



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 November 2020
EMA/HMPC/487459/2017
Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on European Union Draft Herbal Monograph on *Species amarae* (EMA/HMPC/44543/2018)

Final

Table 1: Organisations and/or individuals that commented on the draft European Union herbal monograph on *Species amarae* as released for public consultation on 31 May 2020 until 31 August 2020.

	Organisations and/or individuals
1	AESGP - Association of the European Self-Care Industry

Table 2: Discussion of comments

General comments to draft document

Interested party	Comment and Rationale	Outcome

Specific comments on text

Section number and heading	Interested party	Comment and Rationale	Outcome
2. Qualitative and quantitative composition	AESGP	<p>Composition</p> <p>The draft assessment report states that only those herbal substances contained in herbal tea combinations have been considered for which an assessment by the HMPC has already been performed with regard to the indication now proposed in the draft monograph. This concerns e.g., Bitter orange peel (<i>Aurantii amari epicarpium et mesocarpium</i>) and Cinnamon bark (<i>Cinnamomi cortex</i>). These herbal substances were not taken into account in the formulations.</p> <p>As a consequence, the draft table now contains minus variants, which possibly have never been used in the compositions described in the draft monograph. This is contradictory to the collection of formulations initially intended to cover the broadest part of the traditionally used herbal tea combinations as possible.</p>	<p>Not endorsed.</p> <p>HMPC agreed to consider as active partners only herbal substances, for which an EU herbal monograph linked to this therapeutic area (loss of appetite) are already available. The matrix (principle) used in other EU herbal tea combination monographs (e.g. <i>Species diureticae</i>) applying a limit for active partners is not supposed to be exhaustive, but allows to cover a reasonable proportion of the herbal tea combinations in a specific indication with reference to already performed single substance assessments.</p> <p>Additional herbal substances which may be combination partners, but which are not linked to the therapeutic area or are not typical bitter drugs are considered as excipients.</p>

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		<p>In our view, however, this is not convincing since an assessment as a mono-preparation might in any case have no prospect of success if the herbal drug was only or very predominantly used in herbal tea combinations rather than as a single herbal medicinal product. (For both cinnamon bark and bitter orange peel this is the expected outcome as regards their use in the form of an infusion).</p> <p>We therefore strongly advocate to adopt the clearly tradition-based formulation as provided for in Magentee I (German Standardzulassung) without deletion of Bitter orange peel (Aurantii amari epicarpium et mesocarpium) and Cinnamon bark (Cinnamomi cortex).</p> <p>Worth of note, "loss of appetite", the proposed however disputed (see below) indication of the combination monograph, is mentioned as an indication in the HMPC assessment report for the monograph "cinnamon bark".</p> <p>Excipients</p> <p>As already stated in the draft monograph, further herbal substances may be added as excipients, and their number, amount and function should be justified. We are of the opinion that particularly in case of combinations of bitter substances, this option is of high relevance in order to mitigate the bitter taste of this tea combination.</p>	For better understanding how to use herbal tea combination monographs an explanatory section has been added to the introduction of the assessment report.
4. Clinical particularities: 4.1 Therapeutic	AESGP	The traditional indication of the monograph is 'used for temporary loss of appetite'. To our opinion, this indication is almost identical with the claim of an "aperitif" or "appetizer"	Not endorsed. The wording of the indication corresponds to the

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indications		<p>commonly used by healthy populations before meals.</p> <p>From our point of view, an important goal of THMP monographs should be to formulate clear, disease-related indications in order to differentiate with products in other legal categories. Otherwise, in the European market a differentiation between herbal food supplements (botanicals) and THMPs is impossible. The consequence would be a deception of consumers by similar labelling of two groups of basically different products which are used in the healthy or the ill population, respectively.</p> <p>The draft monograph "Species amarae" should therefore contain clear-cut medicinal indications derived from the traditional use as "stomachic" as documented in herbal textbooks, e.g. "Herbal substances with bitter principles are used as stomachic for gastric complaints like stomach pressure, flatulence and bloating, loss on appetite by subacidity and general discomfort".</p> <p>We therefore suggest taking over this or a correspondent wording for the indication of "Species amarae" in order to differentiate the indication from health claims of bitter drinks.</p>	<p>wording of the already approved monographs.</p> <p>For Species digestivae (stomachiae) another European Union herbal monograph is in preparation.</p>