ANVISA
Agência Nacional de Vigilância Sanitária

EXECUTIVE SUMMARY

2025 ANNUAL ACTIVITY REPORT

For more detailed information, consult the full 2025 Management Report

DIRECTOR-PRESIDENT

Leandro Pinheiro Safatle

DIRECTOR OF THE SECOND DIRECTORATE

Daniela Marreco Cerqueira

SUBSTITUTE DIRECTOR OF THE THIRD DIRECTORATE

Marcelo Mario Matos Moreira

DIRECTOR OF THE FOURTH DIRECTORATE

Daniel Meirelles Fernandes Pereira

DIRECTOR OF THE FIFTH DIRECTORATE

Thiago Lopes Cardoso Campos

CHIEF PLANNING ADVISOR (APLAN)

Carlos Eduardo da Silva Sousa

CHIEF COMMUNICATION ADVISOR (ASCOM)

Fábia Galvão Machado

COMMITTEE ON STRATEGIC MANAGEMENT, RISKS, AND INSTITUTIONAL INNOVATION (CGE)

Composition	Full Members	Alternate Members
Director-President	Leandro Pinheiro Safatle (Director)	Diogo Penha Soares (Deputy Director)
Director of the Second Directorate	Daniela Marreco Cerqueira (Director)	Elkiane Macedo Rama (Deputy Director)
Director of the Third Directorate	Marcelo Mario Matos Moreira (Substitute Director)	Suzana Yumi Fujimoto (Deputy Director)
Director of the Fourth Directorate	Daniel Meirelles Fernandes Pereira (Director)	Leandro Rodrigues Pereira (Deputy Director)
Director of the Fifth Directorate	Thiago Lopes Cardoso Campos (Director)	Roberta Meneses de Amorim (Deputy Director)
Office of the Director-President – GADIP	Karina Pires Nogueira ((Chief of Staff of the Director-President)	Thalita Antony de Souza Lima
Federal Attorney's Office at Anvisa – PROCR	Flávia Oliveira Tavares (Chief Attorney)	Vacant
Planning Advisory – APLAN	Carlos Eduardo da Silva Sousa (Chief Advisor)	Marina Torres Uber Bucek
Information Technology General Office – GGTIN	Breiner Araujo Queiroz (General Manager)	Yannie Silveira Gonçalves

Composição	Titular	Suplente
Communication Advisory – Ascom	Fábia Galvão Machado (Chief Advisor)	Átila Regina de Oliveira
International Affairs Advisory – Ainte	Ana Carolina Moreira Marino Araújo (Chief Advisor)	Bianca Zimon Giacomini Ribeiro
People Management General Office – GGPES	Trajano Augustus Tavares Quinhões (General Manager)	Maria Cecília dos Santos de Araújo
Knowledge, Innovation, and Research General Office – GGCIP	Artur Iuri Alves de Sousa (General Manager)	Fábio Gama Alcuri
Administrative and Financial Management General Office – GGGAF	Frederico Augusto de Abreu Fernandes (General Manager)	Ana Cristina Rolins de Freitas Dusi
Regulatory Quality Improvement Advisory – ASREG	Marcelo de Matos Ramos (Chief Advisor)	Henrique Mansano Rosa Oliveira

PLANNING AND STRATEGIC MANAGEMENT COORDINATION (CPGES)

Wanessa Tenório Gonçalves Holanda (Coordinator)

Claudia Passos Guimarães Rabelo

Isis Polianna Silva Ferreira de Carvalho

Juliane Zatelli de Souza

Maria de Fátima Ferreira Francisco

TECHNICAL AND TEXTUAL REVIEW

Isis Polianna Silva Ferreira de Carvalho

Juliane Zatelli de Souza

Maria de Fátima Ferreira Francisco

Wanessa Tenório Gonçalves Holanda

Paula Vidigal Simões Silva

VISUAL DESIGN AND LAYOUT

Paula Vidigal Simões Silva

A ANVISA

The Brazilian Health Surveillance Agency (Anvisa) is a regulatory agency linked to the Ministry of Health (MS, in Portuguese), created by Law No. 9,782/1999, as an autonomous authority under a special regime, with headquarters and jurisdiction in the Federal District (DF, in Portuguese) and operating throughout the Brazilian territory.

MISSION

To promote and protect the health of the Brazilian population, acting with scientific excellence in the regulation of products, services, and environments subject to health surveillance, fostering access, reducing risks, and supporting the Brazil's development in integrated action with the Unified Health System (SUS, in Portuguese).

VISION

To be an innovative and reliable health authority for the whole society.

VALUES

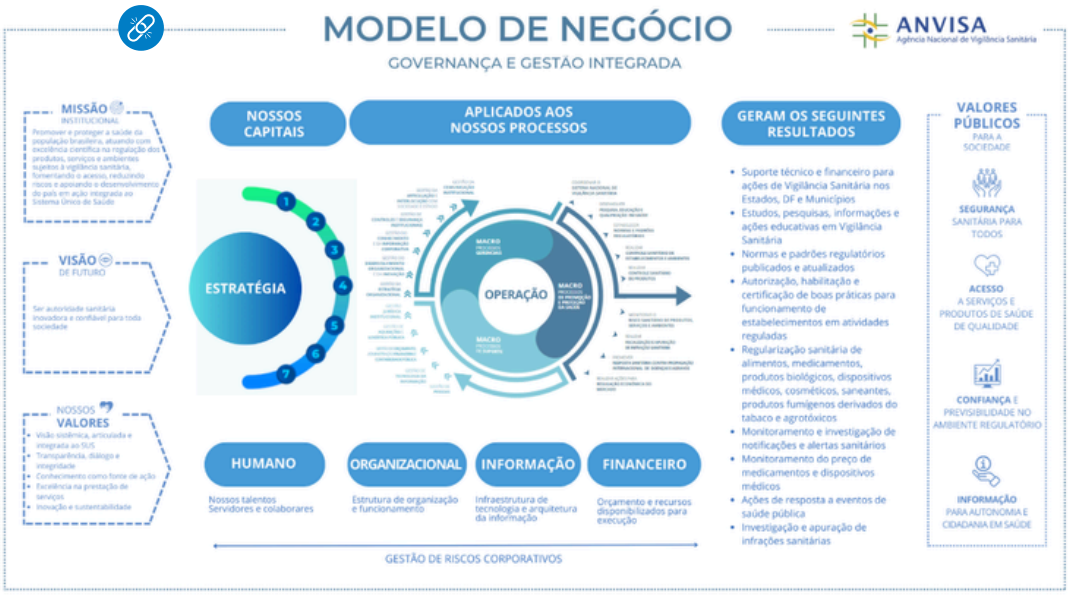
- Systemic and integrated vision with the SUS
- Transparency, dialogue and integrity
- Knowledge as a source of action
- Excellence in service delivery
- Innovation and Sustainability

Anvisa adopts an **integrated governance** and **management model**, which includes strategic and operational dimensions.

The **strategy map** reflects the main priorities for the 2024-2027 cycle, based on the Agency's mission and vision for the future. The **value chain** systematizes the organizational processes established for the fulfillment of its legal responsibilities.

This executive summary presents a synthesis of **the main results** and **deliverables** achieved in 2025.

For more information, we suggest consulting the full Management Report, available on **Anvisa website**.



STRATEGY ACHIEVEMENT IN 2025:

STRATEGIC PLANNING **2024-2027** → **30** KEY RESULTS (KRs)

ANNUAL MANAGEMENT PLAN (AMP) **2025** → **33** KEY RESULTS (KRs)

Overall strategy performance compared to previous years

INTERNATIONAL POSITION

Anvisa has advanced in the process of being recognized as a **Reference Health Authority by the World Health Organization** (WHO Listed Authority – WLA). In 2025, the Agency received the WHO/PAHO evaluation report, implemented improvements, and developed an action plan. Completion is expected by March 2027.

ACTIONS IN 2025

- Anvisa **expanded the international recognition** of its regulatory decisions. The Mexican health authority (Cofepris) began to recognize Anvisa as a **reference authority** in the marketing authorization and inspection processes of medical devices.
- In 2025, memoranda of understanding for **regulatory cooperation** were signed with Cofepris (Mexico), Infarmed (Portugal), Digemid (Peru), and EDA (Egypt).
- Anvisa hosted **the BRICS Regulatory Authorities meeting** in Brasília, strengthening international cooperation.
- **Leadership of Anvisa** in international organizations such as PIC/S, ICMRA, and ICH, holding positions of presidency, vice-presidency and rapporteurship.
- Participation in the conclusion of **Trade Agreements** within the scope of the Latin American Integration Association (ALADI).
- Participation in official health and foreign trade missions.

RESULTS OF MANAGEMENT

PESTICIDES

In 2025, Anvisa's performance in the field of pesticides was marked by regulatory strengthening, a significant increase in productivity in toxicological analyses, greater transparency, and intensified inter-institutional integration, in addition to progress in strategic programs for monitoring and reducing health risks.

Throughout the year, Agency's work focused on **improving the regulatory framework** and **qualifying the toxicological evaluation processes** of pesticides, with relevant results in addressing marketing authorization backlogs and expanding analytical capacity, without compromising health protection.

Optimization Measures

The implementation of optimization measures resulted in a **306% increase** in the completion of analyses of Equivalent Formulated Products (EFP), compared to the average of the previous three years, and a **75% reduction** in the petition backlog, consolidating advances in regulatory efficiency, process predictability, and sanitary safety.

Enhancement of the Regulatory Framework

There was also an improvement in the regulatory framework for pesticides, with emphasis on the progress in regulating **the assessment of occupational and non-dietary risk**, reinforcing Anvisa'S role in the governance of chemical risk and the protection of human health. Anvisa participated in the technical discussions for the regulation of Law No. 15,070/2024 (Bio-inputs Law), concluded in December 2025 under the coordination of the Ministry of Agriculture and Livestock (MAPA, in Portuguese), contributing to the alignment of the regulatory framework with the principles of protecting human health.

Brazilian Pesticide Reduction Program (Pronara)

Within the scope of **the Brazilian Pesticide Reduction Program** (Pronara, in Portuguese), the Agency played a strategic technical role in prioritizing actions aimed at the gradual reduction of pesticide use and the promotion of less hazardous alternatives.

In the context of this transition, **71 toxicological analyses of bio-inputs** were completed, representing a **20.3% increase** compared to the average of the last three years and a **42% increase** compared to 2024, strengthening the technical and scientific basis for more sustainable and safe production models.

RESULTS OF MANAGEMENT

FOOD

Risk and Efficacy Assessment

Anvisa received **270 evaluation requests**, the highest number in the last five years, representing a **31% increase** compared to 2024. The industry's main interests were food additives, processing aids, and new ingredients. The growth in demand was offset by a **reduction** in the average analysis time, which reached **239 days**, the **lowest value** in the entire historical series. This result puts Anvisa on an **equal footing** with important foreign authorities and reinforces the Agency's commitment to balancing technical rigor and encouraging innovation, always preserving the protection of consumer health.

Regulation of Food and Packaging

The new rules for the regulation of food and packaging have brought important changes, especially for formulas for inborn errors of metabolism (FIEM), which now require prior authorization from Anvisa. The measure strengthens safety and efficacy for consumers but presents challenges for manufacturers. Due to the essential nature of these products, Anvisa closely monitored the transition, and all food products available on the market had their marketing authorization requests submitted by the end of 2025.

Another new development that stirred the market was the **mandatory notification** of food supplements. Although notified food products do not require prior approval, notifications can be canceled by Anvisa in case of serious errors or irregularities. By the end of 2025, the Agency had received almost **4,000 notifications**, **96%** related to supplements. Using risk criteria, it reviewed **568**, finding flaws in **81%**.

These regulatory changes also challenged Anvisa, which implemented improvements to avoid hindering the analysis of other foods granted marketing authorization. As a result, the average analysis time was **reduced by 50 days** between 2024 and 2025.

Food Standards and Norms

Food standards and norms constitute the second largest theme of the 2024–2025 Regulatory Agenda (RA). In addition to their significant volume, these topics stand out for their complexity and potential impact on economic agents and consumers.

By the end of 2025, the food standards and regulations prioritized in the Regulatory Agenda (RA) had reached 64% completion, based on an indicator that measures the individual progress of each proposal. **44%** of the topics were completed, resulting in the publication of **51** regulations.

Social participation remained central to the regulatory processes, with **11** public consultations published and **54** sectoral dialogues and **5** webinars held, involving more than **18,000** participants.

RESULTS OF MANAGEMENT

ENVIRONMENTS, PRODUCTS, AND SERVICES IN PORTS, AIRPORTS, BORDERS, AND CUSTOMS AREAS (PAF)

Company Operating Authorization or Special Authorization

545 petitions regarding Company Operating Authorization in PAF **were filed**

average processing time of **34** DAYS

Health Administrative Process in PAF

61 customs warehouses were inspected
FOR COMPLIANCE WITH GOOD STORAGE PRACTICES

Health Administrative Process in PAF

428 health administrative processes **were initiated**

321 individuals charged

1,176 infractions identified

Epidemiological Surveillance in PAF

- The Contingency Plan Guide e the Basic Capacity Monitoring Guide of the International Health Regulations (IHR) for designated ports and airports have been published.

543,314 International Certificates of Vaccination or Prophylaxis (ICVP) **were issued**

308,412 **were issued** automatically

RESULTS OF MANAGEMENT

Health Control of Aircraft and Airports

1,345
inspection actions were carried out at **42 airports in Brazil**

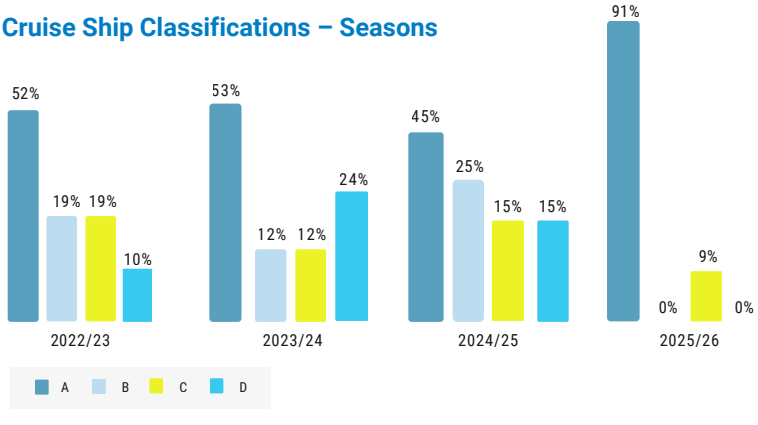
2 internationalization requests were **approved**

Health Control of Vessels and Ports

25 cruise ships
were inspected

The inspected ships are evaluated and classified into **four standards** (from A to D), according to their sanitary conditions. Standard "A" is considered excellent, while "D" indicates unsatisfactory sanitary conditions.

Cruise Ship Classifications – Seasons

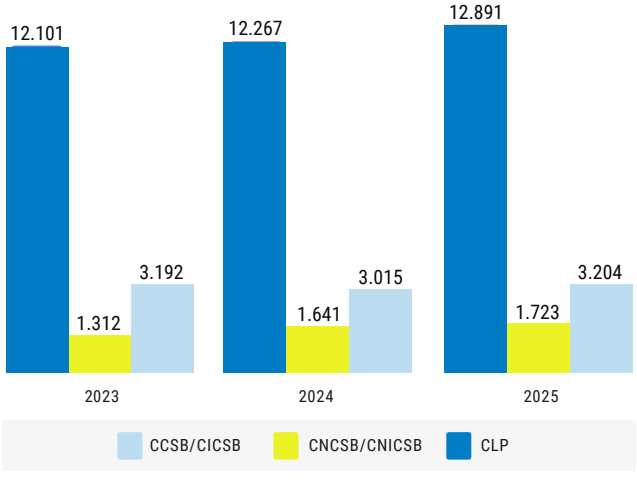


Paperless Port

The Paperless Port (PSP, in Portuguese) improvement process brought **innovation** to inspection scheduling, which favored the optimization of teams, the time spent on conducting analyses, and saved time and resources for the regulated sector.

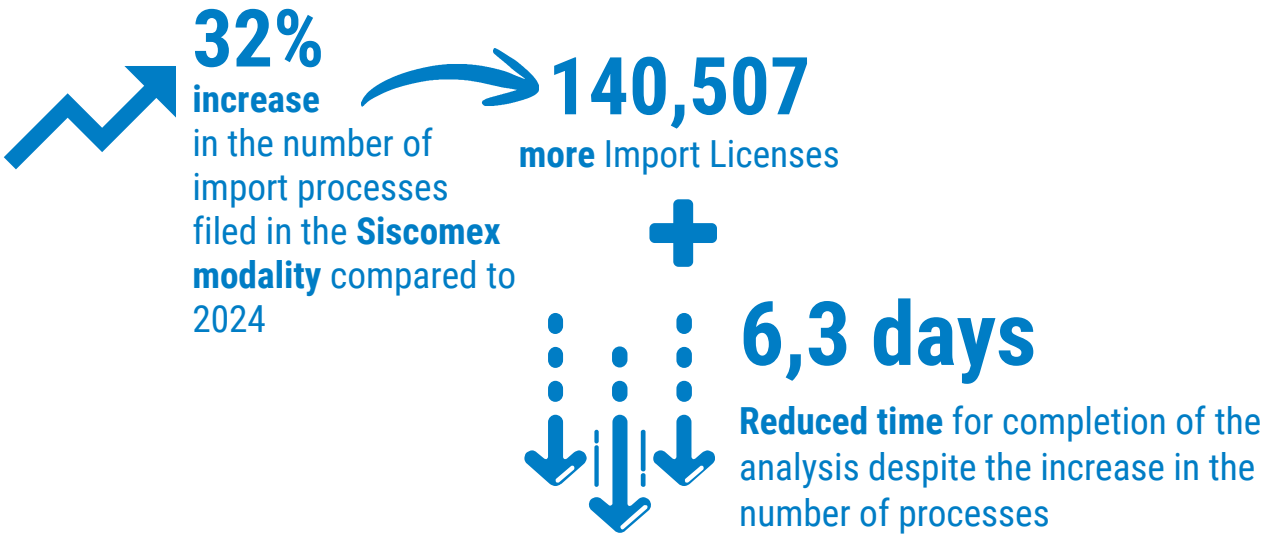
A trend of **stability** in the demand for certificates has been observed since 2023.

Certificates Issued in PSP



RESULTS OF MANAGEMENT

Approval of export and import of products



- Implementation of the phased linking of the Single Import Declaration (Duimp, in Portuguese), in October 2025, with the testing of the strategic modules of Pucomex, including risk management, integration of the fee payment to the Centralized Foreign Trade Payment (PCCE, in Portuguese), issuance of the Physical Inspection Report (RIF, in Portuguese) and the operation of the single parameterization channel among the government authorities.

- The **Authorized Economic Operator Program** is one of the trade facilitation tools, established in the commitments of the Trade Facilitation Agreement of the World Trade Organization (WTO). Its goal is to provide the flow of international trade with agility, predictability, and confidence.

- **11 companies** in the different certification categories (Certified Operators) have been certified, totaling **29 operators** with valid certificates since the Program started in 2024.

RESULTS OF MANAGEMENT

COSMETICS

Regulation of Products Subject to Health Surveillance

1,148 cosmetics marketing authorization petitions **were received**

1,004 were **concluded**

14% **increase** in petitions analyzed in 2025 compared to 2024

Post-Marketing Authorization for Cosmetics

651 cosmetics post-marketing authorization petitions **were received**

596 were **concluded**

Cosmetics Exempt from Marketing Authorization

72,390 new notifications **were received**

1,311 processes **were evaluated** by the Marketing Authorization Exemption Verification Program.

Highlight

- **REGULATORY SANDBOX – COSMETICS CUSTOMIZATION**: publication of Notice No. 18/2025, containing the rules for participation and evaluation of customized cosmetics projects to be included in the experimental agile regulation environment.
- **HAIR POMADES**: **422** products that should have been granted marketing authorization under Resolution RDC No. 814/2023 were cancelled, and **6** marketing authorizations were granted, totaling 75 duly regularized products.

RESULTS OF MANAGEMENT

MEDICAL DEVICES

Regulation of Products Subject to Health Surveillance

Number of medical devices granted marketing authorization and notified

Orthopedic implants	Notifications	NA*
	Marketing authorizations	221
Materials for use in health	Notifications	4659
	Marketing authorizations	313
In-vitro diagnostic devices	Notifications	1285
	Marketing authorizations	628
Equipment	Notifications	1551
	Marketing authorizations	468
	Total	9125

* Notifications do not apply to the category of orthopedic implants.

Authorization, alteration, or cancellation of clinical study

In 2025, **21 petitions** for approval of clinical studies on medical devices were received, and all analyses were completed within the legal timeframe.

Clinical study approvals for medical devices in 2025

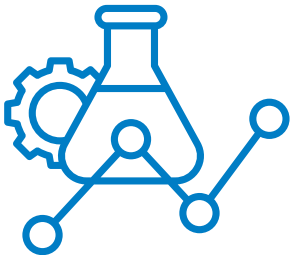
Entries	Approvals	Deficiency Letters	Withdrawals	Under Analysis	Anvisa Average Total Time in Business Days
21	10	8	2	1	50,5

RESULTS OF MANAGEMENT

ANALYTICAL LABORATORIES

Health Analytical Laboratories Network (Reblas, in Portuguese)

193
petitions related to Reblas **were analyzed**



70
new laboratories **were enabled** in Reblas

Supporting actions to control the quality of products

59,808
samples of products subject to health surveillance **analyzed** by RNLVISA

27,309
fiscal analyses **performed**

*RNLVISA = Brazilian Network of Health Surveillance Laboratories

Regulatory data of products subject to health surveillance

- **427** processes from official public and accredited laboratories requesting information on regulated products.

Products of the Brazilian Pharmacopeia

- **6 Public Consultations** on pharmacopeial texts were published, in preparation for the end of the work cycle (2021-2026) of the Brazilian Pharmacopeia collegiate bodies, which will culminate in the release of three compendia.
- **104 vials** of Brazilian Pharmacopeia Reference Chemical Substances (SQR-FB, in Portuguese) were distributed free of charge to official laboratories e **446 vials** were sold (revenue of **R$ 164,160.00**).
- **106** Brazilian Common Denominations (DCB, in Portuguese) were established.

RESULTS OF MANAGEMENT

MEDICINAL PRODUCTS AND PHARMACEUTICAL INPUTS

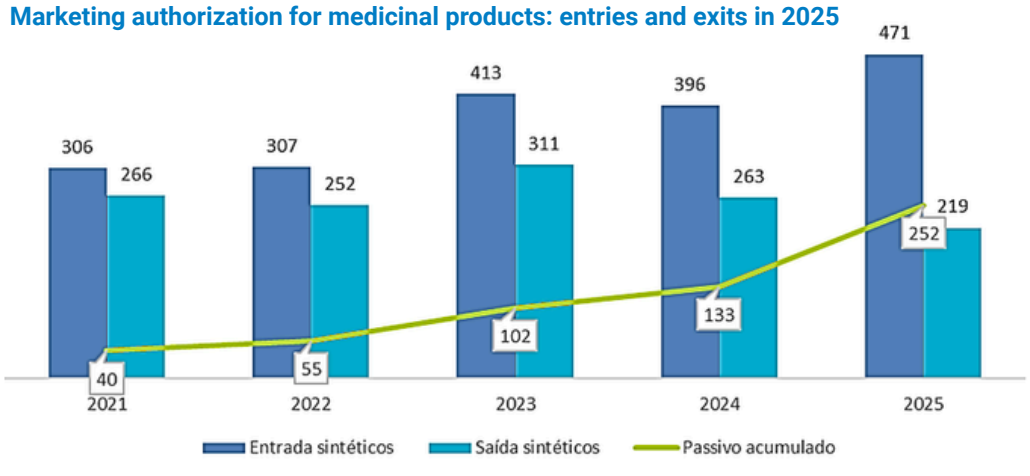
Regularization of products subject to health surveillance

- **237 decisions published** regarding marketing authorization requests for generic, similar, new, innovative, specific, herbal, and dynamized medicinal products, including requests for health authorization for Cannabis products and excluding clone medicines.

Marketing Authorization

In 2025, the number of marketing authorization requests for generic, similar, new, innovative, specific, herbal, and dynamized medicinal products reached a new record, with **471 requests**. This fact signals the interest of pharmaceutical companies in participating in the Brazilian market of medicinal products and may increase access for the Brazilian population to such products, but it imposes a challenge on Anvisa in meeting the demand and legal deadlines, as its staff is limited.

Marketing authorization for medicinal products: entries and exits in 2025



Regulatory Agenda

- **5 guides**, **9 RDCs** (Collegiate Board Resolutions), and **14 INs** (Normative Instructions) related to the regulation of medicinal products were published, highlighting those with the potential for positive impact on the population's access to safe and effective medicines.

NEW REGULATORY FRAMEWORK FOR HERBAL MEDICINES MARKETING AUTHORIZATION AND NOTIFICATION

RDC No. 1,004/2025 | IN No. 412/2025 | IN No. 419/2025 | IN No. 410/2025 | Guia No. 85/2025

The new regulatory framework modernizes and simplifies the marketing authorization and notification processes for herbal medicinal products, bringing greater predictability and agility to the regularization of such products, aligning with international best practices. It contributes to expanding the therapeutic options available to the population, strengthening the policy of access to medicines and innovation through the development of products from the Brazilian biodiversity.

RESULTS OF MANAGEMENT

EXCEPTIONAL AND TEMPORARY MEASURES TO OPTIMIZE THE QUEUES FOR THE ANALYSIS OF MEDICINE REGULARIZATION

RDC No. 987/2025 | IN No. 403/2025

These measures represent important regulatory progress, focusing on improving the management of marketing authorization and post-marketing authorization queues. They aim to reduce waiting times for Anvisa decisions and increase compliance with legal deadlines for medicine regularization through the use of regulatory confidence (reliance), without compromising the technical quality of assessments and assessment management plans (AMPs).

The list of Equivalent Foreign Regulatory Authorities (EFRAs) has been expanded to include Japan's Pharmaceuticals and Medical Devices Agency (PMDA) and to broaden the scope of information from the European Medicines Agency (EMA) and Health Canada for Cadifa analysis, marketing authorization and post-marketing authorization applications for medicinal products, considering product quality information.

CHANGES TO THE PRIORITIZATION CRITERIA FOR THE REGULARIZATION ANALYSIS OF MEDICINAL PRODUCTS AND PHARMACEUTICAL INPUTS

RDC No. 1001/2025

The regulation details specific situations that justify priority analysis, such as: high-impact diseases (neglected, rare, emerging, or re-emerging diseases), new pharmaceutical forms or therapeutic indications for children who do not have available treatment, medicines with all stages of manufacturing or development carried out in Brazil or from Productive Development Partnerships (PDP) or the Local Development and Innovation Program (PDIL, in Portuguese).

BIOLOGICAL PRODUCTS AND RADIOPHARMACEUTICALS – MEDICINAL PRODUCTS

Regularization of products subject to health surveillance

40 marketing authorization processes with completed analysis

30 biological products approved

Among the approved biological products, **15** contain biological molecules that are **new to Brazil** and represent **new treatment opportunities** for the population. These include medications intended for the specific treatment of rare diseases, that is, diseases that affect a very small portion of the population and that usually have a minimal offer of therapeutic options.

RESULTS OF MANAGEMENT

Approval of vaccines

Highlighting **two important immunizations** intended for the prevention of arboviruses that severely affect Brazil:

- IXCHIQ vaccine, intended for the prevention of Chikungunya
- Butantan-DV vaccine, for the prevention of Dengue serotypes 1 and 2

ADVANCED THERAPY PRODUCTS – MEDICINES

Regularization of products subject to health surveillance

In 2025, no new Advanced Therapy Products (ATPs) were granted marketing authorization in Brazil, but Anvisa continued the periodic evaluations of ATPs approved in Brazil under Terms of Commitment (TC), focusing on monitoring long-term effectiveness and safety, publishing the respective reports from 2024 onwards.

Authorization, alteration, or cancellation of clinical investigations

17
clinical trials with approved ATPs
12 interventional
5 observational *
long-term and real-world monitoring

4
national Good Clinical Practice (GCP) inspections **were carried out**

212
reported adverse events **were monitored**

Approval of export and import of products

172
export authorizations for starting material for ATP production **were issued**

RESULTS OF MANAGEMENT

CONTROLLED PRODUCTS

- **Updated lists** – Inclusion of **13 new substances** in Ordinance No. 344/1998.
- **Electronic prescriptions** – RDC No. 1,000/2025 created rules with integration to the SNCR, modernizing the prescription process.
- **International Trade** – RDC No. 988/2025 simplified requirements, reduced regulatory costs, based on innovation and safety, and in alignment with UN guidelines.
- **Brazilian System for the Management of Controlled Products (SNGPC, in Portuguese)** – ·Use of the system fully restored in January 2026, for the whole country.

TOBACCO PRODUCTS

Regularization of products subject to health surveillance

- Guidance materials were produced to assist the regulated sector in implementing the new health warnings on packaging and at points of sale.
- Information was collected to monitor the regulatory outcome of Resolution RDC No. 896/2024, which provides for the marketing authorization of tobacco-derived smoking products.
- Throughout 2025, practical measures were implemented to strengthen the implementation of Resolution RDC No. 855/2024, which establishes the regulation of Electronic Smoking Devices (ESDs).
- Publication of a page about ESDs on the portal with language targeted at the general population.
- Training course for SNVS inspectors through the AVA-Visa platform and training actions for inspection teams in coordination with other inspection bodies.
- Coordinated actions with social media and e-commerce platforms.

Health Inspection

Inspection actions resulted in:

- In the State of Rio Grande do Sul, seizure of **4.7 tons of shredded tobacco** without marketing authorization.
- Seizure of more than **2,000 irregular products** in the State of Alagoas.
- **24,424 advertisements** for tobacco products irregularly disseminated on digital platforms on the internet were removed through partnerships with social media companies.

RESULTS OF MANAGEMENT

SANITIZING PRODUCTS

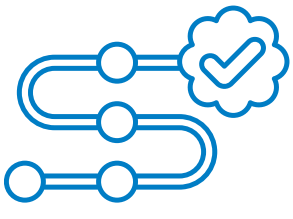
Regularization of products subject to health surveillance

1,243
marketing authorization petitions for sanitizing products **were received**

910
petitions **were completed**

Post-marketing authorization of sanitizing products

916
post-marketing authorization petitions for sanitizing products **were received**



724
were **completed**

Sanitizing products exempt from marketing authorization

6,085
new notifications **were received**

1,632
processes **were evaluated** by the Marketing Authorization Exemption Verification Program

Highlight

COMBATING DENGUE – MOSQUITO USE AUTHORIZATION: Anvisa exceptionally authorized the use of Aedes aegypti mosquitoes containing the Wolbachia bacteria to fulfill a public policy of the Ministry of Health in combating dengue in Brazil.

RESULTS OF MANAGEMENT

BLOOD, TISSUES, CELLS, AND ORGANS

Operating Authorization or Special Authorization

- **195** applications authorizing the flow of approximately **256,000 blood components** were received and analyzed.

Health inspection

- **40** joint inspections with the SNVS (Brazilian Health Surveillance System), representing **80%** of the annual program's execution.

HEALTH SERVICES

Actions of the notification and investigation system in health surveillance – VIGIPOS

- **1** Integrated Plan for the Sanitary Management of Patient Safety in Health Services 2026-2030.
- **1** Brazilian Program for the Prevention and Control of Healthcare-Associated Infections (PNPCIRAS, in Portuguese) 2026-2030.
- **13** Patient Safety and Quality in Health Services Manuals.
- **1** Brazilian guideline for the structuring of State, District, and Municipal Coordination Offices for the Prevention and Control of Healthcare-Associated Infections.
- **2** Patient Safety and Quality in Health Services Bulletins.
- **11** Technical notes for health services.
- **1** Risk alert.
- **9** Forms for collecting HAI and ADR indicators.
- **4** Brazilian Protocols for HAI Prevention.
- **24** Dashboards with Analysis of HAI and AMR Data reported by health services in states using the national reporting tool. Available in Business Intelligence (BI) format for each state.
- **26** Dashboards with Analysis of Data on Adverse Events reported in Notivisa 2.0 by health services. Available in Business Intelligence (BI) format for each state.
- **2** Public Dashboards for Adverse Event Notification.
- **1** Dashboard on *Candida auris* Outbreak.
- **3** Scientific Articles.
- **2** Brazilian Assessments of Patient Safety Practices: 1 in Hospitals with ICUs and 1 in Dialysis Services.
- **1** Assessment of Patient Safety Culture.

Health Risk in Healthcare Services and Services of Interest to Health

Project for Improving the Sanitary Inspection Process in Healthcare Services and Services of Interest to Health: this initiative seeks to improve sanitary inspection work in Healthcare Services and Services of Interest to Health throughout Brazil, promoting the qualification and standardization of actions performed.

RESULTS OF MANAGEMENT

In the context of the Project, the following results were achieved in 2025:

- **6,055** new evaluations were received with MARP®/ROI.
- **4** new monitoring panels for the Inspection Objective Guide (ROI, in Portuguese) were developed.
- The Health Surveillance Inspection Manual was developed to harmonize Good Inspection Practices in Healthcare Services throughout Brazil.
- In-person training was conducted for 2 groups of health surveillance inspectors, in partnership via ProadiSUS, benefiting 76 professionals from 32 municipalities in the South and North Regions.
- Maintenance of 25 distance learning courses on AVAVisa, with 5,627 new enrollments.
- Publication of the Integrated Panel by CNES, bringing together data on patient safety, infection control, and ROI monitoring to guide strategic actions of the SNVS (Brazilian Health Surveillance System).

Investigation of Health Infractions

- **222** complaints were received regarding services of interest to health, mostly concerning aesthetics and beautification.
- **892** complaints about health services, an increase of **689%** compared to the previous year.

Developing Research, Education, and Qualification in Health

In 2025, Anvisa conducted **12 seminars** on topics related to health services and services of interest to health, such as the logical design of responsibilities in Long-Term Care Facilities for the Elderly (ILPI, in Portuguese), notification of adverse events related to health care, and sanitary requirements for dental care.

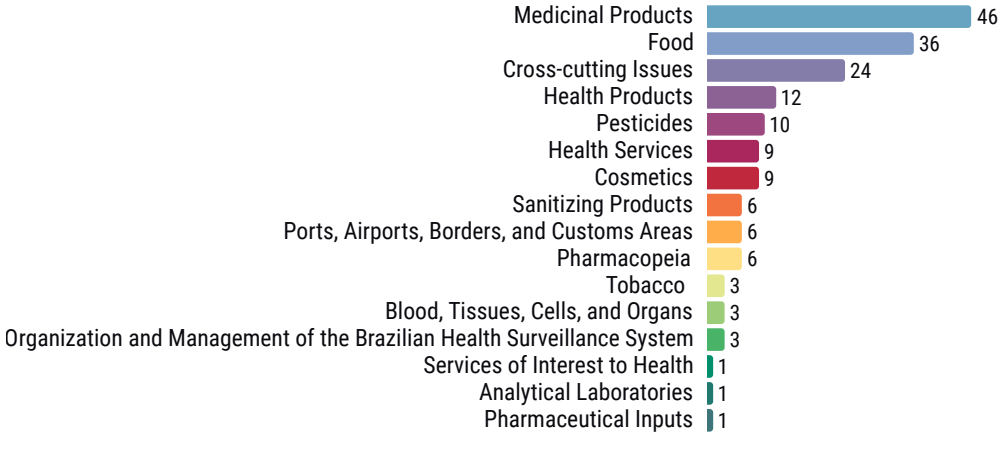
REGULATORY SYSTEM

Update to the Regulatory Agenda

The list of regulatory topics on the Agenda for the period 2024-2025 now consists of 176 topics, distributed across 16 macro-themes of the Agency's work.

Establishment of Regulatory Norms and Standards

176 regulations published:



RESULTS OF MANAGEMENT

Coordination of the Brazilian Health Surveillance System

Transfers from the Brazilian Health Fund 2025

Financing Modality	Amount (R$)	Destination
PF Visa (states and Federal District)	67,604,820.00	Execution of actions by the states
PF Visa (municipalities)	156,361,464.00	Execution of actions by the municipalities
Finlacen-Visa (states and Federal District)	23,280,000.00	Incentive for actions and projects to strengthen health surveillance actions
PV-Visa (municipalities)	25,753,716.00	Execution of actions in public health laboratories
Finlacen – Visa (INCQS)	2,316,000.00	Execution of actions in public health laboratories
Total	275,316,000.00	

HEALTH INSPECTION AND ENFORCEMENT ACTIONS

Health Inspection Actions

In 2025, Anvisa carried out several inspection actions to verify compliance with health requirements, including scheduled inspections, investigative inspections, and actions in partnership with state and municipal health surveillance agencies.

Main inspection data

Product group	Type of action	Total
Food	Inspections in industries	12
Cosmetics	Investigative inspections	14
Medical devices	National inspections	14
Medical devices	International inspections	4
Medicinal products and pharmaceutical inputs	Inspections in compounding pharmacies (sterile products)	12
Sanitizing products	Inspections in companies	5

RESULTS OF MANAGEMENT

Investigation of Sanitary Infractions

The investigation of sanitary infractions included investigative inspections, analysis of complaints, risk screening, and the opening and closing of dossiers.

Investigation data

Product group	Investigative Inspections	Measures Published	Dossiers Opened	Dossiers Closed
Food	12	165	411	454
Cosmetics	14	172	195	349
Medical devices	18	101	314	510
Medicinal products and pharmaceutical inputs	7	185	545	470
Sanitizing products	6	58	78	109

HEALTH ADMINISTRATIVE PROCESS

The Health Administrative Process is initiated when there is confirmation of authorship and materiality of a health infraction.

Health Administrative Processes

Product group	Processes Initiated	Responsible Parties Fined	Infractions Identified
Food	115	102	158
Cosmetics	89	79	146
Medical devices	8	8	49
Medicinal products	103	90	182
Pharmaceutical inputs	20	20	29
Sanitizing products	18	18	32

RESULTS OF MANAGEMENT

AUTHORIZATIONS AND CERTIFICATIONS

Operating Authorization or Special Authorization

In 2025, Anvisa concluded relevant actions related to operating authorizations and special authorizations, such as the complete reformulation of the electronic petitioning system and the automatic cancellation of inactive establishments.

Operating authorizations and special authorizations by product group

Grupo de produtos	Concessões deferidas	Alterações deferidas	Cancelamentos	Concessões indeferidas	Alterações indeferidas
Cosmetics	1,377	1,245	68	164	65
Medical devices	2,409	2,534	179	248	150
Medicinal products and pharmaceutical inputs	1,684	878	60	176	43
Sanitizing products	1,084	772	32	159	28

Good Manufacturing Practices Certification

The assessment of compliance with Good Manufacturing Practices by companies was carried out through national and international inspections, with a more representative number for medical devices, medicinal products, and pharmaceutical inputs.

Good Manufacturing Practices Certification

Product group	Approved (Brazil)	Rejected (Brazil)	Cancellations (Brazil)	Approved (Abroad)	Rejected (Abroad)	Cancellations (Abroad)
Medical devices	241	9	2	1,512	37	14
Medicinal products and pharmaceutical inputs	108	1	0	700	28	1

Good Distribution and Storage Practices Certification

The Good Distribution and Storage Practices Certification is granted to companies responsible for the distribution, storage, or import of products subject to health surveillance.

In 2025, there was **significant growth** in the number of certificates issued, especially for medical devices (178) and medicinal products (118).

RESULTS OF MANAGEMENT

POST-MARKET MONITORING

Nutritional Surveillance (Food)

Monitoring of adverse events and technical complaints involving processed and handled foods.

Comparison of reported categories (2024 → 2025):

- Foods for special purposes: **81 (64,8%) → 50 (37,9%)**
- Food supplements: **12 (9,6%) → 39 (29,5%)** (tripled))

Change in the profile of notifiers:

- Healthcare professionals: **59% (2024) → 34,8% (2025)**
- Citizens/consumers/family members: **41% (2024)→ 60,6% (2025)**

Brazilian Food Monitoring Programs

Launch of the AMR Program Pilot Project (2025–2026).

- **Objective:** to identify antimicrobial residues and resistant microorganisms in retail food**.**
- **Scope:** coordination by Anvisa with participation from local health surveillance agencies, official laboratories, and Fiocruz.

Cosmetic Surveillance

- Consolidation of the Good Practices (GP) Regulation (RDC) for Cosmetic Surveillance.
- Strategic Deliverables:
  - Publication of the **Cosmetic Surveillance GP Inspection Manual**.
  - **6 inspection courses** conducted in partnership with state/municipal surveillance agencies, training **185 professionals**.
  - Publication of the **4th edition of Questions and Answers** for RDC No. 894/2024.
  - **First inspection** of Cosmetic Surveillance GPs after the regulation came into effect.
  - **2,562 notifications** of adverse events related to cosmetics
  - **1,015% increase** compared to 2024
  - Predominance: dental care products
  - **5 investigations** of serious events, resulting in the following regulatory measures: 1 report and 2 safety alerts (hair styling pomades; toothpastes).

RESULTS OF MANAGEMENT

Technovigilance (Medical Devices)

25,277 notifications **were received** in Notivisa

184 involving deaths

1 case with confirmed causality

9 Good Practices in Technovigilance inspections **were carried** out in selected companies

Development of **7 technoscientific materials** in partnership with UFCG

348 Technovigilance Alerts related to field action **were published**

Farmacovigilância (Medicamentos e Insumos Farmacêuticos)

- 58,700 Adverse Drug Reaction (ADR) notifications were received (276 per million inhabitants, exceeding the target of 200 per million inhabitants per year).
- 68 Risk Management Plans (RMP) were analyzed.
- The new strategy for submitting Periodic Benefit-Risk Reports (PBRR) was published.
- 10 Good Pharmacovigilance Practices inspections were carried out.
- 5 medicinal products were analyzed for classification as OTC (over-the-counter) medicines.
- Participation in #MedSafetyWeek.
- The approval of RDC No. 967/2025 made the use of WHODrug mandatory in notifications made in VigiMed by Holders of Marketing Authorization for Medicinal Products from 21 March 2026.
- The migration of notifications from the information system From the São Paulo state Periweb pharmacovigilance system to the national VigiMed system was adjusted, resulting in 38,799 notifications added to VigiMed.
- 8 Pharmacovigilance Alerts and 12 letters to healthcare professionals were published.

Surveillance of Sanitizing Products

17 adverse events were recorded

Notivisa = **12**

e-Notivisa = **5**

140 technical complaints were recorded (Notivisa + e-Notivisa):

Quality deviation = **62**

Suspected product without marketing authorization = **45**

Main effects: allergies and irritations from disinfectants

RESULTS OF MANAGEMENT

Hemovigilance

17,738 notifications **were registered**

EVENT PROFILE
92% non-serious
1,527 serious

59,52% completion rate

TRATAMENTO PELA ANVISA

1,481 serious notifications **were analyzed**

703 mild reactions **were concluded**

923 reports **were issued** to local health authorities

Biovigilance (Cells, Tissues, and Organs – CTO)

552 notifications **were registered**

- Organs = **313 (57%)**
- Cells = **127 (23%)**
- Tissues = **103 (19%)**
- Assisted Human Reproduction = **9 (1%)**

100% notifications **processed** by Anvisa

Analysis and Judgment of Health Administrative Sanctioning Processes

1st Instance
1,290 decisions **were issued**

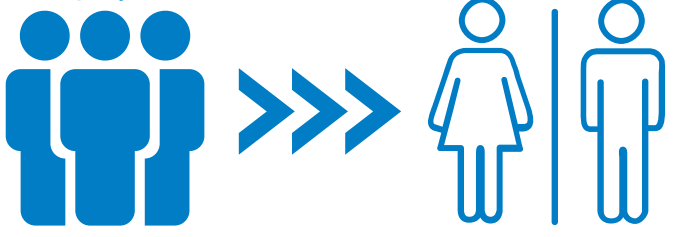
2nd Appeal Instance
846 appeals **were deliberated**

COMPLIANCE AND EFFICIENCY IN MANAGEMENT

HUMAN RESOURCES MANAGEMENT

Anvisa's Workforce:

1,508 employees



Public Competition

The competition for the position of Specialist in Regulation and Health Surveillance was authorized in January 2024 (Notice No. 1). 50 vacancies were offered, filled in 2024, with candidates summoned, appointed, and taking office. In October 2025, a new act authorized the additional provision of 100 positions (Decree No. 12,647/2025), and ANVISA subsequently published a notice summoning those approved for the second stage of the competition (training course – 2nd group).

People Development

In Anvisa´s 2025 People Development Plan (PDP), based on competency assessments, 633 development needs were prioritized. Following prioritization, 2,915 training actions were programmed to develop related knowledge, skills, and attitudes.

845 training actions were carried out → **2.964** certificates Issued → **11.2** certifications per action performed

Ava Visa

38,933 registered users

19,088 enrolled users

7,981 people trained

216 active courses

22% development actions carried out by Anvisa employees

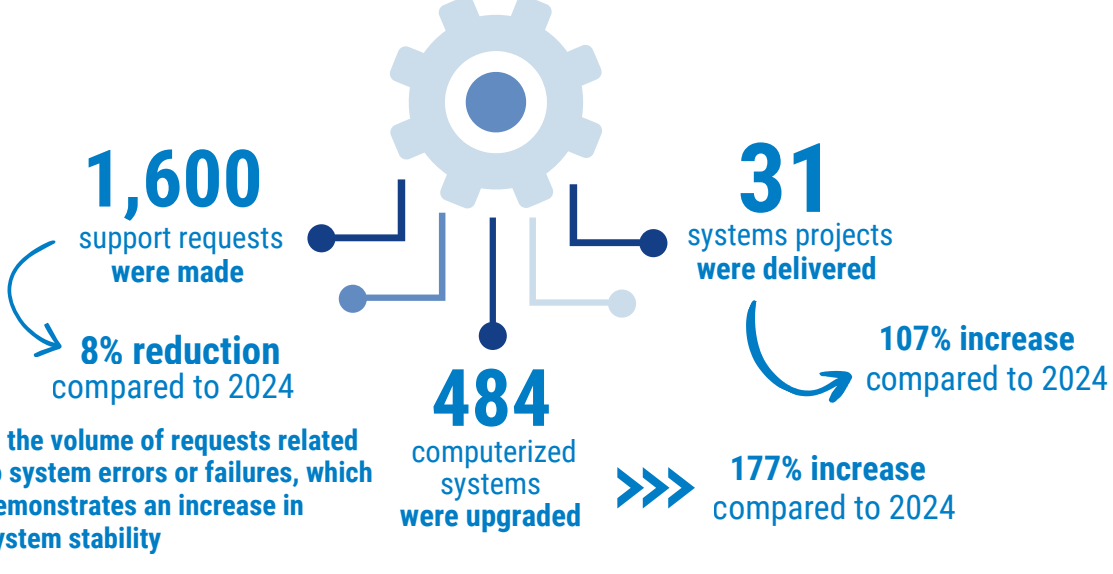
COMPLIANCE AND EFFICIENCY IN MANAGEMENT

People Performance

Ordinance No. 776/2025 regulated Performance Management at Anvisa, covering institutional and individual performance. It brought regulation to issues that were already in practice, such as institutional performance measures, encompassing indicators defined in the Strategic Plan, indicators of digital services, and indicators of external user satisfaction, in addition to management OKRs and process KPIs.

To operationalize the assessment of individual performance, Anvisa chose to use the AvaliaGov application. AvaliaGov is being developed by the Ministry of Management and Innovation in Public Services (MGI) to meet the needs of the various bodies and entities of the Federal Public Administration, unifying the evaluation processes of the different careers of civil servants on the same platform.

INFORMATION TECHNOLOGY MANAGEMENT



BUDGET MANAGEMENT

R$ 1,013 million was committed, corresponding to 98.95% of the available budget. During the same period, expenses paid totaled **R$ 889.7 million**.

Description	2025
UPDATED BUDGET	1.032.026.457
COMMITTED EXPENSES	1.013.480.301
LIQUIDATED EXPENSES	978.278.296
PAID EXPENSES	889.750.134

Source: Treasury Management – 14 January 2026 –SIAFI attribute (Budgetary Unit – Agency)

ANVISA
Agência Nacional de Vigilância Sanitária