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

Answers from pharmacopoeias
1. Name of pharmacopoeia

- European Pharmacopoeia
  (Pharmacopoea Europaea – Ph.Eur.)

- Additional: Swiss Pharmacopoeia
  (Pharmacopoea Helvetica – Ph.Helv.)
2. Pharmacopoeia referred to in national/regional legislations

- Legal basis is Swiss law
  - Art. 4, 8 and 52 of the Law on Therapeutic Products
  - Ordinance regulating the issue of the Pharmacopoeia by Swissmedic
  - Ordinance putting the Pharmacopoeia into force
National/regional legislation includes reference to other

- national pharmacopoeia: *Swiss Pharmacopoeia*
- regional pharmacopoeia(s): *European Pharmacopoeia*
- international pharmacopoeia: *No*
4. Publication of latest edition

- European Pharmacopoeia: 1\textsuperscript{st} January 2012 (Ph.Eur. 7.3)
- Pharmacopoeia Helvetica: 1\textsuperscript{st} July 2010 (Ph.Helv. 10.3)
- New edition planned for this year (Ph.Helv. 11.0)
5. Update frequency

- Ph.Eur.: 3 times per year
- Ph.Helv.: Every 1-2 years
6. For which products does the pharmacopoeia provide specifications?

- APIs,
- herbal products,
- biologicals,
- traditional medicines,
- hospital and retail pharmacy preparations (Ph.Helv. only)
7. Number of texts included in the pharmacopoeia

- Ph.Eur.
  - More than 2,000 monographs
  - More than 300 general methods of analysis

- Ph.Helv.
  - Approximately 135 monographs

8. Collaboration with and/or being part of a (different) national/regional pharmacopoeia

Participation in elaboration of European Pharmacopoeia
- Based on a convention (contract between states, signed by CH)
- Ph.Eur. texts are to be implemented in Swiss law

International collaboration
- No direct collaboration outside Europe
- Indirect collaboration via EDQM‘s participation in PDG
- Results of this process are incorporated in Ph.Eur.
9. Publication of harmonized pharmacopoeial texts within the pharmacopoeia

- Harmonization between Ph.Eur., USP and JP
- Harmonized texts are published in Ph.Eur.
10. Interaction with stakeholders, including regulators

Stakeholders from industry, universities, authorities and hospital and retail pharmacies are organized in expert groups for:

- Complementary medicine (TCM, Homoeopathy)
- Phytochemistry (herbals)
- Chemical substances
- Pharmaceutical technology
- Biological products (vaccines, blood products)
11. Strategy for the future

- Active participation in the activities of the Ph.Eur. These are based on a legally binding mandate (Ph.Eur. Convention)

- An extension of pharmacopoeial activities beyond the participation in the activities of the Ph.Eur. would require a legal mandate