COMMISSION IMPLEMENTING DECISION

of 3 February 2012

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(2012) 516)

(Text with EEA relevance)

(2012/68/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) *Vitis vinifera* L. can be considered as a herbal substance, a herbal preparation or a combination thereof within the meaning of Directive 2001/83/EC and it complies with the requirements set out in that Directive.

(2) It is therefore appropriate to include *Vitis vinifera* 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 to 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, 3 February 2012.

For the Commission
John DALLI
Member of the Commission

[1] OJ L 311, 28.11.2001, p. 67.
[2] OJ L 328, 6.12.2008, p. 42.

ANNEX

Decision 2008/911/EC is amended as follows:

(1) in Annex I, the following substance is inserted after *Thymus vulgaris* L., *Thymus zygis* Loefl. ex L., aetheroleum:

'*Vitis vinifera* L., folium'

(2) in Annex II, the following is inserted after the entry on *Thymus vulgaris* L., *Thymus zygis* Loefl. ex L.:

'COMMUNITY LIST ENTRY ON *VITIS VINIFERA* L., FOLIUM

Scientific name of the plant

Vitis vinifera L.

Botanical family

Vitaceae

Herbal substance

Grapevine leaf [1]

Common name of herbal substance in all EU official languages

BG (bălgarski): лоза, лист

CS (čeština): Červený list vinné révy

DA (dansk): Vinblad

DE (Deutsch): Rote Weinrebenblätter

EL (elliniká): Φύλλο Αμπέλου

EN (English): Grapevine leaf

ES (español): Vid, hoja de

ET (eesti keel): Viinapuu lehed

FI (suomi): Aitoviiniköynnös, lehti

FR (français): Feuille de vigne rouge

HU (magyar): Bortermő szőlő levél

IT (italiano): Vite, foglia

LT (lietuvių kalba): Tikrųjų vynmedžių lapai

LV (latviešu valoda): Īstā vīnkoka lapas

MT (malti): Werqa tad-dielja

NL (nederlands): Wijnstokblad

PL (polski): Liść winorośli właściwej

PT (português): Folha de videira

RO (română): Frunze de viță-de-vie

SK (slovenčina): List viniča

SL (slovenščina): List vinske trte

SV (svenska): Blad från vinranka

IS (íslenska): Vínviðarlauf

NO (norsk): Rød vinranke, blad

Herbal preparation(s)

Soft extract (2.5-4:1; extraction solvent water)

European Pharmacopoeia monograph reference

Not applicable

Indication(s)

Traditional herbal medicinal product to relieve symptoms of discomfort and heaviness of legs related to minor venous circulatory disturbances.

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

Type of tradition

European

Specified strength

Please see "Specified posology".

Specified posology

Adults and elderly

Soft extract (2.5-4:1; extraction solvent water) in a cream base (10 g contain 282 mg soft extract).

Apply a thin layer on the affected area 1-3 times daily.

The use in children and adolescents under 18 years of age is not recommended (see section "Special warnings and precautions for use").

Route of administration

Cutaneous use.

Duration of use or any restrictions on the duration of use

Adults and elderly

The recommended duration of use is 4 weeks.

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.

Any other information necessary for the safe use

Contraindications

Hypersensitivity to the active substance.

Special warnings and precautions for use

If there is inflammation of the skin, thrombophlebitis or subcutaneous induration, severe pain, ulcers, sudden swelling of one or both legs, cardiac or renal insufficiency, a doctor should be consulted.

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 and adolescents below 18 years of age is not recommended.

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

Contact allergy and/or hypersensitivity reactions of the skin (itching and erythema, urticaria) have been reported. 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.

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) The material complies with the monograph of the Pharmacopée Française X., 1996.'