

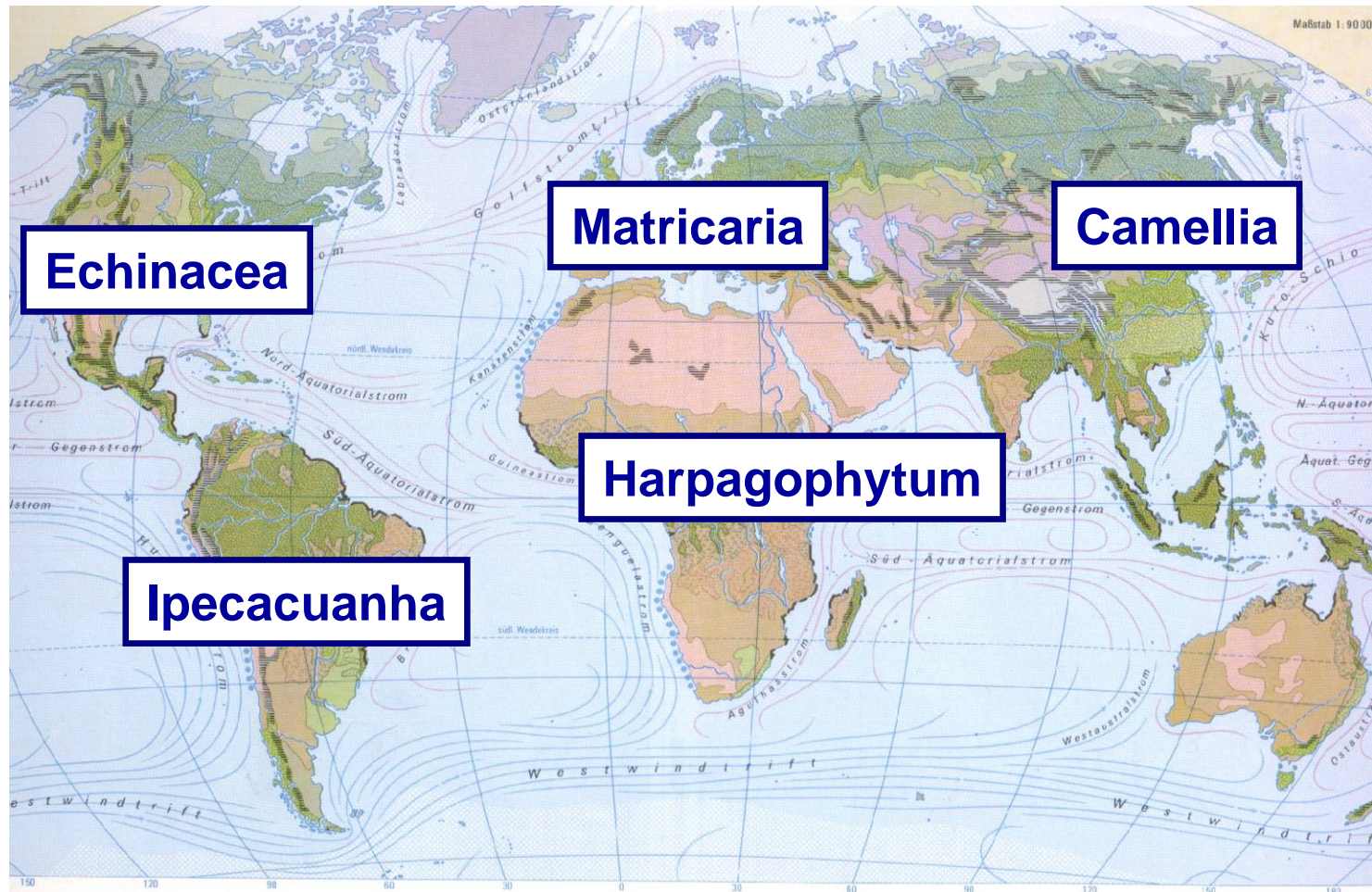


Viewpoint of the German Regulatory Authorities

PD Dr. Werner Knöss

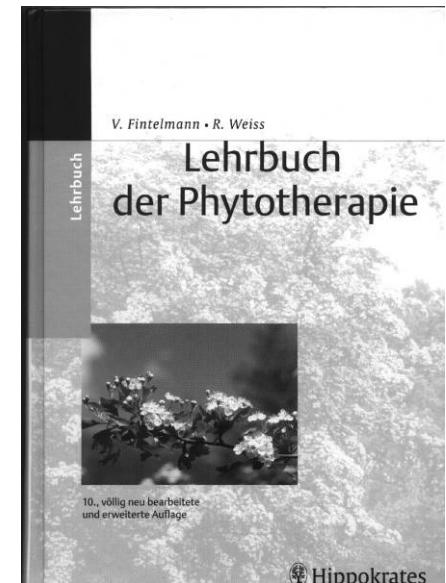
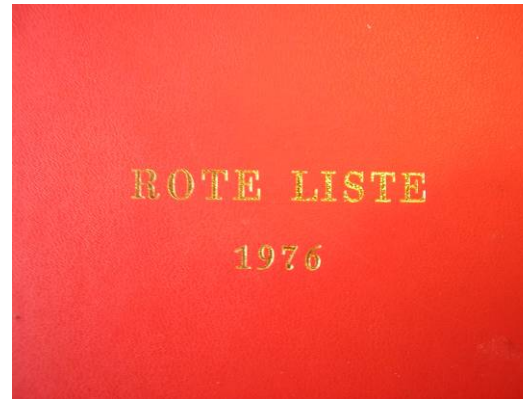
**BfArM (Federal Institute for Drugs and Medical
Devices, Bonn, Germany)**

Traditional Use of Plants

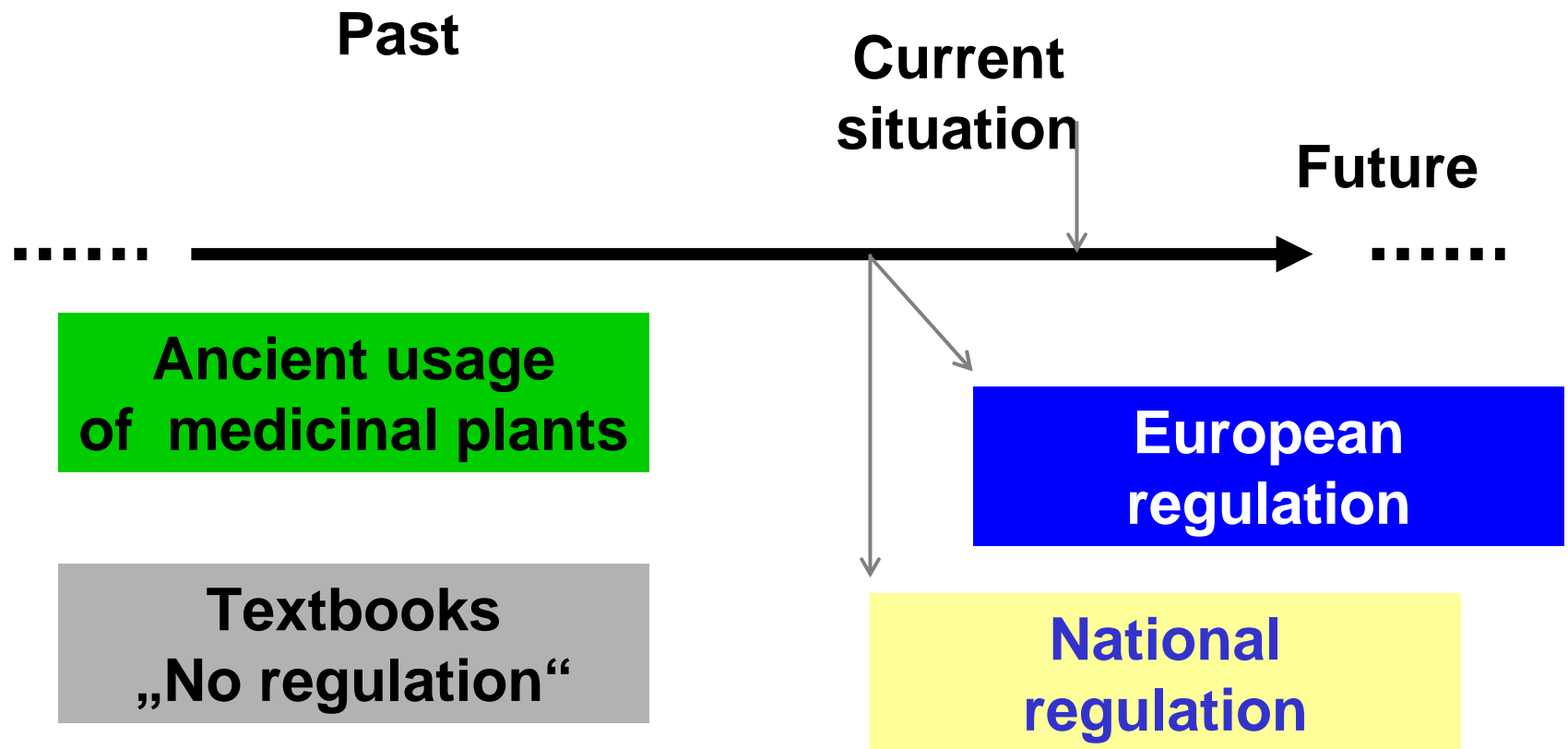


Selection and Documentation

D. Leonhart Fuchs sein alteres im xlii. Jar.

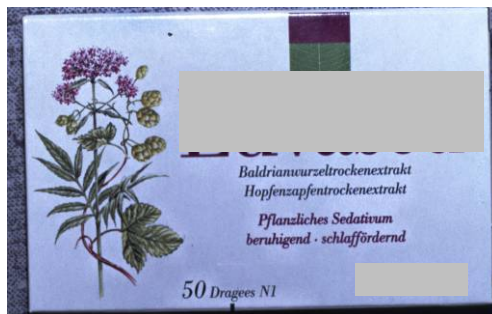


Regulatory Environment



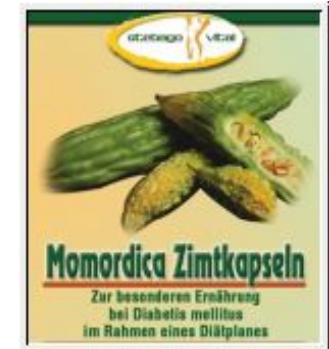
Challenges

Food



Herbal Medicinal Products

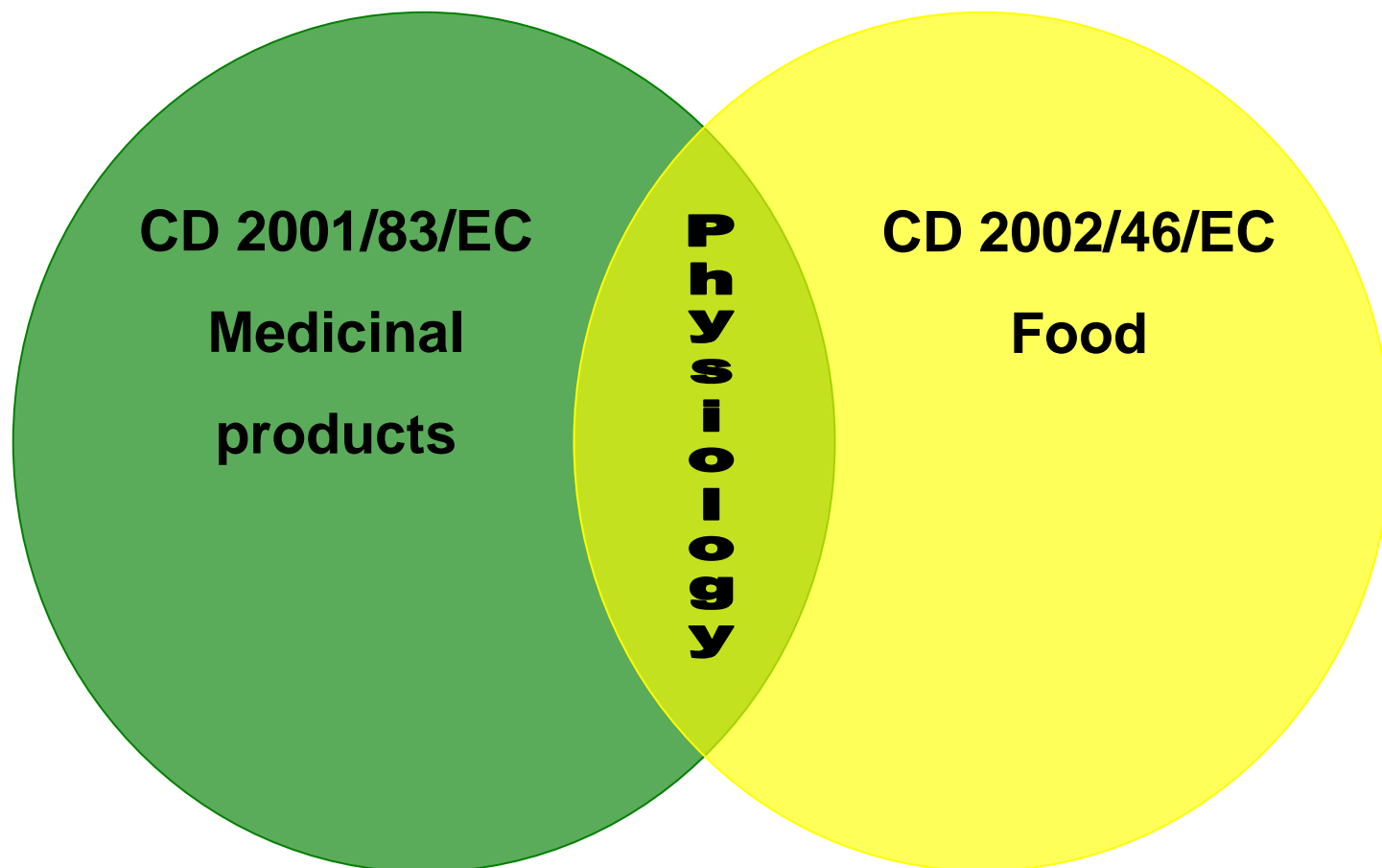
Food Supplements



Traditional

Herbal Medicinal Products

Boarder-line or Boarder-area



Definition Medicinal Product

- (a) Any substance or combination of substances **presented** as having properties for **treating** or **preventing disease** in human beings; or
- (b) Any substance or combination of substances which may be used in or admitted to human beings either with a view to restoring, correcting or modifying **physiological** functions by exerting a pharmacological, immunological or metabolic action, or to making a medicinal diagnosis.

In cases of doubt ...

Article 2 No 2 of Directive 2001/38/EC

In **cases of doubt**, where, taking into account all its characteristics, a product may fall within the definition of a "medicinal product" and within the definition of a product covered by other Community legislation **the provisions of this Directive shall apply.**

Situation in Germany



- Long-standing tradition in applying particular therapeutic systems.
- Emphasis on therapeutical pluralism by the German government in 1976 – German Medicines Act
- § 25 Abs. 7 AMG (German Medicines Act)
... Medicinal products of a particular therapeutic system (Phytotherapy, Homeopathy, Anthroposophy), ...
- Revision of the „old market“ – finished in December 2005 / 2007
- Food and Medicinal Products Regulation separated

German Market

Complementary and Alternative Medicines

- SME
 - about 700 pharmaceutical companies
 - about 11.000 medicinal products marketed
 - Long-standing tradition of medicinal products
 - Highly accepted by patients
 - Reimbursement stopped with few exceptions
 - Manyfold interested parties
-
- Competition of Medicinal Products and Health Products

Basic Figures – CAM and Traditional Medicines in Germany

Regulation since 1976 – German Medicines Act

- 2400 herbal medicinal products
 - 1900 licensed herbal medicinal products
 - 500 licensed trad. herbal medicinal products
- 1500 licensed homeopathic medicinal products
- 1000 licensed anthroposophic medicinal products
- 4000 registered homeopathic and anthroposophic medicinal products

European Regulation



European Community Directives

- **CD 2001/83** (“basic” regulation)
- CD 2003/63 of 25 June 2003 (Annex I, **criteria**)
- CD 2004/24 (**Traditional herbal medicinal products**)
- CD 2004/27 of 31 March 2004 (**HMPC**)
- **Further Guidance Documents (www.emea.eu.eu)**

„Traditional Use Directive“

30.4.2004

EN

Official Journal of the European Union

L 136/85

DIRECTIVE 2004/24/EC OF THE EUROPEAN PARLIAMENT

of 31 March 2004

on the approximation of laws, regulations, administrative provisions and an act of the Council of the European Union relating to medicinal products for human use

and an act of the Council of the European Union

and an act of the Council of the European Union on the market of medicinal products for human use currently in force

the Member States may hinder trade in traditional medicinal products and lead to competition between them. They may also have a negative impact on public health since the quality and efficacy are not guaranteed.

Commission (1).

Economic and

shown in Article



characteristics of these products. Long tradition, it is a simplified registration procedure for certain traditional medicinal products. However, this simplified procedure should be used

Definition Traditional Herbal Medicinal Products

A herbal medicinal product that fulfils the conditions laid down in Article 16a(1).

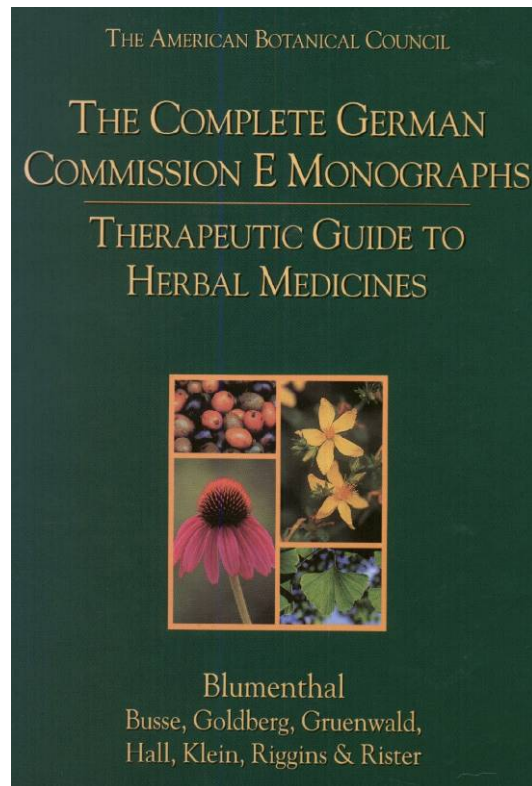
Vitamins and minerals may be added if their action is ancillary to the herbal constituent(s) (Article 16a(2)).

European Medicines Agency - EMA

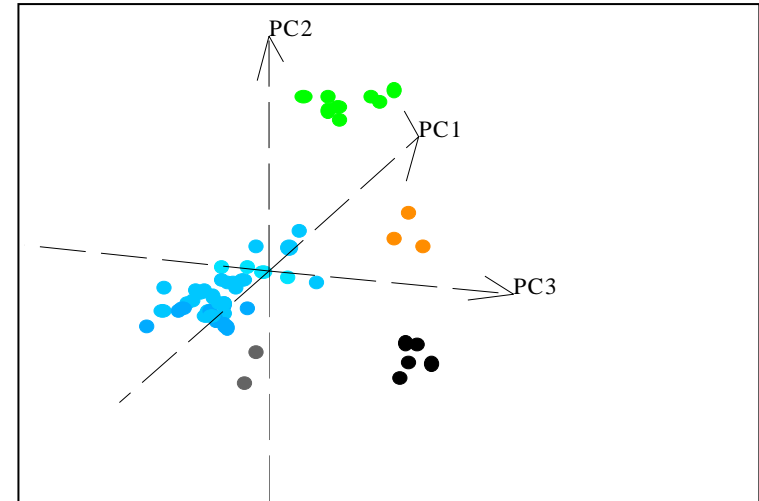
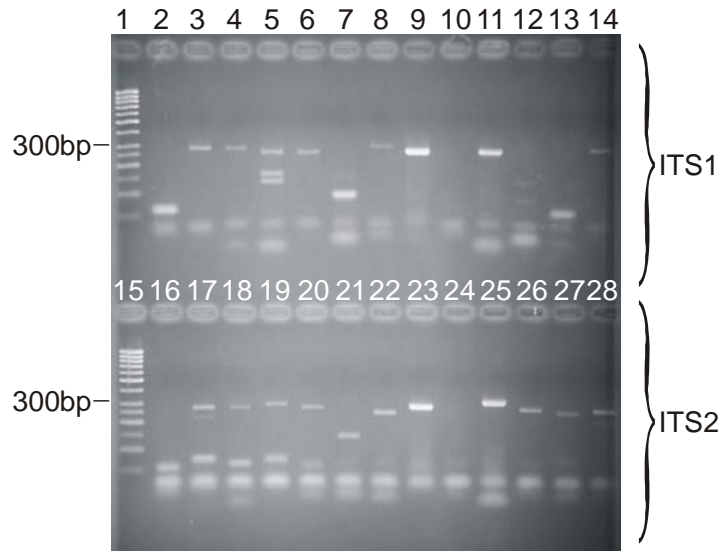
- Central European Authority with specified tasks
- Committees and Working Parties
- Herbal Medicinal Products Committee – HMPC
- Monographs and List Working Party - MLWP
- Coordination of National Competent Authorities
- Guidance Documents (www.emea.eu.eu)



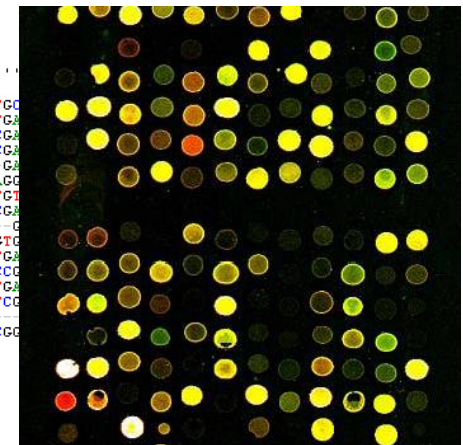
Monographs from Commission E to HMPC



Future Impact of Research – New Methods



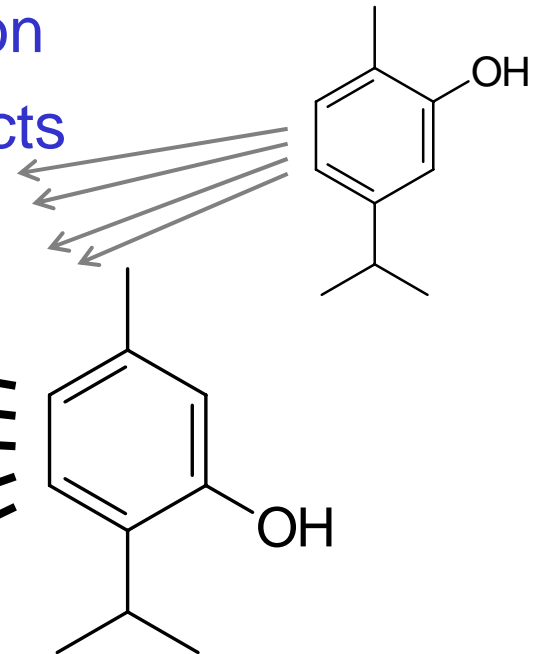
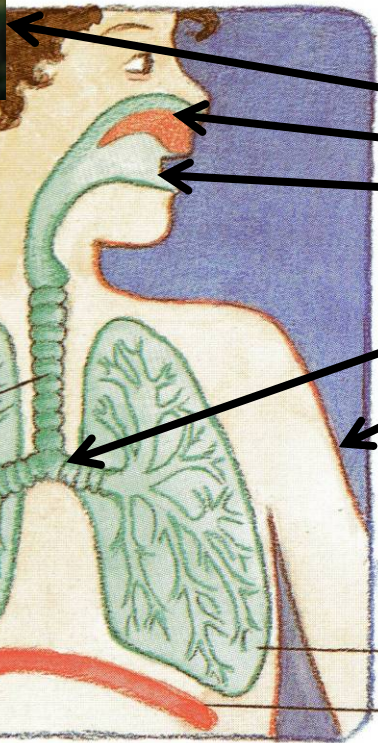
	650	660	670	680	690	700	710	720	730	740
Amomi Rotundus Fructus	TGTGCGTGAATGGAACTGTC	CCCCCGATGCTTGGG	ATGTGTCCTCGAGAGACCC	TGTGCGATTGCGGACCGTGTGAAAGTGTGCTGC						
Astragali Radix	CGAGTTAGCACC	AGACCCATCATGTGTA	CGCTCCCCATAATATGGCTT	CGATGACCCACATGCGTCT	TT	TGA				
Atractylodis Rhizoma	TGTAATGC CCCTCC	TATCGAGCCGTGCGTCGCGAGCCGCAAGGGAAGCGCTCG	ACAAAGACCCCAACGCGTCC	CCTCAGCAGCA						
Carthami Flos	TGTAAGGC ACTTCC	TAAAGAGCCGTCTT	GATGCTAGGGAATTGCTCT	CTAAAGACCCCTAACGCTGTC	TCTTACGACGA					
Clematidis armandii Caulis	TGTAATCTC ATCCCC	CAAAAGACAGAAACGACGCGCAGCCCTCGCCACGCAAGGC	CTAACGAAACCCAGAGAACCC	CTCCCCG	CA					
Codonopsis Radix	GATTAACAAGCCCTCC	CGTCCCGTCTGCGCA	CGTCTCGGATGGCTTGGCTC	TGCTGACCCCTGACCGCTCTAGGCTTAAAGCCTAAGC						
Fritillariae cirrhosae Bulbus	GAGCACCAGCAGGATGTTG	CCCCCTGTCGCCCTTAAAG	GGC	CTCAAGACAGCCCG	AACGGGCGATCCGTGCTCCGTACGAGGAGGGCGTGT					
Houttuyniae Herba	CTTTTGGGCGCGATTGTCGG	ATGTTGTGTCGCTGTTTGGCCGTGTTGGCCAGCGAGGAGCC	GTATTGCGATCG	ACCTCCGACCTCCGGAGGCACGA						
Isatidis Radix	GAATTAACACCT	CGTCATACCGT TGGC	CGCTCCTGTCTGATGCTCT	CGATGACCCAAA						
Ledebouriellae Radix	TGTAAGAG ACCCTCT	TCTCTGTGCGCGCAATCCTCGTCATCTTAGAGAGATCC	AGGACCCCTTAGGCAAGCA	CACACTCTGTG						
Moutan Cortex	TGTAATAGCTATTTCG	TGTTGTGCTTGTCTC	GTCCCCCTGTGA	CTTC	ACAAAAACCCAGAGCATCG	TC	ACGATGA			
Oldenlandiae diffusae Herba	TCAAACTTCAACTCG	ATCGTAGCCGTGACCG	AGAACG	CATT	GTAGCCCTCTAAAGAC	CCTGGAGCCT	CGG			
Paeoniae Radix rubrae	TGTAATAGCTATTTCG	TGTTGTGCTTGTCTC	GTCCCCCTGCGA	GCTC	ACAAAGACCCCAAGCATCG	TC	ACGATGA			
Scutellariae Radix	TGTTT CCTCAACTCG	CGTCTGTCTGTGCGC	AAGCCCTCTCTCCCTTCCG	GAGAGAAATCGAAAGATGAGA	CCCAACGCCCATCG					
Stephaniae tetrandrae Radix	GACGACAATCCTTGTG	AAGCAAGTACGCCCGT	CGGACCGGCACCCATCGCG	CGCCAGCACCCAT						
Ziziphi Semen	TGTCCAACCCCTC	CGCTCCCTGCTGCGTCCGCGGATCGCTGTCCG	GCCTC	ACAGAGACCCCAATGCGCTG	CC	AATGCGG				



Future Impact of Research – New Concepts „Systems Biology“



Multi-target action
of natural products



Volatile, membrane-acting,
Amphipolar, bioavailable

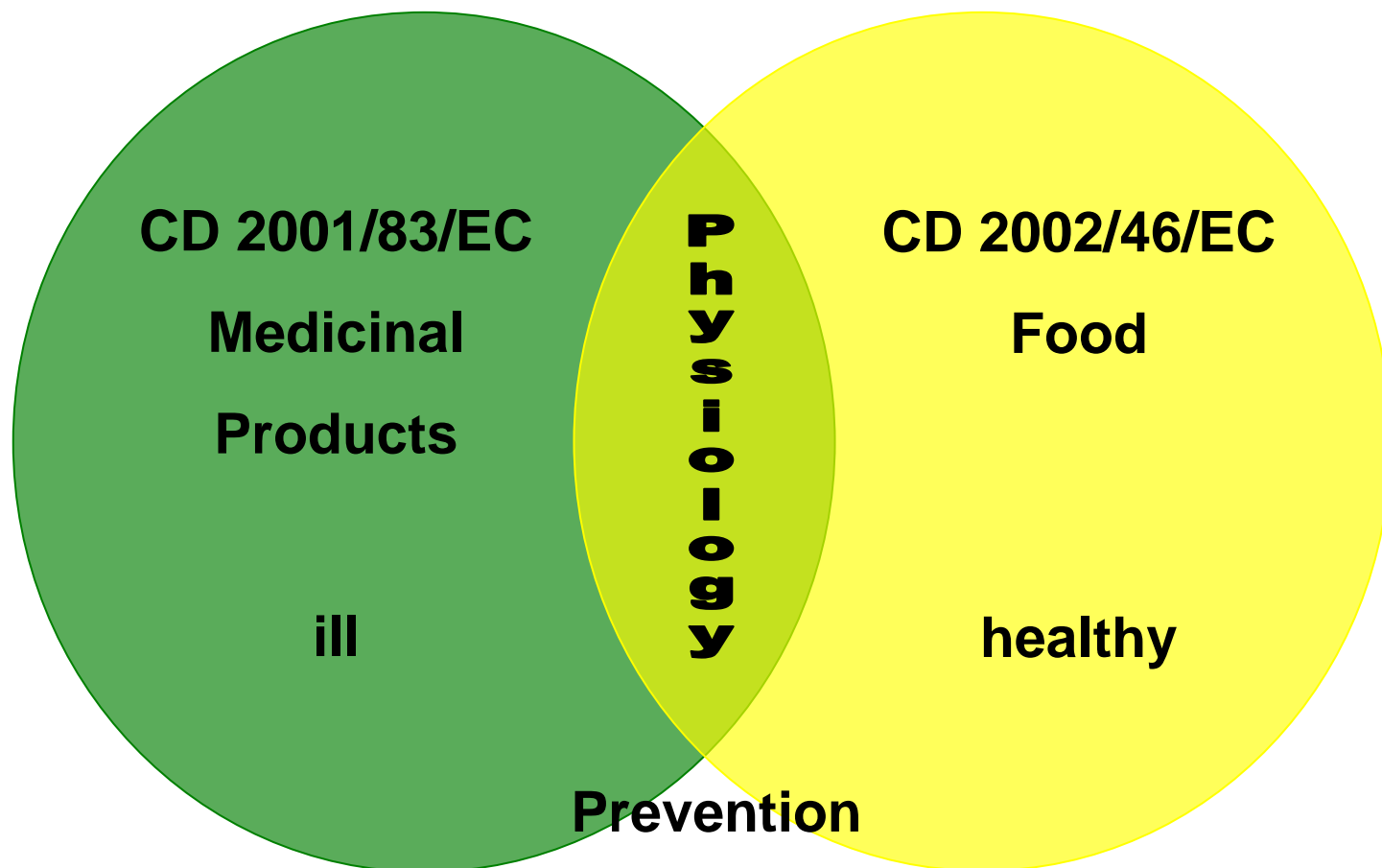
Conclusions (1)

- There is a clear regulatory framework for (traditional) herbal medicinal products in the European Union.
- Requirements on quality, efficacy and safety are clearly defined.
- Access to the market is controlled and a post-marketing-surveillance system is established.
- Currently, different traditions in the Member States are being harmonised by the work of MLWP and HMPC.
- Within the next three years about 100 monographs will be adopted, growing number of combination products

Conclusions (2)

- Transition period from national to European market(s).
- Growing acceptance of monographs, network of authorities and worksharing. (map of participating countries ...).
- Future research will generate new knowledge on herbal medicinal products and their usage. Tradition and Well-established use may contribute to develop phytotherapy.
- The regulatory framework has to be adjusted, communication and coordination concerning regulation of similar products have to be optimised.
- Supply with suitable medicinal products vs. overregulation.
- The border-area will stay but may be get more harmonised.

Boarder-line or Boarder-area



Every tradition is a part of Europe !

