



**OPINION OF THE COMMITTEE ON HERBAL MEDICINAL PRODUCTS ON A
COMMUNITY HERBAL MONOGRAPH ON**

***Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung, fructus**

Opinion

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

The divergent positions are appended to this opinion.

The Icelandic and the Norwegian HMPC members agree with the above-mentioned recommendation of the HMPC.

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

The Community herbal monograph and assessment report will be published on the EMEA website.

London, 5 July 2007

On behalf of the HMPC
Dr Konstantin Keller, Chairman

ANNEX I: COMMUNITY HERBAL MONOGRAPH (EMEA/HMPC/263293/2006)

APPENDIX I: ASSESSMENT REPORT (EMEA/HMPC/137426/2006)

APPENDIX II: DIVERGENT POSITIONS

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

I do not support the above mentioned monograph due to the decision made on the traditional use and posology in children from 4 to 12 years of age only in indication a. "Traditional herbal medicinal product for symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating" and flatulence". I would have supported the monograph, if children from 3 month to 4 years would have been included in indication a, for in my country nearly all babies receive fennel tea to soothe mild spasmodic complaints, there is also wide use in Austria and the Netherlands in babies as well. Due to discussions on genotoxicity and lacking data on long term observation of children, who had been treated with fennel tea this position could not be implemented. Therefore the use in children was restricted to the years 4-12 in indication a with short term use (less than one week) only in mild transitory complaints, which is nonsense in an indication of mild spasmodic complaints, which is a mild transitory indication as such. Since this age range was implemented, it should have been broadened to indication c : "Traditional herbal medicinal product used as an expectorant in cough associated with cold." at least and according to my position as well to indication b "Traditional herbal medicinal product for symptomatic treatment of minor spasm associated with menstrual periods." where applicable in girls below the age of 12 years of age. No risks can be substantiated why girls from 10-12 suffering from indication b: "Traditional herbal medicinal product for symptomatic treatment of minor spasm associated with menstrual periods." should not take fennel tea while they could use them suffering from indication a. There are no medical or safety reasons why these indications should not have been implemented with an adequate posology in the described age groups.

London, 6 July 2007

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

Regarding the Final Community herbal monograph on *Foeniculum vulgare* Miller subsp. *vulgare* var *dulce*, fructus EMEA/HMPC/263293/2006, I expressed my negative vote on the monograph, at the HMPC Plenary meeting, July 5th 2007, for the following reasons:

Restricting the traditional use and posology in children to the age of 4 to 12 years, especially related to indication part a: "Traditional herbal medicinal product for symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating and flatulence", does not reflect the core of the traditional use, which is widespread in children also under the age of 4.

Taking into account that the content of this Monograph is exclusively based upon long-standing use and experience, the whole range of use in children should be covered, to guarantee a safe use of this herbal substance, or –preparation.

Moreover, the additional restriction under 4.2 Posology and method of administration:

"4-12 years of age: 3-5 g of crushed fruits as an infusion for short-term use in mild transitory symptoms (less than one week)" in particular related to part a) of the indication, makes no sense from a medical point of view.

London, 7 September 2007