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Public statement on *Paeonia lactiflora* Pall. and/or *Paeonia veitchii* Lynch, radix (Paeoniae radix rubra)

Final

Discussion in Working Party on European Union Monographs and List (MLWP)	March 2015 November 2015
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PROBLEM STATEMENT

The HMPC/MLWP decided to prepare a European Union herbal monograph on *Paeonia lactiflora* Pallas, radix and on *Paeonia veitchii* Lynch, radix as announced in the July 2013 HMPC meeting report. A call for submission of scientific data was published on the EMA website with a submission date 17 February 2014.

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 Paeoniae radix rubra is 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)(b) of Directive 2001/83/EC that the herbal substance or herbal preparation is “exclusively for administration in accordance with a specified strength and posology”

- 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”

- 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 acknowledges the existence of numerous publications on Paeoniae radix or constituents thereof. However, often an appropriate description of herbal substance or herbal preparations used are missing. Available data are not sufficient to establish a European Union monograph at present.

CONCLUSIONS

Based on the above-mentioned information, the HMPC is of the opinion that a European Union herbal monograph for Paeoniae radix rubra cannot be established.

To read more about the assessment carried out, a link is provided to the page where to access the assessment report on Paeoniae radix rubra and its list of references.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000213.jsp&mid=WC0b01ac058001fa1d