



Europäische Arzneimittel-Agentur,  
London

**Pflanzliche Arzneimittel in der EU**  
Neue Chancen für pflanzliche Arzneimittel

Konstantin Keller  
Bundesministerium für Gesundheit, Bonn  
Vorsitzender des Ausschusses für Pflanzliche Arzneimittel der EU



Bundesinstitut  
für Arzneimittel



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**Die Pflanzenheilkunde in der ärztlichen Praxis**

DIE PFLANZENHEILKUNDE  
IN DER  
ÄRZTLICHEN PRAXIS

Verlesungen  
an der Berliner Akademie für ärztliche Fortbildung

VON  
DR. MED. R. FRITZ WEISS  
BERLIN



Hippokrates-Verlag, Marguardt & Cie., Stuttgart-B.

R. Fritz Weiss

„Die Pflanzenheilkunde steht heute an einem bedeutsamen Wendepunkt. Sie kämpft darum, eine Wissenschaft zu sein, und mehr noch: ein eigener Wissenschaftszweig mit einem besonderen und wichtigen Aufgabengebiet.“

„Es gilt zu zeigen, dass die Pflanzenheilkunde an wissenschaftlicher Gründlichkeit und praktischer Brauchbarkeit in nichts hinter anderen Teilgebieten der Medizin zurücksteht.“

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**European Union Legislation**

**Regulation (EC) No 726/2004**  
of the European Parliament and of the Council of  
31 March 2004

laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

New EU Committee on Herbal Medicinal Products

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EMA Committee on Herbal Medicinal Products

Chair / Vice-Chair: Dr. Konstantin Keller/ Dr. Heribert Pittner AU

Austria	France	Lithuania	Slovenia
Estonia	Germany	Luxembourg	Spain
Belgium	Greece	Malta	Sweden
Cyprus	Hungary	Netherlands	United Kingdom
Czech Rep.	Ireland	Poland	
Denmark	Italy	Portugal	
Finland	Latvia	Slovak Republic	

4 co-opted Members:

Clinical Pharmacology, Pharmacology, Toxicology, Pediatrics

EEA Members:  
Norway, Iceland

Observer: EDQM/Europ. Pharm.  
Romania, Bulgaria,  
Croatia, Turkey

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Offering scientific support and advice

EMA

Regulation 726/2004 EC of 31 March 2004

TITLE IV, Article 57

The Agency through its committees shall

- j) upon request provide technical and scientific support to the Community, Member States, international organizations and third countries ...
- n) advise undertakings on the conduct of the various tests and trials in quality, safety, efficacy

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Co-operation with external partners

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Regulation 726/2004 EC of 31 March 2004

TITLE IV  
Article 78 (2)

The committees and any working party shall in general matters establish contacts, on advisory basis, with parties concerned ... in particular with patient organizations and health care professional organizations ...

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### Co-operation with external partners

- Invitation to EU organizations to express their willingness to be regarded as an interested party to the HMPC (November 2004);
- Preparation of *alist of 18 parties* with an interest at European level in (traditional) herbal medicinal products, with whom to establish contacts;
- Public hearing with 14 attending parties from industry, health professionals, patients' organisations
- Hearing with AESGP and ESCOP on support for monographs
- Co-operation with patients' and consumers' organizations
- Co-operation with health professionals' organizations

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### Facilitating access to the market

#### Directive 2001/83/EC

The Committee for Herbal Medicinal Products will prepare:

Article 16f

A list of traditional herbal drugs/-preparations/combinations

Article 16h

Community herbal monographs on herbal drugs or herbal drug preparations that may be used for full marketing authorisations of well-established herbal medicinal products or simplified registrations

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### Community Herbal Monographs / List Status of assessment work



European Medicines Agency  
Post-authorisation Evaluation of Medicines for Human Use

London, 26 September 2006  
Doc. Ref. EMEA/HMPC/278067/2006

#### COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

Overview of status of HMPC assessment work  
SEPTEMBER 2006

*The list is subject to changes following HMPC decisions*

*Listed in alphabetical order*

**R:** Rapporteur assigned, **D:** Draft under discussion, **P:** Draft published,  
**PE:** Assessment close to finalisation (pre-final), **E:** Final opinion adopted

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**Richtlinie 2004/24/EG**  
zur Änderung der RL 2001/83 EG  
vom 31.03.2004

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Das ... Gemeinschaftsrecht stellt einen wichtigen Schritt zur Verwirklichung des *freien und sicheren Verkehrs mit Humanarzneimitteln und des Abbaus von Hemmnissen beim Handel* mit diesen Arzneimitteln dar.

Alle Vorschriften ... sollten *in erster Linie dem Schutz der öffentlichen Gesundheit* dienen. Dieses Ziel sollte jedoch mit Mitteln erreicht werden, die die Entwicklung der pharmazeutischen Industrie und den *Handel mit Arzneimitteln innerhalb der Gemeinschaft nicht hemmen*.

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**Deutscher Bundestag**  
Ausschussbericht vom 28.04.1976  
BT-Drucksache 7/5091

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„ ... von der Tatsache ausgegangen, dass auf dem Gebiet der Arzneimitteltherapie mehrere Therapierichtungen nebeneinander bestehen, die von unterschiedlichen theoretischen Denkansätzen und wissenschaftlichen Methoden ausgehen ...“

„ ...politische Zielsetzung, ... dass sich im Zulassungsbereich der in der Arzneimitteltherapie vorhandene Wissenschaftspluralismus deutlich widerspiegeln muss.“

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**Arzneimittel der Besonderen  
Therapierichtungen in Deutschland**  
Bewertungsstand AMG 1976

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8432 Arzneimittel der Besonderen Therapierichtungen wurden mit positivem Ergebnis gem. AMG 1976 geprüft

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4585 Arzneimittel der Besonderen Therapierichtungen sind zugelassen oder nachgelassen, davon  
1998 fixe Kombinationen (44 %)

3847 homöopathische Arzneimittel sind registriert oder nachregistriert

BfArM vom 15.05.2006

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**Pflanzliche Arzneimittel in Deutschland  
Bewertungsstand AMG 1976**

pflanzliche Arzneimittel

2460 mit positivem Ergebnis gem. AMG 1976 geprüft

	Zulassung	Nachzulassung	Summe
Monopräparate	875	1081	1956
Kombinationen	67	437	504

ca. 40 Zulassungsanträge für Phytopharmaka in Bearbeitung

Zahl der Phytopharmaka mit Standardzulassung ist nicht ermittelbar  
(> 10 000 Tees / Teemischungen)

BIArM vom 15.05.2006

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**European Council Directive 2001/83/EC**  
of 06 November 2001

*Article 6*

Marketing authorization

1. No medicinal product\* may be placed on the market of a Member State unless a marketing authorization has been issued by the competent authorities ...

\* applies to industrially produced medicinal products (Art. 2); products prepared following a medical prescription (magistral formula), products prepared in accordance with a pharmacopoeia and supplied directly to the patient, intermediate products intended for further processing are excluded from the scope by Art. 3

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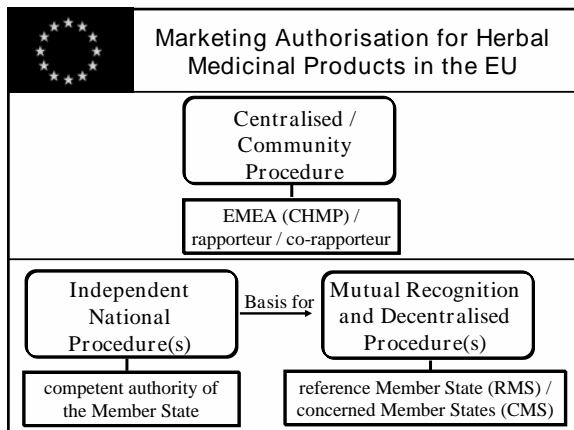
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Herbal Medicinal Products in the EU  
Access to the market

Marketing Authorization

1. Full documentation with new tests and trials
2. Full bibliographic documentation (well-established use)
3. Mixed Applications

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Herbal medicinal products in the EU  
Marketing Authorization (bibliographic)

2001/83/EC as amended by CD 2004/27/EC  
Article 10a

...  
By way of derogation from Article 8(3)(i), ... the applicant shall not be required to provide the results of pre-clinical tests or clinical trials if he can demonstrate that the active substances of the medicinal product have been in well-established medicinal use within the Community for at least ten years, with recognized efficacy and an acceptable level of safety in terms of the conditions set out in the Annex.

In that event, the test and trial results shall be replaced by appropriate scientific literature.

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What types of evidence may be used?

Annex 1 to CD 2001/83 EC  
amended by CD 2003/63 of 25 June 2003

... The documentation ... should cover all aspects of the safety and/or efficacy assessment and must *include or refer to a review of the relevant literature, taking into account pre- and post-marketing studies and published scientific literature concerning experience in the form of epidemiological studies and in particular of comparative epidemiological studies.* ... With respect to the provisions on "well-established medicinal use" it is in particular necessary to clarify that "bibliographic reference" to *other sources of evidence (postmarketing studies, epidemiological studies, etc.) and not just data related to tests and trials may serve as a valid proof of safety and efficacy* of a product if an application explains and justifies the use of these sources of information satisfactorily. ...

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Herbal medicinal products in the EU  
Access to the market

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New option for access to the market:  
Directive 2001/83 EC, Chapter 2a, Articles 16 a – 16 i

Registration

4. “Simplified dossier” for *traditional herbal* medicinal products

National procedure with limited access to mutual recognition procedure (monograph or list from the HMPC required)

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The new simplified registration procedure

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Preference to full marketing authorisation, if possible  
CD 2004/24 EC

Whereas...

(4) ... it is desirable to provide a special, simplified registration procedure for certain traditional medicinal products. However, this simplified procedure should be used *only where no marketing authorisation can be obtained* pursuant to Directive 2001/83/EC, in particular *because of a lack of sufficient scientific literature* demonstrating a well-established medicinal use with recognised efficacy and an acceptable level of safety. It should likewise not apply to homeopathic medicinal products eligible for marketing authorisation or for registration under Directive 2001/83/EC.

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The new simplified registration procedure

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Registration of traditional herbal medicinal products applicable to *traditional* herbal medicinal products

Article 16c 1 (c)

medicinal use within the EU throughout > 30 years

or

> 15 years in and > 15 years outside the EU

Deviations may be decided by the Herbal Committee if requested by a Member State

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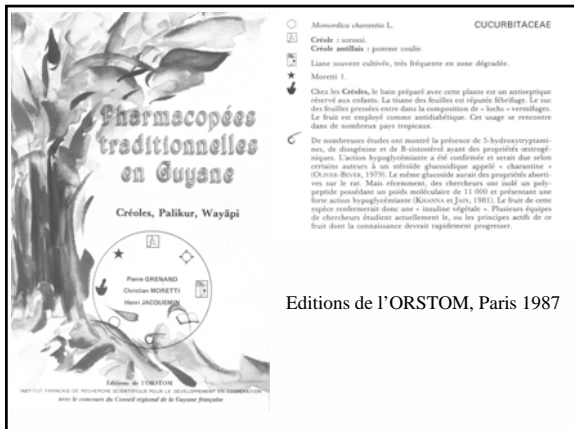
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## Decisions with direct regulatory impact

Directive 2004/24/EC of 31 March 2004

The Committee for Herbal Medicinal Products shall

- at the request of a MS draw up an opinion on the adequacy of the evidence of the long-standing use
- after referral of a MS draw up a Community Herbal Monograph on traditional herbal products used < 15 years within the Community



Editions de l'ORSTOM, Paris 1987

The new simplified registration procedure

Details relating to the period of traditional use

Article 16 c

(2) A corresponding product, as referred to in paragraph 1(c), is characterised by having the same active ingredients, irrespective of the excipients used, the same or similar intended purpose, equivalent strength and posology and the same or similar route of administration as the medicinal product applied for.

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The new simplified registration procedure

Details relating to the period of traditional use

Article 16 c

(3) The requirement to show medicinal use throughout the period of 30 years, referred to in paragraph 1(c), is satisfied even where the marketing of the product has not been based on a specific authorisation. It is likewise satisfied if the number or quantity of ingredients of the medicinal product has been reduced during that period.

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Legal clarification of terms

Article 1 of Directive 2001/83 EC  
as amended by 2004/24/EC

- 30. Herbal medicinal product:  
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.
- 31. Herbal substances:  
... 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.

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### Legal clarification of terms

Article 1 of Directive 2001/83 EC  
as amended by 2004/24/EC

32. Herbal preparation:  
preparations obtained by subjecting herbal substances to  
treatments such as extraction, distillation, expression,  
fractionation, purification, concentration or fermentation.  
These include comminuted or powdered herbal substances,  
tinctures, extracts, essential oils, expressed juices and  
processed exudates.

*Isolated, chemically defined constituents of medicinal herbs such  
as Menthol, Eugenol, Digitoxin etc. are not "herbal  
preparations"!*

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### The new simplified registration procedure

Vitamins and minerals may be added if their action is  
ancillary to the herbal constituent(s)

Article 16 a (2)

2. Notwithstanding Article 1(30), the presence in the herbal  
medicinal product of vitamins or minerals for the safety of which  
there is well-documented evidence shall not prevent the product  
from being eligible for registration in accordance with paragraph 1,  
provided that *the action of the vitamins or minerals is ancillary to  
that of the herbal active ingredients regarding the specified claimed  
indication(s).*

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### The new simplified registration procedure

Examples of traditional medicinal *products that do not have access*  
to the simplified registration because they are *not* traditional *herbal*  
medicinal products:

- products containing as active ingredients chemical  
substances, (however, the presence of Vitamins and Minerals  
with ancillary action is allowed for traditional herbal  
combinations)
- pure / isolated plant constituents such as menthol, eucalyptol,
- amino acids,
- constituents from animal origin, including honey, propolis ...

For such medicinal products, a  
marketing authorisation is mandatory

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The new simplified registration procedure

*Future development*

CD 2004/24/EC

*Article 16 i*

Before 30 April 2007, the Commission shall submit a report to the European Parliament and to the Council ...

The report shall include an assessment on the possible extension of traditional-use registration to other categories of medicinal products.

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The new simplified registration procedure

Article 16c

Dossier requirements

- Administrative and Pharmaceutical dossier identical to "full" marketing authorisation
- Bibliographical or expert evidence on traditional use of the product or a corresponding product
- Expert report on safety  
all safety-studies that are necessary may be requested by the Agency

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The new simplified registration procedure

Acceptance 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.

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## HMPC statement on “external preparation”

### Definition of “external preparation”

Public Statement on the Interpretation of the term "External Use" for use in the field of traditional Herbal Medicinal Products (adopted January 2006) (EMEA/HMPC/31897/06)

*“For the purpose of traditional use registration, the term ‘external use’ shall be interpreted as ‘application to the skin’; however if the traditional use of a herbal substance, preparation or medicinal product refers to the delivery to the oral, nasal, rectal, vaginal mucosae or to ocular or auricular use, such use may be acceptable if no safety concerns exist and if local action is intended.”*

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## The new simplified registration procedure

### Acceptance Criteria (Article 16a)

- sufficient data on traditional use of the product
- in particular to prove safety
- pharmacological effects / efficacy plausible on the basis of long-standing use and experience

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## The new simplified registration procedure

### Implementation

First registration granted by BfArM on 13 December 2005



Klosterfrau Melisengeist: Flüssigkeit; M.C.M.Klosterfrau Vertriebs-GmbH	
Eintragungsnr.	Z164514
Arzneimittelname	Klosterfrau Melisengeist
Darreichungsform	Flüssigkeit
Anmelder	3031430: M.C.M.Klosterfrau Vertriebs-GmbH
Zustandigkeit	BfArM
Sitzort	Registrierung homöopathischer Arzneimittel nach Par. 36 / 39 AMG und Registrierung traditioneller Arzneimittel nach Par. 35b / 35c AMG
Beschreibungsdatum der Zulassung	13.12.2005
PSZ-Code zum Zulassung	13.12.2005
letzte Bescheidart	POSTIV - Dem Antrag/Untertrag wurde zugestimmt
Verfallsdatum	
Zulassungs-Reg.Nr. (AMG76)	2005A.0010
letzte Bescheiddatum	13.12.2005
letzte PSZ-Code zum	13.12.2005
Zulassung	
Pharmaziecode	
Anzahl Wirkstoffe	13

Fixed combination of 13 active substances

Database AJ29 (26 January 2006): WWW.DIMDI.DE

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### The role of EU herbal monographs

#### Article 16 h (3)

#### Community herbal monographs

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....

When Community herbal *monographs within the meaning of this paragraph* have been established, they shall be taken into account by the *Member States* when examining an application. ....

When new Community herbal monographs are established, the *registration holder* shall consider whether it is necessary to modify the registration dossier accordingly. The *registration holder* shall notify any such modification to the competent authority of the *Member State* concerned.

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### The role of the EU list

#### Article 16 f

2. If an application for traditional-use registration relates to a herbal substance, preparation or a combination thereof contained in the list referred to in paragraph 1, the data specified in Article 16c(1)(b)(c) and (d) do not need to be provided. Article 16e(1)(c) and (d) shall not apply.

3. If a herbal substance, preparation or a combination thereof ceases to be included in the list referred to in paragraph 1, registrations pursuant to paragraph 2 for herbal medicinal products containing this substance shall be revoked unless the particulars and documents referred to in Article 16c(1) are submitted within three months.

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### The new simplified registration procedure

#### Labelling / Package leaflet (Article 16g)

*includes a statement that*

the product is a traditional herbal medicinal product for use in specified indications *exclusively based upon long-standing use* and

the user should consult a doctor or qualified health care practitioner if the symptoms persist during the use of the product or if adverse effects not mentioned in the package leaflet occur

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**EU requirements related to  
quality of herbal medicinal products**

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Pharmaceutical Development and Quality Control

- All guidelines apply to herbal medicinal products
- The legislation does not allow a “second class quality” for registered herbal medicinal products

Criteria established by:

1. European Pharmacopoeia
2. European Medicines Evaluation Agency, EMEA

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**Safety / Efficacy**

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Guideline on *non-clinical documentation* for herbal medicinal products in applications for marketing authorisation (bibliographical and mixed applications) and in applications for simplified registration (adopted September 2006) EMEA/HMPC/32116/05

Guideline on the assessment of *clinical safety and efficacy* in the preparation of monographs for well-established and of monographs/lists for traditional herbal medicinal products/substances/preparations (adopted September 2006) EMEA/HMPC/104613/05

Guideline on the *clinical assessment of fixed combinations* of Herbal Substances / Herbal Preparations (adopted January 2006) EMEA/HMPC/166326/05

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**Guideline on the non-clinical documentation**

September 2006

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In general, the documented *experience in human use* will be the *main basis* of the non-clinical assessment of traditional and well-established herbal medicinal products.

- old studies (non-GLP) should be judged for credibility
- new investigations if a safety concern is recognised or suspected
- *the lack of some specific studies may also pose a safety concern*
- the potential for pharmacokinetic interactions between the herbal substance / preparation and other medicinal products should be clarified

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## Guideline on the non-clinical documentation

September 2006

The *genotoxic potential of herbal preparations should be assessed.*

When an adequate assessment cannot be made, further genotoxicity testing is required.

first *in vitro* tests

negative results *in vitro*

→ negative results *in vivo* expected

positive results *in vitro*

→ are to be clarified by appropriate (*in vivo*) investigations

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## Herbal medicinal products in the EU

How to assess efficacy ?



The Life of a British Sailor saved by Morrison's Pill Box 1834/1835

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 lists for traditional herbal medicinal products / substances / preparations

September 2006

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EMA Committee on Herbal Medicinal Products

Assessment of clinical safety and efficacy

Guidance on monographs for well-established products

- Documented, systematic review of literature including searches in databases
- all aspects related to clinical safety and efficacy must be addressed by literature
- all types of bibliographic data and studies may be used;
- In general, at least one controlled clinical study (clinical trial, post-marketing study, epidemiological study) of good quality is required
- Other studies may be acceptable in a case-by-case assessment, taking into account the type of data, the indication and the risks of the product

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### Therapeutische Wirksamkeit

BVerwG vom 14.10.1993, Az. 3 C 46.91

BVerwG vom 14.10.1993, Az. 3 C 21.91

Der Begriff meint die Ursächlichkeit der Anwendung des Arzneimittels für den Heilungserfolg. Erst wenn die Anwendung des Arzneimittels zu einer größeren Zahl an therapeutischen Erfolgen führt als seine Nichtanwendung, ist der Schluss gerechtfertigt. Maßstab bei bekannten und unbekanntem Stoffen gleich. Ein PU mag die Erleichterung in § 22 Absatz 3 AMG nicht nutzen können, weil sich die Wirksamkeit aus dem anderen Erkenntnismaterial nicht herleiten lässt, sodass er gezwungen ist, eine klinische Prüfung durchzuführen. Auch auf die Zulassung eines Naturheilmittels findet die Regelung uneingeschränkt Anwendung.

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### EMA Committee on Herbal Medicinal Products

#### Guidance on monographs/lists for traditional products

5 pivotal pieces of information:

- time in medicinal use (>30 years, >15 years within the EU)
- therapeutic indication (must be appropriate and plausible)
- strength / type of preparation
- posology
- information on safe use (no medical supervision for diagnosis, prescription, monitoring necessary) and evidence on safety

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### Guideline on the clinical assessment of fixed combinations of herbal substances / preparations

The rationale of the combination must be given:

- The function of each constituent of the herbal medicinal product must be clarified, taking into account the indication of the combination, the profile of the active substance and its dosage / concentration.
- It must be clarified if a constituent of the fixed combination has to be considered as an active substance or as an excipient, e.g. to improve the taste or to influence physical properties of the product.

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## Guideline on the clinical assessment of fixed combinations of herbal substances / preparations

The rationale of the combination must be given:

- Well-established fixed combination products will only be considered acceptable if the proposed combination is based on valid therapeutic principles.
- Traditional fixed combination products must be plausible within the relevant system of traditional medicine. The requirements relating to efficacy will be reduced to the level of plausibility, whereas considerations related to safety will become more critical in an overall benefit/risk-assessment, because scientific evidence on efficacy is not available for traditional herbal medicinal products.

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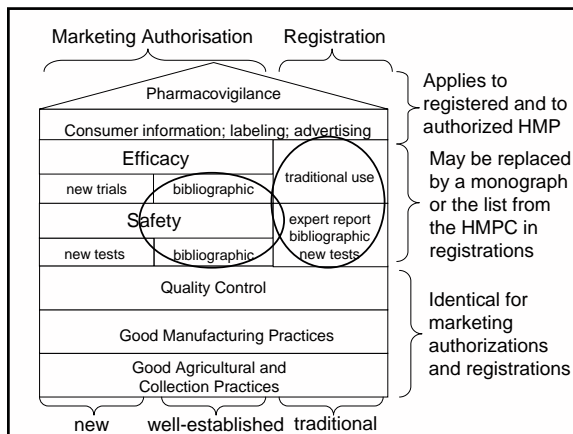
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The Life of a British Sailor saved by Morrison's Pill Box 1834/1835

### Nutzen / Risiko-Abwägung bei unklarem Nutzen?



Singular effects of the universal vegetable pills in a green grocer, 1834/1835

"...vegetable pills have taken root in my nose. It was reddish before but now it is carotty" Morrison's universal vegetable pills, 1834/1834

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## Die Pflanzenheilkunde in der ärztlichen Praxis

R. Fritz Weiss

1. Auflage 1944

“Zu meiner Bestürzung und Enttäuschung musste ich sehen, wie diese modern gewordene Art der Beschäftigung mit heimischen Heilpflanzen zunehmend auf Abwege geriet ... Aus alten Kräuterbüchern, aus dem Schrifttum aller Jahrhunderte wurde herausgesucht, was irgendwo und irgendwann einmal empfohlen wurde. ... Man kümmerte sich nicht mehr darum, was die Behandlung ... überhaupt zu leisten vermag und wie der unbeeinflusste Verlauf zu sein pflegt. Auf diese Weise geriet die ganze Pflanzenheilkunde in Gefahr, auf Abwege und in Misskredit zu kommen und in die Breite zu verflattern, statt in die Tiefe zu gehen.“

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### *Perspektiven*

Im europäischen Bereich ist eine Konsolidierung der fachlichen und gesetzlichen Vorgaben eingetreten.

Pflanzliche Arzneimittel sind in der EU Gesetzgebung klar angesprochen.

Es bilden sich auf regulatorischer Ebene klarere Zuständigkeiten und Kompetenzzentren heraus, die europäische Zulassung und Registrierung wird erleichtert.

Breiteres Angebot von europäischen und nicht-europ. Herstellern.

Globalisierung der technischen Anforderungen, z.Bsp. ICH

Der Spielraum für rein nationale Lösungen ist gering, europäische Entscheidungen werden auf den nationalen Markt einwirken.

Die europäischen Gremien sind auf Kooperation mit europäischen wissenschaftlichen Fachgesellschaften angewiesen.

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### *Perspektiven*

Phytopharmaka stehen, auch nach Abschluss der Nachzulassung, in großer Zahl zur Verfügung.

Zugelassene und regulär nachzugelassene Phytopharmaka entsprechen den EU-Kriterien zur Qualität, Sicherheit und, soweit Indikationen angegeben sind, Wirksamkeit.

Eine große Zahl von Arzneimitteln ist in Deutschland auf Grund von De-Regulierungsmechanismen (Standardzulassung) ohne individuelle Prüfung verkehrsfähig.

Die Grenzziehung zwischen traditionellen und zulassungsfähigen Phytopharmaka und die Festlegung der wissenschaftlichen Kriterien zu Qualität, Wirksamkeit und Unbedenklichkeit werden zunehmend im Ausschuss für pflanzliche Arzneimittel der EMEA erfolgen.

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