MANAGEMENT RESULTS

PRE-MARKET

DRUGS

10 new treatments for rare diseases
24 first-time generic drugs
04 new biosimilar products
21 new therapeutic options
19 innovating drugs
187 reference drugs
Total authorized: **827**

HEALTH PRODUCTS

1,106 new products authorized **4,674** new products registered

FOOD

911 authorization requests analyzed
111 post-authorization requests analyzed

SANITIZERS

1,027 new products authorized
5,324 new products exempt of authorization
13 inclusions of active ingredient monograph for household cleaning products

COSMETICS

1,356 new products authorized **50,679** new products exempt of authorization

BLOOD, CELLS, TISSUES, AND ORGANS

190 reports issued for the import of cells and embryos
37 inspections conducted

40 interstate transportation requests analyzed

CANNABIDIOL

3,610 import and authorization requests granted

SMOKING PRODUCTS

1,426 requests analyzed

PESTICIDES

106 inclusions/ alterations of active ingredient monographs
94 toxicological assessment processes analyzed
4 toxicological re-assessments of active ingredients

Medicamento Genérico

18 years of registration

REDUCTION IN THE QUEUE FOR ANALYSIS

End of the queue for the authorization of generic and similar drugs

95% reduction on the authorization of active pharmaceutical ingredients

End of the queue for food authorization and post-authorization

Time average for the first manifestation regarding requests for the authorization of food reduced to 55 days

Time average for the first manifestation regarding requests for the post-authorization of food significantly reduced reduced to 87 days

88% of the health product authorization processes had their first manifestation in up to 90 days

96% of health product submission processes with first manifestation in up 90 days

POST-MARKET

COMPLAINTS ANALYZED

355 health interest services

241 drug pricing practices (63.9% already completed)

140 penalties applied for violations of drug pricing practices

170 health infraction notices recorded on smoking products

FISCALIZATION

953 investigation files opened

781 investigation files completed

408 resolutions published

PORTS, AIRPORTS, AND BORDERS

823,498 International Certificates of Vaccination and Prophylaxis issued

9,135 inspections performed in facilities, services, and means of transportation

390 public health events registered

Reduction of the time frame for import license: 5 to 10 days, on average

ADVERSE EVENTS ANALYZED

11,810 related to drugs

202 related to vaccines

124 related to the therapeutic use of human cells, tissues, and organs

61 related to cosmetics

13 related to sanitizers

44 related to food

3,975 related to health products

15,570
notifications of reactions to transfusions analyzed, of which

73%
have already been completed

TECHNICAL COMPLAINTS ANALYZED

28 related to food

13,227 related to health products

309
alerts issued on health products

National Registry of Implants (RNI)

Launch of the RNI, system for the registration of surgical procedures of osteoarticular prosthesis (hip and knee) and coronary stent implantation. It will improve the the regulation of such products and indicate the best therapeutic conduct and the most appropriate materials.

VigiMed

Launch of VigiMed system, which will facilitate the notification of adverse events related to the use of drugs and vaccines, and will contribute to the monitoring of such products in Brazil.

REGULATION

NORMS

12 norms edited with expected monitoring indicators of the **29** norms published in the year

Expectation that **18%** of the regulatory stock will be eliminated by the guillotine

PILOT-STUDIES

RDC no. 183/2017 regulatory result assessment

Administrative burden measurement of RDC no. 185/2006

PUBLIC CONSULTATIONS

44 on the building of regulatory instruments

2 on the evidences of regulatory actions

9 on the need of revisions to guidelines

DIALOGUES

1st Public Information Gathering for the assessment of the regulatory impact of a norm on for nutrition labelling of food

7 sectoral dialogues on the regulatory process

MAIN RESOLUTIONS

Regulation of food supplements - RDC no. 239/2018, RDC no. 240/2018, RDC no. 241/2018, RDC no. 242/2018, RDC no. 243/2018, IN no. 28/2018

Improved traceability in the use of stents for coronary arteries, pharmacological stents for coronary arteries, implants for hip and knee arthroplasty - RDC no. 232/2018

New rules for toxicological re-assessment of the active ingredients of pesticides - RDC no. 221/2018

New rules for display and commercialization display and commercialization of tobacco-derivative smoke products - RDC no. 213/2018

New rules for the use of human cells in therapeutic procedures and clinical research - RDC no. 214/2018

New rules for waste management in health services - RDC no. 222/2018

Increased access to imported goods and products subject to health surveillance - RDC no. 208/2018, RDC no. 228/2018

Qualification of health surveillance actions - RDC no. 207/2018

SNVS COORDINATION

R$ 265 million available to finance health surveillance actions

218 courses offered, with particular emphasis on the Health Surveillance Introduction Course at the Government Virtual School, more than **9,000** professionals trained

COMPLIANCE AND MANAGEMENT EFFICIENCY

- Execution of **94.3% of the budget**
- **868 fines** for health infraction

- **40** corporate training events for civil servants

- Elimination of **1,408** linear meters of documents that have complied with the legal custody time limits
- **8,211,158** document pages scanned, mitigating the risk of loss and generating greater accessibility

INFORMATION TECHNOLOGY

Implementation of the Toxicology Petition System (Siptox)

Improvement in the Electronic Petition System

Implementation of the International Certificate of Vaccination or Prophylaxis Issue System (Civnet)

Improvement in the Parlatory System

Improvement in the Market Monitoring System for Medicinal Products (SAMMED)

Automation of the Electronic Surveillance File

INNOVATION

- Launch of Anvisa Innovation Program
- Inauguration of Anvisa Innovation Laboratory (Lab-i Visa)
- Creation of the *Design Thinking Facilitators Network*
- Launch of the Innovation Toolkit
- Launch of the ACELERA Program

KNOWLEDGE EXCHANGE

4 meetings with industry and academia, which gathered approximately **1,200 participants**

13 meetings with innovative and emerging technology developing centers

SCIENTIFIC SUPPORT

16 contracts for scientific research

7 experimental studies conducted

65 *ad hoc* reports, totaling **332** studies

12 projects

Ordinance no. 1,440/2018
new Information and Communication Security Policy (Posic)

Ordinance no. 343/2018
improvement in the contracting planning

ANVISA'S GOVERNANCE

Anvisa is an autarchy linked to the Ministry of Health, with administrative independence, stability of its directors and financial autonomy. It is part of the Unified Health System (SUS) as the coordinator of the National Health Surveillance System (SNVS), and is active throughout the Brazilian territory through the coordinations of ports, airports, and borders (PAF) and customs offices.

MISSION

To protect and promote the health of the population by intervening in the risks associated with production and use of products and services subject to health surveillance, in a coordinated and integrated action within the framework of the Unified Health System (SUS).

VISION

To be an institution that promotes health, citizenship, and development, that operates in an agile, efficient, and transparent manner, consolidating itself as a leading actor in the field of regulation and health control, both national and internationally.

VALUES

- Ethics and responsibility as a public agent.
- Interaction and integration capability.
- Excellence in management, with focus on results.
- Knowledge as a source for action.
- Transparency.

STRATEGIC PLANNING

ANVISA's strategic planning cycle for 2016-2019 includes 9 strategic objectives. The strategic objectives guide Anvisa's performance and relate to the vision range and the strategic guidelines of the organization.

1. To broaden the safe access of the population to products and services subject to health surveillance.
2. Improve the regulatory framework on health surveillance.
3. Optimize pre-market actions, based on health risk assessment.
4. Improve post-use surveillance actions, focusing on control and monitoring.
5. Strengthen the coordination actions of the SNVS.
6. Increase the efficiency of PAF operations.
7. Improve cooperation and regulatory convergence actions at international level.
8. Implement a governance model that promotes integration, innovation, and institutional development.
9. Strengthen education and communication actions in health surveillance and the institutional relationship model.

13 STRATEGIC PROJECTS

38 STRATEGIC TARGETS

INTEGRITY PLAN 2018-2019

Anvisa has been a forerunner in joining to the Public Integrity Promotion Program (Profip) and in the elaboration and implementation of the Integrity Program. The first Integrity Plan of the Agency, established for the period of 2018-2019, embeds the risk of integrity in the Corporate Risk Management Process.

INTERNATIONAL LEADING PERFORMANCE

Anvisa has signed 36 international cooperation agreements. In 2018, 18 international cooperation activities were developed within the framework of the partnerships signed, both old and new ones.

TECHNICAL INFORMATION

DIRECTOR-PRESIDENT
William Dib

DIRECTORS
Renato Alencar Porto
Fernando Mendes Garcia Neto
Alessandra Bastos Soares

DEPUTY CHIEF OF STAFF
Marcus Aurélio Miranda de Araújo

HEAD OF PLANNING
Leonardo Batista Paiva

PLANNING AND STRATEGIC MANAGEMENT COORDINATION (CPGES)
Adelson Teodoro Ramos Filho
Denise Ferreira Leite
Denise Regina Horn
Fabio Gama Alcuri
Juliane Zatelli de Souza
Paulo Henrique de Souza Cortonesi

COLABORATORS:
Flávio Resende (Proativa Communication)

20 anos ANVISA
SUS
ANVISA Agência Nacional de Vigilância Sanitária
MINISTÉRIO DA SAÚDE
PÁTRIA AMADA BRASIL GOVERNO FEDERAL

MANAGEMENT REPORT

2018

BRAZILIAN HEALTH REGULATORY AGENCY

A N V I S A

INTERACTION WITH SOCIETY

Call Center
(0800 642 9782)

92.66% of the protocols opened received immediate response and were finalized at the moment of the call

Talk to Us

47.19% of growth in the number of electronic services

Citizen Information Service (SIC-Anvisa)

Face-to-face and not-scheduled service (Monday to Friday, from 8 a.m. to 6 p.m.)

489 requests for information or clarification

e-SIC

2,415 protocols opened

System managed by the Comptroller General of Brazil (CGU) for requests of information to public bodies according to the Law of Access to Information (Law no.12,527/2011)

Responses in 9.6 days, on average. (Well bellow the legal time frame of 20 days)

Knowledge Base / Anvisa Clarifies

291 updates in 2018

Content repository developed by the agency in a more accessible language to the citizen

Parlatory

It is a scheduling service for face-to-face and virtual hearings

219 Virtual hearings

1,787 Presential hearings

Portal

In 2018, Anvisa's website had a total of **8,728,623** visitors

The number of accesses remained between 600,000 and 800,000 a month

Ombudsman
ouvidoria@anvisa.gov.br

7,486	14,172	2,332	3,711
Reports	Complaints	Pieces of Information	Others

The Ombudsman's Blog had over 70,120 views in 2018

Digital and Social Networks

Facebook (@AnvisaOficial)
74,452 likes
76,917 followers

Twitter (@anvisa_oficial)
377,700 views

Instagram (@anvisaoficial)
30,000 followers

YouTube
Youtube.com/AudiovisualAnvisa

Webinar

46 Seminars **18,000** participations **400** participants on average