



BIONORICA

The **phytoneering** company

DRA-Workshop – GA Congress



Importance of HMPC Community Monographs and Community List Entries for the MA and Registration of HMPs in Europe

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HMPC MONOGRAPHS

Acceptance of the procedure within the MS



Member State	Applications	Under assessment	Finalised	
			Positive	Negative
Austria (AT)	6	3	1	-
Belgium (BE)	5	5	-	-
Cyprus (CY)	None	-	-	-
Czech Republic (CZ)	1 ¹	1 (under validation)	-	-
Denmark (DK)	2	2	-	-
Germany (DE)	27	13	4	6 (+4 (withdrawals))
Estonia (EE)	None	-	-	-
Spain (ES)	6 Implementation imminent	6	-	-
Finland (FI)	1	1	-	-
France (FR)	Dir partially implemented	4	-	-
Greece (GR)	12	12	-	-
Hungary (HU)	None	-	-	-
Ireland (IE)	Dir not implemented	X	X	X
Iceland (IS)	Dir not implemented	X	X	X
Italy (IT)	4	4 (under validation)	-	-
Lithuania (LT)	4	4	-	-
Luxembourg (LU)	None	-	-	-
Latvia (LV)	1	1	-	-
Malta (MT)	None	-	-	-
Netherlands (NL)	2		2	-
Norway (NO)	Dir not implemented	-	-	-
Poland (PL)	2 (under validation)	X	X	X
Portugal (PT)	None	-	-	-
Sweden (SE)	7	7	-	-
Slovenia (SI)	3	1	2	-
Slovakia (SK)	1	1	-	-
United Kingdom (UK)	26	22	4	-
Croatia (HR) ⁺	Dir not implemented	X	X	X
Romania (RO)	None	-	-	-
Bulgaria (BG)	None	-	-	-

STATUS

13 approvals
6 rejections
65 pending procedures

⇒ Procedure is getting in progress

Source:

<http://www.emea.europa.eu/pdfs/human/hmpc/statusreports/14850507en.pdf>

HMPC Monographs



Member States	2005-2007	
	R	[Co-R]
Austria (AT)	5	-
Belgium (BE)	4	-
Bulgaria (BG)	-	-
Cyprus (CY)	-	-
Czech Republic (CZ)	1	-
Denmark (DK)	1	-
Estonia (EE)	1	-
Finland (FI)	-	-
France (FR)	2	-
Germany (DE)	16	-
Greece (EL)	1	-
Hungary (HU)	3	-
Ireland (IE)	2	-
Italy (IT)	4	-
Latvia (LV)	1	-
Lithuania (LT)	-	-
Luxembourg (LU)	-	-
Malta (MT)	-	-
The Netherlands (NL)	2	-
Poland (PL)	1	-
Portugal (PT)	3	-
Romania (RO)	-	-
Slovakia (SK)	-	-
Slovenia (SI)	4	-
Spain (ES)	3	-
Sweden (SE)	3	-
United Kingdom (UK)	1	-
Iceland (IS)	1	-
Norway (NO)	4	-
G. Laekeman*	-	1
O. Pelkonen*	-	1
K. Widhalm*	-	-
U. Wissinger-Gräfenhahn*	1	1
Total	64	[3]

Sharing of the workload?

encouragement by
DE, AT, BE, SI, IT, HU, NO

Drawing up monographs does
facilitate to structure unregulated
markets

Why are MS with relevant
markets for HMPs seem to
have minor interest to take
part in this work?

Source:

<http://www.emea.europa.eu/pdfs/human/hmpc/statusreports/36928807en.pdf>

HMPC Monographs adopted W = WEU / T = traditionally used



<u>Aloe</u> <i>Aloe barbadensis</i> Miller; Aloe (mainly <i>Aloe ferox</i> Miller and its hybrids) (barbados aloes; cape aloes)	W
<u>Anisi fructus</u> <i>Pimpinella anisum</i> L. (aniseed)	T
<u>Anisi aetheroleum</u> <i>Pimpinella anisum</i> L. (anise oil)	T
<u>Foeniculi amari fructus</u> <i>Foeniculum vulgare</i> Miller subsp. v	T
<u>Foeniculi amari fructus aetheroleum</u> <i>Foeniculum vulgare</i> Miller subsp. v	T
<u>Foeniculi dulcis fructus</u> <i>Foeniculum vulgare</i> Miller subsp. v	T
<u>Frangulae cortex</u> <i>Rhamnus frangula</i> L. (frangula bark)	W
<u>Linum semen</u> <i>Linum usitatissimum</i> L. (linseed)	WT
<u>Plantaginis ovatae semen</u> <i>Plantago ovata</i> Forssk. (ispaghula seed)	W
<u>Plantaginis ovatae seminis tegumentum</u> <i>Plantago ovata</i> Forssk. (ispaghula husk)	W
<u>Psyllii semen</u> <i>Plantago afra</i> L.; <i>Plantago indica</i> L. (psyllium seed)	W
<u>Sennae fructus</u> <i>Cassia senna</i> L.; <i>Cassia angustifolia</i> Vahl (senna pods)	W
<u>Sennae folium</u> <i>Cassia senna</i> L.; <i>Cassia angustifolia</i> Vahl (senna leaf)	W
<u>Valerianae radix</u> <i>Valeriana officinalis</i> L. (valerian root)	WT

public interest to know who is responsible

- for drafting the monographs
- which MS did vote for and who did vote against the monograph

HMPC Monographs – childrens use



Safety bases on a long-term use of at least 30 years

e. g.

bitter fennel fruits
bitter fennel fruit oil

sweat fennel fruits

DRAFTS

calendula flower
hop strobiles

**Why is the use in children
such restrictive?**

> 4 years of age
> 18 years of age

> 4 years of age

> 6 years of age
> 12 years of age



Approved Indications of Finalised Procedures

THMPs – selected registrations granted



Germany

Klosterfrau Melissengeist (13 herbs combination)	12.2005
Weißdorn Tee (Hawthorn Tea)	02.2007
Canephron N CT, OD (3 herbs combination)	03.2007

UK

Arnica Gel (Arnica montana extract)	11.2006
FlexiHerb (Devil's Claw extract)	01.2007
MigraHerb (Feverfew herb)	04.2007
MenoHerb (Black Cohosh extract)	06.2007

Austria

Passionflower Tablets (Passiflora extract)	06.2007
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Granted indications - Germany



Klosterfrau Melisengeist

T. u. for improve state of health...for relief of nerviness and restlessness on nerves and the cardiovascular system...for improve of the gastrointestinal function...for uncomplicated cold and for strengthening

Weißdorntee (Hawthorn Tea)

T. u. to support the cardiovascular system

Canephron N CT, OD

T. u. to support excretion of the kidney

- how to differentiate from Dietary Supplements?
- what's the added value for investments made to produce profound quality and to protect public health?

Granted indications - Austria



Passiflora

T. u. for treatment of nervous restlessness like inner unrest, excitation, tension, feelings of oppression or anxiety. For treatment of nervousness caused disorders and problems of falling asleep and of sleeping through the night.

The administration exclusively bases on a long-standing use.

**advanced
indication**

COMMUNITY HERBAL MONOGRAPH ON PASSIFLORA INCARNATA L., HERBA - DRAFT

Traditional herbal medicinal product for relief of mild symptoms of mental stress and to aid sleep.

The product is a traditional herbal medicinal product for use in the specified indications exclusively based upon longstanding use.

Granted indications - UK



Arnica Gel

T. u. for the symptomatic relief of muscular aches, pains and stiffness, sprains, bruises and swelling after contusions, exclusively based on long-standing use.

Devil's Claw

T. u. for the relief of backache, rheumatic or muscular pain in muscles and joints based on evidence of traditional use only.

very strong indications!

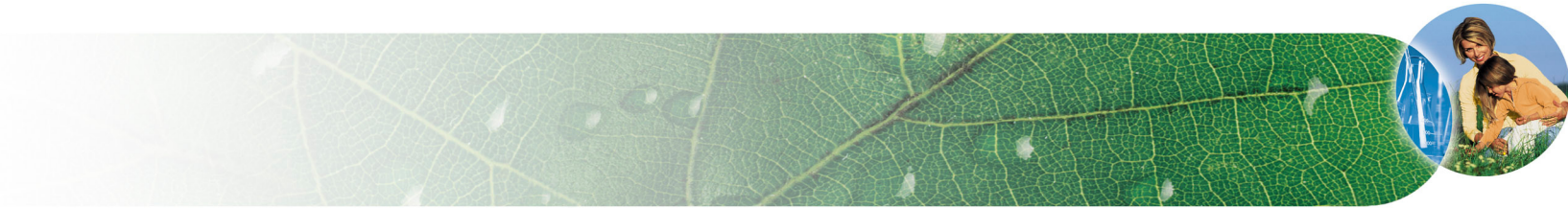
What's left for WEU?

Feverfew

T. u. for the prevention of migraine headaches based on traditional use only.

Cimicifuga

T. u. for the relief of symptoms of the menopause, such as hot flushes, night sweats and temporary changes in mood based on traditional use only.



Q u e s t i o n

Dir. 2001/83/EC / Dir. 2004/24/EC are intended to provide a legal basis for HMPs/THMPs throughout the EU

Why do MS not seek harmonisation on basis of a system offering approval and registration equally?

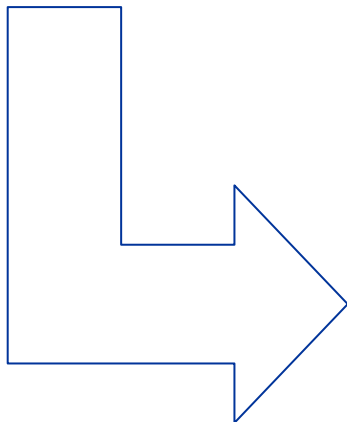
Art. 16d, Dir. 2001/83/EC (consolidated)



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... each MS shall, when
application for traditional
account of registrations of
State in accordance with

**How to harmonize the
differing interpretations of
the Directive?**



kind of Mutual Recognition Procedure

CONCLUSIONS



- The acceptance of the Traditional Procedure seems to perform well. Nevertheless some MS haven't yet accomplished the legal basis (transition period ended 10.2005)
- an elaboration of community monographs is highly appreciated, nevertheless
 - existing knowledge (e.g. ESCOP / KOOP Phyto monographs) should be more considered
 - differing knowledge on and acceptance of phytotherapy lead to poor compromises of community monographs
 - Votes of the representatives should be made public to ease concerted procedures

CONCLUSIONS



- children's use should be more considered on basis of a 30 years use
- different levels of evidence should furthermore allow to position THMPs and HMPs distinctly from each other
- equally a differentiation from dietary supplements is absolutely necessary
 - to guarantee profound quality and to protect public health, but also to make research and investments profitable
- A mutual recognition of the MS's decisions is highly desirable, since dietary supplements have full access to the EU market



THANKS
for your attention