COMMISSION IMPLEMENTING DECISION (EU) 2016/1658

of 13 September 2016

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(2016) 5747)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard 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 16f thereof,

Having regard to the opinion of the European Medicines Agency, formulated on 25 March 2014 by the Committee for Herbal Medicinal Products,

Whereas:

(1) In 2008 an opinion of the European Medicines Agency established that *Eleutherococcus senticosus* (Rupr. et Maxim) Maxim complied with the requirements set out in Directive 2001/83/EC as a herbal substance, a herbal preparation or a combination thereof within the meaning of that Directive and it was therefore included 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]).

(2) As part of its review of monographs and list entries to keep them relevant, the Committee for Herbal Medicinal Products has reviewed the list entry *Eleutherococcus senticosus* (Rupr. et Maxim) Maxim and adopted an opinion to change the list entry with regard to the name of the herbal substance in certain EU official languages, the phrasing of the herbal preparations, update of the reference to the European Pharmacopoeia and update of some information necessary for the safe use, e.g. revision of the contraindications. Some of those changes are the result of an update of the template for list entries.

(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

Annex II to Decision 2008/911/EC is amended in accordance with the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 13 September 2016.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

([1]) OJ L 311, 28.11.2001, p. 67.
([2]) Commission Decision 2008/911/EC of 21 November 2008 establishing of a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products (OJ L 328, 6.12.2008, p. 42).

ANNEX

In Annex II to Decision 2008/911/EC, the entry *Eleutherococcus Senticosus* (Rupr. et Maxim) Maxim., Radix is amended as follows:

(1) The section 'Common name in all EU official languages of herbal substance' is amended as follows:

(a) After 'FR (français): racine d'éleuthérocoque (racine de ginseng sibérien)' the following is inserted:

'HR (hrvatska): Korijen sibirskog ginsenga'

(b) 'Všehojovcový koreň' related to SK (slovenčina) is replaced by 'Koreň eleuterokoka';

(2) The section 'Herbal preparation(s)' is amended as follows:

(a) 'Comminuted herbal substance for preparation of herbal tea' is replaced by 'Comminuted herbal substance';

(b) 'Liquid extract (1:1, ethanol 30-40 % v/v)' is replaced by 'Liquid extract (DER 1:1, extraction solvent ethanol 30-40 % v/v)';

(c) 'Dry extract (13-25: 1, ethanol 28-40 % v/v)' is replaced by 'Dry extract (DER 13-25:1, extraction solvent ethanol 28-40 % v/v)';

(d) 'Dry aqueous extract (15-17:1)' is replaced by 'Dry aqueous extract (DER 15-17:1)';

(e) 'Tincture (1:5, ethanol 40 % v/v)' is replaced by 'Tincture (ratio of herbal substance to extraction solvent 1:5, extraction solvent ethanol 40 % v/v)';

(3) In the section 'European Pharmacopoeia monograph reference' '6.0' is replaced by '7.0';

(4) In the section 'Type of tradition' 'Chinese, European.' is replaced by 'European, Chinese.';

(5) In the section 'Specified strength' 'Not applicable.' is replaced by 'Please see "Specified posology".';

(6) The section 'Specified posology' is amended as follows:

(a) 'over 12 years of age' is deleted;

(b) 'Daily dose.' is replaced by 'Average daily dose.';

(c) 'The use is not recommended in children under 12 years of age' is replaced by 'The use in children under 12 years of age is not recommended';

(7) The section 'Any other information necessary for the safe use' is amended as follows:

(a) 'Contra-indications' is replaced by 'Contraindication';

(b) The words 'Arterial hypertension.' are deleted;

(c) The sentence 'The use in children under 12 years of age is not recommended because sufficient experience is not available' are replaced by 'The use in children under 12 years of age is not recommended due to lack of adequate data';

(d) After 'If the symptoms worsen during the use of the medicinal product, a doctor or a qualified healthcare practitioner should be consulted.' the sentence 'For tinctures and 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.' is inserted;

(e) The title of subsection 'Pregnancy and lactation' is replaced by 'Fertility, pregnancy and lactation';

After the sentence 'In the absence of sufficient data, the use during pregnancy and lactation is not recommended.' 'No fertility data available.' is inserted;

(f) In subsection 'Undesirable effects' after 'The frequency is not known.' The sentence 'If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.' is inserted;

(g) After subsection 'Overdose' the following subsections are inserted:

'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.'