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SCIENCE MEDICINES HEALTH

2 February 2016
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Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a European Union herbal monograph on *Pistacia lentiscus* L., resin (mastic)

Opinion

The HMPC, in accordance with Article 16h(3) of Directive 2001/83/EC, as amended, and as set out in the appended assessment report, establishes, by a majority of 23 out of 27 votes a European Union herbal monograph on *Pistacia lentiscus* L., resin (mastic) which is set out in Annex I.

The Norwegian HMPC member agrees with the above-mentioned recommendation of the HMPC.

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, 2 February 2016



Annex I: European Union herbal monograph (EMA/HMPC/46758/2015)

Appendix I: Assessment report (EMA/HMPC/46756/2015)

Appendix II: Divergent positions

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

Austria is against the adoption of the monograph of *Pistacia lentiscus* L., resin (mastix), because the assessment report does not provide sufficient evidence of traditional use in the European Union related to certain indications and certain posologies as requested by article 16a of Dir. 2001/83 as amended.

Reinhard Länger, HMPC member from Austria

London, 2 February 2016

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

Denmark is against the adoption of the monograph of *Pistacia lentiscus* L., resin (mastix), because the assessment report does not provide sufficient evidence of traditional use in the European Union related to certain indications and certain posologies as requested by article 16a of Dir. 2001/83 as amended.

Steffen Bager, HMPC member from Denmark

London, 2 February 2016

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

We do not support the traditional use. In our view the data provided are insufficient to support a traditional use in accordance with article 16a Directive 2001/83/EC, as amended.

From the data provided the continuous use of the posologies described in the monograph cannot be derived.

Jacqueline Wiesner, HMPC member from Germany

London, 2 February 2016

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

We do not agree with the assessment report of *Pistacia lentiscus*, as in our opinion there is not enough traditional evidence on this product as presented today at the HMPC meeting. The traditional use is based on clinical studies rather than on the 30-year traditional use of the single herbal medicinal product.

Everaldo Attard, HMPC member from Malta

London, 2 February 2016