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Agência Nacional de Vigilância Sanitária  
Brazilian Health Surveillance Agency

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## General overview of the Brazilian Health Surveillance Agency and System

*Sâmia Rocha de Oliveira Melo*

**Drug Registration in Brazil – General Office of Medicines**

*Fabiane Quirino de Paula Silveira*

**International Affairs Office**



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## ANVISA's Responsibilities



**Food**



**Cosmetics**



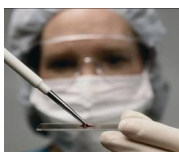
**Sanitizing  
Products**



**Tobacco**



**Toxicology  
(pesticide  
s)**



**Health  
services**



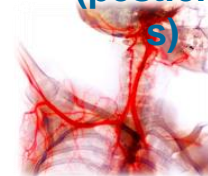
**Drugs**



**Medical Devices**



**Laboratories**



**Blood and blood  
products**



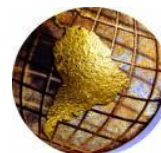
**Post-market  
surveillance**



**Marketing  
control**



**Ports, airports  
and frontiers**



**International**



**Market  
regulation**



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## A little bit about ANVISA

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### The Brazilian Health Surveillance Agency (Anvisa)

Regulatory Agency: Administrative Independence and finance autonomy

- Linked to the Ministry of Health
  - Management Contract (indicators and targets)
  - Stability of the Directors (mandate)
  - Board of Directors – 5 Directors named by the President of Republic, for a mandate of 3 years, renewed once for another 3 years.
  - Science-based technical decisions
  - Predictability and transparency of the regulatory process
- 15 years since its creation (Lei 9.782/1999)



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## Mission:

“To promote and protect the health of the population and to act on the risks that arises from the production and use of products and services subject to health surveillance, acting coordinately with federal states, municipalities and the Federal District, following the Unified Health Systems (SUS) principles, to improve the quality of life of the Brazilian population”

## Vision:

“To be legitimated by society as an institution that is part of the SUS, expedited, modern and transparent, a national and international reference on health regulation and control.



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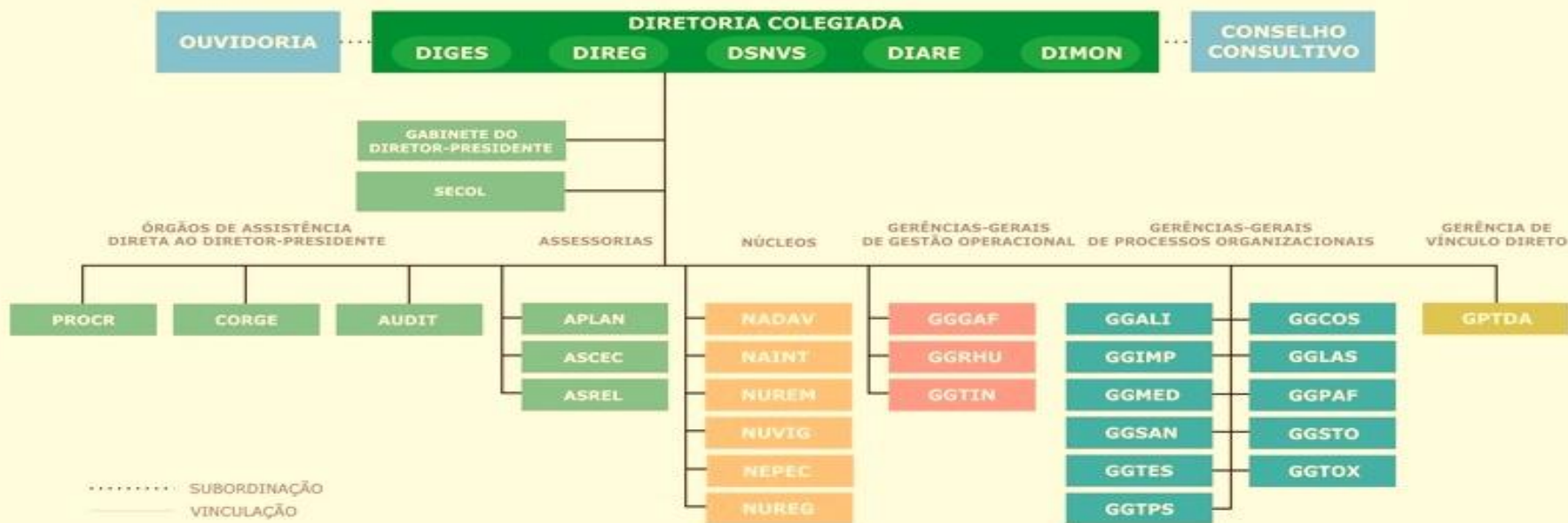
## ANVISA ORGANIZATION CHART



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### ORGANOGRAMA



Portaria nº 354, de 11 de agosto de 2006  
Publicada no DOU de 14 de agosto de 2006



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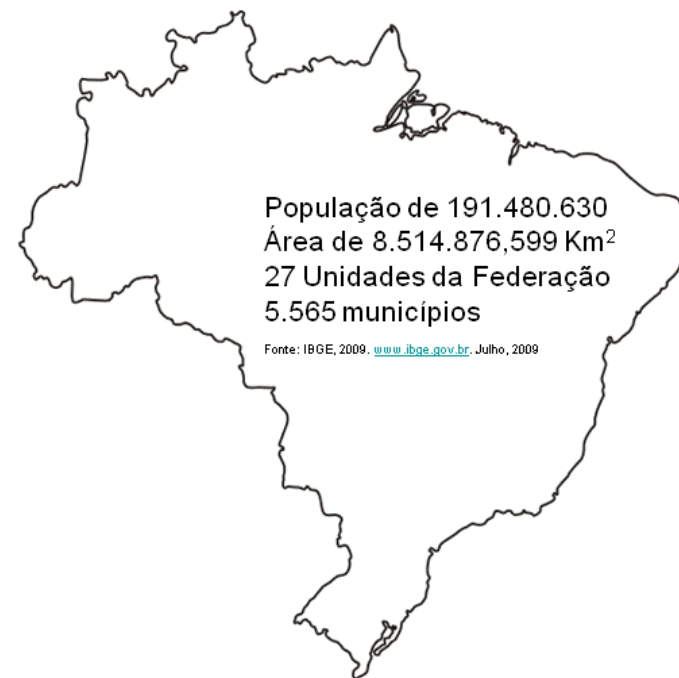
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## National Health Surveillance System (SNVS)

- Integrates the Unified Health System (SUS)
- Integrated by the Federal, State and Local level
- Coordinated by Anvisa
- Characteristic: articulation and decentralization



### Federal

Ministry of Health

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National Institute for Quality Control in Health

### State Level

State Secretary of Health

State Health Surveillance

Laboratories of Public Health - LACEN

### Municipal Level

Local Secretary of Health

Local Health Surveillance



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@ghiapereira

- Anvisa's headquarter is located in the capital, Brasília
- Nowadays we have around 3.000 employees working through the country, most part in Brasília
- **Nº companies regulated**
  - Pharmacies and drugstores: 80.000
  - Inputs and health products: 15.000
  - Drugs: 3.000
  - Total: ~98.000



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**Anvisa (high complexity activities)**



- Regulation (ex. GMP guidelines elaboration)
- Coordination of National System of Sanitary Surveillance
- Activities Execution (ex. borders control, counterfeiting products combat, local inspection when requested by States or Municipalities)
- Companies Authorization, Marketing Authorization, GMP certification, etc.

**States and Federal District (medium complexity activities)**



- Activities Execution (Ex. GMP inspections)
- Complementary regulation
- Coordination of state activities

**Municipalities (basic health services)**



- Activities Execution (Ex. GMP inspections)
- Complementary regulation
- Coordination of local activities
- Companies Licensing



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## The Brazilian pharmaceutical market

- Health products: **9.256** companies<sup>1</sup>, being **1.774** producers
- Cosmetics: **6.050** companies<sup>1</sup>, being **3.022** producers
- Sanitizing products: **4.870** companies<sup>1</sup>, being **3.267** producers
- Food: **81.100** supermarkets
- <sup>1</sup>Includes all companies that are authorized by ANVISA for any activity - storing, distributing, selling, transporting, import, manufacture, etc. Sources: Datavisa; GGIMP; Dez/11
- **27** Central Laboratories of Public Health - LACEN
- **33.571** services of diagnostics by Images
- **6.700** hospitals
- **4.113** Hemotherapy Services
- Source: National Register of Health Establishments in Brazil - CNES - Dez/11



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## Marketing Authorization / Drug Registration

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- In Brazil, drugs are registered, not licensed.
- The registration must be renewed every five years.
- Categories of Drugs registered in Brazil:
  - “New” drugs (innovative and others)
    - Synthetic and semi-synthetic drugs
    - Biologicals
    - Herbal medicines
  - “Copies”
    - Generic Drugs
    - Similar Drugs



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**Proven safety of use  
Quality Standard  
Proven therapeutic efficacy**



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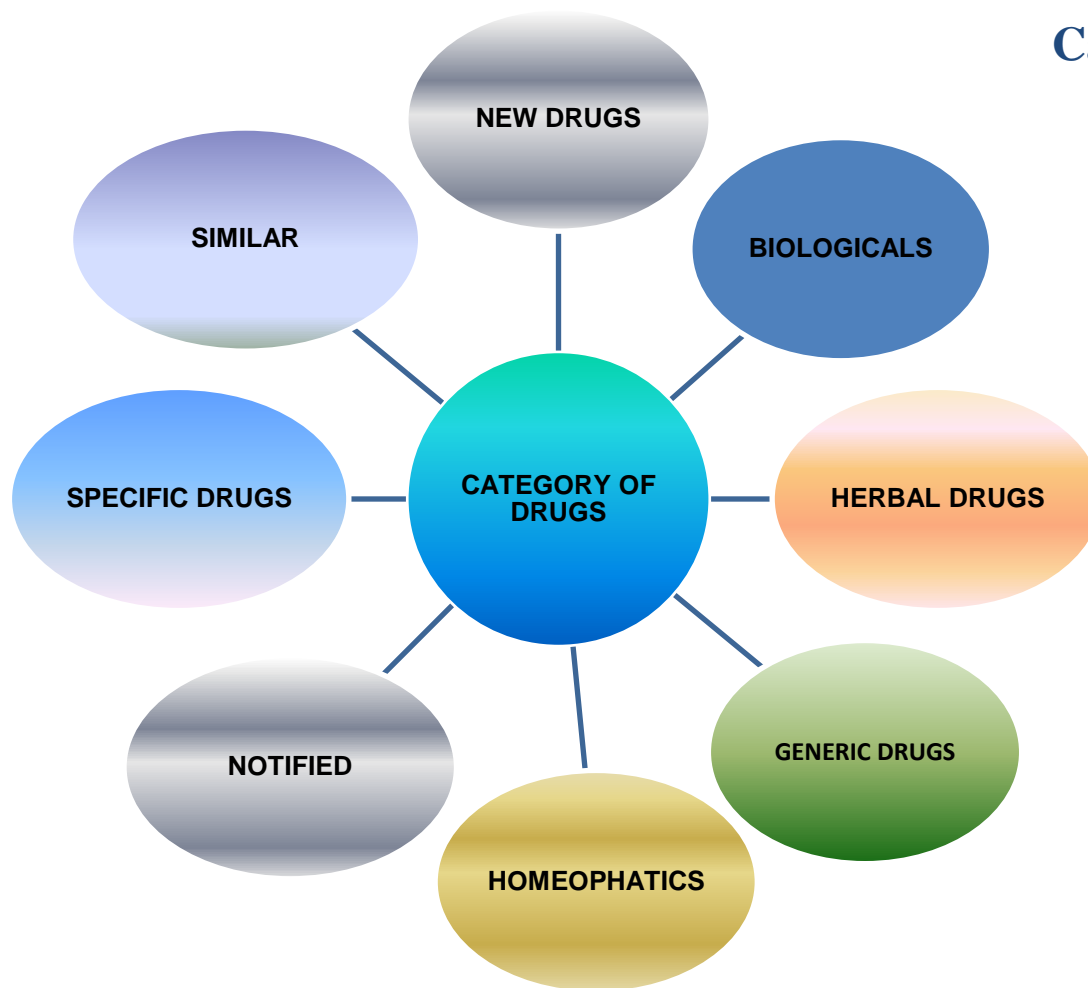
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# Marketing Authorization / Drug Registration

## Category of Drugs



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# Definitions

<b>Reference drug</b>	<b>“innovative product registered in the federal agency responsible for health surveillance and marketed in the country, whose efficacy, safety and quality have been scientifically proven before the competent federal agency, at the time of registration” (included by Law no. 9.782 (10/Feb/99))</b>
<b>Similar drug</b>	<b>“the one that contains the same active ingredient (s), presents the same concentration, pharmaceutical form, route of administration, dosage and therapeutic indication, and which is equivalent to the drug registered at the federal agency responsible for health surveillance, and may differ only in relation to product characteristics such as size and form, expiring date, packaging, labeling, excipients and vehicles, and must always be identified by a brand name or trademark”( MP 2.190 - 34(23/Aug/2001))</b>



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# Definitions

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## Generic drug

**“drug similar to a reference or innovative product, which is intended to be interchangeable with it, generally produced after the expiration or waiver of patent protection or other exclusivity rights, having its efficacy, safety and quality proven, and being designated by BCD or, in its absence, by ICD” (Included by Law no. 9.782(10/Feb/99)).**



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## Drug Registration Lifecycle

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**MARKETING AUTHORIZATION  
REGISTRATION  
OF DRUGS**

**POST-MARKETING  
ALTERATIONS**

**REVALIDATION / RENEWAL  
OF  
REGISTRATIONS**



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## Drug Registration LAW Nº. 6.360/1976 and DECREE Nº. 79.094/77

Art. 12. None of the products object of this Law, including imported products, may be industrialized, exposed for sale or delivered for consumption before being **registered** at the Ministry of Health.

First Para. The registration referred to in this article will be **valid for 5 (five) years and may be revalidated for equal and successive periods,** and the number of the initial registration will be maintained.

Fourth Para. The acts referring to registration and registration revalidation will only have effect as of the date they are **published in the Federal Gazette.**



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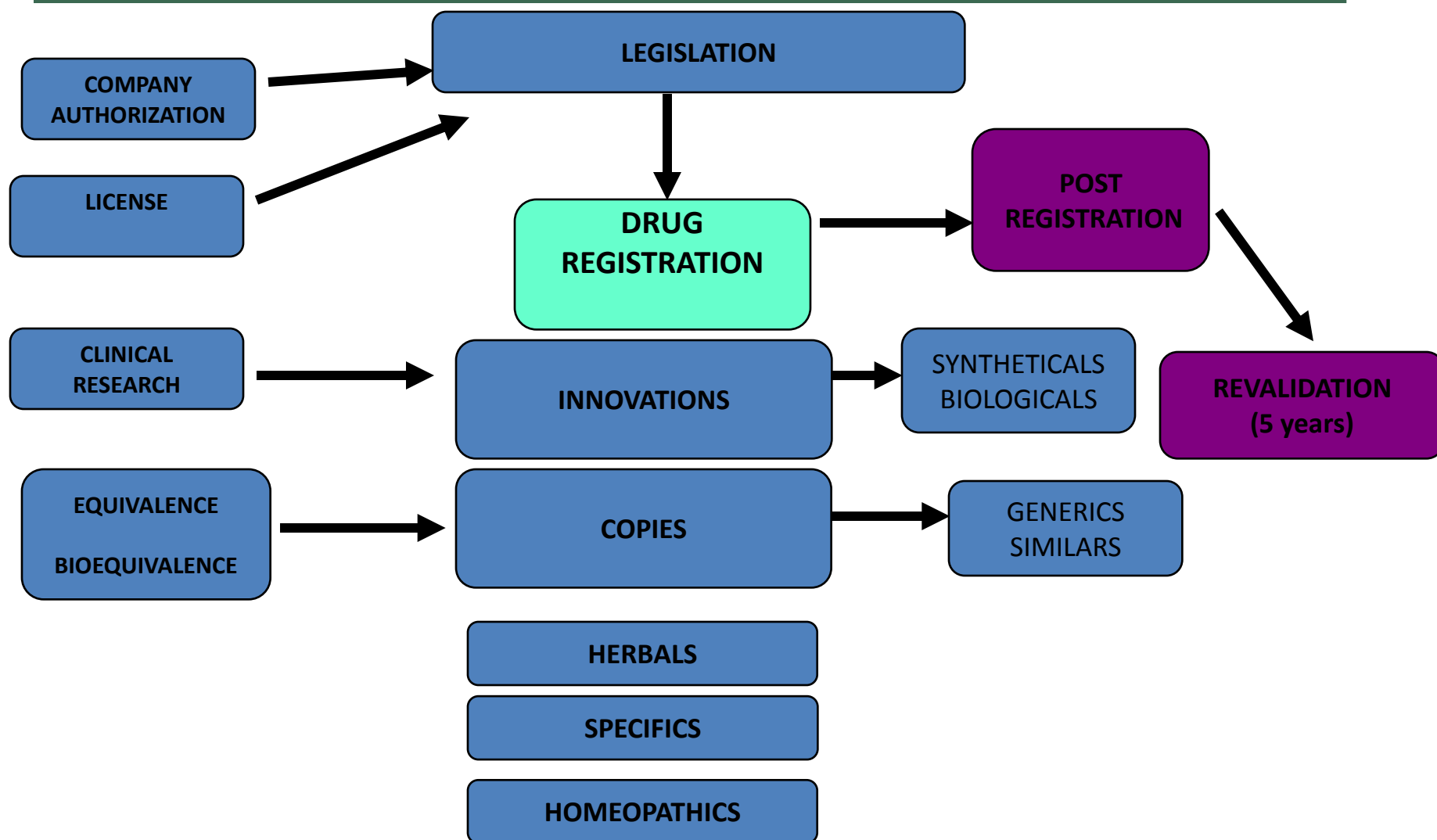




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## Prior Measures

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- **GOOD MANUFACTURING PRACTICES**
- **INFORMATION ABOUT API USED – DRUG MASTER FILE**
- **PRODUCTION OF 3 PILOT BATCHES – COMPLETE BATCH RECORDS**
- **QUALITY CONTROL AND SPECIFICATION**
- **ANALYTICAL METHOD VALIDATION**
- **STABILITY STUDIES OF 3 PILOT BATCHES**
- **PHARMACEUTICAL EQUIVALENCE**
- **BIOEQUIVALENCE**



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## Legislation

Registration	Resolution RDC
Specific Drug	Nº. 24/2011
Similar Drug	Nº. 17/2007
Generic Drug	Nº. 16/2007
New Drug	Nº. 136/2003
Homeopathic Drug	Nº. 26/2007
Herbal Drug	Nº. 14/2010
Biological Drug	Nº. 55/2010
Drug Post Registration	Nº. 48/2009

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## MAIN GMP RELATED LEGISLATION

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- Resolution RDC nº 17/2010 (GMP guide for Drug Products);
- Resolution RDC 249/2005 (GMP guide for APIs);
- Resolution RE nº 01/2005 (stability studies);
- Resolution RDC nº. 50/2011 (stability studies for biological products);
- Resolution RE 899/2003 (analytical methods validation);
- Resolution RDC 39/2013 (GMP Certificate);
- Resolution 25/1999 (International Inspections);
- Decree nº 8.077/ 2013;
- Federal Law nº 6360/76;
- Resolution RDC nº. 204/2005 (Deadline to meet the requirements).



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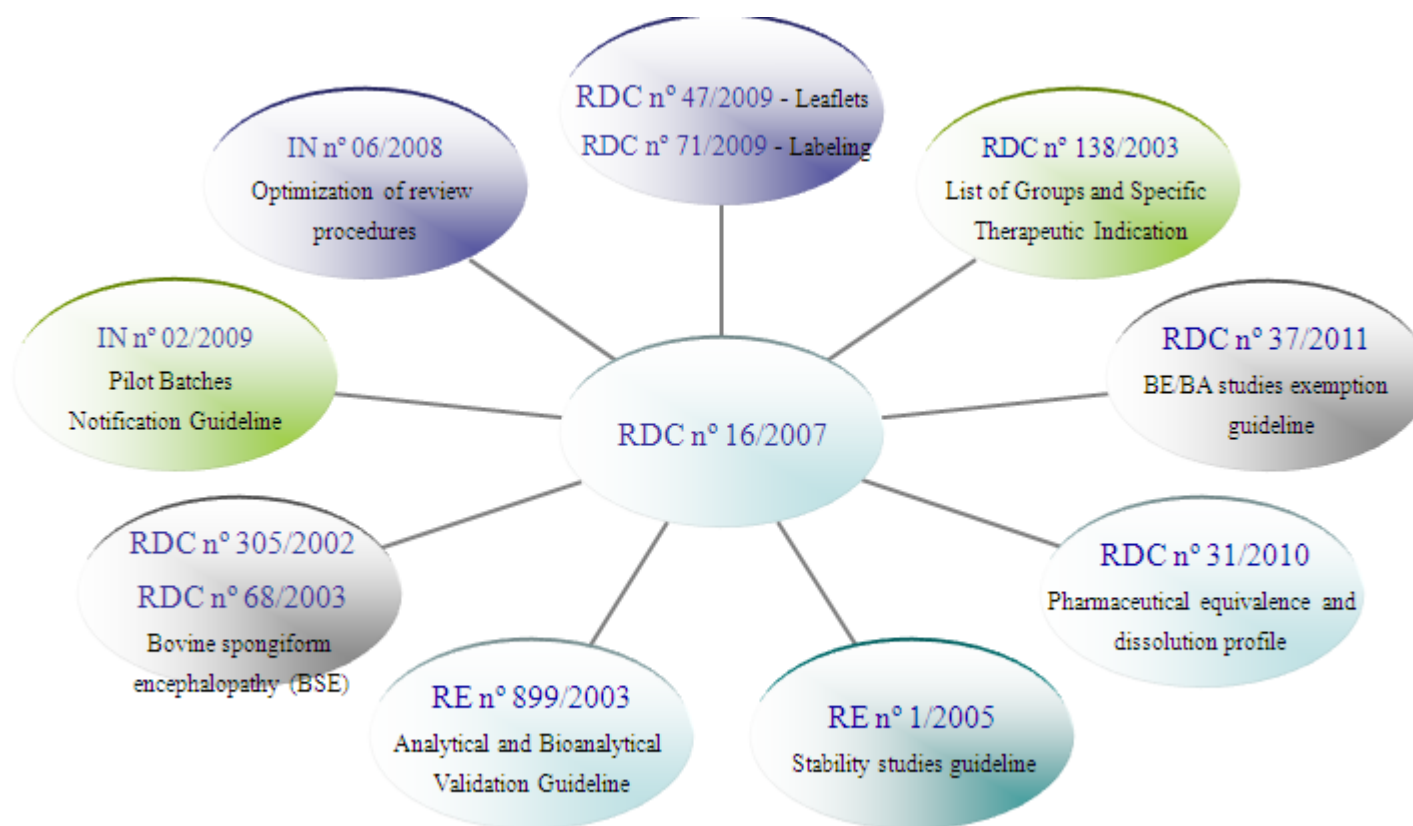




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## *Additional legislation related to generics medicines registration*



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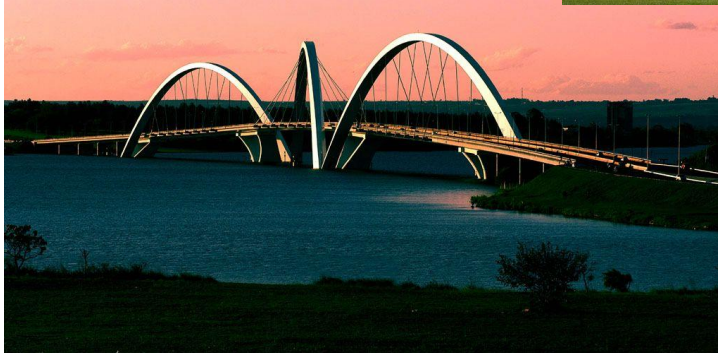
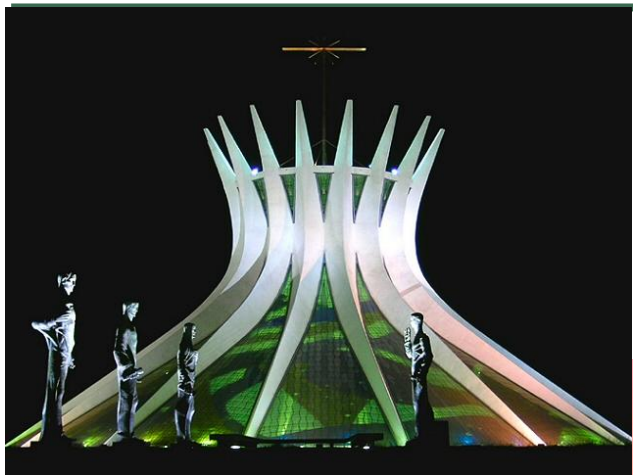




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Thank you!  
Obrigada



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