



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 May 2011
EMA/HMPC/31666/2011
Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on Community herbal monograph on *Cinnamomum verum* J. S. Presl, cortex (EMA/HMPC/246774/2009)

Table 1: Organisations and/or individuals that commented on the draft Community herbal monograph on *Cinnamomum verum* J. S. Presl, cortex as released for public consultation on 15 July 2010 until 15 December 2010.

	Organisations and/or individuals
1.	The European Scientific Cooperative on Phytotherapy (ESCOF)



Table 2: Discussion of comments

General comments to draft document

Interested party	Comment and Rationale	Outcome
<p>ES COP</p>	<p>General comment: We suggest to add one further traditional use indication, i.e. “diarrhoea”, which is documented in several recent and older references, but was not included in the current HMPC draft [Madaus 1938/1988; Brit Herb Pharm 1983; Hänsel 1992; Bradley 2006].</p> <p>Rationale:</p> <p>Traditional use of cinnamon bark in “diarrhoea” has already been documented in 1938 and 1983 [Madaus 1938/1988; Brit Herb Pharm 1983]. Several constituents of cinnamon bark, a.o. the volatile oil, procyanidins/ condensed tannins and cinnamic acid (with spasmolytic, antimicrobial and anti-inflammatory activity) can have a positive effect in diarrhoea. In vivo studies report astringent activity [Barceloux 2009] and also inhibition of intestinal propulsion and inhibition of peristalsis in the gut of mice, by cinnamaldehyde [Harada & Jano 1975; CVMP 2000]. Although these studies were sometimes done with rather high concentrations of cinnamon bark constituents, they partially support this traditional indication.</p>	<p>Endorsed</p> <p>Indeed diarrhoea is documented in the sources mentioned. One of them is Madaus, referring to a tradition of more than 30 years. Madaus has been incorporated in the assessment report and reference list.</p> <p>Plausibility of the indication is supported by preclinical evidence (Harada & Jano, 1975).</p> <p>Cited references in the general comment are added to the reference list.</p>

SPECIFIC COMMENTS ON TEXT

Section number and heading	Interested party	Comment and Rationale	Outcome
4.1 Therapeutic indications	ESCOP	<p>Comment: Older and more recent literature on traditional use and use of cinnamon bark in folk medicine, documents the indication “diarrhoea” [Madaus 1938/1988; Brit Herb Pharm 1983; Hänsel 1992; Bradley 2006].</p> <p>Proposed addition:</p> <p>Traditional herbal medicinal product for the symptomatic and adjuvant treatment of diarrhoea.</p>	<p>Endorsed</p> <p>The indication ‘diarrhoea’ can be included.</p>
4.2 Posology and method of administration	ESCOP	<p>Comment: For Part 1: superfluous dosage, may be due to a typing error. Rationale for Part 2: high amounts of cinnamon bark contained in spicy food, eaten by young and old, i.e. amounts contained in several slices of spiced cake/gingerbread, are in the same order of magnitude as the therapeutic dose. Cinnamon bark has GRAS status. Rationale for Part 3, see § 4.1 above.</p> <p>Part 1, proposed deletion: “; 1.5-4 g daily”</p> <p>Part 2, proposed change: The use in children under 12 (delete 18) years of age is not recommended.</p> <p>Part 3, proposed addition: Add to “Duration of use”.</p> <p>In case of “diarrhoea”, if symptoms persist longer than three days, a doctor or a qualified health care practitioner should be consulted.</p>	<p>Part 1: endorsed</p> <p>Indeed, there is a typing error which is corrected accordingly.</p> <p>Part 2: not endorsed</p> <p>There are no data available on the use by adolescents. It is not clear if the use by patients under 18 years is an intended tradition.</p> <p>Part 3: partially endorsed</p> <p>The formulation can be accepted provided that the duration should be limited to two days.</p>

Section number and heading	Interested party	Comment and Rationale	Outcome
4.4. Special warnings and precautions for use	ESCOP	<p>Comment: For the rationale, see Part 2 in § 4.2.</p> <p>Proposed change, delete 18, add 12: The use in children under 12 years of age has not been established due to lack of adequate data.</p>	Not endorsed: see former remark

References to comments on Cinnamon bark:

1. Madaus G. Cinnamomum, Ceylonzimt. In: Lehrbuch der biologischen Heilmittel. 1938 (reprinted 1988, Mediated Verlag). Bd. 5, pp. 998-1002.
2. British Herbal Pharmacopoeia 1983. Cinnamomum. ISBN 0-903032 / 0-903032-07-4. Bournemouth, Brit. Herbal Med. Assoc., 1983.
3. Hänsel R, Keller K, Rimpler H, Schneider G. editors. Cinnamomi cortex. In: Hagers Handbuch der Pharmazeutischen Praxis. Berlin. Springer-Verlag; 1992, 902–906.
4. Bradley P. Cinnamon, Cinnamomi cortex. In: British Herbal Compendium Volume 2. 2006, pp. 108-112.
5. Barceloux DG. Cinnamon (Cinnamon Species). Dis. Mon. 2009, 55:327-55.
6. Harada M., Yano S. Pharmacological studies on Chinese Cinnamon. II. Effects of cinnamaldehyde on cardiovascular
7. and digestive systems. Chem. Pharm. Bull. 1975, 23:941-947.
8. CVMP Committee for Veterinary Medicinal Products. Cinnamomi ceylanici cortex. Summary report.
9. The European Agency for the Evaluation of Medicinal Products. Evaluation of Medicines For Veterinary Use.
10. EMEA/MRL/713/99-FINAL; Jan 2000, 1-3.