8 July 2020
EMA/HMPC/358928/2020
Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on European Union herbal monograph on *Tanacetum parthenium* (L.) Schulz Bip., herba (EMA/HMPC/48715/2017)

QUESTION

Do patients consider that the posology and duration of use, as included in section 4.2 of the draft monograph, can be easily understood by patients? If not, any suggestion to reformulate the text in a more patient-friendly way is welcomed.

Table 1: Organisations and/or individuals that commented on the draft European Union herbal monograph on *Tanacetum parthenium* (L.) Schulz Bip., herba as released for public consultation on 15 October 2019 until 15 January 2020.

	Organisations and/or individuals
1	Interested group of patient representative

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Table 2: Discussion of comments

General comments to draft document

Interested party	Comment and Rationale	Outcome
Comment 1 - 7	There is general agreement that the proposed posology can be easily read and understood by patients; however, patient representatives have proposed minor adjustments to the posology and duration of use. The main comments pointed out the need to better clarify to the patient the duration of use of two months and the need to increase the dose gradually.	The following changes are made to the section 4.2 of the monograph based on the comments received. **Adults and Elderly** Single dose: 100 mg of powdered herbal substance once daily or 200 mg of powdered herbal substance three times daily Daily dose: 100 mg–600 mg The daily dosage of 100 mg may be gradually increased until obtaining an effect, not exceeding the daily dose of 600 mg. The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** If migraine headaches recur after using the medicinal product for 2 months (usual period of treatment to obtain an effect), a doctor or a qualified health care practitioner should be consulted.

Specific comments on text

Section number and heading	Comment and Rationale	Outcome
Comment 1	It is suggested to better clarify in section 4.2 why the duration of use of 2 months has been proposed. For duration of use, the sentence could be rewritten as "If migraines recur after using the product for 2 – 3 months (the time often needed to see a change), a doctor or a qualified healthcare practitioner should be consulted." rr something like that. Otherwise, the time of use is hard to understand.	Partially endorsed. The proposed rewording is accepted as is acknowledged the importance to clarify to the patient under "Duration of use" that a period of 2-3 months is necessary to observe a clinical effect for feverfew. The choice to limit the duration of use to 2 months is based on the current version of the monograph. It is supported by products on the market, clinical trials (i.e. Palevich *et al.* 1997), literature (e.g. ABC Cinical Guide 2003) and on safety considerations. It is up to physician the possibility to extend the duration of use further. The sentence under "Duration of use" in section 4.2 of the monograph has been reworded as "*If migraine headaches recur after using the medicinal product for 2 months (usual period of treatment to obtain an effect), a doctor or a qualified healthcare practitioner should be consulted."*
Comment 2	To change in section 4.2 the expression of single dose to "100 mg of powdered herbal substance once daily or 600 mg of powdered herbal substance daily, taken three times per day in dosages of 200 mg each." To change the sentence in section 4.2 to "The daily dose of 100 mg may be increased until obtaining an effect, however not	Not endorsed. The proposed changes are not supported by a clear rationale and are not deemed considerable.

Section number and heading	Comment and Rationale	Outcome
	exceeding the daily dose of 600 mg." With regard to the duration of use, the following text is proposed: "If migraine headaches recur during the use of the medicinal product, a doctor or a qualified healthcare practitioner should be consulted after 2 months of treatment."	
Comment 3	The daily dose of 100 mg may be slowly increased to 600 mg until an effect is obtained. It is important that doses more than 200mg must be taken as divided doses during the day, for example 400mg as 200mg twice per day and 600mg is to be taken as 200mg three times a day. It is important not to exceed the daily dose of 600 mg. If migraine headaches recur during the use of this powdered herbal substance, a doctor or a qualified healthcare practitioner must be consulted after 2 months.	Partially endorsed. It is agreed that the daily dose should be increased gradually to avoid sharp jumps of the dosage. There is no need to point out in the monograph that the dosages of 400 mg and 600 mg should be taken as 200 mg two or three times a day, as the single dose reported in the monograph is 100 mg or 200 mg. The proposed change to the duration of use is not considerable. Based on the comment, the following change has been made in section 4.2 with regard to the posology: *"The daily dose of 100 mg may be gradually increased to 600 mg until an effect is obtained.*
Comment 4	The following change is proposed to single dose in section 4.2: "Single dose: 100 mg of powdered herbal substance once daily up to 200 mg of powdered herbal substance three times daily". This is more consistent with the following information.	Not endorsed. The HMPC decided during the revision process of the monograph to report only the information of single dose based exclusively on the evidence of traditional use. 100 mg daily is the posology reported in the SmPC of

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		products in UK, AT and other countries, whereas 200 mg three times a day is the posology reported in the SmPC of products registered in FR and ES and currently present in food supplements.
Comment 5	A recommendation about how to manage the increasing of the daily dose (e.g. 100mg more each day) is suggested.	Endorsed (see comment 3)
Comment 6	Fully agreed with the text proposed by HMPC.	
Comment 7	Fully agreed with the text proposed by HMPC.	