



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 September 2010
EMA/HMPC/559432/2010
Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on Community herbal monograph on *Arctium lappa* L., radix (EMA/HMPC/246763/2009)

Table 1: Organisations and/or individuals that commented on the draft Community herbal monograph on *Arctium lappa* L., radix as released for public consultation on 15 February 2010 until 15 June 2010.

	Organisations and/or individuals
1	AESGP



Table 2: Discussion of comments

GENERAL COMMENTS		
Interested party	Comment and Rationale	Outcome
AESGP	AESGP welcomes the preparation of the above-mentioned Community herbal monograph which should facilitate mutual recognition in Europe by harmonising the assessment criteria.	

SPECIFIC COMMENTS ON TEXT			
Section number and heading	Interested party	Comment and Rationale	Outcome
4.1. Therapeutic indications	AESGP	<p>Comments:</p> <p><i>Arctii radix</i> has long been considered to be useful, internally or externally, in the treatment of skin disease [MOCKLE, 1960 quoted by BRADLEY, 1992; GARNIER, 1961; BEZANGER-BEAUQUESNE, 1980] notably in case of acne [VAN HELLEMONT, 1986].</p> <p>The herbal drug was the subject of a monograph in the British Herbal Pharmacopoeia published in 1976. This monograph mentioned the traditional use of <i>Arctii radix</i> in 'cutaneous eruptions'.</p> <p>The traditional use of <i>Arctii radix</i> "in the seborrheic conditions of the skin" has been endorsed by the French Authorities since</p>	<p>There is indeed a long-standing tradition for use in dermatological conditions.</p> <p>The ICD-10 terminology uses 'Seborrhoeic dermatitis'.</p> <p>The proposal made by AESGP has been discussed and compared with the ICD-10 wording considering also the essential conditions to accept the indication such as posology for a well-defined preparation.</p> <p>Bradley (1992) refers to Mockle et al. (1960) and displays a distinct posology of well-defined preparations. Information is also given in the BHP.</p> <p>Endorsed. Traditional herbal medicinal product used in seborrhoeic skin conditions.</p>

SPECIFIC COMMENTS ON TEXT			
		1998, and also previously since 1990 under a different wording, i.e., "in cases of mild acne" [Bulletin Officiel N°90/22 bis, Direction de la Pharmacie et du Médicament].	