



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 July 2013
EMA/HMPC/681574/2012
Committee on Herbal Medicinal Products (HMPC)

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

Final

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 ¹)	15 April 2013
Rediscussion in MLWP	May 2013
Adoption by HMPC	9 July 2013

Keywords	Herbal medicinal products; HMPC; Community herbal monographs; Community list entries; Public statements; <i>Angelica sinensis</i> (Oliv.) Diels, radix; Angelicae sinensis radix; Angelica sinensis root
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¹ No comments were received during the period of public consultation. Therefore the final public statement is published together with the final assessment report and list of references, without an 'Overview of comments received during the public consultation'.



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 containing *Angelica sinensis* (Oliv.) Diels, radix 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” 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.

To read more about the assessment carried out, a link is provided to the page where to access the assessment report on *Angelica sinensis* (Oliv.) Diels, radix and its list of references.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000197.jsp&mid=WC0b01ac058001fa1d