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EMA/HMPC/681519/2012
Committee on Herbal Medicinal Products (HMPC)

Public statement on *Withania somnifera* (L.) Dunal, radix Final

Discussion in Working Party on Community Monographs and Community List (MLWP)	September 2012
Adoption by HMPC for release for consultation	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>Withania somnifera</i> (L.) Dunal, radix; <i>Withaniae somniferae</i> radix; Winter Cherry root
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¹ No comments were received during the period of public consultation. Therefore the final monograph 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 *Withania somnifera* (L.) Dunal, radix

Problem statement

The HMPC/MLWP decided to prepare a Community herbal monograph on *Withania somnifera* (L.) Dunal, radix as announced in the July 2011 HMPC meeting report. A call for the submission of scientific data was published on the EMA website with a submission period from 15 July 2011 until 15 November 2011.

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 *Withania somnifera* (L.) Dunal, radix are not fulfilled:

- the requirement laid down in Article 1 of Directive 2001/83/EC on the definition of the 'herbal preparation' as the HMPC has not been able to find adequate evidence allowing a description of the herbal preparations (insufficient extract specification according to pharmaceutical requirements²) (despite the existence of data on the uses within the European Union of products containing *Withania somnifera* (L.) Dunal, radix)
- the requirement laid down in Article 16a(1)(d) of Directive 2001/83/EC that "the period of traditional use as laid down in 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.

Conclusions

Based on the above-mentioned information, the HMPC is of the opinion that a Community herbal monograph on *Withania somnifera* (L.) Dunal, 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 list of references.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000187.jsp&mid=WC0b01ac058001fa1d

² Reference is made to the HMPC scientific guidelines on quality:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000365.jsp&mid=WC0b01ac0580029569