Commission Implementing Decision of 28 November 2011 amending Decision 2008/911/EC establishing a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products (notified under document C(2011) 7382) (Text with EEA relevance) (2011/785/EU)

COMMISSION IMPLEMENTING DECISION

of 28 November 2011

amending Decision 2008/911/EC establishing a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products

(notified under document C(2011) 7382)

(Text with EEA relevance)

(2011/785/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on European Union and 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 16f thereof,

Having regard to the opinion of the European Medicines Agency, formulated on 15 July 2010 by the Committee for Herbal Medicinal Products,

Whereas:

(1) *Hamamelis virginiana* L. can be considered as a herbal substance, a herbal preparation or a combination thereof within the meaning of Directive 2001/83/EC and complies with the requirements set out in that Directive.

(2) It is therefore appropriate to include *Hamamelis virginiana* L. in the list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products established by 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

Annexes I and II of Decision 2008/911/EC are amended in accordance with the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 28 November 2011.

For the Commission

John DALLI

Member of the Commission

ANNEX

Annexes I and II to Decision 2008/911/EC are amended as follows:

1. in Annex I, the following substance is inserted after *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung (sweet fennel fruit):

   Hamamelis virginiana L., *folium et cortex aut ramunculus destillatum;*

2. in Annex II, the following is inserted after the entry relating to *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung, fructus:
   COMMUNITY LIST ENTRY ON *HAMAMELIS VIRGINIANA* L., *FOLIUM ET CORTEX AUT RAMUNCULUS DESTILLATUM*
   Scientific name of the plant

   Hamamelis virginiana L.
   Botanical family

   Hamamelidaceae
   Herbal preparation(s)

   1. Distillate prepared from fresh leaves and bark (1:1.12 – 2.08; extraction solvent ethanol 6 % m/m)

   2. Distillate prepared from dried twigs (1:2; extraction solvent ethanol 14-15 %)[3]

   European pharmacopoeia monograph reference

   Not applicable
   Indication(s)
   Indication (a)

   Traditional herbal medicinal product for relief of minor skin inflammation and dryness of the skin.
   Indication (b)

   Traditional herbal medicinal product to be used for the temporary relief of eye discomfort due to dryness of the eye or to exposure to wind or sun.

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

   European
   Specified strength

   Please see ‘Specified posology’.
   Specified posology
   Children over six years of age, adolescents, adults and elderly
   Indication (a)

   Distillate in a strength corresponding to 5-30 % in semi-solid preparations, several times daily.

   The use in children under six years of age is not recommended (see section ‘Special warnings and precautions for use’).
   Adolescents, adults and elderly
   Indication (b)

Eye drops[4] Distillate (2) diluted (1:10), 2 drops/each eye, 3-6 times daily.

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

Route of administration

Cutaneous use.

Ocular use.

Duration of use or any restrictions on the duration of use

Children over six years of age, adolescents, adults and elderly

Indication (a)

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

Adolescents, adults and elderly

Indication (b)

The recommended duration of use is four days. If the symptoms persist longer than two days 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

Contraindications

Hypersensitivity to the active substance.

Special warnings and precautions for use

Indication (a)

The use in children under six years of age has not been established due to lack of adequate data.

Indication (b)

If eye pain, changes in vision, continued redness, or irritation of the eye is experienced, or if the condition worsens or persists for more than 48 hours during the use of the medicinal product, a doctor or a qualified healthcare practitioner should be consulted.

The use in children under 12 years of age has not been established due to lack of adequate data.

For extracts containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.

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

Indication (a)

Allergic contact dermatitis may occur in sensitive patients. The frequency is not known.

Indication (b)

Conjunctivitis cases have been reported. 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.

Pharmaceutical particulars [if necessary]

Not applicable.

Pharmacological effects or efficacy plausible on the basis of long-standing use and experience [if necessary for the safe use of the product]

Not applicable..

(**1**) OJ L 311, 28.11.2001, p. 67.

(**2**) OJ L 328, 6.12.2008, p. 42.

(**3**) According to USP (USP-31- NF 26, 2008 Vol 3:3526).

(**4**) The medicinal product complies with the Ph. Eur. monograph on eye preparations (01/2008:1163).'.

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Decision of 28 November 2011 amending Decision 2008/911/EC establishing a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products (notified under document C(2011) 7382) (Text with EEA relevance) (2011/785/EU).