

(ANVISA)

(Agencia Nacional de Vigilancia Sanitaria)

(Brazilian Health Surveillance Agency)

Rasmita Jena
Assistance Professor
SoPLS, CUTM, BBSR

Contents:

- ❑ Introduction
- ❑ ANVISA mission
- ❑ ANVISA vision
- ❑ Responsibility of ANVISA
- ❑ offices of ANVISA
- ❑ Regulations by ANVISA
- ❑ Registration of new drug
- ❑ References

Introduction

- ▶ ANVISA is regulatory body of BRAZIL. Brazil is biggest country of South America. Some of the small countries nearby Brazil are following the rules according to ANVISA.
- ▶ ANVISA means “Agencia Nacional de Vigilancia Sanitaria”. This abbreviation is in Portuguese language. In English, it means “National Health Surveillance Agency” or sometimes it is written as “Brazilian Health Surveillance Agency”.

- ▶ ANVISA is established on 26th January, 1999. Thus it does not have long historical backgrounds.
- ▶ The National Health Surveillance Agency was established in 1999 by president Fernando Henrique Cardoso. Linked to the Ministry of Health, the agency coordinates: -

The National Sanitary Surveillance System - The National Program of Blood and Blood Products - The National Program of Prevention and Control of Hospital Infections

Anvisa's Mission

- ▶ "To protect and promote health, ensuring the hygiene and safety of products and services and taking part in developing access to it."

Values:

- ▶ Transparency
- ▶ Knowledge (as a springboard for action)
- ▶ Co-operation

Vision

- ▶ The National Health Surveillance Agency was established by Law 9.782, of January 26, 1999. The Agency is designated an autonomous agency operating under a special regime.
- This means that ANVISA is an independently administered, financially-autonomous regulatory agency, with security of tenure for its directors during the period of their mandates. The Agency is managed by a Collegiate Board of Directors, comprised of five members.
- Within the structure of Federal Public Administration, the Agency is linked to the Ministry of Health, under a Management Contract. The agency incorporated additional attributions:

- ▶ Coordination of the National Sanitary Surveillance System (SNVS), the National Program of Blood and Blood Products and the National Program of Prevention and Control of Hospital.
- Infections; monitoring of drug prices and prices of medical devices; attributions pertaining to regulation, control and inspection of smoking products; technical support in granting of patents by the National Institute of Industrial Property.

ANVISA is responsible for :

- ▶ monitoring drug prices
- ▶ prices of medical devices
- ▶ control and inspection of smoking products
- ▶ technical support in granting of patents by the National Institute of Industrial Property.
- ▶ protection of the health of the population by exercising sanitary control over production
- ▶ marketing of products and services subject to sanitary surveillance, controlling ports, airports and borders
- ▶ linked to the Brazilian Ministry of Foreign Affairs and foreign institutions over matters concerning international aspects of sanitary surveillance.

ANVISA is a part of NSSS

- ▶ National System of Sanitary Surveillance (NSSS) is an organization of Brazil whose responsibility is:
 - ▶ To keep a watch over certain professional activities
 - ▶ To put a stop to charlatanism
 - ▶ To inspect ships, cemeteries and places where food was on sale to the public.

OFFICES OF ANVISA:

- ▶ Advisory Council
- ▶ Office of Ombudsman

ADVISORY COUNCIL:

- ▶ It monitors and follows up the development of activities carried out by ANVISA. Council comprise of Representatives from...
 - Public Administration Institutions
 - Organized Civil Society
 - Scientific Community
- The main function of advisory council is to provide information upon request by any citizen, patient, industrialist or health professional on any topics. Unlike other well known regulatory bodies, ANVISA does not have specific offices for each topic to provide specific information only. It has a general functioning common Advisory council.

OFFICE OF OMBUDSMAN:

- ▶ It is an independent body for direct communication of Citizens or Institutes to attend the Complaints.
- ▶ It is characterized by impartiality and transparency.
- ▶ It has no direct or indirect linking with ANVISA. It is regulated directly under the Brazilian ministry of health.
- ▶ It Start action against complaints within 2 days, if appropriate.

Regulations by ANVISA:

- Blood and blood products
- Drugs
- Food
- International Affairs
- Medical devices
- Ports, airports and borders
- Tobacco
- REBLAS - Brazilian network of Analytical Laboratory Products
- Cosmetics
- Generic Drugs
- Health services
- Market regulations
- Pharmacovigilance
- Sanitizing
- Toxicology

REGISTRATION OF NEW DRUG:

Registration procedure of new drug is divided in mainly 3 parts as follows...

1. Pre-registration measures

- Protocol for Clinical study

2. Registration

- Documents to be submitted
- Protocol for the new drug
- Protocol for import of new drug

3. Post-registration

- Alteration in Registration, Renewal of Registration

Thus, these three parts can be considered similar to IND, NDA and Supplementary NDA as per US FDA.

I. Pre-registration measures

- ▶ In case of a new national drug product, the protocols of the clinical studies and the results or current status of the studies in compliance with the legislation in force has to be submitted.
- ▶ In case of a new imported drug product that will undergo phase III clinical studies in Brazil, the study protocol and the results or current status of the studies in compliance with the legislation in force has to be submitted.
- ▶ Whenever phase III will take place with a new product manufactured in the country, pre-notification for the production of pilot batch according to the **GUIDE FOR THE NOTIFICATION OF PILOT BATCHES OF MEDICINES** has to be submitted.

II. Registration:

1. Documents to be submitted

- Registration petition forms
- Proof of payment of Sanitary Surveillance Inspection
- copy of the company's Operation License
- Technical Responsibility Certificate by the Regional Pharmacy Council
- Copy of the notification protocol of pilot batch production
- Good Manufacturing Practices certificate (GMP) emitted by ANVISA

2. Protocol for the new drug:

General data: package insert text, label etc...

- Expiry date by Stability studies
- All Toxicity study reports
- Clinical trial data with statistical treatments
- For Combination - Maximum 3 is allowed for oral or injectable preparations. Four combinations are allowed only if the fourth ingredient is caffeine.

- ▶ Physico-Chemical parameters of drug
- ▶ Synthesis route (all reagent, solvent, condition)
- ▶ Pharmacodynamic parameters
- ▶ Pharmacokinetic parameters
- ▶ Production Report (Batch size, methods and equipments used)
- ▶ Q.C. of raw material and finished products

3. Protocol for the import of new drug :

- GMP of importing country or Inspection by ANVISA.
- Documentation is allowed in Portuguese, English or Spanish language.
- Label, Package Insert must be in Portuguese (Brazilian) language
- Official Documents like certificates given by importing country, if it is in foreign language that must be translated with Legal translator only.
- In some cases, applicator wants to import Bulk drug from foreign and then Pack the product in Brazil. In such cases, Expiry Date must be counted from Manufacturing date in foreign, and not the packaging date in Brazil

III. Post-registration measures:

- ▶ Any registration changes shall follow the procedures specified in the **GUIDE FOR MAKING POST-REGISTRATION ALTERATIONS AND INCLUSIONS IN MEDICINES**.
- ▶ ANVISA may undertake a control analysis of commercialized batches in official laboratories in order to monitor the quality and conformity of the drug with the drug registered. Whenever necessary, ANVISA may request that the companies train their technicians in order to enable them to undertake this monitoring.

In-vitro Diagnostic product:

ANVISA had classified in vitro diagnostic product into 4 classes as follows...

- ▶ Group A - Materials, devices, accessories and inputs for support of in vitro diagnostic products.
- ▶ Group B - for diagnosis of non-transmissible diseases.
- ▶ Group C - for diagnosis of infectious-contagious diseases, except those classified in Group D.
- ▶ Group D - for diagnosis of infectious-contagious diseases, sexually transmissible diseases or diseases spread by blood and blood products, as well as identification of blood groups, transfusion or preparation of blood products

Documents required for Registration...

- ▶ • Application form, Fee payment receipt.
- ▶ • Copy of License or Permit for Manufacturing.
- ▶ • Label on the package of product, Instruction for Use
- ▶ • Technical Report.
- ▶ • If imported, proof of Registration at competent health agency of importing country

OTHER FUNCTIONS OF ANVISA:

- ▶ Brazilian Network of Analytical Laboratories. It is the laboratory network and every analysis and clinical studies must be performing at any one of the REBLAS center approved by ANVISA.

- ▶ Along with Drugs and Cosmetics, ANVISA have also regulation on...
 - Medical devices
 - Food
 - Tobacco products
 - Toxic products
 - Pharmacovigilance

Travelers Information:

- ▶ This section is covered under a specific part of ANVISA related to Airport and Border regulation. Any new visitor of Brazil has to take Vaccine against YELLOW FEVER at least 10 days before his arrival to Brazil. And on arrival he has to show “International Certificate of Vaccination (ICV)”.
- ▶ If he had taken Vaccine against yellow fever, before 10 years, then he has to take it again a booster dose.
- ▶ Anvisa's Public Health Care Centers and Vaccination Rooms (in Portuguese) are ready to provide the vaccine and to issue the International Certificate of Vaccination (ICV), which is yellow.

RECENT TRENDS OF ANVISA:

- ▶ Launched the project to prevent the resistance against Antibiotic drugs
- ▶ The site is among the ten best in two categories of the iBest Awards. ANVISA's site is among the ten finalists in two categories i.e. "Government" and "Health and Well-being"
- ▶ Launched the project to prevent the resistance against Antibiotic drugs.

INDIAN PHARMA IN BRAZILIAN MARKET:

Prominent product exporters:

- ▶ Zydus Cadila
- ▶ Torrent Pharmaceuticals
- ▶ Dr. Reddys Labs
- ▶ Ranbaxy Pharmaceuticals
- ▶ Intas Pharmaceuticals
- ▶ Sun Pharmaceuticals

Major Drugs exported:

- ▶ Losartan Potassium
- ▶ Zolpidem tartarate
- ▶ Alprazolam
- ▶ Enalapril Maleate
- ▶ Nortryptiline
- ▶ Carbamazepine
- ▶ Clonazepam
- ▶ Fluconazole
- ▶ Fluoxetine, etc.

REFERENCE:

- ▶ www.anvisa.gov.br
- ▶ www.brazilanlawblog.com

THANK YOU