# GENERAL OVERVIEW OF BRAZILIAN REGULATION OF HEALTH PRODUCTS

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Director Chairman

São Paulo – SP, 02 August 2014

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ANVISA
Agência Nacional de Vigilância Sanitária

Ministério da Saúde

Governo Federal

# Brazilian Health Surveillance Agency

## GOAL

Promote and protect the health of the population and intervene at the risks involved in the production and use of products and services subject to sanitary surveillance, in coordinated action with states, municipalities and the Federal District, in accordance with the principles of the Unified Health System, to improve the quality of life of the Brazilian population.

## VISION

Be legitimized by society as a member institution of the Unified Health System, agile, modern and transparent, with national and international reference in regulation and sanitary control.

## VALUES

- Ethics and responsability as public agent
- Capacity of articulation and integration
- Excellence in management
- Knowlegde as a source for action
- Transparency
- Accountability

# Directorates

| | |
|---|---|
|  Authorization and Sanitary Registration | **Dirceu Brás Aparecido Barbano** |
|  Coordination and Articulation of National Surveillance Health System | **José Carlos Magalhães Moutinho** |
|  Sanitary Regulation | **Renato Alencar Porto** |
|  Control and Sanitary Monitoring | **Jaime César de Moura Oliveira** |
|  Institucional Management | **Ivo Bucaresky** |

# STRATEGIC PLANNING
# Organizational Restructuring

**Ordinances No. 422 and 424, of 16/03/2012**

**Board of Institutional Management**

**Responds for the areas related to the management and operation of the Agency.**

**Board of Coordination and Articulation SNVS**

Formulates guidelines and establishes actions for coordination and strengthening policy of the National Sanitary Surveillance (SNVS).

**Board of Sanitary Regulation**

Operates in the formulation of policies and actions that are used to strengthening the regulatory practices of ANVISA.

**Board of Control and Health Monitoring**

Responds by setting guidelines and actions to the actions of monitoring and inspection of goods, products and services regulated by the Agency.

**Board of Authorization and Sanitary Registration**

Responsible for the formulation of policies and the establishment of actions and procedures for registration, authorization to operate the businesses, assets, products and services subject to sanitary surveillance.

# Complexity and Scope of Practice

# SCALE OF BRAZIL MARKET

- 81.159 pharmacies
- Drugs: 6.741 distributors e 450 industries
- Health products: 9,256 companies [1], and 1,774 producers
- Cosmetics: [1] 6,050 companies, with 3,022 producers
- Sanitizing: [1] 4,870 companies, with 3,267 producers
- Food: 81.100 supermarkets

*[1] Includes all companies that are authorized by ANVISA for any activity - store, distribute, sell, transport, import, manufacture, etc. Sources: Datavisa; GGIMP; Dec/11*

- 90 public health laboratories - LACEN
- 33,735 diagnostic imaging services
- 106,366 diagnostic imaging equipment (in use)
- 6,280 hospitals
- 4,166 hemotherapy services

*Source: National Register of Health Establishments of Brazil - CNES - Dec/13*

- Over the past 05 years were filed on average about 230 thousand documents at the headquarters of ANVISA.

# Performance of Anvisa

**PROTECT** THE HEALTH OF THE POPULATION

Minimize health risks from the production and consumption of goods and services

**PROMOTE** THE HEALTH OF THE POPULATION

Expand the access to goods and services that improve the health and quality of life

# ANVISA'S LEGISLATION

Competency to edit legislation related to health surveillance subjects – Resolution of the Board of Directors (RDC)

RDC – elaborated following the Guide of Good Regulatory Practices

Process of previous public consultation and notification to WTO

Regulatory Agenda – annual prevision of priority themes to be regulated

Transparency: legislation is published on the Official Newspaper (Diário Oficial da União) and is on ANVISA's website

# SOCIAL AND POLITICAL CIRCUMSTANCES

✓Social mobility;

✓Change of the demographic basis;

✓Competitive environment around innovation;

✓Increased complexity and volatility of the technologies;

✓Increasing pressure sanitary protection;

✓The need of getting answers in appropriate periods and increasingly shorter;

✓Requirement of rigor with public spending and the efficiency and transparency in management;

✓Economic growth and expansion of regulated markets;

✓Demand for repositioning of health surveillance as a tool to support the development.

# MARKETING AUTHORIZATION OF DRUGS

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

# MARKETING AUTHORIZATION OF DRUGS

**PRIOR MEASURES:**

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

# DRUG REGISTRATION LIFECYCLE

**MARKETING AUTHORIZATION**

**REGISTRATION**

**OF DRUGS**

**POST-MARKETING**

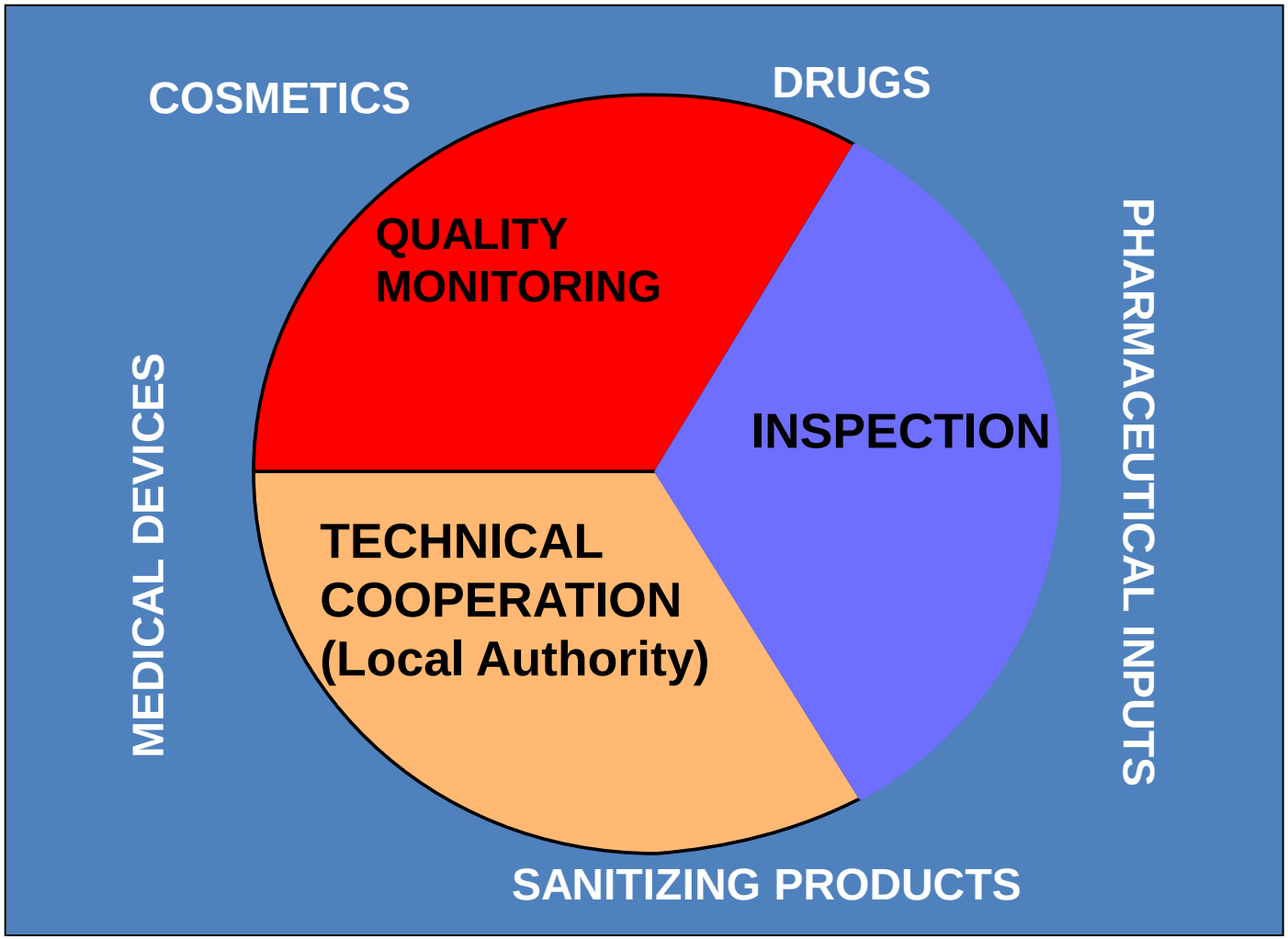
**ALTERATIONS**

**REVALIDATION / RENEWAL**

**OF**

**REGISTRATIONS**

# REGULATORY INSPECTIONS



# REGULATORY INSPECTION
# MAIN RESPONSABILITIES

- Approve/issue and cancel GMP certificate and Company's authorization
- Inspect companies located in Brazil in co-operation with Local Authorities
- Inspect companies located outside the country
- Mutual co-operation and integration with Local Authorities
- Coordinate special quality monitoring programs
- Investigate frauds and quality issues
- Coordinate plan to prevent counterfeit in co-operation with WHO
- Propose and apply fine and penalties

# NEW REGULATORY FRAMEWORKS

## Simplification the analysis of clinical trials

Was instituted the simplified process of analysis for certain applications for approval of clinical trials, as the case of clinical research has evaluated and approved by regulators in Europe, America, Japan, Australia or Canada (RDC No. 36 of 27/06/2012 ). With this new procedure, there is an expectation to reduce for a half the time it takes to ANVISA to authorize these studies.

## Reduction of deadlines

With the creation of the electronic protocol for issuance of Certificate of Registration of Drug Registration and the Certificate for Export of Drugs (RDC No. 2/2012), was reduced to five minutes the time for issuance of these two documents. Both are declaratory documents containing information about a particular drug registered in Brazil and are of interest of drug manufacturers.

## Simplification of the Process

Changes in labeling and leaflet of drugs will be automatically notified to ANVISA by pharmaceutical laboratories, according to the provisions of the Resolutions RDC No. 60 and No. 61/2012. Thus, applications that previously had to wait in line for the analysis of the Agency shall be authorized immediately.

## IMDRF - Brazilian Participation

- The safety of products made available to the public and health systems is a shared responsibility between regulators, health services and the entire chain involved on the access to these products.

- ANVISA values the importance of the active participation of national sectors on the discussions of IMDRF, and the representation of these sectors at the designated places of the structure, such as the Open Forum for Stakeholders, working groups and public consultations.

# INTERNATIONAL FORA - MDSAP

•The Medical Device Single Audit Program - MDSAP is a joint work program based on regulatory audits under development for four countries in order to enable a manufacturer of medical devices to have a single audit in their own quality system, so as to meet the requirements of regulatory authorities of all four participants.

Therapeutic Goods Administration (TGA)


Agência Nacional de Vigilância Sanitária (ANVISA)

Health Canada (HC)

Food and Drug Administration (FDA)

Observes

## ICH - International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

- ANVISA is reassessing the relation with ICH initiatives. ANVISA hopes to contribute to the ICH reform discussion in order to include important aspects for regions initially outside the scope of ICH.

# International Strategies

1. Participation in international forums that establish the technical and scientific references to be used on Brazilians regulation:

WHO, IMDRF, ICH, IGDRP, IPRF, Codex Alimentarius, PIC/s, ICCR, ICDRA, Heads Summit…;

2. Attendee at forums that promotes regulatory convergence with direct impact on trade:

WTO, WIPO, Mercosur ...

3. Cooperation Projects signed with international organizations to support the achievement of national and international objectives in a more quickly, flexible and comprehensive way

ISAGS and TC PAHO

# International Strategies

4. Technical Cooperation provided through partnership with the Brazilian Cooperation Agency – ABC

Focused on Latin American and Portuguese Speaking African Countries

5. Bilateral Approach to the ANVISA's Counterparties ANVISA

to avoid duplication of efforts , make better use of available resources and especially use the existing international tools to assist the agency to achieve its duties in regulation and monitoring.

ANVISA has 35 agreements, including MOUs, Letters of Confidentiality Arrangements, such as with MHLW/PMDA


6. Launch of International Internship Program

# Future Collaboration Brazil - Japan

. Exchange of strategic information within a friendly and confidential environment;

. Start of concrete joint activities:

. seminars, training and maybe permanent programs on medical devices, drugs, price regulation of medical devices and drugs, pharmacopeia and other areas of mutual interest;

. Possibility of an internship of ANVISA and MHLW/PMDA staff to exchange best practices and promote mutual reliance between both institutions.

*Arigato!*
*Thank you*

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