Executive Summary

MANAGEMENT REPORT 2022

BRAZILIAN HEALTH REGULATORY AGENCY

A N V I S A

ANVISA
Brazilian Health Regulatory Agency

CHAPTER

1

GOVERNANCE

Organizational Governance

The Brazilian National Health Surveillance Agency (Anvisa) is a national regulatory agency whose operation is linked to the Brazilian Ministry of Health. The Agency's headquarters and jurisdiction are located in the Federal District (DF). The agency operates throughout the whole country, carrying out activities in Ports, Airports, and Borders.

For more information, you can check Anvisa's website.

Mission, Vision and Values

MISSION

To protect and promote the health of the population, by intervening in risks related to the production and use of products and to services subject to health surveillance, in a coordinated and integrated action within the Brazilian Unified Health System.

VISION

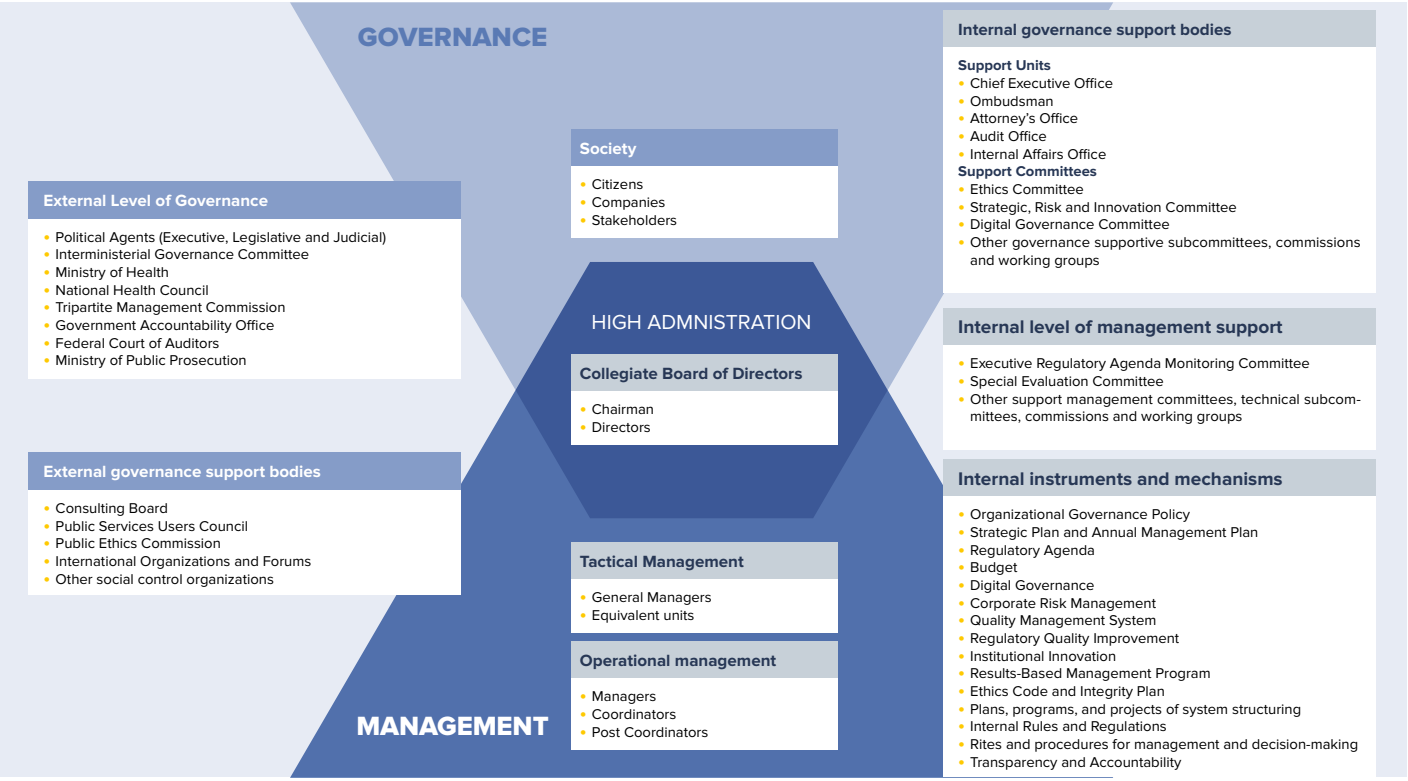
To be an institution that promotes health, citizenship, and development, whose actions are agile, efficient, and transparent, consolidating its national and international role in the field of health regulation and control.

VALUES

- Systemic vision
- Ethics and responsibility
- Transparency and dialogue
- Articulation and integration with the Brazilian Health Surveillance System
- Knowledge as the source of action
- Excellence in service provision to society

System and Policy of Governance and Organization

In 2022 Anvisa undertook a significant revision of its Governance System to improve communication and society's awareness of how the Agency works and the way it is organized. The Governance System includes a broad view that comprises internal and external actions, the main stakeholders, and mechanisms that provide society with positive results, according to an integrated perspective of governance and management.



Anvisa's Governance Policy was enacted for the first time in 2022 (Ordinance No. 60, of January 24, 2022).

The Agency also approved and published the revision of its Integrity Plan e da Corporate Risk Management Policy.

Decision-Making

The Board of Directors is Anvisa's top management collegiate body. It is the highest level of internal governance, being responsible for evaluating, directing, and monitoring the organization.

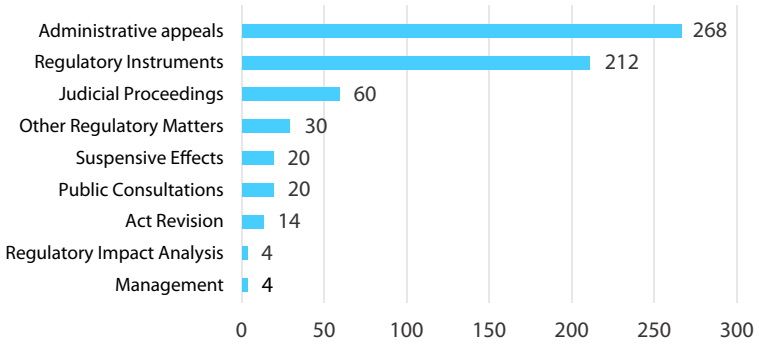
Meetings held in 2022:

46 meetings:

24 regular public meetings
16 extraordinary public meetings
6 closed extraordinary meetings

In addition to in-person meetings, Anvisa has implemented a procedure called Deliberative Circuit (DC), which is a decision-making method that collects votes electronically. In 2022, 1,301 DC meetings were held.

Items dealt with at The Board of Directors' meetings in 2022



Source: Dicol/Anvisa

Strategic Management and Institutional Performance

Strategic Plan 2020-2023

Accordance with government policies and programs

In 2022 Anvisa took part as a pilot body of the Ministry of Economy, within the scope of the TransformaGov Program (a program designed to implement changes in Brazilian government). The program is responsible for defining the methods to be used for strategic alignment with the Brazilian Federal Development Strategy. Thus, the method was used to assess Anvisa's alignment with the Sustainable Development Goals, established in the 2030 Government Agenda.

Strategic Projects

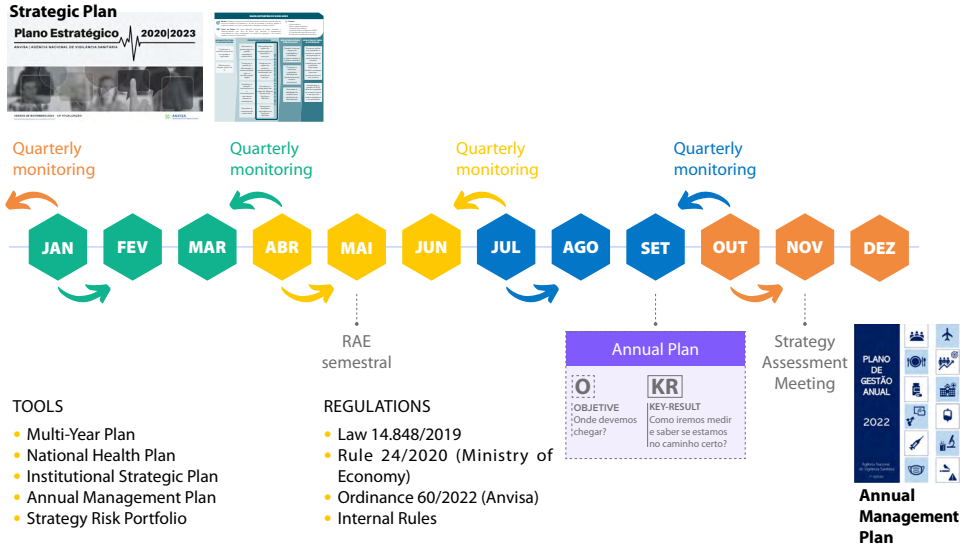
Six new strategic projects were considered a priority to be finished by 2023. Since 2022, Anvisa's strategic-project portfolio contains 17 projects. One of those projects was discontinued.

Annual Management Plan

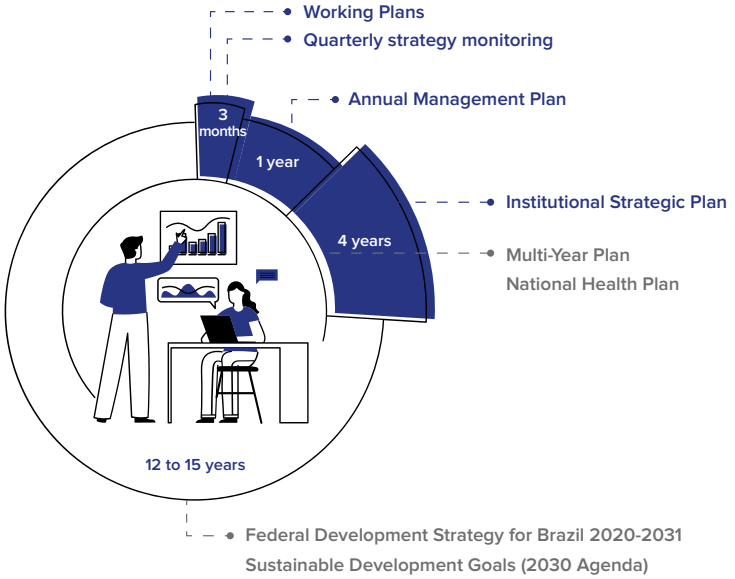
The Annual Management Plan in 2022 started with 41 key-results, some of which were adjusted throughout the year. At the end of December 2022, Anvisa had 40 ongoing key results. All of them have been monitored quarterly, along with the strategic goals and projects of the 2020-2023 Strategic Plan.

Strategy Monitoring

Anvisa's annual planning and strategic management cycle



Strategic alignment: vision of short, medium and long term

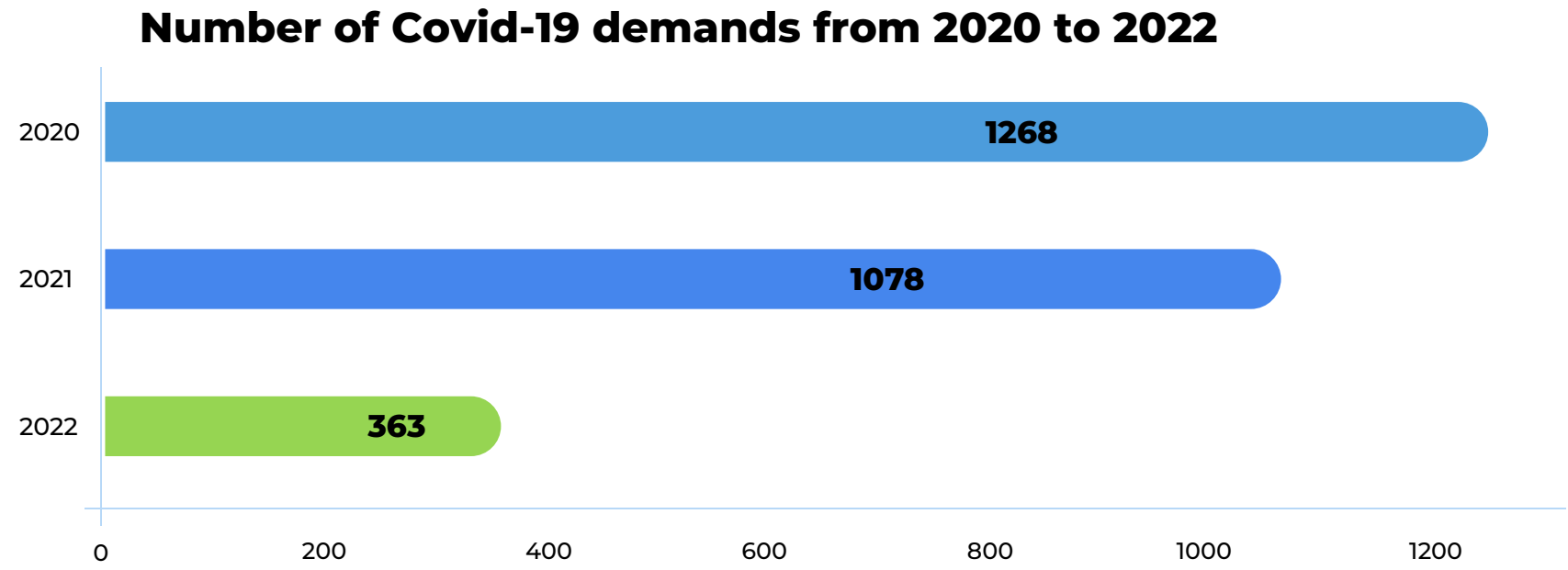


In terms of strategy, an innovation was brought about in 2022 by the Organizational Governance Policy: the implementation of the Strategy Assessment Meetings (SAM). Those meetings are held every six months by the Agency's top-level management to monitor and evaluate strategic actions. The 1st SAM within the 2020-2023 Strategic Plan cycle was held on December 8, 2022.

A level of 74% of the strategy was achieved. This was the best result since the goal was created in 2020. This was possible due to a series of actions to improve the performance of key results, goals, and strategic projects. It was also relevant the work to foster a monitoring culture in the Agency by using the Objectives and Key Results (OKR) methodology.

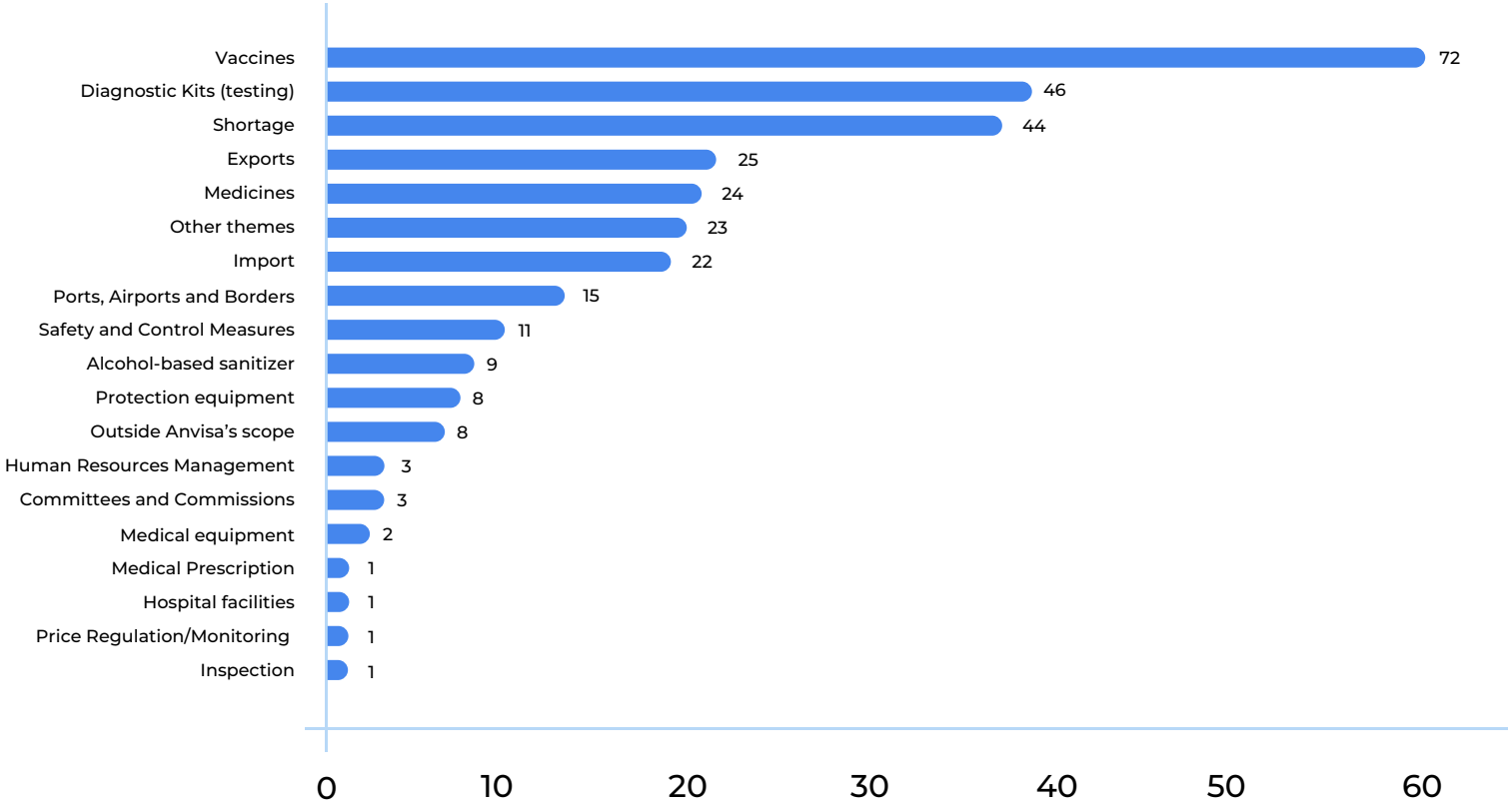
Proceedings Related to the Covid-19 Pandemic

In 2022 Anvisa carried out the analysis and articulation of 158 legislative proposals related to the combat against the Covid-19 pandemic. Two proposals resulted in Law No. 14,305/2022, which created the Covid-19 Pro-Research Priority Program, 'as long as the public health emergency caused by the Covid-19 pandemic continues'. The Agency's work also allowed enaction of Law No. 14,510/2022, which "amends Law No. 8,080/1990 (that authorizes and disciplines the practice of telehealth in national territory), and Law No. 13,146/2015; and repeals Law No. 13,989/2020".



Source: Gadip/Anvisa

Number of demands of Covid-19-related themes



Source: Gadip/Anvisa

Accountability and Institutional Control

Corporate Risk Management

Main achievements in 2022:

- Definition of the corporate risk appetite and tolerance,
- Review of the Corporate Risk Management Policy (CRMP), and
- Updating tools for applying the CRMP Manual in Anvisa's Quality Management System (QMS).

Risk monitoring was undertaken by 91.5% of Anvisa's departments

Concerning the treatment of the risks found, 43% of the controls were considered effective.

Internal Audit

Main achievements in 2022:

- The Agency performed five audit proceedings related to the following subjects: Operation authorization; Product Quality Control; Good Practices Certification; Health Control of Foreign Trade, Ports, Airports, Borders, and Customs Facilities; Budget, Financial and Accounting Management.
- The Internal Audit Department monitored 148 recommendations, some of which were issued during the year and some before.
- A total of 58% of the recommendations were implemented, which resulted in 67 non-financial positive impacts to Anvisa.

Internal Affairs Office

INTERNAL AFFAIRS OUTCOMES IN 2022	AMOUNT
Pending admissibility analysis	80
Admissibility analysis carried out	17
Filings after admissibility analysis	6
Conduct Correction Agreements Proposed	3
Conduct Correction Agreements Reached	1
Corrective proceedings to be started	3
Corrective proceedings in progress	7
Corrective proceedings under trial	9
Fixes or correctional inspections	4 correction measures

Source: Coger/Anvisa

Anvisa's Ethics Committee

- Publishing of the new Ethics Code, which entered in force on May 2, 2022.
- An institutional video was launched, containing the main information about the operation and scope of the Ethics Commission. In addition, the Federal Ethics Management System, launched in November 2022, awarded Anvisa with the maximum score (10) in relation to its prominent level of maturity regarding its internal management of ethics.

Results achieved in 2022:

- Number of services provided: 50
- Number of meetings: 20
- No. of processes related to conflict-of-interest: 22
- Number of processes concerning ethics: 9
- Preliminary proceedings: 8
- Proceeding to investigate ethic matters: 1

Interfederative Articulation and Institutional Relations

Coordination of the National Health Surveillance System (NHSS)

Financing of NHSS bodies in States, the Federal District and Municipalities:

FINANCING METHOD	AMOUNT COMMITTED (BRL)
PF-Visa (states and the Federal District)	BRL 67,208,685.00
PF-Visa (municipalities)	BRL 152,711,305.80
Finnacen-Visa	BRL 23,280,000.00
Finlacen – Visa (INCQS)	BRL 1,800,000.00
PV-Visa	BRL 29,799,980.70
Total	**BRL 274,799,971.50**

The Antimicrobial Resistance Plan (Pan-Visa) Monitoring

The activities stablished in the Antimicrobial Resistance Plan (PAN-VISA) was completely monitored, regarding the execution of the goals contained in the Plan for 2022, with 80.3% of the activities concluded.

Coordination of the Health Analytical Laboratories Network

- 2 courses were offered to the National Health Surveillance System (NHSS) on the AVA-Visa learning platform. The first one was entitled "Good Laboratory Practices", with a workload of 24 hours, and 185 people enrolled in 2022. The second course dealt with the "Basic fundamentals for laboratory analysis in products subject to health surveillance", with a workload of 20 hours and 124 people enrolled in 2022.
- Anvisa identified the training needs of the National Health Surveillance Lab Network (RNLVISA). Altogether Anvisa received 141 training proposal-forms, which will work as a basis for planning the training activities to be offered by the National Institute for Quality Control in Health (INCQS) in 2023.

Citizen Service, Transparency and Social Engagement

Call Center 0800 642 9782

- 185,569 phone calls received.
- 99.21% issues resolved.
- 84.85% user satisfaction.

Webchat Service

- 54,249 services conducted via WebChat.
- 78.08% issues resolved via WebChat.

Chat Channel

- 142,943 requests received through the Chat Channel.
- 36.6% of the total citizen services provided by Anvisa.

Citizen Information Service (CIS-Anvisa)

- 264 face-to-face service conducted via CIS-Anvisa.
- of attendances in relation to the previous year in CIS-Anvisa.
- 96.6% issues resolved.

Fala.BR

- 6,245 requests for information received on the Fala.BR Channel.
- 100% issues resolved via Fala.BR.

Reception Room

- 1,809 hearings held.

Open Data

- 31 databases available on the Federal Government's open data website.
- 6 analytical database panels published externally.

Anvisa Webinars

- 53 webinars conducted.

Social media

- Facebook: 161k followers
- Instagram: 711k followers
- LinkedIn: 160k followers
- YouTube: 32.6k subscribers
- Twitter: 183.5k followers

Ombudsman Office

- 14,160 requests received (20% less than 2021).

*The Fala.BR system started to be adopted to receive all demands in 2022. It has artificial intelligence that helps classifying and directing demands. This avoids mistaken requests/issues/demands to be forwarded to the Agency.

International Relations and Government Articulation

International Cooperation

Technical Cooperation with International Organizations

3 Technical Cooperation Agreements were signed with International Organizations:

- Cooperation Agreement no. 116: "Strengthening the National Health Surveillance System to Promote Access and Universal Health Coverage"
- Cooperation Agreement BRA 10/008: "Structuring Surveillance and Monitoring System for Health Products"
- Project 914BRZ2026: "Developing Anvisa's Human Resources, Technology and Communication".

International programs, projects, and activities

- **The Global Benchmarking Tool (GBT) - Tool developed by WHO for evaluating National Health Authorities regulatory systems:** Anvisa aims to be acknowledged worldwide as a regulatory reference authority. Thus, one of the Agency's main Strategic Projects for the 2020-2023 period is "Anvisa Assessment as a WHO Listed Authority (WLA)". In 2022, Anvisa took part in meetings with the Pan-American Health organization (PAHO), the World Health Organization (WHO), as well as with other regulatory authorities that have already gone through the WHO's appraisal, for the exchange of experience, and negotiations on its operating standards.
- **Regulatory trust:** RDC 741/2022 establishes general criteria, so that Anvisa may consider in its own analysis the information and work developed by Equivalent Foreign Regulatory Authorities (EFRA), which are those authorities reckoned by Anvisa as reliable in the regulatory field.
- **Orbis Project:** In 2022, Anvisa participated in the evaluation of ten indications and approved seven new drug indications through joint evaluation.
- **Harmonization process, regulatory convergence, and international instruments incorporation:** Anvisa sent 41 GMP inspection reports from Brazilian manufacturers to Argentina and Uruguay and received 20 reports from those countries. The Agency conducted regulatory discussions with Argentina, Chile, United States, The United Kingdom, and Uruguay.
- **World Trade Organization:** 62 norms were notified to the Sanitary and Phytosanitary Measures (SPS) Committee; 90 rules were notified to the Technical Barriers Treaty (TBT) Committee.

Highlight

- **Meeting of National Regional Reference Authorities (NRAr/PAHO/WHO)**

Anvisa hosted the meeting in Brasilia on November 29 and 30, resuming activities to expand technical cooperation among the eight authorities and to advance in strengthening the region regulatory capacities.

- **Progress in negotiating bilateral regulatory cooperation agreements with the following authorities**

Actions taken with South Africa, Canada, Colombia, Denmark, Ecuador, United States, WHO and Switzerland.

- **211** technical queries sent to foreign authorities
- **69** technical queries received from foreign authorities

Legislative Power

- **1,076** legislative proposals on health surveillance monitored, 201 of those proposals were mapped in 2022.
- **8 legislative proposals that had been monitored by Anvisa were converted into Law**

Anvisa's participation in public hearings:

- **15** public hearings in the Chamber of Deputies
- **14** public hearings in the Federal Senate

CHAPTER

2

MANAGEMENT RESULTS

Regulation

- **Regulatory Agenda (AR) 2021-2023:** the agenda contains 159 regulatory projects, organized into 16 macro themes comprising Anvisa's activities.
- **Regulatory Proceedings:** Anvisa opened 93 Regulatory Proceeding Documents.
- **Regulatory Impact Analysis (RIA):** 3 RIAs conducted, according to the new standards established by Decree No. 10,411/2020).
- **Regulatory Stock:** The Agency concluded the fifth and last step of a 3-year review and consolidation work, which comprised all regulations and norms. As a result, there was a 52% reduction in the regulatory stock, resulting in 929 norms.

Qualification, Accreditation and Certification

Operating Authorization and Special Authorization Granted to Companies

Operating permit

52,748 Company Operating Authorization and Special Authorization petitions. **49,621** petitions analyzed:

7,426 operating authorizations granted to pharmacies and drugstores

Establishment Authorization to operate in ports, airports, borders and customs facilities

PRIMARY COMPANY OPERATING AUTHORIZATION PETITIONS FROM COMPANIES THAT RENDER SERVICES IN PORTS, AIRPORTS, AND BORDERS (PAB) IN THE YEAR 2022				
Service rendered	**Number of primary petitions**	**Number of approvals published**	**Number of rejections published**	**Average time for publication (days)***
Storage of goods subject to health surveillance in PAB	24	14	0	113
Import preceded by predetermined intermediation	63	46	1	48
Other services of public health interest in PAB	342	111	35	102

Good Practice Certification

- 92 inspections aimed at granting the Good Manufacturing Practices Certification (GMPC) in national territory and 208 inspections in foreign territory
- • 2,976 Good Manufacturing Practices Certifications (GMPC) granted, 602 nationally and 2,374 internationally
- • 538 Good Distribution and Storage Practices Certifications (GDSPC) granted in national territory
- • 300 inspections for GMPC purposes. The number of national and international inspections increased significantly in 2022 compared to the previous year. In 2021 175 inspections were conducted. The increase is due to the end of the Public Health Emergency of International Concern (PHEIC)

Certificate of Good Manufacturing Practices for Advanced Therapy Products

In 2022, Anvisa resumed inspections for GMP, in order to verify Advanced Therapy Products (ATP). Those inspections had been paused during the Covid-19 pandemic. Five inspections were carried out in foreign territory, resulting in 15 ATP GMPC. This number was much higher than what was achieved in previous years (4 GMPC in 2020 and none in 2021).

International Audit

In 2022, Anvisa remained listed among the health authorities with equivalent status to the European Union standards, regarding Active Pharmaceutical Ingredients (APIs). The equivalence was assessed by the international audit carried out in April 2022: Importation of active substances - Listing of third countries.

Qualification, Accreditation and Certification of Laboratories and Research Centers

- 89 petitions were analyzed for the purpose of qualification of the Brazilian Network of Health Analytical Laboratories (in Portuguese: Reblas). Anvisa achieved an average time of 24 days from the submission of the petition to an effective decision or discontinuation, which shows a decrease in the average analysis time (in 2021 it took 26 days in average).

Product Regulation

Medicines

Clinical trials

- 308 clinical trial petitions were submitted, 302 of which were evaluated, including requests submitted in 2022 and requests from the previous year.
- Clinical trials for rare diseases accounted for about one third (103 clinical trials) of all clinical trials evaluated in 2022.

Assistance Programs Authorization

- Compassionate use: 106
- • Expanded access: 06
- • Post-study supply: 51

Drug Authorization

- 635 requests for the registration of cannabis drugs and products were analyzed. More than 90% of them were approved.

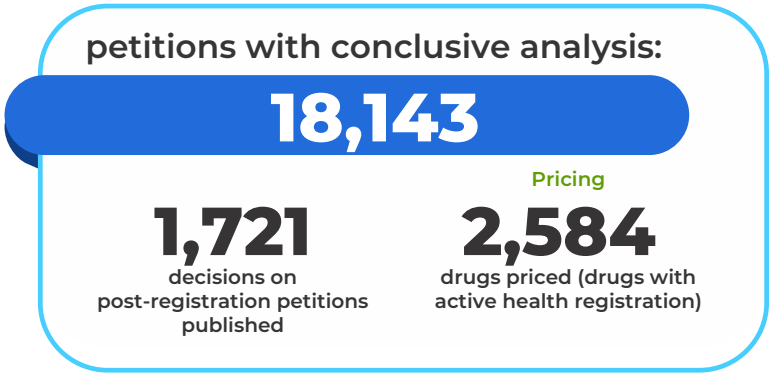
Registration of drugs for rare diseases

- 4 granted registrations of drugs for rare diseases.

Evolution of Liabilities

The liability of drug registration (registration requests not yet analyzed) has reduced considerably in the last 5 years. This is particularly due to the reduction in the waiting queue for the registration of drugs under simplified procedure, which reduced from 486 in 2018 to 74 in 2022.

Post-registration changes



Biological Products and Advanced Therapy Products

Biological Product Authorizations

- 34 concluded analysis of registration requests, 28 requests granted
- 8 registrations granted, 15 of them related to new molecules in the country, accounting for new treatment opportunities for the population.

Radiopharmaceuticals Authorizations

- 5 new authorized products.

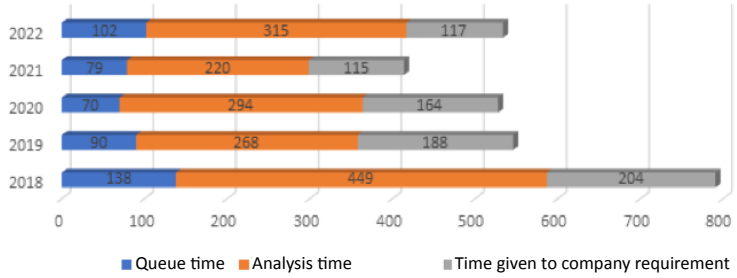
Advanced Therapy Products Authorizations

- 3 new authorized Advanced Therapy Products.
- The average time Anvisa takes to approve Advanced Therapy Products registrations is similar or shorter than the time taken by the Food and Drugs Administration (FDA), with an average analysis time of 265 days, and by the European Medicines Agency (EMA), with an average time of 325 days.

Clinical Trial Dossier with Investigational Advanced Medicinal Product

- 20 clinical trial dossiers submitted.

Average analysis time: biological products registration



post-registration petitions

60% **increase in the conclusion of post-registration petitions compared to 2021**

Actions to Response Threats to Public Health: Covid-19

Vaccines Timeline

- December 7 – approval of the booster dose Comirnaty vaccine (Pfizer), for children aged 5 years and older and for adolescents.
- November 22 – emergency use authorization for the bivalent versions of the Comirnaty vaccine, with higher specificity for the Omicron variant.
- September 16 – approved the use of the Comirnaty vaccine for children aged 6 months-4 years old.
- July 13 – approved the temporary and emergency use of the CoronaVac vaccine (Butantan Institute) for children aged 3-5 years old.
- April 5 – approved the definitive registration of the Janssen vaccine, which had been authorized on a temporary and emergency basis since March 31, 2021.
- January 20 – Expanded the use of the CoronaVac vaccine to include the population between 6 and 17 years old.
- January 7 – approved the production of the Fiocruz Covid-19 vaccine ingredient, allowing the manufacture of a 100% national vaccine.

Two new vaccine registration requests were submitted and are still under review:

- July 9 – request for the definitive registration of the Coronavac vaccine (Instituto Butantan).
- May 12 – Request for the registration of the Convidecia vaccine, produced by the Chinese company CanSino, represented in Brazil by Biomm S.A.

Biological Products Timeline

Evusheld (cilgavimabe + tixagevimabe), developed by Astrazeneca:

- February 24 – approved the emergency use for the prophylaxis in immunocompromised individuals or for people to whom vaccination is not recommended.
- Dezember 16 – new therapeutic indication approved for the treatment of Covid-19.

Monkeypox

- Anvisa published Resolution RDC 747, allowing the temporary registration-exemption of products acquired by the Ministry of Health for the prevention or treatment of Monkeypox.

Exemptions granted:

- Jynneos vaccine (also called Imvanex), manufactured by Bavarian Nordic, for the prevention of Monkeypox in adults aged 18 years and older.

Food

- 88 new products registered, 45% of them referring to children food
- 230 concluded post-registration petitions
- 225 concluded safety and efficacy assessment petitions

Health Products

- 7,811 new medical devices authorized for marketing
- 218 new orthopedic implants rectified
- 4,844 new health materials rectified
- 1,490 new in vitro diagnostic devices rectified
- 1,259 new health equipment rectified

Cosmetics and Sanitizing

- 3,255 verified cosmetic and sanitizing products exempt from registration, of which 1,500 accounted for cosmetics and 1,755 accounted for sanitizing products.
- 73,999 registration-exempt cosmetic products rectified
- 445 cosmetics registration processes granted
- 373 post-registration petitions for cosmetics granted
- 3,136 cosmetics certificates issued
- 4,435 registration-exempt sanitizing products rectified
- 697 registration processes for sanitizing agents granted
- 802 post-registration of sanitizing products granted
- 738 sanitizing agents free-trade certificates issued
- 25 sanitizing agents export-certificates issued

Pesticides

- 782 registration petitions granted
- 672 post-registration petitions granted
- 495 temporary special registration petitions concluded

Tobacco Products

- 84 new tobacco products rectified
- 114 products registered for export

Monitoring, Inspection and Health Control

Products and Services Health Risk Monitoring

Products

Technovigilance: 3,479 adverse events notifications and 14,234 technical complaints notifications.

Pharmacovigilance: face-to-face inspections were resumed, to check good pharmacovigilance practices at facilities of companies that hold drug registrations. Priority was given to companies holding registration of medicines and vaccines against Covid-19. Altogether 8 inspections were carried out.

Biovigilance: 249 adverse events reports

Hemovigilance: 16,544 adverse events notifications

Cosmetovigilance: 56 adverse events reports

Sanitizing Surveillance: 17 adverse events reports

Nutrivigilance: 43 adverse events and technical complaints notifications

Risk Announcements, Safety Alerts and Letters to Healthcare Professionals

» Safety Alerts: 261

Surveillance of Controlled Products:

» In 2022, 193 authorizations were issued for the prescription of thalidomide, regarding indications not included in the package leaflet.

Blood, Tissues, Cells and Organs

» 842 risk assessments and/or inspection reports carried out by the National Health Surveillance System and received by Anvisa

» 12 facilities prioritized to monitor adjustments after inspection conducted by Anvisa

» 15 facilities inspected by Anvisa

» 139 authorization requests analyzed for interstate transport of blood and components

Sentinel Network

» 18 classes of the course *Quality in Health Services with Tele simulation*

Health Services

Health Regulation and Control

» Two joint inspections conducted with state health surveillance organs (one with the Federal District/DF and another one with Espírito Santo/ES)

» 8 publications (1 Collegiate Board Resolution and 7 Regulatory Instructions)

Surveillance and Monitoring

» 42 indicators related to Healthcare-Associated Infections (HAI) and Microbial Resistance (MR)

» on-site technical support and surveillance actions to control 5 outbreaks, in the states of Espírito Santo, Mato Grosso, Pernambuco, Ceará and Rondônia

Patient safety

» 123 notifications received

Health Care-Related Adverse Events Monitoring

» 266,704 notifications health care-related events received in the Notivisa system

Procedures to follow-up complaints about Health Services and other Health-Related Services

» 97 complaints about health services sent either to the Ombudsman office or to other public service channels

» • health services most complained: hospitals (23.94%); outpatient services (14.08%); ICU and emergency rooms (9.85%)

» • 76 complaints about health-related services

» • health-related services most complained: aesthetics services (54.5%), beauty services

» hotels (13.6%) and Long Stay Institutions for the Elderly (9.1%)

Customer Service

» 1,136 responses given by the Citizen Information Service

» subjects with higher number of technical doubts: equipment and materials (124 requests), professional practice (103 requests) and waste disposal (91 requests)

Economic Monitoring of Medicines and Medical Devices

Drug Market Monitoring

- 163 complaints related to infringement of the price of medicines in public procurements and 18 complaints involving private purchases
- 254 Sanctioning Administrative Proceedings started
- 252 decisions issued, 250 of which were condemnatory and 2 were acquittals
- BRL 71,775,768.10 was the total in fines enforced

Foreign Trade and Facilities Health Control at Ports, Airports, Borders and Customs Areas

- 1,577 cargo inspections (on-site and remote inspections).
- 2,728 inspections at Facilities, Services and Aircraft
- 2,130 health risk assessment actions on vessels
- 363,236 import licenses granted
- 204,860 analyzed import/export requests for the “Express Shipping” category. 133,494 of those were related to imports and 71,366 were related to exports.
- 281 technical consent reports for import shipments of semen, oocytes, embryos for Assisted Human Reproduction (AHR) and

Hematopoietic Progenitor Cells (HPC) for unrelated donor bone marrow transplantation

- 5 technical opinions of consent for the export of plasma to produce blood products
- 528,608 International Certificates of Vaccination or Prophylaxis (ICVP) issued. Compared to 2021, this number shows an increase of 42.1%. There was a 38.7% increase in digital certificates and 53.0% in the number of in-person certificates.
- 2,275 Public Health Events (PHE), most of them (92%) related to Covid-19
- 217 Health Administrative Processes started
- 88,115 petitions analyzed for national and international trade of substances, drugs, and products under special control
- 5,961 import license authorizations for substances, drugs, and products under special control
- 106,441 import processes conducted by individuals, 103,466 (97.2%) accounted for cannabidiol-based products imports

Product Quality Control

- 41,347 analyzes conducted
- 11,1176 fiscal conformity analyzes performed

Fiscal conformity analyzes conducted by official laboratories

- 9,290 foodstuffs
- 211 cosmetics, personal care products and perfumes
- 34 diagnostic kits and reagents
- 131 drugs
- 87 health products
- 410 sanitizers
- 149 water
- 864 dialysis facilities

Inspection and Sanitary Infringement Assessment

Product Inspection

- 553 Sanitary Administrative Proceedings opened
- 489 accounted people charged
- 797 health violations registered
- 67 investigative inspections carried out
- 1363 investigation dossiers opened
- 959 research dossiers concluded
- 725 measures published
- BRL 90,900,240.00 is the estimated sum of fines applied
- 103 complaints received related to tobacco products

Inspection of internet products under health surveillance

The following data refer to the innovative project called Irregular Products Exclusion from the Internet (IPEI), designed by Anvisa, in partnership with the UNDP. The project aims at conducting artificial intelligence inspections of products under health surveillance, which are sold illegally on the internet.

- about 90,000 irregular products identified
- + 85,500 notifications
- 1,000+ different internet domains notified
- 99% of content removed
- 32% of the removed irregular content was related to dietary supplements
- 722 ads referring to tobacco products removed, 600 of the ads were about electronic smoking devices, posted on Facebook and Instagram

CHAPTER

3

MANAGEMENT ADEQUACY AND EFFICIENCY

Management

Human Resources Management

Legal compliance

Payroll Management

- Analysis and detection of several inconsistencies identified by the audit diagnoses conducted by the Ministry of Economy Management and Personnel Performance Secretariat. The purpose of the analysis was to qualify the data related to active civil servants, retirees and civil pension beneficiaries who are registered in the Federal Public Administration human resources systems.
- Creation of a tool for sharing and updating the workflow to forward, control, and monitor the demands from the Brazilian Federal Audit Court. The demands were related to human resources management proceedings which have been analyzed by the Federal Audit Court as well as payroll auditions conducted by the Court.
- Creation of a tool for sharing and updating the workflow to forward, control, and monitor the findings and identification of non-compliance. The tool helps to conduct a thorough analysis/audit of the workflow payment and registration, or to analyze and confirm data inconsistency regarding registration and financial records, as identified by the Ministry of Economy Management and Personnel Performance Secretariat.

Conformity assessment

- Number of Administrative Processes: 22
- Reimbursement amount paid to the Brazilian Public Treasury: BRL 132,643.28

Workforce Assessment

- Number of active civil servants: 1,604 (709 male and 895 female)
- Civil servants working in the management field: 372
- Civil servants working in specific fields: 1,232
- 86% of managerial positions are occupied by public officials

Recruiting strategy

- 7 recruitment processes conducted
- 95 internal position/job swaps analyzed
- 194 interns hired
- 119 vacant positions
- 9% lag of the number of civil servants in relation to the total of positions established in Law 10,871/2004

Performance rewarding strategy

- Strategic communication actions: telework good practices addressing 11 topics; knowledge pills with 6 articles
- Launch of the Human Resources Development Plan Management System. The tool was developed within the Health Surveillance Virtual Learning Environment (in Portuguese: AVA Visa). The system was made available after the 2nd revision of the 2022 People Development Plan.

Results-Oriented Management Program

- Implementation of a new computing system to manage servants' productivity. The system was implemented on January 1st, 2022.
- 991 people under the program: 819 in full-time telework, 170 in partial time telework and 2 people working on-site

Qualification and training

- 88 training courses designed at the Health Surveillance Virtual Learning Environment (AVA Visa)
- 3,341 courses concluded in the AVA Visa environment, considering all available user profiles
- 22 courses offered on Regulatory Impact Analysis (RIA)
- 189 servants took individual training courses, free of charge, in government schools and other institutions

- 76 servants enrolled in the Foreign Language Program, 70 of them were accepted
- 9 out of 13 requests for sabbatical leave to attend postgraduate programs were granted.

Appreciation of Working Environment and Conditions

- 260 services
- 17 actions such as chat sessions, podcasts, welfare campaigns and workshops

Civil Servant Health Care Integrated Subsystem (in Portuguese: SIASS) and Occupational Safety

- 1,079 medical assessments carried out
- 889 on leave civil servants
- 12,321 occupational safety assessments undertaken

Actions to combat Coronavirus

- No testing strategies were adopted towards employees. Only 43 workers underwent RT-PCR tests to meet international boarding rules during international missions.
- 91 Covid-19 cases notified, 435 of them were confirmed.

Organizational Processes Management

Organizational Processes

- Alignment of the Agency's organizational processes to WHO's focus areas – medicines and vaccines. This alignment was established to meet the requirements of the Global Benchmarking Tools (GBT) evaluation model.
- Incorporation of organizational processes as items of the Agency's corporate risk management. For that reason, Anvisa carried out a revision of Ordinance No. 1,211, of December 19, 2022.

Quality management

- In 2022, Anvisa started to implement its Quality Management System (QMS)
- Enactment of Anvisa's Quality Policy: Ordinance No. 1,032/2022
- Institution of the Quality Officials Network and appointment of officials by means of Ordinance No. 608/Anvisa
- Anvisa's Quality Policy documents approved: 1 manual, 2 management proceedings, 2 quality proceedings and 4 final proceedings, and 23 forms
- Review of Anvisa's plan for becoming a WHO reference authority
- Quality Management System implementation initiated

Information Technology Management

- 306 services were mapped considering the citizen's point of view

DIGITAL SERVICES DELIVERED TO SOCIETY

Pharmacies and Drugstores

- **Operating Permit for Drugstores and Pharmacies:**
  Automation with the Federal Revenue database

Medicines

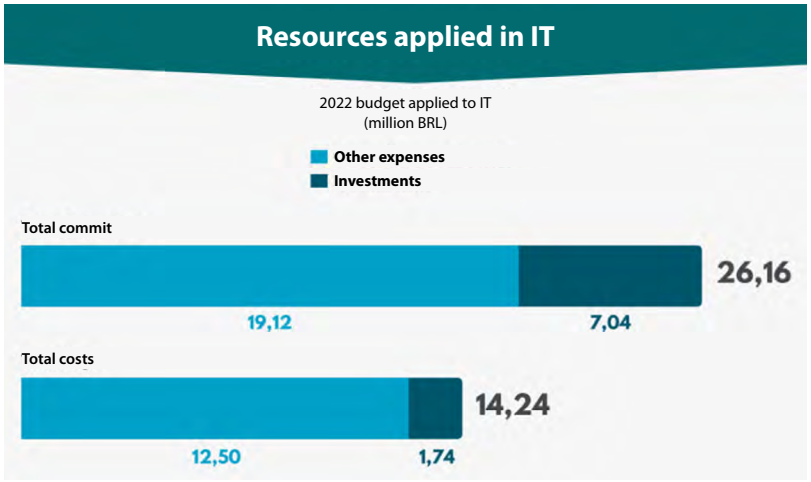
- **Active Pharmaceutical Ingredient Registration and Active Pharmaceutical Ingredient Dossier:**
  Application service was digitalized
- **Drug manufacturing discontinuation:**
  Physical process was digitalized.

Health Products

- **Health products registration:**
  Improvements to make it easier for companies to fill in the forms and to speed up the analysis by Anvisa technicians
- **Health-product-price monitoring:**
  The process was standardized to improve the price management of health products

Social control and digital safety

- **Incorporation of 35 services to the assessment of age retirement:**
  It allowed monitoring the quality of Anvisa services
- **2 open data panels:**
  Embryo Production National System Panel and Hemovigilance Notifications Panel
- **Services rendered to the Information Safety and Privacy Program**



Digital Transformation Plan

- 250 services transformed, which represents 81% of the total of services to be transformed
- For the 3rd consecutive year, Anvisa continues to be the leader in the general agencies ranking of digital transformation

Infrastructure Improvements:

- **286** situations handled
- **20** ongoing upgrade and modernization projects
- **19** service hirings, contract renewals, or new acquisitions in progress

Support:

- out of 9,998 requests, **97.04%** were classified as **"satisfactory"** or **"very satisfactory"**.

Information safety

Anvisa takes part in the Privacy and Information Safety Program (PISP). The aim of this program is to raise the level of maturity of Federal Government bodies and entities, in terms of personal data protection and information safety actions. During 2022, the Vulnerability Management Policy was designed, the Asset Management Policy was implemented. Besides that, the double authentication factor was implemented to access the Virtual Private Network (VPN) and information was collected for implementing the General Data Protection Law (GDPL).

274 "nothing on record" statements issued

238 digital certificates requests answered

138 vulnerability scans completed

10 corporate systems inactivated due to safety vulnerabilities

9 corporate systems with improved access safety

4 services delivered to the Privacy and Information Safety Program

3 standards revised

Communication Management

- News published on Anvisa's website: 645
- Press inquiries received: 3,236
- Norms and regulations published: 7,886

Budgetary, Financial and Accounting Management

- 84.7% % of the budget was implemented.
- Management of fines: 886 fines were issued, corresponding to 87 million BRL.

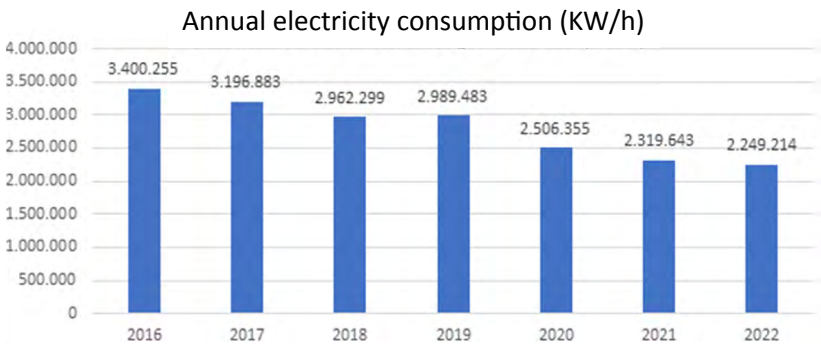
Procurement and Logistics Management

Relevant changes

- Relocation of the Paranaguá Post, ending the previous rental agreement and changing its address to facilities offered by the Federal Revenue Service in Paranaguá port.
- Collaboration with other Anvisa posts to vacate properties, such as Maranhão Post and Ceará Post. Both posts are now occupying facilities at São Luis and Fortaleza airports, respectively.

Environmental Sustainability

- **Economic dimension:** The year 2022 was marked by the consolidation in the use of the virtual warehouse nationwide, for the acquisition of material for administrative consumption. 291 orders were fulfilled with a total value in the virtual warehouse in 2022 of BRL 318,878.16.
- **Enviromental dimension:** the terms of reference and contracts managed by Anvisa provide for the selective disposal of waste and the requirement for a Certificate of Final Disposal for electronic waste. Also, the application of measures to reduce the consumption of electricity and water continues and, in 2022, the reduction in consumption of these two items has reduced over the years, including in relation to the years before the Covid-19 pandemic.



- **Social dimension:** observation of safety and hygiene standards at work; adoption of good practices for electricity consumption, water consumption, solid waste, selective collection and safety at work; encouraging the hiring of people who live in the surrounding area, through the adoption, in the planning, of the average ticket price including values for transport in the surrounding area.

Public bids and contracts

- Number of contracts signed: 84
- Total amount allocated in contracts: BRL 140,415,567.39
- Number of online auctions held: 29
- Total amount allocated in online auctions: BRL 87,217,390.02
- Number of contracts signed directly with suppliers: 55
- Total amount allocated in direct contracts: BRL 53,198,177.37
- Number of contracts that do not compel bid proceedings: 46
- Number of contracts dispensing bid proceedings: 9
- Number of contracts signed for training courses: 30

Information, Research and Knowledge Management

Management of documents and corporate memory

- **Management of documents and corporate memory:** maintenance of 186,000 boxes containing registration and post-registration documents.
- **Digital Library:** In 2022, the Digital Library added 2,662 new contents. The Brazilian Pharmacopoeia monographs are now available for consultation.
- **Data Governance, Science, and Intelligence:**
  - » 25 data intelligence solutions rendered
  - » 112 servers trained in data analysis and science
  - » 14 servers trained in analytical tools
  - » 45 civil servants (Anvisa, Ministry of Health and health surveillance organs in states and municipalities) attended post-graduation courses in Data Science and Artificial Intelligence

Brazilian Pharmacopoeia

- **Collegiate Board of the Brazilian Pharmacopoeia:** 2 new Working Groups (EG) were created: the Group for Correlation In vivo / In vitro, and the Group for Monocyte Activation Test (an alternative method to the use of animals in research)
- **Public consultations:** contribution to 10 (ten) public consultations sent by the World Health Organization
- **Brazilian Pharmacopoeia: 6**2 new Common Brazilian Nomenclatures (CBN) were approved and 4 CBNs were updated. Important to highlight the recombinant and inactivated Covid-19 vaccine, the bivalent Covid-19 vaccine (recombinant) and the Molnupinavir Covid-19 antiviral drug. It is also noteworthy the CBN definition of the chikungunya vaccine (recombinant and attenuated) and the tecovirimat nomenclature, applicable to the treatment of monkeypox disease.
- **Standard Chemical Substances Program of the Brazilian Pharmacopoeia:** 758 flasks of Standard Substances were distributed. Out of those samples, 674 flasks were sold and 84 were donated to official laboratories. The total amount collected: BRL 256,120.00.

Judicial Affairs Activities

- 5,370 1st instance administrative appeals received. Out of those, 160 decisions were reconsidered. This number accounts for 3% of the total administrative appeals submitted to Anvisa.
- 3,480 2nd instance administrative appeals were pr0ocessed for analysis and judgment.
- Judged appeals: 2,402 1st instance appeals, and 410 2nd instance appeals were judged.
- More than 426 legal advice documents were issued, helping technical departments to reach correct decisions.
- Legal defense parameters were established in about 300 lawsuits in which Anvisa is either a party or an interested party.
- The judicial success rate is close to 75%, the same rate reached in 2021.

CHAPTER

4

FINANCIAL STATEMENTS

Budgetary, Financial and Accounting Information

- **Equity Result:** BRL 10.76 million in surplus.
- **Financial Result on the Balance Sheet (available cash):** BRL 27.3 million in deficit.
- **Budget Result:** BRL 283.81 million in deficit.

ANVISA
Agência Nacional de Vigilância Sanitária

MINISTÉRIO DA SAÚDE

GOVERNO FEDERAL
BRASIL
UNIÃO E RECONSTRUÇÃO