Pharmaceutical and cosmetics regulation in **Brazil**: a brief overview

By Daniele Scalco Vasconcelos

Feb 2020

Who regulates?

Brazilian Health Regulatory Agency – **(Anvisa)**

- Anvisa is an autarchy linked to the Ministry of Health, part of the Brazilian National Health System (SUS) as the coordinator of the Brazilian Health Regulatory System (SNVS), present throughout the national territory.
- Role - to promote the protection of the population's health by executing sanitary control of the **production**, **marketing** and **use** of products and services subject to health regulation.
- ICH member
- Website: http://portal.anvisa.gov.br/english

Pharmaceuticals
Pre-market approval

- It is the legal act that recognizes the suitability of a product to the Brazilian sanitary regulation, issued by Anvisa
- The companies which own the registration of the product, manufacturers or importers, are responsible for ensuring quality, safety and efficacy of products
- 120 days from the submission date → drugs in the prioritized category;
  365 days from the submission date → drugs in the ordinary category
- Foreign companies shall have partner companies legally constituted in Brazil that will be legally responsible for the imported products
- Publication of the awarded registration in The Brazilian Official Journal (DOU) - Valid for 10 years.

Anvisa Responsibilities

- Registration;
- Authorization to operate and inspection of pharmaceutical laboratories and other companies in the pharmaceutical chain;
- Price regulation through the Medicines Market Regulation Chamber (CMED).
- Other actions are shared with states and municipalities, such as inspection of manufacturers, quality control of medicines and post-market surveillance, such as regulation of drug advertising.
- Analysis of patent applications;

- Ensure drug effectiveness, safety, quality and cost.
- Operates in accordance with the guidelines of the National Medicines Policy.

Categorization

category	pertinent regulation
• New synthetic drugs:	Resolution RDC 200/2017
• Generic drugs:	Resolution RDC 200/2017
• Similar drugs:	Resolution RDC 200/2017
• Potentized medicines:	Resolution RDC 238/2018
• Specific medicines:	Resolution RDC 24/2011 and Resolution RDC 242/2018
• Notified medicines:	Resolution RDC 199/2006 and Resolution RDC 242/2018
• OTC drugs:	Resolution RDC 98/2016, Norm IN 11/2016 and Resolution RDC 242/2018
• Herbal medicines:	Resolution RDC 26/2014
• Medicinal gases:	Resolution RDC 70/2008
• Biologic products:	Resolution RDC 55/2010
• Radiopharmaceuticals:	Resolution RDC 64/2009

Source: portal Anvisa

Marketing and distribution

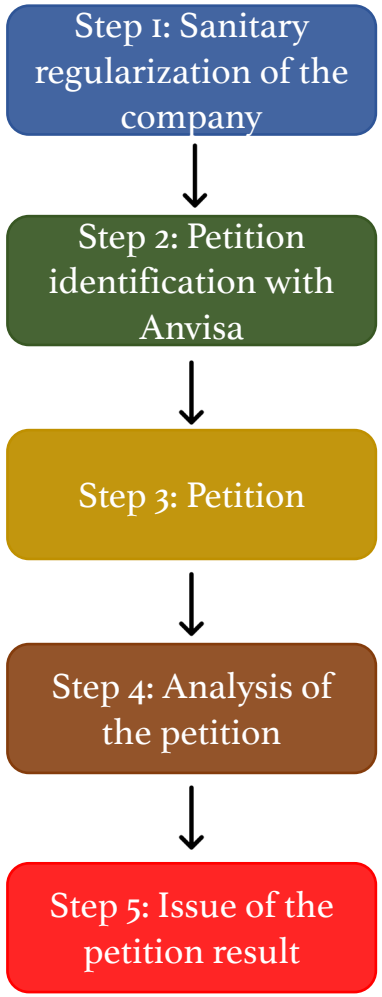
Pharmaceutical products can be marketed and distributed if the following requirements are met:

- They are registered with ANVISA;
- Their price is approved by CMED (Chamber of Drug Market Regulation);
- They are manufactured or imported by establishments duly authorized and licensed by the authorities with Good Manufacturing Practice (GMP) certification for control of the raw-material, ANVISA can issue it
- Verification of reproducibility quality (quantities between batches);
- Safety and therapeutic efficacy of medicinal products by means of laboratory evidence or clinical studies;

For generic and biosimilar drugs the pharmaceutical equivalence and bioequivalence tests are required

It can only be carried out by reference centers authorized by ANVISA

Drug registration



License to operate/registration + Company size

Identification of the code and necessary documentation

Submit the documents →

Assessment of the documents

Decision

If the API is not present in the Brazilian Common Denomination (DCB) list, the registrant should request to the Brazilian Pharmacopoeia for the inclusion of the API

Generic or Similar: The applicant should consult the **list of reference medicines** available on the Anvisa portal.

Modules

1. API: contains information regarding the manufacturer of the active pharmaceutical ingredient
2. Product: contains information regarding the production and quality of the pharmaceutical form
3. Medication: contains the drug information in its final packaging
4. Safety and Efficacy: contains studies that prove the safety and efficacy of the medicine.

Documentation - RDC No 200, 26 Dec 2017

Administrative documents:

- I - petition forms (FP1 and FP2) completed and signed;
- II - proof of payment of the Sanitary Surveillance Inspection Fee - TFVS and respective Union Collection Guide-GRU, or exemption, when applicable;
- III - label text template;
- IV - layout of the primary and secondary packaging of each drug presentation, referring to each manufacturing location;
- V - copy of the valid GMP certificate, for the production line in which the drug will be manufactured, or copy of the inspection request protocol for the issuance of the product;

Technical documents

- Technical report on active pharmaceutical ingredient, formulation development, finished product, finished product production, raw material quality control, finished product quality control, primary packaging and functional secondary packaging, intermediate wrap, accompanying accessories, finished product stability studies
- If it is a New synthetic drug also: the safety and efficacy report according to specific guide, containing the report of non-clinical and clinical trials, and a pharmacovigilance plan.

Cosmetics
Definition

- **Products for external use, intended to protect or beautify different parts of the body…**

includes products such as makeup, nail polishes, talcum powder, beauty cream, hand cream, hair dyes, hair bleaching agents.

- Products applied to the skin for **cleansing are excluded**, they are considered as hygiene products, and perfumes has its own category.

Categorization

Personal Care Products, Cosmetics and Perfumes are allocated in two groups

- **Grade 1** products: Characterized by having basic or elementary properties, evidence of which is not initially necessary and not require detailed information on their mode of use and restrictions of use due to the intrinsic characteristics of the product.
- **Grade 2** products: Have specific indications, whose characteristics require proof of safety and/or efficacy, as well as information and cautions, mode and restrictions of use.
- Grade 2 products need pre-market approval
  - sunscreen and suntan
  - hair strengtheners
  - topical insect repellents
  - antiseptic gels for hands

Marketing authorization and Regulation

- No need of product registration, only **notification**

Except for certain products (Grade 2), pre-market approval is required, for product registration

- Foreign companies shall have **partner** companies legally constituted **in Brazil** that will be **legally responsible** for the imported products
- GMP Compliance to be able to manufacture
- The general regulation applicable to market authorization for personal hygiene products, cosmetics and fragrances is the Resolution RDC 07/2015 (amended by Resolution RDC 237/2018).
- **Animal testing:** Law that prohibits testing of ingredients for cosmetic products on animals, and trade of products that have been tested is **ongoing** in National Congress.

Applicable regulations

These are the main regulations applicable relating to the market authorization (pre-market approval and notification) of personal hygiene products, cosmetics and fragrances exported to Brazil:

- Resolution RDC 237/2018: Amends RDC 07/2015
- Resolution RDC 142/2017: Disposable personal hygiene products for body hygiene, which include toothbrush and dental hygiene rods, dental wires and tapes, disposable sanitary napkins, menstrual pads and flexible rods.
- Resolution RDC 178/2017: Amends RDC 142/2017.
- ~~Resolution RDC 15/ 2015: Technical requirements for the pre-market approval of personal hygiene products, cosmetics and fragrances for children~~
- Resolution RDC 30/2012: Technical Regulation on Sunscreens in Cosmetics.
- Resolution RDC 19/2013: Technical requirements for pre-market approval of topical insect repellent.
- Resolution RDC 481/1999: Microbiological parameters for personal hygiene products, cosmetics and fragrances.
- Resolution RDC 83/2016: List of substances that cannot be used in personal hygiene products, cosmetics and fragrances.
- Resolution RDC 3/2012: Lists of substances which personal hygiene products, cosmetics and fragrances should not contain except under specific conditions and with specific restrictions.
- Resolution RDC 15/2013: Approves the use of lead acetate, pyrogalol, formaldehyde, and paraformaldehyde in cosmetics.
- Resolution RDC 29/2012: Preservatives permitted for personal hygiene products, cosmetics and fragrances.
- Resolution RDC 44/2012: Colorants permitted for personal hygiene products, cosmetics and fragrances.
- Resolution RDC 69/2016: UV-filters permitted for personal hygiene products, cosmetics and fragrances.

Source: portal Anvisa

Prospects and Market

- Brazil is the sixth largest pharmaceutical market
- Brazilian cosmetic market valued at €22.8bn

- Mercosur is negotiating with the EU on a free trade agreement

  "A future EU-Mercosur Association Agreement should boost trade integration among the Mercosur countries and create new opportunities for trade and investment with the EU by removing tariff and non-tariff barriers to trade and FDI" (*European commission website*).

Bibliography

- http://www.planalto.gov.br/ccivil_03/leis/L6360.htm (accessed in 9 Dec)
- https://www.statista.com (accessed in 9 Dec)
- https://www.cosmeticseurope.eu/files/4715/6023/8405/Socio-Economic_Contribution_of_the_European_Cosmetics_Industry_Report_2019.pdf (accessed in 9 Dec)
- http://www.planalto.gov.br/ccivil_03/leis/L5991.htm#art4i (accessed in 9 Dec)
- http://www.planalto.gov.br/ccivil_03/_Ato2011-2014/2013/Decreto/D8077.htm (accessed in 9 Dec)
- http://portal.anvisa.gov.br/documents/10181/2718376/%286%29RDC_81_2008_COMP.pdf/cc803562-3b9d-433b-85ec-fd046af72111 (accessed in 9 Dec)
- http://portal.anvisa.gov.br/documents/10181/2718376/%282%29RDC_71_2009_COMP.pdf/3ff7e308-df4e-4a3c-bac3-b779d9d5c7f1 (accessed in 28 Dec)
- http://portal.anvisa.gov.br/documents/10181/2867685/%283%29RDC_07_2015_COMP.pdf/b6bca3b2-454d-4b05-8749-2a264b096bc8 (accessed in 11 Dec)
- http://portal.anvisa.gov.br/documents/10181/2867685/%282%29RDC_07_2015_COMP.pdf/471cee74-d310-4b49-bd8f-ee8c744b142d (accessed in 28 Dec)
- http://portal.anvisa.gov.br/documents/10181/3836387/%281%29RDC_200_2017_COMP.pdf/edeff7d2-4675-4a0b-adbe-2bbe17e053c9 (accessed in 9 Dec)
- http://portal.anvisa.gov.br/documents/10181/3836387/RDC_200_2017_COMP.pdf/3b8c3b31-24cb-4951-a2d8-8e6e2a48702f (accessed in 14 Jan)
- https://www25.senado.leg.br/web/atividade/materias/-/materia/118217 (accessed in 11 Dec)
- http://portal.anvisa.gov.br/documents/10181/2718376/%282%29RDC_71_2009_COMP.pdf/3ff7e308-df4e-4a3c-bac3-b779d9d5c7f1
- https://cosmeticseurope.eu/cosmetics-industry/understanding-cosmetics-regulation/ (accessed in 7 Jan)
- https://ec.europa.eu/trade/policy/countries-and-regions/countries/brazil/ (accessed in 7 Jan)
- http://www.in.gov.br/web/dou/-/resolucao-rdc-n-317-de-22-de-outubro-de-2019-223312999 (accessed in 6 Feb)
- http://portal.anvisa.gov.br/noticias/-/asset_publisher/FXrpx9qY7FbU/content/cosmeticos-e-saneantes-mudanca-na-validade-do-registro/219201?p_p_auth=FqrZsPb1&inheritRedirect=false (accessed in 6 Feb)