



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/HMPC/254082/2010
Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on Community herbal monograph on *Rosmarinus officinalis* L., folium (EMA/HMPC/13633/2009)

This document was valid from 15 July 2010 until 29 May 20204.

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

	Organisations and/or individuals
1	The European Scientific Cooperative on Phytotherapy (ESCOP)
2	Dr Václav Bažata, Industrial Pharmacist



Table 2: Discussion of comments

SPECIFIC COMMENTS ON TEXT			
Section number and heading	Interested party	Comment and Rationale	Outcome
2. QUALITATIVE AND QUANTITATIVE COMPOSITION	ESCOP	Proposed change: To be added under ii) Herbal preparations: Liquid extract (1:1, 45% ethanol V/V) Tincture (1:5, 70% ethanol V/V) Comments: Other galenical preparations are described in the literature beside 'rosemary wine'. In accordance with the ESCOP Monograph "Rosmarini folium", the use of these two proposed herbal preparations is listed into different handbooks. The liquid extract (1:1, 45% ethanol V/V) has also been described in the British Herbal Pharmacopoeia 1983 (Rosmarinus) and the French Pharmacopoeia, 9th ed., Fiches de Pratiques Officinale, 1980 (Romarin).	Endorsed. The liquid extract 1:1 in 45% ethanol V/V is mentioned in the British Herbal Pharmacopoeia 1979 (Rosmarinus). According to the French Pharmacopoeia 9th ed., Fiches de Pratique Officinale, 1980 (Romarin), there is no indication about the type of liquid extract used.
3. PHARMACEUTICAL FORM	ESCOP	Proposed change: Herbal preparations in solid or liquid dosage forms for oral use. Herbal preparations in liquid or semi-solid dosage forms for cutaneous use. Comments: Based on herbal preparations listed under '2. QUALITATIVE AND QUANTITATIVE COMPOSITION' and '4.2. Posology and method of administration', only herbal preparations in liquid dosage forms should be described under "3".	Endorsed for the use as bath additive. There are products on the market in solid dosage forms for oral use.
4. CLINICAL PARTICULARS 4.1. Therapeutic	Dr Bažata	The wording of Therapeutic indications in Community Herbal Monographs is generally too soft in case of Traditional use to distinguish it from herbal non-medicinal products Indication is not reflecting the totality of evidence, f.i. ESCOP	Not endorsed. The therapeutic indication is directed to the symptoms based on the traditional use and with plausibility and not to the pharmacological action.

SPECIFIC COMMENTS ON TEXT			
indications		Monograph ROSMARINI FOLIUM , where is given at heading Therapeutic indications : Improvement of hepatic and biliary function and in dyspeptic complaints (EMA draft of Herbal Monograph is mentioning only <u>„Oral use</u> Traditional herbal medicinal product for symptomatic relief of dyspepsia and mild spasmodic disorders of the gastrointestinal tract“, despite in Inventory of herbal substances for assessment – Alphabetical order , Doc.Ref.EMA/HMPC/494079/2007 are ESCOP herbal monograph on Rosmarini folium 1560/5 listed on page 12) Proposed change (if any): To include “Improvement of hepatic and biliary function, with deleting the words “Traditional herbal medicinal product” as redundant (given in disclaimer of each THMP label)	
4. CLINICAL PARTICULARS 4.2. Posology and method of administration	ESCOP	Proposed change: Indication 1) <u>Oral use</u> a. Herbal substance as herbal tea preparation”: the “daily dose: 2-6 g” should be replaced by the “daily dose: 4-6 g” based on single dose given just below. e. Liquid extract (1:1, 45% ethanol V/V): 1.5-3 ml daily. f. Tincture (1:5, 70% ethanol V/V): 3-8.5 ml daily. Comments: In accordance with the ESCOP Monograph “Rosmarini folium”, oral use of liquid extract and tincture has been reported in different handbooks with dosages described above.	According to the British Herbal Pharmacopoeia 1979 (Rosmarinus), the proposed dosage of the liquid extract is 2-4 ml. The dosage for the herbal tea has been corrected to 1-2 g, 2-3 times daily.
4. CLINICAL PARTICULARS 4.2. Posology	Dr Bazata	Policy of precautionary principle to exclude all children bellow age of 12 years of age in Posology without any justification or only “lack of data” substantiation is dubious and may be	Not endorsed. The explanation is on the “Special warnings and precautions for use”. The safety is not related only with the lack of data but also because

SPECIFIC COMMENTS ON TEXT			
and method of administration		harmful to SME businesses	medical advice should be sought in ages below 12 years.