## 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

### 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

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### 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 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 to 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

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 regulation of such products and indicate the best therapeutic conduct and the most appropriate materials.

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
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)
- Implementation of the International Certificate of Vaccination or Prophylaxis Issue System (Civnet)
- Improvement in the Market Monitoring System for Medicinal Products (SAMMED)
- Improvement in the Electronic Petition System
- Improvement in the Parlaratory System
- 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.

**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)
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

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)

2,415 protocols opened

Responses in 9.6 days, on average. (Well below 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

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