

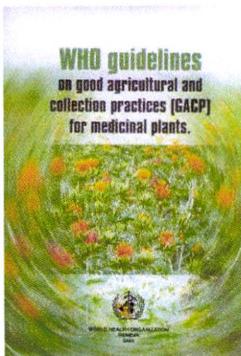
WHO Guidelines on Good Agricultural and Field Collection Practices (GACP) for Medicinal Plants

- Primarily intended to provide general technical guidance on obtaining herbal materials of good quality for the sustainable production of herbal medicines.
- Apply to the cultivation and collection of medicinal plants, including post-harvest operations.
- Raw medicinal plant materials should meet all applicable national and/or regional quality standards – thus may need to be adjusted according to each country's situation.

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WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants Objectives:



- Contribute to quality assurance of medicinal plant materials used as the source for herbal medicines, which aims to improve the quality, safety and efficacy of finished herbal products
- Guide the formulation of national and/or regional **GACP guidelines** and **GACP monographs** for specific medicinal plant, and **related standard operating procedures**
- Encourage and support the sustainable cultivation and collection of medicinal plants of good quality in ways that respect and support the **conservation of medicinal plants** and the environment in general

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WHO Guidelines on Good Agricultural and Field Collection Practices (GACP) for Medicinal Plants

Major expected outcomes in the implementation

- Development of national/regional general guidelines on GACP for medicinal plants
- Development of national/regional GACP monograph on selected medicinal plants
- Establishment of **national/regional quality standards and specification** of herbal materials
- Development of **national inventory of medicinal plants**

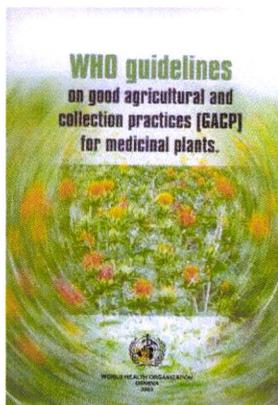
19



Major WHO documents on herbal medicines

Quality Assurance and Control

- **WHO Guidelines on Good Agricultural and Collection Practices (GACP) for medicinal plants** (2003) - available in A,C, E,F,R,S
 - Good Agricultural Practices of medicinal plants
 - Good Field Collection Practices of medicinal plants



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Conservation and sustainable use of medicinal plants

Promote sustainable use and cultivation of medicinal plants



- WHO guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants (2003)
- WHO model GACP monograph on *Artemisa Annu*a L. (2006)
- *Update of WHO/WWF/IUCN guidelines on conservation of medicinal plants – printed in 1993 – an inter-agency activity*

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Conservation and sustainable use of medicinal plants

- *International Consultation on Conservation of Medicinal Plants (Chiang Mai, Thailand, 1988)*



- Chiang Mai Declaration
"Save the plants that Save Lives"
- Proceedings of the Meeting
- WHO/WWF/IUCN guidelines on conservation of medicinal plants (1993)

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Resolution on traditional medicine and medicinal plants (WHA41.19, 1988)

- Referring to the "Chiang Mai Declaration"
- Endorsing the call for international cooperation and coordination to establish programmes for the conservation of medicinal plants, to ensure that adequate quantities are available for future generations
- Requested WHO
 - to promote the dissemination of knowledge and the exchange of experience on the subject;
 - to collaborate with Member States in the design and implementation of programmes for the conservation and sustainable utilization of medicinal plants



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Resolution on traditional medicine (WHA 56.31, 2003)

- Requested WHO to collaborate with other organizations of the United Nations system and nongovernmental organizations in various areas related to traditional medicine, including
 - research,
 - protection of traditional medical knowledge, and
 - conservation of medicinal plants resources



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Conservation and sustainable use of medicinal plants

Update of WHO/WWF/IUCN guidelines on conservation of medicinal plants (1993)



- *an inter-agency activity among WHO, WWF, IUCN and TRAFFIC*
- *Recognize the important guidance provided by the guidelines*
- *Needs for update in order to reflect the knowledge that has been gained through international framework and conventions, such as*
 - *United Nations Conference on Environment and Development (UNCED)*
 - *United Nations Convention on Biological Diversity (CBD)*

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Traditional Medicine in Primary Health Care



- WHO interregional workshop on the use of traditional medicine in primary health care (Ulaanbaatar, Mongolia, 23-26 August 2007)
- Benefit from using traditional medicines through self-care to meet primary health care needs
- Some communities have developed different forms of implementation:
 - using a "medikit" in Mongolia
 - "your medicine in your garden" booklets in south Asian countries
 - Haichi model in Japan
 - These experiences are significant in making health services accessible, available and affordable.
- Member States must be cautious about the quality, safety, and efficacy of traditional medicine therapies and products.

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Conservation and sustainable use of medicinal plants



- **Update of WHO/WWF/IUCN guidelines on conservation of medicinal plants – printed in 1993 – an inter-agency activity**

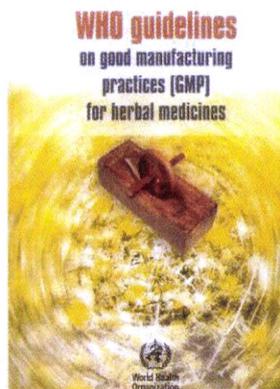
- *WHO consultation on conservation of medicinal plants*
- *WHO inter-regional workshop on the conservation and sustainable use of medicinal plants in primary health care*

27



Major WHO documents on herbal medicines

Quality Assurance and Control



- **WHO guidelines on Good Manufacturing Practices (GMP) for herbal medicines (2007)**
 - Good Manufacturing Practices: Main principle for pharmaceutical products (2003)
 - Good manufacturing practices: **Updated** supplementary guidelines for the manufacture of herbal medicinal products (2006)

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Coverage of processes by GACP and GMP



- **Cultivation and collection of medicinal plants, as the starting materials for herbal medicines**
- **Harvesting of medicinal plants**
- **Post harvest processing including primary cutting, in general**
- **The first critical step of production of herbal medicines where the application of GMP starts** should be clearly designated.
- This is of particular importance for those **products which consist solely of comminuted or powdered herbal materials**
- The rationale of this designation should be stated and documented.

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Major WHO documents on herbal medicines

Quality Assurance and Control

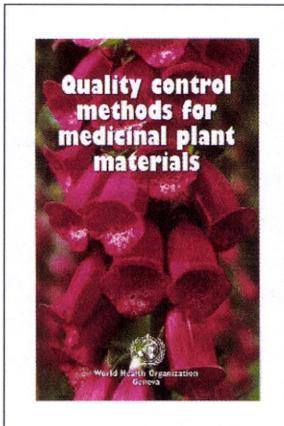
- **WHO guidelines on assessing quality of herbal medicines with reference to contaminants and residues (2007) - *being translated into F, S***
 - Present general consideration on potentially hazardous contaminants and residues in herbal medicines
 - include guiding principles of assessing quality of herbal medicines, in terms of major contaminants and residues.
 - recommends analytical methods for qualitative and quantitative determination of such contaminants and residues.



30



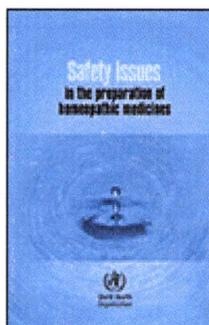
Update of the "Quality control methods for medicinal plant materials (1998)"



- **Quality control methods for herbal materials** (proposed title)
- Chapters: 16 - 22 updated texts
- Separate chapter on Aflatoxin
- "WHO good practices for pharmaceutical quality control laboratories" included as Annex
- Glossary added

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Safety issues in the preparation of homeopathic medicines (2010)

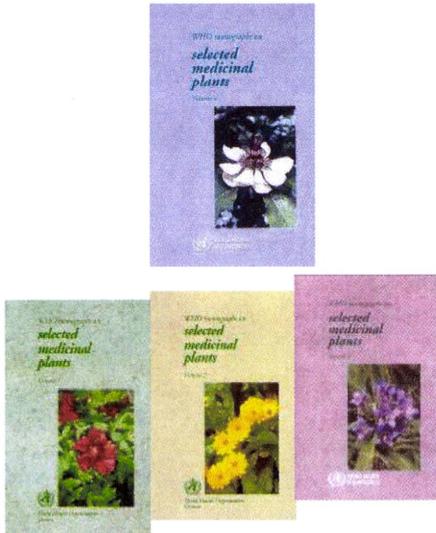


- WHO's response to requests and recommendations made by relevant World Health Assembly resolutions, by Member States, as well as international conferences of drug regulatory authorities, and is a part of the implementation of the WHO Traditional Medicine Strategy and the WHO Medicines Strategy.
- provides guidance to Member States on technical aspects of the production and manufacture of homeopathic medicines that potentially have implications for their safety.
- Is of relevance for establishing national quality standards and specifications for homeopathic medicines, as well as for controlling their quality.
- The document, however, does not address issues of efficacy or clinical utilization.

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Major WHO documents on medicinal plants

WHO monographs on selected medicinal plants, Volumes 1, 2, 3, 4

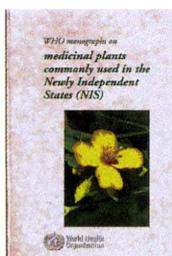


- Provides scientific information on the safety, efficacy and quality control of widely-used medicinal plants
- Provides models to assist Member States in developing their own monographs or formularies
- Facilitates information exchange

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WHO monographs on selected medicinal plants commonly used in the Newly Independent States (2010)



- includes 30 monographs
 - ✓ 17 monographs: most popularly/widely used medicinal plants adopted from the existing WHO monographs on selected medicinal plants
 - ✓ 13 new monographs: unique set of most commonly used medicinal plants developed using the same format employed for the WHO monographs on selected medicinal plants.
- available in two languages (English and Russian)
- intended to be used as a mutually recognized authoritative information source for national regulatory activities among participating countries.

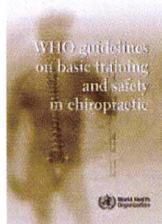
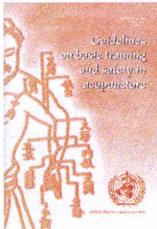
Participating countries (15):

Armenia, Azerbaijan, Belarus, Bulgaria, Georgia, Iran, Kazakhstan, Kyrgyzstan, Moldova, Romania, Tajikistan, Turkey, Turkmenistan, Ukraine, Uzbekistan

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Quality of Practice: Basic training guidelines and benchmarks



- Acupuncture (1999)
- Manual therapies
 - Chiropractic (2005)
 - Osteopathy (2010)
 - Tuina (2010)
 - Nuad Thai (2010)
- Therapies using herbal medicines
 - Traditional Chinese Medicine (2010)
 - Ayurveda (2010)
 - Unani Medicine (2010)
 - Naturopathy (2010)
- National capacity building by organizing a series of training workshops

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Quality and safety of herbal medicines

- *Guidelines for selecting substances for quality control of herbal medicines* (in preparation)
- *Good processing practices for herbal materials* (in preparation)
- *Guidelines on safety management of toxic medicinal plants and monograph on selected commonly used toxic medicinal plants* (in preparation)

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"The two systems of traditional and Western medicine need not clash. Within the context of primary health care, they can blend together in a beneficial harmony, using the best features of each system, and compensating for certain weaknesses in each. This is not something that will happen all by itself. Deliberate policy decisions have to be made. But it can be done successfully."

Dr Margaret Chan, Director-General, WHO

- opening address at the WHO congress on traditional medicine, Beijing, China, November 2008 -

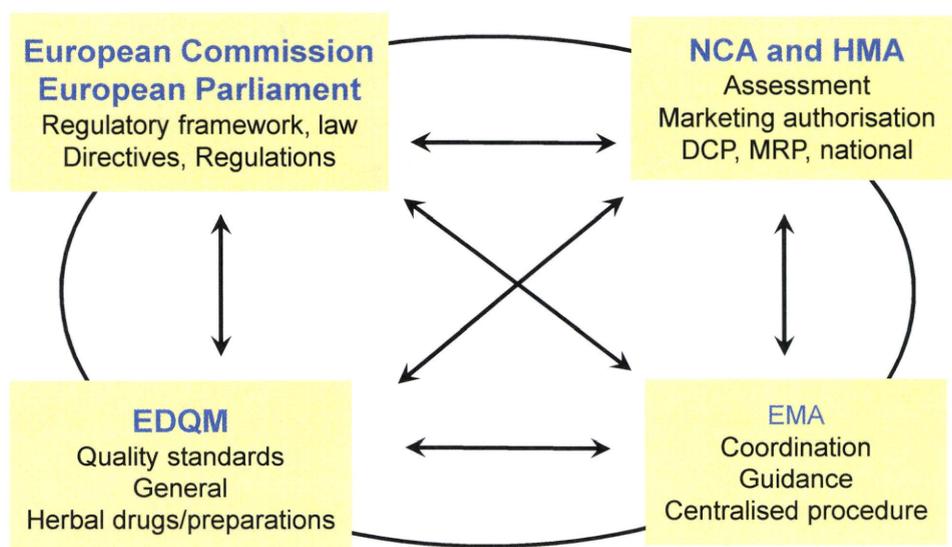


European Situation: Overview of Regulatory Framework of Herbal Medicines and GACP Implementation

PD Dr. Werner Knöss
BfArM

The BfArM is a Federal Institute within the portfolio of the Federal Ministry of Health

Herbals: The European Network



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Overview

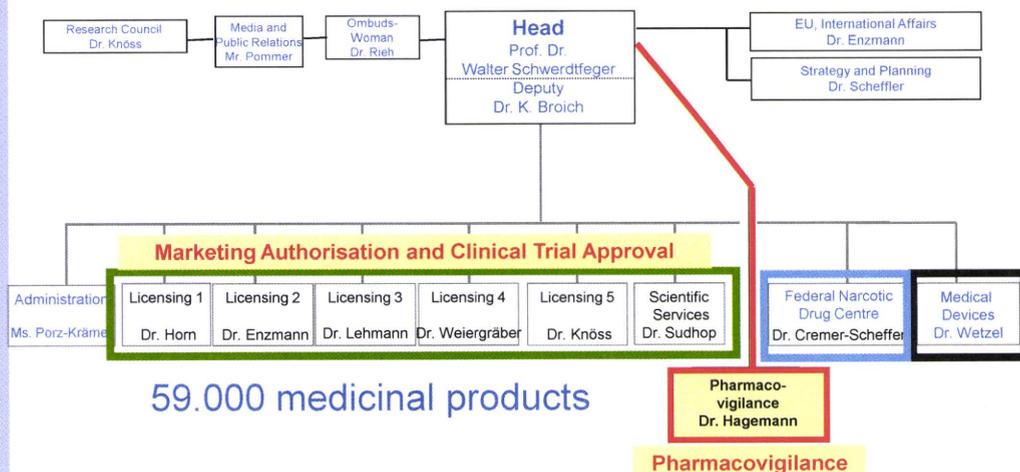
Short introduction to the situation in Germany

Basics of the European regulatory framework

Quality and implementation of GACP

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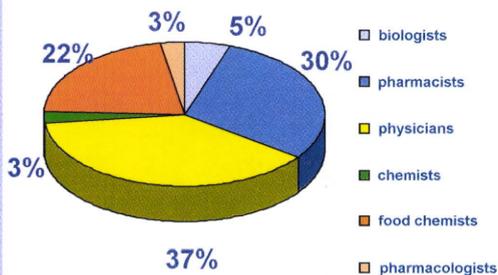
BfArM



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Licensing 5, BfArM
PD Dr. W. Knöss

Complementary and Alternative
Medicines
and Traditional Medicines
(55 staff members)



Unit 51
Procedural Management

D. Diller

Unit 52
Herbal and Traditional Medicinal
Products

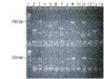
K. Reh

Unit 53
Homoeopathic and
Anthroposophic Medicinal
Products

C. Werner



Research
Medicinal Plants



Medicinal Products for Public Health

Quality
Efficacy
Safety

German Parliament:

- Pluralism of therapeutic options
- Consideration of particulars of CAM and tradition



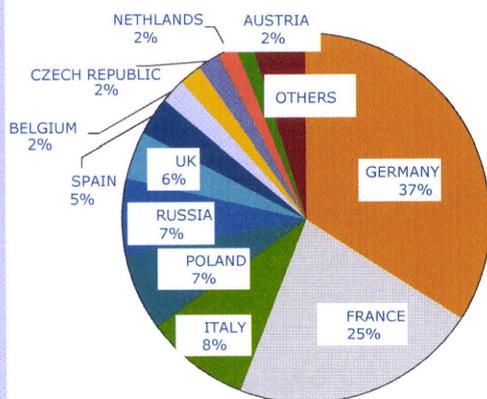
Medicinal Products

Chemically defined	Dose-dependent effect
Herbal	Dose-dependent effect
Traditional herbal	Plausible effect
Homoeopathic	Homeopathic principle
Anthroposophic	Anthroposophic principle
TCM	Mixed approach
Ayurvedic	Mixed approach
Kampo	... I am here to learn ...

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Market for Herbal Medicinal Products

Herbal Medicinal Products
In Europe, ~ 4 Bill. €



Source: IMS 2005

Germany (CAM and TM)

- longstanding tradition
- department at BfArM with 55 staff members
- about 700 pharmaceutical companies
- about 10,000 medicinal products marketed
- about 2300 (traditional) herbal medicinal products

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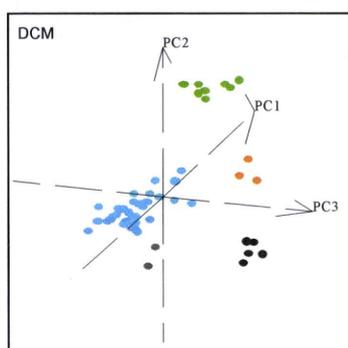
Basic Figures – CAM and Traditional Medicines in Germany

Regulation since 1976 – Medicinal Products Act

- 2300 herbal medicinal products (23% combinations)
1800 licensed herbal medicinal products (15%)
500 licensed trad. herbal medicinal products (49%)
40 registered trad. herbal medicinal products (40%)
- 1350 licensed homeopathic medicinal products (86%)
- 1050 licensed anthroposophic medicinal products (62%)
- 3900 registered homeopathic and anthroposophic (48%)
medicinal products

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Research: Medicinal Plants



- *Matricaria recutita*
- *Chamaemelum nobile*
- *Anthemis cotula*
- *Tripleurospermum perforatum*
- *Matricaria discoidea*

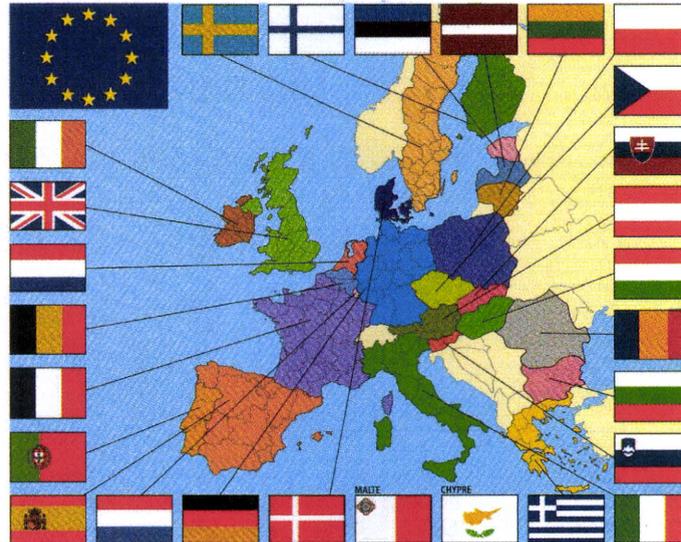
NMR
PCA

PCR and sequencing



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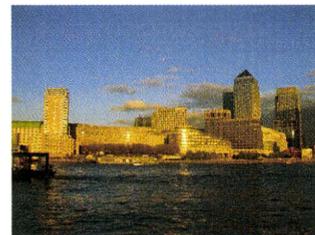
European Regulation



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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)



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European Community Directives

Implementation into national laws

- **CD 2001/83** (“**basic**” **regulation**) amended by
- CD 2003/63 (Annex I, **CTD criteria**)
- CD 2004/24 (**Traditional herbal medicinal products**)
- CD 2004/27 (**Review**)

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 Herbal Medicinal Products

Any medicinal product **exclusively** containing as active ingredients

one or more **herbal substances** or

one or more **herbal preparations**, or

one or more such herbal substances in combination with one or more such herbal preparations.

Herbal Substances

All mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried, form, but sometimes fresh.

Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances.

Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author).

(Article 1 No. 31 of Directive 2001/83 EC of the European Parliament and of the Council of 6 November 2001 amended by Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004)

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)).

Traditional Herbal Medicinal Products

Inclusion Criteria (Article 16a)

- **Indication(s) appropriate** to traditional herbal medicinal products,
- use **without the supervision** of a medical practitioner for diagnosis, prescription or monitoring of treatment,
- specified **strength / posology**,
- only **oral use, external use and inhalation**,
- **sufficient data** on traditional use of the product (... safety),
- **pharmacological effects / efficacy plausible** on the basis of long-standing use and experience.