



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/HMPC/26003/2013
EMA/HMPC/M/H/0128
Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a Community herbal monograph on *Paullinia cupana* Kunth ex H.B.K. var. *sorbilis* (Mart.) Ducke, 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 27 out of 28 votes a Community herbal monograph on *Paullinia cupana* Kunth ex H.B.K. var. *sorbilis* (Mart.) Ducke, semen which is set out in Annex I.

The divergent position is 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, 15 January 2013

On behalf of the HMPC

Dr. Werner Knöss, Chair



Annex I: Community herbal monograph (EMA/HMPC/897344/2011)

Appendix I: Assessment report (EMA/HMPC/897384/2011)

Appendix II: Divergent positions

One member of the HMPC did not agree with the HMPC's opinion on *Paullinia cupana* Kunth ex H.B.K. var. *sorbilis* (Mart.) Ducke, semen for the following reason:

We do not support the proposed Community Monograph for *Paullinia cupana* Kunth., semen. We have concerns regarding the potential safe use of this herbal substance "for symptoms of fatigue and sensation of weakness", therefore, in our view this indication is not acceptable for a traditional herbal medicinal product in line with Directive 2004/24/EC.

15 January 2013