



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 July 2010
EMA/HMPC/254083/2010
Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on Community herbal monograph on *Rosmarinus officinalis* L., aetheroleum (EMA/HMPC/235453/2009)

Table 1: Organisations and/or individuals that commented on the draft Community herbal monograph on *Rosmarinus officinalis* L., aetheroleum as released for public consultation on 16 July 2009 until 15 December 2009.

	Organisations and/or individuals
1	The Association of the European Self-Medication Industry (AESGP)



Table 2: Discussion of comments

SPECIFIC COMMENTS ON TEXT			
Section number and heading	Interested party	Comment and Rationale	Outcome
<p>4. CLINICAL PARTICULARS</p> <p>4.1. Therapeutic indications</p>	AESGP	<p>Rosemary oil has also been traditionally used to increase the peripheral blood circulation and as an adjuvant therapy in rheumatic conditions and for the improvement of the peripheral blood circulation. Indeed the following rosemary essential oil-containing medicinal products have been registered with this indication in Europe: oil for bath milk –Zulassungsnummer 6633805.00.00 and oil – Zulassungsnummer 6636979.00.00). Further, the ESCOP mentions the use of rosemary folium cum flore (“containing not less than 1.5% V/m of volatile oil”) in rheumatic conditions and peripheral circulatory disorders.</p> <p>Proposed change: Modification to indication 2 as follows: “2. “traditional herbal medicinal product used in peripheral circulatory disorders and as adjuvant in the relief of minor muscle and articular pain or in rheumatic conditions”</p> <p>Comments: Rosemary oil is the active ingredient of the medicinal product “Retterspitz Äußerlich T” which has been marketed for over 30 years in Germany with the indications: <i>“Traditionelles pflanzliches Arzneimittel zur Anwendung bei leichten Entzündungen der Haut, bei kleineren, geschlossenen, oberflächlichen Wunden sowie bei Verletzungsfolgen wie Zerrungen.”</i> (<i>Traditional herbal medicinal product for use in case of minor inflammations of the skin, smaller, closed, superficial wounds and for conditions after injuries such as muscle strains.</i>) In addition a registration procedure as a</p>	<p>The indication “minor peripheral circulatory disorders” is endorsed.</p> <p>The preparations mentioned are included in the monograph.</p> <p>The medicinal product “Retterspitz Äußerlich T” is marketed in Germany as a chemical product. Rosmary oil is there as an excipient and not as an active substance.</p>

SPECIFIC COMMENTS ON TEXT			
		<p>traditional herbal medicinal product in Austria is on-going; however the traditional use has already been accepted and the indication was formulated according to the requirements of the Austrian authority (approved leaflet attached). The plausibility of efficacy is justified by literature and long-standing use (cf. attachment).</p> <p>Proposed change (if any): <u>Cutaneous use</u> We suggest adding: 3. Traditional herbal medicinal product for use in case of minor inflammations of the skin, smaller, closed, superficial wounds and for conditions after injuries such as muscle strains.</p>	<p>In the French publication - <i>Pharmacopée Française - Préparation Officinale, 1980 (Romarin)</i>, the alcoholic solution 2% V/V essential oil is indicated for wound healing and as an antiseptic.</p> <p>However, the essential oil is a rubefacient and should not be used in cases of inflammation of the skin. As the requirement for safety data related to the use of the essential oil in these conditions is not fulfilled, this indication is not endorsed.</p>
4. CLINICAL PARTICULARS 4.2. Posology and method of administration		<p><u>Cutaneous use</u></p> <p>Posology <u>Indication 2)</u></p> <p>The restrictions of use in children are not justified by the long term traditional use (over 30 years) and the toxicological data available (cf. ESCOP monograph). These medicines are contra-indicated for children under 3 years old. Hence a limitation to children over 12 years is proposed.</p> <p>Proposed change: <u>Indication 2)</u> "the use in children and adolescent under 18</p>	<p>Not endorsed, as there are no adequate data/safety data on the use of the essential oil in adolescents and children.</p>

SPECIFIC COMMENTS ON TEXT			
		<p>12 years of age is not recommended”.</p> <p>Proposed change (if any):</p> <p>As a consequence of the above suggested modification under 4.1, we propose to add to the Community herbal monograph the following on posology and duration of use:</p> <p><u>Indication 3)</u></p> <p>Adults, adolescents and children over 12 years</p> <p>0.1% in liquid dosage form</p> <p>Pure or diluted in water as wet-pack or overlay, 1-3 times daily</p> <p>Duration of use:</p> <p><u>Indication 3)</u></p> <p>If symptoms persist longer than 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted (see section 4.4, Special warnings and precautions for use’).</p>	<p>The proposed indication is not endorsed.</p> <p>Also, evidence of 30 years of use related to this posology and strength was not sent. The Pharmacopée Française - Préparation Officinale, 1980 (Romarin) and also the ESCOP monograph refer to an alcoholic solution 2% V/V essential oil.</p>
4.3 Contraindications		<p>Proposed change (if any):</p> <p>As a consequence of the above suggested modification, we propose to add to the Community herbal monograph the following to “contraindications”:</p> <p>Proposed change (if any):</p> <p><u>Cutaneous use</u></p> <p><u>Indication 3)</u></p> <p>Not to be used in cases of open wounds and near mucous membranes.</p> <p>This is in line with the text accepted for the above referred product.</p>	<p>The proposed indication is not endorsed.</p>
4.4 Special warnings and precautions for		<p>Proposed change (if any):</p> <p><u>Cutaneous use</u></p> <p><u>Indication 2)</u></p>	<p>The warning ‘Articular pain accompanied by swelling of</p>

SPECIFIC COMMENTS ON TEXT

use	<p>In case of acute rheuma symptoms, for instance wit reddening, swelling or heating of the articulations, as well as in cases of unexpected disorders, consult a doctor or a qualified health care practitioner. This is in accordance with the texts accepted for registered products containing rosemary essential oil.</p> <p>Indication 3)</p> <p>Avoid contact with the eyes. Not to be used near mucous membranes.</p> <p>If symptoms persist longer than 1 week during the use of the medicinal product or if fever, changes of the skin, purulent surface on the wound or a rash occur, a doctor or a qualified health care practitioner should be consulted.</p> <p>This is in accordance with the texts accepted for the above-mentioned product. („Bei Beschwerden, die länger als 1 Woche andauern, bei Auftreten von Fieber, bei Hautveränderungen, bei Bildung von eitrigen Belägen auf der Wunde oder bei Bildung von roten Strängen ist ein Arzt aufzusuchen.“)</p>	<p>joint, redness or fever should be examined by a doctor' is already mentioned.</p> <p>The warning to avoid contact with the eyes and use near mucous membranes is accepted.</p>
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