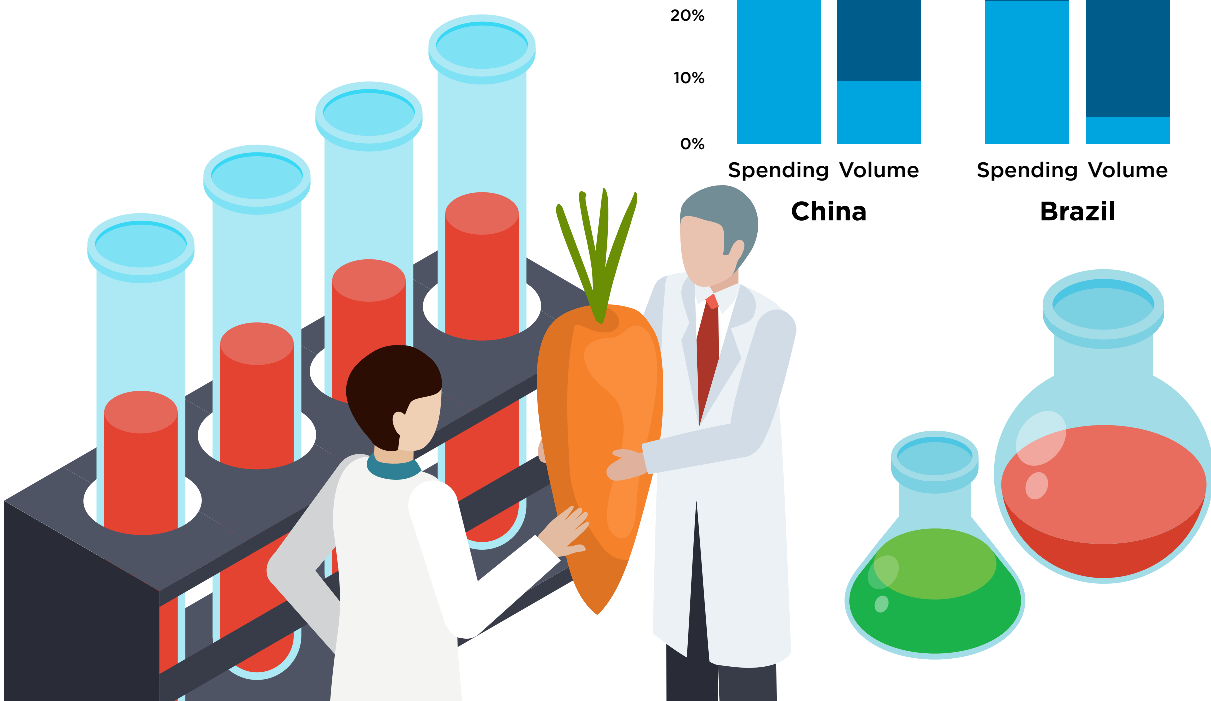
Global spending on medications reached US$ 1.2 trillion in 2018, and is expected to surpass US$ 1.5 trillion in 2023.



Spending on medications in Brazil

The Brazilian pharmaceutical market is expected to move between US$39 billion and US$43 billion in 2023, selling approximately 238 million units. In terms of revenues, the domestic market is expected to be well-balanced in terms of prescription drugs, similar medications, non-prescription drugs, and generic medications.





Global pharmaceutical market

Brazil is expected to rise two slots in the world ranking of pharmaceutical markets by 2023. The country's size encourages this growth because it is home to a significant market. On the other hand, difficulties related to access in Brazil impede it from rising further among the nations which lead these ranks worldwide.

2013

Rk	Country	% of US
1	United States	100
2	▲1 China	28
3	▼1 Japan	24
4	▲1 Germany	12
5	▼1 France	10
6	Italy	7
7	▲1 UK	6
8	▲3 **BRAZIL**	**5**
9	▼2 Spain	5
10	▼1 Canada	5
11	▲3 India	3
12	▼2 South Korea	3
13	▼1 Australia	3
14	▲5 Russia	3
15	▼2 Mexico	2
16	▲7 Saudi Arabia	2
17	▲1 Poland	2
18	▼1 Belgium	2
19	▼3 Netherlands	2
20	Switzerland	1

2018

Rk	Country	% of US
1	United States	100
2	China	28
3	Japan	18
4	Germany	11
5	France	7
6	Italy	7
7	▲1 **BRAZIL**	**6**
8	▼1 UK	6
9	Spain	5
10	Canada	5
11	India	4
12	South Korea	3
13	▲1 Russia	3
14	▼1 Australia	3
15	Mexico	2
16	▲1 Poland	2
17	▲9 Turkey	2
18	▼2 Saudi Arabia	2
19	▲27 Argentina	1
20	▼2 Belgium	1

2023

Rk	Country	% of US
1	United States	100
2	China	27
3	Japan	12
4	Germany	10
5	▲2 **BRAZIL**	**7**
6	Italy	6
7	▼2 France	6
8	UK	5
9	▲2 India	5
10	▼1 Spain	4
11	▼1 Canada	4
12	▲1 Russia	4
13	▼1 South Korea	3
14	▲3 Turkey	3
15	▲4 Argentina	2
16	▼2 Australia	2
17	▼2 Mexico	2
18	▼2 Poland	2
19	▼1 Saudi Arabia	2
20	▲6 Vietnam	1

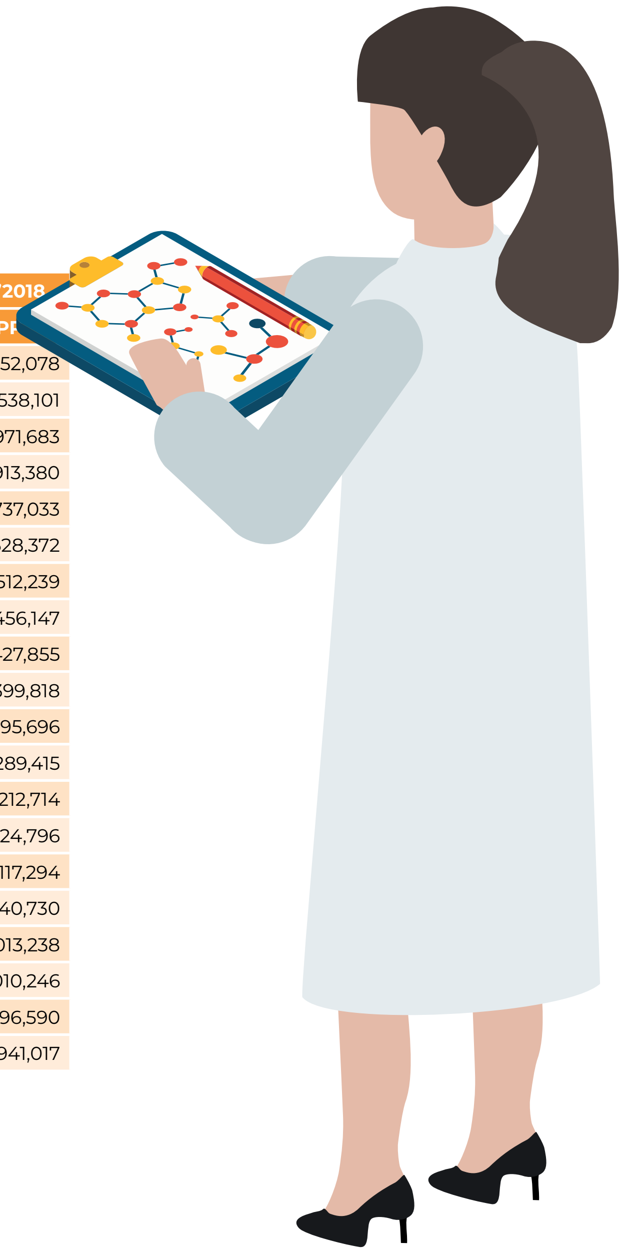
Source: IQVIA, The Global Use of Medicine in 2019 and Outlook to 2023, JANUARY 2019. Obs: Change in Ranking over Prior Five Years.

Brazilian industry rankings

Six of the ten companies with the highest revenues in Brazil are domestic. Revenues from the top five companies combine to equal 82.5% of the revenues from the other fifteen companies.

		MAT DEC'2014		MAT DEC'2015		MAT DEC'2016		MAT DEC'2017		MAT DEC'2018	
Rk	Laboratories	Rk	PPP	Rk	PPP	Rk	PPP	Rk	PPP	Rk	PPP
1	ACHE	1	2,304,465	1	2,790,332	1	3,301,477	1	3,816,857	1	4,152,078
2	EMS PHARMA	2	2,252,012	2	2,502,476	2	2,853,119	2	3,192,572	2	3,538,101
3	EUROFARMA	4	1,542,850	4	1,835,850	4	2,184,716	4	2,595,496	3	2,971,683
4	SANOFI	3	2,171,444	3	2,405,972	3	2,650,431	3	2,812,900	4	2,913,380
5	NOVARTIS	6	1,205,480	6	1,316,290	6	1,493,565	5	1,626,476	5	1,737,033
6	NEO QUIMICA	5	1,214,204	5	1,466,338	5	1,544,160	6	1,585,644	6	1,628,372
7	MANTECORP FARMASA	12	850,091	10	1,047,341	8	1,239,585	7	1,421,431	7	1,512,239
8	LIBBS	11	858,639	11	1,013,981	11	1,158,530	9	1,314,967	8	1,456,147
9	BIOLAB-SANUS FARMA	8	968,024	7	1,112,602	7	1,253,389	8	1,357,450	9	1,427,855
10	TAKEDA PHARMA	13	806,682	14	889,097	14	992,836	12	1,182,897	10	1,399,818
11	MEDLEY	7	1,015,611	8	1,110,765	9	1,216,433	10	1,248,729	11	1,395,696
12	BAYER PHARMA	9	961,558	9	1,061,745	10	1,166,578	11	1,224,243	12	1,289,415
13	CIMED	19	641,411	20	715,809	20	816,108	17	1,027,140	13	1,212,714
14	PFIZER	10	940,036	12	1,002,360	12	1,101,460	13	1,132,831	14	1,124,796
15	BOEHRINGER ING	22	594,478	19	716,300	16	907,568	15	1,042,662	15	1,117,294
16	GSK FARMA	21	610,727	18	729,433	19	827,927	18	975,943	16	1,040,730
17	FQM GRUPO	15	757,700	13	989,890	13	1,031,277	14	1,056,962	17	1,013,238
18	ASTRAZENECA BRASIL	18	691,464	17	773,080	17	869,962	19	933,093	18	1,010,246
19	HYPERA CH	14	787,243	15	865,029	15	921,401	16	1,029,063	19	996,590
20	JOHNSON JOHNSON	16	724,181	16	813,368	18	864,342	20	913,973	20	941,017

Source: IQVIA. In reais. PPP - Price with discount at time of sale.



Medications in Brazil with highest sales

The muscle relaxant Dorflex and Xarelto, a medication to treat deep venous thrombosis, have sales which significantly exceed the third-place medication in the worldwide rankings, by up to 95%.

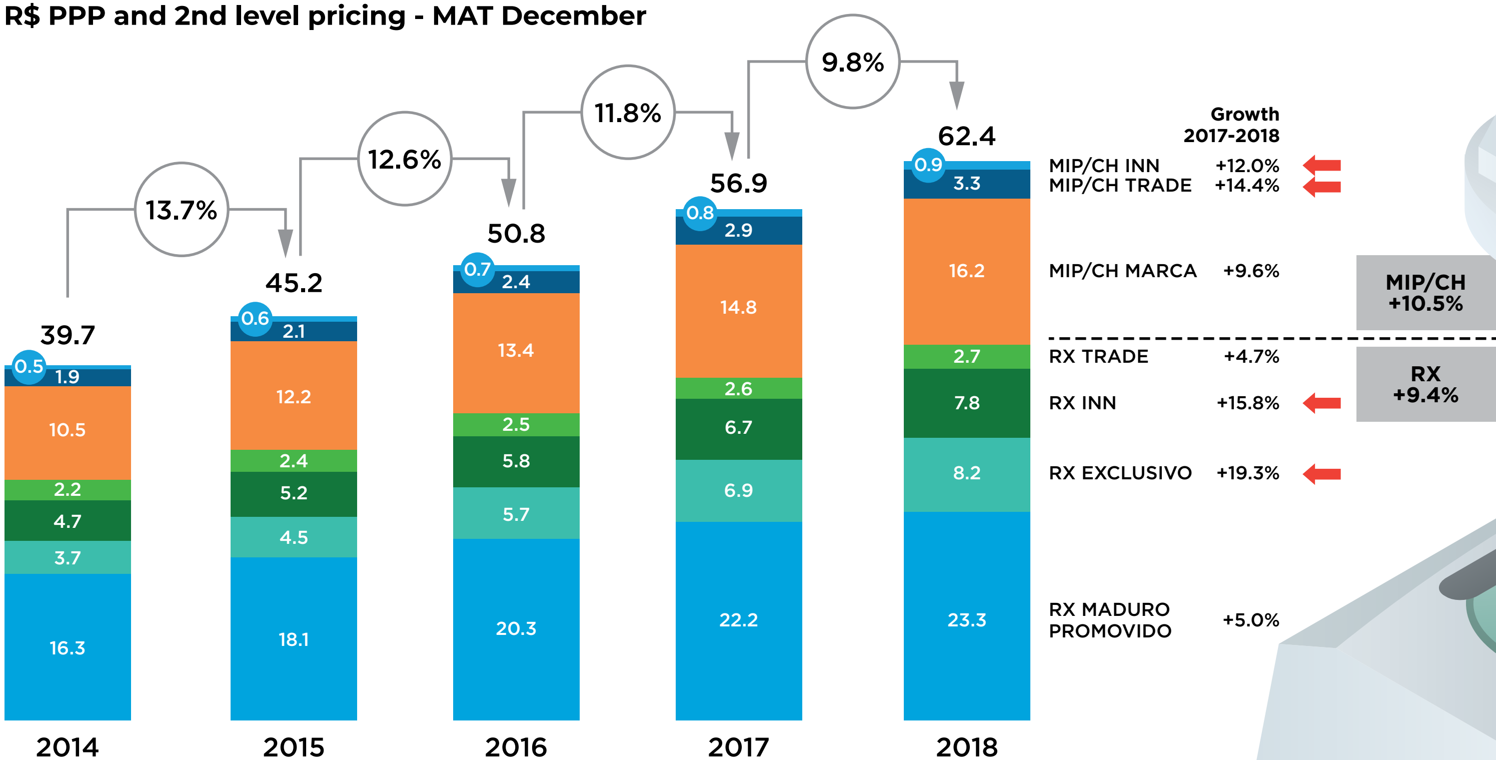
		MAT DEC'2014		MAT DEC'2015		MAT DEC'2016		MAT DEC'2017		MAT DEC'2018	
Rk	Laboratórios	Rk	PPP	Rk	PPP	Rk	PPP	Rk	PPP	Rk	PPP
1	DORFLEX (S.A)	1	373,255	1	416,568	1	470,304	1	506,473	1	554,422
2	XARELTO (BYP)	8	142,228	3	20,082	2	286,488	2	365,139	2	447,673
3	SAXENDA (N-N)	10,678	0	10,762	0	595	21,123	16	168,025	3	284,299
4	NEOSALDINA (TAK)	2	201,061	2	21,134	4	222,402	4	249,054	4	268,858
5	ADDERA D3 (MF+)	210	35,764	19	122,142	8	194,906	3	2,533	5	253,015
6	GLIFAGE XR (MCK)	3	175,115	5	193,876	7	202,536	8	212,387	6	246,794
7	TORSILAX (N.Q)	7	14,641	6	179,044	5	215,362	5	234,929	7	233,978
8	VICTOZA (N-N)	14	122,096	17	126,886	11	18,097	12	199,067	8	231,665
9	ANTHELIOS (LRP)	19	110,671	11	147,076	9	189,093	10	200,736	9	223,088
10	PURAN T-4 (S.A)	11	130,801	9	148,715	13	172,728	9	204,302	10	2,227
11	SELOZOK (AZN)	4	164,016	4	198,669	3	230,263	6	234,722	11	21,645
12	ARADOIS (BS2)	5	153,112	7	177,408	6	212,278	7	228,161	12	207,763
13	SAL DE ENO (GKC)	29	94,238	8	152,156	15	169,439	13	195,861	13	203,321
14	NOVALGINA (S.A)	40	83,536	31	100,888	22	123,416	21	140,788	14	200,325
15	JARDIANCE (B.I)	10,678	0	561	20,231	86	77,484	26	133,771	15	197,771
16	ALENIA (A4H)	52	75,591	30	101,573	17	134,102	20	156,161	16	179,919
17	PROLOPA (ROC)	48	774	34	99,373	20	129,614	18	157	17	174,482
18	GALVUS MET (NVR)	10	137,033	12	145,969	14	172,083	15	172,558	18	17,151
19	NINHO FASES 1+ (NES)	238	32,631	132	54,265	48	99,231	28	131,291	19	167,599
20	VENVANSE (SHI)	256	31,667	145	50,851	78	81,246	43	114,803	20	165,054

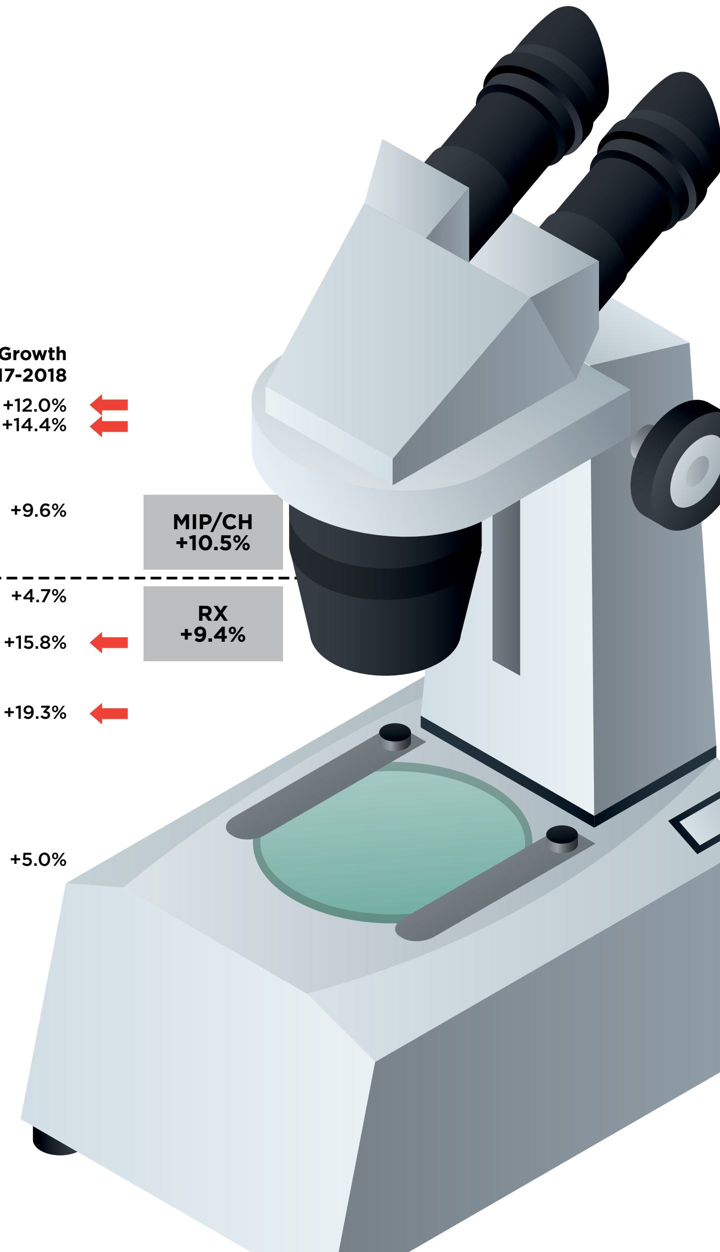
Source: IQVIA. In reais. PPP - Price with discount at time of sale.

Brazilian retail

The retail pharmaceutical industry in Brazil grew by almost 10% in 2018 to reach R$ 62.4 billion. Mature prescription drugs with expired patents represent the largest share of this market, with R$ 23.3 billion (growth of 5% between 2017 and 2018). However, the greatest growth compared to the previous year was seen in new medications (under patent), which increased by 19.3% to reach R$ 8.2 billion.

R$ PPP and 2nd level pricing - MAT December





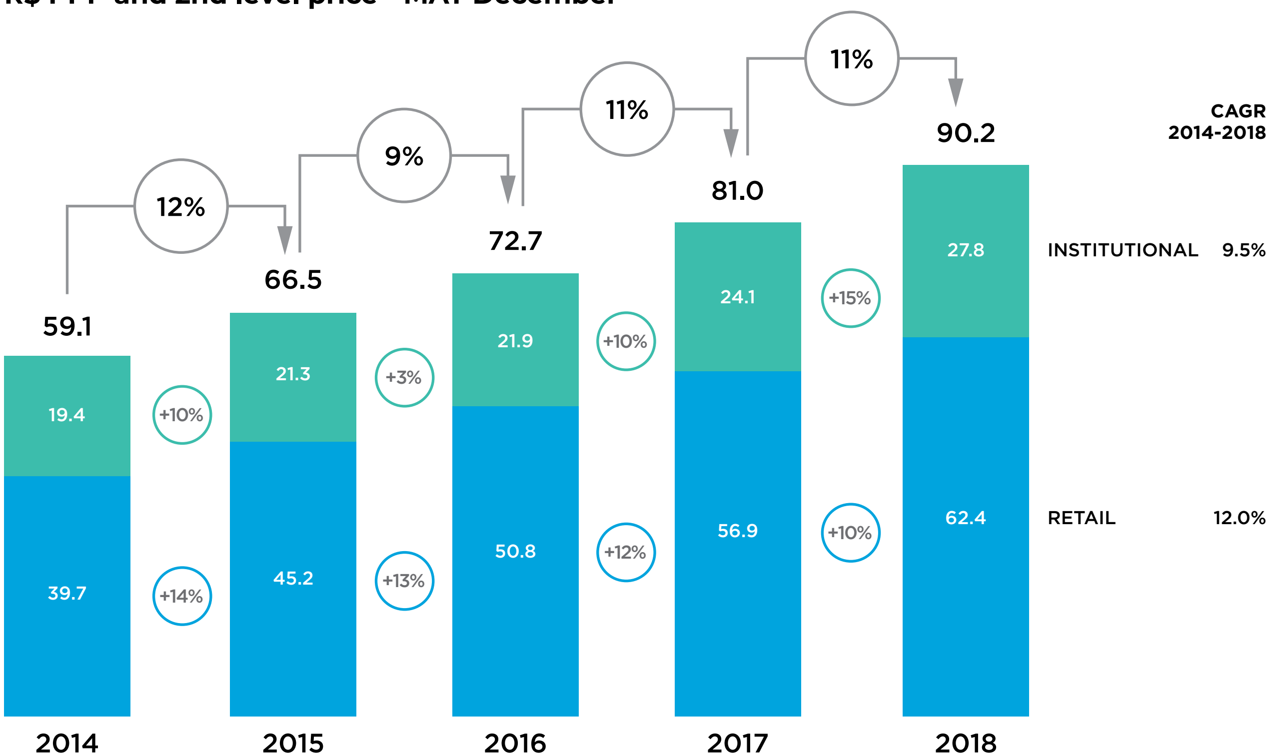
Source: PMB MAT Dec-18 (Pharmacy Purchase Price).

MIP/CH INN: Non-prescription drugs (Generics); MIP/CH TRADE: Non-prescription drugs (Brand names/Similars), high discount; MIP/CH MARCA: Non-prescription drugs (Brand names/Similars), low discount; RX TRADE: Prescription medications - high discount; RX INN: Prescription medications (Generics); RX EXCLUSIVO: Prescription medications (patented); RX MADURO PROMOVIDO: Prescription medications (patent expired, but low discount)

Brazilian pharmaceutical market

The pharmaceutical market grew 11% in 2018 in Brazil, reaching R$ 90 billion. The most significant variation between 2014 and 2018 was seen in retail, with 12% growth, while the institutional market (sales to the government, clinics, hospitals, and health plans) increased by 9.5%. However, this market exhibited the greatest variation compared to the previous year (15%), while the retail sector grew 10%. This was the first time that institutional growth exceeded expansion in pharmacy sales.

R$ PPP and 2nd level price - MAT December



Source: IQVIA. PMB MAT Dez-18 (Pharmacy Purchase Price) e NRC MAT Dez-18 (2° nível de preço).

Average discount for pharmaceutical retail – per year*

2015	2016	2017	2018	2019
41%	42%	41%	40%	39%

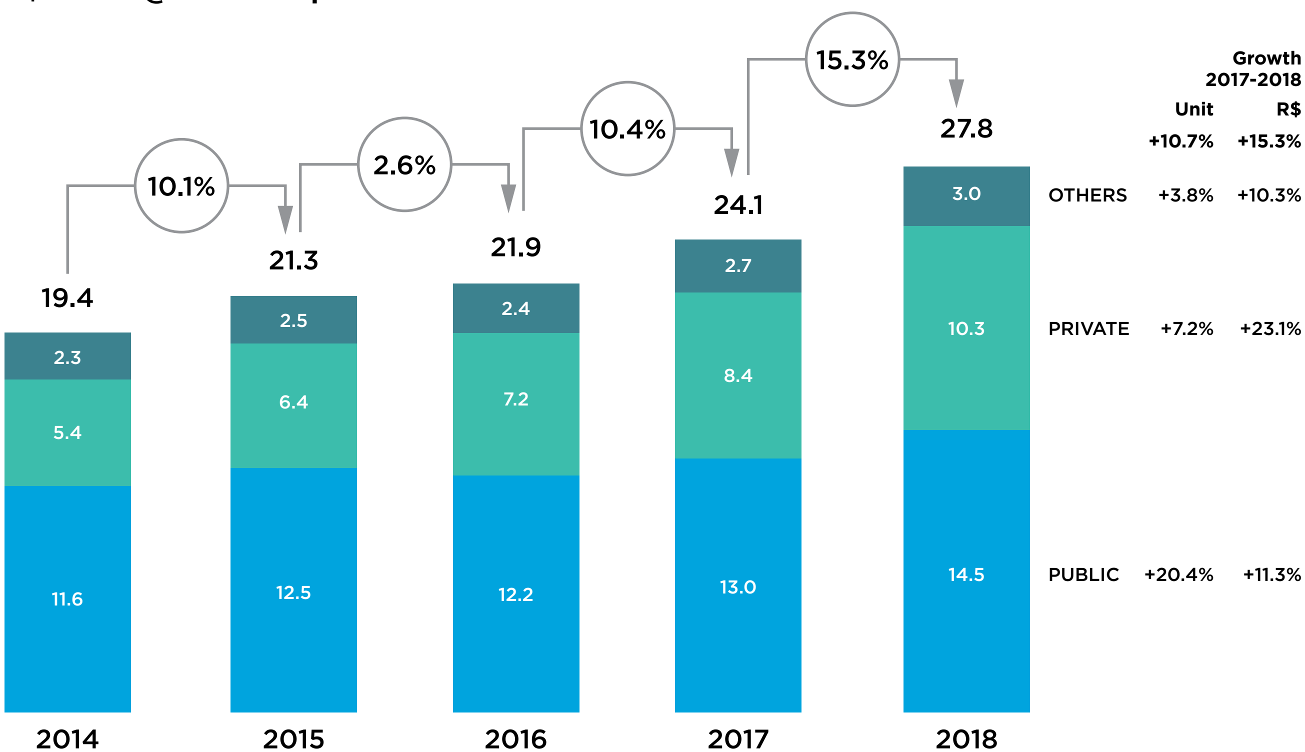
Source: IQVIA; Created by: INTERFARMA *12 months, rolling to June (MAT)

The prices for medications in Brazil are regulated by CMED, the Medication Market Regulating Chamber, which establishes a maximum value known as the list price. This does not mean that the price is fixed, since discounts can be offered. As a result, the same medication can be found for different prices at different pharmacies, leading to the false impression that the industry is not regulated. Over the past five years, the average discount practiced by retail pharmacies ranged from 39% to 42% of list price.

Institutional market

The institutional pharmaceutical market in Brazil grew 15% in 2018, reaching R$ 27.8 billion. This increase was mainly driven by the private market, which grew from R$ 8.4 billion to R$ 10.3 billion, an increase of 23%. A significant elevation of 11.3% was also seen in public purchases, from R$ 13 billion to R$ 14.5 billion.

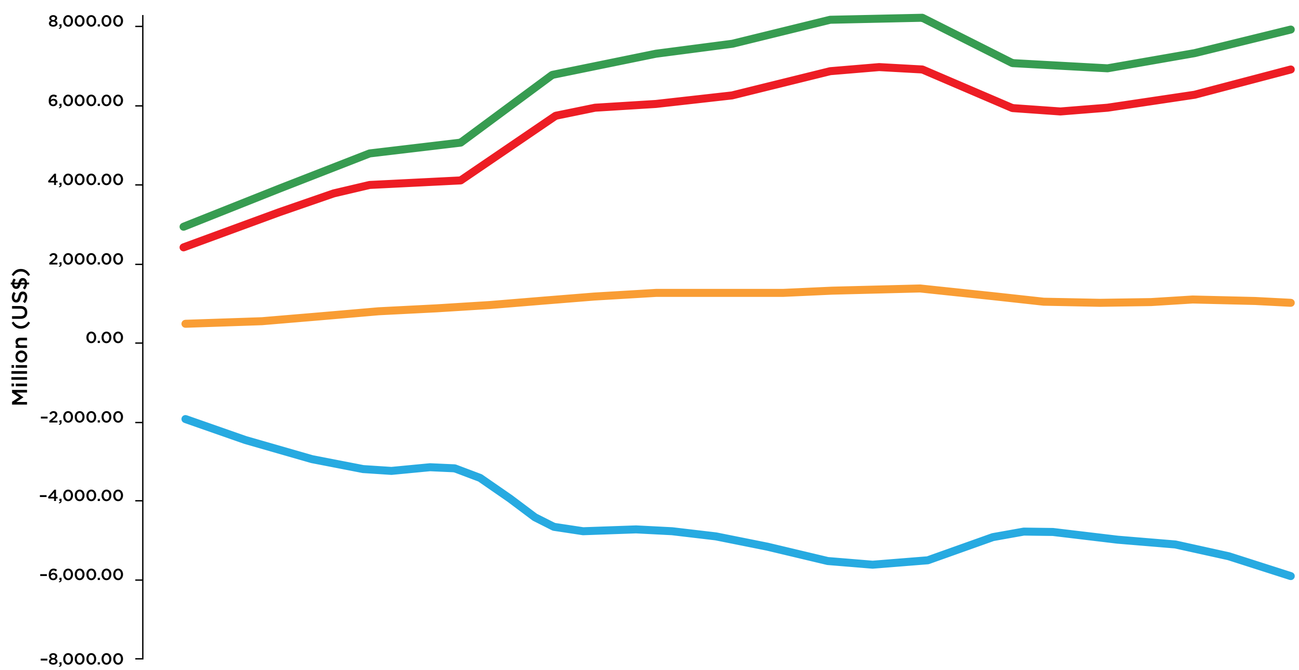
R$ billion @ 2nd level price - MAT December



Source: NRC Brasil MAT DEZ-18

Trade Balance

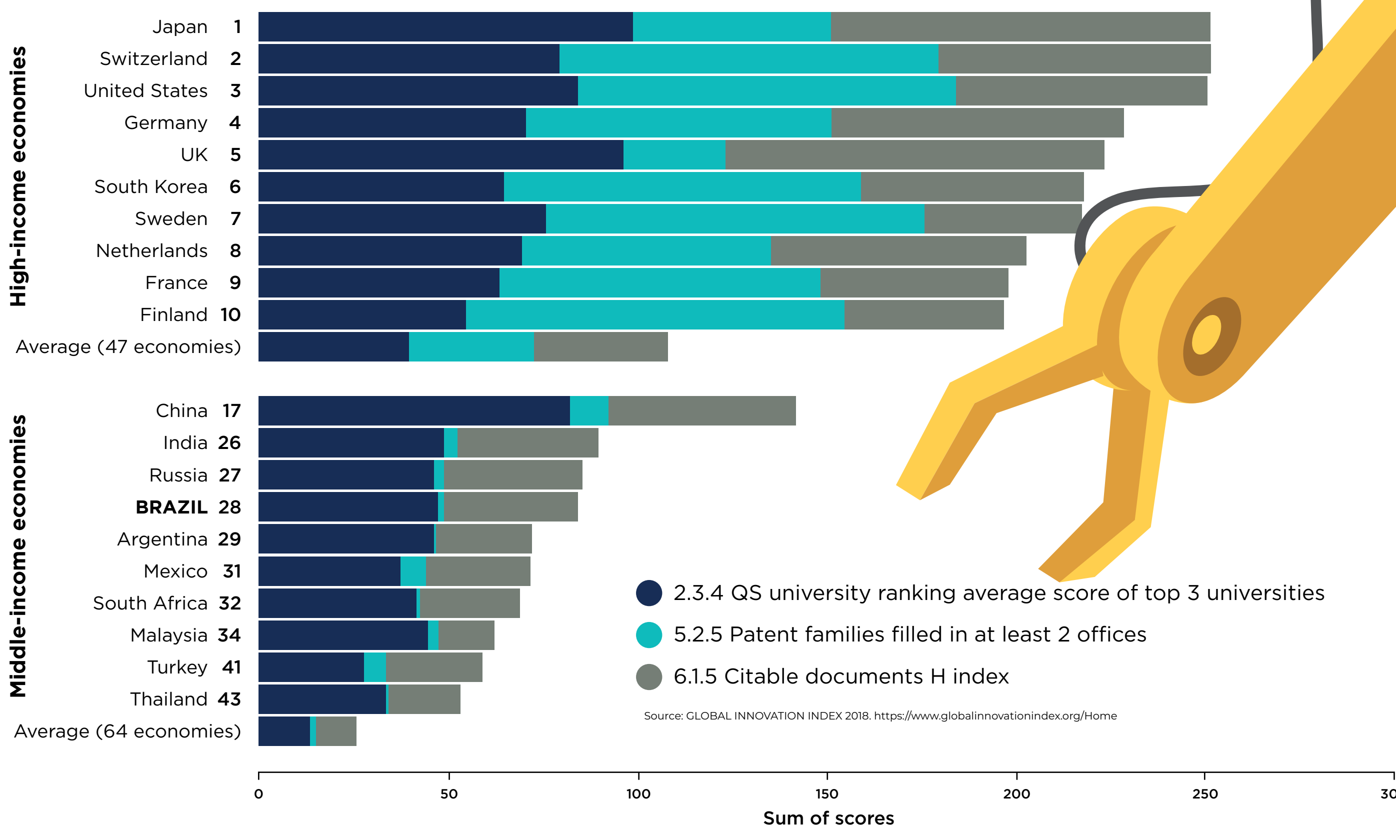
The trade balance for pharmaceutical products currently has a deficit of US$ 5.8 billion. This negative balance has gradually increased in recent years, with rare exceptions. It is understood to result from barriers to investment in innovation which are found in Brazil, and since innovation is taking place in other countries, Brazilian access comes through imports. Even so, the sector does not advocate restrictions on imports, since no country is self-sufficient in this industry, but rather supports investments in innovation in order to boost exports.



	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Export	495.57	585.29	779.08	901.45	1,078.79	1,234.33	1,288.24	1,294.26	1,351.75	1,121.32	1,004.49	1,064.07	1,008.42
Import	2,436.01	3,295.37	3,997.24	4,130.78	5,712.57	5,982.00	6,271.98	6,811.34	6,859.52	5,918.35	5,930.97	6,283.90	6,896.55
Chain of Commerce	2,931.58	3,880.67	4,776.31	5,032.23	6,791.36	7,216.34	7,560.22	8,105.60	8,211.27	7,039.67	6,935.46	7,347.97	7,904.96
Balance (deficit)	-1,940.44	-2,710.08	-3,218.16	-3,229.32	-4,633.78	-4,747.67	-4,983.74	-5,517.07	-5,507.77	-4,797.03	-4,926.48	-5,219.82	-5,888.13

Source: Comexstat/MDIC; Prepared by Interfarma

Innovation

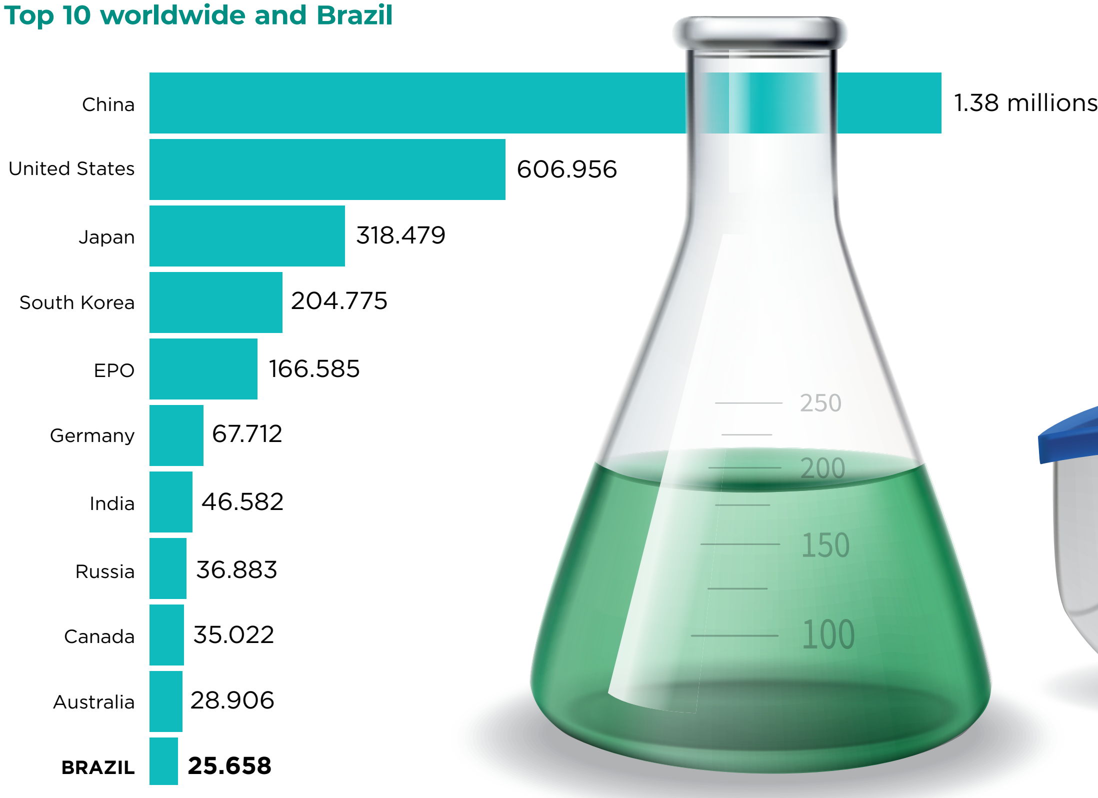


Source: GLOBAL INNOVATION INDEX 2018. https://www.globalinnovationindex.org/Home

Patents

The number of patent applications in Brazil in 2017 was 25,658, while the US, which led the world rankings, had 1.38 million requests. The backlog at the National Industrial Property Institute (INPI), which is responsible for issuing patents in Brazil, reached 14 years at that time, but during the first half of 2019 measures were announced to reduce this backlog by 80% by 2021.

Applications for Patents, 2016 and 2017
Top 10 worldwide and Brazil



Source: WIPO IP Facts and Figures 2018 https://www.wipo.int/edocs/pubdocs/en/wipo_pub_943_2018.pdf

Most patents expire in 2019

In developed markets, this fact is expected to have an impact of US$ 121 billion between 2019 and 2023. Of this total, US$ 95 billion will be concentrated in the US alone. And by the end of 2023, only two of the 20 current leading brand name medications will not have competing generic or biosimilar drugs.

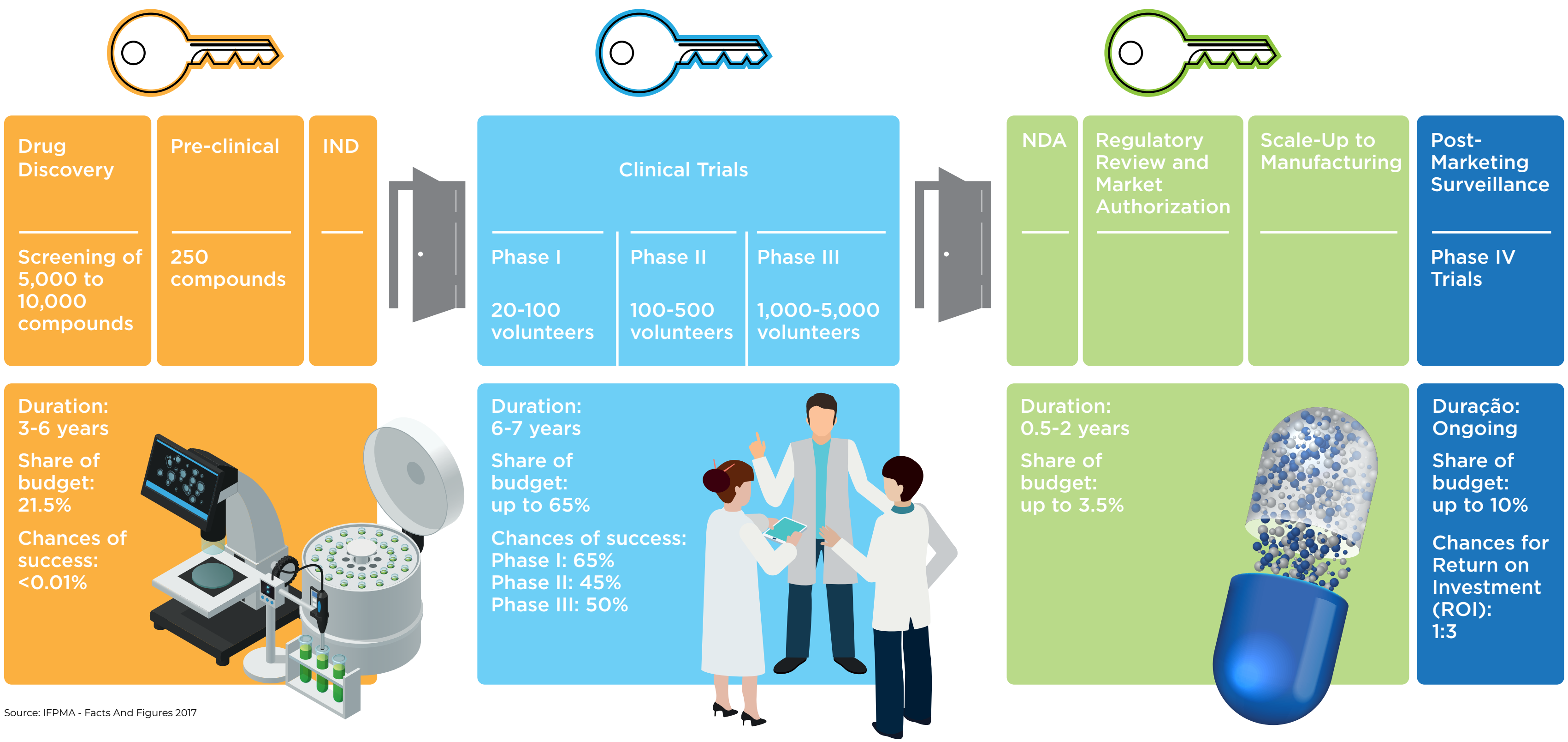
Source: Predictions and areas to watch in the global pharma market ahead, 2019-2023

(https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/predictions-and-areas-to-watch.pdf?la=en&hash=628FD60B66FB1C2B1989781C17914E72A8C63749&_=1563909186256)

Development of medications

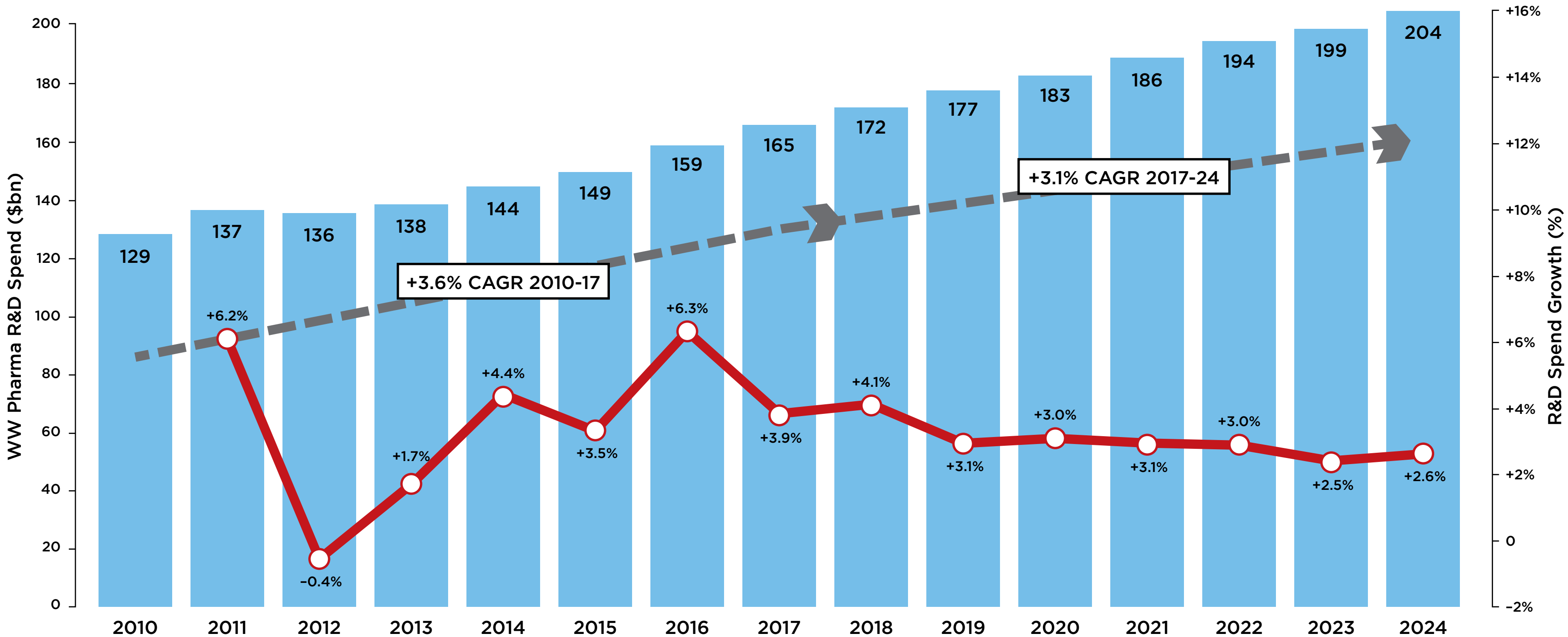
It takes an average of 10 years to create a new drug, considering all stages of development. Laboratories research up to 10,000 molecules for each one that is considered safe and effective. Study data are then submitted to health agencies for analysis; if it is approved, the medication then moves on to the market. Some specific segments of the pharmaceutical industry, such as biological medications, require even greater investment, surpassing twice the average spending.

Steps for creating medications



Source: IFPMA - Facts And Figures 2017

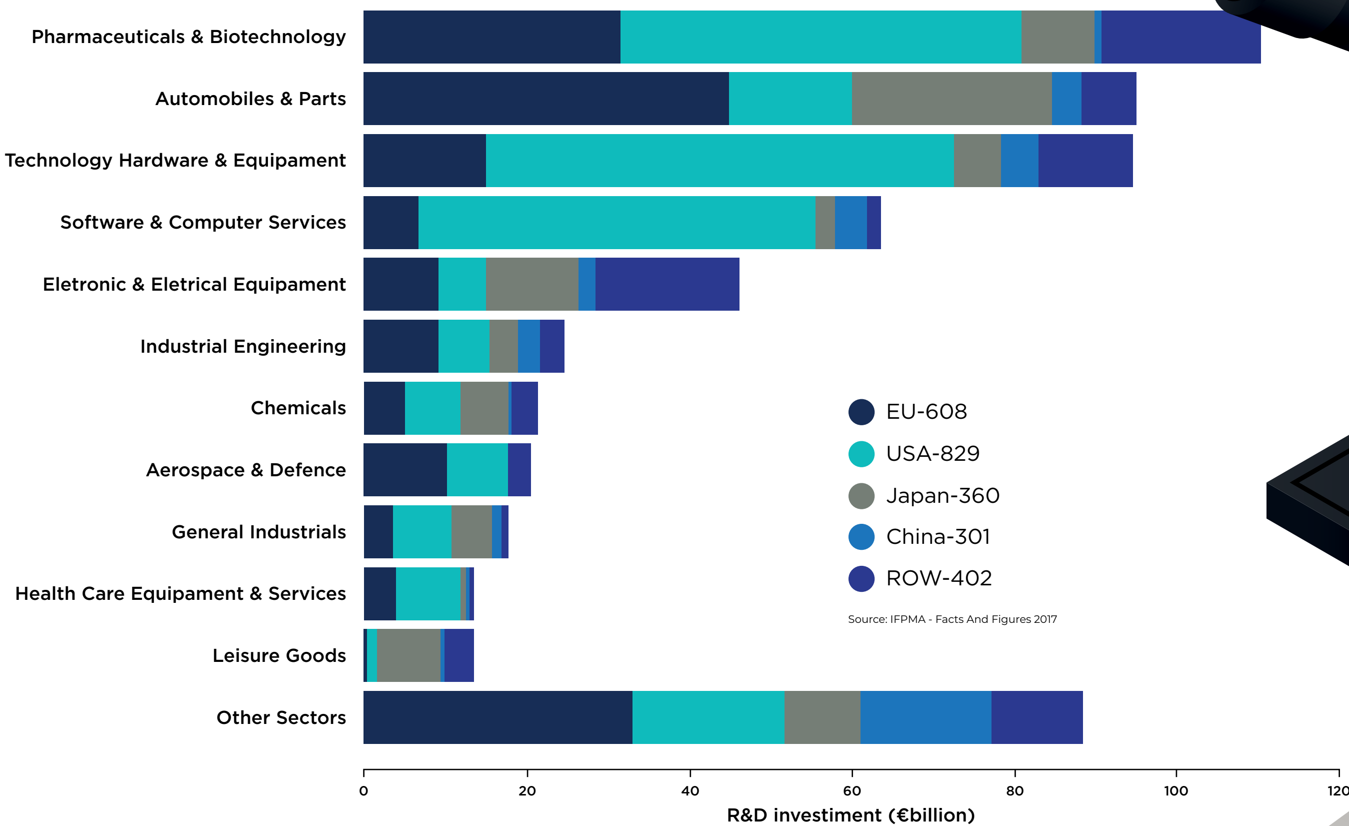
R&D

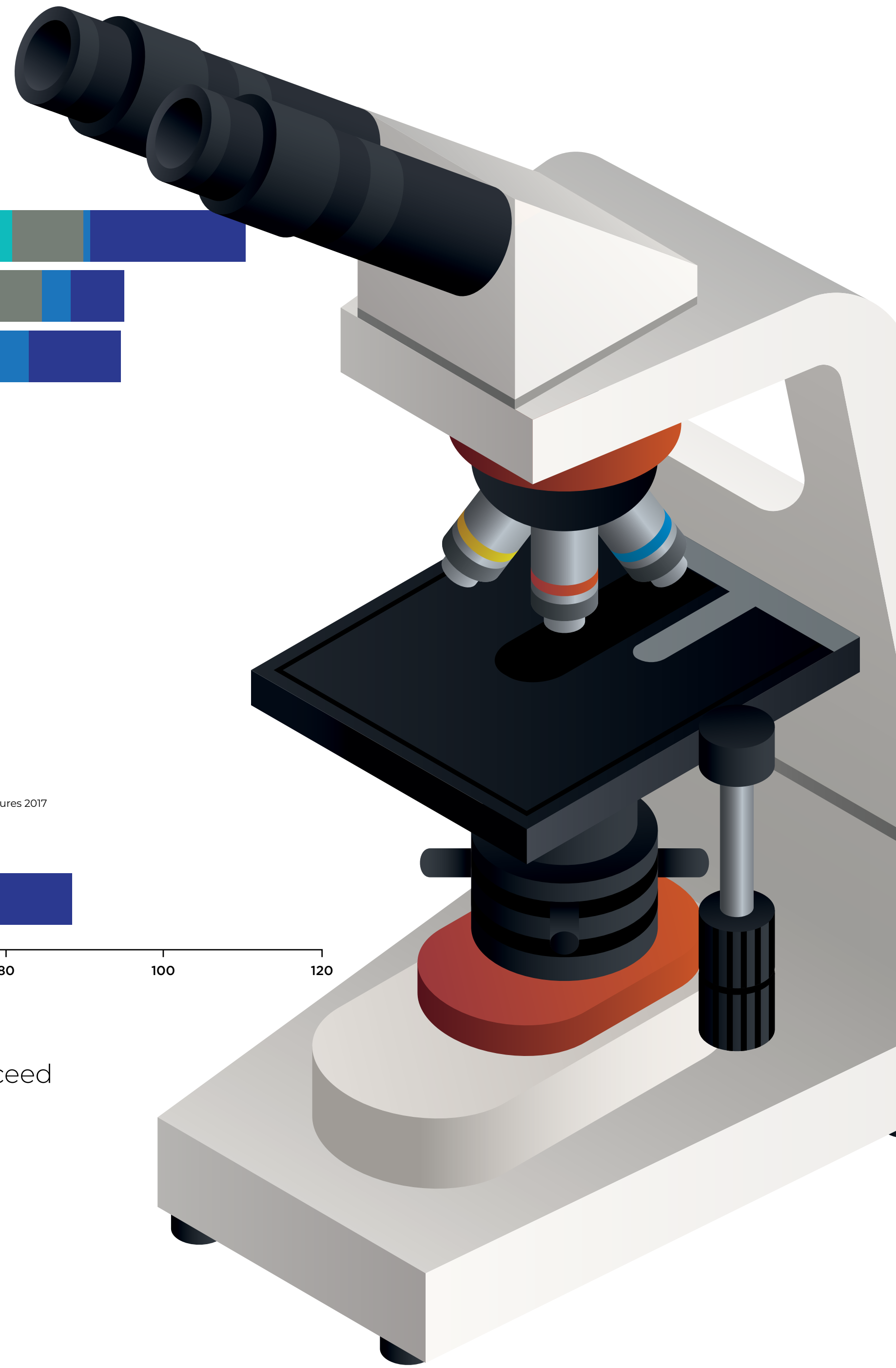


Source: EvaluatePharma®, World Preview 2018, Outlook to 2024. Accessed April 12, 2019

The pharmaceutical industry is among the world's largest investors in research and development. In 2018, this investment was US$ 172 billion, and this number is expected to reach US$ 204 billion in 2024. These high investments are justified by the risk involved in innovation and the need for new therapies, since chronic and complex diseases are becoming more frequent as the population ages.

R&D by sector





The pharmaceutical industry's investments in research and development exceed those made in the global automotive, hardware, and software sectors.

Therapies under Development

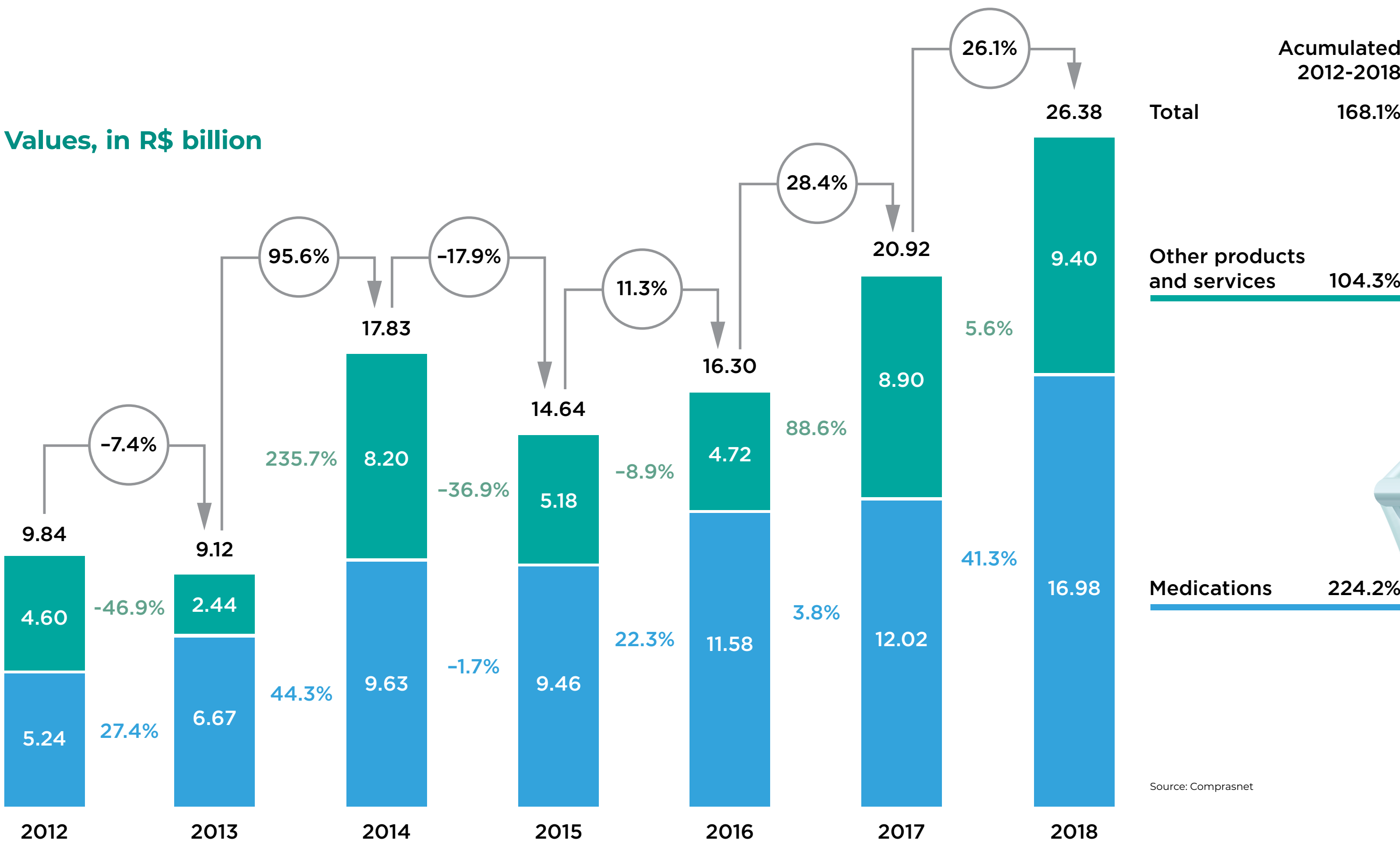
Infectious diseases	1,261
Cardiovascular	563
HIV/AIDS	208
Neurology	1,308
Cancer	1,919
Imunology	1,123
Diabetes	401
Mental Disorders	510

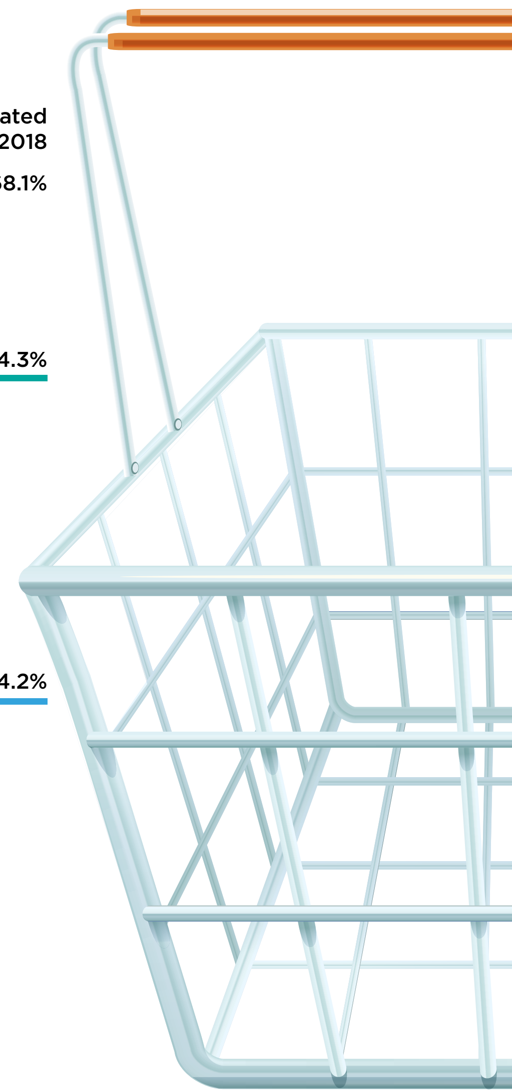
Source: IFPMA - Facts And Figures 2017

Cancer and neurological diseases, with an emphasis on degenerative diseases, are at the forefront of the worldwide pharmaceutical pipeline. This trend has emerged in recent years as chronic and complex diseases have become more frequent around the world.

Public Procurement - Ministry of Health

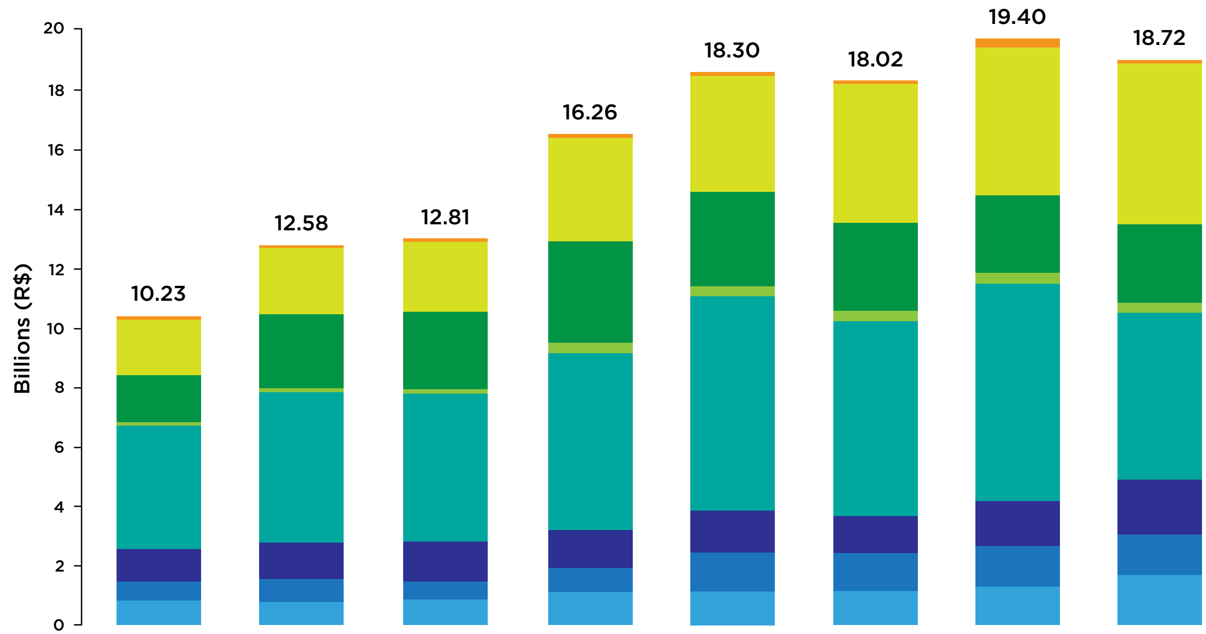
Values, in R$ billion





In 2018, the Brazilian Ministry of Health purchased R$26.38 billion in medications, services, and other products. Medications accounted for 64% of the total purchased by the Ministry of Health's Division of Logistics. Compared to the previous year, spending on medications increased by 41.3%. Over a six-year period, spending on medications more than doubled in comparison with other products and services: 224.2% versus 104.3%.

The Brazilian Ministry of Health's Pharmaceutical Assistance Budget

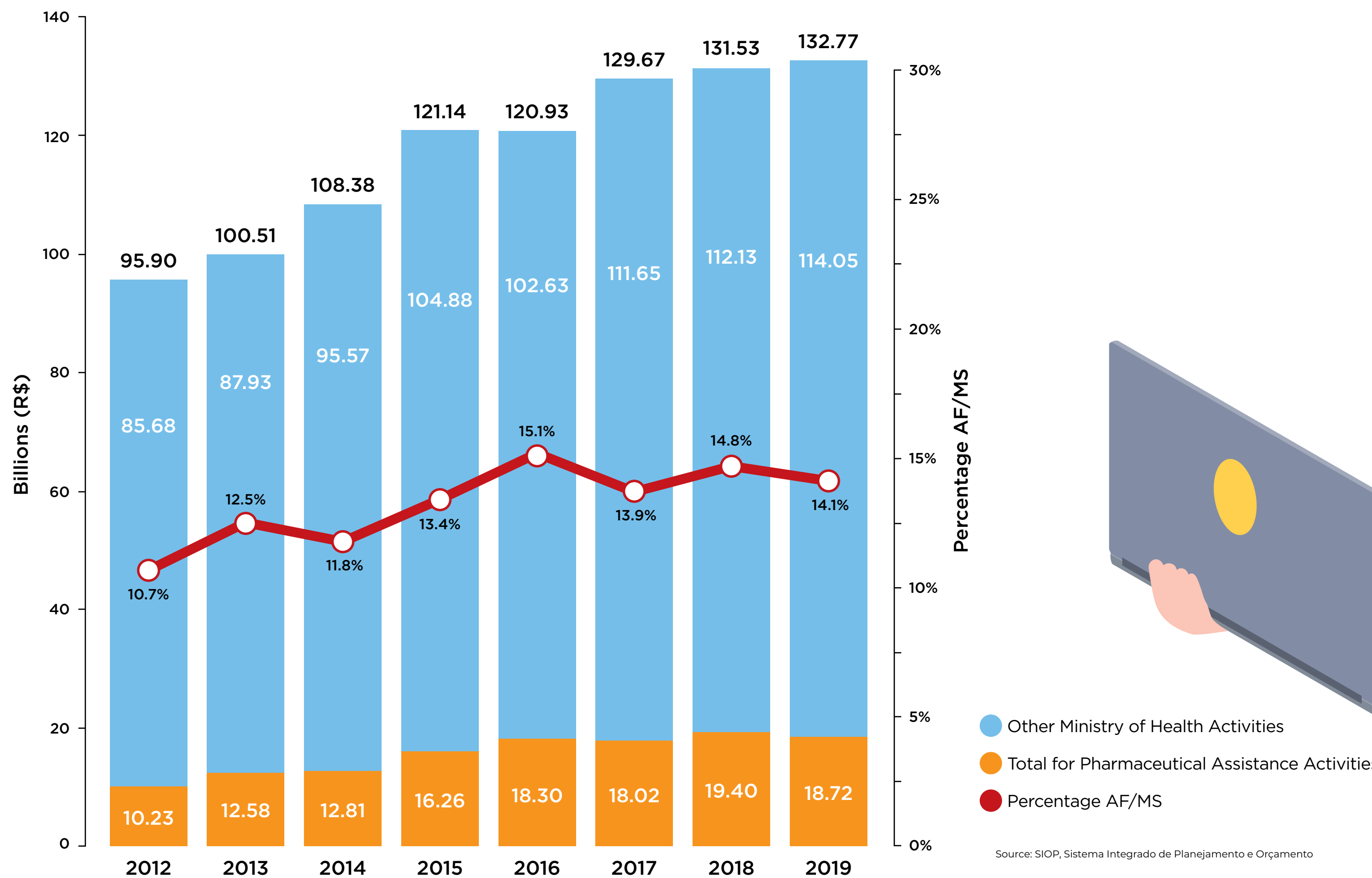


	2012	2013	2014	2015	2016	2017	2018	2019
Other Pharmaceutical Assistance activities	0.11	0.09	0.13	0.13	0.14	0.13	0.27	0.14
Immunobiologicals (serums and vaccines)	1.84	2.18	2.30	3.42	3.81	4.59	4.90	5.30
Farmácia Popular (own network and Aqui Tem Farmácia Popular)	1.55	2.46	2.57	3.36	3.14	2.91	2.55	2.60
Strategic Component of Pharmaceutical Assistance	0.13	0.13	0.17	0.34	0.31	0.31	0.34	0.33
Specialized Component of Pharmaceutical Assistance	4.08	4.98	4.89	5.87	7.15	6.48	7.22	5.54
Basic Component of Pharmaceutical Assistance	1.09	1.22	1.31	1.24	1.35	1.21	1.50	1.81
Care for Patients with Blood Disorders	0.61	0.75	0.58	0.80	1.30	1.27	1.36	1.35
AIDS and Sexually Transmitted Infections (STI) - National	0.82	0.77	0.86	1.10	1.10	1.13	1.26	1.65

Source: SIOP, Integrated Planning and Budget System

In 2019, appropriations for pharmaceutical assistance dropped 4% in relation to the previous year. The greatest reduction was seen in the specialized component (medicines for chronic, degenerative, and complex diseases), which dropped 23%. This reduction raises concern, since the majority of Brazilians can only access these treatments through the Brazilian Unified Health System (SUS).

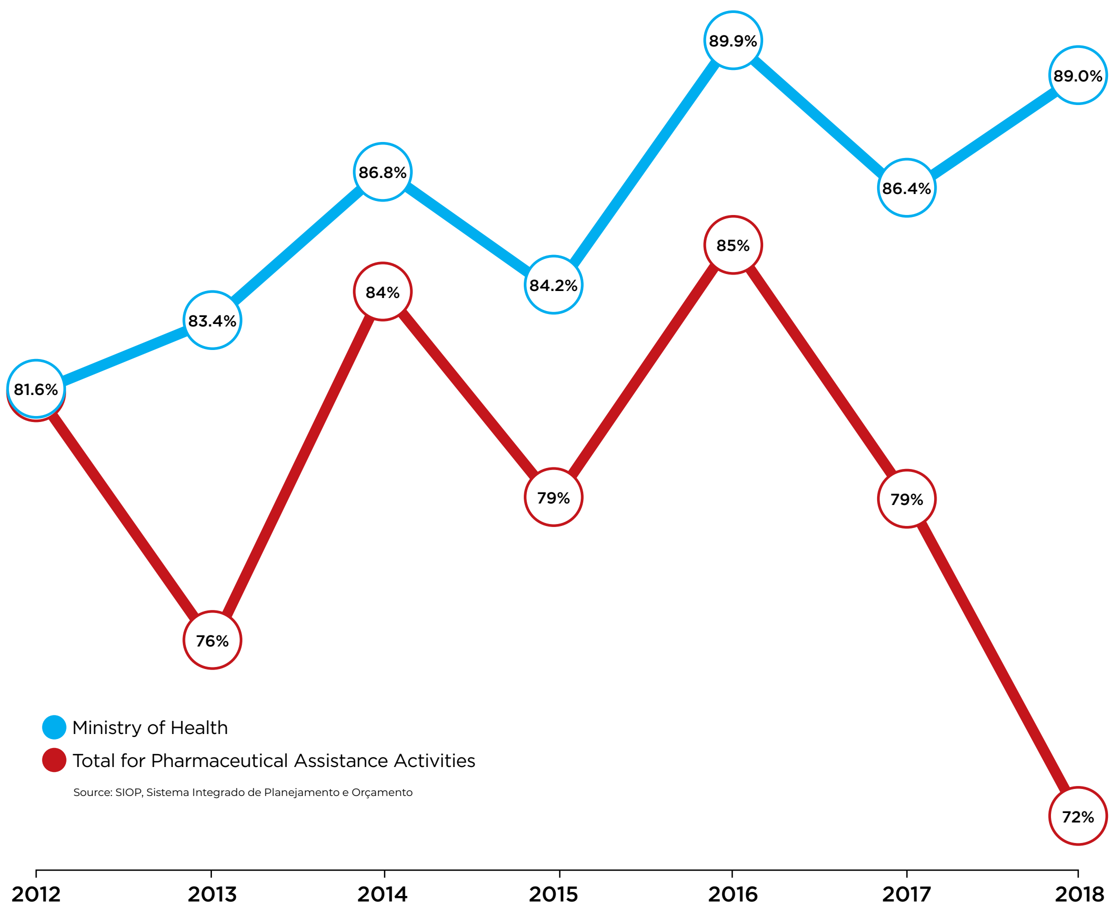
Share of Pharmaceutical Assistance in the Ministry of Health Budget



Source: SIOP, Sistema Integrado de Planejamento e Orçamento

Over the past seven years, appropriations for the Ministry of Health have grown 38%, while pharmaceutical assistance increased 83%.

Budget Execution



Of the Ministry of Health’s annual budget, 89% is effectively utilized as planned, while for pharmaceutical assistance this level is lower, only 72%. This has a direct impact for patients who depend on the SUS for access to therapies they need.

Budget Execution for Pharmaceutical Assistance

Actions	2012	2013	2014	2015	2016	2017	2018	2019*	Total Geral
AIDS and Sexually Transmitted Infections (STI) - National	70.7%	75.0%	75.2%	75.9%	80.4%	69.4%	84.8%	47.6%	76.3%
Care for Patients with Blood Disorders	43.7%	27.2%	62.5%	71.3%	84.1%	81.4%	87.9%	35.8%	70.9%
Basic Component of Pharmaceutical Assistance	89.4%	87.9%	85.1%	80.7%	89.7%	94.2%	88.4%	45.7%	87.9%
Specialized Component of Pharmaceutical Assistance	92.3%	87.0%	91.4%	86.9%	93.2%	80.4%	63.4%	31.4%	83.9%
Strategic Component of Pharmaceutical Assistance	43.9%	61.9%	66.5%	72.9%	62.7%	44.3%	41.7%	13.4%	56.3%
Farmácia Popular (own network and Aqui Tem Farmácia Popular)	94.0%	77.4%	85.6%	85.7%	87.7%	99.1%	99.5%	53.2%	89.6%
Immunobiologicals (serums and vaccines)	64.4%	60.2%	78.3%	62.9%	71.5%	66.0%	58.8%	38.3%	65.5%
Other Pharmaceutical Assistance activities	57.9%	68.2%	46.1%	75.5%	41.7%	65.7%	74.7%	41.1%	63.0%
Total for Pharmaceutical Assistance Activities	81.6%	75.9%	84.0%	79.2%	85.1%	79.4%	71.8%	39.2%	79.3%

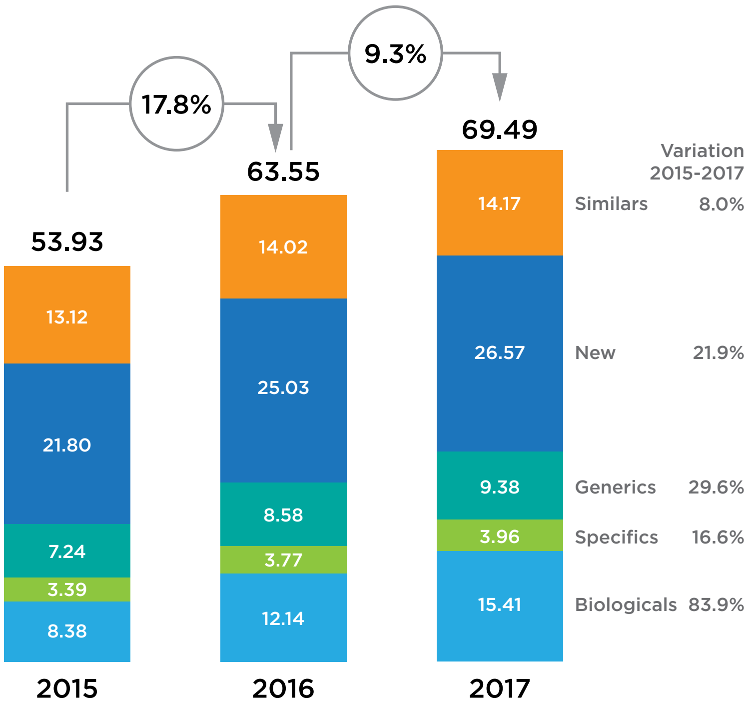
Source: SIOP, Integrated Planning Budget System

* Accounted Performance until August 23, 2019

The specialized component (medicines for chronic, degenerative, and complex diseases) had the lowest rate of budget execution in 2018, with only 63.4%.

The Pharmaceutical Market

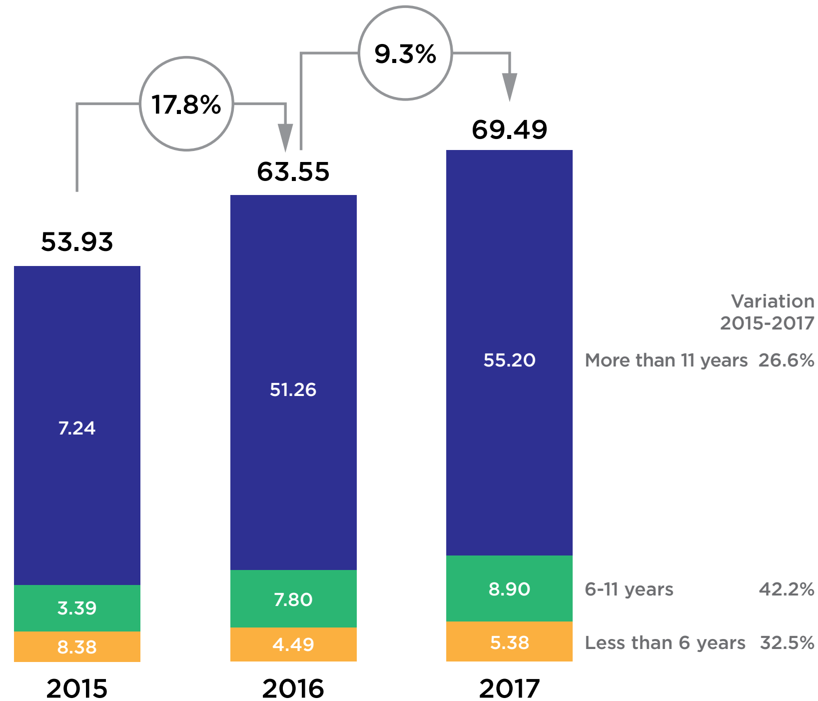
Type of Medication (Values, in R$ billion)



Source: Anuários Estatísticos CMED (2015-2017)

New medicines were responsible for a greater share in the pharmaceutical market, with R$ 26.5 billion, while biologicals grew the most, increasing 84% between 2015 and 2017.

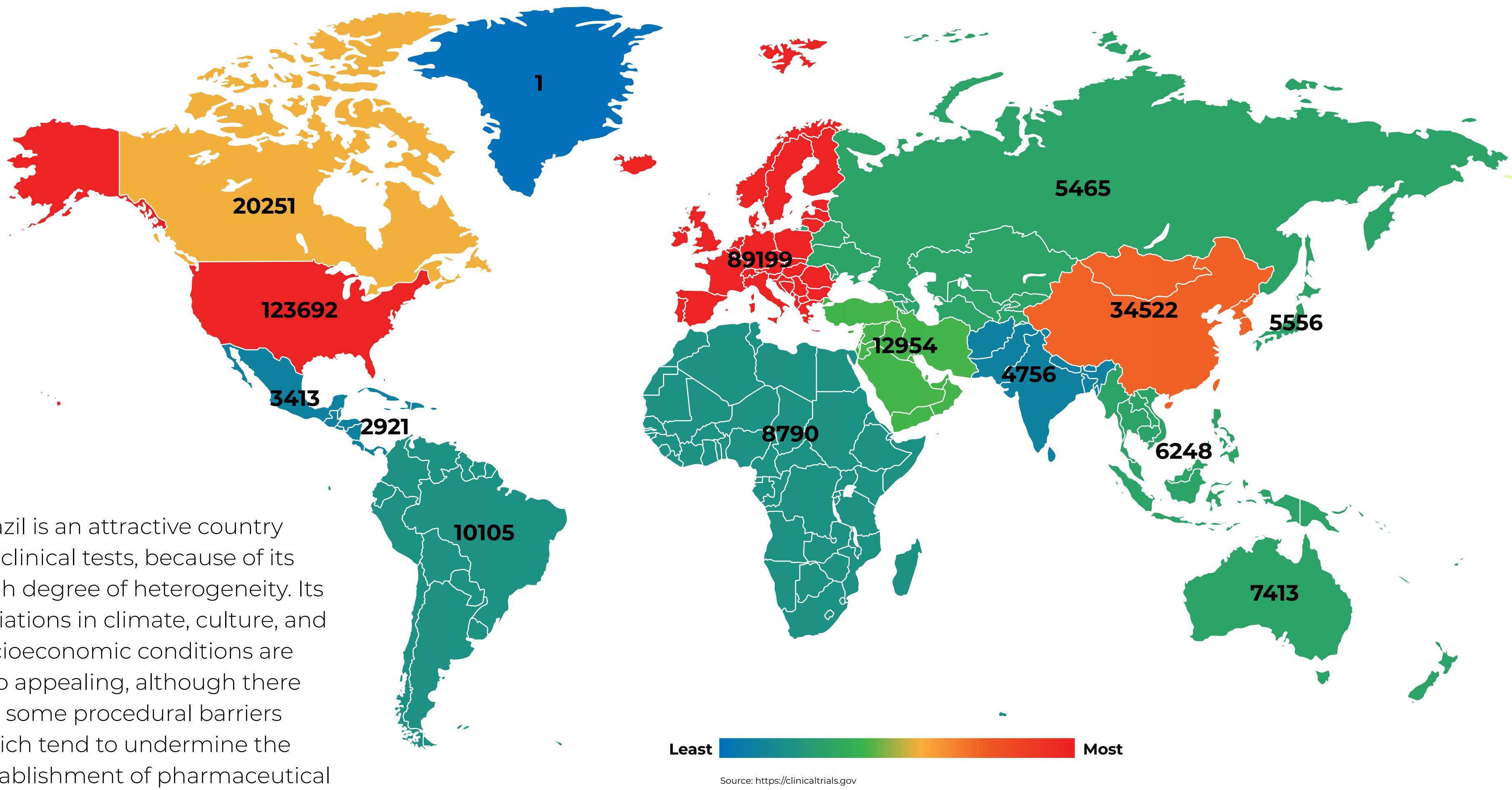
Time until Price Approval



Source: Anuários Estatísticos CMED (2015–2017)

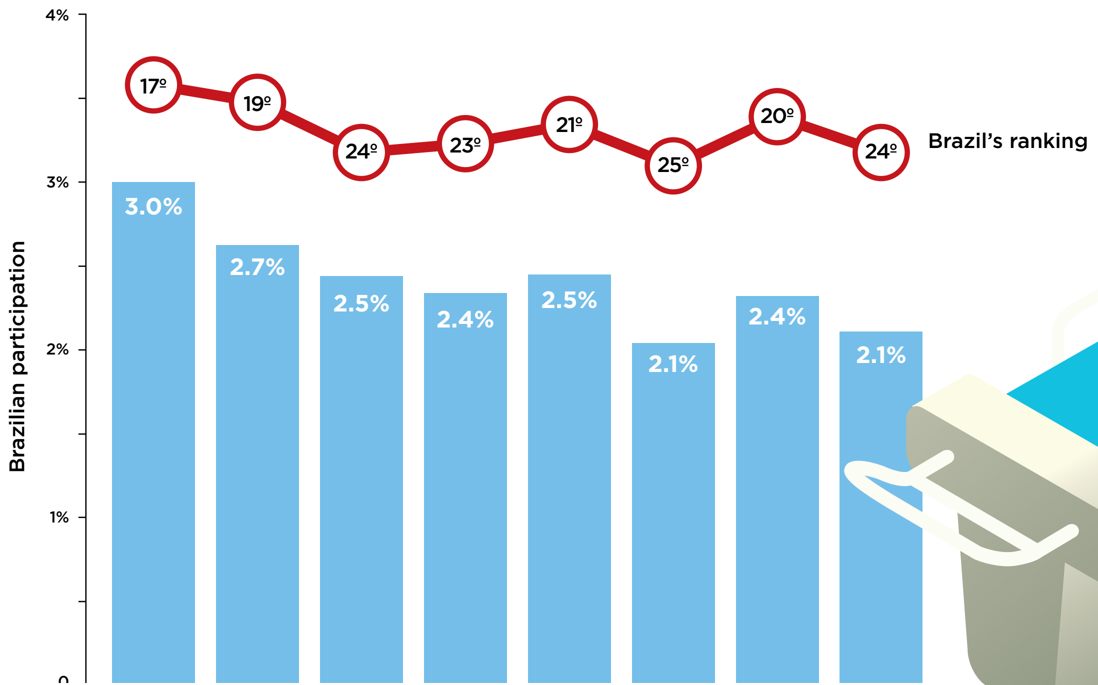
New medicines which are less than six years old account for less than 10% of revenues from mature medications (more than 11 years old).

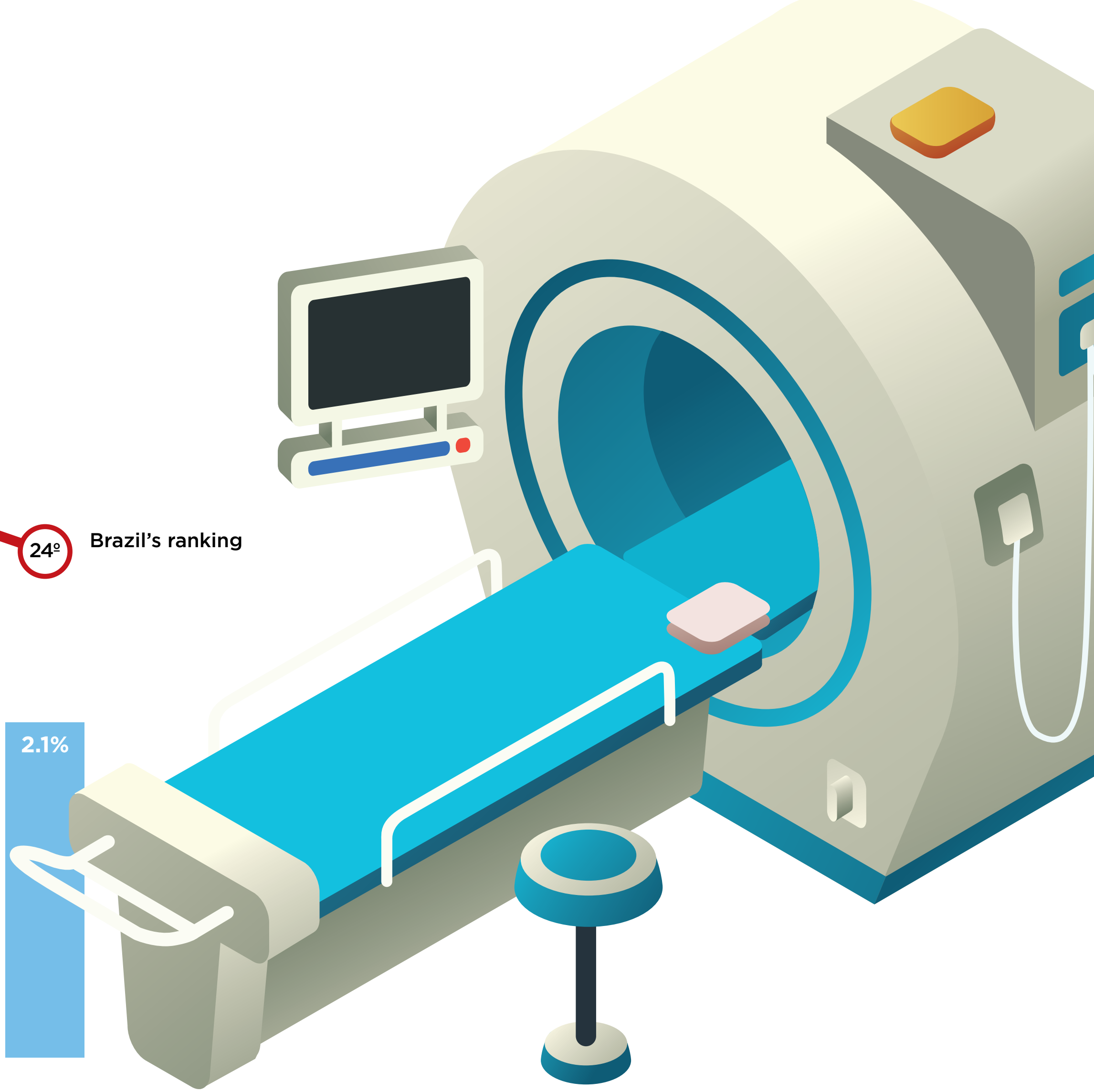
World Map of Clinical Trial



Brazil is an attractive country for clinical tests, because of its high degree of heterogeneity. Its variations in climate, culture, and socioeconomic conditions are also appealing, although there are some procedural barriers which tend to undermine the establishment of pharmaceutical innovation in Brazil.

Brazil's Participation and Global Ranking in Clinical Studies





Source: Citeline (base global de estudos clínicos)

In the world rankings for clinical trials Brazil holds only 24th place, accounting for 2.1% of studies carried out worldwide. Although the country is attractive for research for several reasons (such as its expansive area and ethnic diversity), there are procedural barriers involving sanitary and ethical issues that lead to extensive wait times when applications for clinical studies are submitted for approval, undermining the country's potential for pharmaceutical innovation.

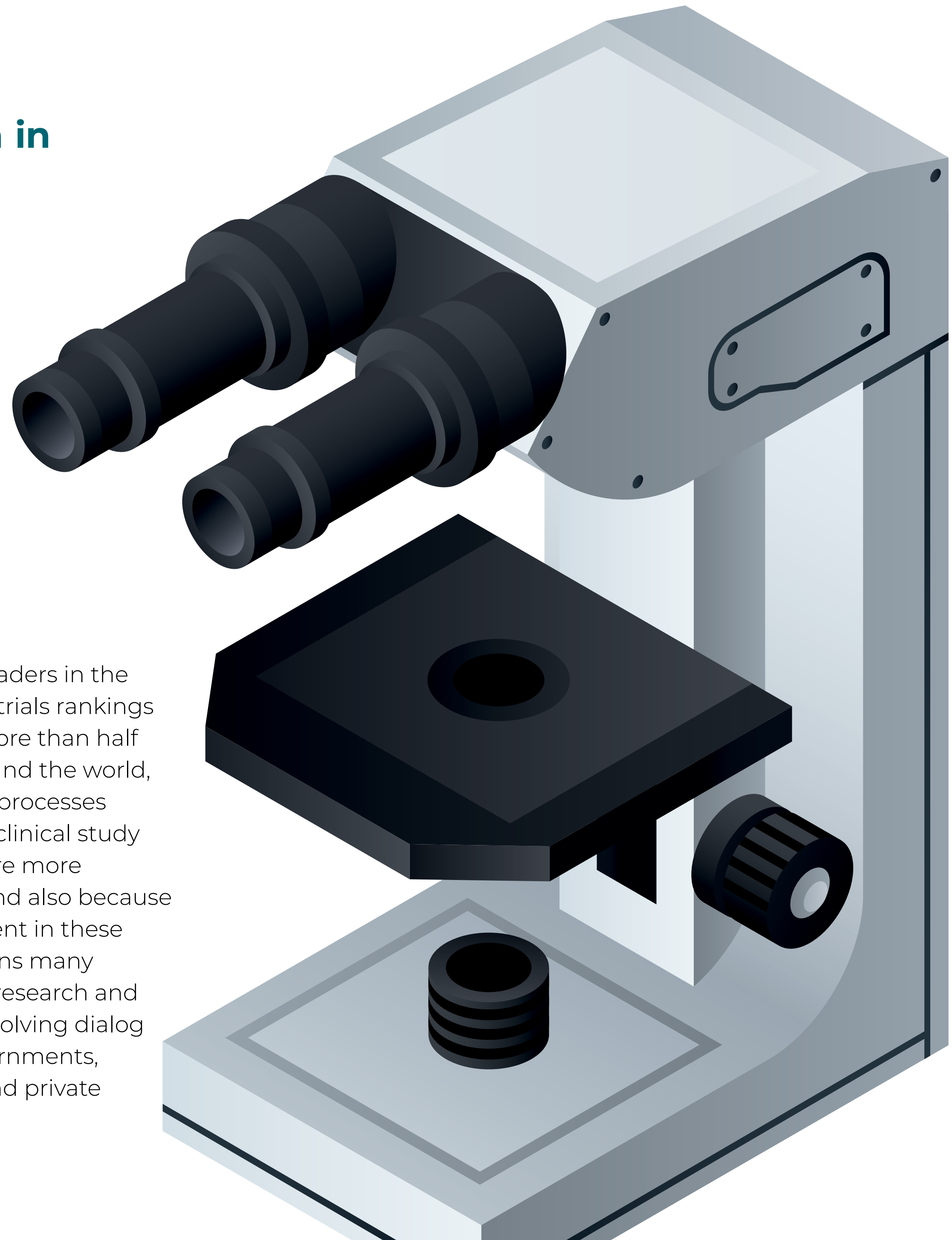
National rankings of participation in clinical studies

Rk	Country	Clinical Studies	%
1	United States	4,007	34.8
2	China	2,657	23.1
3	UK	782	6.8
4	Germany	746	6.5
5	France	741	6.4
6	Canada	736	6.4
7	Japan	732	6.4
8	Spain	691	6.0
9	South Korea	563	4.9
10	Australia	548	4.8
11	Italy	542	4.7
12	Belgium	448	3.9
13	Netherlands	431	3.7
14	Poland	402	3.5
15	Russia	365	3.2
16	Iran	348	3.0
17	India	307	2.7
18	Taiwan	297	2.6
19	Egypt	278	2.4
20	Denmark	267	2.3
21	Israel	261	2.3
22	Czech Republic	249	2.2
23	Hungary	249	2.2
24	**BRAZIL**	**245**	**2.1**
25	Turkey	221	1.9

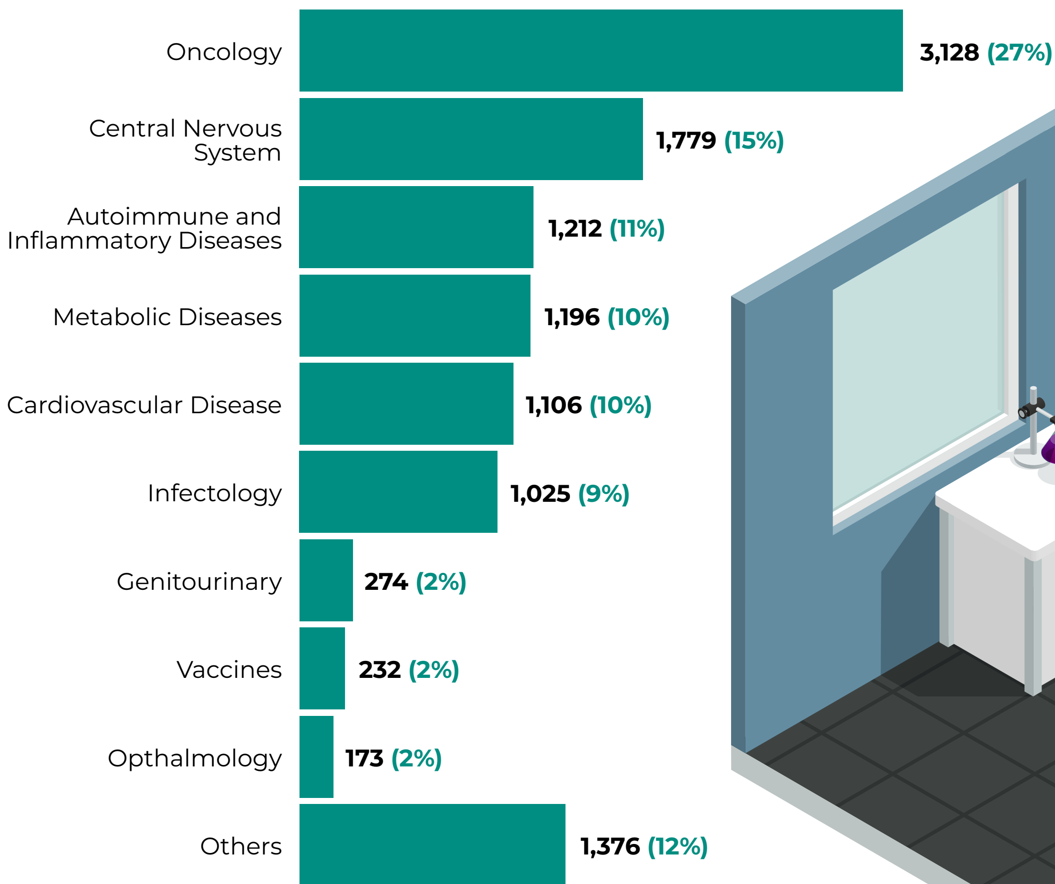
Fonte: Citeline (base global de estudos clínicos)

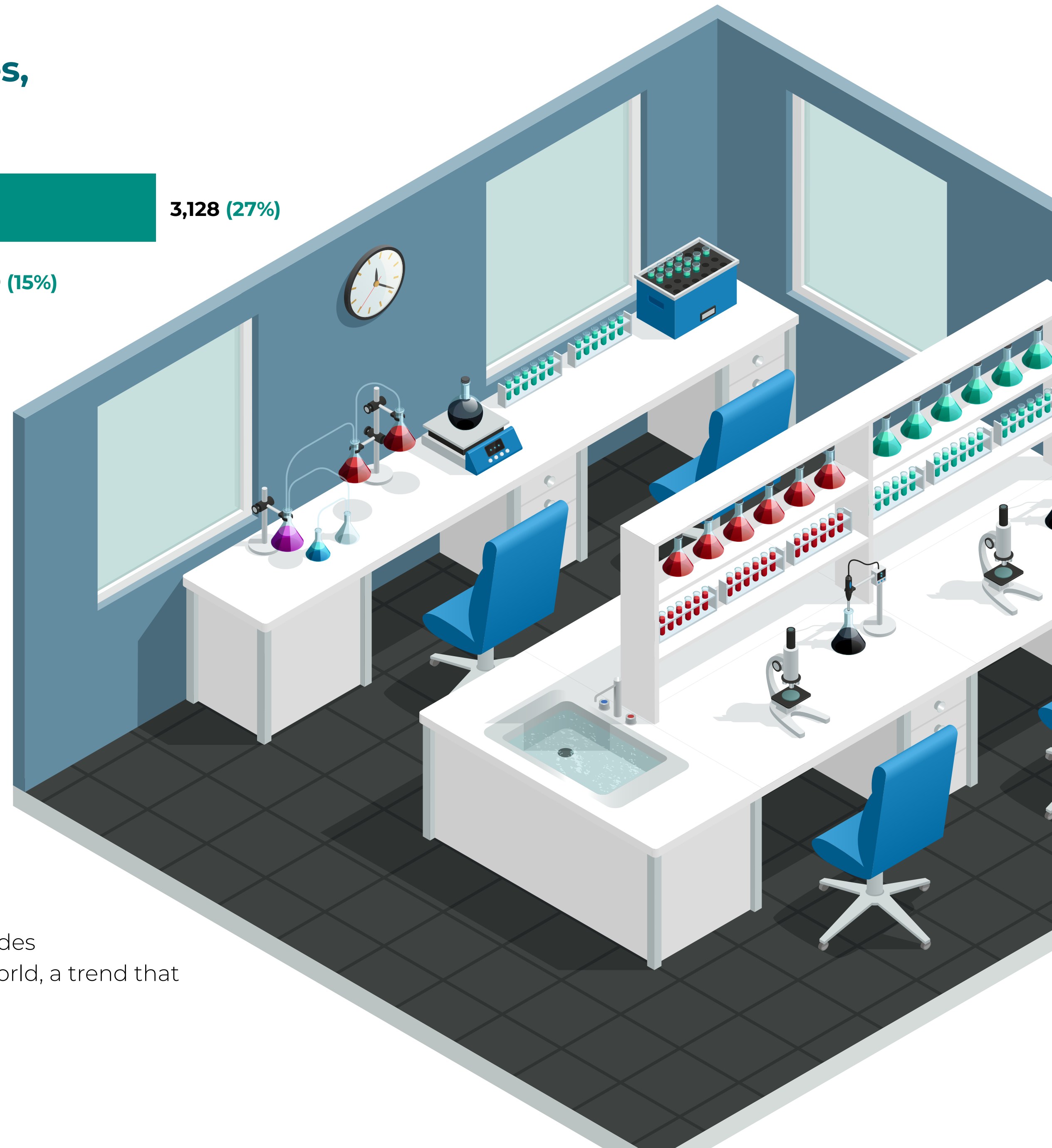
11,501 Clinical studies

The top two leaders in the global clinical trials rankings account for more than half of studies around the world, because their processes for approving clinical study applications are more expeditious, and also because the environment in these nations contains many incentives for research and innovation, involving dialog between governments, universities, and private initiative.



Global quantity of clinical studies, by therapeutic area

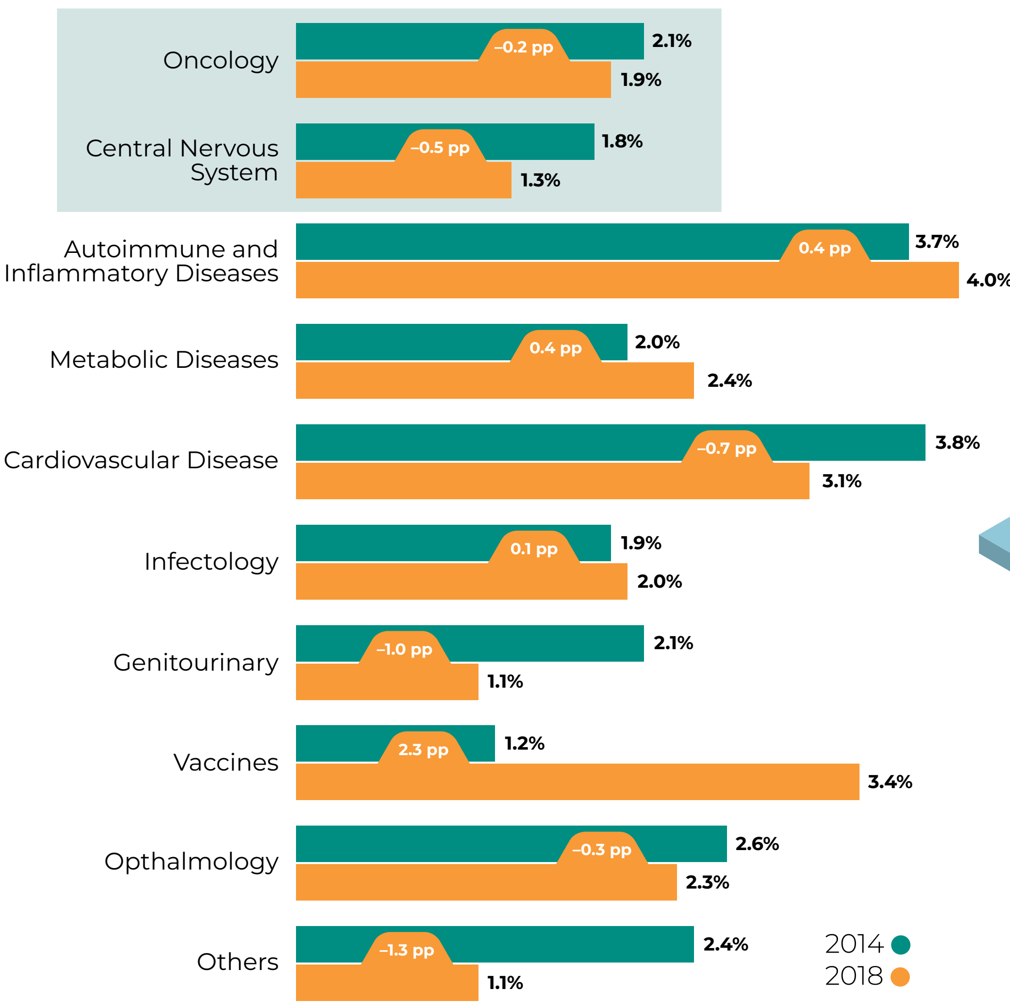




Oncology and the central nervous system, which includes degenerative diseases, lead clinical trials around the world, a trend that has been observed for some years in this sector.

Source: Citeline (base global de estudos clínicos)

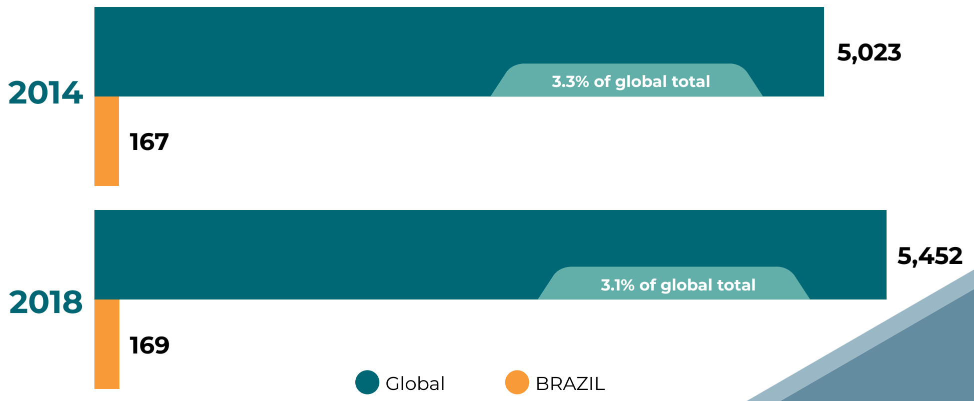
Brazilian participation in clinical studies, by therapeutic area



In most therapeutic areas surveyed, Brazil has been losing ground in terms of study participation.

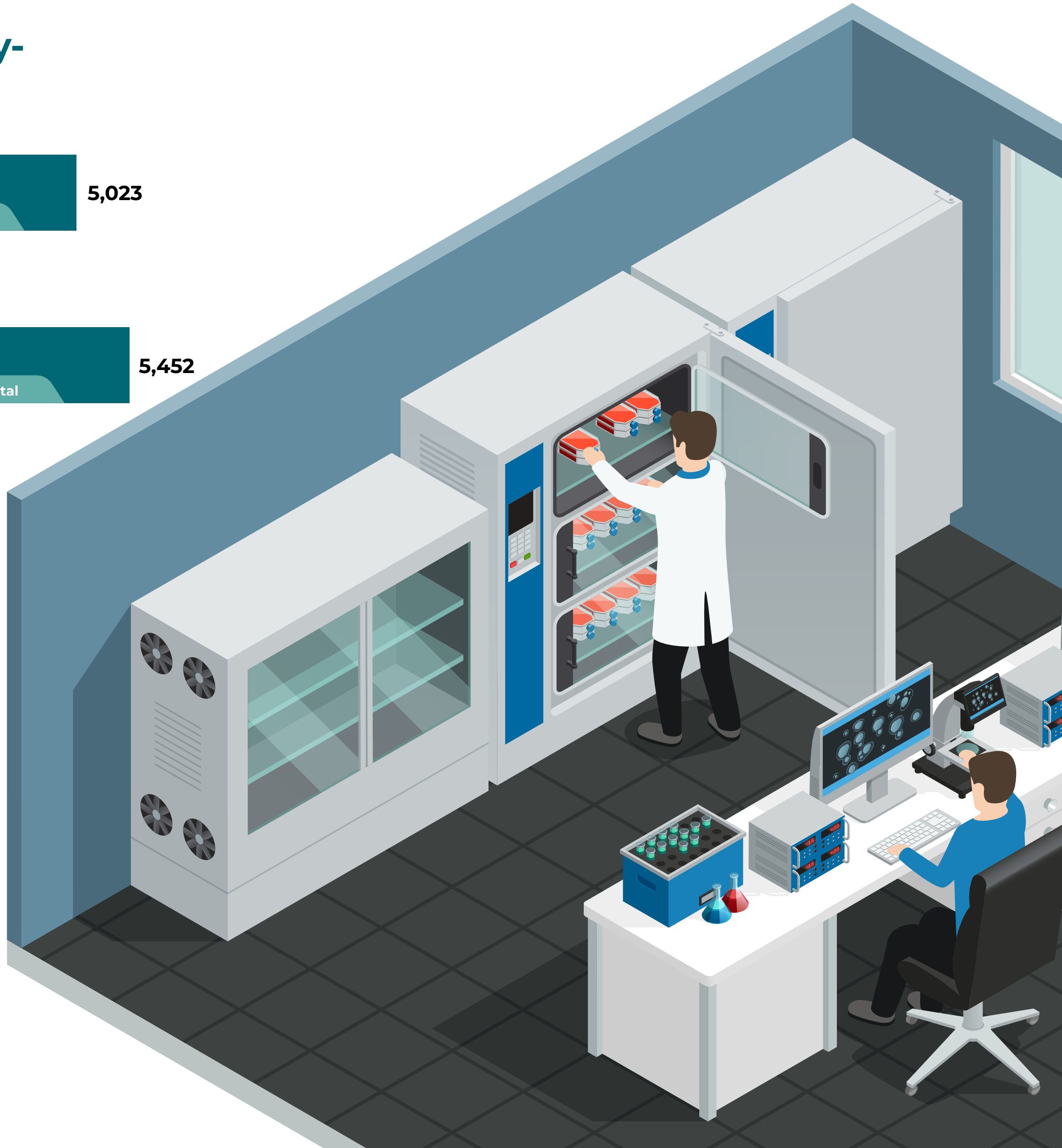
Source: Citeline (base global de estudos clínicos)

Brazilian Participation in Industry-Sponsored Clinical Studies

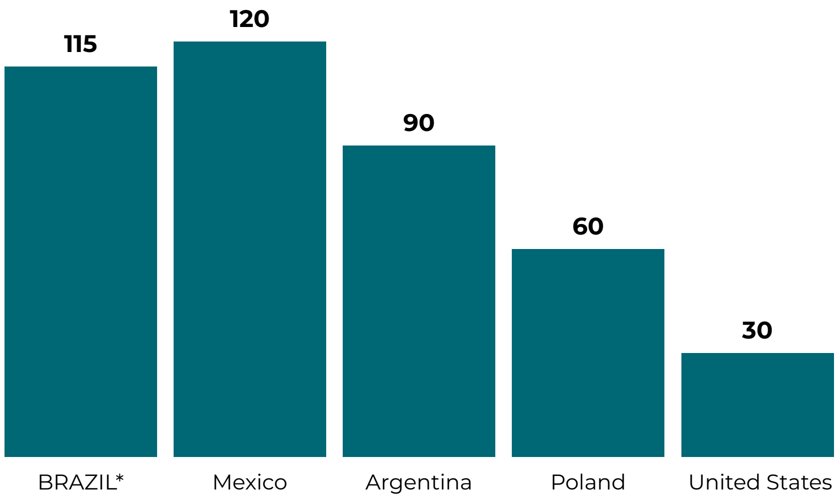


Source: Citeline (base global de estudos clínicos) – filtro adicional: Sponsor Type = "Industry" ou "Contract Research Organization"

Brazil's participation in studies sponsored by the pharmaceutical industry has dropped slightly in comparison with the global total.



Total analysis times

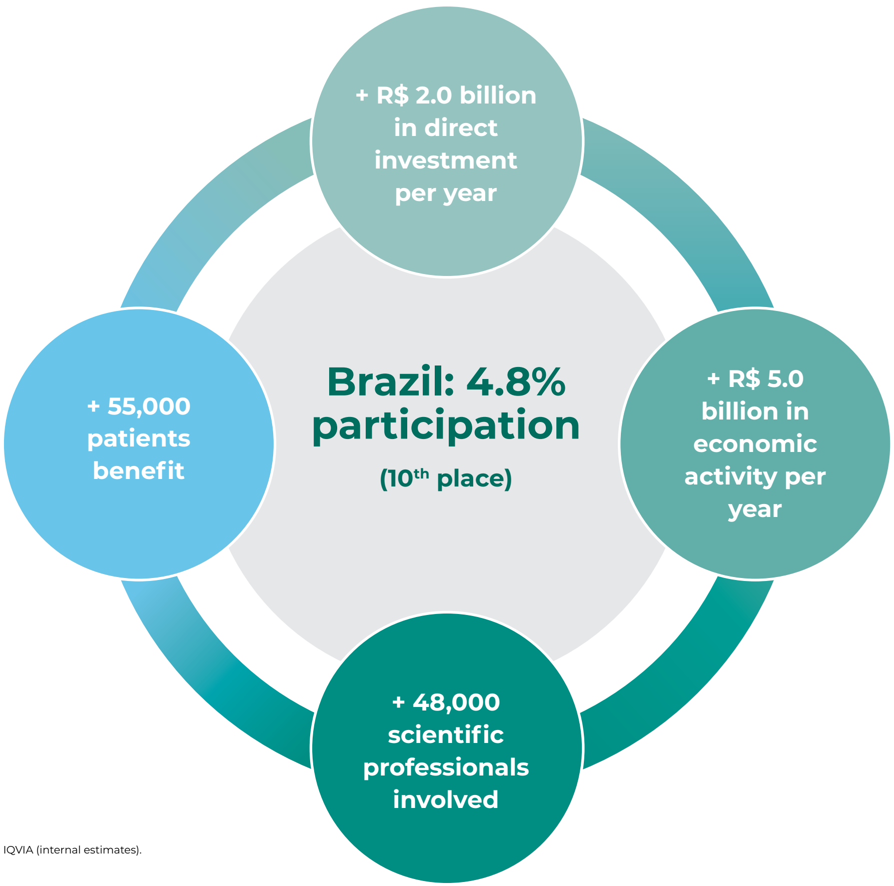


*Note: Considering the deadline for ethical assessment by the CEP Coordinator (10 days to accept documents and 30 days for analysis), followed by CONEP (15 days to accept documents and 60 days for analysis), concomitant with ANVISA regulation (90 days).

Sources: IQVIA (internal) and DRC 15/096 and Operating Instruction 01/2011.

In the United States, the country which leads with the most clinical studies, clinical study application times are almost four times shorter than in Brazil.

Benefits if Brazil expands its share of clinical studies



Source: IQVIA (internal estimates).

It is currently considered possible that Brazil could rise from 24th place to 10th place in the global ranking of clinical studies. If this occurred, the country could reap an estimated R$ 2 billion in investments every year and benefit over 55,000 patients, along with other improvements.

Benefits from direct investment in clinical trials

Global spending on clinical research in 2018: US$ 112 billion

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Number of studies in progress in 2018*: Approx. 55,000

= Annual spending of US$ 2.0 million per study

× Brazil cost index 44%

× 303 new studies per year in Brazil

= Additional annual spending in Brazil of US$ 543 million

Note (*): Studies currently underway at the beginning of 2019, not considering studies completed or suspended in 2018.

Sources: Citeline, EvaluatePharma, IFPMA, IQVIA (internal estimates).

Code of Conduct

The **Code of Conduct** was created to guide the relationship between pharmaceutical producers associated with INTERFARMA and healthcare professionals as an effective channel for self-regulation. This document was first launched in 2007, making INTERFARMA the first entity in Brazil within the pharmaceutical sector to have a Code of Conduct. The content is fully based on values such as ethics, trust, transparency, and integrity, placing the welfare of society and patients above all else.

In 2012, INTERFARMA signed an unprecedented commitment with the Federal Medical Council (CFM), the Brazilian Medical Association (AMB), and the Brazilian Society of Cardiology (SBC) to strengthen the values which should permanently govern the industry's relationship with medical providers. Another innovation was the creation of an Ethics Committee comprised not only of associate representatives, but also representatives without links to associated companies who are recognized for their knowledge and experience, allowing them to be fully independent in their decisions.

In 2016, the current version of the Code of Conduct was released, and commitments to the medical entities listed above were renewed. This new version provides two new and important channels: an oversight department charged with encouraging and implementing activities related to education, prevention, and monitoring of the industry's relations with all its audiences, and a conciliation department to resolve conflicts and create harmonious ethical understandings.

Guided by the need to continuously update the rules that govern practices in the pharmaceutical industry, in 2019 INTERFARMA again began to revise and update its Code of Conduct, reaffirming its commitment to actions and attitudes guided by strict ethical criteria.

Social and Environmental Responsibility

INTERFARMA and its associates are aware that their role goes beyond promoting and encouraging health innovation and research in Brazil. Their activities affect people's lives, the healthcare system, and the dynamics of the pharmaceutical market.

For this reason, since 2009 INTERFARMA has dedicated part of its actions to strengthening joint social activities in the sector.

In addition, INTERFARMA also added an ethical commitment by its member companies to an environment that transcends the marketing impact of their decisions, contributing to society through performance targeting responsibility and business sustainability.

One result of this effort is the Report on Social and Environmental Responsibility. This report is published every two years, and compiles all the actions put into practice by member companies in recent years. All the editions of this report can be found **here**.

Social responsibility, which includes aspects of ethics, transparency, and integrity, is only one pillar of the concept of sustainability; economic and environmental aspects also must be considered.

In order to develop projects and programs for this sector that can help us reach our economic, social, and environmental goals, INTERFARMA is creating a materiality grid. This tool prioritizes the material issues which are essential for external stakeholders as well as the organization, so that sector-wide projects can be carried out in the short, medium, and long term. Our materiality grid will soon be available **here**.

INTERFARMA

Associação da Indústria Farmacêutica de Pesquisa