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Committee on Herbal Medicinal Products (HMPC)

Public statement on *Sambucus nigra* L., fructus

Draft

Discussion in Working Party on Community Monographs and Community List (MLWP)	January 2012 March 2012 May 2012 September 2012 November 2012 January 2013
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End of consultation (deadline for comments). Comments should be provided using this template . The completed comments form should be sent to hmpc.secretariat@ema.europa.eu	15 July 2013
Rediscussion in MLWP	
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Public statement on *Sambucus nigra* L., fructus

PROBLEM STATEMENT

The HMPC/MLWP decided to prepare a Community herbal monograph on *Sambucus nigra* L., fructus as announced in the September 2011 HMPC meeting report. A call for the submission of scientific data was published on the EMA website with a submission period from 15 October 2011 – 15 February 2012.

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 requirement for the establishment of a Community herbal monograph on traditional herbal medicinal products containing *Sambucus nigra* L., fructus is not fulfilled:

- 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”. For elderberry preparations, complete information on traditional use with a specified posology is missing in order to establish a monograph that fulfills the requirements of medicinal use for at least 30 years (including at least 15 years within the European Union).

CONCLUSIONS

Based on the above-mentioned information, the HMPC is of the opinion that a Community herbal monograph on *Sambucus nigra* L., fructus 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 *Sambucus nigra* L., fructus and its list of references.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000193.jsp&mid=WC0b01ac058001fa1d