

E/S/C/O/P

The role of the European Scientific  
Cooperative on Phytotherapy

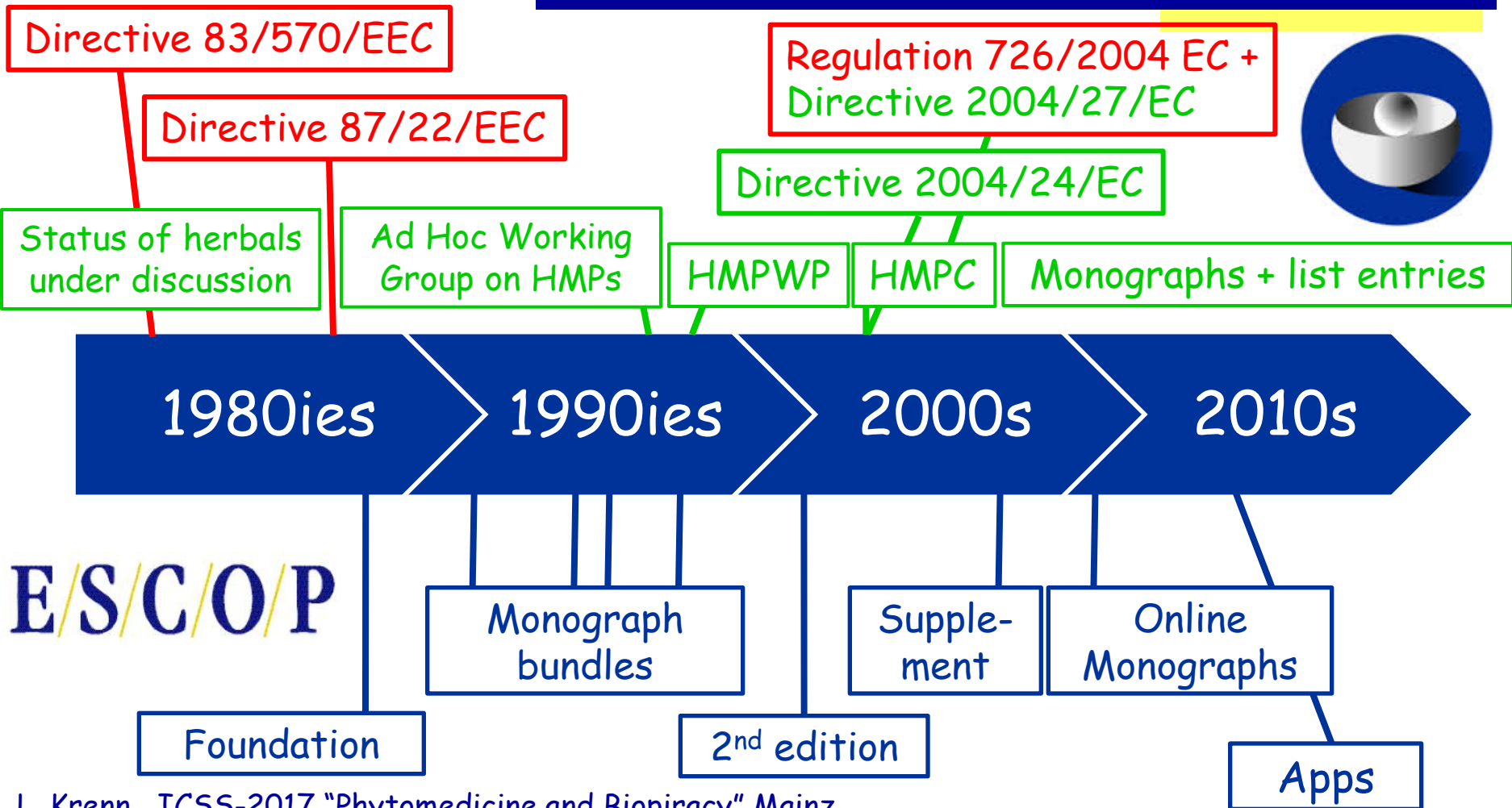
E/S/C/O/P

in Phytomedicine/Phytotherapy

Liselotte Krenn  
Mainz, 25. 07. 2017



# Development of legal framework for HMPs in Europe



# History and Aims of E/S/C/O/P

- founded 18 June 1989 in Cologne
- umbrella organisation of national associations of phytotherapy/herbal medicine across Europe
- since 1996 association according to UK law
- Aims:
  - assistance in the harmonisation of the regulatory status of HMPs
  - advancement of the scientific status of HMPs



# Objectives of E/S/C/O/P

- Creation of harmonised criteria for efficacy and safety
- **Scientific monographs** on the therapeutic use of herbal drugs
- Promotion of phytotherapy on a European level, especially within general medical practice
- Strengthen the cooperation among national associations of phytotherapy to advance these aims and objectives

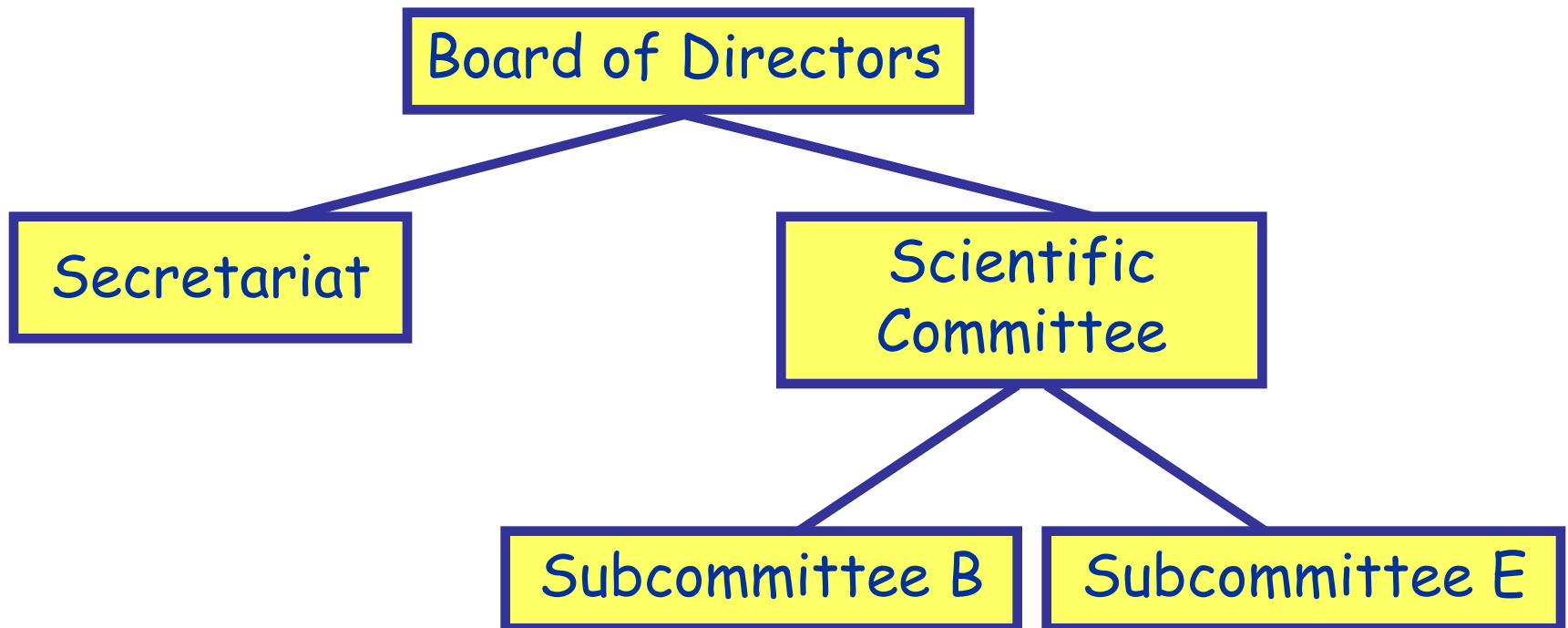




# E/S/C/O/P members

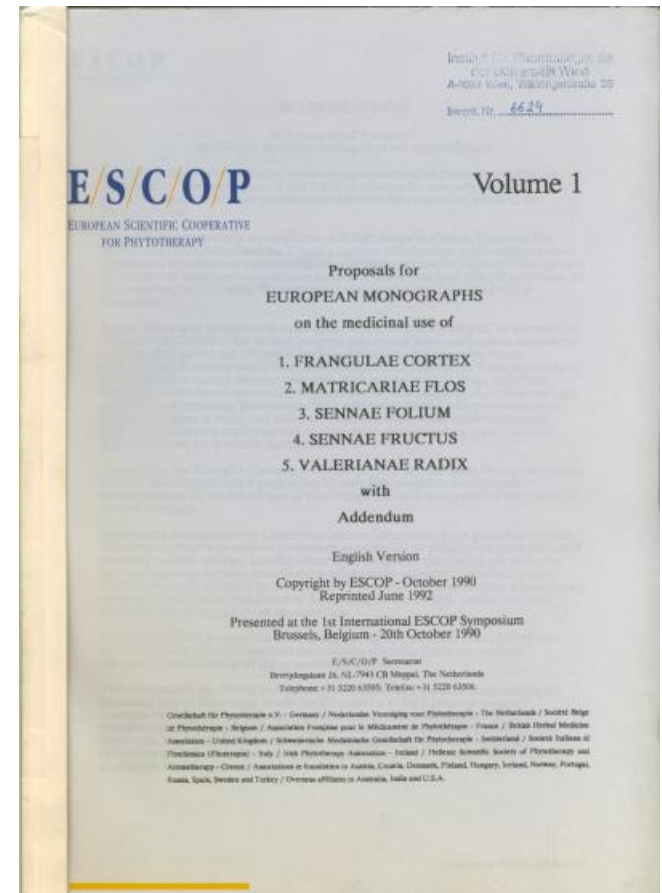
<b>Austria</b>	Österreichische Gesellschaft für Phytotherapie
<b>France</b>	Association Française pour le Médicament de Phytothérapie
<b>Germany</b>	Gesellschaft für Phytotherapie eV
<b>Hungary</b>	Hungarian Society of Pharmaceutical Sciences -Medicinal Plant Section
<b>Italy</b>	Società Italiana di Fitochimica (Fitoterapia)
<b>Netherlands</b>	Nederlandse Vereniging voor Fytotherapie
<b>Poland</b>	Polish Herbal Committee
<b>Portugal</b>	Sociedade Portuguesa Fitoquímica e Fitoterapia (SpFito)
<b>Romania</b>	National Inter-Professional Organization of Associations in the Field of Medicinal and Aromatic Plants
<b>Spain</b>	Sociedad Española de Fitoterapia (SEFIT)
<b>Switzerland</b>	Schweizerische Medizinische Gesellschaft für Phytotherapie
<b>Turkey</b>	Turkish Society of Pharmacognosy and Phytotherapy Türk Fitoterapi Derneği
<b>United Kingdom</b>	British Herbal Medicine Association

# Structure of E/S/C/O/P



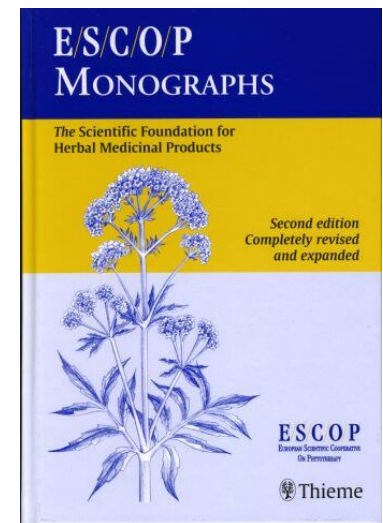
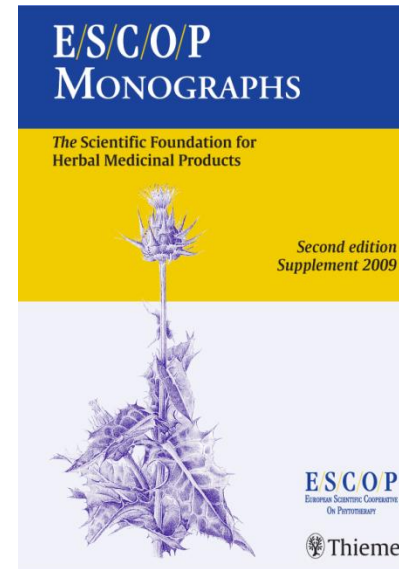
# Development of E/S/C/O/P-Monographs

- ❑ **1989**  
ESCOP Scientific Committee starts work on the monographs
- ❑ **1990/1992**  
first publication of monographs and submission to the CPMP
- ❑ **1996/1997/1999**  
publication of 60 monographs



# Development of E/S/C/O/P-Monographs

- **2003**  
Second edition  
completely revised and expanded  
80 monographs
- **2009**  
Supplement with  
27 new monographs  
+ 8 revised monographs



# Structure of E/S/C/O/P-Monographs



1. Definition
2. Constituents
3. Clinical particulars
4. Pharmacological properties
5. References

Follows the format of the **Summary of Product Characteristics (SPC)** as in applications for marketing authorisation of a herbal medicinal product in the EU



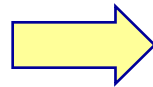
# Structure of E/S/C/O/P-Monographs

- ❑ Definition
- ❑ Constituents
- ❑ **Clinical particulars** 
- ❑ Pharmacological properties
- ❑ References

- Therapeutic indications
- Posology and method of administration
- Contraindications
- Special warnings and special precautions of use
- Interactions
- Pregnancy and lactation
- Effects on ability to drive and use machines
- Undesirable effects
- Overdose

# Structure of E/S/C/O/P-Monographs

- Definition
- Constituents
- Clinical particulars
- **Pharmacological properties**
- References



- Pharmacodynamic properties
  - In vitro and in vivo experiments
  - Pharmacological studies in humans
  - Clinical studies
- Pharmacokinetic properties
  - Pharmacokinetics in animals
  - Pharmacokinetics in humans
- Preclinical safety data
  - Acute toxicity
  - Chronic toxicity
  - Mutagenicity, carcinogenicity, teratogenicity and embryotoxicity
- Clinical safety data

# Advantages of E/S/C/O/P-Monographs

- ❑ Balanced evaluation of literature due to the composition of the Sci. Comm. covering a broad panel of preparations
- ❑ Comprehensive compilations of relevant pharmacological, toxicological and clinical studies
- ❑ inclusion of dosages for children from reputable text books and bibliographic data about usage during pregnancy and lactation
- ❑ Publication of revisions

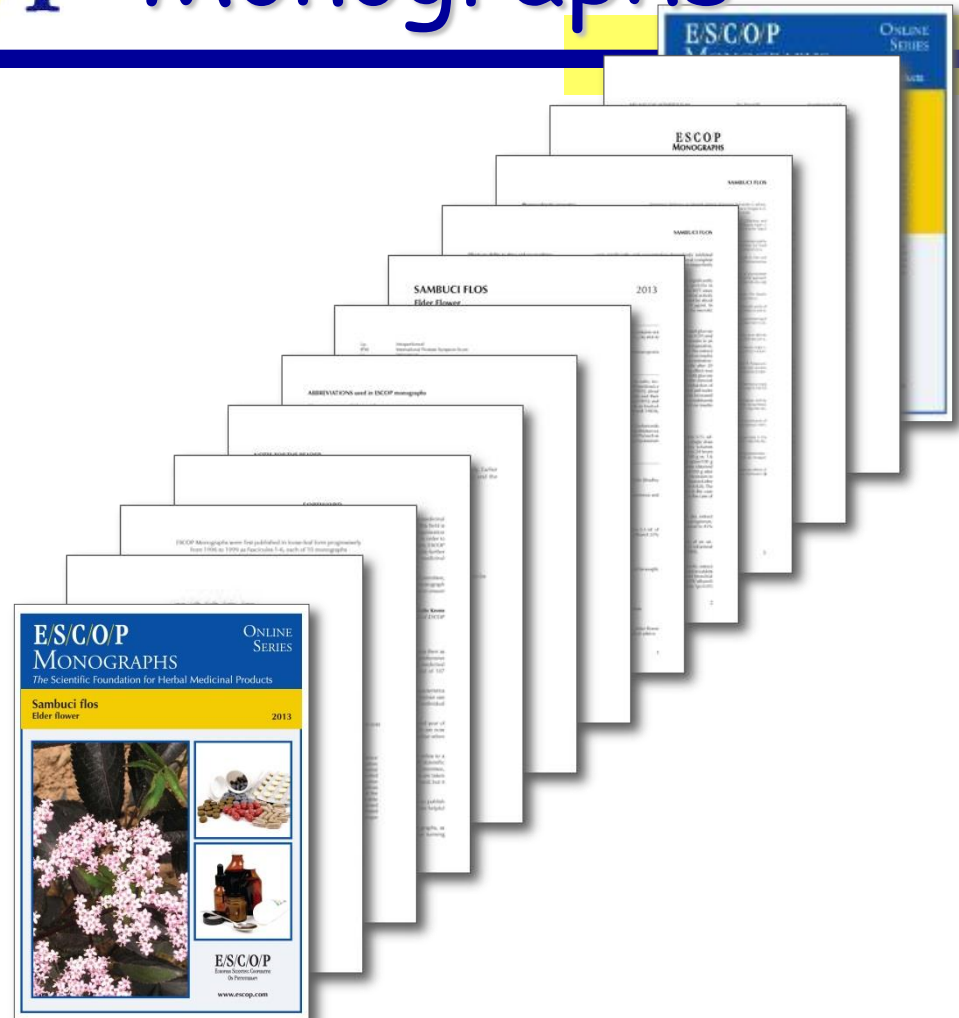
# Development of E/S/C/O/P-Monographs

- **2011**  
Start of online series  
available via [www.escop.com](http://www.escop.com)  
Revision of *Cimicifugae rhizoma*
- **2012 - 2017**  
28 revised + 13 new monographs
- **Upcoming**  
*Salicis cortex*, *Oleae folium*,  
*Althaeae radix*, *Echinaceae pallidae radix*,  
*Equiseti herba*,...



# Advantages of on-line E/S/C/O/P-Monographs

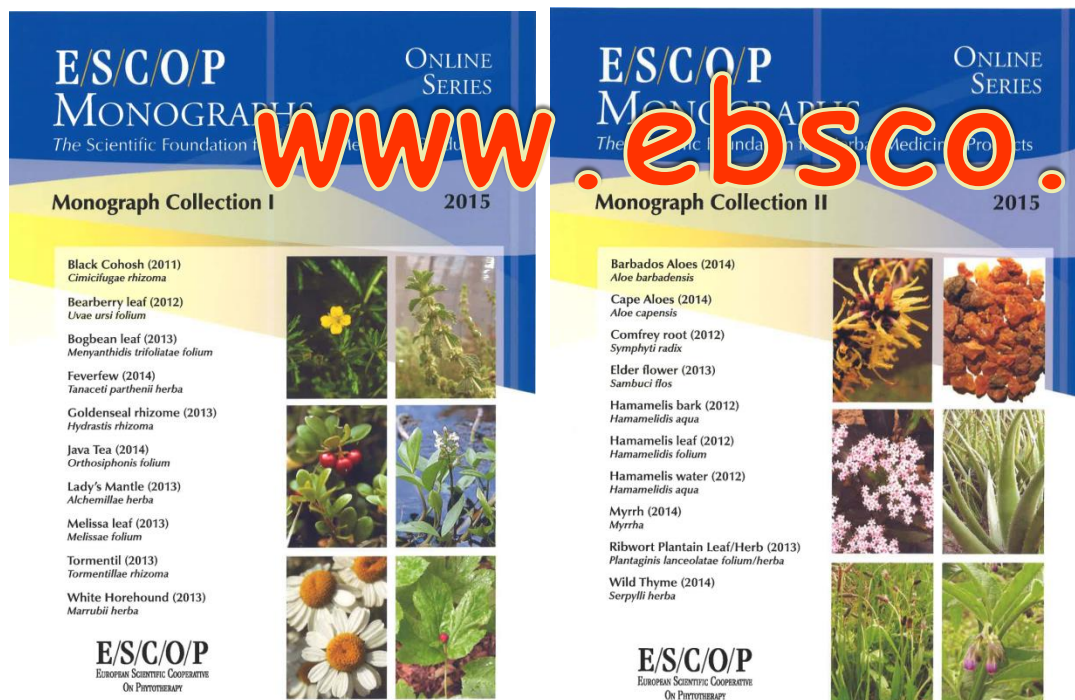
- ❑ individual download of single monographs
- ❑ prompt publication
- ❑ convenient payment
- ❑ reasonable price
- ❑ immediate availability





# E/S/C/O/P monographs for institutions

- Bundles of 10, each, available with EBSCO



## Monograph Collection III 2016:

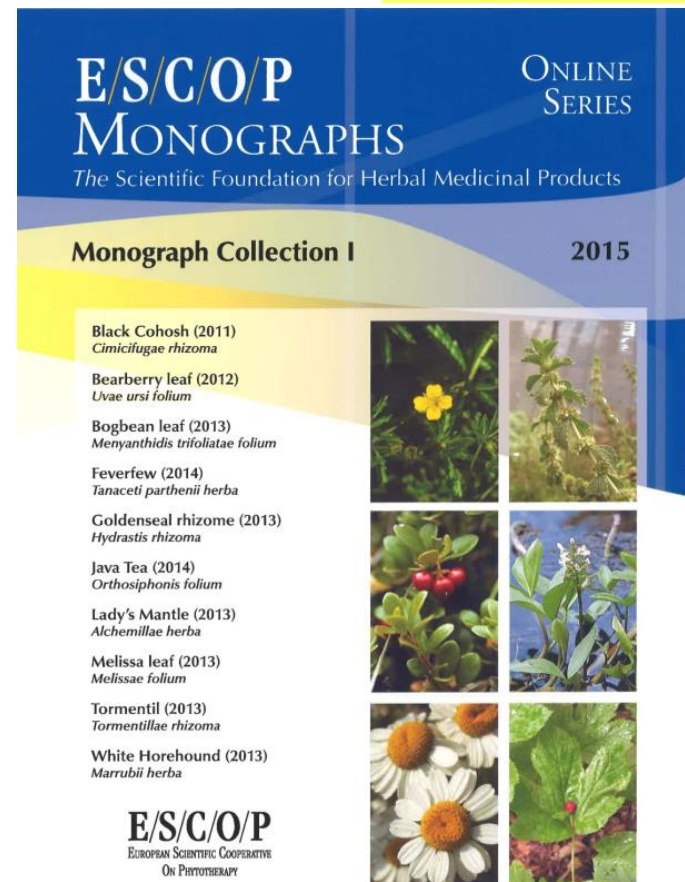
- Aniseed (*Anisi fructus*)
- Bilberry fruit (*Myrtilli fructus*)
- Birch leaf (*Betulae folium*)
- Clove oil (*Caryophylli aetheroleum*)
- Cola (*Colae semen*)
- Gentian root (*Gentianae radix*)
- Meadowsweet (*Filipendulae ulmariae herba*)
- Pelargonium root (*Pelargonii radix*)
- Nettle root (*Urticae radix*)
- Wild pansy (*Violae herba cum flore*)

## Upcoming:

Monograph Collection IV 2017

# Advantages of EBSCO on-line E/S/C/O/P-Monographs

- ❑ convenient payment for institutions
- ❑ very reasonable price for universities
- ❑ immediate availability



# Elaboration of E/S/C/O/P -Monographs

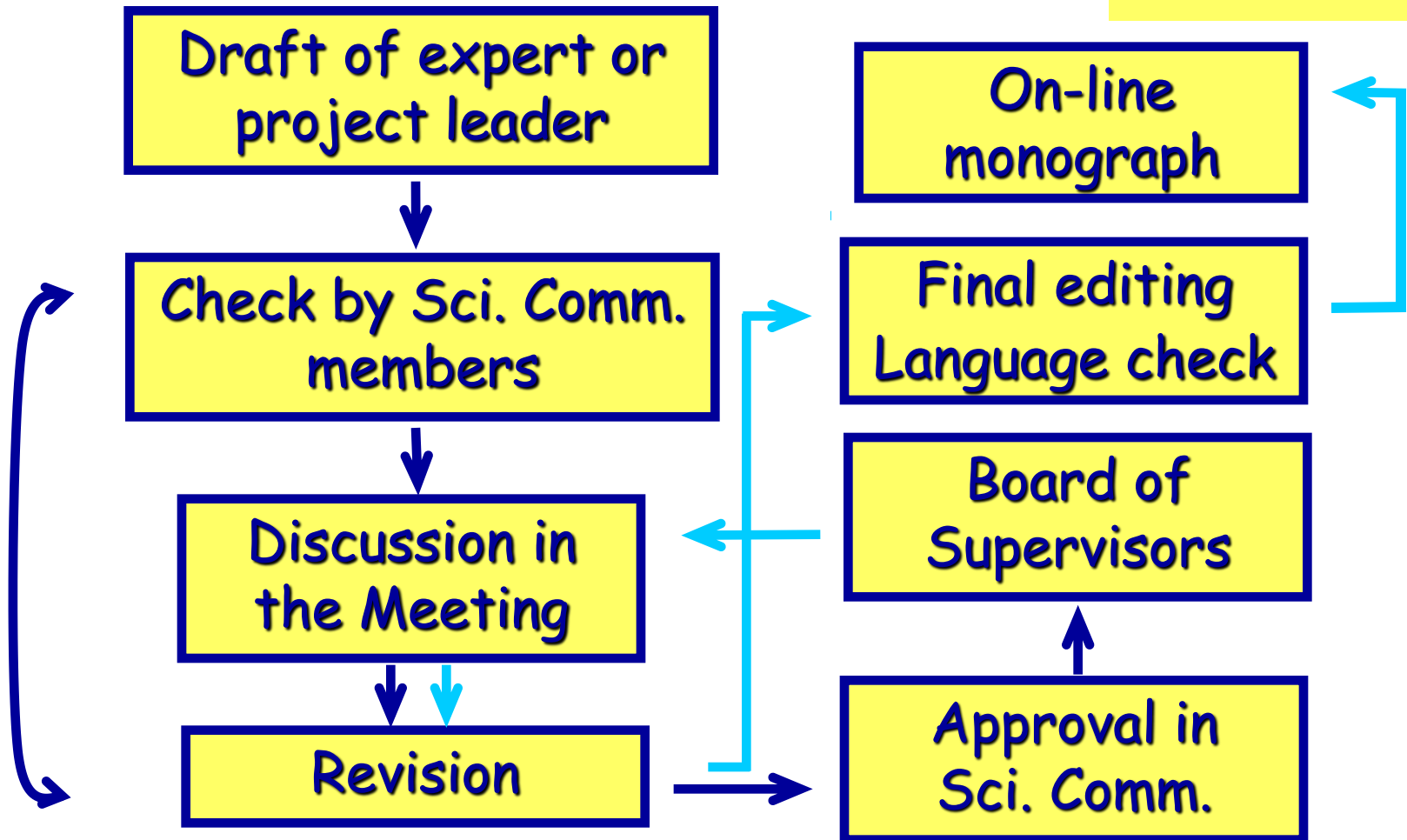
- ❑ by Scientific Subcommittees B and E
- ❑ currently 21 members from 15 countries nominated by national associations
- ❑ members from universities, special interest groups and industry
- ❑ pharmacists, pharmaceutical biologists, physicians, practising phytotherapists, specialists in regulatory affairs, botanist,.....
- ❑ supported by external experts from industry and science

# Current Members of the Scientific Committee

- **Anna Rita Bilia** - Italy
- **Jozef G. Corthout** - Belgium
- **Maria do Céu Costa** - Portugal
- **Dezső Csupor** - Hungary
- **Jürgen Drewe** - Switzerland
- **Frans van den Dungen** - Netherlands
- **Sarah Edwards** - United Kingdom
- **Marijke Frater-Schröder** - Switzerland
- **Lene Gudiksen** - Denmark
- **Didier Guédon** - France
- **Dr. Ingrid Hook** - Ireland
- **Stephan Horsten** - (Co-Chairman) - Netherlands
- **Roberta Hutchins** - UK
- **Liselotte Krenn** - Austria
- **Frédérique Lafforgue** - France
- **Radu Moldavan** - Romania
- **Andrzej Ostrowicz** - Poland
- **Georg Seidel** - Germany
- **Barbara Steinhoff** - (Co-Chairman) - Germany
- **Sonja Sturm** - (Co-Secretary) - Austria
- **Funda Nuray Yalçın** - (Co-Secretary) - Turkey



# Work-flow of E/S/C/O/P-Monographs





# Uses of E/S/C/O/P-Monographs

- ❑ support of applications for marketing authorisations or registrations
- ❑ calculations of dosages in animal studies or clinical studies
- ❑ to substantiate and harmonize indications
- ❑ teaching in the field of phytotherapy



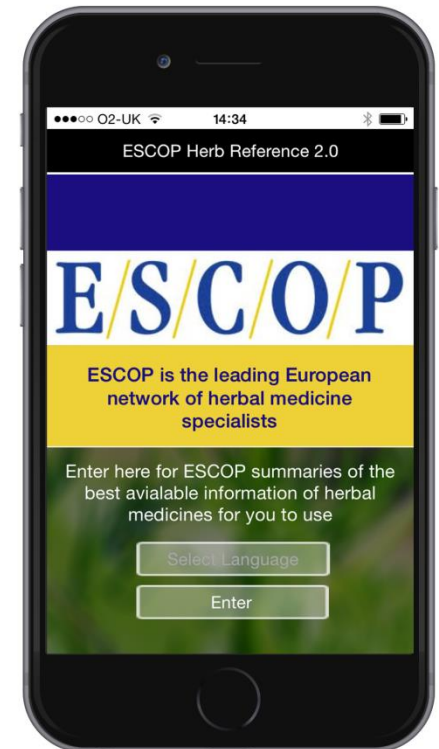
# Other activities of E/S/C/O/P

- ❑ Cooperation among national associations of phytotherapy
    - biennial joint congresses
    - joint statements on EU documents,...
  - ❑ Networking for HMPs and services to health practitioners, companies, health authorities
  - ❑ Statements in the journal "Phytomedicine"
  - ❑ Promotion of acceptance of HMPs within general medical practice and the public
    - ➔ offer for laypersons
- the E/S/C/O/P App for iOS® (iPhone®) and Android® operating systems

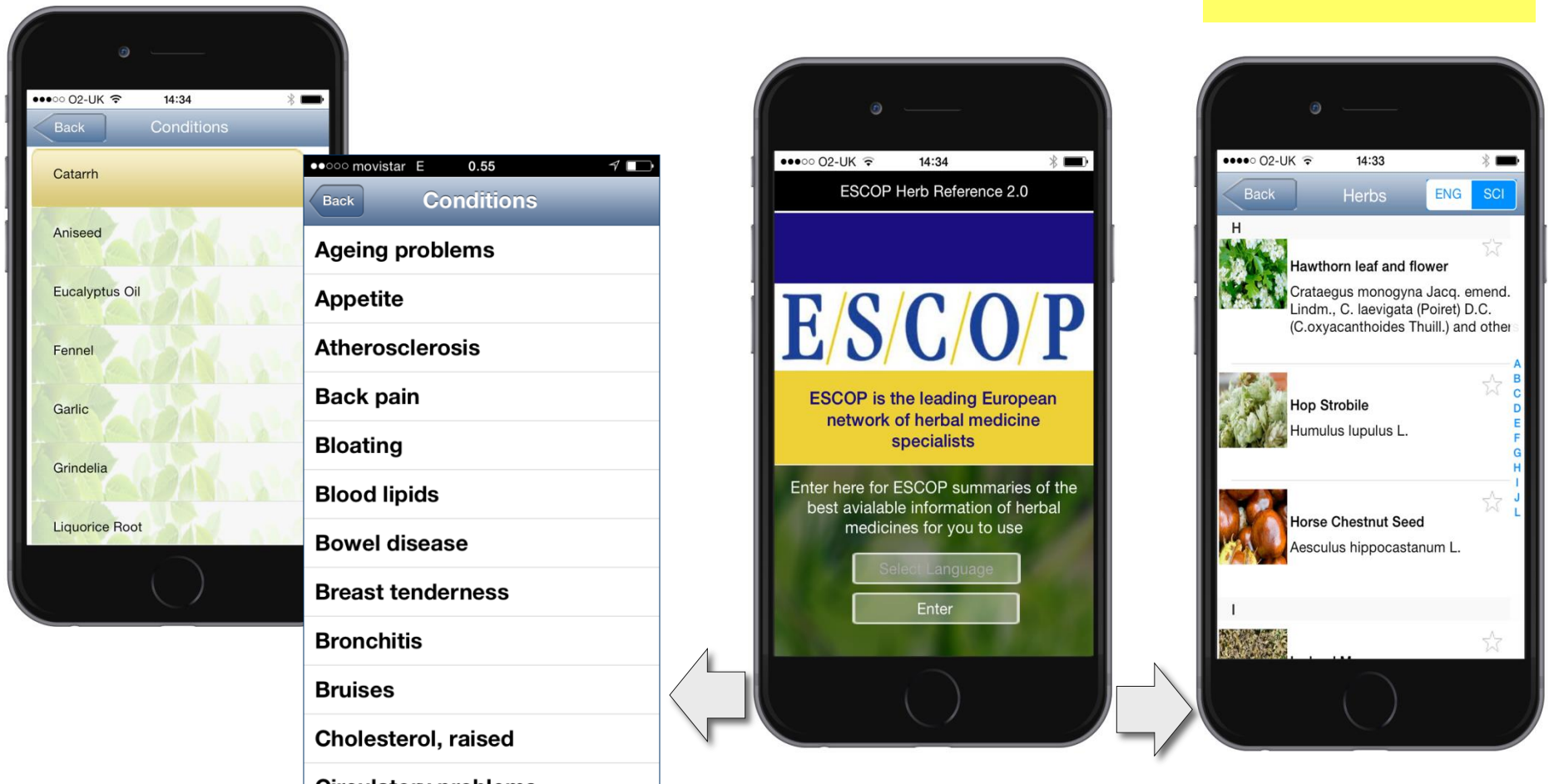


# E/S/C/O/P Herb Reference App

- ❑ information about more than 100 herbs and their uses for everyday health conditions
- ❑ over 50 searchable health conditions
- ❑ all important information, distilled from the ESCOP monographs
- ❑ terminology adapted to laypersons
- ❑ available in English and German at iTunes and GooglePlay  
upcoming in Portuguese and Spanish



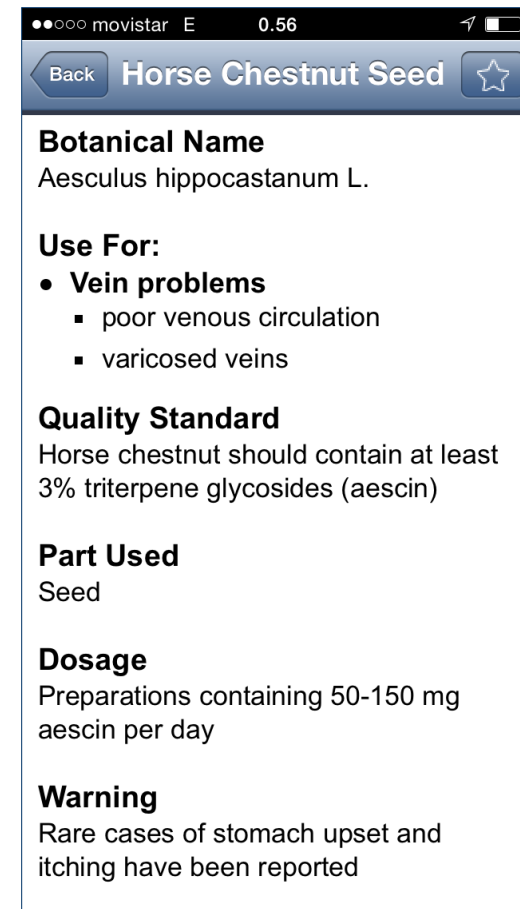
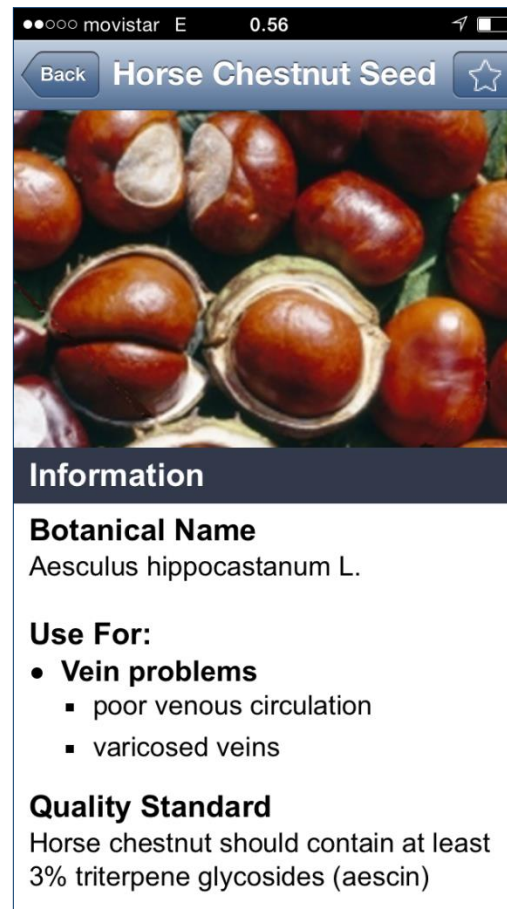
# E/S/C/O/P App Search





# E/S/C/O/P App Informations

- ❑ common name
- ❑ plant picture
- ❑ botanical name
- ❑ uses
- ❑ minimum quality criteria
- ❑ plant part used
- ❑ dosage
- ❑ special warnings
- ❑ contraindications





# Conclusions

- ❑ ESCOP took a major role in lobbying for a balanced legal framework for HMPs in Europe
- ❑ The two major current ESCOP developments are:
  - ❑ ESCOP monographs, now published individually on-line
  - ❑ The ESCOP herb reference app
- ❑ With these two developments ESCOP is giving sound scientific service to:
  - ❑ Health practitioners, companies, health authorities, teachers of phytotherapy, general population

Thank you for  
your kind  
attention!

