Viewpoint of the German Regulatory Authorities

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Traditional Use of Plants

- Echinacea
- Matricaria
- Camellia
- Harpagophytum
- Ipecacuanha
Selection and Documentation
Regulatory Environment

Past

Ancient usage of medicinal plants

Textbooks „No regulation“

Current situation

European regulation

National regulation

Future
Challenges

Food

Herbal Medicinal Products

Food Supplements

Traditional Herbal Medicinal Products
Boarder-line or Boarder-area

CD 2001/83/EC
Medicinal products

 Physiology

CD 2002/46/EC
Food
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

Source: IMS
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.eur.eu)
DIRECTIVE 2004/24/EC OF THE EUROPEAN PARLIAMENT and of the COUNCIL of 31 March 2004

establishing the European Community code relating to medicinal products for human use

and an act of marketing on the market and a procedure that currently the Member States may hinder trade in traditional herbal medicinal products within the Community and lead to a competition between products which may also have the same efficacy and safety characteristics of these products. Having regard to the long tradition, it is felt that 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 - EMEA

- 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.eur.eu)
Monographs from Commission E to HMPC
Future Impact of Research – New Methods

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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

CD 2001/83/EC
Medicinal Products
ill

CD 2002/46/EC
Food
healthy

Prevention
Every tradition is a part of Europe!