



Homoeopathy and European Pharmacopoeia: current status and future development

Isabelle Mercier

EDQM

Homoeopathy Working Party

- Homoeopathic Directive 92/73/EEC
 - Reference to European Pharmacopoeia
- Working Party fully established 1997
- Membership restricted to national authorities
- To prepare monographs for European use (harmonisation of national German and French monographs)
- Working Party not reappointed in Nov. 2004
but call for candidates in September 2006

Homoeopathic section of the European Pharmacopoeia

Introduction

All general texts and monographs of the Ph. Eur. that are relevant to homoeopathy are applicable.

The "Homoeopathy" chapter of the Ph. Eur. contains general monographs and individual monographs on starting materials and stocks...

Achievements: general monographs

- Homoeopathic preparations
- Mother tinctures for homoeopathic preparations
- Herbal drugs for homoeopathic preparations

Apply to all relevant
homoeopathic
preparations (having a Ph. Eur.
specific monograph or not)

Achievements: inorganic monographs

- Arsenious trioxide
- Barium chloride dihydrate
- Cadmium sulphate 2.7 hydrate
- Calcium iodide tetrahydrate
- Copper
- Copper acetate monohydrate
- Iron

Achievements: herbal and other monographs

- Common stinging nettle
- Garlic
- Hedera helix
- Hyoscyamus
- Hypericum
- Oriental cashew
- Saffron
- Honey bee

Sticking points

- Parts of plants used: differences
- Freshness of plants:
 - Visual inspection
 - Loss on drying
- Foreign matter:
 - Visual inspection to minimise
 - Measurement: default limit max. 2%

Sticking points

- Mother tinctures
 - Density
 - Ethanol content
- Time of maceration
- Methanol content of mother tincture

Sticking points

- Pillules

- Composition of core -
undiluted stocks?

- Tests
 - uniformity of mass
 - impregnation
 - disintegration

- Nomenclature

Symposium Feb. 2005: results

- General monograph on methods of preparation described in HAB and Ph. Fr. = harmonisation
- HAB methods 1a to 4b + 2 Ph. Fr. methods adopted June 2006 (implementation 1.07.2007)

Symposium Feb. 2005: results

- Twin-track monographs where differences between HAB and Ph. Fr. (method of preparation; density/ethanol content; foreign matter...)
- List of specific monographs based on proposals made by industry with respect to MRP priorities

Symposium Feb. 2005: results

- Pending:

- consensus on fresh/dried material to be found with HMPWG (two monographs?)
- pillules
- nomenclature: list of materia medica

Future developments

- Harmonise other HAB and Ph.Fr. methods of preparation (nosodes = low priority)
- Draft specific monographs on basis of priorities listed by Industry