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**COMMITTEE ON HERBAL MEDICINAL PRODUCTS
(HMPC)**

DRAFT

**COMMUNITY HERBAL MONOGRAPH ON *FOENICULUM VULGARE* MILLER SUBSP.
VULGARE VAR. *VULGARE*, FRUCTUS**

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST	May 2006 September 2006 October 2006
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KEYWORDS	Herbal medicinal products; HMPC; Community herbal monograph; traditional use; bitter fennel fruit; <i>Foeniculum vulgare</i> Miller subsp. <i>vulgare</i> var. <i>vulgare</i>
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**DRAFT COMMUNITY HERBAL MONOGRAPH ON *FOENICULUM VULGARE* MILLER
SUBSP. *VULGARE* VAR. *VULGARE*, FRUCTUS**

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION^{1,2}

<u>Well-established use</u>	<u>Traditional use</u>
With regard to the marketing authorisation application of Article 10(a) of Directive 2001/83/EC as amended	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended <i>Foeniculum vulgare</i> Miller subsp. <i>vulgare</i> var. <i>vulgare</i>), fructus (Fennel, Bitter) i) Herbal substance: dried fennel, bitter ii) Herbal preparation: dried fennel, bitter, comminuted

3. PHARMACEUTICAL FORM

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

¹ The material complies with the Ph. Eur. monograph.

² The declaration of the active substance(s) 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>
	<p>a) Traditional herbal medicinal product for symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating and flatulence.</p> <p>b) Traditional herbal medicinal product for symptomatic treatment of minor spasm associated with menstruation period.</p> <p>c) Traditional herbal medicinal product used as an expectorant in cough and cold.</p> <p>The product is a traditional herbal medicinal product for use in specified indications exclusively based on long-standing use.</p>

4.2. Posology and method of administration

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Posology</p> <p><i>Adults</i> 1.5 to 2.5 g of (freshly³) comminuted fennel fruits with 0.25 l of boiling water (brew for 15 minutes) three times daily as a herbal tea.</p> <p><i>Children, Indication a)</i> Average daily dose: 3 months-1 year of age: 1-2 g of crushed fruits as an infusion 1-4 years of age: 1.5-3 g of crushed fruits as an infusion 4-12 years of age: 3-5 g of crushed fruits as an infusion</p> <p><i>Adolescents over 12 years of age, Indication a)</i> Adult dose</p> <p>Method of administration Oral use.</p> <p>Duration of use</p> <p><i>Adults</i> Not to be taken for more than 2 weeks.</p> <p><i>Children, Indication a)</i> The use in children may be considered in case of acute symptoms. Administration for more than 1 week is not recommended because of the lack of adequate safety data on long-term use.</p> <p>If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p>

³ For commercial preparation of crushed fennel fruits 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> Known hypersensitivity to the active substance or to Apiaceae (Umbelliferae) (aniseed, 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> Patients with known hypersensitivity to Asteraceae (Compositae) should avoid the use of fennel and its preparations, because of cross-reactivity risk.
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4.5. Interactions with other medicinal products and other forms of interaction

<u>Well-established use</u>	<u>Traditional use</u> Not known.
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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 fennel fruit in pregnant patients. It is unknown if fennel constituents are excreted in human breast milk. In 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>
	<p>Allergic reactions to fennel, affecting the skin, the respiratory and gastro-intestinal system may occur.</p> <p>If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.</p>

4.9. Overdose

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

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

<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.</p> <p>The traditional medicinal use of fennel has been largely due to antispasmodic, secretolytic and antibacterial effects of its essential oil.</p> <p>Secretolytic and expectorant effects may be due to the content of anethole and fenchone.</p>

5.2. Pharmacokinetic properties

<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.</p> <p>No data available for bitter fennel in human beings or animals.</p> <p>After oral administration the compound trans-anethole is rapidly absorbed. 54 - 69% of the dose is eliminated in the urine and 13 - 17% in exhaled carbon dioxide. Trans-anethole is reported to be metabolised by O-demethylation and by oxidative transformation of the C3-side chain. The bulk of elimination occurred within 8 hours. The principal metabolite is 4-methoxyhippuric acid.</p>

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>For trans-anethole anti-implantation, early abortifacient and antifertility activity has been reported in rats.</p> <p>Trans-anethole is reported as “generally recognised as safe” (GRAS) at the intake of 54 µg/kg body weight/day).</p> <p>The acceptable daily intake (ADI) of trans-anethole established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) should not exceed 2 mg/kg body weight.</p> <p>An aqueous extract was tested in an Ames test on <i>Salmonella typhimurium</i> strains TA98, TA100 and turned out as negative. Results from studies carried out in laboratory animals showed a weak mutagenic activity of anethole.</p> <p>The genotoxic risk⁴ related to estragole is not considered to be relevant due to the small amount present in herbal infusions prepared from fennel.</p>

6. PHARMACEUTICAL PARTICULARS

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

7. DATE OF COMPILATION/LAST REVISION

26 October 2006

⁴ Please refer to the HMPC Public statement on the use of herbal medicinal products containing estragole (EMEA/HMPC/137212/2005).