



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 November 2020
EMA/HMPC/483757/2020
Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on European Union Draft Herbal Monograph on *Species sedativae* (EMA/HMPC/438183/2017) Final

Table 1: Organisations and/or individuals that commented on the draft European Union herbal monograph on *Species sedativae* as released for public consultation on 29 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
	none	

Specific comments on text

Section number and heading	Interested party	Comment and Rationale	Outcome
2. Qualitative and quantitative composition	AESGP	<p><u>Composition</u></p> <p>The Assessment Report states that herbal preparations which are not linked to the therapeutic area in the corresponding HMPC monograph have not been considered in this assessment report after internal discussion at the MLWP and with reference to Article 16a of Directive 2001/83/EC as amended (traditional use), stipulating that the pharmacological effects or efficacy of the medicinal product shall be plausible on the basis of long-standing use and experience.</p> <p>In our view, however, this is not a sufficient justification, 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 in this specific indication.</p> <p>Peppermint leaves are used as active substance at least in</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 (relief of mild symptoms of mental stress and to aid sleep) is developed. This matrix (principle) used in other EU herbal tea combination monographs (e.g. <i>Species diureticae</i>) applying a limit of 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>Only herbal substances linked to the therapeutic area (Traditional herbal medicinal product for relief of mild</p>

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		<p>Beruhigungstee I, III, V, VI and VII (German Standardzulassung). Therefore, the use of Peppermint leaves in the respective herbal tea combinations is clearly “traditional” by the standards of the legislation traditionally proven and it is plausible on the basis of long-standing use and experience.</p> <p>We therefore advocate to adopt the formulations as provided for in Beruhigungstee I, III, V, VI and VII (German Standardzulassung), correctly and consequently considering peppermint leaves (<i>Menthae piperitae folium</i>) as active substance instead of excipient.</p> <p><u>Number of active substances</u></p> <p>The number of active substances refers to 3 or 4. However, according to Art. 16c 3. Dir. 2001/83/EC the option of only 2 active substances should also be possible: <i>“The requirement to show medicinal use throughout the period of 30 years, referred to in paragraph 1(c), is satisfied even where the marketing of the product has not been based on a specific authorisation. It is likewise satisfied if the number or quantity of ingredients of the medicinal product has been reduced during that period.”</i></p> <p><u>Footnote 4</u></p> <p>The footnote is not explained below the table.</p>	<p>symptoms of mental stress and to aid sleep) are included in the EU herbal monograph on <i>Species sedativae</i> and corresponding assessment report.</p> <p>Additional herbal substances which may be combination partners but which are not linked to the therapeutic area or which are not considered typical combination partners of traditional <i>Specie sedativae</i> mixtures are considered as excipients.</p> <p>For better understanding how to use herbal tea combination monographs an explanatory section has been added to the introduction of the assessment report.</p> <p>Endorsed</p> <p>Based on data obtained from marketed medicinal products, historical data and the literature references, HMPC agreed to limit the number of active substances in an herbal tea combination (<i>Species sedativae</i>) to a maximum of 4.</p> <p>Endorsed</p> <p>The footnote will be deleted.</p>
4. Clinical particularities:	AESGP	The traditional indication of the monograph is “relief of mild symptoms of mental stress and to aid sleep”. This indication is	<p>Not endorsed</p> <p>The wording of the indication corresponds to the</p>

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4.1 Therapeutic indications		<p>close to health claims like “contribution to normal mental or psychological function” as commonly used for vitamins and minerals in healthy populations.</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 “<i>Species sedativae</i>” should therefore contain clear-cut medicinal indications derived from the HMPC draft Assessment Report (EMA/HMPC/438185/2017) on page 12:</p> <p>“In summary it can be stated, that the main ingredients of the herbal tea combinations indicated as sedative are the following herbal substances: <i>Valerianae radix</i>, <i>Lupuli flos</i>, <i>Lavandulae flos</i>, <i>Melissae folium</i>, and <i>Passiflorae herba</i>.”</p> <p>The term “Sedative” refers to a medicine that acts on the central nervous system. Correspondent wordings are found in the draft Assessment Report (draft) for the labelling of these products such as “relief of restlessness, nervous exhaustion, sleep disturbances”.</p> <p>We therefore suggest taking over this or a correspondent wording for the indication of “<i>Species sedativae</i>” in order to</p>	wording of the already approved monographs, e.g. on <i>Valeriana officinalis</i> L., radix, and is appropriate for a traditional herbal medicinal product (such as <i>Species sedativae</i>) which is intended to be used without the supervision of a medical practitioner.

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		differentiate the indication from health claims.	
4. Clinical particularities: 4.2. Posology	AESGP	<p>The proposed daily dose of 2 to 4 g of the herbal tea combination 3 to 4 four times daily is rather high. With regard to the individual dosage of sleep and nerve teas, we suggest a range starting from 1.20 g for the individual dosage.</p> <p>As evidence for this determination, the bulk density of "concis" teas and the weight per tablespoon calculated from it (according to German Standardzulassung) as well as common tea bag fillings of traditional tea products on the German market can be used.</p> <p>a) Bulk density calculation</p> <p>The following bulk density ranges were determined and specified for different concis-cut medicinal teas (German Standardzulassung) (company data of Bad Heilbrunner Naturheilmittel GmbH & Co. KG).</p> <p>For blends with an increased proportion of components with a relatively low bulk density (including lavender flowers, hops) a significantly lower weight than 2.0 g per tablespoon should be considered.</p> <p>Calming Tea IV (Zul.-Nr. 1949.93.99)</p> <p>Active ingredients:</p> <p>30% Valerian root</p> <p>25% Lemon balm leaves</p>	<p>Partly endorsed</p> <p>Based on the information from marketed products the single dose of herbal tea combinations is mainly in the range of 1.5 to 4 g (see assessment report: posology). Therefore, the single dose of 1.5 to 4 g will be included in the EU herbal monograph.</p>

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		<p>20% Passionflower herb</p> <p>10% Peppermint leaves</p> <p>Other components:</p> <p>5% Chamomile flowers</p> <p>5% Yarrow herb</p> <p>5% liquorice root</p> <p>Bulk density 65 - 85 g / 500 ml</p> <p>At a bulk density of 65 - 85 g / 500 ml, a tablespoon (15 ml) corresponds to a single dose of 1.95 - 2.55 g</p> <p>Calming tea VII (Zul.-Nr. 1949.96.99)</p> <p>Active ingredients:</p> <p>50% Lemon balm leaves</p> <p>50% Lavender flowers</p> <p>25% Hop strobiles</p> <p>Other components:</p> <p>5% Fennel</p> <p>5% Rosemary</p> <p>5% Liquorice root</p> <p>Bulk density 40 - 80 g / 500 ml</p>	

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		<p>At a bulk density of 40 - 80 g / 500 ml, a tablespoon (15 ml) corresponds to a single dose of 1.20 - 2.40 g</p> <p>b) Product examples</p> <p>In Germany, various sleep and nerve teas with a lower individual dose than 2.0 g are available on the market (examples):</p> <ul style="list-style-type: none"> • Bad Heilbrunner sleep and nerve tea (Zul.-Nr. 6297276.00.00): 1.75 g per filter bag, 2 cups 2 times daily • Bombastus calming tea (Zul.-Nr. 1949.95.99): 1.3 g per filter bag, 1 cup 2 to 3 times a day • elkos VIVEDE Sleep & Nerve Tea (Zul.-Nr. 1949.93.99): 1.75 g per filter bag, 1 cup 2 to 3 times a day • Kneipp nerve and sleep tea (Zul.-Nr. 1949.97.99): 1.8 g per filter bag, 1 cup 2 to 3 times a day 	