



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/HMPC/742266/2012
EMA/HMPC/M/H/0122
Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a Community herbal monograph on *Cucurbita pepo* L., semen

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 28 out of 30 votes a Community herbal monograph on *Cucurbita pepo* L., semen which is set out in Annex I.

The divergent positions are appended to this opinion.

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 appendix.

The Community herbal monograph and assessment report will be published on the European Medicines Agency website.

London, 20 November 2012

On behalf of the HMPC

Dr. Werner Knöss, Chair



Annex I: Community herbal monograph (EMA/HMPC/136024/2010)

Appendix I: Assessment report (EMA/HMPC/136022/2010)

Appendix II: Divergent positions

Two members of the HMPC did not agree with the HMPC's opinion on *Cucurbita pepo* L., *semen* for the following reason:

The proposal for a Community monograph for *Cucurbita pepo*, *semen*, cannot be agreed because of the inclusion of "or related to an overactive bladder" as part of the indication, based on traditional use only.

This divergent opinion is based on the following arguments:

1. the condition "overactive bladder" is not sufficiently defined and therefore not suitable as part of an indication for traditional use.
2. the period of 30 years medicinal use, is not sufficiently demonstrated for the condition "overactive bladder"
3. the condition "overactive bladder" should only be accepted, on the basis of proper clinical evidence.

20 November 2012