



28 January 2015
EMA/HMPC/161476/2014
Committee on Herbal Medicinal Products (HMPC)

Public statement on *Picrorhiza kurroa* Royle ex Benth, radix

Final

Discussion in Working Party on Community Monographs and Community List (MLWP)	March 2014 May 2014
Adoption by HMPC for release for consultation	1 July 2014
End of consultation (deadline for comments) ¹ .	31 October 2014
Rediscussion in MLWP	November 2014
Adoption by HMPC	28 January 2015

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; European Union list entries; Public statements; <i>Picrorhiza kurroa</i> Royle ex Benth, radix; Bitter root, Katula
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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 list of references, without an 'Overview of comments received during the public consultation'.



Public statement on *Picrorhiza kurroa* Royle ex Benth, radix

PROBLEM STATEMENT

The HMPC/MLWP decided to prepare a European Union herbal monograph on *Picrorhiza kurroa* Royle ex Benth, 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 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 European Union herbal monograph on traditional herbal medicinal products containing *Picrorhiza kurroa* Royle ex Benth, 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.

CONCLUSIONS

Based on the above-mentioned information, the HMPC is of the opinion that a European Union herbal monograph on *Picrorhiza kurroa* Royle ex Benth, 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_000183.jsp&mid=WC0b01ac058001fa1d