BfArM
Bundesinstitut für Arzneimittel und Medizinprodukte

Regulatory Options for Traditional Herbal Medicinal Products

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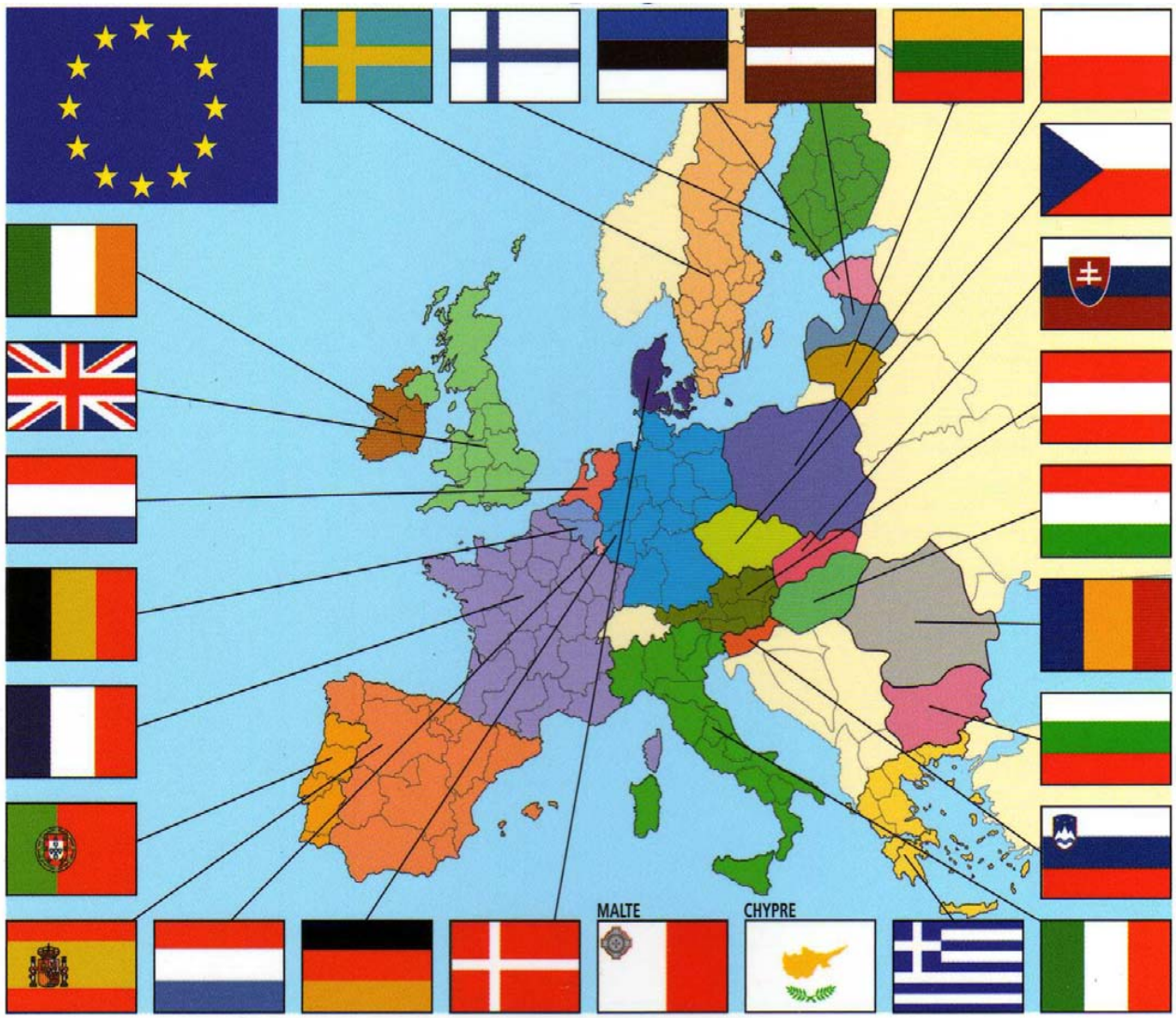
Disclaimer

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

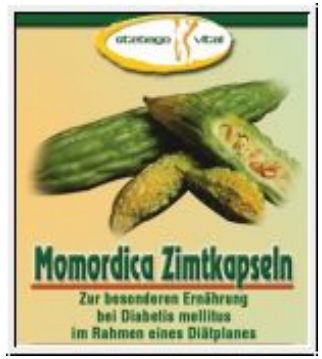
In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a ”medicinal product” and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply.

Classification ... Borderline Products

Food

Food supplements

Cosmetics



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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 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.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“

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

traditional herbal medicinal products, l
unity code relating to medicinal products f

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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)

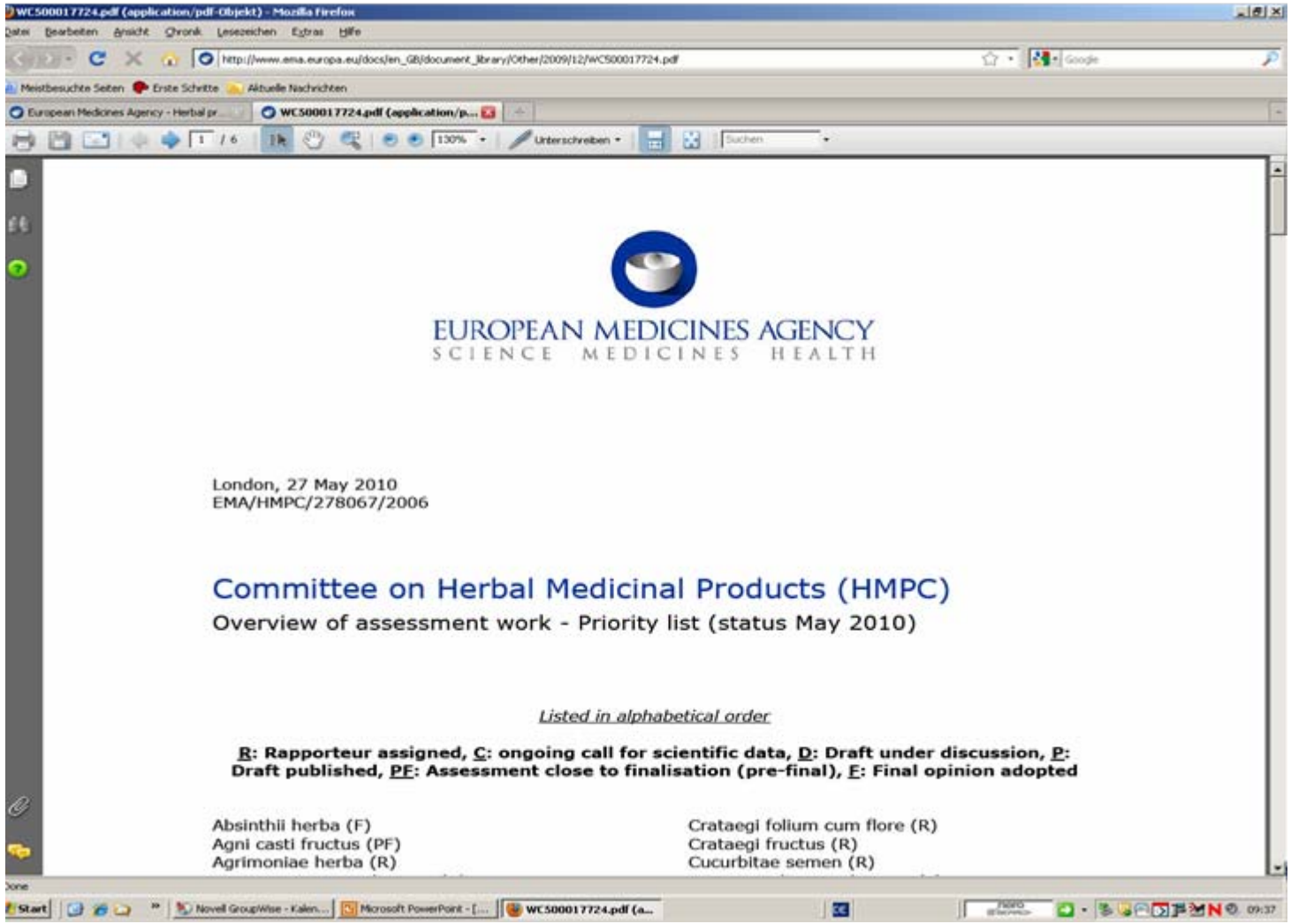
Guideline on Specifications: Test procedures and Acceptance Criteria for Herbal Drugs, Herbal Drug Preparations and Herbal Medicinal Products/Traditional Herbal Medicinal Products (CPMP/QWP/2820/00 Rev. 1)

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*

Public Information



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

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

Absinthii herba (F)
Agni casti fructus (PF)
Agrimoniae herba (R)
Crataegi folium cum flore (R)
Crataegi fructus (R)
Cucurbitae semen (R)

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*

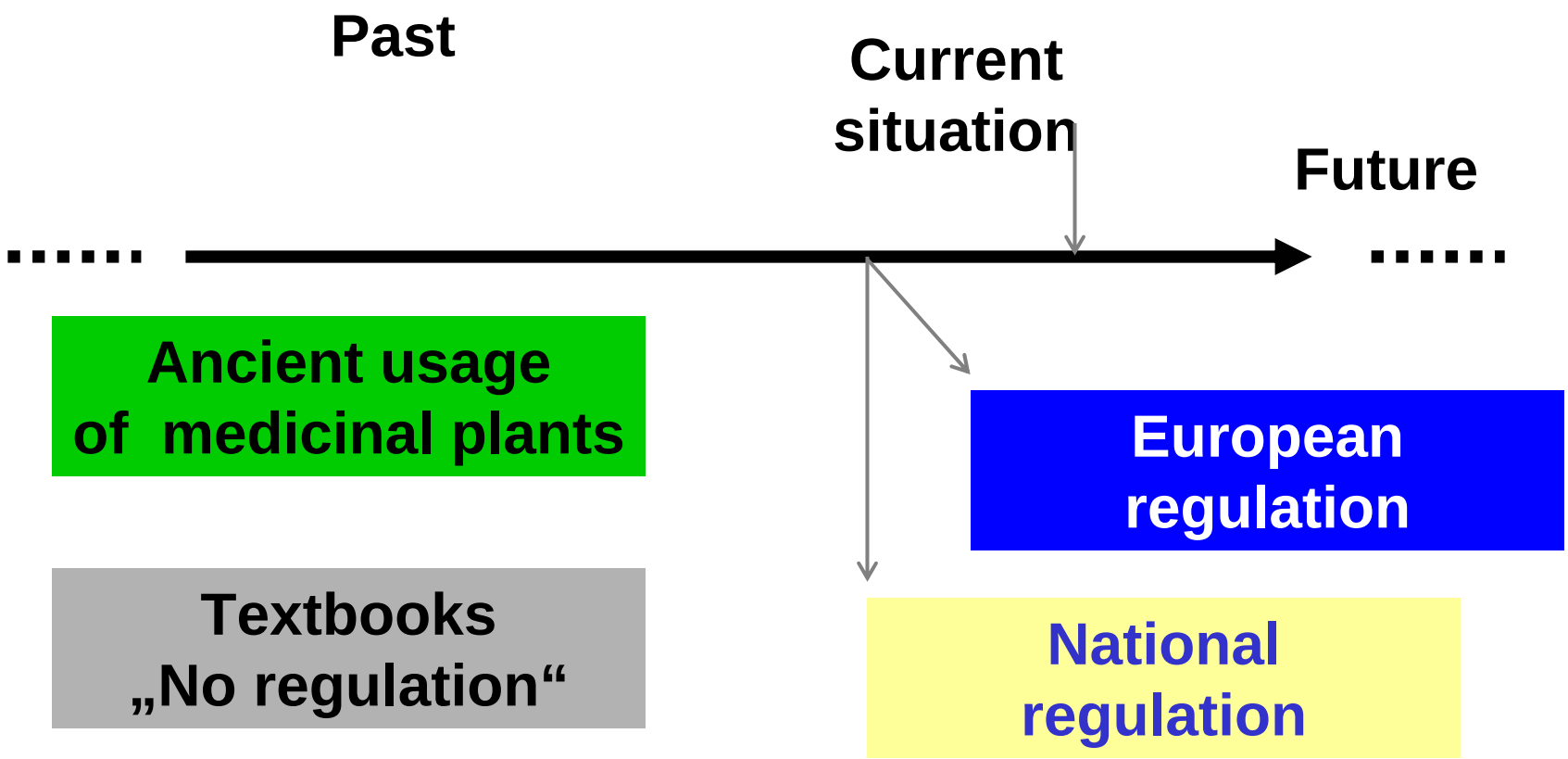
Individual prescriptions (Member States)

Conclusions (1)

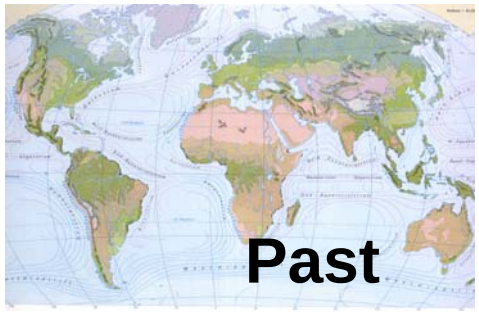
1. **There is a clear regulatory framework for (traditional) herbal medicinal products in the European Union.**
2. **Access to the market is controlled and a post-marketing-surveillance system is established.**
3. **Currently, different traditions in the Member States are being harmonised by the work of HMPC.**

4. ***Existing regulatory framework for borderline products is only partially applied.***
5. ***Transparency for patients and consumers is essential.***

Regulatory Environment



Future Impact from Globalisation



Past

Current situation

Future

Ancient usage of medicinal plants

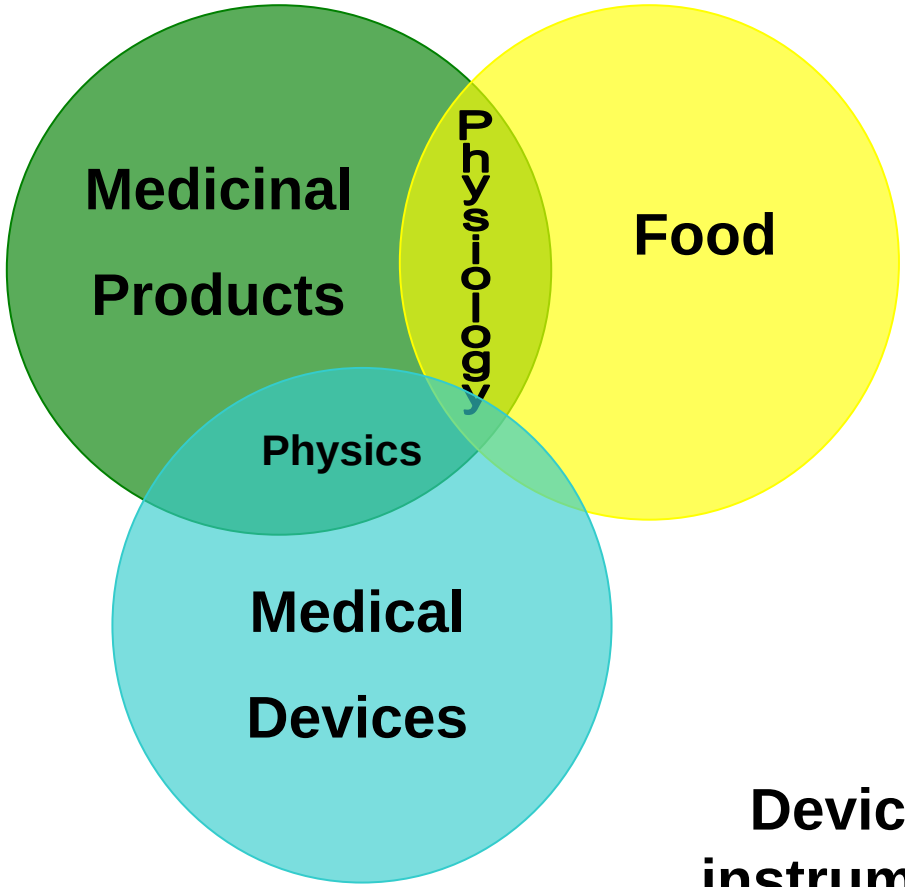
European regulation

Textbooks „No regulation“

National regulation

Understanding the Origin !

Therapy



Prevention,
healthy
Nutrition

Devices,
instruments

Thanks to Arnold Vlietinck

Thank you …

… for your attention!