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Bundesinstitut für Arzneimittel und Medizinprodukte

EMEA Homeopathic Workshop

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HMPWG in the view of the NCA

Objectives , Achievements, Roles and Responsibilities

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Overview

Introduction

HMPWG

Network of Organisations

Routes to harmonisation

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HMPWG - Homeopathic Medicinal Products Working Group

HMPWG - Working Group of the HMA

BfArM organized 1st informal meeting in 1999

BfArM will host the 4th and 5th formal meeting in November 2006 / March 2007 in Bonn

Homeopathy – a traditional therapeutic system

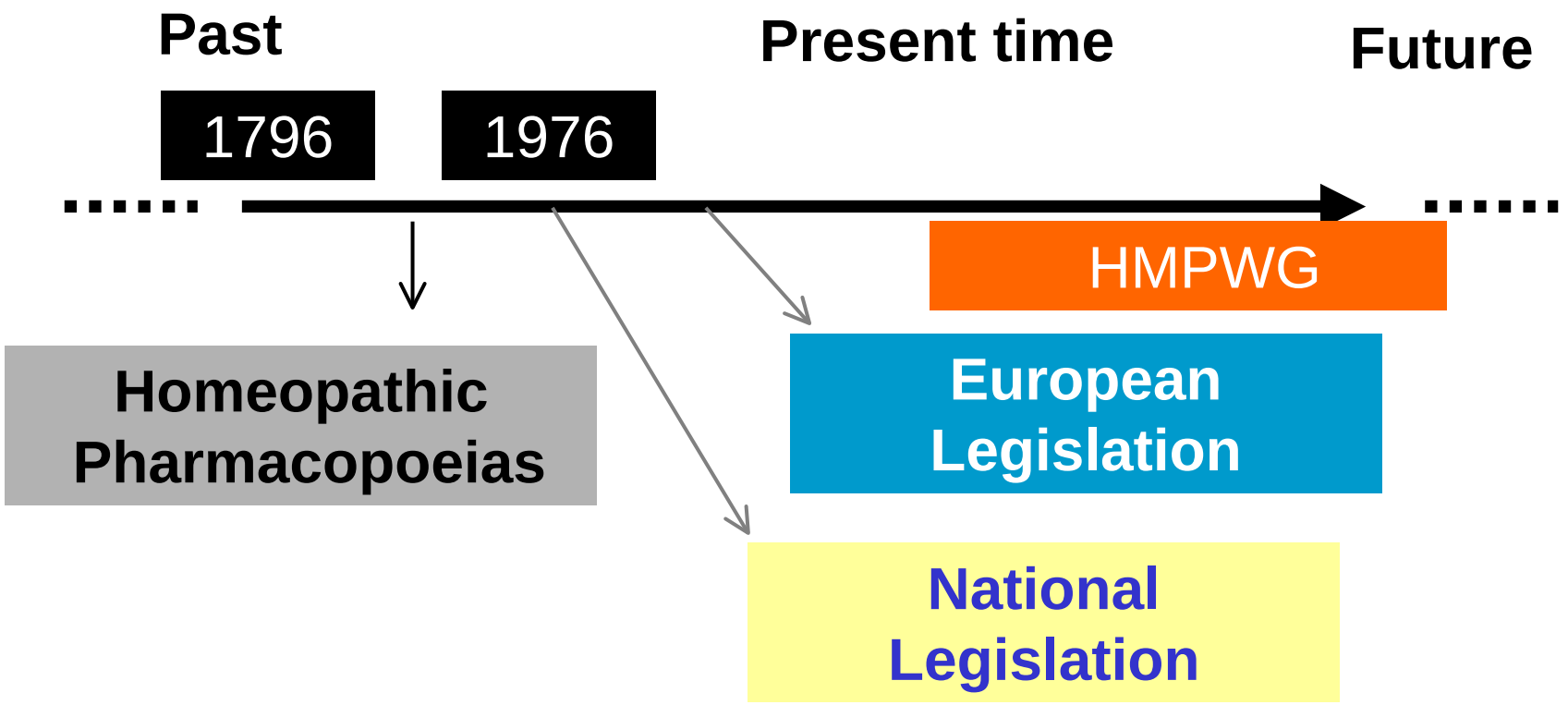
Samuel Christian Hahnemann
1755 – 1843

1796 „Essay on a New Principal for Ascertaining the Curative Powers of Drugs“

„similia similibus curentur „ - let likes be cured by likes

Homeopathy is an experience-based traditional therapeutic system – nevertheless subjected to an ongoing evolutionary process.

The „Homeopathic“ Regulatory Framework - from national concepts towards a European market



WHY HMPWG ?

! Need for a European solution for regulation of homeopathic medicinal products with regard to the particular characteristics of this therapeutic system !

- Developing harmonisation of the assessment of homeopathic medicinal products
- Developing common interpretation of criteria
- Guidance for the assessment
- Need for communication and harmonisation

HMPWG Mandate

Formal mandate in November 2004 by the Heads of Agencies (HoA):

- Forum of exchange of regulatory and scientific expertise

- To provide guidance

-To provide advice and expertise

Challenges of the future (program, strategy)

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Participation in the HMPWG

Assessors and regulatory experts from

National Agencies

Representative of European Commission

Representative of European Pharmacopoeia

Representative of EMEA

Representative of WHO

Observer

HMPWG – Rules and Roadmap

Rules of procedure:

Organisation of meetings

Communication amongst the participants

Contact and communication with interested parties

Transparency of work – publishing of documents

Roadmap – facilitate the process of mutual recognition

Current Topics – ongoing discussion

- Safety of homeopathic products from biological origin
- Non-clinical safety of homeopathic medicinal products
- General practice in the assessment
- European Pharmacopoeia requirements
- Different homeopathic traditions
- Quality issues

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Guidance Documents

Points to consider on safety of homeopathic medicinal products for human and veterinary use from biological origin.

March 2005 - available on the HMA Website

Points to consider on non –clinical safety of homeopathic medicinal products of botanical, mineral and chemical origin for human use

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Guidance Documents

Common dossier template

Draft Guidance on Module 3 – CTD

To be adopted on the next HMPWG meeting

Modul 1: Administrative part for homeopathic medicinal products for human use

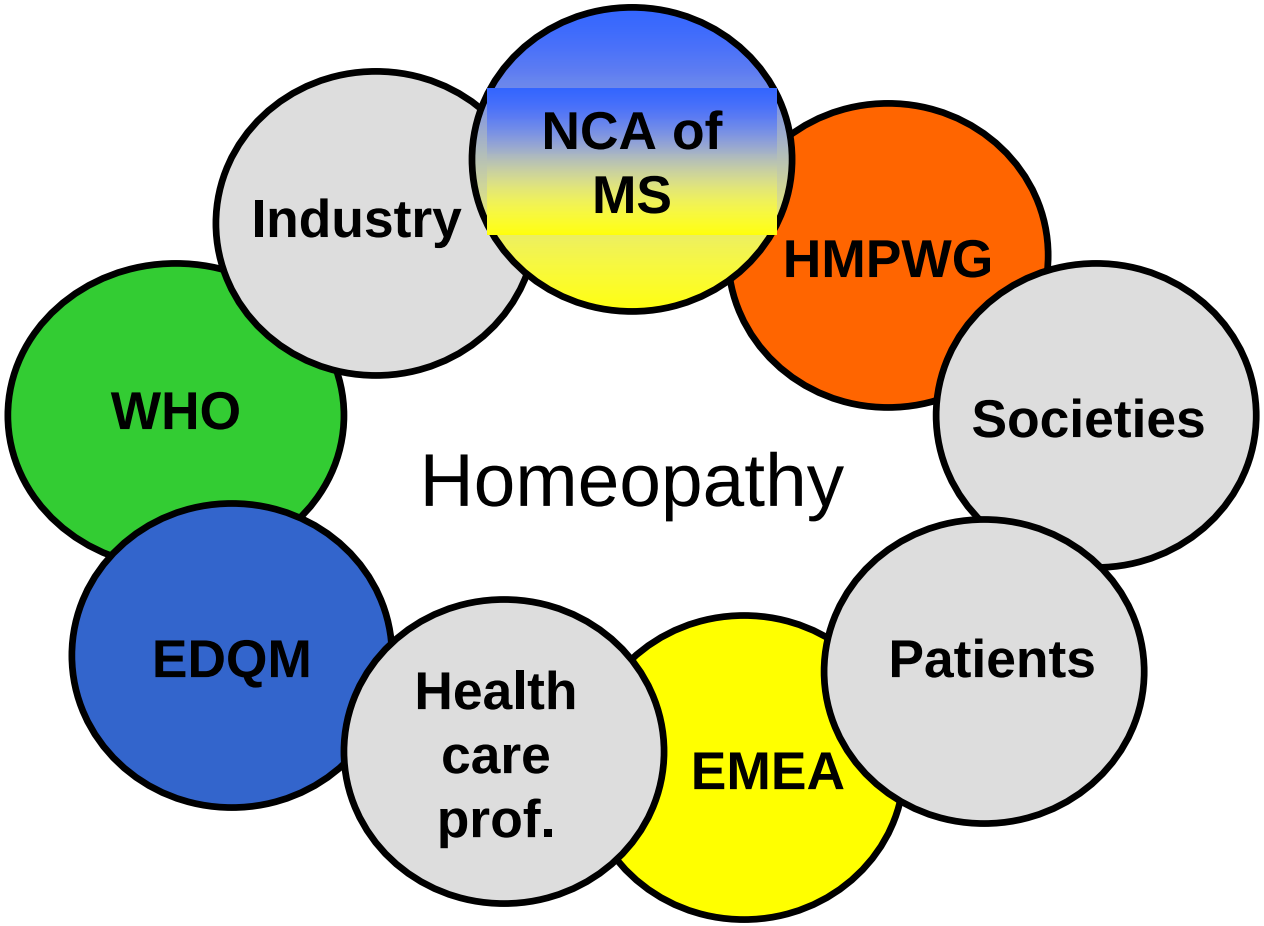
Published in NTA December 2005

Guidance: Nice to publish or binding (or at least urgently recommended consense) ?

Legislation on Homeopathic Medicinal Products

- National legislation for Homeopathic medicinal products before 1992
- 1992 Council Directive 92/73 EC
- Review of the EU pharmaceutical legislation
- Council Directive 2001/83/EC as amended by Directive 2004/27/EC

Network of organisations



National Competent Authorities

Application + Assessment → Decision

Requirements
Regulatory Framework

National Competent Authorities - **EU**

- RMS or CMS in the MRP/DCP
- Support of the HMPWG
- Organization of Meetings, sending Experts,
  supporting elaboration of guidance documents
- Addressing regulatory and scientific issues for further
  harmonization resulting from the assessment of
  dossiers concerning homeopathic products

HMPWG

- Forum for exchange
- Elaboration of Guidance Documents
- Provide expertise and advice on request on procedural, regulatory and scientfic issues arising from the MR- /DC-Procedure
- Provide Guidance for Applicants on the assessment of quality and safety

EDQM

General and specific homeopathic monographs

Monographs on substances „for homeopathic use

Implementation of homeopathic manufacturing methods into the European Pharmacopoeia

Quality assurance

WHO

Homeopathic medicinal products: European origin, meanwhile worldwide usage

Elaborating Guidelines on quality control for safety of traditional medicines (homeopathic products)

Exchange of information among the WHO Member States

Clarify definitions

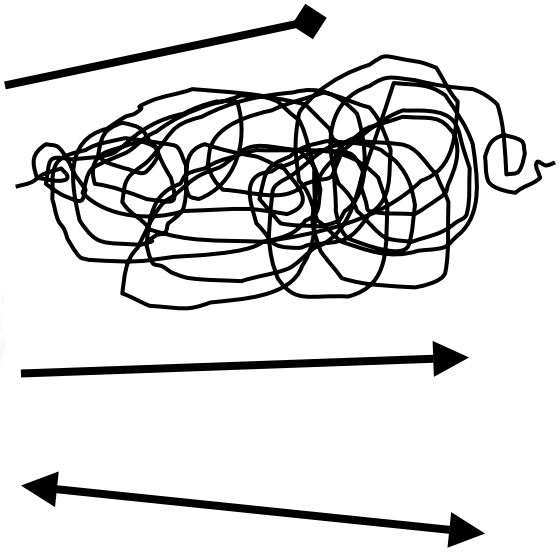
EMEA

- legislation
- support
- contact network
- communication
- ? ? ?

Harmonisation - tasks

- Scientific Assessment
- Common interpretation of requirements
- Non-clinical safety (safe dilution grade)
- Safety of material of biological origin
- Labelling /Nomenclature requirements
- Interpretation of regulatory issues arising from the MR-DCProcedure
- Technical issues

Routes to Harmonisation - possibilities



Road to nowhere

Labyrinth

One-way-ticket

Best practice (hopefully)

Routes to Harmonisation - suggestions

Exchange of Information between HMPWG European Commission, National Authorities, Interested Parties, Applicants, Manufacturers

HMPWG – Guidance

MRP/DCP Procedure (ASAP – tomorrow?)

Chances

Developing Homeopathy

Economical use of ressources

Integrating (different) traditions on the European level

Improving transparency

Creating a real European market

Problems

Final decisions have to be found within a short period during the MR-Procedure

Sufficient resources

Different Schools /Tradition

Defining the Homeopathic use

Integrating Anthroposophic Medicines

Outlook

Guidance is necessary

Harmonisation is necessary

Harmonised interpretation is necessary

Time is limited

European procedures should and will start in near future

Existing network platforms must be used

MS should be prepared to invest resources and to make compromises in establishing a European solution