EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 March 2014
EMA/HMPC/32373/2014
Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on Community herbal monograph on *Eucalyptus globulus* Labill., *Eucalyptus polybractea* R.T. Baker and/or *Eucalyptus smithii* R.T. Baker, aetheroleum (EMA/HMPC/307781/2012)

Final

Table 1: Organisations and/or individuals that commented on the draft Community herbal monograph on *Eucalyptus globulus* Labill., *Eucalyptus polybractea* R.T. Baker and/or *Eucalyptus smithii* R.T. Baker, aetheroleum as released for public consultation on 14 May 2013 until 15 November 2013.

	Organisations and/or individuals
1	Dianthus Medical Limited, London, United Kingdom
2	European Botanical Forum (EBF)

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Table 2: Discussion of comments

General comments to draft document

Interested party	Comment and Rationale	Outcome
AJ, Dianthus	I realise that you are only following the rules and that there is probably little you can do about this comment, but I find it unfortunate that you are prepared to license a product on the basis of "traditional use" in the absence of evidence about efficacy and safety. This is likely to mislead the public, who will often believe that a "licensed product" has been through some kind of testing. At the very least, I would urge you to conduct research into how common it is for members of the general public (or even healthcare professionals: I have heard anecdotally that some pharmacists are confused about traditional use licenses) to assume that herbal products licensed on the basis of traditional use are proven to be effective.	It should be taken into account that EU-Legislation (Directive 2001/83) is differentiating between marketing authorisation (e. g. for herbal medicinal products with well-established use) and registration (for traditional herbal medicinal products). The legislation also demands a specific labeling for traditional herbal medicinal products which is clearly stating that the indication is traditional and based on long-standing use.

SPECIFIC COMMENTS ON TEXT

Section number and heading	Interested party	Comment and Rationale	Outcome
4. Clinical particulars **4.1. Therapeutic indications**	EBF	Indication 1) Traditional herbal medicinal product used for relief of cough associated with cold. *It is proposed to be ammended as follows:* **Traditional herbal medicinal product used for relief of cough and catarrh associated with cold.** Reference from ESCOP Monographs, EUCALYPTI AETHEROLEUM	Not endorsed. The wording has been elaborated based on all existing information and also, as far as appropriate, taking into account consistency with other monographs with indications for this therapeutic area.

Section number and heading	Interested party	Comment and Rationale	Outcome
		book chapter, page 150, 2nd Edition, year of publication 2003 (copy of the cited reference enclosed)	
4.8 Undesirable effects	AJ, Dianthus	The draft monograph says “None known”. This is simply wrong. Adverse events of eucalyptus oil are well known in the literature. Please see attached case report by Patel & Wiggins for just one example. Please note that this is just one example. A thorough literature search would doubtless reveal many more examples of the harms of eucalyptus oil.	Not endorsed. Patel & Wiggins and several other publications regarding the safety have already been cited and considered in the AR (section 5). Intoxications have been described in literature, therefore special warning and contraindications have been worded in the monograph in accordance with other monographs. Side effects have been reported in literature, have only been described in case of accidental overdoses, highly exceeding the traditional posology. The monograph is describing an appropriate short-term use and is differentiating with respect to route of application and different patient groups. Regarding reported overdose in literature, section 4.9 is now given in accordance with other monographs of essential oils as follows: • Cutaneous use Accidental overdose may cause skin irritation. •Inhalation No case of overdose has been reported. • Oromucosal use Accidental overdose may cause gastro-intestinal symptoms, vomiting, diarrhoea, nausea, loss of consciousness, apnoea, respiratory problems, tachypnea, ataxia and other CNS problems, dilated or constricted pupils.