



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/HMPC/888906/2011
EMA/HMPC/M/H/106
Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a Community herbal monograph on *Cola nitida* (Vent.) Schott et Endl. and its varieties and *Cola acuminata* (P. Beauv.) Schott et Endl., 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 29 votes a Community herbal monograph on *Cola nitida* (Vent.) Schott et Endl. and its varieties and *Cola acuminata* (P. Beauv.) Schott et Endl., semen which is set out in Annex I.

The divergent positions are appended to this opinion.

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 European Medicines Agency website.

London, 22 November 2011

On behalf of the HMPC

Dr Werner Knöss, Chair



Annex I: Community herbal monograph (EMA/HMPC/722367/2010)

Appendix I: Assessment report (EMA/HMPC/722365/2010)

Appendix II: Divergent positions

Two members of the HMPC did not agree with the HMPC's opinion on *Cola nitida* (Vent.) Schott et Endl. and its varieties and *Cola acuminata* (P. Beauv.) Schott et Endl., semen for following reason:

We have concerns regarding the potential safe use of this herb for 'symptoms of fatigue and sensation of weakness' therefore in our view this indication is not appropriate for a traditional herbal medicinal product, in line with Directive 2004/24/EC.

London, 22 November 2011