Opinion of the HMPC on a European Union herbal monograph on *Olea europaea* L., folium

**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 23 out of 28 votes a European Union herbal monograph on *Olea europaea* L., folium which is set out in Annex I.

The divergent positions are appended to this opinion.

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. They replace those adopted 18 April 2012.

London, 31 January 2017
Annex I: European Union herbal monograph
(EMA/HMPC/359238/2016)
Appendix I: Assessment report (EMA/HMPC/359236/2016)
Appendix II: Divergent positions
The member of the HMPC mentioned below did not agree with the HMPC’s opinion for the following reason:

The proposed therapeutic indication for Olea europea L., folium is “Traditional herbal medicinal product used to promote renal elimination of water, in mild cases of water retention after serious conditions have been excluded by a medical doctor. The product is a traditional herbal medicinal product for use in specified indication exclusively based upon long-standing use.” The validity and safety of this indication is not endorsed by the Dutch delegate.

From Directive 2004/24/EC (article 16a) the following criteria for a THMP are quoted:

"they have indications 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;"

Water retention (edema) can be caused by a number of serious conditions and diseases, e.g. cardiovascular conditions which cannot be excluded by the medical examination as proposed in the indication. Therefore I am of the opinion that the indication is not guaranteeing the safe use as a traditional herbal medicinal product.

Emiel van Galen, HMPC member from The Netherlands

London, 31 January 2017
The member of the HMPC mentioned below did not agree with the HMPC’s opinion for the following reason:

The therapeutic indication in the EU monograph on Olea folium is: “Traditional herbal medicinal product used to promote the renal elimination of water, in mild cases of water retention after serious conditions have been excluded by a medical doctor.”

This indication implies that Olea folium has diuretic properties. Medicinal products with diuretic effects are indicated in conditions which are characterized by edema, such cardiac, renal, hepatic or pulmonary edema. Diuretics may also be indicated for hypertension. Such conditions are not acceptable within the framework of safe self-medication with traditional herbal medicinal products.

The therapeutic indication in the EU monograph of Olea folium does not specify which “mild cases of water retention” are intended for treatment. In the absence of this information, which is necessary for safety reasons, the indication is not considered acceptable for self-medication.

Eeva Sofia Leinonen, HMPC member from Finland

London, 31 January 2017
The member of the HMPC mentioned below did not agree with the HMPC’s opinion for the following reason:

The therapeutic indication in the EU monograph on Oleae folium is: “Traditional herbal medicinal product used to promote the renal elimination of water, in mild cases of water retention after serious conditions have been excluded by a medical doctor.”

This indication implies that Oleae folium has diuretic properties. Medicinal products with diuretic effects are indicated in conditions which are characterized by edema, such cardiac, renal, hepatic or pulmonary edema. Diuretics may also be indicated for hypertension. Such conditions are not acceptable within the framework of safe self-medication with traditional herbal medicinal products.

The therapeutic indication in the EU monograph of Oleae folium does not specify which “mild cases of water retention” are intended for treatment. In the absence of this information, which is necessary for safety reasons, the indication is not considered acceptable for self-medication.

Per Claeson, HMPC member from Sweden

London, 31 January 2017
The member of the HMPC mentioned below did not agree with the HMPC’s opinion for the following reason:

The proposed therapeutic indication for *Olea europaea* L., folium is “Traditional herbal medicinal product used to promote the renal elimination of water, in mild cases of water retention after serious conditions have been excluded by a medical doctor”.

This indication cannot be accepted as traditional one in the meaning of the Directive 2004/24/EC (Article 16a): “they have indications 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;”

In case of water retention it is not enough to exclude serious condition by a medical doctor at the beginning of the treatment but it needs continuous monitoring.

Zsuzsanna Bírone Sândor, HMPC member from Hungary
London, 31 January 2017
The member of the HMPC mentioned below did not agree with the HMPC’s opinion for the following reason:

As a general remark it can be said that during the plenary meeting of the HMPC, appropriate changes were made in the monograph. Part of the changes are related to prevent unexpected events, more particularly events with patients at cardiovascular risk (hypertension, heart failure). As to my opinion the actual wording used in the monograph is sufficient to protect cardiovascular patients at risk. Why do we not take another step forward by accepting a light cardiovascular indication, instead of using an indirect wording in the actual monograph?

Hypertension or control of blood pressure is mentioned for products in Germany, Spain, Bulgaria, Portugal, Greece and Italy (cf. assessment report). Serious conditions must be excluded by a medical doctor. There is a warning related to severe cardiac or renal disease. Why not open the use of Oleae folium to light cardiovascular conditions? These are conditions for which conventional medication may not yet be justified, but nevertheless a light approach can be considered.

Conclusion: I cannot approve the actual monograph, not because of what it covers, but because of what it does not cover, as all conditions are fulfilled to move to a cardiovascular indication.

Gert Laekeman, Co-opted member of the HMPC
London, 31 January 2017