INTERNATIONAL MEETING OF WORLD PHARMACOPOEIAS
29 February to 2 March 2012
WHO, Geneva, Executive Board Room

Answers from pharmacopoeias
1. Name of pharmacopoeia

- Brazilian Pharmacopoeia
  - Homeopathic Pharmacopoeia
  - National Therapeutic Formulary
  - National Herbal Formulary
2. National/regional legislation includes reference to other

- **National Pharmacopoeia(s):**
  

- **Regional Pharmacopoeia(s):**
  
  European Pharmacopoeia.

- **International Pharmacopoeia(s):**
  
  International Pharmacopoeia.
3. Publication of latest edition

Brazilian Pharmacopoeia, 5th edition

Published in 2010.

Available on the Internet: www.anvisa.gov.br/farmacopeia

Homeopathic Pharmacopoeia – 3ª edition (2011)

National Therapeutic Formulary - 2ª edition (2011)

National Herbal Formulary - 1ª edition (2011)
4. Update frequency

- There is no defined periodicity for the Brazilian Pharmacopoeia publications.
5. For which products does the pharmacopoeia provide specifications?

- APIs and excipients,
- dosage forms,
- herbal products,
- biological products,
- medical devices.
6. Number of texts included in the pharmacopoeia

- Monographs for APIs: 284
- Monographs for finished dosage forms: 207
- Monographs for biological: 51
- Monographs for herbal: 58
7. Collaboration with and/or being part of a (different) national/regional pharmacopoeia

- The Brazilian Pharmacopoeia is part of the MERCOSUR Pharmacopoeia, comprising Argentina, Brazil, Paraguay and Uruguay.

- Texts and chapters are being discussed for inclusion in the MERCOSUR Pharmacopoeia.
8. Publication of harmonized pharmacopoeial texts within the pharmacopoeia

ICH texts are considered in the discussions of the Brazilian Pharmacopoeia committees.
9. Interaction with stakeholders, including regulators

- Anvisa (the health regulatory authority) is legally responsible for the review and update of the Brazilian Pharmacopoeia.

- Members of the Brazilian Pharmacopoeia Commission and its various Technical Committees are nominated to this function.

- We have stakeholders from the Ministry of Health, universities, the pharmaceutical industry and Anvisa itself.
10. Strategy for the future

Continue our integration with the MERCOSUR pharmacopoeia.

Align the Brazilian Pharmacopoeia with public health needs and with public policy development in the Brazil.