Brazilian Pharmacopoeia: vision and expectations for cooperation and convergence

Brazilian Pharmacopoeia Coordination
Brazilian Health Regulatory Agency – ANVISA
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The views expressed herein are those of the presenter; they do not necessarily reflect the views of the ANVISA.
Brazilian Pharmacopeia: vision and expectation for cooperation and convergence

- ANVISA and Brazilian Pharmacopeia
- Brazilian Pharmacopeia
- International cooperation
- Expectations
ANVISA and Brazilian Pharmacopeia (FB)

- Linked to the Ministry of Health
- Board of 5 directors (Collegiate Directorate Anvisa Resolution)

By Law: to promote the periodic review and updating of the pharmacopoeia (Federal Law n. 9782/1999)
Brazilian Pharmacopoeia

1926
1955
1976
1988 to 2005
2010
2016
2017
2019

✓ 6th edition
2019
Brazilian Pharmacopoeia

Monographs – 6th edition

- Pharmaceutical ingredients - 349
- Finished products - 237
- Herbal medicines - 149
- Biologicals - 65
- Medical devices - 9
- Blood products - 22
- Medicinal gases - 4
- Rhadiopharmaceuticals - 5
FB Structure

Previous structure:
FB Structure

- Reviewing the approach: new structure for The Brazilian Pharmacopoeia

- Change in our Internal Rules
- Number of Experts Committees
- Number of experts in each committee

Board of 5 Directors (ANVISA)

Steering Committee (ANVISA)

Experts Committees

FB Coordination (ANVISA)
Brazilian Pharmacopoeia - Products

- Brazilian Pharmacopoeia;
- Brazilian Homeopathic Pharmacopoeia, 3rd ed. (2011) – 85 monographs
- National Formulary, 2nd ed. (2013) – 133 monographs
- Herbal Medicines Formulary, 1st ed. (2011) – 83 monographs;
  - 2nd ed. – Public consultation – 89 monographs.

http://portal.anvisa.gov.br/farmacopeia
Brazilian Pharmacopoeia - Products

- Homeopathic Formulary
  - 1st ed. (2016) – 84 monographs;
- Brazilian Nonproprietary Names (DCB) ~12,000
- Chemical Reference Substances (SQR) – 84

http://portal.anvisa.gov.br/farmacopeia
Methods & Tech Transfer

- Monographs/ methods
  - Own development (partner labs)
  - Adoption/ adaptation
  - Submission by sponsor

- Analytical validation: Anvisa Resolution n. 166, July 2017
In absence of monographs and methods in the Brazilian Pharmacopoeia, the following pharmacopoeias recognized by Anvisa can be used:

- Argentine Pharmacopoeia
- British Pharmacopoeia
- European Pharmacopoeia
- French Pharmacopoeia
- German Pharmacopoeia
- International Pharmacopoeia
- Japanese Pharmacopoeia
- Mexican Pharmacopoeia
- Portuguese Pharmacopoeia
- United States Pharmacopeia

Resolution Anvisa n. 37, July 6, 2009
International Cooperation

✓ Anvisa Strategic Planning

✓ Strengthen international operations and compromises with actors and strategic partners (OB 12)

✓ Promote a friendly regulatory environment to social and economic development (OB 4)
International Cooperation

Memorandum of Understanding - MoU

Purpose
- Strengthen relations and promote cooperation on standard setting efforts of the Pharmacopoeias

Argentinian Pharmacopoeia (ANMAT)
- Signed on October, 2007
- Remain effective for two years, with automatic renewal

United States Pharmacopoeia (USP)
- Signed (renewed) on August, 2018
- Remain effective for 3 years

International Pharmacopoeia (WHO)
- Signed on May, 2019
- Remain effective for three years, with automatic renewal

European Pharmacopoeia (EDQM)
- Signed on April, 2017

Japanese Pharmacopoeia (MHLW)
- Signed on September, 2015
- Remain effective for five years, with automatic renewal
ICH

International Cooperation

Q3C Residual Solvents

Q3D Elemental Impurities

Q4B Pharmacopoeias
Expectations

- **Collaboration among pharmacopoeias**
  - Prospective harmonization

- **International reality of Pharmacopoeias**
  - Improvement of GPhP

- **Expansion of cooperation between Pharmacopoeias**
  - MoU

- **Increase the accuracy of decisions**
  - Sharing information and approaches

- **Alert network**
  - Quick responses to global urgencies
Thank you!

Getting in touch

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