

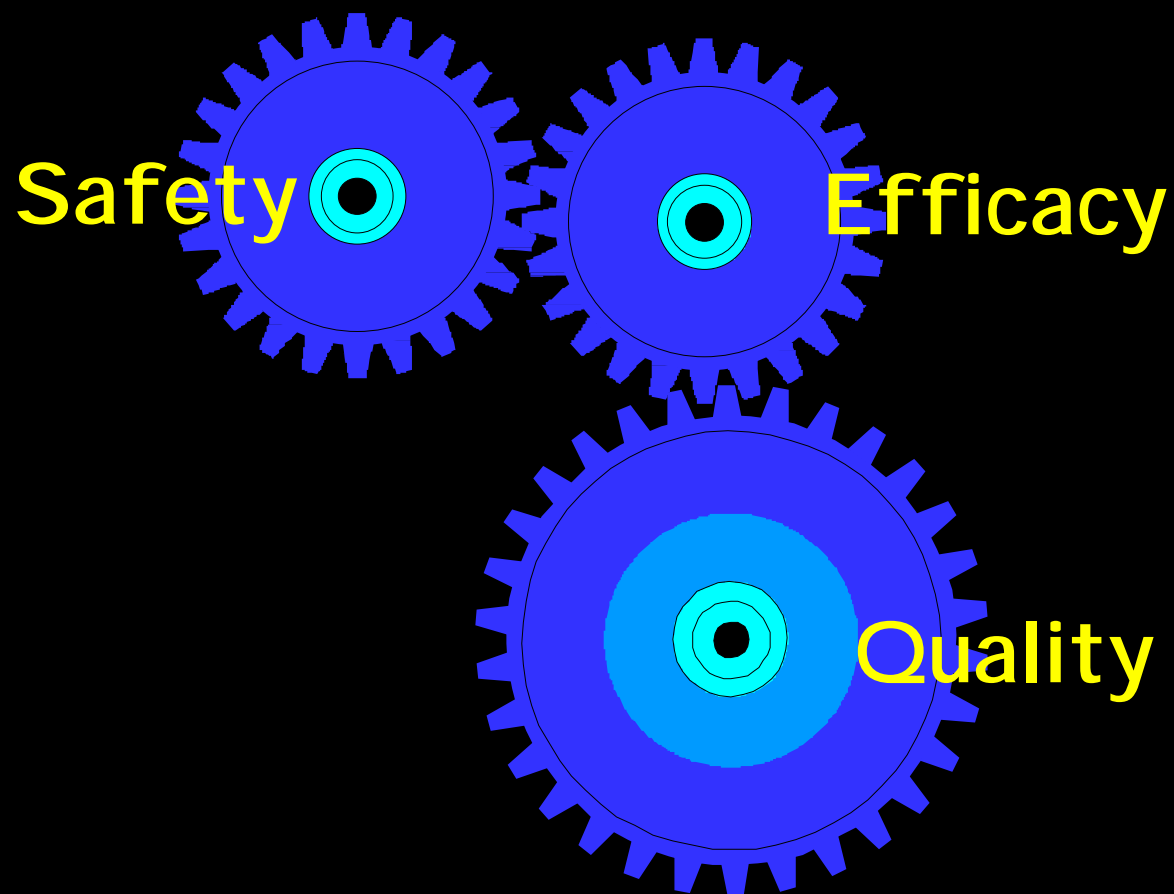
Efficacy and Safety – Basic Requirements for HMP in Self-medication and Prescription



A.o.Univ.Prof.
Dr. Liselotte Krenn



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European Legal Framework – Proof of Efficacy and Safety



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◆ Annex of Council Directive 2001/83/EC

Part 3

Toxicological and
pharmacological tests

Part 4

Clinical documentation

Part 3

Toxicological and pharmacological tests



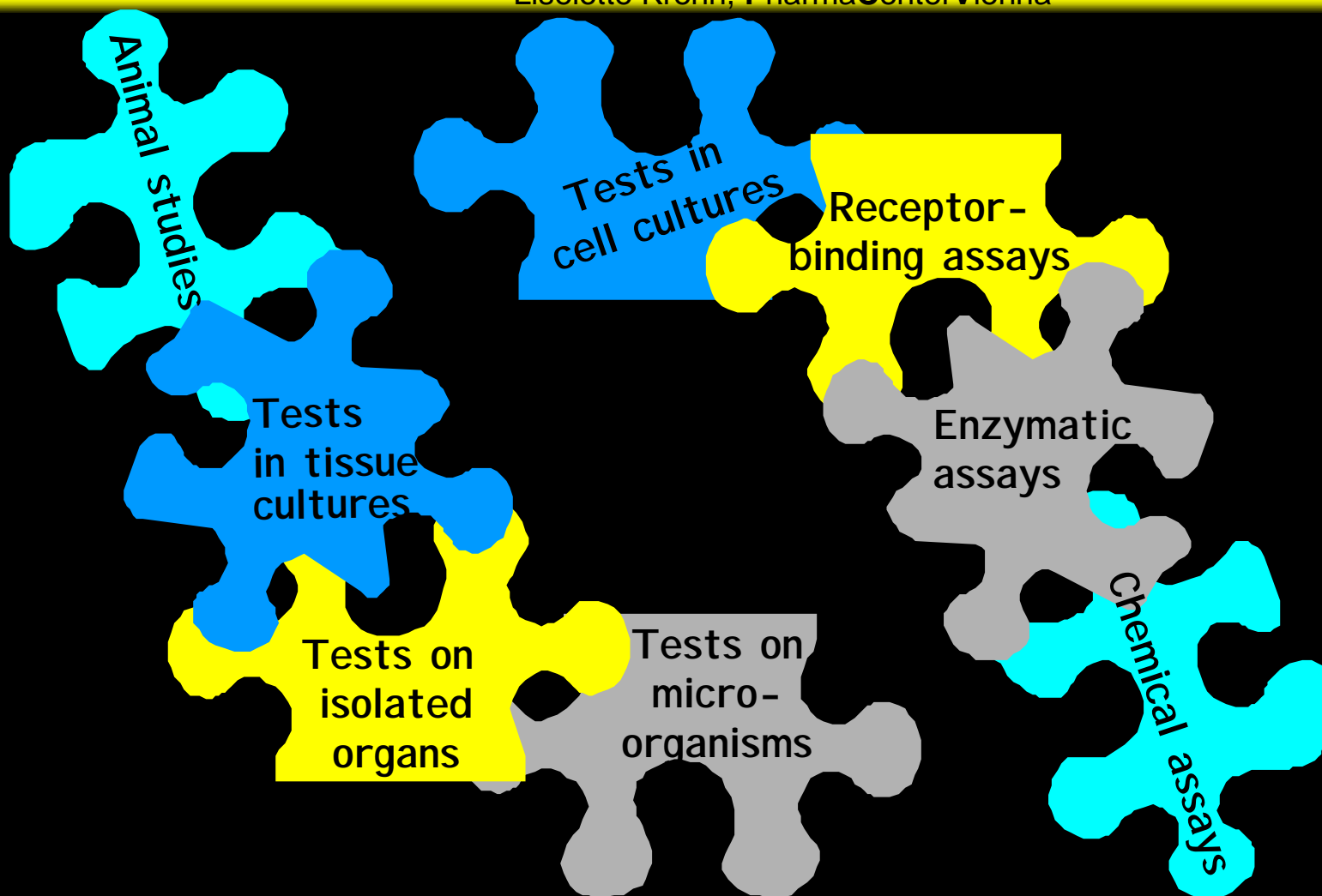
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- ◆ Single and repeated dose toxicity
- ◆ Examination of reproductive function
- ◆ Foetal and perinatal toxicity
- ◆ Mutagenic potential
- ◆ Carcinogenic potential
- ◆ Pharmacodynamics
- ◆ Pharmacokinetics
- ◆ Local tolerance



Network of in vitro- and in vivo-assays

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Part 4

Clinical documentation

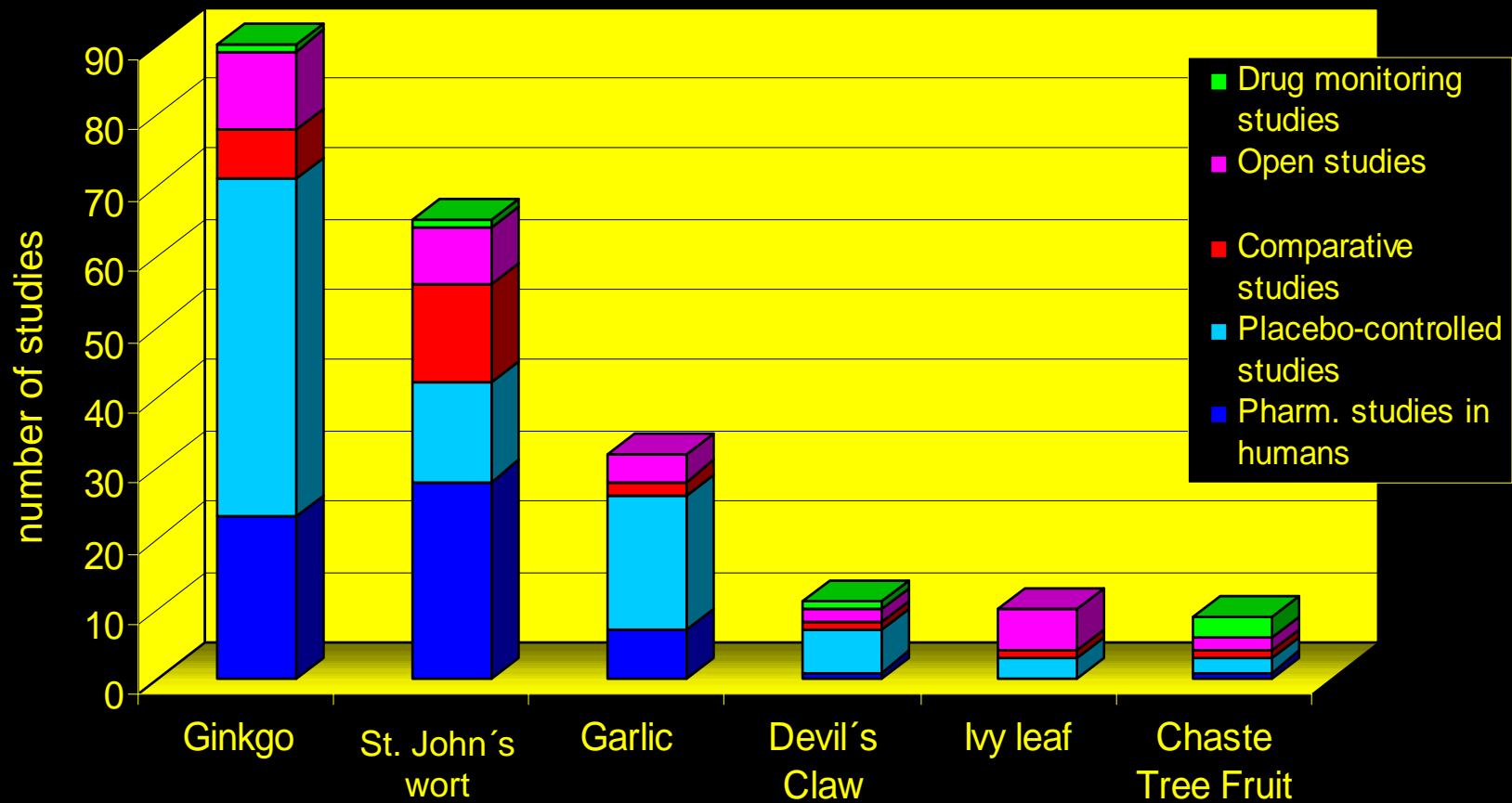
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- ◆ Clinical pharmacology
- ◆ Bioavailability/bioequivalence
- ◆ Clinical efficacy and safety
- ◆ Applications under special circumstances
- ◆ Post-marketing experience



Clinical studies since 1990

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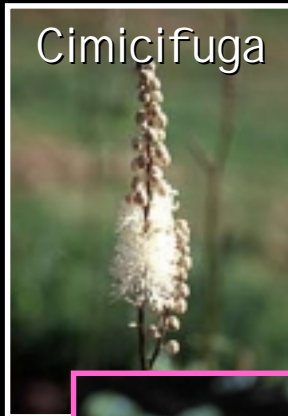


Based on ESCOP-Monographs and MEDLINE



Meta-analyses and Reviews

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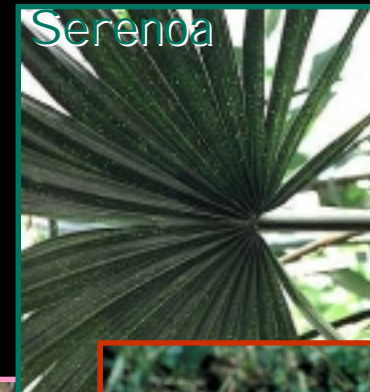
Cimicifuga



Ginkgo



Echinacea



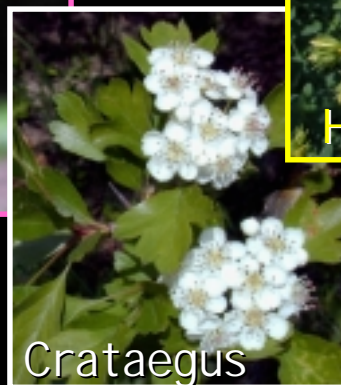
Serenoa



Cynara



Hypericum



Crataegus



Allium



Aesculus

Recent clinical research on less investigated monoHMPs



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Passiflora



Calendula



Betula



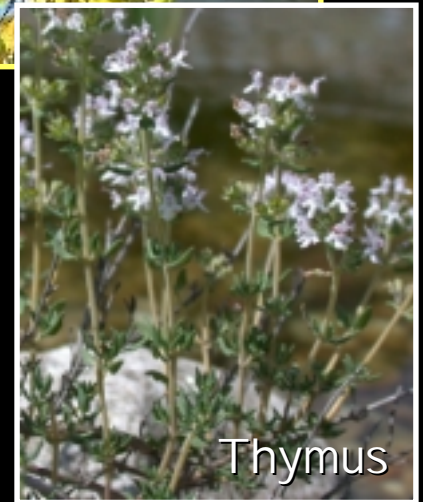
Gentiana



Lavandula



Thymus





Bibliographic application

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- ◆ Article 10.1 a (ii) of Council Directive 2001/83/EC
- ◆ HMPWP Draft Notes
 - Draft points to consider on the evidence of safety and efficacy required for well-established HMP in bibliographic applications
EMA/E/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
EMA/adhocHMPWP/114/98



Necessary Documentation

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



ESCOP-Monographs

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- ◆ 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**

E/S/C/O/P Monographs

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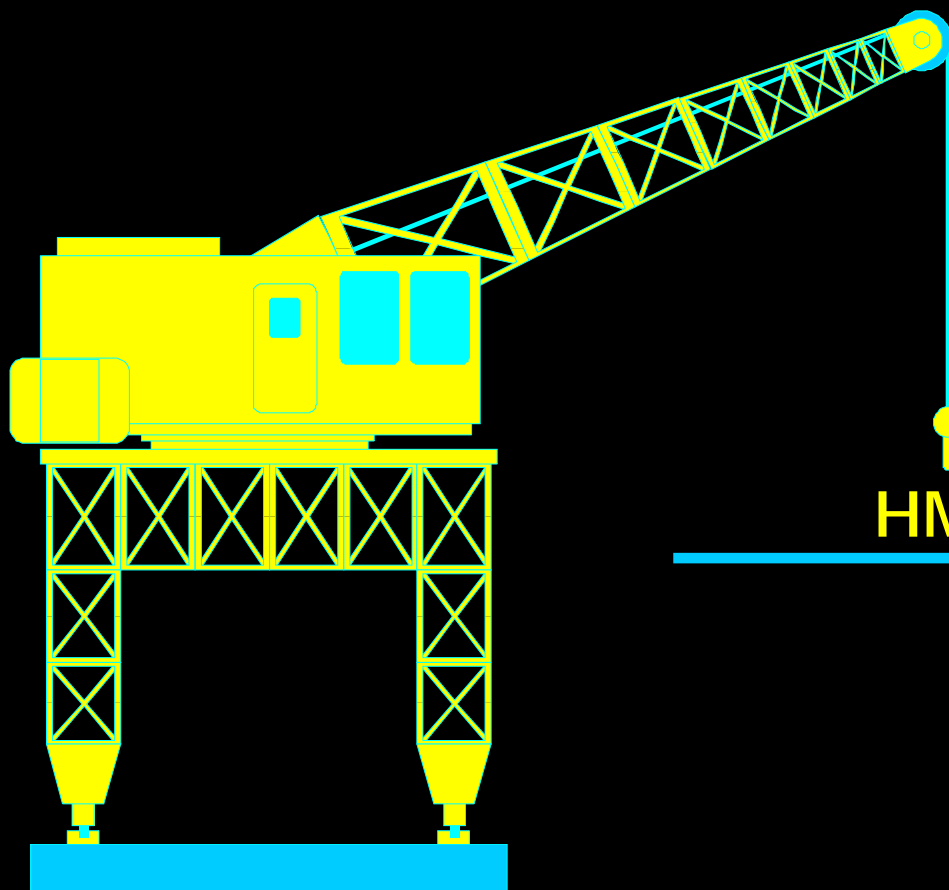
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HMP

Synthetic



Ginkgo preparations in Austria

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- ◆ excluded from reimbursement since 1. 1. 2002
- ◆ at constitutional court
- ◆ immediately food supplements marketed via physicians



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