South South Cooperation: the experience of ANVISA in the Americas, Africa and Asia

Mateus Rodrigues Cerqueira
International Affairs Office

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ANVISA / Ministry of Health – The Brazilian Health Surveillance Agency

**Mission:**
- “To protect and promote health, ensuring the quality and safety of products and services and taking part in developing access to them.”

**Values:**
- Technical and scientific knowledge as basis for action
- Transparency
- Cooperation
- Accountability
Agency under special regime

Administrative and financial autonomy (linked to the Ministry of Health)
- Stability of executives (Mandate of Directors)
- Decisions based on technical criteria
- Stability and predictability of regulation

Coordinates the National Health Surveillance System (SNVS)

Created by Law # 9.782, of January 26 1999
Coordinates the National Health Surveillance System (SNVS) and integrates the Unified Health System (SUS)
• DESCENTRALISATION – SNVS

– Follows the directives of the Unified Health System – SUS
– Responsible for the strengthening of the health surveillance system of the federal states and municipalities
– Transfer of financial resources to federative levels
– Establishes commitments and goals with all federative levels through health pacts
– Need to achieve goals agreed with the Ministry of Health
– Conventions e partnership with municipalities, states, universities, etc.
Brazil:
- Population: 187,017,118
- Area: 8,514,876,599 Km²
- 27 Federative States
- 5,560 Municipalities

ANVISA
Complexity and broadness

Industrial, Technological and Foreign Trade Policies (PITCE)

National Policy of Science, Technology and Innovation in Health (PNCTIS)

National Health Policy (and other references to the Health Surveillance System - VISA)

Health Surveillance

Governmental “Program for expanding the growth” – PAC and PAC for Innovation

“Health Plus” Program (Mais Saúde)
ANVISA
Areas of Action

Food
Cosmetics
Sanitizing Products
Tobacco
Toxicology (pesticides)

Health services
Drugs
Medical Devices
Laboratories
Blood and blood products

Post-market surveillance
Publicity control
Ports, airports and frontiers
International
Market regulation
Main sites and services under health surveillance action

- 80,000 drug stores
- 450 pharmaceutical industries
- 3,700 cosmetic manufactures
- 3,300 medical devices manufactures
- 3,000 sanitizing products manufactures
- 2,000 drug distributors
- 3,900 laboratories of clinical analyses
- 15,500 radio-diagnostics services
- 6,600 hospitals
- 3,000 Blood therapy services
INTERNATIONAL RELATIONS
PRINCIPLES AND GUIDELINES

• Brazilian Foreign Policy
• Unified System of Health (SUS)
• Transparency (WTO)
• National treatment (WTO)
• Non discrimination (WTO)
Strategies:

– Aligned with the priorities of the Brazilian Foreign Affairs Policy (PEB)
– Aligned with the guidelines of the Brazilian Health Policy
– Promote solidarity among nations
– Focus on the strengthening of partnerships with countries
– Strengthening of institutional representation
– Promote new spaces for cooperation
– Promotion of Dialogue (exchange of information and experiences) between regulators and the WHO and regional offices
INTERNATIONAL COOPERATION

- Foreign Policy of Brazil
  - Active role in international affairs: also Presidential Diplomacy
  - International acknowledgement of its emerging power
  - “System affecting country1”: act as a mediator between developing countries interests and developed countries ones
  - Development agenda: leadership and innovative mechanisms
  - Principles: solidarity, international law and multilateralism, democratic values, peace
  - Institutionalized foreign policy (state policy rather than a governmental one) : Itamaraty

INTERNATIONAL COOPERATION

International Cooperation:

- State policy and an instrument to achieve international interests and national development interests
- Brazilian Agency for International Cooperation (ABC): coordinates the Brazilian Technical Cooperation, institutionalized agency with financial resources and autonomy to carry out bilateral projects – linked to the Ministry of Foreign Affairs
- South south cooperation as a clear priority of the Brazilian Foreign Policy: based on technical capacity of Brazil in different areas, experience is shared with other countries – mutual benefits
- UNDP: principles of south south cooperation: horizontality, consensus, equity
INTERNATIONAL COOPERATION

– Brazilian Constitution and National Health Policy:
  • Universal access to health and to health services
  • Partnership with Ministry of Foreign Affairs and Brazilian Agency for International Cooperation in order to coordinate and implement projects of International cooperation in health
  • Health as a “soft power\textsuperscript{2}” in the agenda of foreign policy
  • Structuring cooperation in health: cooperation with “friend nations” in order to help strengthen and structure their health systems
  • It achieves a double objective as it promotes our model internationally and help strengthen our own system through the revision of our work flow and processes – mutual benefits of south south cooperation

INTERNATIONAL COOPERATION

• International Affairs Office of ANVISA:
  – International Cooperation Unit
  – International Health Regulations Unit
  – Regional Integration

• Follows the Foreign Affairs Policy of Brazil, the Health Policy of Ministry of Health and priorities of our Board of Directors.

• Initiatives of cooperation by which we share our experiences and best practices with foreign medicines regulatory authorities in order to learn from their experience and improve our own system and also in order to strengthen the regulatory capacity and the regulatory authority of least developed countries.
## INTERNATIONAL COOPERATION

<table>
<thead>
<tr>
<th>MOUs signed by ANVISA with Health Authorities until 2008</th>
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<tbody>
<tr>
<td>TOTAL</td>
<td>12</td>
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<tr>
<td>Argentina</td>
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<tr>
<td>Cape Verde</td>
<td>01</td>
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<tr>
<td>Cuba</td>
<td>02</td>
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<tr>
<td>Mexico</td>
<td>01</td>
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<tr>
<td>Mozambique</td>
<td>01</td>
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<tr>
<td>Nigeria</td>
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<td>Portugal</td>
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<td>Uruguai</td>
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Cooperation Projects in execution:

<table>
<thead>
<tr>
<th>TOTAL</th>
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<tbody>
<tr>
<td>Cape Verde</td>
<td>Capacity building in drugs and food regulation</td>
<td>01</td>
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<tr>
<td>Cuba</td>
<td>Drugs, Medical devices, blood, cells and tissues, post-market surveillance, Laboratories</td>
<td>03</td>
</tr>
<tr>
<td>Dominican Republic</td>
<td>Medicines and Food</td>
<td>01</td>
</tr>
<tr>
<td>El Salvador</td>
<td>Blood and Blood Products</td>
<td>01</td>
</tr>
<tr>
<td>Mozambique</td>
<td>Medicines</td>
<td>01</td>
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<tr>
<td>Peru</td>
<td>Implementation of IHR</td>
<td>01</td>
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<tr>
<td>Uruguai</td>
<td>BE/BA and Blood</td>
<td>02</td>
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</table>
Confidentiality Commitments signed by ANVISA and foreign regulatory authorities for the exchange of non-public information – 2005 to 2010

<table>
<thead>
<tr>
<th>Country and Authority</th>
<th>Count</th>
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<tbody>
<tr>
<td>Argentina (ANMAT)</td>
<td>01</td>
</tr>
<tr>
<td>Cuba (CECMED)</td>
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</tr>
<tr>
<td>Canada (Health Canada)</td>
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<tr>
<td>United States of America (FDA)</td>
<td>01</td>
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<tr>
<td><strong>TOTAL</strong></td>
<td><strong>04</strong></td>
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</table>
Cooperation Projects in negotiation with the Brazilian Agency for International Cooperation – ABC

Argentina, Paraguai, Uruguai – Pharmacopoeia
Chile – Cooperation for the implementation of IHR
Colombia – cooperation for the implementation of IHR
Peru – drugs
Venezuela – capacity building in food and drugs inspection
Cooperation Working Plans:

ANVISA-Health Canada (Health Products and Food Branch)

Main topics:
1. Radiopharmaceuticals
2. Tecnovigilância
3. Registration of in vitro diagnostic
4. Network of Sentinel Hospitals
5. Active Pharmaceutical Ingredients - API
6. Bioequivalence and bioavailability
7. Methodology of risk analysis applied to inspection of GMP
8. Herbal Medicines
9 - Inspection - project CTI
10 - Food (food safety): nutrition labeling foods functional claims property,
11 - Regulatory Impact Analysis
12 - Clinical Research
13 - Biological (Biosimilars)
14 - Cooperation with the WHO Prequalification of vaccines
15 – Electronic Petition of Drug Registration
16 - Tobacco
Cooperation Working Plans:

ANMAT – Argentina
Main topics: pharmacopoeia standards, food, drugs inspection and medical devices

INFARMED – Portugal
Main topics: BD/BE drugs, inspection of drugs, cosmetics and medical devices

FDA – USA
Main topics: Medicines, biologicals, medical devices, food, GMP inspections
Preliminary initiatives of cooperation:

- Bolivia - food, drugs, toxicology and airports, ports and borders
- Colombia (INVIMA) – drugs and IHR cooperation
- Chile (ISP) – drugs
- India (CDSCO) – drugs and vaccines
- China (SFDA) – drugs and medical devices
- Burkina Faso (National Laboratory of Health Control)
- France (AFSSAPS) – GMP inspections
- United Kingdom (MHRA)
• ANVISA is the focal point for WTO - Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)

• Follow up the WTO - Technical Barriers to Trade Agreement (TBT Agreement)

• Follow up the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) - DOHA Declaration on TRIPS and Public Health
• ANVISA is the focal point for International Narcotics Control Board (INCB)

• ANVISA is the focal point for the Inter-American Drug Abuse Control Commission (CICAD) under the Organization of American States (OAS)

• Follow World Intellectual Property Organization (WIPO) meetings

• Ibero American Meeting of Medicine Authorities – EAMI

• United Nations – UN (e.g. JIFE)
MULTILATERAL AREAS OF ACTION

WHO MEETINGS

- International Conference of Drug Regulatory Authorities (ICDRA)
- Developing Country Vaccine Regulator's Network (DCVRN)
- Active participation of ANVISA’s experts in WHO technical meetings
- Active participation in meetings organized by WHO for the implementation of International Health Regulation (IHR)
MERCOSUR
Economic integration sphere that encompasses 4 countries:
- Argentina
- Brasil
- Paraguai
- Uruguai

Targets:
- Harmonization of legislations (mandatory)
- Elimination of tariffs
- Establishment of External Common Tariff (TEC)
Working Group SGT-11 – HEALTH

• Commission of Health Products
• Commission of Epidemiological Vigilance and Sanitary Control of Ports, Airports and Boarders
• Commission of Health Services
Working Group SGT-3 – Technical Regulations and Conformity Assessment

Commission of Foods (CA):

- Ad Hoc Groups: Diary Products; Fruits and Vegetables; Food Additives; Beverages; Packaging and Food Claims.
Active participation in the following arenas non mandatory:

– Codex Alimentarius FAO/WHO
– Pan American Network for Drug Regulatory Harmonization (PANDRH/PAHO)
– Forum for the Regulation of cosmetics in the Americas (RASA)

Observer:
- Global Harmonization Task Force (GHTF)
- International Cooperation for Harmonisation (ICH)
WHO PREQUALIFICATION PROCESS

- Qualification of ANVISA by WHO in the area of vaccines
- Pre authorization for WHO to purchase Brazilian vaccines to countries in situation of emergency and calamity.

- Certification by PAHO as Regulatory Authority of Reference in the area of medicines
- PAHO issued ANVISA with the high level qualification. This evaluation will impact the process of drugs pre-qualification of PAHO, as well as it will help guide regional cooperation in the field of health surveillance.

- ANVISA has also presented its Official Application to PIC/S.
- This will strength the relation among ANVISA and the main regulatory agencies in the area of inspection. It also represents a recognition of ANVISA`s requirements and procedures.
INTERNATIONAL INSPECTIONS

- Manufacturing companies of products under health control for Good Manufacturing Practice Certification
  - Medicines
  - Medical devices: products of class risk 3 and 4 (Risk classification based on GHTF guideline SG1-N15:2006)
- Bioequivalence centers to verify the compliance with operative technical requests for the conduction of bioavailability and bioequivalence studies for certification / habilitation
Challenges of the Brazilian Health Regulatory System

• Point out ways in order to boost the country’s economic growth and social inclusion

• Improve the Brazilian Health Regulatory System

• Enhance transparency and modernize Public Administration Management

• Ensure predictability and stability of regulations to companies and citizens

• Increase access to health with quality and contribute to the development and innovation of the pharmaceutical sector
Facing the challenges: Strategic Definitions

- Construction and maintenance of stable regulatory environment
- Increase transparency in the decision making process and action
- Modernization in management and improvement of work flow and process
- Commitment with the Country’s development: Consequences on economic development, employment and income
- Work closely to strategic partners for the implementation of international technical cooperation
Obrigado!

Thank you!

rel@anvisa.gov.br

Phone #: + 55 61 3462-5406  Fax #: +55 61 3462-5414