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

Answers from the German Pharmacopoeia Authority
1. Name of official pharmacopoeias

- European Pharmacopoeia (Ph.Eur.)
- German Pharmacopoeia (Deutsches Arzneibuch - DAB)
- German Homoeopathic Pharmacopoeia (Deutsches Homöopathisches Arzneibuch - HAB)
1a. Non official compendia

- German Drug Codex (Deutscher Arzneimittel Codex – DAC)
- New Extemporaneous Formulas (Neues Rezeptur Formularium - NRF)
- Manufacturing Formulas of German Hospital Pharmacists
1b. Ordinance on Standard Registration

- Standard Registration on Pharmaceutical Preparations

  299 pharmaceutical preparations are listed
2. Official Pharmacopoeia referred to in regional legislations

- European Directive 2001/83 ON THE COMMUNITY CODE RELATING TO MEDICINAL PRODUCTS FOR HUMAN USE

- European Directive 2003/94 On Good Manufacturing Practice, e.g. Part II: Basic Requirements for Active Substances used as Starting Materials

- “Notice to applicants” for marketing authorization refers to the CTD

- Variation regulations of EU

- other EU regulations, e.g. medical device regulations
2a. Official Pharmacopoeia referred to in German legislations

- MEDICINAL PRODUCTS ACT (THE DRUG LAW - ARZNEIMITTELGESETZ – AMG) of the FEDERAL REPUBLIC OF GERMANY

- Legal German Ordinance on the GMP implementation (Arzneimittel- u. Wirkstoffherstellungs-verordnung - AMWHV)

- Legal German Ordinance on internal regulations in pharmacies (Apothekenbetriebsordnung)
3. National/regional legislation includes reference to other

- national pharmacopoeia(s),

- international pharmacopoeia(s)

see : Annex I to Directive 2001/83/EC:

“In case where starting and raw materials, active substance(s) or excipient(s) are described neither in the European Pharmacopoeia nor in the pharmacopoeia of a Member State, compliance with the monograph of a third country pharmacopoeia can be accepted. In such cases, the applicant shall submit a copy of the monograph accompanied by the validation of the analytical procedures contained in the monograph and by a translation where appropriate.”
4. Publication of latest edition

European Pharmacopoeia (Ph.Eur.)
supplement 7.5 published in Dezember 2011

German Pharmacopoeia
(Deutsches Arzneibuch – DAB 2011)

German Homoeopathic Pharmacopoeia
(Deutsches Homöopathisches Arzneibuch – HAB 2011)
5. Update frequency

- annually
6. For which subjects does the pharmacopoeia provide specifications?

- APIs,
- dosage forms,
- herbal products,
- biologicals / traditional medicines,
- excipients
- homoeopathic raw materials
- homoeopathic manufacturing methods
- TCM
- vaccines
- general monographs on different product groups
- analytical methods
- analytical procedures
- microbiological requirements
- statistical methods
- Packaging materials and containers
6a. For which products does the non official German compendia provide specifications?

- Extemporaneous preparations
- Magistral formulas
- APIs, excipients used for these preparations
- Test procedures used in pharmacies
- Formulas used in hospital pharmacies
7. Number of texts included in the pharmacopoeia

- Monographs for APIs and excipients: DAB – 91, HAB - 639
- Test Methods: DAB – 23, HAB – 17
- Homoepathic manufacturing methods: HAB - 120
7a. Number of texts included in non official German compendia

- monographs for APIs, excipients, extemporaneous preparations, magistral formulas: DAC – 281, NRF - 274
- Test Methods
8. Collaboration with and/or being part of a (different) national/regional pharmacopoeia

- *Ph.Eur.* being part of the legal German pharmacopoeia

- collaboration with *Ph.Helv.* and ÖAB especially translation of *Ph.Eur.* into the German language
9. Publication of harmonized pharmacopoeial texts within the pharmacopoeia

- *ICH II PDG texts in the Ph.Eur.*
10. Interaction with stakeholders, including regulators

yes,

- the members of the German- and Homoeopathic-Pharmacopoeia-Commission including its expert groups are stakeholders,

- inspectors and assessors are members or participants in the sessions of the commission and expert groups
11. Strategy for the future

- Identification of materials by the evaluation of analytical fingerprints

- Use of non-destructive spectroscopic methods

- Imaging techniques for the intact pharmaceutical preparations

- Trace analysis of impurities

- Simplified analytical identification tests for certified substances