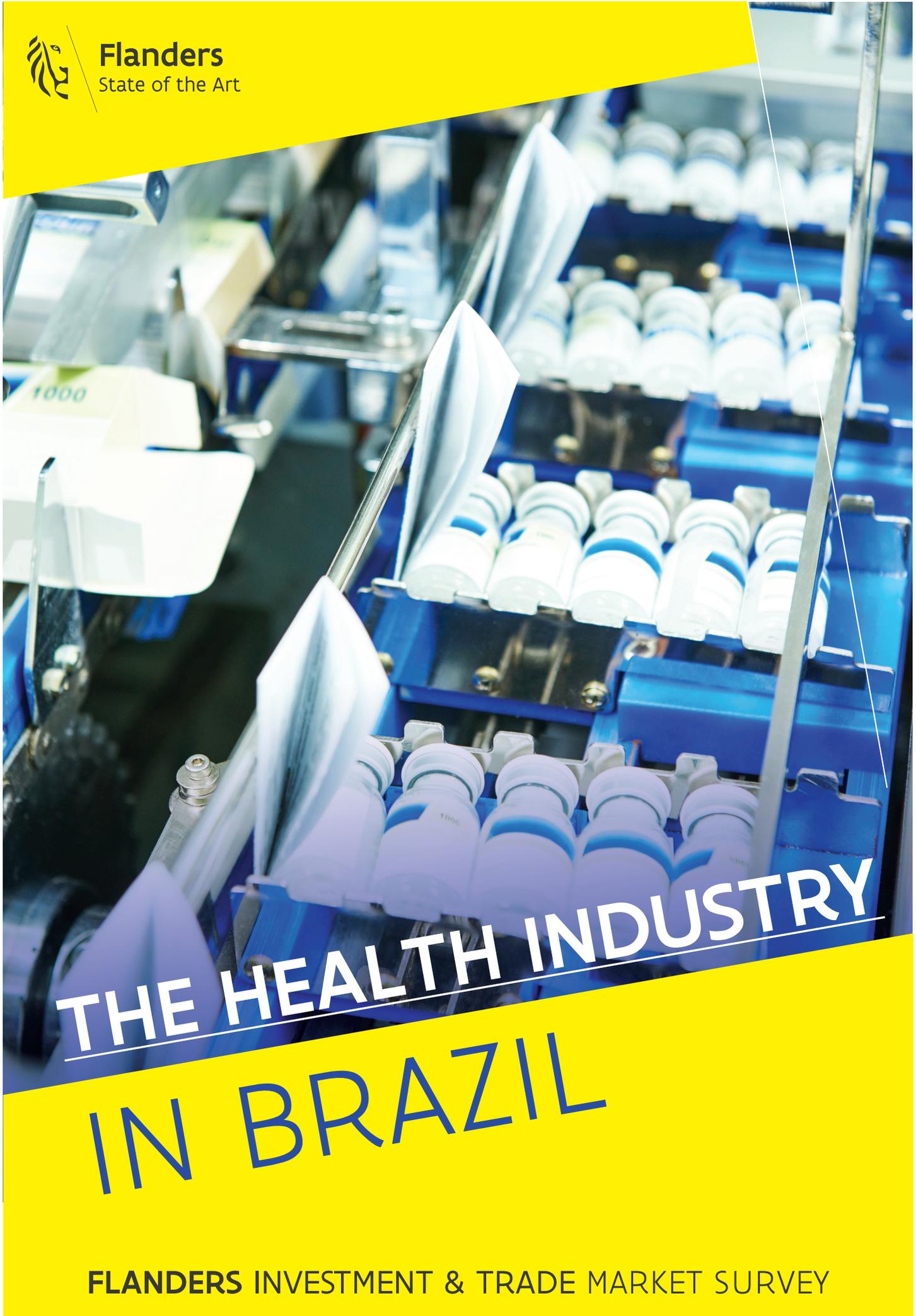




Flanders
State of the Art



THE HEALTH INDUSTRY IN BRAZIL

FLANDERS INVESTMENT & TRADE MARKET SURVEY



THE HEALTH INDUSTRY IN BRAZIL

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has been increasing their purchasing power over the last 15 years, many of the consumers with highest demand for health care, i.e. elderly with chronic diseases, are still faced with a constrained budget, which means that they will not choose products solely based on quality, but also on price.¹⁰ To analyze particularities consumer behavior is thus critical for companies who seek to establish their operations in the emerging Brazilian market (see consumer preferences).

It has been argued in the past that the Brazilian healthcare system was lacking proper funding. In order to accommodate the growing demand, significant investments are needed by both public and private actors. In 2014 the ratio of beds per 1000 inhabitants stood at 2,3 and the ratio of doctors per thousand inhabitants is just 2,17. As the demand for health services are set to increase, more investment is needed to supply the market. There have been policy implementations to address the need for investment. In March 2015 the government opened up the market by allowing foreign companies to invest in Brazilian hospitals. Moreover, in the budget for 2018, the Brazilian government has pledged to dedicate 130 billion BRL to the health sector, which is significantly higher than the 114 billion R\$ pledged to health care in the budget of 2017. The increased spending and liberalization of FDI should be seen as attempts to respond to the projected future demand for the health sector. There are currently around 6500 hospitals and 18 000 diagnostic laboratories operating in the Brazilian market, as well as about 4000 domestic manufacturing factories for medical devices. Some studies suggest that up to 80% of all medical pharma fine chemicals used in Brazil are imported from other markets, which highlights the attractiveness of the Brazilian health sector.¹¹

When reading this report, it is important to keep in mind that the Brazilian economy has changed dramatically over the past years. Despite the vast improvements which have occurred under the last decades, the image of Brazil has gone from being seen as a rising star in the world economy and member of the BRIC countries, to being considered one of the sick men, suffering under political turmoil. It is clear that the Brazilian economy has undergone some heavy storms. Figure 2 shows the evolution of the Brazilian Real against the Euro. From being a relatively strong currency, the Brazilian Real devaluated heavily against the Euro in 2014-2015 and after appreciating against the Euro in 2016 again, the Real now seems continue to depreciate back to the levels of 2015. Hence it should not be forgotten that, although Brazil has great growth potential, there is still a lot of uncertainty as to how the development of the Brazilian economy will manifest itself. In the following chapters of this report, different sub-sectors will be discussed more in detail to give an outline of the key facts and trends in the health sector important contact details of organizations and actors operating in the Brazilian health market. In addition, in the annex, an overview of the registration procedure for medicines can be found and the contact details of organizations who can assist in this process. It is the intention that this report will provide a thorough introduction to actors in the healthcare segment who want to expand their operations in Brazil.

¹⁰ Information available at https://www.mckinsey.com/~media/mckinsey/dotcom/client_service/pharma%20and%20medical%20products/pmp%20new/pdfs/emerging_markets_compendium_2012.ashx

¹¹ Information available at <http://globalhealthintelligence.com/ghi-analysis/2018-brazilian-health-market-outlook/>



Figure 2: Exchange rate development Euro/Brazilian Real, 2008-2018¹³

SOCIOECONOMIC STATISTICS

- Life expectancy of 75,72 years in 2017 (up 0,28% from 2015)
- The Brazilian population reached 207 660 000 (yearly increase rate 0,75%)

BRAZILIAN HEALTHCARE STATISTICS SEP

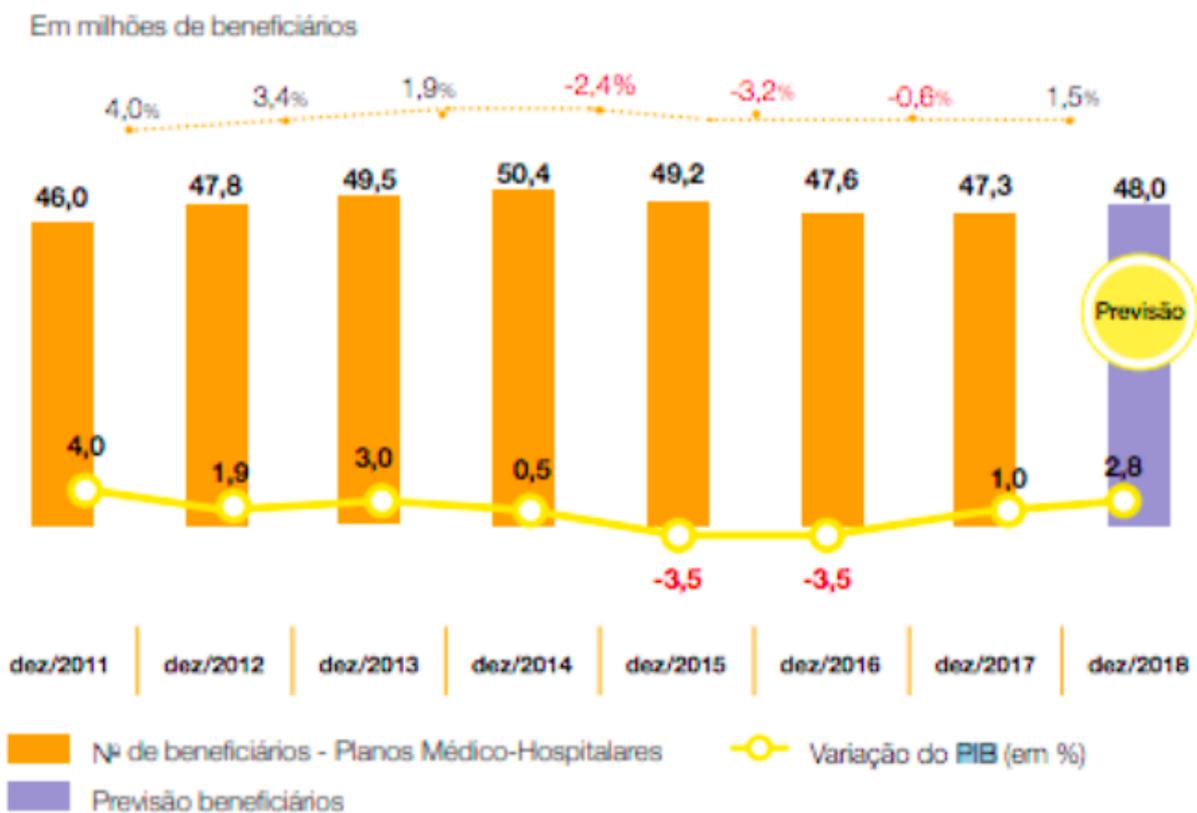
- 47,1 million people had health plans in March 2018¹⁴
- 22,9 million Brazilians have a health plan which include dental care (March 2018)
- 240.385 health establishments
- 6 678 hospitals in 2016 (70% private, 30% public)
- 2.3 beds per 1000 person (2014)
- 18.081 laboratories
- 451.000 active doctors
- 2,17 doctor per 1000 inhabitants
- 1.649.770 nursing professionals
- 7,4 nurses and midwives per 1000 inhabitants (2013)
- 3 million direct jobs
- 5 million indirect jobs
- Budget of the Ministry of Health 2018: R\$130,58 billion

¹³ Information available at: https://www.ecb.europa.eu/stats/policy_and_exchange_rates/euro_reference_exchange_rates/html/eurofxref-graph-brl.en.html

¹⁴ Information available at <http://www.ans.gov.br/perfil-do-setor/dados-gerais> SEP

bottlenecks remain, as the number of hospital beds is currently 2.3 beds per 1000 people, well below other developed countries. There are also significant discrepancies in regards to the prevalence of private health insurance in regards to geography.^[1] In the southeast and southern Brazilian states, more than 20% of the population have access to private health care. Figure 4 obtained from the national regulatory agency for private health insurance and plans (ANS¹⁹) visualizes the strong difference between states when it comes to private health care coverage. Although most of the players in this markets are relatively small, there has been some consolidation as several mergers and acquisition have taken place. In addition to this, several foreign companies have acquired Brazilian health insurances companies. For example, in 2015, Amil Participações and Intermedica were bought by a UnitedHealth Group and Bain Capital LLC.²⁰

Figure 3: Growth of GDP and private health plans (2011-2018)²¹

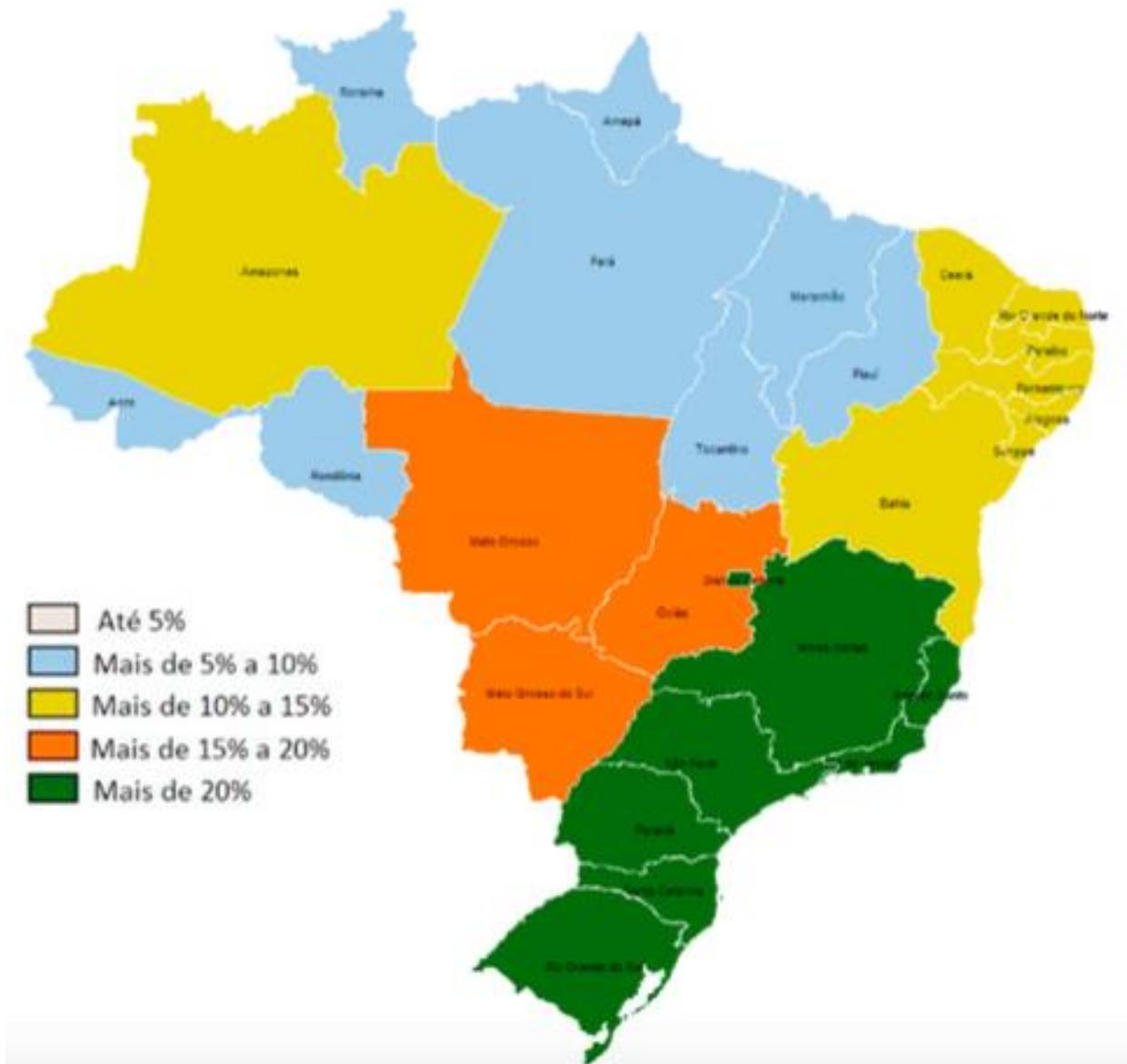


¹⁹ Agência Nacional da Saúde suplementar^[1]

²⁰ Information available at <http://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-2015-health-care-outlook-brazil.pdf>^[1]

²¹ Information available at http://www.abramge.com.br/porta1/files/cenario-saude/cenario_da_saude_ed11.pdf

Figure 4: Private health care coverage in Brazil (data for 2018)²²



²² Information available at <http://www.ans.gov.br/perfil-do-setor/dados-gerais> [1]

3. THE BRAZILIAN PHARMACEUTICAL INDUSTRY

3.1 THE MARKET SIZE AND ITS CHARACTERISTICS

Brazil is the biggest pharmaceutical market in Latin America. Growth in the Brazilian pharmaceutical market took off during the 1990's, due to the expansion and modernization of pharmaceutical manufacturing in Brazil. During this time, laboratories achieved important economies of scale and increased their productivity, which resulted in a tendency towards stability in the average price of medicines and greater competitiveness of Brazilian products. As an emerging economy with a population over 200 million (of whom over 100 million belongs to a middle class) the Brazilian pharmaceutical market is one of the world's most profitable. Since the introduction of the Brazilian patent law in 1996, the research-based pharmaceutical industry in the country has seen substantial investments in the improvement of operational infrastructure, expansion of its industrial parks, and R/D. These investments have paid off. In 2016, Brazil was ranked as the top seventh pharmaceutical market in the world and predictions are that Brazil may occupy the place as the fifth largest pharmaceutical market by 2020.²³ These estimates are supported by a projected compounded annual growth rate of 3,5%, which would grow the value of the Brazilian pharmaceutical market from US\$25,3 billion (2016) to a value of US\$30 billion by 2021.²⁴ To supply the market, the pharmaceutical industry in Brazil currently comprises about 550 companies, both national and multinationals, including laboratories, distributors, and importers. The leading domestic pharmaceutical companies on the Brazilian market are EMS, Hypermarcas, Medley, Europharma, and Aché. All major pharmaceutical MNEs are operating in the Brazilian market, of which the biggest firms are Pfizer, Novartis, Sanofi, and Roche.²⁵ These companies distribute their products to the Brazilian market through the approximately 60.000 pharmacists and drug stores that serve the public in general; 27 networks of drug stores, and 6.600 hospitals, clinics, and first aid posts. The medicines are available throughout all of Brazil, thanks to the logistic support of a network of 130 distributors. The Brazilian population has access to the same products which are available throughout the world. Today, the market offers 13.300 different packaging sizes. Introductions of new medicines are simultaneous with those introduced in Europe and the United States. The Brazilian industry produces 75% of the products demanded by the market, and when the product is not available, it is either imported by the manufacturers themselves or by intermediation of trade agreements.

Historically, the local Brazilian pharmaceutical companies have been reliant on imports of raw materials and active ingredients for generic drugs for its biotechnology sector. However, these companies are currently seeing new opportunities aided by government initiatives such as the Growth Acceleration Program and the Greater Brazil Plan were introduced to increase domestic production. The former is focused on modernizing public infrastructure, while the latter encourages local production of innovative

²³ Information available at <http://www.pgifarma.com.br/dev/wp-content/uploads/pdf/oportunidades-publicitarias.pdf>^[1]

²⁴ Information available at <http://globalhealthintelligence.com/ghi-analysis/2018-brazilian-health-market-outlook/>

²⁵ Information available at <https://www.prnewswire.com/news-releases/brazilian-pharmaceutical-market-outlook-2017-2027-300531307.html>

drugs and promotes public-private partnerships in the form of technology transfer to public pharma laboratories for the development of higher-priced biosimilars. In 2016, original drugs were responsible for the largest market share in Brazil. However, this is forecasted to change in the future as generic drugs are increasing their share of the market and are set to overtake original drugs, the largest market segment.²⁶ Sales volumes have expanded heavily in the past years for Brazil. The main driver of the Brazilian pharmaceutical market remains its growing middle-class and the changing demographics, with an aging population. However, negative factors on the market are the intensified competition between local producers and a higher penetration of generics, which are affecting the margins in the sector negatively. The falling margins can also be seen in a wider perspective of consumers are becoming more price sensitive, which indicates that MNEs needs to adopt specific strategies to capture the growing Brazilian demand for pharmaceuticals. For those who succeed to penetrate the market, there are several gains to be made in this big emerging market.

Figure 5: Largest pharmaceutical laboratories in Brazil (2017)²⁷

1 SANOFI	11 BAYER
2 NC FARMA	12 MSD
3 HYPERMARCAS	13 ABBOTT
4 NOVARTIS	14 TAKEDA PHARMA
5 ACHE	15 BIOLAB
6 ROCHE	16 LIBBS
7 GSK	17 BOEHRINGER INGELHEIM
8 EUROFARMA	18 UNIAO QUIMICA F N
9 J&J	19 ASTRAZENECA BRAZIL
10 PFIZER	20 MERCK KGaA

²⁶ Information available at <https://www.prnewswire.com/news-releases/brazilian-pharmaceutical-market-outlook-2017-2027-300531307.html>

²⁷ Information available at <https://pharmaboardroom.com/facts/top-20-pharma-companies-in-brazil-ranking-2017/>

3.2 ACCESS TO MEDICINE

The pharmaceutical market, particularly in developing countries, depends essentially on income. Class C, which corresponds to 53% of the Brazilian population, is nowadays responsible for 42% of the consumption. The top income classes namely classes A & B, are the traditional medicine consumers and are responsible for the other 48%. Still, approximately 55% of people cannot afford all the medicines they need (IBGE). Basic medicines are offered in public clinics, but this is not enough for everybody and demand many times outputs the medicine stocks. In a consumer study from 2017 Interfarma found that a majority (54%) stated that they rarely, or never, are able to find their prescribed medication.²⁸ The pharmaceutical industries face some obstacles such as the slowdown in economic growth, the burdensome economic regulations valid in Brazil (e.g. slow procedure for the recognition of new medicines). Another obstacle and one of the major hampering factors are price controls by the Brazilian government. With exception of the public services concessionaries (phone, electricity, sanitation, etc.), the pharmaceutical sector is the only one in Brazil to be submitted to an annual price readjustment.²⁹

Therapeutical Class - 2nd Level ³⁰								
RANKING				US\$				
MES	AC			Market Share (%)		Average Price (US\$)		
MTH	YTD	Code	Therapeutical Class	MTH	YTD	MTH	YTD	
TOTAL				100,00	100,00	6,32	5,80	
1	1	G03	HOR.SEX.PRO.EF.DES.SISTEM	6,97	6,84	5,32	5,04	
2	2	N02	ANALGESICOS	5,41	5,48	5,54	5,16	
3	3	J01	A/INFEC SIST/TRIMETOP	4,91	5,27	7,57	7,14	
5	4	M01	A/INFLAM/REUMAT	4,27	4,25	5,51	5,09	
4	5	C09	P.C/AC.SIST.REN-ANGIOTE.	4,39	4,13	13,85	12,36	
6	6	N05	PSICOLEPTICOS	3,64	3,59	5,21	4,75	
10	7	A11	VITAMINAS	3,20	3,49	6,19	5,51	
12	8	R05	A/TUSS/A/GRIPAS	2,90	3,36	6,82	5,84	
7	9	A02	ANTIAC/ANTIPLAT/ANTIULC	3,49	3,31	6,81	6,29	
8	10	N06	PSICOANALEPT EXC ANOREX	3,39	3,29	11,45	10,65	
9	11	S01	OFTALMOLOGICOS	3,27	3,10	5,93	5,50	
11	12	G04	UROLOGICOS	2,91	2,94	19,56	17,98	
13	13	C10	PREP.A-ATEROMA/LIPID-REG	2,53	2,47	19,17	18,00	

²⁸ Information available at <https://www.interfarma.org.br/public/files/biblioteca/pesqu-interfarma.pdf>

²⁹ Information available at <https://www.interfarma.org.br/noticias/1342>

³⁰ Information available at IMS Health - December-2015

15	14	R01	DESCONG/A/SEPT.NASAL	1,89	2,18	4,52	4,15
14	15	R03	A-ASMATICOS E COPD PROD	2,06	2,15	8,03	6,97
17	16	D07	CORTCOESTEROIDES TOPICOS	1,78	1,78	5,79	5,48
16	17	A10	FARMACOS PARA DIABETES	1,83	1,72	7,62	6,86
19	18	M03	RELAXANTES MUSCULARES	1,75	1,71	9,69	9,13
18	19	N03	A/CONVUL.INCL. A/EPILEP.	1,77	1,71	4,09	3,72
21	20	C07	BETABLOQUEANTES	1,58	1,61	4,63	4,32
20	21	D10	ANTIACNEICOS	1,59	1,60	7,17	6,91
22	22	A03	FAR.DES.FUN.GASTRO-INTES	1,54	1,54	4,38	4,02
27	23	H02	CORTICOSTEROIDES SIST	1,25	1,34	4,69	4,41
26	24	C08	ANTAGONISTAS DO CALCIO	1,28	1,32	8,09	7,44
23	25	A06	LAXANTES	1,34	1,31	5,10	4,62
28	26	G01	A/INFEC GIN	1,20	1,30	6,57	6,12
29	27	C04	TERAP VASC-CEREB E PERIFE	1,16	1,21	9,74	8,96
25	28	C05	ANTIVARICOSOS/ANTIHEMORR.	1,29	1,20	8,03	7,38
30	29	B01	TROMBOLITICOS	1,15	1,08	11,16	10,03
24	30	D02	EMOL/PROTETORES DERM	1,32	1,08	9,15	7,57

3.3 CONSUMER PREFERENCES

In 2017, Interfarma produced a study for consumer preferences for pharmaceutical drugs. What they found was that the decisive factor for most consumers (54%) was the price, followed by quality (34%). The implications of this are that most Brazilians will always prefer to find a generic drug, compared to a brand name, when it is available. According to the study, 74% of the Brazilian consumers have the habit of asking for cheaper alternatives at the counter of the pharmacies, which indicates that the overall majority of Brazilian consumer will prefer a cheaper over the prescribed drugs when applicable. This assumption is backed up by figures from the same study which indicates that when pharmacist indicate a different drug than prescribed, it will be a generic alternative in 89% of the cases. The takeaway from this study is: that even as the Brazilian middle class has been increasing their purchasing power over the last 15 years, many of the consumers with the highest demand for healthcare, i.e. elderly with chronic diseases, most consumers are still faced with a constrained budget, which means that they will be demonstrating elastic consumer preferences.³¹ To incorporate this consumer behavior in the business strategy is critical for any who seek to establish their operations in the emerging Brazilian market.

³¹ Information available at

https://www.mckinsey.com/~media/mckinsey/dotcom/client_service/pharma%20and%20medical%20products/pmp%20new/pdfs/emerging_markets_compendium_2012.ashx

4. GENERIC MEDICINES

A generic medicine is one that contains the same active substance in the same dose and pharmaceutical form and is administered in the same way and with the same therapeutic dosage as a reference drug. A generic can also be taken with the same degree of safety as the reference drug and can be totally interchangeable with the latter. As a consequence of the low R&D costs for producing generic drugs, they are much cheaper than reference equivalent. On an average, a generic drug will be sold at a 35% lower price than that of the brand drug.³² Through *the Brazilian Health Surveillance Agency* (ANVISA), the Ministry of Health, tests for bioequivalence between the generic version and reference drugs when the product is submitted by the manufacturers for quality testing. The pharmaceutical equivalence and bioequivalence tests needed for registering generic drugs can only be carried out by reference centers duly authorized by ANVISA. Generic drugs are identified with a large letter "G" in blue, printed over a yellow emblem, located in the lower part of the package. This is all set forth in Resolution RDC 47, of March 28th, 2001 (see legislation).

Currently, there are 120 manufacturers of generic drugs active in Brazil; together they are responsible for more than 3,8 thousand drug registrations at ANVISA. In 2017, the revenues from the Brazilian generic sector amounted to R\$7,4 billion (2 billion USD). During 2018, the sales of generics are projected to grow by 10%, thereby becoming the driving growth sector in the Brazilian pharmaceutical market. By all accounts, there is growth potential for generic drugs in Brazil. In 2017, generic drugs were responsible for 32,75% of all pharmaceutical sales. This number can be compared with countries like France and Germany and Spain, where the corresponding figures are 42%, 66% and 31%. Nine of the ten biggest pharmaceutical companies operating in the Brazilian market carry generic lines in their product portfolio. Since the liberation of the generic drugs, through passing the Generic Drug Act of 1999, companies have invested heavily in order to comply with the regulatory framework and safety control of generics. During the last ten years, this investment has amounted to over R\$1,5 billion in expansion and contraction of manufacturing plants.³³ For Brazilian consumers, generic alternatives are available for 95% of pharmaceutical treatments occupied by reference medication. These generic drugs cover treatments of circulatory system diseases, digestive tract/metabolism, central nervous system, hormonal and non-hormonal, dermatological anti-inflammatories, respiratory diseases, urinary/sexual system, ophthalmological, helminthic/parasitic, oncological and contraceptive illnesses, among others. Furthermore, the coming years will see the expiration of important patents for cardiology products, nervous system diseases and Parkinson's, which will soon have their generic versions available to consumers.³⁴ In Brazil, generics are becoming increasingly popular as consumers perceive generics as equivalent to the branded medication, but at a significantly lower price. This growing consciousness about generics beginning to penetrate the market, as prescriptions for generics increased by 65% between 2015 and 2018. This can be compared with the increase in the domestic production of generics,

³² Information available at <http://progenericos.org.br/dados-do-setor>

³³ Information available at <http://progenericos.org.br/mercado>

³⁴ Information available at <http://progenericos.org.br/acesso>

which grew by 130%, from 146 generic medication products, up to 336 (2014-2017).³⁵ However, there is still room for more growth, as generic drugs only make up 33% of drugs prescribed by physicians and little over 32% of all medication consumed. This suggests that the market for generic drugs will continue to be an attractive sector for future investment.

Top ten producers of generic drugs in terms of sales (2016)³⁶

- 1 EMS
- 2 Sanofi
- 3 Hypermarcas/ Hypera
- 4 Europharma
- 5 Novartis
- 6 Aché
- 7 Teuto Brasileiro
- 8 Nova Química
- 9 Prati-Donaduzzi
- 10 Merck

Facts about the generic drug sector in Brazil³⁷

- The Brazilian generic sector amounts to revenues of R\$7,4 billion (2017)
- 17 companies make up 84% of the market for generics drugs in Brazil
- 79% of consumers buy, or have bought generic drugs
- 33% of drugs prescribed by physicians are generic
- 32% of drugs consumed on the market are generic
- Generic drugs are on average 35% cheaper than reference drugs
- *The Brazilian Health Surveillance Agency (ANVISA)* is responsible for processing

4.1 PRODUCERS OF GENERIC PHARMACEUTICALS

ACHÉ GROUP

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<http://www.ache.com.br/en/who-we-are/about-ache/>

³⁵ Information available at http://portal.anvisa.gov.br/noticias/-/asset_publisher/FXrpx9qY7FbU/content/registro-de-medicamentos-genericos-faz-18-anos/219201?p_p_auth=RZ33XenP&inheritRedirect=false

³⁶ Information available at <https://exame.abril.com.br/negocios/as-10-farmaceuticas-que-mais-venderam-genericos-ate-marco/>

³⁷ Information available at <http://progenericos.org.br/dados-do-setor>

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Decisions are made in India, where the company HQ is.

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5. INTERNATIONAL TRADE OF HEALTH CARE PRODUCTS

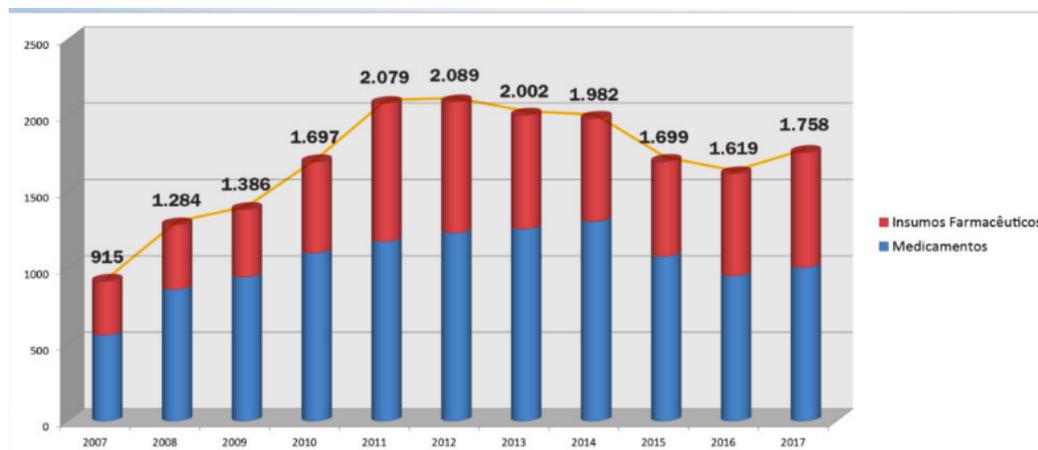
5.1 EXPORT^{38 39}

According to data from the Ministry of Foreign Trade (SECEX), there was an 8,5% increase in the export of Brazilian pharmaceutical products in 2017. The revenue increased to 1758 million USD, up from 1619 million USD in the previous year. From these numbers, medications stood for 1006 million USD and (up 5,6% from 2016) and pharmaceutical inputs and adjuvants stood for revenues of 752,5 million USD (up 5,6% from 2016). It is noteworthy to add that from the pharmaceutical inputs and adjuvants highly technological products, such as auxiliary substances represented 142 million USD (up 17,3% from 2016) and that bile acids and heparin amounted to 70,3 million USD respectively 31,4 million USD. Although the Brazilian export of pharmaceutical products has declined from its peak in 2012 (see figure 6), the increased revenue of 140 million USD in 2017 compared to 2016 shows that the Brazilian pharmaceutical manufacturing is becoming more competitive. The increased competitiveness in the Brazilian pharmaceutical industry can be credited to the efforts made through government policies to foster development within domestic producers. The main project to develop exports in the pharmaceutical sector is *Brazilian Pharma Solutions* (BPS), which is a collaboration mainly driven by *the Brazilian Association for Pharmaceuticals and Pharmaceutical Components* (ABIQUIFI) and *the Brazilian Agency for the Promotion of Export and Investments* (APEX-Brasil). The goal of the Brazilian Pharma Solutions is to support and grow revenues from exports in the pharmaceutical sector by attracting foreign investments and partnerships for product development. The target segments for BPS is biotechnology, medical equipment, pharmaceutical products, e-health, nutrition, and Active Pharmaceutical Inputs (APIs). To encourage development within the Brazilian pharmaceutical industry, BPS mobilized a multitude of actions to encourage higher productivity within the industry, by promoting innovation and improved regulatory frameworks. However, as the following section will demonstrate, Brazil is still predominately reliant on imports to supply the main segments of its healthcare market.

³⁸ Information available at http://abiquifi.org.br/mercado_/

³⁹ Information available at <http://www.inovacao.usp.br/biominas-abiquifi-e-apex-brasil-mapeiam-startups-para-conectar-com-investidores-internacionais/>

Figure 6: Brazilian exports of medications (blue) and pharmaceuticals inputs (red) (2007-2017)⁴⁰



5.2 IMPORTS

The Brazilian health market is largely dependent on imports to supply the needs of consumers. Despite the efforts of the Brazilian government to increase the self-sufficiency of the pharmaceutical industry, imports remain very important for the Brazilian industry when it comes to pharmaceutical fine chemicals. The same is true for medical devices, of which the majority are imported from the U.S. As a consequence, the trade balance is negative for the health industry and over time imports has been growing faster than exports.

For pharmaceutical products, the main driver for imported products is that the overall demand is growing faster than domestic investment. Throughout the last 10 years, the revenues in the pharmaceutical segments have increased by 79%, up to 16,1 billion USD (up from 8,4 billion USD in 2005). During the same time, imports have increased by 212% and now stand at a value of 5,9 billion USD. Furthermore, when looking at the domestic production of drugs, it is worth noting that it is also fundamentally dependent on imports of key Active Pharmaceutical Inputs (APIs) in order to maintain its production. Between 2005 and 2015 the imports of APIs grew by 129% to 2,5 billion USD. In total, the import of pharmaceutical fine chemicals in the Brazilian market went from 33% (2005) up to 52% (2015). Thus is there an overall growth in the pharmaceutical sector (imports of raw material production and even exports of medicines to other Latin American neighbour countries), of which imports are representing the fastest increase.

Part of the explanation for the high presence of the imported pharmaceutical fine chemicals and APIs (Active Pharmaceutical Ingredients) is that the legal, regulatory (international patents must be validated locally), as well as the complexity of Brazilian tax system cause a costly and risky structure which makes it unfavorable to invest in the Brazilian pharmaceutical fine chemical market as local producer.

⁴⁰ Information available at <http://abiquifi.org.br/mercado/>

6. DIGITAL HEALTH CARE

Even though the Health IT of Brazil sector has taken a discernible hit recently of the current economic environment, the long-term potential of IT companies in the healthcare industry is positive. The current Health IT market size is estimated between \$500 million and \$1 billion, with low levels of dedicated investment and minimal regulations in place. The Brazilian government has not signaled near-term plans to introduce a Health IT deployment strategy. However, as Brazil has the world's ninth largest GDP, a population, over 200 million and an increasing rate of over-60 populations, there is a huge growth potential for Health IT products and services.

Brazil scores as mid-ranking concerning ICT market development in international reports. However, as a consequence, there is little competition in the field which is an advantage for first movers. Without a political commitment to e-health, the estimates project a declaration of the growth rate from the average of 10.1% (2010 to 2015) to a growth rate of 7.6% (2016 to 2020). The fact that foreign investment into Brazil's health system will aid the country's pharmaceuticals and healthcare market development as Brazil's economy becomes more open to external funding. As one of the world's largest emerging markets, encouraging foreign investment could further improve Brazil as an attractive and profitable destination over the long-term. In December 2016, the Brazilian Health Ministry announced that they would invest R\$67 million in purchasing three supercomputers that will enable them to integrate all previous computer systems in order to share resources and unifying electronic medical records. This process will lead to the migration of all paper documents to electronic documentation within the public health care system (SUS).⁴⁷ To integrate all health records (EHR, RES, and EMR) the SUS will need to make an investment in new technology, like blockchain, in order to ensure accessibility and usage for medical staff, as well as the integrity of the patients.⁴⁸ Another area where e-health has a great potential for market penetration is the area of TeleHealth. Almost 92% of Brazilians had access to 3G mobile connections in mid-2015, particularly in the south and south-east regions (where coverage is close to 100%), but availability in the central-west, north and north-east regions of Brazil remains below 85%. In 2013 the digital development arm of regional company Telefónica, acquired Brazilian chronic care management company Axismed. Through this acquisition, Telefónica could provide Health Monitoring services that also have Outpatient Care and Self Care applications to 180,000 Axismed patients. The acquisition allowed Telefónica's Vivo unit to provide Health Monitoring services that also have Outpatient Care and Self Care applications to 180,000 Axismed patients by integrating Axismed into Vivo's infrastructure to contact and monitor patients using mobile apps, SMS and video streams to cover biometric data around glucose levels and blood pressure.⁴⁹ This is only one example of how e-health can use existing technological infrastructure in order to introduce new ways of providing health care services to the Brazilian population. According to the GSMA trade association, mobile health projects could benefit 45.7 million Brazilians and save the healthcare market \$14.1 billion in care costs. This

⁴⁷ Information available at <https://techinbrazil.com/e-health-market-in-brazil>

⁴⁸ Information available at <http://portalhospitaisbrasil.com.br/tecnologia-blockchain-pode-ajudar-a-vencer-barreiras-da-interoperabilidade-parte-1/>

⁴⁹ Information available at <https://techinbrazil.com/e-health-market-in-brazil>

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Local production - Approx. 8.000 US\$ - 14 months

* The product registration process by law should take 90 days but it is rarely completed in less than 6 months and in some cases it can take up to one year. The values do not include the ANVISA fees.

Source: Latini & Associadias

10.4 HOW TO REGISTER?

There are basically three ways to register your product:

1. Create your own Brazilian subsidiary

This approach involves the creation, registration of your subsidiary and products in order to import your product to Brazil. This option is usually slow and costly (medical staff hiring, etc...) and best justified for proven market and business with high investment capacity and international infrastructure.

2. Register with a local distributor/importer

The foreign company will need to find and negotiate with a local distributor knowing that it usually carries several competing brands and often focus on one region or state of the country. The importer/distributor has to register the products in his own name. Statistically speaking, this option results most of the time in failure within 24 months and becomes very costly.

3. Register with a third party/authorized representative recognized by ANVISA (master distributor)

This procedure is cost effective, time saving and money saving for foreign companies. A master distributor will register the products with Anvisa and sign a contract with the foreign company; the foreign company will have to pay a monthly fee to the master distributor for maintaining the registration active. It is also the foreign company that will give authorization to the master distributor for granting sales licenses to regional distributors.

Usually these companies offer the following services:

- Determination of product category;
- Definition of regulatory prerequisites;
- Evaluation of classification with definition of ANVISA;
- Identification of other requirement certifications such as INMETRO;
- Pre-audit for certification of good manufacturing practice for registration request;
- Relay for any commercial, regulatory and administrative operations (product tracking, regulation changes, import letters).

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