

DEMAREST

**LIFE SCIENCES
REGULATORY
TRENDS IN BRAZIL
2026**

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Medicine pricing

Developments in 2025

- CMED Resolution No. 3/2025 was published, setting out criteria for pricing new products and new presentations of medicines.

Expectations for 2026

- CMED Resolution No. 3/2025 will enter into force in April 2026, effectively applying to new cases occurring from that point onward, in addition to the following scenarios:
 - » Dossier analysis proceedings pending a first instance ruling with the CMED Executive Secretariat;
 - » Products classified as omitted cases pending a first instance ruling by the Technical-Executive Committee; and
 - » Products whose provisional prices established under CMED Resolution No. 2/2004 have not yet become final.



Cannabis products



Developments in 2025

- The Superior Court of Justice (“STJ”) extended, until March 2026, the deadline for the Federal Government and the Brazilian Health Regulatory Agency (“ANVISA”) to regulate the cultivation of industrial hemp for medicinal and pharmaceutical purposes.



Progress achieved in 2026

- A new set of resolutions was published, exhaustively regulating the production of cannabis for exclusively medicinal and pharmaceutical purposes in Brazil.



Expectations for 2026

- Publication, by ANVISA, of the public call for contributions to the regulatory sandbox established by ANVISA RDC No. 1,014/2026. In summary, the sandbox enables the assessment of health risks in a controlled and supervised environment; testing technical, production, and operational arrangements on a small scale and outside the industrial model; generating data and evidence on quality and safety; and supporting ANVISA's future regulatory decisions.



Sale of medicines in supermarkets



Developments in 2025

- The Federal Senate approved Bill No. 2,158/2023, amending the law on the sale of drugs, medicines, pharmaceutical inputs, and related products (Law No. 5,991/1973) and authorizing the sale of medicines in supermarkets



Progress achieved in 2026

- Brazil's House of Representatives approved Bill No. 2,158/2023.
- The President of the Republic sanctioned Bill No. 2,158/2023, without vetoes.
- Law No. 15,357/2026 was published, amending Law No. 5,991/1973. Among other provisions, the law addresses the sanitary control of the trade of drugs, medicines, pharmaceutical inputs, and related products. Additionally, the law regulates the commercialization of medicines in pharmacies or drugstores located within supermarkets' sales areas.



Expectations for 2026

- Regulation of the matter by ANVISA.



Advertising of medicines



Developments in 2025

- The Brazilian Association of Radio and TV Broadcasters filed ADI 7788, concerning the advertising of medicines and ultra-processed foods (RDCs No. 24/2010 and No. 96/2008).



Expectations for 2026

- Judgment of ADI 7788 by the STF, which may result in changes to ANVISA's regulation on the matter.



Health Economic-Industrial Complex (“CEIS”), Productive Development Partnerships (“PDPs”), and Local Development and Innovation Program (“PDIL”)



Developments in 2025

- The results of proposals submitted in 2024 were released.
- Informative Note No. 17/2025 was published, establishing methodological criteria for pricing technology transfers by public institutions and private partners within the scope of PDPs.
- Court of Accounts Case No. 034.653/2018-0 was closed. It concerned the monitoring of PDPs executed within the scope of the Ministry of Health.



Expectations for 2026

- Monitoring of a period for submitting proposals.
- Publication of complementary documentation by the Ministry of Health detailing the calculation to price technology transfers based on the methodological criteria presented in Informative Note No. 17/2025.

Agora Tem Especialistas Program



Developments in 2025

- The “Agora Tem Especialistas” Program (“Now We Have Specialists,” in English) was launched to expand public access to specialized consultations, exams, and surgeries through partnerships with for-profit and non-profit private hospitals.
- Notice No. 2/2025 was published by the Ministry of Health and the ANS, announcing a public call for contributions to the voluntary adherence of private healthcare plan operators to the program.



Progress achieved in 2026

- The Ministry of Health published Notice No. 1/2026, seeking to identify partners and innovative technological solutions to advance digital transformation, including within the scope of the program.



Expectations for 2026

- Progress of the public call arising from Notice No. 1/2026, with results scheduled for April 8, 2026.



Access to medicines through the courts



Developments in 2025

- Direct action for the declaration of unconstitutionality (“ADI”) was ruled on. It addressed the coverage by healthcare plan operators of treatments not listed in the National Supplementary Health Agency (ANS) list of mandatory procedures.
- The theses established under Topics 1234 and 6 saw effective application.
- Ordinance GM/MS No. 8,477/2025 was published, implementing the Oncology Pharmaceutical Assistance component within SUS (“AF ONCO”) and restructuring the Brazilian model of pharmaceutical care in oncology.



Progress achieved in 2026

- Brazil’s Federal Supreme Court (“STF”) ratified the agreement establishing new reimbursement guidelines and jurisdiction for lawsuits involving access to cancer therapies in SUS.
- The STF updated a precedent under Topic 1234, particularly regarding jurisdiction to rule on lawsuits involving oncology medicines already incorporated into SUS.
- The beta version of the National Platform on Medicine Demands in SUS was delivered to the National Council of Justice (“CNJ”).
- Brazil’s Medicines Market Regulation Chamber (“CMED”) opened Public Consultation No. 1/2026, proposing a resolution on criteria for setting and increasing medicine prices in sales made to the government to meet court-ordered medicine supply.



Expectations for 2026

- Effective application of the thesis established in ADI 7265, setting specific criteria for healthcare plan coverage of treatments or procedures outside the mandatory list of the ANS.
- Submission of contributions and publication of a norm arising from CMED Public Consultation No. 1/2026.
- Publication by the CNJ of operating instructions and consolidation of the platform’s internal routines, to enable full nationwide implementation of the tool.



AI regulation



Developments in 2025

- The working group established to discuss AI incorporation into medicine concluded discussions.



Progress achieved in 2026

- Brazil's Federal Council of Medicine ("CFM") published Resolution No. 2,454/26, which regulates the use of AI in medicine.



Expectations for 2026

- CFM Resolution No. 2,454/26 will enter into force 180 days from its publication.
- Progress of Bill No. 2,338/2023, which seeks to establish a general legal framework for AI.
- Legislative advances in this field may significantly impact sector-specific regulations already in force, including in health, emphasizing the importance of a dynamic and forward-looking compliance approach.

Clinical Research



Developments in 2025

- Decree No. 12,651/2025 was published, regulating the Clinical Research Law.
- A Temporary Working Group (“GTT”) was established to support the implementation process of the National System for Ethics in Research with Human Subjects and the National Ethics in Research Authority (“INAEP”).
- INAEP’s members were appointed.
- The Brazilian Society of Bioethics filed ADI 7875 before the STF, seeking a declaration of unconstitutionality of certain provisions of Law No. 14.874/2024.



Progress achieved in 2026

- The Technical Monitoring Committee of the National Platform for Research Involving Human Subjects was instituted within the Ministry of Health’s Secretariat of Science, Technology, and Innovation in Health (SCTIE Ordinance No. 8/2026).
- The Brazilian Society of Bioethics and the National Confederation of Health Workers (“CNTS”) filed for an injunction before the STF to suspend the effects of the regulatory framework and INAEP’s decisions.



Expectations for 2026

- Progress of Bill No. 4172/2024, a proposed amendment to Law No. 14,874/2024 that would dismiss the prohibition against remunerating participants in human and social sciences research that involves minimal risk and no medical interventions.
- Progress of ADI 7875, previously mentioned in the 2025 developments.
- Formal dissolution of the National Research Ethics Commission (“CONEP”).
- Regulation of Law No. 14,874/2024 and its regulatory decree by INAEP.

Discount cards



Developments in 2025

- The STJ ruled that Law No. 9,656/1998 requires the ANS to regulate and oversee any product, service, or contract that, in addition to offering a guarantee of financial coverage related to medical, hospital, or dental care, has features that set it apart from an exclusively financial activity, as is the case with discount cards in health services (Motion for Clarification in Interlocutory Appeal in Special Appeal No. 2183704).



Expectations for 2026

- Following the STJ's decision on the matter, there is a growing expectation that the ANS will issue a specific regulation on discount cards and establish regulatory parameters and registration, transparency, and oversight requirements.





Fertilizers



Developments in 2025

- Decree No. 12,502/2025 was published, regulating Law No. 14,515/2022, to establish:
 - » rules and procedures applicable to the administrative procedure of agricultural inspection;
 - » the Special Appeals Committee for Agricultural Defense; and
 - » criteria for entering into settlement agreements.



Progress achieved in 2026

- The legislation on inspection and oversight of the production and trade of fertilizers, correctives, inoculants or biofertilizers, remineralizers, and substrates for plants intended for agriculture was updated (Decree No. 12,858/2026 amends the Annex to Decree No. 4,954/2004, which regulates Law No. 6,894/1980).



Expectations for 2026

- Additional regulation of the subject mentioned above at the sub-regulatory level.

RELATED PARTNERS



ELYSANGELA RABELO
erabelo@demarest.com.br



NICOLE RECCHI AUN
naun@demarest.com.br

RELATED LAWYERS

Giovanna Malfatti
gmalfatti@demarest.com.br

Giulio Gatti
ggatti@demarest.com.br

SÃO PAULO
RIO DE JANEIRO
BRASÍLIA
BELO HORIZONTE



demarest.com.br

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