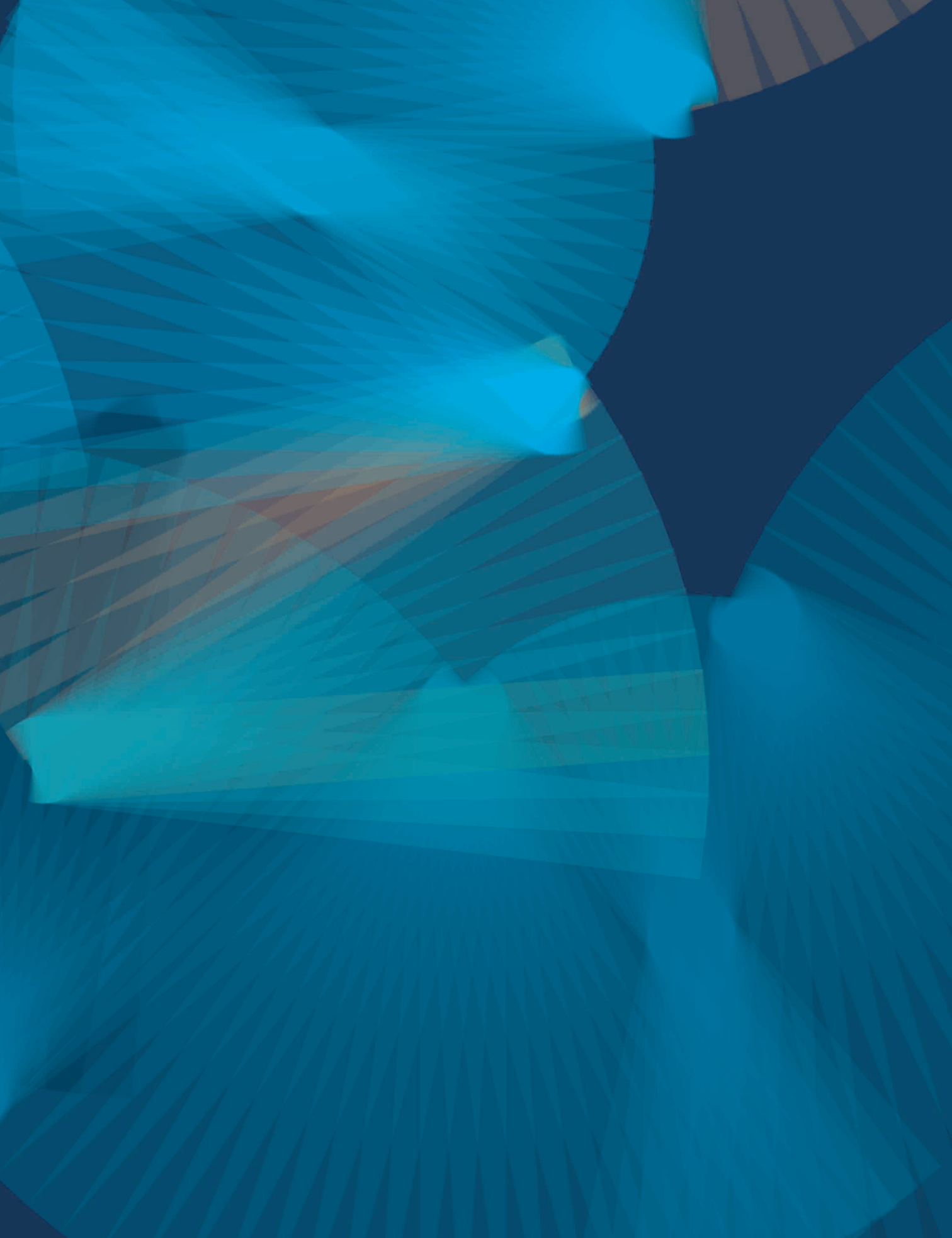
ABIIS | Aliança Brasileira da Indústria Inovadora em Saúde

CHALLENGES AND PROPOSALS FOR THE MEDICAL DEVICES SECTOR IN BRAZIL



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CHALLENGES AND PROPOSALS FOR THE MEDICAL DEVICES SECTOR IN BRAZIL

2021

ABIIS Staff

Achievement

Aliança Brasileira da Indústria Inovadora em Saúde (ABIIS)

Collaboration

DocPress Comunicação

Duplo Z Inteligência de Comunicação

Laika Design

WebSetorial Consultoria Econômica

Vero Verbo Serviços de Editoração

Acknowlegment

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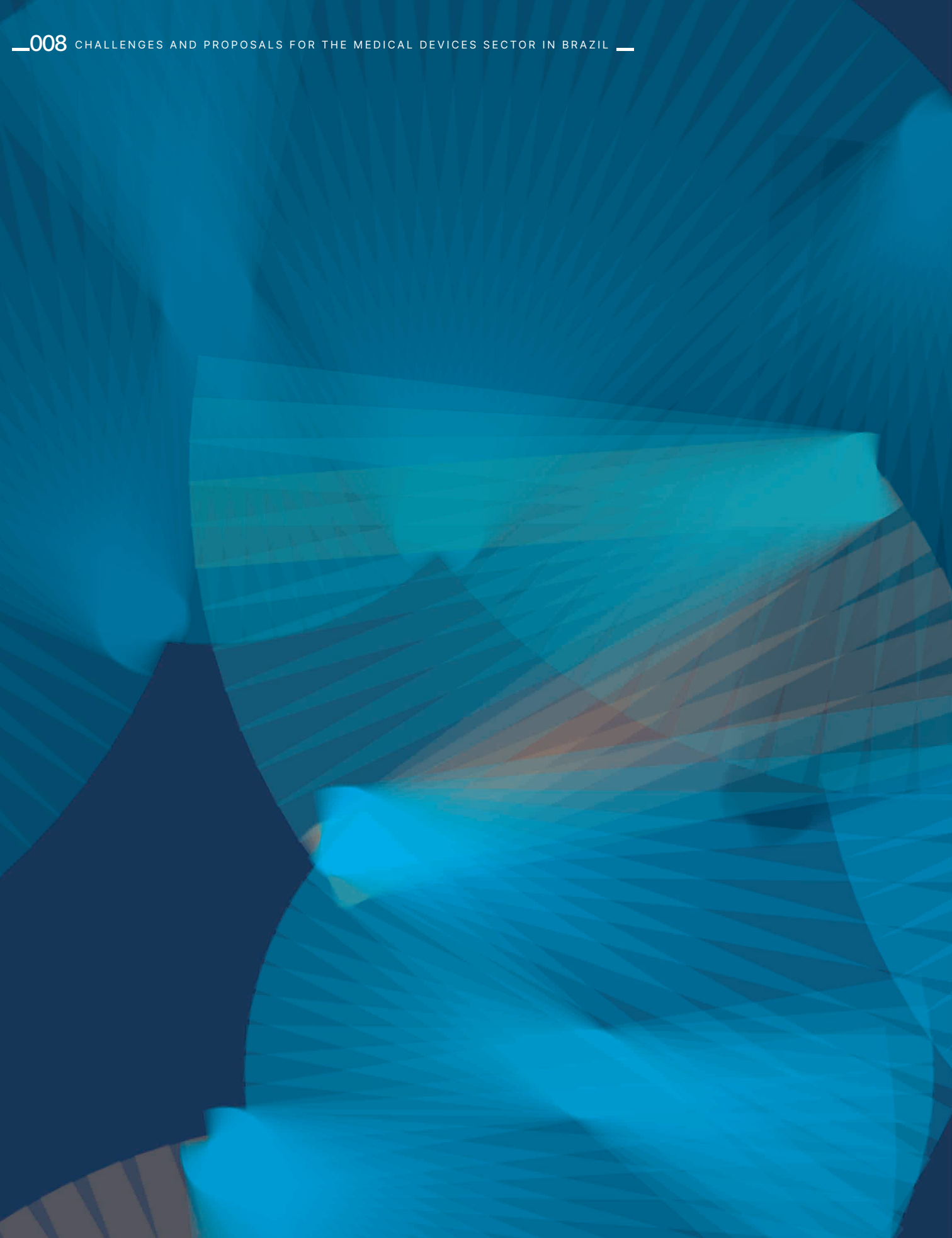

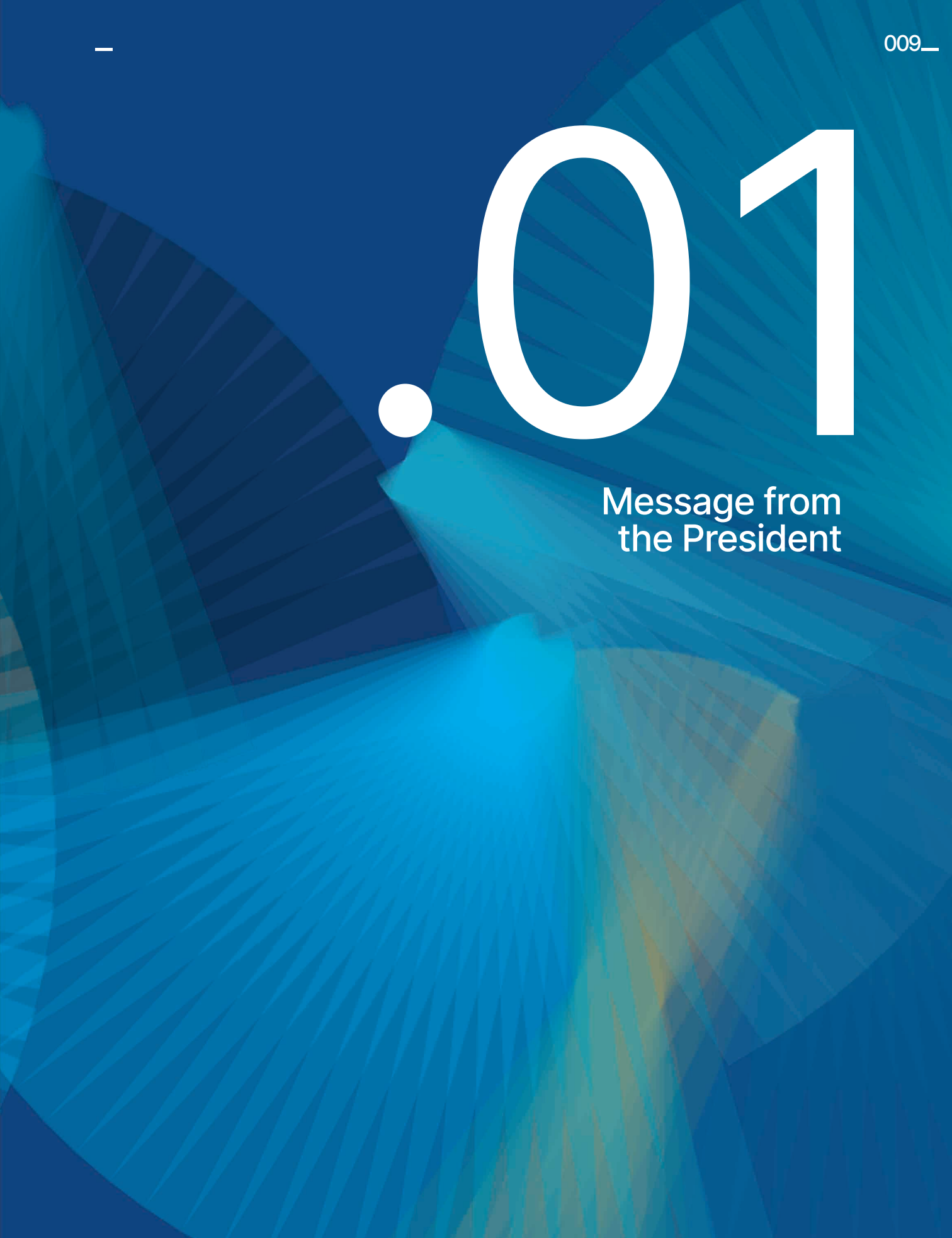

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Message from the President

Message from the President

This publication, Challenges and proposals for the device medical sector in Brazil, is launched at a particularly unusual moment in national and world life. We are living in a transition period. We are still suffering the effects of a pandemic that has profoundly affected the order of things, but which apparently is beginning to subside, although its behavior continues to bring us many uncertainties.

The importance of the health area has become exponential amid this panorama of challenges and uncertainties generated by Covid-19. The same happened with the medical devices (MD) sector – with its lab tests, respirators, ECMO (the artificial heart-lung machine widely used in severe cases of Covid-19), protective equipment, infusion pumps, and countless other intensive care and rehabilitation products – which has been working hard to fulfill its function and respond promptly to the urgency of the hour.

The aftermath of this turbulent period that began in March 2020 and still brings us many challenges, which add up to a complex set of structural problems that we were already facing in healthcare and, more specifically, in the medical devices sector.

However, amidst this still foggy scenario, we can see a light at the end of the tunnel. We are convinced that the worst is over, and this is a time to think about reconstruction, improvement, and renewal. It is the moment to discuss proposals that will help us to overcome the obstacles and move towards a more efficient, innovative, and sustainable healthcare system.

To this end, Aliança Brasileira da Indústria Inovadora em Saúde (Brazilian Alliance of Innovative Health Industry – ABIIS) has prepared **Challenges and proposals for the medical devices sector in Brazil** as a qualified contribution of the medical devices sector to the national public debate on health and specifically on this segment.

The pandemic has taught us many lessons. It helped us to better understand the importance of our role as manufacturers, importers and distributors of equipment, products, medical supplies and in vitro diagnostics that cover the entire spectrum

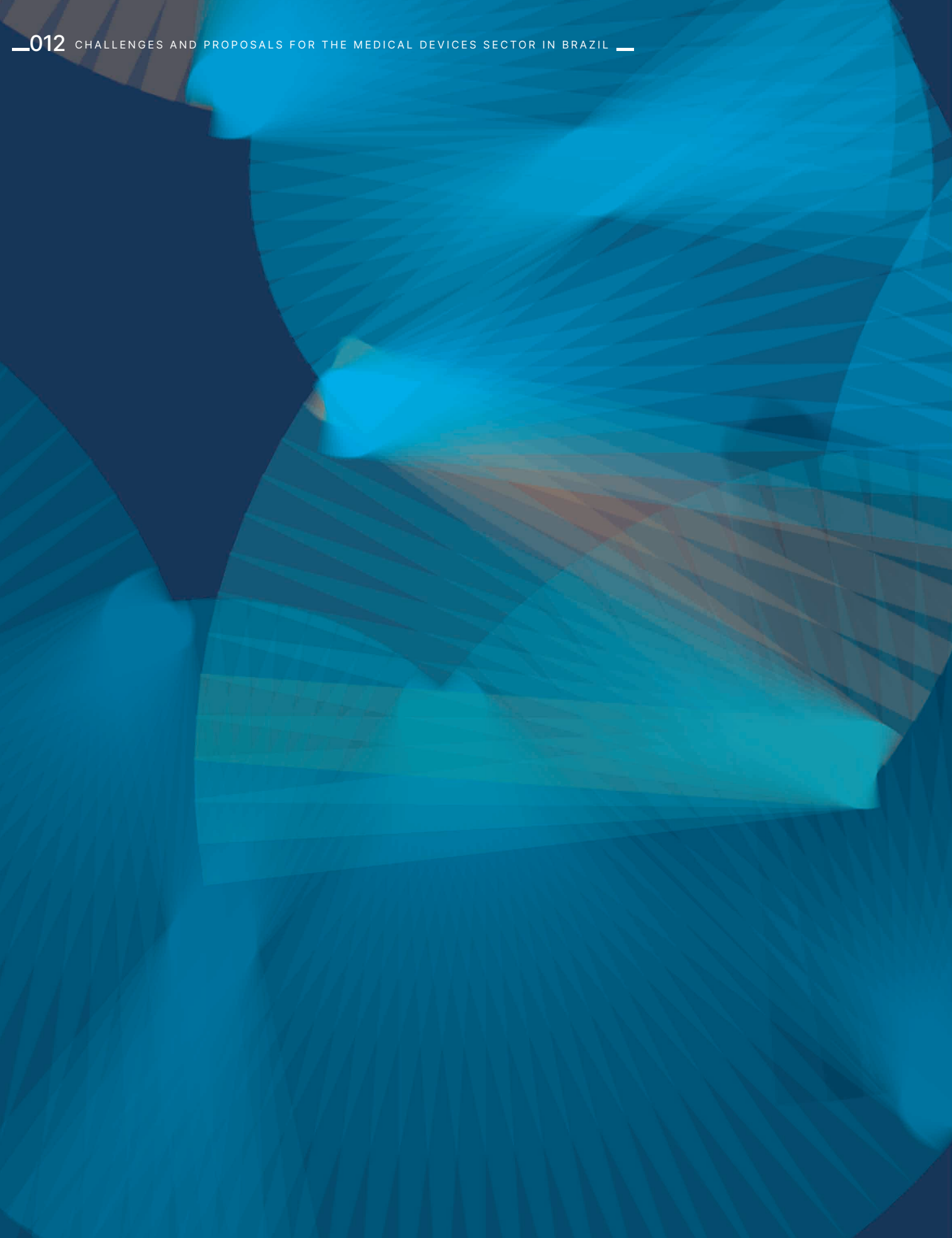
of human health. As an industry that invests heavily in technological advances and has research, development and innovation at its core. Relevant in the economy, that employs a highly qualified workforce and contributes to the continuous training of professionals in the sector, raising the level of health and the country.

The pandemic also showed us – in a painful way, many times – the need and relevance of Brazil being more inserted in global value chains in the health area, improving its insertion in the world and, internally, providing more effective responses to the health of the Brazilian population. To generate broader and more equal access to quality healthcare that does not exclude our population from the innovations that save and improve the lives of millions of people around the world.

The year 2022 is just around the corner and, with it, a political calendar and important decisions that will occupy the center of the national debate. For ABIIS, it will be another opportunity to present its contributions, ideas and proposals for the Brazilian health, so that the medical devices sector, which has had such a relevant participation in recent events, is indeed considered strategic, actively collaborating in the effort to boost Brazilian socioeconomic development.

Bruno Boldrin Bezerra

President of the Board of Directors



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Aliança Brasileira da Indústria Inovadora em Saúde (ABIIS)

Aliança Brasileira da Indústria Inovadora em Saúde (ABIIS)

The Aliança Brasileira da Indústria Inovadora em Saúde (Brazilian Alliance of Innovative Health Industry – ABIIS) brings together the medical devices sector in Brazil, which includes the national and international industry, importers and distributors of equipment, Orthotics, Prosthetics and Special Materials (OPSM), consumables, and the diagnostic tests (IVD) segment.

Created in 2011, the Alliance aims to produce and disseminate knowledge and formulate proposals so that the sector's social, economic and regulatory environment is appropriate to health innovation in Brazil.

By generating relevant content, data and information, ABIIS contributes to the development of public policies that increase the population's access to modern, effective and safe technologies, promote a broad and lasting sustainability for the health and society system.

As a practical example of its performance, the Alliance has maintained a technical cooperation agreement with the Brazilian Health Regulatory Agency (Anvisa) since August 2019. In addition, it has played a relevant role in discussions and propositions regarding the main topics that impact the medical devices (MD) sector, such as price regulation, technologies incorporation, ports, airports and borders issues, ethics and compliance, among others.

Health is one of the main themes of the contemporary world due to its importance, diversity and challenges, both sanitary – as Covid-19 has just shown – and economic. Nowadays, health managers, specialists and stakeholders from several countries, including Brazil, are looking for measures that balance the finiteness of financial resources with the growing demand for specialized and costly care, generated mainly by the aging of the world population. They also focus, in the health area, on ethical, philosophical and environmental issues inherent to the sector and which concern the general welfare of humanity.

The challenges are many and still growing, and ABIIS aims to be an active and responsible partner of the Brazilian government in the search for solutions that address the needs of the State and promote the best benefits for those who occupy the center of the health area: the patients.

MISSION

Develop and disseminate suggestions for public policies, legal traits and regulation, mobilizing public and private agents to make the Brazilian business environment increasingly attractive for investments in research, development, local production, and commercialization of innovative medical technologies.

OVERVIEW

To be the most relevant partner of the Brazilian government in the debate and implementation of public policies that guarantee and expand the population's access to innovative medical technologies, inducing national socioeconomic development.

PRINCIPLES

Ethics, loyalty, perseverance, efficiency and technical accuracy.

BACKGROUND

Discussions for the formation of an alliance that would bring together associations in the medical devices sector began in the second half of the 2000s. Considering that some entities already represented the various segments that make up the area – hospital equipment and supplies, in vitro diagnostics, and import and distribution of these products –, ABIIS has proposed to concentrate its activities on macro themes that were of transversal interest to all associations and represent them in important decision-making forums, such as the Ministry of Health and Anvisa.

On the agenda, there were issues that had not yet consistently entered the health debates, such as the differences between medical devices and medicines, and the innovation development ecosystem and its importance for patients and for Brazil. Themes that still need to be studied in the country and that, therefore, are part of the scope of this publication.

In 2011, ABIIS was formally established as a legal entity and, since then, it has sought to enrich the sector's discussions and subsidize the actions of the Federal Executive and Legislative branches, promoting forums and discussions, preparing studies and positionings, holding events and participating in national and international forums on MD and public policies.

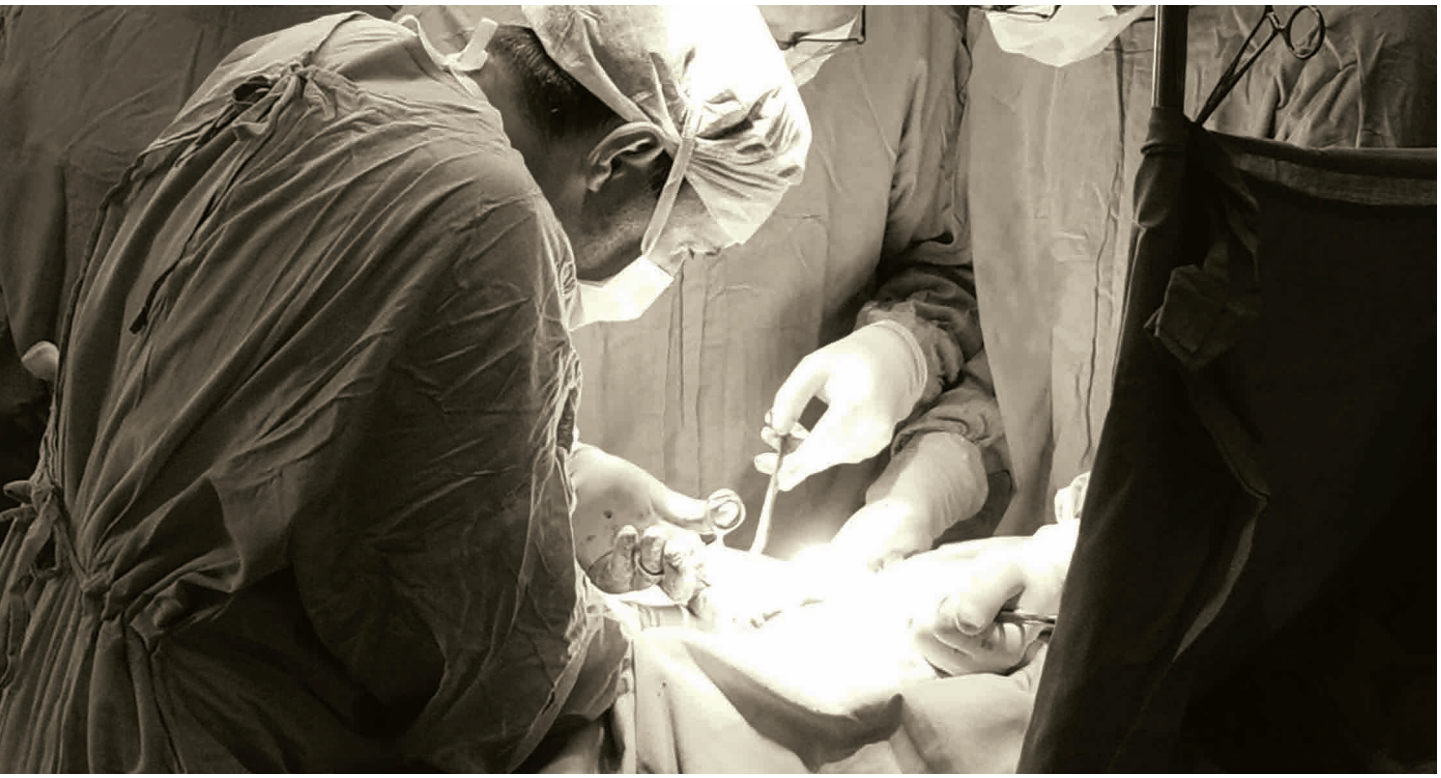
Who We Are

ABIIS is an alliance of class entities formed by the Associação Brasileira da Indústria de Importadores e Distribuidores de Produtos para Saúde (Brazilian Association of Importers and Distributors of Health Products – Abraidi), the Câmara Brasileira de Diagnóstico Laboratorial (Brazilian Chamber of Laboratory Diagnostics – CBDL) and the Advanced Medical Technology Association (AdvaMed), in the United States.

Abraidi is formed by 300 companies across the country that manufacture, import, and distribute products, equipment, medical and hospital materials, implantable devices, among other items used in health. The association maintains solid interaction with government agencies and other entities of the health sector. Founded in 1992, it is headquartered in São Paulo (SP).

CBDL represents the industries that operate in the in vitro diagnostics sector and has 35 members, including national and multinational companies. One of its main goals is to promote the exchange of information aimed at improving the technical fundamentals of the sector. It has worked together with entities in Brazil and abroad. Created in 1991, it is headquartered in São Paulo (SP).

AdvaMed is the largest association in the world's advanced medical technology industry. It has more than 400 members and maintains a global presence in countries throughout Europe, India, China, Brazil and Japan. It represents from the largest to the smallest innovative medical devices, diagnostic products, and digital medical technology companies. Founded in 1974, it is headquartered in Washington, DC (USA).



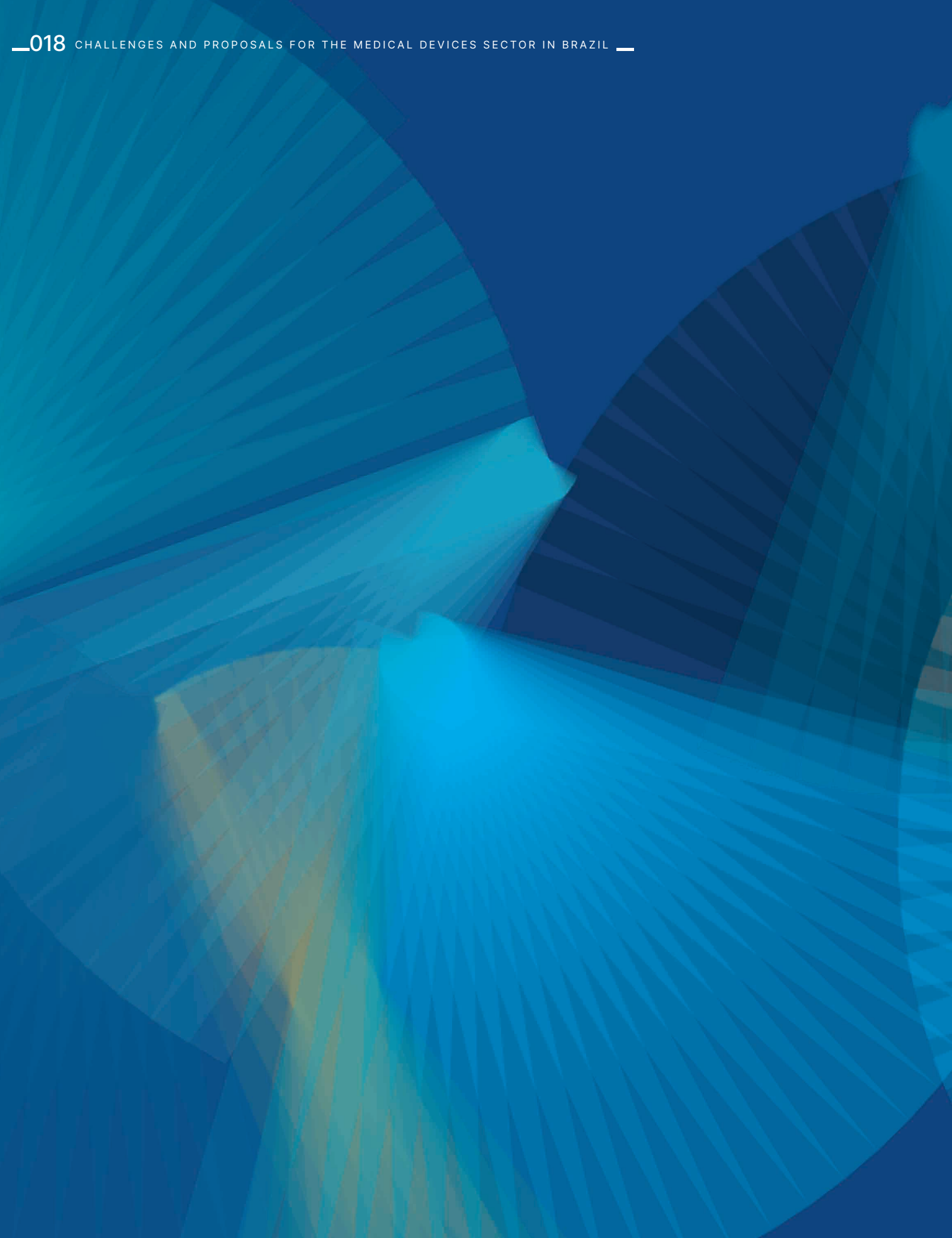
Representativeness

ABIIS is a member of the Executive Group of the Health Industrial Complex (Gecis), coordinated by the Ministry of Health, the Inter-American Coalition for Business Ethics in the Medical Devices Sector, and has a seat on the Advisory Board of the Instituto Ética Saúde (IES). It is also one of Brazil's representatives in the Inter-American Coalition for Regulatory Convergence of the Medical Technology Sector, which seeks to achieve regulatory convergence among member countries and implement good regulatory practices in the Americas.

In addition, the Alliance is a partner of the Global Medical Technology Alliance (GMTA), the Aliança Latino-Americana para o Desenvolvimento do Diagnóstico in Vitro (Latin American Alliance for the Development of In Vitro Diagnostics – ALADDiV) and the Gremio Latinoamericano de Dispositivos Médicos (Latin American Association of Medical Devices – Aldimed).

Working Group

ABIIS has the collaboration of a Working Group (WG), composed of several companies in the medical devices sector, which discusses regulatory, tax, access and public health policy issues. The WG works directly with the Alliance's board of directors, identifying and proposing issues that guide their decisions and actions, in addition to contributing to the preparation of propositions, data and positionings that are forwarded to the Executive and Legislative branches. WG participants are appointed by the associations that make up ABIIS.



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What Are Medical Devices (MD)?

What Are Medical Devices (MD)?

Medical devices are, according to Anvisa, all medical, dental and laboratory equipment, apparatus, material, article, system of use or application intended for the prevention, diagnosis, treatment, rehabilitation, and contraception of human beings. The Agency classifies them as "Health Products".

In Brazilian legislation, they also appear as "Correlated". That is, medical devices, health products and related products refer to the same category of products and to a market subject to sanitary surveillance and highly regulated – as indeed should be all products whose safety and efficacy directly impact the population health.

Brazil currently has about 70,000 valid registrations of MDs, including equipment, medical and hospital materials, implants, reagents, and other materials for in vitro diagnostics, according to Anvisa.

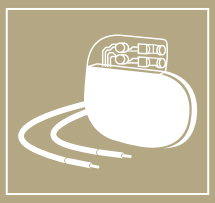
Globally, the World Health Organization (WHO) estimates that there are 2 million types of medical devices on the market, categorized into more than 7,000 different groups.

Not all countries include, like Brazil, in vitro diagnostic products in the medical devices category. In these locations, they are classified as a separate category.

Brazil currently has about 70,000 valid registrations of MDs, including equipment, medical and hospital materials, implants, reagents, and other materials for in vitro diagnostics, according to Anvisa.

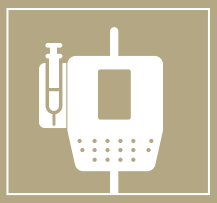
What does Medical Devices Mean?

It is a term used to encompass:

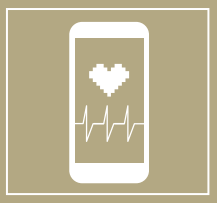


ORTHOSES, PROSTHESES AND SPECIAL MATERIALS

IN VITRO DIAGNOSTIC



MEDICAL EQUIPMENT



E-HEALTH

Medical devices are with you for life.

From birth

to the last moment.

It is estimated that there are 2 million medical devices in the world.

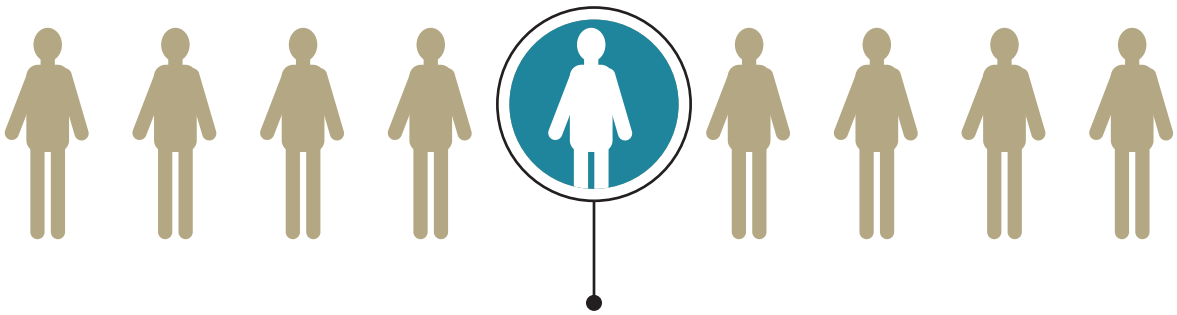
Benefits of Medical Devices (MD)

How can medical devices reduce healthcare costs?

MD limit the costs of caring for patients with chronic diseases

- EARLY DIAGNOSIS + MONITORING
- TREATMENT
- COST OF HOSPITALIZATION

MD limit the use of unnecessary and inefficient treatments, allowing for the personalization of care through prevention

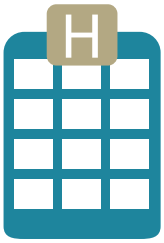


BY PERMITTING THE IDENTIFICATION OF RISKS OF A PATIENT HAVING A PARTICULAR DISEASE

MD limit the cost of treatment

MOST EFFECTIVE TREATMENT

SHORTER HOSPITALIZATION TIME



MD IMPROVE THE QUALITY OF HOSPITAL CARE

MD HELP DIRECTING CARE TOWARDS THE BEST COST--BENEFIT LOCATION

MD reduce treatment costs

HIGHER EFFICIENCY

LESS DUPLICATION

E-health

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

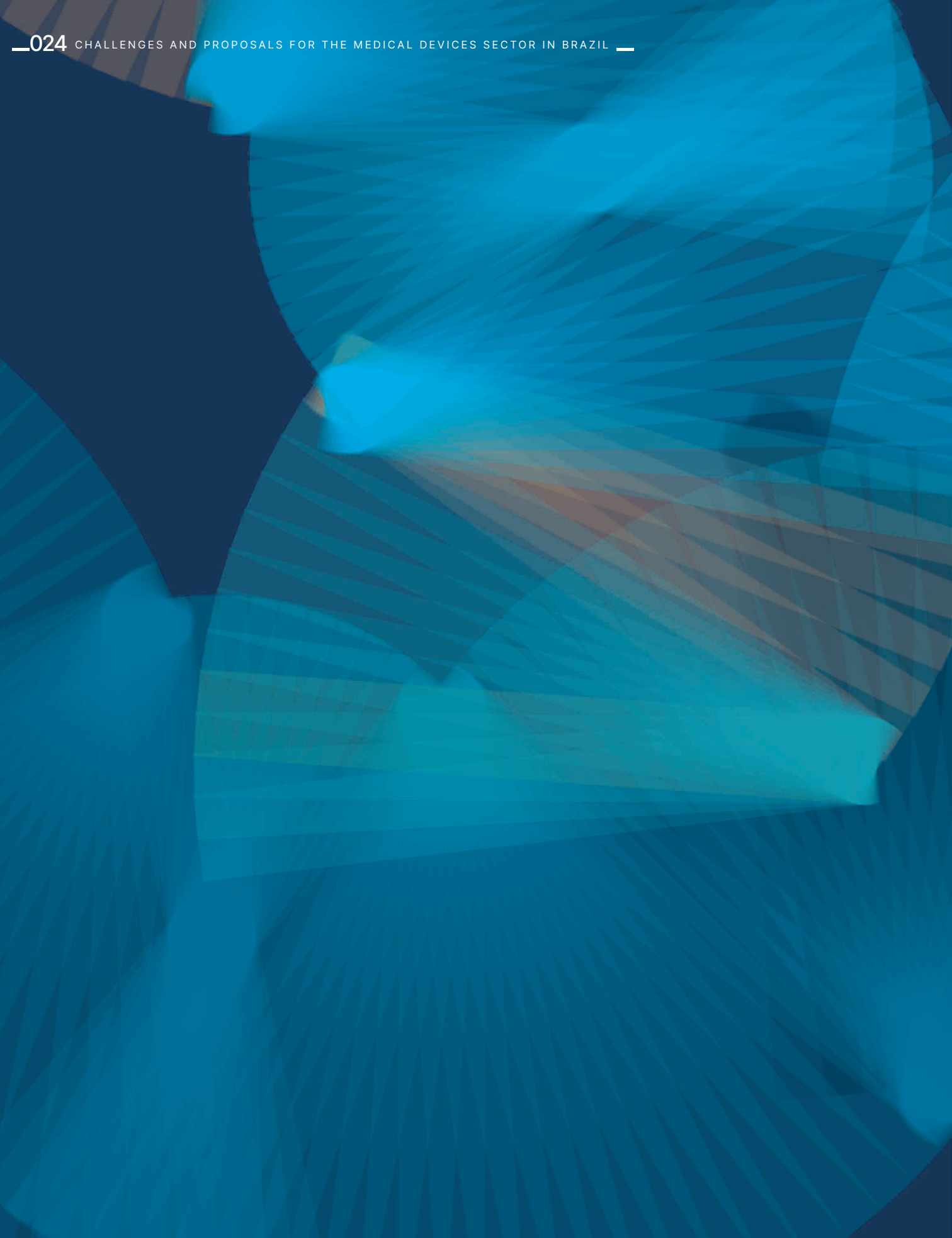
E-health will enable better management of the health system

E-health will also allow the integration of big data to identify the need for new product development + tracking + inventory control and replenishment + information maintenance.

What Is Big Data?

This term is used to describe large volumes of data and is becoming increasingly relevant as society faces an unprecedented increase in the number of information generated each day.

Source: Adapted by Websetorial from MedTech Europe. Available in: http://www.medtecheurope.org/publications/95/64/Infographic-The-MedTech-Industryin-Europe. Access on: Sept. 9, 2013.



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Differences between Medical Devices and Medicine

Differences between Medical Devices and Medicines

In the health sector, a mistaken view that equates medical devices (MD) with medicines has crystallized over time. Although the regulations that control these products clearly position them as two distinct categories, it still prevails – especially for public opinion, legislators, public policy makers, and technicians in charge of evaluating technologies for incorporation into the Brazilian Health System (SUS) – the perspective that these two universes are equivalent.

Excluding the fact that both medical devices and medicines are essential in promoting health and well-being of the population and subject to Sanitary Surveillance regulations, the similarities between the two groups of products end there.

The constant innovation that characterizes the medical devices industry makes new products available on the market on average every 18 to 24 months, the result of high investments and the combination of knowledge advances in several areas. It is a sector with a very fast cycle of technological development and that requires equivalent agility from regulators, managers and technicians, for example, in decision-making processes on the incorporation of new technologies in the public system and in supplementary health. Otherwise, there is a risk of creating a technological abyss between Brazilian patients and those in the rest of the world.

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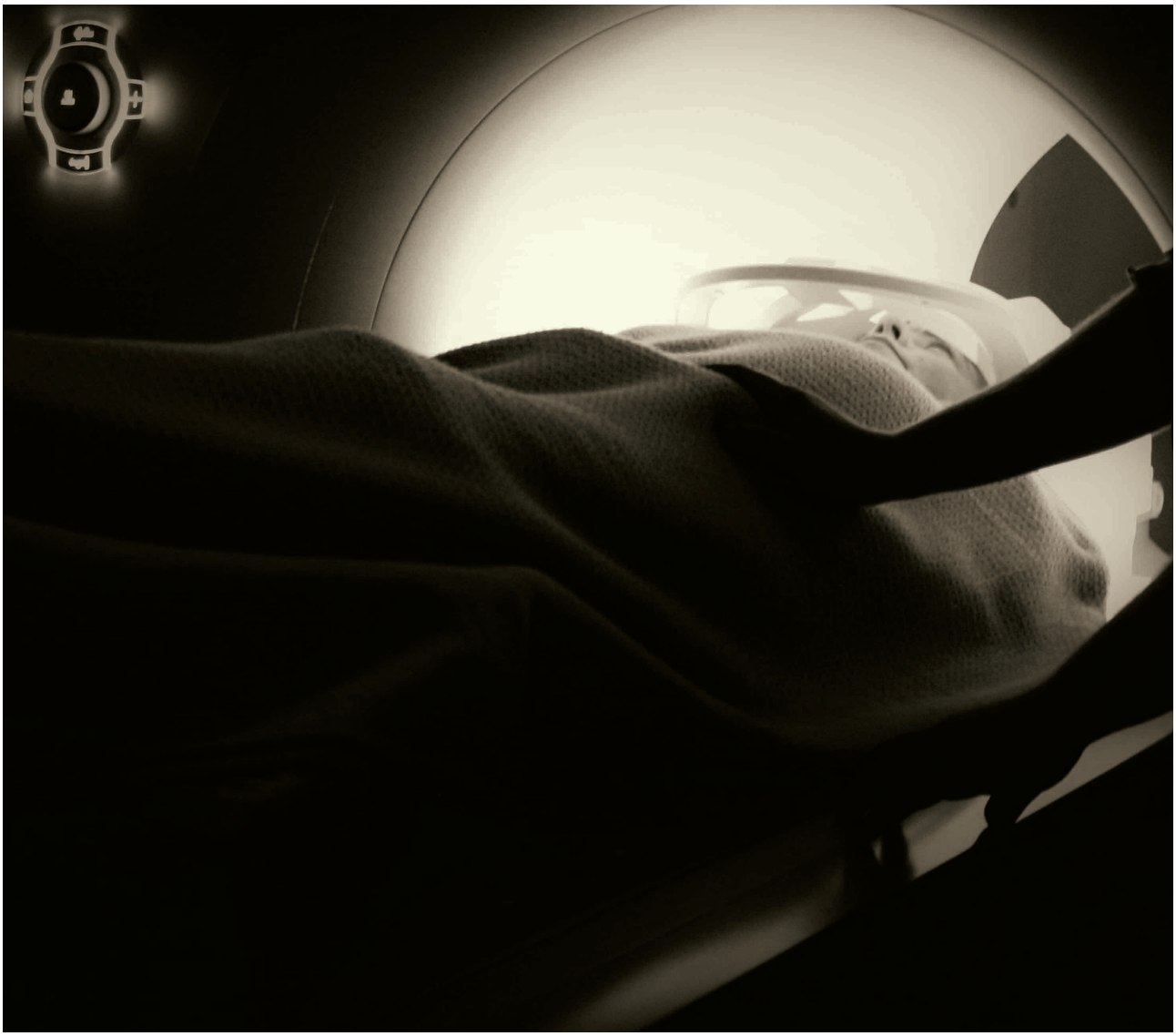
In the pharmaceutical industry, which is also experiencing a new era of technological development that is transforming the care and approach to treating patients, the innovation cycle – from the discovery process to the development of new drugs and medicines, through extensive clinical research and a series of projects that do not achieve the expected results – is much longer. The industry takes on average 10 to 15 years to launch and commercialize a new medicine, according to PhRMA, an association that represents the biopharmaceutical research industry in the United States.



Although they serve similar purposes, the entire process of innovation, development, handling and commercialization of medical devices and medicines is intrinsically different. It is the differences and peculiarities of each of these universes that make more than 2 million medical devices available globally, compared to around 20,000 medicines, according to WHO.

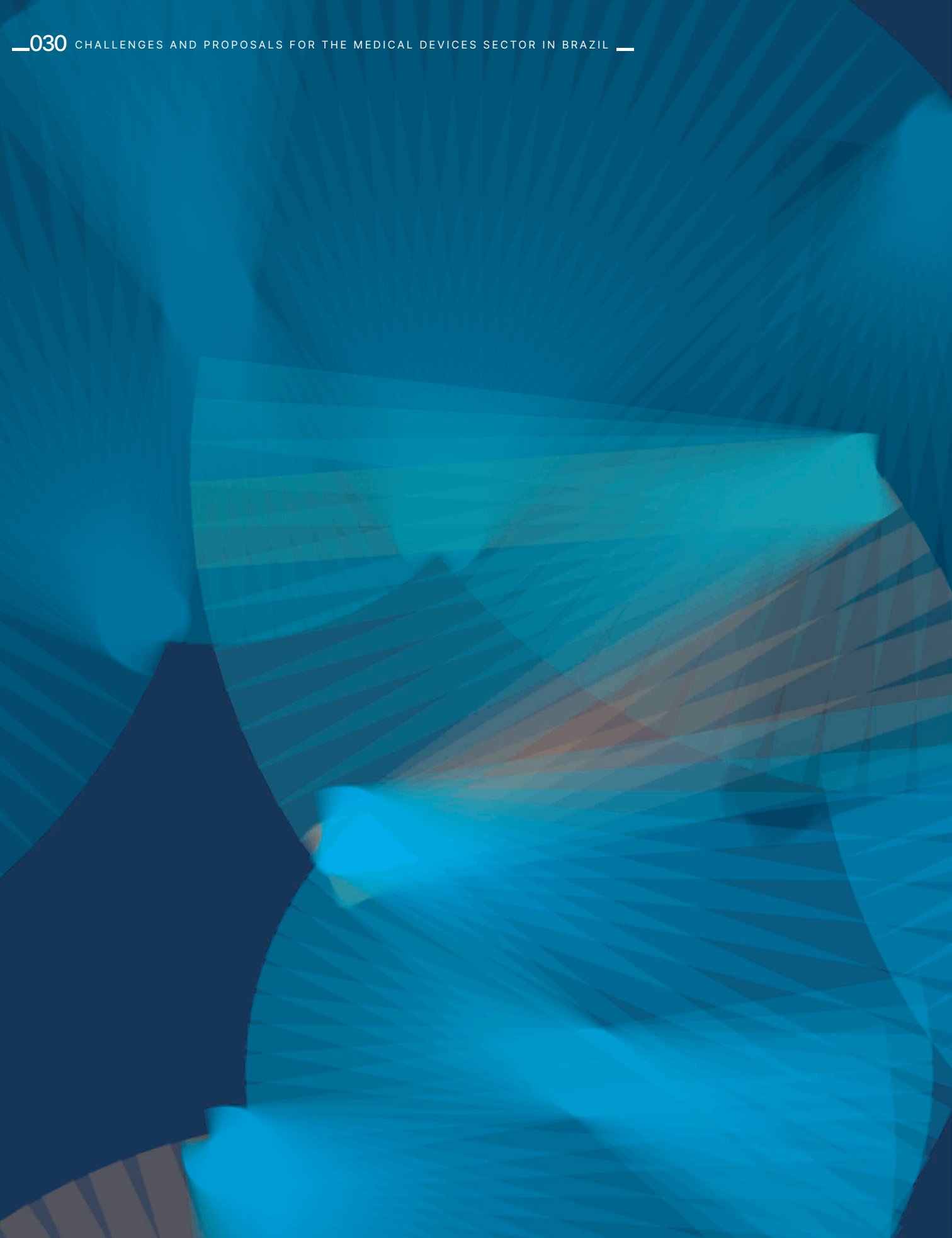
In the following tables, you can see some of the main differences between medical devices and medicines, and the industries in these two segments.

Differences between the Medical Devices and Medicine Industries

	MEDICAL DEVICES	MEDICINES
INDUSTRY COMPOSITION (INCLUDES IMPORTERS AND DISTRIBUTORS)	More than 80% are small and medium-sized companies. Relatively young industry, also formed by large manufacturers with global operations. General absence of patent protection for medical devices creates a very dynamic market with multiple competitors and rapid price erosion. Market forces themselves set fair and competitive prices.	Domain of large companies. Consolidated industry, formed by large multinational companies. Presence of patents for medicines.
SPECIFICITIES	Continuous innovation and interactive improvements based on new science, new technology, and new materials. Short product lifecycle and investment recovery (on average 2 years on the market). Lowest possible bond with patent. Data exclusivity is important. Most new products bring additional functions and clinical value based on incremental improvements.	Extensive research and development of a specific compound or molecule; it takes several years for a new medicine to enter the development and testing process. Intense patent protection, including data exclusivity and patent binding, necessary due to the long product lifecycle and long recovery period.
MAIN CONTRIBUTIONS	Large investment in production, distribution and training/education; it is often necessary to provide service and maintenance (for many high-tech devices).	Low production and distribution costs and, in most cases, training, service, and maintenance costs.

Differences between Medical Devices and Medicines

	MEDICAL DEVICES	MEDICINES
TECHNOLOGY CHARACTERISTICS	Generally based on mechanical, electrical and materials engineering.	Based on pharmacology and chemistry, including now biotechnology and genetic engineering. Pharmacological properties and action of active ingredients are known, based on preclinical and clinical studies. Standardized batch size, production process and raw materials. Product stability. Stored generally at room temperature and with a long shelf life.
PRODUCT DEVELOPMENT	Extensive range of products and applications – from thermometers and dressings to pacemakers and x-rays. Designed to perform specific functions and approved based on safety and performance. Many products are developed by doctors or nurses. Most act by interacting with the body or parts of the body.	Products usually in the form of pills, solutions, aerosols or ointments. Products developed through discovery, test, and approved based on safety and efficacy. Products developed in laboratories by chemists and pharmacologists. Products administered by mouth, skin, eyes, inhalation or injection and biologically activated; effective when absorbed by the human body. In general, they act systemically on the entire body.
USER TRAINING	Medical devices rely heavily on the skills and training of the operator (in many cases, surgeon or interventional physician). Medical devices require frequent service, professional education and, in some cases, technical assistance for their safe and proper use.	Medicines outcomes depend largely on the patient's response to therapy.
PATIENT OUTCOME	Medical devices are intended for professional use, increasing compliance. The outcome depends largely on the skills of the surgeon or interventional physician. Long period of interaction with the body, being able to be implanted for the rest of the patient's life.	Medicines are generally consumed by the patient (who can also choose to discontinue them). Responses depend largely on the patient. Short period of interaction with the patient's body.
PRODUCT DEVELOPMENT	Medical devices tend to be used in a wide range of indications and populations.	Medicines are primarily used to treat patients in specific, clinically indicated populations according to the product license.



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The Global Medical Devices Market

The Global Medical Devices Market

The medical devices market is one of the most dynamic in the global economy. It has a rapid innovation cycle – ranging from 18 to 24 months – and is characterized by continuous employment and training of a highly qualified workforce.

Although large companies hold the largest share of the global market for MD, more than 80% of the sector is composed of medium and small-sized companies, which generally employ less than 50 persons, according to SelectUSA, an American entity that works with foreign trade investments and services. Besides this characteristic was initially observed in the United States, the pattern is repeated practically all over the world, including Brazil.

The United States is the largest global market for medical devices and represents, in terms of revenue, more than 40% of the total, according to SelectUSA. Next appear, in descending order, Germany, Japan, China, France and the United Kingdom. North America and Europe together control about 70% of the global MD supply chain.

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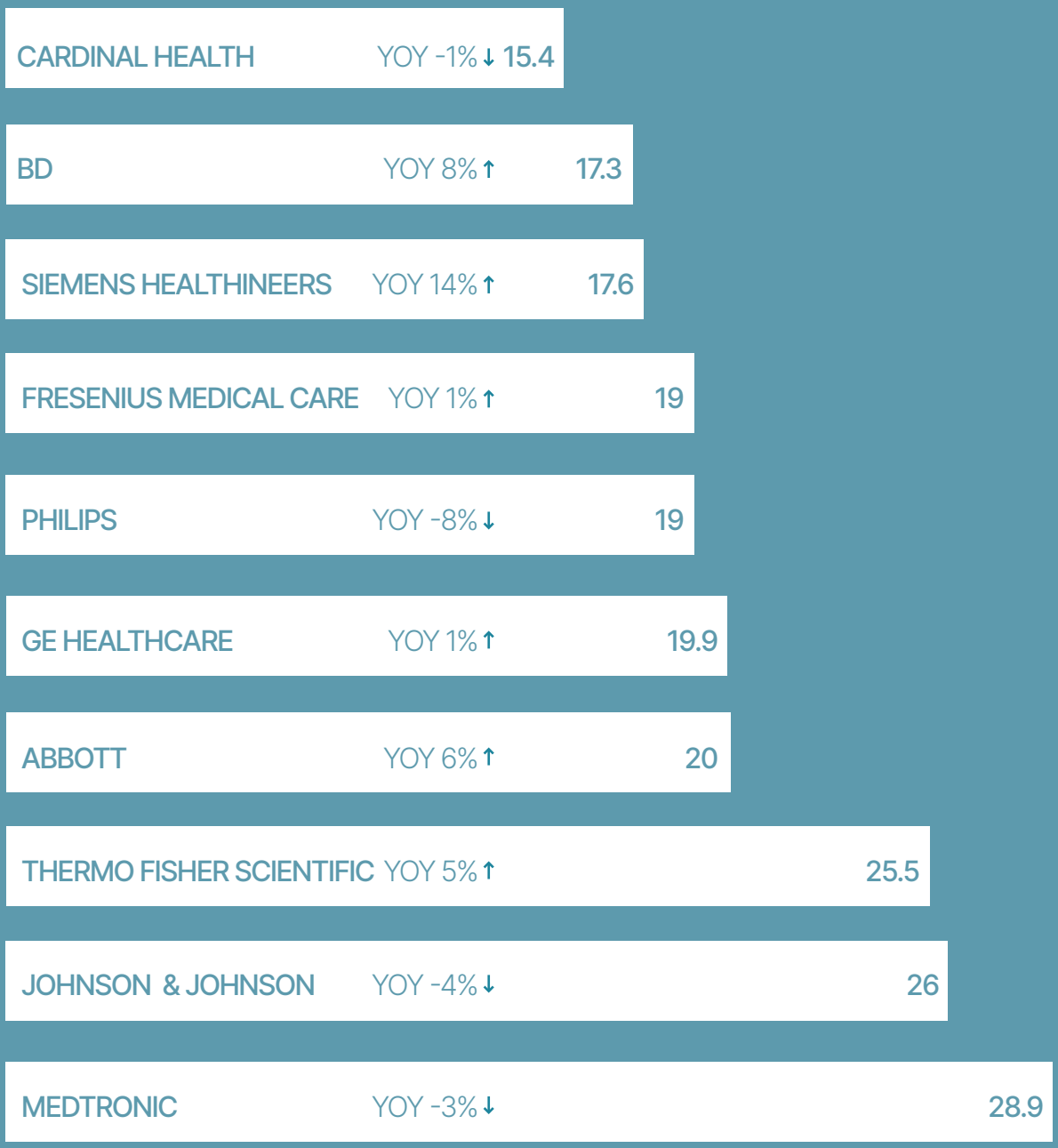
According to Proclinical,[1] the 10 largest global MD companies concerning revenue in 2020 are:

CHART 01

Total Revenue from the Medical Devices Segment
In US$ billion



YOY = year over year

[1] BURKE, Hannah. Who are the top 10 medical device companies in the world? **Proclinical,** Sept. 9, 2020. Available at: https://www.proclinical.com/blogs/2020-9/who-are-the-top-10-medical-device-companies-in-the-world. Access on: July 29, 2021.

HIGH TECHNOLOGY AND INNOVATION

Among the main characteristics of the MD sector are the production and use of advanced technology, large investments in research and development, and an ecosystem of constant innovation and improvement of existing technologies.

According to SelectUSA, R&D disbursements represent, on average, 7% of the MD companies' revenue – a higher percentage than that invested by other industries that also depend on technology, such as automotive, defense and telecommunications.

MARKET TRENDS

The *Medical Devices 2030*,[2] carried out by KPMG, states that the MD sector is in transformation. It has maintained sustainable growth in recent years and is expected to expand at around 5% annually through 2030. This projection is based on the increased demand for innovative devices, such as wearables, and services, as lifestyle-related chronic diseases – such as diabetes and hypertension – become more prevalent.

At the same time, the study points out that this growth perspective coexists with a brake on expansion: the need for governments around the world to reduce the rising healthcare costs and achieve, with the same resources, greater efficiency and better outcomes. This background is driving profound changes in the industry. In addition to transforming the value chain, these changes must impact the current healthcare model itself.

NEW BUSINESS MODELS

KPMG states that the traditional MD industry business model based on manufacturing a product sold through a distributor to healthcare providers is no longer sustainable and does not meet the demand. The entry of new players in this market, such as information technology companies, has changed the composition of forces and added new challenges to the traditional industry.

Considering this scenario, in recent years, these companies have started to reshape their business and operate models that add intelligence and service provision to the product. This strategy, which is beginning to consolidate, is part of this process and, at the same time, makes broader modifications that should change the profile of healthcare practiced in the country.

Among the new paradigms, the study points out a greater focus on prevention and a payment system based on the results achieved with the patient, instead of reimbursement for the volume of procedures performed. Called Value Based Healthcare, this concept, already implemented in some countries, is starting to be debated in Brazil, where some specific projects are being tested.

Another point in the value chain reconfiguration process in the MD market includes strengthening the current business-to-business (B2B) relationship and establishing a direct connection with companies and patients and consumers (B2C), which should reduce hospitals visits and lower healthcare costs, according to the study, in specific cases.

In some ways, the Covid-19 pandemic has contributed to accelerating this trend, as we will see in the next page.

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[2] HEUVEL, Roger van den *et al*. Medical devices 2030: making a power play to avoid the commodity trap. **KPMG International**, 2018. Available at: https://advisory.kpmg.us/articles/2018/medical-devices-2030.html. Acesso em: July 29, 2021.

COVID-19

Impacts

In 2020, the global MD market – as well as the Brazilian market – was heavily impacted by the Covid-19 pandemic. The global retraction was 3.2%, from a revenue of US$ 456.9 billion in 2019 to US$ 442.5 billion last year, according to GlobeNewswire.

The cancellation of elective procedures and surgeries and the restriction on movement of people and goods around the world contributed to the drop on revenue. This situation compromised the supply chain in the medical devices industry and the end-products market, causing shortages of some items. This is what happened, for example, with personal protective equipment (PPE) at the beginning of the pandemic, when China, the world's largest producer, closed its factories.

At the same time, there was a significant increase in the demand for and manufacture of products aimed at tackling Covid-19, such as PPE, clothing and other types of disposables, as well as respirators. Even so, the expansion of sales in these segments was not enough to avoid a negative result for the sector in most countries.

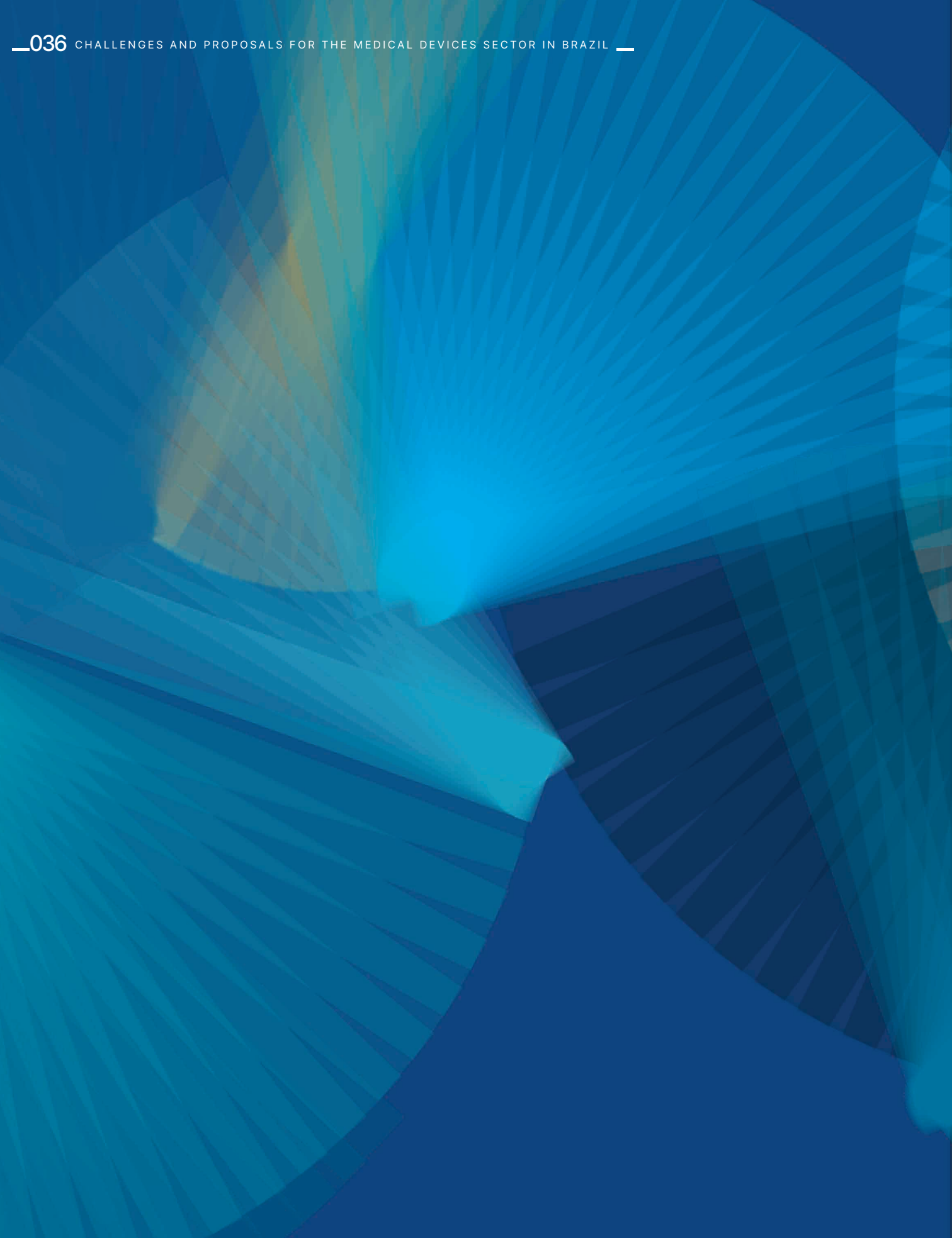
Nevertheless, GlobeNewswire understands that this is a momentary issue and bets on a global market recovery as of 2021. It expects sustainable growth over the decade and projects a result of US$ 603.5 billion in 2031.

New Technologies and Usage

The pandemic produced a redirection of MDs, expanding the usage of products for personal or remote use, given the need to diagnose, treat and monitor patients without human contact to prevent contamination by Covid-19.

Previously products were primarily developed for use in hospitals, clinics and laboratories, but in the last year the use of apps and technologies, such as electronic medical records, teleconsultation and wearables, has grown, enabling healthcare professionals to treat their patients remotely at the hospital or at home, supporting home care.

This change of axis also occurred in Brazil.



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The National Medical Devices Market

The National Medical Devices Market

The national DM market has peculiarities that influence the business dynamics and distinguish it from other sectors. Such as the long payment cycle, which can last 4 months on average, from delivery of the product to actual receipt.[3] Another specificity is related to the fact that, besides the supply of products, in some cases there is also the provision of services, training, delivery of additional material on consignment, and even equipment lending. This happens because quite often a health professional can only decide on the products that will be used at the time of surgery.

Due to its innovative and technological profile, the sector also requires highly specialized and continuously trained workforce to develop and use the advanced technologies that are part of the segment.

In 2020, the 15,700 companies operating in the MD sector employed around 145,000 workers – which represents more than the sum of workers hired by France, Spain and Sweden in this sector. It is a highly specialized workforce in continuous training, which contributes to raising the level of Brazilian human resources.

Although the medical devices industry is highly innovative and technological, most of the R&D activity in the sector is still carried out outside Brazil. The ratio between expenditure on internal R&D activities and net sales revenue of local MD companies was 1% in 2017, the last date of the Industrial Technological Innovation Survey (Pintec), produced by IBGE.

[3] **Anuário Abraidi 2021:** o ciclo de fornecimento de produtos para saúde no Brasil, 110.

A set of structural factors in the country possibly contribute to this scenario, such as the absence of a robust policy to encourage innovation and the lack of coordination among government, industry and universities.

EXTERNAL MARKET

Historically, imports surpass exports in the Brazilian MD market. This behavior was also repeated in 2020, when imports totaled US$ 6.3 billion – about eight times the amount achieved by exports.

China (23% of imports), United States (17%) and Germany (13.7%) form the bloc of main countries of origin of Brazilian MD imports. Purchases from China tripled from 2019 to 2020, possibly due to the Covid-19 pandemic and the purchase of protection products and laboratory tests. Immunological products, reagents and false tissue artifacts were the most imported products by Brazil last year.

Exports are destined mainly to the United States. Among European countries, Switzerland and Belgium buy from Brazil. It is interesting to note that the top ten countries to which Brazil exports, six are from Latin America: Argentina (the second destination for Brazilian exports), Paraguay, Mexico, Chile, Colombia and Peru, according to the Comex Stat, which concentrates the Brazil's foreign trade statistics. Diagnostic or laboratory reagents, heart valves and suture threads were the most exported products in Brazil in 2020.

COVID-19 AND THE INTERNAL MARKET

The national medical devices consumer market is made up of more than 320,000 healthcare service providers, including hospitals, clinics and laboratories in the public, philanthropic and private networks, in addition to home care companies.

It is a large and vigorous market, but it was heavily impacted by Covid-19. In 2020, the industry's revenue shrank by 1.5% – a smaller drop than the 3.2% retraction registered by the global MD market. However, a closer analysis of the indicators reveals that national production was the area most affected by the pandemic, showing a 22% decline compared to 2019.

The retraction in national production of MDs was about five times greater than that presented by other sectors and by the Brazilian manufacturing industry, which shrank by 4.6% last year. The main cause was the same one that disrupted the global market: the cancellation of surgeries and elective procedures, reducing the demand for implants, equipment, materials and supplies for medical and hospital use.

In 2020, the number of hospitalizations carried out by SUS decreased 20.5% compared to 2019. About 462,000 persons were hospitalized for Covid-19 treatment, but even so the sector registered a drop in procedures and a decrease in the rate of surgeries.

Last year, 3.7 million surgeries were performed by SUS, 25.9% less than in 2019, when nearly 5 million surgical procedures were performed. The performance of clinical examinations by SUS also dropped 21.2% in the period.

PERSPECTIVES

Despite the challenges, ABIIS expects a recovery of the sector in 2021, but believes it will be modest. This perspective is based on the gradual resumption of consultations, procedures and surgeries, and on the advancement of Covid-19 vaccination in the country.

PROFILE OF SECTOR'S COMPANIES

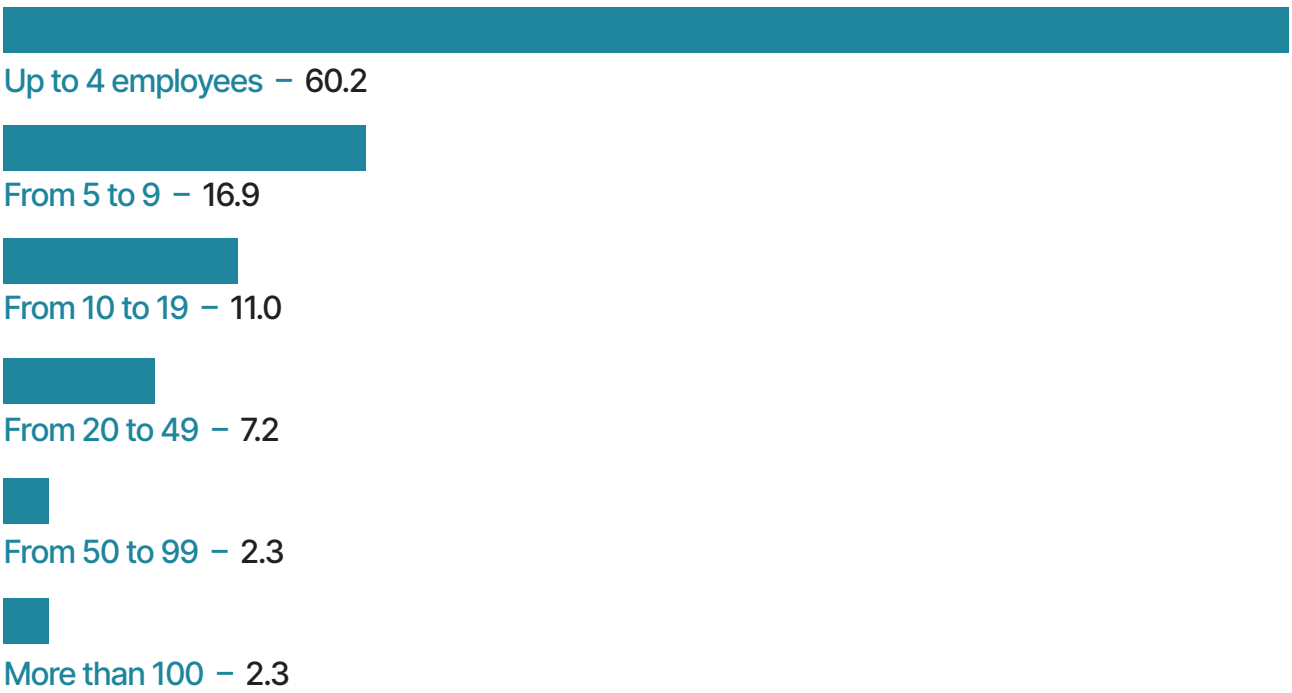
There are 4,596 industrial medical technology companies in Brazil and 11,167 that operate in the distribution and commercialization of these products.[4] Small-sized companies (SMEs) represent 88% of industrial companies and 94% of Brazilian medical devices distributors, and most of them employ less than 20 people (small and micro-sized enterprises).

CHART 02

CHART 02

Brazil: Distribution of Industrial Companies in the Medical Devices Sector, by Size

In percentage, by employee number range



Source: RAIS (2019).

[4] RAIS (MTE).

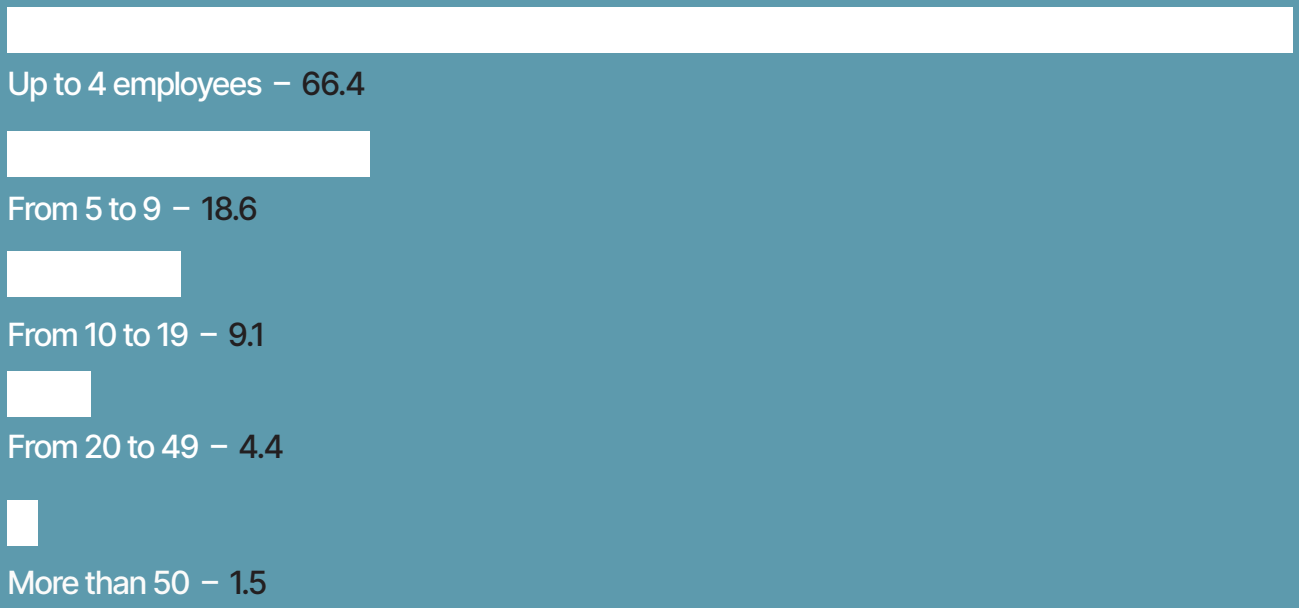
JOB GENERATION

The Brazilian medical technology industry directly employs 67,000 people and the commerce, that is the product distributors, employs 77,500 workers, which represents the generation of 144,500 direct jobs. CHART 03

CHART 03

Brazil: Distribution of Commercial Companies in the Medical Devices Sector, by Size

In percentage, by employee number range

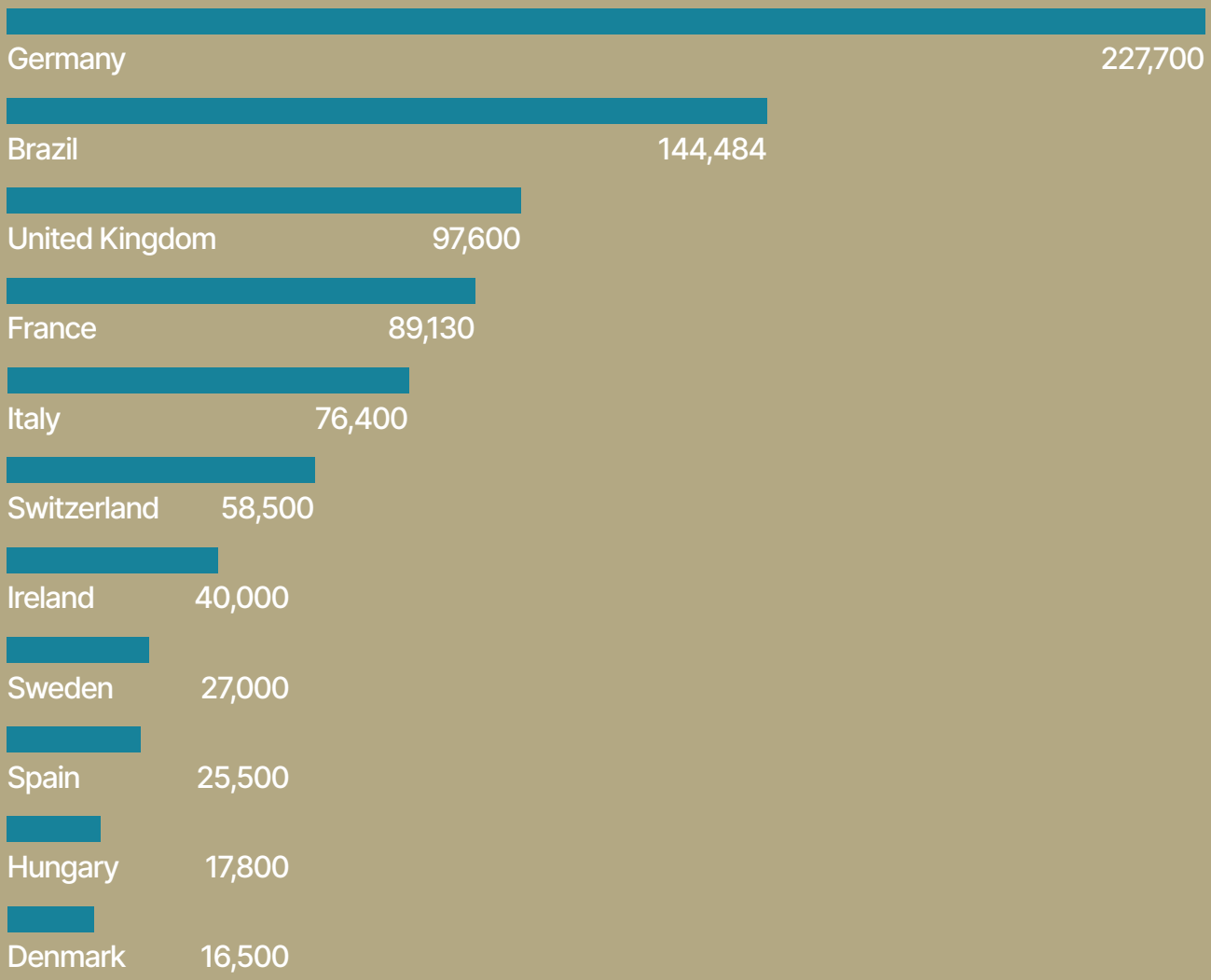


Source: RAIS (2019).

CHART 04

Direct Employment in the Medical Devices Sector in Compared Countries and in Brazil[5]

In number of employees



Source: RAIS (2019) e MedTech Europe.

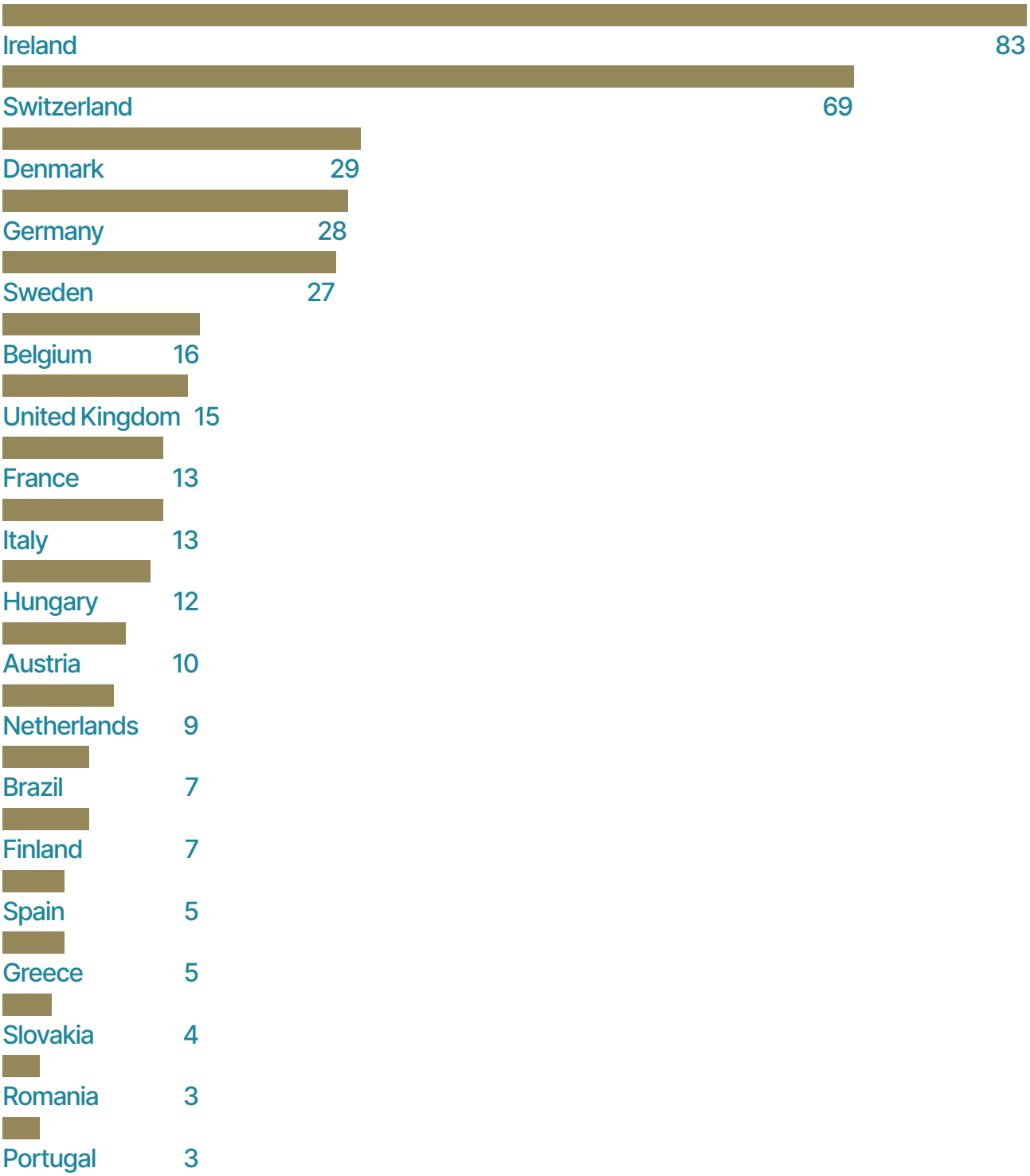
The employment of people dedicated to the activity of manufacturing and distributing medical devices per capita is 7 per 10,000 inhabitants, a figure like that of Finland, according to MedTech Europe, the representative entity of the sector in Europe. CHART 05

[5] Source: MEDTECH EUROPE. *The European Medical Technology Industry*: in figures 2020. p. 18 e 19. Available at: https://www.medtecheurope.org/wp-content/uploads/2020/05/The-European-Medical-Technology-Industry-in-figures-2020.pdf. Access on: July 29, 2021. RAIS/MINISTÉRIO DO TRABALHO E EMPREGO

CHART 05

Direct Employment in the Medical Devices Sector in Compared Countries and in Brazil

In number of employees per 10,000 inhabitants



Source: RAIS (2019) e MedTech Europe.

TECHNOLOGY INVESTMENTS

- Medical technology is characterized by a constant flow of innovations, which are the result of a high level of research and development in the industry and close cooperation with users. The global average rate of R&D investment (R&D spending as a percentage of sales) is estimated to be around 8% in the medical technology sector.[6]

- In Brazil, the ratio between the expenditure of industrial medical devices companies on internal research and development activities, and net sales revenue was 1.0% in 2017, according to the Pintec, produced by IBGE.

- Products generally have a lifecycle of only 18 to 24 months and need to be constantly improved.

LOCAL PRODUCTION

- The national production of medical devices, materials and support equipment in Brazil **decreased 22%** in 2020, compared to 2019, reaching the value of **R$ 11.5 billion or US$ 5.7 billion** at the Purchasing Power Parity (PPP) exchange rate.[7]

- It is important to emphasize that for the conversion of the health sector data it is conventional to use the PPP exchange rate. Using this conversion rate facilitates international comparisons by minimizing distortions caused by different exchange rates, living costs and incomes of a country's population.

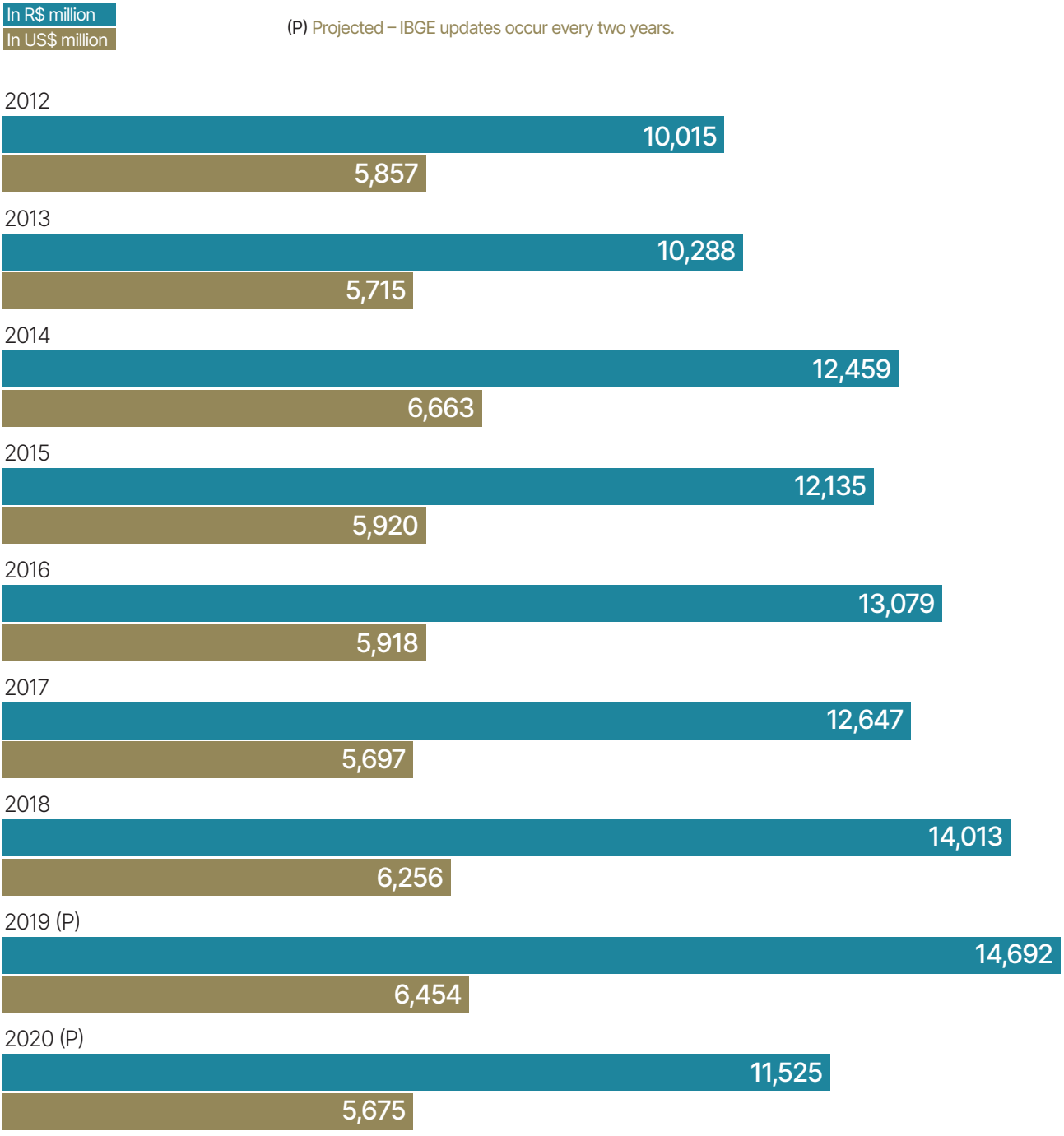
[6] Source: Pesquisa Industrial de Inovação Tecnológica (Pintec), by IBGE and MedTech Europe. p. 13. Available at: https://www.medtecheurope.org/wp-content/uploads/2020/05/The-European-Medical-Technology-Industry-in-figures-2020.pdf. Access on: July 29, 2021.

[7] R$/US$ = 2.37 in December 2020.

CHART 06

Brazilian Production of Medical Devices[8]

In R$ million and in US$ million



Source: IBGE/PIA Produto 2018.

[8] In 2020, due to the PIA 2018 update, the values of production were revised.

CUSTOMER PROFILE

The Brazilian domestic consumer market for medical devices is very strong, as it comprises 323,000 establishments providing healthcare services, distributed among the public, philanthropic and private networks, in addition to healthcare plan operators.

The number of hospital beds is 356,500 in the public network and 176,000 in other establishments in the non-public network.

TABLE 01

Number of Health Service Establishments – Brazil – December 2020

In unit

	SUS	NON-SUS	TOTAL
HOSPITALS (SPECIALIZED, GENERAL AND DAY HOSPITALS)	2,706	2,499	5,205
SPECIALIZED CLINICS/AMBULATORIES	5,511	41,311	46,822
OFFICES	866	154,074	154,940
HOME CARE	47	829	876
DIAGNOSTIC AND THERAPEUTIC SUPPORT SERVICE	1,941	23,737	25,678
POLYCLINIC	1,602	7,395	8,997
GENERAL EMERGENCY SERVICES	1,213	105	1,318
GENERAL AND SPECIALIZED EMERGENCY SERVICES	273	95	368
CENTRO DE ATENÇÃO PSICOSSOCIAL (PSYCHOSOCIAL CARE CENTER – Caps)	3,117	1	3,118
OTHERS	70,753	5,043	75,796
TOTAL	88,029	235,089	323,118

Source: CNES Datasus 2020.

TABLE 02

Number of Hospital Beds – Brazil – December 2020
In unit

	SUS	NON-SUS
TOTAL BEDS	313,038	134,766
SURGICAL	71,230	40,940
CLINICAL	38,466	48,042
OBSTETRIC	129,416	12,700
PEDIATRIC	37,535	10,056
OTHER SPECIALTIES	31,388	16,708
HOSPITAL/DAY	5,003	6,320
TOTAL OF SUPPLEMENTARY BEDS	43,427	41,414
ADULT ICU II COVID-19	8,988	10,871
PEDIATRIC ICU II COVID-19	84	595
INTERMEDIATE CARE UNIT	5,922	3,563
NEONATAL INTERMEDIATE CARE UNIT	311	19
ISOLATION UNIT	4,606	1,458
ADULT ICU	15,418	17,264
PEDIATRIC ICU	2,711	2,301
NEONATAL ICU	4,895	4,463
ICU SPECIALIZED IN BURN PATIENT	158	73
CARDIAC ICU TYPE II (CICU)	334	807
GRAND TOTAL	356,465	176,180

Source: CNES Datasus 2020.

THE BRAZILIAN MARKET SIZE AND COMPOSITION

The Brazilian market, evaluated by the apparent consumption of implantable medical devices, materials and support equipment, including products for in vitro diagnosis (IVD) – calculated by the sum of national production and imports, minus exports, is estimated at **US$ 11,2 billion** and represents about 3% of the global market, which invoiced **US$ 442.5 billion**[9] in 2020. The Brazilian segment showed a decrease of 1.5% in 2020, compared to 2019, due to the cancellation of elective procedures caused by Covid-19.

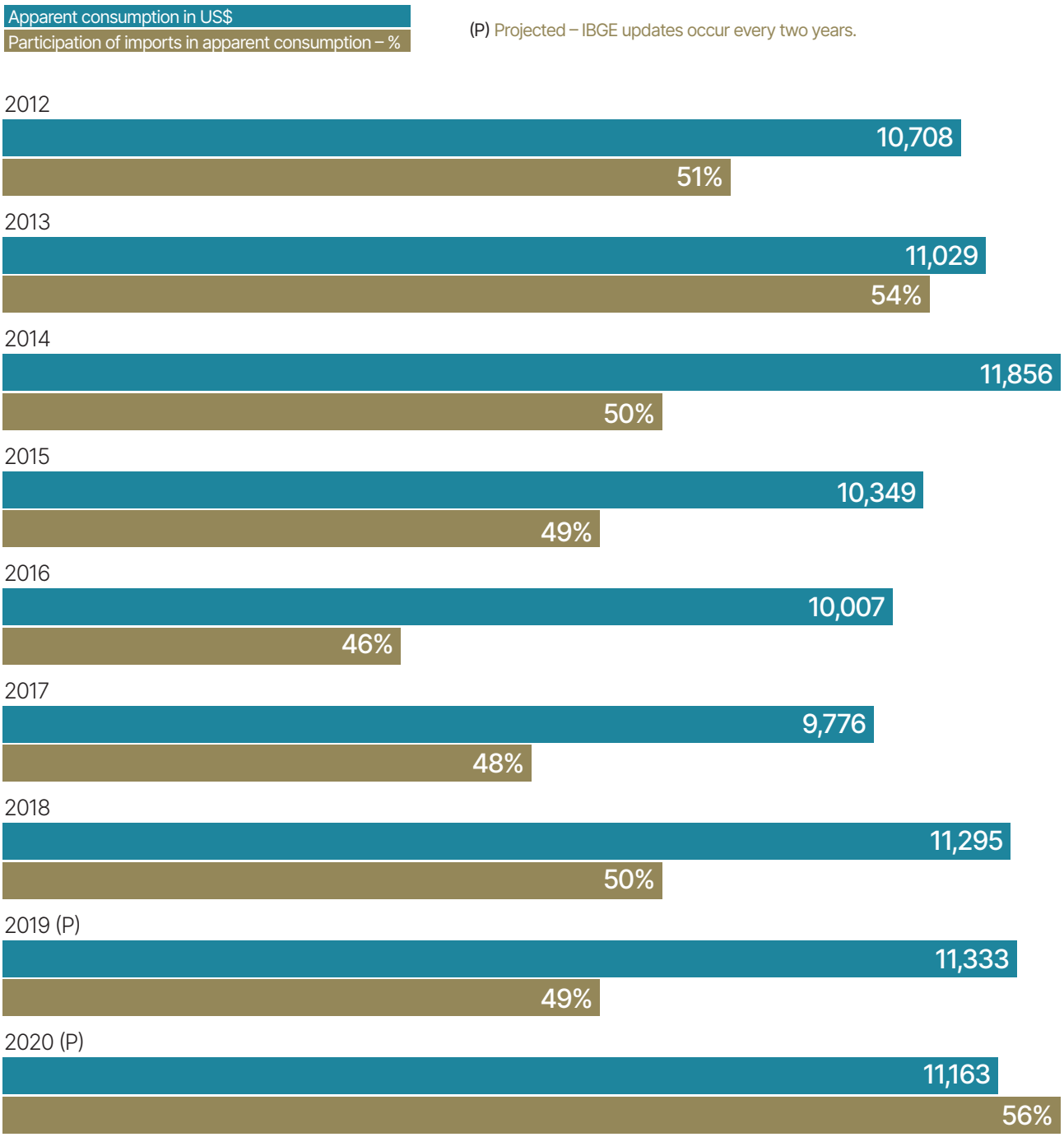
There was an increase in the share of imports in relation to apparent consumption, from **51%** in 2012 to **56%** in 2020, indicating a drop in the share of national production in the period.

[9] GlobeNewswire.

CHART 07

Apparent Consumption of Medical Devices and Percentage Share of Imports[10]

In R$ million and in US$ million



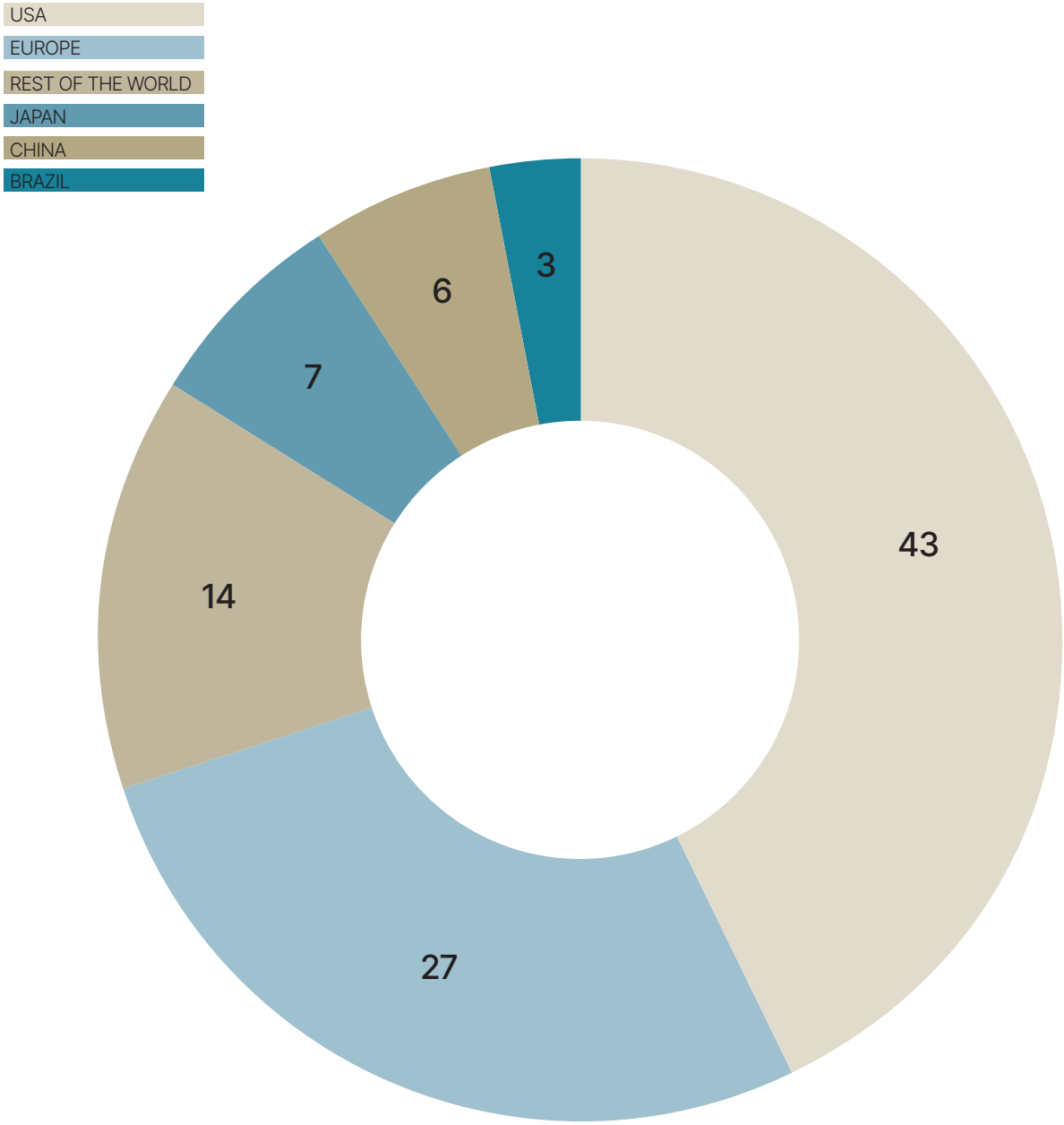
Source: Comex Stat; IBGE/PIA Produto 2018.

[10] Apparent consumption: sum of national production and imports, minus exports.

CHART 08

Brazil's Participation in the Global Market

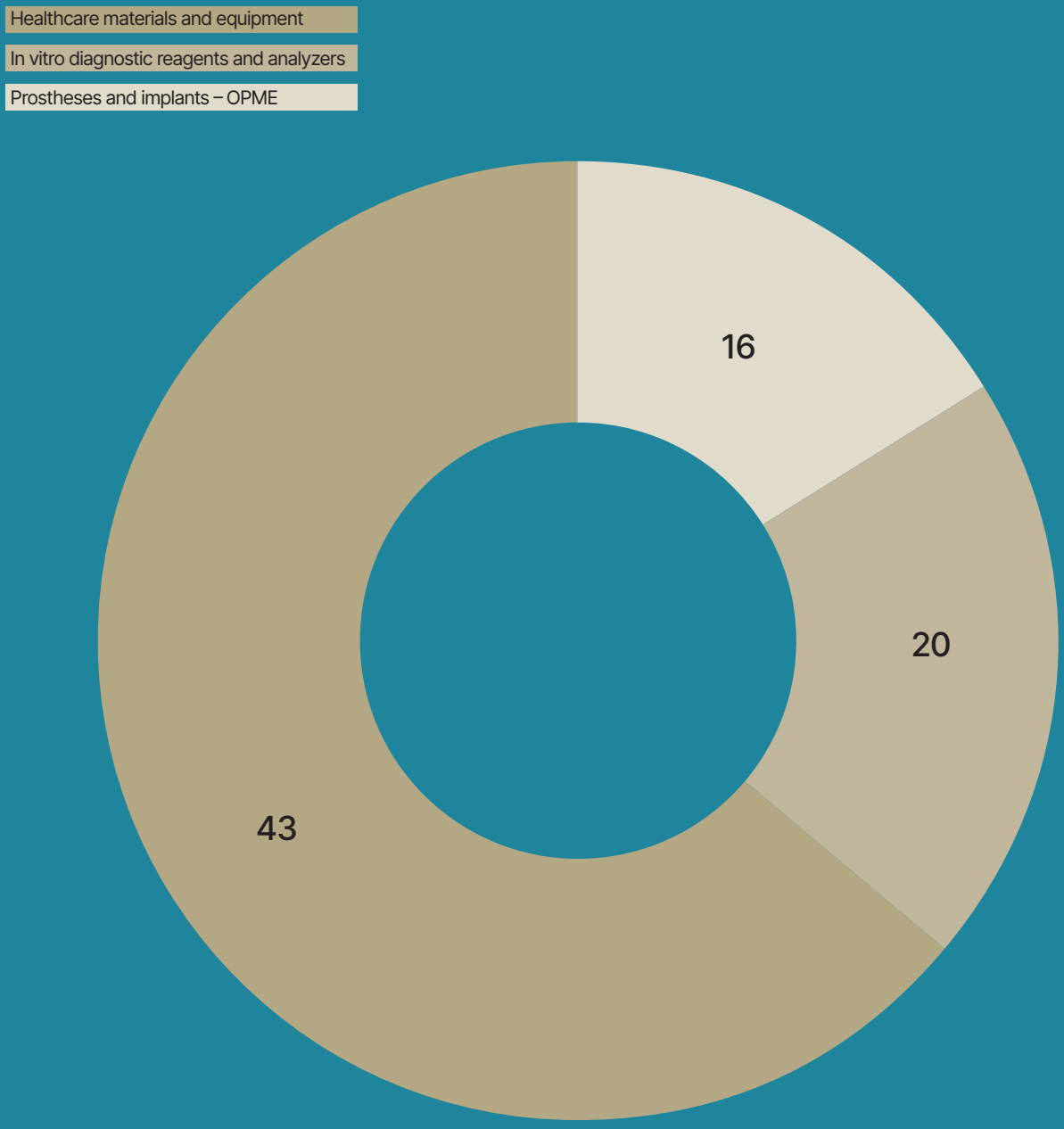
In percentage



Source: Websetorial e MedTech Europe.

CHART 09

Medical Devices Market Share by Segment – Brazil[11]
In percentage



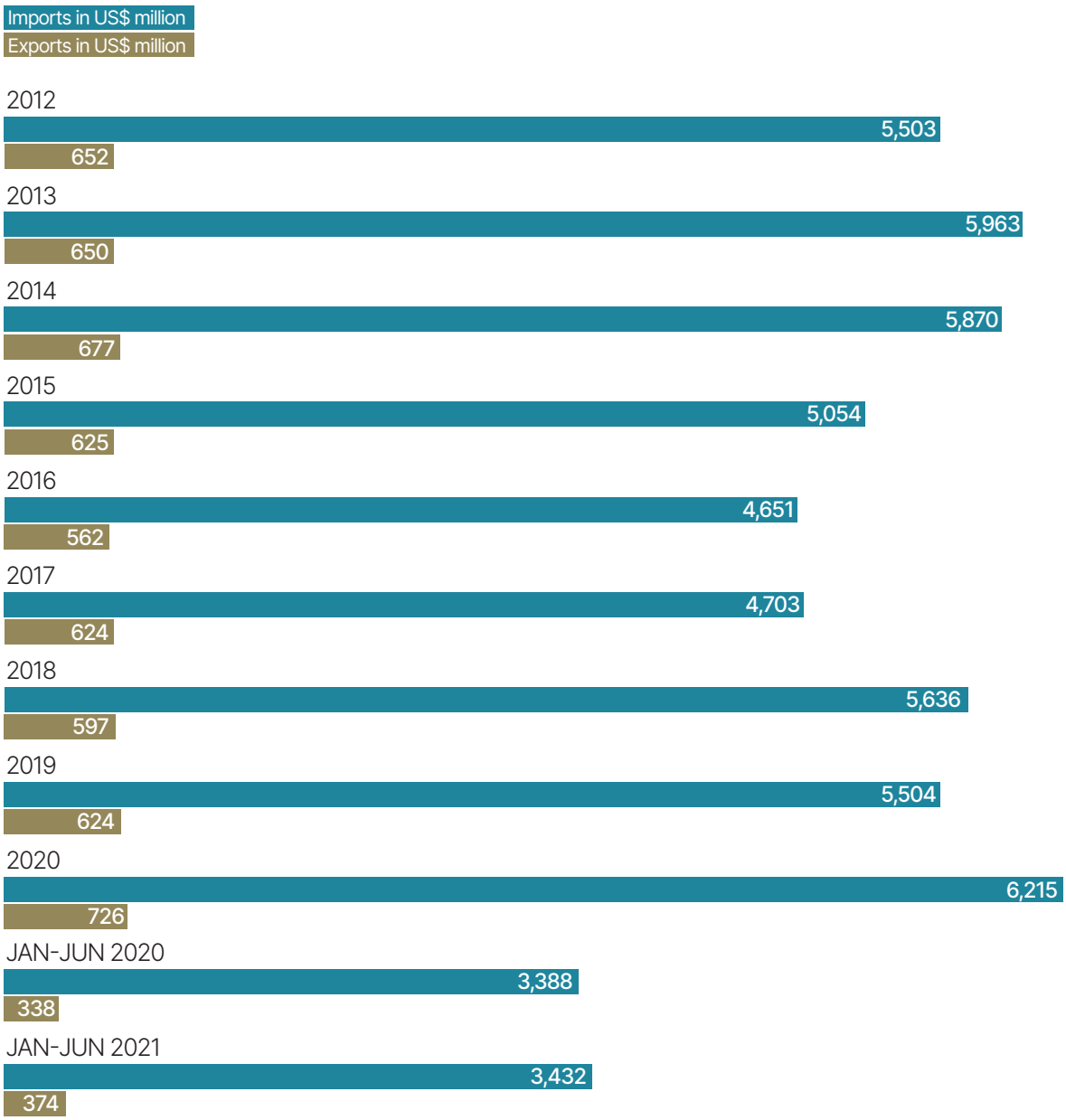
Source: Websetorial Consultoria Eletrônica.

[11] In 2020, due to the PIA 2018 update, the values of production were revised.

The import value of medical devices, materials and support equipment in Brazil has been much higher than exports in every year since the start of the series in 2012. In 2020, imports (**US$ 6.3 billion**) were equivalent to almost 8.6 times exports (**US$ 726 million**).

CHART 10

Medical Devices Trade Scale
In US$ million



Source: IBGE/PIA Produto 2018.

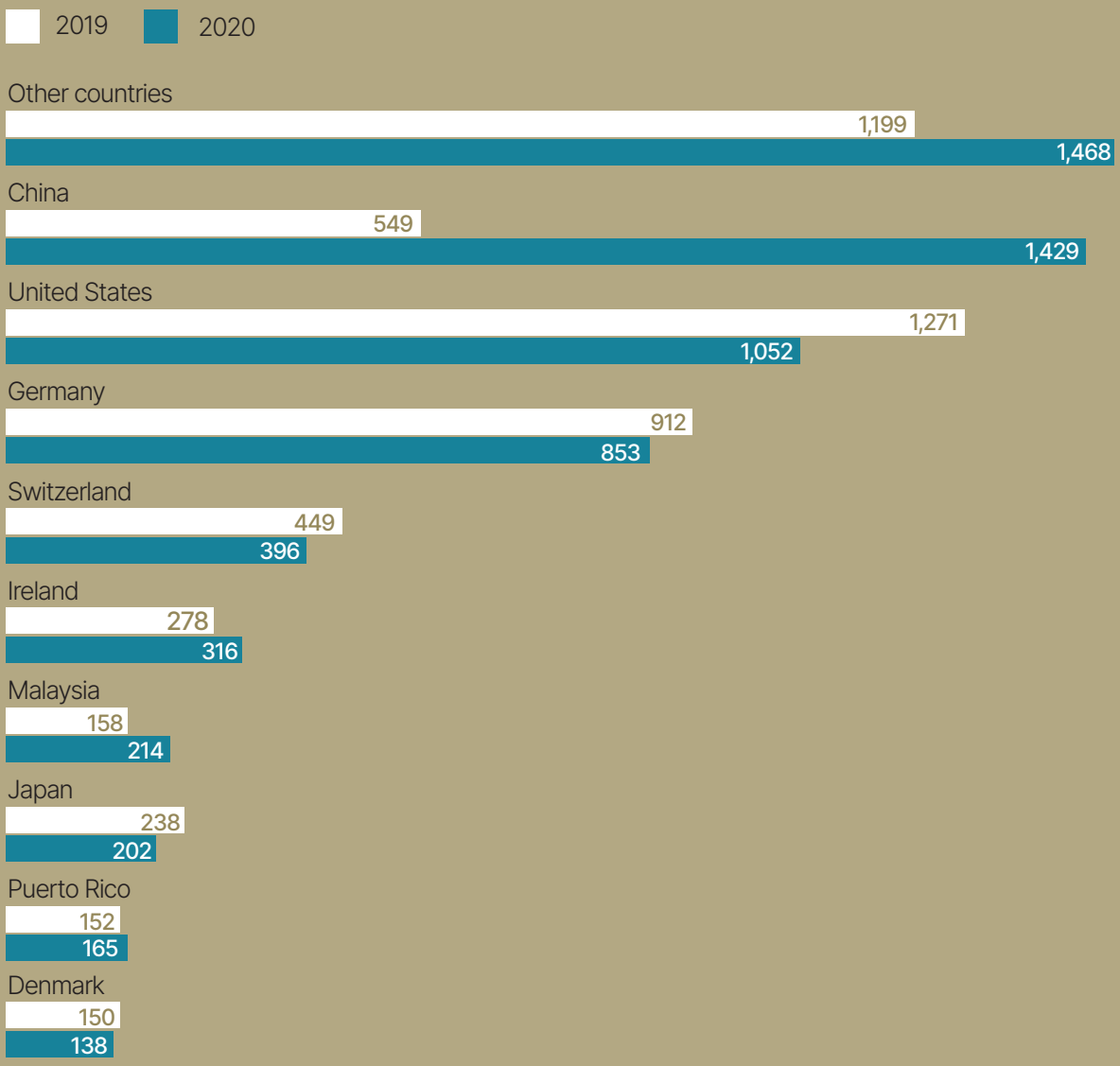
In 2020, **US$ 6.2 billion** in medical devices, materials and support equipment were imported, equivalent to **9.2 million tons of products**.

China remained the main supplier of medical devices to Brazil, accounting for **23%** of the total in 2020. Together with the **United States** and **Germany**, these three countries represented **54%** of Brazilian imports in this sector.

Nine **countries** together accounted for **76%** of Brazilian imports.

CHART 11

Main Countries of Origin of Medical Devices Imports
In US$ million



Source: Comex Stat.

In 2020, **US$ 726 million** in implantable medical devices, materials and support equipment were exported, equivalent to **294,800 tons of products**.

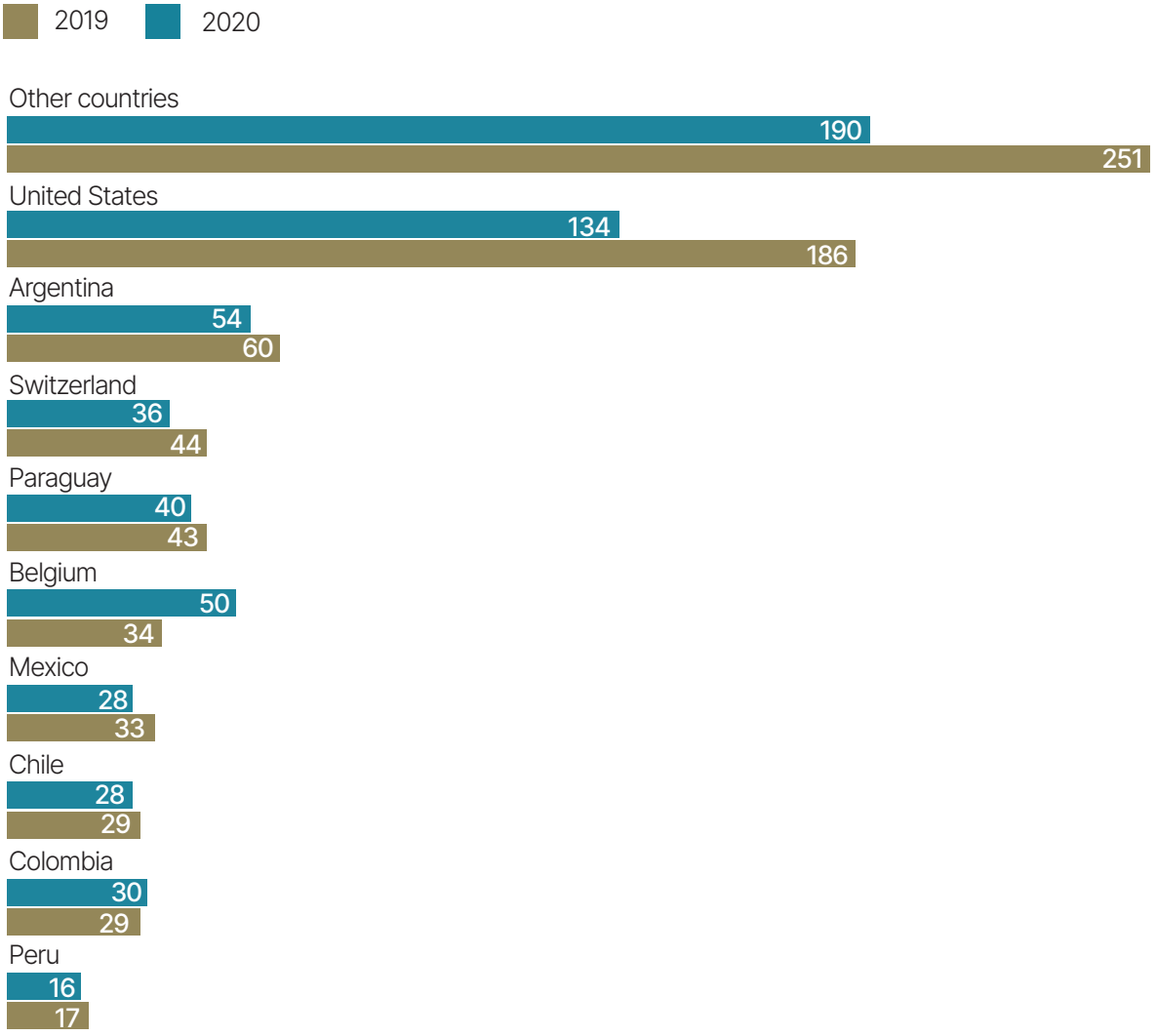
The **United States** was the main destination for exports, accounting for **26%** of the total in 2020. Together with **Argentina** and **Switzerland**, the three countries represented **40%** of Brazilian exports.

The **ten largest** export destination countries together accounted for **65%** of Brazilian exports.

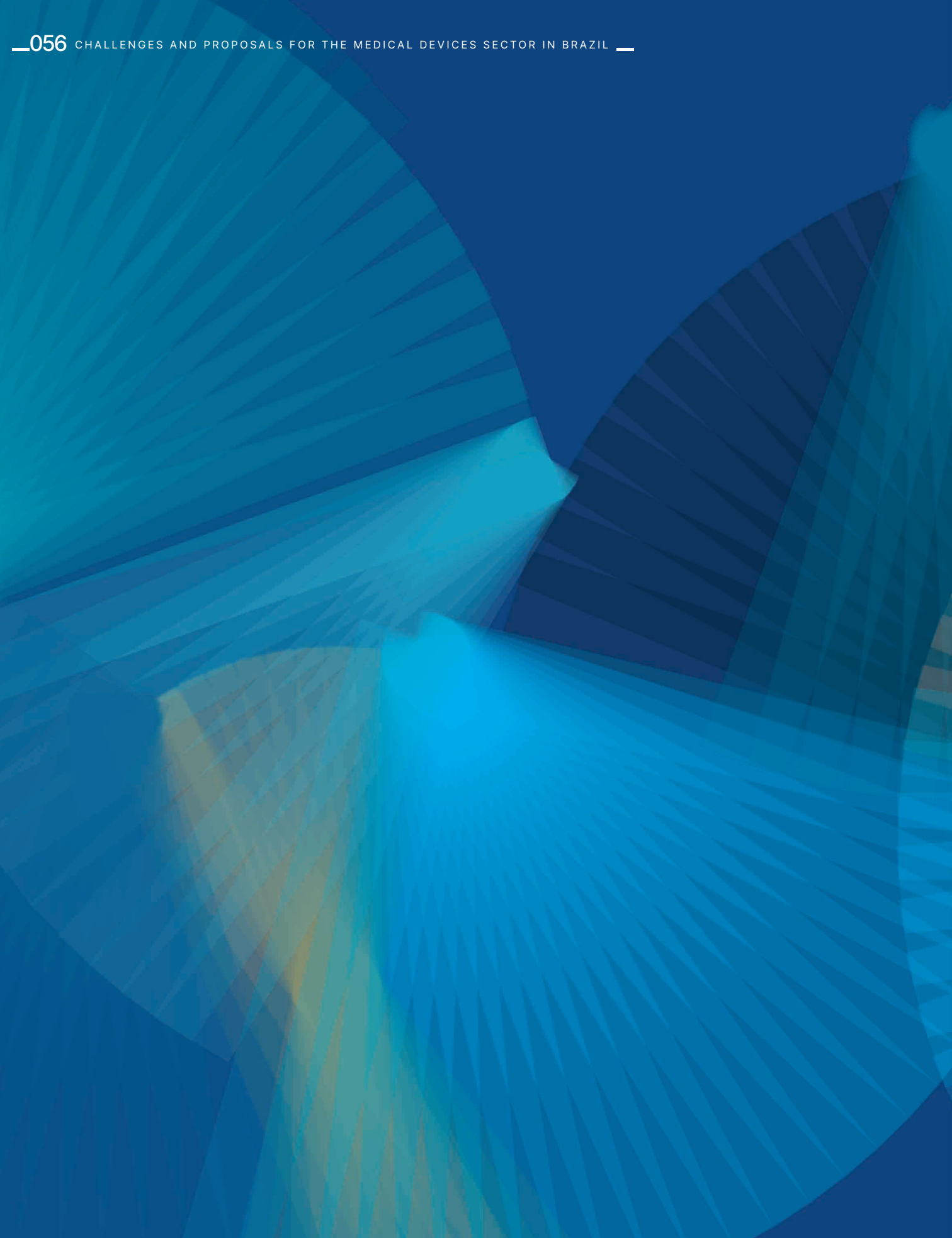
CHART 12

Main Destination Countries for Medical Devices Exports

In US$ million



Source: Comex Stat.



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ABIIS Pillars of Action and Proposals for the Medical Devices Sector

ABIIS Pillars of Action and Proposals for the Medical Devices Sector

ABIIS pillars of action were defined when the Alliance was formed in 2011 and, over these ten years, they have supported the entity's performance, guiding its projects, proposals and actions.

Despite the advances, the systematic maintenance of these pillars for a decade also indicates that the work is not complete. There is still a lot to be done to improve the country's innovation ecosystem, expand the population's access to new technologies – two of ABIIS' main mottos – and dissolve the barriers that stand in the way.

Brazil is an expensive and complex country, which hinders and discourage investments, stifle technological activity and innovation, in addition to compromising its participation in the world market and in the global value chain.

Brazil's performance in global competitiveness indicators is below expectations. In 2017, the country ranked 80th among 137 economies in the Global Competitiveness Index, produced by the World Economic Forum.

The country still has a facet that undermine business activity and tarnishes the business environment: corruption. The perception of corruption in Brazil has remained stagnant for about a decade at a very negative level, below the BRICS average, the regional average for Latin America and the Caribbean and the world average. According to the Corruption Perception Index 2020, prepared by Transparency International, Brazil ranks 94th among 180 countries and territories, behind Colombia, Turkey and China.

Last year, Brazil also registered setbacks in its institutional environment and dropped from fourth to sixth position in the 2021 Capacity to Combat Corruption Index (CCC). The country had the biggest drop among 15 cases analyzed, behind Uruguay, Chile, Costa Rica, Peru and Argentina.

To reverse this set of situations that put the country at a clear disadvantage in the world, the Doing Business Subnational Brazil 2021 points a way out: "Good rules and processes generate positive results for the entrepreneur and stimulate economic activity. For this, it is important that governments – which play a vital role in supporting private sector development – promote smart regulations".

The premise is simple: clear laws and regulations provide entrepreneurs with security and investment opportunities. Rules must be efficient, transparent, accessible and enforceable. And all of this applies to fostering innovation as well.

Considering the need to create a more favorable environment for access to healthcare and innovation, we will detail below the ABIIS' positionings and its proposals to address the main challenges faced by the medical devices industry in the country. They are directly related to the five strategic pillars that support the Alliance's operations: **smart regulation, institutional improvement of regulators, rational incorporation of technologies, improvement of the business environment, and ethics and compliance.**

Smart Regulation

The health sector is one of the most regulated in Brazil and in the world, and regulation, more than necessary, is essential when it comes to products aimed at prevention, diagnosis, treatment and rehabilitation, such as medicines and medical devices.

When regulation is carried out responsibly, it protects the reduction or prevention of health risks and the guarantee for a market for products of proven quality and safety for all users of the system, from patients to professionals who handle these products.

Note, however, that regulation, in addition to being responsible, must also be smart. This means acting as a mediator between the interests and needs of users and the sustainability of the health system, without creating bureaucratic obstacles and unnecessary barriers to the development and entry of innovation in the country.

When ABIIS defends smart regulation, it pleads for the adoption of Good Regulatory Practices in the country.

The term Good Regulatory Practice "means the quality and consistency of the national regulatory process. It refers to the internal coordination and review process by which the entire government works to ensure that rules and regulations are created in an open, transparent and participatory manner, and that results are based on risks and the best available data", as defined by MedTech Europe.[12]

In other words, it is about maintaining a robust and agile regulatory framework, compatible with the Brazilian reality, inserted in the international context and capable of keeping up with the advancement of global technology and the evolution of regulatory practices around the world. Regulation should not represent a barrier to new market entrants and investments and should not lead to an unjustified increase in the cost of products and technologies essential to Brazilians.

An example of a positive initiative that aims to mitigate the impacts that regulatory obstacles can cause to healthcare in Brazil is the Agreement on Trade and Economic Cooperation Relating to Trade Rules and Transparency, signed by Brazil and the United States in October 2020, with the collaboration and support of ABIIS. The agreement aims to reduce non-tariff barriers in bilateral trade, which increase the costs of importing medical and hospital products by up to 60%. The technical barriers arising from regulation alone account for 20% of these costs.

Another initiative whose purpose is to implement good regulatory practices in the Americas to remove barriers is that of the Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector, of which ABIIS is a member. The entity brings together industry, governments, healthcare professionals, patients and providers in a joint effort to seek compliance and harmonize the member countries' regulations. The goal is to maximize patient access to innovative medical technologies.

[12] Available at: https://interamericancoalition-medtech.org/wp-content/uploads/2020/12/Microsoft-Word-Good_Regulatory_Design_Portuguese.pdf. Access on: July 29, 2021.

Proposals for Smart Regulation

PROPOSAL 1

Implementation of the Good Practices chapter of the Protocol to the Agreement on Trade and Economic Cooperation between Brazil and the United States of America related to trade rules and transparency (MSC 165/2021).

Why?

The Good Regulatory Practices (GRP) chapter of the protocol is cross-cutting, as it applies broadly to development regulations in most sectors of the Brazilian economy. The implementation of the chapter will improve the business environment by requiring governments to adopt modernized "best practices" in regulations, including:

- practices to promote the use of the best scientific, technical and economic information as a basis for regulations, using proven statistical methods, avoiding duplication;
- publication of information on online regulatory processes, annual regulatory agendas, use of plain language in texts, publication of regulatory drafts and supporting materials, and the opportunity for stakeholders' comments within reasonable timeframes, with online access;
- openness to expert advice and use of regulatory impact assessments as appropriate;
- publication of final regulations, explaining the decisions taken and reacting to substantive issues, facts and data raised; retrospective review of regulations to determine whether modifications or repeals are appropriate.

It will also deepen the implementation, in Brazil, of trade commitments under the World Trade Organization Technical Barriers to Trade Agreement, accelerating the country's alignment with the technical regulations of the global community and reducing the operating cost of the productive sector by eliminating rules that only exist in Brazil and tend to isolate the Brazilian market from global value chains.

How?

It is necessary to approve the trade protocol in the National Congress. It is currently in the Foreign Relations and Defense Committee of the House of Representatives. After this stage, it will be returned for approval by the President of the Republic and may be implemented by the Federal Executive Branch.

PROPOSAL 2

Implementation of mechanisms to strengthen the Regulatory Impact Analysis (RIA) in the Federal Executive Branch, especially in Anvisa, ANS, Anatel, Ministry of Health, Inmetro, among others.

Why?

For Brazil, with its immense potential, to be relevant in global production chains, it is extremely important to have a simple, objective regulation, capable of achieving the expected results, without hindering the performance of the productive sector. The ideal tool for this measure is RIA, in which both regulatory bodies and regulated agents have a chance to assess the chosen regulatory proposal and its effects.

How?

The Federal Executive Branch should require the performance of a Regulatory Impact Analysis (RIA) for regulatory bodies, and the Regulated Sector should collaborate with discussions of proposed regulations. For this, in the first case, Decree No. 10,411, of June 30, 2020, should be strictly applied, and exceptions to conducting RIA should be robustly justified. In the second case, it is important to create a strong culture of collaboration between the regulated and the regulators so that the dialogue is permanent.

PROPOSAL 3

Creation of a central external body in charge of conducting RIAs, even if only partially.

Why?

Considering that the official central regulatory body will tend to have a less critical perspective on regulation due to the nature of its performance, ABIIS defends a broad debate on the possible creation of an external body for RIA, or the use of some existing government structure.

As in other countries, a central coordinating body may be placed in the office of the President of the Republic, in a strong ministry or as an independent internal oversight office. Regardless of location, a central oversight body exercises its authority most effectively and efficiently when it is close to a place of power in government, with access to influential government decision-makers.

In the case of Brazil, ABIIS understands that one of the options for locating a central body to conduct RIAs, even if only partially, would be the Secretariat for Competition Advocacy and Competitiveness of the Special Secretariat of Productivity, Employment and Competitiveness of the Ministry of Economy (SEPEC), within the structure of that ministry.

For the record, in the Americas, the following countries have established Central Regulatory Coordination, with authority attributions that vary by country:

- Canada: Treasury Board – An institution linked to the Treasury Board of the Government of Canada.
- Chile: Oficina de Productividad y Emprendimiento Nacional (Open) – An institution linked to the Ministry of Economy, Development and Tourism.
- Colombia: Departamento Nacional de Planeación (DNP) – An institution linked to the Presidency of the Republic.
- El Salvador: Organismo de Mejora Regulatoria (OMR) – An institution linked to the Presidency of the Republic.
- Mexico: Comisión Nacional de Mejora Regulatoria (Conamer) – An institution linked to the Secretariat of Economy.
- Peru: Secretaría de Gestión Pública – Presidencia del Consejo de Ministros (SGP) – An institution linked to the Presidency of the Council of Ministers.
- United States: Office of Information and Regulatory Affairs (OMB/Oira) – An institution linked to the Office of Management and Budget of the Presidency of the Republic.

How?

Defining by law that the RIAs are prepared, even partially, by a central external body to the regulatory agent. For this, it will require amending Law No. 13,848, of June 25, 2019, and Decree No. 10,411, of June 30, 2020.

Institutional Development of Regulators

As well as regulations advance and undergo a continuous process of review and improvement, the implementation of Good Regulatory Practices requires that regulators also monitor these changes and undergo a constant updating process.

This need is directly related to the specificities of the medical devices industry, such as the short innovation cycle and the constant development of new and increasingly sophisticated technologies. Getting in touch with innovations and following the evolution of the sector – in a constant process of training and recycling – is a natural development so that the technicians in charge of evaluating them can adequately perform their functions.

Another important aspect, in ABIIS' assessment, is that the regulatory agency itself has adequate infrastructure – for example, enough professionals – to handle the scope of its mission.

Proposals for Institutional Development of Regulators

PROPOSAL 1

Adequate structuring of the Brazilian Health Regulatory System (SNVS), especially in states and municipalities.

Why?

Nowadays, there is a general lack of resources in part of local health surveillance agencies, both state and municipal, especially in terms of human resources. It is essential that these units are properly equipped for the proper exercise of their functions. The financing of state, Federal District and municipal surveillance units is done by the country, through the Brazilian Health Regulatory Agency.[13] However, as observed, these resources have not been enough.

How?

Review the legal framework on the financing of the SNVS and regulate the sanitarians activities. These measures must be discussed by the National Congress with broad participation from society and the health industry.

PROPOSAL 2

Constant training of SNVS' employee and replacement of analysts and technicians through public tender.

Why?

Considering that the medical devices industry is multidisciplinary and requires highly specialized professionals, it is essential that regulatory agents have permanent training programs that prepare them to analyze innovative technologies and maintain a uniform interpretation in all SNVS units.

It is notorious the reduction of Anvisa's staff, mainly due to the retirement of public servants in recent years, without replacement of staff. The problem tends to get worse with new retirements in the next five years. To solve this issue, it is important to have a public tender planned to recompose the operational structure of the health surveillance system.

How?

Establish in the Anvisa's Strategic Plan and Annual Management Plan[14] robust training target for SNVS employees, especially those who work in areas where there is great innovation in technology. In addition, a public tender must be held for the agency to replenish its staff.

[13] See: https://www.gov.br/anvisa/pt-br/assuntos/snvs.

[14] Law No. 13,848, of June 25, 2019.

PROPOSAL 3

Requirement of technical and ethical accuracy in the nominations for the board of regulatory agencies (especially at Anvisa, ANS, Anatel, Inmetro), so that the nominees have "an unblemished reputation and notorious knowledge in the field of their specialty", in accordance with Law No. 9,986/2000.

Why?

Regulatory agencies in the health area and others, such as Inmetro and Anatel, have enormous responsibilities, and their decisions have a decisive impact on the lives of the population. Therefore, it is essential that their leaders have the technical capacity to assess the demands they receive. Likewise, it is important that the names appointed to compose the board are not merely political, considering that their actions should only follow the general interest of society.

How?

Constantly reinforce this position before the Senate and suggest social participation, such as a public consultation with a list of pre-selected names, in the choice of names indicated by the President of the Republic to integrate the agencies.

PROPOSAL 4

Adequacy of Anvisa's information system to the dimensions and amplitude of its activities.

Why?

Anvisa regulates several relevant sectors, including medical devices, medicines, active ingredients, cosmetics, sanitizing products, tobacco products, pesticides and blood products. It is estimated that 20% of the Brazilian GDP passes through the agency, which is the most important in the country. However, the information system technology used by Anvisa is precarious and obsolete. The modernization of this structure is essential to speed up processes and reduce dependence on personnel. There is also the issue of preparing the agency's technical staff in relation to the technological horizon of health (IoT and Telehealth) and the digital transformation that the world is experiencing.

How?

Allocate specific financial resources in the 2022 budget and subsequent years, if necessary, to contract a new IT system for Anvisa and establish a schedule for implementation of a new system in the Agency's Strategic Plan and Annual Management Plan.

Rational Incorporation of Technologies

The incorporation of technology in the public health system and in supplementary health is one of the most challenging issues for health, especially for the medical devices sector and for its highly innovative profile.

SUS and supplementary health have different technology incorporation processes. However, in general, bureaucracy, slowness, non-compliance with legal deadlines and lack of transparency in decisions are just some of the ghosts that haunt this universe, especially in public health. In addition, they act as major obstacles for Brazilian patients to benefit from products and procedures proven to be more effective and already available to the population of several countries.

At the root of this situation, there is a mistaken and unproven belief: innovation is synonymous with increased costs. A mathematics focused only on the price of the product or procedure and that does not consider the cost reduction promoted by factors, such as shorter hospital stays, reduction in the rate of hospital infection, faster return to activity, early detection of diseases, among a multitude of other benefits.

It is this perspective, which only contemplates costs and prevails in technology incorporation analysis processes, that ABIIS strives to help transform. Evidently, there is no system in the world that has the resources to keep up with the speed of medical innovation and incorporate everything that is developed.

It is important to find ways to better balance the demands of society and the financial sustainability of the health system.

It is justified, therefore, that the technology assessment processes are very careful and undergo major extensive analysis. However, on the other hand, it is important to find ways to better balance the demands of society and the financial sustainability of the health system. The cost should not be the only criterion, under penalty of barring the entry of new technologies in the country, with losses for the entire population.

ABIIS also defends the development of a specific analysis protocol for medical devices, which require a different type of assessment from the one that usually done for medications. See below how the processes of incorporation of medical technology in SUS and in supplementary health take place.

The process of evaluating and incorporating medical technologies in the public health system has been carried out by the National Committee for Health Technology Incorporation (Conitec) since 2011, when the committee was created to advise the Ministry of Health in this function.

Process of Incorporating Technologies into SUS

Assisted by the Department of Management and Incorporation of Technologies and Innovation in Health (DGITIS), Conitec is responsible for deciding on the incorporation, exclusion or alteration of technologies, as well as the constitution or alteration of clinical protocols and therapeutic guidelines.

In order to make the analysis of the incorporation of health technologies more efficient, Law No. 12,401/2011 established a period of 180 days, extendable for 90 more days, for technicians to make decisions in incorporation processes.

The legislation also establishes the basic principles that must be taken into account into the analysis: 1) "scientific evidence on the efficacy, accuracy, effectiveness and safety of the medicine, product or procedure that is the object of the process, accepted by the competent body for registration or authorization of use", and 2) "the comparative economic evaluation of benefits and costs in relation to technologies already incorporated, including with regard to home, outpatient or inpatient care, when applicable".

Decree No. 7,646/2011 regulates the technology assessment process and the functioning of the plenary, the body responsible in Conitec for recommending the incorporation, alteration or exclusion of technologies. The plenary is composed of representatives from each of the seven secretariats of the Ministry of Health, a member from the Federal Council of Medicine (CFM), one from the National Health Council (CNS), one from Conass, one from Conasems, one from ANS, and one from Anvisa.

The plenary recommendations are submitted to public consultation for a period of 20 days, in the case of non-urgent procedures, or for 10 days in urgent cases. At the end of this phase, a report is prepared and submitted to the analysis of the secretary of Science, Technology and Strategic Inputs (SCTIE/MS), who makes the decision and may also open a public hearing to address the issue.

In order to make the analysis of the incorporation of health technologies more efficient, Law No. 12,401/2011 established a period of 180 days, extendable for 90 more days, for technicians to make decisions in incorporation processes.

The decree also lists the documents and formalities required for the request for the opening of the administrative proceedings for the incorporation of health technologies.

From a legal point of view, both the law that created Conitec and the decree that regulates the health technology assessment process define objective requirements for this analysis, establishing the composition, competencies and operation of Conitec, elements that, at least formally, regulate the proper functioning of this process.

Technology Incorporation Process in Supplementary Health

The National Agency of Supplementary Health (ANS) is responsible for establishing the mandatory minimum coverage that must be offered by healthcare plans to users. This is done through the elaboration of the so-called Health Procedures and Events List, which defines the products and procedures to which beneficiaries will be entitled for health promotion, prevention, diagnosis, treatment, recovery and rehabilitation of all diseases.

The procedures list update rite has recently changed and is now regulated by Normative Resolution (NR) No. 470/2021, published on July 12, 2021, effective from October 1 of the same year.

In this context, the update of the procedures list, which under NR No. 439/2018 took place every two years, will occur every six months with the continuous submission of propositions through the electronic form (FormRol) available on the ANS website.

The Normative Resolution establishes a series of guidelines to be observed in the updating process, including the guarantee of the defense of public interest and the use of the Health Technology Assessment (HTA) principles, which ensure the evaluation of clinical, social and economic impacts of health technologies, under the aspects of efficacy, effectiveness, safety and other relevant characteristics to support decision making by managers.

The Proposal for List Update (PAR) can be formulated by individuals or legal entities and includes requests for the incorporation of new health technology, disincorporation of technology already classified on the list, inclusion, exclusion or change in the Guideline for Use (DUT) or alteration in name of a procedure or health event already classified on the list. The Normative Resolution establishes specific criteria for the eligibility analysis for each of the update submissions listed above, and the fulfillment of these criteria will be analyzed by the Directorate of Standards and Qualification of Products (Dipro).

Dipro is responsible for the technical eligibility analysis of the Proposal for List Update (PAR) and it is also responsible for summoning the members of the Supplementary Health Chamber (CAMSS) and the author of the proposal for technical meetings to discuss the proposition submitted.

Once the discussions are closed, Dipro will present the Preliminary Recommendation Technical Note (NTRP) for the Collegiate Board's (Dicol) appreciation and deliberation. After this phase, the NTRP will be submitted to public consultation for the participation of the society, and then the Final Recommendation Technical Note (NTRF) will be prepared, which, if approved by Dicol, will be published in the normative resolution that updates the Health Procedures and Events List. NR No. 470/2021 establishes that the Normative Resolutions to update the list of mandatory care coverage and guidelines for use that make up the procedures list will always come into force in January and July of each year.

Proposals for Rational Incorporation of Technologies

PROPOSAL 1

Creation of a regulatory agency for the Assessment of Incorporation and Deregistration of Health Technologies, independent of the Ministry of Health and ANS.

Why?

Currently, assessments are carried out by agencies linked to the Ministry of Health and ANS. However, it is quite clear that both institutions have a bias in the result of the analysis, as well as political pressure. To bring more transparency and technicality to the process, it is important that the HTA is carried out by an independent technical body.

How?

Create a regulatory agency exclusively to carry out an assessment of technology incorporation, both for the public sector (SUS) and the private sector (ANS).

PROPOSAL 2

Establish appropriate deadlines, procedures and processes for the analyses.

Why?

The medical devices industry has a very different dynamic from the pharmaceutical industry, as explained. Product innovations or even product updates occur very quickly. Considering this fact, it is extremely important that the deadlines for HTA are also faster.

How?

Establish in specific regulations (laws, decrees, ordinances and resolutions) shorter deadlines for analysis, which should not exceed 120 days.

PROPOSAL 3

Creation of specific HTA protocols for medical devices.

Why?

Considering the differences between medical devices and medicines, the logic used for the analysis of technology incorporation of the two categories of products must also be different, according to the specificities of each. The benefits that a new MD technology can bring to the patient's life produce impacts that go beyond the user and extend to the entire health system, such as hospital costs reduction, for example. For this reason, it is essential that these products are evaluated from a specific perspective and better suited to their characteristics.

How?

Develop specific protocol for HTA of medical devices under the coordination of the Ministry of Health, with the participation of industry and academia.

PROPOSAL 4

Inclusion of a specific allocation of resources, in the annual budget of the Ministry of Health, for the incorporation of new technologies.

Why?

The Annual Budget Law (LOA) establishes the Brazil budgets. In its preparation, the National Congress is responsible for evaluating and adjusting the proposal that the Executive Branch sends to Parliament. However, the Ministry of Health's budget established in the LOA has no specific line for the incorporation of new technologies. Considering the benefits that innovation can bring in the health area, both to patients and to the system, especially to SUS, it is necessary to create a financial reserve to incorporate the technologies considered better for society. This measure will positively impact investments in research and innovation in the medical devices sector in the country.

How?

Propose to the Ministry of Health and the National Congress that the LOA present a specific line for the incorporation of new health technologies.

VALUE-BASED AGREEMENTS

César Abicalaffe, MD/M.Sc/MBA

Physician and Master in Health Economics. He is president of the Instituto Brasileiro de Valor em Saúde (Brazilian Institute of Health Value – IBRAVS) and CEO of 2iM S.A.

Value-Based Healthcare (VBHC) is one that delivers the best outcomes, those that really matter to patients, at the lowest possible cost (ICHOM, 2018).

Value-Based Agreements (VBA) should have this rationale and can be used for any contractual arrangement between payer and supplier that has this logic, that is, producing optimal outcomes at an adequate cost.

Medical devices and medicine supply industries have been discussing the so-called Managed Entry Agreements (MEA) for several years, starting from financial agreements (discounts, volume-based negotiation, budget limits, cost sharing and volume-based cost capping) to outcome-based agreements (pay per response and pay per performance) (FERRARIO, 2013). Figure 01 shows the MEA types.

FIGURE 01

Managed Entry Agreements

Source: Adapted from FERRARIO, Alessandra; KANAVOS, Panos. *Managed entry agreements for pharmaceuticals*: the European experience. Brussels, Belgium: EMiNet, 2013.

Value-Based Healthcare (VBHC) is one that delivers the best outcomes, those that really matter to patients, at the lowest possible cost.

Something more comprehensive than outcome-based agreements is starting to be discussed. These are value-based agreements, in which value is the basis of negotiation, not just an isolated outcome or a certain risk to be shared.

The biggest challenges, beyond the legal aspects, obviously, are in what and how to measure value. Kaplan and Porter state that "we are measuring the wrong things in the wrong way". Having an adequate value metric is a condition for starting to discuss compensation models and value-based incentive policies and VBAs.

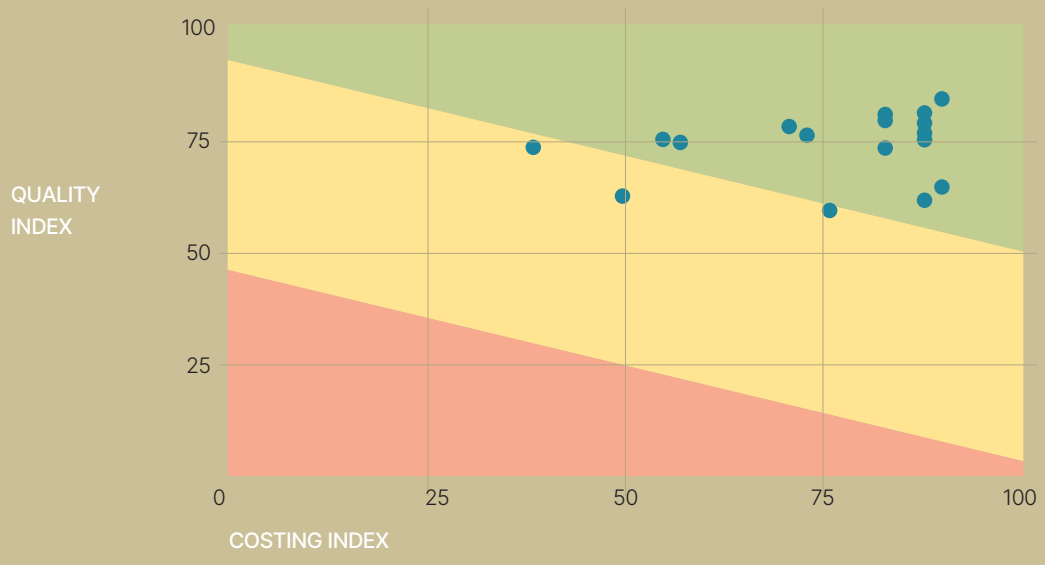
The proposal for a feasible metric, which is already in practical application in Brazil, is the Health Value Score (EVS). It is represented by a score from 0 to 5, which correlates the Quality Index (QI) to the Costing Index (CI), obtained in the evaluation process over a period. The QI includes metrics of care processes, clinical outcomes and patient reports. In the formula, the QI, weighted at 70% of the EVS, is correlated with the costing index, which can also include a set of cost indicators, that are related to the care provided to the patient, who is the subject of evaluation. The CI, therefore, is weighted at 30% of the EVS. Thus, the value metric is a composite metric, that is, a set of indicators grouped into domains and weighted that are correlated, producing a single score from 0 to 5. With this metric defined, any VBA or value-based payment model is possible to be applied. EVS already has practical application for evaluating networks of hospitals, physicians, patients with specific clinical conditions and other health services and structures (ABICALAFFE, 2020).

In Figure 02, the EVS of patients with a certain clinical condition is plotted on a chart correlating the QI with the CI. Each patient with their EVS is represented by a dot on the graph, which shows the different tertiles, which are represented by colors. The green band represents the third tertile, in which the quality and cost ratio is more adequate.

FIGURE 02

QI and CI Ratio

Quality Index/Costing Index



Source: 2iM.Analytics, 2021.

Some practical examples of VBA using EVS are already happening. For example, the price of a technology will have a lower discount the higher the EVS, or even if the ratio of the quality produced to its cost is low, the lower the value generated to the patient and, therefore, the lower the value to get paid for the technology.

VBAs are considered one of the most important actions to enable a value-based healthcare system. No matter how much suppliers, hospitals or industries invest in "value offices" in their companies, if payers, whether public or private, do not innovate or invest in this practice through VBAs and/or value-based compensation models, VBHC will hardly happen in its entirety.

Improved Business Environment

According to Doing Business 2020, carried out by the World Bank and which compared 190 economies, Brazil ranks 124th on the ease of doing business.

Brazil is close to Uruguay (101st), Paraguay (125th) and Argentina (126th), but very far from Chile (59th), Mexico (60th) and Colombia (67th). The country is also behind all BRICS countries: Russia (28th), China (31st), India (63rd) and South Africa (84th).

Regarding the tax payments, Brazil is among the 10 worst countries in the world, occupying the 184th position.

A specific study on Brazil carried out by the World Bank, Subnational Doing Business in Brazil 2021,[15] which compares the business environment in 26 states and the Federal District with that of 190 other economies, reveals that time-consuming and complex processes are among the main challenges faced by Brazilian entrepreneurs in all areas of business regulation.

In the 27 locations measured, companies spend an average of 1,500 hours per year to comply with their tax obligations. There are 97 in total, with 4,377 federal, state and municipal taxation rules, according to the Brazilian Institute of Planning and Taxation (IBPT). Furthermore, the rules are constantly being modified, with an average of 36 daily changes.

According to the National Confederation of Industry (CNI), this set of structural, bureaucratic, labor and economic difficulties, also known as "Brazil Cost", hinders the country's growth, negatively influences the business environment, increases product prices and logistics costs, compromises investments and contributes to the excessive tax burden. CNI estimates that companies based in Brazil pay R$ 1.5 trillion per year more than the member countries of the Organization for Economic Cooperation and Development (OECD) to conduct their business, which is equivalent to 20.5% of the Gross Domestic Product (GDP).

When it comes to global competitiveness, Brazil also appears to be at a great disadvantage compared to developed countries. The Brazil Competitiveness Report 2019-2020, prepared by the entity, showed that the country occupies the 17th position, compared to 18 other economies in the world that have similar characteristics to Brazil. According to the survey, even though there has been an improvement in the business environment over the last 10 years, it has not been enough to produce an expressive growth curve.

In this context, also considering the phenomenon of global value chains, defined by FGV/EESP "as a set of activities necessary for the production and delivery of the product to the final consumer",[16] it is essential that Brazil becomes more competitive with measures that reduce bureaucracy in business, making local production more fluid and simpler.

[15] Available at: https://portugues.doingbusiness.org/pt/reports/subnational-reports/brazil. Access on: July 29, 2021.
[16] CADEIAS globais de valor. São Paulo: FGV/EESP, c2014. Available at: https://ccgi.fgv.br/pt-br/cadeias-globais-de-valor. Access on: July 29, 2021.

From the same FGV/EESP document, it is also highlighted:

"The set of steps can be performed in the same firm or by more than one firm. If the set of chained firms are in more than one country, then we will have a value chain that is global. The recent interest in economic literature in the new production paradigm has occurred for two main reasons: (i) trade flows resulting from the outsourcing of production stages are intensifying; and (ii) because such flows occur in poor and rich countries. In this context, we have an indication that this new relationship has been beneficial to the poorest, considering that there has been an increase in the share in world income and exports earned by emerging countries in recent decades."

In other words, for a country to be included in this global chain, it must be aligned in terms of timing, regulation and practicality of the operations involved.

The debates related to the tax reform proposals that are being discussed in the National Congress are also important. The Alliance recognizes the importance of discussions to modernize the tax system, making it less complex and bureaucratic, in order to boost the country's economic growth.

However, the entity believes that any proposal for tax reform should give different treatment to the health sector, especially due to the negative impacts that an eventual increase in the tax burden could bring to patients and the sector, mainly public health services – one of the main clients of the medical devices sector –, which will produce a possible price increase.

A study carried out by the National Health Confederation (CNSaúde)[17] indicates, in a survey of 117 countries, that in 78% of them there is no tax on medical care/healthcare. And in another 4% there is a reduced rate. The exception granted to the health sector is justified because it is a good of public interest.

High taxation makes investments difficult and products and services more expensive, making them unaffordable to most of the population and leading to a worsening of service due to lack of public budget.

17 O PL 3.887/2020 de reforma tributária e seus impactos para o consumidor do setor de saúde privada. Brasília: CNSaúde, 2020. Available at: http://cnsaude.org.br/wp-content/uploads/2020/08/Position-CNSaude-Reforma-Tribut%C3%A1ria-PL-2020-08-05_compressed.pdf. Access on: July 29, 2021.

Proposals for Improving the Business Environment

PROPOSAL 1

Unburden and simplify the medical devices sector taxation.

Why?

The MD sector is inserted in the context of the constitutional right to health. In art. 196 of the Constitution, we have the command so that the State guarantee this right through social and economic policies aimed at reducing the risk of disease and other illnesses.

The State itself is the main buyer of health products and services. Thus, it can be said that, in the case of MD taxation, the State collects the tax with one hand and pays it with the other.

A tax-free health system will certainly impact the expansion of access to products and services by the population, as well as investments in the country.

How?

Review the regulatory system of taxation in Congress to unburden the health sector. ABIIS has already presented proposals to change the texts that are being processed in the National Congress on the tax reform in this regard. Another important measure is the conversion of ICMS Agreement No. 01/1999 into a definitive measure. The agreement has been renewed since its creation in 1999. After 22 years, it is believed that it is high time to become definitive. This discussion could be carried out in the context of the tax reform proposals that are being discussed in the National Congress, in the interest of the entire productive sector.

PROPOSAL 2

Insert Brazil in global production chains.

Why?

Given the need to accelerate Brazil's economic and social development, the country's insertion into global production chains is considered one of the most relevant measures for all productive sectors. It is a unique opportunity to bring innovation and technology, expand the market, generate qualified jobs, and retain talent in the country, if we assess the increased demand for high-level academic training.

How?

Both the Executive Branch and the National Congress must discuss and create, with the participation of society and the health industry, a State Policy that includes reducing bureaucracy in business; cost reduction in export/import commercial operations; expansion of places in academic technology courses; and the mitigation of regulatory barriers.

Ethics and Compliance

Brazilian population works an average of 29 days a year just to pay the bill for corruption, according to a study by the Brazilian Institute of Planning and Taxation (IBPT). In consonance with the survey, corruption consumes 8% of everything that is collected in the country – about R$ 160 billion per year. To reach this conclusion, the Institute took into account the deviations found by Operation Car Wash and processes involving corruption in the Federal Court of Accounts (TCU) and in the State Courts of Audit.

Ethics and Compliance are directly linked to people's access to a quality healthcare. Besides causing unfair competition, raising prices and affecting the country's economy, corruption sabotages the population health.

An article published in *The Lancet* on November 19, 2019[18] estimates that, of the total $7 trillion spent on healthcare worldwide, up to 25% is wasted because of corruption. The publication also makes a disturbing estimate: each year, around the world, health corruption causes the death of 140,000 children and sabotages disease control efforts.

ABIIS considers it essential for Brazil to adopt measures that curb commercial practices that may affect patients and the health system. The Alliance supports the legislative propositions that criminalize corruption and unethical conduct and defends the inclusion on the heinous crimes list crimes of conspiracy, passive and active corruption, embezzlement and crimes against bidding related to contracts, programs and actions in public health or education areas.

It also defends PL 221/2015, which adds an article to Law No. 8,078, of September 11, 1990, of the Consumer Defense Code, to typify the obtaining of illicit advantages for the referral of procedures, the sale of medicines, orthoses, prostheses or implants of any kind.

In its efforts to contribute to the fight against corruption in the health area, ABIIS supports the actions of Instituto Ética Saúde and is part of the entity's Advisory Board. Created in 2014 as a voluntary movement of companies affiliated with Abraidi, the Institute's mission is to promote best practices in commercial and institutional relations among healthcare representatives, such as distributors, manufacturers, hospitals, physicians, operators, healthcare plans and regulatory bodies. Its members defend self-regulation as a mechanism to create a fair and transparent competitive environment and ensure patient safety.

ABIIS is also a member and founding partner of the Inter-American Coalition of the Business Ethics for Medical Devices, which seeks to strengthen ethical business practices in the Americas. The coalition brings together industry and governments and interacts with healthcare professionals and providers and patients and is the first public-private partnership in the region with this focus.

[18] Available at: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)32527-9/fulltext?rss=yes. Access on: July 29, 2021.

Proposals for Ethics and Compliance

PROPOSAL 1

Typify in the Penal Code the obtaining of undue advantage that involves actions resulting from the indication of the use of medical devices.

Why?

It is necessary to forcefully curb the undue indication of MD, as well as the search for an undue economic advantage in health treatments in which these products are indicated, whether by the physician or by any other actor in the system. For this, it is believed that, by criminalizing these actions, the subjects involved will be discouraged from performing this practice.

How?

Speed up the processing and approval of PL 221/2015 in the National Congress.

PROPOSAL 2

Strongly support the actions of the Instituto Ética Saúde.

Why?

The IES has been doing an admirable work in promoting a more ethical business environment in healthcare in Brazil. Through the reporting channel, it receives complaints of bad practices in the sector and produces reports for forwarding to the competent authorities. The IES has cooperation agreements with the National Association of the Public Ministry in Defense of Health (Ampasa), Anvisa, TCU, Administrative Council for Economic Defense (Cade), Comptroller of the Union (CGU), among other entities.

How?

State and government agencies should support the actions of the IES and encourage companies and entities to adhere to the program established by the Institute, strengthening its performance as an essential entity for Brazilian society.

PROPOSAL 3

Support initiatives of associations and companies in the Americas to debate business ethics in the medical devices industry.

Why?

It is very important that the discussion on business ethics is widely disseminated and encouraged, with clear demonstrations of intolerance to those who insist on obtaining undue economic advantage in commercial transactions in the health area. When entities from countries unite for this purpose, we see new ideas, partnerships and proposals to increase actions that discourage these practices.

How?

The Brazilian government can promote and participate in debate and discussion forums in the Americas, including the support of the diplomatic corps, in the search for practical, measurable and feasible actions that can be applied to all countries involved.

PROPOSAL 4

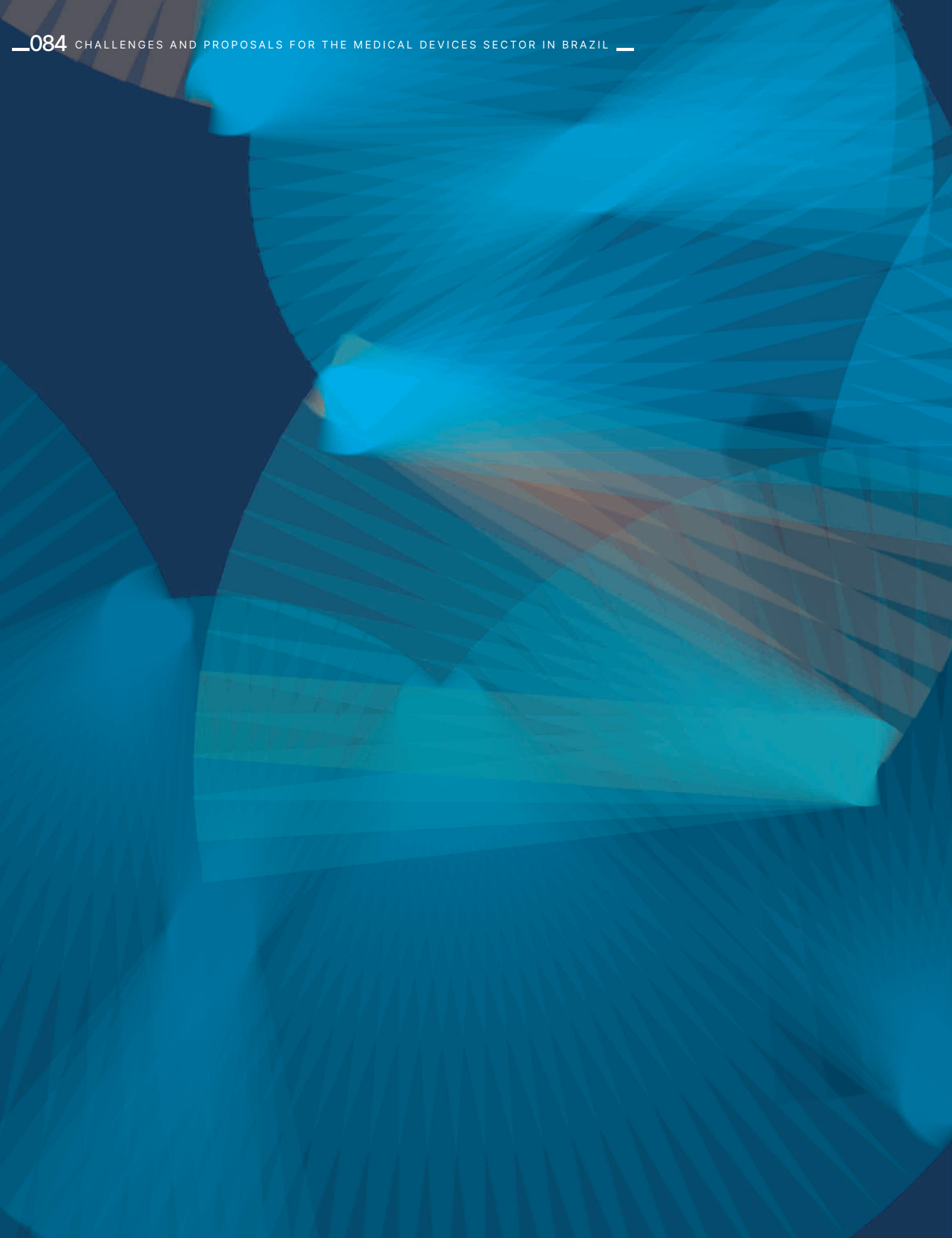
Propose to the National Congress to make it mandatory for associations and companies to have codes of conduct, which must be updated frequently.

Why?

The codes of conduct or ethics of associations and companies are the closest guiding documents for the actors involved in the discussion on business ethics. They work as primers that guide the actions of professionals in the sector and serve as a guide for field work. Therefore, they must be encouraged and constantly updated. They must also be easily accessible to all professionals.

How?

Submit a bill proposal to the House of Representatives that makes it mandatory for associations and companies to have codes of conduct, providing technical support for this measure.



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Research, Development & Innovation (RD&I)

Research, Development & Innovation (RD&I)

RD&I is one of the most important topics for the medical devices sector in Brazil and in the world, as it is the core of performance and survival of the entire manufacturing and supply chain of products and services that are part of this segment.

Advanced technology, labor specialization, smart regulation, regulators qualification, scientific level rise, socioeconomic development, competitiveness, Brazil's insertion in global value chains are some of the many microcosms that make up the innovation ecosystem of any country.

By adopting innovation as one of the main pillars of its performance, ABIIS understands that Brazil needs to improve this area. And it needs to do it quickly, so as not to miss the timing of global scientific development.

It also knows – and wants to contribute to undoing – the countless barriers that stand in the way of those who wish and need to innovate. Barriers that also act as breaks to the development of the country itself.

The Alliance believes that Brazil has the necessary framework for doing more R&D locally. It has internationally recognized research centers, scientists and universities of excellence. It has a thriving, structured and enterprising industry, financers and investment funds, companies and development institutions.

RD&I is one of the most important topics for the medical devices sector in Brazil and in the world, as it is the core of performance and survival of the entire manufacturing and supply chain of products and services that are part of this segment.

The Covid-19 pandemic revealed to the world the importance of science and technological advancement. Investing mainly in innovation was the solution that many countries found to face the health crisis, according to a study carried out by the Institute for Applied Economic Research (Ipea) in May 2020.[19]

"More than ever, there is a recognition that the way out of the health, economic and social crisis caused by Covid-19 will strongly depend on the capacity to produce knowledge and new technologies", says Ipea.

The survey showed that countries that traditionally invest in R&D, such as Germany, the United States, Canada and the United Kingdom, have made resources available not only for Covid-19 research but also to preserve the innovative capacity of companies and strengthen research and development (R&D) projects that invest in science and technology of public health supplies.

Successful international experience shows that attitudes like these also result from a strong articulation among governments, the scientific community of universities and research institutes, and industry. In the United States, for example, the country that allocates the largest absolute volume of public investment in science and technology (US$ 130 billion per year, or about 0.8% of its GDP), the Executive Branch has a council that advises the president on S&T themes, formed by scientists from universities, research institutions, companies and non-governmental organizations.

The model of partnerships among universities, companies and government, known as the Triple Helix, was developed in the 1990s to guarantee technological development and the transformation of theoretical knowledge into practical applications.

Countries that bet on this model, in general, align their industrial policies with those of innovation to foster collaboration. Brazil, however, still has a long way to go if it wants to follow this path and promote innovations that meet society's demands, in ABIIS assessment.

The Alliance proposes that efforts to develop a national policy that comes up with innovation also involve development agencies and society in a broad debate.

Concerning health, it understands that the assessment of medical technologies should be done in line with government funding efforts and S&T policy. And that decision-making is based on multiple criteria in addition to price, such as scientific literature, real-life data and the comparison between the budgetary impact and the benefits for the population's health and quality of life.

ABIIS also considers it important to improve communication channels so that managers can express their needs to the market and to a global technological trend prospection, the so-called technological horizon. ABIIS believes that, in this way, it will be possible to encourage an innovation that promotes better patient care.

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[19] DE NEGRI, Fernanda; KOELLER, Priscila. *Políticas públicas para pesquisa e inovação em face da crise da covid-19*. Brasília: Ipea, 2020. Nota Técnica nº 64, maio de 2020, Diset – Diretoria de Estudos e Políticas Setoriais de Inovação e Infraestrutura. Available at: https://www.ipea.gov.br/portal/images/stories/PDFs/nota_tecnica/200520_nota_tecnica_diset_n_64.pdf. Access on: July 29, 2021.

INNOVATION IN HEALTH

Patrícia Braile

Chairman of Braile Biomédica.
With collaboration of Rafael Braile, RD&I director at Braile Biomédica,
and Glaucia Basso Frazzato, Research coordinator at Braile Biomédica.

Talking about research, development and innovation (RD&I) and health in Brazil is a challenging topic!

I would say that it can be exhausting and, most of the time, it can discourage us because we do not see a way out and we do not see a will or focus.

Unfortunately, our country is still in the process of understanding this issue and its importance for building a nation.

If we try to understand the development in countries, we will see that it is intrinsically linked to how much this country has valued and invested in research, development, technologies and the expansion of the search for knowledge.

The mentality that still resists in our country brings traces of "Colonial Brazil" and deeply stains the self-esteem in Brazil. We still have the fallacy that we are less capable than other people and that everything they develop and produce abroad is better than what we develop and produce here. Confidence in ourselves needs to be encouraged, valued and put into practice.

At the core of the problem, we can find several reasons, but we choose here to declare that the Brazilian State does not have a strategic plan for RD&I in the health area.

We are not talking about governments here. Governments are transient, they come and go all the time. We are talking about the State and the State strategy.

Let's look at examples from some countries:

South Korea developed its strategy for growth in RD&I by investing in training engineers. It is the country with the most engineers per population in the world. They believed that training engineers would be the basis of the country's technological foundation.

China's strategy, on the other hand, bet that the development of advanced technologies would require the "international transfer of technology", a process of learning by doing. And they learned.

The United States decided to inject capital into both state-based science and private companies. And so they have done and continue to do, so that ideas are formed, and research, development and innovation are strengthened.

Israel is a startup nation, it does not have a base industry, but it has a very strong RD&I front, financed by the country's innovation agency. It encourages the emergence of startups and then reap the rewards of innovative technology.

Regardless of which, there is always a strategic plan. And that is how the country grows, gets stronger and develops.

Let us now ask the question that does not want to remain silent: What is Brazil's plan regarding development, innovation and technology in the health area? Does it exist? Is there any strategy? Are our governors (Executive, Legislative and Judiciary branches) working to build a real health RD&I program in Brazil? Do we know what are the national strengths? What are our weaknesses? What are our opportunities? And what are the threats? How can Brazil differentiate itself in the face of global innovation? How are we going to accelerate this process? Or are we always adrift, always waiting for others to do it for us?

The Covid-19 pandemic has exposed the problem. We are a country dependent on others in the health area.

And what is the lesson we have learned?

A country that is aware of what is relevant to its independence invests in and encourages innovation and a high-tech and strategic industry.

This is not to say that we should be an isolated country. No, not at all, but truly a sovereign country. A nation cannot be totally dependent on the "good will" of other countries, a nation needs to invest in itself and in its own competences and capacities.

In Brazil, except for some "islands of excellence", innovating is very difficult and lonely. It is almost a medieval adventure, in which the fighter faces dragons and all sorts of endless battles. There are years and years of struggle and piles and piles of papers and files that come and go in an almost endless process.

The latest IBGE Survey of Innovation showed that Brazilian companies invest only 1.95% of their net sales revenue in RD&I

(PINTEC 2017). It was also noted that only 26% of innovative companies benefit from some type of innovation support.

Despite the discouraging numbers and the problems and obstacles to innovate and reasons not to innovate, we cannot deny that today there are excellent programs and extremely intelligent and effective initiatives for the innovation development.

If minds are opened, models for promoting innovation in industry such as those of the Brazilian Company of Research and Industrial Innovation (Embrapii) will multiply and we will be facing a real possibility of turning the key.

Embrapii is an excellent example of a partnership model that works and needs to be multiplied and multifaceted. The model, which is less bureaucratic, has really worked and helped, in a proactive and effective way, in the development of new technologies in Brazil.

We also have Law No. 11,196/2005, the well-known "Law of Good", which makes it possible to grant tax benefits to companies that carry out RD&I, which also encourage innovation.

The technological, personal and financial union and partnership among the State, technological institutes and companies works.

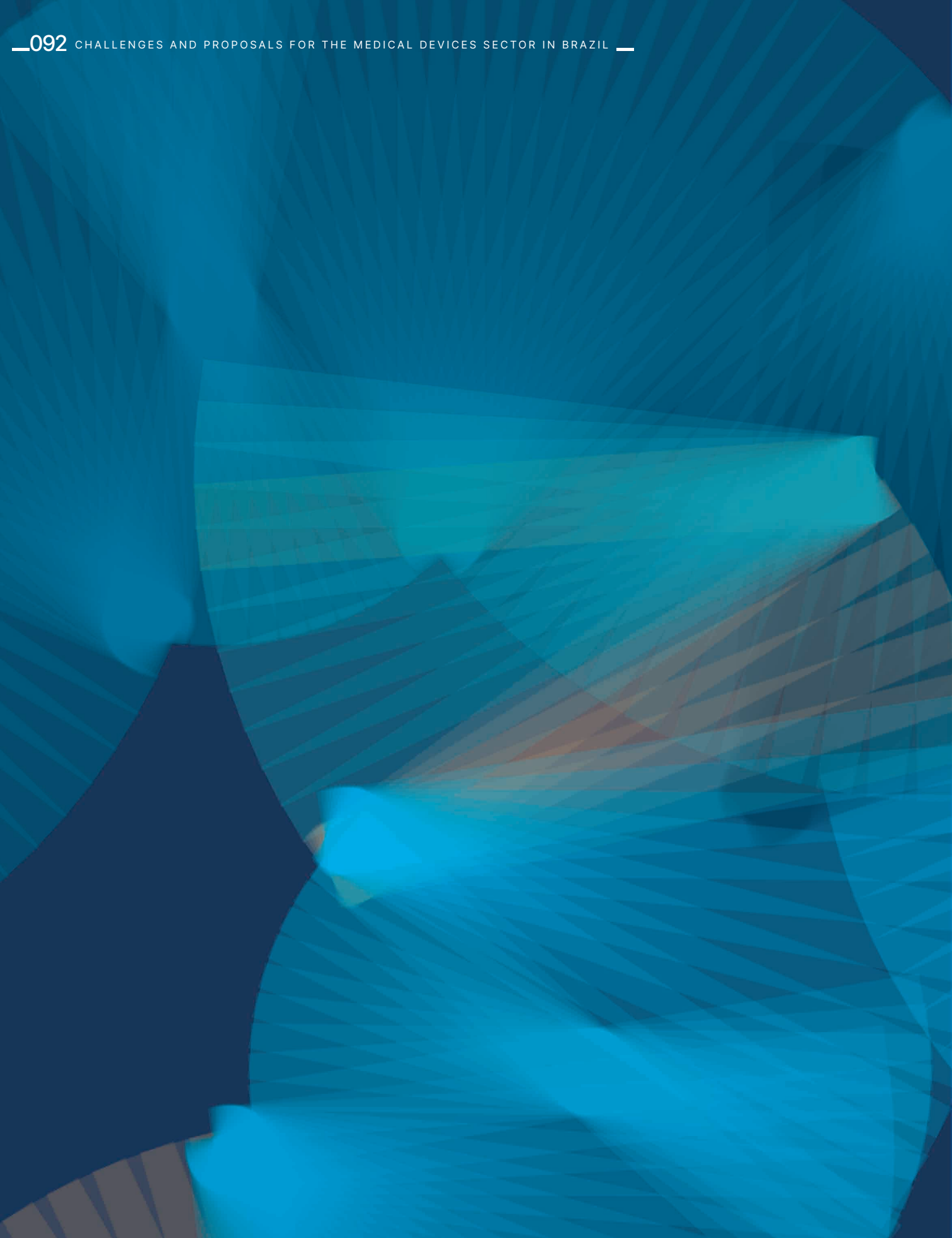
It is important to understand that you cannot get very far alone. If you share you multiply yourself, it is in the union of efforts that geniality shines.

We will work tirelessly so that the minds of all involved are open and ready to break down the barriers and shackles that bind us to bureaucracies and outdated, closed models that pull us into the depths of apathy and sameness.

The construction of a strategic RD&I plan for our country is the central point so that our Brazil opens up in opportunities and progress and thus finds our way to invest in what is most intelligent in each one of us!

"To be great, be whole: nothing that's you / Should you exaggerate or exclude. / In each thing, be all. Give all you are / In the least you ever do. / The whole moon, because it rides so high, / Is reflected in each pool."
*Ricardo Reis**

*Translated by Edouard Roditi. Available at: https://www.poetryfoundation.org/poetrymagazine/poems/26781/odes. Access on: Aug. 22, 2021.



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Health 4.0 and MD Sector


TREND TABLE
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PUBLIC POLICIES FOR IOT IN HEALTH

Daniel T. Stivelberg

The Internet of Things (IoT) is the connection among physical objects, through the internet, to communicate data and information, promoting a true symbiosis between the physical and digital worlds. According to Cisco,[20] machine-to-machine (M2M) communication will represent 50% of the connections among devices as of 2023, surpassing other types of connected devices, such as smartphones, TV, PCs and tablets. The expected average growth for M2M communication in 2018 and 2023 is 33% per year, and it is estimated that more than 14 billion devices will be connected by the end of this period. Thus, IoT becomes the prevailing system from which people, processes, data and things will connect to the internet and to each other. The connections among household devices, such as white goods, urban devices, such as traffic lights and motor vehicles, and health devices, such as patient monitoring and automatic emergency notifications, are considered the main verticals to be impacted for the use of IoT solutions in Brazil and worldwide.

Brasscom[21] estimates that, by 2024, approximately R$ 415 billion should be invested in digital technologies in Brazil, of which R$ 74.3 billion will be allocated to IoT solutions. The technology adoption impacts all areas of economic and social life: (I) agriculture, with the use of precise cultivation techniques; (ii) industry, with the phenomenon of advanced manufacturing; (iii) services, with the automation of techniques and assistance; (iv) government, for the provision of digital and data-intensive public services; and (v) citizenship, heir to important legacies such as electronic voting and increased social participation in public decisions.

The socioeconomic benefits of IoT solutions are undeniable and, to some extent, well-known, but their wide adoption depends on structuring and long-term public policies. The exemption of M2M communication in Brazil, for example, represented an important step in encouraging investments in IoT. The sanction of Law No. 14,108/2020 exempted this

20 Cisco Annual Internet Report, 2018-2023.

21 Associação das Empresas de Tecnologia da Informação e Comunicação e de Tecnologias Digitais (Brasscom), com dados do IDC (Black Book, 3ª Plataforma 2020 H1) e Frost & Sullivan (Brazil's Total Telecommunications Services Market, Forecast to 2025 – Latin America ICT Growth Opportunities, Forecast to 2025).

type of communication from four taxes as of January 2021, namely, the Installation Inspection Fee (TFI), the Operation Inspection Fee (TFF), the Contribution for the Promotion of Public Broadcasting (CFRP) and the Contribution to the Development of the National Film Industry (Condecine). It is, therefore, a great advance as it has reduced the cost of connectivity among machines and thus more investments in its dissemination are expected. On the other hand, important challenges remain for the wide adoption of IoT solutions in the country, such as the speed and availability of the internet connection and full compliance with personal data protection rules, which aim to safeguard the rights of holders and promote legal certainty for investments and technological innovation.

Brazil faces major challenges regarding the expansion of internet coverage and availability. The lack of pervasive connectivity is inhibiting the IoT adoption on a large scale. While 4G internet made the connection among people possible, the expansion of ultrafast connectivity, as is the case of 5G, will enable the connection between everything and everyone, allowing the dissemination of smart meters, use of high-definition video monitoring systems, monitoring through medical devices, transit of autonomous vehicles, sensing of crops, tracking and monitoring of assets in the supply chain, among others. By 2024, approximately R$ 430 billion should be invested in mobility and connectivity (mobility, data and broadband) in Brazil.[22] The full materialization of large-scale investments will only be possible in an environment of regulatory predictability and legal certainty.

For 5G, the main challenge is a rapid conclusion of the frequency auction by Anatel and the effective implementation of investments by the private sector, in a balance between market interests and public demands for universal access. In this regard, an important step was taken with the sanction of Law No. 14,109/2020, which authorized the use of resources from the Fund for Universalization of Telecommunications Services (Fust) for broadband investments, until then restricted to fixed telephony. More than ever, it is essential that the Fund's resources are in fact used for the purpose of expanding coverage. 5G will enable the massification of IoT and the use of solutions in critical applications due to the combination of features such as higher speed (10 Gps, or 30 times that of 4G), more connection points (1 million/ km^2, or 100 times that of 4G) and lower latency (between 1 and 4 milliseconds), that is, the data communication time between one point and another. Another important aspect is the need for flexibility in licenses and authorization for the installation of telecommunications infrastructure, such as antennas. 5G technology deepens this challenge as it will require a greater number of access points. At

[22] Associação das Empresas de Tecnologia da Informação e Comunicação e de Tecnologias Digitais (Brasscom), com dados do IDC (Black Book, 3ª Plataforma 2020 H1) e Frost & Sullivan (Brazil's Total Telecommunications Services Market, Forecast to 2025 – Latin America ICT Growth Opportunities, Forecast to 2025).

the same time, it is important to encourage, through the elimination of regulatory barriers, the adoption of other forms of connectivity, such as the new generation of wireless networks, Wi-Fi 6, and the exemption of data communication via satellite.

In the reality of healthcare, which is intensive in critical applications, the speed of data transmission for IoT solutions is fundamental and will enable the expansion of the use of innovations such as: (i) telehealth, with the digital exercise of medical and health assignments; (ii) health monitoring devices, such as blood pressure and heart rate monitoring through smart pacemakers and electronic wristbands; (iii) connected beds, which assist in monitoring patients at risk of falling or in automated posture adjustment; (iv) specialized sensors installed in hospitals and nursing homes with the objective of identifying the health conditions of patients and the elderly people; (v) wearable devices, such as smart watches, which allow continuous monitoring, encouraging the adoption of healthy habits; (vi) prenatal and chronic disease monitoring, supporting predictive intervention and, as appropriate, automatically administering medications according to the conditions; (vii) smart medical devices for general use, equipped with radio frequency identifiers (RFID), such as blankets, gloves, furniture and other hospital instruments; and (viii) surgical robots, a frontier innovation that, like other technologies, should be used to help promoting health and within ethical and regulatory limits; between others.

The new techniques employed through digital technologies allow for an unprecedented increase in the human capacity to deal with large volumes of data. Through them, we are able to gather, store, communicate, analyze, treat and use information in a way that is incomparable in history. Data use raises concerns about information security and privacy. Cisco[23] predicts that by 2022 global data traffic, including personal data, will reach 400 exabytes[24] per month, and the IDC[25] estimates that by 2025 the total amount of data stored across the planet will be about 175 zettabytes.[26] The Cost of Data Breach 2020 report,[27] published by IBM Security, shows that, for the tenth year in a row, the healthcare industry has had the largest average loss from data breach. The report surveyed 524 affected organizations, located in 17 countries and regions and belonging to 17 different sectors. For the universe surveyed, the loss of the health sector with data breach was about US$ 7 million, an increase of 10.5% compared to 2019.

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[23] Cisco Visual Networking Index (VNI), Complete Forecast Update, 2017-2022.

[24] Unit of measurement of information that equals 1,000,000,000,000,000,000 (number 1 followed by 18 zeros).

[25] IDC White Paper, nov. 2018 – The Digitalization of the World – From edge to core.

[26] It would take 1.8 billion years to complete the download of the entire datasphere predicted for 2025, if we consider an average rate of 25 Mb/s.

[27] This is the 15th year that the Ponemon Institute has conducted a research to produce the annual Cost of Data Breach report, including the last five years. It was sponsored and published by IBM Security.

In the reality of healthcare, which is intensive in critical applications, the speed of data transmission for IoT solutions is fundamental and will enable the expansion of the use of innovations such as telehealth, prenatal and chronic disease monitoring, and general-purpose smart medical devices.

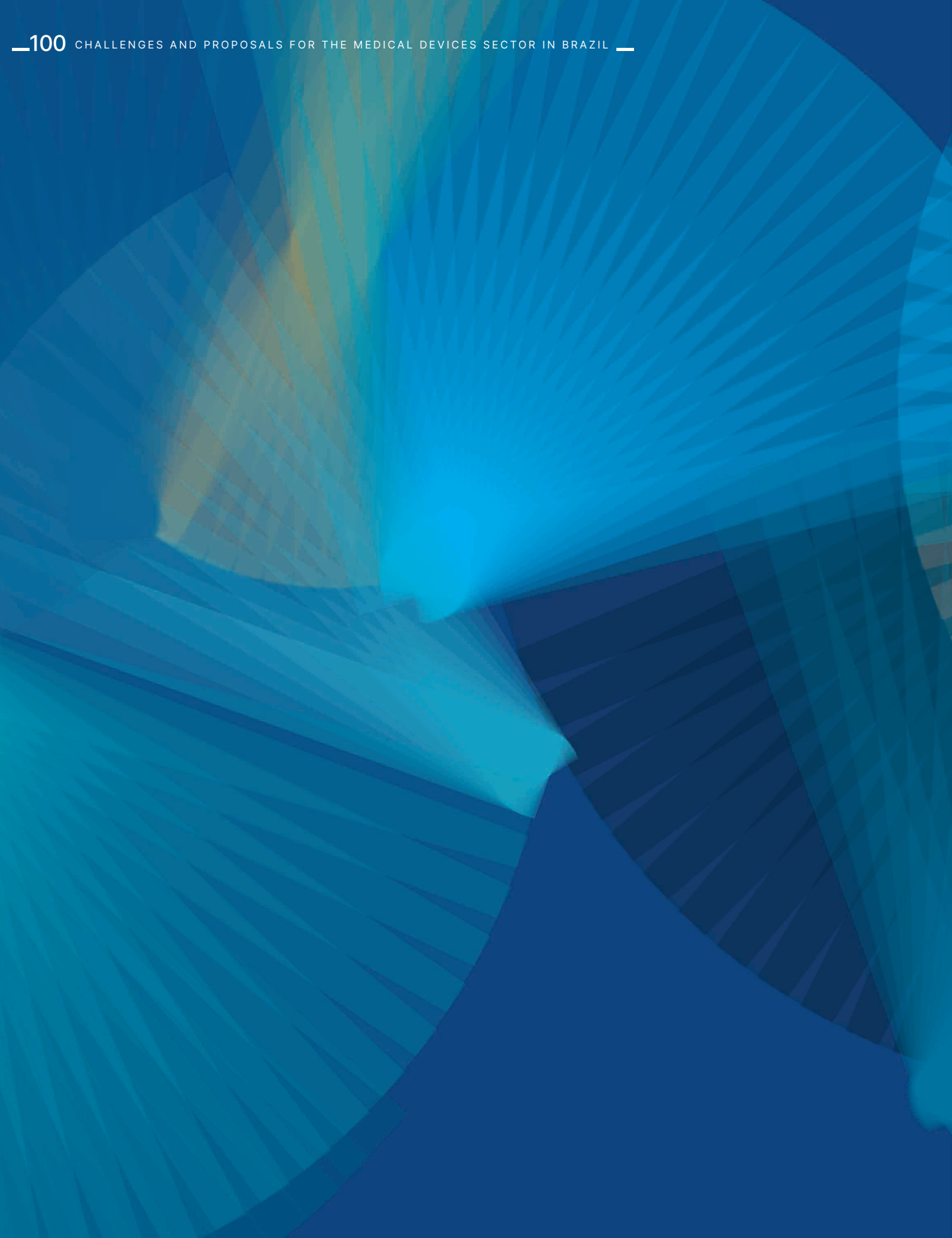
However, in addition to the challenge of information security, the intensive use of new techniques and digital technologies has also triggered the most diverse reactions and controversies that permeate the public debate on privacy risks. Sensor network enables health professionals to collect and process data, analyzing them or sharing them with legitimately interested parties to allow preventive or interventional medical treatment, reducing costs and human failures. The collection and processing of personal data, especially sensitive data such as health data, is a challenge that emerges from the intensive use of IoT in this vertical. Regarding compliance, the productive sector needs to recognize and value the existence of a legal framework for the protection of personal data in Brazil. Law No. 13,709/2018, also known as the General Data Protection Act (LGPD), is considered a modern and principled legislation that, as it protects fundamental rights and guarantees, can also be an instrument to stimulate innovation and security legal framework for investments. The proper handling of the LGPD, especially the full understanding of the articulation of its fundamental principles, such as the legitimate and specific purpose of data processing, the need, that is, the collection of the necessary data to achieve the stated purpose, and the adequacy, or the compatible treatment of personal information collected to achieve the informed purpose, as well as the adoption of the proper legal basis, are highly relevant and urgent tasks that need to be handled with transparency and responsibility.

Regarding legal bases, the LGPD brings a list of 10 hypotheses that authorize the processing of personal data. For the health sector, the most commonly used hypotheses are the protection of health, consent, contract fulfillment and compliance with legal or regulatory obligation. The adoption of the legal basis of legitimate interest, on the other hand, should be preceded by a careful and responsible preparation of Legitimate Interest Assessment (LIA), in order to give market agents the security to improve the implementation of health innovations. This legal basis, however, should not be used for the processing of sensitive personal data, as in the case of health data, but it is able to authorize the processing of personal data for a very wide range of situations in business life, even in the healthcare vertical.

Finally, regarding the regulation of the LGPD, the market has an important role of undertaking effective participation in the taking of subsidies and public consultations, which have already been carried out by the National Data

Protection Authority (ANPD), as well as active participation in the National Commision for Data Protection and Privacy (CNPD), either through representative associations or individually. This activity is a public function and essential for strengthening the institutional dialogue with the ANPD and other bodies that are responsible for supervising the sector, such as Anvisa. In these and other topics, the work of institutional relations before agencies and autarchies needs to pursue the following objectives: (i) the promotion of educational actions, in order to disseminate knowledge on data protection standards and provide an environment of greater trust among data holders, agents in the processing chain and public authorities; (ii) the inductive normative production, that is, the LGPD regulation that does not discourage investments, but provides legal certainty for innovation, without losing sight of the necessary protection of the fundamental rights of data subjects; and (iii) the induction of a high degree of compliance, that is, providing agents in the processing chain with the necessary instruments for an effective compliance with the rules.

The Internet of Things is already a reality and important steps have been taken recently with the exemption of M2M communication and the reorientation of Fust for broadband investments. However, important challenges for the full adoption of IoT are still on the agenda, such as the urgency of completing the 5G auction and the necessary speed in municipal authorizations for the implementation of connectivity infrastructures (antennas). Other points of legal and regulatory uncertainty still hang over the fate of Wi-Fi 6 and the cost of satellite internet connections. The use of personal data, another crucial issue when employing IoT solutions in the healthcare vertical, calls for an adequate and unprejudiced understanding of the importance and usefulness of the LGPD to provide legal certainty, reduce information security risks, protect data subjects and enable innovative processes. For this, it is necessary to go beyond the construction of personal data protection governance in the organization. It is also necessary to advance in the continuous institutional dialogue with the competent public bodies, such as the ANPD and Anvisa, aiming at a normative and regulatory production that induces economic growth, innovation and digital transformation.



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Conclusion

Conclusion

Historically, the performance of the medical devices industry has been linked to continuous innovation of products designed to improve patient care outcomes and facilitate their use by healthcare professionals, increasing the effectiveness and safety of the medical care.

However, the successful sustainable development of innovative products depends on addressing two issues that directly impact the results: **public policies that encourage R&D (Research and Development) and a regulatory environment favorable to innovation.**

Brazil is still faltering on its ST&I (Science, Technology and Innovation) policy. Some focal points of the problem are the distance that separates the production of knowledge from the country's social interest and the disarticulation among the actors that can put innovation at the service of society and socioeconomic development: government, universities and the medical devices industry.

Regarding the regulatory sphere, there are undeniable advances and a clear willingness of regulatory agencies to break down barriers to innovation. However, there is still a long way to go towards a smart regulation, which does not create unnecessary bureaucracy and ties, and which takes into account the possible impacts of regulatory decisions.

Added to this scenario is the need for an agile technology incorporation system that keeps pace with the global development of medical technologies, at the risk of creating a gap between the benefits available to Brazilian patients and those accessible to patients around of the world.

The success of this set of requirements to create a favorable framework for the development of science, technology and innovation in the medical devices sector obviously also depends on the qualification and continuous training of technicians responsible for the regulatory and technology incorporation areas in SUS and in supplementary health.

The principles defended by ABIIS are old and continue to guide its performance as a representative of the medical devices industry and its dialogue with the Executive, Legislative and other stakeholders.

PERSPECTIVES

The Brazilian health sector, in its various sub-segments (mainly hospitals, healthcare plans and clinical analysis laboratories), has been going through an important business consolidation, through mergers and acquisitions, which tends to continue in the coming years. This process has given rise to large conglomerates and business groups and has induced changes in market dynamics and in the interaction among industry players. ABIIS understands that these new configurations demand greater attention from the government authorities responsible for regulating these activities, observing the interest of patients and the sustainability of the sector.

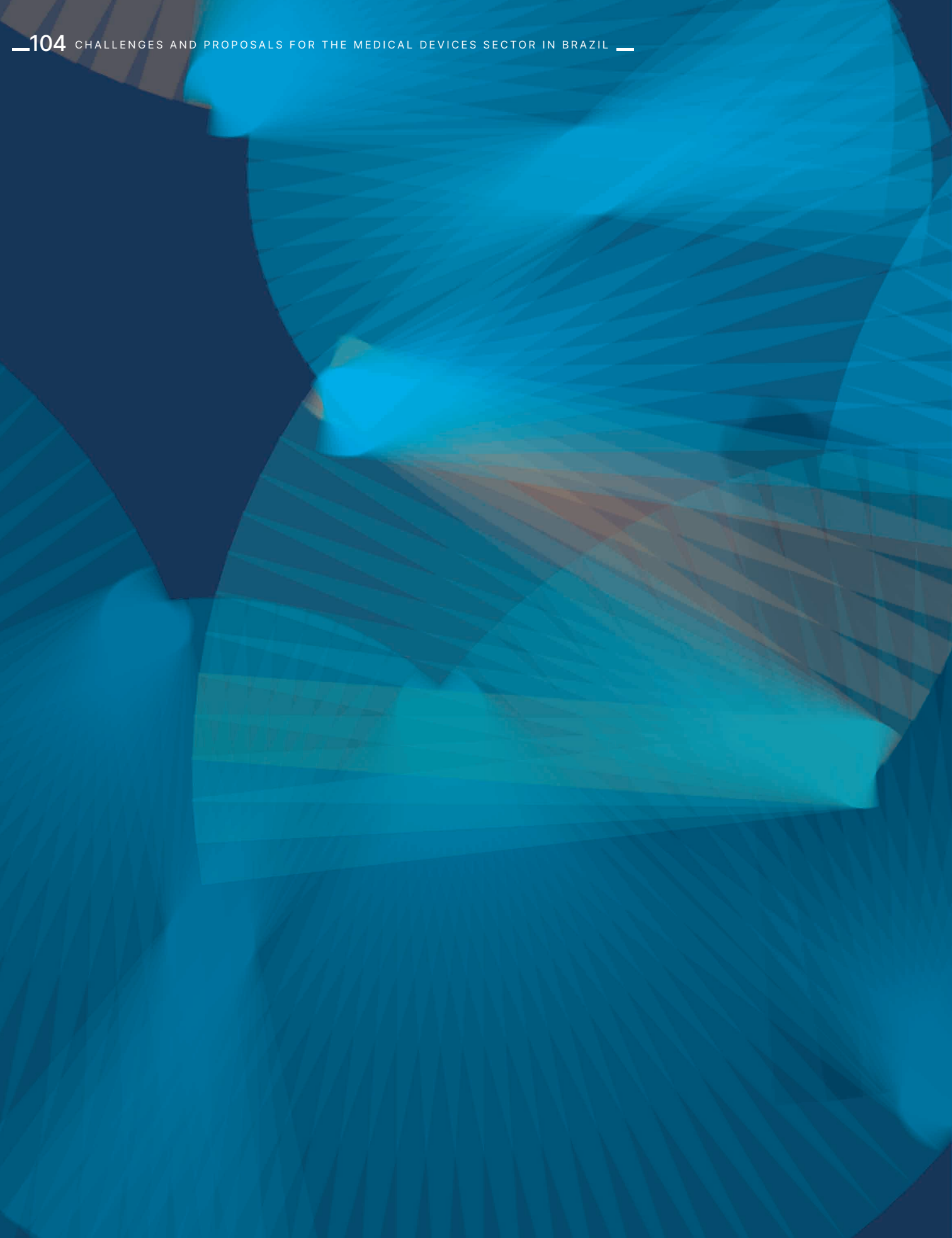
The General Data Protection Act (LGPD) is also starting to significantly change the interaction among health players, especially regarding patients, which demands a permanent dialogue between government and civil society bodies.

These two factors are backed by technological advances, especially in communications, which add complexity to regulators, while representing a great opportunity for the country to expand patient care and access to the health system, mainly in more distant locations.

ABIIS also believes that the combination of MD and information technology should be deepened. In this process, technical, regulatory and ethical issues will certainly arise that will demand a lot from all health players. For this, Brazil needs to overcome the challenges outlined in this book.

The relationships among companies, governments and citizens will need to be reassessed so that, more than ever, the common good prevails. In order to have more equity in health, a profound reassessment of our health system will be essential, with a focus on patient care, without neglecting the responsibility for the economic sustainability of the entire chain, the epidemiological challenges and the production of clean technologies to ensure that all the changes to come will only be positive.

We hope that the government itself will act as a facilitator, stimulating a broad debate among all healthcare representatives so that we can seek joint solutions to our complex and structural problems.



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Consolidated Propositions

Consolidated Propositions

PROPOSALS FOR SMART REGULATION

PROPOSAL 1

Implementation of the Good Practices chapter of the Protocol to the Agreement on Trade and Economic Cooperation between Brazil and the United States of America related to trade rules and transparency (MSC 165/2021).

PROPOSAL 2

Implementation of mechanisms to strengthen the Regulatory Impact Analysis (RIA) in the Federal Executive Branch, especially in Anvisa, ANS, Anatel, Ministry of Health, Inmetro, among others.

PROPOSAL 3

Creation of a central external body in charge of conducting RIAs, even if only partially.

PROPOSALS FOR INSTITUTIONAL DEVELOPMENT OF REGULATORS

PROPOSAL 1

Adequate structuring of the Brazilian Health Regulatory System (SNVS), especially in states and municipalities.

PROPOSAL 2

Considering that the medical devices industry is multidisciplinary and requires highly specialized professionals, it is essential that regulatory agents have permanent training programs that prepare them to analyze innovative technologies and maintain a uniform interpretation in all SNVS units.

PROPOSAL 3

Requirement of technical and ethical accuracy in the nominations for the board of regulatory agencies (especially at Anvisa, ANS, Anatel, Inmetro), so that the nominees have "an unblemished reputation and notorious knowledge in the field of their specialty", in accordance with Law No. 9,986/2000.

PROPOSAL 4

Adequacy of Anvisa's information system to the dimensions and amplitude of its activities.

PROPOSALS FOR RATIONAL INCORPORATION OF TECHNOLOGIES

PROPOSAL 1
Creation of a regulatory agency for the Assessment of Incorporation and Deregistration of Health Technologies, independent of the Ministry of Health and ANS.

PROPOSAL 2
Establish appropriate deadlines, procedures and processes for the analyses.

PROPOSAL 3
Creation of specific HTA protocols for medical devices.

PROPOSAL 4
Inclusion of a specific allocation of resources, in the annual budget of the Ministry of Health, for the incorporation of new technologies.

PROPOSALS FOR IMPROVING THE BUSINESS ENVIRONMENT

PROPOSAL 1
Unburden and simplify the medical devices sector taxation.

PROPOSAL 2
Insert Brazil in global production chains.

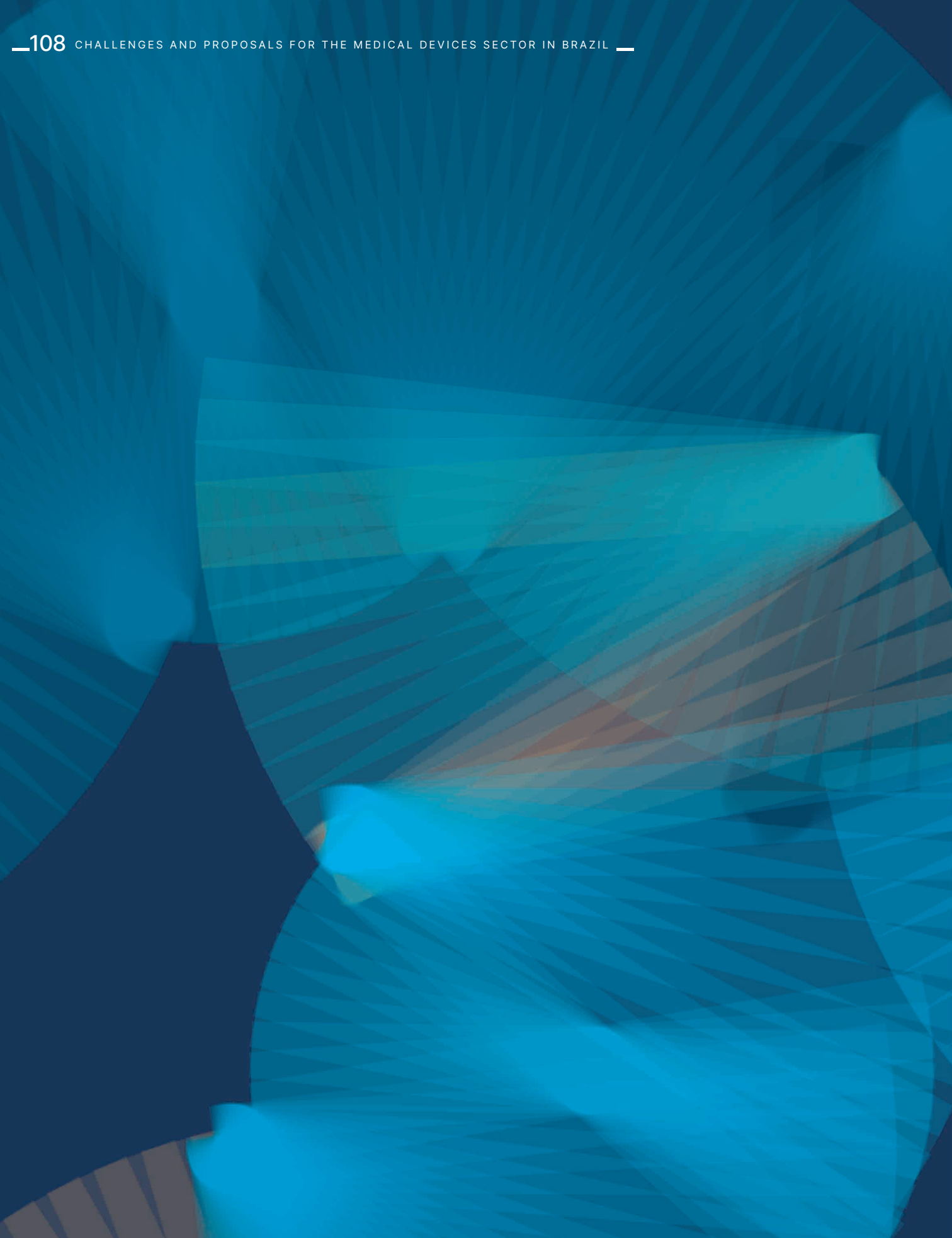
PROPOSALS FOR ETHICS AND COMPLIANCE

PROPOSAL 1
Typify in the Penal Code the obtaining of undue advantage that involves actions resulting from the indication of the use of medical devices.

PROPOSAL 2
Strongly support the actions of the Instituto Ética Saúde.

PROPOSAL 3
Support initiatives of associations and companies in the Americas to debate business ethics in the medical devices industry.

PROPOSAL 4
Propose to the National Congress to make it mandatory for associations and companies to have codes of conduct and that these be updated frequently.



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Legislative Agenda

Legislative Agenda

ABIIS monitors some priority legislative propositions in the National Congress. Some of them converge with the Alliance's ideals and others are considered harmful to the health sector. We have selected those that are of greatest interest to the entity. See below.

HOUSE OF REPRESENTATIVES

PL 221/2015

Congresswoman Jô Moraes (PCdoB/MG) – Adds an article to Law No. 8,078, of September 11, 1990, Consumer Defense Code, to typify the obtaining of an advantage for the referral of procedures, for the marketing of medicines, orthoses, prostheses or implants of any nature.

PL 1,539/2015

Congressman Eros Biondini (PTB/MG) – Establishes the obligation of conducting a Regulatory Impact Analysis (RIA) by Regulatory Agencies within the scope of the Federal Administration.

PL 2,453/2015

Author: Parliamentary Commission of Inquiry aimed at investigating Cartel in the Pricing and Distribution of Orthoses and Prostheses – Amends Law No. 8,080, of September 19, 1990, to dispose on the creation of the System of Continuing Education in New Technologies and Medical Devices in the scope of SUS.

PL 2,452/2015

Author: Parliamentary Commission of Inquiry aimed at investigating Cartel in the Pricing and Distribution of Orthoses and Prostheses – Criminalizes the conduct perpetrated by the "Mafia of Orthoses and Prostheses".

PL 380/2015

Congressman Fábio Mitidieri (PSD/SE) – Amends Law No. 10,742, of October 6, 2003, to provide for the economic regulation of the sector of orthoses, prostheses, health products and include in the jurisdiction of the Drug Market Regulation Chamber (CMED) the fixation and adjustments of prices in the sector.

PL 7,990/2017

Congressman Geraldo Resende (PSDB/MS) – Provides for transparency and publicity of financial relationships established between the healthcare industry and physicians.

PL 7,082/2017

Senator Ana Amélia (PP/RS) – Provides on clinical research involving human beings and establishes the National System of Ethics for Clinical Research Involving Human Beings.

PEC 45/2019

Congressman Baleia Rossi (MDB/SP) – Alters the National Tax System and makes other provisions.

PL 3,887/2020

Executive Branch – Institutes the Social Contribution on Operations with Goods and Services (CBS) and alters the Federal Tax Legislation.

PL 3,243/2020

Maurício Dziedricki (PTB/RS), Eduardo Costa (PTB/PA), Pedro Lucas Fernandes (PTB/MA), Emanuel Pinheiro Neto (PTB/MT) and others – Provides for the conception of the National Portal of Prices for Products, Equipment and Services of Any Nature to be used as a monetary reference by the country, States and Municipalities for purchases or contracts when in an emergency or in a state of public calamity.

PL 1,008/2020

Congressman Túlio Gadêlha (PDT/PE) – Provides for the State control in combating manipulation and abuse of prices in cases of pandemic or state of public calamity.

PL 2,583/2020

Dr. Luiz Antonio Teixeira Jr. (PP/RJ), General Peternelli (PSL/SP), Dra. Soraya Manato (PSL/ES), Dr. Zacharias Calil (DEM/GO), Mariana Carvalho (PSDB/RO), Carmen Zanotto (Cidadania/SC) and others – Institutes the National Health Strategy aiming to establish a national strategy to encourage national industries that produce essential items for the national health system, as well as the research and development of products, supplies, medicines and materials, in order to give our country autonomy in terms of production of these items.

PL 1,998/2020

Congresswoman Adriana Ventura (Novo/SP) and others – Authorizes and defines the practice of telemedicine throughout the national territory.

FEDERAL SENATE

PL 1,759/2020

Fernanda Melchionna (PSOL/RS), Luiza Erundina (PSOL/SP), Sâmia Bomfim (PSOL/SP), David Miranda (PSOL/RJ), Talíria Petrone (PSOL/RJ), Ivan Valente (PSOL/SP), Marcelo Freixo (PSOL/RJ), Edmilson Rodrigues (PSOL/PA), Áurea Carolina (PSOL/MG) and others – Provides for the creation of the Emergency Productive Reconversion Plan (PERP) to ensure the reorganization of the productive and economic sector in order to generate essential supplies to protect health professionals and the population against the Covid-19 pandemic; institutes the Emergency Fund for Productive Reconversion and makes other provisions.

MSC 165/2021

Text of the Protocol to the Agreement on Trade and Economic Cooperation between the Government of the Federative Republic of Brazil and the Government of the United States of America Relating to Trade Rules and Transparency, signed in Brasilia and Washington, on October 19, 2020.

PL 2,337/2021

Executive Branch – Alters the legislation on Individual and Legal Entities Income Tax and Social Contribution on Net Income.

PL 1,613/2021 (PLS 415/2015)

Senator Cássio Cunha Lima (PSDB/PB) – Amends Law No. 8,080, of September 19, 1990 (Organic Health Law), to provide for the processes for incorporating technologies into the Brazilian Health System (SUS) and for the use, by SUS, of medicines whose indication for use is different from that approved in the registry of the National Health Regulatory Agency (Anvisa).

PLS 17/2015

Senator Ana Amélia (PP/RS) – Defines regulatory standards for the market for orthoses, prostheses and special materials.

PEC 156/2015

Senators José Serra (PSDB/SP), Aloysio Nunes Ferreira (PSDB/SP), Ana Amélia (PP/RS), Antonio Anastasia (PSDB/MG), Antonio Carlos Valadares (PSB/SE), Ataídes Oliveira (PSDB/TO), Blairo Maggi (PL/MT), Cássio Cunha Lima (PSDB/PB) and others – Includes §§ 13, 14 and 15 in art. 37 of the Federal Constitution to provide for the recruitment of directors of regulatory agencies and limit the number of positions on commission in these entities.

PLS 299/2016

Senator Telmário Mota (PDT/RR) – Amends Law No. 6,437, of August 20, 1977, to prohibit the reuse of health products that cannot be reprocessed.

PEC 110/2019

Senators Davi Alcolumbre (DEM/AP), Acir Gurgacz (PDT/RO), Alessandro Vieira (Cidadania/SE), Alvaro Dias (Podemos/PR), Antonio Anastasia (PSDB/MG), Arolde de Oliveira (PSD/RJ), Carlos Viana (PSD/MG), Chico Rodrigues (DEM/RR) and others – Alters the National Tax System and makes other provisions.

PL 2,641/2019

Senator Alessandro Vieira (Cidadania/SE) – Adds art. 15-A to Law No. 8,666, of June 21, 1993, which regulates art. 37, item XXI, of the Federal Constitution, establishes norms for bidding and contracts of the Public Administration and makes other provisions to determine requirements for the purchase of equipment used in diagnostic or therapeutic procedures within the scope of the Brazilian Health System (SUS).

PL 2,526/2020

Senator Paulo Paim (PT/RS) – Amends Law No. 13,979, of February 6, 2020, to provide for a simplified procedure for the production, marketing and use of ventilators, allow the requisition of equipment and supplies, and authorize fines and penalties to be applied to public officials and private individuals who commit acts of improbity or crimes against the Public Administration related to purchases and contracts signed based on the provisions of Law No. 13,979/2020, among other provisions.

PL 1,932/2021

Senator Jayme Campos (DEM/MT) – Amends Law No. 8,080, of September 19, 1990, which provides for the conditions for the promotion, protection and recovery of health, the organization and operation of the corresponding services and makes other provisions, to determine that the medicine and products of interest supplies to health in the entities of the federation will be controlled through an integrated system of real-time monitoring of consumption and stock.

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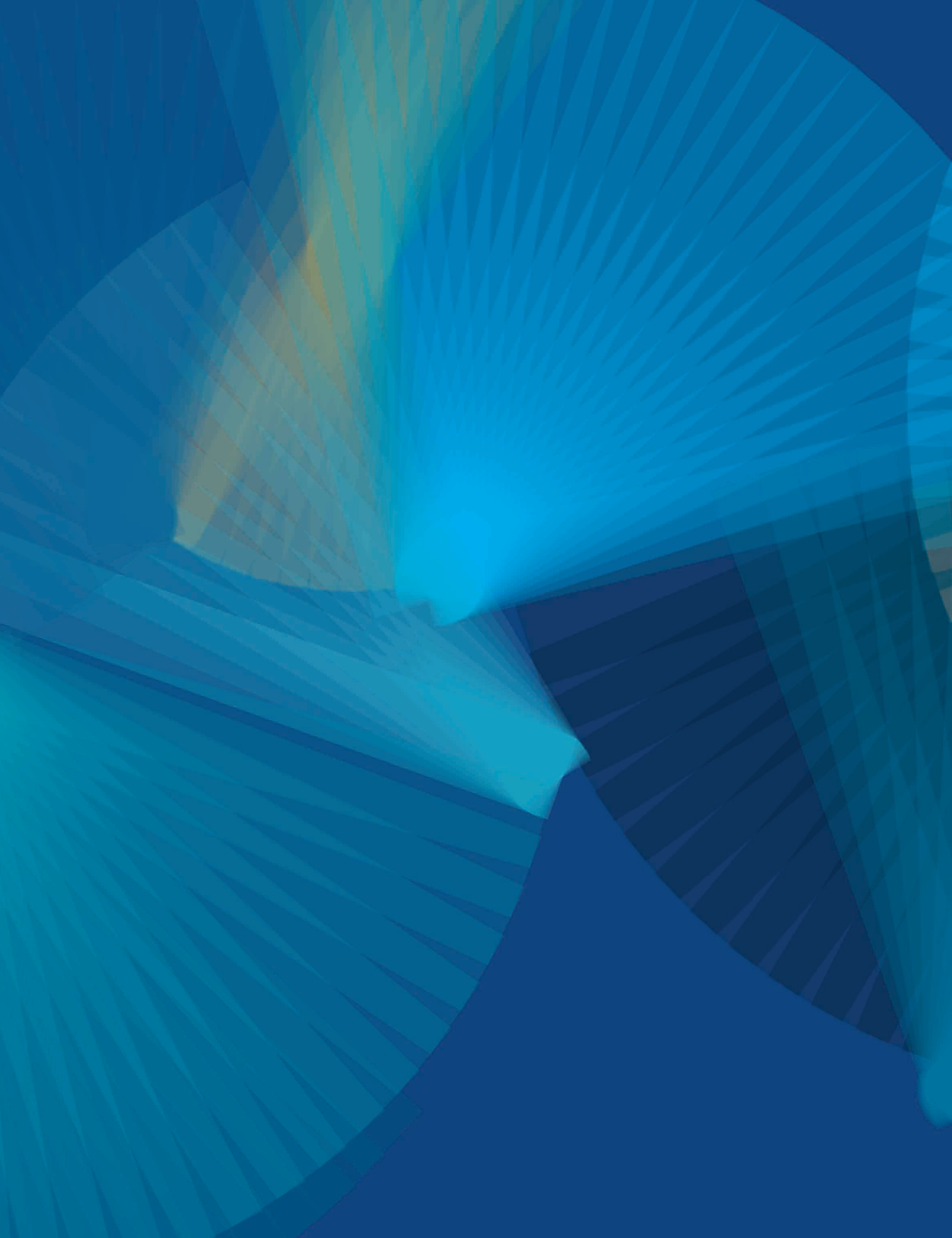

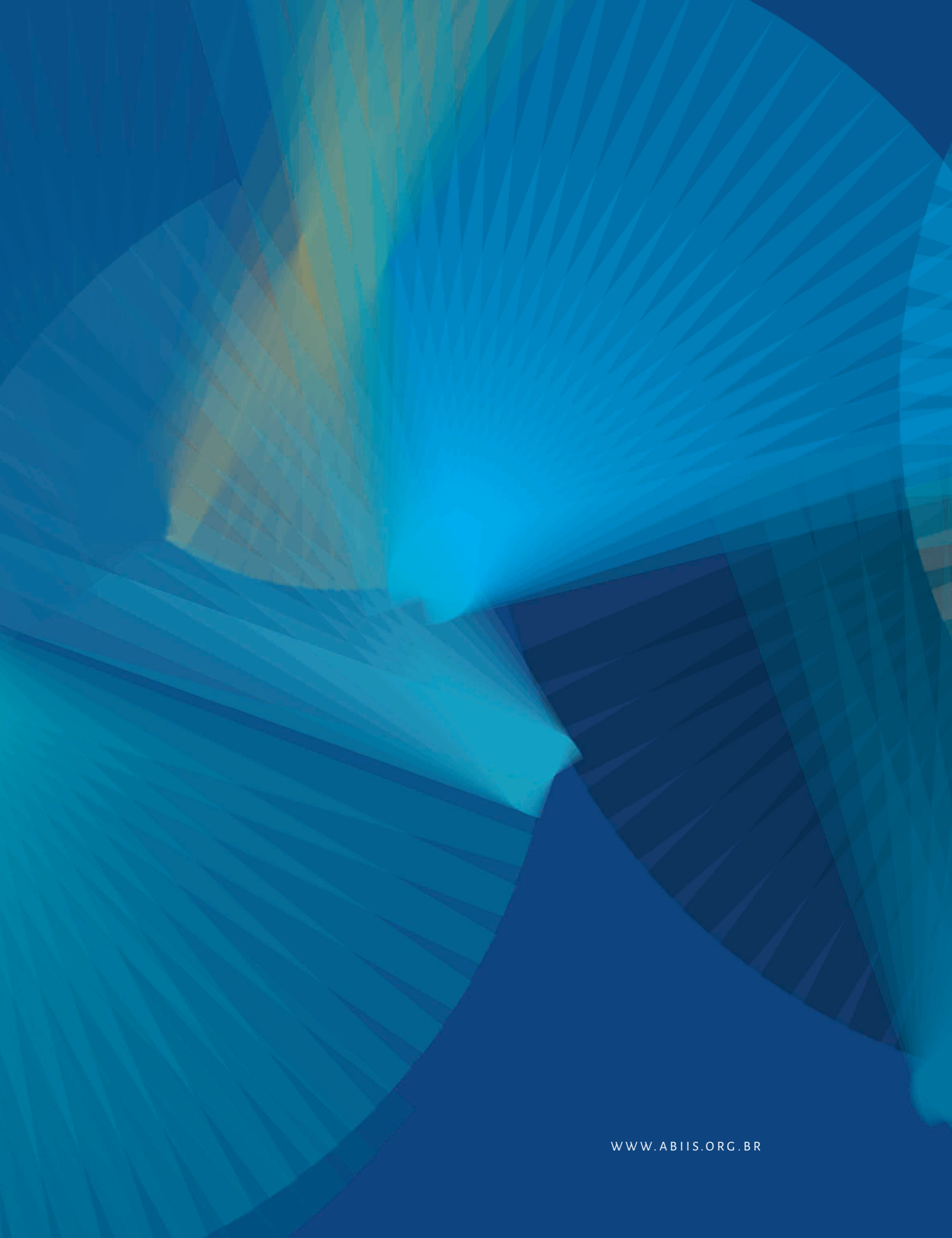

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