EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 May 2010
EMA/HMPC/5687/2010
Committee on Herbal Medicinal Products (HMPC)

This document was valid from 6 May 2010 until 19 September 2017.

Overview of comments received on Community herbal monograph on *Ribes nigrum* L., folium (EMEA/HMPC/142986/2009)

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

	Organisations and/or individuals
1	ESCOP (European Scientific Cooperative on Phytotherapy), Argyle House, Gandy Street, Exeter, Devon EX4 3LS, United Kingdom

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Table 2: Discussion of comments

GENERAL COMMENTS		
Interested party	**Comment and Rationale**	**Outcome**
ESCOP	ESCOP appreciates the draft for a Community Herbal Monograph on "blackcurrant leaf" prepared by the Committee on Herbal Medicinal products (HMPC). However, we consider the following modification necessary.	

SPECIFIC COMMENTS ON TEXT			
Section number and heading	**Interested party**	**Comment and Rationale**	**Outcome**
4. CLINICAL PARTICULARS **4.2. Posology and method of administration**	ESCOP	**Proposed change:** We propose to change "The herbal substance is traditionally used over a period of 2 (indication 1) to 4 weeks (indication 2)" into **"Indication 1) Not to be taken for more than 4 weeks" and "Indication 2) The herbal substance is traditionally used over a period of 4 weeks".** **Comments:** According to ESCOP Monograph, no restriction of duration of administration of blackcurrant leaf preparations is justified when used as an adjuvant in the treatment of rheumatic conditions, based on available literature. According to the recommendation made in other HMPC Monographs with an identical indication 'traditional herbal medicinal product for the relief of minor articular pain' (i.e. Devil's claw root, Nettle herb, Willow bark), the duration of use is 'not to take the product for more than 4 weeks'. Indeed, this duration is more appropriate than a period of 2 weeks to benefit usual gradual and	**Partially endorsed: the periods of use are 4 weeks (indication 1 or a) and 2 weeks (indication 2 or b).** There seems to be a cross-over in the proposal. Indication 1) or indication a) in the monograph is: … *Traditional herbal medicinal product for relief of minor articular pain …* For this indication a period of 4 weeks is accepted formulated as follows: *… The herbal substance is traditionally used over a period of 4 weeks…* ESCOP refers correctly to the monographs of *Harpagophyti radix, Urticae herba* and *Salicis cortex*. Indication 2) or indication b) in the monograph is: … *Traditional herbal medicinal product to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints …* For this indication a period of 2 weeks is accepted. The

SPECIFIC COMMENTS ON TEXT			
		progressive onset of effects for the relief of minor articular pain.	most recently accepted monograph is the one on *Juniperi pseudo-fructus.* It is formulated as follows: *… If symptoms persist after 2 weeks during the use of the medicinal product, a doctor or a qualified health-care practitioner should be consulted …* This formulation is in accordance with *Orthosphoni folium*, another monograph under preparation.
4. CLINICAL PARTICULARS **4.3. Contraindications**	ESCOP	**Proposed change:** We propose to change "Oedema due to limited heart or kidney function" into **"Condition where a reduced fluid intake is recommended (e.g. severe cardiac or renal disease)"** **Comments:** Based on the wording of the contraindication made in different finalized HMPC Monographs having the indication 'traditional herbal medicinal product to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints' (i.e. Birch leaf, Goldenrod, Horsetail herb, Nettle herb), it may be preferable to replace 'oedema due to limited heart or kidney function' by the contraindication mentioned in the cited HMPC Monographs.	**Endorsed.** ESCOP correctly refers to the formulation used in the cited monographs. There is no urgent reason to change the formulation. The formulation: *… Condition were a reduced fluid intake is recommended (e.g. severe cardiac or renal disease) …* is inserted under 4.3.