

**Vaccine  
Regulatory  
Requirements in  
Brazil**

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Cells and Organs – GGPBS**

**Training for professionals of the vaccine industry**

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# Anvisa's Mission

Agência Nacional de Vigilância Sanitária - Anvisa

To protect and promote public health and to intervene in the risks caused by the production and use of products regulated by health surveillance. This mission must be carried out in coordination with states, municipalities and the Federal District, according to the Brazilian Health System principles, in order to improve the quality of life of the population.

# Areas of action

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**Food**



**Cosmetics**



**Sanitizing  
Products**



**Tobacco**



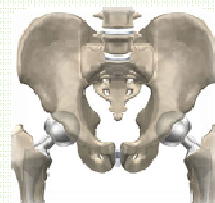
**Toxicology  
(pesticides)**



**Health services**



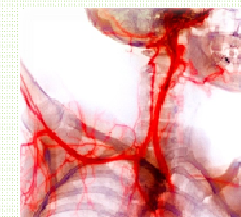
**Drugs**



**Medical Devices**



**Laboratories**



**Blood, Cells, Tissues  
and Organs**



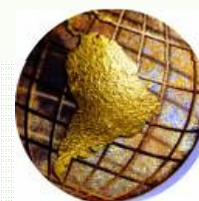
**Post-marketing  
surveillance**



**Marketing  
control**



**Ports, airports and  
frontiers**



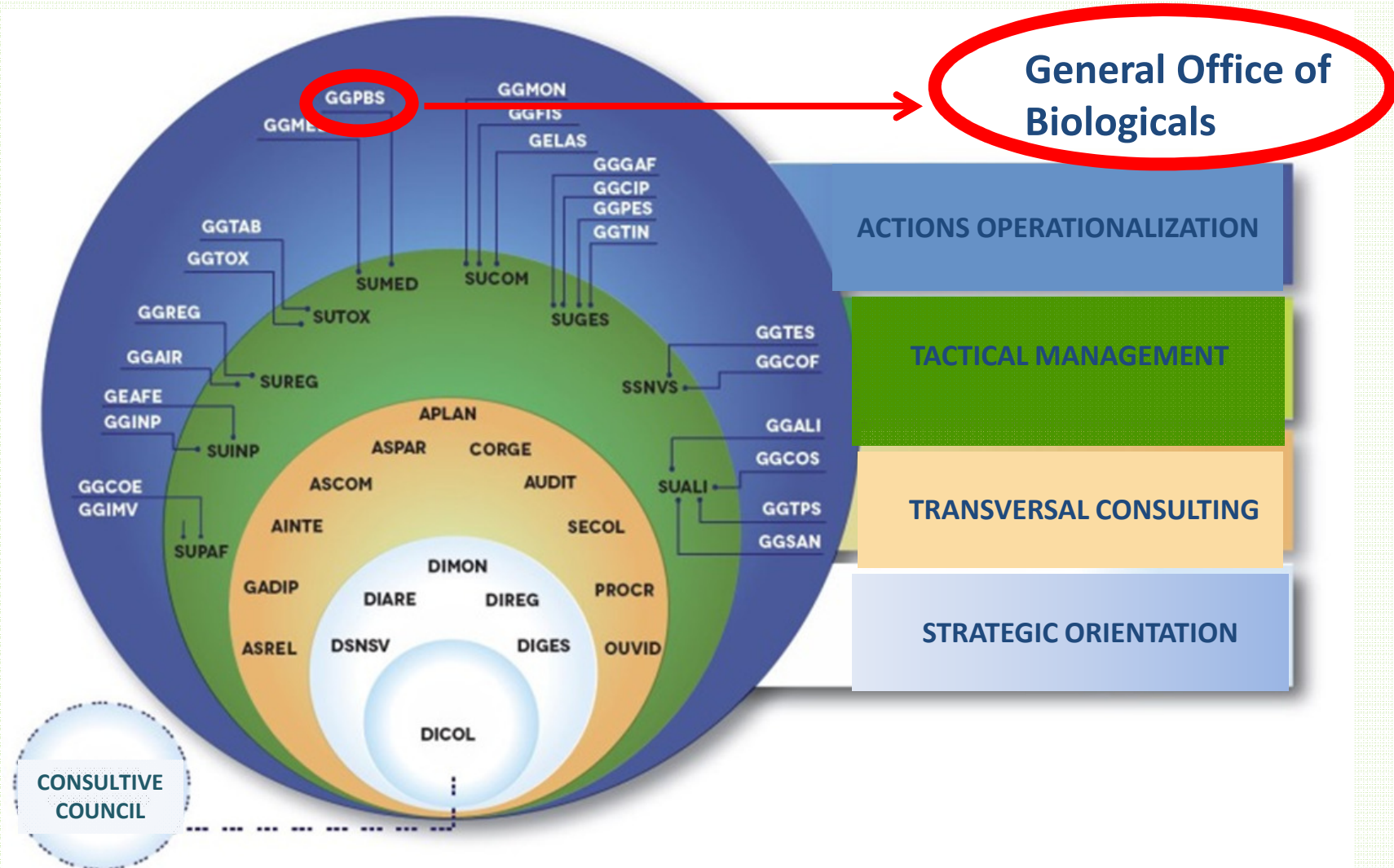
**International**



**Market regulation**

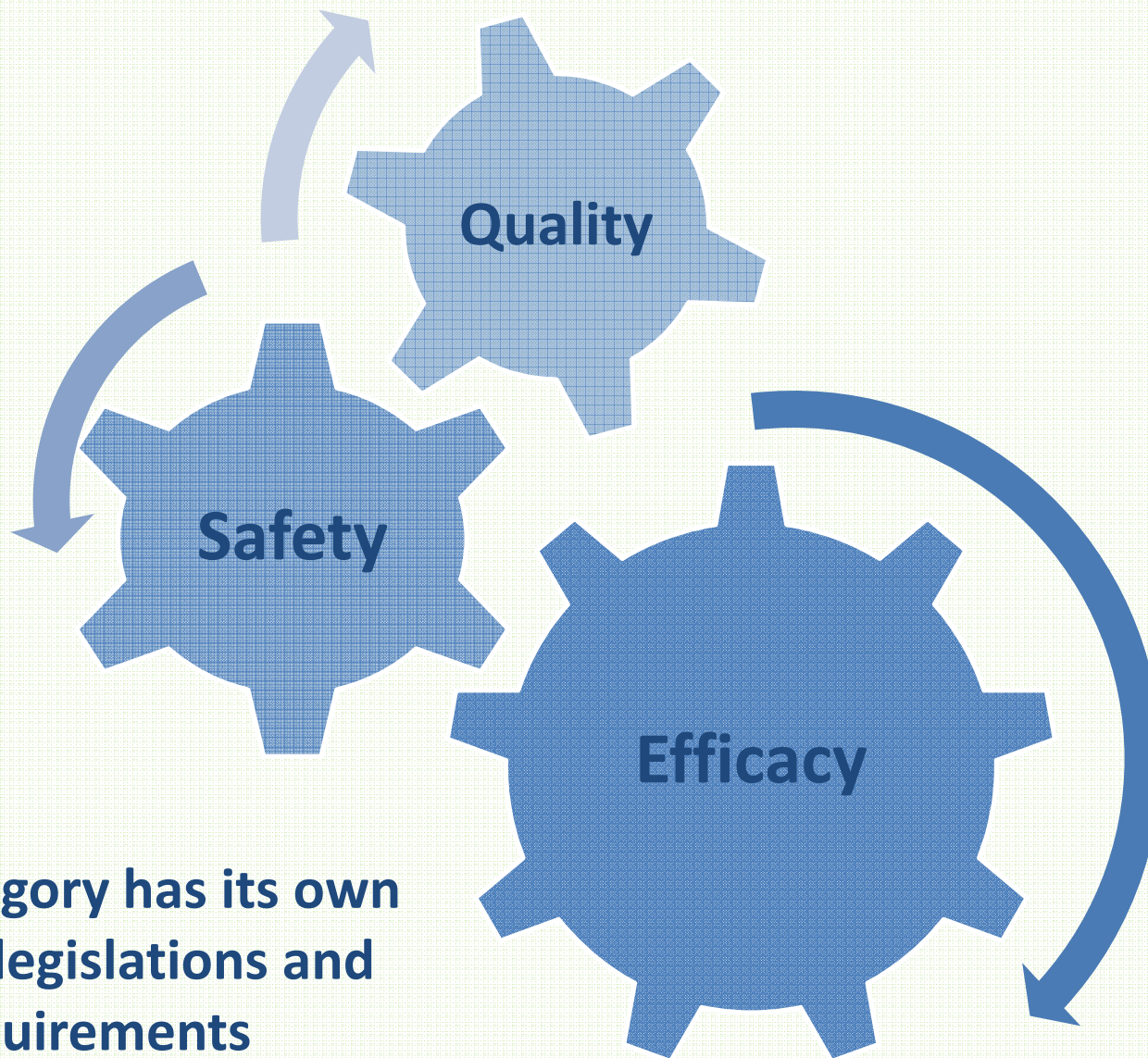
# Organization chart

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# Drugs Registration

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**Each category has its own  
specific legislations and  
requirements**

# Regulatory acts concerning biological products

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**RDC 47/09 e 60/12**  
**Package insert**

**RDC 71/09, RDC 168/02**  
**RDC 61/12**  
**Label**

**RDC 81/08**  
**Import**

**RDC 234/05**  
**RDC 38/10**  
**Quality control**

**RDC 17/10**  
**Good Manufacturing**  
**Practices**

**Law 6360/76**  
**Decree 8.077/13**

**RDC 55/10**  
**Registration**

**RDC 49/11 e 24/13**  
**Post-approval**

**RDC 46/00**  
**Blood products**

**RDC 233/05**  
**Allergenic**

**RDC 323/03**  
**Probiotics**

**RDC 50/11 and 25/13**  
**Stability**

**Ordinance 174/96**  
**Antivenom serums**

# Board Directors Resolution – RDC nº 55/2010

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## 1. Vaccines

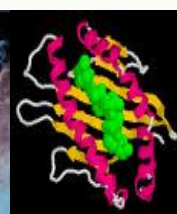
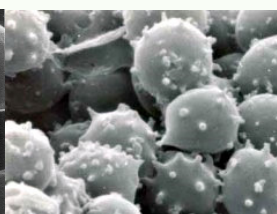
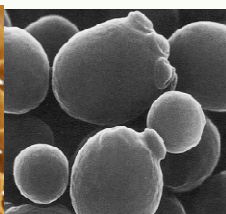
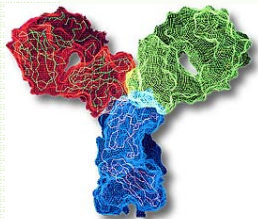
## 2. Hyperimmune sera

## 3. Blood products

## 4. Biomedicines:

- medicines obtained from biological fluids or animal tissues;

- medicines from biotechnologic procedures



# Board Directors Resolution – RDC nº 55/2010

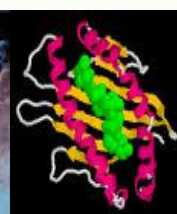
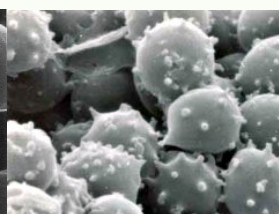
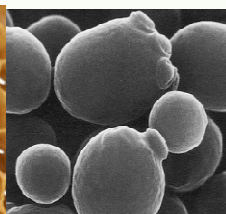
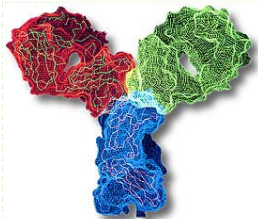
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**5. Monoclonal antibodies**

**6. Medicines containing live, attenuated or dead microorganisms**

**7. Probiotics**

**8. Allergens**





# Board Directors Resolution – RDC nº 55/2010

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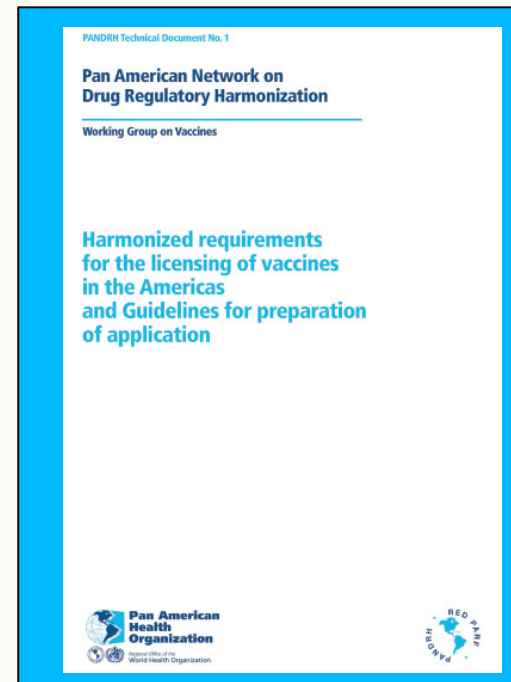
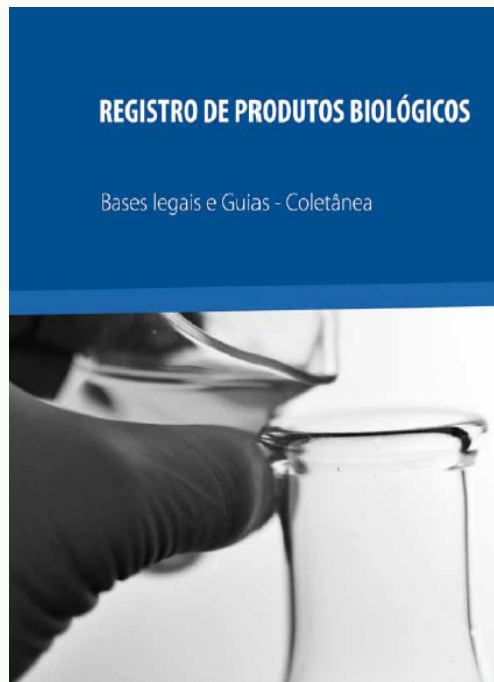
**1. Vaccines are immunobiological drugs containing one or more antigenic substances that, when inoculated, are able to induce specific active immunity, in order to protect against, reduce the severity or fight the disease(s) caused by the agent that originate the antigen(s);**



# Board Directors Resolution – RDC nº 55/2010

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1. RDC 55/2010
2. Harmonized requirements for the licensing of vaccines in the Americas and Guidelines for the preparation of application



# Board Directors Resolution – RDC nº 55/2010

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## ❖ Dossier must support all evidence for license

1. Legal documentation
2. Vaccine manufacture and quality control documentation
3. Nonclinical and clinical reports



# Board Directors Resolution – RDC nº 55/2010

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## 1. Legal documentation



- Licenses, authorizations and certificates

**GMP must be assessed by ANVISA's inspectors**



# Board Directors Resolution – RDC nº 55/2010

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## 2. Quality



- Manufacturing stages and Quality Control information
- Transport chain validation protocol and report
- Stability studies protocol and report
- Description of the used strains
- Description of the master and working seed batches of the virus and cell lineage used
- Description of the master and working cell bank system



# Board Directors Resolution – RDC nº 55/2010

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## 3. Safety and Efficacy

- Report of all nonclinical studies
- Protocols and reports of the clinical studies, phases I, II and III
- Pharmacovigilance plan and a risk minimization plan



# Board Directors Resolution – RDC nº 55/2010

Agência Nacional de Vigilância Sanitária - Anvisa

## ❖ Guideline for Elaboration of Clinical Study Reports

Guia para Elaboração de Relatórios  
de Estudos Clínicos para fins de Registro  
e/ou Alterações Pós-registro de  
Produtos Biológicos


<http://s.anvisa.gov.br/wps/s/r/lg>




# Board Directors Resolution – RDC nº 55/2010

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## ❖ Drug Approval and Refusal Letters

Ministério da Saúde 

 Bases Técnicas e Científicas da Conclusão da Análise do Registro de Medicamento

**Bases Técnicas e Científicas da Conclusão da Análise do Registro de Medicamento**


Medicamento:

Empresa:

Período de Publicação:  a

Registros por Página:

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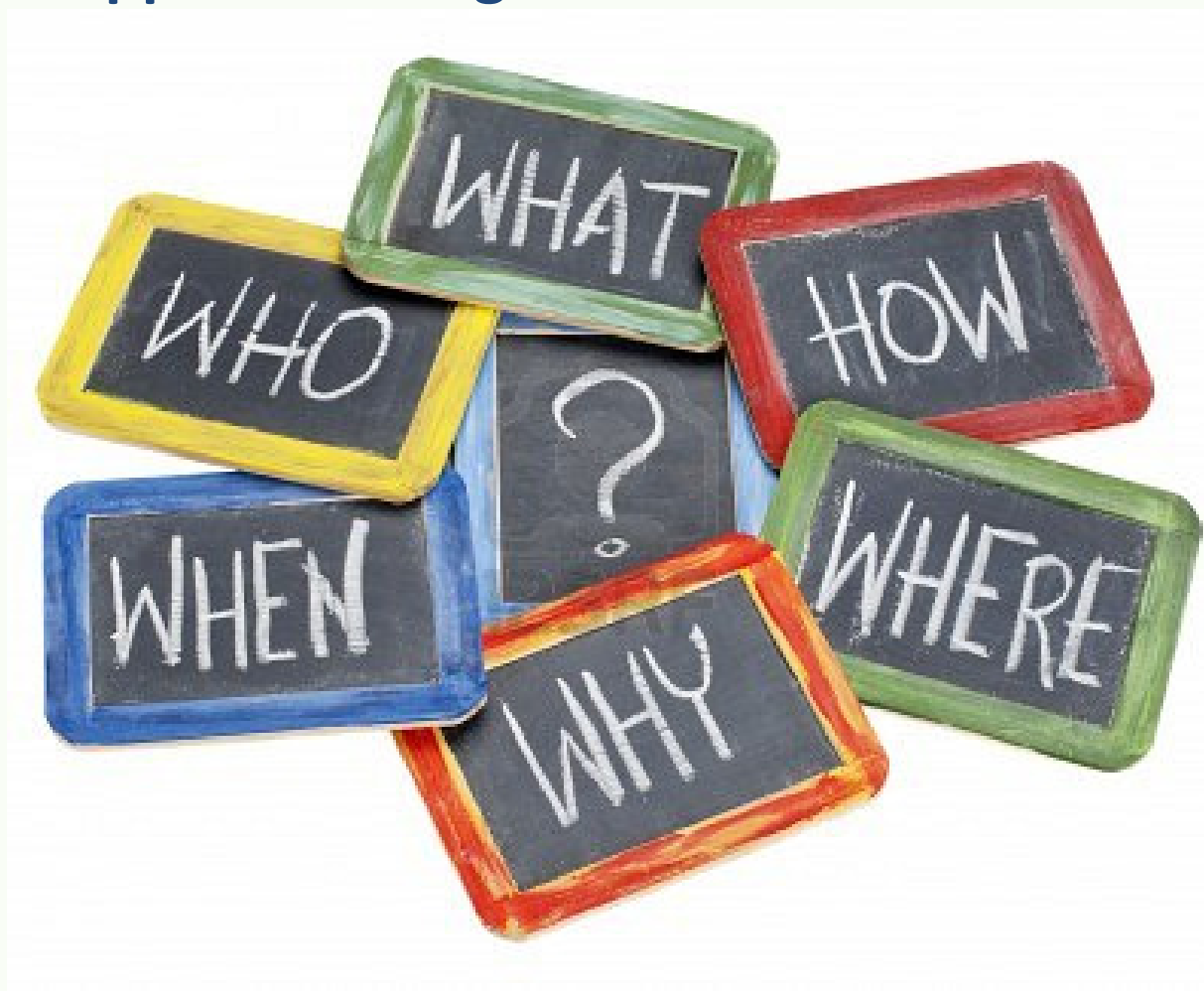
[http://www.anvisa.gov.br/datavisa/Fila\\_de\\_analise/index.asp](http://www.anvisa.gov.br/datavisa/Fila_de_analise/index.asp)



# Board Directors Resolution – RDC nº 49/2011

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## ❖ Post approval changes



# Board Directors Resolution – RDC nº 49/2011

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## ❖ Post approval changes



**Level 3 change (major changes)  
Tell and Wait**

**Level 2 change (moderate changes)  
Tell and Do**

**Level 1 change (minor changes)  
Do and Tell**

# Brazilian Scenario

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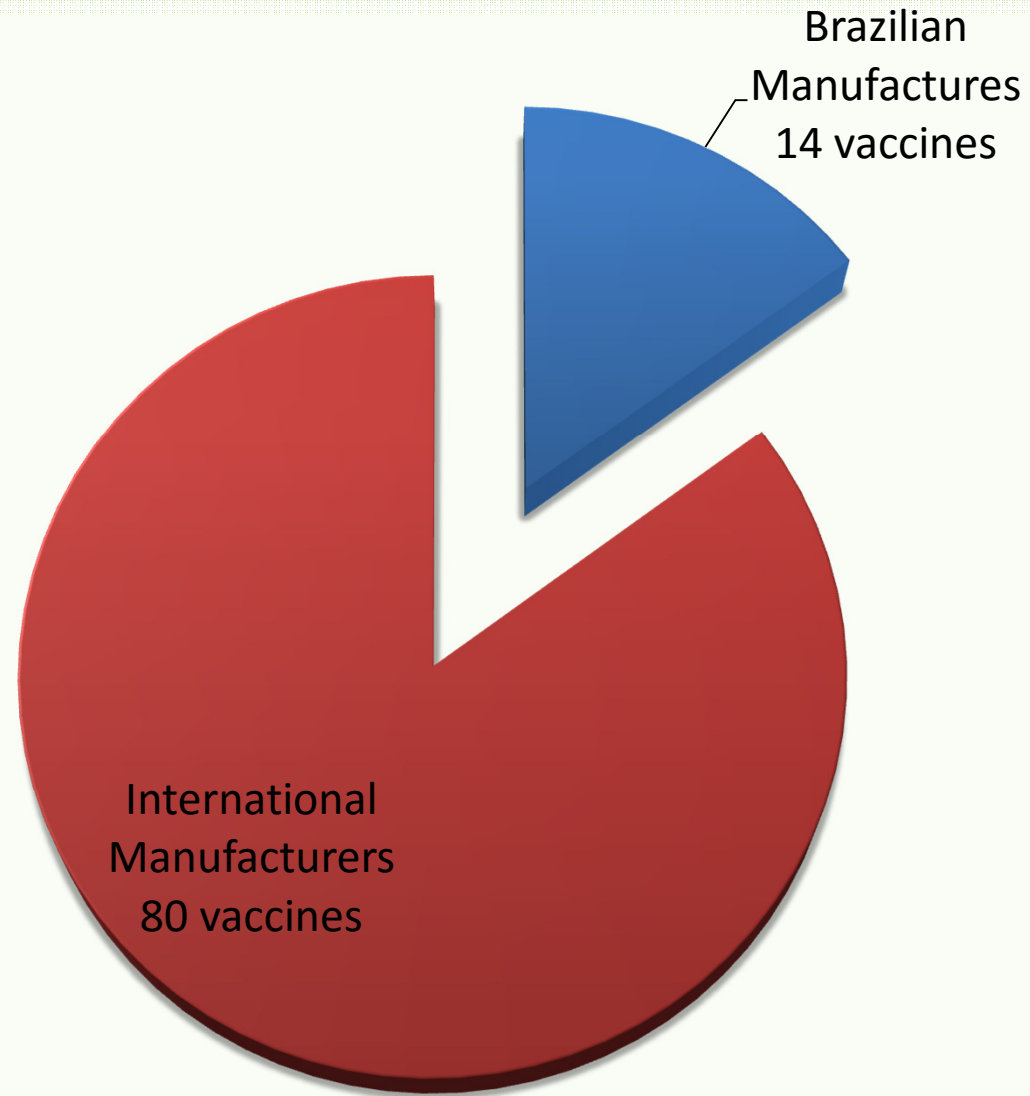
❖ **94 vaccines licensed in Brazil**

❖ **05 Brazilian Manufacturers**

- **Fundação Ataulpho de Paiva**
- **Fundação Ezequiel Dias – FUNED**
- **Fundação Oswaldo Cruz/Bio-Manguinhos**
- **Instituto Butantan**
- **Instituto de Tecnologia do Paraná – TECPAR**

# Brazilian Scenario

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# Top 3 Challenges 2015-2016

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1

**Dengue vaccine license**

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2

**tOPV to bOPV<sub>1&3</sub>**

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3

**Pre-qualified PAHO Vaccines**

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# References

Agência Nacional de Vigilância Sanitária - Anvisa

- **Brazil, Resolution RDC n° 55, December, 16th, 2010, Anvisa**
- **Brazil, Resolution RDC n° 50, September, 20th, 2011, Anvisa**
- **Brazil, Resolution RDC n° 49, September, 20th, 2011, Anvisa**
- **Brazil, Law n° 6360, September, 23th, 1976**
- **[www.anvisa.gov.br](http://www.anvisa.gov.br)**

# Thank you

Agência Nacional de Vigilância Sanitária - Anvisa

## Acknowledgments

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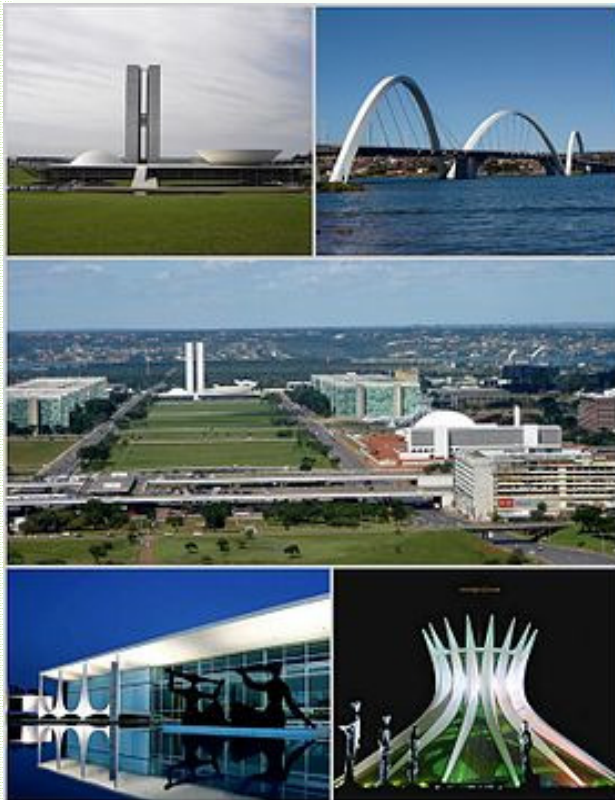
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