



London, 3 July 2008
Doc. Ref. EMEA/HMPC/66605/2008

This document was valid from 03 July 2008 until 27 March 2018.

**OVERVIEW OF COMMENTS RECEIVED ON
'COMMUNITY HERBAL MONOGRAPH ON
SAMBUCUS NIGRA L., FLOS'
(EMEA/HMPC/283166/2007)**

Table 1: Organisation providing comment on the 'Community herbal monograph on *Sambucus nigra* L., flos' as released for consultation on 7 September 2007 until 15 December 2007.

Organisation	
1	The Association of the European Self-Medication Industry (AESGP)

Table 2: Discussion of comments

SPECIFIC COMMENTS ON TEXT		
2 QUALITATIVE AND QUANTITATIVE COMPOSITION		
Paragraph no. line no.	Comment and Rationale	Outcome
2. Qualitative and quantitative composition	<p>An interested party informed us on another product marketed in Germany: Dry extract (4-6:1, water)</p> <p>The extract is marketed in Germany as "Holunder Kräuter Tabletten"</p> <p>The interested party wishes to add this information to the monograph.</p>	<p>In the information from BfArM to our request for MA status in Germany it was stated that they only had combination products on the market. According to the information we have found on the internet on this product "Holunder Kräuter Tabletten", the products seems to be a combination of Sambuci flos and Sambuci fructus:</p> <p>http://www.salus.de/htmls/p_detail.php?art_nr=01002936&c_art_gruppe=ALL&c_indikation=0&c_marke=2&c_swort=&c_typ=0 Retrieved 2008-02-05.</p> <p>Holunder- Kräutertabletten, 40 St. zur Besserung des Befindens bei Erkältungskrankheiten.</p> <p>Artikel-Nr.: 01002936</p> <p>Allgemeine Informationen Holunder - Kräutertabletten enthalten neben Holunderblüten und -beeren in Pulverform auch noch einen wirkstoffreichen Holunder-Trockenextrakt und bieten somit die volle Wirkstoffbreite des Holunders in konzentrierter Form. In der Gesamtwirkung aller Inhaltsstoffe unterstützt die Einnahme der vorliegenden Holunder-Kräutertabletten die Abwehrkräfte des Körpers, besonders bei Erkältungsgefahr. Holunder wirkt außerdem schweißtreibend.</p> <p>Zusammensetzung:</p> <ul style="list-style-type: none"> • 1 Filmtablette enthält: • Arzneilich wirksame Bestandteile: • 75 mg Holunderblüten-Pulver • 75 mg Holunderbeeren-Pulver • 140 mg Trockenextrakt aus Holunderblüten (4-6:1) • Auszugsmittel: Wasser <p>Due to lack of information on this product, this recommendation is not endorsed.</p>