Efficacy and Safety - Basic Requirements for HMP in Self-medication and Prescription

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Safety  Efficacy  Quality
European Legal Framework - Proof of Efficacy and Safety

  - Part 3
    - Toxicological and pharmacological tests
  - Part 4
    - Clinical documentation
Part 3
Toxicological and pharmacological tests

- Single and repeated dose toxicity
- Examination of reproductive function
- Foetal and perinatal toxicity
- Mutagenic potential
- Carcinogenic potential
- Pharmacodynamics
- Pharmacokinetics
- Local tolerance

Gaedcke, Steinhoff, Herbal Medicinal Products, CRC Press 2003
Network of in vitro- and in vivo-assays

- Receptor-binding assays
- Animal studies
- Tests in cell cultures
- Tests in tissue cultures
- Tests on isolated organs
- Tests in tissue culture
- Tests on micro-organisms
- Enzymatic assays
- Chemical assays

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Part 4
Clinical documentation

- Clinical pharmacology
- Bioavailability/bioequivalence
- Clinical efficacy and safety
- Applications under special circumstances
- Post-marketing experience

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Gaedcke, Steinhoff, Herbal Medicinal Products, CRC Press 2003
Clinical studies since 1990

Based on ESCOP-Monographs and MEDLINE
Meta-analyses and Reviews

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Photos: R. Länger, J. Saukel, Institute of Pharmacognosy, and Henriette’s herbal homepage
Recent clinical research on less investigated monoHMPs

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Bibliographic application

- HMPWP Draft Notes
  - Draft points to consider on the evidence of safety and efficacy required for well-established HMP in bibliographic applications
    EMAE/HMPWP/23/99 draft
  - Non-clinical testing of herbal drug preparations with long-term marketing experience - Guidance to facilitate mutual recognition and use of bibliographic data
    EMEA/adhocHMPWP/114/98
Necessary Documentation

- Review of the respective literature
- National harmonised assessment criteria e.g.
  - Commission E
  - Avis aux fabricants
- European harmonised assessment criteria = ESCOP - Monographs
- WHO - monographs
ESCOP-Monographs

- compiled by the Scientific Committee
  - delegates from each member state
- structured like SPCs
- containing definition, constituents, clinical particulars, pharmacological properties and detailed references
- 1992 - 1997 60 monographs published
- new, completely revised edition with 20 new monographs soon
Liselotte Krenn, Pharmacia Center Vienna – a new authority on herbal medicine!

IN PRESS!

Order from www.escop.com
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HMP Synthetic
Ginkgo preparations in Austria

- excluded from reimbursement since 1.1.2002
- at constitutional court
- immediately food supplements marketed via physicians