RESULTS 2017

BRAZILIAN HEALTH REGULATORY AGENCY

ANVISA

About Brazilian Health Regulatory Agency – ANVISA

Anvisa is an autarchy linked to the Ministry of Health and its headquarters are located in the Federal District, Brazil. Anvisa has got administrative independence and financial autonomy, as well as stability for its board of directors. The agency is a part of the National Health System (SUS), as coordinator of the Brazilian Health Regulatory System (SNVS). In addition, the actions of Anvisa are spread throughout the national territory with the Coordination of Ports, Airports, Borders and Customs.

Anvisa's role is to promote and protect the health of the population by executing sanitary control of the production, marketing and use of products and services subject to health regulation – which includes related environments, processes, production inputs and technologies.

Mission

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

Vision

To be nationally and internationally recognized as an institution that promotes health, citizenship and development, operating in an efficient and transparent manner, demonstrating itself as a leader in the field of regulation and health control.

Core Values

- Ethics and responsibility as a state actor.
- Ability to articulate and integrate to achieve goals.
- Management excellence: focus on results.
- Knowledge as a source of action.
- Transparency.

Strategic planning

Anvisa's Strategic Planning cycle for 2016-2019 includes 9 strategic objectives, 13 projects and 37 goals. It was developed based on the assessment of the 2010 Strategic Map and other management tools that guide the Agency's work: the 2016-2019 Multi-Year Plan (PPA), the 2016-2019 National Health Plan (PNS), the Anvisa Management Agreement with the Ministry of Health and the Institutional Performance Assessment (ADI).

Resulting objectives

1. Increase the population's safe access to goods and services subject to health regulation.
2. Improve health regulatory framework.

Enabling objectives

3. Optimize premarket activities based on health risk assessment.
4. Improve postmarket regulatory activities, focusing on control and monitoring.
5. Strengthen the coordination activities of the Brasilian Health Regulatory System.
6. Increase the efficiency of operations in ports, airports and borders.
7. Improve the activities of international cooperation and regulatory convergence.
8. Implement a governance model that encourages integration, innovation and institutional development.
9. Strengthen the acticities of education and communication in health regulation field and the model of institutional relations.

Scope of operation

- Pre-market authorization of products – registration prior to its manufacturing, market exposure or delivery to consumers.
- Inspections to verify manufacturing quality, as well as post-market and post-use activities (monitoring, oversight, receipt of complaints, etc.).
- Enforcement of health regulations.
- Control of the import, export and circulation of ingredients and goods subject to health control.
- Coordination of sanitary control actions carried out by the laboratories in the Official Network of Health Quality Control Laboratories.
- Health surveillance of patient care services (in both routine and emergency care) and hospitalisation; diagnostic and therapeutic support; and other health services which require the use of new technologies.
- Coordination of special programs for the monitoring of products and services subject to health regulation.
- Actions related to ports, airports, borders and customs to ensure the health control of facilities, services and transportation systems involved in export-import processes, as well as to protect the health of travelers.
- Adoption of preemptive measures and health control actions in case of outbreaks, epidemics and public health emergencies.

Institutional relationship

Anvisa acts in alignment with other Executive Branch sectors; it is committed to harmonising procedures and to promoting greater integration between state and municipal health departments. To achieve those goals, Anvisa has invested in improving institutional relations with society, National Congress and industry.

International relevance

Anvisa has been improving to achieve the highest standard of health regulation, in accordance with scientific and technical work. The current position of the agency at the international level is evidence of its advance:

- In 2017, the Pan American Health Organization (PAHO) re-endorsed Anvisa as a National Regulatory Authority of Regional Reference (NRAr) after rigorous evaluation.
- In 2016, Anvisa became a member of the *International Conference on Harmonisation* (ICH), the main forum for technical regulations in the field of pharmaceutical products.
- In 2015, controls performed by Anvisa for pharmaceutical ingredients were recognized as equivalent to those of the European Community.
- Since 2012, Anvisa co-founds the International Medical Device Regulators Forum (IMDRF).
- The agency runs the Brazilian International Internship Program for the Training of Specialists from Regulatory Institutions of Latin American Countries.

Current challenges

There were important advances in 2017, especially the simplification of critical working processes, as well as the reduction of waiting times for the registration of essential products and health technologies. However, there are still challenges to be completed:

- Moving forward in promoting international regulatory convergence in alignment to the best current practices and expanding adherence to the harmonisation initiatives.
- Improving and modernising critical working processes which could enable faster deliveries, maintaining quality, safety and efficacy of products.
- Strengthening post-market and post-use vigilance models.
- Reducing waiting times for registration, inspection and import licenses.
- Reaching a workforce compatible with the broad scope of Anvisa's actions.
- Defining, joining all three levels of government, responsibilities of each of them in health control actions.
- Consolidating a consistent assistance policy in accordance with good governance, expanding the access to information, communication and transparency.

ANVISA 2017
BRAZILIAN STATISTICS AT A GLANCE

More access to produts and services

1,063 **health products were registered** and 776 revalidated

784 **medicines, biological products** and active pharmaceutical ingredients were registered

403 foods registered
258 new foods, **78** foods with functional properties and **30** foods for children

33 biological products registered
11 for rare diseases and **8** anticancer drugs

The drug Spinraza® (nusinersen) was registered in Brazil for the treatment of **Spinal Muscular Atrophy 5q (SMA)**

3 biosimilar products
trastuzumab, etanercept e glargine insulin were registered for the first time

The 1st medical product made with *Cannabis sativa* (Mevatyl®)
was registered in Brazil, for specific cases

Anvisa reduced **waiting times** for register and post-register analysis

Registration

↓ **55%** | Generic and similar drugs
↓ **16%** | Innovator drugs

Post-registration

↓ **18%** | Generic and similar drugs (more complex)
↓ **26%** | New drugs (more complex)
↓ **85%** | Generic, new and similar (less complex)

There was a **36% reduction** on the **average time** to publish such authorizations, from 400 to 255 days

Cosmetics and sanitizers

Registration

1,064 sanitizers
2,699 cosmetics

Regularization

43,680 new cosmetics exempt from registration
8,218 new low-risc sanitizers

1st and 2nd editions of **Statistical Pharmaceutical Industry Yearbook** were published

Customer services

19,665 demands were answered by phone by the Ombudsman's Office

88% of problem-solving in the 1st call
(Satisfaction Survey 2017)

292,165
calls were received by the call center

The 2017-2020 Regulatory Agenda
was published with **126 priority themes**

R$ 265.3 million available **to states and municipalities** for health regulatory actions

Technical-scientific support

260 **feedbacks *ad hoc***
support for the analysis – registration of innovator products

Anvisa **approved**

Public notice for a partnership
between Anvisa and The Brazilian National Council for Scientific and Technological Development (CNPq)
13 research lines and
16 projects of **7** organizational units

Public notice | Proadi
48 projects received
5 projects completed

Experimental studies on new technologies
7 themes, **27** projects, **23** companies

17 dossiers on research development
16 clinical trials on cancer therapy
1 for an experimental vaccine against the Zika virus

Training

More than 1,700 management specialists trained for the SNVS in 9 years of partnership Proadi – Sírio-Libanês Hospital

Public employees **trained**

131 **Self-management and leadership**
Communication and feedback
Strategical and systemic vision

60 **Performance management**
monitoring and assessment

Information managment

In 2017, after the **Electronic Information System (SEI)** started running, 13,218 processes e 228 document models were issued without the use of paper

Greater agility and innovations in work processes

Telecommuting and flexible journeys were implemented – Public employees who joined those programs increased productivity in at least **20%**

The average time for 50% of **product importing** processes was of **9 days**

489 **decisions on requests** for assessment of **toxicity of pesticides** were published

Analytical Information Portal **was launched with 5 open panels** available for public debate

PAHO re-endorsed Anvisa as a National Regulatory Authority of Regional Reference in the Americas

Exchange of knowledge

Brazil hosted the **Global Summit on Regulatory Science – 2017,** main international forum on regulatory science

7ª Semana do CONHECIMENTO

7th Knowledge Week
39 activities
15 research works presented
27 works received
44 speakers
650 participants
10.384 remote accesses

Chatting with Directors
6 events were held
677 people participated in person
5.000 participated online

webinar seminários virtuais

Webinars
6 sessions
14.389 online participations

Updating of the Regulatory framework

56 published **resolutions**

132 **public consultations** on regulatory issues

Highlights

RDC 136/2017 | Established rules for labelling of foods which contain lactose.

RDC 153/2017 | Established the risk level classification for economic activities subject to sanitary control, for licensing purposes.

RDC 157/2017 | Established the National Drug Control System.

RDC 168/2017 | Established the administrative procedure for the prior approval of patents.

RDC 172/2017 | Reduced the bureaucracy and simplified importation of products used solely for human research.

RDC 184/2017 | Simplified toxicology assessment for registration and post-registration of technical products, pre-mixtures, pesticides and its derivatives, as well as wood preservatives.

RDC 183/2017 | Updated rules on inspection and administrative procedures for the concession of GMP certification of health products manufacturers outside Brazil and Mercosul.

RDC 207/2018 | Defined sanitary actions to be carried out by Federal Government, States, Federal District and Districts related to Authorisation, Licensing, Registration, Certification of Good Practices, Oversight, Inspection and Standardizing within SNVS.

HOW THE POPULATION PARTICIPATES IN HEALTH ACTIONS

Public debate

In 2017, Anvisa held 132 public debates on regulatory matters. Contributions were made via the electronic system FormSUS within a time limit. Those actions show how important suggestions from the community are important to the Board of Directors of Anvisa in their decision-making process.

http://portal.anvisa.gov.br/consultas-publicas

Public audiences

Public audiences are held to expand the debate on regulatory issues. They are open to the general public and the population can participate in person or online. The agenda is published on the Brazilian Official Gazette as and it includes information about registration, date, time and venue. Anvisa provides information on its website fifteen days before the scheduled audience.

http://portal.anvisa.gov.br/audiencias-publicas

Public notices

Public notices provide the opportunity for collection of data, information and public opinion on regulatory matters. They are published on the Brazilian Official Gazette and on Anvisa's website.

http://portal.anvisa.gov.br/editais-de-chamamento

Getting in touch

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anvisa.gov.br

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