



London, 12 March 2009  
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**OVERVIEW OF COMMENTS RECEIVED ON  
'COMMUNITY HERBAL MONOGRAPH ON *CENTAURIUM ERYTHRAEA* RAFN, HERBA'  
(EMEA/HMPC/105536/2008)**

**This document was valid from 12 March 2009 until 24 November 2015.**

Table 1: Organisations providing comments on the draft 'Community herbal monograph on *Centaurium erythraea* Rafn, herba' as released for consultation on 17 July 2008 until 15 November 2008.

Organisation
1. PhytoLab GmbH & Co. KG, Germany

**Table 2: Discussion of comments**

<b>4. CLINICAL PARTICULARS</b>		
<b>Paragraph no.</b>	<b>Comment and Rationale</b>	<b>Assessor's Comment</b>
<b>4.2. Posology and method of administration</b>	<p><u>Traditional use</u></p> <p>According to the HMPC monograph (draft) for Centaurium erythraea "The use in children and adolescents under 18 years of age is not recommended because of lack of data."</p> <p>Although there are no data on the use of centaury in this age group, this restriction is regarded to be not adequate and should be modified because of the following reasons:</p> <ol style="list-style-type: none"> <li>1. There are no data pointing to any risks associated with the use of the drug in children or adolescents.</li> <li>2. According to the ESCOP monograph on Centaurii herba the dose recommendation for children is the "proportion of adult dose according to age or body weight, in ethanol-free dosage forms".</li> </ol> <p>Two traditional herbal combination products, containing among others aqueous-ethanolic extracts from centaury, are on the market in Germany (Montana Haustropfen N, Canephron® N Tropfen). Both products are indicated for the use in adults and adolescents over 12 years of age.</p> <p>Therefore we suggest the following modifications of the monograph:</p> <p><b>4.2 Posology and method of administration:</b></p> <p><b>"Adolescents over 12 years of age: Proportion of adult dose according to age or body weight."</b></p> <p><b>"The use is not recommended in children under 12 years of age (see section 4.4 Special warnings and precautions for use)."</b></p>	<p>Not endorsed.</p> <p>The safety has not been demonstrated in children and adolescents under 18 years, because no studies or exposure data have been submitted.</p>

<b>4.4. Special warnings and precautions for use</b>	<p><u>Traditional use</u></p> <p><b>4.4 Special warnings and precautions for use:</b></p> <p><b>"The use in children under 12 years of age is not recommended because of lack of data."</b></p>	<p>Not endorsed.</p> <p>The safety has not been demonstrated in children and adolescents under 18 years, because no studies or exposure data have been submitted.</p>
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Superseded