COMMISSION DECISION

of 9 December 2009

amending the list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products

(notified under document C(2009) 9703)

(Text with EEA relevance)

(2010/30/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on European Union and to the Treaty on the Functioning of the European Union,

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(f) thereof,

Having regard to the opinions of the European Medicines Agency, formulated on 10 January 2008 and 6 March 2008 by the Committee for Herbal Medicinal Products,

Whereas:

(1) '*Eleutherococcus senticosus* (Rupr. et Maxim.) Maxim' and '*Echinacea purpurea* (L.) Moench' comply with the requirements set out in Directive 2001/83/EC. '*Eleutherococcus senticosus* (Rupr. et Maxim.) Maxim' and '*Echinacea purpurea* (L.) Moench' can be considered as herbal substances, herbal preparations or combinations thereof.

(2) It is therefore appropriate to include '*Eleutherococcus senticosus* (Rupr. et Maxim.) Maxim' and '*Echinacea purpurea* (L.) Moench' in the list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products established in Annex I to Commission Decision 2008/911/EC [2].

(3) Decision 2008/911/EC should therefore be amended accordingly.

(4) 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:

Article 1

Decision 2008/911/EC is amended as follows:

1. Annex I is amended in accordance with Annex I to this Decision;

2. Annex II is amended in accordance with Annex II to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 9 December 2009.

For the Commission
Günter VERHEUGEN
Vice-President

[1] OJ L 311, 28.11.2001, p. 67.

[2] OJ L 328, 6.12.2008, p. 42.

ANNEX I

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

— '*Echinacea purpurea* (L.) Moench'

— '*Eleutherococcus senticosus* (Rupr. et Maxim.) Maxim'

ANNEX II

In Annex II to Decision 2008/911/EC, the following is inserted after the entry relating to '*Calendula officinalis* L':

'**COMMUNITY LIST ENTRY ON *ECHINACEA PURPUREA* (L.) MOENCH, HERBA RECENS**

Scientific name of the plant

Echinacea purpurea (L.) Moench

Botanical family

Asteraceae

Herbal substance

Purple coneflower herb

Common name in all EU official languages of herbal substance

BG (bălgarski): пурпурна ехинацея, пресен стрък

CS (čeština): čerstvá nať třapatky nachové

DA (dansk): Purpursolhat, frisk urt

DE (Deutsch): Purpursonnenhutkraut, frisch

EL (elliniká): Πόα Εχινάκεας της πορφυράς

EN (English): purple coneflower herb

ES (español): Equinácea purpúrea, partes aéreas incluidas sumidades floridas

ET (eesti keel): punane siilkübar

FI (suomi): kaunopunahattu, tuore verso

FR (français): parties aériennes fraîches d'échinacée pourpre

HU (magyar): bíbor kasvirág virágos hajtása

IT (italiano): Echinacea purpurea, pianta fresca

LT (lietuvių kalba): rausvažiedžių ežiuolių žolė

LV (latviešu valoda): purpursarkanās ehinacejas laksti

MT (malti): Echinacea Vjola

NL (nederlands): rood zonnehoedkruid

PL (polski): jeżówka purpurowa, świeże ziele

PT (português): Equinácea, partes aéreas floridas

RO (română): iarbă proaspătă de Echinacea, pălăria soarelui

SK (slovenčina): echinacea purpurová, čerstvá vňať

SL (slovenščina): sveža zel škrlatne ehinaceje

SV (svenska): röd solhatt, färsk ört

IS (íslenska): Sólhattur

NO (norsk): Rød solhatt

Herbal preparation(s)

Expressed juice and dried expressed juice from fresh flowering aerial parts.

European Pharmacopoeia monograph reference

N/A

Indication(s)

Traditional herbal medicinal product for treatment of small superficial wounds.

The product is a traditional herbal medicinal product for use in a specified indication exclusively based on long-standing use.

Type of tradition

European.

Specified strength

10 to 20 g/100 g of expressed juice or equivalent amount of dried expressed juice in liquid or semi-solid dosage forms.

Specified posology

Adolescents over the age of 12 years, adults, elderly

Small amount of ointment is applied on the affected area 2-3 times a day.

The use in children under 12 years of age is not recommended (see below "Special warnings and precautions for use").

Route of administration

Cutaneous use.

Duration of use or any restrictions on the duration of use

Do not use the medicinal product for more than 1 week.

If the symptoms persist during the use of the medicinal product, a doctor or a qualified healthcare practitioner should be consulted.

Any other information necessary for the safe use

Contra-indications

Hypersensitivity to the active substance or to plants of the Asteraceae (Compositae) family.

Special warnings and precautions for use

If signs of skin infection are observed, medical advice should be sought.

The use in children below 12 years of age is not recommended because a safe use has not been sufficiently documented.

Interactions with other medicinal products and other forms of interaction

None reported.

Pregnancy and lactation

There are no data on cutaneous use during pregnancy or lactation.

Products containing Echinacea should not be applied to the breast of breastfeeding women.

Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

Undesirable effects

Hypersensitive reactions (local rash, contact dermatitis, eczema and angioedema of the lips) may occur.

The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a qualified healthcare practitioner should be consulted.

Overdose

No case of overdose has been reported.

COMMUNITY LIST ENTRY ON *ELEUTHEROCOCCUS SENTICOSUS* (RUPR. ET MAXIM.) MAXIM., RADIX

Scientific name of the plant

Eleutherococcus senticosus (Rupr. et Maxim.) Maxim.

Botanical family

Araliaceae

Herbal substance

Eleutherococcus root

Common name in all EU official languages of herbal substance

BG (bălgarski): елеутерокок, корен

CS (čeština): eleuterokokový kořen

DA (dansk): Russisk rod

DE (Deutsch): Taigawurzel

EL (elliniká): Ρίζα Ελευθεροκόκκου

EN (English): Eleutherococcus root

ES (español): Eleuterococo, raíz de

ET (eesti keel): eleuterokokijuur

FI (suomi): venäjänjuuren juuri

FR (français): racine d'éleuthérocoque (racine de ginseng sibérien)

HU (magyar): Szibériai ginszeng gyökér (tajga gyökér)

IT (italiano): Eleuterococco radice

LT (lietuvių kalba): Eleuterokokų šaknys

LV (latviešu valoda): Eleiterokoka sakne

MT (malti): Għerq ta' l-elewterokokku

NL (nederlands): Russische ginsengwortel

PL (polski): korzeń eleuterokoka

PT (português): Raiz de Ginseng Siberiano

RO (română): Rădăcină de ginseng siberian

SK (slovenčina): Všehojovcový koreň

SL (slovenščina): korenina elevterokoka

SV (svenska): Rysk rot

IS (íslenska): Síberíu ginseng, rót

NO (norsk): Russisk rot

Herbal preparation(s)

Comminuted herbal substance for preparation of a herbal tea

Liquid extract (1:1, ethanol 30-40 % v/v)

Dry extract (13-25: 1, ethanol 28-40 % v/v)

Dry extract (17-30: 1, ethanol 70 % v/v)

Dry aqueous extract (15-17:1)

Tincture (1:5, ethanol 40 % v/v)

European Pharmacopoeia monograph reference

Eleutherococcus — Eleutherococci radix (ref.: 01/2008: 1419 corrected 6.0)

Indication(s)

Traditional herbal medicinal product for symptoms of asthenia such as fatigue and weakness.

The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

Type of tradition

Chinese, European.

Specified strength

Not applicable.

Specified posology

Adolescents over 12 years of age, adults, elderly

Herbal preparations.

Daily dose.

Comminuted herbal substance as herbal tea: 0,5-4 g.

Tea preparation: 0,5 to 4 g of comminuted herbal substance for infusion in 150 ml of boiling water.

Dosage frequency: 150 ml of tea infusion should be divided in one to three doses taken during the day.

Liquid extract: 2-3 ml.

Dry extracts (ethanol 28-70 % v/v) corresponding to 0,5-4 g dried root.

Dry aqueous extract (15-17:1): 90-180 mg.

Tincture: 10-15 ml.

The daily dose can be taken in one to three doses.

The use is not recommended in children under 12 years of age (see below "Special warnings and precautions for use").

Route of administration

Oral use.

Duration of use or any restrictions on the duration of use

Not to be taken for more than 2 months.

If the symptoms persist for more than 2 weeks during the use of the medicinal product, a doctor or a qualified healthcare practitioner should be consulted.

Any other information necessary for the safe use

Contra-indications

Hypersensitivity to the active substance.

Arterial hypertension.

Special warnings and precautions for use

The use in children under 12 years of age is not recommended because sufficient experience is not available.

If the symptoms worsen during the use of the medicinal product, a doctor or a qualified healthcare practitioner should be consulted.

Interactions with other medicinal products and other forms of interaction

None reported.

Pregnancy and lactation

Safety during pregnancy and lactation has not been established.

In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.

Undesirable effects

Insomnia, irritability, tachycardia and headaches may occur. The frequency is not known.

Overdose

No case of overdose has been reported.'