COMMISSION IMPLEMENTING DECISION (EU) 2022/1316

of 25 July 2022

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(2022) 4341)

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,

Whereas:

(1) *Achillea millefolium* L., herba 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 *Achillea millefolium* L., herba 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

The Decision is addressed to the Member States.

Done at Brussels, 25 July 2022.

For the Commission
Stella KYRIAKIDES
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

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

(1) In Annex I, the following substance is inserted before *Calendula officinalis* L:

'*Achillea millefolium* L., herba (Yarrow)'

(2) In Annex II, the following is inserted before 'COMMUNITY LIST ENTRY ON *CALENDULA OFFICINALIS* L':

'UNION LIST ENTRY ON *ACHILLEA MILLEFOLIUM* L., HERBA

Scientific name of the plant

Achillea millefolium L.

Botanical family

Asteraceae

Herbal substance

Millefolii herba

Common name in all EU official languages of herbal substance

BG (bulgarski): Бял равнец, стрък
CS (čeština): Řebříčková nať
DA (dansk): Røllike
DE (deutsch): Schafgarbenkraut
EL (elliniká): Πόα αχιλλείας
EN (English): yarrow
ES (español): Milenrama, sumidades floridas de
ET (eesti keel): Raudrohuürt
FI (suomi): siankärsämö, verso
FR (français): Achillée millefeuille (parties aériennes d')
GA (Gaeilge): Athair thalún
HR (hrvatski): Stolisnikova zelen
HU (magyar): Közönséges cickafark virágos hajtás
IT (italiano): Achillea millefoglie parti aeree
LT (lietuvių kalba): Kraujažolių žolė
LV (latviešu valoda): Pelašķu laksti
MT (Malti): Ħaxixa tal-morliti
NL (Nederlands): Duizendblad
PL (polski): Ziele krwawnika
PT (português): Milefólio
RO (română): Iarbă de coada şoricelului
SK (slovenčina): Vňať rebríčka
SL (slovenščina): Zel navadnega rmana
SV (svenska): Rölleka, ört
IS (íslenska):
NO (norsk): Ryllik

Herbal preparation(s)

Comminuted herbal substance

Dry extract (DER 6-9:1), extraction solvent water

Dry extract (DER 5-10:1), extraction solvent water

European Pharmacopoeia monograph reference

Yarrow – Millefolii herba (07/2014:1382)

Indications

Indication (1)

Traditional herbal medicinal product used for temporary loss of appetite.

Indication (2)

Traditional herbal medicinal product for the symptomatic treatment of mild, spasmodic gastrointestinal complaints including bloating and flatulence.

Indication (3)

Traditional herbal medicinal product for the symptomatic treatment of minor spasm associated with menstrual periods.

Indication (4)

Traditional herbal medicinal product for treatment of small superficial wounds.

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

Adolescents, adults and elderly

Single dose

Indications (1) and (2)

Herbal tea: 1,5-4 g of the comminuted herbal substance in 150-250 ml of boiling water as a herbal infusion 3-4 times daily between meals.

Daily dose: 4,5 to 16 g

For indication (1), the liquid preparations are to be taken 30 minutes before meals.

Indication (2)

Dry extract (DER 6-9:1), extraction solvent water: 334 mg dry extract 3-4 times daily.

Daily dose: 1,002-1,336 g

Indication (3)

Herbal tea: 1-2 g of the comminuted herbal substance in 250 ml of boiling water as a herbal infusion 2-3 times daily.

Daily dose: 2-6 g

Dry extract (DER 5-10:1), extraction solvent water: 250 mg dry extract 2-3 times daily.

Daily dose: 0,50-0,75 g

Indication (4)

Comminuted herbal substance for infusion preparation for cutaneous use: 3-4 g of the comminuted herbal substance in 250 ml of boiling water 2-3 times daily.

Daily dose: 6-12 g

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

Route of administration

Indications (1), (2) and (3)

Oral use.

Indication (4)

Cutaneous use: to be applied as an impregnated dressing to the affected area.

Duration of use or any restrictions on the duration of use

Indications (1) and (2)

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.

Indications (3) and (4)

If the symptoms persist longer than 1 week 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 substances and to other plants of the *Asteraceae* (*Compositae*) family.

Special warnings and precautions for use

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

Indications (1), (2) and (3)

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

Indication (4)

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

Interactions with other medicinal products and other forms of interaction

None reported.

Fertility, 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.

No fertility data available.

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 of the skin 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

Not applicable

Pharmacological effects or efficacy plausible on the basis of long-standing use and experience.

Not applicable.’