



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 March 2012
EMA/HMPC/729132/2011
Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on the draft Community herbal monograph on *Echinacea angustifolia* DC., radix (EMA/HMPC/688216/2008)

Table 1: Organisations and/or individuals that commented on the draft Community herbal monograph on *Echinacea angustifolia* DC., radix as released for public consultation on 31 March 2011 until 15 August 2011.

	Organisations and/or individuals
1	European Scientific Cooperative on Phytotherapy (ESCOP)
2	European Botanical Forum (EBF)



Table 2: Discussion of comments

General comments to draft document

Interested party	Comment and Rationale	Outcome
ESCOP	ESCOP welcomes the draft Community herbal monograph on narrow-leaved coneflower root prepared by the Committee on Herbal Medicinal Products (HMPC). ESCOP would like to comment on one particular issue of this monograph.	
EBF	No comments.	

SPECIFIC COMMENTS ON TEXT

Section number and heading	Interested party	Comment and Rationale	Outcome
3. Traditional use	ESCOP	The use of tincture is a well known traditional use and mentioned in different references. We would like to include this pharmaceutical form.	Endorsed.
4. Clinical particulars 4.1 Therapeutic indications	EBF	Indication „Traditional herbal medicinal product for supportive treatment of common cold.” is proposed to be amended as follows: „Traditional herbal medicinal product for supportive treatment and prophylaxis of recurrent infections such as common cold (nasopharyngitis acuta).” Rationale in the ESCOP Monographs, 2nd Edition, Suppl.2009 and WHO classification of diseases.	Not endorsed. a) The use (30 years period) for prophylaxis of recurrent infections within the EU is not sufficiently documented. b) This indication is based on data presented and in accordance with other indications in this therapeutic area.
4.4 Special	ESCOP	Replace 'immune diseases last line first paragraph by autoimmune	Not endorsed.

Section number and heading	Interested party	Comment and Rationale	Outcome
warnings and precautions for use.		<p>diseases. All the diseases listed are somehow immunologically mediated where autoimmune is more specific.</p> <p>Replace in the first line third paragraph "sensitive" by "sensitized".</p> <p>The first three paragraphs are based on a theory. Therefore we would like to replace these paragraphs by:</p> <p>On theoretical basis, as with all immunostimulants, not recommended in cases of progressive systemic disorders and autoimmune diseases such as tuberculosis, leucosis, collagenoses, multiple sclerosis, AIDS or HIV infections. At the present, there is a lack of reliable clinical evidence to support this view, although in view of the seriousness of the condition listed, it is appropriate to avoid use in these conditions until further information is available.</p>	<p>Not endorsed.</p> <p>Not endorsed.</p> <p>Special warnings and precautions for use point to concerns where there is often insufficient data and theory; otherwise they would be contraindications.</p>