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Gaining insight into 2024 trends in Brazil's Life Sciences and Healthcare market and why

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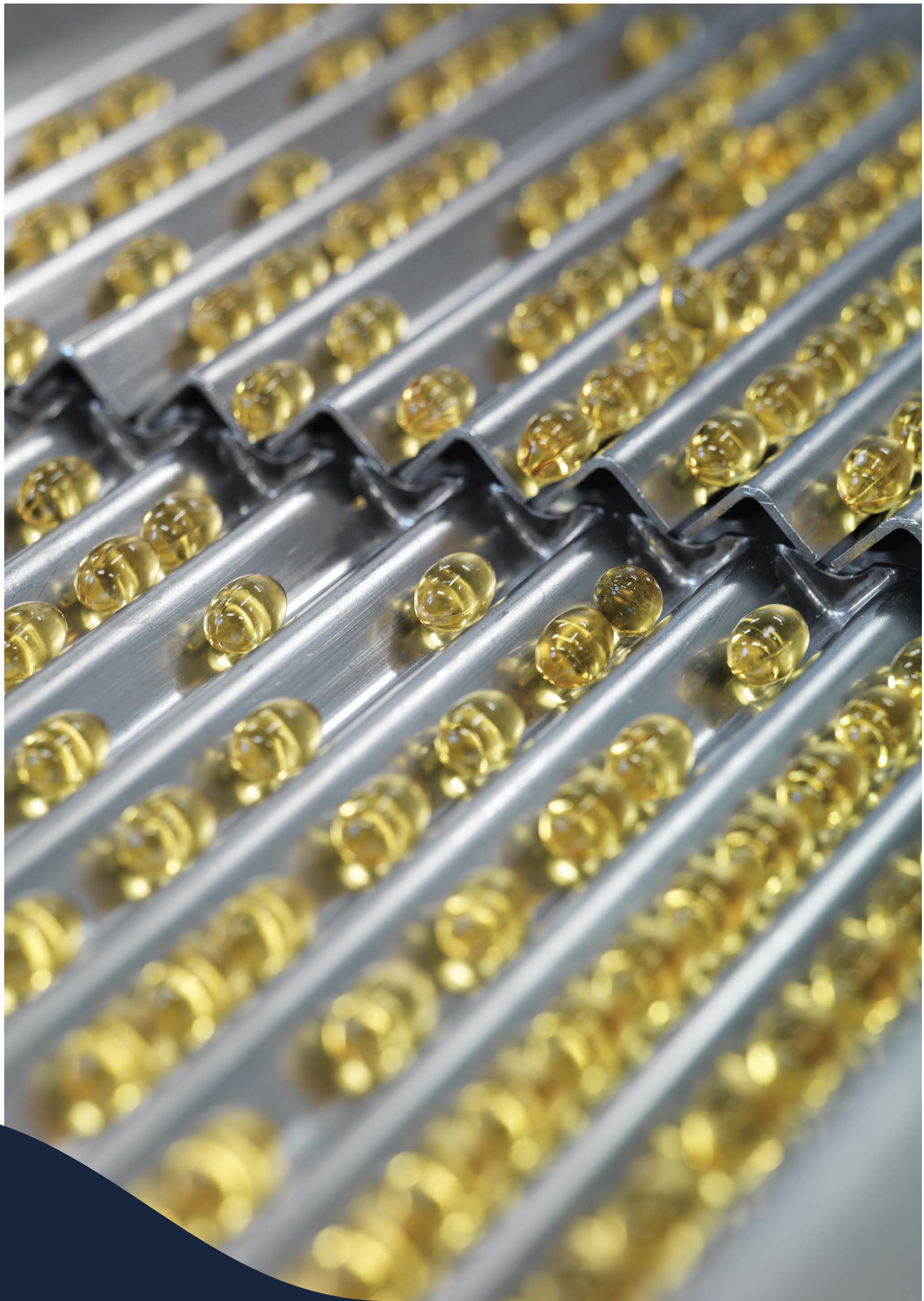
Transactional



Transactional

The years 2022 and 2023 presented significant challenges for the industry, with a post-pandemic market correction and macroeconomic pressures resulting in one of the worst performances in decades. Depreciations made capital raising difficult for both private and publicly traded companies, reflecting in the transactional landscape of 2023.

As we enter 2024, the pharmaceutical industry faces unprecedented challenges. Market volatility remains high, driven by changes in capital dynamics and geopolitical issues, global inflation, and economic uncertainties. Sector-specific issues such as talent competition, politicization of drug pricing, health-related litigation, diversification in clinical trials, and the growing pressure to demonstrate commitment to environmental, social, and governance (ESG) issues may make the horizon difficult to perceive with the necessary clarity. Nevertheless, the new year yet begins with the prospect of being a busy year, characterized by a high volume of transactions – notable are the transactions already announced by industry giants such as Sanofi, JnJ, Biogen, etc. – although lower valuations reflect economic factors and ongoing trends observed in recent years towards smaller and more manageable transactions.

> **Innovative therapies such as cell and gene therapy, as well as medtechs, are expected to continue generating exciting developments in this field, while venture capital remains crucial for sector financing. Partnerships and licensing agreements between companies are seen as promising investment strategies.**

Furthermore, with a growing focus on core assets, divestments are also expected to create value and allow large groups to redirect their efforts. Notable recent spin-offs include the consumer health divisions of GSK/Pfizer (creating Haleon) and J&J (creating Kenvue), as well as the separation of GE HealthCare from GE. Sanofi is the latest to join this trend, seeking to spin off its consumer health division in the fourth quarter of 2024. In the context of the overall economy, the biopharmaceutical and medtech industries stand out as predominant components of the healthcare sector, which, in turn, maintains a strong position compared to other leading economic sectors on the stock exchange.

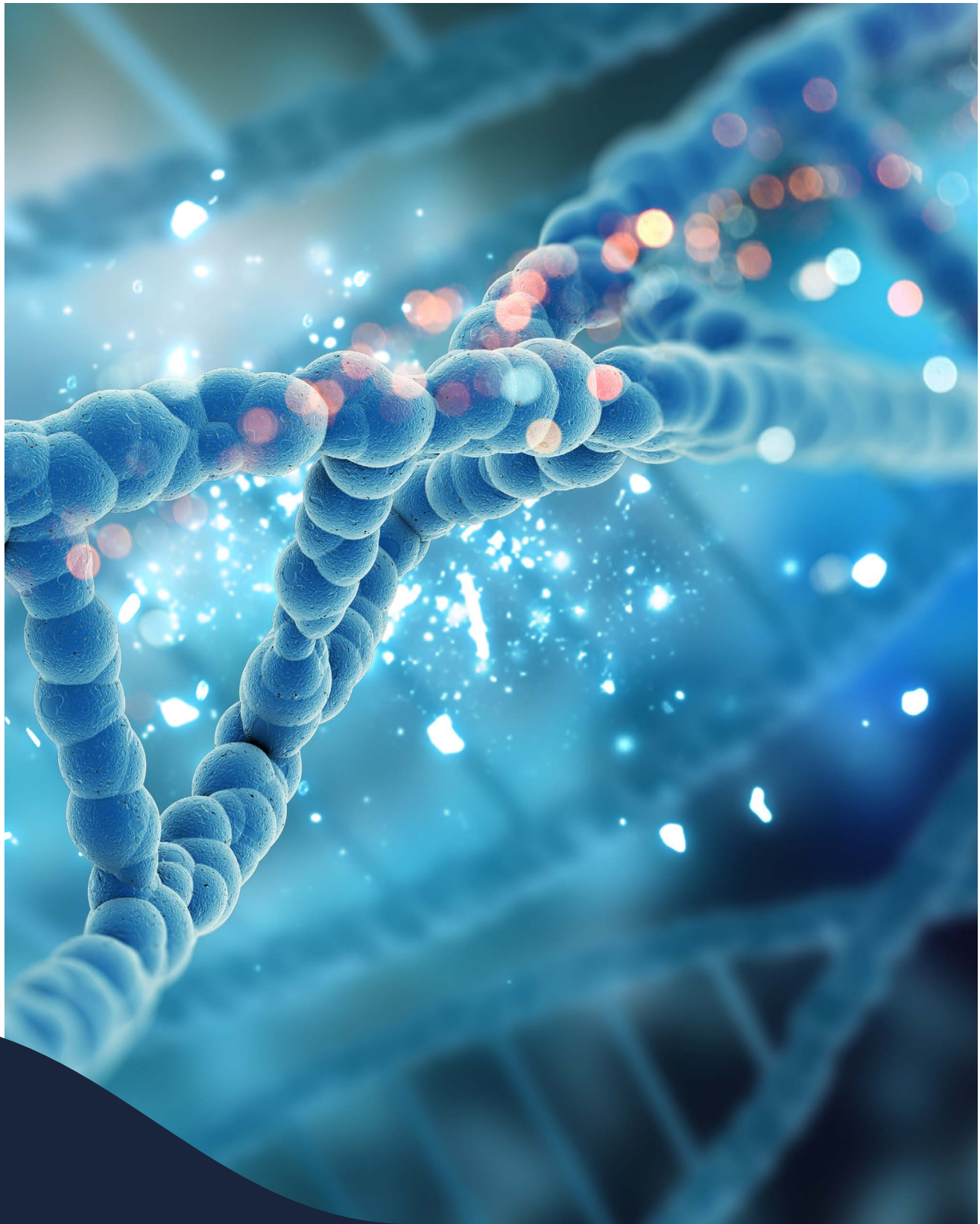
> **From a competition standpoint in the life sciences and healthcare sectors, we can expect rigorous scrutiny from regulators, especially regarding excessive drug pricing and obstructing market entry by generics or biosimilars in an anticompetitive manner.**

In the first case, with health budgets under pressure, the government is interested in keeping pharmaceutical prices low. If a competition authority believes that prices are excessively high and not aligned with costs or prices of similar products, enforcement measures may be taken. In the second case, competition and health authorities continue to critically examine any measures implemented by "originators" to continue benefiting from patent protection after patent expiration. Strategies for dealing with loss of exclusivity or so-called life cycle management are not an issue per se, but companies must be careful not to employ practices that may be seen as obstructing market entry by generics or biosimilars in an anticompetitive manner.

In straightforward business relationships, it is relevant to mention the high attention given to contracts that make up the supply networks in the life sciences and healthcare sectors. This is because recent years have been marked by disruptions in the supply chain, with global shortages of essential products, unprecedented raw material prices, and more, highlighting the importance of having contractual mechanisms to deal with these eventualities and facilitate business continuity. At a time when supply shortages are highly possible, contractual flexibility is likely to be much better than companies having to rely on the more radical button of dispute or termination.

> **Truth is that, despite these hurdles, the new year holds promise with a flurry of transactions, exciting developments in innovative therapies and medtechs, and a strategic landscape gaining prominence through partnerships, licensing agreements, and divestments. Furthermore, the heightened attention to contractual mechanisms in supply networks underscores the industry's commitment to ensuring resilience. Successfully maintaining a robust position amid evolving challenges will necessitate adept navigation of the intricate and dynamic landscape in the coming year.**

Technology, Artificial Intelligence, and Digital Transformation



Technology, Artificial Intelligence, and Digital Transformation

In the scene of life sciences and healthcare, the noteworthy themes of Technology, Artificial Intelligence, and Digital Transformation took center stage in 2023 and are poised to remain prominent in 2024.

The recurrent usage of these headlines reflects the industry's trajectory and anticipates a continuation of these trends into the coming year. Indeed, as we project ahead to 2024 and beyond, it is apparent that significant investments in these industry sectors are likely to be channeled towards innovative technologies, building on the momentum observed in recent years.

From 2020 onwards, we have witnessed the ascent and proliferation of diverse transformative technologies that are actively shaping and gaining prominence in the healthcare landscape, marking significant progress. Noteworthy examples include personalized medicine, health virtual assistants or BOTs, digital twins, virtual and augmented reality, and the impact of the Internet of Things (IoT) on wearable devices, telemedicine, and the advent of virtual hospitals. Additionally, the utilization of 3D printing technology for medical tools and even organs exemplify the array of technological and digital innovations unfolding.

It is also imperative to underscore the central role that **AI** is poised to play in shaping these upcoming healthcare trends, particularly with the advent of generative AI, anticipated to wield a substantial influence in the next 12 months. This form of AI is expected to democratize access to various applications, streamline implementation processes, facilitate result interpretation, and generate personalized recommendations. Moreover, generative AI is anticipated to play a pivotal role in creating synthetic data for training medical algorithms without compromising patient privacy, thereby paving the way for the development of chatbots and virtual assistants that can aid across all stages of the patient journey.

The global emergence of artificial intelligence, particularly generative AI, signifies one of the most significant opportunities and challenges confronting professionals, consumers, and regulators across various industries. Notably, it is within the life sciences and healthcare sectors that this transformative wave assumes an exceptionally pivotal role. Advocates argue that, given their dedication to enhancing quality of life and promoting public health, these sectors possess not only the greatest potential for reaping benefits from AI utilization but also confront the most substantial risks, particularly concerning ethical and regulatory considerations.

Precisely because it emerges as a tool with numerous potential benefits for the sector, artificial intelligence has already sparked considerable interest and attracted substantial investments – as highlighted by Stanford University, the health sector led in private AI investment in 2022, raising a total of $6.1 billion[1].

[1] Stanford University. The AI Index Report. Measuring trends in Artificial Intelligence. Available on:

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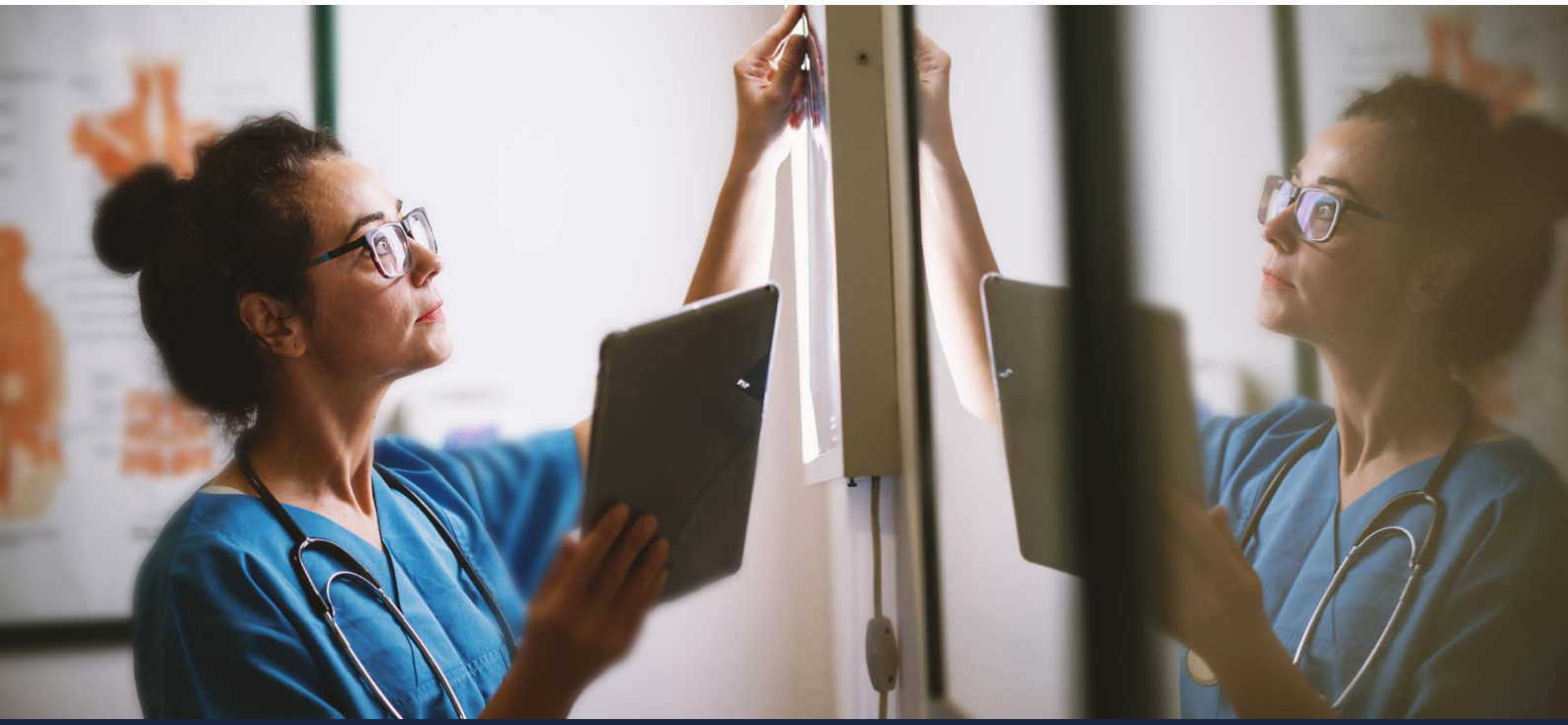

Recent developments involving the use of AI in life sciences and healthcare have the power to revolutionize how data is analyzed, how doctors interact with patients, and how diseases are diagnosed and managed. AI-driven data analysis can provide faster and more accurate insights, facilitating clinical decision-making and contributing to more efficient diagnoses. The interaction between doctors and patients can also be enhanced, promoting a more personalized and patient-centered approach. Moreover, disease management can significantly benefit from AI algorithms, which can predict patterns and identify preventive interventions. This technological revolution has the potential to enhance the efficiency of healthcare systems, providing faster, more accurate, and personalized care.

The prospect of substantial improvements in public health instills optimism, yet it is imperative to approach the ethical and regulatory challenges associated with the use of AI and other technologies and digital innovations in healthcare pragmatically.

From an ethical standpoint, safeguarding the confidentiality of sensitive patient data, ensuring privacy, and bolstering security in terms of processing and sharing emerge as critical global concerns. Furthermore, the issue of equitable access to technological advancements takes center stage – ensuring that all segments of society can equally benefit from the digital transformation in healthcare is pivotal to prevent disparities in medical care and access to innovative treatments.

In Europe, an expanding landscape of new laws addressing privacy and data regulation is evident. The United States continuously introduces new elements into the intricate mosaic of state privacy laws. Across the globe, data privacy laws inspired by the General Data Protection Regulation continue to evolve, with Saudi Arabia and India representing the latest instances where companies will need to augment their compliance and privacy programs in 2024. In Brazil, the significance of **LGPD** (General Data Protection Law) stands out as part of this global movement towards more stringent data privacy regulation.

General Data Protection Law (LGPD). Available on:

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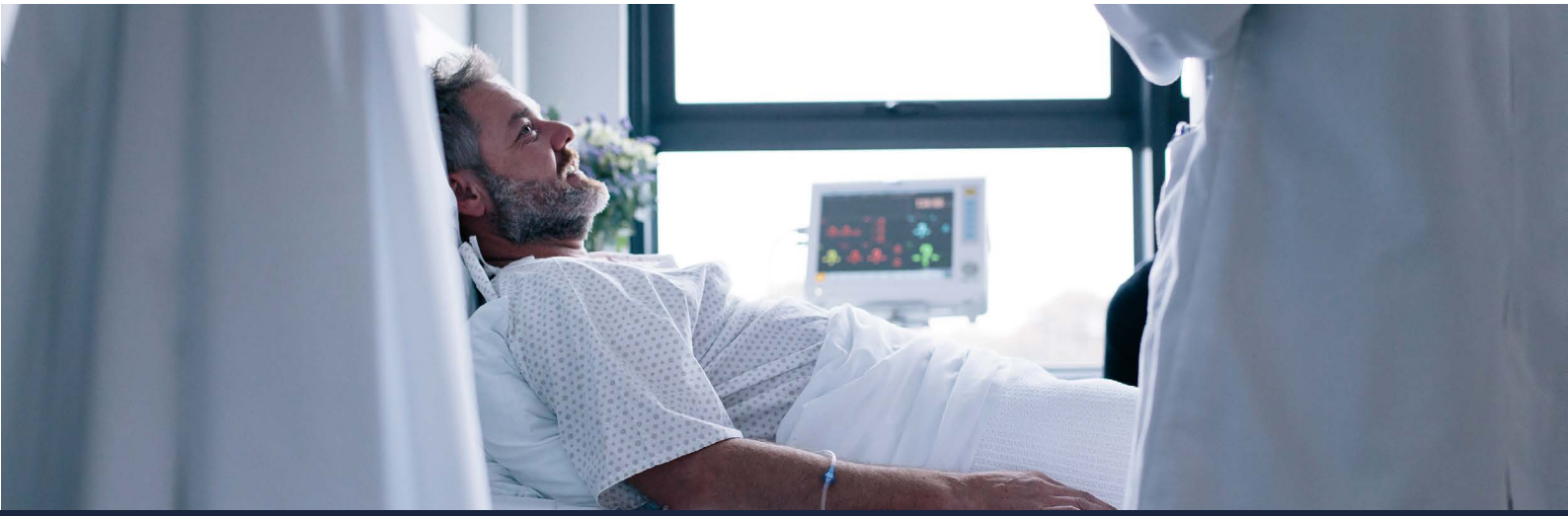
Where specific legislation is lacking and the utilization of artificial intelligence in business is on the rise, it becomes paramount for participants in the service chain to possess a clear, transparent, and real-time understanding of both opportunities and risks. Vigilantly tracking legislative debates, adhering to ethical principles, and meticulously formulating rules and contracts emerge as indispensable measures in this environment.



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> In the regulatory domain, the swift evolution of technology poses a challenge for regulatory bodies to keep pace. It is crucial to establish clear guidelines for the implementation of AI and other technologies in healthcare to ensure safety, efficacy, and compliance with ethical standards. The absence of adequate regulation can lead to gaps that compromise the integrity of the digital healthcare system.

Turning to the regulation of AI in Brazil, a key focus is on its application in medical devices and software. In 2022, Anvisa introduced specific requirements for the regularization of software as medical devices, known as SaMD (Software as a Medical Device), through **Resolutions of the Collegiate Board No. 657/2022** and **751/2022**.

Resolutions of the Collegiate Board No. 657/2022. Available on:

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Resolutions of the Collegiate Board No. 751/2022. Available on:

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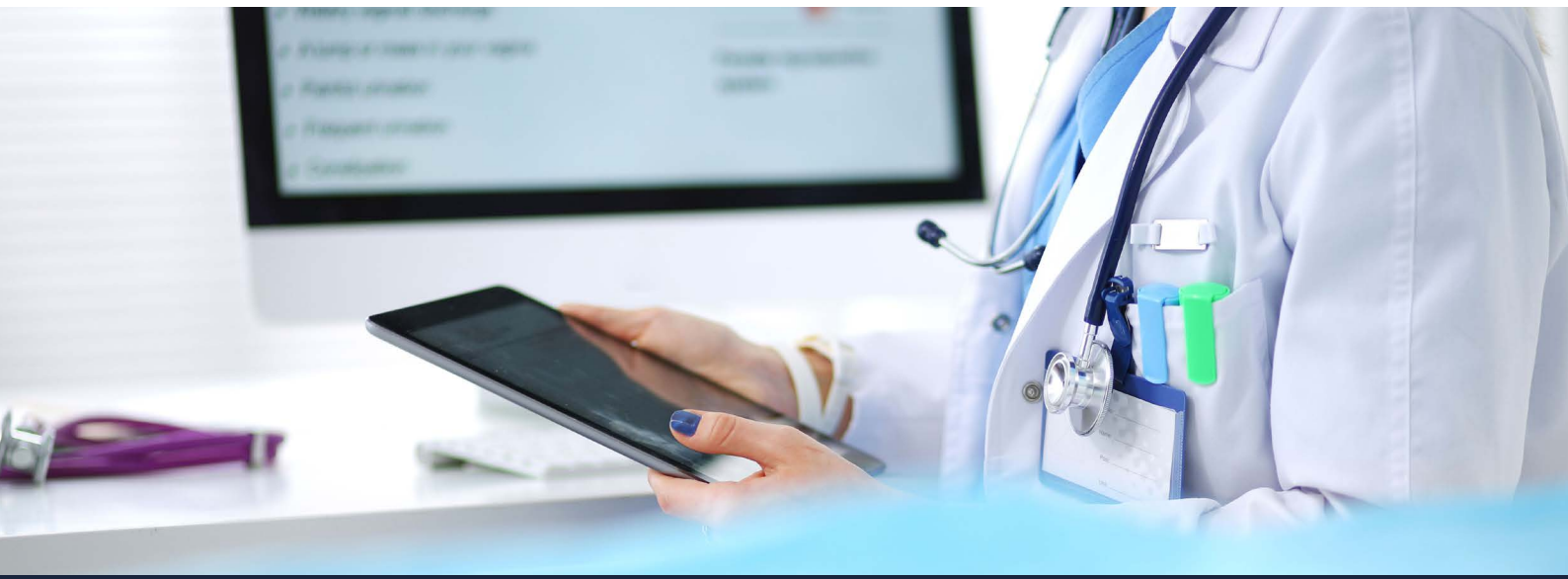

> **Although the regulation does not explicitly mention AI systems, the definition of SaMD, covering software that uses AI systems and tools for medical purposes, necessitates adherence to rules applicable to medical devices. This includes risk classification, notification and registration, labeling, usage instructions, and providing detailed information on the databases used for AI training, learning, and verification at the time of regularization, under the risk of non-approval of the request.**

It is noteworthy that Anvisa, beyond granting registrations to various AI-incorporating products, integrates this technology into its regulatory activities. An example is the use of AI to identify the irregular commercialization of health-harmful products on the internet, showcasing Anvisa's commitment to technological innovations for enhancing the regulatory process and safeguarding public health.

In the Brazilian regulatory landscape, the response to the growing use of AI materialized with the introduction of the Artificial Intelligence Legal Framework Bill (**PL 2338/2023**) in the first half of 2023. This legislative proposal aims to establish comprehensive nationwide standards for the development, implementation, and responsible deployment of AI systems in Brazil. Termed the AI Legal Framework, this initiative represents a substantial legislative effort by the National Congress to comprehensively regulate AI. Essentially, the project seeks to safeguard the rights of individuals affected by AI-driven systems, address risks associated with these systems, and delineate the interactions of these individuals with AI providers and operators.

PL 2338/2023. Available on:

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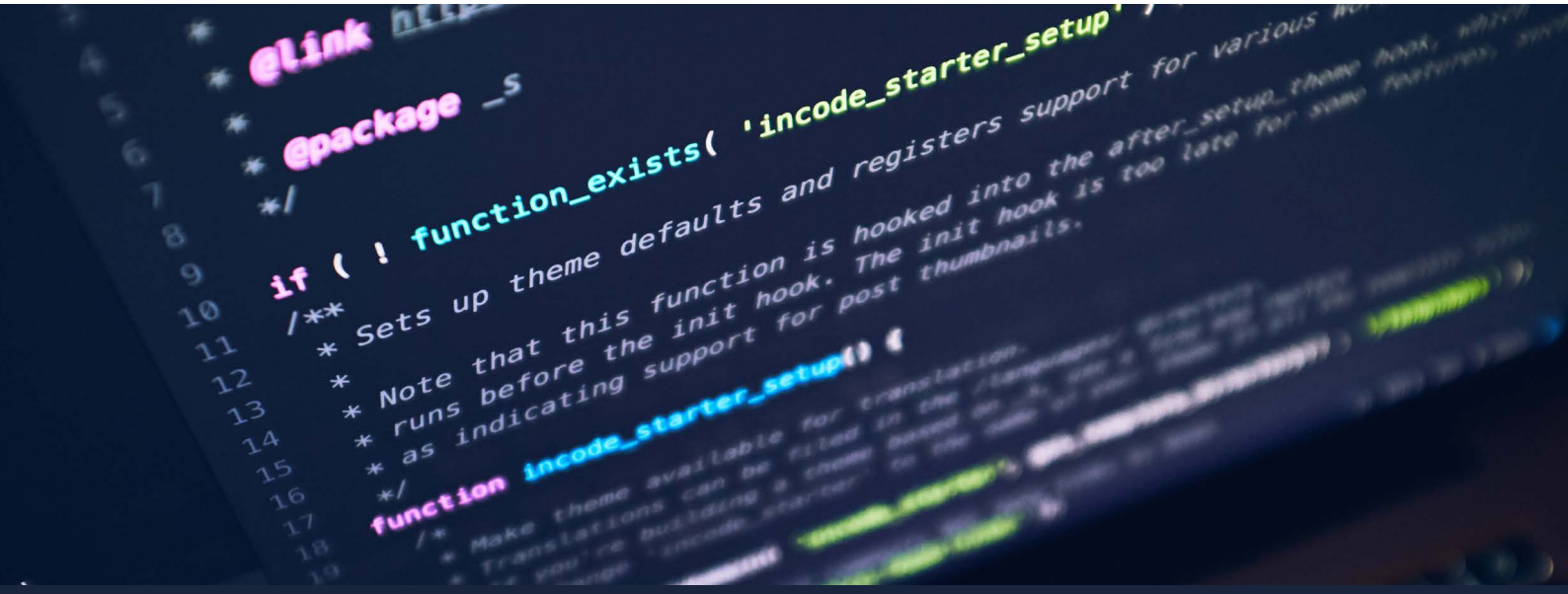

In the health sector, the initial high-risk classification of AI use, particularly in aiding diagnoses and medical procedures, was removed in the **substitute text for PL 2338/2023** published in November 2023. The current version of the text suggests that various wearables and AI-based SaMDs have the potential to be classified as high-risk AI systems.

Substitute text for PL 2338/2023. Available on:

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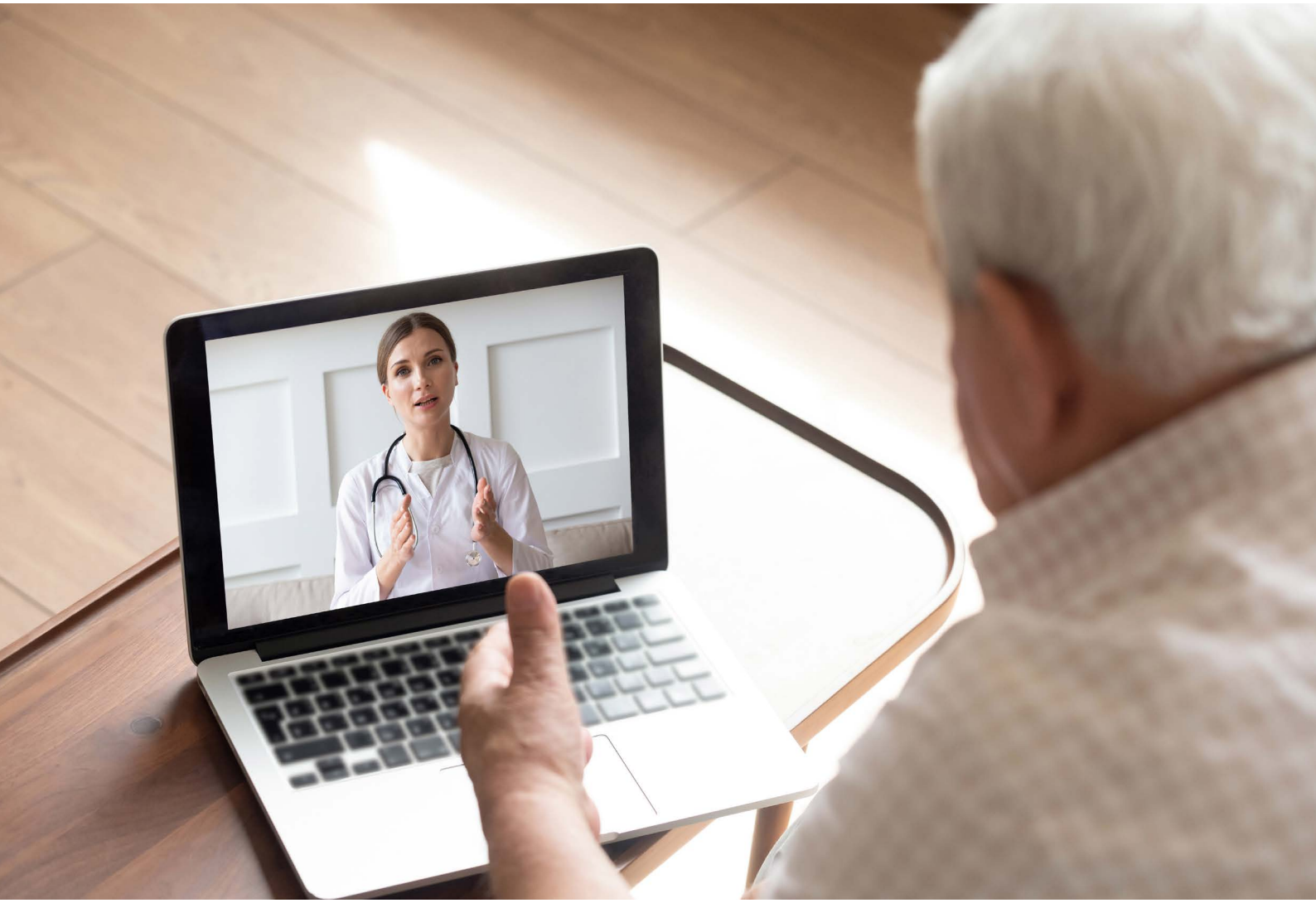

This underscores the constant need for industry players to monitor **(i)** the increased cost attributed to the use of AI in health, given greater obligations to its agents and operators, and **(ii)** to avoid risks associated with the improper development or irregular use of AI technology in their operations. Such risks may include frequent inspections, fines, interruption of commercial activities, among other consequences.

Lastly, it is crucial to mention AI applications in the country's supplementary health sector. Within the framework of the **Digital Transformation Plan** of the National Supplementary Health Agency (ANS)[2] and the Artificial Intelligence Solutions (AI) for the Public Power project, the agency has signed three contracts with startups for the development of AI projects aimed at facilitating administrative activities. There is also a significant rise in the use of AI by health insurance providers and other entities in the supplementary health sector, particularly for process optimization and automation.

Undoubtedly, this constitutes the primary focus for 2024 in the country. Now the central discussion revolves around which company will adapt, possibly allowing newcomers to surpass them, and which company will take the necessary steps to advance with the right partners, embracing changes for the development of better and safer products in more markets and at a faster pace.

Digital Transformation Plan. Available on:

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[2] National Supplementary Health Agency. ANS signs contracts for Artificial Intelligence projects. Available on:

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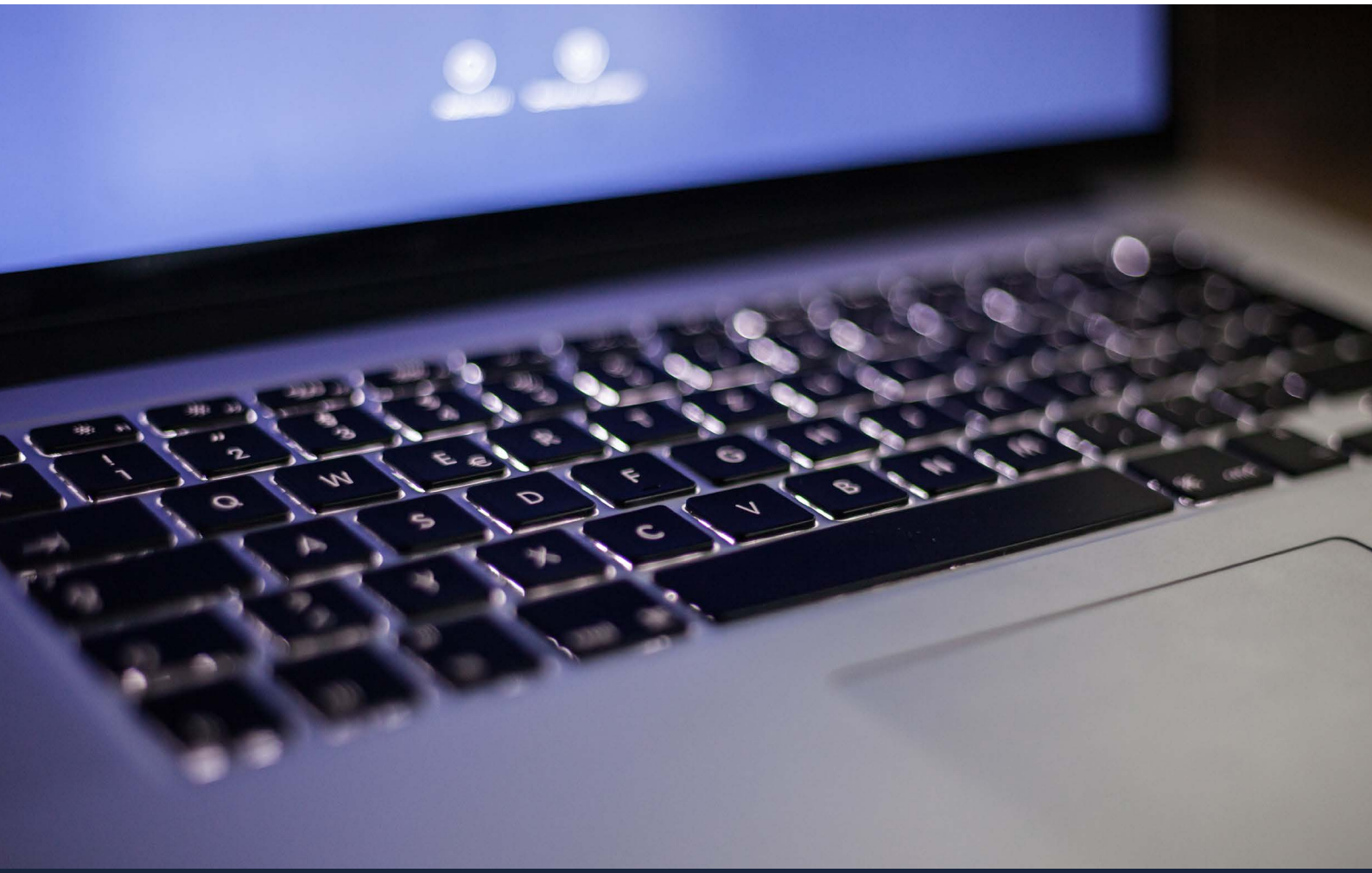

Globalization and International Collaboration

Globalization and International Collaboration

The coronavirus pandemic prompted a rapid mobilization of the global scientific community, directing efforts towards the development of strategies and solutions. The imperative for international collaboration, dedicated to safeguarding and enhancing public health, became more evident than ever. Looking ahead to 2024, there is an anticipation of sustaining and solidifying this environment of international collaboration in health. The emphasis remains on proactively envisioning solutions for potential global public health challenges, particularly in light of emerging threats from new pandemics.

In July 2022, Brazil entered into a Cooperation Strategy with the Pan American Health Organization/World Health Organization (PAHO/WHO) for the period spanning 2022 to 2027. This initiative is designed to outline the strategic priorities that the country will pursue, with a particular focus on enhancing and fortifying health services and priority programs affected by the pandemic, notably the Brazil's Public Health System (SUS). The strategy also underscores the promotion of research, innovation, and the generation of scientific and technological knowledge in the health sector, encompassing the development and manufacturing of pharmaceuticals, vaccines, herbal medicines, and other related products.

During 2023, the Brazilian Hospital Services Company (EBSERH) and the Pan American Health Organization (PAHO) also formalized a Cooperation Agreement, aiming to bolster the integration between federal university hospitals and Brazil's SUS. Simultaneously, the United Nations and the Brazilian government inked the new Brazil-UN Cooperation Framework for the period 2023-2027, delineating five thematic pillars: Economic Transformation for Sustainable Development; Social Inclusion for Sustainable Development; Environment and Climate Change for Sustainable Development; Governance and Institutional Capacities; and Humanitarian and Sustainable Development Actions.

At the Latin American level, amid the growing prominence of the regulatory reliance movement, discussions are intensifying regarding a potential shift in how Latin American markets collaborate with their respective health regulatory authorities. In April 2023, regulatory bodies in Mexico (Cofepris), Colombia (Invima), and Cuba (Cecmed) formally endorsed the Acapulco Declaration, setting the stage for deliberations on the establishment of a new regional regulatory entity overseeing pharmaceuticals in Latin America and the Caribbean, referred to as the Latin American and Caribbean Medicines Agency, or simply AMLAC. Furthermore, several other nations, including Bolivia, Dominica, Ecuador, El Salvador, Honduras, Jamaica, and the Dominican Republic, have expressed their interest in participating in this initiative.

The Acapulco Declaration acknowledges the challenges faced by the region in health, production, the economy, and society, particularly during emergencies such as the coronavirus pandemic. However, taking into account the regional context and specific needs, it is worth recognizing that the proposal to create a regional pharmaceutical organization for Latin America and the Caribbean is rooted in the necessity to address numerous obstacles encountered by some domestic regulatory frameworks in this domain. These include a lack of workforce and insufficient financial provisions, inconsistencies in regulatory capacities, and the absence of synchronization and harmony in regulatory requirements and procedures. Additionally, the region faces challenges related to obtaining essential drugs, maintaining the quality of pharmaceutical products, and combating the spread of fraudulent or substandard drugs.

> **Although not yet operational, the concept of creating a regional pharmaceutical agency for this area has been a subject of deliberation and discussion in various conferences over time.**

Within the broader context of internationalization, it is noteworthy that, in recent years, Anvisa has championed a comprehensive agenda aimed at fortifying the reputation of the Brazilian regulatory environment in international markets and with global authorities. This initiative entails active engagement in bilateral, regional, and multilateral forums, where processes of harmonization and regulatory convergence unfold, establishing the technical-scientific foundations for the Agency's regulatory framework. By embracing the concept of "regulatory convergence" introduced by Anvisa itself, the Agency has positioned itself as one of the primary global authorities in drug regulation. The noteworthy technical prowess of Anvisa has been instrumental in paving the way for global initiatives, underscoring the Agency's deep involvement in an all-encompassing process of internationalization.

An instance of ongoing regulatory harmonization and convergence in Brazil, with potential implications for 2024, involves the establishment of a regulated framework for **electronic cigarettes**. Presently, the sole operative regulation is a prohibition. However, recognizing the evolving global landscape, Anvisa initiated a regulatory review process in 2019 to reassess this decision. As part of this initiative, a Public Consultation (CP) was released in December 2023 to solicit public input on the matter.

It is recognized that, across various regions globally, electronic cigarettes are being subjected to regulation as part of harm reduction strategies for individuals already using traditional cigarettes. Approximately 80 countries, including the United States, the United Kingdom, and Canada, have opted to regulate these products[3]. Within the Americas region, eight countries have chosen a complete ban, such as Argentina, Brazil, Mexico, Nicaragua, Panama, Suriname, Uruguay, and Venezuela[4].

Last but certainly not least, it is imperative to acknowledge the relevance of China. As the transatlantic equilibrium gradually shifts away from Europe towards the United States, China emerges as a new influential power. The local pharmaceutical market has sustained a consistent double-digit growth rate for several years, coupled with robust domestic Research and Development (R&D) endeavors. According to EFPIA estimates, China's R&D growth stands at an impressive 12.9% Compound Annual Growth Rate (CAGR). If the present trajectory is maintained, China is poised to surpass Europe in the next 10 to 15 years, solely in terms of expenditure, though other indicators suggest this turning point may occur even sooner. Furthermore, notwithstanding the challenges posed by the COVID-19 pandemic, China persists in its pursuit of originality, positioning itself to become one of the world's top 10 most innovative countries. In the latest 2023 Global Innovation Index ranking, China secured the 12th position as the most innovative economy worldwide and the leading innovator among 36 upper-middle-income[5] countries.

[3] Banned in Brazil, sale of electronic cigarettes (E-Cigarettes) is approved in 80 countries.
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[4] Pan American Health Organization.
Eight countries in the Americas ban electronic cigarettes (E-Cigarettes).

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[5] Global Innovation Index.
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As an illustration on the fact that China has become a life sciences and healthcare sectors powerhouse, AstraZeneca has recently disclosed an acquisition plan of up to $1.2 billion for a Chinese cell therapy biotech company. Bayer and RTW Investments have recently revealed an equity investment in a clinical-stage Chinese company, aiming to introduce new medicines for Chinese patients dealing with serious cardiovascular and eye diseases.

> **The sustained growth of major pharmaceutical companies' local presence in China is exceptionally robust, underscoring the importance of the Chinese market. Now is the opportune moment for Brazil to strengthen ties with this nation, with the healthcare sector emerging as one of the most prominent avenues for collaboration.**

Research and Development

Research and Development

Clinical Research took a significant leap in November 2023 when the Chamber of Deputies approved the bill ("**PL 7082/17**"), ushering in new regulations for clinical research involving human subjects and establishing the National System of Ethics in Clinical Research with Human Subjects to govern such studies in Brazil.

PL 7082/17. Available on:

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The approved text, championed by federal deputy and rapporteur Pedro Westphalen, meticulously outlines the rights of voluntary research participants. It places special emphasis on ensuring privacy guarantees, proper data treatment, fair compensation, the requirement for explicit and prior authorization for participation, among other provisions. Moreover, it delineates the responsibilities assigned to investigators, study personnel, sponsors, and entities involved in proposing, authorizing, and conducting and concluding research.

The bill also introduces crucial changes to existing regulations, including:

(i) reducing the deadlines granted to competent entities for analysis and approvals;

(ii) transferring the role of registering, accrediting, and overseeing Research Ethics Committees (CEP) to the Executive Branch, shifting from the National Commission for Ethics in Research (CONEP), an entity linked to the CNS;

(iii) affiliating the CEP with the institution responsible for the research; and

(iv) modifying the rules concerning participants' access to approved methods and diagnostics in clinical research.

A point of intense debate revolves around the participant's right to access post-study medications. While sponsors currently must provide the medication free of charge for as long as the participant needs it, **PL 7082/17** allows for the discontinuation of experimental medication in clinical trials for various reasons, such as the participant's decision, disease cure, introduction of a satisfactory alternative, lack of continuous benefit, adverse reactions, or technical and safety impossibility in obtaining or manufacturing. However, the bill mandates that sponsors provide an equivalent or superior alternative. Furthermore, discontinuation may occur after five years of commercial availability in Brazil or when the experimental drug is available in the Brazil's SUS.

The prospect of positioning Brazil among the top ten countries in the global Clinical Research ranking is particularly intriguing. The bill's approval is seen as a catalyst for establishing a legally sound, ethical, and scientifically robust system in the country. Recognition of the competence of Brazilian researchers, their significant participation in clinical studies during the pandemic, and unique national characteristics, such as ethnic diversity and a robust healthcare ecosystem, will contribute to Brazil's competitiveness globally.

Looking ahead, the bill is expected to undergo Senate consideration in 2024, paving the way for new perspectives in clinical research involving human subjects in Brazil and subsequently opening a myriad of opportunities for business development in this sector in the country.

PL 7082/17. Available on:

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A final note on the significance of R&D this year is that, during the world's largest healthcare symposium, JPM, held in San Francisco in early January 2024, it became evident that the year's expectations center around accelerating medical innovation and drug development through new deals and partnerships. Additionally, it was observed that investors supporting the sector seem to have fresh capital available for reinvestment in promising companies. These well-funded entities are better positioned to support the research and development necessary to attract major pharmaceutical companies, enabling the transformation of scientific advancements into market-ready new drugs. Anticipated progress in manufacturing, a persistent challenge, and advancements in clinical trials for in vivo cell therapies are expected this year.

Major pharmaceutical companies themselves have also announced an extensive pipeline of R&D, particularly in an effort to counter the loss of market share due to the end of patent periods. Oncology is anticipated to maintain its position as the most active area in initiating clinical trials over the last decade, closely followed by gene therapies and orphan drugs for the treatment of rare diseases, as well as new drugs for the battle against obesity. Unlike traditional approaches involving extracting a patient's cells for external engineering before reinfusion, in vivo therapies aim to provide a more efficient treatment directly within the patient's body. Again, the first indications expected to undergo testing in trials are likely to be for cancer and autoimmune diseases.

> **Having said all this, research and development represent a significant focus in the life sciences and healthcare industry for both the short-term and medium-term.**

Preventive Medicine VS. Precision Medicine

Preventive Medicine VS. Precision Medicine

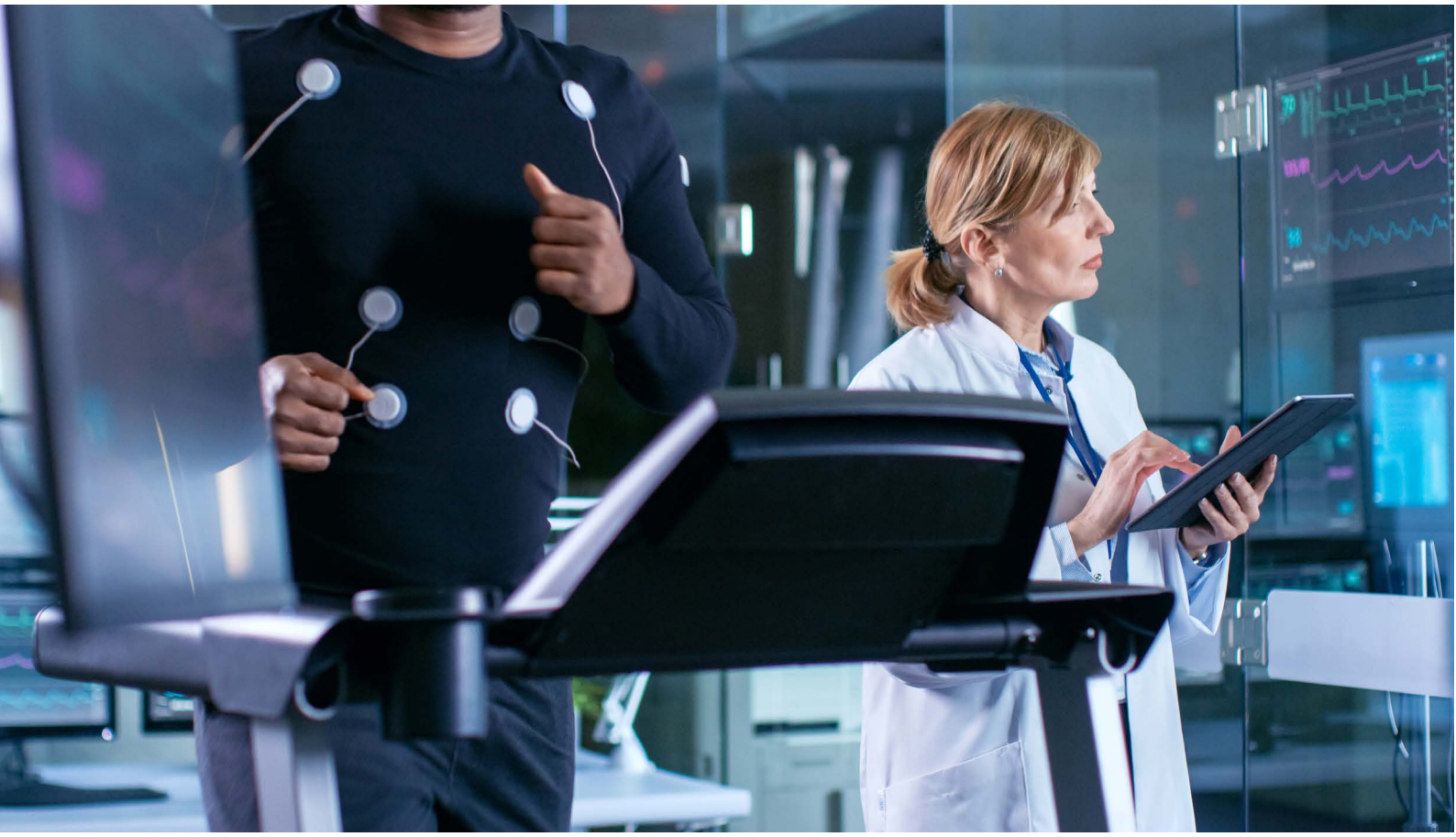
> **Preventive medicine spans a broad spectrum of subjects, covering areas such as exercise, well-being, mental health, and immunizations, underpinned by the timeless wisdom that "prevention is better than cure."**

In practical terms, preventive medicine establishes daily practices that contribute to well-being, involving regular check-ups, adopting a balanced and healthy diet, and engaging in consistent physical exercise. These holistic approaches reduce the likelihood of individuals developing diseases that may exacerbate over time, such as hypertension and diabetes.

Vaccines play a crucial role in this context, administered to prevent the manifestation of specific viruses or bacteria. By averting contact with these pathogens, vaccines impede the development of more severe diseases, including hepatitis A, influenza, tetanus, tuberculosis, and even COVID-19.

Indeed, the shift from a reactive care model to preventive care is a trend that has gained momentum since the coronavirus pandemic and remains a strategic priority for healthcare providers in the coming years. Technological advancements, such as artificial intelligence and wearable devices, will play a pivotal role in enabling early alerts and rapid interventions.

This is underscored by research highlighting the myriad and substantial long-term benefits of preventive medicine, contributing to the reduction of costs associated with treating avoidable conditions. The importance of this approach is heightened amid the accelerated global aging trend, aiming to mitigate the challenges posed by the rapidly aging world population to healthcare systems worldwide.



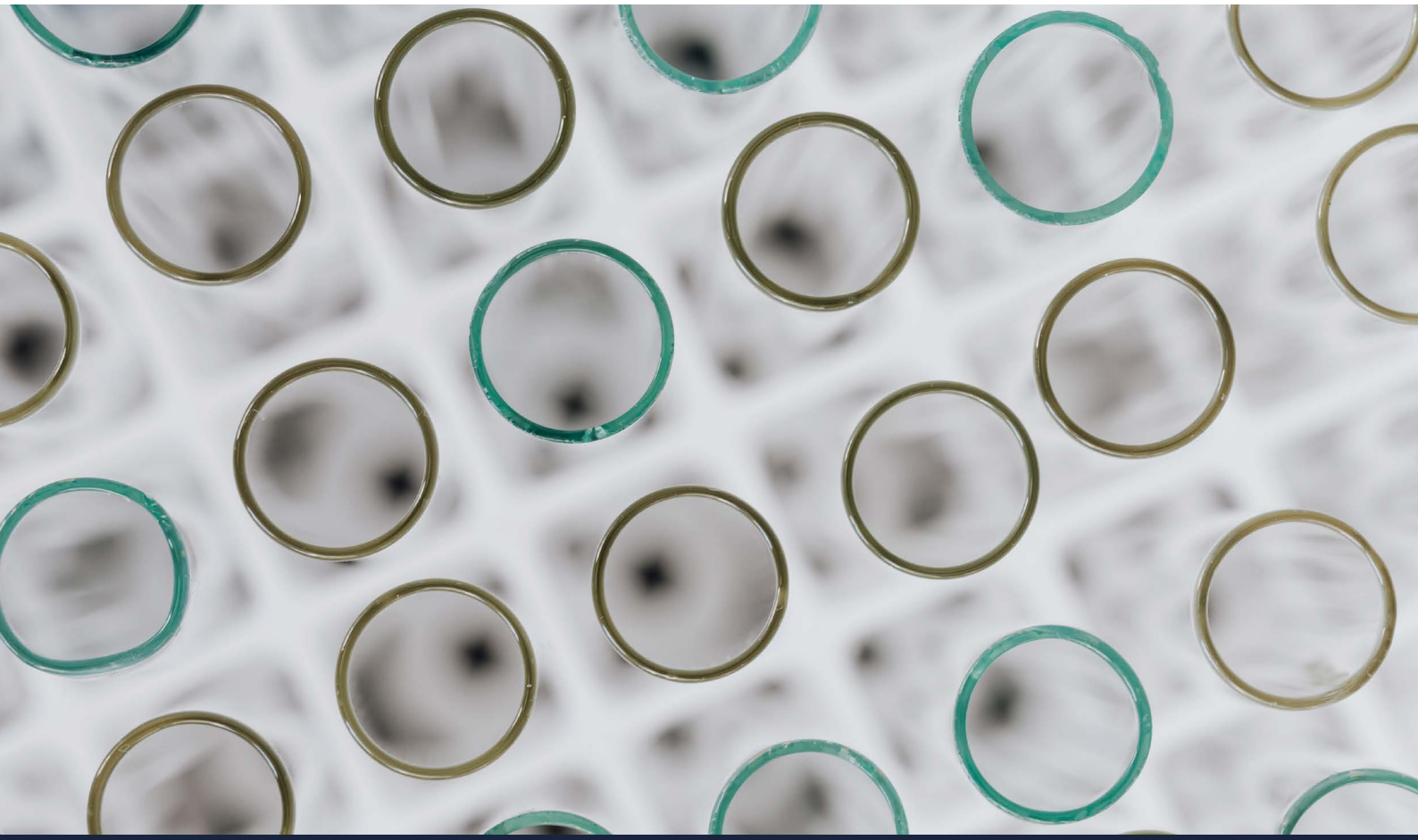
In this context, the current ascent of precision medicine and/or personalized medicine merits attention, aiming to enhance the prevention, diagnosis, and treatment of diseases with a particular emphasis on the individual. Precision medicine, instead of solely focusing on symptoms and medical history, integrates data conventionally used for diagnosis and treatment, such as signs, symptoms, family history, and complementary tests, with specific genetic profile information for each individual.

> **This approach seeks to achieve a more comprehensive and personalized understanding of each individual's health. By considering the genetic uniqueness of each person, healthcare professionals can adopt more precise preventive and therapeutic strategies tailored to individual needs.**

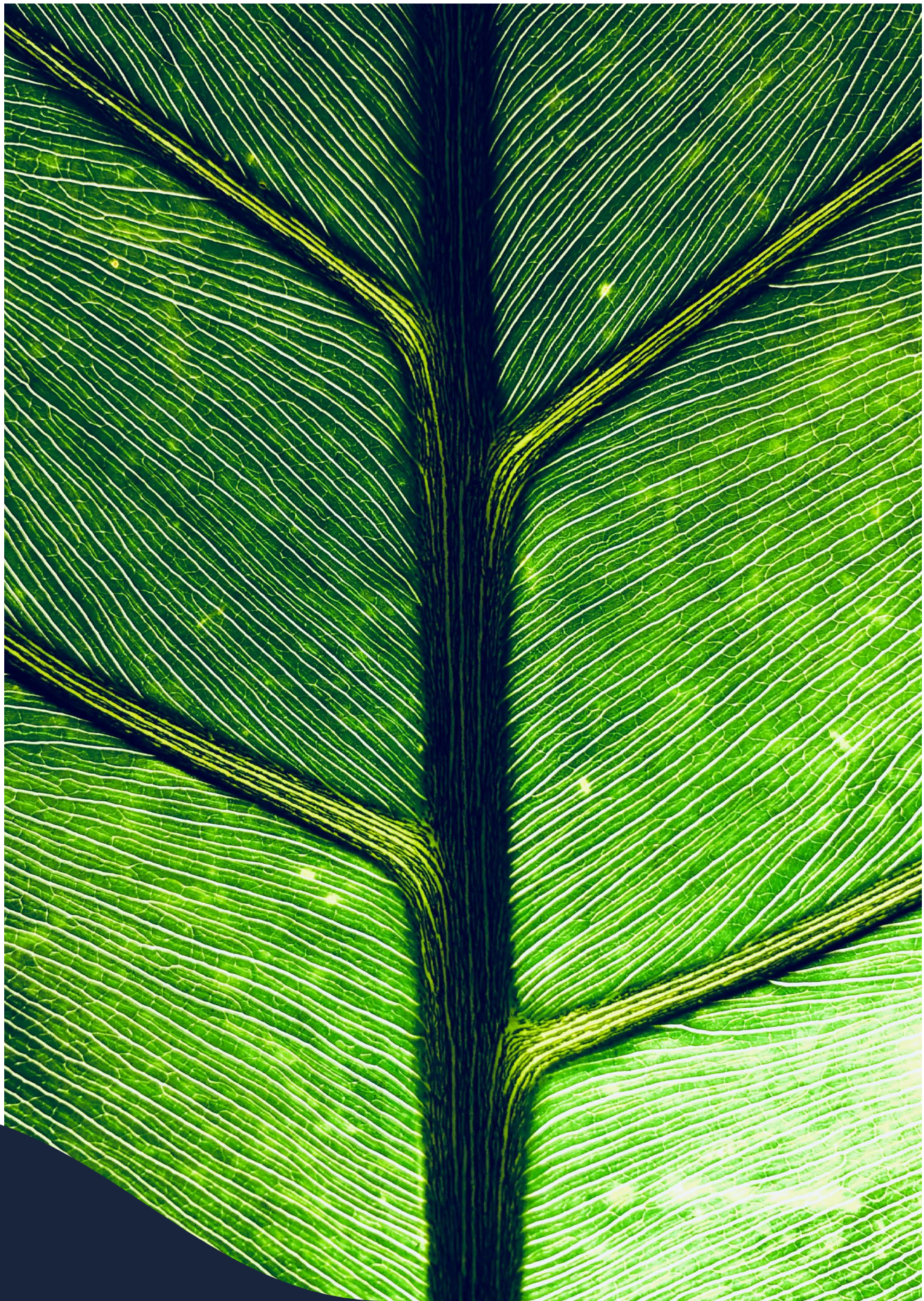
We also foresee that, in the upcoming years, the utilization of artificial intelligence to tailor therapies will escalate. This technological integration not only holds the promise of more effective treatments with fewer side effects but also presents a more economically viable option for healthcare systems grappling with budgetary constraints. This scenario gains particular relevance amid the global financial strain on healthcare services, and it falls upon scientists to conclusively demonstrate the benefits of pharmacogenetic tests for a specific drug to patients.

Yet, despite the potential efficacy of personalized therapies based on genetic profiles, their implementation often proves unpredictable and costly. In certain instances, simpler solutions can achieve comparable results. Furthermore, the acceptance of this approach necessitates significant trust from individuals in governmental entities and companies responsible for managing their genomic data. One more critical concern highlighted is the lack of regulatory preparedness to handle therapies tailored for individual patients. Obtaining the requisite data for regulatory approval frequently relies on clinical trials with hundreds or thousands of participants, presenting substantial challenges for personalized therapies.

In light of these considerations, although the potential of personalized medicine is thrilling, it is imperative to tackle practical, ethical, and regulatory challenges to guarantee that this approach can genuinely and safely deliver affordable benefits to patients.



ESG



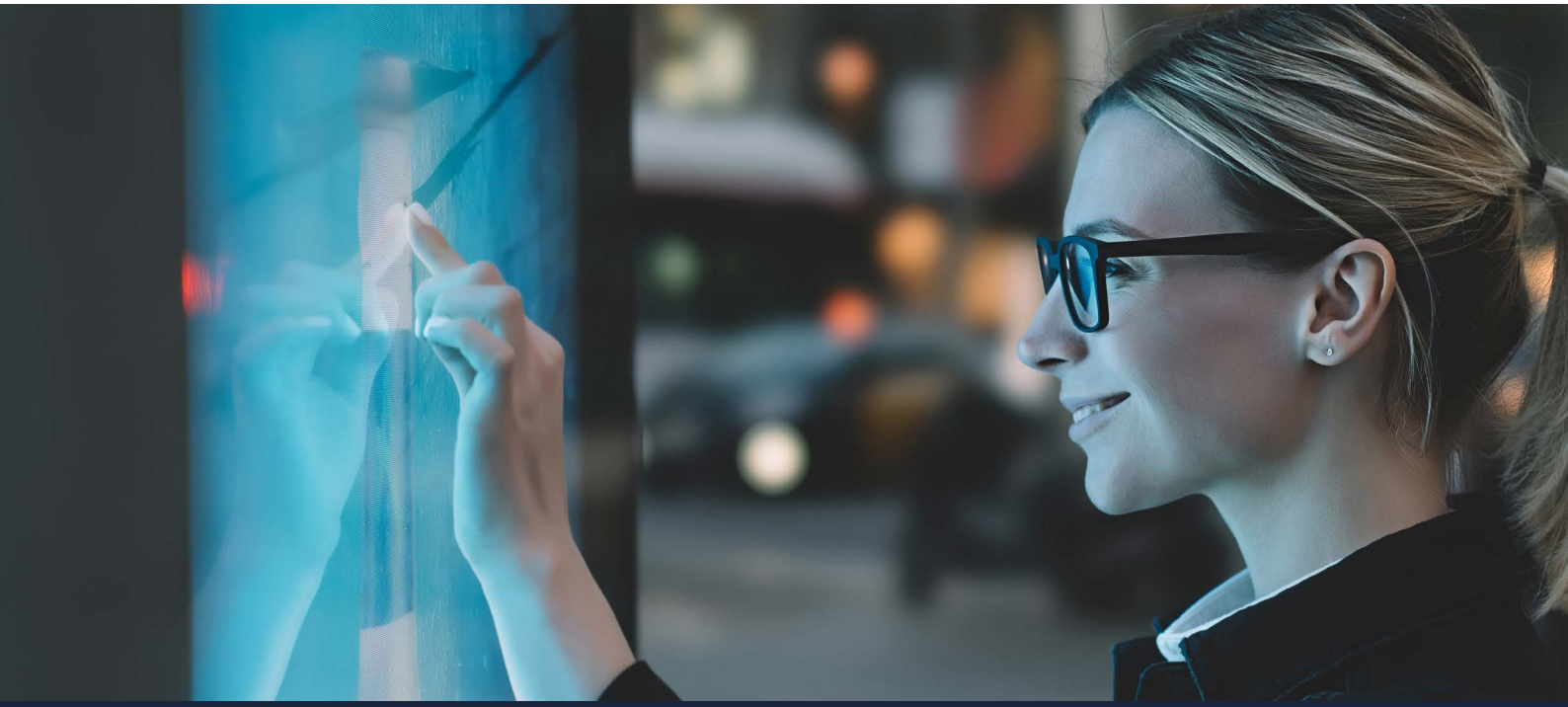
ESG

> **The ESG approach has gained prominence in recent years, fueled by the growing awareness of socio-environmental issues and the increasing demand from investors for enhanced transparency and sustainability. Consequently, compliance practices have become integral components of corporate agendas across various industries.**

The life sciences and healthcare sectors, entrusted with a continuum of institutions committed to enhancing people's quality of life, are no exception. Playing a pivotal role in tackling global challenges like pandemics and ensuring widespread, unhindered access to healthcare, these sectors have progressively adopted stringent compliance measures in these domains, recognizing them as pivotal.

Companies in the sector are taking significant steps to mitigate environmental, social, and governance risks, aiming for broader compliance and excellence. They are adopting effective strategies across all their operational processes, driven not only by the inherent competitive advantage and profitability associated with compliance but also to distinguish themselves in the eyes of consumers who seek ESG-compliant companies.

In this industry, companies recognize the importance of demonstrating the integrity of their supply chains. This includes a commitment to patient access, transparency in clinical trials, ethical use of data, accessibility, and technological advancements.



It is worth noting that ESG issues are expected to become more relevant in mergers and acquisitions transactions in Brazil in 2024. Following COVID-19, many sector companies have adjusted their corporate and M&A strategies to use stronger balance sheets to address imminent ESG issues, focusing on the safety and resilience of supply chains. This trend is expected to accelerate, with life sciences and healthcare companies increasingly using M&A as a tool to enhance overall ESG performance while adding environmental expertise and capabilities. Besides impacting M&A strategy, ESG will also become more critical in business execution. This primarily concerns identifying the ESG impact of a transaction on the buyer, considering corporate strategy and capital structure, as well as mitigating risks during due diligence, especially regarding crucial ESG issues like waste reduction, energy efficiency, and carbon emission reduction.

In turn, emissions, particularly in light of the growing carbon market, are becoming a central concern for life sciences companies. Achieving sustainability is no longer a choice but a business imperative. Companies aspiring to lead the fight against climate change are addressing not only their direct emissions (Scope 1 and 2) but also focusing on indirect emissions (Scope 3) within their value chains. These Scope 3 emissions, though challenging to control, can constitute a substantial portion of a company's total emissions.

In the pursuit of sustainability and ethics, the life sciences industry is leading by example. The B3 stock exchange in Brazil introduced the Efficient Carbon Index ("ICO2 B3") to recognize and promote companies and financial institutions committed to emission transparency and a low-carbon economy. Even sectors like agriculture and livestock are taking steps to reduce their carbon footprint.

While the path toward ESG compliance, particularly in terms of sustainability, holds promise, it is imperative to distinguish authentic sustainability efforts from greenwashing. Some companies may overstate their sustainable initiatives without substantial actions, risking harm to their reputation and undermining trust. This underscores the motivation behind companies adopting stringent supply chain management procedures, refining partner selection criteria, enhancing compliance verification processes, and fostering collaborative efforts within their network to improve supply chain management.

From a social perspective, companies undergo evaluation for workplace equity, diversity, and inclusion, adherence to human rights, employee health and safety, and corporate social responsibility. Investors and, more importantly, consumers closely scrutinize this commitment.

Finally, well-defined and effectively managed corporate governance enhances positive visibility for companies, serving as a reflection of their integrity. Although the current scenario among companies in the sector already demonstrates commitment and adherence to ESG practices, the topic holds great promise and is anticipated to garner increased momentum in 2024. This expectation is particularly heightened due to the pressing legislative and regulatory agenda surrounding the theme in the country this year.

Economic-Industrial Health Complex – CEIS

(In Portuguese, "*Complexo Econômico-Industrial da Saúde – CEIS*")

Economic-Industrial Health Complex – CEIS
(In Portuguese, *"Complexo Econômico-Industrial Da Saúde – CEIS"*)

In September 2023, the Federal Government signed **Decree No. 11,715/2023**, instituting the National Strategy for the Development of the Economic-Industrial Health Complex (CEIS), aiming to promote the country's reindustrialization with inclusion and sustainability, focusing on one of the most important sectors for Brazilian industrial policy – life sciences and healthcare.

Decree No. 11,715/2023. Available on:

link

By spearheading this initiative, the State plays a crucial role, establishing policies that regulate and promote actions considering primary objectives such as reducing vulnerability in the Brazil's SUS, adhering to SUS principles, and expanding public access to products and services.

The project comprises six structural programs focused on expanding the national production of items prioritized for the SUS, aiming to decrease the country's dependence on foreign inputs, medications, vaccines, and health products, as well as providing broad access to healthcare for all.

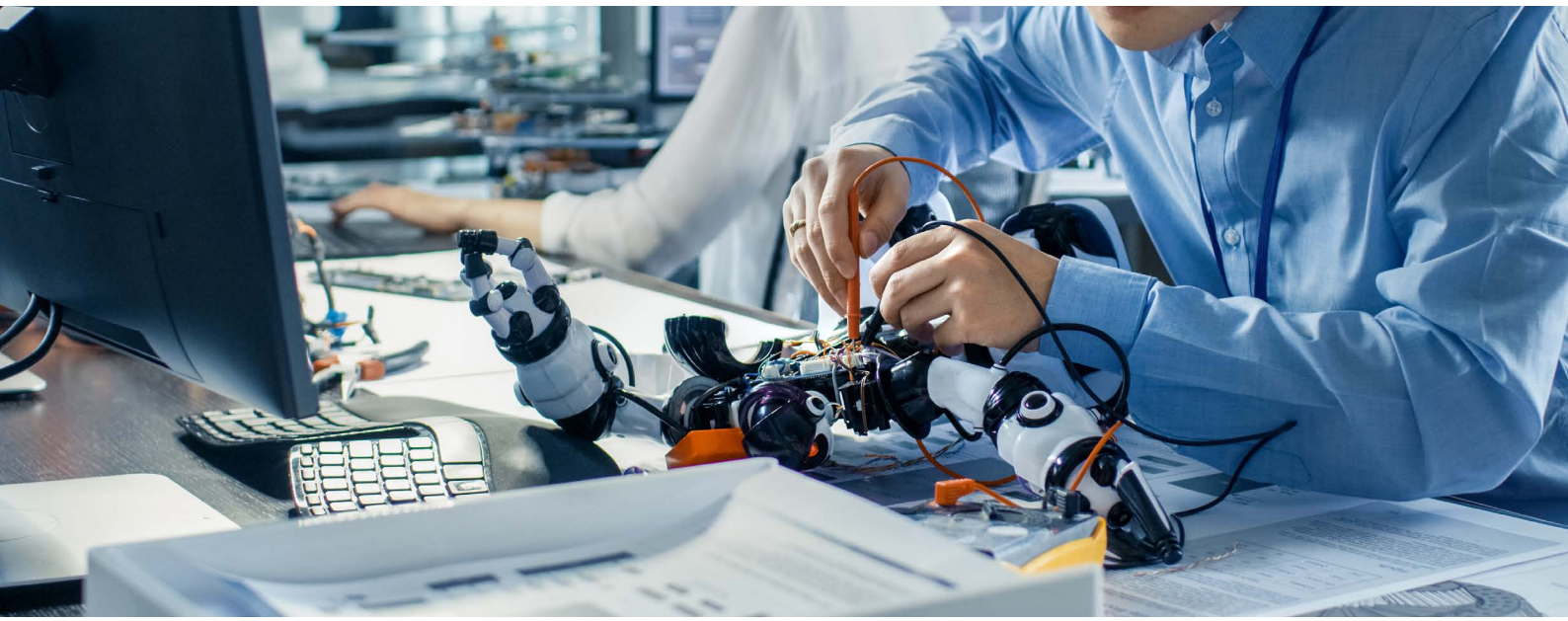
> **Eleven ministries actively participate in this initiative, under the coordination of the Ministries of Health and Development, Industry, Trade, and Services, alongside various public agencies, and institutions.**

The strategy is structured around three key industrial sectors:

(i) a foundation in chemical and biotechnological advancements,

(ii) a comprehensive sector covering mechanical, economic, and material aspects, including medical devices, and

(iii) health services, fostering institutional, economic, and political collaborations with a specific focus on innovation and health production.



The initiative is set to redefine Brazil's industrial development globally, advocating for official laboratories to shoulder the responsibility of providing medications across the entire public network. This undertaking is marked by the integration of development projects with income generation, fostering national self-sufficiency. As a result, a promising outlook emerges, particularly for domestic production, including active pharmaceutical ingredients, orphan drugs for treating rare diseases, and enhancements in the structure of direct healthcare provision. Inevitably, there is considerable anticipation for an upswing in solutions and products subjected to CONITEC scrutiny.

This is intricately connected to the thorough analysis conducted by various experts and government authorities on Brazil's supply chain and the essential investment needed in domestic alternatives to address product shortages.

Regarding investments, the total is projected to reach 42 billion reais by 2026. With this, the government seeks to equip the SUS with local production and technology, while also mitigating the growth of the healthcare trade deficit, currently at 80% over the past 10 years.

Medicinal Cannabis

Medicinal Cannabis

> **The year 2023 proved to be tumultuous for Brazil's medicinal cannabis sector. Despite heated discussions, from the prohibition of importing plant flowers under RDC 660/2022 to the decriminalization of drug possession and Anvisa's stringent regulatory measures against advertising, the overall result is positive.**

The utilization of medicinal cannabis products is increasing, propelled by enhanced medical education and progress in clinical research. In Brazil, access to these products, when prescribed, can be acquired either through direct importation by the patient, regulated by Anvisa's Collegiate Board Resolution RDC No. 660/2022, or through the purchase of approved products from pharmacies, as stipulated in Resolution RDC No. 327/2019, currently undergoing review and update.

According to the Brazilian Association of Cannabinoid Industries (BRCANN), commercial flow of medicinal cannabis products more than doubled in 2021 compared to the previous year. In 2022, requests exceeded the previous year by over 100%, and in 2023, an increase of nearly 150% is expected compared to the previous year.

It is anticipated that in 2024, with the update of RDC No. 327/2019, pharmacy sales will surpass direct patient importation. Clear regulation of the sector not only expands access to these products, reducing the financial impacts of litigation but also ensures patient safety by requiring therapeutic protocols approved by health authorities. Furthermore, such regulatory measures stimulate the market, enhance the patient journey, and offer increased security for healthcare professionals engaged in the process.

Concurrently, scientific studies and clinical research in this field have surged by 650% in the last 12 years. Research conducted by Prohibition Partner indicates that in 2022, 60 scientific studies with characteristics of randomized and controlled clinical trials were published worldwide. By August 2023, 49 clinical trials involving cannabinoid-based medications had already commenced. Presently, the United States leads in clinical trial production, followed by the United Kingdom, Canada, Israel, and, finally, Germany and Italy, closely competing. While many studies aimed to understand how cannabinoids could alleviate bodily pain, there is a significant increase in research investigating potential benefits in treating mental disorders such as anxiety, depression, and degenerative diseases.

Despite Brazil's considerable potential for advancing scientific studies on the subject, the country's involvement remains restricted, primarily due to challenges in conducting clinical research. The approval of PL 7082/2017 has the potential to alter this landscape.

Moreover, despite evidence of the efficacy of medicinal cannabis products, the absence of federal regulation hinders their supply through the SUS, prompting many patients to seek legal remedies. Although some states, such as São Paulo (**Law No. 17,618/2023**), have already enacted laws and regulations for the free distribution of these products through SUS, practical implementation is still underway.

Law No. 17,618/2023. Available on:

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All-in-one, 2024 will undoubtedly witness substantial regulatory and legislative advancements in the country, offering clearer guidelines for this sector, including product commercialization, service intermediation, and even plant cultivation. Once accomplished, the country will finally take its inaugural steps toward the forefront of this global market.

Agribusiness

Agribusiness

At the end of the year 2023, the approval of **Bill No. 1,459/2022**, which establishes a new legal framework for the production, registration, commercialization, and use of agricultural pesticides, their components, and related products, represented a significant development for the sector.

Bill No. 1,459/2022. Available on:

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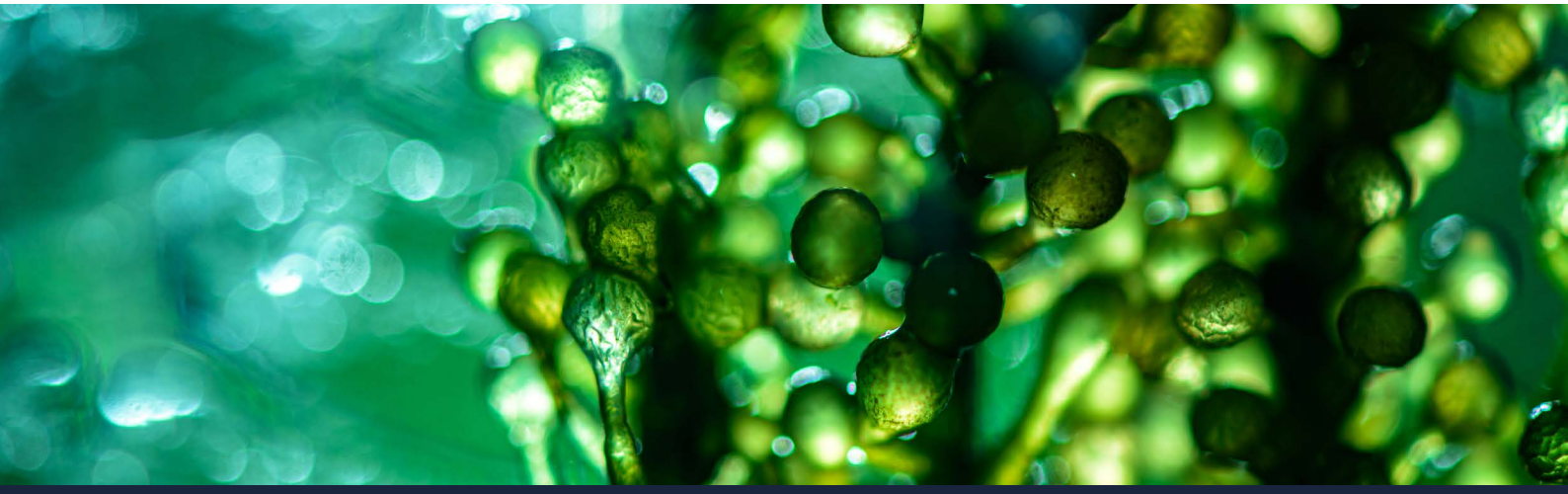
The bill will now move on to the presidential sanction phase, and once sanctioned, it will introduce substantial changes aimed at improving the speed and efficiency of new product registration procedures. This will bring tangible benefits to companies, fostering innovation, expanding the variety of available products, and creating a more attractive business environment for investments.

Still within this overarching theme, noteworthy is the current regulatory effort regarding the regulation of sanitary requirements for plant-based foods by the Ministry of Agriculture and Livestock (MAPA), especially concerning minimum identity and quality requirements, visual identity, and labeling rules for plant-based analog products.

After the conclusion of the Public Consultation (CP) in September 2023, we are now entering the phase of analyzing the received contributions and subsequently crafting the final instrument intended for publication. Thus, the imminent arrival of a new regulatory framework for the topic is anticipated, with a future regulation also expected from Anvisa as part of its Regulatory Agenda 2024 – 2025.

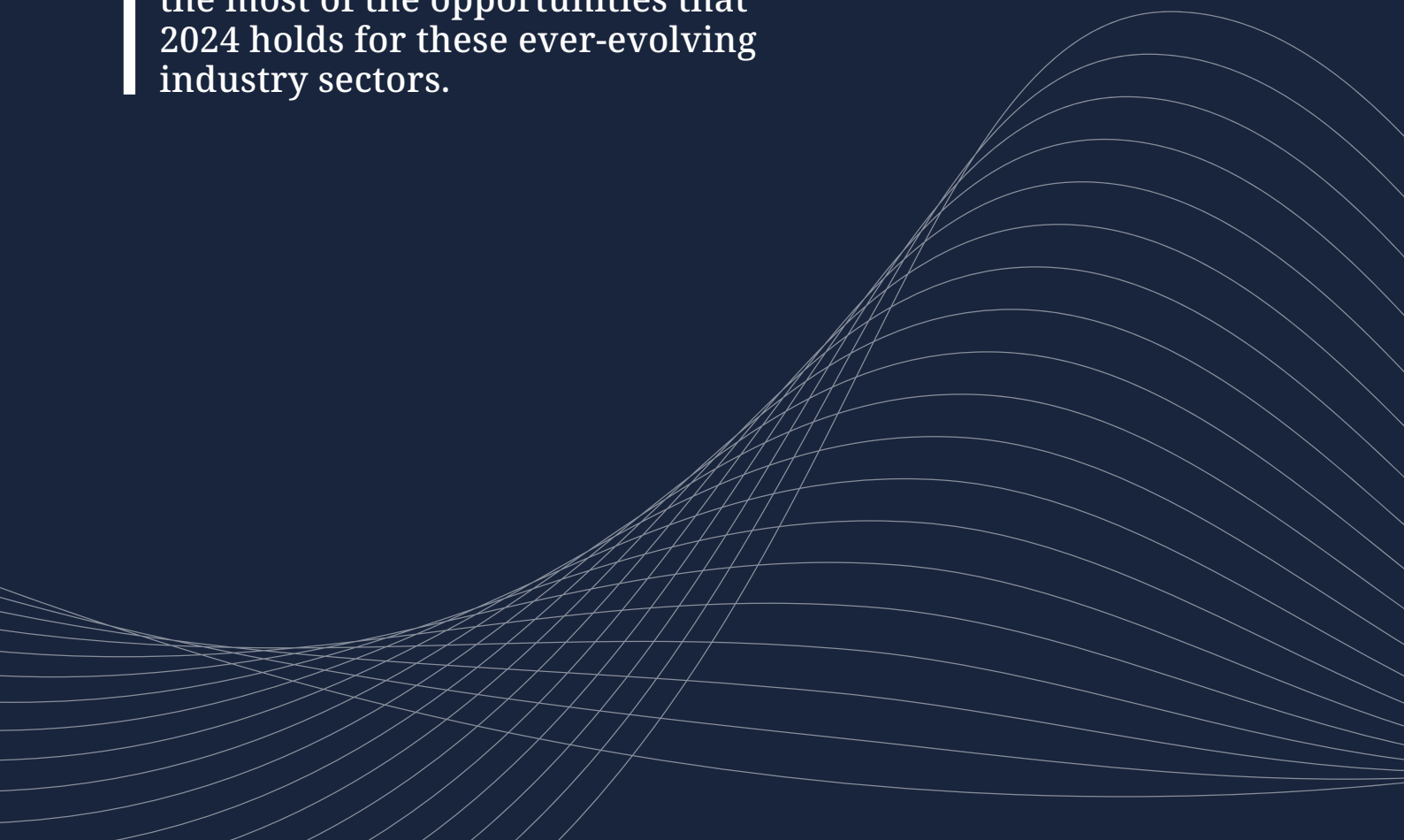
So, in 2024, we can once again expect significant strides in regulatory and legislative developments in the agribusiness sector.



How can we assist you today?

As seen, the landscape of the life sciences and healthcare sectors in Brazil in 2024 is filled with opportunities and significant challenges. In this dynamic context, we are committed to providing strategic support to our clients, guiding them through the complexities and emerging opportunities. Whether in implementing efficient tax solutions for transactional businesses in the health field, monitoring constantly evolving regulations to ensure compliance, or maximizing the benefits offered, we are here to be the partner that helps our clients navigate this challenging landscape.

> Our commitment goes beyond providing services; we indeed seek to empower the growth and innovation of our clients, making the most of the opportunities that 2024 holds for these ever-evolving industry sectors.



Areas of practice

Areas of practice

Campos Mello Advogados, in cooperation with DLA Piper, is a full-service law firm with offices located in the leading financial centers in Brazil. Our capillarity positions us in the best place to assist clients with their legal needs throughout the country.

For more than ten years, we have been working in cooperation with DLA Piper, one of the most significant law firms in the world (dlapiper.com), with lawyers located in more than 40 countries, including the Americas, Europe, the Middle East, Africa, and Asia Pacific.

Campos Mello Advogados, in cooperation with DLA Piper, has a comprehensive services platform and market presence to meet the needs of virtually any type or size ofour Life Sciences, Healthcare, and Cannabis clients.

Clients value the ability of law firms to understand their business context and to provide legal advice accordingly. Campos Mello Advogados, in cooperation with DLA Piper, has the depth of expertise to meet the legal needs of our clients wherever they choose to do business. We seek to understand our client's challenges while attempting to enable the most comprehensive competitive advantage.

Through DLA Piper's structure, we overlay our global practice groups with international sector teams explicitly designed to reflect our client's business markets. Sector teams are cross-practice, and when advice is required, the Campos Mello Advogados, in cooperation with DLA Piper lawyers acting on a specific matter, will be well-versed in that relevant specialism and jurisdiction.

To that end, Bruna B. Rocha is the focal points of contact for our Life Sciences, Healthcare, and Cannabis group sector and its related matters.

In cooperation with DLA Piper's work, Campos Mello Advogados is supported by 12 different practice areas focused on creating value solutions. Our divisions are based on excellent management models, also adopted by some of the best global law firms, and seek to ease the ways of working.

This way, we guarantee that the professionals who work in each folder have the level of specialization and are up to date in the area, besides having the necessary knowledge to offer quality support aimed at the individual needs of each of our customers. In search of solutions that can add value to our work, CMA focuses, through its areas of operation, on the hunt for a global understanding of the business context of each of its clients, knowing market segments and challenges. We want to be perceived not only as a law firm but also as a partner in solutions and support of the development of Brazilian and foreign companies.

Our client portfolio ranges from multinational, Global 1000, and Fortune 500 enterprises to emerging companies developing industry-leading technologies. They include more than half of the Fortune 250 and nearly half of the FTSE 350 or their subsidiaries. We also advise governments and public sector bodies.

ESG

Committed to our purpose of bringing practical solutions to our customers and having the mindset that our operation and growth must be healthy, sustainable, conscious, and consistent with our values, we apply the most modern and innovative management methods to support us in the constant search for improvements.

Among the methods used by Campos Mello Advogados in cooperation with DLA Piper is the use of ESG (Environment, Social, and Governance) principles, both within the working practices with our clients and in the establishment of internal relationships with our employees.

Find out more about our practice areas below:

Transactional

Our mergers, acquisitions, and transactional lawyers have extensive experience structuring, financing, negotiating, documenting, and closing deals involving Life Sciences, Healthcare, and Cannabis companies.

We have handled numerous mergers and acquisitions; acquisitions and sales of substantial healthcare assets; corporate restructuring; joint ventures and strategic alliances among providers, physicians, and payors; development of provider networks; secured loans; and structuring syndications and other securities transactions.

We also represent emerging Life Sciences, Healthcare, and Cannabis companies in such areas as venture capital and other private financings, corporate partnering including research and development arrangements, IPOs, intellectual property, and growth and exit strategies.

Data Privacy

Personal information is an increasingly valuable – and increasingly risky – business asset.

As businesses struggle to keep up with the critical, fast-changing data protection laws and face an increased risk of serious data breaches, Campos Mello Advogados, cooperating with DLA Piper, is uniquely positioned to help guide clients.

With data protection lawyers around the globe, we can provide highly sophisticated data management, data security, and privacy law advice wherever our clients do business.

Regulation & Policy Issues

Our fully integrated multi-disciplinary team is accustomed to working with clients on cross-border issues or, by contrast, on regulatory challenges in a single jurisdiction.

Businesses in the life sciences, healthcare, and cannabis industries often face significant regulatory burdens. We help clients in this space navigate a rapidly evolving landscape of rules and regulations. We constantly monitor policy changes and their impact on the industry, including innovative policies or guidance on processes, technologies, and sustainability solutions (importantly, both reverse logistics of packaging of drugs and reusability/recyclability of materials).

With years of first-hand experience and excellent working relationships with most regulators, we can provide competent, well-informed commercial advice tailored to our client's needs. That advice is available from considering entering a particular market or starting a new clinical trial to assessing local distribution frameworks' regulatory implications.

To this end, we can advise on the critical financial regulatory issues impacting life sciences businesses, such as the Anti-money laundering Act in Brazil (AML/KYC regulations).

Our regulatory lawyers in Brazil have already advised several businesses on the regulatory issues which impact the manufacture, R&D, and marketing of biologics, biotech, and biosimilar products. We have experience with both human and animal health regulatory issues affecting health-regulated products. Our local presence in key markets for this sector enables our regulatory team to exchange information unique to the problems being faced by the industry in different jurisdictions.

Our lawyers also bring comprehensive experience in tackling cutting-edge issues in artificial intelligence, telehealth and telemedicine, apps and wearable technology, Health IT, big data, cybersecurity, and privacy. Artificial intelligence and potential changes driven by technology are issues facing the industry. These changes will cause the quality of care, how care is defined, and by whom care is delivered.

Intellectual Property & Technology

Intellectual property and technology law is at the core of any significant business transaction or strategic dispute for Life Sciences, Healthcare, and Cannabis companies and has become one of the most critical legal areas as companies continue to expand and protect their technologies, brands, products, data, and services around the globe.

Our global technology transactions and strategic sourcing lawyers have the market knowledge, legal experience, and regional presence to provide you with the highest quality legal services worldwide.

We focus on developing, protecting, exploiting, and using intellectual property and technology-related assets through the stages of a company's growth and sourcing strategic investments and services for use in a company's operations.

ESG

Sustainability and resilience are core business issues in the Life Sciences, Healthcare, and Cannabis sector, given the sector's central role in addressing systemic global challenges, including pandemics, access to medicine, and fundamental human rights.

Although the specific factors from the sustainability, environmental, social, and governance (SESG) perspective in the life science, healthcare, and cannabis industry differ from those of other industries, creating new and sustainable value in this sector space will depend upon how companies address relevant SESG risks.

SESG is a risk that broad members must actively identify for their companies, mitigate effectively, and ensure compliance with varying regulations throughout the world to avoid pitfalls, maintain profitability, and keep their businesses competitive.

Based on our experience in the sector, we believe (and focus on) the following sustainability-related themes to be the core SESG issues that will continue to affect life science businesses such as access and affordability, supply chain compliance, business ethics, transparency and access to clinical trials, net-zero decarbonization and optimization of processes.

Product Liability & Product Safety Counseling

Our broader product liability and product safety counseling practice also enable us to assist whenever a regulator takes an interest in your business, from the call of a whistleblower to a raid or a workplace accident.

As required, we are there for you and with you, providing legal advice and representation at every stage of the regulatory process. We appreciate that many regulators have far-reaching powers to investigate allegations of criminal or regulatory breaches.

> **We represent clients before national, supranational, and sub-national governments and administrative organizations on public policy, legislative, regulatory, and executive issues.**

Patents Prosecution and Strategic Counseling

Effectively and strategically prosecuting patents is critical to business, especially for innovative life sciences and healthcare companies. Success may depend on protecting unique technology and revenue streams, while at the same time advancing patents to increase the likelihood they would successfully survive litigation in the future.

Our patent lawyers in Latin America, more specifically in Brazil, working with a network of other DLA Piper offices around the world, regularly handle patent prosecution for clients on five different continents, including major global pharma corporations, emerging biotech companies, and innovative institutions such as health-regulated product manufacturers, health service providers, and universities.

Cybersecurity @

Our fully integrated multi-disciplinary team is accustomed to working with clients on cross-border issues or, by contrast, simply on regulatory challenges in a single jurisdiction.

Businesses operating in the Life Sciences, Healthcare, and Cannabis industries often face significant regulatory burdens. We help clients in this space navigate a rapidly evolving landscape of rules and regulations.

We constantly monitor policy changes and the impact it is having on the industry, including innovative policies or guidance on processes, technologies, and sustainability solutions (importantly, both for the reverse logistic of packaging of drugs and the reusability/recyclability of materials).

With years of first-hand experience and excellent working relationships with most regulators, we can provide competent, well-informed commercial advice, which is tailored to our individual clients' specific needs. That advice is available from the moment you are considering entering a specific market or starting a new clinical trial through to assessing the regulatory implications of local distribution frameworks.

To this end, we are also able to advise on the critical financial regulatory issues impacting life sciences businesses, such as the Anti-money laundering Act in Brazil (AML/KYC regulations).

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These changes will drive the quality of care, how care is defined, and by whom care is delivered.

Strategic Patent Counseling

Engaging experienced counsel on strategic patent portfolio analysis has become essential to life sciences and healthcare clients who want to maximize their revenue-generating opportunities.

As part of our counseling activities, we regularly advise on patentability, validity, and freedom to operate issues, provide opinions, conduct due diligence, address other matters connected with corporate mergers and acquisitions, and handle litigation support as representative examples.

Our patent lawyers have detailed knowledge of a wide array of complex technologies – from semiconductors of MD to stem cells - to help you make the most of your IP assets.

Taxes

Our tax group assists clients in structuring a wide range of transactions, from private equity deals to corporate acquisitions, reorganizations, and disposals.

Throughout the world, Campos Mello Advogados, in cooperation with DLA Piper, also offers our clients sophisticated, innovative, and creative tax and business planning advice in connection with domestic and multi-jurisdictional transactions and investments. We provide these international tax services while at the same time offering clients the benefits of attorney-client and work product privileges.

> **Our tax lawyers draw upon the experience of colleagues in numerous areas of law, including intellectual property and technology, regulatory, corporate, and finance.**

Financial (Finance)

In cooperation with DLA Piper, Campos Mello Advogados advises on all aspects of financing across borders, sectors, and financial products. We help our clients realize their financial strategies in whichever market they do business in.

Our clients include the full range of market participants, whom we often support on first-of-a-kind deals and in new markets.

We share knowledge and skills in deals involving, for example, lending and borrowing, debt securities, derivatives, funds, portfolios, and FinTech solutions.

Commercial Contracts

Our Commercial Contracts practice combines legal knowledge with deep sector experience and a can-do approach covering the full spectrum of commercial and business law issues.

When it comes to multi-jurisdictional transactions, our worldwide presence and experience managing sophisticated cross-border commercial deals set us apart.

Our scope of work includes naming a few, the business-critical national and international commercial transactions, among them sourcing and procurement, sales, agency and distribution, e-commerce, joint ventures and collaborations, manufacturing, logistics, licensing arrangements, research and development, digital and business transformation, Everything-as-a-Service, etc.

Compliance and Investigations

Over the years, compliance programs and mechanisms have become more than mere instruments to combat illegal acts in companies.

> **Currently, there is an excellent legislative evolution on the subject, combined with the maturation of Brazilian companies. Today, compliance programs are a significant asset of companies and are present from contracts with the Public Administration to M&A transactions.**

We help clients avoid investigations and ensure that their compliance programs with the numerous statutes and regulations that govern life sciences, healthcare, and medicinal cannabis operations.

We understand how enforcement decisions are made and represent clients who are the target of an investigation, facing allegations that they committed fraud, or are the victims of the fraud committed by others.

Litigation and Arbitration

> **We have the local knowledge to apply the regulatory, economic, political, and cultural context to legal issues and develop case strategies. We regularly handle technically challenging and complex multi-jurisdictional matters.**

We are positioned to defend claims of any scope around the region. We help our clients keep ahead of the game on compliance with product safety legislation and product liability claims and engage with government legislatures and public regulatory authorities if necessary.

Handling crises that involve product recalls, governmental investigations, insurance coverage, and environmental concerns are also part of our routine. We also advise on environmentally friendly supply chain management.

Public and Administrative Law / Government Contracting and Government Affairs

In the area of Government Contracts, CMA's efficient legal solutions allow the treatment of complex issues of Public Law.

> **We provide tailored advice and legal services on government contracting and public procurement, from bid strategy to potential challenge. These services include the preparation of strategic alliance agreements and teaming arrangements, bid protests and challenges, and contract administration and claims.**

Our lawyers also litigate contract disputes and claims involving contractors. Our Government Affairs team in Brazil also assists in helping clients understand the machinations of local government and can assist in preparing responses to public consultations and inquiries to prepare for appearances before select committees. We can also work with your selected external government affairs teams to identify core issues and how best to message specific governments.

Labor and Social Security

In cooperation with DLA Piper's employment practice, Campos Mello Advogados advises clients on employment legislation, helping them meet their workforce objectives.

We can assist with outsourcing, expansions or reductions-in-force, local employee relations, and risk management.

Cybersecurity

In today's interconnected world, virtually all companies, their suppliers and their customers are potential targets for cyber attacks. The risks associated with such incidents require a robust cybersecurity program to manage this fast-changing risk and remain in compliance.

Our multidisciplinary team of lawyers and operational consultants advise on all issues surrounding cyber security, from building cyber resilience, through incident response, and post-incident remediation, to providing a holistic and tailored client service.

For questions, please contact:

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IN COOPERATION WITH DLA PIPER

2024