



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a European Union herbal monograph on *Silybum marianum* (L.) Gaertn., fructus

Opinion

The HMPC, in accordance with Article 16h(3) of Directive 2001/83/EC and as set out in the appended assessment report, establishes, by a majority of 21 out of 25 votes a European Union herbal monograph on *Silybum marianum* (L.) Gaertn., fructus radix which is set out in Annex I.

The divergent positions are appended to this opinion.

The Norwegian HMPC member was not present during the meeting.

This opinion is forwarded to Member States, to Iceland and Norway, together with its Annex I and appendices.

The European Union herbal monograph and assessment report will be published on the European Medicines Agency website.

London, 5 June 2018



Annex I: European Union herbal monograph (EMA/HMPC/294187/2013)

Appendix I: Assessment report (EMA/HMPC/294188/2013)

Appendix II : Divergent positions

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reason:

The criteria for WEU are regarded fulfilled for one of the herbal preparations included in the monograph. In line with clinical data publicly available this preparation is currently in medicinal use for supportive treatment of the impaired liver. The finally proposed TU-indication mainly referring to digestive disorders and the support of the liver function is thus not agreed for this herbal preparation.

Astrid Obmann, HMPC alternate member from Austria

London, 5 June 2018

The members of the HMPC mentioned below did not agree with the HMPC's opinion for the following reason:

We do not support the proposed European Union herbal monograph for *Silybi mariani fructus*.

We do not agree with the HMPC's opinion for the following reasons:

In our view the proposal for traditional use "*to support liver function after serious conditions have been excluded by a medical doctor*" is not a recognised medicinal indication and, in any event, is not suitable for self-diagnosis/self-medication.

Linda Anderson, HMPC Member from United Kingdom

Rachel Cox, HMPC Member from Ireland

London, 5 June 2018

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reason:

The wording "*to support the liver function*" in the indication is not a medical claim and a very vague term with no clear meaning to the patients. A traditional use indication should be related to symptoms of a disease appropriate for self-medication and the symptoms should be easy to recognise by self-medicating patients.

In addition, in accordance with the Directive 2001/83/EC, Article 16a(1)(a), traditional herbal medicinal products should have indications intended and designed for the use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment. Symptoms from the liver should be under medical supervision and therefore, an indication including claims about the liver function or symptoms from the liver is not suitable for traditional herbal medicinal products.

Erika Svedlund, HMPC Member from Sweden

London, 5 June 2018