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

Pimpinella anisum L., 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 26 out of 27 votes a Community herbal monograph on *Pimpinella anisum* L., fructus which is set out in Annex I.

   The divergent position is 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
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ANNEX I: COMMUNITY HERBAL MONOGRAPH (EMEA/HMPC/137423/2006)

APPENDIX I: ASSESSMENT REPORT (EMEA/HMPC/137421/2006)

APPENDIX II: DIVERGENT POSITION

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

I disagree with the inclusion of the following statement in the monograph.

"The use is not recommended under 12 years of age due to lack of adequate data for safety assessment."
While it is true that no clinical data on the tolerability of aniseed preparation exist in children we would like to emphasise that, in the case of traditional use, it is definitely not necessary to prove the tolerability with clinical studies. In many parts of Europe, and in my country as well, the combination of aniseed with fennel and /or caraway is the most popular remedy for mothers as lactagogue and for mothers and for their babies and small infants as treatment for intestinal spasm since decades or even centuries. Moreover, in several established national and international monographs (German Commission E, 1988, ESCOP 1997, 2003, British Herbal Compendium) there is no restriction of age. A dose regimen for children is given in the ESCOP Monograph (1997, 2003) based on the suggestion of Kooperation Phytopharmaka (Empfelungen zu Kinderdosierungen von monographierten Arzneidrogen und ihren Zubereitungen Bonn, 1993: 22-3).

The other argument presented to avoid using aniseed for children was its estragol content. However, not the content of the herbal drug but that of the preparation for use should be taken into account! The estragole content in the herbal infusions made from Aniseed is not considered to be relevant from a safety point of view due to the small amount present in herbal infusions. According to „Final position paper on the use of herbal medicinal products containing estragole" (EMEA/HMPWP/338/03) the intake should be minimised but it is not prohibited for sensitive groups such as children, pregnant and breastfeeding women.

In my country Aniseed has been widely used in combination preparation for children above 1 year to relieve spasmodic complaints or for coughing for short-time use. Aniseed can also be found in lactagogue tea-mixtures, again for short-time use exclusively, i.e. no longer than 2 weeks to promote the start of the production of mother's milk.

That is the reason why I can not accept the monograph on Aniseed in its present version.

London, 7 September 2007