



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 November 2010
EMA/HMPC/564675/2010
Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on Community herbal monograph on *Quercus robur* L., *Quercus petraea* (Matt.) Liebl., *Quercus pubescens* Willd., cortex (EMA/HMPC/3203/2009)

Table 1: Organisations and/or individuals that commented on the draft Community herbal monograph on *Quercus robur* L., *Quercus petraea* (Matt.) Liebl., *Quercus pubescens* Willd., cortex as released for public consultation on 15 February 2010 until 15 June 2010.

	Organisations and/or individuals
1	The Association of the European Self-Medication Industry (AESGP)



Table 2: Discussion of comments

General comments to draft document

Interested party	Comment and Rationale	Outcome
AESGP	AESGP welcomes the preparation of the above-mentioned Community herbal monograph which should facilitate mutual recognition in Europe by harmonising the assessment criteria.	

SPECIFIC COMMENTS ON TEXT

Section number and heading	Interested party	Comment and Rationale	Outcome
4.1 Therapeutic indications	AESGP	<p>Comments:</p> <p>The use of oak bark preparation in the inflammation of the skin in case of haemorrhoids is a traditional indication. This external use (in bath) has been described by Fintelmann and Weiss [1].</p> <p>Proposed change:</p> <p>We suggest adding the underlined part for indication b): "... symptomatic treatment of minor inflammation of the oral mucosa or skin <u>as well as for treatment of haemorrhoids.</u>"</p> <p>Reference:</p> <p>[1] Fintelmann V, Weiss R. Lehrbuch der Phytotherapie. 10th edition. Stuttgart: MVS Medizinverlage, 2002: 111.</p>	Accepted for the specified condition of medically diagnosed haemorrhoids.