The Brazilian Pharmacopoeia and the deletion of ATT

HSI Symposium on Global Harmonization of Vaccine Testing Requirements

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COFAR/GGMED/DIRE2/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 organs
- Pharmacovigilance
- Advertisement
- Ports, airports and borders
- International affairs
- SNVS coordination
Anvisa’s Organizational Chart
Brazilian Pharmacopoeia’s Organizational Structure

Brazilian Pharmacopoeia Comission

- Deliberative Council
- Experts Committees
- Pharmacopoeia Coordination (COFAR)
Brazilian Pharmacopoeia’s Organizational Structure

- Deliberative Council
- Anvisa
- Manufacturer Associations
- Ministry of Health
- Ministry of Science
- National Institute for Quality Control
- Brazilian Pharmacy Council
- Universities
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

Brazillian 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

➤ 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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