Commission Decision of 25 March 2010 on 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(2010) 1867) (Text with EEA relevance) (2010/180/EU)

COMMISSION DECISION

of 25 March 2010

on 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(2010) 1867)

(Text with EEA relevance)

(2010/180/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 6 November 2008 by the Committee for Herbal Medicinal Products,

Whereas:

(1) *Mentha x piperita* 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 *Mentha x piperita* 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) In order to avoid duplications and possible contradictions between the Annexes and Articles 1 and 2 of Decision 2008/911/EC, it is appropriate to remove the references to single substances in those Articles.

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

(5) 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. Articles 1 and 2 are replaced by the following:

Article 1

A list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products is established in Annex I.

Article 2

The indications, the specified strengths and the posology, the route of administration and any other information necessary for the safe use of the herbal substance as a traditional medicinal product relevant for the herbal substances listed in Annex I are set out in Annex II..

2. Annexes I and II are amended in accordance with the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 25 March 2010.

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):

   Mentha x piperita L.;

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 *MENTHA x PIPERITA* L., AETHEROLEUM

Scientific name of the plant

Mentha x piperita L.

Botanical family

Lamiaceae (Labiatae)

Herbal preparation(s)

Peppermint oil	:	essential oil obtained by steam distillation from the fresh aerial parts of the flowering plant

European Pharmacopoeia monograph reference

Peppermint oil — Menthae piperitae aetheroleum (01/2008:0405)

Indication(s)

Herbal medicinal product traditionally used:

1. for the relief of symptoms in coughs and colds;
2. for the symptomatic relief of localised muscle pain;
3. for the symptomatic relief of localised pruritic conditions in intact skin.

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

Indications 1, 2 and 3

Single dose

Children between 4 to 10 years of age

Semi-solid preparations 2-10 %

Hydroethanolic preparations 2-4 %

Children between 10 to 12 years of age, adolescents between 12 to 16 years of age

Semi-solid preparations 5-15 %

Hydroethanolic preparations 3-6 %

Adolescents over 16 years of age, adults

Semi-solid and oily preparations 5-20 %

In aqueous-ethanol preparations 5-10 %

In nasal ointments 1-5 % essential oil.
Specified posology

Up to three times daily

The use in children under 2 years of age is contraindicated (see "Contraindications").

The use is not recommended in children between 2 to 4 years of age (see "Special warnings and precautions for use").
Route of administration

Cutaneous and transdermal.
Duration of use or any restrictions on the duration of use
Indication 1

Not to be used for more than 2 weeks.
Indications 2 and 3

It is not recommended to use the medicinal product continuously for more than 3 months.

If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.
Any other information necessary for the safe use
Contraindications

Children under 2 years of age, because menthol can induce reflex apnoea and laryngospasm.

Children with history of seizures (febrile or not).

Hypersensitivity to peppermint oil or menthol.
Special warnings and precautions for use

Eye contact with unwashed hands after the application of peppermint oil may potentially cause irritation.

Peppermint oil should not be applied on broken or irritated skin.

The use is not recommended in children between 2 to 4 years of age, as there is no sufficient experience available.
Interactions with other medicinal products and other forms of interaction

None reported.
Pregnancy and lactation

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

Hypersensitivity reactions such as skin rash, contact dermatitis, and eye irritation have been reported. These reactions are most of the time mild and transient. The frequency is not known.

Irritation of the skin and mucosa of the nose is possible, after local application. The frequency is not known.

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

Overdose

No case of overdose has been reported.

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

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

Changes to legislation:
There are currently no known outstanding effects for the Commission Decision of 25 March 2010 on 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(2010) 1867) (Text with EEA relevance) (2010/180/EU).