



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a Community herbal monograph on *Plantago ovata* Forssk., seminis tegumentum

Opinion

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 30 out of 31 votes a revised Community herbal monograph on *Plantago ovata* Forssk., seminis tegumentum which is set out in Annex I.

The Norwegian HMPC member agrees 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 revised Community herbal monograph and assessment report will be published on the European Medicines Agency website. They replace those adopted on 13 July 2006.

London, 14 May 2013

On behalf of the HMPC

Prof. Dr. Werner Knöss, Chair



Annex I: Community herbal monograph (EMA/HMPC/199774/2012)

Appendix I: Assessment report (EMA/HMPC/199775/2012)

Appendix II: Divergent position

One member of the HMPC did not agree with the HMPC's opinion on *Plantago ovata* Forssk., seminis tegumentum for the following reason:

The data are not sufficient to prove recognized efficacy for the indication Irritable Bowel Syndrome. Therefore it is not justified to include IBS in the indication which is applying in general "to patients to whom an increased fibre intake may be advisable" The indication constipation is already addressed in indication 1. Clinical data are not complying with existing guidance, so a benefit/risk for Irritable Bowel Syndrome cannot be established.

In the same indication applying to patients to whom an increased fibre intake may be advisable, reference is made to hypercholesterolemia, while only a small effect compared to statins is demonstrated. For hypercholesterolemia, a positive Benefit/Risk cannot be established according to the relevant guidance documents.

14 May 2013