



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

## Overview of comments received on Community herbal monograph on *Fucus vesiculosus* L., thallus (EMA/HMPC/313674/2012)

Table 1: Organisations and/or individuals that commented on the draft Community herbal monograph on *Fucus vesiculosus* L., thallus as released for public consultation on 14 May 2013 until 15 November 2013.

	Organisations and/or individuals
1	European Botanical Forum (EBF)



Table 2: Discussion of comments

### General comments to draft document

Interested party	Comment and Rationale	Outcome
N/A		

### SPECIFIC COMMENTS ON TEXT

Section number and heading	Interested party	Comment and Rationale	Outcome
2. Qualitative and quantitative composition	EBF	<p>ii) Herbal preparations Powdered herbal substance</p> <p>Herbal preparations of TU status should be amended by <b>Dry aqueous extract</b> due to TU in Spain from 1950:  <a href="http://www.vademecum.es/medicamento-zimema_17238">http://www.vademecum.es/medicamento-zimema_17238</a>                      Composition of ZIMEMA                      Active principles:                      Alcachofa extr. 25 mg/1 tablet                      Cáscara sagrada polvo 100 mg/1 tablet                      Fucus vesiculosus extr. 175 mg/1 tablet</p> <p>Produced from: 01/11/1950</p>	<p>The preparation has been included in the market information of the assessment report.</p> <p>It is a multicomponent mixture. Therefore the extract of <i>Fucus vesiculosus</i> incorporated in the composition is not included in the monograph.</p>