



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 May 2012
EMA/HMPC/510064/2011
Committee on Herbal Medicinal Products (HMPC)

Public statement on *Tilia tomentosa* Moench, flos

Final

Discussion in Working Party on Community Monographs and Community List (MLWP)	May 2011 July 2011
Adoption by HMPC for release for consultation	13 September 2011
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 February 2012
Rediscussion in MLWP	March 2012
Adoption by HMPC	22 May 2012

Keywords	Herbal medicinal products; HMPC; Community herbal monographs; Community list entries; Public statements; <i>Tilia tomentosa</i> Moench, flos; <i>Tiliae tomentosae</i> flos; silver lime flower
-----------------	---



Public statement on *Tilia tomentosa* Moench, flos

PROBLEM STATEMENT

The HMPC/MLWP decided to prepare a Community herbal monograph on *Tilia tomentosa* Moench, flos as announced in the March 2010 HMPC meeting report.

After reviewing information on the products containing *Tilia tomentosa* Moench, flos and preparations thereof marketed in the European Union, it appears that no products (single-ingredient or combination) are available.

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 Community herbal monograph on traditional well-established herbal medicinal products containing *Tilia tomentosa* Moench, flos 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)(d) of Directive 2001/83/EC that “the period of traditional use as laid down on Article 16c(1)(c) has elapsed”.

CONCLUSIONS

Based on the above-mentioned information, the HMPC is of the opinion that a Community herbal monograph on *Tilia tomentosa* Moench, flos cannot be established.

To read more about the assessment carried out, a link is provided to the page where to access the draft assessment report on *Tilia tomentosa* Moench, flos and its list of references.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000160.jsp&mid=WC0b01ac058001fa1d