Ministry of Foreign Affairs

Brazil LSH Market Study Final

Commissioned by the Netherlands Enterprise Agency

>> *Sustainable. Agricultural. Innovative. International.*

Task Force +Health Care
Dutch platform for the life sciences & health sector

Netherlands Enterprise Agency

BRAZIL

Market Studies

Business Opportunities for the Dutch Life Sciences & Health sector in Brazil

EXECUTIVE SUMMARY

Brazil has the 9th largest economy in the world, with a GDP of US$ 1.868 trillion. The Brazilian government operates one of the largest universal health care systems to date, providing free services to over 210 million people. Brazil has the second largest pharmaceutical market in the world and is the leading medical device market in Latin America. The Brazilian healthcare market structure is on the verge of transformation as the coupled effect of a rapidly ageing population and new government catalyse change in healthcare demand and supply.

Like is the case in many countries around the globe, healthcare demands in Brazil are on the rise. The system is becoming increasingly pressured by a changing national demographic profile, marked by a growing elderly population and fast-increasing burden of non-communicable, chronic disease. At the same time, welfare retrenchments increase pressures on Brazil's public universal healthcare system: the Sistema Único de Saúde (SUS), which currently serves approximately 75% of the population. Austerity measures are expected to exacerbate inequality in access to health care across regions and income groups.

Together, these circumstances have led to the growth of Brazil's private healthcare market (66.7% of total health expenditure in 2016), which, in recent years, has seen large growth compared to public healthcare budgets. However, the private health sector has seen some turbulence, caused by the 2014-2016 Brazilian economic crisis. In this way, during periods of economic growth, Brazil's market share of private health plans increase, while during recessions the population shifts towards SUS.

In this market cycle, the Brazilian private health providers find themselves in an increasingly competitive environment. This has led to an increase in pilot projects and the adoption of cutting-edge innovative technologies. Likewise, in the public sector health providers under pressure from austerity measures are hungry for disruptive innovations that increase efficiencies whilst reduce costs. This demand provides opportunities for Dutch Smart Solutions within the strengths Hospital Design and Build, eHealth, Medical Devices & Supplies and Mobility & Vitality.

This report was commissioned by the Netherlands Enterprise Agency (RVO.nl) and is produced by the Task Force Health Care (TFHC) in cooperation with the Netherlands consulate-general in São Paulo and the Netherlands Business Support Office Porto Alegre. It aims to align the respective Life Sciences & Health sectors of the Netherlands and Brazil. In an effort to increase mutual understanding and inspire collaboration between these countries, this report provides useful insights into the Brazilian health system and sector and identifies potential areas of opportunity.

OUR APPROACH

TASK FORCE HEALTH CARE

IMPROVING HEALTHCARE TOGETHER

Established in 1996, Task Force Health Care (TFHC) is a public-private not-for-profit platform that represents and supports the Dutch Life Sciences & Health (LSH) sector. Our platform has a reach of 1200 LSH organisations in the Netherlands, with 130 dedicated and diverse partners. Our partners include government, industry, knowledge institutes, NGOs, and healthcare providers.

Our core mission is to improve healthcare and well-being internationally in a sustainable and demand-driven manner, with the use of Dutch expertise. We are currently actively engaged with over 20 countries to stimulate and facilitate relationships across government, knowledge institutes, and businesses. Our partners are active around the world and provide innovative and sustainable solutions relevant to both global and local healthcare challenges.

A PROGRAMMATIC APPROACH

- Bridging **Knowledge**, Aligning Interests and Identifying Opportunities
- Fostering and Strengthening **Networks**
- Facilitating **Dialogue** on Health Themes and Opportunities to Collaborate

OUR FOCUS

- Mutual Interests and Benefits
- Developing Sustainable and Long-Term Approaches
- Demand-Driven and Context Specific

CONTENT

OUR APPROACH 3

CONTENT 4

LIST OF FIGURES AND TABLES 6

THE BRAZILIAN HEALTH SECTOR 7

HOW DOES BRAZIL COMPARE? 8

1 ABOUT THIS REPORT 9

1.1 Background & Purpose 9
1.2 Methodology 9

2 MAPPING DUTCH INTEREST IN BRAZIL 10

2.1. Surveying the Dutch Health Sector 10

3 INTRODUCING BRAZIL 12

3.1 History & Geography 12
3.2 People and Demography 12
3.3 Economy 13
3.4 Trends in Brazil's Health Status and Interventions 13
3.5 Variance in Health Status and Outcomes 15

4 THE BRAZILIAN HEALTH SYSTEM 18

4.1 The Health System 18
4.2 Health Expenditure 20

5 MARKET STRUCTURE AND ACCESS 27

5.1. Market Structure, Size and Trends 27
5.2. Market Entry, Regulatory Affairs and Registration 30
5.3. Brazil's Life Sciences & Health Sector 25

5.4. TIPS FOR ORGANISATIONS EXPLORING THE BRAZILIAN HEALTHCARE MARKET 31

6 ALIGNING DUTCH STRENGTHS WITH BRAZILIAN OPPORTUNITIES 34

6.1. ANNUAL HEALTH PROGRAMME (PROGRAMAÇAO ANNUAL SAUDE PAS) 34
6.2. HOSPITAL DESIGN AND BUILD 34
6.3. EHEALTH 37
6.4. MEDICAL DEVICES & SUPPLIES 40
6.5. MOBILITY & VITALITY 43

REFERENCES 46

ANNEXES 51

ANNEX 1 – LIST OF INTERVIEWEES IN BRAZIL 51
ANNEX 2 – LIST OF INTERVIEWEES IN THE NETHERLANDS 54
ANNEX 3 – LIST OF RELEVANT EVENTS AND TRADE FAIRS 2019 55
ANNEX 4 – POPULATION PYRAMID 58
ANNEX 5 – LIST OF KEY BRAZILIAN MEDICAL INDUSTRY ASSOCIATIONS 59
ANNEX 6 – LIST OF IMPORTERS OF MEDICAL DEVICES & SUPPLIES 60
ANNEX 7 – LIST OF HOSPITALS IN BRAZIL 61
ANNEX 8 – ANVISA MEDICAL DEVICE REGISTRATION AND APPROVAL IN BRAZIL 63
ANNEX 9 – NATIONAL MEDICAL DEVICE MANUFACTURERS 64
ANNEX 10 – SELECTION OF BRAZILIAN ORGANISATIONS IN THE LSH SECTOR 65

LIST OF FIGURES AND TABLES

Figure 1: Respondents per Strength 10
Figure 2: Activity in the LSH sector in Brazil 10
Figure 3: Do you see growth potential in Brazil? 11
Figure 4: Do you experience market barriers in Brazil? 11
Figure 5: Population density and population pyramid (2050) in Brazil 12
Figure 6: Top 10 Causes of Death in 2017 and Percent Change, 2007-2017, all ages, number 14
Figure 7: Map showing HCC distribution in Brazil 16
Figure 8: Organisation of the Health System in Brazil 19
Figure 9: Geographic locations of Brazilian hospitals with pharmacists 23
Figure 10: Concentration of hospitals by state 23
Figure 11: Medtech segmentation in the Brazilian market 27
Figure 12: Projection of the number of Health Services provided by (supplementary) medical schemes by age in Brazil (2013- 2030) 44

Table 1: Geographic, Demographic, Economic, Business and Health context compared between countries. 8
Table 2: Income groups in Brazil 13
Table 3: Economic indicators for Brazil *indicates projected numbers 13
Table 4: Public (SUS) versus Supplementary Healthcare 15
Table 5: Health Professionals in Brazil 25
Table 6: Typical segmentation of the expenditure of ANAHP members 29
Table 7: Hospital projects in Brazil 35
Table 8: Import share of medical products in Brazil 41

TOP OPPORTUNITIES IN BRAZIL

Growth

Brazil's private healthcare market is competitive, but has seen explosive growth over recent years, creating a lively market environment for Dutch companies to explore. Read more about the Brazilian economy in **Section 3.3**.

Innovative Private Hospitals

Incentivised by increased competition, the private sector has become the main driver and adopter of innovation in healthcare in Brazil. Read more about trends in **Section 6.1**.

Telemedicine/Health

The use of telemedicine solutions in both urban and rural areas is a fast-growing trend in Brazil. A large project is the Tele-health network, made-up of 57 university hospitals. In homecare, Brazilian industry also see opportunities in solutions which allow Brazil's population to age and heal at home.

Growth of Pharma

Changing demographics and an increase in NCDs has driven growth in Brazil's pharma industry. The pharmaceutical market in Brazil is predicted to rise from $25.5 billion in 2016 to $29.9 billion in 2021— a growth rate of 3.5%

Healthy Ageing

As the number of people aged 60 years and older continues to rise, the demands of this 6.5 million person population continue to grow in terms of their healthcare needs. Brazil's government and private sector are thus investing in innovations that assist seniors achieve healthy, independent lives. Read about trends in Mobility and Vitality in **Section 6.2**.

Electronic Health Record

The Ministry of Health announced potential investments of up to US$ 450 million in the digitization of public basic care units of the SUS. Private hospitals are also investing in technology and several new hospitals are formalizing their progress by obtaining international certificates for data management and the reduction in paper use.

Thriving Industry

Brazil has a competent local industry which continues to succeed in supplying medical devices and pharmaceuticals to the Brazilian population.

Chronic Disease Control

Brazil's growing challenge with chronic diseases (NCDs) presents enormous opportunities for Dutch Smart health solutions. The Brazilian Ministry of Health is eager to find solutions relating to behaviour change, such as reducing tobacco usage, alcohol consumption, increasing activity and reducing salt intake.

HOW DOES BRAZIL COMPARE?

Table 1: Geographic, Demographic, Economic, Business and Health context compared between countries. (BMI, 2017)

	Brazil	Chile	Colombia	Mexico	Netherlands
Land Size (km^2)	8 515 767 049	756 950	1 109 500	1 972 550	33 690
Population (2019)	212 000 000	18 00 0000	49 853 630	132 343 600	17 109 189
expected annual growth rate (%)	0.8	1.4	1.5	1.1	0.6
65 years and older (%)	9.6	12.2	9.1	7.6	19
expected in 2050 (%)	22.7	24.9	21	17	25
Maternal Mortality Rate (100 000 births)	58	17	71	38	7
Life Expectancy at Birth	76	80	75	77	82
Life Expectancy Global Rank (2017)	125	51	95	92	25
Economic Context					
GDP (in current US$) (2017)	1 868 626 09	298 231 14	330 227 87	1 223 808 89	826.2
expected growth (2020)	1.1	4	2.7	2	2.09
GDP per capita (US$)	8 920 8	15 923 4	6 651 3	9 698 1	52 978 4
annual growth rate (%)	0.3	2.6	1.1	0.9	2.54
(Health) Business Context					
Ease of Doing Business Rank	109	56	65	54	36
Logistics Index	56	34	58	51	6
Pharmaceutical Market (bln US$-2016)	20 547	3 520	3 140	16 190	6 000
Expected growth 2016-2021 (%)	8.6	8.6	6.0	5.1	0-0.5
Medical Device Market (mln US$ – 2016)	5 500 0	800 1	1 197 1	4 655 3	3 486 1
Expected growth 2016-2021 (%)	5.2	9.0	8.5	8.1	5.0
Medical Device Import from the Netherlands 000s US$	24 329	13 670	9 787	n/a	-
Ranking	17th	12th	16th	n/a	-
Medical Device Export to the Netherlands 000s US$ (%)	n/a	737	n/a	69 879	-
Ranking	n/a	5th	n/a	4	-
Health Context					
Health Expenditure (bln US$)	155.3	2.8	21.1	64.2	81.7
Health Expenditure as % of GDP	11.77	8.53	7.4	6.1	10.69
Health Expenditure per Capita (US$)	1 015 93	1 190 55	358	461 79	4 746 01
Public Health Share of HE	46%	51.5%	75.5	52.1	86.7
Type of Health System	Social Health Insurance and supplementary private insurance	Social Health Insurance	Social Health Insurance	Social Health Insurance	Social Health Insurance
Top three causes of death 1.	Ischemic heart disease	Ischemic heart disease	Ischemic heart disease	Ischemic heart disease	Ischemic heart disease
2.	Stroke	Stroke	Stroke	Chronic kidney disease	Alzheimer's Disease
3.	Lower respiratory infect	Alzheimer's disease	Interpersonal violence	Diabetes	Lung cancer

1 ABOUT THIS REPORT

1.1 Background & Purpose

Aligning the interests & strengths of the Dutch Life Sciences & Health (LSH) sector with the health sector dynamics and interests of Brazil

This market report was commissioned by the Netherlands Enterprise Agency (RVO) in The Netherlands. It is delivered by Task Force Health Care (TFHC), in close cooperation with the Netherlands Consulate general in São Paulo and the Economic Diplomacy Network in Brazil. It provides an analysis of the Brazilian healthcare sector, identifies business opportunities for organisations active in the Dutch Life Sciences and Health sector, and makes recommendations for organisations in The Netherlands that are interested in the Brazilian market. The main objective is to get a better understanding and gain insights into the Brazilian healthcare market to raise awareness and increase interest among Dutch health organisations.

1.2 Methodology

Step 1: Identification & mapping of Dutch interest and perceived barriers in the Brazilian LSH sector

In order to obtain a better understanding of the interests of the Dutch Life Sciences & Health sector in Brazil, historical data, Dutch representation in Brazil, and results of a survey and interviews were referenced. The survey was sent out to over 1,200 Dutch actors within the Life Sciences & Health sector to share their activities, ambitions, and perceived opportunities and barriers in relation to Brazil. Data was classified into type of organisation, strength (e.g. Medical Devices or eHealth), current or past activity in Brazil, and perception of Brazil in terms of market growth. Section 2 shows the data out of the survey and interviews. This data has furthermore been used in Section 6 to align challenges and opportunities in Brazil with Dutch expertise and solutions.

Step 2: Desk Research

In order to obtain a better understanding of the Brazilian health sector and its dynamics, desktop research was conducted. A range of documentation was studied, including government documents, academic articles, and reports from various organisations and federations. The information gathered was analysed in order to provide a thorough overview of the Brazilian sector. This desk research was then used in the design of the programme of the factfinding and structured interviews in 'Step 3'.

Step 3: Fact finding visit to Brazil

An important element of the study was the fact-finding visit, to São Paulo and Porto Alegre, whereby a delegation from TFHC, accompanied by representatives of The Netherlands Consulate General in São Paulo and the Netherlands Business Support Office Porto Alegre, gained insights from key stakeholders in the Brazilian health sector. The fact-finding visit included meetings and discussions with representatives from the public and private sector, operating at the national, regional and local level. Concrete examples in this market study reflect activities in these two states. Other Brazilian state were not visited or interviewed for this study. The list of interviewees located in Brazil is presented in Annex 1, whilst the list of interviewees based in the Netherlands is presented in Annex 2.

Step 4: Finalising Report

The Desk Research and Fact finding visit to Brazil enabled the collection of information with regards to additional sources and provided valuable insights into the sector. The data from these interviews allowed for cross-checking of data that had previously been obtained, resulting in the development of an objective and realistic report.

2 MAPPING DUTCH INTEREST IN BRAZIL

2.1. Surveying the Dutch Life Science & Health Sector

In order to gain an understanding of the degree to which the Dutch are interested in the Brazilian market, an online survey was sent out to 1 200 unique Life Sciences & Health organisations and companies in the Netherlands. The survey was also shared with multiple networks and cluster organisations in order to extend its reach. Combined data from the survey, Task Force Health Care, and the Netherlands representation in Brazil yielded 63 unique respondent organisations with activity and interest in Brazil. Figures 1- 4 below show the current data available by 'Strength', 'Activity in Brazil', 'Potential Growth Market' and 'Perceived Market Barriers'.

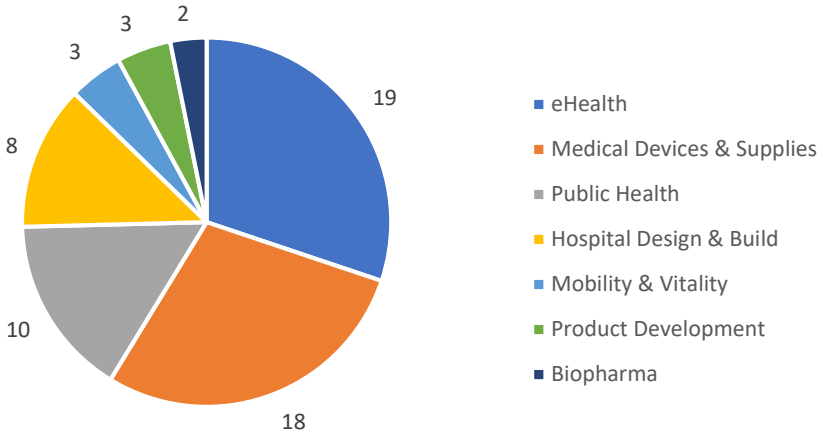


Figure 1: Respondents per Strength

Which Dutch strengths are active in Brazil or have been in the past? In terms of export, research, projects or otherwise.

36 of the 63 respondents who were active in Brazil, were medium-sized companies. The largest group consists of eHealth companies which represent a diverse mix of solutions mainly aimed at big data, analytics and telemedicine. This is followed by Medical Devices with both sophisticated devices and disposables, Hospital Build companies, mainly active in building specific parts (no architects) and Public Health which represent mainly universities/UMCs.

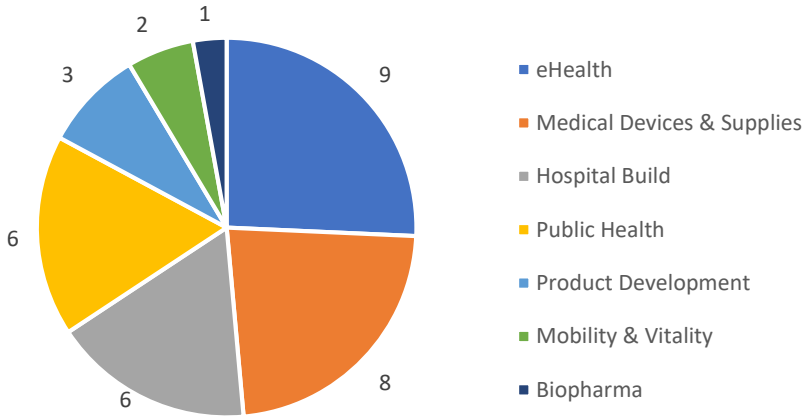


Figure 2: Activity in the LSH sector in Brazil

Which strengths see the most potential in Brazil?

53 of 63 respondents see business opportunities to grow their activity in Brazil. eHealth and Medical Device companies are most optimistic, highlighting their propositions to make SUS more efficient and link-up with Brazil's large and vibrant private hospitals. Hospital Build and Public Health companies see most potential in Brazil's Ageing Society and respective capacity problems in both curative and elderly care.

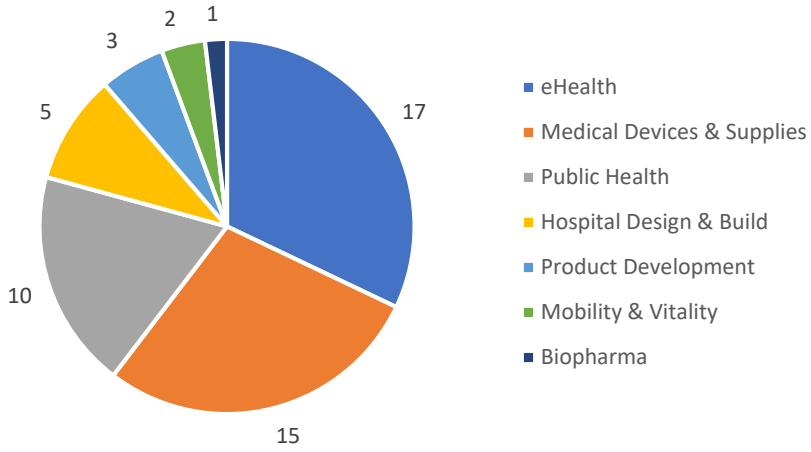


Figure 3: Do you see growth potential in Brazil?

Do you experience any market barriers in Brazil? *Experienced or anticipated*

19 of 63 respondents foresee or have experienced market barriers in Brazil. The most noted barriers are problems with achieving reimbursement for innovative devices and market acceptation by Brazilian decisionmakers. Other barriers include, bureaucracy, intensive regulation and registration process and connecting with the right decisionmakers and business partners.

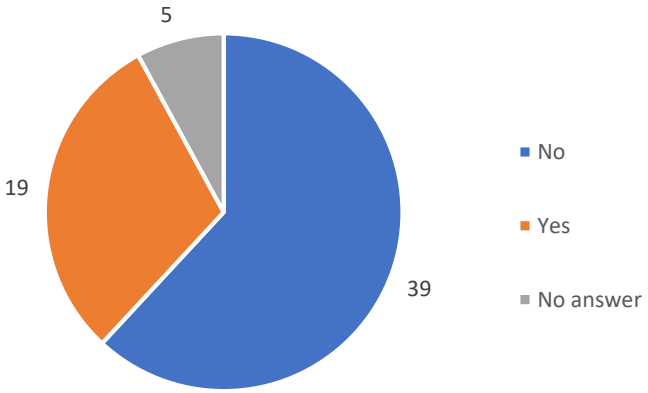


Figure 4: Do you experience market barriers in Brazil?

3 INTRODUCING BRAZIL

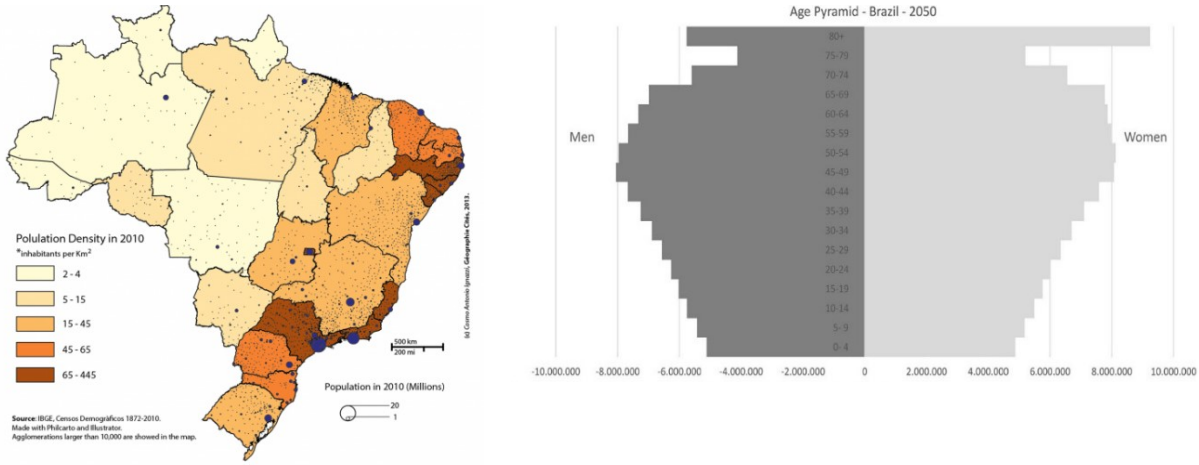
3.1 History & Geography

The 1988 Brazilian Constitution initiated the decentralization of health services in the country. This eventually culminated in the creation of the SUS (Unified Health System), distributing responsibility of the majority health services, delivery and spending to municipalities. Since SUS was established, Brazil has seen an increase in life expectancy from around 64.4 years in the 1990s to 75.3 years in 2017 - although this is still lower than countries such as Argentina, Ecuador and Chile. However, three decades into decentralization and there remains huge social and economic variation across Brazilian municipalities, impacting their ability to deliver quality health care services to their respective populations.

3.2 People and Demography

Brazil has a population of approximately 212 million people. The population is relatively young with 7.8% of the population aged 65 years or older (United Nations, 2017). The Brazilian population is expected to grow modestly with a compound annual growth rate (CAGR) between 0.4-0.6% between 2019-2030 which would amount to 223 million people by 2030 (United Nations, 2017). Brazil only recently became an "Ageing" society as the number of people aged 65 years and older tripled to 18.3 million between 1988 – 2018. This growth trend is forecasted to continue to 49 million in 2048 (BMI, 2017) (see Annex 4 for more population pyramids). Brazil is a highly urbanised country, with over 80% of the population living in urban districts.

Figure 5 Population density and population pyramid (2050) in Brazil (IBGE, 2019) (United Nations, 2017) (Noronha, 2018)



Brazil is a country with a highly unequal distribution of wealth, a fact that is supported by its Gini coefficient of 53.33. This high rate of inequality means that different segments of the population have widely different budgets in terms of their ability to purchase supplementary or private health services. There are several different concepts of social classes in Brazil, but the one that is most widely adopted by the market classifies society in letters from A to E. These are the classes as defined by the Brazilian Institute for Geography and Statistics, known as Instituto Brasileiro de Geografia e Estatística or simply IBGE in Portuguese. IBGE defines the income based social classes in multiples of the national minimum salary which is currently R$ 998 (Nes, 2016) (Trading Economics, 2019). Many of these classes, and especially the poorer once, are primarily dependent on the Sistema Único de Saúde (SUS) as their main provider of health services (Section 4). The five classes are displayed in table 2.

Table 2 Income groups in Brazil (Nes, 2016) (ABEP, 2016)

Classification	Proportion of Population	Household Gross Monthly Income
Class A	2.9%	Above R$ 15,760
Class B	22.3%	Above R$ 7,880
Class C	47.8%	Above R$ 3,152
Class D	14.1%	Above R$ 1,576
Class E	12.5%	Below R$ 1,576

3.3 Economy

Brazil is an upper middle income country and ranks and has the 9th largest economy in the world. In 2017 the Brazilian economy was composed of 72.7% service sector, 20.7% industry, and 6.6% agriculture (CIA, 2019). In terms of the labour force, 58.5% work in the service sector, 32.1% work in industry, whilst 9.4% work in agriculture (CIA, 2019). The Brazilian economy has been going through a prolonged period of recession. The countries growth rate has been slowing for the past 2 decades with the annual growth rate dropping from 4.5% between 2006-2010 to 2.1% between 2011-2014. In 2018 the Brazilian economy is recovering slowly and grew by 1.1%. Key economic indicators are displayed in table 3.

Text Box 1: The Brazilian Population's Relatively Low Purchasing Power

Although Brazil ranks as the world's 9th biggest economy, its GDP in terms of purchasing power parity (PPP) is more typical of an emerging market. In 2018 Brazil's GDP per capita (purchasing power parity) was 16.15 thousand US$. This is much lower than the purchasing power in regional neighbours Chile (25.98 thousand) and Mexico (20.6 thousand). To illustrate, PPP GDP per capita comparison: the United States (62.61 thousand), the United Kingdom (45.7 thousand), or the Netherlands (56.38 thousand). (IMF, 2018).

Find out more information at IMF's World Economic Outlook

*Table 3: Economic indicators for Brazil *indicates projected numbers (IMF, 2019)*

	Netherlands	Brazil					
	2018	2016	2017	2018*	2019*	2020*	2023*
GDP PPP (bn US$)	972	3160	3250	3370	3500	3660	4160
real growth (%)	2.8	-3.3	1.1	2.1	2.1	2.5	2.2
per capita PPP (000)	56.57	15.41	15.74	16.15	16.66	17.32	19.32
Inflation rate (%)	1.4	8.7	3.4	3.7	3.6	4.1	4
Unemployment (%)	3.9	11.3	12.8	12.3	11.4	10.2	9.3
Government net lending/borrowing (% of GDP)	1.1	-9	-7.9	-6.8	-7.3	-7	-6.2
Government gross debt (% of GDP)	54.4	78.3	84.1	87.9	90.4	92.4	96.5

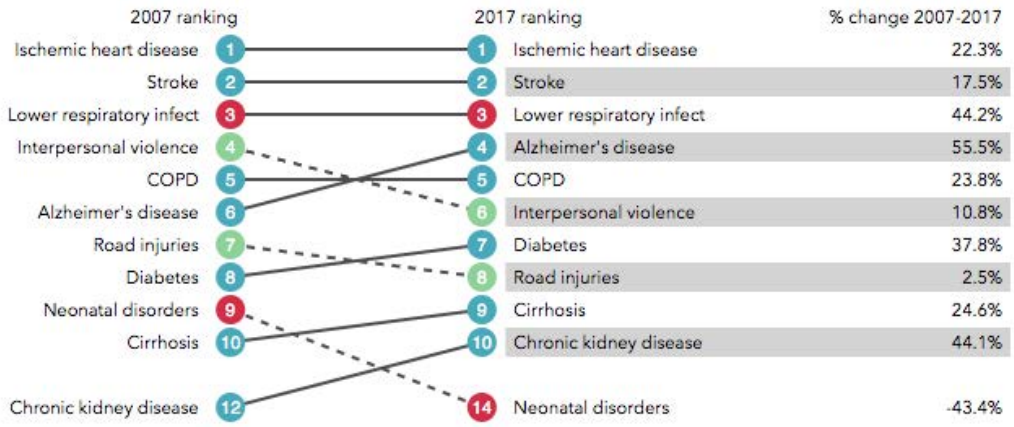
3.4 Trends in Brazil's Health Status and Interventions

Brazil has a triple epidemiological burden: the persistence or re-emergence of infectious diseases, the upward trend of Chronic Noncommunicable Diseases (NCDs) and increasing cases of death by external cause.

3.4.1 Rise in Noncommunicable Diseases (NCDs)

The biggest health challenge in Brazil comes from the persistent increase in chronic noncommunicable diseases. In 2018 these caused 74% of all deaths in Brazil. Life years lost to NCDs are projected to grow by 10% by 2030 with diabetes, cancer, neuropsychiatric conditions, and cardiovascular disease amongst the top conditions responsible. In 2017 the leading cause of death in Brazil was heart disease, followed by stroke (World Health Organization, 2018). Noncommunicable diseases are becoming a severe challenge to Brazil's public health system, which currently acts only on the consequences of these diseases. However, NCDs require a different approach, and effective interventions bring economic benefits since they often cost less than treating these diseases.

Figure 6: Top 10 Causes of Death in 2017 and Percent Change, 2007-2017, all ages, number (Healthdata.org, 2017)



Decreasing but Persistent Burden of Communicable Diseases Burden

Mortality rates from communicable diseases have reduced significantly over the last few decades (from 45% in the 1930's to 7.5% in 2018). This was achieved through improvements in basic sanitation and infrastructure, and targeted public policies. However, the burden of communicable disease in Brazil still deserves attention. In recent years multiple diseases were declared a "Public Health Emergency of International Concern" including the Zika virus in 2016 and the measles epidemic in 2017. This has led to the Brazilian government vaccinating approximately 11 million children under 5 years old (Lima-Costa, 2018) (UNICEF, 2019). Other emerging infectious diseases and major influenza epidemics (e.g. SARS, H1N1), which require specific measures for quick and mass intervention are also proving burdensome for the Brazilian health system.

Slight Decrease in Brazil's Maternal/Child Health Status

After dropping for 26 consecutive years, infant mortality saw a relative increase of 5% in Brazil in 2016. There exists some controversy regarding the cause of the increase with some Brazilian stakeholders pointing to budget cuts on the primary care level while others see the 2016 Zika and chikungunya epidemics as main causes. (Collucci, 2018) (The Guardian, 2018).

Maternal deaths or near-misses caused by pregnancy-related complications were associated with barriers to access to specific healthcare services and with inadequate monitoring of complications in the hospital setting (Pacagnella, et al., 2018) (Pacagnella, et al., 2018).

In Brazil, there is an unmet demand for contraceptives, estimated at 7.7%, which affects between ~3.5 to 4.2 million women of reproductive age. Of the total number of births in the last five years, only 54% were planned, and unintentional pregnancies were reported by 55.4% of postpartum women (Pacagnella, et al., 2018).

Ageing Population

Mainly due to high inequalities in Brazil's economy, the health status and life expectancy of its population, lags behind that of countries with comparable or even lower developed economies. In Brazil the life expectancy at birth is 71.4 and 78.9 for males and females respectively, while the average healthy life expectancy is 66.0 (compared to 72.1 in the Netherlands). These figures are similar to that of Peru, Thailand, Saudi Arabia and Bulgaria while regional countries such as Mexico and Chile score higher than Brazil (World Health Organization, 2016).

The longevity and healthy life expectancy of Brazilians has increased significantly over the past decade, partly thanks to the improvements in the country's healthcare system, leading to fast growth in the senior population (Lima-Costa, 2018).

Disability is a major concern in the context of population aging caused by increase of the segment of frail people within the senior population (Noronha, 2018). A recent study estimated that about 6.5 million Brazilians aged 60 years or older need help to carry out activities of daily living, 360,000 did not get help although they needed it, and at least 5.7 million relatives or friends provide informal (nonpaid) care for older adults (Lima-Costa, 2018).

Enabling seniors to live independently is an end-goal of Brazilian policy. The number of seniors spending significant amounts of time in isolation (loneliness) however is also on the rise. This is a negative development as this has been associated with a worse health status and health-related habits (Negrini, 2018). There are therefore policies aimed at social cohesion.

3.5 Variance in Health Status and Outcomes

Brazil's healthcare access is not equal across the country, with those using the public healthcare system far less likely to receive treatment. In 2017 the public health system was serving a population of 207.7 million people and the private health system was serving 42.5 million people. Yet, those receiving chemotherapy in the SUS was just 3.1 million people (1.5% of the total population served) compared to 2.3 million in the private sector (5.4% of the total population served). Thus, those able to afford supplementary private health insurance were almost 4 times more likely to receive chemotherapy treatments should they be diagnosed with cancer. To further compare SUS and Supplementary health view table 4.

Table 4: Public (SUS) versus Supplementary Healthcare (Montone, 2019)

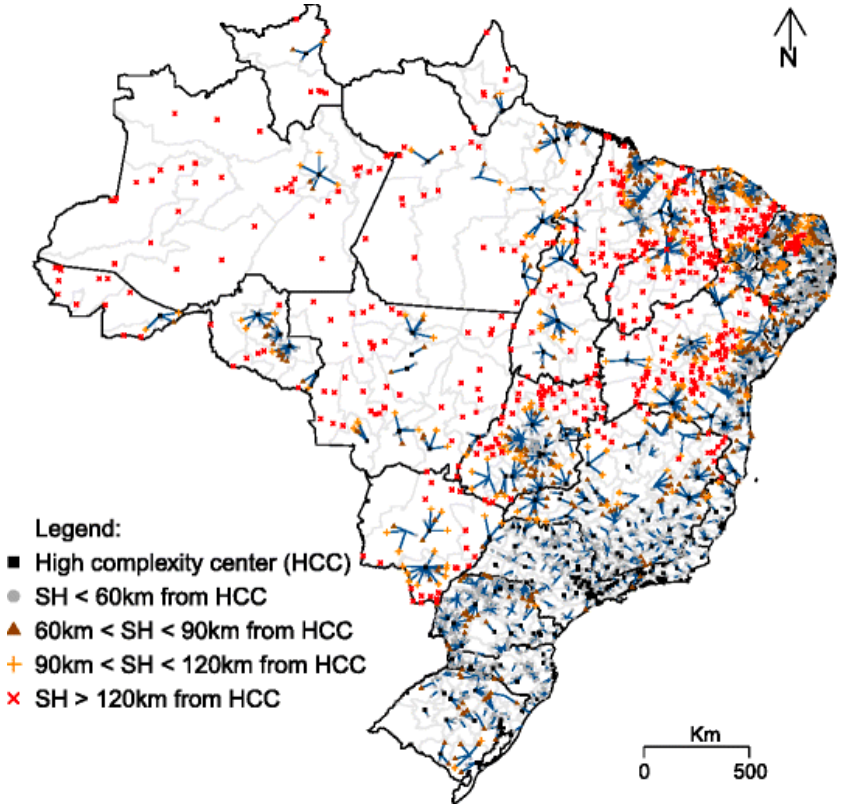
Description	Public (SUS) (million)	Supplementary (Private) (million)
Served Population	207.7	42.5
Moved Resource (R$)	268,060.0	198,800.0
Admissions	11.4	8.0
Appointments	501.7	270.0
Exams	902.1	817.0
Chemotherapy	3.1	2.3

3.5.1 Rural Health

There are large regional disparities in health outcomes, infrastructure, and availability of public services in Brazil, and these are often along urban-rural divides (Mullachery, Silver, & Macinko, 2016). According to the World Bank, an estimated 14% of the Brazilian population live in rural areas (Trading Econmics, 2016). There is a shortage of

physicians in rural areas and this is one of the factors that contribute to poor health outcomes associated with remote regions of Brazil. Brazil's Northeast region is the poorest and least developed area in the country and hosts the most concentrated population of rural poverty in all of Latin America. As can be observed in Figure 9 below, most of the hospitals in the Northeast region are small hospitals (less than 50 beds) and are situated more than 120km away from a high complexity centre.

Figure 7 Map showing HCC distribution in Brazil (Rocha, 2017)



A recent study also found that out of 5565 municipalities, as many as 824 (14%) did not have access to a high complexity centre (where essential surgery services are offered) within a 2-hour drive (Rocha, 2017). As with most other countries in the world, the shortage of physicians in rural areas is one of the contributing factors to poor health outcomes associated with remote regions. In 2014, 14 percent of the Brazilian population was considered to be living in rural areas. The north, northeast and midwest regions are areas experiencing the greatest shortage of physicians. The northeast is a well-developed region of Brazil.

3.5.3 Indigenous and Rural Populations

Brazil is home to roughly 240 indigenous tribes, totalling around 90 000 people (Survival International, 2019). These populations live in 690 designated territories which are almost all within the territory of the Amazon rainforest. Brazilian tribes come in many shapes and sizes, from tribes who are well integrated into mainstream Brazilian society to a few rare tribes who live deep within the Amazon. Some of these tribes are yet to have 'first contact' with modern Brazil. What all indigenous populations have in common, however, is a lower health status. This is mostly caused by a lower use of quality health services, caused by geography, finances and/or a deficit in health literacy. The Brazilian government tries to combat these discrepancies through the FUNAI (Fundação Nacional do Índio) which executes policies relating to indigenous peoples. Many indigenous groups live in rural areas of Brazil, and since only 6.2% of the total rural population has supplementary private health insurance, most depend on public health services (Almeida, 2018).

3.5.4 Urban Health Status in Communities

22.3% of the Brazilian population live in poor, neglected and underdeveloped urban communities. Brazil's last census 6 329 communities were identified in the country with a population of approximately 11.4 million people (IBGE, 2010). Communities house many of Brazil's poorest and in many cases lack the most basic infrastructure, utilities and sanitation that are commonplace in modern countries. This causes a range of health issues due to lack of hygiene and insufficient access to quality health services. The Brazilian government and international organisations aim to decrease this health discrepancy by investing in Brazil's underserved populations (Gragnolati et al., 2013).

4 THE BRAZILIAN HEALTH SYSTEM

4.1 The Health System

Brazil's health system is a decentralized, two-part public-private system that grants access to care to the poor and the wealthy through two parallel yet partially overlapping tracks. It does this through a network of public facilities that provide access to care to all Brazilians free of cost, and a parallel private system of operators that provide access to care primarily to those who hold supplementary private health plans or can afford to pay out-of-pocket. There is some overlap in the public and private spheres, since individuals with private plans are also entitled to use public facilities (McGregor, Siqueira, Zaslavsky, & Blendon, 2017). In 2018 the public healthcare system served over 75%[1] of the Brazilian population, funded by approximately 281 million reais. The private system on the other hand serves 25% of the population and is funded by approximately 208 million reais (FIPE - Institute for Economic Research, 2019).

4.1.1 Policy

In 2017 the Ministers and Secretaries of Health in the countries of the regions of the Americas unanimously endorsed the Sustainable Health Agenda for the Americas 2018-2030 (SHAA2030) as the strategic policy instrument that provides directions and political vision for health development in the region for the next 13 years. The goals identified in this agenda include (Pan American Health Organization, 2017).:

- The expansion of equitable access to health services, with an emphasis on health promotion and illness prevention
- Strengthening of stewardship and governance of the national health authority; Strengthening of the management and development of human resources for health
- The achievement of adequate and sustainable health financing
- Ensure access to essential medicines and vaccines; Strengthening of information systems;
- Development of capacity for the generation, transfer, and use of evidence and knowledge in health;
- Strengthening national and regional capacities to prepare for, prevent, detect, monitor, and respond to disease outbreaks; Reducing morbidity, disabilities, and mortality from noncommunicable diseases, injuries, violence, and mental health disorders
- Reducing the burden of communicable diseases and eliminate neglected diseases
- Reduction of inequality and inequity in health

In January 2019 Brazil elected a new government administration into power. With this comes a revised focus and changes to current health objectives. The latest objectives are yet to be published, however, in his inaugural speech the new Minister of Health, Luiz Henrique Mandetta stated that "*We will write together a new page in public health*" and pointed out his priorities: health promotion and disease prevention with the strengthening of Primary Care, strengthening of vaccination rates and computerization of the whole Health network (Louzada, 2019). Brazil's Health Goals for the period 2018-2030 precede the new administration but remain relevant.

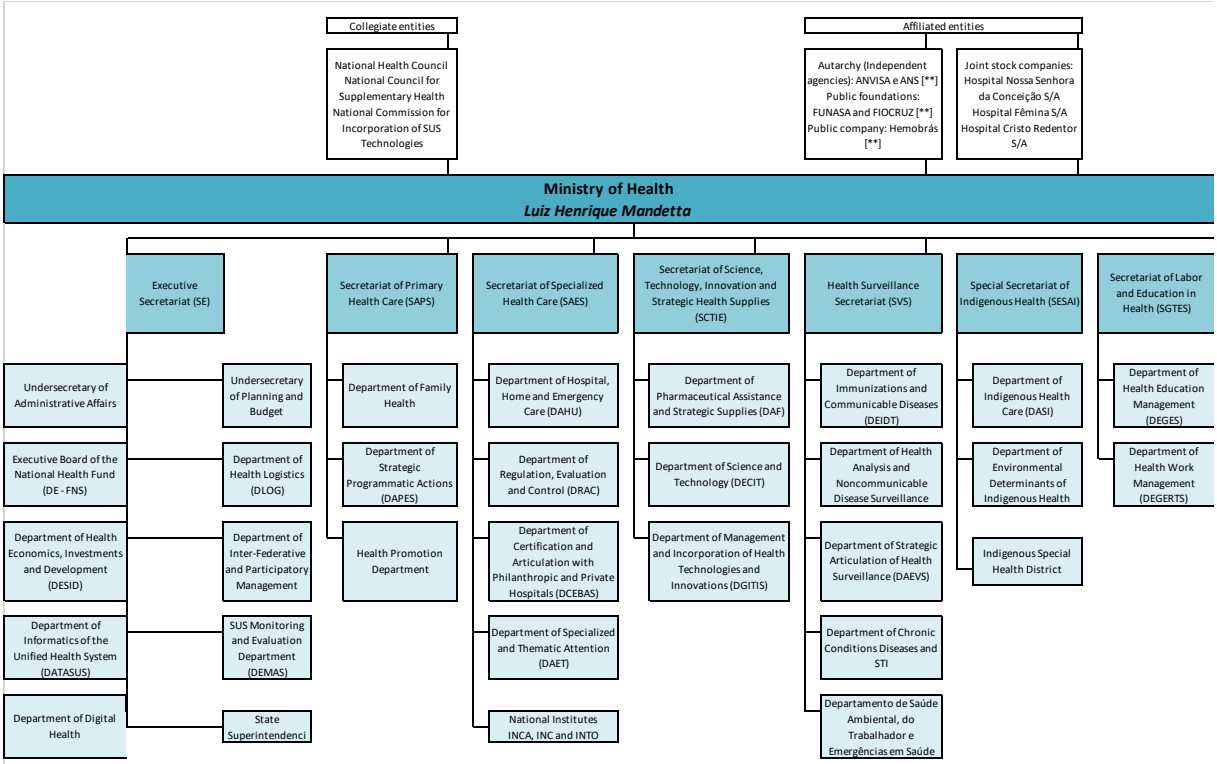
4.1.2 Governance

Brazil's Ministry of Health (Ministério de Saúde) is responsible for all national health policies, the coordination and financing of the public health system, environmental health, health information, health supplies, health surveillance, and scientific research (Saude.gov, 2019). There are 7 secretaries of health within the ministry, who govern with the supportive of collegiate and affiliated entities (see Figure 10 below). National policies are implemented in a decentralised manner by states and municipalities. The implementation of primary care is a municipal responsibility,

[1] *Brazilian sources disagree slightly on the market share of SUS compared to private health insurers, estimating a SUS coverage between 70-75%.. This is caused mainly by the supplementary nature of private insurance, which lead many patients (particularly with multiple morbidities) to use both public and private insurance.*

which means that political accountability for primary care is located principally at the municipal level. Each level of government is obliged by constitution to apply a minimum amount of its own funding resources to health. Thus, public health financing is a common responsibility for the federal government, states and municipalities.

Figure 8 Organisation of the Health System in Brazil (Saude.gov, 2019)



According to Decree No. 9,795, published in the Official Gazette (DOU) of 20 May 2019

[*]
INTO, National Institute of Traumatology and Orthopedics Jamil Haddad
INC, National Cancer Institute José Alencar Gomes da Silva
INC, National Institute of Cardiology

[**]
ANVISA, National Health Surveillance Agency
ANS: National Agency for Supplementary Health
FIOCRUZ: Oswaldo Cruz Foundation
HEMOBRÁS: Empresa Brasileira de Hemoderivados e Biotecnologia

4.1.3 Health Coverage

Health care services in Brazil are provided in two ways: publicly, through the Unified Health System (SUS) and privately, through supplementary health service operators, regulated by the ANS (National Agency for Supplementary Health), and other private establishments (hospitals, clinics, laboratories and autonomous medical professionals). There is no clear cut separation between the public and supplementary private system. Complex medical cases that might have been first treated under supplementary private coverage, can be reverted back to public tertiary specialised hospitals. Moreover, many private hospitals also work in and for the public domain as part of a philanthropic approach.

Public sector: Sistema Único de Saúde (SUS)

In 1988, the Brazilian Constitution determined that "*Health is a right of all people and a duty of the state, guaranteed by social, economic policies that reduce the risk of disease and other adversities and by universal and equal access to actions and service*." This statement allowed for the creation of the Unified Health System, known as the SUS (Sistema Único de Saúde). The main principles of the SUS are universal access, comprehensive care, and equity of actions

(Stein & Ferri, 2017). The SUS serves approximately 208 million people (98 % of the population), providing free universal healthcare to all Brazilians (Montone, 2019).

The SUS is funded from the social security budget and is financed by taxes and contributions from employees and businesses. The funds are distributed to 27 state health departments, which are responsible for providing public health services. The majority of inpatient care is carried out by private providers, which are reimbursed by the state authorities. While free medical care is readily available at government hospitals, they are often crowded with long waiting times for non-emergency medical treatment. Although the SUS has functioned well between 1990-2010, the Brazilian economic crisis, political agendas, and cases of corruption have resulted in a break down in the system. Many of the issues facing the SUS are caused by a lack of funding to the system.

Supplementary Health System (SHS)

Approximately 42.2 million Brazilians (22.4% of the population) make use of the Supplementary Health System (SHS) (Montone, 2019). The SHS consists of private insurers, giving Brazilian businesses and individuals who can afford it the ability to purchase health care that is easier to access with shorter waiting times. There are currently 737 medical schemes active in Brazil.

In 2015 restrictions on foreign investment in the Brazilian health market were relaxed, allowing foreign investment in/foreign ownership of private hospitals in Brazil. This resulted in the consolidation of the private health sector as overseas investors became interested in the market. Deals include US-based UnitedHealth Group paying US$4.9bn to buy Amil Participações, Brazil's biggest private health insurer, and US private equity group Bain Capital buying insurer Notredame Intermedica (the 4th largest insurer) for US$620m in 2014 (KPMG, 2019).

Text Box 2: AMIL - Brazil's Largest Private Healthcare Company

AMIL is Brazil's largest private healthcare company providing both medical and dental insurance plans, as well as hospital services. Since October 2012, AMIL has been 90% owned by the UnitedHealth Group, the biggest health insurance company in the US. Founded in 1972, AMIL serves some 4.6 million people, primarily located in the states of São Paulo, Rio de Janeiro, Parana and the Federal District. More recently, the company has expanded into the states of Minas Gerais and Recife. AMIL operates 29 hospitals, 42 clinics and 221 satellite offices.

4.2 Health Expenditure

4.2.1 Public Sector: SUS

One of the main hurdles in implementing the activities of the SUS is the lack of financial resources available. In 2016 Brazil spent 11.7% of its GDP on health, and although this level of total health expenditure is comparable to other countries in Latin America. Public expenditure per capita in Brazil is US$ 426.50, which is one of the lowest proportions of public spending on health in Latin America (Montone, 2019). In 2018, the Federal government's SUS expenditure reached US$ 32.2 billion whilst the SUS budget reached was US$ 69 billion (Montone, 2019) (Massuda et al., 2018).

In May 2016, the previous Brazilian government adopted an extensive reform agenda. This resulted in the approval of Constitutional Amendment 95, which created the New Fiscal Regime and established a spending cap for the federal budget. The amendment imposes a ceiling on public expenditures and prevents the expansion of investments in sectors such as health and education for twenty years. In other words, until the year 2036, public spending on public services will be frozen in Brazil. Beginning in 2017, the maximum possible variation for public spending corresponds to inflation for the year. The impact of this amendment presents a particularly negative outlook for Brazil's public healthcare services given recent cuts to the government's 2016 budget. The Ministry of Health's 2016 budget was reduced to US$ 27.5 billion from US$ 28.2 billion (Roznai & Kreuz, 2018).

4.2.2 Supplementary Private Health Insurance

Private spending continues to represent more than half of all healthcare expenditure. In 2016 approximately 66.7% of total health expenditure was accounted for by the private sector, with just 33.2% accounted for by general government expenditure. This is unusual since the majority of Brazilians make use of the SUS, yet the private sector trumps the public sector in terms of spending (Montone, 2019).

4.2.3 Health Service Provision

Decentralization is a major aspect of Brazilian governance and a key feature of the SUS. The provision of most primary health services and nearly half of hospital care has been transferred to municipal governments, which are responsible for the majority of health care provision in SUS.

Primary Care

The majority of primary care in Brazil is delivered through the public health system, although people are free to choose whether they wish to make use of the public versus the private system. The management and provision of public primary health care is the responsibility of Brazil's 5 570 municipalities (Macinko, Harris, & Gomes, 2017). In order to provide comprehensive primary health care (PHC) the SUS model has emphasized the rapid scaling-up of community-based care. Among a number of important initiatives undertaken to develop this approach is the introduction of the Community Health Agents Programme (Programa Agentes Comunitários de Saúde) and subsequently the Family Health Strategy (FHS) (Estratégia de Saúde da Família. The FHS delivers primary care for free at point of use. There are over 41 000 FHS teams across the country, each compromising of GPs, nurses, auxiliary nurses, and lay health workers, with each team providing primary health care to a defined population (Stein & Ferri, 2017). One's GP generally guides patients through second and tertiary care should they need it. Unfortunately, the majority of healthcare resources remain concentrated in the largest cities, with many remote communities still lacking proper healthcare assistance in primary care (Marcolino, et al., 2016).

Text Box 3: Filling the Gap Between the Inefficiencies in SUS and Expensive Private Healthcare

Dr Consulta has spotted a business opportunity somewhere between the existing inefficiency in SUS (Brazilian Unified Healthcare System) and unaffordable private healthcare. What is now a chain of 60 medical centers in three Brazilian capitals and revenue of R$ 225 million in 2018 has started in 2011 as a pilot clinic in Heliópolis, a heavily populated poor community in the city of São Paulo. EBITDA is still negative, but Dr Consulta has had five rounds of investment and raised US$ 95 million among investors such as Madrone Capital Partners, Kaszek Ventures and LGT, the social impact fund from the royal family of Liechtenstein.

Dr Consulta is a chain of medical centers that Currently Dr Consulta offers primary care and other 40 specialized care, 100 types of exams and 30 kinds of low-complexity surgeries and aims at speeding up the experience of the patient by offering consultation 25 times faster than the public healthcare system at a price point 60% to 90% lower than the average price from private services. The concept is based on filling the gap of inefficiencies in the healthcare system. Of a demand of 1.3 billion consultations annually in SUS, around 800 million are not held due to mismanagement and inefficiencies in monitoring patients. Specialized care may take an average of three months to be scheduled and a diagnosis may take up to a whole year to be ready.

Its founder Thomaz Srougi is now taking the first steps towards turning Dr Consulta into a healthtech company. In its eight years of existence, 1.3 million patients were served and the collected data can now be used in preventive measures, in the communication with patients and allow for virtual consultations, ultimately adding value to the healthcare value chain. It is possible that the new direction is a reaction to exhausted market potential, coupled with increased costs and need to further scale up the business. Expanding is expensive – a new medical center is estimated at R$ 1 million. Margins are tight, especially as exams have been incorporated into the set of services, as care is not complete based solely on consultations. Dr Consulta is now partnering with insurance companies to offer primary and secondary care to their clients.

By moving to a technology-driven company, Dr Consulta is aiming at a model similar to that of Good Doctor, marketplace by the Chinese insurer Ping An, that connects physicians and patients. The business model implemented by Dr Consulta has now been copied by such brands as Cia. da Consulta, Amparo and GlobalMed.

Secondary/Tertiary care

Public hospitals in Brazil are mostly used by SUS patients, with many functioning beyond capacity (Business Sweden, 2015). Although there are good quality public hospitals, many are in bad condition with waiting times for procedures varying from 3 months to a year. Approximately 75% of all hospitals in Brazil are private/non-profit hospitals. These are mostly attended by those who have supplementary private insurance plans and are generally high quality.

The national healthcare system is increasingly relying on private actors to deliver more healthcare services and marry the ever-growing demands of the public system with the financial power of the private sector (Costa, 2017). The National Association of Private Hospitals (ANAHP) had 118 members with 25 118 hospital beds (December 2018). This corresponds to approximately 10% of all available beds in for-profit and non-profit private hospitals in Brazil.

Although Brazil has the largest hospital infrastructure market in Latin America the market remains fragmented. While there are over 7 800 hospitals in the country, the average hospital is relatively small (24 beds) (Global Health Intelligence, 2016). The majority of healthcare resources are concentrated in the largest cities, with many communities having difficulties accessing specialists and diagnostic examinations (Marcolino, et al., 2016). These types of shortages of specialty services, coupled with limited administrative capacity have led to poor quality services in many public hospitals with long waiting times. These tend to be in more rural areas in the Northern parts of Brazil, where there is a limited number of hospital and medical staff and thus less capacity to meet the demands of the population (see Figure 10).

Figure 9 Geographic locations of Brazilian hospitals with pharmacists (blue circles) and without pharmacists (orange circles) (Santos, 2018)

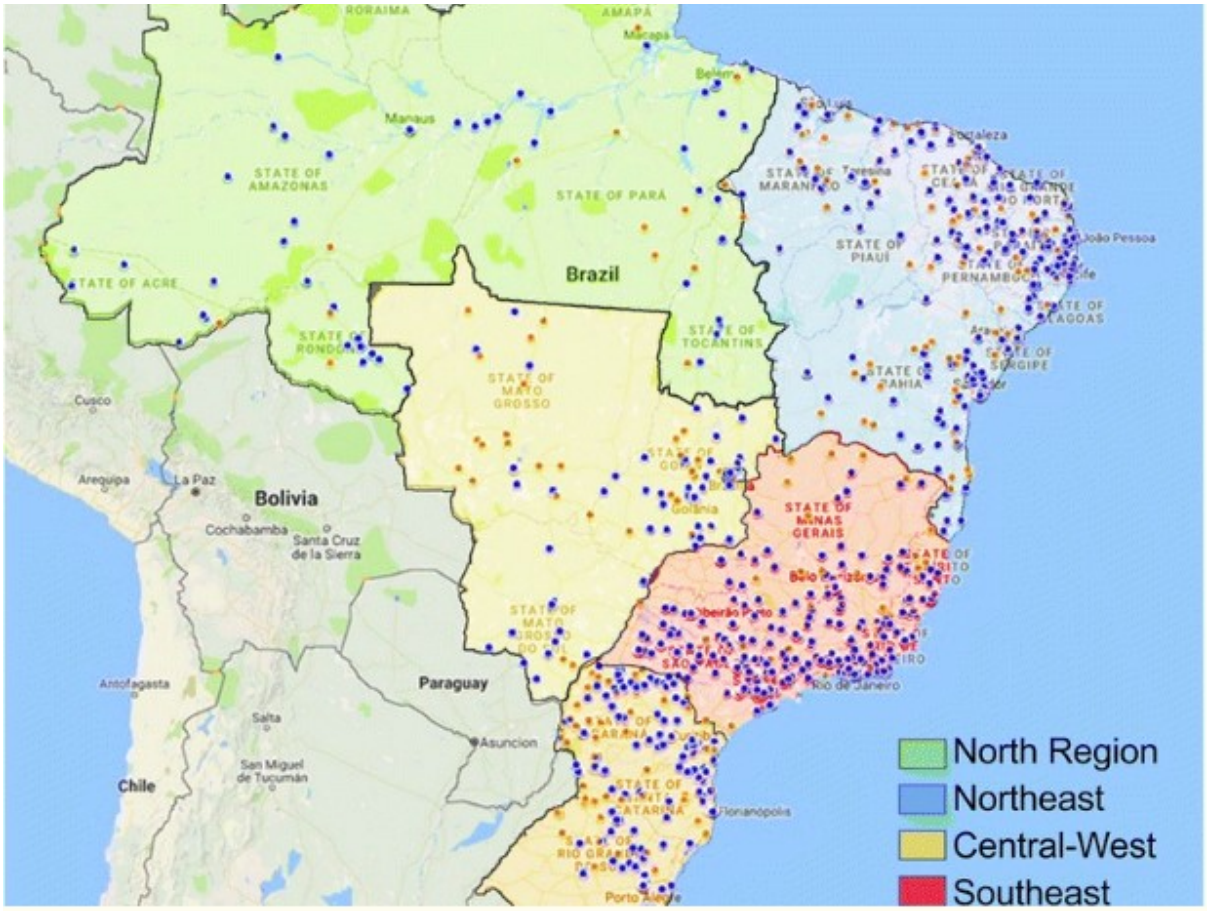
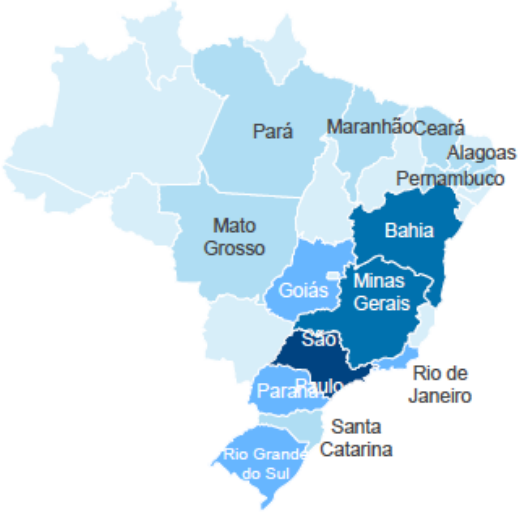


Figure 10 Concentration of hospitals by state (Business Sweden, 2015)

HIGHEST CONCENTRATION OF HOSPITALS IN SOUTHERN AND SOUTH EASTERN BRAZIL

SÃO PAULO IS THE STATE WITH THE MOST HOSPITALS OF WHICH 79% ARE PRIVATE



NUMBER OF HOSPITALS PER BRAZILIAN STATE

- More than 1 000
- Between 600 and 1 000
- Between 300 and 600
- Between 150 and 300
- Less than 150

TOP 14 STATES IN NUMBER OF HOSPITALS

Brazilian State	Region	Hospitals	% Public	% Private
São Paulo	Southeast	1 065	21%	79%
Minas Gerais	Southeast	684	19%	81%
Bahia	Northeast	634	46%	53%
Paraná	South	509	32%	68%
Rio de Janeiro	Southeast	499	32%	68%
Goiás	Central West	434	41%	59%
Rio Grande do Sul	South	341	15%	85%
Ceará	Northeast	275	49%	50%
Santa Catarina	South	255	17%	83%
Pernambuco	Northeast	244	50%	50%
Maranhão	Northeast	243	73%	27%
Pará	North	238	46%	54%
Mato Grosso	Central West	164	40%	60%
Paraíba	Northeast	159	55%	45%

Text Box 4: The National Restructuring Programme of University Hospitals (REHUF)

The National Restructuring Programme of University Hospitals (REHUF), developed and funded in partnership with the Ministry of Education, has been set up to provide financial support for the restructuring and modernisation of university hospitals. It has seen investment of around R$ 2.5bn (US$ 0.6bn) between 2010 and 2014. Through the REHUF funding programme, university hospitals are being increasingly integrated into the SUS as providers of reference services and cutting-edge technologies. In addition to REHUF funding, the Ministry of Health transfers each year approximately R$ 1.2bn (US$ 0.3bn) to help fund medium and high complexity treatment provided by these establishments. Currently, 46 hospitals and the two other health facilities attached to universities are part of the programme. These institutions are located in 33 cities across the country, including 24 capitals.

Access to medical services is not equal across Brazil and the number of hospital beds has not kept pace with the growing population (BMI, 2017). According to the Ministry of Health, the reduction in beds available to the SUS reflects a move towards more ambulatory treatment and home care. New technology has also decreased the length of stay and allowed procedures such as vasectomy to be performed on an outpatient basis. Other trends include greater use of primary care services and emergency units as well as mobile health teams to reduce the pressure on hospitals (BMI, 2017).

Long-Term Care (LTC)

One of the major challenges facing Brazil's health system is the rapid aging of its population over few decades. Brazilians are getting older before the country becomes richer. By 2050, the elderly will make up close to 29% of the population. This is a concerning issue due to the high costs of long-term care. At the household level long-term care in Brazil is fragmented, and there is no national policy to support such care. A recent study estimated that 6.5 million Brazilians aged 60 years or older need help to carry out activities of daily living, with 5.7 million relatives or friends providing this informal (non-paid) care (Lima-Costa, 2018). Thus, Brazil's legislation has bestowed the main responsibility on the family, with LTC not covered under the SUS health plan. Older people are eligible for institutional placement only if they are indigent and completely lacking family support. Care homes in Brazil are very limited, and available in fewer than 30 percent of Brazilian municipalities, specifically concentrated in the Southeast and in the larger cities. The majority of care-homes are philanthropic in nature or linked to private health plans. As a result, fewer than 1 percent of older people reside in care homes (Garcez-Leme & Leme, 2014).

Text Box 5: Rede D'Or São Luiz: Brazil's largest independent hospital operator

Founded in 1977 by the Moll family, Rio de Janeiro-based Rede D'Or São Luiz is the largest independent hospital operator in Brazil, with a presence in Rio de Janeiro, São Paulo, Pernambuco and Brasilia DF. Rede D'Or has over 4,500 beds in 27 owned and two managed hospitals, in addition to 30 oncology clinics. On an annual basis these facilities provide 270,000 inpatient treatments, 170,000 surgeries and over 2.7mn emergency room visits. Rede D'Or had revenue of R$ 5.5bn (US$2.3bn) in 2014 with an EBITDA of R$ 930mn (US$396mn). Following the lifting of restrictions on foreign investment in hospitals in January 2015, the Moll family has reduced its holding in Rede D'Or to around 60%, having sold an 8.3% stake to the private equity firm Carlyle Group in April 2015 and a 7%-8% stake to Singapore's sovereign wealth fund GIC in May 2015. GIC has also acquired equity from Rede D'Or's other main investor, the Brazilian investment bank BTG Pactual, giving an overall stake of around 15%. Rede D'Or will use funds raised from these transactions to accelerate its growth plans, which include the construction of new hospitals, the expansion of existing facilities and strategic acquisitions.

Find out history here

4.2.4 Workforce

Brazil has a severe shortage of doctors, with 2.1 doctors per 1000 people, compared to the Netherlands who have 3.4 doctors per 1000 people, and the OECD average which is 3.0 doctors per 1000 people. The number of health professionals, including GPs, who have adequate qualifications, are thus insufficient to provide universal coverage in every part of the country (Stein & Ferri, 2017).

One of the biggest problems with retaining healthcare workers is insufficient remuneration for doctors working in the public sector. Some reports therefore indicate doctors working multiple jobs to sustain themselves and their families.

Privately initiated programmes have been developed to tackle the problem of a shortage of doctors. Such a programme is "Program Talentos", which was inspired by the shortage of engineers in Brazil. The program involves 60 different schools and develops young Brazilian talent for careers in which there are professional shortages.

Table 5: Health Professionals in Brazil (Stein & Ferri, 2017)

Health Professionals		
	Total (2017)	*Per 1000 people (2017)*
Medical Doctors	450,009	2.1
Dentists	258,842	1.2
Pharmacists	141,968	0.7
Nurses and Midwives	1,246,347	5.9

4.3 Brazil's Life Sciences & Health Sector

The Medical Technology industry in Brazil consists of 14,482 companies. Of these, 4,032 are manufacturers and 10 450 are engaged in the marketing and distribution of products (EMERGO, 2019). The health industry mainly consists of small and medium-sized enterprises (SME). In the last survey of the Brazilian Alliance for Innovation Healthcare Industry (ABIIS) the sector consisted of 3% micro businesses, 15% small, 59% medium, 13% medium to large, and 10% large enterprises (Marrone, 2015). 60% of these companies are located in the south-east region, which includes the state of São Paulo, accounting for 32% (4.639) of these companies.

The Brazilian medical industry, as is the case in most countries, has a very diverse composition. The Hospitalar exhibitors list and ABIIS can be used to find specific companies.

Brazil's domestic health industries were hit by the most recent economic recessions but are now expected to gradually recover as the country invests in the development of its industries (BMI, 2017). The development strategy for a large part of the MedTech sector itself has been put forward by ABIIS in the document Health 4.0.

An influential investment tool for Brazil's health industries is the programme: Productive Development Partnerships (PDP). For foreign suppliers this programme forms an alternative way to enter the Brazilian market through Productive Development Partnerships (Export.gov, Brazil - Healthcare, 2019). PDPs are designed to allow international companies to partner with local laboratories to supply the public system for a period of up to five years, with a reserved market share, and with the goal of a technology transfer at the end of the contract. Companies should be well-prepared and fully investigate all terms before committing to a PDP.

Further Reading

If you would like to expand your understanding of the Brazilian health system, the following publications provide excellent overviews:

- The Brazilian health system at crossroads: progress, crisis and resilience: This resource provides a historical overview of the past and present challenges associated with the Unified Health System (SUS): Massuda, A., Hone, T., Leles, F. A. G., de Castro, M. C., & Atun, R. (2018). The Brazilian health system at crossroads: progress, crisis and resilience. BMJ global health, 3(4), e000829.
- The Health Industry in Brazil: This resource provides an overview of the private health market in Brazil including the pharmaceutical and digital health markets.

5 MARKET STRUCTURE AND ACCESS

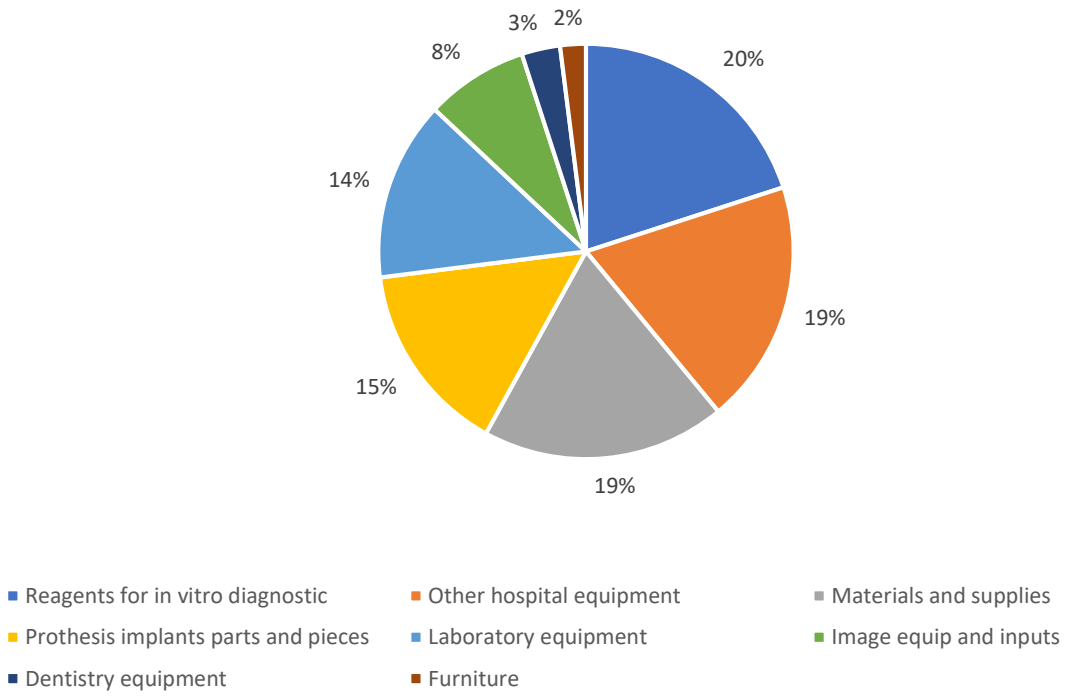
5.1. Market Structure, Size and Trends

5.1.1 Modest Growth in Latin America's Biggest Healthcare Market

Brazil is Latin Americas largest healthcare market. However, estimates of the actual market size vary considerably. Export.gov ranks Brazil as the world's 6th largest market for pharmaceuticals, with sales of US$ 24.9 billion in 2018 (BMI, 2017). In terms of medical devices, BMI ESPICOM reports an estimated total market size of US$ 5.5 billion, Brazil's healthcare market (pharmaceuticals and medical devices) is expected to experience modest growth going beyond 2021. Sources indicate CAGR's between 1-3% growth between 2018-2021 (BMI, 2017) (Export.gov, 2019).

Looking at the segmentation of health product consumables in Brazil, findings from an industry survey conducted by IBGE in 2013 are still the most accurate. This is according to interviews conducted during Fact Finding (Annex 1) (IBGE, 2019).

Figure 11 Medtech segmentation in the Brazilian market (IBGE, 2013)



5.1.2 Public Healthcare Market: Doing Business with Brazil's Leading Purchaser

The SUS is the leading purchaser of medicines and technology in Brazil's healthcare market. Looking at numbers alone, the public healthcare market is actually smaller than the private healthcare market, but the collective purchasing power possessed by SUS represents 30% of the total health expenditure and covers 75% of the Brazilian population. ABRAIDI (Brazilian Association of Importers and Distributors of Implant) members alone sell around US$ 300 million worth of implants to SUS annually (ABRAIDI, 2019). In cases where there is a strong domestic supply, public purchasers tend to prioritise locally produced products and services (Export.gov, 2019).

Text Box 6: Macroeconomics Influencing Brazil's (Public) Healthcare Market

Growth, demand, and purchasing power within the dual Brazilian healthcare market has historically mimicked the pattern of the country's economic cycle, forming a pendulum. In times of economic expansion (growth) more patients opt to enter the private sector, whilst in periods of contraction (recession), for example in 2014 when Brazil was hit hard by a recession, patients return to SUS. Shifts in the utilisation of health services in the public and private sector lead to shifting demands for technology and services in Brazilian hospitals.

Public Healthcare Reimbursement and Procurement

In order to have your product or service included as an SUS reimbursed item, supplier send in a funding request to the National Commission for the Incorporation of Technologies in the SUS (CONITEC – Comissão Nacional de Incorporacão de Tecnologias). CONITEC advises the Ministry of Health on inclusion of technologies in SUS. Technologies which are registered with ANVISA, comply with efficacy and safety criteria, demonstrate cost effectiveness, and show significant budgetary impact may be eligible for inclusion of reimbursement by SUS.

Procurement in Brazil's public health sector is governed by the 1993 Public Procurement Act (Law 8,666) (Barbosa & Straub, 2017). Procurement mainly takes place through tenders for healthcare products and services. The procurement landscape is complex as it is conducted independently by more than 5,500 municipalities, 26 states and the Federal District, the Federal Government, as well as hospitals under indirect public administration at both the federal and state/municipal level. For the acquisition of standardized goods and services, such as bandages, medical gloves, syringes, and off-patent pharmaceuticals, the Procurement Act determines that public bodies must rely on auction-based mechanisms to award contracts. High-value contracts must be acquired through open competitive bidding, while those of lower values can be acquired through invited bidding. Each administrative entity has its own portal. Federal tenders can be found at Ministério da Saúde.

5.1.3 Private Healthcare Market:

Brazil's private healthcare sector covers roughly 30% of the population but also represents 75% of the total health expenditure. Private hospitals are responsible for large investments in innovative technologies and are therefore a sought after partner for many foreign suppliers. The private market is highly fragmented, which makes it difficult to estimate the total value or identify trends. Through its 118 members, ANAHP (Brazil's National Association of Private Hospitals) reports are good indicators of the status of the private healthcare market.

ANAHP's figures on trends in the volumes of treatments and procedures, as well as the net income and expenses of its members all show a small but stable increase between 2017-2019 (ANAHP, 2019). On average, the net income for ANAHP's members grew from $R 18.345,56 to $R 20.875,22, with a standard deviation of $R10.559,50 million.

Table 6: Typical segmentation of the expenditure of ANAHP members (ANAHP, 2019)

Expenses (%)	2015	2016	2017	2018	Standard deviation 2018
Personnel	36.25	36.18	37.44	37.32	12.03
Technical And Operational Contracts	12.97	13.04	14.01	13.72	8.73
Drugs	10.99	10.81	10.73	10.79	4.35
Orthotics, Prosthetics And Special Materials	8.21	8.45	7.83	7.18	5.36
Other Costs	6.21	6.92	6.61	8.18	8.52
Materials	6.60	6.20	6.57	6.37	2.77
Support And Logistical Contracts	5.34	4.87	3.98	4.27	3.30
Other Supplies	2.99	3.18	3.24	2.77	2.02
Depreciation	3.00	2.91	2.83	2.87	1.22
Financial Expenses	2.80	3.05	2.44	2.06	2.35
Utilities	2.43	2.30	2.04	2.24	1.32
Maintenance And Technical Support	1.91	1.75	1.96	1.91	1.21
Medical Gases	0.39	0.34	0.31	0.32	0.31

The growing net income of the ANAHP members does not necessarily translate into larger investments in technology as can be seen in *Table 7*. The categories Orthotics, Prosthetics and Special Materials, Materials and Other Supplies show slight decreases in 2018 compared to earlier years. Brazil's largest private hospital reflects this trends, showing a decrease in investments in property and equipment on the 30th of June 2019 ($R 239,478 thousand) when compared to a year earlier ($R 256,530 thousand) (Rede D'or São Luiz S.A., 2019).

Private hospitals in Brazil focus on delivering excellent care in order to attract patients. They therefore tend to invest in sophisticated equipment to improve their quality of care. Sources report that Brazil's private hospitals are more willing to experiment with innovative technologies compared to more conservative public hospitals (Evidera, 2017).

Text Box 7 : Brazilian private Hospitals Drive Innovation

Besides everyday type expenses shown in *Table* 7, Brazil's private hospitals continuously invest large sums of money into innovative projects. These projects may be of interest to the Dutch LSH Sector (more to follow in Section 6). Examples include the AC Camargo Cancer Center which has allocated roughly US$ 6 million in 2019 to generate knowledge and experience in terms of new treatments and technologies. Hospital Albert Einstein also invests several millions in research projects on leukaemia (LMA), Oncology and Haematology (AMIGOH).

Private Healthcare Reimbursement and Procurement

For reimbursement in private health plans, suppliers may send in proposals to the Healthcare Regulatory Committee (COSAÚDE - Comitê Permanente de Regulação da Atenção à Saúde), consisting of health plan operators, consumer

protection bodies and ANS staff (BMI, 2017). COSAUDÉ is affiliated with the National Private Health Insurance Regulatory Agency (ANS - Agencia Nacional de Salud Suplementaria). COSAUDÉ maintains a *List of Procedures and Treatments* (Rol de Procedimentos e Eventos em Saúde) that are covered by private health insurance plans, which is reviewed every two years. The process includes public consultations. COSAUDÉ normally considers proposals made through the Brazilian Medical Association (AMB - Associação Médica Brasileira) and other professional associations. These should therefore be considered as valuable counterparts to Dutch suppliers.

Procurement in Brazil's private hospitals usually goes directly through individual procurement departments. The National Supplemental Health Agency (*Agência Nacional de Saúde Suplementar*) (ANS) have their own public procurement regulations for all administrative contracts entered into.

5.2. Market Entry, Regulatory Affairs and Registration

Brazil is not a typical market for export starters as it is one of the least open economies amongst the G20 countries (Srinivasan, 2018). This is reflected in Brazil's relatively low ranking in the World Bank's Ease-of-doing-business-index, 109th (compared to the Netherlands 32nd) out of 190 countries (World Bank Group, 2019). However, Brazil has shown some progress in improving its business climate for foreign suppliers by making company registration easier through the introduction of electronic certificates of origin.

With the right market entry strategy Brazil's market barriers can be overcome as indicated by the 36 Dutch organisations (mainly SMEs) which this study identified to be active in Brazil (Section 2).

5.2.1 Registration Process

Entering the Brazilian market takes a significant amount of time, with the registration process alone taking 6 months to 2 years to complete (BMI, 2017) (Export.gov, 2019).

The dominant market entry strategy for major multinationals are sales and distribution through subsidiaries, while a growing number operate manufacturing facilities in Brazil, such as Fresenius, General Electric, Johnson & Johnson, Medtronic, Philips etc. (BMI, 2017). Most foreign SMEs active in the Brazilian healthcare market make use of trusted local partners. Given the vast size of the country and its regional differences, it is not possible to cover the entire territory from a single distribution point. It is therefore important to verify the reach of a local partner or appoint multiple distributors. The most important areas to cover for most Dutch suppliers is the triangle of São Paulo, Rio de Janeiro and Belo Horizonte in the south-east region. Other important zones are located near Curitiba, Florianopolis, and Porto Alegre in the south and Salvador and Recife in the north-east. Even within the south-east region it is advisable to appoint agents in both Rio de Janeiro and São Paulo (BMI, 2017) (Export.gov, 2019). Brazil's industry associations are listed in Annex 5, whilst a list of key stakeholders can be found in Annex 10.

Text Box 8: Receive Support on Market Entry Strategies and Distributor Search

More than 90% of the Dutch Life Sciences & Health sector (LSH) make use of local agents and distributors to facilitate their export (TFHC, 2018). The Dutch LSH sector however also lists "finding good agents and distributors" as the most frequent barrier to enter a foreign market. The use of professional services to find a local business partner may be advised in countries with complex distributor landscapes. RVO's (Netherlands Enterprise Agency) business partner scan (Learn more) and TFHC's distributor search enable acceleration of this process. Learn more.

After establishing a representative or securing a trusted local partner, these entities can be appointed as the Registration Holder for a specific product/service. Registration Holders are responsible for regulatory affairs, including Good Manufacturing Practice certification, as well responsibility for authorising other parties to import the registered product (Export.gov, Brazil - Selling to the Government of Brazil, 2019).

The National Health Surveillance Agency (ANVISA - Agencia Nacional de Vigilância Sanitária) is the regulatory agency responsible for product registration. Registration is valid for a period of 5 years, after which registration can be renewed for a similar period. Applicants for registration will be required to submit additional documentation including risk management summaries and Good Manufacturing Practices (GMP). Furthermore, Brazil requires all labels to be in Portuguese. Brazilian public institutes are open to collaborate with Dutch suppliers with innovative products to adapt them to local context. Examples of institutes are IPT, ITA en EMBRAPA (Compernolle, 2015).

Once export starts, imported products from Dutch suppliers are subject to several taxes and fees in Brazil, which are usually paid during the customs clearance process. There are three taxes that account for the bulk of import costs: the Import Duty (abbreviated in Portuguese as II), the Industrialized Product tax (IPI) and the Merchandise and Service Circulation tax (ICMS) (Export.gov, Brazil - Customs, Regulations and Standards, 2019).

More information on medical device registration processes can be found in Annex 8.

To enter government procurement, foreign companies can participate in tenders through local representatives or by establishing a local presence (Section 5.1). The government may not make a distinction between domestic and foreign-owned companies during the tendering process. However, when two equally qualified vendors are considered, the law's implementing regulations provide a preference to Brazilian goods and services.

Text Box 9: Receive Support on Regulatory Affairs in Brazilian Market Entry

Regulatory requirements put forward by ANVISA are complex and subject to change as Brazil's healthsector responds to events in global health(industries). To stay up-to-date on current affairs professionals such as EMERGO offer free information packets and checklists to ensure a smooth registration process Learn more.

5.3. Tips for organisations exploring the Brazilian healthcare market

5.3.1 Unique Selling points as seen by Brazilians

Imported healthcare products and services are generally considered attractive in the Brazilian market when they:

- **Operate a Blue Ocean Strategy**: Brazilian purchasers' favour locally produced/manufactured products. Imported products in general have limited competition from domestic industries.
- **Have a Strong Local Presence/Connection**: Pre-and-post sale support are important in the Brazilian market. Suppliers with a local entity or partner are therefore favoured.
- **Are High Quality**: Brazilian hospitals have high standards. Public hospitals fall under government procurement, which upholds strict guidelines for suppliers. Private hospitals, many of whom operate world class facilities, carefully source the best quality products and services available.
- **Improve Cost-Effectiveness**: Cost-saving concepts are seen as a key feature and should be highlighted as a benefit for Brazilian stakeholders.
- **Are Priced Favourably**: Both the public and private healthcare market are price-driven especially when it comes to established technologies. For newer technologies price is a less important factor.

- **Use Sustainable Business Practice**: As Brazilian companies become more concerned with environmental stewardship, it is also advisable to demonstrate commitment to sustainable development practices when introducing new products into this market.

Text Box 10: **Generating and Validating Demand Through Pilots and Trials**

Competition in the Brazilian healthcare industry is strong, enabling Brazilian hospitals to carefully source new innovations. Evidence which demonstrates the efficacy of innovations in local context is therefore a key consideration for many Brazilian health decision-makers and consumers.

A common practice for foreign suppliers to enter the Brazilian market is therefore through running pilots and trials preferably in large renowned hospitals. In many cases, foreign suppliers offer these pilots and trials for free or against a limited fee.

The benefit of successful pilots is that these build confidences and generate interest from Brazilian stakeholders, opening-up opportunities at other hospitals in the large Brazilian market. Before starting a pilot, it is recommended to carefully prepare and guard investments, commitment from partner(s) and protection of IP.

Text Box 11: Tips for Doing Business In Brazil

- Many Brazilian counterparts speak English but are more comfortable speaking Portuguese. Translators or hiring local personnel may provide an edge in negotiations.
- It is essential to establish a presence in Brazil before proceeding with projects. This, not just to deliver support but to understand the Brazilian mindset and connect on a deeper level with clients and business partners.
- Brazil's strict and bureaucratic authorities make managing regulatory affairs complicated. Make sure to be well equipped and have insight in local processes.
- Brazil is a large country which complicates communication and logistics. Be prepared to invest time to make operations run smoothly.
- Commitment from a client/business partner is key. Every project needs a champion within a counterpart to increase the chances of success.
- Reimbursement rates in Brazil are lower compared to the United States and Western Europe. Respondents in Fact Finding have compared the reimbursement level to India.
- Finding the right price is a key challenge for many foreign suppliers in Brazil. The best method to establish correct pricing is to compare to other products.

5.3.2 Market Access Database EU

The Market Access Database (MADB) gives information to companies exporting from the EU about import conditions in third country markets. The database provides an extensive overview on market data and regulations in Brazil that apply to specific HS codes. Find our more here: MADB

5.3.3 Useful Organisations For Market Entry and Further Information

Find useful Dutch organisations below. For a list of Brazilian organisations please view Annex 10.

- The Netherlands Consulate-general in São Paulo, and the Netherlands Business Support Office Porto Alegre the Netherlands Business Support Office Belo Horizonte promote and support business cooperation between Brazil and the Netherlands through the Departments of "Economy & Trade"

- The Innovation Attaché Network/ Holland Innovation Network in Brazil, with focus on collaboration between the Netherlands and Brazil in Science, Technology and Innovation
- Netherlands Enterprise Agency (RVO.nl), stimulates entrepreneurs in sustainable, agricultural, innovative and international business.
- Embassy of Brazil in the Hague. promotes and supports cooperation between Brazil and the Netherlands.
- The Enterprise Europe Network Brazil (EEN Brazil), provides information and support for SMEs in the fields of international business cooperation, innovation, knowledge and technology transfer and cooperation in EU programmes.
- Task Force Health Care, one of the Dutch organisations maintaining bilateral relations between the Life Sciences & Health sectors in Brazil and the Netherlands (platform TFHC Latin America) through trade missions and business support.
- Brazilian Dutch Chamber of Commerce, expands, develops and supports business between Brazil and the Netherlands.

The Inter-American Development Bank (IDB)

The Inter-American Development Bank (IDB) focuses on and finances projects that stimulate economic development in Latin American and Caribbean countries (Inter-American Development Bank, 2019). The IDB has set up a multi-year country strategy for the period of 2019-2022 for Brazil, in which they address the challenges Brazil is facing, as well as highlighting the opportunities available. These opportunities can be of interest for the Dutch LSH sector.

An overview of Brazil's country strategy can be found here: https://www.iadb.org/en/countries/brazil/overview. For more information about potential opportunities in cooperation with the IDB, you can contact Corinne Abbas or Jules van Son from the Dutch Enterprise Agency (RVO).

- Corinne Abbas: corinne.abbas@RVO.nl
- Jules van Son: jules.vanson@RVO.nl

Additional information about doing projects with international organizations can be found on the following website: https://www.rvo.nl/onderwerpen/internationaal-ondernemen/netwerken-en-contacten/internationale-organisaties

6 ALIGNING DUTCH STRENGTHS WITH BRAZILIAN OPPORTUNITIES

Using desk research and the factfinding, TFHC has identified a number of matches between the Dutch supply of Smart Solutions for healthcare in the strengths of *Hospital Design and Build, eHealth, Medical Devices & Supplies & Mobility & Vitality* and related health challenges in Brazil. These matches are potential indicators of market opportunities. The following section starts with a summary of the SUS plans and budget set-out in the Annual health programme (Programaçao Annual Saude PAS) followed by key trends in the Brazilian health market related to the aforementioned strengths.

6.1. Annual health programme (Programaçao Annual Saude PAS)

The Annual Health Programming (PAS) is a publication which displays concrete goals, activities and budgets set by the Brazilian government to be achieved/implemented on the short term, usually within a four-year period. A new National Health Plan is expected in late 2019. The current data on gross investment amounts allocated to various projects included in the PAS is therefore not accurate. Nonetheless, the document gives an indication of potential market opportunities based on public investments.

The National Health Plans (Plano Nacional de Saúde PNS) for the period 2016-2019 are available in Portuguese here, The Annual Health Schedule 2019 (Programação Anual de Saúde PAS) can be found here. Health priorities are published in the National Health Council (Conselho Nacional de Saúde CNS).

6.2. Hospital Design and Build

The strength 'Hospital Design and Build' encompasses solutions which help public and private health systems to expand and improve health infrastructure. Organisations within this strength offer solutions in design (architecture), engineering, build, planning of operations and maintenance, and project management. Providers of such solutions typically partner with public or private hospital project developers and assigned project managers.

Trends

Brazil as a large country knows many challenges related to keeping its health infrastructure functioning and efficient. While in rural and/or remote areas distance to and accessibility of health facilities remains a challenge, in urban areas overcrowding of specific departments within hospitals and waiting lists are a challenge (Chapter 4). Next to making hospitals more efficient, both public and private health providers look to expand existing facilities or develop entire new facilities. Find a list of flagship hospitals in Annex 7.

Text Box 12: The fluctuating capacity/market share of Brazil's private health sector

Due to a large part of the Brazilian health system consisting of private hospitals, the capacity of its total health infrastructure (number of facilities and beds) can fluctuate heavily, correlated to the economic cycle. In periods of recession, when private health insurance coverage drops, many, especially small to medium-sized facilities, can be hit hard. The economic crisis of 2014 for example reportedly led to the closing of 1,797 private hospitals across Brazil, leading to a loss of 31,454 beds between 2010 and 2018. During this period however 1,367 new health facilities were created (FBH, 2018).

After a period of decline, the number of health facilities in Brazil are on the rise again. The number of health facilities grew by 4.8% in December 2017 compared to December of 2016 (FEHOESP, 2017). The number of private clinics has also grown by 8.1% while doctors' offices grew by 4.1% in 2017. The number of home care units grew with 34% growth in the same period.

Sources estimate around 214 new health care facilities being planned or built throughout Brazil, being 112 in execution and other 102 in the planning stage (e-Construmarket, 2018). The state of São Paulo concentrates the largest number (74) of hospital projects, followed by Minas Gerais (26), Rio de Janeiro (18), Rio Grande do Sul (17) and Paraná (11).

Text Box 13: ANAHP, representing Brazil's private hospitals

ANAHP – the National Association for Private Hospitals – represents the interests of 109 Brazilian private hospitals, predominantly [63%] large hospitals [150 – 400 beds] and special size [500+ beds]. Its members have made a total of R$ 38.6 billion in gross revenue in 2018, having performed 84 million exams, 1,5 million surgeries and 10,5 million first aid care in their ERs in 2018. The 109 hospitals corresponded to 25,2% of the country's total expenditure in supplementary health care. ANAHP has grown by 10% in number of members from 2017 to 2018 and, between January and May 2019, ANAHP has added 9 new members to the association. ANAHP points out that 49 institutions had a 24% increase in the number of beds from 2010 to 2017. Those institutions are located in cities with a strong economy and a large customer base (over 150 beds).

ANAHP is gathering data from the overall healthcare industry and producing analysis to guide the operational improvement of its members, while fulfilling its purpose of advocating in favor of private hospitals nationwide. The Association is particularly committed to producing data on clinical outcomes, at first following the standard sets from ICHOM for Congestive Heart Failure and now expanding to stroke and sepsis and planning of implementing a standard set for patient experience by 2020.

The focus on clinical outcomes and the investment in following ICHOM standards put ANAHP closer to a value-based approach to healthcare, as standards are patient-centered, aimed at monitoring patient demographic profile, line of treatment, outcome and quality of life. Members of ANAHP are also producing their own data, as 99% have electronic prescription in place, 86% have EMR, 91% have PACS [Picture Archiving and Communication Systems] and 74% make use of those data for BI.

The annual Observatório published by ANAHP is a rich source on the development and plans of its members. It also provides a detailed overview of its members and trends in the healthcare sector.

Opportunities

Many of the hospitals in Brazil have expansion plans for new or refurbished hospitals or clinics. While some of them are ongoing projects, others are awaiting final funding approval, and subsequent tender. Examples are displayed in table 7.

Table 7 Hospital projects in Brazil

Hospital	**Value (estimated in US$ in millions)**	**Description**
Hospital de Clinicas de Porto Alegre	100	Expansion of general (outpatient clinic)

Hospital Sírio-Libanês	42	Construction of a new hospital with 144 beds and 6 surgical rooms in Brasília
Hospital Sírio-Libanês	32	Construction of a technological park and improvements to the hospital's main area, in order to accommodate a larger educational unit and research lab.
Hospital Beneficência Portuguesa	50	Construction of a new hospital with 200 clinics and capacity for 3.5 thousand physicians in 2018
Hospital Albert Einstein	200	Plans to invest further in an expansion plan that includes a new building of high complexity with surgical centers and an ICU.
Hospital Oswaldo Cruz	137	Robotic surgical center and the creation of a new clinical protocols system, It opened the Vergueiro unit in São Paulo, with 260 beds
Hospital Oswaldo Cruz	46	Innovation Between 2018 and 2022
Rede D'Or	250	Construction of three cancer hospitals in Sao Paulo, Rio and Brasilia
CHN (Niterói Hospital Complex)	25	Expansion of 194 beds.
Diagnostic and therapy services	-	ABIIS (2019) highlights the opening of 280 new establishments

Text Box 14: ANAHP, representing Brazil's private hospitals

Hospital de Clinicas de Porto Alegre, close to 50 years of existence, has a unique model of funding. Being a teaching hospital, HCPA is allowed to sum up funding from the Ministry of Health and the Ministry of Education. Hospital de Clinicas payroll – of 6,000 civil servants – is funded by the Ministry of Education. As a result, the Hospital de Clinicas is very prolific in advanced research – including product development, research with DaVinci robots, clinical trials – and student exchanges. Their main challenge is in patient flow. Their current expansion – of two new buildings and designed to double the number of ORs from 20 to 40 – was idealized 20 years before, when their financial situation was more solid and predictable. Now that the expansion is ready, in times of more unstable funding, their challenge is to fit the new spaces into the current patient flow, equip the new buildings and make it operational.

A new and gowing opportunity in Brazilian hospital build market is a growth of investments by international companies in enterprises related to healthcare services in Brazil after the foreign participation law (Law 13,097/2015) was passed in January 2015.New incoming investments led to consolidation of the sector by the acquisition of smaller health units. With more capital and less dependency from credit lines, these groups have been investing in new units or in expanding their existing structures (Switserland Global Enterprise, 2018). Since many of these companies work with global supplies chains, it could be seen as an additional channel into the Brazilian market.

One such example is the American Network of Dialysis Clinics DaViTa, that intends to invest about US $ 500 million in the Brazil until 2023. Since entering the country, it has acquired 31 dialysis clinics. Brazil and Germany are the priority markets for DaViTa. (ABIIS, 2018)

Market Entry Considerations

Entering the Hospital Design and Build market in Brazil is not easy with strong competition from local and international companies. Some market entry considerations are:

- As for all market segments, establishment of local company in Brazil to develop local market is important to show dedication and commitment. At least, partnerships with local companies should be established and frequent visits to Brazil planned for.
- Identification of investment source is key to identify relevant decisionmakers. Although the need for public infrastructure is high, public spending is capped and governed by (bureaucratic) regulations. Nonetheless opportunities do exist in the public hospital build market.
- Investment decisions by private hospitals are driven by market factors taking into consideration the bottom-line. Propositions that can increase quality, efficiency and effectiveness of the hospital are sought.
- Since the market was opened to foreign investors, international care providers have entered the Brazilian market. Many of these organizations are global companies with global procurement channels. In addition to local contacts, international contacts with stakeholders at the global level can facilitate access to projects in Brasil.
- Some insurance companies also operate and build hospitals. Therefore the link between care provider and reimbursement is very direct. Engaging with insurance company to discuss propositions to increase the cost-effectiveness of hospitals can be an additional market entry strategy.
- Hospital build solutions should have a proven added value in terms of increased quality or efficiency, substantiated by a clear business case. This holds both for greenfield, as well as brownfield (refurbishment), projects.

6.3. eHealth

The Dutch havef strengths in the eHealth sphere, which encompasses solutions which help connect actors in the health systems, often through the exchange and storage of health information. Organisations within this strength offer solutions in health information exchange, interoperability, telemedicine, serious gaming and personal health monitoring. These organisations typically partner with health care providers and consumers.

Trends

The digital health transformation of Brazil and therefore its health market is highly fragmented. High discrepancies are reported between rural and urban areas and between different hospitals in both the public and private sector. In rural areas and smaller cities there is little use of technology – patient records in small cities is manual while in the front runner states, most notably São Paulo, impressive progress has been made (FIPE - Institute for Economic Research).

Of an estimated 500 000 doctors in Brazil, only 30% makes use of some sort of electronic registry (RedPointVentures, 2019). The minority of doctors who do have access to electronic registries are spread over an estimated 5 000 different (health) information systems. Currently digital information systems are scattered and not interoperable. Nonetheless, some private hospitals are trying to follow international standards when implementing digital systems. Brazil doesn't have a national digital ID yet and therefore 18 different nationwide ID systems exist, making identification of patient cumbersome.

To work towards digitizing the Brazilian health system, the Ministry of Health announced possible investments of more than $450 million by 2019 to digitalize the public basic care units of the country's Unified Health System (SUS). Private hospitals are also investing in technology, and several new hospitals are formalizing their progress by obtaining international certificates for data management and reduction of paper use.

Furthermore the Ministry of Health is working on a SUS National Health SUS card which should tackle the problem of nationwide identification. PIS/PASEP is the most unified and updated, but only covers employed citizens.

Text Box 15: Digital Health Innovation in the State of São Paulo

The Secretariat of Health of the State of São Paulo is working on an ambitious and comprehensive digital health innovation strategy. The project consists of four pillars: telemedicine, big data, digitalizing the access to health scheduling and building a digital record centered on the patient. Those themes are meant to tackle the main inefficiencies of the health system run by the state of Sao Paulo: respectively, reducing pressure on the healthcare network run by the State; improving processes and controls through data, patients waiting for exams that in the recent past has amounted to one million patients in line, and collecting patient data to allow monitoring the overall healthcare. The project design phase has been completed and implementation has started.

There are some interesting developments going on in the telemedicine market of Brazil. The Federal Council of Medicine (CFM), in May 2019, proposed a resolution allowing doctors to make consultations, diagnoses and Online surgeries. Nonetheless, discussions on its application are ongoing. Formal consultation rounds are still taking place before this resolution can be implemented. Distance consultations may be useful for bring assistance to cities that cannot attract professionals but the patient's first consultation must be in person. In the case of larger communities distant, teleconsultation is allowed the first time, provided the patient is accompanied by another healthcare professional. (ABIIS, 2019).

Opportunities

Digitalization, eHealth and telemedicine are on the rise in Brazil, creating potential market opportunities. However, the market is still very fragmented, making it cumbersome to enter. Moreover, many 'homegrown' solutions, developed by hospitals, insurance companies or local companies and start-ups are competing for market share, illustrated by the AGHU Project (Text box 16). Understanding and connecting to existing digital infrastructures is key. Opportunities exist in systems that increase interoperability and effective use of already capture data. However, for the technical implementation of these solutions, inhouse services might be preferred.

Text Box 16: Digitalisation in Hospital de Clinicas de Porto Alegre

Hospital de Clinicas de Porto Alegre started developing its own proprietary EHR (electronic health record system in the 1980's called AGH (Hospital Management Applications). In 2009, based on the management model at HCPA and with AGH as tool to support best practices in care and administrative management, the Ministry of Education (MEC) decided to transfer the developed knowledge to 47 university hospitals (HU). Thus was born the AGHU Project (University Hospital Management Applications), developed in partnership by HCPA, MEC and the Brazilian Company of Hospital Services (Ebserh), with the purpose of defining and implementing effective, lasting, comprehensive and participative solutions for structural problems of HUs across the country.

The system has been developed internally with funding from the Ministry of Education. The system is currently web based, migrating to cloud and assuring that it goes to paperless controls. Nationwide developments are the development of a data repository on ongoing clinical research that also track the evolution of research (with shared data within the hospital). A team is developing tools for machine learning, big data analysis and artificial intelligence.

In the larger flagship hospitals the move has been made to the *second wave* in the digitalization process. These hospitals are proficient in gathering clinical and treating data and are now moving to create value from this data. Opportunities exist for AI solutions or algorithms that increase the clinical decision making processes or improve

the efficiency. For instance Hospital Albert Einstein, São Paulo, has been investing since 2017 in a modern Patient Electronic Record system based on big data. Another group which is investing in health information management systems are private diagnostic groups such as Dasa the largest diagnostics group in Latin America (Text box 17).

Text Box 17: Private diagnostic group Dasa invests in eHealth

Dasa, the largest diagnostics group in Latin America, with 23,000 employees and 600 diagnostics units, is building a strong transformation of culture and business mode within the company. It has created its own innovation hub within the company, with 34 projects around services and apps, following Agile methods. This is to realize a new strategy of guiding business to a full service company guided by the patient life cycle, integrating the ecosystem: primary care, technology and hospital attention.

Dasa is very much interested in Artificial Intelligence (AI) in processing information, optimizing processes and also to predict malfunction of 4,000 equipments they own across their units. Dasa applies AI in diagnostics (in xray) and has invested 2 million dollars in AI in two years. Dasa executives are connected internationally – in collaboration with Harvard Center of Clinical Data Sciences [CCDS] – and seek to increment international collaboration in the future with a particular focus on AI supported analysis and prediction models.

Value-based healthcare is a development that could drive the need for reliable data and underlying management information systems. Improving (hospital) management by increasing efficiency and cost effectiveness are top priorities for many of the hospital boards. However, in various interviews it was mentioned that reliable data and systems to base decisions on are not readily available. Moreover, the most prevalent payment method in Brazil remains the Fee-for-service model (FFS). This model places incentives on volume over value. The medical inflation in Brazil in 12 percentage points above general inflation as compared to 4 percentage points above general inflation in Germany (IESS, 2019).

Text Box 18: ANAPH advocating Value-based Healthcare

ANAHP, the National Association of Private Hospitals, has been championing improving cost-effectives for a long time. However they do not consider models of remuneration based on value-based care, yet. Nonetheless, the traditional models of implementing medical devices in Brazilian hospitals is changing: the is more and more recognized that the use of machines is not efficient, making the return on investments very long. The industry of medical equipment is not yet service-based and pay for performance an exemption. For business models to change in the future eEverything needs to come together: integration of services and systems. ANAHP has been pushing for a Value-based Healthcare and changing the remuneration model. They consider they are on the way to getting there and to find sustainability. But they are far from reaching an equation [a business model]. ANAHP is looking for international models of implementation to bring to Brazil and wants to put clinical outcomes in the center of discussion. They expect to lead Value-based HC in Latin America.

Many hospitals have developed or piloted their own telemedicine projects, such as: Einstein has conducted telemedicine projects for adults and Moinhos de Vento has conducted telemedicine projects for children in the pediatric ICU. Moreover, telemedicine solutions create opportunities to provide healthcare in remote or underprivileged areas. Although current legislation might still be an hindrance to role out projects on a large scale, individual Dutch companies are already active with Telemedicine solutions in the Brazilian market. The general sentiment is that legislation will catch up with developments on the ground.

Market Entry Considerations

In order to enter the eHealth market in Brazil, the following items should be taken into consideration:

- Establishment of local company in Brazil to develop local market is important to show dedication and commitment. At least, partnerships with local companies should be established and frequent visits to Brazil planned for.
- The eHealth market (especially for start-ups) is booming. "When is the time to come to Brazil? Now!"
- Home grown solutions will compete with international offers. Local development cost of software is almost comparable to a market such as India.
- The biggest uncertainty is regulation. Telemedicine will happen in Brazil, but how exactly is in the future.
- Some insurance companies, such as Amil, Bradesco, Omint –have a departments for telemedicine. They might be driving part of the adoption of telemedicine.
- Solutions should have a proven (clinical) added value, and a clear business case.

6.4. Medical Devices & Supplies

The strength 'Medical Devices & Supplies' encompasses solutions which improve health delivery. Organisations within this strength offer solutions for diagnostics, treatment and related processes, and typically partner with providers of primary, secondary and tertiary care services and/or intermediate organisations.

Trends

The market of Medical Devices is growing in Brazil. The consumption rate Medical Devices in 2018 grew 13.5% between January to December (ABIIS, 2018). Between industry segments, consumption of IVD products (In Vitro Diagnosis) increased by 15.8% and that of OPMEs (Prostheses and Implants) of 5.4% in the period in question (ABIIS, 2018).

In 2018, Brazilian imports of medical devices totalled US $ 5.4 billion, with growth of 21.8% compared to the same period of 2017. Exports from the sector, in turn, presented a decrease of 7.3% in the year 2018. In value totalling U S$ 644 million compared to US$ 694 million in 2017. The trade balance in medical devices in 2018 registered a deficit of$ 4.8 billion. (ABIIS, 2018).

In order to get a better understanding of the international competition for particular medical devices in Brazil, the database for the Ministery of Exterior is an excellent source for indepth research on particular HS-codes (NCM in Brazil). More detailed information can be found here. Associations such as ABIIS (Aliança Brasileira da Indústria Inovadora em Saúde) or ABRAIDI (Associação Brasileira de Importadores e Distribuidores de Produtos para Saúde) provide data and reports on the imports conducted through there members.

Opportunities

The large healthcare market in Brazil makes the country an important export destination for many of the world's larger exporting countries in medical devices (BMI, 2017) (Caritá, 2018). Brazil's public and private health sector offer opportunities for innovative technologies which increase the quality of health services and which the health infrastructure operate more efficient.

A large part of the consumption of medical devices, an estimated 40%-50% (compared to 80-90% in most countries in the world), is however supplied by imports (BMI, 2017). It is therefore useful to look at import numbers to determine the potential for foreign medical devices in Brazil. The higher the import share of a product group, the higher the potential for foreign solutions.

In general, Brazil's import share varies considerably across different product groups. This is caused by the segmentation of Brazil's medical industry which mainly produces and exports low-complexity equipment and medicines and relies on imports for more complex products. Table 8 shows complex devices and machines used as patient aids and used for diagnostic imaging to be have the highest import reliance in Brazil.

Table 8: Import share of medical products in Brazil (BMI, 2017)

Product Group	% Imported	Best Performing Sub-Groups
Consumables	40%	Syringes, needles & catheters are the largest segment of Brazil's consumable market with an import share of 65% (40% supplied by US).
Diagnostic Imaging	75%	Electrodiagnostic Apparatus shows the highest growth. Philips Healthcare is a principal player in this field.
Dental Products	>25%	(Dental) Instruments & supplies are the largest segment and shows the highest growth. The import share is roughly 20% of the total market. Brazil's MOH has announced to continue to invest in local production of this segment.
Orthopaedics & Prosthetics	>50%	Other Artificial Body Parts (excluding fixation devices and artificial joints) are the largest segment with the highest import share of roughly 50% as domestic production focuses on artificial joints and orthopaedic & fracture appliances.
Patient Aids	>75%	Portable aids (hearing aids, pacemakers etc.) are the largest sector in the patients aids market, boasting a high import share of 90%/ Therapeutic appliances also show growth numbers and has an import share of around 50%.
Other Medical Devices	55%	Domestic production is strong for wheelchairs, hospital furniture and sterilisers, but under-developed for ophthalmic instruments and dialysis equipment which therefore are imported more than other products within this product group at around 60%.

As indicated above, the medical device market is big and growing and could offer – with the right strategy and determination – interesting opportunities for Dutch companies.

Text Box 19: Hospital Moinhos de Vento investing in medical devices

Hospital Moinhos de Vento is a privately owned, non-profit general hospital with 471 beds - being 81 in intensive care - and 165.814 consultations in 4 units in the city of Porto Alegre. It averaged 149.739 patients per day in 2018 and has recorded R$ 805-million gross revenue in the same period. Has invested R$ 40,7 million, in particular in updating equipment in ORs, acquiring monitors, anesthetics equipment and full HD video laparoscopy. Annual spending of Hospital Moinhos de Vento in K/PACKS is close to US$ 30 million.

Strategically, the hospital diversify their suppliers, but are keen on demanding from them local technical support, responsiveness of local teams, and quality of equipment at a fair price point, with flexible negotiations. If compliant to those expectations, and ready to establish their businesses locally, Dutch companies are more than welcome to do business with the Hospital.

According to ABIIS, most of the health sector's growth is due to the verticalization of the health insurance plans, which have been investing in their own hospitals and clinics in order to reduce costs. Through verticalization Brazilian insurance companies have become care providers themselves. A 2014 study by the National Agency for

Supplementary Health, ANS, showed that around 40% of the insurance health plans in Brazil already count with their own health units for attending their clients. In the past years, with the decline of private health beneficiaries and the scaling costs in the health sector, the verticalization has become one of the main strategies of the private insurance health plans to remain competitive. The verticalization also brings more control over the chain and reduces their dependence of third-parties.

As an example, some insurance companies are importing medical devices directly from the foreign manufacturers, without the intermediation of a distributor. This option reduces the importation costs and allows the insurance plans to avoid frauds that could burden the system. For Dutch companies interested in the Brazilian market, this means a new opportunity to sell directly to the health insurance plans and be more competitive in terms of prices. (Switzerland Global Enterprise, 2018)

Market Entry Considerations

The Brazilian market for medical devices is highly competitive. In the higher segment large multinationals supply the market with GE, Siemens and Philips being the main suppliers while Toshiba has a relatively smaller market share. In the lower segment, many Brazilian suppliers and major Chinese and Korean suppliers are active (Evidera, 2017). Consolidation trends are currently in place for the Brazilian medical device industry. Governmental investment in local production and incentives for Brazilian companies to produce locally will continue.

To be succesful in this competitive environment it is important for Dutch organisations with Smart Solutions in healthcare to take into account Brazil's price-driven healthcare market. Therefore discussions on contracting and rebates should be commenced early on in the market entry process. Medical devices are strictly scrutinised on quality and affordability. Cost-saving concepts are desirable and have a higher chance of eligibility for reimbursement.

One source to gauge price levels in Brazil is the online platform Portal do Médico (Textbox 21).

Text Box 20: Enter Brazil's eHealth market using Portal Médico

Portal do Médico is the largest online marketplace and market leader in Brazil for medical equipment and hospital products, having reported, in 2019, R$ 1,2 billion in quotations, 12 million hits, 70.000 products and 40,000 clients. Established in 2016, Portal do Médico integrates B2B and B2B players by connecting vendors and physicians, healthcare professionals and companies, hospitals, Government entities, students and individuals looking to buy, sell and promote healthcare products online.

Its content is organized in 47 categories and 70 medical specialties and potentially allows the access to the Brazilian market, where the healthcare industry trades on average US$ 100 billion in medical equipment and products every year, and is made up of 6,000 hospitals, 100,000 medical clinics and 300,000 active health facilities.

The Portal provides market analytics on Brazil and covers the process from certification to go-to-market. To do so, Portal do Médico is partner with DOMO Salute, a regulatory intelligence consultancy that enables the access and permanence of health technologies and cosmetics in the Brazilian market by conducting registrations by ANVISA (Brazilian Health Surveillance Agency), INMETRO (National Institute of Metrology, Quality and Technology, linked to the Ministry of Economy) and ANATEL (National Telecommunications Agency) and acting as legal representative of the products in the country. Portal do Médico charges a business intermediation fee between 5% and 15%, depending on the amount negotiated. Learn more here.

A relative new development is the stricter use of Health Technology Assessment (HTA) by CONITEC, which is likely to become more robust with more medical devices undergoing assessment. The robustness of technology evaluation is also expected to increase in the private sector.

For many Brazilian clients, evidence of efficacy in a local context is important, although no formal criteria exist and evaluation processes are relatively new. Pilots conducted at prestigious/representative health institutions are therefore a frequently used way to enter the market. A good economic analysis needs local data, whereas clinical data does not need to be local - foreign studies in reliable centres around the world are acceptable. However, acceptance should be verified at the beginning of the registration process.

Heavy investments on medical devices are concentrated in the hospitals (Evidera, 2017). In the public sector capital and national budgets are distributed amongst regional / municipal bodies and governed by public procurement regulations. In the private sector ANS is the main stakeholder making decisions on the annual budget. The private sector is predicted to grow, resulting in attractive opportunities for medical device companies. However, access to the private market seems to be more limited to regions with more money (e.g. Sao Paulo).

For market entry of medical devices a local registration required and a distributor or agent recommend (see Chapter 5). Examples of local distributors are included in Annex 6.

Text Box 21: Angiolux

Angiolux is an importer and distributor of implantable devices and accessories for minimally invasive surgical procedures, in the fields of hemodynamic, vascular surgery, endoscopy and oncology. A privately held company established in 1998 in the city of Porto Alegre, Angiolux is currently partners with Ella-CS, Acrostak, Bard, Svelte, Eucatech AG, Comed BV, PHS Medical and Simeks.

Angiolux's value is in actively seeking small to medium manufacturers around the world and connecting them to Brazilian distributors, which are their end clients. Additionally, Angiolux gathers distributors in a pool or cooperative-like model to share marketing and regulatory costs. Angiolux focuses on innovative yet cost effective devices and is now looking into expanding its business beyond their current portfolio. In fact, the company is developing partnerships with ultrasound manufacturers.

Angiolux is certified by ANVISA (Brazilian Health Surveillance Agency) for Good Storage and Distribution Practices for Medical Devices (GSDPMD). The company is also associated with the Brazil-Germany Chamber of Commerce and the Medical Valley in Porto Alegre. Learn more here.

Text Box 22: Developing your solution in Brazil

Brazil houses a lively innovation climate which can be leveraged on to develop medical devices in Brazil. Many incubators (particularly in the state of São Paulo) welcome foreign innovators. For a list of accelerators/incubators view the *Market Scan Healthy Ageing in Brazil (p. 61-64)* written by Intelligence Hub in assignment of the Dutch government.

6.5. Mobility & Vitality

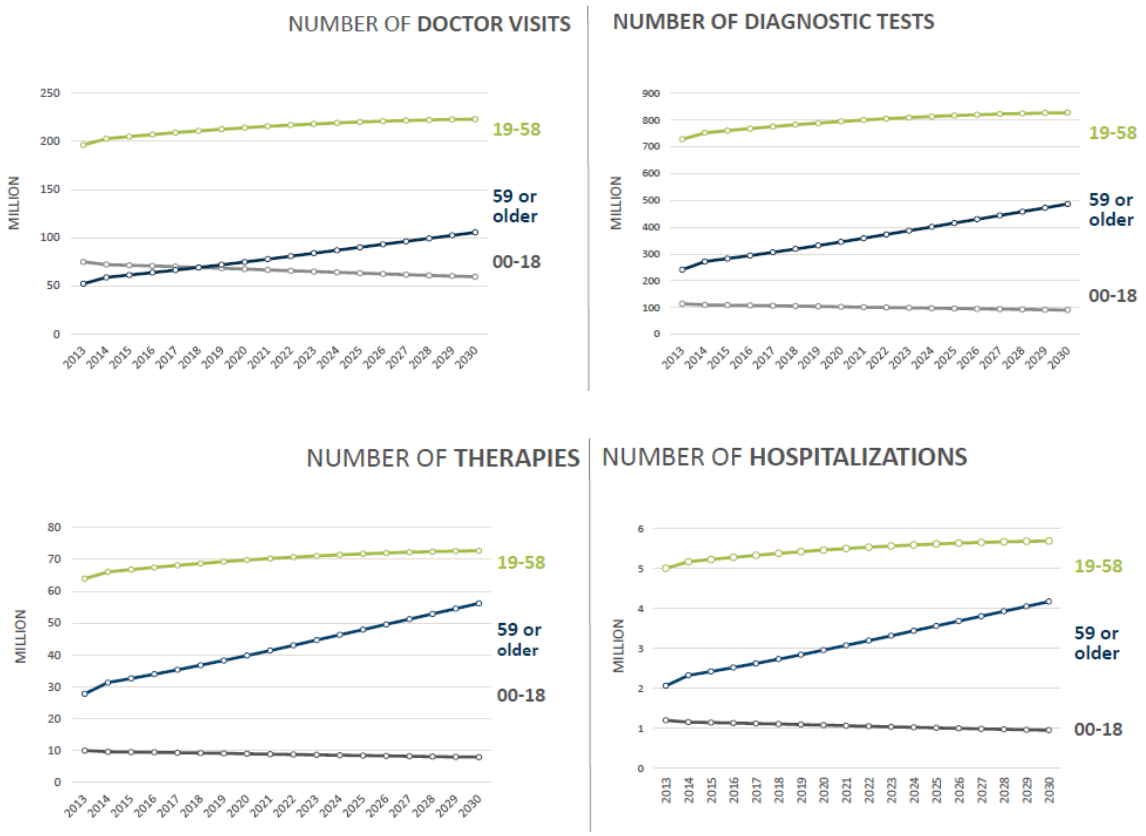
Mobility & Vitality encompasses solutions which help people live and age healthily. Dutch organisations within this strength offer solutions in areas such as mobility aids and monitoring systems and typically partner with organisations which deliver elderly care, primary health care, rehabilitation services and care to vulnerable groups, such as mental health and special needs patients.

Trends

Brazil's market for Mobility & Vitality solutions is still traditionallly directed mostly on rehabilitation and patient aids (roughly 70% imported Chapter 5) and less on for example prevention. The market is growing fast as the number of medical beneficiaries of 60 years or older in the supplementary healthcare system (main target group within the

Mobility & Vitality market) is projected to increase from 14.3% in 2015 to 20,5% in 2030 (IESS, 2019). Simultaneously, as indicated below, the projection of growth of health services provided by medical schemes towards 2030 is within the >59 or older category.

Figure 12 Projection of the number of Health Services provided by (supplementary) medical schemes by age in Brazil (2013- 2030) (IESS, 2019)



Opportunities

A big opportunity in Brazil is a steep increase in the demand for homecare services, allowing seniors to age at home (FP Analytics et al, 2018).

The supply of public care services and solutions towards the older segment of the population however lacks a comprehensive national approach (Center for the Study of Aging, 2019). SUS leaves a vacuum on the market, which private players, notably NGO's increasingly step in to fill. On the technology side, start-ups are the most active force to increase the accessibility of digital devices for seniors

Due to a growing (private) demand, new companies are established offering nursing homes, elderly spas and high end services. Over 60 laboratories for professional activities of the elderly have been established (IESS – Institute for the Studies of Supplementary Health).

Health promotion and prevention are not top policy priorities, yet. Prevention is dependent on behavioral chance and financial incentives. (IPE - Instituto de Assistência a Saúde dos Servidores Públicos do Rio Grande do Sul). Insurance companies also hardly promote prevention, because they believe the patient will migrate to another insurer and the original insurance companies won't directly benefit from the effort that it made (IESS – Institute for the Studies of Supplementary Health). However, efforts have been made to get private health providers and insurers involved. ANS has issued a regulation in 2010 allowing insurance companies to offer reduced premium if users join a prevention program (IESS – Institute for the Studies of Supplementary Health). Currently, not many large scale examples of health promotion, or movement towards healthy lifestyle, can be identified.

REFERENCES

AARP. (2018). The Aging Readiness & Competitiveness Report. Opgehaald van http://www.silvereco.org/en/wp-content/uploads/2017/07/ARC-Report-Brazil.pdf

ABEP. (2016). Brazilian Criteria 2015 and social class distribution update for 2016. Opgeroepen op July 2, 2019, van http://www.abep.org/Servicos/Download.aspx?id=13

Akindo, P. (2016). An Assessment of Equity in the Brazilian Healthcare System: Redistribution of Healthcare Professionals to Address Inequities in Remote and Rural Healthcare. Clinical Social Work and Health Intervention, https://www.clinicalsocialwork.eu/wp-content/uploads/2016/08/04-Akindo.pdf.

Almeida, M.E. (2018). It is time for rural training in family medicine in Brazil! RBMFC, https://rbmfc.emnuvens.com.br/rbmfc/article/viewFile/1696/902.

Beneficios RH. (2018). Beneficios RH. Opgehaald van 10 Maiores Operadoras de Planos de Saúde para sua Escolha [2019]: https://www.beneficiosrh.com.br/maiores-operadoras-planos-de-saude/

Bliss, K. (2017). Brazil's Sistema Único da Saúde (SUS): Caught in the Cross Fire. Opgeroepen op August 2019, van CSIS: https://www.csis.org/blogs/smart-global-health/brazils-sistema-unico-da-saude-sus-caught-cross-fire

BMI. (2017). Brazil Medical Devices Report Q4 2017. London: Business Monitor International Ltd.

Business Sweden. (2015). THE BRAZILIAN HEALTHCARE SECTOR. Online: https://www.business-sweden.se/contentassets/d66e1faed2614637b7f1da59f84ef1e3/brazil_fact_pack_health-care_august-2015.pdf: Business Sweden.

CIA. (2019). The World Factbook. Opgeroepen op June 26, 2019, van https://www.cia.gov/library/publications/the-world-factbook/geos/br.html

Collucci, C. (2018). Brazil’s child and maternal mortality have increased against background of public spending cuts. BMJ, https://www.bmj.com/content/362/bmj.k3583.full.

Compernolle, P. (2015). Den Haag: AWTI.

Costa, N. (2017). Brazilian healthcare in the context of austerity: private sector dominant, government sector failing. Ciência & Saúde Coletiva, https://pdfs.semanticscholar.org/5fe9/486c905400eee9f46edc1bf82a4247f8d130.pdf.

Daniels, S. (2018). Brazilian consumers seeking healthier products, but not necessarily from supermarkets: Mintel. Opgehaald van FOODnavigator-latam.com: https://www.foodnavigator-latam.com/Article/2018/08/30/Brazilian-consumers-seeking-healthier-products-but-not-necessarily-from-supermarkets-Mintel

De Lange, C. (2014). Brazil’s billion-dollar gym experiment. Opgehaald van Mosaic: https://mosaicscience.com/story/brazils-billion-dollar-gym-experiment/

de Souza, C., Morbeck, R., Steinman, M., Hors, C., Bracco, M., Kozasa, E., & Leao, E. (2017). Barriers and Benefits in Telemedicine Arising Between a High-Technology Hospital Service Provider and Remote Public Healthcare Units: A Qualitative Study in Brazil. Telemedicine and e-Health, https://www.liebertpub.com/doi/full/10.1089/tmj.2016.0158.

EMERGO. (2019). BRAZIL – Overview of medical device industry and healthcare statistics. Opgehaald van EMERGO: https://www.emergobyul.com/resources/market-brazil

European Commission. (2019). Mercosur - factsheets. Opgehaald van http://trade.ec.europa.eu/doclib/press/index.cfm?id=2038

Export.gov. (2019). Brazil - Customs, Regulations and Standards. Opgehaald van Export.gov: https://www.export.gov/article?id=Brazil-Customs-Regulations-Standards

Export.gov. (2019). Brazil - Healthcare. Opgehaald van Export.gov: https://www.export.gov/article?id=Brazil-Healthcare

Export.gov. (2019). Brazil - Selling to the Government of Brazil. Opgehaald van Export.gov: https://www.export.gov/article?id=Brazil-Selling-to-the-government-of-Brazil

Farah, A. (2013). The Brazil Business. Opgehaald van Cost of Health Services : https://thebrazilbusiness.com/article/cost-of-health-services

FP Analytics et al. (2018). The Aging Readiness & Competitiveness Report - Brazil. AARP & FP Analytics.

Garcez-Leme, L. E., & Leme, M. D. (2014). Costs of elderly health care in Brazil: challenges and strategies. MedicalExpress, 11, http://www.medicalexpress.net.br/details/36/costs-of-elderly-health-care-in-brazil--challenges-and-strategies1.

Global Health Intelligence. (2016). Brazil Hospital Demographics 2016 – Latin America's second largest hospital market can still gain efficiencies. Opgehaald van ghi: https://globalhealthintelligence.com/ghi-analysis/brazil-hospital-demographics-2016-latin-americas-second-largest-hospital-market-can-still-gain-efficiencies/

Global Health Leaders. (2018). Public and Private Sector Leaders Take Action in the Fight against Non-communicable Diseases in Brazil: Report Out on Third Intersectoral NCD Forum. Opgeroepen op July 2, 2019, van https://globalhealthleaders.org/third_forum_fight_ncds_brazil/

Global Health P.R. (2015). Opgehaald van Brazil: http://www.globalhealthpr.com/services/brazil/

Harvard TH Chan School of Public Health, P. H.-A. (208, July). NCBI. (P. H.-A. Harvard TH Chan School of Public Health, Redacteur) Opgeroepen op August 2019, van The Brazilian health system at crossroads: progress, crisis and resilience: https://www.ncbi.nlm.nih.gov/pubmed/29997906/

Healthdata.org. (2017). Brazil. Opgeroepen op June 26, 2019, van http://www.healthdata.org/brazil

Hone, T. E. (2017). Large reductions in amenable mortality associated with Brazil's primary care expansion and strong health governance. Health Affairs 36.1, 149-158.

Human Rights Watch. (2018). Life for people with disabilities living in homes for people with disabilities in Brazil.

Hummel, G. (2016). Brazil eHealth - Opportunities, Investments and Targets. EMI – eHealth Mentor Institute.

IBGE. (2010). 2010 Census: 11.4 million Brazilians (6.0%) live in subnormal agglomerates. Opgeroepen op July 2, 2019, van https://censo2010.ibge.gov.br/en/noticias-censo.html?busca=1&id=1&idnoticia=2057&t=2010-census-11-4-million-brazilians-6-0-live-in-subnormal-agglomerates&view=noticia

IBGE. (2017). In 2016, life expectancy was 75.8 years . Opgehaald van IBGE: https://agenciadenoticias.ibge.gov.br/en/agencia-press-room/2185-news-agency/releases-en/18490-in-2016-life-expectancy-was-75-8-years

IBGE. (2019). Geographic Mapping. Opgehaald van IBGE.gov.br: https://ww2.ibge.gov.br/english/geociencias/cartografia/default_geog_int.shtm

IHME. (2018). Financing Global Health 2018. Seattle: University of Washington.

IHRSA. (2018). The 2018 IHRSA Global Report. Boston: IHRSA.

IMF. (2018). IMF DataMapper. Opgeroepen op July 2, 2019, van https://www.imf.org/external/datamapper/PPPPC@WEO/OEMDC/ADVEC/WEOWORLD/BRA/MTQ

IMF. (2019). International Monetary Fund DataMapper. Opgeroepen op June 26, 2019, van https://www.imf.org/external/datamapper/GGXWDG_NGDP@WEO/OEMDC/ADVEC/WEOWORLD/BWA/BRA/NLD

Inter-American Development Bank (2019). About us. Retrieved from: https://www.iadb.org/en/about-us/overview

KPMG. (2019). Healthcare in Brazil - Meeting Future Challenges . Opgehaald van KPMG: https://home.kpmg/xx/en/home/insights/2019/04/meeting-healthcare-challenges-in-brazil.html

LAVCA. (2018). Inside Latin America's Breakout Year in Tech. LAVCA.

Lima-Costa, M. F. (2018). The Brazilian Longitudinal Study of Aging (ELSI-Brazil): objectives and design. American journal of epidemiology, 1345-1353.

Louzada, D. (2019). Brazil has a new minister of health. Opgehaald van Domo Salute: https://www.domosalute.com.br/blog-1/brazil-has-a-new-minister-of-health-luiz-henrique-mandetta

Macinko, J., Harris, M., & Gomes, M. (2017). Brazil's National Program for Improving Primary Care Access and Quality (PMAQ): Fulfilling the Potential of the World's Largest Payment for Performance System in Primary Care. Journal of Ambulatory Care Management, https://journals.lww.com/ambulatorycaremanagement/FullText/2017/04001/Brazil_s_National_Program_for_Improving_Primary.2.aspx.

Mantovani, L. (2016). The new Brazilian law for the inclusion of persons with disability and its effects on patients with serious mental illness. Revista Brasileira de Psiquiatria, 38, http://www.scielo.br/pdf/rbp/v38n4/1516-4446-rbp-38-04-00347.pdf.

Marcolino, M., Figueira, R., dos Santos, J., Cardoso, C., Ribeiro, L., & Alkmim, M. (2016). The Experience of a Sustainable Large Scale Brazilian Telehealth Network. Telemedicine and e-Health, https://www.liebertpub.com/doi/10.1089/tmj.2015.0234.

Marrone, P. M. (2015). Health 4.0 Proposals to boost the innovation cycle in Medical Technology (MedTech) in Brazil. Goiânia: Centro Gráfica.

Massuda, A.E. (2018). The Brazilian health system at crossroads: progress, crisis and resilience. BMJ global health, 3(4), e000829.

Massuda, A., Hone, T., Leles, F., de Castro, M., & Atun, R. (2018). The Brazilian health system at crossroads: progress, crisis and resilience. BMJ Global Health, https://gh.bmj.com/content/3/4/e000829.

McGregor, A., Siqueira, C., Zaslavsky, A., & Blendon, R. (2017). Do elections matter for private-sector healthcare management in Brazil? An analysis of municipal health policy. BMC Health Serv Res., https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5508633/.

Menicucci, T. M. (2019). The Brazilian Unified Health System: Thirty Years of Advances and Resistance. Opgeroepen op August 2019, van intechopen: https://www.intechopen.com/online-first/the-brazilian-unified-health-system-thirty-years-of-advances-and-resistance

MGMH. (2018). Current state of the Mental Health Policy in Brazil. Opgeroepen op July 2, 2019, van http://www.globalmentalhealth.org/resources/current-state-mental-health-policy-brazil

Montone, J. (2019). The SUS and the Social Organization in Sao Paulo. Presentation .

Mullachery, P., Silver, D., & Macinko, J. (2016). Changes in health care inequity in Brazil between 2008 and 2013. Int J Equity Health, 15, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5112635/.

Negrini, E. L. (2018). Elderly persons who live alone in Brazil and their lifestyle. Revista Brasileira de Geriatria e Gerontologia, 523-531.

Nelson, R. (2018). Multilateral Development Banks: Overview and Issues for Congress. Opgeroepen op July 3, 2019, van https://fas.org/sgp/crs/row/R41170.pdf

Nes, E. (2016). Social Classes in Brazil. Opgeroepen op June 26, 2019, van https://thebrazilbusiness.com/article/social-classes-in-brazil-1453802521

Noronha, J. C. (2018). The future of the Brazilian Health System: a short review of its pathways towards an uncertain and discouraging horizon. Ciencia & saude coletiva 23.6, 2051-2059.

Pacagnella, R., Nakamura-Pereira, M., Gomes-Sponholz, F., de Aguiar, R., Guerra, G., Diniz, C., . . . Filho, O. (2018). Maternal Mortality in Brazil: Proposals and Strategies for its Reduction. Revista Brasileira de Ginecologia e Obstetrícia, 40(9), http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0100-72032018000900501.

Paim, J. S. (2018). Thirty years of the Unified Health System (SUS). Opgeroepen op August 2019, van SCIELO Public Health: https://www.scielosp.org/article/csc/2018.v23n6/1723-1728/en/

Pan American Health Organization. (2017). Sustainable Health Agenda For The Americas 2018-2030: A Call To Action For Health And Well-Being In The Region. Washington D.C. USA ; Online: http://iris.paho.org/xmlui/bitstream/handle/123456789/49170/CSP296-eng.pdf?sequence=1&isAllowed=y: Pan American Health Organization.

Rocha, T. e. (2017). Addressing geographic access barriers to emergency care services: a national ecologic study of hospitals in Brazil. International Journal for Equity in Health, 16, https://link.springer.com/article/10.1186/s12939-017-0645-4.

Roznai, Y., & Kreuz, L. (2018). CONVENTIONALITY CONTROL AND AMENDMENT 95/2016 - A Brazilian case of unconstitutional constitutional amendment. Direitos Fundamentais na Nova Ordem Mundial, Editora Ithala.

Rute. (2019). Rute. Opgehaald van Rede Universitária de Telemedicina

Santos, T. (2018). Hospital pharmacy workforce in Brazil . Hum Resour Health, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5755413/.

Saude.gov. (2019). Estrutura Organizacional. Opgehaald van Saude.gov.br: http://www.saude.gov.br/o-ministro/681-institucional/40011-estrutura-organizacional

Silva, D. A. (2018). Results from Brazil's 2018 report card on physical activity for children and youth. Journal of Physical Activity and Health, 323-325.

Simões, N., Coury, W., Ribiero, J., & Araújo, G. (2016). Policy in Focus, Edition: Health policy in emerging economies: innovations and challenges. São Paulo: International Policy Centre for Inclusive Growth (IPC-IG) - United Nations Development Programme (UNDP).

Srinivasan, S. &. (2018). Brazil: Boom, Bust and the Road to Recovery. Washington DC: International Monetary Fund. Opgehaald van IMF.org: https://blogs.imf.org/2019/03/18/chart-of-the-week-trades-impact-on-brazils-industries/

Stein, A., & Ferri, C. (2017). Innovation and achievement for primary care in Brazil: new challenges. BJGP Open, https://bjgpopen.org/content/1/2/bjgpopen17X100857.

SUAS. (2014). Sistema único de assistência social: Orientações para gestores, profissionais, residentes e familiares sobre o Serviço de Acolhimento Institucional para Jovens e Adultos com Deficiência em Residências Inclusivas. Opgeroepen op July 3, 2019, Available via: https://www.mds.gov.br/webarquivos/publicacao/assistencia_social/Cadernos/caderno_residencias_inclusivas_perguntas_respostas_maio2016.pdf

Survival International. (2019). Brazilian Indians. Opgeroepen op July 2, 2019, van https://www.survivalinternational.org/tribes/brazilian

TechinBrazil. (2019). E-health market in Brazil. TechInBrazil: https://techinbrazil.com/e-health-market-in-brazil.

TFHC (2018). Prioriteitslanden Overzicht 2018. Request via info@tfhc.nl

The BMJ. (2018). The end of Brazil's More Doctors programme? Opgeroepen op July 2, 2019, van https://www.bmj.com/content/363/bmj.k5247

The Commonwealth Fund. (2016). Brazil's Family Health Strategy: Using Community Health Care Workers to Provide Primary Care. Opgehaald van https://www.commonwealthfund.org/publications/case-study/2016/dec/brazils-family-health-strategy-using-community-health-care-workers

The Conversation. (2019). Brazil and Venezuela clash over migrants, humanitarian aid and closed borders. Opgeroepen op July 2, 2019, van https://theconversation.com/brazil-and-venezuela-clash-over-migrants-humanitarian-aid-and-closed-borders-112913

The Guardian. (2018). Brazil: judge shuts border to Venezuelan migrants fleeing hunger and hardship. Opgeroepen op July 2, 2019, van https://www.theguardian.com/world/2018/aug/06/brazil-shuts-border-venezuelan-migrants

The Guardian. (2018). Zika and health cuts blamed for rise in baby death rates in Brazil. Opgeroepen op 2019, van https://www.theguardian.com/global-development/2018/jul/17/zika-health-cuts-blamed-rise-baby-death-rates-brazil

The World Bank. (2019). World Bank Country and Lending Groups. Opgeroepen op June 26, 2019, van https://datahelpdesk.worldbank.org/knowledgebase/articles/906519

The World Health Organization. (2019). Global Health Observatory Data Repository. Opgeroepen op July 3, 2019, van http://apps.who.int/gho/data/node.main.HWFGRP_0040?lang=en

Trading Econmics. (2016). Brazil - Rural population. Opgeroepen op July 2, 2019, van https://tradingeconomics.com/brazil/rural-population-percent-of-total-population-wb-data.html

Trading Economics. (2019). Brazil Minimum Monthly Wages. Opgeroepen op June 26, 2019, van https://tradingeconomics.com/brazil/minimum-wages

UNICEF. (2016). UNICEF Municipal Seal of Approval. Opgeroepen op July 2, 2019, van https://childfriendlycities.org/brazil-municipal-seal/

UNICEF. (2019). Alarming global surge of measles cases a growing threat to children – UNICEF. Opgeroepen op June 26, 2019, van https://www.unicef.org/press-releases/alarming-global-surge-measles-cases-growing-threat-children-unicef-0

United Nations. (2017). World Population Prospects: The 2017 Revision. Opgehaald van Online Demographic Profiles: https://population.un.org/wpp/Graphs/DemographicProfiles/

World Bank Group. (2019). Doing business 2019. Washington DC: International Bank for Reconstruction and Development / The World Bank.

World Health Organization. (2016). Global Health Observatory data repository. Opgeroepen op June 26, 2019, van http://apps.who.int/gho/data/view.main.61060?lang=en

World Health Organization. (2018). Noncommunicable diseases country profiles 2018. Opgeroepen op June 26, 2019, van https://www.who.int/nmh/countries/2018/bra_en.pdf?ua=1

ANNEXES

Annex 1 – List of Interviewees in Brazil

An important element of the study was the fact-finding visit to São Paulo and Porto Alegre, whereby a delegation from TFHC gained insights from key stakeholders in the Brazilian health sector. The fact-finding visit took place over a period of one week and included meetings and roundtable discussions with representatives from the public and private sector, operating at the national, regional and local level. These organisations are listed in chronological order below:

Nature of business | Industry	**Nature of business | Industry**	**Position**
Hospital Moinhos de Vento Porto Alegre	Private non-profit general hospital	CEO and President of the Scientific Commission of CONAHP 2019
		CNO
		CAO
Grow+. Porto Alegre	Startup Accelerator	COO
		Head of Operations and Innovation
		Investment Management Lead
Unimed Encosta da Serra Porto Alegre	The Unimed System	Controlling and Finance Director
		Managing Director
		Corporate Executive
		Director of UNIMED Institute
		Vice President of Institutional Relations
		Business and Innovation Director
		Actuarial Advisor
		Vice President
TECNOSINOS - Unisinos - Sao Leopoldo Tech Park Porto Alegre	Tech park	CEO, Director of the Innovation and Technology Center
		Adjunct Director, Department for Commercial Promotion and International Matters
		International and Institutional Relations Coordinator
		SEBRAE [National Agency to Support and Foster Entrepreneurship]
		Hemocord
		SoftwareLab
		Interprocess
		CEO Angiolux [import and export of medical devices]
		Portal do Médico

IPERS – Instituto de Previdência do Estado do Rio Grande do Sul	Health Care Institute for the Public Servants of the state of Rio Grande do Sul	Managing and Financial Director
		Insured Relationship Officer
		Health Care Director
Hospital de Clínicas de Porto Alegre - HCPA	Teaching hospital, general public hospital	CEO
		Coordinator of the Digital Governance Committee
		Teaching Group
		Chief of Staff
		Chief Medical Doctor
		Research and Postgraduation Coordinator
		Surgical Assistant
		Managing Director and member of the board
		Innovation Center
Municipal Health Secretariat of Porto Alegre	Municipal Health Secretariat (SMS2)	Secretary of Health
		Adjunct Secretary of Health
Redpoint eventures, SP	Venture Capital fund	Managing Partner
School of Medicine São Paulo/UNIFESP	In the Federal University of São Paulo - UNIFESP	Director
Philips	Dutch company manufacturer of technology, consumer and lifestyle products	Solutions Business Leader
ANAHP - National Association of Private Hospitals	National Association of Private Hospitals	President
Dasa - Diagnostics of America	Diagnostics company	Technical Director
		Coordinator for Studies and Analysis
		Imaging Director
	Public Teaching Hospital	Thoracic surgeon
Hospital das Clínicas, SP	Public Teaching Hospital of the School of Medicine of the University of São Paulo	Chief of Staff
		Director of Innovation and Executive Director of the Institute of Radiology
		Coordinator of Infrastructure and Logistics Center
State Secretary of Health, SP	State Secretary of Health, SP	Coordinator of Digital Innovation
Independent Consultant	Private non-profit organization created in 1973 to support	[Former Secretary of Health for the city of São Paulo (2007 to 2012), responsible for the

	the Economics Dept of the Economics and Busines School of the University of São Paulo	creation of the National Agency of Supplementary Health (ANS)]
	Private philantropic Hospital	Aide to International Relations
AC Camargo Cancer Center	Private philantropic Hospital	Executive Director of Operations
ANS - National Health Agency of Supplementary Health	National Health Agency of Supplementary Health [Regulation Agency for Health Insurance]	Director of Sectorial Development
IESS	Institute of Supplementary Health Studies	Managing Superintendent

Annex 2 – List of Interviewees in the Netherlands

An important element of the study was the interest survey held in the Dutch LSH-sector. To complement the interest survey, TFHC interviewed 20 Dutch LSH stakeholders who are active in Brazil. These organisations are listed in chronological order below:

1. Cordaid
2. ZonMW/ Nederlandse Organisatie voor Wetenschappelijk Onderzoek (NWO)
3. Spectator Video Technology
4. Dräger Nederland B.V.
5. Elsevier
6. Enraf-Nonius B.V.
7. Erasmus MC
8. Forbo Flooring Systems
9. IMS Medical BV
10. IQVIA
11. Nutricia Advanced Medical Nutrition, Danone
12. Philips Healthcare
13. Sakura FInetek Europe B.V.
14. Bayards Heliport Solutions
15. Eurotape
16. Technomed
17. UMCG
18. Quero Systems Jantine Dirksen: Business Climate Brazil
19. DPI
20. Topicus

Annex 3 – List of Relevant Events and Trade Fairs 2019

Feira Hospitalar

https://www.hospitalar.com/pt/

PITCH: Hospitalar is recognized as the most important showcase of the national and international market in the sector, an ideal space for launching and presenting innovative products, solutions and services and stage for the most diverse congresses, lectures, realistic demonstrations and meetings promoted by entities. and leading healthcare companies.

São Paulo

21 - 24 May 2019

Conahp

https://www.conahp.org.br/

PITCH: Held by Anahp, the National Congress of Private Hospitals, Conahp, is the main hospital sector event in Brazil. The program encompasses knowledge, innovation and relationship. In 2019, the theme “Value-Based Health: The Hospital's Role as a System Integrator” will be discussed from the perspective of patient experience, care models, and information and technology. The axes that will be addressed at the Congress were built on the Triple Aim concept, endorsed by the Institute for Healthcare Improvement (IHI).

São Paulo

26 - 28 Nov 2019

Metrosaúde

https://www.metrosaude.tmp.br/o-simposio

PITCH: The Health Metrology Symposium, organized by Remesp, contributes to health sector experts such as biomedical doctors, clinical engineers, nursing professionals, dental-hospital equipment operators and metrology laboratory professionals to update their knowledge of metrological management. , technical standards and regulations, conformity assessment processes, proficiency testing and risk management.

São Paulo

14 - 15 Aug 2019

CLAVS 2019

https://clavs.ibravs.org/

PITCH: The 1st Latin American Congress of Health Value promises to gather big names to discuss with the community, exclusive content and experiences on the main health challenges for Brazil.

São Paulo

18 - 19 Mar 2019

Global Summit Telemedicine & Digital Health

http://telemedicinesummit.com.br/

PITCH: An unprecedented international event in the country, the Global Summit Telemedicine & Digital Health arrives in São Paulo to bring Congressmen to the new era of Digital Health and the future of Telemedicine in Brazil and worldwide. Conceived by the Paulista Medical Association (APM), and, in partnership with the Transamerica Expo, the Global Summit will have a distinctive schedule prepared by the Curator Council, whose leaders are leading names in the industry today: Dr. Antonio Carlos Endrigo and Professor. Dr. Jefferson Gomes Fernandes. The event will address the most relevant and current market topics such as: Telehealth, Digital Health, Wearables, Artificial Intelligence, Internet of Medical Things, Patient Experience & Health, Telemedicine, Mobile Health, Analytics & Big Data, Internet of Me, Health Promotion and Prevention and Machine Learning. All content will be taught by national and international Key Speakers, who will share their experiences.

São Paulo

4 - 6 Apr 2019

2º CONDEPE

http://condepe.com.br/

PITCH: The CONDEPE is the first Congress of national proportion fully focused on all Nursing classes: Nurses, Technicians, Assistants and Students. “Technology and Challenges of Modern Nursing” will be the theme for this edition, being given by renowned speakers who will share their experiences through: Lectures, Workshops, Workshops, Talk shows and Realistic Simulation.

São Paulo

23 - 24 Apr 2019

SAHE 2019

https://grupomidia.com/sahe/tag/sahe-2019/

PITCH: Healthcare managers, influencers, professionals and investors united by one common purpose: to do business! Besides the stands and important entities of the sector, the fair includes scientific committees formed by the best specialists in the area and promotes vocational education through forums, congresses, lectures, conferences and workshops.

São Paulo

12 - 14 Mar 2019

HospitalMed

https://hospitalmed.com.br/feira2019/

PITCH: HOSPITALMED is considered the best and most complete health event in the North and Northeast Regions of the country. It presents innovations, trends and industry launches, as well as creates opportunities to strengthen relationships with suppliers and customers.

Recife

23 - 25 Oct 2019

NEXT FRONTIERS 2019 — CONVERGÊNCIA — O FUTURO DA ONCOLOGIA

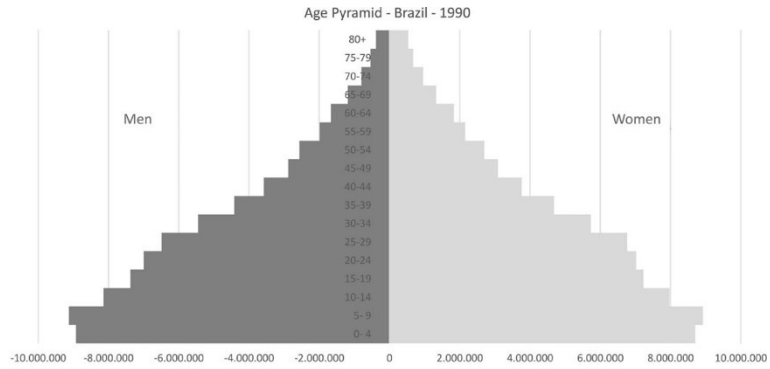
http://nextfrontiers.com.br/

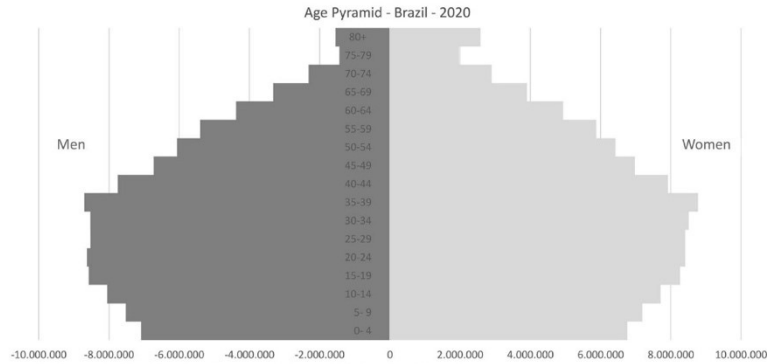
PITCH: The Next Frontiers to Cure Cancer, in its the fourth edition, is the annual congress of the A. C. Camargo Cancer Center that brings together professionals to discuss the latest advances in Oncology to Brazil. Considered one of the largest and most important oncology events in Latin America, it will be attended by hundreds of national guests and dozens of international guests who will share their professional experiences and discuss advances and innovations in cancer research, prevention, diagnosis and treatment. The 2018 edition had over 240 speakers, about 350 abstracts submitted and around 1,800 participants. The central theme of the congress in 2019 was “Convergence - The Future of Oncology”, a new concept that brings together scientific knowledge from various areas and that has been changing the course of Medicine and Oncology at an exponential speed.

São Paulo

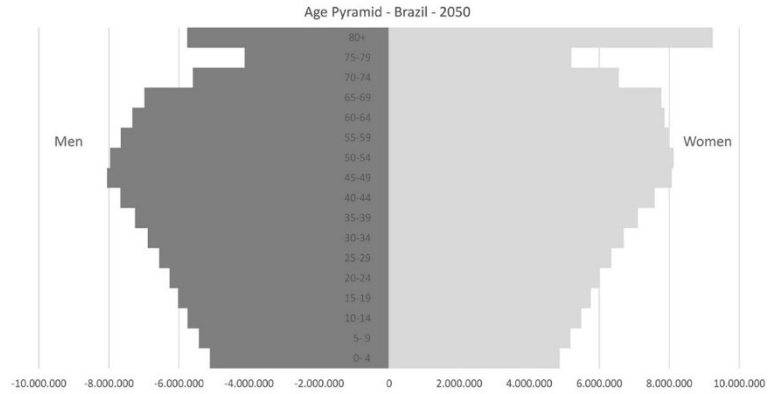
16 - 18 May 2019

Annex 4 – Population Pyramid





Source: IBGE, Projection of the Brazilian Population and Federation Units, 2013.



Source: IBGE, Projection of the Brazilian Population and Federation Units, 2013.

Annex 5 – List of key Brazilian Medical Industry Associations

Principal Business Associations

Brazilian Distributor	Products/Services
ABENUTRI	The Brazilian Association of Nutritional Products
ABIIS	Brazilian Alliance for Innovation Healthcare Industry/Aliança Brasileira da Indústria Inovadora em Saúde is a consortium that brings together four associations of the hospital medical product industry.
ABIMED	Associação Brasileira da Indústria de Alta Tecnologia de Produtos. Brazilian High-Technology Health Products Industry Association
ABIMO's	Members account for over 80% of the Brazilian medical market
ABRAIDI	Associação Brasileira de Importadores e Distribuidores de Implantes [Brazilian Association of Importers and Distributors of Implants
AdvaMed	Advanced Medical Technology Association
BRASNUTRI	Brazilian Association of Manufacturers of Nutritional Supplements and Special Food
Câmara Brasileira de Diagnóstico Laboratorial - CBDL	Brazilian In-Vitro Diagnostics Chamber
Interfarma	Brazilian Association of Pharmaceutical Research Industry/Associação da Indústria Farmacêutica de Pesquisa
Sindusfarma	Sindusfarma is the business association in the São Paulo State's pharmaceutical industry.

Annex 6 – List of Importers of Medical Devices & Supplies

Please note that there are many importers in Brazil, with varying degrees of quality and scope. Finding a suitable importer is an important process that might require an extensive investment of time.

Brazilian Distributor	Products/Services	Website
Cremer	Brazil's largest distributor of disposable healthcare products with a network of six distribution centres for healthcare products located throughout Brazil.	www.cremer.com.br
Imex Medical Group	Lead supplier in diagnostic imaging, acting as a distributor for several multinationals.	www.imexmedicalgroup.com.br
Smith & Nephew (S&N)	Leading supplier for orthopaedics & endoscopy and advanced wound management (AWM) products.	www.smith-nephew.com
Dimebras	Large distributor of pharmaceuticals	https://dimebras.com.br
Anbfarma	Large distributor of pharmaceuticals	www.anbfarma.com.br
Panpharma	Large distributor of pharmaceuticals	www.panpharma.com.br
Mercantil Farmed ltda	Large distributor of pharmaceuticals	www.medicamentosbrasil.com
Selectchemie IMP. EXP. E reprecentacoes LTDA	Agent and importer of raw materials, equipment and packaging, representing more than 50 foreign companies amongst which DMV (Netherlands).	-
Altmann S.A. Importação E Comércio	Agent and importer of instruments and equipment for the pharmaceutical and laboratory industry and equipment for quality control. They represent the English companies MALVERN, LEICA, GRETAG MACBETH (USA), etc.	www.altmann.com.br

Annex 7 – List of Hospitals in Brazil

The Best-Equipped Hospitals in Brazil for Hosting Patients (total number of beds) ((Global Health Intelligence, 2018).

Rank	Hospital Name	No. of Beds
1	Hospital das Clínicas da Faculdade de Medicina da Univ. De São Paulo	1,185
2	Hospital Central – Santa Casa de São Paulo	1,083
3	Hospital São Joaquim Beneficência Portuguesa	919
4	Instituto de Medicina Integral Prof. Fernando Figueira (Imip)	818
5	Instituto Americo Bairral de Psiquiatria	817
6	Hospital Nossa Senhora da Conceição Sa	793
7	Hospital de Base — São José do Rio Preto	644
8	Hospital São Paulo – Hospital Universitário da Unifesp	642
9	Casas André Luiz	610
10	Hospital do Rocio	599

Hospitals in São Paulo. For a complete list of all (public/affiliated) hospitals go to DATASUS

Name	No. of Beds
Hospital Saha	407
Hospital San Gennaro	1333
Hospital Da Face	155
Hospital Regional Sul Sao Paulo	270
Hcloe Hospital De Olhos	240
Hospital Sirio Libanes	91
Medina Servicos Medicos E Hospitalares	7434
Lifecare Assistencia Medica Domiciliar E Hospitalar	178
Hospital Dia Sepaco	515
Hospital Adventista De Sao Paulo	49
Hospital Dia Da Rede Hora Certa Vila Prudente	108
Hospital Dia Da Rede Hora Certa Cidade Ademar	433
Hospital Dia Da Rede Hora Certa Penha Maurice Pate	55
Hospital Dia Da Rede Hora Certa Sao Miguel Tito Lopes	348
Hospital De Olhos Paulista	218
Hospital Santa Virginia	2294
Hospital Cantareira	3050
Day Hospital De Ermelino Matarazzo	2576
Hospital Da Luz	113
Hospital Igesp	276
Hospital Israelita Albert Einstein	S/N
Hospital Infantil Darcy Vargas Uga Iii Sao Paulo	34
Hospitalita Atend Domiciliar	1586
Hospital Maternidade Interlagos	211
Hospital Geral De Pedreira	251
Hospital Da Luz	92
Hospital Universitario Da Usp Sao Paulo	2565
Hospital Amparo Maternal	1901
Hospital Sao Paulo Hospital De Ensino Da Unifesp Sao Paulo	715
Hospital Geral De Sao Mateus Sao Paulo	540

Unidade De Gestao Assistencial Ii Hospital Ipiranga Sp	28
Conjunto Hospitalar Do Mandaqui Sao Paulo	4301
Hospital Geral Santa Marcelina De Itaim Paulista Sao Paulo	6035
Hospital Geral Do Grajau Prof Liber John Alphonse Di Dio Sp	180
Hospital E Maternidade Leonor Mendes De Barros Sao Paulo	2477
Hospital Da Crianca	295
Hospital Da Cruz Vermelha Brasileira Do Estado De Sao	699
Hospital E Pronto Socorro Portinari	455
Hc Da Fmusp Hospital Das Clinicas Sao Paulo	225
Centro Hospitalar Do Sistema Penitenciario Sao Paulo	15
Hospital Sao Camilo Ipiranga	850
Hsanp Hospital	2786
Hospital Infantil Candido Fontoura Sao Paulo	1757
Hospital Geral Jesus Teixeira Da Costa Guaianases Sao Paulo	135
Hospital Dia da Rede Hora Certa Itaim Paulista	6577
Ama Hospital Ignacio Proenca De Gouvea	151
Hcloe Hospital De Olhos	317
Hcloe Hospital De Olhos	472

Annex 8 – ANVISA Medical Device Registration and Approval in Brazil

Cadastro vs. Registro Registration Routes in Brazil

The first step in the Brazil regulatory process is to determine the correct classification of your medical device. Lower risk Class I and II devices will follow the Cadastro registration route, which includes a simplified application. Higher risk Class III and IV devices must follow the Registro registration process.

If your device is Class I* or II, you must submit an application and legal documents to ANVISA for review and approval. Class I and II device manufacturers must also compile a comprehensive technical dossier for their Brazil Registration Holder (BRH) to keep on file, along with proposed labelling and IFU, in case of an ANVISA audit.

Class III and IV device manufacturers must prepare a Technical File that includes clinical data, clinical studies, and additional device information. Legal documents, IFUs, and proposed labelling are also included in the Technical File. Class III and IV registrations expire after ten years; Class I and II registrations do not expire.

Appointing a Brazilian Registration Holder

Foreign medical device manufacturers that do not have a physical location within Brazil must appoint a Brazilian Registration Holder (BRH). Your BRH will submit your registration application to ANVISA and maintains control of your device registration and Brazil Good Manufacturing Practice (BGMP) certification, if applicable. Hiring an independent BRH instead of a distributor gives you the freedom to change distributors at any time.

INMETRO certification requirements

ANVISA requires certain medical devices be certified by The National Institute of Metrology, Standardization and Industrial Quality (INMETRO), which is responsible for the establishment of technical standards in Brazil. INMETRO certification is often required for electro-medical devices subject to IEC 60601, as well as some other medical devices. Emergo can assist with selecting an INMETRO certifier and communicate with them on your behalf.

For more information on registering a medical device in Brazil, click here.

Annex 9 – National Medical Device Manufacturers

Source: (BMI, 2017)

Organisation	Description
Alliage	Large manufacturer of dental appliances
BARRFAB	Large manufacturer of surgical tables and accessories for all specialties
Baumer	Baumer specialises in the production, marketing, importation and exportation of medical & hospital, healthcare and scientific equipment.
Cremer	Cremer is Brazil's leading consumables manufacturer specialising in textiles, adhesive tapes and plastic products
EDLO	Large manufacturer of surgical instruments
Erwin Guth	Large manufacturer of surgical instruments
Fanem	Fanem is the market leader for neonatology products in Brazil, claiming an 85% market share.
FirstLine	Large manufacturer of devices for use in vascular surgery
GMReis	GMReis is a company specialised in the research, development and manufacture of orthopaedic, neurosurgical and bucomaxilofacial medical devices
Innovatech/Scitech	Innovatech manufactures precision medical devices processed by Nd:YAG laser
JP Industria Farmaceutica & Olidef	The company is the leading Brazilian producer of Large Volume Parenteral Solutions
Labcor	Labcor specialises in biological prostheses and is a leading supplier of heart valves and cardiovascular grafts in the Brazilian market
Lifemed	Lifemed specialised in the production of surgical disposables, including surgical clothing and drapes.
Medicophacos	Mediphacos specialises in R&D, manufacturing, marketing and distribution of ophthalmic products.
Neoortho	Neoortho is a manufacturer of orthopaedic implants.
Olsen	Olsen specialises in dental treatment units and medical examination chairs.
Ortosintese	Ortosintese manufactures orthopaedic products
Protec	Protec is a producer of life support equipment and supplies
Samtronic	Samtronic specialises in hospital infusion equipment & devices.
Silimed	Silimed is Latin America's leading manufacturer of silicone implants
Sismatec	Sismatec specialises in equipment for surgical centres and is a market leader for surgical lights using LED technology

Annex 10 – Selection of Brazilian Organisations in the LSH Sector

Organisation	Function	URL
ABIMO (Medical device industry association)		URL
ALAMI - Latin American Association of Private Health Systems	The Latin American Association of Private Health Systems - ALAMI - is a non-profit Civil Association brings together the Associations of Entities, with and without profit, that provide private medical coverage, either by contracting services provided by third parties, as well as, with services performed in their own healthcare structures, legally based in Brazil, in the State of Sao Paulo.	URL
ANS (Agência Nacional de Saúde Suplementar)	The National Supplementary Health Agency (ANS) is the regulatory agency linked to the Ministry of Health responsible for the health insurance sector in Brazil.	URL
ANVISA (Brazil National Health Surveillance Agency)	The National Health Surveillance Agency or ANVISA (Agência Nacional de Vigilância Sanitária) is the Brazilian regulatory agency that is responsible for the approval and supervision of food, cosmetics, tobacco, pharmaceuticals, health services, and medical devices, among others. The agency is connected to the Ministry of Health, which manages ANVISA through a management contract signed periodically.	URL
Brazilian Association of Collective Health *(Associação brasileira de saûde coletiva (ABRASCO)*	To support individuals and institutions engaged in undergraduate and postgraduate education, research, cooperation and service delivery in Public / Collective Health, aiming at expanding professional qualification, strengthening knowledge production and improving policy formulation health, education and science and technology to confront the health problems of the Brazilian population.	URL
Brazilian Association of Nursing *(Associação Brasileira de Enfermagem) ABEn*	ABEn is an association of cultural, scientific and political character, with own legal personality, of private law and that congregates people Nurses; Nursing Techniques; Nursing Assistants; students of Undergraduate courses in Nursing and Professional Education of Technical Level in Nursing; Schools, Courses or Faculties of Nursing; Associations or Societies of Specialists who associate with it, individually and freely, for non-economic purposes.	URL
Brazilian Society of Health Informatics *(Sociedade Brasileira de Informática em Saúde)* SBIS	A professional society created in November 1986. It has the mission of promoting the development and the interchange of ideas and results in the fields devoted to the information technologies applied to the health sciences (Medical informatics, Telemedicine, Bioinformatics, etc.).	URL
CONASEMS		

Conselho Nacional de Secretários de Saúde (CONASS)	The National Council of Health Secretaries (Conass) is a private, non-profit entity which brings together the Secretaries of State of Health.	URL
FIOCRUZ (Oswaldo Cruz Foundation) *(Fundação Oswaldo Cruz)*	The Oswaldo Cruz Foundation (FIOCRUZ) promotes health and social development through scientific and technological knowledge.	URL
Hospital Central *(Santa Casa De São Paulo)*	The Central Hospital has grown and established itself as one of the most important hospital referral centers in the State of São Paulo, pioneering innumerable areas of health care and Brazilian hospital education.	URL
Ministry of Health *(Ministério da Saúde)*	The Ministry of Health is the Federal Executive Branch responsible for the organization and elaboration of plans and public policies aimed at the promotion, prevention and health care of Brazilians.	URL
ProGenéricos, Brazilian Generic Medicine Drugmakers Association	The Brazilian Association of Generic Medicines Industries (PróGenéricos) is the sector entity that congregates the main laboratories that act in the production and commercialization of generic medicines in the country.	URL
School of Public Health - Universidade de São Paulo - USP	The School of Public Health, University of São Paulo, a center of national and international reference in the field of Public Health, has the mission to produce and disseminate knowledge and educate human resources in public health and nutrition by means of teaching, researching, and extension, contributing to improve the population health into a better condition, and formulating public policies.	URL
The Brazilian Medical Association *(Associação Médica Brasileira)*	The national class association of physicians in Brazil. With more than 140,000 associates, is the second largest in the Americas.	URL
The Family Health Association (ASF) *(Associação Saúde da Família)*	NGO runs primary care and family health clinics, outreach sites, mental health clinics and halfway houses to provide vital health services to the people of São Paulo. ASF has become one of the Municipality of São Paulo's most important partners and a cornerstone of the state's public health service.	URL
University of São Paulo Faculty of Medicine Clinics Hospital *Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo*	A complex of health institutions, located in various regions of the city of São Paulo, Brazil.	URL

This is a publication of
Netherlands Enterprise Agency
Prinses Beatrixlaan 2
PO Box 93144 | 2509 AC The Hague
T +31 (0) 88 042 42 42
E klantcontact@rvo.nl
www.rvo.nl

This publication was commissioned by the ministry of Foreign Affairs.

Publication number: RVO-159-1901/RP-INT

NL Enterprise Agency is a department of the Dutch ministry of Economic Affairs and Climate Policy that implements government policy for Agricultural, sustainability, innovation, and international business and cooperation. NL Enterprise Agency is the contact point for businesses, educational institutions and government bodies for information and advice, financing, networking and regulatory matters.

Netherlands Enterprise Agency is part of the ministry of Economic Affairs and Climate Policy.