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SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

## Public statement on *Uncaria tomentosa* (Willd. ex Schult.) DC., cortex

### Draft

Discussion in Working Party on European Union Monographs and List (MLWP)	May 2014 July 2014 September 2014 January 2015
Adoption by HMPC for release for consultation	10 March 2015
End of consultation (deadline for comments). Comments should be provided using this <a href="#">template</a> . The completed comments form should be sent to <a href="mailto:hmpc.secretariat@ema.europa.eu">hmpc.secretariat@ema.europa.eu</a>	15 July 2015
Rediscussion in MLWP	
Adoption by HMPC	

<b>Keywords</b>	Herbal medicinal products; HMPC; European Union herbal monographs; European Union list entries; Public statements; <i>Uncaria tomentosa</i> (Willd. ex Schult.) DC., cortex; <i>Uncariae tomentosae</i> cortex; Cat's Claw
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# Public statement on *Uncaria tomentosa* (Willd. ex Schult.) DC., cortex

## PROBLEM STATEMENT

The HMPC/MLWP decided to prepare a European Union herbal monograph on *Uncaria tomentosa* (Willd. ex Schult.) DC., cortex as announced in the 2012 MLWP work programme. A call for the submission of scientific data was published on the EMA website with a submission period from 7 October 2010 until 15 December 2010.

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 European Union herbal monograph on traditional or well-established herbal medicinal products containing *Uncaria tomentosa* (Willd. ex Schult.) DC., cortex 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”.

Herbal preparations of the stem bark are in medicinal use within the European Union since more than 15 years but less than 30 years. Information regarding the medicinal use outside the European Union for more than 30 years is insufficient regarding the plant part used, the herbal preparation, the indication and the posology.

## CONCLUSIONS

Based on the above-mentioned information, the HMPC is of the opinion that a European Union herbal monograph on *Uncaria tomentosa* (Willd. ex Schult.) DC., cortex 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 *Uncaria tomentosa* (Willd. ex Schult.) DC., cortex and its list of references.

[http://www.ema.europa.eu/ema/index.jsp?curl=/pages/medicines/landing/herbal\\_search.jsp&murl=menu/medicines/medicines.jsp&mid=WC0b01ac058001fa1d](http://www.ema.europa.eu/ema/index.jsp?curl=/pages/medicines/landing/herbal_search.jsp&murl=menu/medicines/medicines.jsp&mid=WC0b01ac058001fa1d)