Regulatory Options for Traditional Herbal Medicinal Products

PD Dr. Werner Knöss
Chair HMPC, EMA, London
Head Department Licensing 5, BfArM, Bonn, Germany
Disclaimer

I do not represent HMPC. The views expressed here are my personal views and may not be understood or quoted as being made on behalf of the HMPC or reflecting the position of the HMPC.
European Regulation
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.
Classification ... Borderline Products

Food
Food supplements
Cosmetics

§§

Neue Lebensmittel für die Gesundheit

Novel food
Medical devices
European Commission on Classification

“Classification of products is within the responsibility of the Member States of the European Union.”
Borderline Questions

There is a need for transparent information to patients/consumers and health care professionals !!!
European Community Directives

- CD 2001/83 ("basic" regulation)
- CD 2004/24 (Traditional herbal medicinal products)
- CD 2004/27 of 31 March 2004 (HMPC)

Further Guidance Documents (www.ema.europa.eu)
Definitions – Directive 2001/83 EU

Medicinal product
Herbal medicinal product
Traditional herbal medicinal product
  (longstanding tradition, plausibility)

Herbal substance (Eur. Ph. “Herbal drug”)
Herbal preparation (Eur. Ph. “Herbal drug preparation”)
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.
„Traditional Use Directive“

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 additional 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.ema.europa.eu)
HMPC - Tasks

- Monographs
- List entries
- Scientific opinions
- Coordination
- Scientific advice
- Questions
HMPC - Composition

• 27 Member states
• 5 Coopted members
• Norway, Iceland
• European Commission
• Observers: EDQM, EU candidates

Chair: PD Dr. Werner Knöss
Vice-Chair: Prof. Dr. Ioanna Chinou
Harmonisation in the EU

Guidance towards harmonised evaluation and assessment of (traditional) herbal medicinal products

Quality
Efficacy
Safety
Guidance – Examples

Guideline on the assessment of clinical safety and efficacy in the preparation of community herbal monographs for well-established and of community herbal monographs / entries to the community list for traditional herbal medicinal products / substances / preparations (EMA/HMPC/104613/2005)

Guideline on Quality of Combination Herbal Medicinal Products/Traditional Herbal Medicinal Products (EMEA/HMPC/CHMP/CVMP/214869/2006)

Guideline on Quality of Herbal Medicinal Products/ Traditional Herbal Medicinal Products (CPMP/QWP/2819/00 Rev. 1)

Guideline on Specifications: Test procedures and Acceptance Criteria for Herbal Drugs, Herbal Drug Preparations and Herbal Medicinal Products/Traditional Herbal Medicinal Products (CPMP/QWP/2820/00)
Community Monographs

- About 80 Monographs adopted
- Rapporteurships assigned
- Priority setting
- About 20 new monographs per year
- Growing acceptance, use by industry

- > 300 registrations; > 150 in second half of 2010
London, 27 May 2010
EMA/HMPC/278067/2006

Committee on Herbal Medicinal Products (HMPC)
Overview of assessment work - Priority list (status May 2010)

Listed in alphabetical order:

B: Rapporteur assigned, C: ongoing call for scientific data, D: Draft under discussion, P: Draft published, PF: Assessment close to finalisation (pre-final), R: Final opinion adopted

Absinthii herba (F)  Crataegi folium cum flore (R)
Agni casti fructus (PF)  Crataegi fructus (R)
Agrimoniae herba (K)  Cucurbitae semen (K)
Access to the Market - Options

Marketing authorisation
- full, bibliographic or hybrid application

Registration
- (simplified with respect to the proof of efficacy)

Procedures: national, MRP, DCP, CP

Individual prescriptions (Member States)
Conclusions (1)

1. There is a clear regulatory framework for (traditional) herbal medicinal products in the European Union.

2. Access to the market is controlled and a post-marketing-surveillance system is established.

3. Currently, different traditions in the Member States are being harmonised by the work of HMPC.

4. *Existing regulatory framework for borderline products is only partially applied.*

5. *Transparency for patients and consumers is essential.*
Regulatory Environment

Past

Current situation

Future

Ancient usage of medicinal plants

European regulation

Textbooks „No regulation“

National regulation
Future Impact from Globalisation

Past

Current situation

Future

Ancient usage of medicinal plants

Textbooks „No regulation“

European regulation

National regulation
Understanding the Origin!

Therapy

Medicinal Products

Prevention, healthy Nutrition

Food

Devices, instruments

Physiology

Physic

Medical Devices
Thanks to Arnold Vlietinck
Thank you ...

... for your attention!