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Life Sciences 2026

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Brazil: Law and Practice & Trends and Developments

Bruna Rocha, Jessica Filka, Juliana Marcondes and Victoria Cristofaro
COSRO

BRAZIL

Law and Practice

Contributed by:
Bruna Rocha, Jessica Filka, Juliana Marcondes and Victoria Cristofaro
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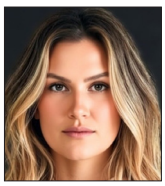
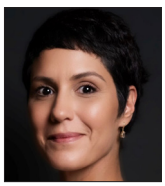
COSRO delivers sector-focused legal counsel built for speed and impact. The life sciences and healthcare team combines 15+ years of senior practitioner experience across Brazil and Latin America with deep regulatory fluency (ANVISA pathways, CMED pricing, and public and private market access), enabling clients to move products from lab bench to commercial launch with precision. Transactional to the core, COSRO structures complex cross-border acquisitions, builds regulated entities, designs investment platforms for emerging markets, and executes asset transfers and restructurings. Coverage spans CEP/CONEP submissions, GCP/GMP compliance, pharmacovigilance, technology transfer and LGPD-compliant digital engagement. COSRO integrates HEOR into CONITEC dossiers and payer negotiation and design distribution models, tendering strategies, and patient support programmes for SUS and private payers. The firm deploys generative AI governance frameworks for pharma and device clients, embedding privacy-by-design, GxP validation, model risk classification and human-in-the-loop oversight for compliant deployment in R&D, pharmacovigilance, field force enablement and patient engagement. Clients include global biopharma, medtech, digital health, CROs and agriscience companies.

Authors

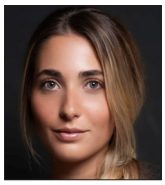
Bruna Rocha advises clients across the healthcare and life sciences spectrum, including pharmaceutical, biotech, medtech, digital health, CROs, hospitals and agribiotech, structuring transactions and regulatory frameworks that drive growth while managing risk. Her practice centres on corporate transactions, joint ventures, strategic alliances, licensing arrangements, R&D partnerships and spin-offs, with particular strength in regulated entity formation, compliance architecture and complex restructurings. Her experience spans emerging sectors including AI in healthcare, SaMD, connected devices, wearables, biofabrication and digital care models, advising on regulatory strategy, data protection and pathways to registration and reimbursement. She guides clients through development, regulatory approval and market access.



Jessica Filka is a corporate lawyer and advises Brazilian and international companies across the life sciences and healthcare sectors. Her extensive experience in complex transactions, particularly in large-cap and mid-market deals, has positioned her as a trusted adviser in the field for the past decade. Jessica holds postgraduate degrees in Corporate Law, Contract Design and Taxation in Corporate Transactions from Fundação Getulio Vargas (FGV/SP). Her practice encompasses deal structuring, negotiations of key contracts and thorough analysis of legal risks.



Juliana Marcondes represents medical technology manufacturers, biotechs, diagnostics companies and distributors of medical products. Her practice centres on pre-litigation counselling and dispute avoidance. She partners with cross-disciplinary teams to deliver specialised, industry-specific advice across the life sciences and healthcare sector.



Victoria Cristofaro represents pharmaceutical companies, clinical research organisations, biotechs and digital health providers. She advises on transactional and regulatory matters. Her work spans regulatory compliance and commercial contracts. She counsels on clinical trial regulation and quality system regulation. She leads public policy strategy and advocacy before national, supranational and sub-national governments and administrative bodies. She is an associate-to-watch and a member of the Special Commission on Bioethics and Bio-Law of OAB-SP.

COSRO

Avenida Brigadeiro Faria Lima, No 201
11th Floor, Suite 112
Pinheiros, São Paulo – SP
Brazil

Tel: +55 11 3038 7111
+55 21 3031 2876
Email: bruna.rocha@cosro.com
Web: www.cosro.com

1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation

Brazil regulates medicines and medical devices through a layered federal regime anchored in statute and fleshed out by ANVISA's technical rules. The core legal framework consists of four primary laws:

- Law 6,360/1976 (sanitary control and marketing authorisation);
- Decree 8,077/2013 (implementation);
- Law 6,437/1977 (infractions and penalties); and
- Law 9,782/1999 (establishing the National Health Surveillance System and ANVISA's mandate).

Medical Devices

Device regulation builds on Law 6,360/1976 through numerous National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária* – ANVISA) formal regulatory resolutions (*Resoluções da Diretoria Colegiada* – RDCs), including RDC No 751/2022 (risk classification and regularisation) and RDC No 665/2022 (GMP). The regulatory scope covers dossier content, labelling/instructions for use (IFU) standards, clinical investigations, in vitro diagnostics (IVD) performance evaluation, post-market vigilance, field safety actions, software as a medical device, sterilisation, import licensing, advertising, unique device identification, and special pathways for notifications and compassionate use. Normative Instructions and guidance documents supplement these RDCs.

Medicines

Medicines are governed by a similar RDC matrix, with ANVISA RDC No 658/2022 establishing general GMP requirements. Additional rules address registration pathways (new drugs, generics, biologics, biosimilars, radiopharmaceuticals, advanced therapies), stability, bioavailability/bioequivalence (BA/BE), dissolution, labelling, pharmacovigilance, controlled substances, clinical research, importation, serialisation and advertising. Obligations are category- and life cycle-dependent.

Pricing and Reimbursement

Price controls fall under Law No 10,742/2003, administered by the Pharmaceutical Market Regulation Chamber (*Câmara de Regulação do Mercado de Medicamentos* – CMED) with ANVISA as executive secretariat. Public reimbursement decisions are informed by the National Committee for the Incorporation of Technologies in the SUS (*Comissão Nacional de Incorporação de Tecnologias no SUS* – CONITEC) (created by Law No 12,401/2011), which conducts health technology assessments (HTAs) for SUS incorporation.

Institutional Roles

ANVISA serves as the central federal sanitary authority, handling registration, company authorisations, good manufacturing practice (GMP) certification, border controls and post-market surveillance. State and municipal bodies manage local licensing, inspections and first-instance proceedings under Law No 6,437/1977. CMED sets medicine price caps, while CONITEC advises the Ministry of Health on public coverage.

Legal Structure

ANVISA is a special-regime autarchy with enhanced autonomy, fixed-term directors and partial fee-based funding, linked to but independent from the Ministry of Health. State and municipal authorities co-ordinate through the SNVS without hierarchical reporting to ANVISA. CMED is an interministerial collegiate without separate legal personality, and CONITEC is a permanent advisory body within the Ministry of Health.

1.2 Challenging Decisions of Regulatory Bodies

From a regulatory perspective, challenging decisions in the pharmaceutical and medical device space primarily involves contesting individual administrative acts issued by ANVISA and other health surveillance authorities within the National Health Surveillance System (*Sistema Nacional de Vigilância Sanitária* – SNVS) at the state and municipal level. These challenges typically relate to case-specific decisions directly affecting a company or product, such as refusals or restrictions in registration/regularisation procedures, technical requirements issued during regulatory review, post-market measures (including suspensions of commercialisation, recalls or field actions), GMP-related outcomes (eg, inspection findings or certification impacts) and enforcement actions or penalties (including infraction notices and fines).

The primary avenue for challenge is usually administrative review within the competent authority. In the case of ANVISA, regulated parties may file administrative appeals within the relevant proceeding, seeking review by higher internal instances and, depending on the decision and applicable procedural rules, potentially by ANVISA's Collegiate Board (*Diretoria Colegiada da ANVISA* – DICOL). In sanctioning proceedings, challenges generally begin with a formal defence or impugnation in the administrative case file, followed by successive appeals as the proceeding advances. While ANVISA applies sector-specific procedural rules, general federal administrative law principles also apply, including due process, reasoned decisions and the right to be heard.

For an administrative challenge to be admissible and effective, it generally requires: (i) standing (the challenger must be directly affected by the act); (ii) timely filing, in accordance with the applicable deadline; and (iii) a reasoned submission clearly identifying the contested act and setting out legal and technical grounds (such as illegality, procedural flaws, insufficient reasoning, inconsistency with applicable regulations or disproportionality), supported by appropriate documentation and technical evidence.

Where administrative relief is insufficient or inadequate, decisions may also be challenged through judicial review, often combined with requests for urgent injunctive relief in cases of immediate operational impact or risk of irreparable harm.

These challenge mechanisms are largely consistent across other ANVISA-regulated product categories (such as food), as they derive from general administrative due process and sanitary enforcement principles, with differences arising mainly from sector-specific technical standards, rather than from the availability of review pathways.

1.3 Categories of Pharmaceuticals and Medical Devices

In Brazil, both pharmaceuticals and medical devices are subject to tiered regulatory categories, and the applicable requirements (such as the market authorisation pathway, dispensing and supply chain controls, labelling and post-market obligations) vary depending on the product's classification and risk profile.

For pharmaceuticals, the most practical "regulatory split" is based on dispensing status. A key category is over-the-counter (OTC)/non-prescription medicines (*medicamentos isentos de prescrição* – MIPs). ANVISA explains that MIPs are medicines that do not require a prescription and are generally available for self-selection in pharmacies and drugstores, and they do not carry the classic red or black stripes on the outer packaging. ANVISA periodically updates the official list of MIPs (LMIP), and recent rules set criteria for a product to be classified as non-prescription. By contrast, prescription medicines must display a red or black stripe and the wording *Venda sob prescrição médica* ("prescription-only medicines"), under ANVISA's labelling rules. Within prescription medicines, there is a further sub-category of controlled/special substances, governed by Ordinance of the Secretariat of Health (*Portaria SVS/MS*) No 344/1998, which establishes lists and stricter controls for dispensing, record-keeping and prescription handling.

Beyond dispensing status, Brazil also classifies medicines by regulatory type, which affects the applicable dossier and evidence requirements. In practice, the main categories are reference (innovator) products, generic medicines and similar medicines, each subject to specific rules on quality documentation and, where applicable, BE/interchangeability standards. In addition, biological products are regulated under a distinct framework from small-molecule drugs, and biosimilars are generally assessed through a comparability pathway.

For medical devices, the core differentiator is risk classification. ANVISA classifies devices into Classes I–IV (from low to maximum risk) under Collegiate Board Resolution (*Resolução da Diretoria Colegiada* – RDC) No 751/2022, and this classification drives the regulatory route and intensity of review: lower-risk products typically follow lighter regularisation mechanisms, while higher-risk devices are subject to more robust pre-market review, stricter technical documentation expectations and reinforced post-market surveillance obligations.

2. Clinical Trials

2.1 Regulation of Clinical Trials

In Brazil, clinical trials of pharmaceuticals and medical devices are regulated under a dual oversight model that combines ethics review of research involving human beings with sanitary oversight by ANVISA. The general governance of human research was recently reinforced by Law No 14,874/2024, as regulated by Decree No 12,651/2025 (effective 8 October 2025), which reorganises the national ethics framework and seeks to increase legal certainty and foster clinical research investment. Decree No 12,651/2025 confirms that the current Research Ethics Committee (*Comitê de Ética em Pesquisa* – CEP)/National Research Ethics Commission (*Comissão Nacional de Ética em Pesquisa* – CONEP) system will remain in operation until the new National Research Ethics Body established under Law No 14,874/2024 becomes fully operational. Ethics and ANVISA reviews are conducted in parallel and are independent, but a trial may only start once the applicable ethics and regulatory clearances are in place.

For pharmaceuticals (including biologics), ANVISA's core framework is RDC No 945/2024, and is structured around submission and life cycle management of a clinical development dossier for medicines (*dossiê de desenvolvimento clínico de medicamentos* – DDCM) and a trial-specific dossier (*dossiê específico de ensaio clínico* – DEEC), including requirements for essential supporting documentation (eg, development plan, investigator's brochure, investigational product quality dossier and statistical analysis plan), safety reporting, amendments and substantial changes, and import logistics (with import documentation supporting logistics and the formal authorising act published in the Official Gazette).

For medical devices, clinical investigations follow a separate ANVISA pathway under RDC No 837/2023, with a risk-based distinction in which higher-risk devices (ie, Classes III and IV) generally require prior ANVISA assent through a clinical investigation dossier (*dossiê de investigação clínica de dispositivos* – DICD), while lower-risk devices (ie, Classes I and II) are typically not subject to prior ANVISA review and proceed under ethics approval and good clinical practices, with importation handled under the rules applicable to research-use products.

2.2 Securing Authorisation to Undertake a Clinical Trial

Clinical trial authorisation in Brazil requires two parallel clearances:

- ethics approval through the CEP/CONEP system, which covers the protocol and informed consent documents and provides ongoing oversight of amendments and reportable events; and
- ANVISA regulatory clearance, which varies by product type (pharmaceuticals and biologics follow clinical trial dossier submission routes with import controls, while medical devices require a device clinical investigation dossier).

Before enrolling patients, sponsors must also complete operational prerequisites, including trial registration, executed agreements with sites and vendors, appropriate insurance/indemnity coverage, General Data Protection Law (*Lei Geral de Proteção de Dados* – LGPD)-compliant data governance for cross-border transfers, and defined responsibilities for safety reporting and quality oversight.

2.3 Public Availability of the Conduct of a Clinical Trial

The conduct of clinical trials involving pharmaceuticals and medical devices in Brazil is subject to mandatory registration and transparency requirements, although public disclosure does not extend to full protocols or complete clinical study reports.

Under Law No 14,874/2024, clinical research involving humans must be registered in a publicly accessible platform, with information kept up to date throughout the study life cycle. This obligation applies to both medicinal products and medical devices and is implemented through national registries integrated with the Brazilian research ethics system.

From a sanitary regulatory standpoint, ANVISA RDC No 837/2023 requires that clinical investigations involving medical devices be registered in a public clinical trials database recognised by the World Health Organization (WHO) International Clinical Trials Regis-

try Platform or the International Committee of Medical Journal Editors, as a condition for authorisation by ANVISA.

It is worth noting that public databases in Brazil provide third parties with access to high-level information on authorised clinical trials (eg, sponsor identification, investigational product/device, general design and recruitment status). However, Brazilian rules are designed to preserve confidentiality and do not require full public disclosure of commercially confidential technical documentation, such as investigational dossiers or complete clinical study reports, which remain protected, including as trade secrets. In parallel, Law No 14,874/2024 requires that the return of research results to participants be addressed (typically through the consent and study communication framework), but broader public dissemination of results is not necessarily uniform and will depend on applicable registry/journal requirements and sponsor publication practices, always subject to confidentiality and personal data protection obligations.

Accordingly, while clinical trials are listed in publicly accessible databases in Brazil, public access is typically limited to structured summary information, and the availability of detailed results is partial and regulated, rather than automatic or unrestricted.

2.4 Use of Online Tools to Support Clinical Trials

Brazilian rules on clinical trials do not create a blanket prohibition on online tools – eg, digital recruitment, eConsent platforms, electronic case report forms (eCRFs), remote visits or remote monitoring. Instead, the permissibility of such tools is assessed under the applicable clinical trial framework for medicines and medical devices, and they must be implemented in a way that preserves participant protection, data integrity and regulatory inspection capability.

In practice, online tools used for recruitment, such as social media ads, online prescreening forms, landing pages etc, are treated as participant-facing materials and processes, and as such, must be consistent with the approved clinical trial documentation and the applicable ethics requirements overseen by the CEP system and, where applicable, CONEP, including proper informed consent processes and safeguards against undue influence and misleading information.

For monitoring and conduct, such as remote source data verification, telemedicine visits, wearable data capture, decentralised procedures, etc, online tools remain acceptable where they are appropriately described in the protocol and supporting documents, and where the sponsor and investigator ensure confidentiality and controlled access, auditability and traceability (including for electronic records), and readiness for inspection and oversight by the competent authorities within the applicable ANVISA clinical trial framework for medicines and medical devices.

2.5 Use of Data From Clinical Trials

Data processing in the context of clinical research in Brazil must comply both with data protection rules, and with the ethical and regulatory standards applicable to human-subject research. In practice, clinical trial datasets will generally qualify as personal data, because they relate to an identified or identifiable participant, even where the study adopts subject codes and the sponsor/Contract Research Organisation (CRO) does not directly hold the participant's name. Moreover, in most cases such datasets will qualify as sensitive personal data, because clinical trials inherently generate and analyse health-related information, which is expressly protected as sensitive data under Article 5, II of the Brazilian GDPR (*Lei Geral de Proteção de Dados* – LGPD). Depending on the protocol and endpoints, datasets may also include genetic and/or biometric information, which typically demands heightened governance, security and access controls.

It is important to highlight that if the dataset is properly anonymised, meaning participants are no longer identifiable by reasonable means, it is not treated as personal data for LGPD purposes. However, fully irreversible anonymisation is often impracticable during trial conduct, because sponsors and regulators may require traceability for monitoring, audits, safety follow-up, data integrity checks and inspection readiness. For that reason, most operational datasets are maintained in a coded/pseudonymised form, with strict controls over who can access the re-identification key and under what conditions.

Resulting data may be transferred to a third party or an affiliate, but the transfer must comply with the LGPD governance framework and the specific rules applicable to clinical research. Under Law No 14.874/2024, the research institution must protect confidentiality and share only anonymised or coded data; where coded data is shared, the re-identification key must remain with the data manager, so the recipient should not be able to re-identify participants. Where a transfer would involve identifying information (or access that enables re-identification), Brazil's ethics framework generally expects that such flows are foreseen and justified in the protocol and/or relevant contracts, implemented through secure channels and handled under the oversight of the CEP/CONEP system, with appropriate documentation governing the transfer and responsibilities. Affiliates are not automatically exempt from these requirements: unless the recipient is clearly within the same controller structure and access is demonstrably restricted on a need-to-know basis, they should be treated as a third party for compliance purposes.

Finally, if the recipient is located outside Brazil, international transfer must meet the conditions set out in Articles 33–36 of the LGPD (eg, adequacy, contractual safeguards or another valid legal mechanism).

2.6 Personal or Sensitive Data

In Brazil, creating a database is not subject to a standalone authorisation merely because it contains personal or sensitive data; however, once the database is created for research purposes, it becomes subject to specific governance and ethics requirements, in addition to the LGPD's general duties.

In particular, CNS Resolution No 738/2024 regulates the constitution and use of research databases involving human subjects and requires that the protocol be submitted to the CEP/CONEP system when the project intends to constitute a database or use an existing one for research. It also expects the protocol to define key governance elements (eg, identifying the controller(s), describing the categories of data, the confidentiality/security mechanisms and the criteria for sharing/transfer), with an emphasis on risk/benefit assessment and, where possible, anonymisation.

Separately, Law No 14.874/2024 reinforces database design constraints in clinical research by requiring mechanisms to protect confidentiality and limiting sharing to anonymous or coded data, with the re-identification key retained by the data manager. The LGPD applies subsidiarily in this context and fills in broader privacy duties (security, accountability and, if applicable, international transfer mechanisms).

3. Marketing Authorisations

3.1 Product Classification

In Brazil, the classification of a health product as a medicinal product or as a medical device follows well-defined legal and technical criteria, centred on the product's primary mechanism of action, its intended purpose and how the intended therapeutic effect is achieved.

The legal and regulatory framework is primarily based on Law No 5,991/1973 and Law No 6,360/1976 and, with respect to medical devices, on ANVISA RDC No 751/2022 and related subsequent and supplementary resolutions.

For medicinal products, ANVISA adopts the statutory concept of a medicine as a pharmaceutical product, obtained or technically prepared, intended for prophylactic, curative, palliative or diagnostic purposes. In practice, products whose primary intended action is achieved through a pharmacological, immunological or metabolic effect tend to fall within the medicinal product framework. A health product classified as a medical device, in turn, is intended for use in human beings for specific medical purposes whose principal action is not achieved by pharmacological, immunological or metabolic means, even though such actions may be ancillary.

For medical devices, the assessment focuses on the concept of a device within the medical device regulatory framework and on the product's intended purpose. For example, ANVISA's own guidance on "materials for use in healthcare" describes them as non-active health products, meaning that their operation does not depend on an external energy source other than that generated by the human body or by

gravity. This is one element within the broader device framework and does not replace the full definition of "medical device" set out in the applicable device regulations.

In some circumstances, the main characteristics of health products, such as composition, mode of action, indications for use or presentation, do not clearly determine their classification. Such products fall into a grey area (often referred to as "borderline products") and require an in-depth technical assessment to ensure appropriate classification, resulting in the designation of a specific regulatory pathway in accordance with the applicable laws and regulations.

Companies responsible for these hybrid products, which do not clearly fall within a single regulatory category, must submit a classification request using ANVISA's Product Classification or Determination of Whether a Product Is Subject to Sanitary Regulation Form (*Formulário de Classificação de Produtos ou Determinação de Sujeição à Vigilância Sanitária*). The classification is then determined by the participation of the Committee for the Classification of Products Subject to Sanitary Surveillance (*Comitê de Classificação de Produtos Sujeitos à Vigilância Sanitária* – COMEP), which supports ANVISA's board of directors (*Diretoria Colegiada da ANVISA* – DICOL) in borderline determinations.

3.2 Marketing Authorisation for Biologic Medicinal Products

The primary ANVISA regulation governing biological product registration is RDC No 55/2010. To obtain authorisation, a company must submit comprehensive documentation to ANVISA demonstrating the product's safety, efficacy and quality prior to commercialisation. In practice, marketing authorisation for biological medicinal products in Brazil requires compliance with regulatory obligations that are more stringent than those that apply to non-biological (chemical/synthetic) medicines, due to the biological complexity and inherent risks associated with their production and use.

3.3 Period of Validity of Marketing Authorisations

Definition of Marketing Authorisation

Under Brazilian sanitary law, a marketing authorisation is the administrative act by which ANVISA permits commercialisation of a product in Brazil after verifying compliance with legal, technical and sanitary requirements. This authorisation is granted through sanitary registration or, where applicable, product notification, pursuant to Law No 6,360/1976, Law No 9,782/1999 and implementing ANVISA RDCs.

For non-low-risk medicinal products, registration certifies compliance with quality, safety and efficacy requirements and is an indispensable prerequisite for manufacture, importation, distribution and commercialisation.

For medical devices, authorisation takes two forms: Classes III and IV (higher risk) require registration, while Classes I and II require notification. Both confirm compliance with essential safety, performance, quality and user information requirements under ANVISA RDC No 751/2022.

Validity Periods

For medicines that are not classified as low risk, the registration is valid for a period of ten years, as established by Law No 6,360/1976 and ANVISA RDC No 912/2024. ANVISA RDC No 912/2024 also provides for variations depending on the nature of the approval. Specifically, for drugs approved with preliminary evidence under a commitment term (*termo de compromisso*), the marketing authorisation is initially valid for three years. Upon the first renewal, the validity extends to five years, and after the second renewal, it extends to ten years, consecutively. By contrast, for low-risk medicines subject to notification rather than registration (*medicamentos de baixo risco sujeitos à notificação*), the notification is valid for ten years from the date of activation, as established by ANVISA RDC No 576/2021, and holders must submit a declaration of interest in continuing commercialisation every ten years through ANVISA's electronic system

For medical devices subject to registration (Classes III and IV), the validity period is also ten years under ANVISA RDC No 751/2022. Notifications applicable

to Class I and II medical devices do not have a fixed validity period; they remain effective as long as the technical, regulatory and compliance conditions that supported the product's regularisation are maintained, subject to ongoing data update and post-market surveillance obligations under ANVISA RDC No 751/2022.

Renewal Mechanisms

For medicines, renewal may be requested by the registration holder following ANVISA-defined deadlines and procedures. ANVISA may require additional evidence or new studies supporting quality, safety and efficacy. The agency currently uses both ordinary and simplified renewal mechanisms based on sanitary risk and the holder's regulatory compliance history.

For Class III and IV medical devices, renewal for an equivalent ten-year period applies, provided the request is submitted prior to expiration. Notifications for Class I and II devices do not require periodic renewal but are subject to ongoing data updates and post-market surveillance obligations.

Grounds for Revocation, Cancellation, Suspension, Variation or Withdrawal

The grounds are as follows.

- Non-use (failure to market): Article 21, paragraph 3 of Law No 6,360/1976 authorises ANVISA to cancel a registration when the product is not placed on the market within one year following authorisation.
- Risk to public health: Under Article 7 of Law No 6,360/1976 and Article 7, item XV of Law No 9,782/1999, ANVISA may vary, suspend or withdraw authorisation on a preventive or corrective basis when a product is determined to be harmful, ineffective or unsafe, or presents quality deviations. This includes ordering product recalls.
- GMP non-compliance: The absence, loss or suspension of a GMP certificate, or critical deficiencies identified during sanitary inspections, undermines product quality assurance and authorises ANVISA to adopt restrictive measures, since manufacturing compliance is essential for maintaining registration or notification.
- Post-registration irregularities: Authorisation may be withdrawn for implementing unauthorised changes to the manufacturing process, manufacturing site, composition, therapeutic indications or labelling, as well as failure to comply with pharmacovigilance obligations (medicines) or technovigilance obligations (medical devices).
- Fraud or misrepresentation: Authorisation may be revoked for fraud, submission of false information or omission of relevant data in the regulatory process, as these circumstances undermine the sanitary authority's confidence in the safety, quality and efficacy conclusions supporting the original authorisation.

3.4 Procedure for Obtaining a Marketing Authorisation

In Brazil, the granting of marketing authorisation for medicines and medical devices takes place through formal administrative procedures before ANVISA, structured according to the sanitary risk of the product and its legal nature.

For medicines subject to registration, the procedure begins with the company's authorisation by ANVISA, which requires obtaining an authorisation to operate (*Autorização de Funcionamento de Empresa* – AFE) and, where applicable, a special authorisation (*Autorização Especial* – AE). Subsequently, the applicant submits, through the agency's electronic system, a registration application accompanied by a technical and administrative dossier containing comprehensive information on the medicine, including its composition, pharmaceutical form, manufacturing process, quality controls, stability studies, labelling and package leaflet, as well as data demonstrating safety and efficacy, according to the product category. It is also an essential requirement that the manufacturer holds a valid GMP certificate. ANVISA conducts a technical assessment of the application and, upon verification of compliance with the applicable legal and regulatory requirements, grants the sanitary registration, which constitutes the authorisation for commercialisation of the medicine in the national territory, pursuant to Article 12 of Law No 6,360/1976.

For medicines exempt from registration because they are considered low risk, marketing authorisation is obtained through a simplified procedure, generally in the form of product notification or listing. In this case, the company must also be duly authorised

to operate by ANVISA, but the prior submission of a complete safety and efficacy dossier is not required. The authorisation results from the correct classification of the product within the applicable regulatory category and compliance with the technical and legal requirements set forth in the relevant regulation, with the company remaining responsible for the product's conformity and subject to sanitary inspection.

For medical devices, the procedure for obtaining marketing authorisation varies according to risk classification. For Class III and IV devices, the applicant must submit a registration application accompanied by a technical dossier demonstrating compliance with the essential requirements of safety and performance, including information on design, manufacturing, risk management, clinical evidence where required, labelling and instructions for use. For Class I and II devices, authorisation is obtained through notification, a procedure in which the manufacturer or importer declares the product's conformity with the applicable regulations. These procedures are primarily governed by ANVISA RDC No 751/2022.

Once marketing authorisation has been granted, the legislation allows for its variation. In the case of registered medicines, significant changes, such as modifications to therapeutic indications, formulation, posology, target population, manufacturing process, packaging, labelling or package leaflet, are subject to the post-registration regime, requiring prior approval by or notification to ANVISA, depending on the impact of the change. For medicines exempt from registration, changes must be reflected through updates to the notification or listing whenever they affect the original conditions of classification. For medical devices, variations follow a similar logic and are regulated by ANVISA RDC No 751/2022, according to the risk class and the relevance of the modification.

Brazilian legislation also allows for the transfer of marketing authorisation between holders. For medicines subject to registration, the transfer of registration ownership requires prior approval by ANVISA, with evidence that the new holder fully assumes the corresponding regulatory responsibilities. For medicines exempt from registration and for notified or registered medical devices, the transfer requires the corresponding regulatory update before ANVISA, in accordance with the procedures set forth in the applicable regulations.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

General Framework

While the general rule in Brazil requires that medicines and medical devices obtain a valid marketing authorisation (registration, notification or listing) from ANVISA before being supplied, regulated exceptions allow patient access to unauthorised products in limited and carefully controlled situations when no satisfactory therapeutic alternative is available. These exceptions are established in specific ANVISA regulations.

Medicines: ANVISA RDC No 38/2013

The main regulatory basis for access to unregistered medicines is ANVISA RDC No 38/2013, which governs expanded access programmes, compassionate use and post-trial supply. Prior ANVISA authorisation may be obtained for programmes providing experimental or clinically developing medicines to patients with serious or life-threatening diseases, provided criteria such as disease severity, absence of satisfactory therapeutic alternatives in Brazil and a favourable risk-benefit assessment are met.

- Compassionate use is intended for individual patients suffering from a serious or life-threatening condition for which no registered therapeutic options are available, permitting use of a new, promising medicine not yet registered in Brazil. ANVISA's authorisation is personal and non-transferable, initiated through a request submitted by the sponsor or responsible technical party.
- Expanded access allows supply of medicine still under clinical investigation to larger groups of patients, particularly when there is evidence of potential benefit and no adequate registered therapeutic options exist in the country.
- Post-trial supply ensures continuity of treatment for clinical trial participants who benefited from the medicine after study completion or termination of their participation, in accordance with RDC criteria and monitoring requirements.

Medical Devices: ANVISA RDC No 608/2022

For medical devices without marketing authorisation, ANVISA provides a compassionate use mechanism regulated by ANVISA RDC No 608/2022. This resolution establishes criteria under which patients with serious or life-threatening conditions, for whom no satisfactory market alternatives are available, may access experimental or still-developing devices. The regulation requires a favourable risk-benefit assessment and provides for individualised evaluation of each request based on the patient's clinical condition and the device's development stage.

Key Limitations

These mechanisms do not constitute regular marketing authorisation and do not permit broad commercial distribution in Brazil. They operate as regulated exceptions allowing controlled and monitored access. The sponsor or responsible party must provide the product free of charge or under specific conditions and report safety data as required by ANVISA.

Judicialisation

Beyond the administrative pathways regulated by ANVISA, patients in Brazil frequently seek access to unauthorised medicines through the courts, a phenomenon known as the judicialisation of health (*judicialização da saúde*). This has become a significant challenge for public health administrators, requiring several billions of reais in annual expenditure across federal, state and municipal budgets.

The Supreme Federal Tribunal (*Supremo Tribunal Federal* – STF), in *RE 657.718 (Tema 500)*, decided in May 2019), established binding precedent on the judicial supply of unregistered medicines and upheld the constitutionality of Article 19-T of Law 8.080/1990, which prohibits SUS payment, reimbursement, or refund of experimental medicines or medicines not authorised by ANVISA. The court's thesis, with general repercussion, is in essence as follows.

- The state cannot be compelled to supply experimental medicines under any circumstances.
- The absence of ANVISA registration prevents, as a rule, the judicial supply of medicines.
- Exceptionally, judicial supply of an unregistered medicine may be granted when there is unreasonable delay by ANVISA in deciding a pending registration request, measured against the maximum decision periods established by Law No 13,411/2016, including only the single justified extension of up to one-third allowed by that law, and when three cumulative requirements are met: (i) existence of a registration application pending before ANVISA in Brazil, except for orphan medicines for rare and ultra-rare diseases; (ii) existence of registration in renowned regulatory agencies abroad, such as the US Food and Drug Administration (FDA) or the European Medicines Agency (EMA); and (iii) absence of a therapeutic substitute with registration in Brazil. Any court-ordered supply must also observe CMED price regulation to avoid supra-cap payments.
- Actions demanding the supply of medicines without ANVISA registration must necessarily be filed against the union in federal court.

The STF emphasised that excessive judicialisation has not achieved its intended systemic goals, because individualised injunctions divert scarce resources from collectively designed public policies.

It is also worth noting that two adjacent STF rulings help situate Tema 500 within the broader landscape. In 2021, Tema 1.161 addressed medicines that lack ANVISA registration but have ANVISA authorisation for individual importation, allowing, in exceptional cases, judicial supply upon cumulative proof of clinical indispensability, absence of a SUS-listed substitute and the patient's economic insufficiency. In 2024, the STF also addressed claims involving medicines registered at ANVISA but not incorporated into SUS, imposing stricter evidentiary and procedural requirements and clarifying jurisdictional rules. These later decisions do not alter Tema 500's general bar for unregistered medicines; rather, they delineate separate lanes for import-authorised unregistered products and for registered-but-not-incorporated products while maintaining deference to ANVISA's and CONITEC's roles, and to CMED price discipline.

3.6 Ongoing Obligations Imposed by Marketing Authorisations

ANVISA marketing authorisation creates ongoing obligations for both medicines and medical devices

throughout their product life cycle, aimed at maintaining quality, safety and performance standards.

Medicines: Pharmacovigilance

Authorisation holders must implement and maintain a pharmacovigilance system under ANVISA RDC No 406/2020 and linked instruments. This includes adverse event reporting, periodic safety reports and risk mitigation measures as needed.

Medical Devices: Technovigilance

Authorisation holders must maintain a technovigilance system governed by ANVISA RDC No 67/2009, covering detection, assessment, understanding and prevention of adverse incidents related to product use.

Additional Post-Marketing Obligations

Both product categories require:

- compliance with GMP;
- compliance with good distribution and storage practices (GDSP);
- adherence to post-registration requirements (medicines) or post-regularisation change requirements (medical devices); and
- continuous updating of regulatory information and labelling.

Conditional Requirements

ANVISA may impose additional obligations as conditions for granting or maintaining authorisation for:

- medicines – post-marketing studies such as Phase IV clinical trials, particularly when uncertainties exist regarding safety, efficacy or use in specific populations; and
- medical devices – post-market monitoring or clinical studies for high-risk devices under ANVISA RDC No 751/2022, and field actions.

These additional requirements stem from ANVISA's sanitary police powers.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations

In Brazil, third-party access to information on marketing authorisation procedures (registration or notification before ANVISA) is generally limited to public, high-level regulatory data. Technical dossiers and supporting documentation remain non-public. Disclosure to third parties is constrained by confidentiality and personal data protection rules, notably the Access to Information Law (Law No 12,527/2011) and the General Data Protection Law (Law No 13,709/2018), which protect personal data and industrial or commercial secrecy.

Pending Applications

For pending applications, ANVISA's public databases disclose primarily status and identification data, not the content of dossiers under review. Technical files, correspondence and evidence submitted are typically accessible only to the applicant and ANVISA.

Granted Authorisations

Once an authorisation is granted, third parties may verify key non-confidential information through ANVISA's public consultation systems, including product name, holder, type of regularisation and identifiers. For medical devices under the registration regime, registration is time-limited and subject to revalidation, supporting public traceability of status over time.

Refused Applications

Where an application is refused, third parties may become aware of the outcome through updated public records, but the reasons for refusal and the technical assessment are not disclosed in full.

Practical Implications

Third parties may generally confirm whether a product has been regularised and consult limited non-confidential identifiers but should not expect access to underlying technical dossiers or personal data, except where disclosure is legally justified and appropriately redacted.

4. Regulatory Reliance and Fast-Track Registration Routes

4.1 Fast-Track Registration Routes

The Brazilian regulatory framework provides expedited review mechanisms, particularly for medicines and biological products, through priority review and regulatory reliance–based procedures, as well as stream-

lined clearance routes for lower-risk medical devices, all administered by ANVISA.

For medicines, ANVISA operates a formal priority review regime under the current prioritisation framework established by RDC No 1,001/2025 (effective 15 January 2026), which replaced the former RDC No 204/2017 that was in force since 2008. This framework allows certain marketing authorisation applications, post-approval variations and related regulatory filings to be classified as priority and assessed ahead of the standard review queue, based on objective criteria such as public health relevance, strategic importance to the Brazilian health system or the need to mitigate risks of shortage. Priority status affects review order and timelines but does not waive technical, quality safety or efficacy requirements.

In parallel, Brazil has significantly advanced regulatory reliance as an expedited pathway for medicines and biological products. Under RDC No 741/2022, ANVISA may rely on assessments performed by recognised equivalent foreign regulatory authorities (*autoridades reguladoras estrangeiras equivalentes* – AREEs), enabling an optimised review that focuses ANVISA's analysis on local specificities while leveraging foreign regulatory work products. The practical implementation, scope and eligibility conditions of this reliance-based approach are detailed in Normative Instruction No 289/2024, which applies to both initial marketing authorisations and post-approval life cycle management. While reliance does not amount to automatic approval, it can materially reduce review complexity and timelines.

It is also worth noting that, at the end of 2024, ANVISA introduced a simplified procedure for the registration, post-registration changes and renewals of specific categories of medicines and biological products under RDC No 954/2024. This framework applies, in summary, to products such as generics, similar, specific medicines, herbal medicines, radiopharmaceuticals and biological products, where such products are linked to a "reference" or "matrix" application (eg, within the same economic group or in the context of product development partnerships or technology-transfer arrangements), and relies on a tailored documentation model anchored to the underlying matrix dossier.

In addition, RDC No 997/2025 introduced exceptional and temporary measures to reduce ANVISA's backlog and accelerate the review of procedures related to clinical research, marketing authorisations and post-approval changes for medicines and biological products. The rule provides tools such as the evaluation management plan (*plano de gestão anual* – PGA), allows the creation of dedicated queues and, in limited circumstances, permits adjustments to the chronological order of reviews to increase throughput. It also contemplates reliance and optimised technical assessment approaches, as well as practical mechanisms such as queue substitution upon formal withdrawal and early risk classification of potential deficiencies.

For medical devices, Brazil does not yet operate a standalone fast-track or priority programme equivalent to those available for medicines. However, the regulatory system is inherently risk-based, which produces a de facto expedited pathway for eligible products. Lower-risk devices (Classes I and II) are generally subject to a simplified notification procedure, with limited pre-market review, whereas higher-risk devices (Classes III and IV) require full registration and substantive technical assessment. As a result, time to market varies significantly by risk class, with simplified notification functioning as the primary acceleration mechanism in the device space.

4.2 Regulatory Reliance

Brazil has adopted regulatory reliance as part of ANVISA's decision-making model, in line with international good regulatory practices. Under this framework, ANVISA may give significant weight to assessments, inspection outcomes and regulatory decisions issued by AREEs or trusted institutions, while fully preserving its autonomy and responsibility for the final decision, pursuant to ANVISA RDC No 741/2022 and Law No 9,782/1999.

Reliance is implemented through an optimised review procedure, allowing the use of instructive documentation issued by an AREE as a unique or complementary reference, subject to admissibility and product com-

parability safeguards. Even where reliance applies, ANVISA may request additional information, conduct local checks or revert the application to the ordinary route, remaining solely responsible for the outcome, in line with ANVISA RDC No 741/2022 and Law No 14,313/2022.

Where prior authorisations from recognised foreign regulatory authorities exist, ANVISA may expedite review under an optimised procedure if eligibility criteria are met. For medicines, vaccines, biological products and active pharmaceutical ingredients (APIs), Normative Instruction 289/2024 establishes the requirements and designates a broad group of reference authorities, including the EMA, Swissmedic and the UK's Medicines and Healthcare products Regulatory Agency (MHRA). For higher-risk medical devices (Classes III and IV), Normative Instruction 290/2024 establishes an analogous regulatory reliance pathway, though with a narrower list of AREEs: Australia's Therapeutic Goods Administration (TGA), Health Canada, the FDA and Japan's Ministry of Health, Labour and Welfare (MHLW). Under both pathways, ANVISA preserves its discretion to apply ordinary review where appropriate and clarifies that reliance does not alter petition chronology.

Reliance also applies to GMP certification and inspections, allowing ANVISA to rely on inspections or audit reports from recognised partners under ANVISA RDC No 741/2022 and implementing instruments, such as Normative Instruction No 292/2024 (medicines and APIs) and Normative Instruction No 687/2022 (medical devices), including Medical Device Single Audit Program (MDSAP)-recognised auditing bodies and, in specific cases, Southern Common Market (*Mercado Comum do Sul* – Mercosur) authorities.

5. Manufacturing of Pharmaceuticals and Medical Devices

5.1 Requirement for Authorisation for Manufacturing Plants

Manufacturing plants for pharmaceuticals and medical devices require AFE before operations commence. ANVISA grants AFE upon a successful electronic petition that includes the identification of product classes and activities, responsible personnel credentials, corporate information, proof of payment of the sanitary surveillance fee, and an inspection report or current sanitary licence from the local municipal health surveillance service (*Vigilância Sanitária Municipal* – VISA) documenting technical compliance. For medicines and APIs, GMP is a practical prerequisite for product registration and commercialisation. ANVISA issues certificates of good manufacturing practice (cGMPs) per manufacturing unit based on inspections and risk-based review. For devices, cGMP is likewise issued per unit, with ANVISA able to rely on MDSAP audit outputs to issue cGMP more efficiently.

The AFE authorises the set of activities petitioned and published, which can include manufacturing and activities inherent to manufacturing, such as storing, distributing, packing, repacking, fractioning, expedition and importing for own use. Companies can later expand AFE to add importing, exporting or transporting if not covered inherently. If work involves controlled substances or medicines containing them, AE is additionally required, with the scope matching the controlled activities and substances handled.

AFE effectiveness begins on publication in the Federal Official Gazette. Renewal of AFE is no longer required following statutory change. It remains valid while the establishment upholds requirements and files alteration petitions for changes in activities, scope, address, responsible personnel or corporate data. cGMP for pharmaceuticals and devices is generally valid for two years from publication. For medical device manufacturers operating under MDSAP, ANVISA has extended cGMP validity to four years, contingent upon continuous programme participation and ongoing surveillance audits.

6. Distribution of Pharmaceuticals and Medical Devices

6.1 Wholesale of Pharmaceuticals and Medical Devices

Wholesale distributors and warehouses for pharmaceuticals and medical devices also require AFE. ANVISA grants the AFE upon electronic petition supported by corporate documents, responsible techni-

cal registration, fee payment and an inspection report or current sanitary licence from the local VISA demonstrating compliance with applicable distribution and storage good practices. For device wholesalers, because AFE is per establishment, each warehouse or distribution centre must obtain its own AFE. For pharmaceuticals, the matrix-level AFE covers branches, but each branch must still hold the local sanitary licence, maintain compliant operations and appear in ANVISA's records.

The AFE for wholesale covers distribution and storage as petitioned and published. Companies may add related activities such as transport, export, import or packing/repacking through alteration petitions when permissible for the class and scope. If wholesale involves handling controlled substances, the establishment must also hold an AE covering the controlled activities.

The AFE takes effect on publication and, like manufacturing AFEs, does not require renewal. It remains valid while the company maintains compliance and updates registered information.

A certificate of good distribution and storage practices (cGDSP) exists but is not a legal prerequisite for operation. Nonetheless, adherence to applicable distribution and storage good practices is required and may be assessed during inspections (including ANVISA RDC No 430/2020 for medicines and ANVISA RDC No 665/2022 for medical devices).

6.2 Different Classifications Applicable to Pharmaceuticals

Brazil's ANVISA classifies medicines primarily by dispensing category, identified through package colour stripes and label requirements.

The three main categories are as follows.

- Non-prescription (OTC/MIP): No stripe, and it may be dispensed without a prescription for non-severe conditions and self-care.
- Prescription-only (red stripe): Requires a valid prescription. This category further distinguishes between medicines dispensed without prescription retention and those requiring retention, where the pharmacy must keep the prescription for inspection. Medicines under special control (per *Portaria SVS/MS* No 344/1998) typically fall within the red stripe category with retention requirements.
- Stricter control (black stripe): Subject to reinforced controls and stricter prescribing rules. Prescriptions must be retained by the pharmacist, reflecting heightened safety concerns.

This dispensing-based classification differs from other ANVISA categorisations such as regulatory status or authorisation pathway (reference, generic, similar, new or biological medicines). Those categorisations concern how a product is authorised and its market positioning, including interchangeability rules, rather than whether a medicine requires a prescription.

7. Import and Export of Pharmaceuticals and Medical Devices

7.1 Governing Law and Relevant Enforcement Bodies

Brazil's import and export of medicines, pharmaceutical inputs and health products are governed by both sanitary and customs regulations. On the sanitary side, Law No 6,360/1976 and Law No 9,782/1999 apply, with the latter granting ANVISA regulatory authority over these operations. The primary secondary regulation is ANVISA RDC No 81/2008, which establishes general import/export procedures and is supplemented by product-specific rules, including ANVISA RDC No 753/2022 for medicines, specific ANVISA RDCs for APIs and ANVISA RDC No 751/2022 for medical devices.

On the customs side, Decree No 6,759/2009 (the "Customs Regulation") applies, along with several Normative Instructions from the Brazilian Federal Revenue Service (*Receita Federal do Brasil* – RFB) governing import clearance, export clearance and the Siscomex/*Portal Único*, through which ANVISA's sanitary clearance operates.

Three main authorities oversee these operations:

- ANVISA handles sanitary control at entry points and post-importation enforcement;

- the RFB manages customs and tax control, including post-clearance audits; and
- the Ministry of Development, Industry, Trade, and Services (*Ministério do Desenvolvimento, Indústria, Comércio Exterior e Serviços* – MDIC)/Foreign Trade Secretariat (*Secretaria de Comércio Exterior* – Secex) administers import licensing within the foreign trade framework.

Depending on the product, other consenting authorities such as the Ministry of Agriculture, Livestock, and Supply (*Ministério da Agricultura, Pecuária e Abastecimento* – MAPA), the Brazilian Institute of Environment and Renewable Natural Resources (*Instituto Brasileiro do Meio Ambiente e dos Recursos Naturais Renováveis* – IBAMA) and the National Institute of Metrology, Quality, and Technology (*Instituto Nacional de Metrologia, Qualidade e Tecnologia* – INMETRO) may also be involved.

7.2 Importer of Record of Pharmaceuticals and Medical Devices

The importation of pharmaceutical products and medical devices into Brazil is restricted to legal entities established in the country that possess a compatible corporate purpose, are registered with the National Registry of Legal Entities (*Cadastro Nacional da Pessoa Jurídica* – CNPJ), hold habilitation within the Integrated Foreign Trade System (*Sistema Integrado de Comércio Exterior* – SISCOMEX), and maintain cumulative compliance with applicable sanitary, regulatory and customs requirements.

Importing companies must obtain AFE from ANVISA in accordance with product-specific rules. For certain products, importation is further restricted to the marketing authorisation holder or entities acting on its behalf. Additional authorisations apply where medicines or inputs subject to special control are concerned.

Importers must also adhere to good practice requirements, maintain an appropriate technical infrastructure, including a legally qualified technical officer, and bear ongoing responsibility for product conformity and compliance with applicable traceability, storage and distribution standards.

In exceptional circumstances, such as clinical research, compassionate use, donation or experimental use, importation may be conducted by entities expressly authorised by ANVISA, subject to the conditions established in the relevant regulations.

7.3 Prior Authorisations for the Import of Pharmaceuticals and Medical Devices

Importation of pharmaceutical products and medical devices into Brazil requires prior authorisations, primarily sanitary controls administered by ANVISA, alongside standard customs requirements. Under Law No 9,782/1999 and ANVISA RDC No 81/2008, ANVISA clearance is mandatory and processed through Siscomex/*Portal Único*. Products must be regularised with ANVISA through registration, listing or notification per Law No 6,360/1976 and applicable ANVISA RDCs, with medicines under special control requiring additional specific authorisation. Simplified or differentiated procedures apply to certain categories, including clinical research, compassionate use, donations and non-commercial imports, each governed by relevant specific regulations.

7.4 Non-Tariff Regulations and Restrictions Imposed Upon Imports

Key Regulatory Framework

Brazil operationalises non-tariff import controls within the government's foreign trade single window, *Portal Único*, which is built on the Siscomex platform. The system exposes an administrative treatment for each Mercosur Common Nomenclature (*Nomenclatura Comum do Mercosul* – NCM) subheading and, where needed, refines the trigger through product "attributes", technical descriptors, declared end use or the type of import operation. The administrative treatment entry tells the importer whether a licence is required, whether it is automatic or non-automatic, which consenting authority will analyse it and the legal basis for the requirement. The overarching import licensing framework today is set by *Portaria Secex* No 249/2023, as amended, and *Portaria Secex* No 65/2020 on how agencies insert, alter or remove administrative treatments in Siscomex.

Under the current framework, import licensing is processed either through the legacy import licence module tied to the Import Declaration (*Declaração*

de Importação) or through the licences, permits, certificates and other documents (LPCO) module tied to the Single Import Declaration (*Declaração Única de Importação*), depending on the customs declaration used.

The governing regulation, *Portaria Secex* No 249/2023, sets default review timeframes of up to ten days for automatic licences and up to 60 days for non-automatic licences when a complete request is properly filed, and clarifies that a pre-shipment licence is required only where an agency's specific regulation so provides and the Siscomex entry reflects that stricter timing. In practice, therefore, the trigger is not only the Harmonized Tariff Schedule (HTS)/NCM code; it is the NCM code as further qualified by the agency-defined attributes and the declared operation, which together determine whether, for example, a product is a medicine, an API, a medical device, a telecom terminal, a pesticide, a seed, a live animal, a Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)-listed specimen, a controlled dual-use item or an apparently innocuous good that nonetheless falls into an exception because it is used, quota bound or originates in a country covered by UN measures.

Goods subject to non-tariff requirements

Brazilian law does not maintain a single static annex in a statute listing all goods subject to non-tariff requirements upon import. Instead, the authoritative, binding list is the administrative treatment database that Siscomex/*Portal Único* publishes and continuously updates. *Portaria Secex* No 249/2023 makes that explicit by directing that the list of goods and operations subject to import licensing be published at siscomex.gov.br with four mandatory data points for each entry:

- the NCM classification or a description of the operation subject to licensing;
- the responsible consenting authority;
- the legal basis; and
- whether the licence is automatic or non-automatic.

The general legal basis for automating this publication model and for using Siscomex as the vehicle is Decree No 660/1992, as amended to align Siscomex with Brazil's single-window initiative, and *Portaria Secex* No 65/2020, which governs how consenting agencies are habilitated and how they include, modify or remove administrative treatments in Siscomex. As part of a broader 2023–25 modernisation, Secex consolidated import licensing rules in *Portaria Secex* No 249/2023 and, in August 2024, expressly revoked *Portaria Secex* No 23/2011 in full. The effect of these measures, taken together, is that the product coverage and the competent authority for each category of controlled goods are determined by the Siscomex Administrative Treatment entry, and not by disparate static annexes scattered across older acts.

Licensing Triggers

Although the administrative treatment is the operative list for importers, it points back to sectoral statutes and regulations that define the product universe under each regulator's remit. For sanitary regulated goods, Law No 6,360/1976 defines the categories of products subject to health surveillance, and Law No 9,782/1999 vests ANVISA with the authority to regulate and supervise their importation. ANVISA's comprehensive procedural rule for imports, RDC No 81/2008, as updated, sets the technical import regime for health surveillance goods, ties its coverage to NCM-based listings published on ANVISA's website, and prescribes licensing, pre-shipment authorisation where applicable, documentation, and inspection requirements for medicines, APIs, health products and medical devices, cosmetics and personal care products, foods and food ingredients, and certain biologics and controlled substances.

Cross-Cutting Requirements

Some licensing requirements are driven not by intrinsic product identity but by the nature of the import operation. Brazil subjects used goods to non-automatic import licensing as a matter of policy, with defined exceptions and procedures administered by Secex under *Portaria Secex* No 249/2023. Imports conducted under certain special regimes may be licensed or exempted depending on the regime, as reflected in the administrative treatment. Operations under tariff or non-tariff quotas administered by Secex require non-automatic licensing for quota management; Secex maintains the quota criteria and allocation rules in specific *portarias* and cross references them in Sis-

comex. Goods originating in countries subject to UN Security Council measures, as internalised in Brazil, are captured through non-automatic licensing triggers in Siscomex and may be refused where the applicable resolution so requires. Finally, Secex may, on a risk-based, time-limited basis, subject an importer or defined classes of transactions to non-automatic licensing to combat fraud or to verify the authenticity and accuracy of commercial documents (*Portaria Secex* No 249/2023 codifies that authority and sets notice, scope and duration parameters).

7.5 Trade Blocs and Free Trade Agreements

Brazil is a founding member of Mercosur and a WTO member that has implemented the WTO Trade Facilitation Agreement. In 2022, its modern bilateral Protocol on Trade Rules and Transparency with the United States entered into force, covering customs and trade facilitation, good regulatory practices and anti-corruption, and providing for formal advance rulings, electronic documentation and risk-based controls. These frameworks are implemented through Brazil's foreign trade e-system (Siscomex/*Portal Único*), which integrates licences and customs declarations, enables pre-arrival processing, and supports joint inspections and release-time measurement. Brazil's Authorised Economic Operator (*Operador Econômico Autorizado* – OEA) programme is now complemented by a 2022 OEA mutual recognition arrangement with the United States, improving reciprocal border facilitation for trusted traders.

Mercosur's external agreements with the EU and the European Free Trade Association (EFTA) have been signed but remain pending ratification and are not in force, so their trade facilitation and regulatory co-operation provisions are not yet operative. Within the bloc, the common external tariff (CET) still applies to most imports, tempered by established exception mechanisms such as the list of exceptions to the CET and the *ex tarifário* regime for capital and information and communication technology (ICT) goods not produced domestically.

On the regulatory side, ANVISA participates in global harmonisation fora including the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the International Medical Device Regulators Forum (IMDRF), and it has aligned Brazil's medical device framework through ANVISA RDC No 751/2022 and ANVISA RDC No 830/2023. Brazil accepts MDSAP audit reports to support Brazilian GMP (BGMP) certification for higher-risk devices, and since March 2024 BGMP certificates tied to MDSAP have four-year validity, which reduces life cycle frictions.

Material caveats remain. There is no in-force mutual recognition agreement for pharmaceutical GMP with the United States or the EU. Brazil-specific steps are decisive, including appointing a Brazil-based registration holder, obtaining BGMP certification for Class III and IV devices, and meeting product specific conformity assessments such as INMETRO for electromedical safety and the National Telecommunications Agency (*Agência Nacional de Telecomunicações* – ANATEL) for wireless functionality. While exceptions exist, Mercosur's CET continues to define duty exposure on most imported inputs and finished goods.

8. Pharmaceutical and Medical Device Pricing and Reimbursement

8.1 Price Control for Pharmaceuticals and Medical Devices

Price regulation is substantially more structured for pharmaceuticals than for medical devices in Brazil. Medicines are subject to binding statutory ceilings administered by CMED under Law No 10,742/2003. The framework establishes an ex-factory ceiling prices for manufacturers and importers (*preço fábrica* – PF), a maximum retail ceiling price for pharmacies and drugstores (*preço máximo ao consumidor* – PMC) and a specific ceiling for sales to public entities (*preço máximo de venda ao governo* – PMVG), which applies a mandatory discount to PF for government- and court-ordered purchases. CMED has recently opened Public Consultation No 1/2026 to set criteria for pricing medicines supplied to public entities pursuant to court orders. Until that rule is finalised, PMVG and its mandatory discount logic remain the central reference for judicial and government-facing pricing. Commercial terms and discounts are negotiable, but prices may not exceed the applicable CMED ceilings.

Entry pricing for new products and new presentations is now governed by CMED Resolution No 3/2025, published on 24 December 2025, republished on 30 December 2025, and effective 29 April 2026, after a 120-day transition. This resolution replaces CMED Resolution No 2/2004 and modernises the methodology, categories and documentation for determining official price ceilings, including an expanded and more robust Pricing Information Document (*Documento Informativo de Preço* – DIP) process. Pharmaceutical companies must keep price lists and transactions within PF, PMC, and, where applicable PMVG, maintain required CMED filings and support for DIP submissions, and operationalise public sector sales in accordance with government pricing rules and documentation practices.

Medical devices and IVDs are not subject to a nationwide CMED-style price cap regime. Device pricing is primarily market-based and contract-driven, although public procurement, reimbursement, transparency initiatives and competition law influence market behaviour.

8.2 Price Levels of Pharmaceuticals or Medical Devices

The price level of a new medicine at launch is largely constrained by international prices due to CMED's external reference pricing regime. Under CMED Resolution No 3/2025, which enters into force on 29 April 2026, the PF for new products and new presentations is defined through a category-based assessment supported by a DIP. As a general rule, the PF proposed for Brazil may not exceed the lowest PF observed for the same product in a basket of 14 reference countries (ie, South Africa, Germany, Australia, Canada, Spain, the United States, France, Greece, Italy, Japan, Mexico, Norway, Portugal and the United Kingdom, plus the product's country of origin where applicable), with Brazil's applicable taxes added. For a definitive PF, the medicine must ordinarily be commercialised in at least four reference markets with publicly verifiable prices; if not, CMED will set a provisional PF and require annual updates until the criterion is met. The resolution codifies currency conversion using the Central Bank's average selling rate for the prior 60 business days and allows applicants to update the price sought before a first-instance decision where exchange rate movements are significant, which can be material for launch planning.

Category-specific rules continue to respect this international cap while creating structured exceptions where foreign prices are unavailable – or where incremental innovation, domestic development and manufacturing, or additional therapeutic advantages justify a reasoned departure. These mechanisms are subject to heightened procedural review and do not displace the centrality of external reference pricing in the framework.

By contrast, medical devices and IVDs are not subject to a nationwide CMED price cap regime. International prices may influence commercial negotiations, and ANVISA publishes economic monitoring statistics for transparency, but devices are priced through market and procurement dynamics rather than binding external reference rules.

8.3 Reimbursement From Public Funds

Brazil's SUS finances medicines and medical devices primarily by purchasing and providing them free at the point of care, not by reimbursing patients. Medicines gain the most predictable public funding once formally incorporated through national HTAs led by the Ministry of Health with CONITEC support. Routine supply is organised through the basic, strategic and specialised pharmaceutical assistance components and reflected in the National Medicines List (*Relação Nacional de Medicamentos Essenciais* – RENAME), with routine dispensing through public formularies and standard access lists and higher-cost outpatient therapies accessed under clinical protocols. The Popular Pharmacy Programme (*Farmácia Popular*) complements SUS dispensing by reimbursing accredited private pharmacies to deliver free or subsidised medicines for defined indications. Devices are funded in a procedure-centric, hospital-based model; that is, SUS pays providers for procedures using national coding and payment parameters (Management System for the SUS Table of Procedures, Medicines, and Orthoses, Prostheses, and Special Materials, or *Sistema de Gerenciamento da Tabela de Procedimentos, Medicamentos e OPM do SUS* – SIGTAP), and hospitals procure implants and special materials within those care packages.

Separately, judicialisation has emerged as an increasingly prevalent mechanism in Brazil whereby patients petition courts to compel access to medicines and

medical devices that are otherwise unavailable through conventional channels because:

- the technology has not yet been incorporated into the public formulary;
- the product is temporarily out of stock; or
- the patient does not meet the eligibility criteria.

Stricter requirements apply to the supply of unregistered medicines. Courts may grant such orders upon satisfaction of applicable criteria, thereby imposing exceptional funding obligations on public authorities, particularly with respect to high-cost therapies and rare-disease treatments.

8.4 Cost-Benefit Analyses

The HTA in Brazil is the formal, central pathway for SUS coverage and use conditions, and its appraisals appropriately integrate comparative clinical value with economic consequences, albeit with varying depth of explicit cost-effectiveness modelling in practice.

Pricing is governed by a distinct ceiling-setting regime for medicines that has been modernised through CMED Resolution No 3/2025 to clarify categories, expand external reference pricing, codify provisional prices and fix DIP timing, but that remains administrative rather than value-based. Realised public sector prices for medicines are shaped by procurement structures and fiscal constraints, not by HTA.

For devices and IVDs, there is no national price cap regime; thus, prices are procurement driven, with HTA evidence shaping adoption and specifications. ANVISA's RDC No 478/2021 also adds market transparency for selected device families through mandatory reporting and publication of aggregated, technically comparable price statistics that can be used as references but do not control price.

Judicialisation still persists as an exception channel that can compel funding outside formal incorporation or contrary to protocol criteria.

8.5 Regulation of Prescriptions and Dispensing by Pharmacies

Brazil regulates physician prescribing and pharmacy dispensing through a layered framework combining health surveillance rules enforced by ANVISA and local authorities, with professional oversight from the medical councils (theFederal Medical Council, or *Conselho Federal de Medicina* (CFM), and regional medical councils, or *Conselho Regional de Medicina* (CRMs) and pharmacy councils (the Federal Pharmacy Council, or *Conselho Federal de Farmácia* (CFF), and regional pharmacy councils (CRFs)).

Prescribing and dispensing requirements vary by medicine classification. OTC medicines may be sold without prescriptions but face labelling and advertising restrictions. Prescription-only medicines require clinical gatekeeping, and generic substitution is permitted unless the prescriber forbids it. Antimicrobials require two-copy prescriptions, short validity periods and electronic record-keeping. Special control substances like narcotics and psychotropics demand colour-coded notification forms, identity verification and periodic reporting.

Physicians must adhere to evidence-based prescribing standards and ethical restrictions on conflicts of interest. Pharmacies must comply with ANVISA rules and professional requirements governing dispensing practices.

A notable recent development is CFF Resolution No 5/2025, which attempted to expand pharmacist prescribing authority but was challenged by the CFM and suspended by a federal court, creating legal uncertainty.

Within the SUS, prescribing is shaped by formularies and clinical protocols and therapeutic guidelines (*protocolos clínicos e diretrizes terapêuticas* – PCDTs), while pharmaceutical assistance is organised into basic, strategic and specialised components aligned with disease priorities and budget considerations.

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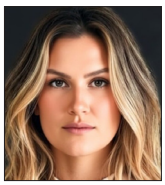
Trends and Developments

Contributed by:
Bruna Rocha, Jessica Filka, Juliana Marcondes and Victoria Cristofaro
COSRO

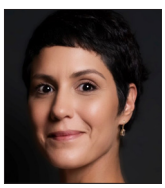
COSRO delivers sector-focused legal counsel built for speed and impact. The life sciences and healthcare team combines 15+ years of senior practitioner experience across Brazil and Latin America with deep regulatory fluency (ANVISA pathways, CMED pricing, and public and private market access), enabling clients to move products from lab bench to commercial launch with precision. Transactional to the core, COSRO structures complex cross-border acquisitions, builds regulated entities, designs investment platforms for emerging markets, and executes asset transfers and restructurings. Coverage spans CEP/CONEP submissions, GCP/GMP compliance, pharmacovigilance, technology transfer and LGPD-compliant digital engagement. COSRO integrates HEOR into CONITEC dossiers and payer negotiation and design distribution models, tendering strategies, and patient support programmes for SUS and private payers. The firm deploys generative AI governance frameworks for pharma and device clients, embedding privacy-by-design, GxP validation, model risk classification and human-in-the-loop oversight for compliant deployment in R&D, pharmacovigilance, field force enablement and patient engagement. Clients include global biopharma, medtech, digital health, CROs and agriscience companies.

Authors

Bruna Rocha advises clients across the healthcare and life sciences spectrum, including pharmaceutical, biotech, medtech, digital health, CROs, hospitals and agribiotech, structuring transactions and regulatory frameworks that drive growth while managing risk. Her practice centres on corporate transactions, joint ventures, strategic alliances, licensing arrangements, R&D partnerships and spin-offs, with particular strength in regulated entity formation, compliance architecture and complex restructurings. Her experience spans emerging sectors including AI in healthcare, SaMD, connected devices, wearables, biofabrication and digital care models, advising on regulatory strategy, data protection and pathways to registration and reimbursement. She guides clients through development, regulatory approval and market access.



Jessica Filka is a corporate lawyer and advises Brazilian and international companies across the life sciences and healthcare sectors. Her extensive experience in complex transactions, particularly in large-cap and mid-market deals, has positioned her as a trusted adviser in the field for the past decade. Jessica holds postgraduate degrees in Corporate Law, Contract Design and Taxation in Corporate Transactions from Fundação Getulio Vargas (FGV/SP). Her practice encompasses deal structuring, negotiations of key contracts and thorough analysis of legal risks.



Juliana Marcondes represents medical technology manufacturers, biotechs, diagnostics companies and distributors of medical products. Her practice centres on pre-litigation counselling and dispute avoidance. She partners with cross-disciplinary teams to deliver specialised, industry-specific advice across the life sciences and healthcare sector.

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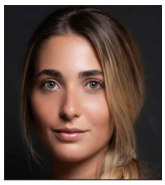

Victoria Cristofaro represents pharmaceutical companies, clinical research organisations, biotechs and digital health providers. She advises on transactional and regulatory matters. Her work spans regulatory compliance and commercial contracts. She counsels on clinical trial regulation and quality system regulation. She leads public policy strategy and advocacy before national, supranational and sub-national governments and administrative bodies. She is an associate-to-watch and a member of the Special Commission on Bioethics and Bio-Law of OAB-SP.

COSRO

Avenida Brigadeiro Faria Lima, No 201
11th Floor, Suite 112
Pinheiros, São Paulo – SP
Brazil

Tel: +55 11 3038 7111
+55 21 3031 2876
Email: bruna.rocha@cosro.com
Web: www.cosro.com

Contributed by: Bruna Rocha, Jessica Filka, Juliana Marcondes and Victoria Cristofaro, **COSRO**

2026 as a Year of Convergence

In February 2026, Brazil's life sciences and healthcare sector entered a year defined less by sweeping regulatory overhauls and more by the convergence of multiple policy and market vectors operating on different timelines. The National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária* – ANVISA) and the National Supplementary Health Agency (*Agência Nacional de Saúde Suplementar* – ANS) are executing forward-looking regulatory agendas, the Pharmaceutical Market Regulation Chamber (*Câmara de Regulação do Mercado de Medicamento* s – CMED) has adopted a new pricing framework with near-term effect, a concentrated patent cliff is reshaping competitive windows, and industrial policy instruments tied to the Unified Health System (*Sistema Único de Saúde* – SUS) are deepening their role in how scale is financed and delivered. The implication for companies is practical and immediate: decisions about regulatory sequencing, pricing and access, supply chains and financing are no longer siloed, and misalignment in any one dimension can erode value quickly across the others.

Convergence as the organising theme for 2026

The central dynamic for 2026 is convergence rather than transformation. Brazil is not embarking on a wholesale rewrite of its life sciences regulatory architecture. Instead, regulators are consolidating reforms and selectively recalibrating sensitive regimes in ways that raise execution thresholds. From a business standpoint, this signals continuity with greater discipline rather than regulatory looseness. At the same time, global pressures, including pricing erosion, loss of exclusivity, geopolitical uncertainty and supply-chain realignment, intersect with domestic policy priorities focused on access, industrial capacity, and public financing. That intersection materially changes how strategy must be made and sequenced.

Regulatory submissions can no longer be treated as isolated milestones. Market access planning must be integrated early with pricing rules, exposure to court-ordered access pathways known in Brazil as judicialisation and public procurement dynamics. Manufacturing and sourcing choices increasingly need to internalise trade facilitation measures, customs modernisation, and cross-border compliance requirements. Financing and investment decisions are now closely tethered to governance, transparency and delivery capacity, particularly where SUS-linked funding or industrial policy instruments are involved. Early market signals in 2026 suggest that companies treating Brazil and Latin America as an integrated portfolio, rather than a sequence of standalone launches, will better manage volatility and capture opportunity, whether defending value through loss of exclusivity or scaling in generics and biosimilars.

Global context and local adaptation

A persistent confidence gap characterises the global context. Many biopharma and medtech executives report optimism about their own organisations' outlooks for 2026 while expressing lower confidence in the broader economy. That divergence reflects the need to reconcile internal momentum, including pipelines and investment in digital health and AI, with external uncertainty driven by trade realignment and sustained pricing pressure. In Brazil, this environment amplifies the premium on local adaptability. Companies must tailor global approaches to Brazilian regulatory, pricing and access realities, moving beyond assumptions of linear replication across markets. Variation across Latin America in policy execution and reimbursement dynamics further increases the value of diversified exposure, agile operating models and robust local partnerships as drivers of durable growth.

Trade signalling, China and EU–Mercosur

International trade signalling will remain salient in 2026. Brazil's federal executive continues to identify market opening and strategic partnerships as priorities, including references to China as a key counterpart and renewed movement on the EU-Mercosur agreement alongside engagement with the European Free Trade Association. For life sciences, the commercial relevance lies not in diplomacy headlines but in the operational spillovers. Sourcing models, customs treatment and tariff profiles can tilt cost structures, timelines, inventory strategies and working capital, especially for companies dependent on imported active pharmaceutical ingredients, intermediates and specialised equipment. China's deepening role as a hub for R&D, clinical development and manufacturing has practical implications for development timelines, competitive entry and cross-jurisdictional co-

ordination in Brazilian portfolios. In medical devices and adjacent supply chains, maturing Asia-facing strategies tighten competitive dynamics. In this context, regulatory capability is a differentiator not only for market entry but also for managing inbound competition and heightened scrutiny.

The patent cliff as an inflection point

A concentrated wave of patent expirations spanning diabetes, obesity, oncology and immunology in 2026 is set to reshape competition. For generics and biosimilars, substitution is a race defined by execution, not regulatory approval alone. Winners synchronise regulatory timing, manufacturing scale-up, distribution capacity and payer or distributor contracting well in advance of loss of exclusivity. In Brazil, where price erosion and volume reallocation can occur quickly, disciplined alignment across these dimensions can be decisive. For originators, the window to defend value is narrowing. Margin pressure and accelerated competition underscore the need to advance innovation pipelines, recalibrate pricing and access strategies, and deploy more sophisticated value defence measures, including real-world evidence generation, targeted post-launch studies and differentiated access planning designed to sustain relevance beyond exclusivity. Practically speaking, loss-of-exclusivity planning in Brazil now demands earlier, cross-functional engagement, not reactive post-approval adjustments.

Regulatory agendas as market infrastructure

Regulatory agendas function in 2026 as market infrastructure. ANVISA's 2026–27 regulatory agenda, comprising a large set of priority topics and already operational, builds on reliance initiatives and process-efficiency measures introduced in 2025. These include greater use of regulatory reliance, grouping of applications sharing technical or clinical reports, and targeted actions to reduce review timelines. At the same time, ANVISA is selectively recalibrating substantive frameworks across medicines, medical devices, food, cosmetics and adjacent sectors, with direct commercial and compliance implications. Key themes include continued development of regulatory sandboxes for innovative health technologies and emerging business models to reduce early-stage legal uncertainty while accelerating access. Long-standing frameworks are under review, including those applicable to medical devices, software as a medical device (SaMD), transfer of product ownership and third-party import operations. These revisions affect compliance design, portfolio management, M&A execution and complex group structures.

The agenda also continues the gradual extension of post-market logic and risk-based oversight into hybrid sectors such as foods for special medical purposes, plant-based products, nutrivigilance and materials in contact with food. Topics that are both politically and technically sensitive, among them medicinal cannabis, aesthetic products with dermal action, accessibility requirements for labelling and consumer information, and codified criteria for administrative settlement agreements, signal a broad emphasis on governance, transparency and legal certainty in enforcement.

In parallel, the ANS has launched a public call for contributions to inform its 2026–28 regulatory agenda. The process is structured around macro-themes that include supervision and enforcement, transparency, economic regulation, access guarantees, beneficiary relations, integration with SUS, information governance and emerging challenges such as judicialisation, discount cards and rare diseases. For companies operating across public and private segments, these parallel agendas elevate the need for co-ordinated regulatory, pricing and access strategies.

Pricing, access and judicialisation

Pricing and access frameworks will remain commercially sensitive in 2026. CMED Resolution No 3/2025, effective 29 April 2026, replaces the long-standing drug pricing regime with a more granular, process-driven model. The new framework introduces differentiated pricing categories, an expanded international reference basket, stronger treatment of incremental innovation, and a tighter coupling between sanitary authorisation and pricing through mandatory and time-bound submission of the Price Information Dossier (*Dossiê de Informações de Preço* – DIP). Transitional rules that address pending, omitted or provisional cases, combined with reinforced regulatory powers, increase both predictability and enforcement risk. Pricing strategy in Brazil now requires earlier alignment with regulatory timelines, disciplined inter-

nal governance and proactive portfolio mapping to preserve optionality.

In parallel, active discussion of pricing criteria for medicines supplied pursuant to court orders underscores the growing regulatory focus on judicialisation as a de facto access pathway. Judicialisation remains a defining feature of the Brazilian market, with direct implications for maximum government sales price parameters, public procurement benchmarks and allocation of supplier risk. Companies operating in litigation-intensive therapeutic areas should integrate legal risk assessment into pricing, contracting and supply strategies rather than treating it as a downstream exception.

Clinical research and legal certainty

In clinical research, Law No 14,874/2024 and its implementing decree consolidate the legal framework and increase certainty while leaving open important operational questions. Post-study supply obligations, ethics committee governance and risk classification continue to shape sponsor decisions about trial budgeting, site selection and long-term exposure. A more predictable legal foundation is welcome, but companies should expect continued evolution in operational detail and should plan governance and contracting around the remaining uncertainties.

Industrial policy instruments and delivery discipline

Industrial policy instruments remain central in 2026. Productive Development Partnerships (*Parcerias para o Desenvolvimento Produtivo* – PDPs), under the umbrella of the Healthcare Economic-Industrial Complex (*Complexo Econômico-Industrial da Saúde* – CEIS) strategy, continue to link innovation, local production and SUS procurement. Participation now demands not only technological readiness but also robust governance, delivery capacity and compliance infrastructure. For private-sector participants, PDPs offer scale and demand visibility but also impose heightened expectations for execution and accountability. Companies should treat governance, audit-ready reporting and credible delivery capacity as prerequisites to access these instruments rather than as afterthoughts.

Capital catalysis and public funding windows

Public funding and industrial policy tools have taken on a catalytic role. Beyond direct funding, they structure demand, reduce execution risk and create bankability conditions for private investment. On the industrial policy side, the Ministry of Health has advanced the PDP pipeline by authorising the execution of commitment terms for projects selected in the 2024 cycle. Publication of excerpts in the Official Gazette triggers the next implementation phase, reinforcing SUS-linked procurement as a demand anchor capable of unlocking investment decisions and local capacity build-out.

In parallel, Brazil has refined the operational framework for mobilising private capital into priority SUS projects through tax-advantaged debentures. Ministry of Health rules establish eligibility, monitoring and oversight criteria for qualifying health infrastructure investments as “priority projects” for the purposes of issuing incentivised debentures under federal statutes and implementing decrees. These instruments embed governance, transparency and accountability requirements into access to funding. For market participants, the practical implication is clear: bankability and adoptability constraints now shape design from the outset.

Artificial intelligence and the internet of medical things

Brazil’s regulatory and legislative landscape is also converging around a more unified framework for AI and connected health, signalling a decisive shift from pilot programmes to production-scale deployment. The pending AI Bill (No 2,338/2023), which the Senate approved in December 2024 – and which is now under review in the Chamber of Deputies – would establish a comprehensive, risk-based governance structure for AI applications, including those in healthcare, modelled in part on the EU AI Act. Under the proposal, the National Data Protection Authority (*Autoridade Nacional de Proteção de Dados* ANPD) would co-ordinate a new national system for AI regulation and governance, working alongside sector-specific agencies such as ANVISA, which already oversees software as a medical device and AI-enabled diagnostics under its own evolving standards. Complementing this legislative momentum, broader health data modernisation

initiatives, including the recently launched National Health Data Network (*Rede Nacional de Dados em Saúde* – RNDS), are laying the groundwork for interoperability and secure data exchange across SUS. The Brazilian Artificial Intelligence Plan 2024–28, backed by roughly BRL23 billion in investment commitments, further underscores the government's intent to position AI at the centre of healthcare transformation.

This regulatory convergence, however, comes with rising compliance expectations. Regulators are recalibrating device and software rules, requiring sponsors to demonstrate robust data lineage, monitor real-world performance, and embed cybersecurity protocols and update pathways as core safety features rather than afterthoughts.

Even as regulatory clarity improves, reimbursement continues to lag behind the technology itself. Digital diagnostics, therapeutics and remote monitoring still navigate fragmented payment pathways, making early payer alignment on units of value and supporting evidence a critical priority for market access. That fragmentation extends to clinical trials as well, where the steady stream of continuous sensor data and algorithmic assessments demands tighter governance over data quality, adverse event detection and mid-study model changes.

Beyond these regulatory and reimbursement dynamics, industrial policy is reshaping competitive positioning in ways that favour locally integrated capabilities. SUS procurement increasingly rewards end-to-end local presence spanning devices, cloud infrastructure and support services, effectively turning service infrastructure into a strategic lever. Public financing, meanwhile, is beginning to treat digital rails, such as remote monitoring, hospital-at-home connectivity and secure data exchange, as essential health infrastructure in their own right, creating new opportunities for companies that can deliver integrated solutions at scale.

2026 in practical terms

Taken together, the evidence suggests 2026 is likely to be defined more by execution quality than by regulatory surprise. Trade liberalisation signals, an accelerated patent cliff, active industrial policy and dense regulatory agendas are unfolding simultaneously under different logics and speeds. This convergence heightens sequencing risk: misalignment in regulatory, operational, commercial or financial dimensions can produce disproportionate downstream effects. Competitive advantage is therefore unlikely to come from correctly predicting a single outcome. It will accrue to organisations that remain institutionally prepared, operationally integrated and strategically agile, being capable of adjusting priorities and execution as signals crystallise over the course of the year. For companies seeking to do business in Brazil, the year ahead offers significant opportunity, but it will reward those who approach the market not as a collection of isolated filings or transactions, but as an interconnected system that demands co-ordination, timing and discipline.

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