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Committee on Herbal Medicinal Products (HMPC)

Public statement on *Myroxylon balsamum* (L.) Harms var. *pereirae* (Royle) Harms, balsamum

Final

Discussion in Working Party on European Union Monographs and European Union List (MLWP)	November 2014 January 2015 March 2015 May 2015 September 2015
Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation	24 November 2015
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End of consultation (deadline for comments ¹).	15 March 2016
Rediscussion in MLWP	April 2016
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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 *Myroxylon balsamum* (L.) Harms var. *pereirae* (Royle) Harms, balsamum

PROBLEM STATEMENT

The HMPC/MLWP decided to prepare a European Union herbal monograph on *Myroxylon balsamum* (L.) Harms var. *pereirae* (Royle) Harms, balsamum, as announced in the July 2013 HMPC meeting report.

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 *Myroxylon balsamum* (L.) Harms var. *pereirae* (Royle) Harms, balsamum, 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)(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”

In the literature, Peru balsam is considered one of the most common contact allergens and adverse reactions described in medicinal handbooks are for example dermatitis, contact urticaria, Quincke's edema, broncho-obstructive and anaphylactic reactions. In patch test studies reported in the scientific literature, prevalence of positive reactions to Peru balsam has been reported to be up to 19.6%. Importantly, in studies in the general population prevalence of positive reactions to Peru balsam has been reported to be up to 2.6%.

In addition, in the Cosmetics Regulation EC No 1223/2009, Cosmetics Directive 76/768/EEC and Inventory of Cosmetic Ingredients, Peru balsam (exudate) is included in Annex II, i.e. the list of substances prohibited in cosmetic products and should not be used as a fragrance. The recommendation is based on a wide variety of test results on the sensitising potential of Peru balsam.

The HMPC considered the documented traditional uses of *Myroxylon balsamum* (L.) Harms var. *pereirae* (Royle) Harms, balsamum, but concluded that in the presence of the high risk of sensitisation in patients, an EU monograph cannot be established.

Safer medicinal products and other treatment options are available in the indication which was considered during the assessment: *Traditional herbal medicinal product for the symptomatic relief of minor inflammations of the skin and as an aid in healing of minor wounds.*

CONCLUSIONS

Based on the above-mentioned extensive safety concerns, the HMPC is of the opinion that a European Union herbal monograph on *Myroxylon balsamum* (L.) Harms var. *pereirae* (Royle) Harms, balsamum 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 *Myroxylon balsamum* (L.) Harms var. *pereirae* (Royle) Harms, balsamum and its list of references.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000218.jsp&mid=WC0b01ac058001fa1d