



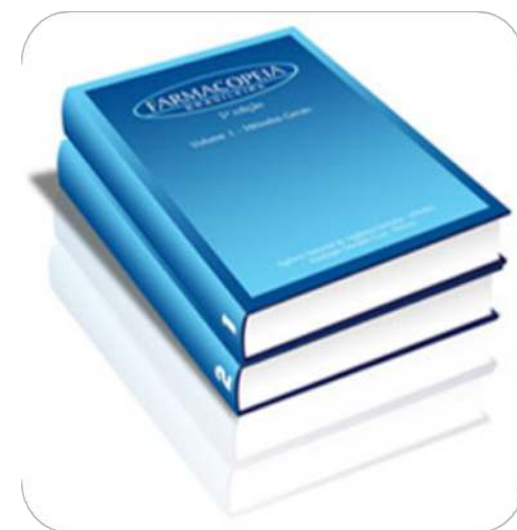
Agência Nacional de Vigilância Sanitária (ANVISA)

Brazilian Health Regulatory Agency

The Brazilian Pharmacopoeia and the deletion of ATT

**HSI Symposium on Global Harmonization
of Vaccine Testing Requirements**

Arthur Leonardo Lopes da Silva
COFAR/GGMED/DIRE2/ANVISA
Rome, March 19th, 2019.



ANVISA

Agência Nacional de Vigilância Sanitária



Anvisa



- ANVISA was established by Federal Law 9.782/99.

- *promote the periodic review and updating of the pharmacopoeia*

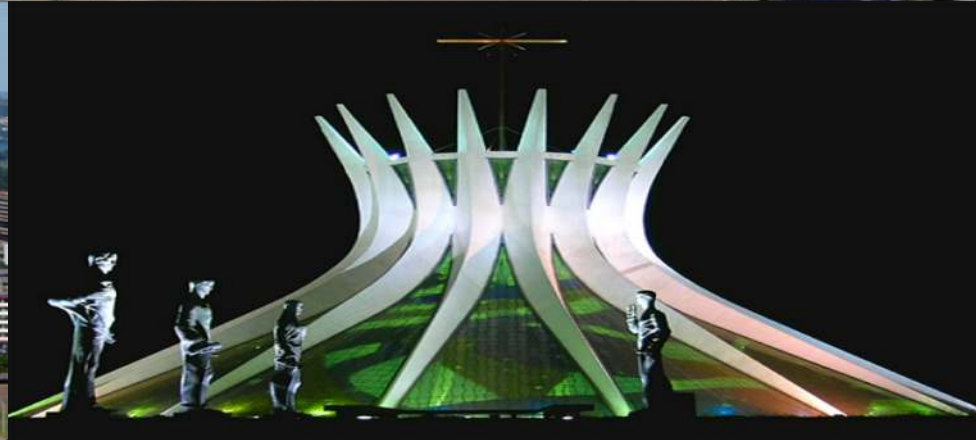
- ANVISA's headquarter is located in Brasília, Brazilian capital.

- Currently ANVISA has approximately 2.200 employees working throughout the country, most of them located in Brasília.





Brasília and Anvisa's headquarter





Anvisa's Regulation Fields



Foods



Cosmetics



Sanitizing agents



Tobacco



Pesticides



Health Service



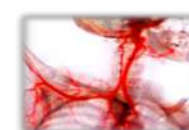
Medicines/API



Medical devices



Official Laboratories



*Blood, Tissues and
e organs*



Pharmacovigilliance



Advertisement



*Ports, airports and
borders*



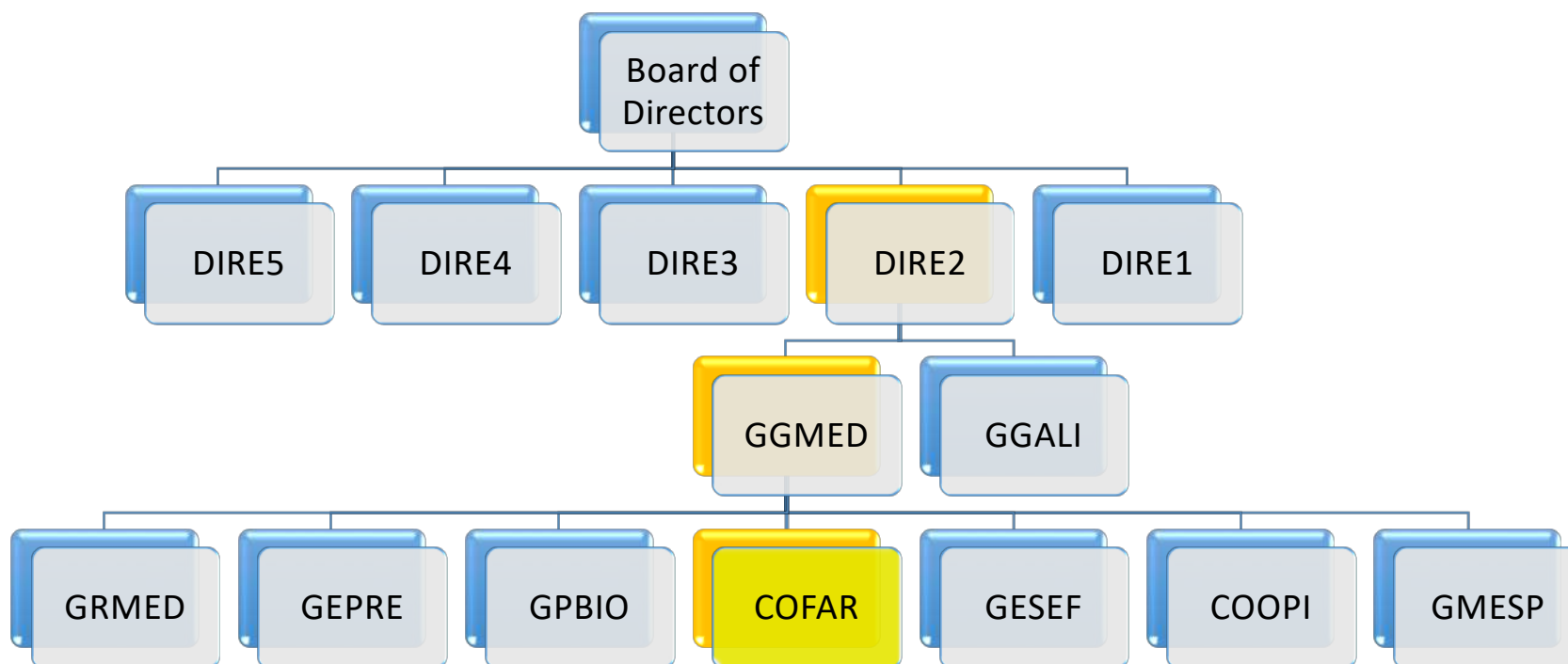
*International
affairs*



SNVS coordination



Anvisa's Organizational Chart





Brazilian Pharmacopoeia's Organizational Structure

Brazilian Pharmacopoeia Commission

Deliberative Council

Experts Committees

Pharmacopoeia Coordination (COFAR)



Brazilian Pharmacopoeia's Organizational Structure





Brazilian Pharmacopoeia's Organizational Structure

EXPERTS COMMITTEES

APF	COR	DCB	EQBIO	ESP	EXC
GNOSIA	GASES	HEMO	HOM	IFA	MAR
MICRO	NOR	BIO	MAG	RADIO	SQR



Deletion of ATT from the Brazilian Pharmacopoeia

2010

- Brazilian Pharmacopoeia, 5th edition
- 1 General method for ATT
- 6 Monographs require ATT

- Meglumine antimoniate, injectable solution;
- Lyophilized coagulation factor IX;
- Lyophilized coagulation factor VII;
- Lyophilized human fibrinogen;
- Nystatin;
- Diphtheria and tetanus and pertussis vaccine, adsorbed.



Deletion of ATT from the Brazilian Pharmacopoeia

2019

- Brazilian Pharmacopoeia, 6th edition
 - Forecast for publication – April, 2019
- 1 General method for ATT
- 1 Monograph requires ATT

- Meglumine antimoniate, injectable solution;
- ~~Lyophilized coagulation factor IX;~~
- ~~Lyophilized coagulation factor VII;~~
- ~~Lyophilized human fibrinogen;~~
- ~~Nystatin;~~
- ~~Diphtheria and tetanus and pertussis vaccine, adsorbed.~~



Deletion of ATT from the Brazilian Pharmacopoeia

Monograph: Meglumine antimoniate, injectable solution

Instigate the discussion with the Deliberative Council and experts to delete ATT from this monograph

By excluding ATT from this monograph, the ATT general method will be removed from the Brazilian Pharmacopoeia.

Deletion of ATT from the Brazilian Pharmacopoeia



Questions?



Obrigado!
Thank you!

Brazilian Pharmacopoeia Coordination

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