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FINAL

COMMUNITY HERBAL MONOGRAPH ON *PIMPINELLA ANISUM* L., FRUCTUS

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	May 2006 September 2006
ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION	7 September 2006
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¹ Minor editorial change in section 4.2 under posology (3 July 2008)

COMMUNITY HERBAL MONOGRAPH ON *PIMPINELLA ANISUM* L., FRUCTUS

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION^{2, 3}

<u>Well-established use</u>	<u>Traditional use</u>
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Pimpinella anisum</i> L., fructus (aniseed)</p> <p>i) Herbal substance Dried aniseed</p> <p>ii) Herbal preparation Dried aniseed, comminuted or crushed.</p>

3. PHARMACEUTICAL FORM

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Herbal substance or herbal preparation as herbal tea for oral use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

² The material complies with the Ph. Eur. monograph (ref. 01/2005:0262).

³ The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

<u>Well-established use</u>	<u>Traditional use</u> a) Traditional herbal medicinal product for symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating and flatulence. b) Traditional herbal medicinal product used as an expectorant in cough associated with cold. The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.
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4.2. Posology and method of administration

<u>Well-established use</u>	<u>Traditional use</u> Posology <i>Adolescents over 12 years of age, adults, elderly:</i> Indications a) and b) 1 to 3.5 g of whole or (freshly ⁴) comminuted or crushed aniseed in 150 ml of boiling water as a herbal tea 3 times daily The use is not recommended in children under 12 years of age (see section 4.4 Special warnings and precautions for use). Duration of use Not to be taken for more than two weeks. If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. Method of administration Oral use.
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⁴ For commercial preparations of comminuted or crushed aniseed the applicant must carry out appropriate stability testing related to the content of essential oil components

4.3. Contraindications

<u>Well-established use</u>	<u>Traditional use</u> Hypersensitivity to the active substance or to Apiaceae (Umbelliferae) (caraway, celery, coriander, dill and fennel) or to anethole.
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4.4. Special warnings and precautions for use

<u>Well-established use</u>	<u>Traditional use</u> The use is not recommended in children under 12 years of age due to the lack of adequate data for safety assessment.
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4.5. Interaction with other medicinal products and other forms of interaction

<u>Well-established use</u>	<u>Traditional use</u> None reported.
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4.6. Pregnancy and lactation

<u>Well-established use</u>	<u>Traditional use</u> There are no data from the use of aniseed in pregnant patients. It is unknown if aniseed constituents are excreted in human breast milk. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.
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4.7. Effects on ability to drive and use machines

<u>Well-established use</u>	<u>Traditional use</u> No studies on the effect on the ability to drive and use machines have been performed.
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4.8. Undesirable effects

<u>Well-established use</u>	<u>Traditional use</u> Allergic reactions to aniseed affecting the skin or the respiratory system may occur. The frequency is not known. If other adverse reactions not mentioned above occur a doctor or a qualified health care practitioner should be consulted.
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4.9. Overdose

<u>Well-established use</u>	<u>Traditional use</u> No case of overdose has been reported.
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5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

<u>Well-established use</u>	<u>Traditional use</u> Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.
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5.2. Pharmacokinetic properties

<u>Well-established use</u>	<u>Traditional use</u> Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.
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5.3. Preclinical safety data

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product.</p> <p>An aniseed extract prepared with water was tested in an Ames test on <i>Salmonella typhimurium</i> strains TA98, TA100, TA102 and turned out as negative. Results from non-clinical studies showed a weak mutagenic potential of anethole.</p> <p>The genotoxic risk⁵ related to estragole is not considered to be relevant in the specified conditions of use due to the small amount present in herbal infusions prepared from aniseed.</p>

6. PHARMACEUTICAL PARTICULARS

<u>Well-established use</u>	<u>Traditional use</u>
	Not applicable.

7. DATE OF COMPILATION/LAST REVISION

3 July 2008

⁵ Please refer to the HMPC 'Public statement on the use of herbal medicinal products containing estragole' (EMEA/HMPC/137212/2005).