



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 November 2012
EMA/HMPC/411398/2006
Committee on Herbal Medicinal Products (HMPC)

Overview of comments received on Community herbal monograph on *Levisticum officinale* Koch, radix (EMA/HMPC/524621/2011)

Table 1: Organisations and/or individuals that commented on the draft Community herbal monograph as released for public consultation on 15 April 2012 until 15 August 2012.

	Organisations and/or individuals
1	Weleda SA, Switzerland



Table 2: Discussion of comments

General comments to draft document

Interested party	Comment and Rationale	Outcome
Weleda SA	N/A	

SPECIFIC COMMENTS ON TEXT

Section number and heading	Interested party	Comment and Rationale	Outcome
2. Qualitative and quantitative composition	Weleda SA	<p>Traditional use</p> <p><i>Levisticum officinale</i> Koch, radix (lovage root)</p> <p>i) Herbal substance Not applicable.</p> <p>ii) Herbal preparations</p> <p>a) Comminuted herbal substance</p> <p>Proposed change:</p> <p>ii) Herbal preparations</p> <p>a) Comminuted herbal substance</p> <p>b) Oil</p> <p><u>Comment:</u> <i>Justification for traditional use since 1968.</i></p> <p><u>References:</u> <i>BfArM (1986/1991); Weleda (1968); BGA (1978); BGA 1990; Weleda (1973); Weleda (1977-1988); Weleda (1993); Weleda (1996); Weleda (1998); Weleda (2000); Otto wolf (2000); Weleda (2005); Weleda (2009); Weleda (2011)</i></p>	<p>Not endorsed.</p> <p>Attached documents refer to preparations of lovage used in antroposophic medicine and are manufactured according to the methods of the German Homeopathic Pharmacopoeia (HAB). In the documents submitted by the manufacturer the same solution either is written as: Öl Levisticum 10% or 10% H Levisticum Öl. It is therefore produced by the method according to HAB 12 d. According this method liquids for external use are prepared from the dried plant material wetted with ethanol, by heating with vegetable oil (olive oil, peanut oil, sesame oil), or by pressing and filtration. The preparation therefore can be characterized as an oil extract of dried vegetable matter.</p>

Section number and heading	Interested party	Comment and Rationale	Outcome
3. Pharmaceutical form	Weleda SA	<p>Traditional use</p> <p>Comminuted herbal substance as herbal tea for oral use.</p> <p>Proposed Change: Comminuted herbal substance as herbal tea for oral use. Oil for external use.</p> <p><u>References</u> <i>BfArM (1986/1991); BGA 1990; Weleda (1996); Weleda (2000); Otto wolf (2000); Weleda (2005); Weleda (2011)</i></p>	Not endorsed, (see above).
4.1. Therapeutic indications	Weleda SA	<p>Traditional use</p> <p>Traditional herbal medicinal product used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints.</p> <p>Proposed change: Traditional herbal medicinal product used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints. Traditionally used to relieve minor ear or nerve pains</p> <p><u>Comment:</u> <i>Justification of plausibility is included in the following references.</i></p> <p><u>References:</u> <i>BfArM (1986/1991); BGA (1978); BGA 1990; Weleda (1996); Weleda (1998); Weleda(2000); Otto Wolf (2000); Weleda (2005); Weleda (2011)</i></p>	Not endorsed, (see above).

Section number and heading	Interested party	Comment and Rationale	Outcome
4.2. Posology and method of administration	Weleda SA	<p>Traditional use</p> <p>Posology <i>Adults and elderly</i> a) Herbal tea Single dose: 2 - 3 g of comminuted herbal substance in 150 ml of boiling water as a herbal infusion, twice daily. Average daily dose: 4 – 6 g The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p>We propose to include the following use under 'posology':</p> <p>b) Oil Nerve pain: 2-3 times a day, oint the painful site with some oil drops. [1] Ear pain: 2-3 times a day, introduce a piece of oil soaked cotton wool in the outer auditory canal.</p> <p>Method of administration ... External use.</p> <p><u>References:</u> <i>BfArM (1986/1991); Weleda (1996); Weleda (1998); Weleda 2000; Weleda (2005); Weleda (2011)</i></p>	Not endorsed, (see above).

Bibliographic references:

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2. BGA 1990. Levisticum H 10 %. Verlängerung der Zulassung nach Artikel 3 § 7 AMNG - Kurzantrag / Eingangsbestätigung. Bundesgesundheitsamt, Berlin, 31.05.1990.
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