



The Brazilian Health System

4th Brazil-Japan Seminar of Regulations
on Pharmaceuticals and Medical Devices

Tokyo, Japan
December 3rd, 2018



Summary of contents

- ❖ The Brazilian Health Regulatory Agency
- ❖ Description of the Brazilian health system
- ❖ Health Technologies Assessment



Characteristics

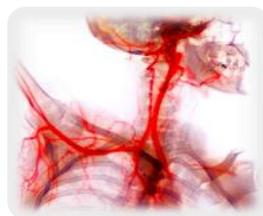
- ❖ Governmental regulatory agency characterized by its administrative independence, financial autonomy and stability of the Directors
- ❖ Ruled by a Board of Directors composed of five Directors designated by the Brazilian President of the Republic for a 3-year mandate, which can be extended for more 3 years
- ❖ Bound to the Ministry of Health, with which ANVISA has a periodic management contract signed
- ❖ Science-based technical decisions, predictability and transparency of the regulatory process as Anvisa's values



Competence

Regulation, Marketing Authorization, Monitoring and Inspecting, Coordination, Research and Education

P
R
O
D
U
C
T
S



S
E
R
V
I
C
E
S



C
O
N
T
R
O
L



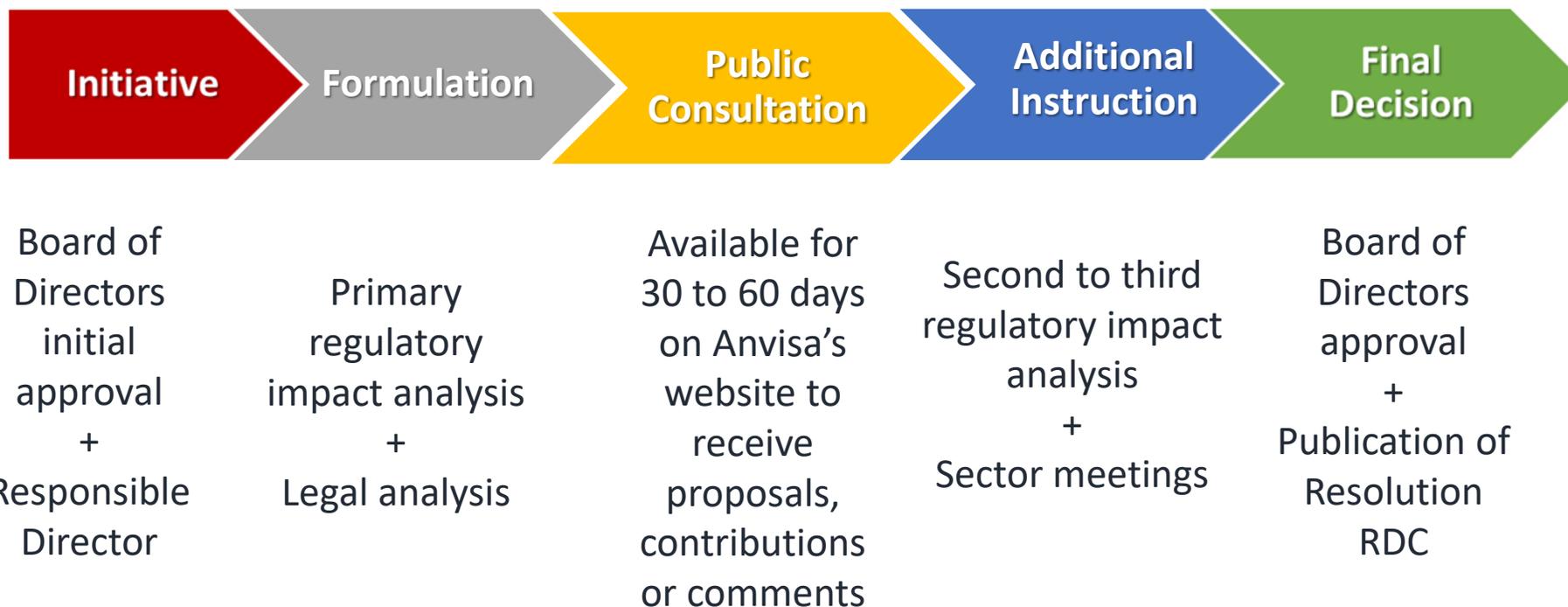
ANVISA

Agência Nacional de Vigilância Sanitária



Regulatory Strategies

Strict regulatory process



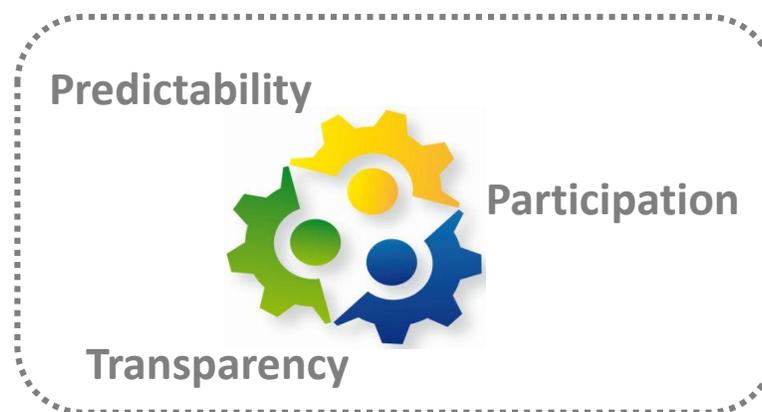


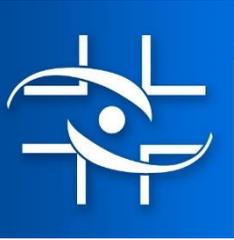
Regulatory Strategies

Regulatory agenda

Aligned with Anvisa's Strategic Plan, the Regulatory Agenda defines priority issues for technical regulation for four-year periods.

Active participation of stakeholders in the priority-setting process





Regulatory Strategies

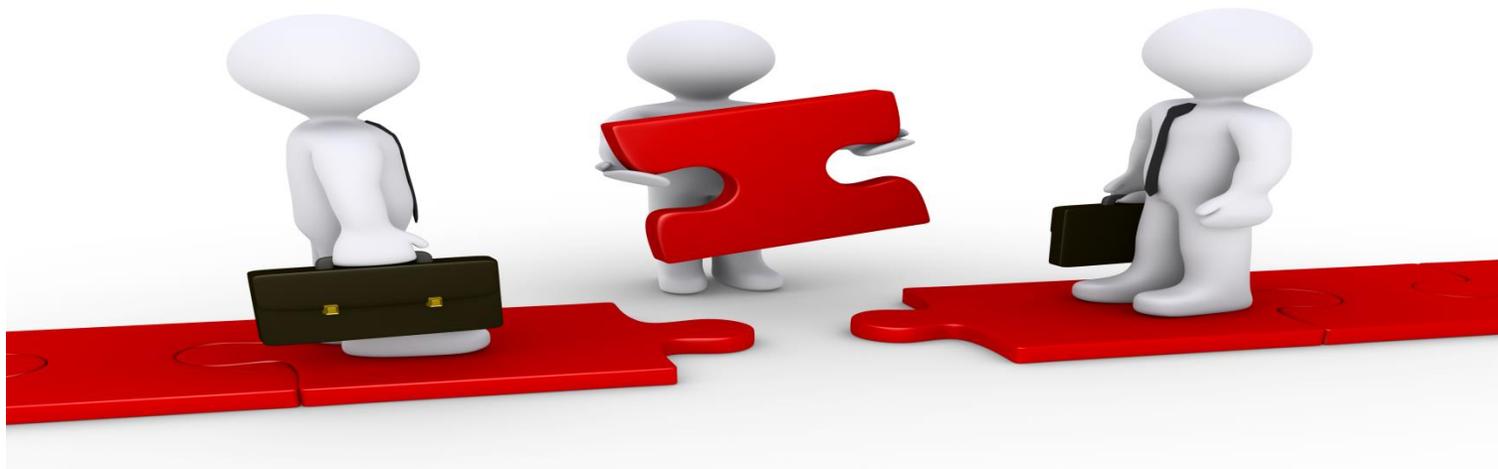
Closer relationship with the private sector

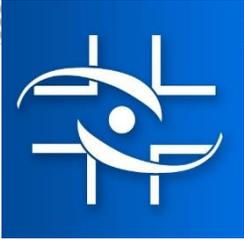
International Dialogues

Understand and act on concerns related to foreign regulation and international standards

Cooperation with APEX Brasil

Enhance and disseminate Anvisa's regulatory image and the quality of national products to improve access to strategic international markets





Regulatory Strategies

Harmonization and Regulatory Convergence

International partnerships for harmonization and convergence of initiatives to develop **common technical standards and guidelines.**





Regulatory Strategies

International Cooperation

37 bilateral Agreements with different countries/organizations

Mercosur countries

PAHO Regional Reference Authorities
(Argentina, Canada, Chile, Colombia, Cuba, Mexico,
United States)

Australia

United States of America

Canada

Denmark

Sweden

United Kingdom

Portugal

Russia

Iran

WHO

(vaccines, medical devices, medical products)

EDQM

(European Directorate for the Quality of Medicines)

France

Germany

Japan

Ireland

Italy

Ukraine

China

Israel

India



Regulatory Strategies

Cooperation Projects

1. Argentina
2. Paraguay
3. Uruguay
4. Peru
5. Dominican Republic
6. Equator
7. El Salvador
8. Venezuela
9. Burkina Faso
10. Cape Verde
11. Colombia
12. Mozambique
13. FARMED

Training Areas:

- Pharmacopoeia
- Pharmacovigilance
- Pharmacoeconomic
- Intellectual Property
- Laboratories
- Food
- Ports, Airports and Borders
- Pharmaceutical Equivalence
- Inspection
- Toxicology
- Actions against Counterfeit Medical Products
- Drug Products



Positive Results

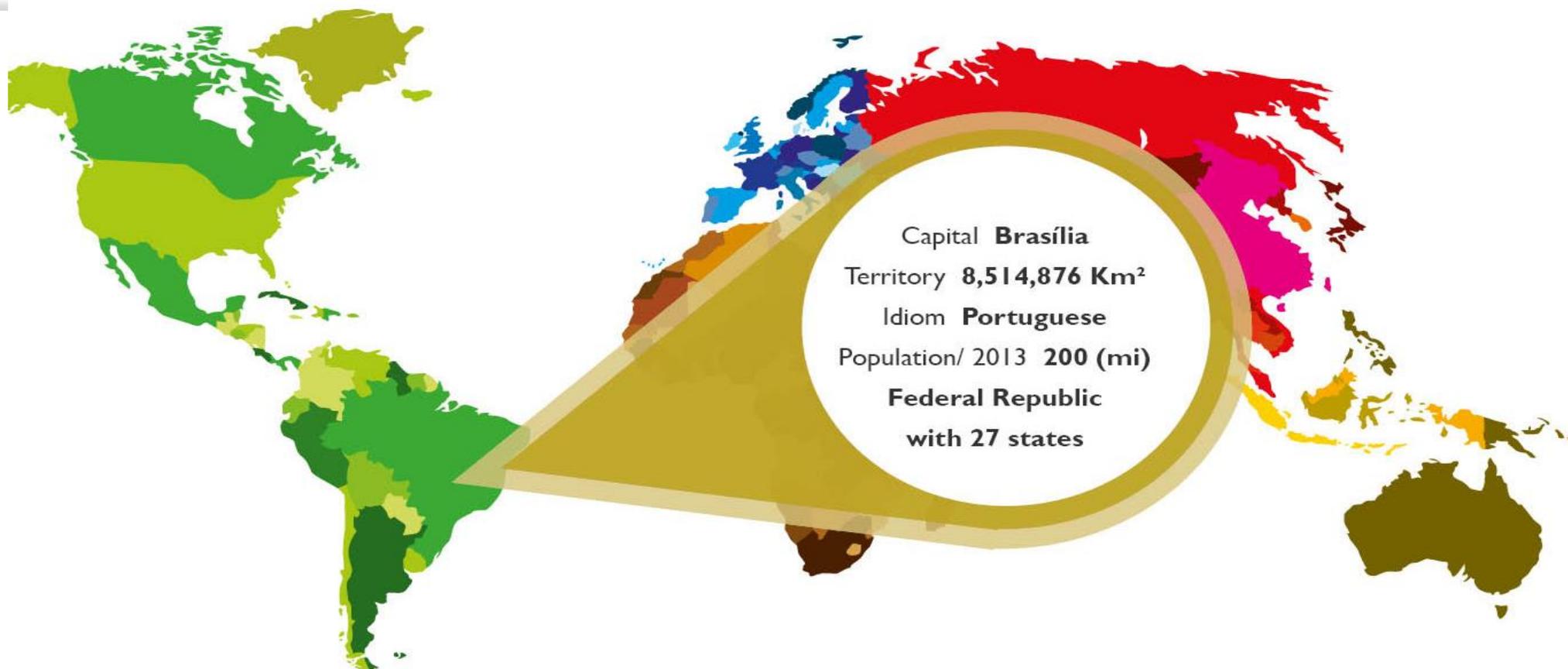
- ❖ Better alignment with Regulatory Authorities worldwide
- ❖ Recognition as a Regional Reference Agency
- ❖ Unilateral recognition of Anvisa's decisions by some countries
- ❖ Others...

Description of the Brazilian Health System





Facts about Brazil



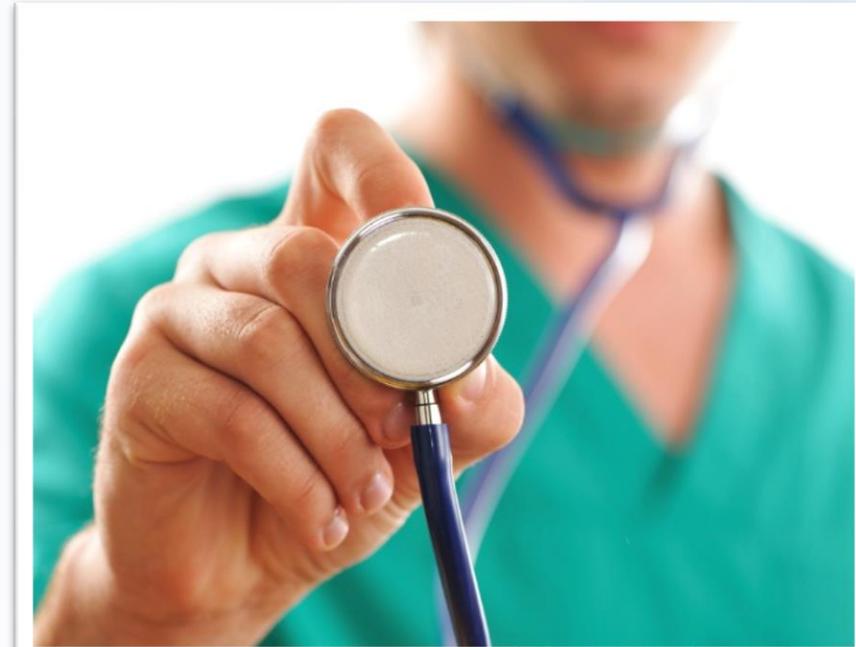
5,560 cities GDP/ 2012 **US\$ 2,25 (tri)**
Life Expectancy at Birth – 2012 **73.6 years**

GPD on health – 2013 **10,2%** (43% Public and 57% Private)
Child Mortality Rate – 2011 **17.7**

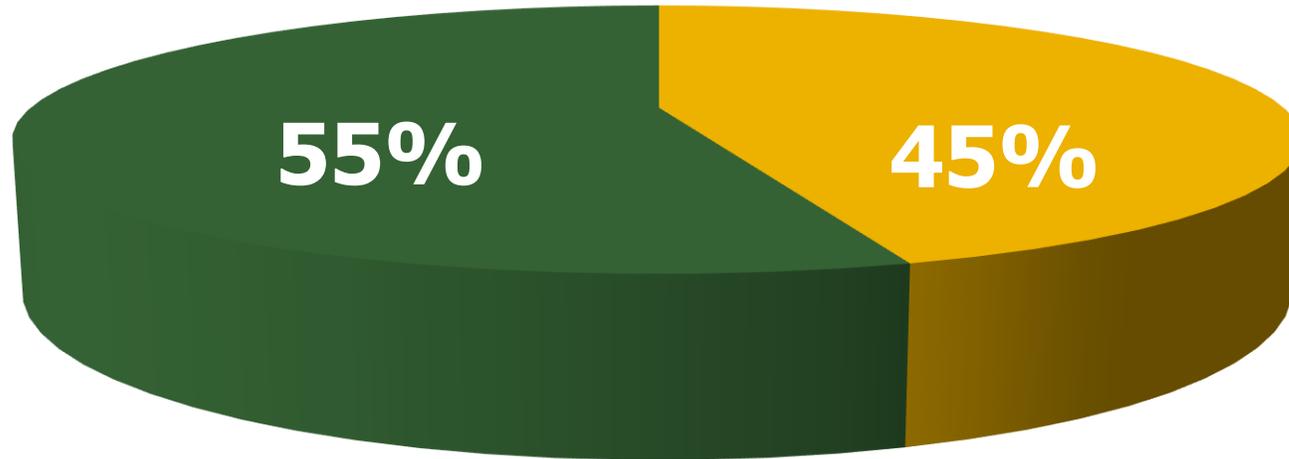
MORE THAN 70% OF THE POPULATION USES THE PUBLIC HEALTH SYSTEM

- ✓ **71.1%** of the Brazilian population* seeks SUS for health care (PNS 2013)
- ✓ About **150 million people** rely exclusively on SUS
- ✓ **47.9 million people** have **health care plans** (ANS - DEC/2016)
- ✓ 22 million have dental plans only (ANS DEC/2016)

*Brazil had 200.4 million inhabitants in 2013 (Source: IBGE)



THE HEALTH SECTOR REPRESENTS 8% OF THE GROSS DOMESTIC PRODUCT



In 2013, public spending accounted for **45%** of health financing. The private sector accounted for **55%**.

■ Private spending % GDP ■ Public spending % GDP

Source: 2010 to 2013 - IBGE / 2014 and 2015 - SIOPS



Federal Law n. 12.401/2011

Creation of CONITEC

Nacional Commission for Incorporation of Technologies in SUS

Rules for the incorporation:

- Evidence-based (safety and efficacy)
 - Economic assessed (cost-effectiveness)
 - Price
 - Available at SUS
- 180 days to 270
- 180 days



Numbers of CONITEC

January 2012 – October 2018

- Meetings: **75**
- Total Requests: **718**
 - External **316**
 - Internal (MoH) **402**



Results of CONITEC

January 2012 – October 2018

• Public consultations	322
• Contributions	104.455
• Incorporated Technologies	231
• Non-incorporated	113
• Excluded technologies	44



Requests by type of technology





ありがとうございました！

Bianca Zimon Giacomini Ribeiro

Specialist in Health Regulation

Office of International Affairs

rel@anvisa.gov.br

www.anvisa.gov.br