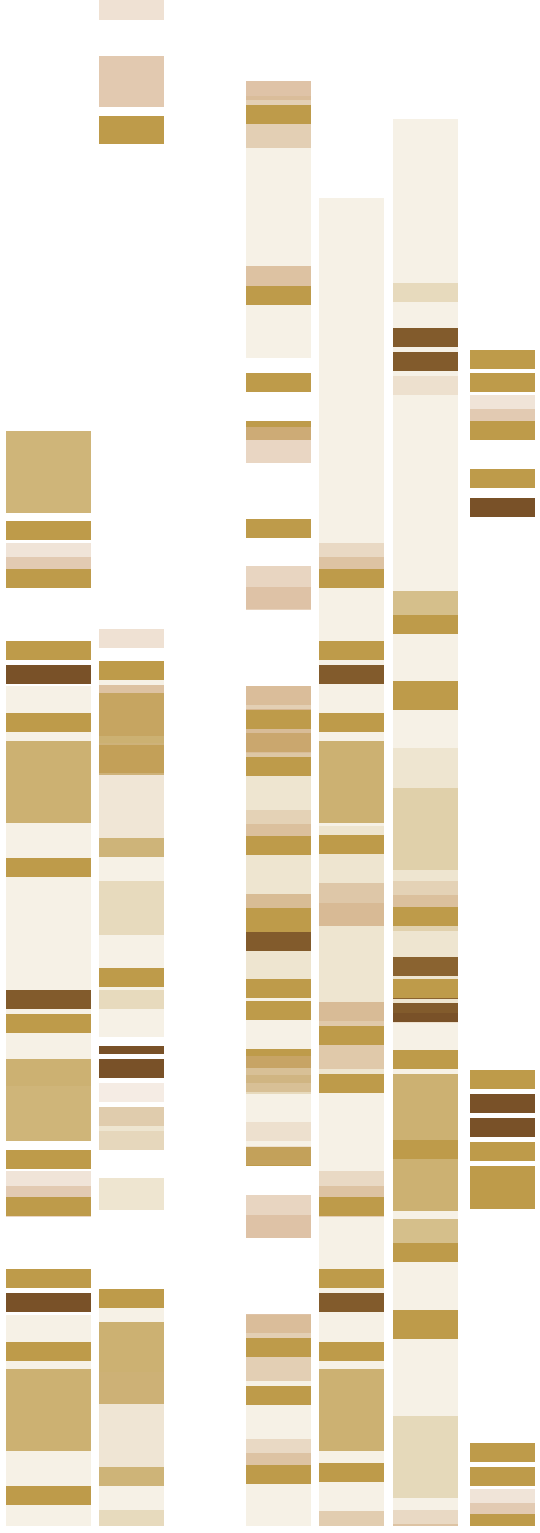

Health 4.0

Proposals to boost the innovation cycle in Medical Technology (MedTech) in Brazil

2015 by *Aliança Brasileira da Indústria Inovadora em Saúde* ABIIS
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2. Brazil: Industrial policy: Health products: Economy
3. Medical Technologies
4. Medical Devices

BY

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Summary

Foreword

Brazil´s health sector is highly fragmented, with many players and thousands of products forming the basis of an industry that generates an estimated US$ 291 billion worth of business annually[1]. Specialized labor services account for 45% of this amount.

It is common knowledge that investments by the health-industrial complex are mainly focused on patient care, while information infrastructure systems tend to play a secondary role. This is one of the reasons for the low level of interaction between the industries and users.

Information sharing by the various players in the productive chain currently leaves much to be desired, and gives rise to a degree of distrust between the players. To improve product supply chain performance it is essential to analyze at least product flow, flow of funds, and flow of information about patients´use of the product, together with feedback to the manufacturer. Feedback can include, for example, shared data on the time of purchase, delivery cycles, prices, location and use of the products.

With the above in mind, the Brazilian Alliance of the Innovative Healthcare Industry (*Aliança Brasileira da Indústria Inovadora em Saúde - ABIIS*) presents this publication "Health 4.0: Proposals to boost the cycle of innovation in Medical Devices (MedTechs) in Brazil". Our main idea is to outline the principles that in our opinion will enable the industry to operate in conformity with the concept created by us known as "Health 4.0".

The term derives from the "Industry 4.0" concept, which has become widely known in recent years, proposing a form of production where manufactured goods are no longer regarded as passive objects but themselves determine what production installations are required in order to undertake a range of functions.

In Industry 4.0, this is possible because the final products and the machines that manufacture them "interact", based on technologies anchored in the Internet of Things (systems that communicate and cooperate with each other and with humans in real time), and online services (communication systems via wireless networks).

With Health 4.0, the supply chain which was once seen as a cost center becomes an opportunity for innovation, given that it can "understand" faster the end users´demands, as well as interpret the regional characteristics that are of great importance in a country the size of Brazil.

Health 4.0 also increases opportunities for collaborative partnerships to be established among players in the same value chain, able to share coordinated production and distribution planning aimed at quickly and efficiently meeting users´requirements. In this scenario, only sufficient stocks are held to satisfy demand, thus avoiding delays or risking non-availability of products.

The main purpose of this publication is to call upon the different healthcare sector stakeholders - government, professional organizations, the public and private healthcare sectors, NGOs and development agencies - to prepare and implement a sustainable *MedTech* (Medical Techology) policy to promote, through rational access to new technologies, the economic and social development of our country.

Carlos Eduardo Paula Leite Couvêa
President of ABIIS

Brasilia, August 2015

1. Source: http://apps.who.int/nha/database/ViewData/Indicators/en

ABIIS

The *Aliança Brasileira da Indústria Inovadora em Saúde (ABIIS)* [Brazilian Alliance for Innovative Health Industry] is a consortium that brings together four associations of the hospital-medical product industry: AdvaMed (Advanced Medical Technology Association), ABIMED - the *Associação Brasileira da Indústria de Alta Tecnologia de Produtos* [Brazilian Association of the High-Technology Industry for Health Products, ABRAIDI – the *Associação Brasileira de Importadores e Distribuidores de Implantes* [Brazilian Association of Importers and Distributors of Implants] and CBDL – the *Câmara Brasileira de Diagnóstico Laboratorial* [Brazilian Chamber of In-vitro Diagnostics].

The above associations comprise around 480 companies operating in Brazil in the production, import, export and distribution of medical products and equipment for diagnosis, prevention and treatment.

MISSION

Develop and disseminate suggestions for public policies, legal frameworks and regulation by mobilizing public and private players to make the Brazilian business environment increasingly attractive for investment in research, development, local production and the marketing and distribution of innovative medical technologies.

VISION

To be the Brazilian Government´s key partner in the discussion and implementation of public policies to expand and ensure access by the population to innovative medical technologies, and thus contribute to Brazil´s socioeconomic development.

PRINCIPLES

Ethics, loyalty, perseverance, efficiency and technical precision.

Representativeness and legitimacy

ABIMED, ABRAIDI, ADVAMED and CBDL, together with the companies associated under ABIIS, serve a market estimated to be worth US$10.6 billion[2]. and directly promote over 14,500 companies that generate more than 132,600 jobs with wages above Brazil´s national average[3].

The products of the MedTech industry represent 3.7% of Brazil´s total health spending. These products, classified as "medical devices", do not include medications, blood products and vaccines.

The companies associated with ABIIS invest over 10% of their annual turnover in R&D, incremental innovation and continuing education. A further 12% of turnover is applied to postmarket activities such as installation, technical assistance, maintenance and training.

2. At the Purchasing Power Parity exchange rate of R$ 2,23/ US$, published by IPEADATA, 2014
3. The ABIIS-affiliates use RAIS (*Relação Anual de Informações Sociais do Ministério do Trabalho*) [Annual List of Social Information of the Ministry of Labor] data , and in specific studies the salaries of the MedTech industry are compared with those of other industrial and commercial sectors.

ABIMED, ABRAIDI, ADVAMED and CBDL, grouped under ABIIS, serve a market worth an estimated US$ 10.6 billion

ABIIS Goals

ABIIS seeks to demonstrate to political entities that continuous improvement of the Brazilian population´s health depends on ensuring people´s access to advanced medical technologies that are incorporated and used pragmatically and responsibly in the dynamic, competitive and isonomic market. As part of this aim to generate a sustainable, virtuous cycle, ABIIS and its associates are convinced that a robust and dynamic local medical devices industry, capable of making a substantial contribution to Brazilian society, depends on a well-organized, stable and competitive business environment to ensure that our industry can explore overseas markets in the same way as other industrial sectors.

MEDICAL DEVICES, DEFINITIONS AND PRODUCT LIFE CYCLE

Health products and MedTechs

Medical technologies or Medical Devices in the broadest sense (MedTech) include devices in the strictest sense as well as prostheses, in vitro diagnostics, imaging equipment and e-health solutions for diagnosing, monitoring, evaluating, preventing and indicating treatment for patients affected by a wide range of diseases.

MedTechs include a substantial variety of products, ranging from the simplest ones, such as gloves, suture lines, adhesives, hospital beds and lenses, as well as smartphone applications, cardiac implants, glucose monitors and MRI scanners.

The prospect of longer, more active, independent lives is to a great extent the result of innovations in the field of medical technology.

The needs of the health industry in Brazil - a continent - sized country with 200 million inhabitants - have been met by locally-manufactured and imported health products.

MedTechs have also helped to improve the productivity, efficiency and sustainability of health systems, and to contribute to reducing inequitable access to healthcare services by lower-income groups often living in remote areas of the country far from urban centers.

Given its rapid cycle of innovation, the MedTech industry - employing a large number of skilled professionals - can also make a vital contribution to enhancing Brazil´s involvement in a wide range of product innovation processes to eventually produce income and contribute substantially to the country´s economic growth.

In view of the variety of different terms used by the MedTech industry it is worth summarizing the definitions published by the World Health Organization and the GHTF2.[4]

4 World Health Organization, 2011 and Global Harmonization Task Force (GHTF), the Definition of Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device', 16/5/12

MedTechs involve the application of organized knowledge and medical practices in the form of equipment, procedures and systems designed to identify, prevent and resolve health problems and improve quality of life. MedTechs include any device, machine, appliance, implant, reagents for in vitro use, diagnostics, software, material or any other item intended by the manufacturer to be used separately or in combination by human beings for one or more specific medical purpose:

- diagnosis, prevention, control, treatment or alleviation of disease;
- diagnosis, control, treatment, alleviation or compensation for injury;
- study, replacement, modification or support of the anatomy or of a physiological process;
- to support or sustain life;
- conception control;
- disinfection of medical devices;
- providing information through in vitro examination of samples derived from the human body.

Medical devices (strict sense):

Articles, instruments, apparatuses or machines used for the prevention, diagnosis or treatment of a disease or symptom of disease in order to detect, measure, restore, correct or modify the structure or function of the human body for any health purpose. The purpose of a medical device is not generally achieved by other means, e.g. pharmacological, immunological or metabolic.

Medical equipment:

Medical devices that require calibration, maintenance, repair and user training. Medical equipment is used specifically for diagnosing and treating health problems. Given that the device can be used alone or in combination with accessories and consumer products, the definition does not include implantable, disposable or single-use health products.

In Vitro Diagnostics:

Any medical device which includes a reagent, instrument, apparatus or system, used alone or in combination, for taking in vitro samples from the human body, to obtain information on the patient´s physiological state of health, disease or congenital malformation[5].

E-health:

Telemedicine ("telessaúde")[6], covers health areas and products that use information and communication technologies for diagnosis, care, self-monitoring, education and "remote" health services provision. The use of IT in the healthcare area for controlling costs and procedures, and assessing the quality of patient care, is a subject of great interest given its potential to produce excellent outcomes. Substantial private and public investment is involved in its development.

5 Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 on health products for in vitro diagnostics
6 http://www.telessaude.uerj.br, http://www.telessaudebrasil.org.br/ and http://dab.saude.gov.br/portaldab/ape_telessaude.php.

The Medical Technology (MedTech) Industry

What does Medical Technology mean?

It is a term used to encompass:

MEDICAL DEVICES

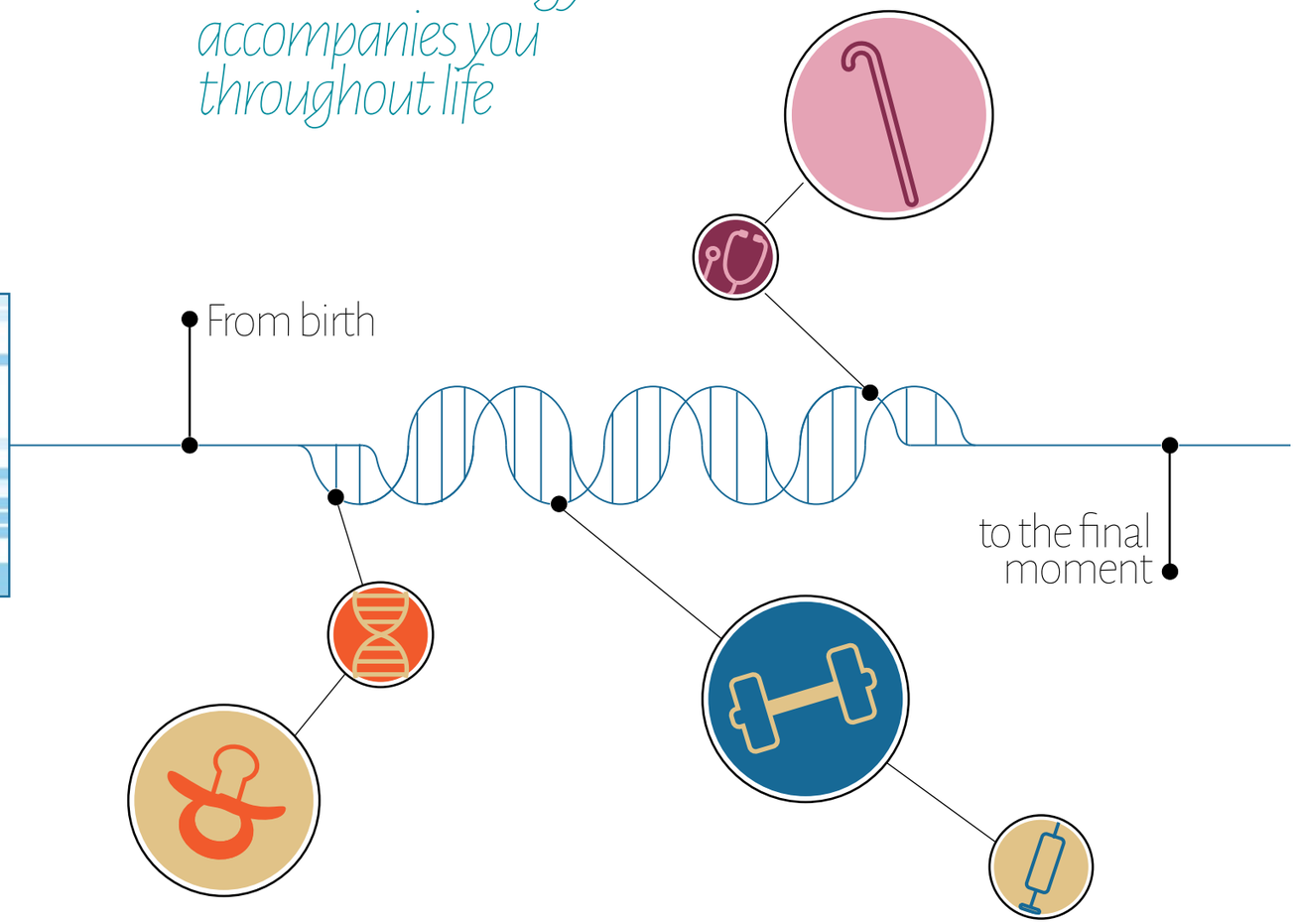
IN VITRO DIAGNOSTICS

MEDICAL EQUIPMENT

E-HEALTH

500,000 Medical Technologies currently exist

Medical Technology accompanies you throughout life

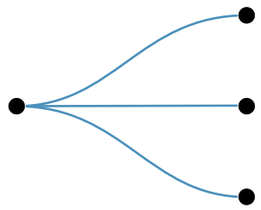


Source: Adapted by the Websetorial MedtechEurope http://www.medtecheurope.org/publications/95/64/Infographic-The-MedTech-Industry-in-Europe published on 9 September, 2013

Benefits of MedTechs

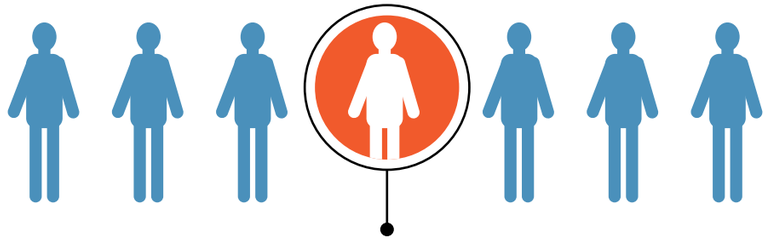
How do they reduce the costs of healthcare?

Limit care costs of patients with chronic diseases



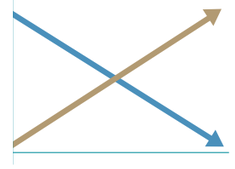
- EARLY DIAGNOSIS + MONITORING
- TREATMENT
- HOSPITAL COSTS

Limit the use of unnecessary and ineffective treatments, allowing customization of care based on prevention



ENABLE PATIENT RISKS TO BE IDENTIFIED (PERSONALIZED MEDICINE)

Limit treatment costs



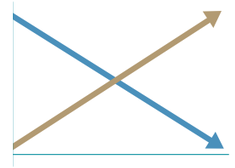
MORE EFFICIENT TREATMENT

REDUCED HOSPITAL STAYS

IMPROVE HOSPITAL CARE QUALITY

HELP TO DIRECT CARE TO THE LOCATION WITH BEST COST-BENEFIT

Reduce treatment costs



GREATER EFFICIENCY

LESS DUPLICATION

E-HEALTH

- Remote self-monitoring
- Cost-effectiveness of access to healthcare

E-health for better health system management

E-health can also enable big-data to be incorporated for identifying the need for new product development, tracking, inventory control/ re-stocking and maintenance data.

What is big-data?

A term to describe large amounts of data. Society faces an unprecedented increase in the daily amount of information generated.

Source: Adapted by Websetorial from MedtechEurope: (http://www.medtecheurope.org/publications/95/64/Infographic-The-MedTech-Industry-in-Europe). Access on: 9 September 2013.

Why Health 4.0?

The term "Health 4.0" is used here to highlight the importance of integrating information technology (IT) with the manufacturing and service sectors (online services and logistics in the healthcare sector). This is important for Brazil and other large countries which contain vast areas of low population density where the health services suffer from the lack of suitable local infrastructure.

Can integrating IT into industry ("Industry 4.0") be considered the "4th Industrial Revolution"?[7] The First Industrial Revolution involved the mechanization of production through water and steam power. The Second Revolution ushered in an era of mass production with the advent of electric power. The "Third" was the Digital Revolution driven by electronic and information technologies increasingly harnessed to automate production.

Industry 4.0 is a term that encompasses technologies and value chain organizational concepts. Based on technological concepts derived from cyber-physical systems and the internet of things and services, Industry 4.0 envisages the relatively new concept of the "smart factory" where systems are used to monitor physical processes and, as a result, enable practitioners to decentralize decision-making.

Through the Internet of Things, cyberphysical systems communicate and cooperate with each other and with humans in real time. Meanwhile, in the Internet of Services, internal and inter-organizational services are supplied for agents to use in each value chain.

The term "Industry 4.0" was first coined in 2012 at the Hannover Fair, during discussions on a project to boost the computerization of Germany's manufacturing industry. A Working Group, presided by Siegfried Dais (Robert Bosch GmbH) and Kagermann (Acatech), presented its report containing recommendations on the subject to the German Federal Government on 8 April 2013.

7 http://en.wikipedia.org/wiki/Industry_4.0.

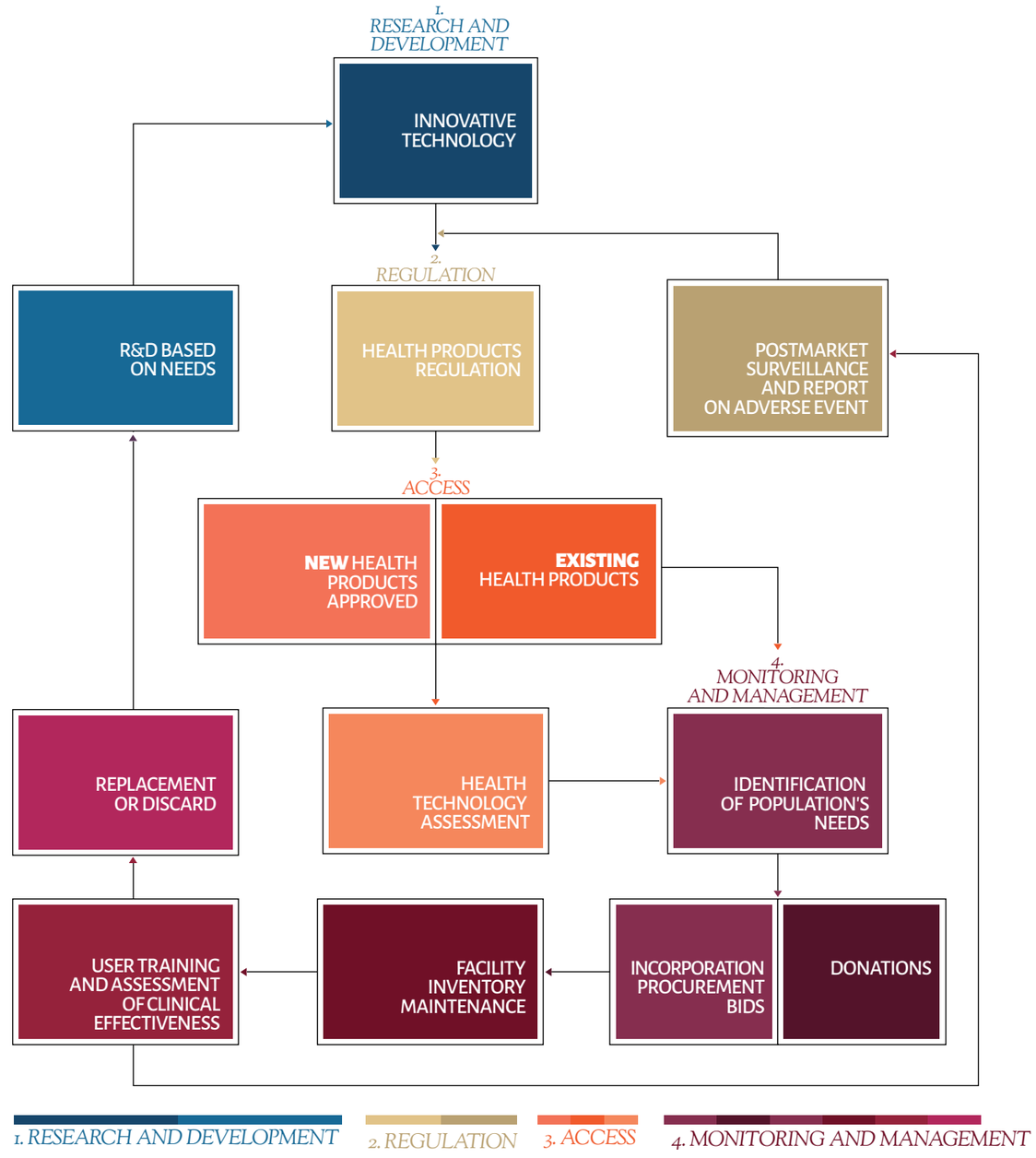
Health product life cycle[8]

Incorporating the most appropriate medical technology tailored to the population profile of a particular country (in this case Brazil) involves a long cycle consisting of, among other things, identification of needs, evaluation and incorporation of the technology into the system, decisions on domestic production or importation of technology, regulatory aspects, procurement management, training on the use, maintenance, replacement and disposal of the technology and, finally, considerations related to incremental product improvement through the development of new technologies.

8 Here we used the term health product, as this cycle also applies to medicines.

FIGURE A

MEDTECH LIFE CYCLE [9]



9 VELAZQUEZ-BERUMEN, Adriana. Development of medical device policies. WHO Medical Device Technical Series, WHO – Organização Mundial da Saúde. Geneva, Switzerland: WHO, 2011. p. 25. Available at: <http://apps.who.int/medicinedocs/documents/s21559en/s21559en. pdf>. Access on:25 Jul. 2015.

Aims of this publication

To present proposals for developing public policies with a view to enhancing the rightful and de facto access of the population to healthcare by considering the cycle of the medical technology product or device (MedTech) to generate the outcomes listed below:

Ensuring compatibility of health product technologies with Brazil´s national and regional public health needs.

Fostering a more innovation-friendly environment

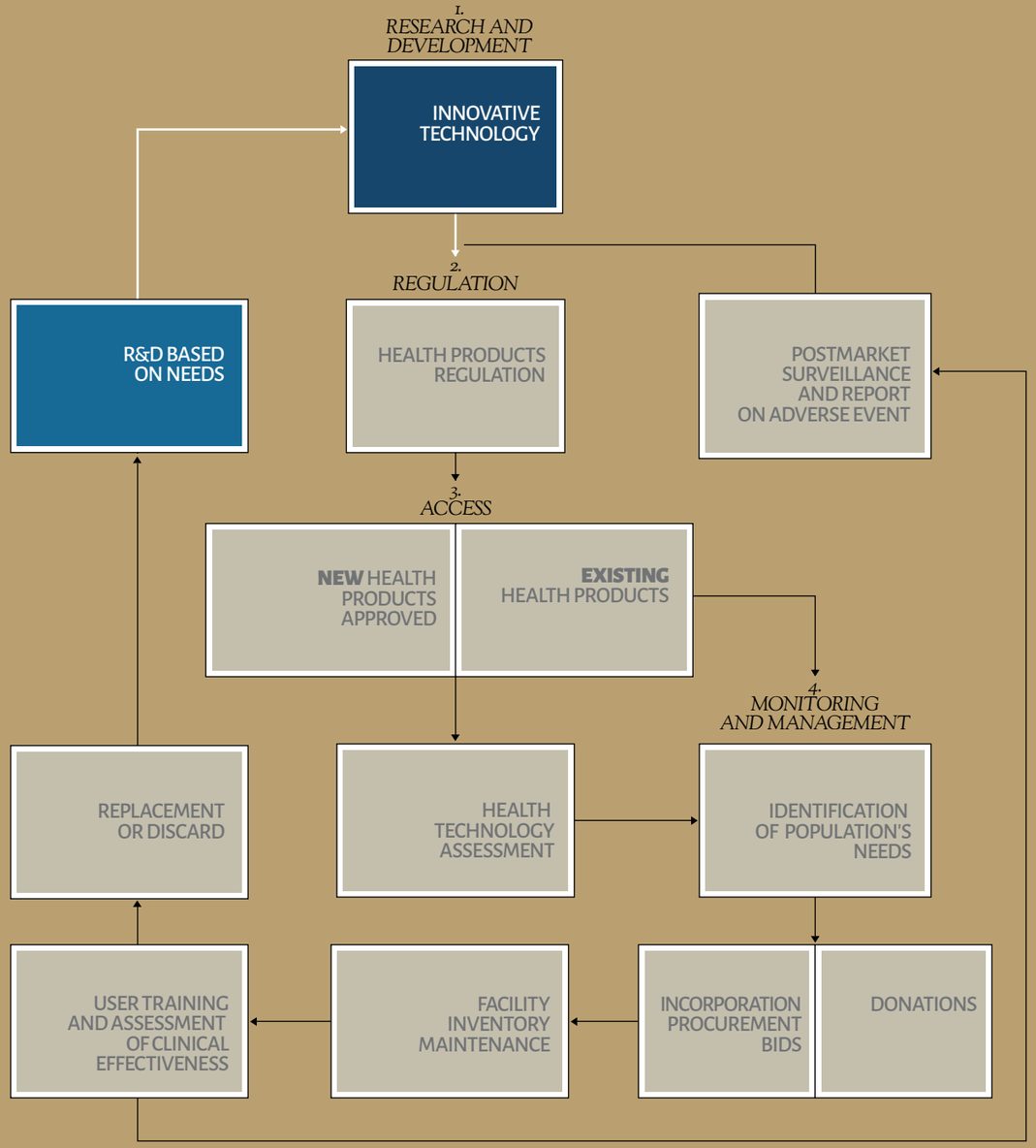
Increasing the value-added of national production

Reducing wastage, product stock-handling and maintenance costs.

Promoting sustainability of the health system overall.

FIGURE A

HEALTH PRODUCT LIFE CYCLE



Summary of R&D proposals

Adopt health technology evaluation methods in line with government Science & Technology (S&T) policy

Expand and enhance channels to enable health managers to signal their purchasing requirements to representatives of the productive sector associations.

Develop channels between government and industry to explore technological trends ("technological horizon") of interest to the health sector.

Maintain and expand private sector/government collaboration to support innovative industrial policies, identifying promising product lines for possible manufacture in Brazil to reflect technology trends of interest to the healthcare system.

Develop and expand financial incentives for promoting innovation, and encourage interest by the venture capital community to invest in the domestic industry.

Expand the supply of human capital focused on MedTech research, and foster cooperation between industry, academia and government

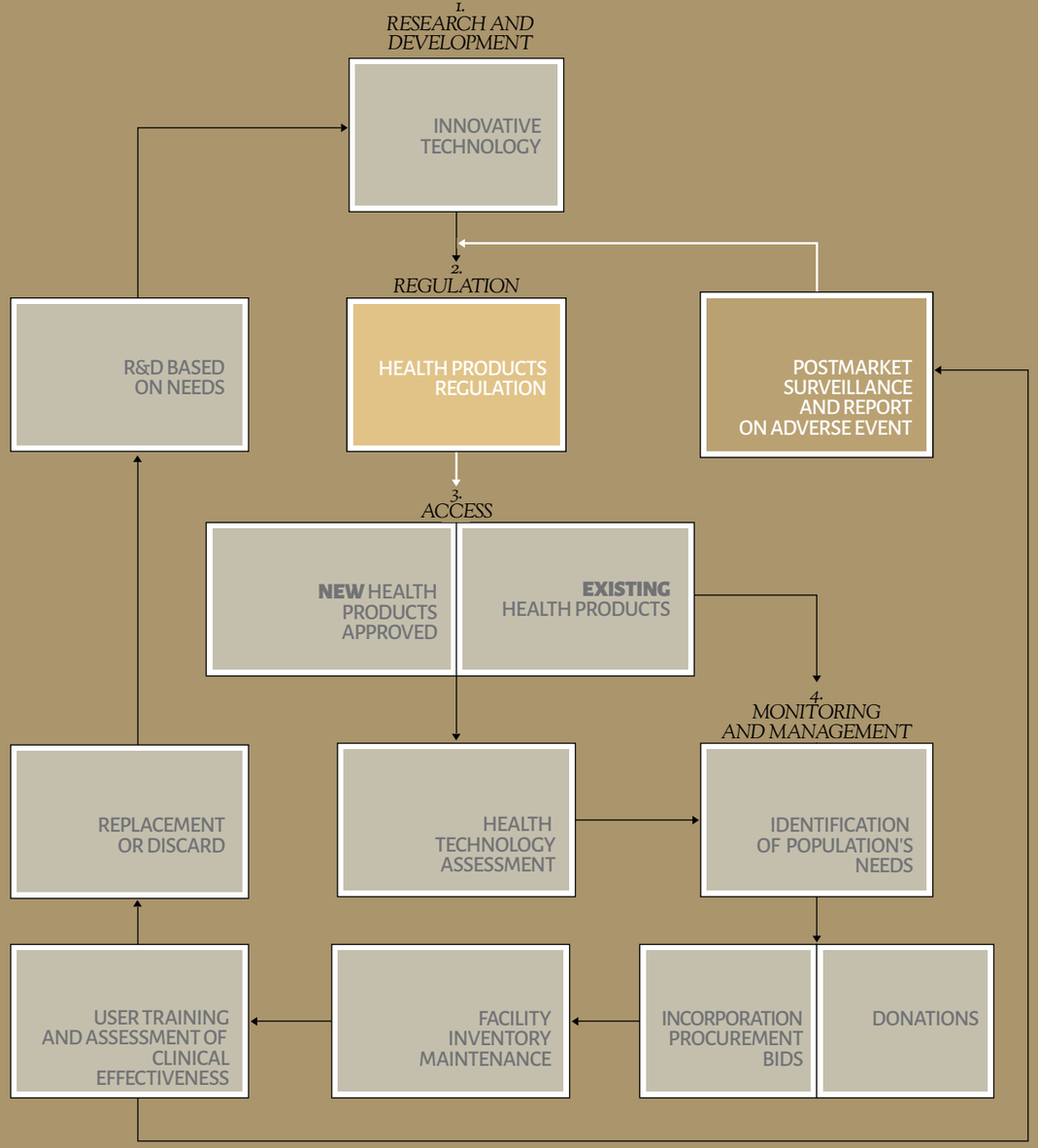
Encourage innovation to promote better patient care. Continuously and assertively improve HTA (Health Technology Assessment) and pay timely attention to new technologies coming onto the market.

Improve health decision-making models. Evaluation and analysis of models to employ multiple criteria, scientific literature reviews, use of real-life data and assessments of budgetary/quality-of-life impacts of the economic costs of healthcare.

Promote digital inclusion of health systems in Brazil.

FIGURE A

HEALTH PRODUCT LIFE CYCLE



Summary of proposals for regulation

Promote intelligent regulation in order to facilitate access of MedTech companies to the market, from speeding release of health licenses through to product sales (i.e. reducing "time to market").

Improve the regulatory procedures by streamlining and speeding the registration process, and emphasize the fieldwork management activities carried out by companies.

Take the following actions:

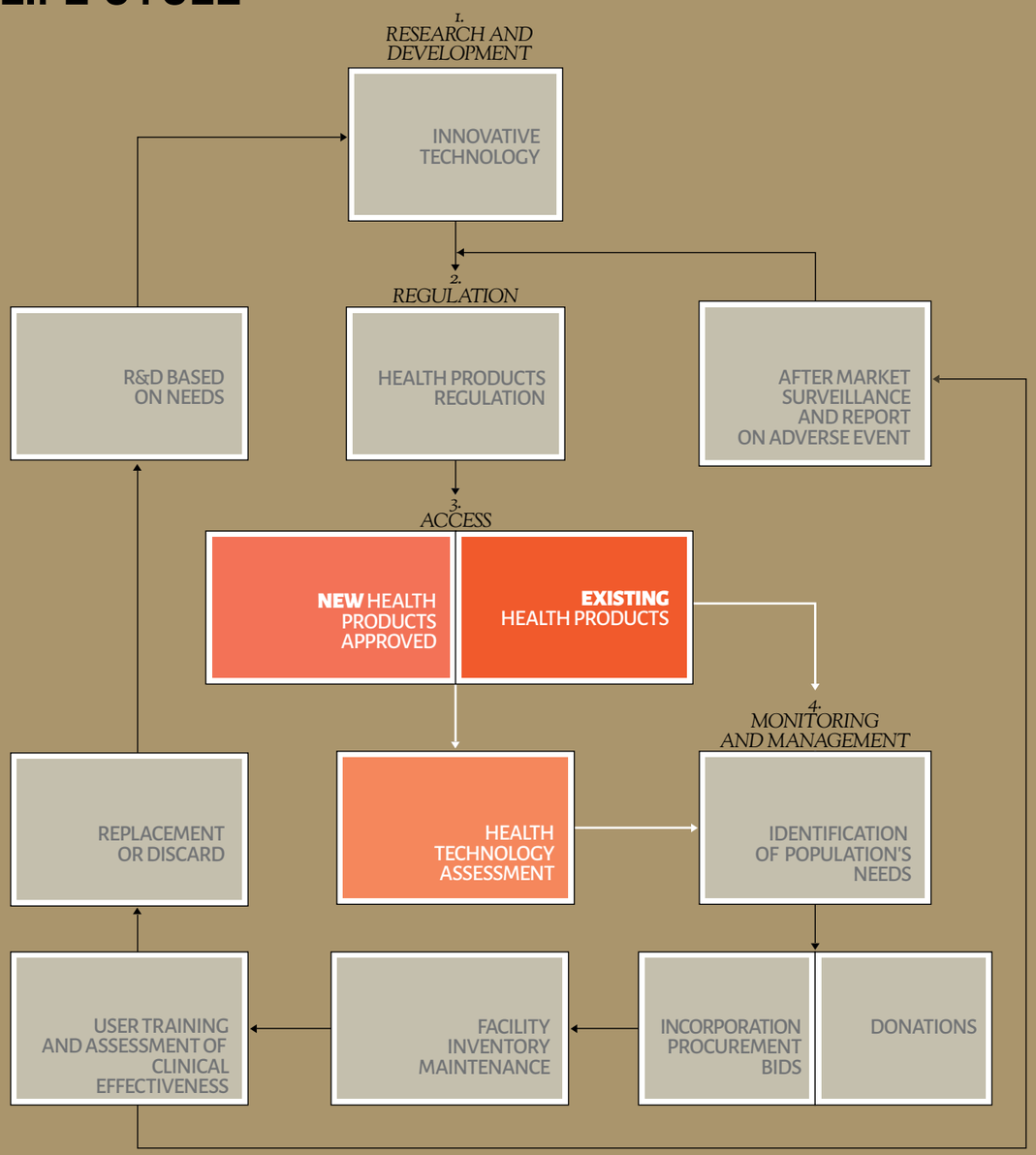
- computerize health surveillance procedures;
- improve exchange of knowledge on medical devices between regulators and regulated companies, and promote greater clarity of the regulatory process;
- aim at maintaining the maximum period of 90 days for ANVISA to issue guidelines on product-listing and registration processes, as established in § 3 of Article 12 of Law 6.360/1976.

Promote the institutional improvement of regulators to ensure that they:

- give priority to analyzing and clarifying the impacts of new rules, and to involve the relevant parties in the process;
- engage industry support for increasing the number of professional staff to strengthen the regulatory agency´s infrastructure.

FIGURE A

HEALTH PRODUCT LIFE CYCLE



Summary of proposals for access

Promote the rational use of technologies, avoiding waste and ensuring the population's access to available health solutions.

Increase database-sharing for better decision making and ensure the participation of all stakeholders in discussions regarding the incorporation of medical devices.

Reduce the tax burden on the MedTech industry's products.

Improve efficiency of the health system.

Support the introduction and use of remote technologies at "point of care".

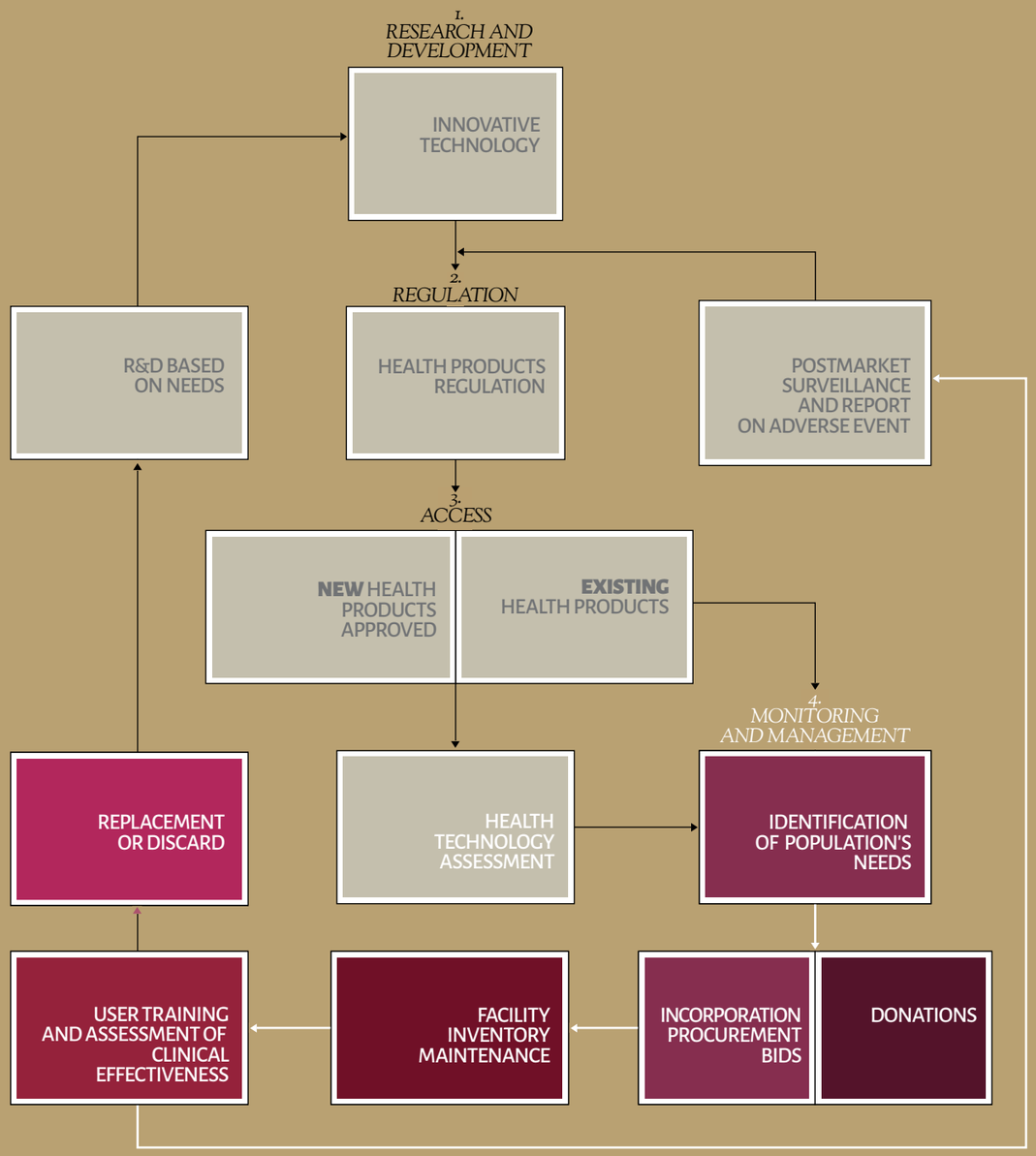
Develop specific policies for incorporating mobile technologies ("mHealth").

Adopt performance and risk - sharing mechanisms similar to those used in the United States and Europe.

Provide information and evidence for improving the adjudication criteria for health-related claims.

FIGURE A

HEALTH PRODUCT LIFE CYCLE



Summary of Monitoring and Management proposals

Promote the application of technical standards in the public and private health systems.

Promote hospital management systems across the network.

Prepare the health sector to adapt to changes resulting from centralized product procurement.

Systematically update the SUS (Brazilian National Health Service) and private health plan charts/tables for reimbursing product suppliers and service providers.

In the ethics and compliance sphere, strengthen good conduct practices between the MedTech industry, healthcare professionals and the government.

Maintain the "UDI - Unique Device Identification" system to ensure tracking of production, marketing and use of health technology products.

THE INDUSTRY IN NUMBERS (GLOBALLY AND BRAZIL)

Overview of global and Brazilian MedTech markets

CHAPTER 1
1.1 The global MedTech industry

Although the major international companies hold the largest share of the global market, over 80% of the industry consists of small and medium companies which generally employ less than 50 people. [1]

Global revenues of US$ 350 billion (2014)[2]

Global exports: US$ 177.7 billion (2012) [3]

Wide range of products on the market: 90 categories with 10,000 product types and 500,000 items . [4]

While the majority of the products are used in medical institutions, products are increasingly developed to be used by patients in non-medical facilities. These include "assistive technologies" such as pacemakers, hearing-aids and glucose meters. [5]

Profit returns have to take account of the need for cost control by purchasers of the products, by the public health system in general, and by hospitals and other healthcare providers in view of limited resource availability.

1 USITC - United States International Trade Commission, June 2014, p. 3.
2 Ibid, p.2
3 Ibid, p.4
4 Ibid, p.2

5 An assistive product is a device, equipment, tool,technology or software, custom-produced or more widely available for preventing, compensating, monitoring, relieving health problems or for neutralizing limitatations on patients' activities. World Health Organization (2010), p. 2.

Table 1.1 lists the top 10 global manufacturers in the industry.

TABLE 1.1

THE 10 LARGEST GLOBAL MANUFACTURERS IN THE MEDTECH INDUSTRY

Global revenues in US$ Billion

01 US$ 28.49 JOHNSON & JOHNSON
Diagnosis, surgical, cardiovascular and orthopedic care

02 US$ 18.42 SIEMENS HEALTHCARE
Diagnostic and imaging

03 US$ 18.20 GE HEALTHCARE
Imaging

04 US$ 16.59 MEDTRONIC
Cardiovascular, orthopedic

05 US$ 15.26 BAXTER INTERNATIONAL
Fluids, hemodialysis systems, surgical care

06 US$ 13.18 PHILIPS HEALTHCARE
Imaging

07 US$ 10.24 COVIDIEN
Surgical care

08 US$ 10.06 CARDINAL HEALTH
Surgical care

09 US$ 10.01 ABBOTT LABS
Diagnosis and cardiovascular

10 US$ 9.02 STRYKER
Orthopedic

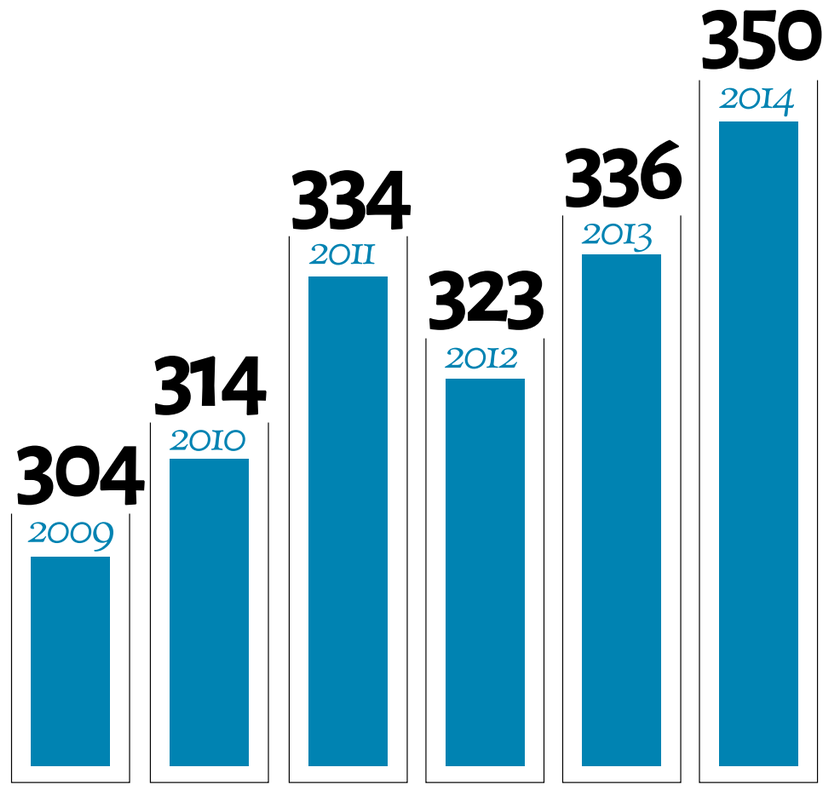
Source: USITC (2014)

Chart 1.1 shows the overall total revenue of the industry and Chart 1.2 the distribution of world exports by country of origin.

CHART 1.1

TOTAL REVENUE OF THE MEDTECH INDUSTRY

(in US$ Billion)

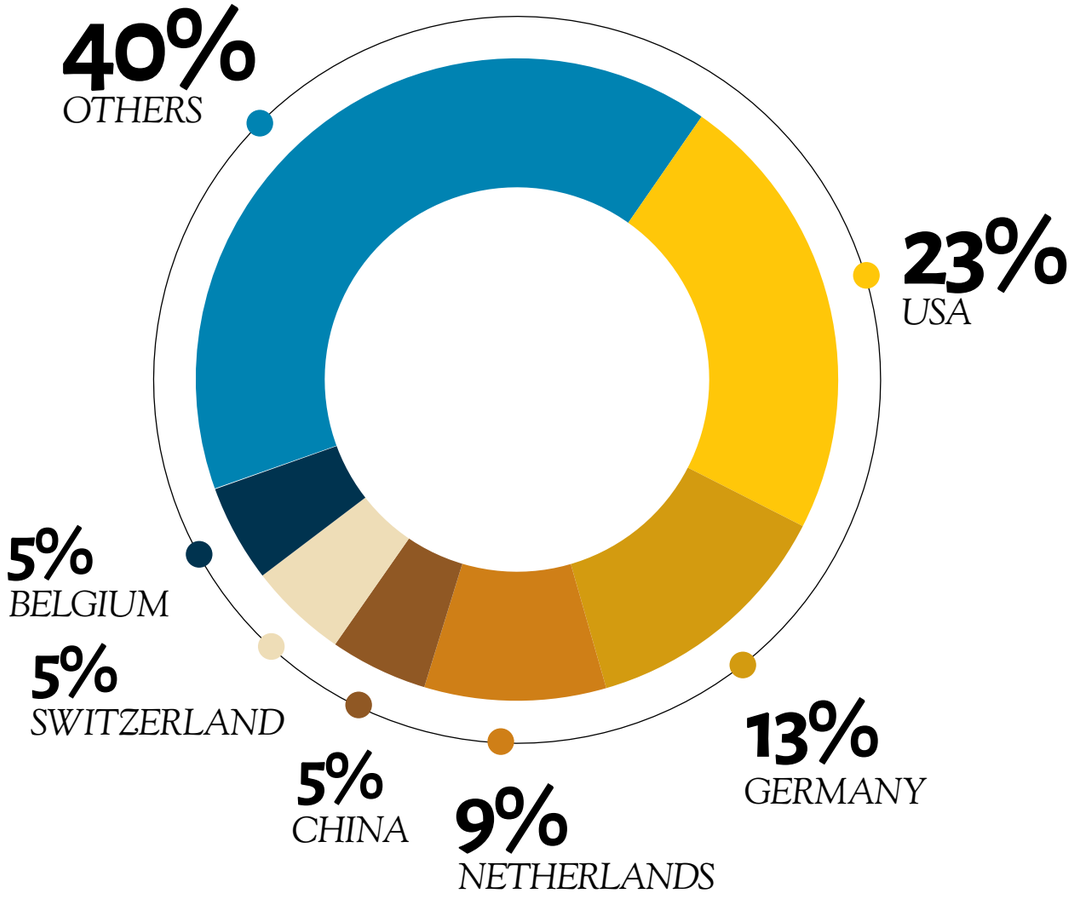


Source: WHO and USITC.

CHART 1.2

WORLD EXPORTS BY COUNTRY OF ORIGIN *(in %)*

Global Exports
US$ 177.7 Billion



Source: USITC (2014).

Table 1.2 shows medical devices costs, as a percentage of total health spending by comparing selected countries.[6]

TABLE 1.2

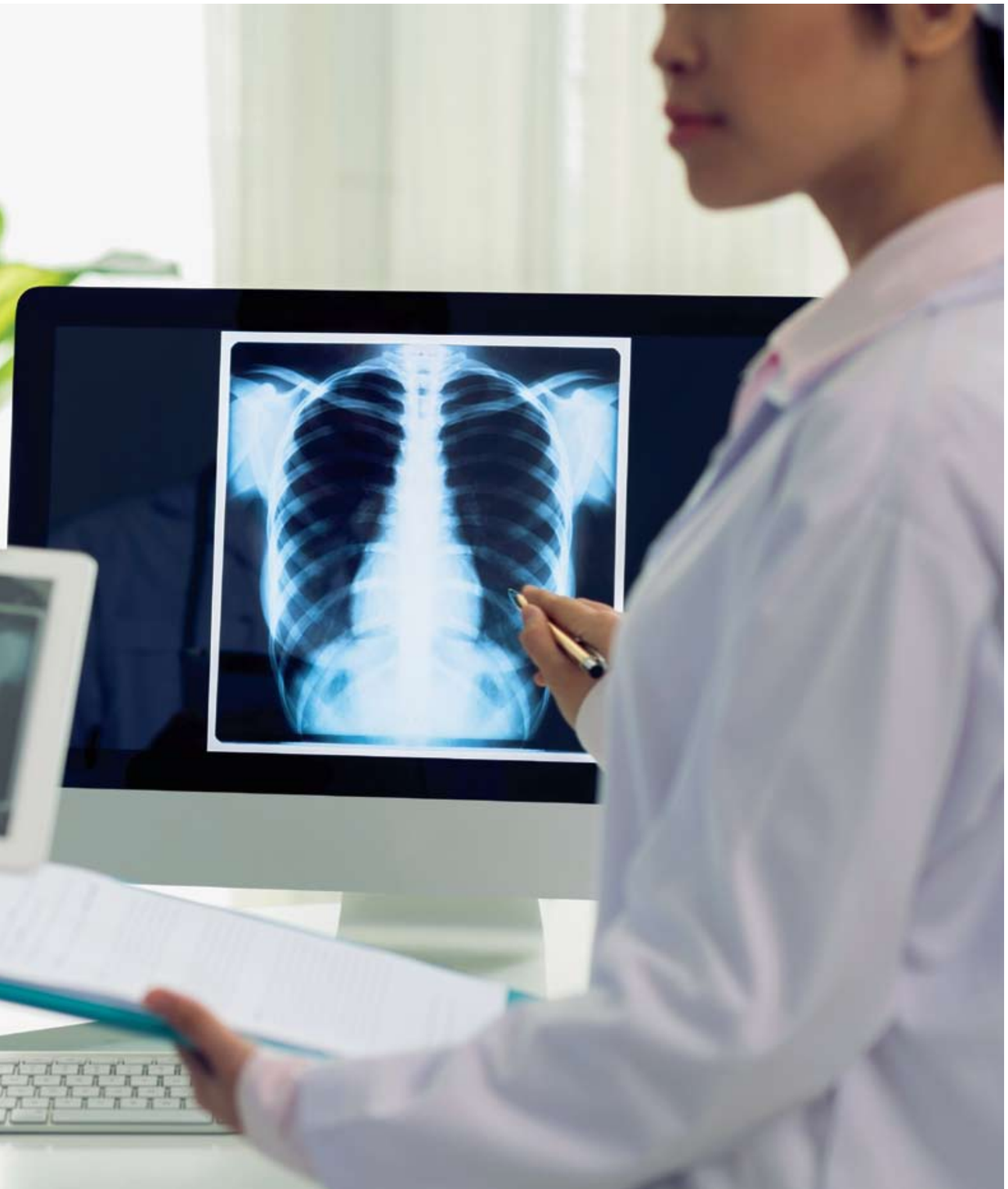
MEDTECH SPENDING AS A PERCENTAGE OF TOTAL HEALTH SPENDING OF SELECTED COUNTRIES – 2013

	Percentage of medtech costs of total health spending
GERMANY	6.49%
JAPAN	6.13%
SOUTH KOREA	5.73%
SWITZERLAND	4.79%
BELGIUM	4.61%
FRANCE	4.60%
UNITED KINGDOM	4.41%
UNITED STATES	4.31%
SPAIN	3.8%
CANADA	3.51%
AUSTRALIA	6.49%
GREECE	3.23%
BRAZIL*	2.35%

Source: Canadian Health Policy Institute – CHPI (2014) * See calculation in Table 1.4 of this chapter

6 CHPI (2010), pg 10. The international comparison of CHPI does not take into account In Vitro Diagnostic reagents and laboratory equipment. If included, for Brazil, it would mean 3.7% of total expenditure on what are considered in this publication as MedTechs. However, there are no international data comparable to this inclusion.

MEDTECH INDUSTRY FIGURES FOR BRAZIL



1.2 Industry figures for Brazil

The MedTech industry in Brazil consists of 14,482 companies. Of these, 4,032 are manufacturers and 10,450 are engaged in marketing and distribution of MedTech products. The State of São Paulo is home to 32% of the companies (4,639).

MedTech companies in Brazil employ 132,642: 61,448 in plants and 71,194 in the sales area.

The industry generates 225,000 indirect jobs in 20,100 companies dedicated to the diagnostic and therapeutic services industry. The sector also contributes to improving the quality of care provided by 1.1 million health professionals in 8,900 hospital establishments. [7]

Brazilian production was US$ 5.5 billion in 2013.[8]

The size of the market (apparent consumption) was US$ 10.6 billion in 2013[9]. Total spending in Brazil on public and private healthcare was US$ 291.3 billion in 2013. MedTech accounted for 3.7% of total spending.

The industry imported US$ 6.0 billion of products in 2013, which represented of 56% of the market.

Exports in 2013 totaled US$ 825 million, and represented 15% of Brazilian production of health products.

The industry trade balance closed the year 2013 negative, at US$ 5.1 billion and US$ 5.0 billion negative, in 2014.

The growth of the market or apparent consumption was 6.4% in 2013 compared to 2012 and 2.4% in 2014 compared to 2013. Domestic production grew 8.6% in 2013, compared to 2012, according to IBGE data shown in Table 1.3.[10]

Spending on medical technology (MedTech) in Brazil is low and below that those determined in many countries, based on international comparisons already shown in Table 1.2.

7 Source: *Relação Anual de Informações Sociais do Ministério do Trabalho* [Administrative Registers of the Ministry of Work and Labor] (2013) under the annual ratings of activities CNAES (86101) and (86402) PIA Product - IBGE 2013 (Data released in June 2015).
8 Estimate Websetorial for ABIIS (2015).
9 2012 and 2013 domestic production data for DMAs were collected from the IBGE PIA Product. To calculate the growth rate, 2012 data in Brazilian real were adjusted to prices of 2013 by the IGP-M index, the result was R$ 11,177,266,999 (2012); R$12,143,732,000 (2013). 2014 IBGE, R$ 13,175,949,220, was estimated by the PIM-PF - Monthly Industry Survey - Physical Production.
10 For calculation in dollars power parity exchange rate obtained from IPEADATA was used

TABLE 1.3

BRAZIL - APPARENT CONSUMPTION OF MEDTECHS: 2012 AND 2013 (ESTIMATED FOR 2014)

In US$ million

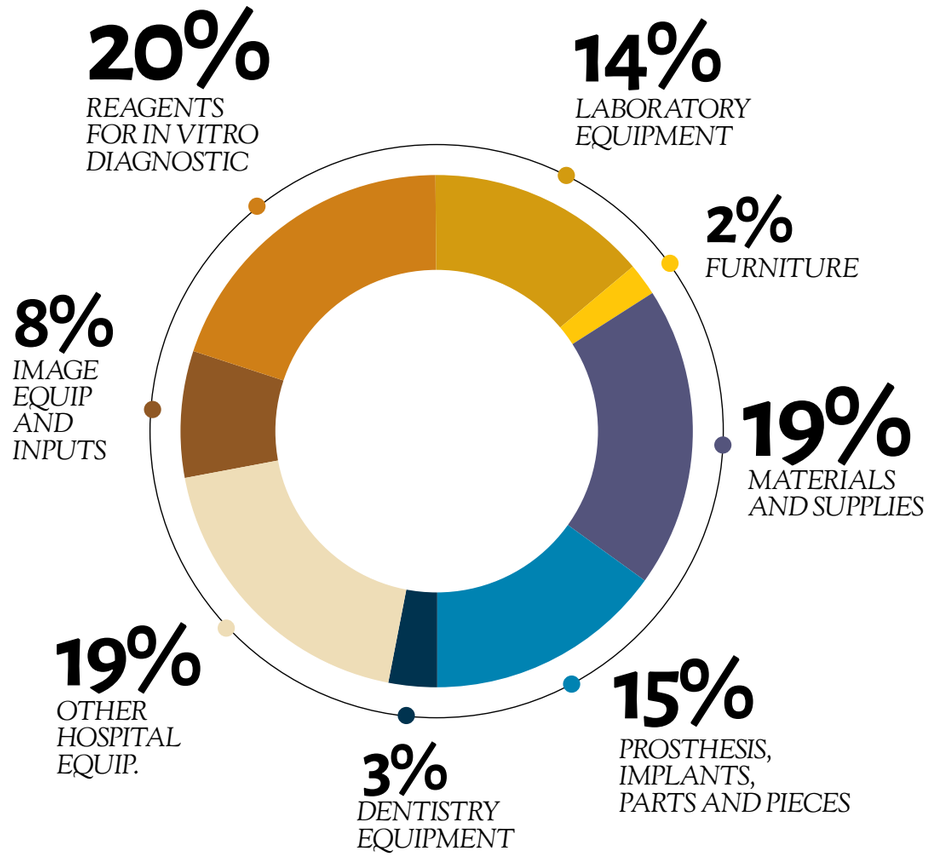
Category	2012	2013	2014*
Materials and Supplies	1.767	2.034	2.063
Prostheses, implants parts and pieces	1.454	1.551	1.627
Dentistry equipment	225	272	293
Other equip. for hospital use, including laser	1.778	1.953	2.038
Image equip. and inputs	859	804	823
Reagent for in vitro diagnostic	2.119	2.195	2.211
Laboratory Equipment	1.599	1.581	1.570
Furniture	188	241	266
MedTech Market in Brazil	9.990	10.631	10.891
Exchange rate (IPEA Data R$/US$ PPC)	2,12	2,22	2,23

SOURCE: Websectorial for ABIIS

Chart 1.3 shows percentage market sharing on DMAs market segments in Brazil.

CHART 1.3

MEDTECH SEGMENTATION IN THE BRAZILIAN MARKET (2013)



Source: Websectorial for ABIIS

Table 1.4 shows MedTechs's share in total health spending among other indicators of these expenses and the same industry.

TABLE 1.4
BRAZIL - MEDTECH SHARE OF TOTAL HEALTH SPENDING IN 2013 AND OTHER INDICATORS

In % and US$ million

Indicator	Amount
*TOTAL EXPENDITURE ON HEALTHCARE IN BRAZIL**	
Share of total health spending as % of GDP	9.67
Share of Government spending on health as % of total health spending	48.0
Share of private health spending as % of total health spending	52.0
Share of out of pocket spending on private health	58.0
Total health spending "per capita" in US$ million	1,454
Total health spending in US$ million	291,306
Government health spending in US$ million	140,376
Private health spending in US$ million	150,930
GDP in US$ million	3,012,197
Exchange rate R$ / US$ as power parity exchange rate	R$ 2.20

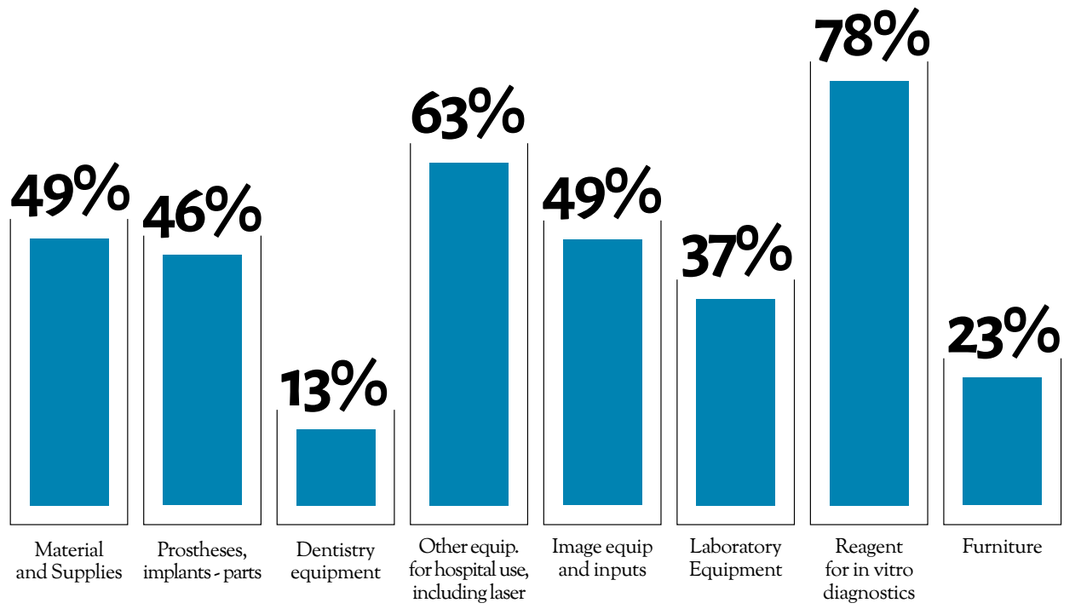
Indicator	Amount
*MedTech SPENDING IN BRAZIL***	
Total MedTech spending in US$ PPC (including laboratory equipment and reagents for in vitro diagnostics)	10,631
MedTech share in total health spending (including laboratory equipment and reagents for in vitro diagnostics)	3.65%
MedTech spending "per capita" (including laboratory equipment and reagents for in vitro diagnostics)	53.06
Total MedTech spending in US$ PPC (excluding laboratory equipment and reagents for in vitro diagnostics)	6,855
MedTech in total health spending (excluding laboratory equipment and reagents for in vitro diagnostics)	2.35%
MedTech spending "per capita" (excluding laboratory equipment and reagents for in vitro diagnostics)	34,21

*Source: (http://apps.who.int/nha/database/ViewData/Indicators/en).
** Calculation: Websetorial for ABIIS (apparent consumption).

Chart 1.4 shows the share of imports inapparent consumption of health products for the year 2013.

CHART 1.4
SHARE OF APPARENT CONSUMPTION OF HEALTH PRODUCTS (2013)

In %



Source: SECEX – Alice Web/ PIA Produto – IBGE

In the health products group, Brazil's import dependence is primarily on in vitro diagnostic reagents and laser surgery equipment (over 70% of these products are imported).

Brazil is least dependent on items such as furniture and dental appliances. Less than 30% of these products are imported to meet local needs.

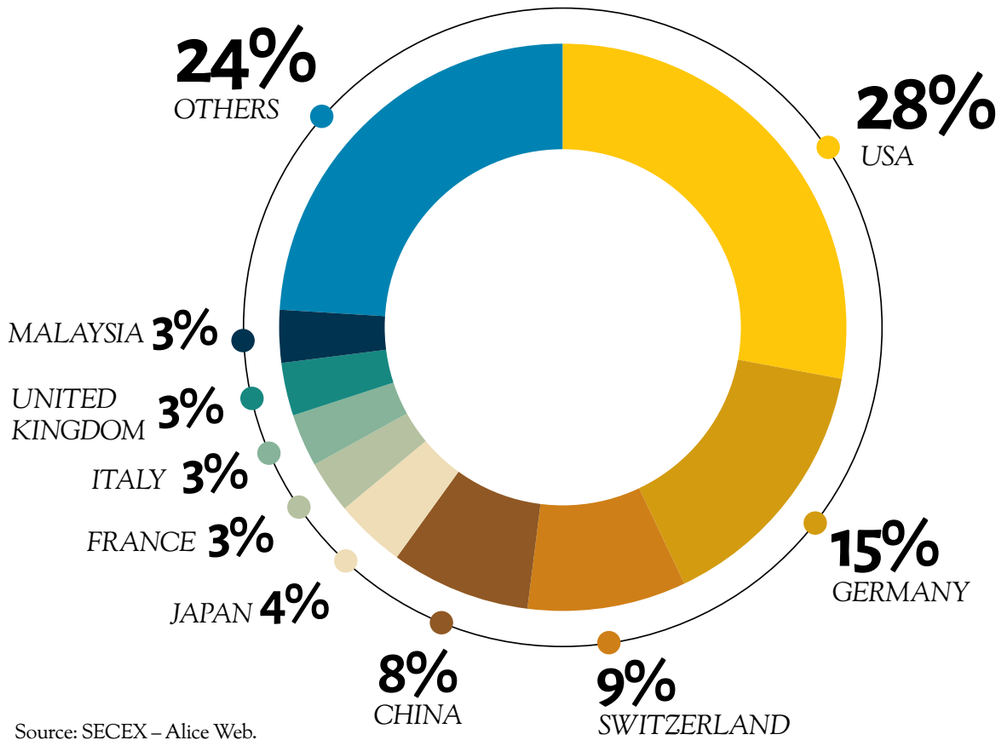
Brazil imports approximately 28% of its MedTechs from the United States the largest source of imports, followed by Germany (15%).

The main countries of origin of MedTech imports in 2014 are shown in Chart 1.5.

CHART 1.5

MAIN COUNTRIES OF ORIGIN OF BRAZILIAN MEDTECH IMPORTS IN 2014

In %



Source: SECEX – Alice Web.

The local presence of global players in Brazil

The largest global companies in the industry are currently present in Brazil: Johnson & Johnson, Siemens Healthcare, GE Healthcare, Medtronic, Philips Healthcare, Covidien, Abbott Labs, Stryker, BD, Boston Scientific, B. Braun, Novartis (Alcon), 3MHealthcare, Terumo, Smith & Nephew. Many are manufacturers and some have R&D facilities in Brazil. Table 1.5 shows that the latter increasingly focus on R&D and other projects in Brazil .

TABLE 1.5

MEDTECH COMPANIES IN BRAZIL: STRATEGY INDICATORS WITH INCREASING FOCUS ON PROJECTS IN BRAZIL (2014)

Company	*Local office*	*Shared service center and technical assistance*	*Sales, marketing and support*	*Manufacturing*	*PSD in TM*	*Design, development*	*Education and training center*
JOHNSON &JOHNSON	✓	✓	✓	✓		✓	✓
SIEMENS HEALTHCARE	✓	✓	✓	✓	✓	✓	✓
PHILIPS HEALTHCARE	✓	✓	✓	✓	✓	✓	
ABBOTT LABS	✓	✓	✓	✓	✓		✓
STRYKER	✓	✓	✓				
BOSTON SCIENTIFIC	✓	✓	✓				✓
SMITH & NEPHEW	✓	✓	✓				✓
MEDTRONIC + COVIDIEN	✓	✓	✓	✓	✓	✓	✓

Source: ABIIS

THE MEDTECH INDUSTRY AND BRAZIL'S NATIONAL HEALTH SYSTEM

CHAPTER 2

The MedTech industry and the National Health System (SUS)

When proposing suggestions for improvement of the MedTech supply chain in Brazil, it is worth considering the context in which the industry operates. At least four aspects are the key to better understanding: health services provision, demand for services, funding and data flows in the healthcare system. (See Figure 2.1)

Services, labor and infrastructure: structure of the public and private health services networks that use MedTechs.

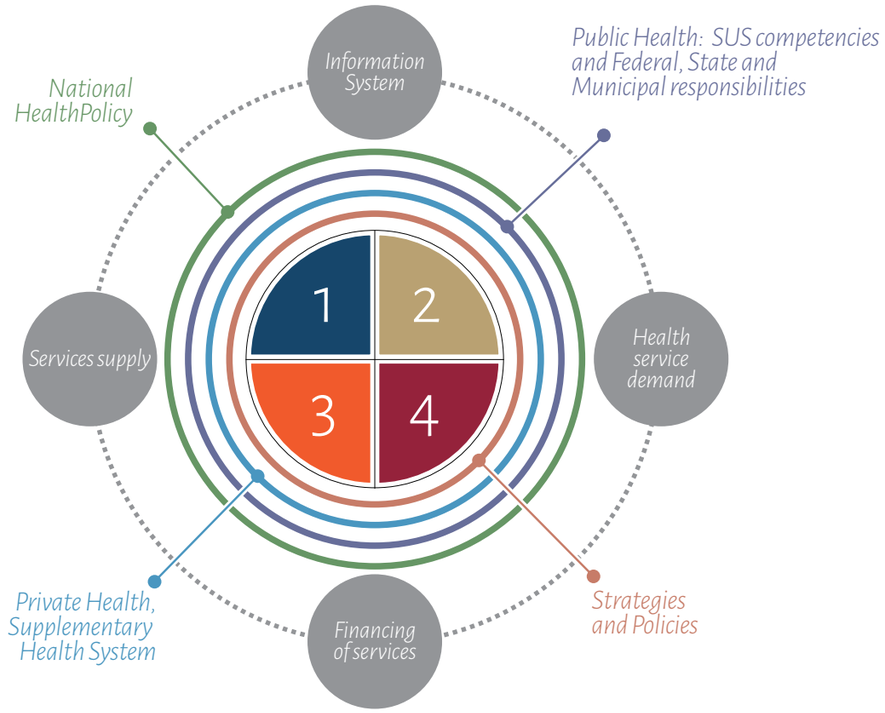
Management of data flows on users, procedures, inventories,and goods and services procurement.

Financing: Knowledge of funding flows in the health system and determining who pays for the services.

Demand for services: The characteristics of healthcare services users.

FIGURE 2.1

MEDTECH POLICY IN THE CONTEXT OF THE NATIONAL HEALTH SYSTEM



Prepared by Websetorial based on WHO (2012)

Several characteristics of supply and demand, the information system and the funding of services are analyzed in the following three sections.

2.1 Healthcare services provided by the public health system

The 1988 Constitution establishes that all Brazilian citizens have the right of access to health. This mandate defines public policy priorities on healthcare, including universal coverage provided by the Brazilian National Health System (SUS). Responsibility for financing the SUS is shared primarily by the Federal Government, the State Governments, the Federal District government and the Municipal governments.

The SUS within the federative system[1]

Implementing social policies in a federative system requires an explanation of the attributes of the different spheres of government and the need to adopt coordination and cooperation mechanisms between them.

Other key concerns are: the inherent complexity of the varied health conditions of the population as a whole, and of individuals living in the states and municipalities (i.e. local diversity of health needs), the range and types of actions and services for addressing these needs, the skills and competences of health workers, the technological and financial resources required, and the complex logistics involved in the marketing of products, equipment and services.

Brazilian federalism impacts the health area in several ways. The municipalities, many of them small, in particular shoulder a considerable burden of responsibility for implementing public policies, including health policies. However, the diversity of Brazilian municipalities in terms of size, political, social and economic development, tax collection capabilities and general institutional capacities can lead to difficulties of implementation by the municipal authorities faced with the above-mentioned challenges.

1 Rehem de Souza (2002).

SUS: range of healthcare and types of treatment

Healthcare in Brazil's national health service ranges from basic care in outpatient departments to highly complex treatments in hospitals and clinics. The basic (primary) care facilities serve as the first stop for users of the health service, and are responsible for promoting, protecting and maintaining people's health, with health activities focused on diagnostics and treatment, rehabilitation, and harm reduction[2].

Management of the basic care network is highly decentralized, and targets specific population groups in an effort to provide comprehensive care and treatment. The system comprises a number of thematic networks and programs, including the Family Health Program, Basic Health Units and the Oral Health Program. The Family Health Program and the Basic Health Units are considered to be the cornerstone of primary health care in Brazil.

The Family Health Program involves 34,702 separate teams serving 56.4% of the population (109 million people).

The Family Health Program covers 56.4% of the population. Its basic work is done by 34,702 teams of health workers organized in 1813 clusters who provide services for 109 million people[3]. 39,861 Basic Health Units are functioning in Brazil.[4] The Oral Health Program consists of 860 specialized dental clinics and 19,946 Oral Health teams.

A number of crosscutting activities are undertaken under the aegis of the SUS: the Psychosocial Care Network (drugs and alcohol issues, etc. in schools); Cancer Prevention and Control; the Emergency Care and Home Visits Network (RUE); the Rede Cegonha program (family planning, ante-natal care, puerperium and child health), and the Network for the Disabled. SUS basic care facilities also include the ambulance service for emergencies and other priority cases. There are also 181 Emergency

2 National Basic Care Policy, Ordinance Num. 2488 of 10/21/ 2011.
3 Each Family Health team must be responsible for, at most, four thousand people, but three thousand is the recommended average. It is recognized that there are more vulnerable areas where the teams are responsible for an even larger population.
4 According to the Basic Health Units Census carried out in 2013. See Improvement Program of ACCESS and of Quality in Basic Care (PMAQ) on: (http://dab.saude.gov.br/ portaldab/cidadao_pmaq2.php.

Centers. 49.2% of the municipalities have access to the SAMU network using this emergency number, resulting in coverage of 72.4% of the population. The Telehealth-Brazil Networks aim to promote the use of modern information and telecommunications technologies for carrying out distance learning activities to allow interaction between health professionals at different points of the network and remote access of diagnostic support in isolated localities lacking appropriate health professionals. At present there are 47 Telehealth-Brazil clusters funded by the Ministry of Health.

Urgent medium and high complexity care, intended to address the main health problems of the population, requires specialized professionals as well as the use of technological resources to support diagnostics and treatment. Medium and high complexity procedures are considered to be those carried out by medical professionals and others with outpatient surgeries, procedures for orthopedic trauma; specialized treatments in dentistry, clinical pathology, anatomopathology and cytopathology; radiology and ultrasound examinations; diagnoses; physiotherapy; specialized therapies; prostheses and ortheses; and anesthetics.

68% of the units are financed by private capital and are at the service of the SUS, while 27% are run directly by the official health authorities at federal, state and municipal level.

Information System in the SUS network

The 2013 Primary Care Units Census5 surveyed patient records retained in the network. 87.6% of the professionals employed in the primary health network said that they kept standard manually-completed patient records, while 18% stated that they kept patient records online. Only 30% of the basic health units possessed one or more consulting rooms with computers connected to the Internet.

As regards the computerization of urgent medium and high complexity care, the health service inspection report published by the Federal Court of Auditors (TCU) in March 2014, based on inspections of 116 federal, state and municipal public hospitals, revealed that Brazil's health system infrastructure is not prepared for integration into the world of information technology (IT)[5].

The units visited by the TCU inspectoral teams contained a total of 27,614 beds, representing around 8% of the beds available for use by the SUS. The final TCU report was compiled on the basis of interviews with State Health Secretaries, representatives of the Federal and State Prosecutor's offices, public defenders and professional councils, in addition to information provided by hospital staff.

The report showed clear evidence of a high level of disorganization in the flow of patients, equipment and supplies between the primary care networks, the medium and high complex facilities, and the intensive care units (ICU).

With regard to digital inclusion of the public health network, the TCU report revealed the general absence of fully-functioning computerized systems. Of the hospitals visited, only 11% possessed working IT systems, while 87% had computers available but with problems in the IT area, according to the staff interviewed. In the majority of the hospitals the existing IT facilities provided no support for good patient care.

A further source of information – the ITC Health Survey[6] – investigated the infrastructure and availability of information technology and communication facilities, and of any applications based on these technologies, in the public and private health institutions in Brazil. The ITC survey also appraised the use made by doctors and nurses of these tools in their work, and the main barriers to the full use by staff of ITC in the hospital and medical environment.

The Survey, carried out annually, aims to cast light onthe extent to which ITC is being adopted. The survey includes indicators on IT management and ITC infrastructure, online health records and data exchange, services provided to patients, and the overall use of the Telehealth system. It also includes information on hospital medical and nursing staff, including professional profiles, access to and use of ITC, and the overall levels of adoption and use of computer technology. See Figure 2.2 for the results of the study.

5 TCU (2014).
6 CETIC (2013).

FIGURA: 2.2

KEY RESULTS OF THE ITC HEALTH SURVEY 2013/2014

Access to computers and the Internet

Data indicate that 94% of health facilities have computers, while 91% have Internet access. The Internet is more present in larger facilities (with more than 50 beds) or in diagnosis and therapy support services, such as laboratories. The Internet deficit, on the other hand, mainly hits primary health care facilities (i.e those without beds and designed for outpatient care only). 20% of these are not connected to the Internet.

Information on patients

Most of the electronically available data on patients, is of a purely administrative nature, such as registration, admission, transfer and discharge data. Electronic clinical data is much less common. While 83% of the facilities using the Internet over the last 12 months report that they retain patient registration data, only 21% have any electronically stored data on vaccines applied to the patients and only 25% report that they store X-ray images electronically.

Figure 2.2: Main results of the ITC Health Survey 2013/2014
Source: ITC Health 2013/2014.

Telehealth Services

Of the health establishments using the Internet over the last 12 months, 22% used it for health-related distance education, 19% carried out other online research activities, and 25% had some real-time interaction (teleconferencing, etc). These activities were more common in the public institutions than in the private ones. Of the total number of facilities with Internet access, 14 % belong to a Telehealth network.

ITC use

Most health professionals have home access to computers and virtually 100% access to the Internet, while 63% of doctors and 72% of nurses have computers available in the workplace.

Main constraints according to healthcare professionals

Alleged by health managers, doctors and nurses, the main restraints against the installation and consistent use of healthcare-related electronic systems are ascribed to infrastructural problems, lack of training and low priority given to IT by public policies. In the specific case of health professionals, internal policies of were also major impediments. 75% of the doctors and 71% of the nursesstated that lack of training was a barrieer to the installation and use of IT systems. Over the last 12 months, only 23% of the doctors and 25% of the nurses did any training or followed a course on the use of ITC in the healthcare sphere.

In addition to the information systems network, the Ministry of Health has created the Health Policy Implementation Support System aimed at assisting states and municipalities to fund and implement appropriate computerized systems in the health care units and services.

Funding of the SUS

In line with a mechanism established by Decree 1232 of 30/08/1994, federal financial resources have gradually begun to be transferred to states and municipalities through direct allocations from the National Health Fund aimed at underpinning healthcare services.

In 2010, the annual direct costs of public health services and activities amounted to R$138.5 billion, accounting for R$62 billion of federal spending, R$ 37.2 billion of state spending and R$39.2 billion of municipal spending. These disbursements represented 3.67% of Brazil's GDP in 2010 (R$ 725.92 per capita)[7].

In addition to National Health Fund transfers, the State and Municipal Health Funds receive contributions from their own respective budgets, with the states using their own resources to replenish the Municipal Health Funds, in accordance with rules established at state level[8].

The weaknesses are reflected in the difficulty of access and delay in scheduling exams and treatments, appointments with specialists and elective surgeries.

Management of the SUS

According to experts, the main weaknesses of the SUS stem from the lack of financial and human resources, as well as from poor management. There is a lack of the type of instruments normally used by state-of-the-art hospitals, such as IT tools to improve bed allocation, monitoring drugs inventories and essential equipment, etc. Experts also argue that the use of "telemedicine" should be expanded, involving training health professionals in, for example, remote analysis of patient scans , etc.

Management weaknesses are also reflected in the substantial difficulties that patients experience to access initial treatment, as well as suffering delays in scheduling examinations, treatment, appointments with specialists and arranging elective surgeries. It is a well known fact that the population is often obliged to confront endless delays in precarious and overcrowded hospitals.

7 (http://portalsaude.saude.gov.br/images/pdf/2013/outubro/02/despesa-total-saude-021013.pdf). Last data available according to consultation on 7/ 20/2015.
8 Government spending on health published by WTO, in Table 1.4 of Chapter 1 of this document includes the abovementioned direct federal, state and municipal expenses, direct contributions from federal entities and other expenses, such as those regarding care provided to civil servants, military officers and their dependents with restricted access to these clientele, funded with public resources or with the beneficiaries' own resources, usually served by the private network system.

2.2 Healthcare provision in the supplementary healthcare system

The various agreements in the public and private healthcare systems in Brazil, built over 60 years, form the basis of the current Brazilian supplementary health system[9]. Law No. 9.656/1998, which provides for private insurance and healthcare plans, established mandatory national health coverage and rules governing the products that can be supplied. The National Health Agency (ANS) was set up in 2000 by Law No. 9961.

The ANS is a public regulatory authority with a mandate to regulate the nexus between the public and private health sectors, given the importance to the population of the supplementary health sector in Brazil. The ANS is responsible not only for evaluating the economic feasibility of the private health operators but also for checking the status and accuracy of the health services information provided by them.

Following approval of the two founding laws, a set of rules was drawn up that can be summarized under six main headings[10].

Creation of norms to cover health insurance policies and healthcare companies.

Establishment of hospital inpatient, outpatient and dental treatment plans, with assured coverage for all the diseases included in the International Disease Classification.

Mandatory registration of detailed plans on offer.

Setting of clear rules for grace periods, hospital stay lengths, policy price increases, pre-existing diseases and conditions of minimum treatment coverage.

Regulation of the sector by the ANS.

Creation of the Supplementary Health Council comprising representatives of the Ministries of Health, Justice and Finance.

9 Brazil. National Council of Health Secretaries Supplemental Health (CONASS - Conselho Nacional de Secretários de Saúde). Coleção para Entender a Gestão do SUS, no 12. Brasília: CONASS 2011
10 CONASS 2011, according to Axiabio, 2014.

Services

The ANS has established a set of rules related to the services to be provided by the private sector, including health plan coverage and restrictions. The main rules are as follows:[11]

- Clear definition of pre-existing disease.
- Determination of conditions under which all patients can be attended.
- Mandatory urgent and emergency care.
- Mandatory coverage for all beneficiaries for procedures listed in the *Rol de Coberturas*[12], revised every two years.
- Definition of the contract terms of the health plans approved by ANS on the basis of this list.
- Despite the obligation to provide coverage, the operators of the supplementary system can refuse payment to service providers in the event of the treatment being incompatible with the disease or with its treatment phase, if it is off-label, or if equally effective and cheaper treatment can be obtained.
- The majority of private health insurance beneficiaries in Brazil are covered by their employers on a collective basis. If the plan holder retires or is dismissed, he/she can continue to receive treatment under the collective contract for a fixed period, paying the same contribution paid while employed.
- Private health operators are responsible for paying to the SUS the costs of procedures (particularly high cost procedures) carried out in the SUS network on patients with health insurance plans.
- The ANS can ban private health insurance companies that are in default, bankrupt, with claims or debts.
- Price adjustments are subject to rigorous rules established by the ANS, and private insurance companies are not allowed to intervene in price-setting.
- Plan holders can opt to retain contracts prior to this regulation, with monthly policy payment adjustments in accordance with the rules.

11 AxiaBio (2014).
12 The List of Health Procedures and Events is a list of procedures, exams and treatments with mandatory coverage by health insurance plans

Healthcare companies and health plan-holders

There were 1417 private healthcare companies in Brazil in 2014. 1199 had "beneficiaries" (i.e. plan holders). 1032 companies (862 with plan holders) sell medical-hospital plans and 385 provide coverage of dental care exclusively (337 with plan holders). Plan holders with private medical plans with or without dental care number 50.8 million, while 21.4 million adults have private dental care plans. In 2014 the majority of plan holders were members of corporate health plans contracted by employers (66.5%) while 13.2% opted to join collective plans as individuals and 19.7% purchased individual or family private health plans. Some 3.5% of holders had dental care plans paid for by their employers. The population covered by private medical assistance is concentrated in the Southeast (São Paulo, Rio de Janeiro and Espírito Santo), with a coverage rate higher than 30% of the rest of the population[13].

13 ANS (June 2015), Other data available at: (http://www.ans.gov.br/perfil-do-setor/dados-gerais#sthash.ZkW32iOt.dpuf).

Private health service structure

Of the total of 208,399 health facilities in Brazil, 117,362 provide treatment for plan holders (see details in Table 2.1).

TABLE 2.1

HEALTH INSTITUTIONS: TOTAL AND THOSE THAT ACCEPT PRIVATE HEALTH INSURANCE PLANS BY TYPE OF FACILITY (SEPTEMBER 2014)

Type of facility	Number of facilities	Facilities accepting private health insurance plans	
		Absolute	In % of total
Clinics or specialized outpatient facility	37,071	19,104	51.5
Isolated practice	137,065	83,688	61.1
Specialized hospital	1,088	439	40.3
General hospital	5,227	1,689	32.3
Policlinic	6,316	2,805	44.4
Specialized emergency room	118	50	42.4
General emergency room	402	60	14.9
Service unit to support diagnosis and therapy	21,112	9,527	45.1
TOTAL	208,399	117,362	47

Source: CNES/MS Caderno de Informação da Saúde Suplementar [Supplementary Health Information Booklet] December/2014 (Table 24)

Table 2.2 shows data about health facilities per type of service and coverage.

TABLE 2.2

HEALTH INSTITUTIONS BY TYPE OF SERVICE PROVIDED AND COVERAGE (SEPTEMBER 2014)

Type of service	Coverage(*)			
	SUS	Private	Public health insurance plan	Private health plan
Outpatient care	75,153	177,572	10,429	111,102
For hospital admission	5,902	3,909	551	2,276
Service to support diagnosis and therapy	23,527	33,250	2,387	17,946
Urgency	9,864	3,759	451	2,040
TOTAL	114,446	218,490	13,818	133,364

Source: CNES/MS Caderno de Informação da Saúde Suplementar [Supplementary Health Information Booklet] December/2014 (Table 26)
(*) The sum of the parts does not match the total facilities, since the same facility may involve more than one type of coverage and be inserted in two or more columns.

Information systems in the supplementary health sector

The supplementary health sector also lacks professional management capable of adopting efficient hospital information (HIS) systems to control costs and results. These systems provide the classic Enterprise Resource Planning[14] solutions focused on administration and finance, as well as on specific aspects such as the clinical segment (which involves the display of key indicators such as more efficient surgical procedures), hospital bed turnover and stocks of drugs and MedTechs.

The new hospitals built by healthcare companies and the large reference hospitals use management systems to ensure a better balance between investments in IT and medical equipment[15]. It is worth noting in this respect that *"IT Guidelines for Private Hospitals"*, published by ANAHP[16], describes hospital sector best IT practices and provides guidance for hospitals wishing to go digital.

New hospitals built by healthcare companies and large reference hospitals use management systems that are able to guarantee a better balance between investments in IT and medical equipment

Supplementary system funding

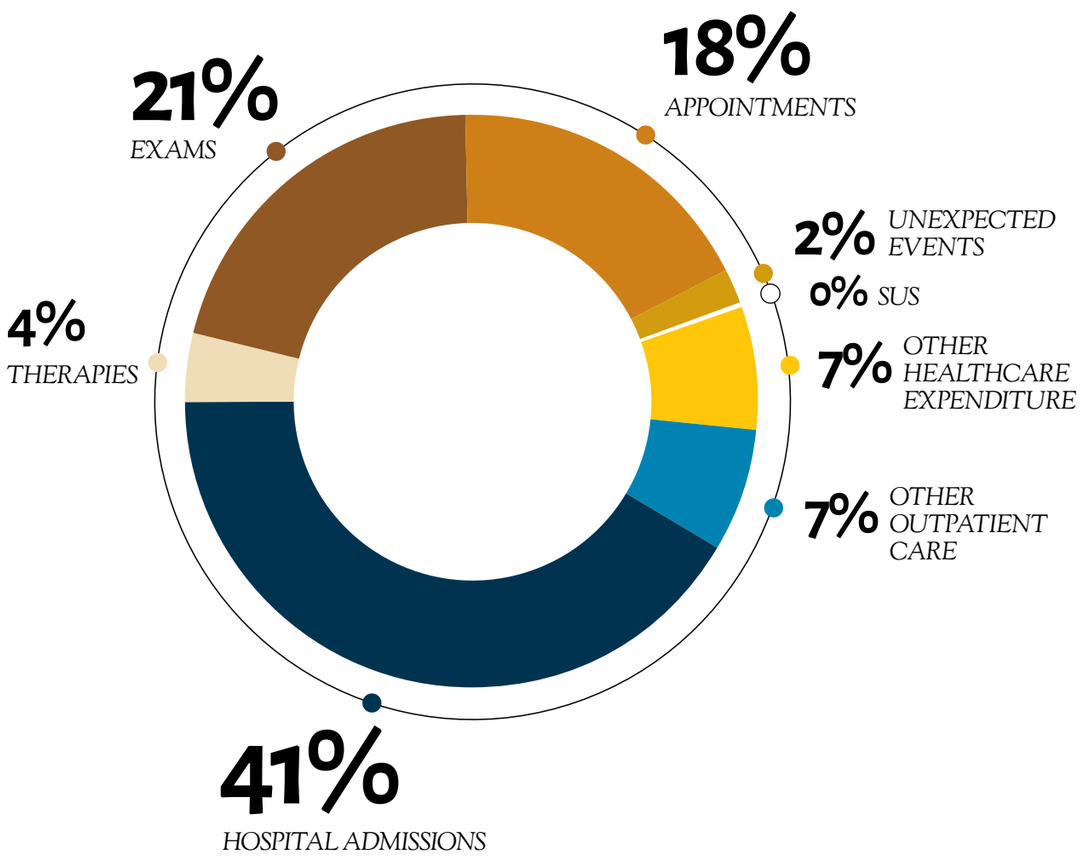
According to the WHO, expenditure on private healthcare in Brazil in 2013 amounted to US$ 150.9 billion[17]. Notwithstanding that the supplementary health service serves only one quarter of the number of people dependent on the public system, it spends as much as the SUS. In 2014, the supplementary health system spent R$ 107 billion, funded by R$127.3 billion collected from health plan regular contributions[18] (See Chart 2.1).

14 ERP (Enterprise Resource Planning) is an IT resource, data and procedures management tool.
15 Extracted from FENAINFO, *"Hospitais privados lideram adoção de sistemas de gestão na área"* [Private hospitals are leading the adoption of management systems in the area] at: (http://www.fenainfo.org.br/info_ler.php?id=35272), on: 21 July 2015

17 Source: (http://apps.who.int/nha/database/ViewData/Indicators/en). The private spending on health published by WTO, in Table 1.4 of Chapter 1 of this document also includes spending on services and drugs, privately and directly accessed by the segment of autonomous private health providers, upon on-the-spot payment.
18 ANS (June 2015).

CHART 2.1

BREAKDOWN OF TOTAL EXPENSES OF HEALTHCARE COMPANIES (2014)



Source: ANS.

Management of the supplementary system

The often precarious service provided by the SUS, together with rising employment and income levels of the lower-income population, has substantially increased demand for private health plans. In the space of 14 years, the private health system has attracted an additional 20 million users, growing at an annual average rate of 4.1% from 2007 and ending 2014 with a total clientele of 50.5 million.

An estimated 26.3% of the population paid for private healthcare in late 2014. Increasing demand is a clear indicator of dissatisfaction with the public health system regardless of complaints that are also made about the private system.

Increased demand has had a powerful impact on the quality of care provided by the private hospitals due to the shortage and inefficiency of the private healthcare infrastructure. Complaints by holders of private health plans focus mainly on coverage issues (75.9%), 18% on contract problems and interpretation of rules, and 5.7% on the levels of monthly policy payments and price adjustments. [19]

According to the National Association of Private Hospitals (ANAHP),[20] in order to meet demand for health services in both the public and private systems, investments of R$4.3 billion and R$ 7.3 billion would be needed by 2016 to finance 30,000 new beds and for expanding and improving premises by installing e.g. more surgical facilities and purchasing information technology systems.

19 ANS (2015) Consolidated supplementary health data of 06/17/2015: (http://www.ans.gov.br/perfil-do-setor/dados-e-indicadores-do-setor). 20 Extracted from TCU (2014).
20 Extracted from TCU (2014).

2.3 Demand for health services and MedTech

Public and private health user population

The population of Brazil stood at 200,600,000 in 2013 (65.1 million households). 56.2% of the population occupied homes registered with the Ministry of Health´s Family Health Program[21].

Brazil's population is heavily dependent on the SUS. 72.1% (144.4 million) use the public health care system compared with only one in four Brazilians with private health insurance.

As for supplementary healthcare, 28% of the population with a health plan in 2013 (medical or dental) tend to be concentrated in urban areas. 31.7% have health insurance in the cities and towns of Brazil - five times more than in rural areas (6.2%)[22].

21 2013 National Health Research published in May 2015
22 ANS – Consolidated Data Supplementary Health Services (10 May 2015)

Around 5.2% of the population have some form of dental insurance (10.3 million people). From 2003 to 2014, the number of subscribers to dental plans increased by 302%, amounting in absolute numbers to 16.1 million new users. In December 2014 there were 21.4 million holders of dental plans.[23] Rapid future growth is anticipated in this area.

Access to health care by income and region

According to the Brazilian Association of Research Companies, the majority of Brazilians belong to classes C, D and E (74% of the population in classes C and D). In the Southeast, South and Midwest half the population belongs to class C, 32.37% to classes A and B and a small segment to class D (15.9%). The situation in the North and Northeast is very different: around half of the population belongs to class D, while 15.2% of the population is in class A and B in the North, and 13.4% in class A and B in the Northeast.

23 Supplementary Health Information Notes – Beneficiaries, operators and plans ANS (2015).

The largest number of health insurance plan holders is concentrated on the more socio-economically developed regions. In the Southeast, 36.7% of the population has health insurance (6% have dental plans), while in the North/ Northeast the figure is substantially lower. Table 2.3 shows the correlation between socioeconomic status and access to health insurance.

It is noteworthy that most of people with private health insurance are university graduates (68.8%). It follows that the number of individuals able to afford private health care increases in accordance with their educational level.

TABLE 2.3

HEALTH INSURANCE PLANS AND SOCIOECONOMIC STATUS

Large Regions, Federative Units	*Private Insurance*		*Socioeconomic Status*		
	Percentage of people with some health insurance plan (medical or dental) in %	*Percentage of people who have some health insurance only for dental care*	*Classes A and B*	*Class C*	*Classes D/E*
North	13.5	3.4	15.2%	42.6%	42.1%
Northeast	15.6	3.6	13.4%	39.4%	47.2%
Southeast	36.7	6.5	32.4%	51.2%	15.9%
South	32.9	5.2	30.8%	53.5%	15.6%
Midwest	30.4	5.4	29.7%	48.5%	21.8%

Source: IBGE, Diretoria de Pesquisas, Coordenação de Trabalho e Rendimento, Pesquisa Nacional de Saúde 2013, and ABEP (Associação Brasileira das Empresas de Pesquisa).

Demographic issues and access to healthcare by geographic area

While Brazil's population is highly concentrated in state capitals and the coastal region, the country has an continent-sized area of 8.5 million km², which means that the logistics of delivering health services to people living in remote areas is complex and costly.

Brazil's 26 states (plus the Federal District), contains 5,570 municipalities. According to the 2010 Census, 84.35% of the population lives in urban areas. In 2010 only 67 municipalities had 100% of their population living in urban areas. The rural population currently accounts for 15.65% of the population.

In the state of São Paulo only 9.07% are beneficiaries of the Bolsa Familia Program, while this state has the largest number of people with health insurance (around 41.8%). By contrast, in the poor state of Maranhão, which contains the highest percentage (49%) of Bolsa Familia families, only 6.8% of the population has private health insurance.

Brazilian states where most of the families receive benefits from the Bolsa Familia program have the lowest percentage of people with health insurance plans and therefore greater dependence on the SUS

The states where most families receive benefits from the Bolsa Familia have the lowest percentage of people with health insurance plans and therefore greater reliance on the SUS. In the 12 months preceding the IBGE National Health Survey interviews, 6% of the Brazilian population (12.1 million people) were hospitalized for more than twenty-four hours, with 67.7% (8 million) treated under the SUS. In the North and Northeastern states, virtually all admissions were to SUS facilities (73.9% and 76.5% respectively). In the Southeast 58% of hospital admissions were in SUS facilities (the lowest percentage of all the regions.

Brazilian population profile, life expectancy and causes of death

According to IBGE (Brazilian Institute of Geography and Statistics), Brazilian life expectancy increased between 1980 and 2013 by 12.4 years. Average life expectancy was 74.9 years in 2013 - higher among women (78.6 years) than among men (71.3 years). It is noteworthy that men are more likely than women to die as the result of homicides and car accidents.

The population under 5 years old and over 70 had the greatest gains in life expectancy. In 2013 the infant mortality rate was 17 per thousand, compared with 1980 (84 per thousand).

Life expectancy increases are due to a number of factors, including public health improvements, a decline in fertility rates, better education of mothers, rising incomes and advances in basic sanitation. Certain government programs have also made a contribution, such as the *Atenção ao Pré-Natal* (Prenatal Care), *Saúde da Família* (Family Health) and *Bolsa Família* (Family Grant) programs. A range of other positive factors included the *Estatuto do Idoso* (Senior Citizens Statute), vaccination programs, improved access by older persons to employment and the rural retirement scheme.

Diseases

Two groups of diseases are the primary public health concerns in Brazil: first, infections, malnutrition and reproductive health problems; and second, chronic diseases. So-called external causes, such as homicides, traffic accidents, and increased crimes of violence, are increasingly common.

According to the 2014 National Health Survey around 40% of Brazilian adults (57.4 million) suffer from at least one non-communicable chronic disease. This survey by the Ministry of Health in partnership with the Brazilian Institute of Geography and Statistics (IBGE) reveals that these diseases mainly affect females (34.4 million females compared to 23 million males).

Diseases of the circulatory system were the main causes of death in 2013 (28%) while, according to the ICD-10 chapter, death from neoplasms accounted for 16.3% of total deaths. So-called external causes accounted for 12.5%.

Table 2.4 shows the percentage of main causes of death in 2013, by ICD-10 chapter, in Brazil as a whole and its regions.

TABLE 2.4 PART 1

MAIN CAUSES OF DEATH PER OCCURRENCE IN 2013, PER ICD-10 CHAPTER, IN BRAZIL AND REGIONS

In %

ICD-10 Chapter	*Brazil*	*North Region*	*Northeast Region*	*Southeast Region*	*South Region*	*Mid-West Region*
I. Certain infectious and parasitic diseases	4.3%	5.4%	4.4%	4.3%	3.7%	4.6%
II. Neoplasm (tumors)	16.3%	12.9%	13.2%	17.2%	20.3%	15.3%
III. Blood and Hematopoietic organ diseases and certain immune disorders	0.5%	0.6%	0.6%	0.5%	0.4%	0.4%
IV. Nutritional and metabolic endocrine disease	6.2%	6.6%	7.6%	5.4%	6.0%	5.5%
V. Mental and behavioral disorders	1.1%	0.5%	1.3%	1.1%	1.0%	1.2%
VI. Nervous system disorders	2.5%	1.6%	1.8%	2.8%	3.2%	2.4%
VII. Eye diseases and attachments	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
VIII. Diseases of the ear and mastoid apohysis	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
IX. Cardiovascular system diseases	28.1%	22.5%	27.8%	28.9%	28.4%	27.3%
X. Respiratory system diseases	11.4%	9.6%	9.4%	12.5%	12.2%	11.0%

TABLE 2.4 PART 2

MAIN CAUSES OF DEATHS IN 2013, BY ICD-10 CHAPTER, IN BRAZIL AND REGIONS

In %

Chapter CID-10	Brazil	North Region	Northeast Region	Southeast Region	South Region	Midwest Region
XI. Diseases of the digestive tract	5.1%	4.4%	5.1%	5.2%	5.0%	5.4%
XII. Skin and subcutaneous tissue	0.3%	0.2%	0.3%	0.4%	0.2%	0.2%
XIII. Musculoskeletal syst and connective tissue diseases	0.4%	0.3%	0.3%	0.5%	0.4%	0.5%
XIV. Diseases of the genital tract	2.5%	1.8%	2.0%	3.0%	2.1%	2.1%
XV. Pregnancy childbirth and the puerperium	0.1%	0.3%	0.2%	0.1%	0.1%	0.2%
XVI. Certain conditions originating in the perinatal period	1.9%	3.8%	2.5%	1.4%	1.2%	2.3%
XVII. Congenital malformations, deformities and chromosomal abnormalities.	0.9%	1.5%	0.9%	0.8%	0.8%	1.3%
XVIII. Symptoms, signs and achad [SIC] abnormality, e.g. clinical	5.9%	9.0%	7.3%	5.8%	4.1%	2.6%
XIV. External causes of morbidity and mortality	12.5%	18.8%	15.2%	10.0%	10.9%	17.7%

Source: CNES/MS Caderno de Informação da Saúde Suplementar December/2014 (Table 24).

Non-communicable chronic diseases consist mainly of cardiovascular disease, cancer, diabetes, respiratory and neuropsychiatric diseases. These are the principal causes of death and loss of quality of life in Brazil, causing physical incapacity and restricting people's work and leisure activities. In 2013, NCDs accounted for 70% of deaths in Brazil. The main causative factors were smoking, excessive alcohol consumption, overweight, high cholesterol, unhealthy diet and physical inactivity. To prevent these diseases, health policies need to focus on prevention based on monitoring risk factors and prevalence.

In 2013, the Northregion had the highest percentage (4.8%) of accident victims

Among the deaths caused by external causes in 2013, 37.4% (56,804 people) were the victims of assault, and 28.6% were due to traffic accidents (43,452 people). According to the 2013 National Health Survey, around 4.5 million people aged 18 or older were involved in traffic accidents in Brazil, with personal injury, during the 12 months prior to the survey (around 3.1% of the population).

The North region had the highest percentage (4.8%) of its population that had suffered accidents, followed by the Midwest (4.4%), the Northeast (3.4%) and the Southeast and South (2.4% and 2.9% respectively).

Table 2.5 lists the main external causes of death in 2013, by Chapter ICD-10, in Brazil as a whole and in its regions.

TABLE 2.5

TRAFFIC ACCIDENTS AND OTHER EXTERNAL CAUSES, 2013

Large Group CID10	Total	North Region	Northeast Region	Southeast Region	South Region	Midwest Region
Traffic accidents	28.6%	28.3%	27.2%	27.0%	33.4%	33.2%
Other external causes of accident injury	19.0%	17.3%	13.9%	23.5%	21.2%	16.5%
Self-harm	6.9%	5.7%	5.2%	7.1%	11.4%	6.9%
Assaults	37.4%	45.8%	45.8%	30.7%	29.1%	40.2%
Events of undetermined intent	6.5%	2.4%	6.5%	9.5%	3.5%	2.4%
Legal interventions and war operations	0.4%	0.0%	0.3%	0.7%	0.2%	0.1%
Surgical medical care complicat.	0.8%	0.3%	0.9%	1.1%	0.5%	0.3%
Sequelae of external causes	0.3%	0.2%	0.2%	0.3%	0.7%	0.4%

Source: Data SUS - Mortality Information System.

Around 10.4% of the population (20.7 million people) was diagnosed with dengue in 2013, with the North and Midwest the most affected regions (16.1% and 14.9% of their respective populations[24]).

Climate and environmental conditions favor the breeding of the dengue-transmitting mosquito, which is rife in the coastal cities and population centers located near rivers or lakes.

24 National Health Survey 2013.

Population connectivity

According to the Pesquisa Nacional por Amostra de Domicílio (National Sample Survey of Households - PNAD), over half of Brazilians have access to mobile communication devices (57.3% of the population). In 2013 the number of people accessing the Internet with these devices increased by 7.2 million. Lower prices and increasingly more mobile devices has led to even easier access to the Internet with the use of smartphones and tablets.

Mobile access to the Internet is growing rapidly in Brazil. In 2014 alone more than 50 million mobile broadband lines were brought into operation according to the National Telecommunications Agency (ANATEL). 97% of the lines were activated for mobile Internet. It is clear that Brazilians are keen to be online and and welcome the increasing availability of mobile access. Internet access has reached virtually every population sector including senior citizens, low-income people and even those of limited educational level.

2.4 Conclusions

A number of conclusions and suggestions can be drawn from an analysis of the scenarios presented in the chapters so far. The following chapters will first address conclusions of a more general nature, followed by more specific conclusions and suggestions for improving the production cycle of the MedTech industry.

Health regionalization in the public and private systems

The data set forth above showed that in Brazil there is great imbalance in the supply of health services among population groups, as they are unevenly distributed in Brazil, and such imbalance favors the most developed regions.

Substantial diversity exists in Brazil's states and municipalities in terms of the spatial allocation of financial resources. Private investments tend to be directed towards areas of higher population density and purchasing power. The significant resources directed towards private health institutions in certain states and larger cities also weigh heavily in decisions by the healthcare companies to allocate some of their services to the public health system. This results in patients being attracted to the metropolitan areas in search of treatment, including basic care, that should otherwise be provided by local municipal health authorities.

In order to boost the delivery of public sector health services, and ensure appropriate remuneration for services provided by the private sector, there is a need for governments to reallocate resources from different programs and activities to ensure more funding for the public healthcare sector. The conflict of political interests among the federative entities is the main barrier to designing workable regional and countrywide healthcare policies.

To increase public healthcare supply, expand total public healthcare funding and ensure appropriate remuneration for other health services, funds need to be raised by reallocating resource priorities from other programs and activities

The development of primary health care in municipalities located outside the major urban centers often depends on events that are unrelated to the health sector, such as public transport and sanitation policies, or public and private investment decisions involving temporary or permanent influxes of job seekers to meet labor demands, without considering the coping capacity of local health services. This is the case, for example, of the hydroelectric power plants under construction in the North, where large influxes of workers are largely neglected by the official health services.

The regionalization of health depends on understanding the different territorial characteristics of the country and realizing the importance of planning, inter and intra-sectoral negotiation and decision-taking between government and society in and beyond the realm of healthcare. The adoption of e-Health mechanisms could help to attenuate some of these problems by providing a range of distance healthcare solutions.

Connectivity in the health sphere

One in five people in the United States use smartphone health applications. Some can be connected to sensors on an individual's body for monitoring vital signs such as heart rate, while others assist diagnoses or perform biological analyses.

A new diagnostic test, for example, has been developed at New York's Columbia University that can diagnose the AIDS virus and other infections within a few minutes. This test detects the presence of biological markers such as antibodies due to an infection by collecting a blood sample from a pinprick on the finger. This sample is placed in a disposable plastic cartridge containing the reagents required for the test and the cartridge is then inserted into a "laboratory chip". The latter connects to the smartphone where an application does the test and immediately displays the result on the screen.[25]

PricewaterhouseCoopers (PwC) estimates that by 2017 the use of mobile technology solutions could save 8.9 million days of doctors' time in Brazil (9% of total working hours) by reducing by 30% the time spent accessing and updating patient data. This would represent savings of US$14.1 billion in Brazil and US$3.8 billion in Mexico[25] (see the comparison in Table 2.6).

25 PwC (2013).

TABLE 2.6

POTENTIAL SAVINGS IN BRAZIL AND MEXICO WITH THE USE OF MOBILE TECHNOLOGY SOLUTIONS UP TO 2017

In US$ billion

	Total saved with health		*Welfare and prevention*		*Diagnosis*		*Treatment and monitoring*		*System efficiency*		*Workforce and health*
Brazil	US$14.1	=	US$12.3	+	US$0.34	+	US$2.59	+	US$0.02	-	US$1.1
Mexico	US$3.8	=	US$3.1	+	US$0.11	+	US$1.02	+	US$0.01	-	US$0.4

Source: PWC (2014)

In 2014 the *Sistema Único de Saúde* (SUS) completed 26 years. Regardless of the significant progress made over the years, the system's basic goal – to provide universal healthcare for all Brazilians – has fallen far short due to the serious deficiencies in the services delivered. For example, users of the system often have to wait months or years for elective surgery (a non-emergency procedure), often in poorly equiped, overcrowded hospitals.

The growing demand for private health plans reflects dissatisfaction with the public health service, the main problem being the lengthy waiting periods that patients have to endure to schedule specialist consultations and tests.

The present crisis in the Brazilian healthcare system results from a mismatch between an epidemiological situation where chronic diseases are predominant, and a healthcare system largely concerned with responding to acute conditions.

The treatment of chronic conditions differs substantially from the treatment of acute health problems. Health systems the world over, including Brazil, are failing to respond adequately to the decline in acute health episodes and the significant rise in the need for treating chronic conditions.

It follows that there is an urgent need for health services to address chronic conditions on the same level as acute cases. This can be done by employing technologies designed to respond to exacerbated chronic conditions (often self-observed by patients) especially in outpatient clinics or hospital emergency units. In short, the health services need to adjust their approach to monitoring and dealing with chronic conditions that threaten to develop into acute cases.

As well as upgrading organizational structures to provide care for acute and chronic conditions, healthcare systems must also deliver continuous and comprehensive care to specific segments of the population. Brazil is a large and geographically diverse country with a sizable segment of the population living in small towns and villages, many of them remote from large urban conurbations. A major problem is the distance that people in need of care have to travel between the smaller population centers and the healthcare institutions that are largely concentrated in the large cities and coastal areas.

Around 44% of the country´s population is located outside the major centers and relies on government financial support channelled to often financially weak local authorities. A further problem is that many of the more remote localities are also home to the majority of the low-income population, which tends to be affected by chronic diseases caused by bad diet, sedentary lifestyle, and typical poverty-related factors.

The expansion of the mobile health resource could significantly contribute to improving basic care, reducing hospital trips and intensive use of medical drugs – saving public funds and, above all, improving the quality of life and life expectancy of the Brazilian people

The high connectivity of the population, the continental size of Brazil, the fact that around 40% of the population inhabit areas that are distant from large urban centers and belong to low-income groups susceptible to chronic diseases, show that expanding the mobile health resource could contribute significantly to improving basic care, reducing hospital trips and intensive use of medical drugs, and save public money spent on healthcare.

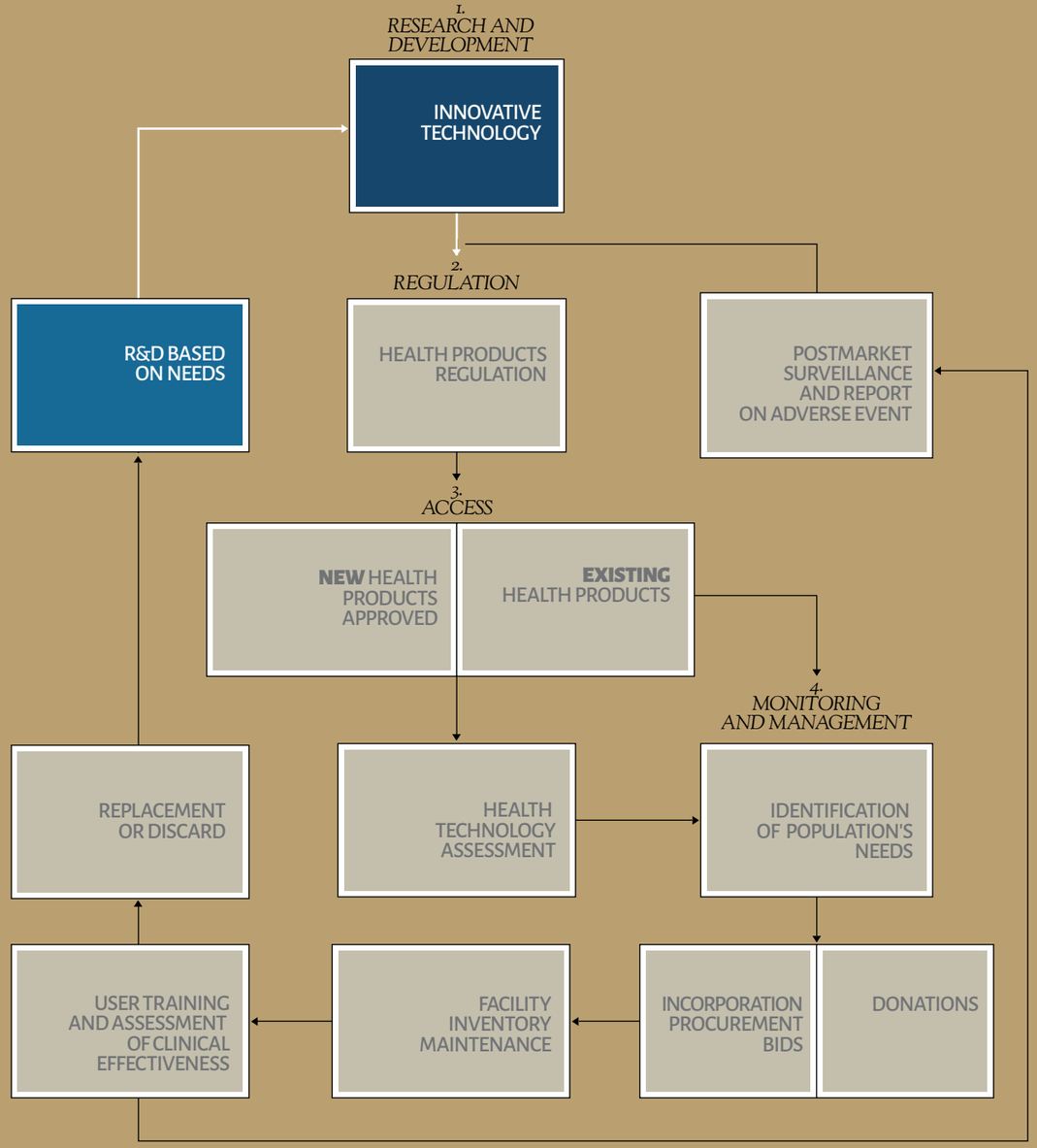
Brazilians are now connected by smartphone even in areas of difficult access. Opportunities exist therefore to resolve some of the current healthcare bottlenecks by encouraging healthcare staff and the population in such areas to adopt the new health technologies already increasingly used in developed countries.

Promoting the use of this mobile health resource could significantly contribute to improving basic care, reducing hospital trips and intensive use of medical drugs - saving public funds and, above all, improving the quality and life expectancy of the Brazilian people.

RESEARCH AND DEVELOPMENT IN THE MEDTECH SECTOR IN BRAZIL

FIGURE A

HEALTH PRODUCT LIFE CYCLE



CHAPTER 3

3.1 Global MedTech R&D: growing innovation and trends in the digital age

Innovation and R&D is part of the MedTech industry´s DNA.

Leading MedTech companies typically allocate between 9 and 10% of their annual revenues to R&D compared with other industrial sectors (between 3 and 4%).

Developed countries lead the field with 97% spending on MedTech R&D[1].

The bulk of the funds is directed to improving existing products that last for about two years, instead of introducing new technologies.

Good information flow between the industry and product users is essential for ensuring development of new products. In the new Health Economy, using digital means to promote healthcare is not only useful but vital.

In the digital age, industry and health professionals share their views and begin working as a team.

Innovation in medical technology has for long been concentrated on the United States. It is now expanding beyond US borders. Innovators in developing countries have begun researching clinical data, registering new products and profiting from products sold to the new markets.

The nature of innovation has changed: developing countries have become a very important market, demanding smaller, faster and more accessible healthcare products that can be accessed at low cost anywhere.

1 Torsekar (2014), p. 5.

The innovation process requires certain preconditions. A PwC survey periodically measures the potential and capacity for MedTech innovation in the nine countries with the highest prospects for market growth. This analytical survey contains 86 indicators that rate five topics of importance to innovation in the countries concerned:

2 PwC (2011).

1.Value-based and systemically-guided incentives: This topic concerns awareness of the type and level of the funds available for the sector to innovate, such as the amount the government spends, or is prepared to spend, on health technology, the quantities and value of private sales, and the possibilities of MedTech companies being reimbursed or otherwise covered for their investments in new technologies in the health system. Given the increasing availablity of mobile healthcare devices, Brazil now has the opportunity to develop low cost initiatives based on better collaboration between payers, suppliers and the medical technology industry for developing and delivering patient-centered care and appropriate health solutions. An evaluation is done, under this topic, to assess whether the country's information technology architecture is capable of disseminating healthcare elements throughout the healthcare system and evaluating the results.

2.Global networks of academic centers in the field of medicine: This topic examines the resources available for innovation and the prospects for establishing partnership agreements and synergies among research centers, (while avoiding research overlaps), the quality and quantity of patents per capita and the availability of scholarships and other research funds.

3.Favorable regulatory system: Scores referring to the national standards required by the regulatory agency related to the safety and effectiveness of medical technologies and the time required for bringing the product to market are essential for speeding the life cycle of the product (Figure A)[3].

4.Payer and consumer attitudes to sharing the costs of the system: This item assesses whether the conduct of private and public sector healthcare payers encourages or discourages innovation. Consideration is also given to demands for new prevention-related products, therapies, services and devices that require the population to take greater responsibility for its own health.

5.Global financial connections: An evaluation of the country's integration with the venture capital community to gauge the prospects of venture capitalists supporting innovation.

3 FIGURE A - Cycle of MedTech products. Please refer to page4 of this chapter.

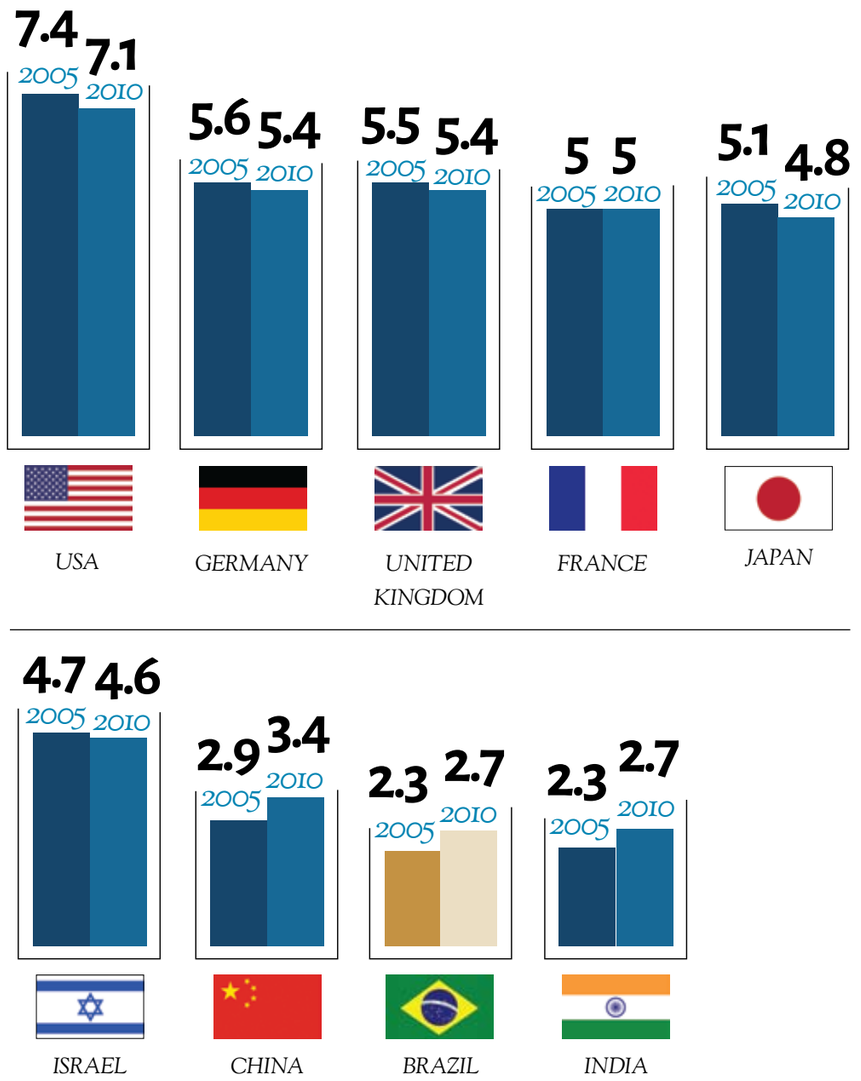
With this methodology it is possible to identify the vulnerable areas affecting innovation in different countries and to work up policies to enhance the conditions for improved value creation in the health products area.

The survey reveals that Brazil, India and China will experience major changes in the next ten years. Meanwhile, China is reportedly showing the greatest progress in health services innovation capacity.

The innovation ratings for 2005 and 2020 for the nine countries analyzed are shown in Chart 3.1.

CHART 3.1

MAIN GLOBAL PLAYERS: INNOVATION SCORECARD FOR HEALTHCARE PRODUCTS (2005 AND 2010)



Source: PwC, Innovation Scorecard 2011.

3.2 MedTech Innovation in Brazil

Chart 3.1 shows that Brazil scores poorly in the MedTech innovation environment. The PwC annual survey suggests that Brazil is lagging behind in all the aspects surveyed

Financial incentives for innovation are lacking (government purchases, taxes, refunds and consumer purchasing power).

The scientific community and companies are not short of good ideas but are discouraged by the lack of cooperation between the various players - which is likely to cause serious delays in bringing products to market.

Human capital dedicated to MedTech research is insufficient and poorly paid, and innovation is discouraged due to the difficulties encountered by researchers to place their inventions in the market.

IT systems are not integrated in the healthcare network. Access to unidentified clinical data is highly bureaucratic and discourages innovation.

Brazil´s score, compared with certain other countries, can be seen at Table 3.1. The regulatory system discourages innovation with excessive requirements and long delays to regulate innovations, resulting in increased costs.

The conduct of the payers and the difficulties for companies and others to obtain reimbursement due from the adoption and utilization of medical technology does not favor innovation.

Little cooperation between the MedTech industry and the venture capital investment community.

Lack of new health products marketing and distribution technologies[4].

Brazil´s score compared with certain other countries can be seen at Table 3.1.

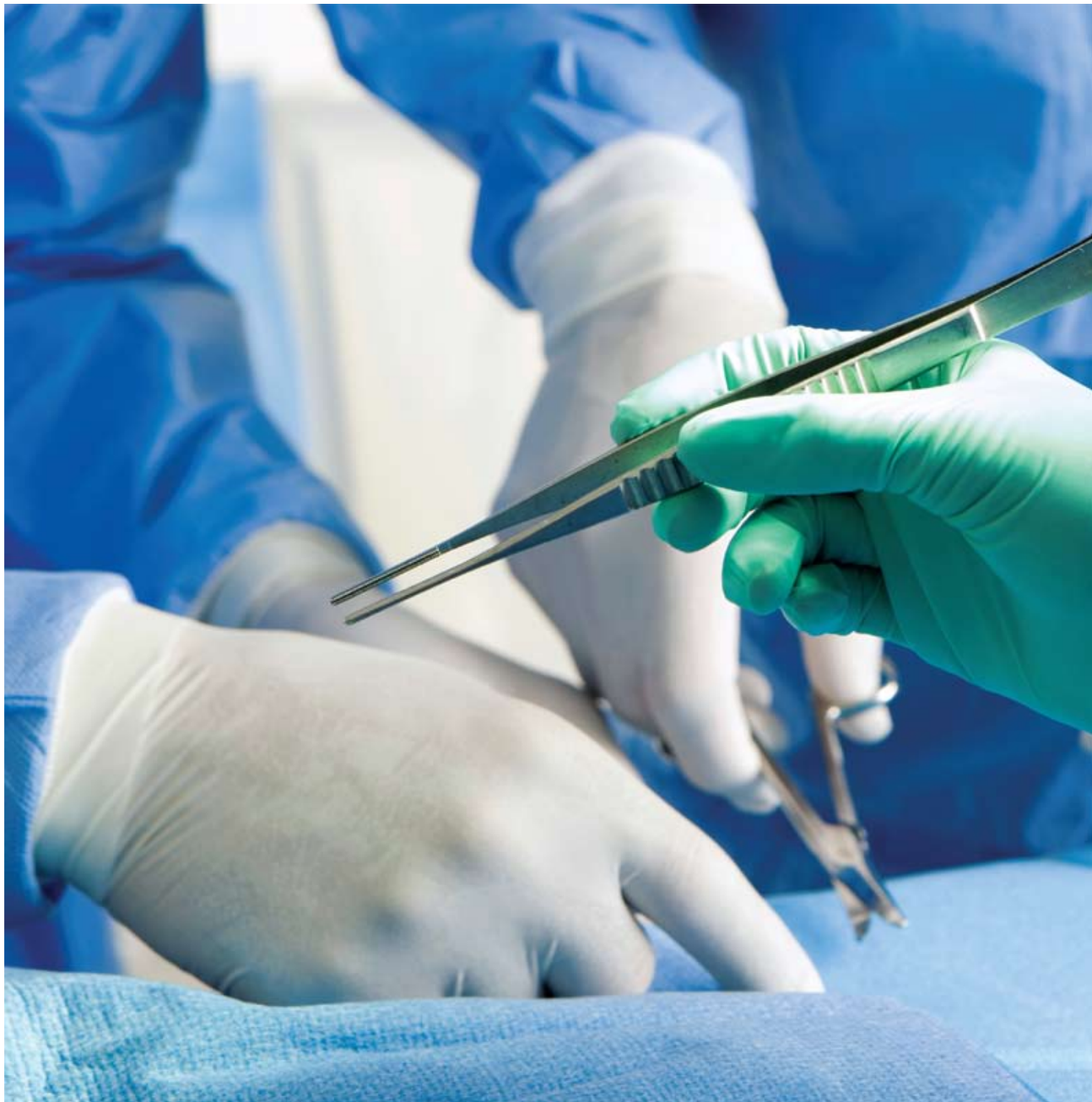
4. In the PwC study, the assessment of the availability of new marketing and distribution technologies of health products is a sub-item of item 1 "Value-based and systemically oriented incentives", but it was deliberately highlighted on Table 3.1 in this study due to its particular relevance in the context of Health 4.0.

TABLE 3.1

CURRENT INNOVATION ENVIRONMENT FOR MEDICAL PRODUCTS IN BRAZIL

Score	2.7	3.4	5.4	2.7	4.8	7.1
Financial incentives to innovation (government purchase, taxes, refunds and consumer purchasing power)	2.1	4.2	4.3	3.0	3.0	7.2
Human capital and integration of the IT system to promote innovation	2.4	2.8	5.4	2.2	6.0	7.3
Regulatory support system (costs, demands and time required by regulator)	3.5	4.9	7.2	4.5	5.8	6.8
Conduct of payers and sensitivity to prices (public and private expenditure on health, ease of reimbursement)	3.1	2.4	5.8	1.8	5.7	7.1
Existence of venture capital investment community	2.4	2.9	4.4	2.2	3.6	7.2
New marketing and distribution technologies for health products	1.9	2.7	5.3	1.4	3.2	8.5

Source: PwC 2014 adapted by Websetorial



STRENGTHENING R&D IN THE MEDTECH SECTOR IN BRAZIL

01

WHAT

TO ADOPT METHODS FOR EVALUATING HEALTH TECHNOLOGIES IN LINE WITH GOVERNMENT FUNDING EFFORTS AND S&T POLICIES

WHY

This will be the best way to bolster existing resources and to focus them on satisfying the main demands of the health system. At the same time this would boost R&D of products and technologies in line with national policies and health programs.

HOW

By involving CONITEC and *Complexo Industrial da Saúde*-CIS (Health Industrial Complex) (CIS) representatives, and other government representatives responsible for developing health and science and technology policies, in discussions related to health technologies evaluation methods. These discussions could take the form of academic study groups in the health economics area and in other forums aimed at aligning and coordinating the programs of different stakeholders.

STAKEHOLDERS:
DEGITS/CONITEC/MS,SCTIE/MS,SAS/MS, SVS/MS. MCT, Complexo Industrial da Saúde [Health Industrial Complex (CIS)], ANVISA.

02

WHAT

TO EXPAND AND IMPROVE COMMUNICATION TO ENABLE HEALTH MANAGERS TO DISCUSS THEIR REQUIREMENTS WITH PRODUCTION SECTOR ASSOCIATION REPRESENTATIVES.

WHY

To boost R&D linked to real needs, thus avoiding wasting effort and resources on products that will not be incorporated into the system in the short and medium term.

HOW

By using existing structures such as the *Complexo Industrial da Saúde* (Industrial Health Complex) (CIS) to explore joint opportunities for new projects in terms of new requirements and funding sources.

By encouraging companies and other producers and R&D practitioners in the public and private sectors to agree on joint and reciprocal requirements after identifying the interests of all the parties concerned.

STAKEHOLDERS:
SCTIE / MS, CONITEC / MS, ANS, ANVISA, MCT, ABIIS, CIS.

03

WHAT

TO DEVELOP CHANNELS BETWEEN GOVERNMENT AND INDUSTRY TO EXPLORE TECHNOLOGICAL TRENDS OF INTEREST TO THE SYSTEM ("TECHNOLOGICAL HORIZON").

WHY

Permanent need for updating technological trends to meet the requirements of the health system and produce beneficial outcomes in terms of access to products by the population and overall improvements in the system.

HOW

By promoting regular seminars on the "Technological Horizon" and providing opportunities for discussing this theme in the CIS meetings.

STAKEHOLDERS:
SCTIE/MS, MCT, ISPOR, Medical Societies, ABIIS, CIS and medical faculties.

04

WHAT

TO MAINTAIN AND INCREASE COMMUNICATION BETWEEN THE GOVERNMENT AND PRIVATE SECTOR IN SUPPORT OF INNOVATION-RELATED INDUSTRY POLICIES

TO IDENTIFY PROMISING PRODUCT LINES FOR PRODUCTION IN BRAZIL, WITHIN PROSPECTIVE TECHNOLOGICAL TRENDS OF INTEREST TO THE HEALTH SYSTEM.

WHY

To develop and produce higher value added products in Brazil that reflect the regional and local needs of the health system.

HOW

By government clearly informing the industry of its requirements so that new products can be developed accordingly.

Through incentives such as government financed purchases and guaranteed access.

STAKEHOLDERS:
Ministry of Health, ABDI, BNDES, FINEP and industry companies with local plant and R&D centers.

05

WHAT

DEVELOP AND EXPAND FINANCIAL INCENTIVES TO INNOVATION.

PROMOTE COLLABORATION BETWEEN THE MEDTECH INSUSTRY AND VENTURE CAPITAL INVESTMENT COMMUNITY

WHY

To seek alternative ways of fostering innovation, establishing sustainable systems that are not exclusively dependent on public support.

Public calls for tender involve complex procedures, and researchers are discouraged from seeking access to public funds .

HOW

By developing ways to support researchers to assess the market potential of innovations and to provide financial information for the researcher that can attract potential investors. Furthermore, to advise the researcher on the types of agreements that can mutually benefit investors and researchers.

By establishing cooperation mechanisms between government, industry and funding sources by organizing professional events, MedTech fairs and business roundtables.

By creating and expanding new funds by attracting public and private donations to fund the R&D of new medical devices and processes.

By funding small businesses and "start-ups" with resources from these funds.

By supporting the creation of partnerships between researcher start-ups and private firms able to provide finance and identify tax incentives, develop skills, etc. to achieve common commercial objectives.

STAKEHOLDERS:
MS, MCT, ABIIS, Accelera/FIESP, banks and venture capital funds

06

WHAT

EXPAND THE NUMBER AND QUALITY OF HUMAN RESOURCES WORKING ON MEDTECH R&D AND ENHANCE COOPERATIOIN BETWEEN THE GOVERNMENT, THE INDUSTRY AND THE ACADEMIC COMMUNITY.

WHY

The supply of human capital in medical technology R&D in Brazil is insufficient and there are few incentives to innovate.

HOW

By investing in HR training in MedTech industry related areas.

By encouraging researchers to stay in Brazil by offering competitive salaries.

By promoting the *"Programa ciências sem fronteiras"* (Science Without Borders Program) to benefit MedTech companies and R&D .

By encouraging exchanges between technology companies and universities with a view to developing training programs of interest to the MedTech sector.

By awards to scholars willing to cooperate with the MedTech industry.

STAKEHOLDERS:
MCT, MS, Academia, CAPES, Ministry of Education.

07

WHAT

INTRODUCE NEW TECHNOLOGIES, ENCOURAGE INNOVATION AIMED AT BETTER PATIENT CARE

CONTINUALLY IMPROVE MECHANISMS TO ENSURE THAT NEW TECHNOLOGIES ARE ASSERTIVELY ACKNOWLEDGED AS SOON AS THEY COME TO MARKET (HEALTH TECHNOLOGIES ASSESSMENT - HTA)

WHY

Rapid introduction of innovative technologies affords early diagnosis followed by increasingly effective and appropriate therapies to meet patients´ needs, thereby reducing the burden on the health system at ever-decreasing cost due to the dynamic and competitive MedTech environment.

HOW

Through objective Health Technology Assessment processes (HTA) focused on medical devices (rather than drugs), supported by knowledge of best global practices including those of stakeholders such as medical societies and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR).

STAKEHOLDERS:
CONITEC/MS, ANS, ANVISA and health insurance companies.

08

WHAT

CONTINUALLY IMPROVE THE MODELS FOR HEALTHCARE-RELATED DECISION MAKING. ASSESSMENT CRITERIA: ANALYSIS USING MULTIPLE CRITERIA; SCIENTIFIC LITERATURE REVIEWS, USE OF REAL-LIFE DATA, HEALTH ECONOMICS, ASSESSMENTS OF QUALITY OF LIFE AND BUDGET IMPACTS.

WHY

Despite the existence of guidelines Brazil still lacks a consensus on how to assess health products.

HOW

By creating study groups and signing accords with academic practitioners in the health economics area.

STAKEHOLDERS:
CONITEC/MS, ANS, Medical Societies, ISPOR, health insurance companies, universities with Health Technology Assessment Centers (NATS).

09

WHAT

TO PROMOTE DIGITAL HEALTH INCLUSION IN BRAZIL

WHY

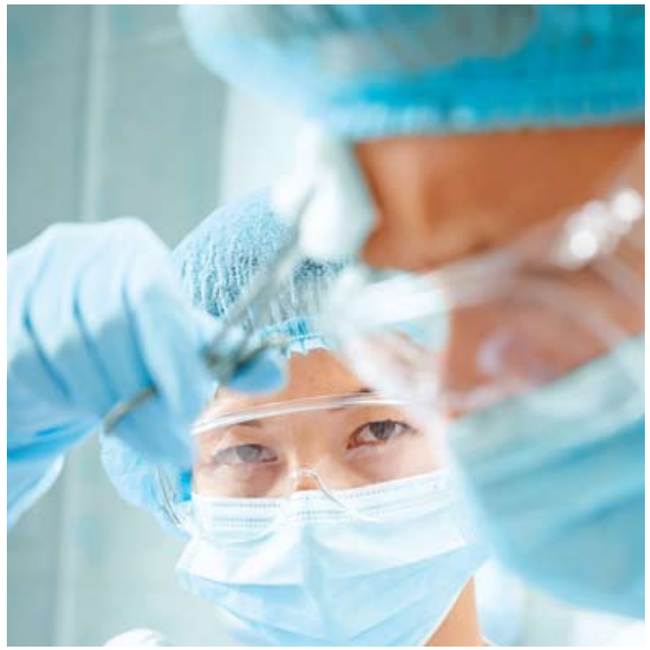
The incorporation of a health technology system is essential for promoting innovation in the sector. However, Brazil's health network is not ready to absorb international trends. It does not possess the minimum infrastructure to incorporate the flow of information to benefit either the MedTech industry or the users of the products. Good information infrastructure is essential for enabling the MedTech industry and health professionals to work together as a team to achieve common goals.

HOW

By improving the information technology infrastructure of the entire public health system and fostering similar initiatives in the private health sector.

By encouraging the development of technologies for remote diagnosis to improve the primary health care clinics´ resolutive capacities and facilitate home treatment for patients.

By developing methods to preserve the confidentiality of patient data, reducing bureaucratic barriers to access of information regarding diagnosis, and monitoring these procedures and results.



With the advent of innovation in the health sector it is essential to monitor the results of procedures in order to constantly improve existing technologies.

By encouraging the development of *"Telehealth"* service providers, including remote monitoring to assist prevention and home treatment.

By disseminating and implementing in the public network the *"IT Guidelines for Private Hospitals"* (ANAHP2015)[6], which outlines best information technology practices for the hospital sector. These practices, if followed, will be of substantial interest to healthcare institutions given that they recommend ways of achieving more effective clinical governance through the improvement of IT in Brazilian hospitals and contain valuable information for bringing "digital hospitals" into operation.

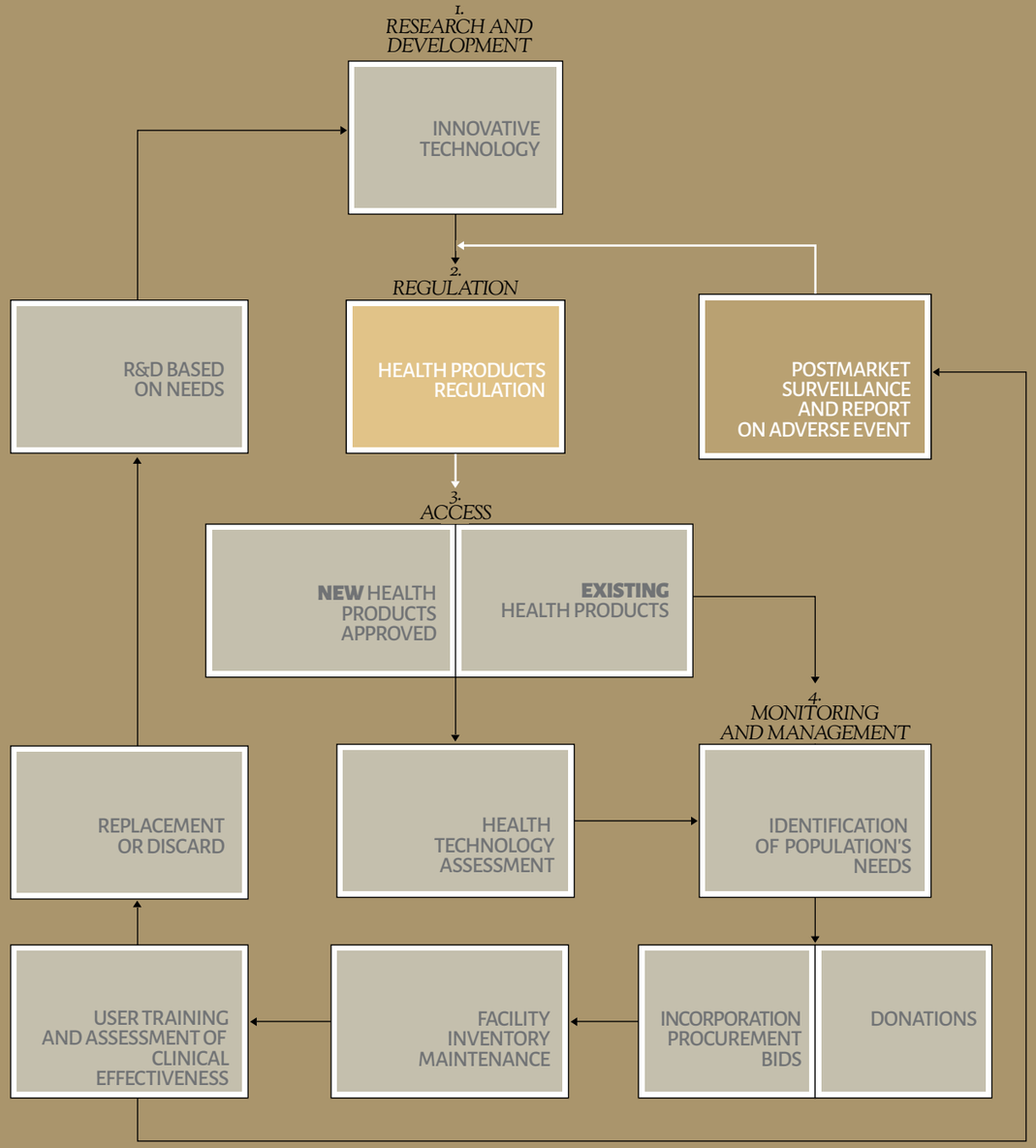
STAKEHOLDERS:
MCT, MS, FENASAÚDE, CND, ANAHP, Santa Casa Hospitals, State and Municipal hospitals, including the Primary Healthcare Network, National Congress.

6 ANAHP (2015)

REGISTRATION AND REGULATION OF MEDTECHs IN BRAZIL

FIGURE A

HEALTH PRODUCT LIFE CYCLE



CHAPTER 4

4.1 Registration procedures globally and in Brazil

Every medical device must be duly listed, notified or registered by a government agency belonging to or linked to the Ministry of Health in the country where the product is sold. This official body is responsible for analyzing the product to ensure that it meets efficacy and safety requirements.

The Food and Drug Administration (FDA) is responsible for registering products in the United States, while the European Commission (EC) is the equivalent body in Europe. In Brazil the responsible agency is the Agência Nacional de Vigilância Sanitária-ANVISA (Brazilian Health Surveillance Agency).

To facilitate identification and regulation, products are rated according to use or risk.

ANVISA, in addition to undertaking health surveillance activities prescribed by Law 9.782/99, is responsible inter alia for regulating the production and importation of medical products and technologies. ANVISA's task is to:

Authorize companies to manufacture, distribute and import certain products of a type specified in current legislation;

Authorize the import and export of the products prescribed in the legislation.

Grant product listing in accordance with the norms of the appropriate area of expertise.

Award or cancel a product's *Certificado de Cumprimento de Boas Práticas de Fabricação - CCBPF* (Certificate of Compliance with Good Manufacturing Practices).

Require institutions, products and services that are subject to health surveillance according to the risk classification to be registered or certified by the National System of Metrology, Standardization and Industrial Quality (SINMETRO).

Close down, on health grounds, any premises engaged in the importation, storage, distribution and sale of products or provision of health-related services in the event of an imminent health risk or violation of applicable legislation.

On health risk or law violation grounds, to ban the manufacture, importation, storage, distribution and marketing of inputs and products.

On health risk or law violation grounds, to cancel companies' operating licenses, including special authorizations [1].

Coordinate and undertake quality control of certain goods and products specified by law, employing analytical methods prescribed in health legislation, or conducting special health quality monitoring programs.

Foster human resources training for the health system and promote technical and scientific cooperation nationally and internationally.

1. For drugs classified as psychotropic and narcotic.

Apply the summonses and penalties prescribed by law.

Monitor the prices of medicines, equipment, components, inputs and healthcare services.

The requirements for MedTech registration are described in Table 4.1.

TABLE 4.1

REQUIREMENTS FOR REGISTERING MEDTECHs

Company regularization	ANVISA –To obtain a Company Operating Permit in accordance with the requirements of RDC No. 16 of 1 April 2014.
	Local ANVISA (Municipality or State) – To obtain Company Operating License
	Compliance with Good Manufacturing Practices (GMP) in accordance with RDC No. 16 of 28 March 2013.
	Alternatively, international manufacturers can name a regularized firm to represent its interests in Brazil.
Compulsory certification of equipment subject to health surveillance requirements	Certain items of electro-medical equipment must carry the INMETRO Conformity Certificate or a consolidated test report as prescribed in RDC No.27 of 11 June 2011. This must be done at the time of applying to ANVISA for registration or product listing.
	The list of technical norms to which companies need to conform in orderto obtain the compliance certification under the Brazilian System of Conformity Evaluation, can be found in Normative Instruction No. 11 of 16 December, 2014.
	For more information see www.inmetro.gov.br.
Certificate of good practice for medical and in vitro diagnostic products	Manufacturers of medical and in vitro diagnosis products must comply with the Good Manufacturing Practice requirements described in RDC No. 16 of 28 March 2013.
	Products classified in risk categories III and IV must have a Good Manufacturing Practice Certificate (CBPF) in order to obtain registration.
	ANVISA does not inspect plants that manufacture products rated in Risk Classes I and II, and does not issue a CBPF in these cases.
	See the ANVISA website (*Produtos para Saúde Inspeções Internacionais*) for English-language versions of the relevant laws, and other information.

Product Classification	Risk classification of medical products is according to rules prescribed in RDC No. 185 of 22 October 2001; risk rating for in vitro products is in accordance with RDC No. of 18 November 2011.
	Access http://www.anvisa.gov.br/datavisa/NomesTecnicosGGTPS/Consulta_inVitro.asp?K=1) to check the risk rating of in vitro diagnosis products against technical names.
Product listing	Medical and in vitro diagnosis products that present lower health risks are subject to a simplified health surveillance control procedure ("product listing").
	See the ANVISA website for details, especially RDC 36/2015 and RDC 40/2015
Registration	The requirements needed for registering medical and in vitro diagnosis products can be found in the following resolutions (or updated versions):
	For medical products: RDC No. 185 of 22 October 2001 and RDC No. 56 of 6 April 2001.
	For in vitro diagnosis products: RDC No. 36 of 26 August 2015.
Clinical research	For specific medical products, a clinical research presentation may be requested as described in RDC No. 10 of 20 February 2015.

To facilitate identification and regulation, products are classified according to their use or level of risk.

Health product classification: due to the wide range and complexity of health products, the regulatory agencies that approve and regulate them prior to them entering the market, and to facilitate their identification and regulation, classify the products according to use or level of risk.

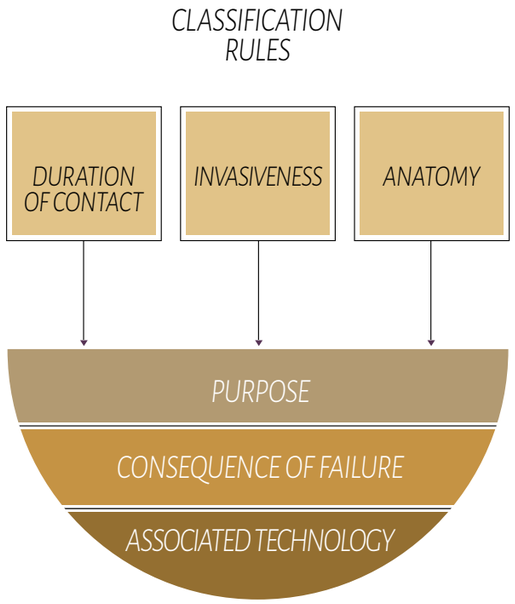
RDC No. 185 (2001), issued by ANVISA, classifies health products using the criteria shown at Figure 4.1.

Globally and in Brazil, the level of the requirements demanded for obtaining product registration from an agency increases in proportion to the potential risk presented by the product.

ANVISA RDC No.185/01 defines four risk classes, with Class I being the lowest risk and Class IV the highest

FIGURE 4.1

MEDTECH CLASSIFICATION CRITERIA



Source: Guidelines for the registration of materials for health use: ABDI, p.48,2011.

4.2 Difficulties of registration in Brazil

"Regulation is effective when consumers receive maximum benefit from the regulated market." [2] According to the International survey conducted with 1400 interviewees in 2014 by EMERGO[3], Brazil, the United States, China and Japan are considered difficult markets for registering medical devices (43%, 45% 56% and 44% respectively). The widespread perception is that levels of difficulty have increased over the years in Brazil, China and the United States

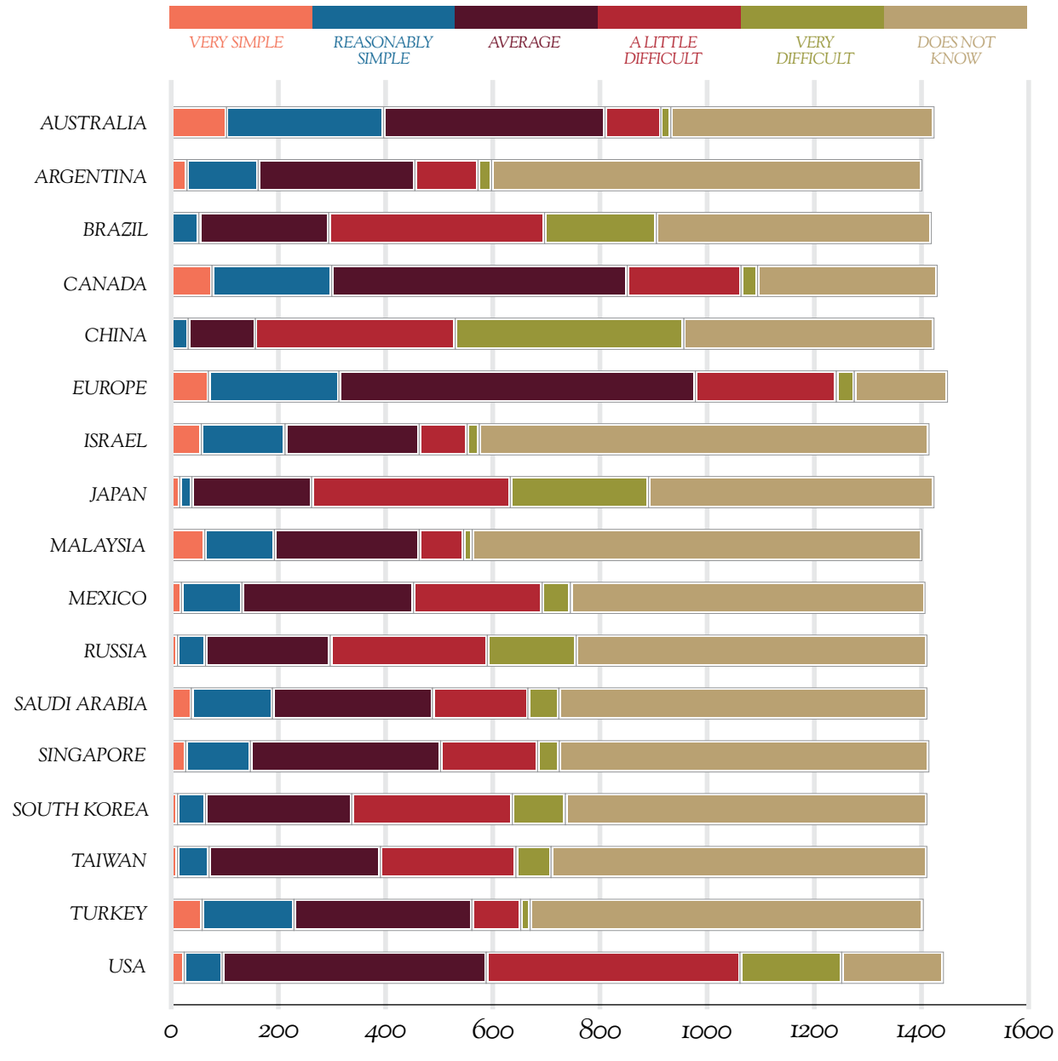
2 Barros and Martinez-Giralt (2012).
3 Emergo (2014).

The EMERGO survey also sought views about the level of difficulty in registering a low or medium risk product in various markets (see the responses in Chart 4.1.).

This international comparison chart indicates that registering a medical device in Brazil is fairly difficult when compared to other countries.

CHART 4.1

INTERNATIONAL COMPARISON OF THE LEVEL OF DIFFICULTY TO REGISTER A LOW OR MEDIUM RISK MEDICAL TECHNOLOGY PRODUCT (2014)

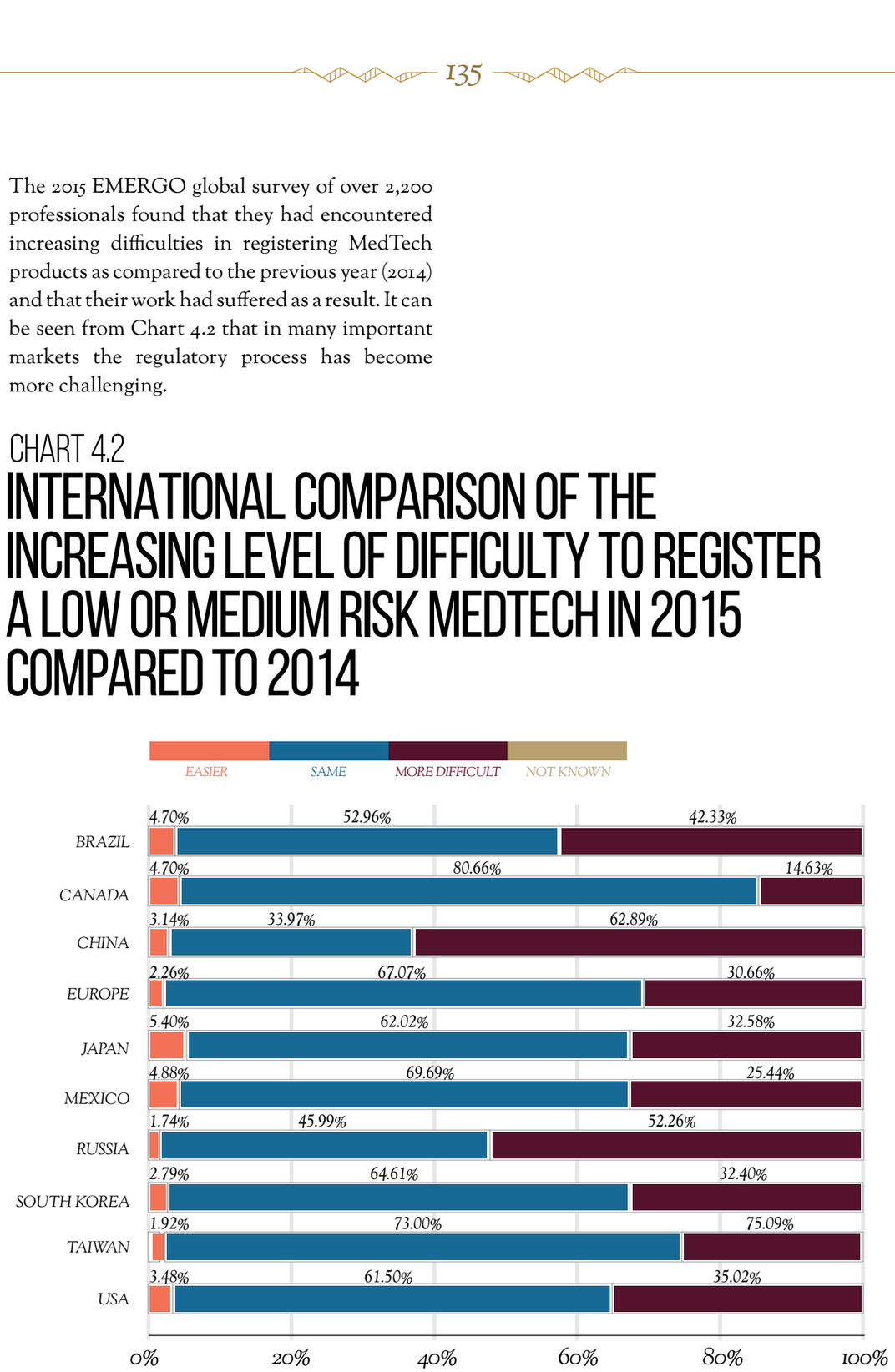


Source: EMERGO (2014).

The 2015 EMERGO global survey of over 2,200 professionals found that they had encountered increasing difficulties in registering MedTech products as compared to the previous year (2014) and that their work had suffered as a result. It can be seen from Chart 4.2 that in many important markets the regulatory process has become more challenging.

CHART 4.2

INTERNATIONAL COMPARISON OF THE INCREASING LEVEL OF DIFFICULTY TO REGISTER A LOW OR MEDIUM RISK MEDTECH IN 2015 COMPARED TO 2014



Source: EMERGO (20015).

42% of the professionals in Brazil interviewed in the EMERGO survey stated that their work was often hampered by long delays in the registration process incurred by ANVISA's failure to approve and register MedTech products in a timely manner. Substantial delays can be expected especially when ANVISA insists on carrying out its GMP (Good Manufacturing Practices) audits.

In their efforts to comply with regulatory standards, MedTech companies are also negatively affected by the lack of communication and understanding among the government's own agents, such as between ANVISA inspectors in ports and airports, National Health Surveillance System (SNVS) practitioners and the personnel of the state and municipal health surveillance agencies.

(...) MedTech companies are negatively affected by the lack of communication and understanding among the government's own agents (...)

Table 4.2, based on data published in the Official Gazette shows the average times, according to ANVISA, that the Agency takes to register a MedTech product.

The average times were based on at least four applications submitted in the different areas (materials, equipment etc.)

TABLE 4.2

AVERAGE TIME FOR REGISTERING A MEDTECH IN ANVISA

AREA	OBJECT	AVERAGE TIME
MATERIALS	Product Listing	01 - 03 months
	Registration	02 - 06 months
	Registration (implants)	06 - 10 months
	Alteration	02 - 04 months
	Renewal of Product Listing	06 - 10 months
	Renewal of Registration	06 - 10 months
EQUIPMENT	Product Listing	03 - 07 months
	Registration	03 - 06 months
	Alteration	04 - 06 months
	Renewal of Product Listing	04 - 08 months
	Renewal of Registration	04 - 08 months
IVD	Product Listing	01 - 03 months
	Registration	01 - 03 months
	Alteration	02 - 04 months
	Renewal of Product Listing	03 - 06 months
	Renewal of Registration	03 - 06 months

Source: EMERGO (2015), based on the last three ANVISA supplements published in the Official Gazette, according to a survey conducted on 06/10/15.

PROPOSALS TO IMPROVE THE REGULATION AND REGISTRATION OF MEDTECHs IN BRAZIL

The following chapters outline seven proposals for improving registration and regulationprocedures for MedTech products in Brazil

01

WHAT

INTELLIGENT REGULATION NEEDED TO OPTIMIZE PROCEDURES FOR SETTING UP MEDTECH COMPANIES IN BRAZIL - FROM OBTAINING A LICENSE TO REDUCING TIME TO MARKET.

WHY?

At present any company wishing to enter the medical devices market in Brazil needs to request a Sanitary License issued by the state or municipal health surveillance authorities, a Company Operating License issued by ANVISA, a CCBPF Good Manufacturing Practices and Control Certificate (for Class III and IV products), and formal product registration.

Brazil is receiving increased attention internationally and needs to be competitive in the health products export area in order to consolidate its presence in the global market. ANVISA rules are not fully aligned with international legislation in the areas of inspection and registration. In particular, the agency lacks an appropriate structure to undertake timely inspections prior to the award of Good Manufacturing and Control Practices certification. This failing needs to be urgently addressed.

Bringing legislation into line with global practices would enhance Brazil's trading relations with the rest of the world and lead to more investment by foreign companies in the domestic healthcare industry.

A speedier approach to international inspectionsand more timely approval of applications forproduct registration would pave the way to quickeraccess by the Brazilian population to newhealthcare technologies.

HOW

All the applications could be submitted simultaneously to the different authorities.

By “regulatory convergence” i.e. aligning ANVISA legislation related to health products registration and product listing with international legislation.

STAKEHOLDERS:
The entire National Health Surveillance System under the aegis of the ANVISA Joint Board of Directors

02

WHAT

TO IMPROVE THE MODUS OPERANDI OF THE REGULATORY AGENCY BY RATIONALIZING AND SPEEDING THE REGISTRATION PROCESS WHILE ALSO TAKING INTO CONSIDERATION THE FIELDWORK MANAGEMENT UNDERTAKEN BY COMPANIES.

WHY?

Excessive technical requirements and delays in registration procedures impact heavily on a company´s operating costs. This can discourage investments and dynamic new technologies from entering the country.

Rationalizing procedures and strengthening post-registration inspection (techno-surveillance) would be of substantial benefit to MedTech companies and users.

HOW

In the case of new companies, by linking the registration procedure with the Company Operating Permit (AFE), and making the granting of registration conditional on the award of the AFE. Another approach would be for ANVISA to accept documents and information provided by regulatory agencies from other countries in the spirit of “regulatory convergence”, and carry out post-market monitoring.

STAKEHOLDERS:
ANVISA and the entire National Health Surveillance System (SNVS), hospitals and other public and private health services, healthcare professionals, logisticians, companies and consumers.

03

WHAT

TO IMPROVE THE MODUS OPERANDI OF THE REGULATORY AGENCY BY COMPUTERIZING HEALTH SURVEILLANCE PROCEDURES.

WHY?

Improving the work processes of ANVISA will afford greater flexibility to the system, benefiting the regulatory agency, the productive sector and consumers alike.

HOW

Increased use of electronic tools in the agency's work processes.

STAKEHOLDER:
SNVS.

04

WHAT

TO IMPROVE THE MODUS OPERANDI OF THE REGULATORY AGENCY BY PROMOTING THE EXCHANGE OF KNOWLEDGE ON MEDTECHS BETWEEN THE REGULATOR AND THE REGULATED COMPANIES, AND TO ADOPT GREATER TRANSPARENCY OF REGULATORY PROCEDURES

WHY?

The regulator needs to remain updated on technological and therapeutic innovations given that innovation in the health products environment is highly dynamic and increasingly tailored to meet specific therapeutic requirements.

Given that the plethora of RDC Resolutions, Normative Instructions and Technical Notes leads to devices being changed, modified or discarded, the analysis, regulation and registration of innovations is a complex task for both the regulatory agency and the regulated company.

HOW

Visits to factories and R&D centers and keeping abreast of medical procedures performed with MedTech tools must form part of the training of regulatory agency personnel. This would facilitate understanding by the regulator of the technology involved and provide invaluable insights into the difficulties encountered by companies to register their products.

The exchange of knowledge between the regulator and the regulated company through seminars and training courses is essential for developing effective regulations designed to benefit and protect users.

Cooperation between the regulator and the regulated company will lead to better understanding of the relevant technologies and will assist the regulatory agency to strengthen its regulations, which in turn should lead to the submission of clearer and more complete registration applications by companies, thereby facilitating the regulator's evaluation procedures.

By revising and consolidating RDCs, Normative Instructions and applicable Technical Notes.

STAKEHOLDERS:
SUALI, Health Products Technology General Management Office (GGTPS), the Competitive Brazil Movement (MBC) and ABIIS.

05

WHAT

TO IMPROVE THE MODUS OPERANDI OF THE REGULATORY AGENCY, INCLUDING TO CONVINCE ANVISA TO MAINTAIN THE MAXIMUM TERM OF 90 DAYS FOR THE REGULATOR TO DELIBERATE ON PRODUCT LISTING/ REGISTRATION PROCEDURES IN ACCORDANCE WITH PARAGRAPH 3, ARTICLE 12, OF LAW NO. 6.360/1976.

WHY?

While the queue for applications to be analyzed shows that ANVISA is complying with the 90-day deadline for initial analysis of product listing/ registration applications, any action taken to improve the regulator's modus operandi could contribute to its retaining this deadline in the medium and long-term.

HOW

By reviewing the rules in order to simplify theprocedure for analyzing low-risk products, as proposed by Public Consultations 23 and 24 held in 2014.

By creating a norm to regulate procedures for altering the registrations according to the degree of health risk involved.

STAKEHOLDERS:
Regulation Board, SUALI, GGTPS and GGINP.

06

WHAT

INSTITUTIONAL UPGRADING OF THE REGULATORY AGENCIES TO ENSURE PRIORITY IS GIVEN TO ANALYZING THE REGULATORY IMPACT OF THE NEW NORMS IN A TRANSPARENT MANNER, WITH THE PARTICIPATION OF THE STAKEHOLDERS

WHY?

Certain regulations, frequently issued with no analysis carried out of the impact on the regulated sector, can risk these rules not being applied and even lead to shortages of the technology in the market.

HOW

By promoting the exchange of knowledge between the regulator and the regulated company on technologies or market practices prior to preparation of a new regulation.

By setting up committees and/or technical groups comprising the various stakeholders in order to analyze the impacts of a future regulation.

STAKEHOLDERS:
ANVISA, the regulated sector and the community.

07

WHAT

INSTITUTIONAL UPGRADING OF THE REGULATORY AGENCIES: SUPPORT PROVIDED BY THE MEDTECH INDUSTRY TO EXPANDING THE PROFESSIONAL PERSONNEL AND STRENGTHENING ITS INFRASTRUCTURE.

WHY?

Given the complexity of ANVISA's work and the substantial amount of products and services regulated by the agency, there is a need for the staff to be expanded and trained on an ongoing and permanent basis.

HOW

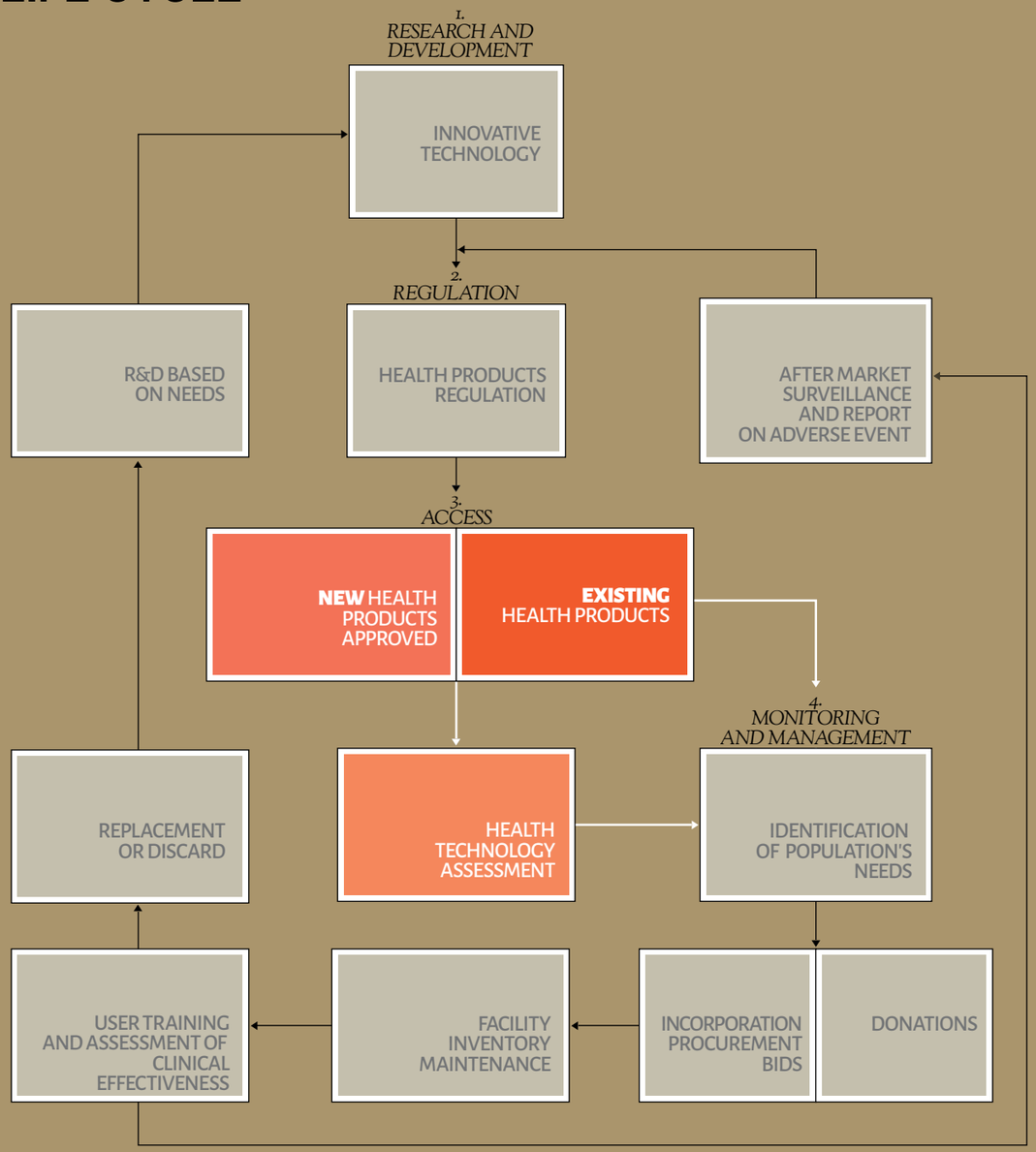
By working with the National Congress and public authorities to convince them of the need regularly to increase ANVISA staff, attracting qualified professionals through public competition. Staff members of the regulatory agency must be trained and retrained periodically and exposed to market realities through visits to MedTech plants, R&D centers, hospitals, clinics and laboratories within the framework of the MBC project.

STAKEHOLDERS:
Ministries of Planning and Health, Presidential Chief of Staff Office, the National Congress and MBC.

ACCESS TO NEW MEDTECH DEVICES AND DISTRIBUTING THEM TO BRAZIL'S POPULATION

FIGURE A

HEALTH PRODUCT LIFE CYCLE



CHAPTER 5

5.1 Introduction

Access by the population to MedTechs[1] depends on an objective assessment of the individual and/or collective benefits that can be obtained from their appropriate incorporation into medical protocols, as well as of the easy availability to patients of the public and private health systems. Access by the population also depends on evaluating two inherently valuable factors when indicating use of the technology: its absolute value (risk-benefit relationship that favors its use) and its relative value (likelihood of producing a benefit better than existing alternatives).

The goal to provide access to the best technologies in Brazil, either traditional or innovative, depends on the health scenario as a whole, taking into consideration the value of such technologies not only to the health system but also to the community as a whole. This goal also considers the more widespread effects over time: broadening the scope and use of medical technology in the country resulting in price reductions for successful technologies and pointing towards successive improvements of products and processes in the medical sciences environment, and especially their impacts on the population's health in general arising from fewer medical complications and lower costs.

1 As previously explained in this study, the definition of a Medical Device in its Broad Sense (MedTech) includes materials, equipment, orthesis, prosthesis, in vitro diagnosis, and applications for mobile health, either implantable or not.

5.1.1 Incorporation, modification, and exclusion of products and procedures in the health systems in Brazil and globally.

Producers and consumers have legitimate interests in adopting technological innovations of value to health, but more widespread use of these innovations is constrained by the limited public and private resources available. Even after the absolute value of a particular technology has been proven it is vital for the health authorities to decide whether its adoption is economically and technically feasible and whether it could have a negative impact on access to other technologies of equal or higher importance. The possibility exists of gradually and initially adopting a technology by focusing it on certain patient groups likely to gain most demonstrable benefits or on specific healthcare facilities whose location and operational capacity hold out the prospect of satisfactory cost-benefits from use of the technology.

The prospective introduction of new products and procedures can also provide a useful opportunity to evaluate the value of technologies in current use and to decide (objectively and supported by approprate facts and figures) whether to maintain or discontinue them if they are assessed to be obsolescent. Continuing to use obsolete technologies in the healthcare area can only lead to a quantitative expansion of the supply of such products and procedures with no qualitative benefits. This approach inevitably causes problems for both health managers and medical practitioners.

Preferably, the conditions mentioned in the previous paragraph must be demonstrated in an objective manner supported by facts and numbers.

5.1.2 Evaluating clinical conclusions prior to adopting a new technology

Throughout the phase of decision to adopt the new technology, the clinical efficacy of products must be evaluated on three levels: diagnostic results, therapeutic results, and health results[2]. This process aims at responding to questions made in the list below.

- Does the technology perform reliably and does it produce accurate information?
- Does the technology contribute to an accurate diagnosis?
- Does it replace or supplement other technologies?
- Do the findings obtained with this technology influence the selection of a treatment?
- Does it contribute to improve the patient's health?
- Does the technology improve cost-effectiveness[3] of care when compared to alternative interventions?

5.1.3 Special approaches to evaluating health products

The methods used to evaluate medical technologies and medical procedures were adapted from practices used to evaluate medicines. However, there are methodology issues, product particularities, and medical procedures that require greater attention during an evaluation[4]. These particularities are presented in Table 5.1.

2 ISPOR (2014), pg. 141. See also Chapter 6 in this document, in the part that discusses the MONITORING AND MANAGEMENT of health products.
3 Cost-Effectiveness Analysis: This is a type of economic evaluation that compares different health interventions whose costs are expressed in monetary units, while the effectiveness is expressed in clinic-epidemiological units (mortality, morbidity, hospitalization, adverse events, etc.).
4 AxiaBio (2014), p. 27.

TABLE 5.1 PART 1

TYPICAL CHARACTERISTICS OF HEALTH PRODUCTS

PARTICULARITY	DESCRIPTION
Learning Curve	Defined as the learning by repeatedly practising the procedure over time. The way to carry out the procedure is fully absorbed by health professionals, leading to improved and more efficient and effective execution. The time needed to learn how to carry out a procedure depends on the complexity of the product and its use: greater complexity requires the procedure to be frequently repeated to facilitate learning. The learning curve can significantly impact the costs of bringing a product to market.
Linked Procedures	The procedure may or may not be described in the tables of the Brazilian Public Health Service (SUS) or in the Procedures Lists of the Brazilian National Supplementary Health Agency (ANS). For a new health product to be incorporated in the SUS, the Department of anagement and Incorporation of Health Technologies (DGITS) requires a description of the procedure that already exists in the Brazilian National List of Health Actions and Services (RENASES) to be entered on the request form. The products may or may not be explicitly described using the terminology used to describe the procedure. In the event that the health product fails to fit an existing procedure, the request for product evaluation will involve a new procedure. If the adoption of a new product in the SUS significantly weighs on the cost of already existing procedures in RENASES, the reimbursement values may need to be revised.
Infrastructure and peripherals	Medical devices of an active, implantable, or invasive type often require peripherals such as specific instruments, equipment, physical space and/or special operating conditions (e.g. air conditioning, radiation shielding, etc.). Such infrastructural and peripheral items affect the cost of the technology and its expected effectiveness. During the evaluation process these extra items must be considered to determine whether they will be exclusive to a product or shared withother procedures, as well as the total cost of ownership (see below).

TABLE 5.1 PART 2

TYPICAL CHARACTERISTICS OF HEALTH PRODUCTS

PARTICULARITY	DESCRIPTION
Embedded technology	This item refers mainly to computer and electronic items that enable the equipment to perform different functions,and facilitate connectivity to other equipment and the external environment.
	The price of items of equipment with specific hardware may vary according to the selection of embedded technologies given that such technologies can endow the same base equipment with different capacities.
	Diagnostic imaging equipment (IMR, tomographs, ultrasound, etc.) usually contain embedded technology in their software.
	Embedded technology may be present in both high and medium complexity products.
	When alternatives exist in the selection of embedded technology it is necessary to compare the medical needs with other options to check whether their characteristics meet the expectations from a cost-benefit and cost-effectiveness standpoint. Each functionality and application of the products is assessed separately and their relevance and costs impacts analyzed.
	The costs of embedded technologies must be taken into consideration when evaluating the sums due to be reimbursed.
Total cost of ownership	If the equipment is of a permanent nature with a long life cycle, it is vital to evaluate total ownership cost to assist the decision-making process.
	This process involves estimating the direct and indirect costs of keeping the equipment operational, and provides a basis for assessing cost-effectiveness.
	Total ownership cost is equal to the sum of the following: Acquisition, Operation, Maintenance, Training, and Replacement.
	Total ownership cost is also calculated as life cycle cost of the equipment.
	This cost must also consider the possibility of sharing the same equipment with various other procedures and ends. Usage volume and potential quiet periods are also to be considered.

Source: AxiaBio (2014), adapted from CONITEC, "Avaliação de produtos para a saúde no Brasil, na ótica do Ministério da Saúde" (Evaluation of health products in Brazil from the standpoint of the Ministry of Health).

5.2 Decision-making process for incorporating new health technologies in the SUS

CONITEC (National Commission for the Incorporation of Technologies in the SUS), is a government agency responsible for the technical and economic evaluation of any technology used in the healthcare field (products, processes, equipment etc.). According to the regulatory norms[5] of this Commission, any physical or legal person can submit a technology to CONITEC or request its exclusion or modification.

The rigorous evaluation process involves scientific data to be submitted that attest to the efficacy, safety, and economic feasibility of a product or procedure compared to the SUS current standard of treatment. The analyses consider the different phases of evolution of a disease.

Analyses by renowned international agencies (NICE/UK, CADTH/Canada, etc.) are important references for CONITEC, but approval of a product, etc. by these foreign agencies does not imply automatic acceptance by the Commission.

CONITEC also evaluates the budgetary impact of approved applications by assessing possible cost increases or decreases to be borne by the SUS over a five-year period.

The same Commission performs analyses and submits its findings to the Ministry of Health (MS), which may or may not ratify them. If the Commission's opinion favors inclusion of the product in the SUS it is forwarded to a Ministry of Health Secretariat for subsequent deployment. CONITEC is responsible for presenting its opinion within a maximum of 180 days (extendable 90 days if necessary). In the event of a favorable opinion the Ministry of Health requires a further 180 days (extendable 90 days) to publish a clinical protocol establishing a new procedure covering the proposed modification.

5 Law no. 12.401 of October 2011.

CONITEC competences

Responsible for issuing reports on incorporation, exclusion or alteration of the health technologies within the context of the SUS[5].

Modify or elaborate a Clinical Protocol and Therapeutic Directive (PCDT).

Update the Brazilian National List of Essential Medicines (RENAME).

CONITEC may request the support of other organs of the Ministry of Health and contract and implement research, budget impact studies, and technical cooperation agreements.

The Commission consists of an Executive-Secretariat and a Plenary, responsible for issuing the conclusions and reports to be used in decision making by the Ministry of Health. The Plenary comprises 13 members, representatives of several authorities, and health-related agencies.[6]

5.2.1 Documentation

Requests for the evaluation of health technologies must mandatorily present the information listed below. The form must be completed in accordance with the model established by CONITEC.[7]

Number and expiry date of the health technology registration with ANVISA.

Scientific evidence to demonstrate that the suggested technology is at least as efficient and safe as those available in the SUS for any given purpose.

Economic evaluation study comparing the proposed technology to the health technologies available in the SUS.

Product samples as necessary.

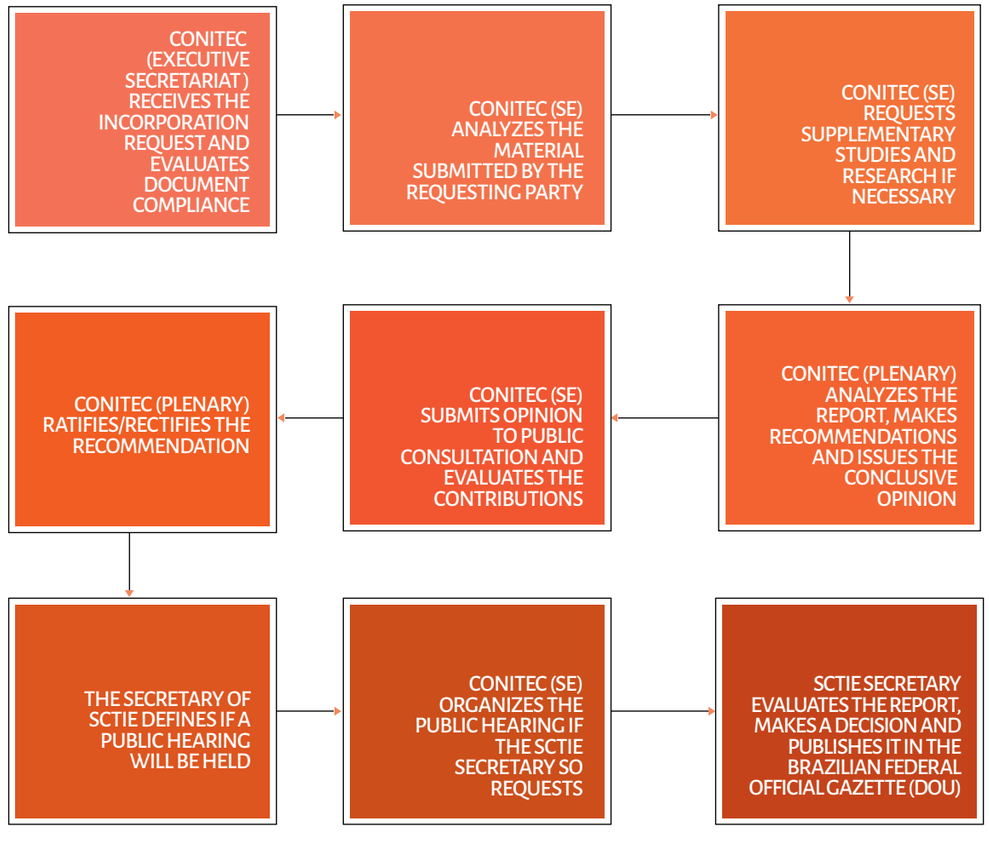
Price fixed by the CMED in the case of medicines.

All submitted documents undergo a prior check by the CONITEC Executive Secretariat, and any application that fails to provide all the information requested is rejected as non-compliant. Figure 5.1 shows the official application flow established by CONITEC.[8]

5 Law 12.401 of October 2011.
6 Secretariat of Science, Technology, and Strategic Inputs of the Ministry of Health, Executive Secretariat of the Ministry of Health – SCTIE, Special Secretariat for Indian Health, Secretariat of Health Attention – SAS, Secretariat of Health Surveillance - SVS, Secretariat of Management, Secretariat of Strategic and Participative Management, Secretariat of Labor Management and Health Education, National Agency of Supplemental Health – ANS, ANVISA, National Health Council – CNS, National Council of Health Secretaries – CONVASS, National Council of Municipal Health Secretariats – CONASEMS, Federal Board of Medicine – CFM.
7 The forms for the submission of proposals for the incorporation of medical technologies are available at CONITEC's website.
8 CONITEC Available at the URL: (http://conitec.gov.br/index. php/fluxo-de-incorporacao-detecnologias-no-sus).

FIGURE 5.1

CONITEC – TECHNOLOGY INCORPORATION FLOWCHART



Adapted from CONITEC –Flow of Technology incorporation SUS

The Table 5.2 summarizes CONITEC functions.

TABLE 5.2
SUMMARIZES CONITEC FUNCTIONS

CONITEC functions	To advise the Ministry of Health on the incorporation, modification, or exclusion of new health technologies in the SUS, including medicines, products, and procedures, as well as the development and revision of PCDTs.
Deadlines for submission of evaluations	There are no fixed periods for submission. Proposals can be submitted at any time of the year.
Confidentiality and conflict of interests	All parties must sign a term of confidentiality and a declaration stating the absence of conflicts of interests related to the subjects discussed within the CONITEC.
Request Processing	Full completion of the required form and obligation to submit the exact technical and economic documents required for evaluation.
Required documents	▪ Number and expiration date of the ANVISA registration and, in the case of medicines, the price registered with CMED's Medicines Market Regulation Chamber. ▪ Scientific evidence to demonstrate that the proposal has at least the same efficacy and safety as those already available in the SUS for the proposed purpose. ▪ Economic evaluation studies comparing the proposal with the treatment currently available in the SUS , to include budget impacts.
Rejection	If the mandatory requirements are incomplete or incorrect ,the request may be rejected without evaluation of merit, but without prejudice to a new submission containing complete documentation being made by the party.
Public Consultation	The public consultation is mandatory before the Commission issues a final recommendation.
Public Hearing	The Secretary of Science, Technology and Strategic Inputs Secretariat - SCTIE may request a public hearing if considered necessary.
Deadline for the analysis of processes and issue of a recommendation	The maximum deadline for evaluation is 180 days from the date the request is registered, with a possible extension of 90 days.
Deadline for incorporation by the SUS	Within a maximum period of 180 days from the date of publication of the decision to incorporate the proposal.
Appeal or reconsideration	According to the Law of Administrative Proceedings (Law No. 9.784 of 29 January 1999).

Source: AxiaBio (2014). Adapted from: Brazilian Ministry of Health, "O que muda da CITEC para a CONITEC" (What changes from CITEC to CONITEC), (http://conitec.gov.br/index.php/mudancaS'da-citec-para'a-conitec)[9].

9 Published: Tuesday, 01 July and 30 July, 2014, 12:02 p.m.
Last updated on Wednesday, July 30, 2014, 11:39 a.m.

5.2.2 Submission of scientific evidence

The Ministry of Health and CONITEC are responsible for the incorporation, exclusion, or modification of new products, medicines, and procedures by the SUS, as well as the modification or constitution of Clinical Protocols and Therapeutic Directives - PCDTs.[10] The CONITEC report must cover the following:[11]

- Scientific evidence of improvement, safety, efficacy, and effectiveness of the health technology (medicine, procedure, or product) under evaluation.
- Economic evaluation of costs and benefits compared to the technologies currently used in the SUS.
- Evaluation initiated by administrative procedure to be completed within 180 days, extendable if necessary to 90 days.
- Public consultation and hearing before making the decision.

Criteria for incorporating medical technologies into the health systems

In view of the variety of health technologies, CONITEC has a range of application forms covering different technologies related to medicines, healthcare products and procedures.

See the CONITEC website for detailed information on submission forms and procedures. In due course ABIIS intends to carry out specific studies on these procedures. An overview of the criteria for the incorporation of MedTechs follows.

10 The PCDTs are documents usually elaborated by the Ministry of Health and, at times, by State Secretariats of Health. They are intended to clearly establish the diagnostic criteria, the treatment algorithm, the mechanisms for clinical monitoring and supervision of potential adverse effects related to specific clinical conditions that may require special attention from the public health authorities.
11 Law no. 12.401 of April 28, 2011.

5.2.3. Sustaining the SUS and meeting the needs of the population.

In addition to collecting scientific evidence for evaluating new technology, CONITEC is responsible for examining aspects that could affect the sustainability of the healthcare system and the population's needs.

The process of incorporation of technology into the SUS is subject to the following criteria:[12]

- Rigorous search of published and unpublished studies.
- Critical evaluation of the best clinically-relevant evidence available.
- Consideration of the health needs of the population and health policy priorities.
- Researching the market and selecting buyers (therapeutic options).
- Evaluation of the logistics and structure needed to deploy the new technology.
- Evaluation of the cost-effectiveness study submitted by the applicant (new study to be presented if requested).
- Budget impacts.
- Evaluation of sustainability: local production or transfer of technology.

CONITEC criteria emphasize that priority must be given to technologies that present relevant clinical data and results, that add value by reducing procedures and hospitalizations and boosting productivity, while improving patients' quality of life and life expectancy. The technologies approved are expected to provide good value to Brazilian citizens in return for the cost of impementing the new technologies across the entire public health system.

CONITEC recommendations frequently reflect these criteria. Meanwhile, both CONITEC and the SUS have become increasingly focused on improving the quality and presentation of the data used in the evaluation process.

12 AxiaBio (2014), extracted from Silva (2014).

5.3 Healthcare coverage in the Supplementary Health System[13]

The Supplementary Health System, managed by private companies and regulated by the National Supplementary Health Agency, serves 50 million people in Brazil.

In compliance with Law No. 9.656/98 regulating the supplementary health system, the ANS formulated (and regularly updates) a list of items requiring minimum mandatory coverage that all health insurance operators must provide to their "health plan" holders. This is officially known as the List of Health Procedures and Events.

The first List was established by Supplementary Health Council (CONSU) Resolution No. 10/98 and subsequently updated: in 2001 by the Joint Board of Directors (RDC) Resolution 67/2001, and in 2004, 2008, 2010, and 2013, by Normative Resolutions 82, 167, 211, 262, and 338.[14]

The "List" review process is undertaken by a technical group consisting of representatives from health insurance companies, medical associations (i.e. health professionals), consumer protection bodies and the ANS.

This group prepares a proposal that is later dispatched for public consultation. Interested parties can participate by accessing the ANS website.

The 2013/2014 list was revised in accordance with the following guidelines:[15]

- To include technologies that present evidence of safety, efficacy, and effectiveness.
- To evaluate technologies already approved by the Brazilian Medical Association (AMB) and incorporated in the Brazilian Hierarchized Classification of Medical Procedures (CBHPM).
- To evaluate technologies approved by the Ministry of Health and recommended for incorporation by CONITEC.

13 The matter related to the reimbursement by the public and supplementary systems will be the object of Section 6.4 of the next chapter.
14 Extracted from AxiaBio (2014).
15 Extracted from AxiaBio (2014), based on ANS (2013)

To exclude obsolete procedures, procedures with no clinical evidence of safety, or demonstrating poor quality evidence-based scientific methodology.

To avoid including technologies rejected by CONITEC and those not incorporated in the CBHPM

To include Usage Guidelines (DUT) and Clinical Guidelines (DC) for the incorporated procedures, with a view to upgrading health care logistics.

Revise and update DUTs and DCs

Evaluate the economic impact of the technologies selected for inclusion in the List.

Evaluate the geographic distribution of the technologies selected for inclusion in the List.

Discuss proposals with the technical group responsible for revising the List, before and after public consultation.

Undertake public consultation to enable community participation in discussions related to the List .

Evaluation must consider ethical and social criteria.

Ensure alignment with the policies of the Ministry of Health.

Compare any new technology to other technologies being used currently for the same purposes.

Retain or change the names of procedures to conform to those currently used in the Brazilian Hierarchized Classification of Medical Procedures (CBHPM).

Prepare the Usage Guidelines (DUT) and prioritize the technologies to be evaluated jointly with the Brazilian Medical Association (AMB), specialized medical societies and health area professional councils.

Evaluate only ANVISA-registered health technologies.

The criteria used to prioritize the proposals to be evaluated by the technical group of revision of the List 2013/2014 were developed as a consequence of these directives. Table 5.3 presents the list of established criteria.

CRITERIA USED FOR PRIORITIZING HEALTH TECHNOLOGIES IN THE SUPPLEMENTARY HEALTH SYSTEM

1	*Evaluation and approval by the National Commission for the Evaluation of Health Technologies (CONITEC)*
2	*Existence of epidemiological data related to the pathologies prevented/treated with the use of the technology (incidence, prevalence, lethality, mortality, morbidity, etc.)*
3	*Existence of updated statuses on the economic impact of the technology (cost-effectiveness), preferably using national data*
4	*Inexistence of other technologies already incorporated to perform the same function.*
5	*Existence of specialized professionals to use/handle the health technology*
6	*Existence of the necessary inputs and raw materials to use the health technology*
7	*Existence of a network of service providers in place, with evidences*
8	*Existence of effective results in clinical endpoints*

Source: AxiaBio (2014), adapted from the ANS.

The complete documentation on the revision processes of the List can be accessed directly on the ANS website[16], in the 'chambers and technical groups' section. The technical group formed to revise the List 2013/2014 comprised several entities and groups from the health sector.[17]

The decision on the revision of the List begins with the procedures to be analyzed, and the work group formed to revise the 2013/2014 List used the selection criteria outlined below:[18]

Compliance with the prioritization criteria (Table 5.3).

Selection of procedures evaluated by the work group: public consultation via the website, requests from the ANS inspection system, and AMB list of procedures contained in the Brazilian Hierarchized Classification of Medical Procedures (CBHPM) that are absent form the List.

16 National Supplemental Health Agency (ANS). Available at the URL: (http://www.ans.gov.br).
17 National Supplemental Health Agency (ANS). General Management of Assistance Regulation (GGRAS), Executive Board of Standards and Product Licenses (DIPRO). Technical Note no. 838/2013. Revision of the List of Health Procedures and Events 2013/2014.
18 Minutes of the 6th meeting on the List, of 18 November 2014.

5.4 Evaluation of the technology incorporation process in Brazil

5.4.1 Evaluation of health products analyses and of the procedures for including products in the SUS reimbursement list.

From 2012 to 2014 the procedures for incorporating technologies in the SUS underwent certain changes. In late 2014 CONITEC published its "*CONITEC Balance for 2012-2014*"[19] describing the results of its first year of operation.

This document stated that: "since its creation CONITEC has received more than 350 proposals for the evaluation of health technologies, mainly medicines. Half of the proposals were submitted by external applicants (manufacturers, medical associations, Judicial Power entities and patient associations, etc.). The remainder were submitted by the Ministry of Health, aimed at generating new health policies or updating existing programs".

19 Ministry of Health (2014).

Most requests for the evaluation of procedures were submitted by government agencies

The following health products were some of the main incorporations under the aegis of CONITEC.

PET-CT[20]

Diagnostic tests for rare diseases (and the establishment of the national policy of attention to rare diseases).

Pulse oximetry/newborn heart test.

Food supplement to implement the NUTRISUS strategy.

Nucleic acids amplification test (NAT).

GeneXpert MTB/RIF test[21]

Pharmacological Stent.

Proposals submitted for evaluation (and outcomes) can be viewed on the CONITEC website.

Up to 31 December 2014, 373 proposals had been submitted to CONITEC. 16% related to medical devices, 20% to procedures, 63% to medicines, and 1% to protocol revisions (See Table 5.4).[22] While a large number of MedTech products have been incorporated during the last three

20 The positron emission tomography, or PET, is a diagnostic imaging technology that enables the mapping of different chemical substances in the organism.
21 This is a nucleic acids amplification test used to detect the M. tuberculosis complex.
22 Extracted from Axia.bio (2014), Table 16.

TABLE 5.4

NUMBER OF REQUESTS FOR THE INCLUSION OF NEW HEALTH PRODUCTS AND PROCEDURES IN THE SUS AND RESULTS OBTAINED[17]

Products + Procedures	MANUFACTURER/ DISTRIBUTOR	GOVERNMENT	HOSPITAL	JUDICIARY	MEDICAL SOCIETY	TOTAL
Total	32	87	5	2	9	135
Incorporation to the SUS	—	60	—	—	1	61
Rejected for non-compliant documentation	18	1	3	—	6	28
Under analysis	1	10	—	1	—	12
Not incorporated into the SUS	5	4	1	1	1	12
Under analysis after public consultation	1	5	—	—	—	6
Closed at applicant's request	—	6	—	—	—	6
Not within CONITEC's scope	6	—	—	—	—	6
Under compliance analysis	1	—	1	—	—	2
Already incorporated into the SUS	—	—	—	—	1	1
Excluded from the SUS	—	1	—	—	—	1

Source: AxiaBio (2014), based on CONITEC Balance.

While a large number of MedTech products have been incorporated during the last three years, the majority of the proposals originated from the Ministry of Health. Many MedTechs are commonly-used, low price, low-complexity products with no formal proof of efficacy and safety, and which quite probably would not need to be subjected to an HTA process, e.g. walking frame, wheelchair or a simple stretcher. On the other hand, most of the proposals submitted by manufacturers, distributors and community entities were rejected because they failed to comply with the required documentation.[17]

5.4.2 Evidences of the access to the products in Brazil, based on international parameters

Length of time required for access in Brazil compared with international practice

Slow approval of MedTechs can delay access by the population to new technology devices and lead to lives being lost.

In the United States, Europe and Brazil, three criteria are considered: the level of complexity or disruption caused by the device; the timeframe of the Health Technologies Evaluation (HTE) process; and the time needed from the time of launching the technology in the national market up to the moment that patients are able to regularly access the technology unhindered by problems of reimbursement or limited procurement by the health services.

Genuine patient access depends on two factors: willingness to pay upfront for the technology if it is an isolated item, or paying an appropriate sum for a procedure containing a particular technology so that the healthcare services provider can use the procedure without incurring a financial loss.

Effective patient access depends on reimbursement by the public or private health systems

In countries with public and private health systems that have different modus operandi, the public system generally takes longer to absorb innovations compared to private sector institutions. The latter can absorb technology more quickly for a variety of reasons ranging from technical and economic circumstances to marketing aspects. User perception regarding the quality of a product or procedure often depends on whether the device/procedure offered by healthcare practitioners appears to be up-to-date and technologically advanced.

The adoption of innovative technologies does not necessarily ensure that they will be successfully incorporated in a health system. Products can fail to be adopted even after favorable technical evaluation if suitable professionals cannot be found and trained to use the new technology, or due to competition from other companies supplying similar technologies.

The more innovative and technologically cutting-edge a product appears to be (especially if linked to some form of risk) the greater will be the requirements for the supplier to produce clear evidence of its risk- and cost-benefits. This is a key consideration at the heart of most discussions about the relative efficacy of product approval processes in different countries. On the other hand, more conservative, lower-risk devices can get access to the market within shorter timeframes (Brazil is similar to the United States and Europe in this respect).

In the United States[23], a patient's access to a MedTech begins with the submission of a request to the FDA. Over the last five years the average time for the incorporation of new products was between 13 and 21 months, of which 8.4 months were taken up with FDA analysis, 4.7 months for comments, and the remaining 8.6 months for the validation or proof of clinical benefits. The United States public health system automatically reimburses the cost of most devices after approval by the FDA. On the other hand, although concrete data is difficult to obtain on the time lags incurred by United States private health operators to make decisions on coverage, available data suggests that final decisions are made a few weeks or months after approval by the FDA, depending on the quantity and quality of the evidence of clinical benefits.

European Union countries first require MedTechs to obtain a certificate of European Conformity (CE). According to some manufacturers this process can take from one to three months. While CE certification may be granted on the basis of clinical data, occasionally less strict than those required by the FDA, European reimbursement rules are often similar to or more rigid than those imposed by the FDA for approval of devices. European countries may require additional data regarding the safety, clinical efficacy and cost-benefit status of the devices.

In the United States, a patient's access to a MedTech begins with the submission of a request to the FDA. Evaluation time ranges from 13 to 21 months.

23 Basu and Hassenplug (2012).

In France, the Agence Nationale de Sécurité Sanitaire de l'Alimentation, de l'Environnement et du Travail (ANSES) makes reimbursement decisions after evaluating the efficacy and safety of individual devices. In Italy, reimbursement decisions are the responsibility of different regional authorities. Meanwhile, the UK and Germany conduct broader evaluations of actual types of devices or procedures rather than focusing on individual devices. Estimated average times taken in Europe on reimbursement: 71.3 months in Germany, 36-48 months in France, 16.4 -26.3 months in Italy, and around 18 months in the UK.

In Brazil, unlike in the United States, the regulatory approval of a technological device does not automatically ensure coverage by the public health system. After registration and approval by ANVISA (Table 4.2 of Chapter 4) the public health system requires an agent to request a CONITEC evaluation of the device before a decision is taken to incorporate it or not in the SUS.

This procedure can be initiated at any time during the life cycle of a product, with CONITEC having 180 days (extendable by 90 days) to issue an opinion approving or rejecting incorporation. After CONITEC's final opinion is presented, the Secretary of Science, Technology and Strategic Inputs of the Ministry of Health must ratify the approval (if given) and advise the relevant MH divisions to prepare usage guidelines and protocols within 180 days (extendable by 90 days).

In Brazil, the estimated timeframe is 24 months. However, when the manufacturing plant is not certified in accordance with RDC nº 16/2013, the time required to obtain the registration is indeterminate.

The minimum period for a technology to be available for SUS uses is 21 months - from the beginning to the end of the regulatory process (average of 9 months), through the CONITEC evaluation (6 months), up to the issuance of usage guidelines (6 months).

The average time taken by ANVISA to approve a device for sale on the market is 24 months. This period may be shorter for products in Risk Classes III and IV, with manufacturing plants already certified under RDC 16/2013 (Technical Regulation of Good Manufacturing Practices of Medical Products and Products for In Vitro Diagnosis). If factories lack certification the approval time cannot be determined. Approval can also be delayed by the fact that certain medical products and equipments need to be obligatorily certified by INMETRO prior to submission to the ANVISA registration process.

International comparison of access to MedTechs in terms of per capita expenditure.

Brazil has the largest market in Latin America, but spending on this type of technology remains low: in 2013, around US$53 per capita for all the products considered by ABIIS as falling within the MedTech category; and US$ 34.21 per capita when in vitro diagnosis and laboratory equipment were excluded. The international consultancy ESPICON, which excludes in vitro diagnosis and laboratory equipment from its international comparative statistics, found that in 2013 the equivalent annual per capita figures were US$ 49 in Chile and US$ 225 in France in annual values per capita.[24] (Table 5.5).

Spending on MedTechs (strict sense) represented only a small portion of Brazil's overall expenditure on health compared with other countries analyzed in the CHPI study (2014) which indicated that the devices were less available to the population of Brazil (in relation to the country's GDP) than in Austria, Canada, Mexico and virtually all the OECD countries. (Table 5.5)

24 Source: CHPI (2014)

TABLE 5.5

PER CAPITA EXPENDITURE ON MEDTECHs AND % SHARE OF TOTAL HEALTH SPENDING IN BRAZIL AND SELECTED COUNTRIES, 2013

COUNTRY	Expenditure per capita on Medtechs (in current US$)	Share of total costs of health expenditure per capita (in %)
Switzerland	396	4.79
USA	399	4.31
Norway	333	3.80
Denmark	301	4.55
Germany	314	6.49
Austria	299	5.52
Sweden	272	4.83
France	233	4.60
Japan	235	6.13
Netherlands	230	3.90
Australia	207	3.44
Canada	208	3.51
United Kingdom	257	4.41
Italy	149	4.42
New Zealand	173	4.38
Israel	141	5.30

COUNTRY	Expenditure per capita on Medtechs (in current US$)	Share of total costs of health expenditure per capita (in %)
Spain	107	3.80
South Korea	105	5.73
Portugal	88	4.29
Singapore	81	3.09
Russia	52	5.73
Chile	42	3.32
Mexico	34	4.76
Brazil	**34,21**	**2.35**
South Africa	24	3.88
Colombia	24	5.02
Argentina	17	1.81
China	13	3.29
Peru	11	3.04
Cuba	8	1.21
India	3	4.84

Source: Websetorial and CHPI (2014), based on Espicon data. The study does not take into account spending on in vitro diagnosis or laboratory equipment. The table refers to medical devices in the restricted sense.

Given that expenditure on MedTechs in Brazil is relatively small in terms of total health spending, any efforts to reduce introduction of these products in the country is unlikely to produce substantial overall savings.

The political efforts and resources invested in keeping the cost of MedTechs low would probably result in even greater savings if the efforts were directed towards containing the cost of other components of the health system that account for a larger slice of total health expenditure.

Regional access to MedTechs

The proportionally low amount spent on MedTechs is unequally distributed among the various regions of Brazil. Access is concentrated mainly on the cities of São Paulo and Rio de Janeiro. The low density of the MedTech market means that access to the products by the population in general is still fairly limited.

Multiple factors influence patterns of regional access to new technologies in both the SUS and the supplementary healthcare system, as illustrated in Figure 5.2

FIGURE 5.2

TOTAL EQUIPMEMT AVAILABLE IN THE SUS: BEST AND WORST RESULTS IN 2013

(per 1,000 inhabitants per state)

Indicator of availability of hospital medical equipment per thousand inhabitants

	Diagnostic imaging equipment	*Infrastructure equipment*	*Dentistry equipment*	*Life equipment*
Best results	DF | 0.98	AM | 1.14	DF | 4.8	DF | 4.37
Worst results	AP | 0.21	TO | 0.14	AP | 0.68	PI | 0.79

Indicator of availability of hospital medical equipment per thousand inhabitants

	Equipment by graphical methods	*Equipment by optical methods*	*Other equipment*	*Audiology equipment*
Best results	MG | 0.24	DF | 0.38	PA | 0.09	RS | 0.06
Worst results	AC | 0.06	MA | 0.077	RJ | 0.23	PI | 0.02

Source: EQUIPMENT.

PROPOSALS TO EXPAND ACCESS TO MEDTECHS IN BRAZIL

01

WHAT

RATIONAL USE OF TECHNOLOGIES TO AVOID WASTE AND ENSURE ACCESS BY THE POPULATION TO AVAILABLE HEALTH SOLUTIONS

WHY?

The costs involved in using MedTech are often blamed for increasing expenditure on Brazil's healthcare services. Governments spend substantial resources to evaluate the cost-effectiveness of medical devices.

Notwithstanding the direct costs of incorporating new technologies consideration must also be given to the benefits involved. Modern and less invasive procedures for example reduce the length of patient's hospital stays and the amount of time they need to be absent from work.

HOW

By continuously improving healthcare decision-making methodologies by using evaluation criteria such as multi-criteria decision analysis (MCDA), scientific literature reviews, real life data, health economy evaluations, assessments of impacts on budgets and quality of life.

STAKEHOLDERS:
Universities, NATS Health Technology Assessment Unit, CONITEC, International Society for Pharmacoeconomics and Outcomes Research (ISPOR).

02

WHAT

INCREASE ALL STAKEHOLDERS´ INVOLVEMENT IN DECISION-MAKING DURING DISCUSSIONS ON THE INCORPORATION OF MEDTECHS

WHY?

It is important to broaden discussions on the inclusion, revision or rejection of MedTechs by ensuring participation by more stakeholders.

HOW

By ensuring society/community involvement in discussions.

STAKEHOLDERS:
Ministry of Health, CONITEC, doctors and patients associations, consumer associations in general and representatives of the productive sector.

03

WHAT

ESTABLISHING A FORMAL AND PERMANENT BASIS FOR DIALOGUE BETWEEN MANUFACTURERS AND OTHER STAKEHOLDERS ON THE INDUSTRY´S "TECHNOLOGICAL HORIZON".

WHY?

So that Brazil can remain fully aware of innovations and maintain a prominent position in global forums and debates on the subject.

It is extremely important to keep abreast of discussions on innovative technologies in view of the advances made by the dynamic MedTech industry and the speed of technological change currently taking place, not only in this industry but in all IT- related areas.

HOW

By maintaining a permanent discussion group on the "technological horizon" in the healthcare area.

STAKEHOLDERS:
Ministry of Health, medical associations and the productive sector.

04

WHAT

TO REDUCE THE TAX BURDEN ON THE SECTOR PRODUCTS

WHY?

The high tax burden on the production and distribution of healthcare products is reflected in increased prices paid by the government (in terms of purchases by the SUS) and the private healthcare sector in terms of increased health plan costs.

HOW

To reduce the tax burden on industry including by ending cascade taxation.

STAKEHOLDERS:
Ministry of Health, Brazilian Internal Revenue Service, MDIC, the National Congress, ABIIS and the *Movimento Brasil Competitivo* (MBC).

05

WHAT

TO IMPROVE THE EFFICIENCY OF THE HEALTH SYSTEM

WHY?

The CHPI Study (2014) showed that the costs ofmedical technology in Brazil are not as high as thoseof other countries with similar health systems[25].

Rather than focusing on keeping the costs of MedTechs low, it would be better to increase efficiency throughout the entire health system.

In order to improve access to MedTechs it is necessary to understand the multiple factors that influence the distribution and use of new technologies in the SUS and the supplementary private system and to take into account the need for spreading the benefits of the new technologies outside of the big urban conurbations (especially São Paulo and Rio de Janeiro), thus contributing to the development of strategies to ensure equitable distribution of the technologies for the people who need them.

By increasing and making optimal use of funding resources for the health sector .

By improving the way health service networks are organized at the three levels of federative government by reinforcing their autonomy, guaranteeing their continuity and reinforcing their State Policy status.

This could contribute much to the development of strategies to promote equitable distribution of technologies to those who need them.

25 CHPI (2014).

HOW

Increasing the availability and optimizing the resources to finance health.

Improving the organization of health service networks, in all the three federative levels, giving it the status of State policy, strengthening its autonomy and guaranteeing its continuity.

STAKEHOLDERS:
National Congress, Ministry of Health, SUS, National Council of Municipal Health Secretariats (CONASEMS), National Council of Health Secretaries (CONASS).

06

WHAT

SUPPORT THE INCORPORATION AND USE OF POINT OF CARE REMOTE TECHNOLOGIES

WHY?

With the increase of chronic diseases the profile of these diseases both globally and in Brazil is changing.

The health system needs to adapt in order to address this new disease profile, contain the costs of services, expand access and improve the quality of universal care for the population. Mobile technologies satisfy some of these needs, but greater coordination is required between the care levels and the adoption of Information Technology for computerizing the entire system so that patient data and protocol analyses can be done online.

HOW

By encouraging discussion and understanding of the possibilities of using health-related mobile technologies (“mHealth”) which facilitate the monitoring of diseases regardless of the patient’s location. Also by helping to educate patients through the respective associations.

STAKEHOLDERS:
Ministry of Health, SUS, the Healthcare Secretariat, and Healthcare Companies

07

WHAT

TO DEVELOP SPECIFIC "mHEALTH" POLICIES – INCORPORATION OF MOBILE TECHNOLOGIES

WHY?

PwC estimates that by 2017 the use of mobile technology solutions will probably save 8.9 million doctor days in Brazil (9% of total working hours) through a 30% reduction of the time spent on accessing and updating patient data. This would represent savings of US$ 14.1 billion in Brazil and US$ 3.8 billion in México[26].

HOW

By following the example of the United States- regulating mobile medical applications by separating those which are subject to regulatory inspection from those which are not.

Mobile applications can be divided into three large categories:

1. Mobile applications that do not qualify as "medical devices";

2. Mobile applications that qualify as medical devices, but do not represent a significant risk to users or patients and would not be subject to ANVISA regulation;

3. Mobile applications that qualify as medical devices and represent a significant risk to patients will be subject to ANVISA oversight.

26 PwC (2013).

Examples of mobile medical applications that do require regulation by ANVISA:

- applications that display behavioral techniques to reduce psychiatric symptoms;
- applications that provide educational or motivational data for physical therapy or smoking cessation;
- tools for monitoring asthma episodes and inhaler use;
- applications that indicate possible medical conditions based on user data;
- applications that accompany drug dosages and schedules;
- applications for collecting and sharing blood pressure data.

Examples of mobile medical applications subject to registration by ANVISA:

- applications with sensors connected to ECG equipment;
- applications with sensors to amplify sounds from electronic stethoscopes;
- applications to measure physiological parameters used in the diagnosis;
- applications used to change the settings of infusion pumps or functions;
- applications that calibrate cochlear implants and hearing aids;
- applications that are connected to nursing stations and display MedTech data for mobile platforms;
- applications connected to bedside monitors to transfer patients data to medical staff;
- applications connected to perinatal monitoring equipment to allow remote monitoring.

STAKEHOLDER:
ANVISA.

08

WHAT

TO ADOPT PERFORMANCE AND RISK SHARING MECHANISMS AS USED IN THE UNITED STATES AND EUROPE.

WHY?

In spite of the transparent submission process for incorporation of new technologies there are no satisfactory mechanisms to help speed up this process in Brazil. The process is usually long and costly for both companies and patients.

The great advantage of these mechanisms is to anticipate the possibility of dialogue with payers within the life cycle of the product, and contribute to receiving early repayment through a risk-sharing agreement based on the actual performance of the product (s).

HOW

By developing the mechanisms suggested by ISPOR based on two performance and risk-sharing mechanisms: performance-related reimbursement and evidence-based coverage.

STAKEHOLDERS:
CONITEC and Ministry of Health (public decision makers), ANS (responsible for creating rules for performance-based mechanisms, probably also providing incentives for healthcare companies to adopt proven mechanisms), healthcare company executives (private decision makers), medical societies (prescribing procedures) and the industry (producers).

09

WHAT

TO PROVIDE INFORMATION AND EVIDENCE TO ASSIST THE FORMULATION OF CRITERIA TO ADDRESS HEALTH-RELATED LAWSUITS.

WHY?

Courts tend to defer by injunction all types of health-related pleas because judges lack appropriate technical knowledge to deal with them.

HOW

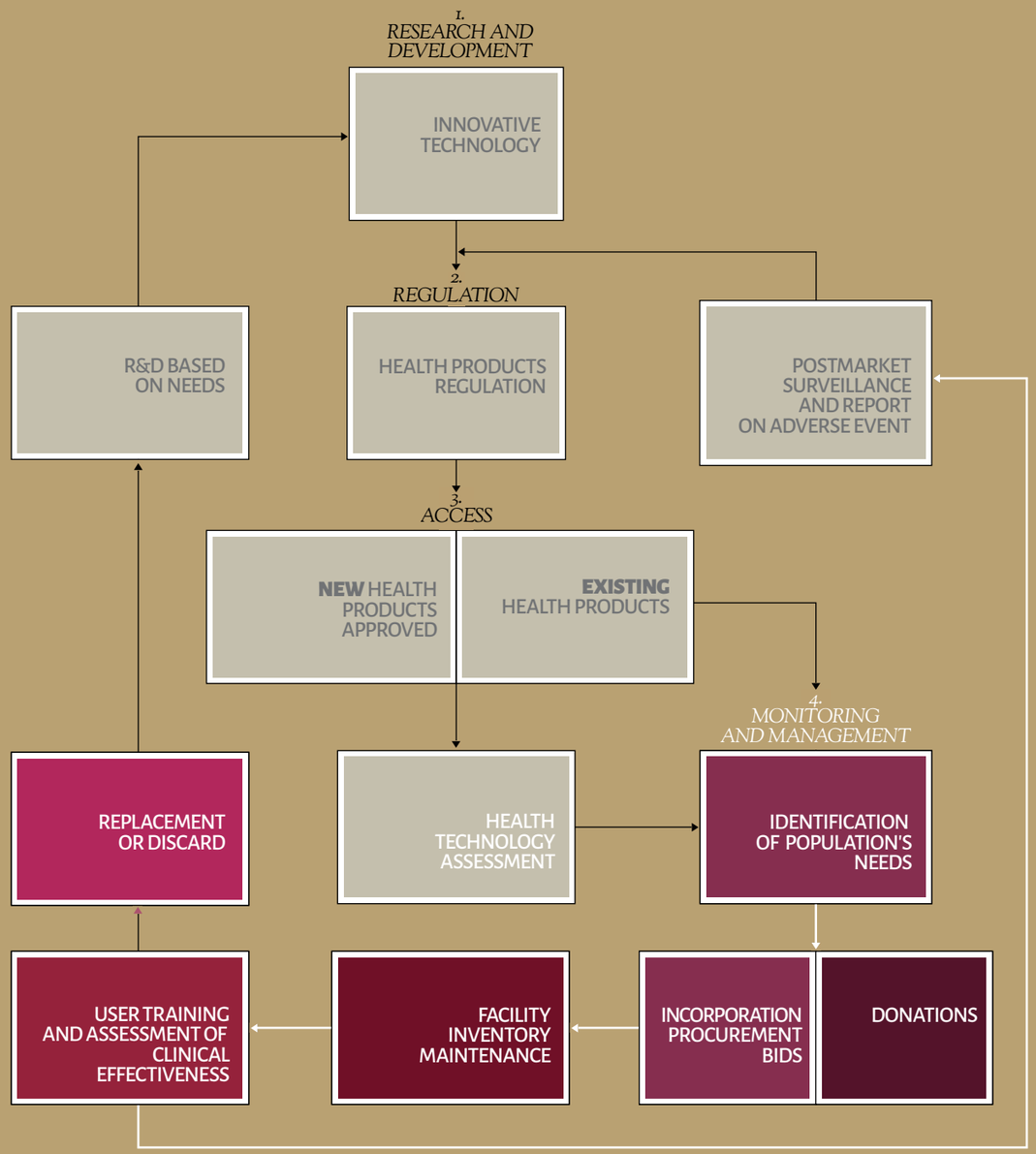
By regularly sending documents containing suggestions or technical guidelines to the High Court of Justice (STJ) and the National Council of Justice (CNJ), with a view to assisting the courts to issue rulings based on unbiased, good quality information.

STAKEHOLDERS:
ABIIS, STJ and CNJ.

MONITORING AND MANAGEMENT OF MEDTECHS IN BRAZIL

FIGURE A

HEALTH PRODUCT LIFE CYCLE



CHAPTER 6

6.1 Monitoring the products worldwide and in Brazil.

The regulation covering a new product guarantees its safety and efficacy in the market and also stipulates a series of after-sales requirements. Following registration by the appropriate authority the product is suitable for use by the SUS and the supplementary health system.

Before the product has been approved for commercial use, the manufacturers have already investigated the systems for guaranteeing quality, tracking and communication and have identified the after-sales tools for detecting and responding to possible malfunctions or other adverse occurrences. Meanwhile, the government selects a number of sentinel (watchdog) hospitals for notifying and registering patients.

From the economic viewpoint, once the new product has been approved and regulated, health managers seek to exploit its benefits to patients at the lowest possible cost. In addition to the product being cost effective, it is important that it is made widely available and that health professionals are correctly to adopt and use it rationally, i.e. in response to real needs.

From the economic viewpoint, once the new product has been approved and regulated, health managers seek to exploit its benefits to patients at the lowest possible cost.

The eventual outcome of the learning curve associated with the new technology is fair reimbursement.

Health managers need also to assess whether, with the introduction of the new technology, there is a need to replace other technologies that have completed their lifecycles.

In Canada and the UK, for example, data systems have been developed that allow monitoring of the technologies used in the system. This data helps managers to decide when to interrupt the repayment of less-than-effective technology and replace it with an improved version.

The management and monitoring processes in Brazil monitoring and administration processes in Brazil are described here, based on information provided in the CONITEC 2012-2014[2] Balance.

2 Ministry of Health – CONITEC (2014) Balance.

BOX 1

Managing and monitoring the incorporation of new products into Brazil's health system.

"After the ordinance ruling incorporation of any new technology in Brazil has been issued, a long road remains to be traveled before the product becomes available to the patient needing it."

Decree 7.646/2011 stipulates that after the ordinance covering incorporation of a new technology into the health system has been published, a period of up to 180 days must be allowed for making the product available for SUS patients. During this period certain measures need to be taken, including: compiling or updating the clinical protocol and establishing therapeutic guidelines of the disease that the technology is designed for; inserting a new procedure on the SUS Table; deciding on how the product should be purchased (directly or via repayment). The states and municipalities are also required to share the responsibilities for delivering the new product or service by determining the infrastructure, logistics and capacity for rational use of the technology and, in many cases, establishing the price for bringing the product into the SUS network.

"...Monitoring reports have been restricted to medicines and not to devices."

To ensure efficiency of this process the SUS launched a system for monitoring technologies introduced in the network. This involved constructing a data bank contracting the technologies, selecting indicators for evaluating the supply process and preparing and issuing specific reports.

The monitoring reports, compiled one year after the product or service has been officially approved and regulated, and feedback has been received, make it possible to construct a picture of of how the technology is supplied and used. The reports are required to cover the following reports cover the following: identification of the particular technology, an indication of its use within the SUS, and deadlines established for supply, consumption, logistics, financing and acquisition, as well as its budgetary impacts. It is to be noted however that monitoring reports have to date been restricted to medicines and not to MedTechs.

6.2 Analysis of clinical effectiveness, investigation of results and technical surveillance

The criteria covering the presentation of scientific evidence on medical technology products have already been identified in Chapter 5.

Given the incremental nature of innovative technological products and services there is an ongoing need for evaluation and monitoring. This is highlighted in this chapter in the context of monitoring the incorporation of new products.

Evaluation prior to incorporation

The Department of Administration and Incorporation of Technologies into Health (DGITS), is a technical body responsible for organizing and managing the process of evaluating technologies in the healthcare field on behalf of CONITEC. In a book published in 2014 the DGITS describes the evaluation of health products at federal level, highlighting the following aspects[3].

3 Taken from 'AxiaBio' (2014).

"The scarcity of scientific evidence on health products has been the greatest drawback for conducting evaluations of these technologies".

In an attempt to remedy the shortage of scientific evidence, the Ministry of Health, through its Departments of Administration and Incorporation of Technologies (DGITS) and Science and Technology (DECIT), established a unit for evaluating healthcare technologies (NATS) in teaching hospitals in a number of different Brazilian states. The NATS are required to carry out specific studies and obtained technical-scientific feedback on health products considered of priority concern.

Certain products in the health system are not analyzed by the DGITS since they are not subject to centralized federal government procurement, expenditure of federal funds or individual repayment. Such products, such as special materials, are generally covered by procedures that have already been included for repayment from the SUS and are not subject to individual repayment.

These products are evaluated at point of use (i.e. by the health services that use them).

Post-registration evaluation - "Technical Surveillance".

Technical Surveillance is for adverse occurrences and technical complaints relating to health products in the after-sales phase, the aim of which is to recommend measures that guarantee protecting and promoting the health of the population[4].

The norm that demands, from the holders of registration, a series of actions for reducing the risks associated with problems that may occur with health products that have already been sold in Brazil, is Resolution RDC no 23, of April 9, 2015. This sets out the procedures and time limits that must be followed should a health product not meet the essential requirements of safety and efficacy.

4 Taken from the site of ANVISA: (http://portal.anvisa.gov.br/wps/content/Anvisa+Portal/Anvisa/Pos+-+Comercializacao+-+Pos+-+Uso/Tecnovigilancia).

6.3 Installation, stocking, maintenance, replacement or disposal of products

Evidence of unavailability of products within the public health system.

"There is considerable disorganization in the flow of patients, equipment and supplies in the SUS primary care hospital network, the emergency services and intensive care units. Regarding patient flow, the low primary care problem-solving capacities, and the problems of arranging appointments in outpatient clinics with specialists, or diagnostic tests and elective surgery, mean that patients often have to to be transferred, leading to hospitals being overloaded. Numerous problems also exist in the equipment and supplies areas: lack of infrastructure and buildings maintenance, often inexistent or poor maintenance of equipment, unoccupied beds caused by the lack of basic equipment, poor management and waste of medicines and materials." [5]

5 TCU (2014).

BOX 2

Diagnosis of the situation in the SUS presented by the Federal Court of Auditors (TCU)

The report by the TCU (Federal Court of Auditors) points out that 53% of the units lack administration instruments in the field of medicines and supplies and that 39% of the units visited confirmed that there was waste of medicines and supplies.

The TCU systemic audit report on health (March 2014) revealed much evidence of considerable disorganization in the flow of patients, equipment and supplies in the SUS primary hospital networks, the emergency services and the intensive care units. The shortage of qualified healthcare professionals is one of the reasons alleged for shortages. The report states that 12% of beds are blocked because of lack of doctors, 16% because of lack of nurses and 18% because of shortages of other health professionals. Other problems included: poor infrastructure and buildings maintenance (18% of all cases), 11% on account of defective equipment, and 7% due to poor or inexistent equipment maintenance.

The TCU report highlighted **hospital overcrowding.** 114 hospitals visited by the TCU team were short of beds, with patients awaiting surgery attended on stretchers or in corridors. Some wards contained excessive numbers of patients. The main causes were low primary care problem-solving capacities, and the problems of arranging appointments in outpatient clinics with specialists, or diagnostic tests and elective surgery. 77% of the hospitals had unoccupied beds because of the lack of basic equipment such as monitors and pulmonary ventilators. The demand for hospital emergency care would be reduced if the primary care network were able to correct these deficiencies.

53% of the health units lacked **medicines/supplies management tools**, and the TCU team confirmed the waste of medicines and supplies in 39% of the units visited. Hospital managers claimed that faults in the bidding and purchasing processes were largely responsible for these deficiencies.

A further serious problem highlighted by the TCU report was the **poor infrastructure** (unfit for purpose) of the hospitals visited. The dilapidated state of many of the buildings made it difficult to install new equipment. Around 23% of the hospitals visited by the team have installed no expensive equipment due to lack of suitable physical structures. The main reasons for the defective infrastructure in the SUS hospitals was attributed to problems with bidding processes and the lack of funds needed for undertaking restoration works.

Evidence on the ideal situation in the state-of-the-art hospitals[6]

Logistics in the health sector basically means inventory control and management: ensuring the availability and control of materials and medicines within the hospitals (outpatient clinics, first aid posts, surgery centers, pharmacies, etc.).

Hospital logistics in Brazil are seriously hampered not only by infrastructural defects and bureaucratic bottlenecks, but also by shortages of materials and medicines in first aid units, and diagnostic facilities and surgical centers. The logistics are highly complex, involving knowledge of the entire medical production chain. Given the complexity of the operations this is precisely why many state-of-the-art hospitals possess automated processes for replacing supplies in critical areas, using supply management software to monitor the stocking and use of products in real time.

It follows that hospital business intelligence needs to be developed, with indicators aimed at cross-referencing product consumption, epidemiology, storage capacity and materials/ medicines replacement.

This methodology has been adopted in several state-of-the-art hospitals such as the Hospital das Clínicas (HC) in São Paulo, where savings of 10% have been recorded on products in the supply chain. This hospital invested R$10 million to build an 8,000 m² distribution and service center, which freed up spaces previously used for storing products for expansion of patient facilities.

An operations control center was also created to manage and monitor the flow of products from the moment of acquisition up to leaving the distribution center for consumption. This initiative was financed by 'Desenvolve SP', a State of São Paulo government development agency.

According to the Hospital das Clínicas, one of the highest logistical costs in the healthcare area is hospitalization - a complex operation demanding a high level of managerial proficiency. Hospitalization costs at the HC are currently 60% on manpower and 35% on hospital products, including medicines. Efficient running of the supply chain presupposes a connection between all elements of the chain. This is the case in theHC but not in most of the other SUS hospitals, where management is divided into different departments with no common goals, targets, or shared facilities for calculating costs, acquiring technical resources, etc. There is no doubt that in the new digital economy, technologies involving cloud computing, remote applications, big data analysis, intelligent machines and 3D printers would increase the efficiency of the system. In the inventory areas, labelling and sensors are capable of informing not only the location and availability of hospital and related products, but also their acidity, humidity, temperature and so on.

6 Based on "Valor Setorial" Logistics Supplement (March 2015).

6.4 Repayment by the public and supplementary systems

Repayment also forms part of the management phase of a medical technology product's life cycle. Fair remuneration to cover the cost of the product as well as to compensate for, among other things, the delay between delivery of the product and payment, are essential for the company that developed the technology. Correctly reimbursed, the company can re-invest the resources in developing new items.

Reimbursement by Brazil's public and private systems varies widely.

Repayment within the public system [7]

Repayment by the SUS depends on the complexity of service provided. The primary (or basic) care level possesses a single funding system, through which the three federative entities (Central Goverrnment, State and Municipal Governments) contribute fixed amounts per inhabitant/year at the municipal level, and the funds are released in monthly quotas to each municipal department of health responsible for compying with the norms and regulations of the basic health care system.

"...The primary (or basic) care level possesses a single funding system, through which the three federative entities (Central Goverrnment, State and Municipal Governments) contribute fixed amounts per inhabitant/year at the municipal level, and the funds are released in monthly quotas to each municipal department of health."

At the secondary and tertiary healthcare levels, two funding sub-systems of financing are used for paying for procedures involving hospitalization, tests or complex treatments. First, for public institutions (hospitals, clinics, laboratories, etc.) funds are not released on a reimbursement basis

7 Text adapted from AxiaBio (2014).

but form part of annual budget expenditure linked to obligations to deliver a given volume of service agreed by health managers.

For private institutions (not-for-profit or philanthropic), such as university hospitals, repayment is based on payment for services for actual procedures and "Related Diagnoses Groups" guidelines based on fixed price tables and criteria defined by the SUS[8].

Decisions to include new procedures and/or products for supply or repayment by the SUS are the responsibility of CONITEC (see Chapter 5).

As for the number of procedures formally accepted by the SUS (on the basis of the SIGTAP Table), the use of medical devices is not separately reimbused (i.e. in isolation). The amounts repaid for a procedure almost always reflect the materials and medicines normally used in a procedure.

8 See: (http://sigtap.datasus.gov.br/tabelaunificada/app/sec/inicio.jsp).

"Defining the amounts repaid for each procedure is an internal SUS procedure which assembles the relevant data from DATASUS, health professionals and elsewhere."

In almost all of the cases, the amount repaid for a procedure already includes any respective materials and medicines that are generally used.

Defining the amounts repaid for each procedure is an internal SUS procedure which assembles the relevant data from DATASUS, health professionals and elsewhere." Again, the amount of the repayment by the SUS must be enough to cover the cost of the entire procedure as a whole, including all the costs incurred by the health provider.

SUS Repayment Chart[9]

The SUS System for Managing the Procedures, Ortheses, Prostheses, Special Materials and Medicines Chart (SIGTAP) was launched in January 2008. It combines the clinical/ hospital procedures charts of the SIA and SIH[10] systems.

The SIGTAP lists the procedures contained in the National Report on Healthcare Actions and Services (RENASES). It also lists the procedures, ortheses, prostheses and materials and medicines (OPM's) covered by SUS together with the national reimbursement amounts.

9 The SUS System for Managing the Procedures, Ortheses, Prostheses, Special Materials and Medicines Chart (SIGTAP) is available at: (http://sigtap.datasus.gov.br/tabelaunificada/app/sec/inicio.jsp). Accessed on: 24 November 2014.

There are no equivalent charts for the regions. The amounts for reimbursement of procedures can be periodically adjusted at any time (i.e. no specific dates for revision).

The diagnostic, clinical, surgical procedures and OPMs reimbursed by the SUS are grouped according to Organs, apparatuses or human systems (see Table 6.1).

10 Clinic Information System (SIA) and Hospital Information System (SIH).

TABLE 6.1
PROCEDURE GROUPS

02 *Procedures for diagnostic purposes*	02.01	*Material collection*
	02.02	*Diagnosis in clinical laboratory*
	02.03	*Anatomic pathology and cytopathology diagnosis*
	02.04	*Radiology diagnosis*
	02.05	*Ultrasonography diagnosis*
	02.06	*Tomography diagnosis*
	02.07	*Magnetic resonance diagnosis*
	02.08	*In vitro nuclear medicine diagnosis*
	02.09	*Endoscopy diagnosis*
	02.10	*Interventional radiology diagnosis*
03 *Clinical procedures*	03.01	*Appointments / Treatment / Observation*
	03.02	*Physiotherapy*
	03.03	*Clinical Treatment (other areas)*
	03.04	*Oncology treatment*
	03.05	*Nephrology treatment*
	03.06	*Hemotherapy*
	03.07	*Dental care treatment*
	03.08	*Externally-caused injury, poisoning treatment and others*
	03.09	*Special therapies*
	03.10	*Labor and birth*
04 *Surgical procedures*	04.01	*Minor surgeries and skin, subcutaneous tissue and mucosal surgery*
	04.02	*Endocrine glands surgery*
	04.03	*Central and peripheral nervous system surgery*
	04.04	*Surgery of the upper airway, face, head and neck*
	04.05	*Eye surgery*
	04.06	*Cardiovascular system surgery*
	04.07	*Gastrointestinal, attached organs and abdominal wall surgery*
	04.08	*Surgery of the musculoskeletal system*
	04.09	*Genitourinary system surgery*
	04.10	*Breast surgery*
05 *Organ, tissue and cell transplant*	05.01	*Collection and tests for organ, tissues and cells donation and transplant purposes*
	05.02	*Brain death evaluation*
	05.03	*Actions related to organ and tissue donation for transplantation*
	05.04	*Tissue processing for transplantation*
	05.05	*Organ, tissue and cell transplant*
	05.06	*Monitoring and complications in pre- and post-transplant*
07 *Ortheses, Prostheses and special materials*	07.01	*Ortheses, Prostheses and special materials unrelated to the surgical procedure*
	07.02	*Ortheses, Prostheses and special materials related to the surgical procedure*

Source: SIGTAP. Accessed on 24/11/2014

The OPM table divides the products into groups related and unrelated to surgical procedures and the subgroups define the final classification of the products in the system. Table 6.2 shows the classification by groups and subgroups.

TABLE 6.2
METHOD OF ORGANIZATION - ORTHESES, PROSTHESES AND SPECIAL MATERIALS

07.01 *Ortheses, Prostheses and special materials unrelated to the surgical procedure*	07.01.01 OPM	*mobility assistive equipment*
	07.01.02 OPM	*orthopedic*
	07.01.03 OPM	*auditory*
	07.01.04 OPM	*ophthalmologic*
	07.01.05 OPM	*in gastroenterology*
	07.01.06 OPM	*in urology*
	07.01.07 OPM	*in dentistry*
	07.01.08 OPM	*oral and maxillofacial anomalies*
	07.01.09	*replacement/exchange of ortheses/ prostheses*
	07.01.10 OPM	*for burns*
07.02 *Ortheses, Prostheses and special materials related to the surgical procedure*	07.02.01 OPM	*in neurosurgery*
	07.02.02 OPM	*in oral and maxillofacial surgery*
	07.02.03 OPM	*in orthopedics*
	07.02.04 OPM	*in cardiovascular events*
	07.02.05 OPM	*common items*
	07.02.06 OPM	*in urology*
	07.02.07 OPM	*in ophthalmic surgeries*
	07.02.08 OPM	*in plastic/reconstructive surgery*
	07.02.09 OPM	*in otorhinolaryngology surgery*
	07.02.10 OPM	*in nephrology*

Source: SIGTAP. Accessed on 24/11/2014.

Evaluations are guided by procedures, rather than by products or techniques, and are firmly based on what is nationally recognized by the Brazilian Hierarchized Classification of Medical Procedures (CBHPM) of the Brazilian Medical Association.

Reimbursement in the supplementary system[11]

Private health system companies are regulated by the National Supplementary Health Agency (ANS), which issues the List of Health Procedures and Events which is the basic reference document on which minimum coverage by private health insurance plans is based.

As with the SUS, any changes in the list are subject to an ANS internal evaluation procedure at two-year intervals. One of the differences observed in the review of the 2015 list was that the ANS only accepted requests from special interest groups or medical societies, unlike the CONITEC process where submissions were received from a wider field.

Evaluations are guided by procedures, rather than by products or techniques and are firmly based on what is nationally recognized by the Brazilian Hierarchized Classification of Medical Procedures (CBHPM) of the Brazilian Medical Association.

The criteria used to judge the merit of requests for revising the List are similar to those used by CONITEC (efficacy, safety, and economy). Note that the List contains only what is considered to be the minimum mandatory coverage that a private health insurance plan needs to have in order to obtain an operating license.

Other procedures, medicines, tests, or medical devices can be used even when they are not included in the list, providing they are correctly licensed by ANVISA and the procedure is recognized by a medical association. In this case, reimbursement is effected at the discretion of the health insurance plan company, which may decide to place a perceived fairer price on the item or not to reimburse at all.

For procedures that apparently do not involve the use of a particular method or technique the health plan company is allowed to reimburse a method of its own choosing. The chosen method s usually based on national guidelines or, if the item is not available in Brazil, by international guidelines.

11 Based on AxiaBio (2014), with modifications to the original text.

6.5 Information systems for incorporated products and reimbursements

In the SUS

The MedTechs incorporated to the SUS health services are listed in the National List of Equipment and Materials (RENEM). The Ministry of Health information systems that contain data on "incorporated" products are:

SIGTAP, which deals with prescribed articles whose direct beneficiary must be the patient.[12] The system also provides data on list values, the respective international classification of diseases (CID), the corresponding Brazilian code of occupation (CBO), the care modality, and licensing.

SIGEM, which deals with the Information and Management of Equipment and Materials permanently financed by the SUS.[13]

Beneficiaries are exclusively SUS-related healthcare institutions. The SIGEM website provides equipment and materials definitions, synonyms, permitted configurations, suggestions for specifications and values, and information on different types of licensed health services.

12 Available at: (http://sigtap.datasus.gov.br).
13 Available at: (www.fns.saude.gov.br/sigem).

"... there is no publicly accessible database, such as DATASUS run by the public healthcare system, for consulting management data regarding the use of funds or clarification of costs related to the services provided to the people who use the supplementary healthcare system".

In the supplementary system[14]

Unified Supplementary Health Terminology (TUSS)

Multiple terminologies have always coexisted in the health insurance sector, leading to confusion and difficulty to exchange information between practitioners. This led to the adoption of a common clinical terminology: the Unified Supplementary Health Terminology (TUSS) was created due to joint collaboration between the ANS, AMB, and the Committee for the Standardization of Supplementary Health Information (COPISS). The resulting terminology is currently based on the Brazilian Hierarchized Classification of Medical Procedures (CBHPM).[15]

Although the three charts used in the supplementary health sector, CBHPM, TUSS, and the List of Health Procedures and Events, are similar in structure and content, they have entirely different functions as described in ANS Note 449/2012.[16]

CBHPM: This list contains procedures that are carried out in Brazil by medical practitioners, but that are not covered by private health plans since the procedures are not targeted at disease prevention or at health recovery and maintenance. "Sports Medicine" examinations fall into this category. A number of other procedures are also excluded from health care insurance plans. While some exclusions are provided for in law (e.g. artificial insemination), others may arise from decisions by the health plan provider regarding the cost-effectiveness of the procedure or the nonexistence of facilities in the country able to perform the procedure.

TUSS: the TUSS Chart is likely to become broader than the CBHPM once it embraces all the health professionals and procedures paid for by the private health insurance companies.

ANS List of Procedures: The contents of the ANS List differ from both the CBHPM and TUSS charts. Certain procedures not covered by the supplementary health sector are categorized under a single title in the ANS List, although they many be separated in the TUSS and the CBHPM charts for reimbursement purposes. Finally, procedures listed in the TUSS and CBHPM charts are sometimes disaggregated in the ANS List due to the segmented types of coverage provided in the health insurance plans.

14 Adapted from AxiaBio (2014).
15 /16 ANS (2012).

The ANS has issued a table containing all the items (supplementary health sector procedures and events) on the List of Health Procedures and Events and their equivalent denominations in the TUSS chart.

The only chart that suggests or determines reimbursement values is the CBHPM (in its different versions). Both the TUSS table and the ANS List determine the specific procedure to be reimbursed, but neither of them mention actual values. The CBHPM chart contains values reimbursement of diagnostic and medical services, while daily hospital fees, tariffs and items consumed are negotiated between the health plan operators and service providers using other mechanisms.

In order to determine the reimbursement value of a surgery, it must be evaluated not only on the basis of the value appearing in the CBHPM chart (referring only to fees due to physicians and for tests), but must also reflect the values of materials, medicines, daily hospital fees, etc.

At present there is no publicly accessible database, such as DATASUS run by the public healthcare system, for consulting management data regarding the use of funds or clarification of costs related to the services provided to the people who use the supplementary healthcare system. Some specialist health technology evaluation companies have private and unidentified access (i.e. without the knowledge of hospitals, physicians, patients and health plan operators themselves) to supplementary health databases with the sole purpose of investigating resource consumption and associated costs.

Whenever there is a need to obtain data on a patient's health status by examining patient medical records or prospective assessments, a proposal andstudy protocol must be submitted, in accordance with Brazilian clinical research norms, to an ethics committee recognized by the National Clinical Research Commission (CONEP).[17]

17 Ministry of Health. Conselho Nacional de Saúde, CONEP. Resolution no. 196/96, version 2012.

6.6 The costs of supplying products and services to the health system

Supplying MedTechs to the public and private health systems in Brazil is even more complex than the systems for obtaining reimbursement of costs.

In Europe and the United States, hospitals are responsible for providing all the basic items for surgical procedures, and reimbursement covers not only MedTechs but also the costs of the services associated with supplying the devices.

In Brazil, the healthcare chain is dysfunctional due to a number of factors, including the lack of hospital infrastructure and the fact that reimbursements are made only for the devices without considering disposables or other items and services related to their use.

Certain hospital responsibilities such as providing equipment, instruments and qualified technicians to assist in surgeries, have been gradually transferred to MedTech suppliers.

According to ANAHP (National Association of Private Hospitals) data, only 10% of the 70,000 items currently purchased by hospitals are stored on the premises. The remaining 90% of the items are furnished by suppliers using a reverse logistics system (items are delivered to the hospitals and returned after use).

MedTech suppliers are also responsible for:

1) training health professionals, nursing teams, and clinical engineering personnel.
2) installation / lease of equipment.
3) consignment of implants / disposables.
4) storage / maintenance of specialized instruments.
5) supplying surgical instrumentation technicians.

This transfer of responsibilities negatively affects the supply chain and, together with the highest tax burden and other factors in Brazil, results in MedTech prices being much higher in Brazil compared to those in other countries.

6.7 Training professionals in the correct use of products and maintenance

To ensure safe and efficient use of MedTechs, the training of the medical, nursing, and clinical engineering teams of a hospital or health system is frequently needed. Medical devices often require calibration, technical support, and regular inspections by the supplier. These procedures vary from hospital to hospital according to the availability of local staff skills for using and maintaining MedTechs.

6.8 Marketing ethics and compliance

The MedTech industry is devoted to fostering and embracing an ethical business environment, through transparent and constructive relationships, with the goal of enabling the population of Brazil to gain access to innovative health technologies.

In this respect ABIIS has prepared a guide to help member associations to develop or adjust their codes of conduct. ABIIS associate companies must sign and abide by these Codes of Conduct. The same obligations also extend to due diligence processes applicable to MedTech distributors.

PROPOSALS TO MAKE THE MANAGEMENT OF PRODUCTS AND THE HEALTH SYSTEM MORE EFFICIENT

01

WHAT

TO ENCOURAGE PUBLIC AND PRIVATE HEALTHCARE SYSTEMS TO COMPLY WITH TECHNICAL STANDARDS

WHY

To enable the physical infrastructure to adjust to incoming technologies.

HOW

By taking steps to strengthen the National Health Surveillance System with a view to ensuring that States and Municipalities have qualified professionals capable enforcing compliance with technical standards.

By developing oversight instruments at federal level to supervise the work of State and Municipal Health Surveillance authorities regarding compliance with technical standards.

By taking steps to make local health surveillance agents accountable in the event of non-observance of the technical standards.

STAKEHOLDERS:
Ministry of Health National Health Surveillance System.

02

WHAT

TO PROMOTE THE USE OF HOSPITAL MANAGEMENT SYSTEMS THROUGHOUT THE NETWORK

WHY

To control inventories in an effective manner in accordance with the needs of the hospital units and thus ensure the restocking of MedTechs.

To contribute to speeding up the flow of information between the user of the product or procedure and the manufacturer with a view to gathering information on new requirements that could lead to further products, as well as the views of users regarding possible improvements, reports of adverse events and technical complaints.

Efficient management anchored in control mechanisms and information technology inspires greater operational transparency and reduces the opportunities for deviations from commitments.

HOW

By adjusting Brazilian healthcare policies to enable the public health system to benefit from private sector management know-how.

"Disseminate *"IT guidelines for Private Hospitals"* throughout the public network. This manual outlines the best practices in information technology for the hospital sector and provides guidance for upgrading IT in Brazil's hospitals".[18]

By developing incentives to encourage adoption of best IT practices.

By improving the flow of information with the use of computers, by standardizing hospital cost accounting systems, by better management and supervision, and by adopting comparative parameters throughout the healthcare network.

By adopting and disseminating appropriate technology for the procurement, distribution and restocking of health products in health institutions throughout the country.

STAKEHOLDERS:
Audit Courts (TCU) and Public Ministries with ANAHP technical support.

18 MoH Conselho Nacional de Saúde, CONEP. Resolution 196/96, 2012.

03

WHAT

TO PREPARE THE MEDTECH INDUSTRY TO ADJUST TO POTENTIAL CHANGES RESULTING FROM THE TREND TOWARDS CENTRALIZING PRODUCT PURCHASING.[9]

WHY

Because distributor profit margins will be narrowed if this occurs.

HOW

By introducing new distribution mechanisms such as on-line services, logistics improvements and other services.

STAKEHOLDERS:
Industry, government, distributors and service providers.

19 Burns (2002).

04

WHAT

SYSTEMATIC UPDATING OF THE PAYMENTS CHARTS OF THE SUS AND PRIVATE HEALTH INSURANCE OPERATORS TO BENEFIT SUPPLIERS OF HEALTHCARE PRODUCTS AND SERVICES

WHY

Brazilian interest rates are very high and the exchange rate is increasingly unfavorable and unstable. Costs associated with inventories, high interest rates, and risky exchange rate fluctuations are very substantial as are the long delays in getting reimbursed for MedTech. The latter problem means that late payments like behind the real values and further business risks for the MedTech industry. There is an urgent need to update the payment system so that the industry can continue to innovate and contribute to the future sustainability of companies in this sector.

HOW

By adopting a more technical approach to updating the repayment charts to reflect current medical practice and in particular to withdraw from the charts obsolete products and techniques. This would bring the charts into line with current procedures and facilitate updating of the values listed therein.

STAKEHOLDERS:
Medical associations, ANS, CONITEC, Ministry of Health, and other health stakeholders such as the Federal Board of Medicine (CFM).

05

WHAT

COMPLIANCE AND ETHICS: ADOPTING GOOD CONDUCT PRACTICES IN THE RELATIONSHIPS BETWEEN THE MEDTECH INDUSTRY AND THE GOVERNMENT AND HEALTH PROFESSIONALS

WHY

To enable self-regulation of MedTech marketing.

HOW

By organizing periodic training sessions on the code of ethics of the entity or company for distributors and company personnel.

To ensure that company personnel sign up to the commitment to comply with the codes of ethics.

STAKEHOLDERS:
Manufacturing companies, distributors and health service providers, ABIIS, medical associations and the CFM.

06

WHAT

TO SUPPORT THE IMPLEMENTATION OF THE UDI (UNIQUE DEVICE IDENTIFICATION) SYSTEM TO ENSURE TRACKING OF THE PRODUCTION, MARKETING AND USE OF HEALTH TECHNOLOGY PRODUCTS.

WHY

To ensure that the classified product is entered in the IT system, thereby assisting the retrieval of incremental information needed for further innovation.

HOW

By using systems that can track products from the factory through to use by patients.

By improving post-market product traceability with the full use of IT, to ensure that product performance data are up-to-date and reliable.

By minimizing the costs of implementing UDI programs by the MedTech industry, its distributors and the entire chain of health service providers.

By reducing barriers to the collection of clinical data on new treatments, without sacrificing ethics and confidentiality.

STAKEHOLDERS:
ANVISA, Ministry of Health, ABIIS, FENASAÚDE, CNS, ANAHP, Santas Casas (Charity Hospitals).

Acronyms and Abbreviations

ABDI – Agência Brasileira de Desenvolvimento Industrial [Brazilian Agency for Industrial Development]
AFE – Autorização de Funcionamento da Empresa [Company Operating Permit]
AMB – Associação Médica Brasileira [Brazilian Medical Association]
ANAHP – Associação Nacional de Hospitais Privados [National Association of Private Hospitals]
ANS – Agência Nacional de Saúde Suplementar [National Agency of Supplemental Health]
ANSES – Agence Nationale de Sécurité Sanitaire de l'Alimentation, de l'Environnement et du Travail
ANVISA – Agência Nacional de Vigilância Sanitária [Brazilian Health Surveillance Agency]
ATS – Métodos de avaliação de tecnologias de saúde [Health technology evaluation methods]
BNDES – Banco Nacional de Desenvolvimento Econômico e Social [Brazilian Development Bank]
CADTH – Canadian Agency for Drugs and Technologies in Health
Capes – Coordenação de Aperfeiçoamento de Pessoal de Nível Superior [Coordination for the Improvement of Higher Education]
CBHPM – Classificação Brasileira Hierarquizada de Procedimentos Médicos [Brazilian Hierarchical Classification of Medical Procedures]
CBPF – Certificação de Boas Práticas de Fabricação [Good Manufacturing Practices Certification]
CCBPF – Certificado de Cumprimento de Boas Práticas de Fabricação [Good Manufacturing Practices Compliance Certificate]
CFM – Conselho Federal de Medicina [Federal Medical Council]
CIS – Complexo Industrial da Saúde [Industrial Health Complex]
CMED – Câmara de Regulação do Mercado de Medicamentos [Drug Market Regulation Chamber]
CND – Conselho Nacional de Desestatização [National Privatization Council], connected to the Ministério do Desenvolvimento, Indústria e Comércio Exterior – MDIC [Ministry of Development, Industry and Foreign Trade].
CNJ – Conselho Nacional de Justiça [National Council of Justice]
CNS – Conselho Nacional de Saúde [National Health Council]
CONASEMS – Conselho Nacional de Secretarias Municipais de Saúde [National Council of Health Secretariats]
CONASS – Conselho Nacional de Secretários de Saúde [National Council of Health Secretaries]
CONITEC – Comissão Nacional de Incorporação de Tecnologias no SUS [National Commission for Technology Incorporation at SUS]
DC – Clinical Guidelines
DGITS – Departamento de Gestão e Incorporação de Tecnologias em Saúde [Department of Management and Incorporation of Health Technology]
DMA – Medical Device in its Broad Sense includes materials, equipment, orthesis, prosthesis, in vitro diagnosis (reagents and laboratory equipment), and applications for mobile health, either implantable or not.

DUT – Use Guidelines
EC – European Commission
ERP – Enterprise Resource Planning, a data management tool through information technology
FDA – Food and Drugs Administration
FENASAUDE Federação Nacional de Saúde Suplementar [National Federation of Supplemental Health]
FINEP – Financiadora de Estudos e Pesquisas [Financing Agency for Studies and Projects]
GGINP – Gerência Geral de Inspeção [General Office of Inspection]
GGTPS – Gerência-Geral de Tecnologia de Produtos para a Saúde [General Office of Healthcare Product Technology]
ISPOR – International Society For Pharmacoeconomics and Outcomes Research
MBC – Movimento Brasil Competitivo [Competitive Brazil Movement]
MCT – Ministério da Ciência e Tecnologia [Ministry of Science and Technology]
MS – Ministério da Saúde [Ministry of Health]
NATS – Núcleo de Avaliação de Tecnologias em Saúde [Health Technology Assessment Unit]
NICE – National Institute for Health and Care Excellence (UK)
WHO – World Health Organization
PCDT – Protocolo Clínico e Diretriz Terapêutica [Clinical Protocol and Therapeutic Directive]
RDCs – Resolução da Diretoria Colegiada ANVISA [Resolution of ANVISA's Joint Board of Directors]
RENAME – Relação Nacional de Medicamentos Essenciais [National Essential Medicines List]
RENASES – Relação Nacional de Ações e Serviços de Saúde [Brazilian National List of Health Actions and Services]
ROL – List of Health Procedures and Events - Minimum mandatory coverage list that all operators of health insurance plans must offer to their beneficiaries.
SAS – Secretaria de Atenção à Saúde do Ministério da Saúde [Secretariat of Health Attention of the Ministry of Health]
SCTIE – Secretaria de Ciência, Tecnologia e Insumos Estratégicos do Ministério da Saúde [Ministry of Health Secretariat of Science, Technology and Strategic Inputs]
SINMETRO – Sistema Nacional de Metrologia, Normalização e Qualidade Industrial [National System of Metrology, Standardization and Industrial Quality]
SNVS – Sistema Nacional de Vigilância Sanitária [National Health Surveillance System]
STJ – Superior Tribunal de Justiça [Higher Court of Justice]
SUALI – Superintendência de Correlatos e Alimentos [Correlative and Food Superintendence]
SVS – Secretaria de Vigilância em Saúde do Ministério da Saúde [Ministry of Health Secretariat of Health Surveillance]
VISA – Health Surveillance, a term commonly used to refer to the state and/or municipal authority

BIBLIOGRAFIA

ADVAMED. Innovation Agenda. **The Medical Innovation Ecosystem,** February 2015.
ANAHP. **Diretrizes de TI para Hospitais Privados – Em busca do Hospital Digital.** Grupo de Estudos de Tecnologia da Informação da Anahp, 2015. Available on: <http://www. sindhosp.com.br/waUpload/001275201516233.pdf>. Accessed on: July 25, 2015.
ANS. **Dados Consolidados Saúde Suplementar.** 17.06.2015
AXIA.BIO LIFESCIENCES INTERNATIONAL. **Procedimentos de reembolso para equipamentos médicos no Brasil.** Relatório desenvolvido por Axia.Bio Life Sciences International. 2014.
BARROS, Pedro e MARTINEZ-GIRALT, Xavier. **Health economics, an industrial organization perspective.** London: ed. Routledge, 2012.
BASU, Saptarshi (M.P.A) and HASSENPLUG, John C. (M.Sc). Patient Access to Medical Devices – A Comparison of U.S. and European Review Processes. **N Engl J Med**, August 2012, vol. 367, p. 485-488, DOI: 10.1056/NEJMp1204170. Available on: <http://www.nejm.org/doi/full/10.1056/NEJMp1204170>. Accessed on: July 25, 2015.
BRASIL. Ministério da Saúde. Comissão Nacional de Incorporação de Tecnologias no SUS. **Balanço Conitec: 2012-2014 / Ministério da Saúde**. Brasília: Ministério da Saúde, 2014. Available on: <http://conitec.gov.br/images/Artigos_Publicacoes/BalancoCONITEC.pdf>. Accessed on: June 10, 2015.
_____. Ministério da Saúde. Secretaria de Atenção à Saúde. **Implantação das Redes de Atenção à Saúde e outras estratégias da SAS / Ministério da Saúde.** Brasília: Ministério da Saúde, 2014.
_____. Agência Nacional de Saúde suplementar (ANS). Gerência-Geral de regulação assistencial (GGRAS). Diretoria de Normas e Habilitação dos produtos (DIPRO). Nota técnica nº 838/2013. **Revisão do Rol de Procedimentos e Eventos em saúde 2013/2014,** Brasília DF. Available on: <http://www.ans.gov.br/images/stories/Particitacao_da_sociedade/consultas_publicas/cp53/cp_53_nota838_revisaodorol2013.pdf>. Accessed on: July 25, 2015.
_____. Agência Nacional de Saúde suplementar (ANS). Nota nº 449/2012/GEAS/GGRAS/DIPRO/ANS. **TEMA: Terminologias – Rol de Procedimentos e Eventos em Saúde, Terminologia Unificada da Saúde Suplementar – TUSS e Classificação Brasileira Hierarquizada de Procedimentos Médicos – CBHPM.** http://www.ans.gov.br/images/stories/Plano_de_saude_e_Operadoras/Area_do_consumidor/nota449_geas_ggras_dipro_11042013.pdf

_____. Congresso. Câmara dos Deputados. CONOF/CD. Núcleo de Saúde da Consultoria de Orçamento e Fiscalização Financeira. Nota técnica nº 12, de 2013. **A participação estatal no financiamento de sistemas de saúde e a situação do Sistema Único de Saúde – SUS**, Brasília, DF, 2013.

_____. Conselho Nacional de Secretários de Saúde. Saúde suplementar / Conselho Nacional de Secretários de Saúde. **Coleção para entender a gestão do SUS**. 12. Brasília: CONASS.2011

_____. Decreto nº 7.508, de 28 de junho de 2011. Regulamenta a Lei nº 8.080, de 19 de setembro de 1990, para dispor sobre a organização do Sistema Único de Saúde – SUS, o planejamento da saúde, a assistência à saúde e a articulação interfederativa, e dá outras providências. **Diário Oficial da União**, Brasília-DF, Seção 1, 29 jun. 2011. Available on: <http://www.planalto.gov.br/ccivil_03/_ato2011-2014/2011/decreto/D7508.htm>. Accessed on: June 28, 2013

_____. IBGE – Instituto Brasileiro de Geografia e Estatística. Informação Demográfica e Socioeconômica, nº 25. **Indicadores Sociodemográficos e de Saúde no Brasil**, 2009.

_____. IBGE, Diretoria de Pesquisas. Departamento de População e Indicadores Sociais. P**esquisa de Assistência Médico-Sanitária**, 2009.

_____. IPEA Instituto de Pesquisa Econômica Aplicada. **Políticas Sociais: acompanhamento e análise – BPS**, nº 21, cap. 3, Saúde, 2014.

_____. IPEA. Instituto de Pesquisa Econômica Aplicada. **Políticas Sociais: acompanhamento e análise – BPS**, nº 22, cap. 3, Saúde, 2014.

_____. Ministério da Saúde. **Balanço Conitec: 2012-2014 / Ministério da Saúde, Comissão Nacional de Incorporação de Tecnologias no SUS.** Brasília: Ministério da Saúde, 2014. Available on: <http://conitec.gov.br/images/Artigos_Publicacoes/BalancoCONITEC.pdf>. Accessed on: June 10, 2015.

_____. Ministério da Saúde. Comissão Nacional de Incorporação de Tecnologias. Histórico Institucional. **O que muda da CITEC para a CONITEC**. Brasília-DF. 2014. Available on: <http://portalsaude.saude.gov.br/index.php/o-ministerio/principal/ leia-mais-o-ministerio/259-secretaria-sctie/areas-da-sctie/dgits/conitec/12-conitec/9036-oque-muda-da-citec-para-a-conitec>. Accessed on Dec 30, 2014.

_____. Ministério da Saúde. Secretaria-Executiva Subsecretaria de Planejamento e Orçamento. **Plano Nacional de Saúde, PNS 2012-2015**. Brasília, 2011 BURNS, Lawton R. et al. T**he Health Care Value Chain, Producers, Purchasers and Providers. 1 edition.** San Francisco: published by Jossey-Bass, copyright John Wiley & Sons, 2002.

CANADIAN HEALTH POLICY INSTITUTE (CHPI). Medical devices and healthcare costs in Canada and 66 other countries, 2008 to 2013CHPI (2014). Toronto: Canadian Health Policy, September 12, 2014.

COMITÊ GESTOR DA INTERNET NO BRASIL – CETIC. TIC Saúde 2013. **Pesquisa sobre o uso das tecnologias de informação e comunicação nos estabelecimentos de saúde brasileiros.** BARBOSA, Alexandre F. (Coord.). São Paulo: Comitê Gestor da Internet no Brasil, julho de 2014. Available on: <http://www.cetic.br/media/docs/publicacoes/2/ticsaude-2013.pdf>. Accessed on: July 25, 2015. 4,77 Mb, pdf.

DILMEGANI, Cem; KORKMAZ, Bengi and LUNDQVIST, Martin. Public-sector digitization: The trillion-dollar challenge. Business Technology Office, **McKinsey,** december 2014, em PDF. Available on: <http://www.mckinsey.com/insights/health_systems_and_services/the_big-data_revolution_in_us_health_care>. Accessed on: July 25, 2015.

EMERGO. Outlook for the medical device industry, em 2014. Available on: <http:// www.emergogroup.com/resources/research/annual-medical-device-industry-survey> Accessed on: July 25, 2015.

ESPICOM. The Medical Device Market: Brazil. Available on: <http://www.espicom.com/brazil-medical-device-market.html>. Accessed on: Feb 5, 2015. [livro à venda no site da companhia/ consultado por meio de compra de acesso, valor pago]

FDA, U.S.A. Mobile Medical Applications. **Guidance for Food and Drug Administration Staff.** february 9, 2015. Available on: <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM401996.pdf>. Accessed on: July 25, 2015.

HUSKINS, Michael; VAN KUIKEN, Steve, and VELAMOOR, Sri. Applying lean IT to healthcare, **McKinsey**, December 2014, em PDF. Available on: <http://www.mckinsey.com/insights/business_technology/Applying_lean_IT_to_healthcare?cid=other-eml-alt-mipmck-oth-1501>. Accessed on: July 25, 2015.

IBOPE. CNI. Pesquisa. Retratos da sociedade brasileira: Saúde pública, de janeiro de 2012

ISPOR–International Society for Pharmaeconomics and Outcomes Research. Investigação de Desfechos de Dispositivos Diagnósticos e Terapêuticos. São Paulo, 2014.

KAYYALI, Basel; KNOTT, David and VAN KUIKEN, Steve. The big-data revolution in US health care: Accelerating value and innovation, McKinsey, April 2013, em PDF. Available on: <http://www.mckinsey.com/insights/health_systems_and_services/the_big-data_revolution_in_us_health_care>. Accessed on: July 25, 2015

MATIJASCIC, Milko. **Política social brasileira, conquistas e desafios.** Instituto de Pesquisa Econômica Aplicada IPEA, texto para discussão 2062, mar. 2015

MENDES, Eugênio Vilaça. As redes de atenção à saúde. Organização Pan-Americana da Saúde. Organização Mundial da Saúde. Conselho Nacional de Secretários de Saúde, Brasília, 2011.

NOMURA, Maria Carolina. Valor Setorial – Logística, **[Complexidade no atendimento, logística hospitalar requer conhecimento de toda a cadeia da área médica, com materiais e medicamentos entregues na hora certa]**. p. 48-50. março de 2015.

PWC. **Medical Technology Innovation Scorecard – The race for global leadership.** january 2011. Available on: <http://www.pwc.com/us/en/health-industries/health-researchinstitute/innovation-scorecard/>. Accessed on: July 25, 2015.

PWC. **Socio-economic impact of mHealth An assessment report for Brazil and Mexico**. june 2013. Available on: <http://www.pwc.com/mx/es/industrias/archivo/2013-06-socioeconomic-impact-of-mhealth-brazil-and-mexico.pdf>. Accessed on: July 25, 2015.

REHEM DE SOUZA, Renilson. O sistema público de saúde brasileiro. In: SEMINÁRIO INTERNACIONAL TENDÊNCIAS E DESAFIOS DOS SISTEMAS DE SAÚDE NAS AMÉRICAS, São Paulo, Brasil, 11 a 14 de agosto de 2002.

SILVA, H. P; PETRAMALE, C. A; ELIAS, F.T.S. Avanços e desafios da política de gestão de Tecnologias em saúde. **Rev. Saúde Pública**, São Paulo, v. 46, supl. 1, p. 83-90, dez. 2012. Available on: <http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0034-89102012000700001>. Accessed on: July 25, 2015.

SKINNER, Brett J. **Medical devices and healthcare costs in Canada and 65 other countries, 2006 to 2011**. Canadian Health Policy Institute (CHPI), Publication Date, may 9, 2013.

STIRLING, Bryan; CRAIG, Mitton and DONALDSON, Cam. Breaking the addiction to technology Adoption. **Health Economics**, v. 23, issue 4, p. 379-383, April 2014.

TORSEKAR, Mihir P. U.S. Medical Devices and China's Market: Opportunities and Obstacles. Washington, DC: Office of Industries Working Paper. U.S. International Trade Commission (USITC), nº ID-036, June 2014.

TRIBUNAL DE CONTAS DA UNIÃO – TCU. **Relatório Sistêmico de fiscalização da Saúde – FISCSAÚDE – TC 032.624/2013-1**, abril de 2014. Available on: <http://portal3.tcu.gov.br/portal/page/portal/TCU/imprensa/noticias/noticias_arquivos/032.624-2013-1%20Fisc%20Saude.pdf >. Accessed on: July 25, 2015.

UBL, Stephen and NEXON, David. How To Restore The Innovation Ecosystem For Medical Technology. **Blog Health affairs**, February 2015. Available on: <http://healthaffairs.org/blog/2015/02/10/how-to-restore-the-innovation-ecosystem-for-medical-technology/>. Accessed on: July 25, 2015.

WHO – World Health Organization. Development of medical device policies. WHO Medical device technical series. June 2011.

_____. **Medical devices: managing the mismatch: an outcome of the priority medical devices project.** 2010.