

# Efficiency of Biological Products Review

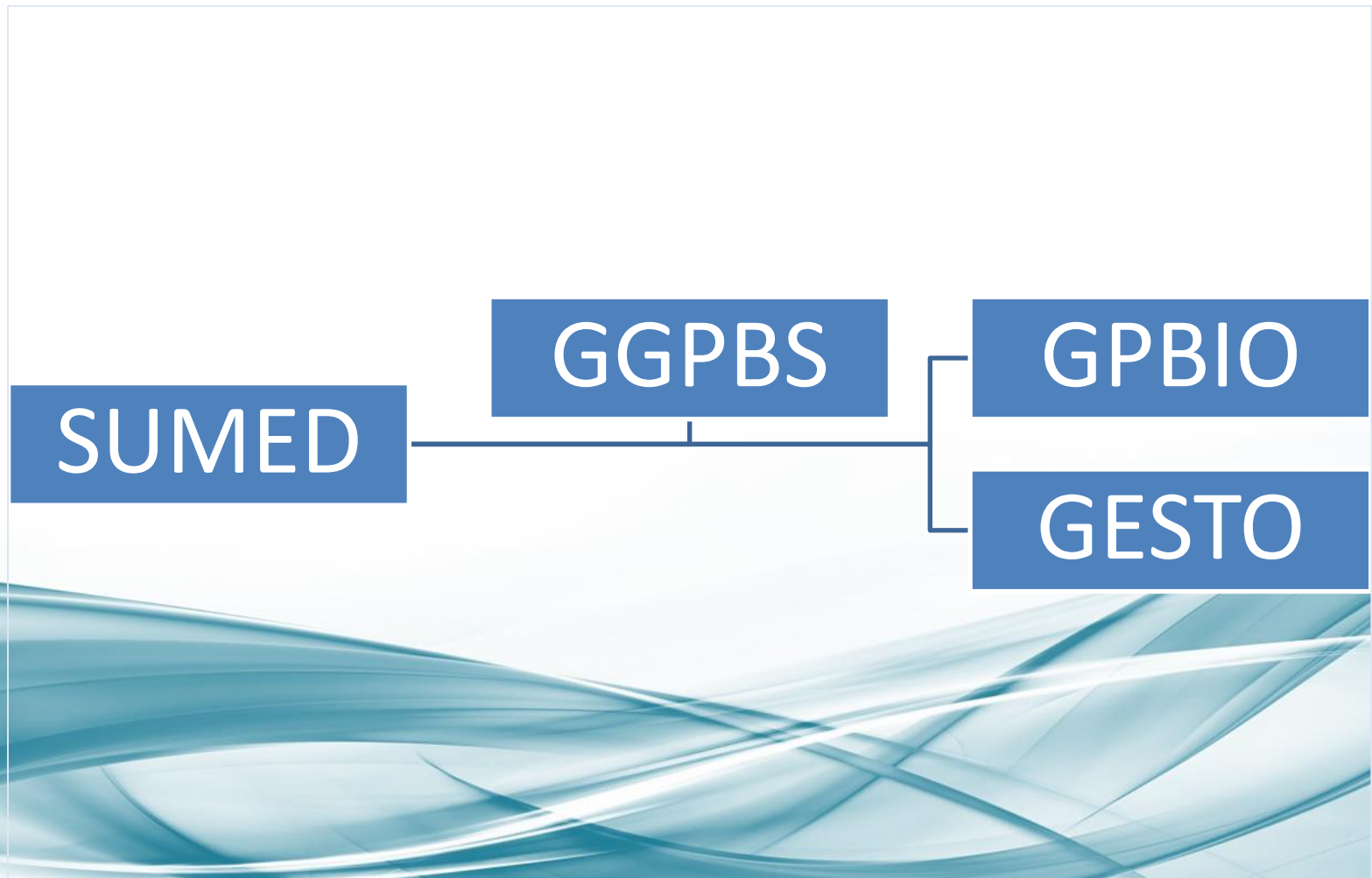
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Brazilian Health Surveillance Agency – ANVISA

São Paulo – August, 2<sup>nd</sup> 2014

# Flow Chart



# Team Reviewing at GPBIO

- ④ 16 Specialists in Regulation and Health Surveillance
  - Biologists
  - Pharmacists
- ④ 03 Technicians Regulation
- ④ 01 Administrative

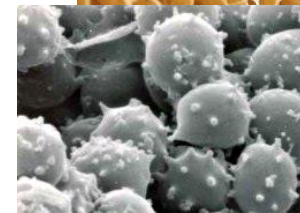
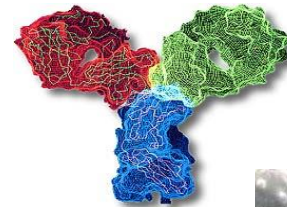


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# Biologicals licensed in Brazil

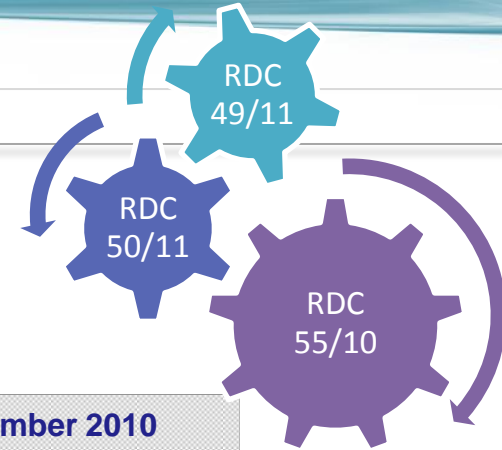
- Ⓜ Vaccines;
- Ⓜ Hiperimmune sera;
- Ⓜ Blood products;
- Ⓜ Biomedicines:
  - ☞ medicines obtained from biological fluids or animal tissues;
  - ☞ medicines from biotechnological procedures.
- Ⓜ Monoclonal antibodies;
- Ⓜ Medicines containing live, attenuated or dead microorganisms;
- Ⓜ Probiotics;
- Ⓜ Allergens.



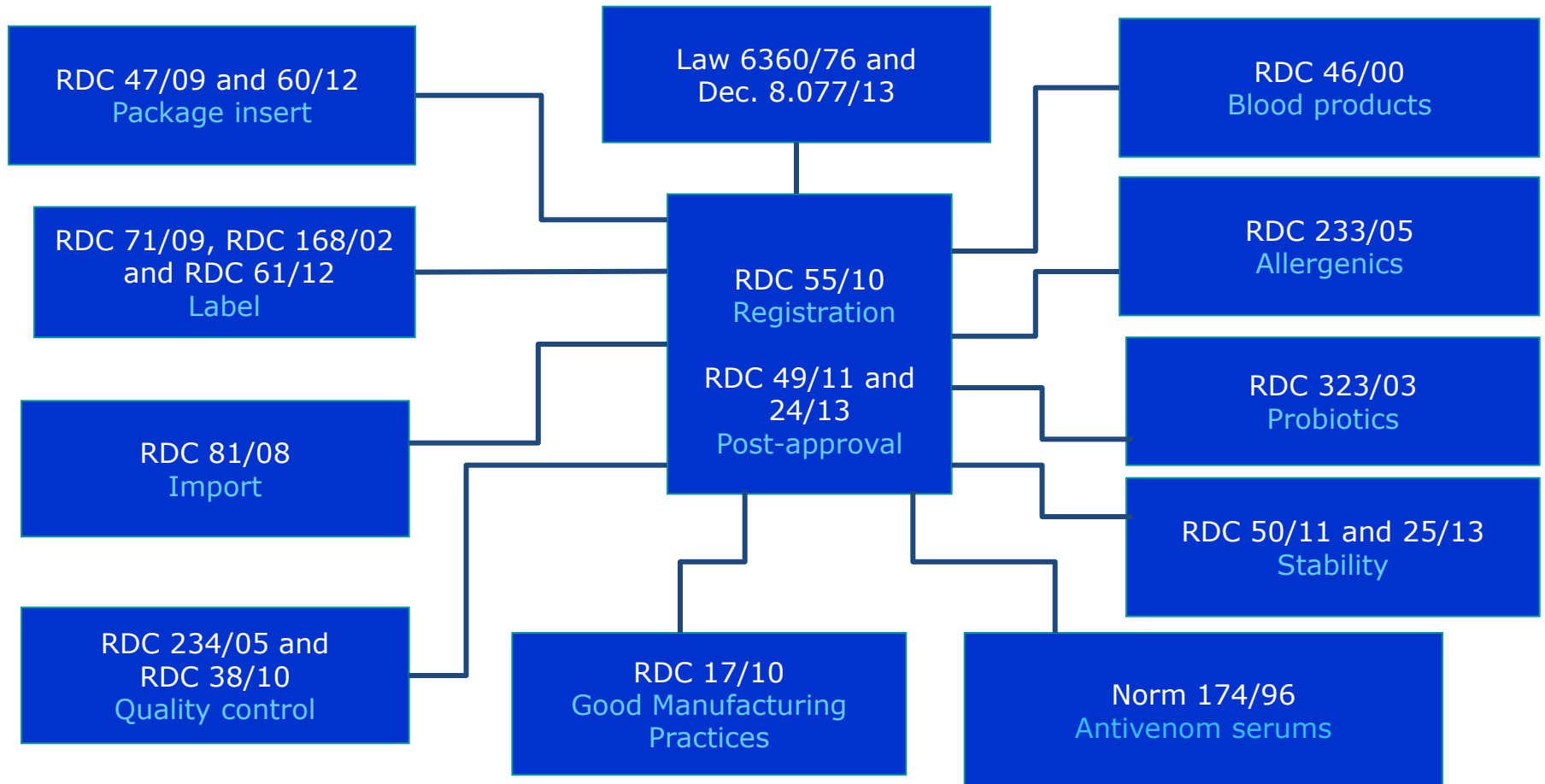
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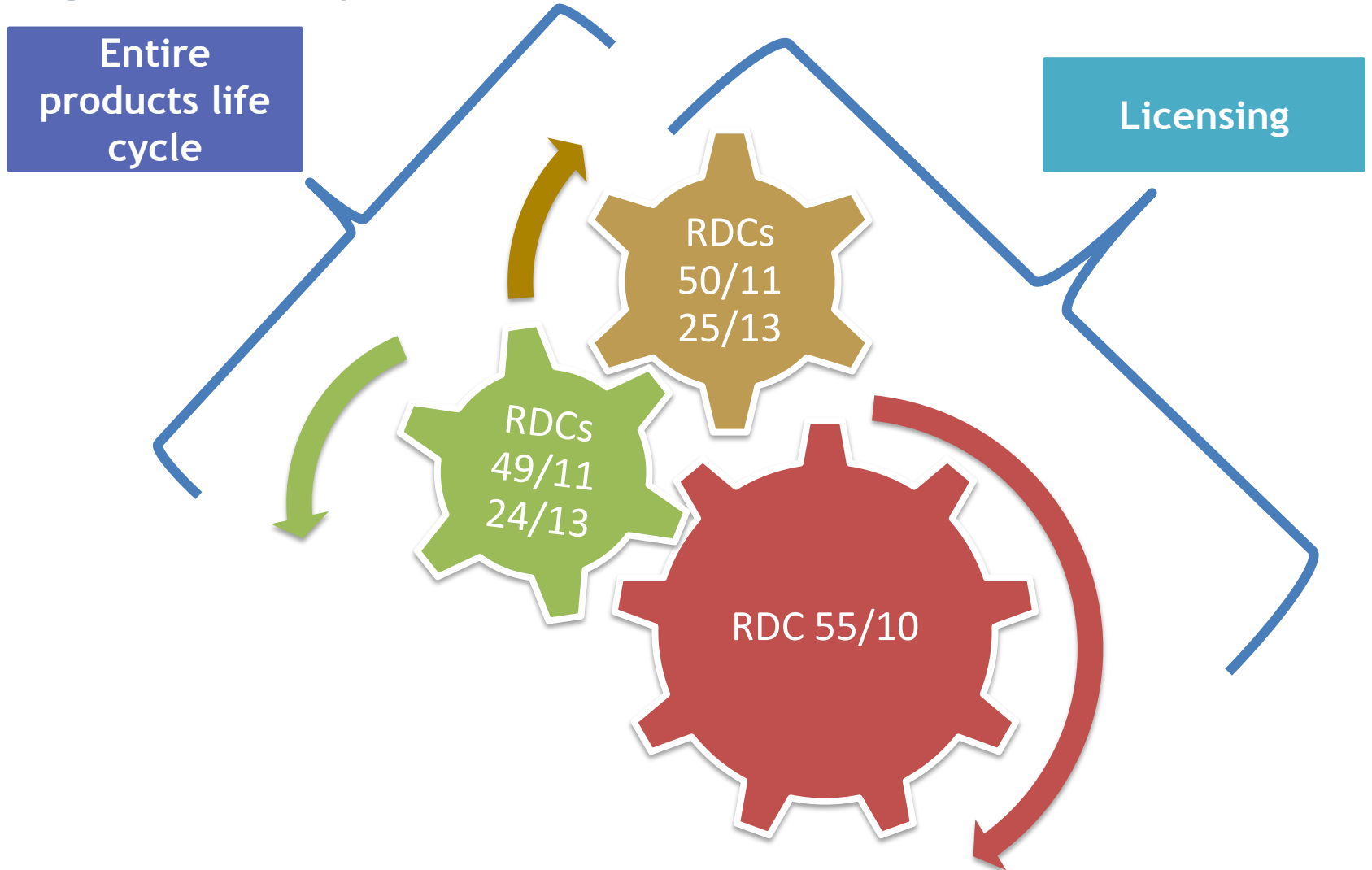
# Legislation Evolution



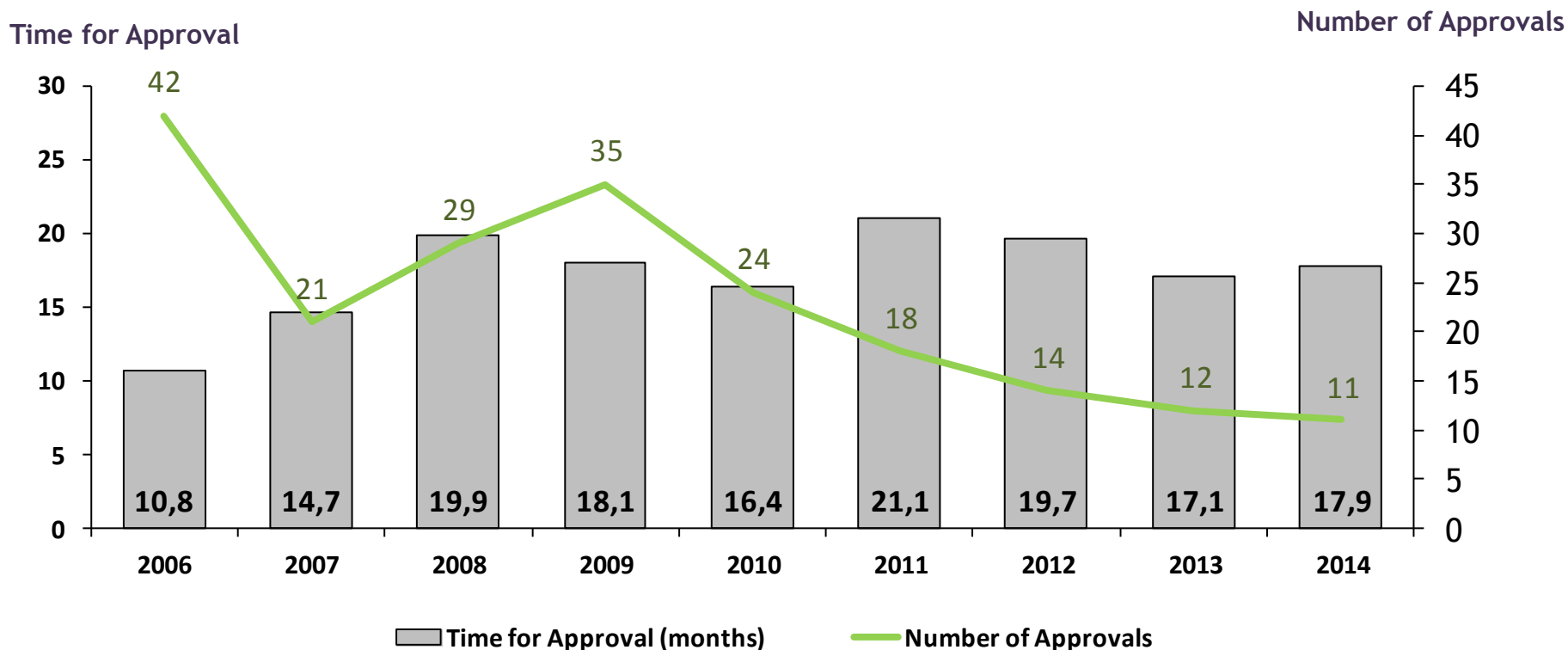
# Regulatory Framework



# Regulatory Framework



# Biologicals – Approval Timeline



Biologicals – Time for Approval  
Approvals from Jan.01.2006 to Jun.30.2014



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# Biologicals – Approval Timeline

Year	Time for Approval	Number of Approvals
2003	8,5	28
2004	13,7	22
2005	15,4	41
2006	10,8	42
2007	14,7	21
2008	19,9	29
2009	18,1	35
2010	16,4	24
2011	21,1	18
2012	18,6	14
2013	17,1	12
2014	17,9	11
<b>Average</b>	<b>16,0</b>	<b>25</b>

Biologicals – Time for Approval  
 Approvals from Jan.01.2003 to Jun.30.2014



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# International Cooperation

- ④ ANMAT
- ④ CECMED
- ④ FDA
- ④ DCVRN – Developing Country Vaccine Regulators' Network
- ④ DVI – Dengue Vaccine Initiative
- ④ IPRF – International Pharmaceutical Regulators Forum
- ④ PAHO – Pan American Health Organization
- ④ WHO – World Health Organization



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# Cooperation Opportunities

- @ Develop Specific Guidelines;
- @ Information Sharing (Drug Approval Letter);
- @ Training seminars on the ICH guidelines;
- @ Training seminars on the implementation of the e-CTD.



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# Take-Home Message

None of us will be better than all together!



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*Thank you!*

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