8 July 2020
EMA/HMPC/400955/2020
EMA/HMPC/M/H/0242
Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a European Union herbal monograph on *Tanacetum parthenium* (L.) Schultz Bip., herba

Opinion

The HMPC, in accordance with Article 16h(3) of Directive 2001/83/EC and as set out in the appended assessment report, establishes by a majority of 19 out of 24 votes a revised European Union herbal monograph on *Tanacetum parthenium* (L.) Schultz Bip., herba which is set out in Annex I.

The divergent position is appended to this opinion.

The Norwegian HMPC member agrees with the above-mentioned recommendation of the HMPC.

This opinion is forwarded to Member States and Norway, together with its Annex I and appendices.

The revised European Union herbal monograph and assessment report will be published on the European Medicines Agency website. They replace those adopted on 25 November 2010.

Amsterdam, 8 July 2020

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Annex I: European Union herbal monograph (EMA/HMPC/48715/2017)

Appendix I: Assessment report (EMA/HMPC/48716/2017)

Appendix II: Divergent positions

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reasons:

I do not support the revised Community Monograph for *Tanacetum parthenium* (L.) Schulz Bip., herba

We have concerns regarding the potential safe use of this herbal preparation 'for the prophylaxis of migraine headaches', and in our view this indication is not acceptable for a traditional herbal medicinal product in line with Directive 2004/24/EC. Furthermore, we are concerned that the revised posology recommends that 'the daily dosage of 100 mg may be gradually increased until obtaining an effect…' for a prophylaxis indication. The statement that this preparation 'should only be used after serious conditions have been excluded by a medical doctor' does not correlate with a prophylaxis indication, nor does not it mitigate our concerns regarding the safe use of this herbal preparation. The revised posology implies that self-medication and self-titration is appropriate if headaches are recurring for 2 months with use of this preparation, with which we are not in agreement.

Sheena Kennedy, HMPC member from Ireland

Amsterdam, 8 July 2020

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reasons:

The divergent opinion only concerns dosages >100 mg daily. As concluded in the monograph, traditional experience suggests that feverfew may stimulate menstrual flow and induce abortion. Although not a GLP study, the study by Yao *et al*., 2006 cited in the assessment report on *Tanacetum parthenium* (L.) Schultz Bip., herba (EMA/HMPC/48715/2017) showed signs of reproductive toxicity in rats. Additional non-clinical reproductive toxicity studies or clinical data on pregnant women are considered necessary for a traditional herbal medicinal product application with daily dosage >100 mg, to show that feverfew is not harmful in the specified conditions of use.

Furthermore, the posology for daily dosage 100-600 mg includes the sentence that the daily dose may be increased until obtaining an effect. This is considered not appropriate for a traditional herbal medicinal product and there is a risk that the posology is not sufficiently clear to the patient. Hence, there is a risk that the patient will not be able to use the product for the prophylaxis of migraine headaches in a safe way.

Karin Erika Svedlund, HMPC member from Sweden

Amsterdam, 8 July 2020

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reasons:

I do not agree with the revised monograph on Tanaceti partenii herba, because I have concerns regarding the potential safe use of a daily intake of 600 mg. Also, in my view there is insufficient evidence for the traditional use for a daily dose between 100 mg to 600 mg and a gradually increase of the dose to 600 mg. Therefore, in my view, a daily intake of more than 100 mg is not in line with Directive 2004/24/EC.

Burt H Kroes, HMPC member from Netherlands

Amsterdam, 8 July 2020

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reasons:

The divergent opinion concerns only dosages >100 mg daily.

As concluded in the monograph, traditional experience suggests that feverfew may stimulate menstrual flow and induce abortion. Although not a GLP study, the study by Yao *et al*., 2006 cited in the assessment report on *Tanacetum parthenium* (L.) Schultz Bip., herba (EMA/HMPC/48715/2017) showed signs of reproductive toxicity in rats. Additional non-clinical reproductive toxicity studies or clinical data on pregnant women are considered necessary for a traditional herbal medicinal product application with daily dosage >100 mg, to show that feverfew is not harmful in the specified conditions of use.

Furthermore, the posology presented for the >100 mg daily dosage is considered not to be clear to the patient, nor is the information on the duration of use. In addition, a titration scheme cannot be derived from the long-standing usage data presented in the AR.

Jacqueline Wiesner, HMPC member from Germany

Amsterdam, 8 July 2020

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reasons:

I do not support the proposed herbal monograph on *Tanaceti parthenii* herba because the posology is not clear enough and does not cover adequately the TU.

Barbara Razinger, HMPC member from Slovenia

Amsterdam, 8 July 2020