



European Medicines Agency
Evaluation of Medicines for Human Use

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**OVERVIEW OF COMMENTS RECEIVED ON
'COMMUNITY HERBAL MONOGRAPH ON
VERBASCUM THAPSUS L., V. DENSIFLORUM BERTOL., AND V. PHLOMOIDES L., FLOS'
(EMEA/HMPC/395213/2007)**

Table 1: Organisation providing comments on the draft 'Community herbal monograph on *Verbascum thapsus* L., *V. densiflorum* Bertol. and *V. phlomoides* L., flos' as released for consultation on 31 October 2007 until 15 February 2008.

Organisation	
1	Pharmaceutical Production Company (Poland)

Table 2: Discussion of comments

GENERAL COMMENTS TO DRAFT DOCUMENT		
Not applicable		
SPECIFIC COMMENTS ON TEXT		
4. CLINICAL PARTICULARS		
Paragraph no. line no.	Comment and Rationale	Outcome
4.2 Posology and method of administration	<p>We propose to replace the text “<i>Adolescents over 12 years of age, adults, elderly</i>” with the text: “<i>Children over 6 years of age, adolescents, adults, elderly</i>”</p> <p>Rationale: See below.</p>	<p>This product is not covered by this monograph The information about Sirupus Verbasci preparations and posology submitted by Poland is not confirmed in handbooks available to us. Since this product has only been on the market since 1997, this preparation is not included in the monograph because 30 years of medicinal use has not been substantiated</p> <p>Since not enough experience on the safe medicinal use of <i>verbasci flos</i> in children between 6 -12 years of age are available, the request is not endorsed. Our recommendation is in accordance with other monographs.</p>

<p>4.4 Special warnings and precautions for use</p>	<p>We propose to replace the text “<i>The use is not recommended in children under 12 years of age due to lack of adequate data</i>” with the text: “<i>The use un children under 6 years of age is not recommended because data are not sufficient and medical advice should be sought</i>”</p> <p>Rationale:</p> <p>“Our product VERBASCI SYRUP has been present on the Polish drug market for more than 10 years and throughout that period it has been used to treat upper respiratory tract infections, as an auxiliary agent in treatment of flu, colds, pharyngitis and bronchitis, also in dry cough with a little secretion in adults and children over 6 years of age.</p> <p>Composition: Mullein liquid extract Dosage form: Syrups Legal status: OTC MZ Permit No.: R/7015 Package: Bottle of 125g Date of first registration: 20.02.1997 Sale’s volume (August 2000 - July 2005): approx. 1 150 000 units. The Period Safety Update Report (PSUR) covers the period since 01.08.2000 to 31.07.2005 and during that time there were no reports of adverse events after use of the mentioned product. Therefore, we believe that our product can be considered as safe for use in children over 6 years of age. Herbal products containing mullein intended to use in children are very popular and commonly recognized by parents and physicians as safe and effective medicines for the treatment of the above ailments. The obligation of introducing the above precaution (i.e. “The use is not recommended in children under 12 years of age due to lack of adequate data”) will lead to elimination of the target group of patients to be treated with our product. The proposal of introducing the text: <i>use in children under 6 years of age is not recommended because data are not sufficient and medical advice should be sought</i> is intended to empower physician to take a decision to prescribe this drug to a child under 6 years of age if one considers it’s necessary”.</p>	<p>Not endorsed. See comments above.</p>
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