



Federal Agency for Medicines and Health Products  
(FAMHP)

Practical implications of changes within the herbals regulatory environment:

02. Applications for HMP authorization and THMP registration:  
what?

Unit Homeo - Phyto



## Procedures

### REGISTRATION (REG)? - MA (AMM)? -> for HERBALS

Before 2004: Registration = AMM

After 2004 : AMM = Authorization

REG = (simplified) Registration

The document reflects the level of evidence of the dossier  
(=> legal basis)

#### AMM:

- 4 page and/or AMM light
- Authorization nr: BE 123456

#### REG:

- Front page ~ front page AMM
- Annexed application form (validated)
- Registration nr: BE-TU 123456



## Procedures

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### REGISTRATION (REG)? - MA (AMM)? -> for HERBALS

#### PROCEDURES:

##### National procedures - NP:

- Full application (mixed) => AMM
- Well Established Use Application => AMM
- Traditional Use (TU) Application => REG

##### European procedures - MRP & DCP:

- Full application (mixed) => AMM
- Well Established Use Application => AMM
- TU Application - List entry - Monograph=> REG

## Authorization Application types:

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### “Full Application” :

#### Article 8(3) of Directive 2001/83/EC

the following documentation shall be included in the dossier:

- pharmaceutical (physico-chemical, biological or microbiological) tests,
- preclinical (toxicological and pharmacological) tests,
- clinical trials.

For such applications, the relevant published literature also has to be submitted and these scientific publications can be used as supportive data.

Where Module 4 and/or 5 consists of a combination of reports of limited non-clinical and/or clinical studies carried out by the applicant and of bibliographical references this kind of application has also to be submitted according to this article

## Authorization Application types:

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### “Well Established Use Application”: Article 10a of Directive 2001/83/EC

replace results of the pre-clinical and clinical trials by detailed references to published scientific literature (information available in the public domain)

=> applicable data!!

the active substances of a medicinal product have been in well established medicinal use within the Community for at least ten years, with recognised efficacy and an acceptable level of safety.

“well established medicinal use”  
does mean “use as an authorised medicinal product”  
proof of medicinal use may not be submitted in the absence of a marketing authorisation

## Registration Application types:

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### “Traditional Use Application”: Articles 16a to 16i of Directive 2001/83/EC

intended for

- herbal medicinal products with a long tradition
- which can not fulfil the requirements for a marketing authorisation

= the registration of herbal medicinal products without requiring particulars and documents on tests and trials on safety and efficacy

-> provided that there is sufficient evidence of the medicinal use (DIR 2004/24/EC Art 16C, 3.) of the product (at least 30 years, including at least 15 years in the Community)

-> bibliographical or expert evidence to the effect that the medicinal product in question, or a corresponding product has been in medicinal use throughout the fixed period

## Registration Application types:

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### “Traditional Use Application”: Articles 16a to 16i of Directive 2001/83/EC

THMP have to fulfil the same requirements as applications for a marketing authorisation with regard to the manufacturing of these products and their quality.

Results of pharmaceutical (physico-chemical, biological or microbiological) tests must be submitted to demonstrate the quality of the traditional herbal medicinal product.

The long tradition makes it possible to reduce the need for clinical data  
-> the efficacy of the medicinal product is plausible on the basis of its long-standing use and experience as testified by bibliographic or expert evidence.

## Registration Application types:

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### “Traditional Use Application”: Articles 16a to 16i of Directive 2001/83/EC

Applicants must substantiate the safety of the medicinal product by the means of a bibliographic review of safety data together with an expert report

-> complemented by any necessary data, which the Member State's competent authority may request.

Claimed indications :

appropriate to traditional herbal medicinal products, which by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment.

## New possibilities relating to TU

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### DIRECTIVE 2004/24/EC

#### The Committee on Herbal Medicinal Products (HMPC):

- established in September 2004
- replaced the CPMP Working Party on Herbal Medicinal Products
- established in accordance with Regulation (EC) No 726/2004 and Directive 2004/24/EC

#### The HMPC's core tasks:

- assist the harmonisation of procedures + provisions concerning HMP
- further integrate HMP in the European regulatory framework.
- provide EU Member States and European institutions its scientific opinion on questions relating to HMP
- the establishment of a draft 'Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products
- the establishment of Community herbal monographs.

## New possibilities relating to TU

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### Community herbal monographs

#### **HMPC:** establish Community herbal monographs

- for the application of both the traditional use and well-established use provisions
- to serve as a basis for simplified registration or bibliographical marketing authorisation applications.

In order to promote harmonisation, Member States should recognise registrations of THMP (use of MRP or DCP procedures):

- granted by another Member State based on Community herbal monographs
- consisting of substances, preparations or combinations thereof contained in the above-mentioned list.

For other products, Member States should take due account of such registrations.

# New possibilities relating to TU

## Community herbal monographs to be found on EMA-website:



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### Community herbal monographs

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#### Searching for community herbal monograph documents

To view all community herbal monograph documents, go to the document library and search using the document type, 'Herbal - Community herbal monograph'.

A Community herbal monograph comprises the scientific opinion of the Committee on Herbal Medicinal Products (CHMP) on safety and efficacy data concerning a herbal substance and its preparations intended for medicinal use. The CHMP evaluates scientifically all available information including non-clinical and clinical data but also documented long-standing use and experience in the Community.

Community monographs are divided into two columns: well-established use (marketing authorisation) and traditional use (traditional monographs).

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# New possibilities relating to TU

## Community herbal monographs to be found on EMA-website:

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## Community monograph

European Medicines Agency  
Evaluation of Medicines for Human UseLondon, 16 July 2009  
Doc. Ref.: EMA/HMP/22519/2008COMMITTEE ON HERBAL MEDICINAL PRODUCTS  
(HMPC)

## FINAL

COMMUNITY HERBAL MONOGRAPH ON *AESCULUS HIPPOCASTANUM* L., SEMEN

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (CWMP)	May 2008 July 2008 September 2008
ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION	4 September 2008
END OF CONSULTATION (DEADLINE FOR COMMENTS)	15 January 2009
REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (CWMP)	May 2009 July 2009
ADOPTION BY HMPC	16 July 2009

<b>KEYWORDS</b>	Herbal medicinal products; HMPC; Community herbal monographs; well-established medicinal use; traditional use; <i>Aesculus hippocastanum</i> L.; Hippocastan semen; horse chestnut seed
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COMMUNITY HERBAL MONOGRAPH ON *AESCULUS HIPPOCASTANUM* L., SEMEN

## 1. NAME OF THE MEDICAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION<sup>1</sup>

Well-established use	Traditional use
With regard to the marketing authorisation application of Article 10(a) of Directive 2001/83/EC as amended: <i>Aesculus hippocastanum</i> L., semen (horse chestnut seed)	With regard to the registration application of Article 16(1) of Directive 2001/83/EC as amended: <i>Aesculus hippocastanum</i> L., semen (horse chestnut seed)
1) Herbal substance Not applicable	1) Herbal substance Not applicable
2) Herbal preparations	2) Herbal preparations:
Dry extracts <sup>2</sup> (40-60% (v/v) ethanol) standardised to: gnicum 16.20%, sarpagosa glycosides, calculated as aescin (phenolic method)	• Dry extract (ethanol 25-50% v/v) in a strength corresponding to ca 1% aescin in an ornamental gel base • Tincture (1:5, extraction solvent: 50% ethanol (v/v), 20% in an ornamental gel base

## 3. PHARMACEUTICAL FORM

Well-established use	Traditional use
Herbal preparations in modified or immediate release dosage forms for oral use.	Herbal preparations in semi-solid dosage forms for cutaneous use.
The pharmaceutical form should be described by the European Pharmacopoeia full standard term.	The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

<sup>1</sup> The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

<sup>2</sup> The composition of the extraction solvent and the content of aescin must be specified in the individual extract.

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## Community monograph

## 4. CLINICAL PARTICULARS

## 4.1. Therapeutic indications

Well-established use	Traditional use
Herbal medicinal product for treatment of chronic venous insufficiency, which is characterised by swollen legs, varicose veins, a feeling of heaviness, pain, tiredness, itching, tension and cramps in the calves.	A) Traditional herbal medicinal product to relieve symptoms of discomfort and heaviness of legs related to minor venous circulatory disturbances.  B) Traditional herbal medicinal product for relief of signs of bruises, such as local oedema and haematoma.  The product is a traditional herbal medicinal product for use in the specified indications exclusively based upon long-standing use.

## 4.2. Posology and method of administration

Well-established use	Traditional use
<b>Posology</b> <i>Adults and elderly</i> Extract (standardised to a content of 50 mg triester glycosides calculated as aescin) 2 mg daily.  The product is not intended for children and adolescents under 18 years of age.	<b>Posology</b> <i>Indication A)</i> <i>Adults and elderly</i> Apply a thin layer on the affected area 1-3 times per day.  <i>Indication B)</i> The product is not intended for children and adolescents under 18 years of age.
<b>Duration of use</b> At least 4 weeks of treatment may be required before any beneficial effect is observed. Long-term use is possible in consultation with a doctor.	<i>Indication B)</i> <i>Adolescents, adults and elderly</i> Apply a thin layer on the affected area 1-3 times per day.  The use in children under 12 years of age is not recommended (see section 4.4 Special warnings and precautions for use <sup>3</sup> ).
<b>Method of administration</b> Oral use.	<b>Duration of use</b> <i>Indication A)</i> If the symptoms persist longer than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

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Well-established use	Traditional use
If the symptoms persist longer than 5 days during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.	<i>Indication B)</i> The product should not be used on broken skin, around the eyes or on mucous membranes.  In the absence of sufficient safety data, the use in children below 12 years of age is not recommended.  <i>Indication A) and B)</i> If symptoms worsen or signs of skin infections occur during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

## 4.3. Contraindications

Well-established use	Traditional use
Hypersensitivity to the active substance.	Hypersensitivity to the active substance.

## 4.4. Special warnings and precautions for use

Well-established use	Traditional use
If there is inflammation of the skin, thrombophlebitis or subcutaneous induration, severe pain, oedema, sudden swelling of one or both legs, confusion or renal insufficiency, a doctor should be consulted.	<i>Indication A)</i> If there is inflammation of the skin, thrombophlebitis or subcutaneous induration, severe pain, oedema, sudden swelling of one or both legs, confusion or renal insufficiency, a doctor should be consulted.  <i>Indication B)</i> The product should not be used on broken skin, around the eyes or on mucous membranes.  In the absence of sufficient safety data, the use in children below 12 years of age is not recommended.  <i>Indication A) and B)</i> If symptoms worsen or signs of skin infections occur during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

## 4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
None reported.	None reported.

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## Community monograph

### 4.6. Pregnancy and lactation

Well-established use	Traditional use
Safety during pregnancy and lactation has not been established.	Safety during pregnancy and lactation has not been established.
In the absence of sufficient data, the use during pregnancy and lactation is not recommended.	In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

### 4.7. Effects on ability to drive and use machines

Well-established use	Traditional use
No studies on the effect on the ability to drive and use machines have been performed.	Not relevant.

### 4.8. Undesirable effects

Well-established use	Traditional use
Gastrointestinal complaints, headache, vertigo, itching and allergic reactions have been reported. The frequency is not known.	Hypersensitivity reactions of the skin (itching and erythema) have been reported. The frequency is not known.
If other adverse reactions not mentioned above occur, a doctor or a pharmacist should be consulted.	If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

### 4.9. Overdose

Well-established use	Traditional use
No case of overdose has been reported.	No case of overdose has been reported.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1. Pharmacodynamic properties

Well-established use	Traditional use
Pharmacotherapeutic group: Vasoconstrictives ATC code: C05	Not required as per Article 16c(1)(a)(ii) of Directive 2001/83/EC as amended.
The exact mechanism of action is not known, but preclinical and clinical pharmacological studies indicate that an effect on venous tone and capillary filtration rate is involved.	

Based on a systematic review (meta-analysis) of 17 clinical trials, it can be concluded that horse chestnut seed extract (standardised on aescin) significantly reduces symptoms of chronic venous insufficiency, such as oedema, pain and itching compared to placebo.

### 5.2. Pharmacokinetic properties

Well-established use	Traditional use
Available data on pharmacokinetic parameters for aescin are of limited validity and not considered relevant for the dosing regimen of the herbal preparation.	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

### 5.3. Preclinical safety data

Well-established use	Traditional use
Available preclinical data indicate low toxicity following oral administration of the herbal preparation.	Not required as per Article 16c(1)(a)(iv) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product.
Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.	Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

## 6. PHARMACEUTICAL PARTICULARS

Well-established use	Traditional use
Not applicable.	Not applicable.

### 7. DATE OF COMPLETION/LAST REVISION

16 July 2009

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## New possibilities relating to TU

### Community list

- a view to further facilitating the registration of certain traditional herbal medicinal products in the EU
- = a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products
- established on the basis of the scientific opinion of the HMPC.

Applicants can refer to the list (for efficacy/safety), instead of submitting data. However they would still need to demonstrate the quality of the medicinal products they seek to register.

List entries are mandatory for Member States. They cannot be refused (for efficacy or safety reasons).

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## New possibilities relating to TU

### Community list

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Community list entries

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To view all community list entry documents, go to the document library and search using the document type, 'Herbal - Community list entry'.

In contrast to the Community herbal monographs, the 'Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products' is legally binding to applicants and competent authorities in the Member States in so far as:

- an applicant will not be required to provide evidence of the safe and traditional use of a medicinal product for which he seeks a traditional use registration if he demonstrates that the proposed product and related claims in the application comply with the information contained in the Community list;

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## New possibilities relating to TU

### Community list

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# Community List : 2008/911/EC

L 328/42    EN    Official Journal of the European Union    6.12.2008

## COMMISSION

### COMMISSION DECISION of 21 November 2008

establishing a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products  
(notified under document number G(2008) 6933)  
(Text with EEA relevance)  
(2008/911/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

(1) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (1), and in particular Article 16(8) thereof,

Having regard to the opinions of the European Medicines Agency, formulated on 7 September 2007 by the Committee for Herbal Medicinal Products,

Whereas:

- (1) *Foeniculum vulgare* Miller subsp. vulgare var. vulgare and *Foeniculum vulgare* Miller subsp. vulgare var. dulce (Miller) Thellung comply with the requirements set out in Directive 2001/83/EC. *Foeniculum vulgare* Miller subsp. vulgare var. dulce (Miller) Thellung can be considered as herbal substances, herbal preparations and/or combinations thereof.
- (2) It is therefore appropriate to establish a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products including the entry of *Foeniculum vulgare* Miller subsp. vulgare var. dulce (Miller) Thellung.

**Article 1**  
A list of herbal substances, preparations and combinations thereof for use as a traditional medicinal product relevant for *Foeniculum vulgare* Miller subsp. vulgare var. dulce (Miller) Thellung and the entry of *Foeniculum vulgare* Miller subsp. vulgare var. dulce (Miller) Thellung.

**Article 2**  
The indications, the specified strengths and the posology, the route of administration and any other information necessary for the safe use as a traditional medicinal product relevant for *Foeniculum vulgare* Miller subsp. vulgare var. dulce (Miller) Thellung are set out in Annex I to this decision.

**Article 3**  
This Decision is addressed to the Member States.

Done at Brussels, 21 November 2008.

For the Commission  
Gunter VERHEUGEN  
Vice-President

List entry: annex I

List entry details: annex II

# List entry: annex I

6.12.2008    EN    Official Journal of the European Union    L 328/43

## ANNEX I

List of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products established in accordance with Article 16(8) of Directive 2001/83/EC as amended by Directive 2004/24/EC

*Foeniculum vulgare* Miller subsp. vulgare var. vulgare (bitter fennel fruit)

*Foeniculum vulgare* Miller subsp. vulgare var. dulce (Miller) Thellung (sweet fennel fruit)

16.1.2010    EN    Official Journal of the European Union    L 11/13

## ANNEX I

In Annex I to Decision 2008/911/EC, the following is inserted:

- *Calendula officinalis* L. is inserted before *Foeniculum vulgare* Miller subsp. vulgare var. vulgare (Bitter fennel fruit),
- *Pimpinella anisum* L. is inserted after *Foeniculum vulgare* Miller subsp. vulgare var. dulce (Miller) Thellung (Sweet fennel fruit).

19.1.2010    EN    Official Journal of the European Union    L 12/15

## ANNEX I

In Annex I to Decision 2008/911/EC, the following two substances are inserted after *Calendula officinalis* L.:

- *Echinacea purpurea* (L.) Moench
- *Echinacea purpurea* (Rupr. et Maxim.) Maxim'

List entry details: annex II

## List entry: details in annex II

<p><b>ANNEX II</b></p> <p>In Annex II to Directive 2002/20/EC, the following is inserted after the entry relating to "Calmidol (Calmidol)":</p> <p><b>COMMUNITY LIST ENTRY ON: ECHINACEA PURPUREA (L.) MOENCH, HERBA RECIENS</b></p> <p><b>Scientific name of the plant</b> Echinacea purpurea (L.) Moench</p> <p><b>Botanical family</b> Asteraceae</p> <p><b>Herbal substance</b> Herbae extractioe herb</p> <p><b>Common name in all EU official languages of herbal substance:</b></p> <table border="0"> <tr> <td>BG (Български): екстракт от екстракт от екстракт</td> <td>CY (Κυπριακά): εκχυλίσμα βοτάνων</td> </tr> <tr> <td>CS (Česky): extrakt z extraktu</td> <td>DE (Deutsch): Extrakt aus Extrakt</td> </tr> <tr> <td>DA (Dansk): Ekstrakt af ekstrakt</td> <td>EL (Ελληνικά): Εκχύλισμα βοτάνων</td> </tr> <tr> <td>DE (Deutsch): Extrakt aus Extrakt</td> <td>ES (Español): Extracto de extracto</td> </tr> <tr> <td>EL (Ελληνικά): Εκχύλισμα βοτάνων</td> <td>ET (Eesti keel): taimede ekstrakt</td> </tr> <tr> <td>EN (English): plant extract herb</td> <td>EU (Ευρωπαϊκή Κοινωνία των Εθνών): εκχύλισμα βοτάνων</td> </tr> <tr> <td>ES (Español): Extracto de extracto</td> <td>FR (Français): extrait d'extraits de plantes</td> </tr> <tr> <td>ET (Eesti keel): taimede ekstrakt</td> <td>GA (Gaeilge): taimíochán</td> </tr> <tr> <td>FI (Suomenkielinen): kasvien uutteita</td> <td>GL (Galego): extracción de plantas</td> </tr> <tr> <td>FR (Français): extrait d'extraits de plantes</td> <td>HU (Magyar): kivonat kivonatból</td> </tr> <tr> <td>GA (Gaeilge): taimíochán</td> <td>IT (Italiano): estratto di estratti</td> </tr> <tr> <td>IT (Italiano): estratto di estratti</td> <td>LT (Lietuvių): augalų ekstraktas</td> </tr> <tr> <td>LV (Latviešu): ekstrakti ekstrakti</td> <td>MT (Maltese): Eżtrakt ta' Eżtrakt</td> </tr> <tr> <td>MT (Maltese): Eżtrakt ta' Eżtrakt</td> <td>PL (Polski): ekstrakt z ekstraktów</td> </tr> <tr> <td>PL (Polski): ekstrakt z ekstraktów</td> <td>PT (Português): extrato de extratos</td> </tr> <tr> <td>PT (Português): extrato de extratos</td> <td>RO (Română): extract de extracte</td> </tr> <tr> <td>RO (Română): extract de extracte</td> <td>SK (Slovensky): extrakt z extraktov</td> </tr> <tr> <td>SK (Slovensky): extrakt z extraktov</td> <td>SL (Slovenščina): ekstrakt iz 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βοτάνων	CS (Česky): extrakt z extraktu	DE (Deutsch): Extrakt aus Extrakt	DA (Dansk): Ekstrakt af ekstrakt	EL (Ελληνικά): Εκχύλισμα βοτάνων	DE (Deutsch): Extrakt aus Extrakt	ES (Español): Extracto de extracto	EL (Ελληνικά): Εκχύλισμα βοτάνων	ET (Eesti keel): taimede ekstrakt	EN (English): plant extract herb	EU (Ευρωπαϊκή Κοινωνία των Εθνών): εκχύλισμα βοτάνων	ES (Español): Extracto de extracto	FR (Français): extrait d'extraits de plantes	ET (Eesti keel): taimede ekstrakt	GA (Gaeilge): taimíochán	FI (Suomenkielinen): kasvien uutteita	GL (Galego): extracción de plantas	FR (Français): extrait d'extraits de plantes	HU (Magyar): kivonat kivonatból	GA (Gaeilge): taimíochán	IT (Italiano): estratto di estratti	IT (Italiano): estratto di estratti	LT (Lietuvių): augalų ekstraktas	LV (Latviešu): ekstrakti ekstrakti	MT (Maltese): Eżtrakt ta' Eżtrakt	MT (Maltese): Eżtrakt ta' Eżtrakt	PL (Polski): ekstrakt z ekstraktów	PL (Polski): ekstrakt z ekstraktów	PT (Português): extrato de extratos	PT 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professional should be consulted.</b></p> <p><b>Any other information necessary for the safe use</b> Contra-indications: Hypersensitivity to the active substance or to plants of the Asteraceae/Compositae family.</p> <p><b>Special warnings and precautions for use</b> If signs of skin irritation are observed, medical advice should be sought.</p> <p><b>The use in children below 12 years of age is not recommended because a safe use has not been sufficiently documented.</b></p> <p><b>Interactions with other medicinal products and other forms of interaction</b> None reported.</p> <p><b>Pregnancy and lactation</b> There are no data on consumer use during pregnancy or lactation.</p> <p><b>Products containing Echinacea should not be applied to the breast of breastfeeding women.</b></p> <p><b>Effect on ability to drive and use machines</b> No studies on the effects on the ability to drive and use machines have been performed.</p> <p><b>Undesirable effects</b> Hypersensitivity reactions (skin rash, contact dermatitis, urticaria and angioedema of the lips) may occur.</p> <p><b>The frequency is not known.</b></p> <p><b>If other adverse reactions are mentioned above occur, a doctor or a qualified healthcare professional should be consulted.</b></p> <p><b>Overdose</b> No case of overdose has been reported.</p>
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## New possibilities relating to TU - WEU

(situation 18/02/2010)

### Community herbal monographs (WEU - TU)

49 final  
22 under preparation

### Entries on the Community list (TU)

9 entries (draft included) : [EMA-website](#)  
6 approved (last update published 19/1/2010) : [2008/911/EC as amended](#)

=> dossier data to be compiled drastically reduced compared to before 2004 due to availability of « pre-compiled » data

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