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

Answers from pharmacopoeias
1. Name of pharmacopoeia

Sweden is a member of the European Pharmacopoeia Commission and use the European Pharmacopoeia

– we have a complement called Swedish Drug Standard (not a Pharmacopoeia) which contain translations to Swedish of the name of the substances and products in the European Pharmacopoeia.
2. Pharmacopoeia referred to in national/regional legislations

Yes,

Sweden signed the Convention on the Elaboration of a European Pharmacopoeia 1975

The Swedish Governments decision 1977 that the English version of the European Pharmacopoeia should be used from 1 January 1978

EU-regulations which states the binding status of the European Pharmacopoeia

For each supplement of the European Pharmacopoeia there is a Medical Products Agency provision which entry all new and revised monographs it into force
National/regional legislation includes reference to other:

- national pharmacopoeia(s)
  - The EU-regulations states that if there is no monograph in the European Pharmacopoeia, compliance with a monograph in a pharmacopoeia of a member state can be accepted

- regional pharmacopoeia(s) / n. a.

- international pharmacopoeia(s) / EU-regulations
  - The EU-regulations states that if there is no monograph in the European Pharmacopoeia or in a pharmacopoeia of a member state, compliance with the monograph in a third country pharmacopoeia can be accepted if the analytical procedures are validated
4. Publication of latest edition

slide 4-9 the description of the European Pharmacopoeia
see Dr S. Keitels presentation about the European Pharmacopoeia
10. Interaction with stakeholders, including regulators 1/3

Sweden contribute to the work in the European Pharmacopoeia expert groups and working parties with experts and specialists from Industry, University, Pharmacy Laboratory and from the Medical Products Agency (experts and specialists from regulatory authority, official medicine control laboratory, and national pharmacopoeia authority)
10. Interaction with stakeholders, including regulators 2/3

The Swedish Pharmacopoeia Commission

- the members are the Swedish Delegation of the European Pharmacopoeia Commission and experts and specialists from Medical Products Agency, Industry, Pharmacy Laboratory and University (most of the experts and specialists are members of an expert group or a working party in the European Pharmacopoeia)
- discuss and recommend comments on all new and revised texts which are published in Pharmeuropa for consultation
- discuss questions of principle on the agenda of the European Pharmacopoeia Commission
- the final decision of which comments should be forwarded to the European Pharmacopoeia is taken by Medical Products Agency
Medical Products Agency and The Swedish Pharmacopoeia Commission arrange meetings where users of the European Pharmacopoeia are invited. The objective is to:

- inform
- answer questions.

about the decisions and work in the European Pharmacopoeia.
11. Strategy for the future

Continue to be active in the elaboration of the European Pharmacopoeia