



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on draft Community herbal monograph on *Potentilla erecta* (L.) Raeusch., rhizoma (EMA/HMPC/5513/2010)

Table 1: Organisations and/or individuals that commented on the draft Community herbal monograph on *Potentilla erecta* (L.) Raeusch., rhizoma as released for public consultation on 15 March 2010 until 15 August 2010.

	Organisations and/or individuals
1	ESCOP
2	Kooperation Phytopharmaka



Table 2: Discussion of comments

GENERAL COMMENTS		
Interested party	Comment and Rationale	Outcome
ESCOP	We welcome the preparation of this Community draft monograph but propose to take into consideration the following specific comments.	
Koop Phyto	Kooperation Phytopharmaka welcomes the preparation of the above-mentioned Community herbal monograph. However, some modifications should be inserted from our point of view, in particular related to the use in children and adolescents.	

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 restriction of use in children and adolescents. For indication 1, there is evidence on the use in children available. The clinical study published by Subbotina (2003; already included in the HMPC reference list) is a randomized, double-blind trial which involved 40 children between 3 months and 7 years suffering from rotavirus diarrhoea. The treatment group (n=20) received 3 drops of tormentil extract (1:10, ethanol 40 %) per year of life, three times daily until discontinuation of diarrhoea or a maximum of 5 days. A significant reduction of the stool output was seen on the second day (p=0.029) and in duration of diarrhoea (p<0.0001) in the treatment group as compared to group. After 48 h diarrhoea decreased in 8 children in the verum	<p>Not endorsed.</p> <p>There is no documented medicinal use of the study medication in the EU. The tincture used in this study is less concentrated compared to the herbal preparations which comply with the requirements on THMPs according to Dir. 2004/24 EC. Additionally, there is no posology for children and adolescents published for any of the herbal preparations included in the monograph.</p> <p>Therefore the use in children and adolescents cannot be recommended.</p>

SPECIFIC COMMENTS ON TEXT			
		group compared to 1 child ($p < 0.0001$) in the placebo group.	
4.2. Posology and method of administration	Koop Phyto	<p>For the internal use in treatment of mild diarrhoea, we propose to include a dosage recommendation for children based on the publication of Subbotina 2003: “Liquid extract (1:10, ethanol 40 %): 3 drops daily per year of life”.</p> <p>A safe use in children has been established in this study in 40 children between 3 months and 7 years suffering from rotavirus diarrhoea. No clinical side effects were detected in the treatment group (20 children) receiving tormentil extract. For this reason the restriction of use (children and adolescents under 18 years) should be deleted from this paragraph as well as from chapter 4.4. The study is available at the HMPC.</p>	See above.
4.4. Special warnings and precautions for use	ESCOP	The same applies as stated under 4.2.	See above.

Reference: Subbotina MD, Timchenko VN, Vorobyov MM, Konunova YS, Aleksandrovih YS, Shushunov S. Effect of administration of tormentil root extract (*Potentilla tormentilla*) on rotavirus diarrhea in children: a randomized, double blind, controlled trial. *Pediatr Infect Dis J* 2003; 22(8):706-10.