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SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare*, fructus

Opinion

The HMPC, in accordance with Article 16h(3) of Directive 2001/83/EC and as set out in the appended assessment report, establishes, by a majority of 25 out of 27 a revised European Union herbal monograph on *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare*, fructus which is set out in Annex I.

The divergent positions are appended to this opinion.

The Norwegian HMPC member does agree with the above-mentioned recommendation of the HMPC.

This opinion is forwarded to Member States and Norway, together with its Annex I and appendix.

The revised European Union herbal monograph and assessment report will be published on the European Medicines Agency website. They replace those adopted on 05 July 2007.

Amsterdam, 31 January 2024.

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Annex I: European Union herbal monograph (EMA/HMPC/372841/2016)

Appendix I: Assessment report (EMA/HMPC/240553/2016)

Appendix II: Divergent positions

The members of the HMPC mentioned below did not agree with the HMPC's opinion for the following reason:

Ireland does not support the Monograph for *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare*, fructus. We do not support the indication for symptomatic treatment of mild, spasmodic gastrointestinal complaints including bloating and flatulence and use as an expectorant in cough associated with cold in children (4-12 years) as this is not appropriate for self-medication in this population. This is in line with our nationally approved THMPs.

Jackie Masterson, HMPC Member from Ireland

Amsterdam, 31 January 2024.

1. The data on the most common medicinal use of herbal teas of fennel fruit in infantile colic, what is probably the most common medical indication in the Europe and the Union, were not included in the Assessment Report and in monographs on bitter fennel fruit and sweet fennel fruit. The indication is commonly known by medical doctors and patients as well and was confirmed in 2007 by the paediatric expert of the HMPC as a valuable area of medicinal use: Fennel is a very important and useful herbal medicine for infants colic etc. Its successful use has been reported by thousand physicians and paediatricians. But the view was neglected by the Committee and was reflected in the assessment. The Assessment Report was presented common for every data for bitter fennel fruit, for sweet fennel fruit and for bitter fennel fruit essential regardless of differences of data available on the subjects of assessment. Omitting the data on a traditional use of fennel herbal teas in children, especially in the infant colic the Assessment Report presented failed to meet the goals set before the Committee in the preamble of Directive 2004/24/EC.

2. Reading the Assessment Report, Poland sees statements indicating that it was dominated by the information on the content of estragole, which is contained in the essential oil of the fruit. But a subject of the assessments had to be data on bitter fennel fruit and sweet fennel fruit and their preparations and only the confirmed data on the preparations should be referred in the assessment report. Data on experiments on bacterial tests in vitro, data on particular isolated substances on animal models are not conclusive for the assessments of preparations when the preparations are in use in humans for centuries without any medical or toxicological concerns and when is evidence of a stable safety profile. Poland cannot support assessment focused on hypothetical safety issues related to the estragole when there is evidence that products are no harmful in normal conditions of use, meeting the requirement of art. 16e(c) of the Directive.

3. In the monographs for bitter fennel fruit and sweet fennel fruit, in chapter 4.4. the sentence The use is not recommended in children under 4 years of age without the advice of a paediatrician was substituted by: due to lack of adequate data. Apart of aspects referred in p.1 this exclude of medicinal use of fennel teas, both sweet and bitter, with pharmaceutical quality of the area of medicinal use in infants. As a result parents which have been using traditionally fennel teas in infant colic, should now use in the mentioned indication another kind of fennel, with a quality not defined by the European Pharmacopoeia. The uncontrolled fennel may contain higher quantities of estragole.

Wojciech Dymowski, HMPC Member from Poland

Amsterdam, 31 January 2024