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Committee on Herbal Medicinal Products (HMPC)

Public statement on *Andrographis paniculata* Nees, folium Draft

Discussion in Working Party on Community Monographs and Community List (MLWP)	May 2012 November 2012
Adoption by HMPC for release for consultation	15 January 2013
End of consultation (deadline for comments). Comments should be provided using this template . The completed comments form should be sent to hmpc.secretariat@ema.europa.eu	15 April 2013
Rediscussion in MLWP	
Adoption by HMPC	

Keywords	Herbal medicinal products; HMPC; Community herbal monographs; Community list entries; Public statements; <i>Andrographis paniculata</i> Nees, folium; <i>Andrographidis paniculatae</i> folium; Kalmegh
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Public statement on *Andrographis paniculata* Nees, folium

PROBLEM STATEMENT

The HMPC/MLWP decided to prepare a Community herbal monograph on *Andrographis paniculata* Nees, folium as announced in the January 2011 HMPC meeting report. A call for the submission of scientific data was published on the EMA website with a submission period from 15 February 2011 until 15 May 2011.

A comprehensive literature search was conducted and available data, including information on products on the market in the European Union, were assessed in relation to the requirements laid down in Directive 2001/83/EC and its Annex I, in particular Article 1, Article 10a and Chapter 2a.

The HMPC/MLWP concluded that the following requirements for the establishment of a Community herbal monograph on traditional and well-established herbal medicinal products containing *Andrographis paniculata* Nees, folium are not fulfilled:

- the requirement laid down in Article 10a of Directive 2001/83/EC that the active substance has a recognised efficacy and an acceptable level of safety and that the period of well-established medicinal use has elapsed
- the requirement laid down in Article 16a(1)(d) of Directive 2001/83/EC that "the period of traditional use as laid down on Article 16c(1)(c) has elapsed".

CONCLUSIONS

Based on the above-mentioned information, the HMPC is of the opinion that a Community herbal monograph on *Andrographis paniculata* Nees, folium cannot be established at present. The HMPC/MLWP will welcome the provision of the necessary data to allow continuation of the assessment work.

To read more about the assessment carried out, a link is provided to the page where to access the draft assessment report on *Andrographis paniculata* Nees, folium and its list of references.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000173.jsp&mid=WC0b01ac058001fa1d