



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 May 2024
EMA/HMPC/322623/2023
Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on European Union herbal monograph on *Rosmarinus officinalis* L., aetheroleum (EMA/HMPC/513893/2021)

Table 1: Organisations and/or individuals that commented on the draft European Union herbal monograph on *Rosmarinus officinalis* L., aetheroleum as released for public consultation on 15 December 2022 until 15 March 2023.

	Organisations and/or individuals
1	Retterspitz GmbH & Co. KG, Laufer Str. 17 -19, 90571 Schwaig, Germany Ms. Dr. Nicole Schuster (Head of Regulatory Affairs)

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Table 2: Discussion of comments

General comments to draft document

Interested party	Comment and Rationale	Outcome
Retterspitz GmbH & Co. KG	<p>1. Deletion of the liquid dosage form for cutaneous use</p> <p>Retterspitz has registered three traditional herbal medicinal products containing rosemary oil as active substance in Austria (national registrations, see attached overview-document, export of Austrian Portal):</p> <ol style="list-style-type: none"> 1. a liquid suspension (0.1 % rosemary oil, registered in 2010): A cloth (e.g. linen/cotton) is soaked with the suspension and wrapped around the skin. Soaking is only possible with a liquid form. 2. a semi-solid cream (2 % rosemary oil, registered in 2015) 3. a liquid emulsion (2 % rosemary oil, registered in 2015): A roll-on-bottle containing the emulsion is applied directly on the skin - only a liquid may pass the roll-on-ball. <p>The cream and emulsion contain 2 APIs (2 % rosemary oil and 5 % arnica tincture) and were not listed in the assessment report of the new revision 1 (2.1.1., page 7-8). The indication for cream and emulsion is the same:</p> <p><i>German (as in SmPC):</i> „Zur schmerzstillenden Anwendung bei Muskelschmerz, Gelenkentzündungen und zur Kreislaufanregung.“</p> <p>English self-translation: “For relief of muscular and articular pain and circulatory stimulation.”</p> <p>Retterspitz kindly asks to keep the “liquid dosage form for cutaneous use” as official pharmaceutical form in the HMPC herbal monograph, as it already has been part of the document since version 1 from 2010. The deletion of the liquid form was justified in the assessment report (p. 12) due to the exclusion of the respective data in the French Pharmacopoeia. However, the German</p>	<p>1. Dosage form</p> <p>Not endorsed.</p> <p>In the original AR and MO, the liquid dosage form was included based on the reference from the Ph Fr: Cutaneous use as Antiseptic and wound healing, Alcoholic solution 2% V/V, 1980.</p> <p>During the revision, it was proposed to eliminate this reference because it had been deleted and there were no products in the market.</p> <p>Other references (Paris and Mouse, 1971 and others included in ESCOP, 1997) include the cutaneous use of alcoholic solution 2% V/V of the essential oil as antiseptic.</p> <p>The product (liquid suspension, concentration of 0.1% V/V rosemary oil) on the Austrian market has been registered as a THMP in 2010; however, the product-specific data supporting the evidence of traditional use are not publicly available and the product in its current composition has not yet been on the market for 30/15 years. Therefore, at the moment, the product will not be considered for assessment and inclusion in the monograph.</p>

Interested party	Comment and Rationale	Outcome
	<p>Comments on the European Pharmacopeia ("Arzneibuchkommentar", 2013, Ph.Eur. 7.0/1846, attached as pdf to this comment) emphasises "Einreibung (= embrocation)" without definition of a specific dosage form. Considering the facts, that our medicinal products are well established and with long traditional use, we are of the opinion, that medicinal products for cutaneous use could be applied on the skin not only as semi-solid cream, but also as liquid pharmaceutical forms (e.g. an emulsion as well as a suspension). Thus, we encourage the HMPC to keep the liquid dosage forms in the herbal monograph of rosemary oil.</p> <p>2. Posology</p> <p>Currently, the concentration of a cutaneous dosage form is set to 6 – 10 % rosemary oil.</p> <p>Our before mentioned medicinal products, our cream and our emulsion, both contain 2 % rosemary oil as API (see point 1) and have a well-established history of traditional use. We would like to encourage the HMPC to widen the posology from currently 6 -10 % up to 2 – 10 %.</p>	<p>2. Posology</p> <p>Not endorsed</p> <p>The medicinal products provided by the interested parties are both combination products containing 2% rosemary oil and 5% arnica tincture as semi-solid cream or liquid emulsion (since 2015), for relief of muscular and articular pain and circulatory stimulation. Thus, these products do not prove the period of traditional use of Rosemary oil for the above cited posology.</p>

Specific comments on text

Section number and heading	Interested party	Comment and Rationale	Outcome
3. Pharmaceutical form	1	<p>Herbal preparations in semi-solid dosage <u>and liquid</u> forms for cutaneous use.</p> <p>The pharmaceutical form should be described by the European</p>	<p>Not endorsed.</p> <p>See above.</p>

Section number and heading	Interested party	Comment and Rationale	Outcome
		Pharmacopoeia full standard term.	
4.2 Posology	1	<p><u>2 -10 %</u> in semi-solid dosage <u>and liquid</u> dosage forms, 2-3 times daily.</p> <p>The use in children and adolescents under 18 years of age is not recommended (see section 4.4 "Special warnings and precautions for use").</p> <p>Duration of use</p> <p>If the symptoms persist longer than 4 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Method of administration</p> <p>Cutaneous use.</p>	Not endorsed. See above.