



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

## Overview of comments received on Community herbal monograph on *Camellia sinensis* (L.) Kuntze, non fermentatum folium (EMA/HMPC/293036/2012)

Table 1: Organisations and/or individuals that commented on the draft Community herbal monograph on *Camellia sinensis* (L.) Kuntze, non fermentatum folium as released for public consultation on 19 April 2013 until 15 July 2013.

	Organisations and/or individuals
1	DEUTSCHER TEEVERBAND E.V. (German Tea Association)*

\*The comments submitted during the public consultation concern only the assessment report and are addressed in Table 2 as General comments.

No comments on Community monograph have been received during the public consultation.



Table 2: Discussion of comments

### General comments to draft document

Interested party	Comment and Rationale	Outcome
DEUTSCHER TEEVERBAND E.V.	<p>Is tea really a medicine and is it consequently necessary to have it included in the pharmacopeiae?</p> <p>Tea is internationally regarded as foodstuff.</p> <p>The ISO definition (+ basic requirements) for green tea is not cited.</p>	<p>The comment is not endorsed.</p> <p>Green tea is widely used as food and is also used in herbal medicinal products. The presence on the European market of herbal medicinal products containing green tea as herbal substance justifies the development of a community monograph.</p> <p>The quality of the herbal substance used in the Herbal medicinal products is covered by the existing French Pharmacopeia's monograph.</p> <p>As it has been concluded in the assessment report, based on available data, the requirements of Directive 2004/24/EC for qualification of green tea as traditional herbal medicinal product are fulfilled for the herbal substance and herbal preparations specified in the monograph (comminuted and powdered herbal substance) in the proposed indication.</p> <p>The monograph only address the green tea as herbal medicinal product and therefore the ISO definition is not of relevance in the assessment report.</p> <p>All comments related to the Assessment Report have been taken into consideration and appropriately addressed in the version revised after public consultation.</p>