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Committee on Herbal Medicinal Products (HMPC)

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

Draft

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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 proposed indication:
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.

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 *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/landing/herbal_search.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001fa1d