



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 November 2011
EMA/HMPC/564527/2010
Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on Community herbal monograph on *Viola tricolor* L. and/or subspecies *Viola arvensis* Murray (Gaud) and *Viola vulgaris* Koch (Oborny), herba cum flore (EMA/HMPC/131734/2009)

Table 1: Organisations and/or individuals that commented on the draft Community herbal monograph on *Viola tricolor* L. and/or subspecies *Viola arvensis* Murray (Gaud) and *Viola vulgaris* Koch (Oborny), herba cum flore as released for public consultation on 11 March 2010 until 15 August 2010.

	Organisations and/or individuals
1	European Scientific Cooperative on Phytotherapy (ESCOP)



Table 2: Discussion of comments

General comments to draft document

Interested party	Comment and Rationale	Outcome
ESCOP	We welcome the preparation of a Community draft monograph on <i>Violae herba cum flore</i> however we propose to take into consideration the following specific comments.	

SPECIFIC COMMENTS ON TEXT

Section number and heading	Interested party	Comment and Rationale	Outcome
4.2. Posology and method of administration	ESCOP	We disagree with the limitation of duration of use to 1 week for cutaneous use and to 2 weeks for oral use. Seborrhoeic skin disorders are generally chronic and a long period of treatment is recommended [1]. We did not find any justification in the literature for the warning "Full baths should only be taken after a doctor or a qualified health care practitioner has been consulted".	Accepted. The proposed changes are as follows: if the symptoms persist longer than 4 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.