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EMA/HMPC/57109/2011
Committee on Herbal Medicinal Products (HMPC)

Public statement on *Viscum album* L., herba

Final

Discussion in Working Party on Community Monographs and Community List (MLWP)	May 2009 September 2009 November 2009 September 2010 January 2011 March 2011 May 2011
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Public statement on *Viscum album* L., herba

PROBLEM STATEMENT

The HMPC/MLWP decided to prepare a Community herbal monograph on *Viscum album* L., herba as announced in the 2012 MLWP work programme May 2012 HMPC meeting report.

A comprehensive literature search was conducted and available data, including information on products on the market in the European Union, are assessed vis-à-vis 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 requirements for the establishment of a Community herbal monograph on traditional herbal medicinal or well-established medicinal products containing *Viscum album* L., herba are not fulfilled:

Cardiovascular indications

The following requirements 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)(a) of Directive 2001/83/EC that the indications are “exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment” is not fulfilled

Cancer therapy

The following requirements are not fulfilled:

- the requirement laid down in Article 16a(1)(a) of Directive 2001/83/EC that the indications are “exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment”
- 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)(c) of Directive 2001/83/EC that the herbal preparation is an oral, external and/or inhalation” preparation

The HMPC also considered use in cancer therapy and concluded that the information available in the public domain was not sufficient to enable a well-established use indication to be supported.

CONCLUSIONS

Based on the above-mentioned concerns the HMPC is of the opinion that no Community herbal monograph on *Viscum album* L., herba can be established.

To read more about the assessment carried out, a link is provided to the page where to access the assessment report on *Viscum album* L., herba and its list of references.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000007.jsp&mid=WC0b01ac058001fa1d