Life Sciences & Healthcare

Bulletin

02 / 2025

Lefosse

Índice

01

Highlights of the Health Sector

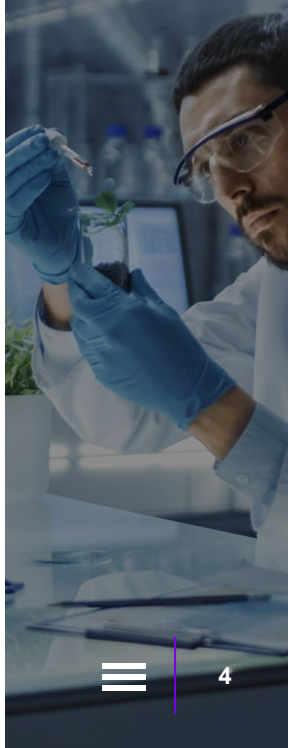
ANS
Presidency

1. Federal Employee Designated as Acting President of ANS

On February 3, 2025, the Brazilian Supplementary Health Agency ("ANS") published Personnel Ordinance No. 10/2025, which appointed Ms. Carla de Figueiredo Soares to temporarily serve as the Acting President-Director and Director of Management of ANS, due to the conclusion of Mr. Paulo Roberto Rebello Filho's term.

The decision was made during the 1st ANS' Board of Directors ("BoD") Meeting of 2025 and took into account the employee's tenure in roles equivalent to General Manager, in accordance with Law No. 13,848/2019.

The appointment remains valid until the Federal Executive Branch defines the agency's new presidency. The ordinance came into effect on its publication date, with retroactive effects as of February 1, 2025.



Fonajus

2. Fonajus Presents 2024 Report and Defines Actions for 2025

On February 4, 2025, the Brazilian Judiciary Forum for Health ("Fonajus") held its first meeting of the year and presented the report on 2024 activities, highlighting a 40% increase in technical note requests through the e-NatJus System compared to the previous year. The system, which supports judicial decisions in health with a technical basis, now comprises over 272,000 registered notes available for consultation. Among the most frequent topics are requests related to childhood Autism Spectrum Disorder ("ASD"), with nearly 10,000 technical notes issued by January 2025.

During the meeting, actions planned for 2025 were also discussed, including the modernization of e-NatJus forms and the expansion of the system to cover supplementary health proceedings, with a pilot project underway at the Bahia State Court of Justice ("TJBA"), in partnership with the Albert Einstein Israelite Hospital and ANS. This initiative aims to integrate technical notes for health plans into the system and use the Preliminary Mediation Notification ("NIP") as a conflict resolution tool.

Additionally, Fonajus announced the resumption of the Fonajus Itinerant calendar, with visits to the Santa Catarina State Courts of Justice ("TJSC"), as well as Amapá ("TJAP"), Minas Gerais ("TJMG"), and the Federal Regional Court of the 6th Region ("TRF-6"). The goal is to identify best practices and improve the judiciary's joint efforts in health-related matters. A research project is also underway in collaboration with the United Nations Development Program ("UNDP") on the judicialization of supplementary health, given the more than 298,000 new cases recorded in 2024.

In celebration of Fonajus's 15th anniversary, April will feature Health Week (from April 7 to 11) and the VII Health Law Conference (on April 24 and 25) in Brasília, during which 117 statements will be reviewed, and new proposals voted on.

Among the year's priorities are the revision of normative acts by the Brazilian Justice Council ("CNJ") based on recent Supreme Federal Court ("STF") decisions, updating Unified Procedural Tables, and improving workflows for enforcing judicial decisions in health.

Beneficiaries growth

3. The Supplementary Health Sector closes 2024 with Record Growth in the Number of Beneficiaries

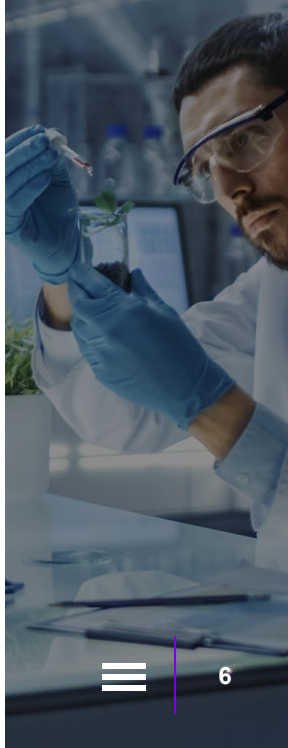
The supplementary health sector experienced significant growth in 2024, setting record numbers of beneficiaries in both medical and dental segments. According to information released by ANS on February 5, 2025, by December, medical plans reached 52,210,290 beneficiaries, while exclusively dental plans reached 34,466,532 beneficiaries.

Also, according to the Agency, over the 12-month period, medical-hospital plans saw an increase of 862,771 beneficiaries compared to December 2023, and dental plans saw an increase of 2,065,209 beneficiaries compared to December 2023. Comparing December to November 2024, medical-hospital and dental plans grew by 156,217 and 178,642 beneficiaries, respectively.

Growth was observed in most states. In the medical-hospital segment, 24 federative units saw increases, with highlights being São Paulo, Minas Gerais, and Amazonas. For dental plans, all 25 federative units experienced growth, with São Paulo, Minas Gerais, and Paraná showing the most substantial increases.

By age group, the largest expansion in medical assistance plans occurred among people aged 45 to 49 (240,336 new beneficiaries over the last 12 months) and 50 to 54 (125,734 new beneficiaries over the last 12 months). In dental plans, the groups that grew the most were those aged 45 to 49 (248,771 new users over the last 12 months) and 70 to 74 (193,557 new beneficiaries over the last 12 months). The number of elderly beneficiaries also increased, representing 15.4% of beneficiaries in medical plans (7.9 million beneficiaries) and 11.4% in dental plans (3.9 million beneficiaries).

Detailed data can be accessed in the Situation Room, available on the ANS website.



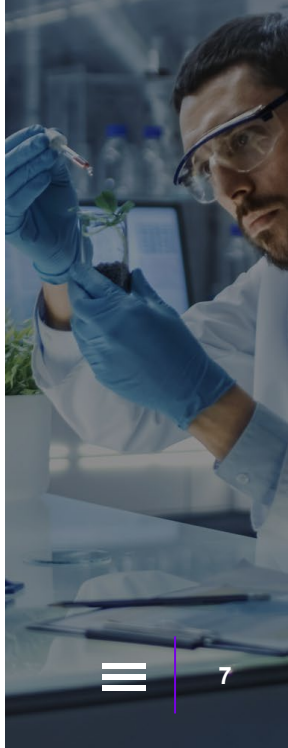
Cannabis cultivation

4. STJ Denies Extension of Deadline for Regulation of Cannabis Cultivation for Medicinal and Pharmaceutical Purposes

On February 12, 2025, the 1st Secction of the Superior Court of Justice ("STJ") rejected the motion for clarification filed by the Office of the Attorney General ("AGU") requesting the extension of the deadline established in the judgment of REsp No. 2,024,250/PR (i.e., IAC 16). The extension aimed to grant the Brazilian Health Surveillance Agency ("Anvisa") and the Union more time – from six to twelve months after the publication of the judgment – to regulate the importation of seeds, cultivation, industrialization, and commercialization of industrial hemp, a variety of cannabis exclusively intended for medicinal and pharmaceutical purposes.

In the ruling, the rapporteur argued that the original six-month deadline for fulfilling this obligation - calculated from the publication of the judgment on November 19, 2024 - had been thoroughly debated by the Court, taking into account the presumed procedural complexity required for regulation of the topic. Furthermore, the rapporteur stated that any additional extension would depend on justification and proof of the effective impossibility of fulfilling the obligation within the designated timeframe.

With the rejection of the motion for clarification and considering that the judgment of REsp No. 2,024,250/PR was published on November 19, 2024, Anvisa and the federal government have until May 19, 2025, to regulate the matter.



ANS List

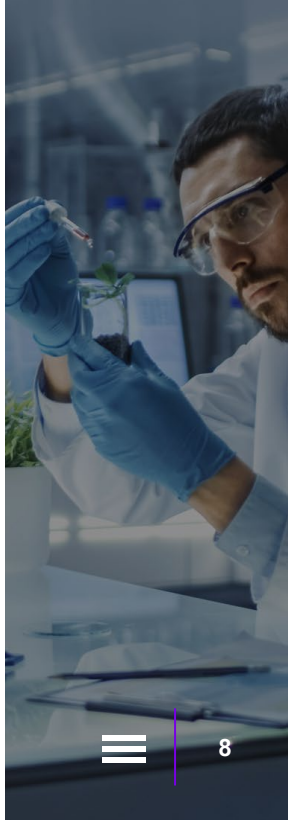
5. STF summons ANS to comment on the legal action discussing the constitutionality of the law regarding the ANS List

On February 12, 2025, the Supreme Federal Court ("STF") ordered the summon of ANS to comment within the scope of the Direct Action of Unconstitutionality ("ADI") No. 7,265/DF filed by the Brazilian Union of Self-Management Health Institutions ("UNIDAS"), which evaluates the constitutionality of Law No. 14,454/2022. This law amended Law No. 9,656/1998 to assign a non-exhaustive character to the ANS List of Healthcare Procedures and Events ("ANS List").

Law No. 14,454/2022 was enacted in response to a STJ judgment on the subject, which had previously defined that the ANS List was exhaustive, albeit with exceptions. Said law established that coverage of treatments not provided for in the ANS List would be mandatory, provided that: (i) there is evidence of efficacy, in the light of health sciences, based on scientific evidence and therapeutic plans; or (ii) the treatment is recommended by the Brazilian Commission for the Incorporation of Technologies in the Unified Health System ("Conitec") or by at least one internationally renowned health technology assessment body.

The Office of the Prosecutor General ("PGR") has already expressed its opinion in the case for the constitutionality of said law, arguing that the provision of exceptional coverage would not impact the regulatory authority of ANS, as it remains responsible for defining and updating the ANS List.

In response to the summons received, ANS submitted its statement on March 10, 2025, in which it, in summary, argues that: (i) any interpretive line suggesting the possibility of requiring coverage from health plans without prior technical analysis by the Agency must be dismissed; (ii) the incompatibility of Law No. 14,454/2022 with the constitutional interpretation established by the STF regarding ANS' competencies; and (iii) Law No. 14,454/2022 could generate adverse effects on the functioning of the supplementary health sector.



Economic freedom

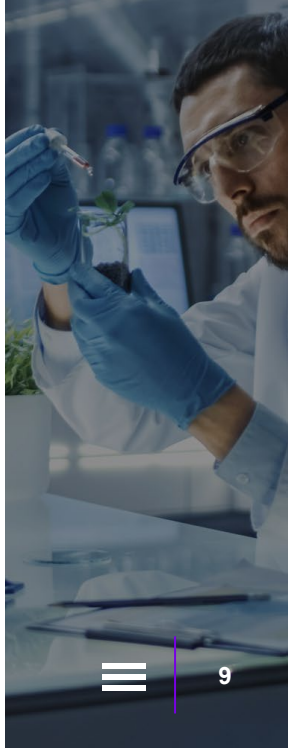
6. ANS regulates deadlines and risk classification for public acts permitting economical activity

On February 14, 2025, ANS published Normative Resolution No. 626/2025, consolidating public acts for the approval of economic activities under its regulation, in compliance with Law No. 13,874/2019 ("Economic Freedom Act") and Decree No. 10,178/2019.

The regulation establishes deadlines and risk classification for 23 administrative acts, such as authorizations, registrations, cancellations, accreditations, and operational changes related to Health Maintenance Organizations ("HMOs") and regulated products. The absence of a decision by ANS within the stipulated timeframe will result in tacit approval of the request, as provided for in Decree No. 10,178/2019.

This regulation represents progress in standardizing the agency's procedures, promoting greater predictability, transparency, and regulatory efficiency.

The regulation came into force on the date of its publication.



Farmácia Popular

7. Ministry of Health extends free access to all medications of the Farmácia Popular Program

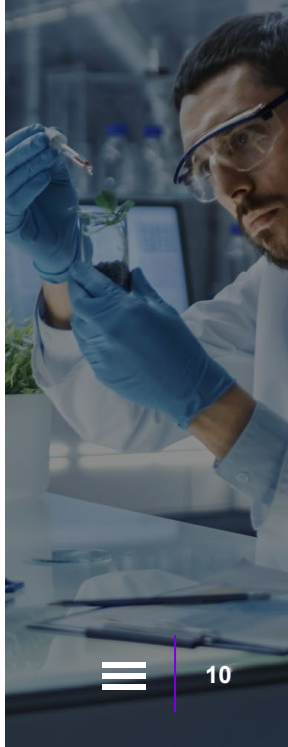
On February 14, 2025, the Ministry of Health published Ordinance No. 6,613/2025, which established free access to medications under the Farmácia Popular Program ("Farmácia Popular") for the treatment of urinary incontinence and diabetes mellitus associated with cardiovascular disease, which were previously available to patients under a copayment modality.

Farmácia Popular is a policy created by the federal government in 2004 to complement the availability of medications used in Primary Health Care. It operates through partnerships with private pharmacy networks, which offer the medications provided by SUS to citizens.

The program covers 12 therapeutic indications, including medications for the treatment of hypertension, diabetes, asthma, osteoporosis, dyslipidemia (high cholesterol), rhinitis, Parkinson's disease, glaucoma, diabetes mellitus associated with cardiovascular diseases, and contraception; as well as adult diapers for patients with urinary incontinence and sanitary pads for beneficiaries of the Dignity Menstrual Program.

With this new amendment, the availability of the medication dapagliflozin – listed for the treatment of diabetes mellitus associated with cardiovascular disease – and adult diapers – listed for the treatment of urinary incontinence – also becomes free of charge.

This regulation came into effect on the date of its publication.



Economic Groups

8. CMED updates list of economic groups

On February 17, 2025, the Brazilian Drug Market Regulation Chamber ("CMED") published Ordinance No. 1/2025, which updated the list of economic groups in the pharmaceutical market (available in its Annex).

The list of economic groups, established based on the definition provided in CMED Communication No. 5/2015, is used to calculate market concentration by therapeutic class through the Herfindahl-Hirschman Index (HHI) methodology. This methodology is employed to determine the three levels of intra-sector relative price factor (Factor Z), which will be applied in the adjustment of durg prices for 2025.

Additionally, Ordinance No. 1/2025 states that the therapeutic classes classified according to the medicine market concentration index, for the establishment of Factor Z, referring to the second half of 2023 and the first half of 2024, are available for consultation through the following link.

This regulation came into force on March 1, 2025.

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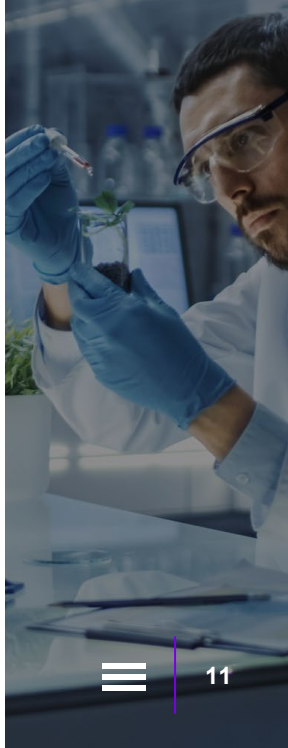


PROMAQ

9. MAPA launches program to boost agricultural mechanization

On February 19, 2025, the Ministry of Agriculture and Livestock (MAPA) published Ordinance No. 775/2025, which establishes the Brazilian Program for Modernization and Support to Agricultural Production ("PROMAQ") and outlines the guidelines for its implementation.

PROMAQ is a policy aimed at boosting Brazilian agricultural production through incentives for mechanization. In essence, the policy involves forming networks and partnerships with federal, state, district, municipal public organizations, as well as private organizations, for the acquisition and donation of agricultural machinery and equipment.

PROMAQ will be implemented nationwide, prioritizing (i) regions with lower rates of agricultural mechanization and weaker competitive participation in agricultural production, (ii) states and municipalities in situations of emergency or public calamity, and (iii) participants who demonstrate greater need for goods, based on evaluations by MAPA's technical area.

To receive the machinery and equipment acquired by MAPA, beneficiaries must:

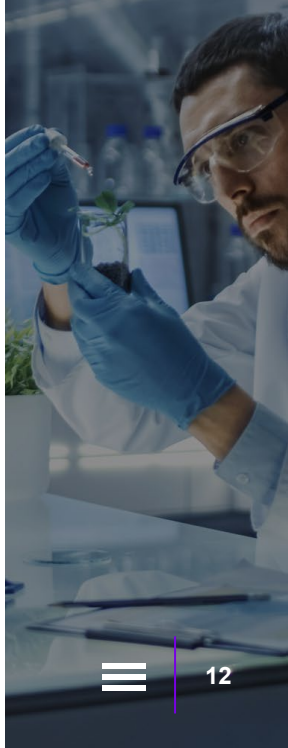
i. Prove their eligibility to receive donations.

ii. Present a diagnosis showing specific demand for machines and equipment, considering the region's agricultural profile, the size of the rural area, and the condition of local roads.

iii. Provide a declaration confirming adequate infrastructure and technical team to operate, maintain, and conserve the donated goods.

iv. Sign a commitment and donation agreement ensuring that the equipment will be used exclusively for PROMAQ's objectives.

This ordinance came into force on the date of its publication.



Regulatory Sandbox ANS

10. ANS proposes regulatory sandbox to test elective consultation and laboratory exam health plans

On February 18, 2025, ANS launched Public Consultation ("PC") No. 151/2025 to collect public contributions on the draft Normative Resolution ("NR") proposing the implementation of an experimental regulatory environment (regulatory sandbox) to test a health plan model restricted to elective consultations and exams.

According to the NR draft, the product to be tested in the sandbox must be (i) a association-based healthcare plan with flexibility to allow contracting by any interested person, without the need to be linked to a legal entity; (ii) without free choice of providers; (iii) with a copayment of up to 30% for consultations and laboratory exams; (iv) with ambulatory, hospital care segmentation, with or without obstetrics and its combinations, excluding dental segmentation; (v) with a waiting period.

Additionally, the NR draft specifies that participant selection will take place through a selection process conducted by a regulatory sandbox committee, which will adhere to eligibility and admissibility criteria outlined in the call for applications to be published by ANS. Participants whose proposals are approved will receive temporary authorization for one year (renewable for an equal period) to offer the new health plan model.

The opening of PC No. 151/2025 was accompanied by Public Hearing No. 52/2025, specifically held to discuss this topic. The full version of Public Hearing No. 52/2025 can be accessed at the following link.

PC No. 151/2025 will be open for contributions until April 4, 2025. Contributions can be submitted trough this link.

Public Health Emergency

11. São Paulo government declares a state of emergency due to dengue

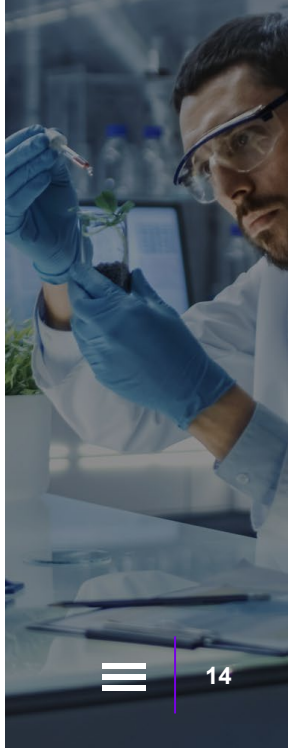
On February 19, 2025, the government of the State of São Paulo issued State Decree No. 69,359/2025, through which it declared a Public Health Emergency in the state due to the dengue epidemic.

To enhance effectiveness and agility in combating the disease, the decree authorizes:

i. The adoption of all necessary administrative measures to contain diseases transmitted by mosquitoes (e.g., dengue, Zika, chikungunya) – notably the direct procurement, by emergency bidding waiver, of supplies, materials, and services necessary to address emergency situations; and

ii. The extension of contracts and administrative agreements that support efforts to combat the mosquito transmitting the dengue virus and other arboviruses, assist patients affected by these diseases, and reinforce epidemiological surveillance actions, according to the needs determined by the technical areas of the Health Department of the State of São Paulo.

The decree came into force on the date of its publication.



Reliance in the food area

12. Anvisa establishes an optimized procedure for the analysis of petitions in the food area

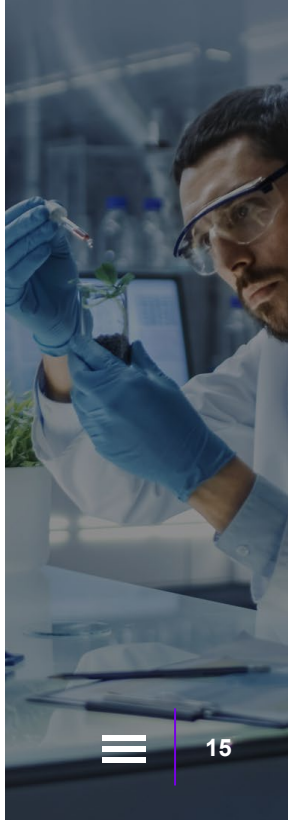
On February 21, 2025, Anvisa published Normative Instruction No. 344/2025, which establishes conditions for the application of the optimized reliance-based analysis procedure for evaluation petitions in the food area.

The optimized reliance-based analysis procedure is a tool provided for in RDC No. 741/2024, which allows Anvisa to leverage the technical analysis and documents issued by an Equivalent Foreign Regulatory Authority ("AREE") for a given product during the process of regularizing this same product in Brazil.

The approved Normative Instruction allows the application of the optimized procedure for the analysis of:

- Food additives, except flavorings from regional botanical species;
- Processing aids;
- Enzymes used as processing aids;
- New substances for materials in contact with food;
- New technology applied to materials in contact with food;
- Safety and efficacy of functional or health properties of novel foods and new ingredients;
- Safety and efficacy of functional or health properties for enzymes as ingredients;
- Safety and efficacy of functional or health properties of probiotics; and
- Risk of veterinary products.

The regulation came into force on March 20, 2025.



Forced degradation studies

13. Anvisa updates requirements for conducting degradation studies in drugs

On February 24, 2025, Anvisa published RDC No. 964/2025, which establishes the general requirements for conducting Forced Degradation Studies in durgs with synthetic and semi-synthetic Active Pharmaceutical Ingredients ("API"), and sets parameters for the notification, identification, and qualification of degradation products in these same products, a subject previously regulated by RDC No. 53/2015.

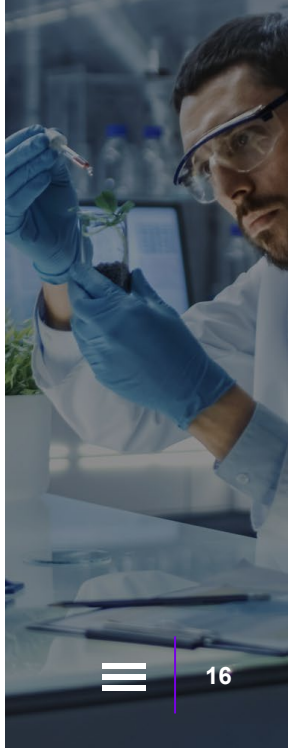
Forced Degradation Studies are conducted to identify possible impurities resulting from chemical alterations of the API that occur during its manufacturing and/or storage and to validate the analytical method used in stability studies.

The revision proposed by RDC No. 964/2025 aims to harmonize Anvisa's regulations for conducting this type of study with international parameters, such as those established by the guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ("ICH").

Among other provisions, the regulation:

- Requires the study to be conducted in at least one batch of the drug and, for comparison purposes, also with the isolated API.
- Determines that the studies be carried out under conditions that promote degradation to an extent sufficient to enable the evaluation of impurity formation.
- Removes the requirement for studies with placebo and for conducting tests in liquid phase for drugs in solid phase.

The regulation came into effect on the date of its publication, repealing RDC No. 53/2015. Despite this, it allows companies to submit Forced Degradation Studies in accordance with RDC No. 53/2015 within up to 730 days from its effective date (until February 24, 2027).



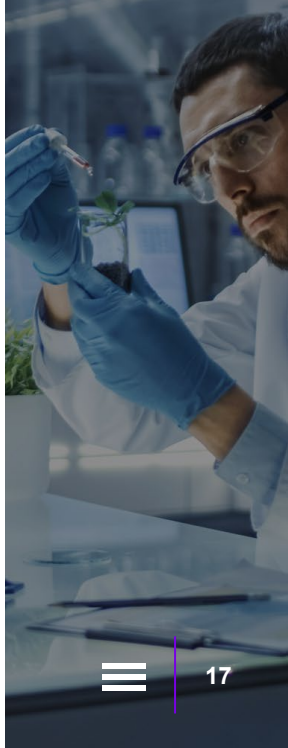
Change in the Ministry of Health

14. Government announces change in the leadership of the Ministry of Health

On February 25, 2025, the President of the Republic announced the departure of Minister Nísia Trindade from the Ministry of Health, which will now be headed by Minister Alexandre Padilha, which was the current Minister of Institutional Relations in the government.

The new Minister of Health is an infectious disease physician and previously served as Minister of Health between 2011 and 2014 during the government of former President Dilma Rousseff.

The change in the leadership of the Ministry of Health was later formalized on March 10, 2025, through the publication of the March 10, 2025, Decree.



Clinical trials

15. Anvisa publishes Manuals with guidelines on the new clinical trials regulation

On February 26, 2025, Anvisa released three manuals to guide the regulated sector on procedures related to the new regulatory framework for clinical trials established by RDC No. 945/2024 and Normative Instruction No. 338/2024.

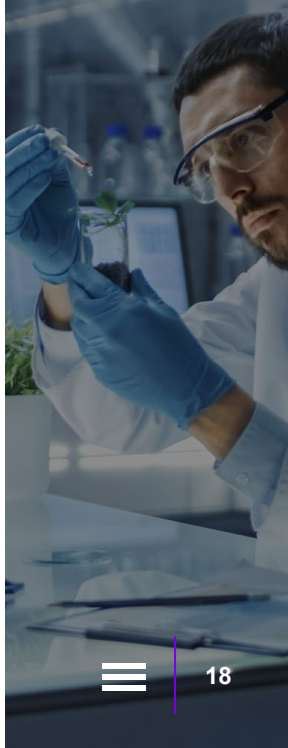
Specifically, Anvisa provided:

i. The Manual for the Submission of the Drug Clinical Development Dossier (DDCM) and the Specific Clinical Trial Dossier (DEEC), which aims to guide professionals in the field with information on how to prepare DDCM and DEEC processes under the new regulation;

ii. The Manual for Reporting Suspected Unexpected Serious Adverse Reactions (SUSARs) and Safety Monitoring in Clinical Trials, which aims to guide (i) the sponsor and delegated Clinical Research Organizations ("CROs") on how to carry out safety monitoring and report SUSARs to Anvisa; and (ii) the investigator on how to perform safety monitoring to minimize risks to clinical trial participants; and

iii. The Manual on the Use of VigiMed Company – Clinical Trial, which aims to guide the proper use of the VigiMed system for reporting SUSARs.

The manuals are non-binding regulatory instruments designed to facilitate the adaptation of the regulated sector to the new clinical research regulations.



02

Relevant Publications

Drug pricing regulations

1. Updates on the process of reviewing drug pricing regulations

On February 19, 2025, CMED participated in a webinar hosted by the Brazilian Association of Private Hospitals ("Anahp"), during which it addressed the review of the current drug pricing regulations, established mainly by Resolution No. 2/2004.

Click here to access the article on the topic published by Lefosse's Life Sciences & Healthcare team.

03

Public Consultations

Public Consultations

Anvisa

PC No. 1,310/2025: Proposal to amend 29 monographs of the List of Active Ingredients of Pesticides, Sanitizers, Disinfectants and Wood Preservatives, published through IN No. 103, of 19/10/2021: A14 - ATRAZINE, A66 - INDOLEACETIC ACID, B26 - BIFENTHRIN, C03 - CARBARYL, C35 - CLOMAZONE, C40 - CHLORFENAPYR, C70 - CHLORANTRANILIPROLE, C88 - CYCLOBUTRIFLURAM, D21 - DIQUAT, E25 - SPIRODICLOFEN, F28 - FENPROPATHRIN, F36 - FLUTRIAFOL, F37 - FENPIROXIMATE, F42 - FLUROXYPYR MEPTYL, F46 - FLUMIOXAZINE, I12 - IMAZAPYR, I18 - ISOXAFLUTOLE, M02 - MANCOZEB, M17 - METHOMYL, M32 - METHOXYFENOZIDE, M40 - MESOTRIONE, M45 - MANDIPROPAMIDE, N08 - NICOSULFURON, O21 - OXATHIAPIPROLIN, P13 - PROFENOFOS, P61 - PYROXASULFONE, P65 - PIDIFLUMETOFEM, S09 - SULFENTRAZONE AND T71 - METHYL THIENCARBAZONE.

Deadline: 2.20.2025 to 4.21.2025

Publication

2.3.2025

2.17.2025

ANS

PC No. 149/2025: Proposal for a Normative Resolution creating the Internal Regulations of the Commission for Updating the List of Procedures and Events in Supplementary Health - COSAÚDE.

Deadline: 11.2.2025 to 3.37.2025

Public Consultations

Publication

2.18.2025

ANS

PC No. 151/2025 : Proposal for a Normative Resolution that establishes the rules for the creation and operation of an experimental regulatory environment (Regulatory Sandbox) called 'Plan for strictly elective medical consultations and exams'.
Deadline: 2.18.2025 to 4.4.2025

2.27.2025

Anvisa

PC No. 1,311/2025 : Proposal for a Normative Instruction to amend Normative Instruction No. 160, of July 1, 2022, which establishes the maximum tolerated limits (MRLs) for contaminants in foodstuffs
Dealine: 3.6.2025 to 4.21.2025

2.28.2025

MAPA

Ordinance No. 1248/2025: Proposal to amend Ordinance No. 795, of May 10, 2023, which defines the hygienic, sanitary and technological standards for establishments that produce bee products and their derivatives.

Deadline: 2.28.2025 to 4.13.2025

Lefosse

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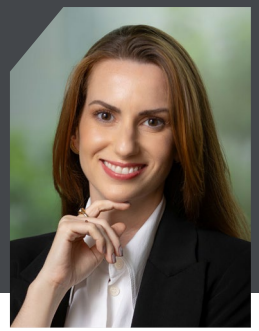

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