

20 November 2012 EMA/HMPC/681574/2012 Committee on Herbal Medicinal Products (HMPC)

Public statement on *Angelica sinensis* (Oliv.) Diels, radix Draft

Discussion in Working Party on Community Monographs and Community List (MLWP)	May 2012 September 2012
Adoption by HMPC for release for consultation	20 November 2012
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	
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Public statement on Angelica sinensis (Oliv.) Diels, radix

PROBLEM STATEMENT

The HMPC/MLWP decided to prepare a Community herbal monograph on Angelica sinensis (Oliv.) Diels, radix as announced in the November 2011 HMPC meeting report. A call for the submission of scientific data was published on the EMA website with a submission period from 15 December 2011 until 15 April 2012.

A comprehensive literature search was conducted and available data, including information on products on the market in the European Union obtained from HMPC members, 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. A link to the list of references assessed by the Rapporteur is provided.

The HMPC/MLWP concluded that the following requirements for the establishment of a Community herbal monograph on traditional herbal medicinal products containing *Angelica sinensis* (Oliv.) Diels, radix are not fulfilled:

- 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" as the HMPC has not been able to find adequate evidence allowing a demonstration of at least 30 years of medicinal use including at least 15 years in the European Union
- the requirement laid down in Article 16a(1)(e) of Directive 2001/83/EC that "the data on the traditional use of the medicinal product are sufficient; in particular the product proves not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the medicinal product are plausible on the basis of long-standing use and experience": the HMPC has found preliminary evidence of toxicological concerns in relation to the phytochemistry of the herbal preparations
- the requirement laid down in Article 16a(1)(a) of Directive 2001/83/EC that the indications are "exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment".

CONCLUSIONS

Based on the above-mentioned information, the HMPC is of the opinion that a Community herbal monograph on *Angelica sinensis* (Oliv.) Diels, radix cannot be established at present. The HMPC/MLWP will welcome the provision of the necessary data to allow continuation of the assessment work.

A link is provided to the page where to access the draft list of references.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_0001 97.jsp&mid=WC0b01ac058001fa1d