International Conference on Rare Diseases and Orphan Drugs (ICORD)

General Office of Drugs/ANVISA

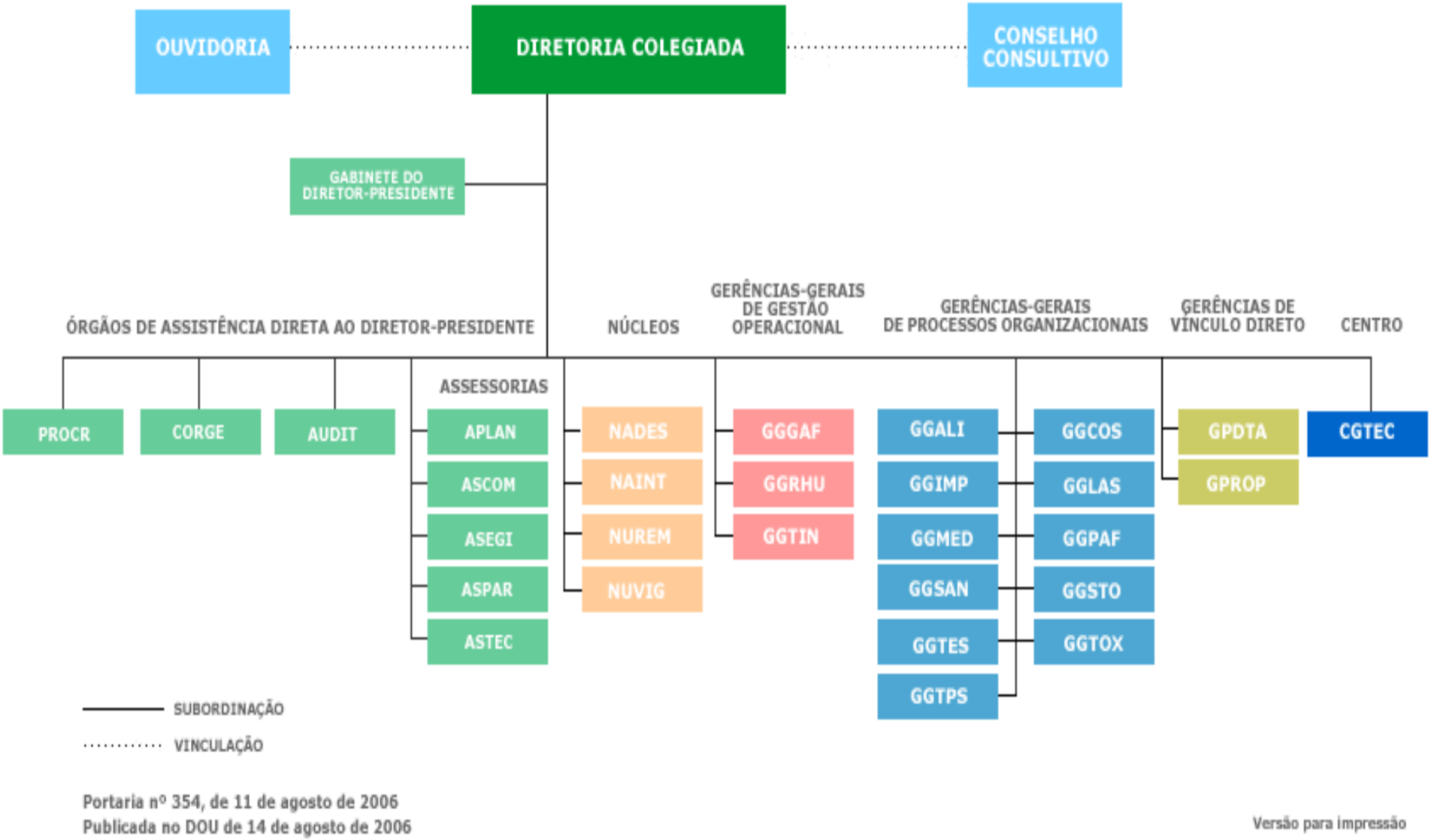
ANTONIO CARLOS DA COSTA BEZERRA

May 20-22

ANVISA'S MANDATE

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

ANVISA ORG CHART



Portaria nº 354, de 11 de agosto de 2006
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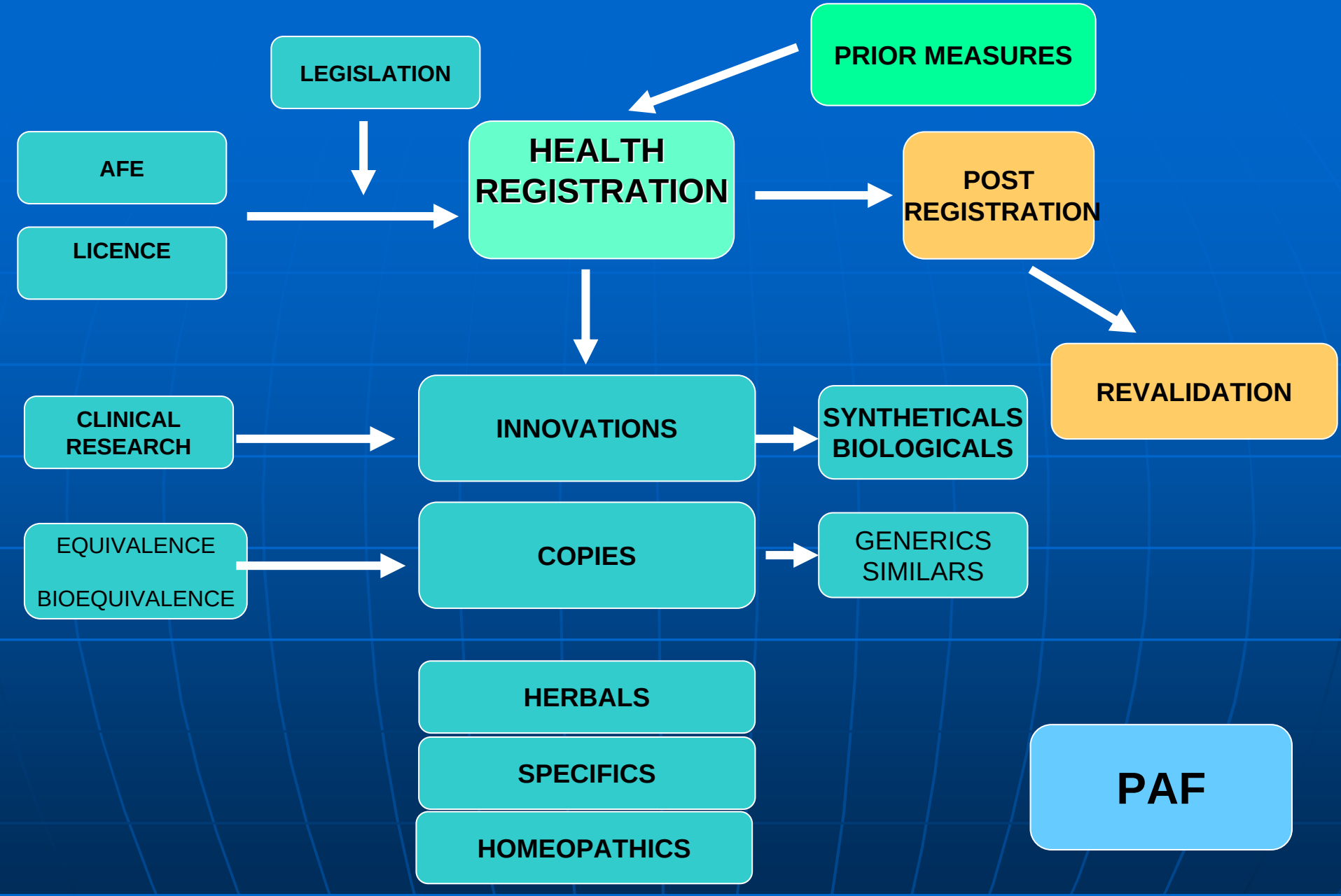
Versão para impressão

Competences of the General Office of Medicines

HEALTH REGISTRATION OF DRUGS

POST-REGISTRATION CHANGES

RENEW OF REGISTRATIONS


PRIOR MEASURES
LEGISLATION
AFE
LICENCE
HEALTH REGISTRATION
POST REGISTRATION
REVALIDATION
CLINICAL RESEARCH
INNOVATIONS
SYNTHETICALS BIOLOGICALS
EQUIVALENCE
BIOEQUIVALENCE
COPIES
GENERICS SIMILARS
HERBALS
SPECIFICS
HOMEOPATHICS
PAF

A. F. E .
OPERATION AUTHORIZATION FOR COMPANIES

Exclusive activity of the Ministry of Health's competent agency, responsible for the Sanitary Surveillance of products referred to in Decree no. 79.094/77, containing authorization for the companies to accomplish their activities under the Health Surveillance regimen, established by Law no. 6360/76.

Legislation

Registration	Resolution RDC
Specific Drug	No. 132/2003
Similar Drug	No. 17/2007
Generic Drug	No. 16/2007
New Drug	No. 136/2003
Homeopathic Drug	No. 139/2003
Herbal Drug	No. 48/2004
Biological Drug	No. 315/2005

Drug Registration

- In Brazil, drugs are registered, not licenced.
- The registration must be renewed every five years.
- Categories of Drugs registered in Brazil
  - "New" drugs (innovating and others)
    - Synthetic and semi-synthetic drugs
    - Biologicals
    - Herbal drugs
  - "Copies"
    - Generic Drugs
    - Similar Drugs

PRIOR MEASURES

- GOOD MANUFACTURING PRACTICES
- PILOT BATCHES
- STABILITY STUDIES
- PHARMACEUTICAL EQUIVALENCE
- BIOEQUIVALENCE STUDIES

“New” Drugs

- Innovating
- New pharmaceutical form
- New strength
- New route of administration
- New indication
- New combination

Registration – New Drug

- Dossier submitted by the industry, containing all documentation needed for the registration
- - Pre-Clinical and Clinical Studies completed
- Documentation related to the active ingredient, manufacturing process, assessment of quality control analyzed by ANVISA's technical team
- GMP Certificate granted by ANVISA after inspection

Registration – New Drug

ANVISA's analysis (2)

- Assessment of safety and efficacy based on phase I, II and III clinical studies
  - Internal (ANVISA's technical team)
  - External ("ad hoc" consultants)

Registration – Biologicals

- ANVISA does not accept the concept of similarity for biologicals
- Evidence of safety and efficacy must be presented for all biological product submitted to registration

ANALYZE PRIORITIZED

RDC 28/2007 => CURRENTLY RDC 16/2008

Rational

- health is right of all and to have of the State;
- actions and services of health are of public relevance;
- the health is a basic right of the human being, having the State to provide the indispensable conditions to its full exercise;
- the necessity to promote use rational of medicine and to guarantee the access of the population to medicines considered essential to the health,

ANALYZE PRIORITIZED

RDC 28/2007 => CURRENTLY RDC 16/2008

Priority Criteria

•Emergent or Re-emergent diseases: used term to assign new conditions of the health state, generally of infectious origin, or known conditions already that get or re-start getting significance epidemiologist in public health;

•Neglected diaseases: used term to assign the illnesses that do not present as attractive economicaly for the research and development of active ingredients, for affecting, predominantly, the population of the developing countries;

• Rare diaseases or orphans: those that affects a small number of people when compared with the general population." (NR);

•Orphan drug: term used to assign medicines that shows efficacy in the treatment or diagnosis of rare diaseases.

ANALYZE PRIORITIZED

RDC 28/2007 => CURRENTLY RDC 16/2008

FIRST ANSWER TIMEFRAME

The timeframe for the answers of the administrative units of the GGMED to the analysis of requests considered as priority, will be of 75 (seventy and five) days for petitions of new product registration, and 90 (ninety) days for after-approval changes requests, counted from the date of priority approval

THANK YOU!

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