



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/HMPC/695912/2013  
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Committee on Herbal Medicinal Products (HMPC)

## Opinion of the HMPC on a Community herbal monograph on *Camellia sinensis* (L.) Kuntze, non fermentatum folium

### 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 Community herbal monograph on *Camellia sinensis* (L.) Kuntze, non fermentatum folium 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 appendices.

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

London, 12 November 2013

On behalf of the HMPC

Prof. Dr Werner Knöss, Chair



## **Annex I: Community herbal monograph (EMA/HMPC/283630/2012)**

## **Appendix I: Assessment report (EMA/HMPC/283629/2012)**

## Appendix II: Divergent positions

One member of the HMPC did not agree with the HMPC's opinion on *Camellia sinensis* (L.) Kuntze, non fermentatum folium for the reason presented below:

I do not support the proposed Community herbal monograph on *Camellia sinensis* (L.) Kuntze, non fermentatum folium. I have concerns regarding the potential safe use of this herbal substance "for symptoms of fatigue and sensation of weakness", therefore, in my view this indication is not acceptable for a traditional herbal medicinal product in line with Directive 2004/24/EC.

Niamh Curran, HMPC member from Ireland

12 November 2013