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

**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 24 out of 29 votes a Community herbal monograph on *Olea europaea* L., folium which is set out in Annex I.

The divergent positions are appended to this opinion.

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

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

London, 22 November 2011

[Signature]

On behalf of the HMPC
Dr Werner Knöss, Chair
Annex I: Community herbal monograph
(EMA/HMPC/430507/2009)
Appendix I: Assessment report (EMA/HMPC/430506/2009)
Appendix II: Divergent positions
One member of the HMPC did not agree with the HMPC’s opinion on *Olea europaea* L., folium for following reason:

In Germany a traditional use “to support cardiovascular system” exist for more than 30 years. Also Spain reported this indication for traditional use even though the requirements of 30 years are not completely fulfilled (25 years only).

In the AR it is pointed out that the tradition and pharmacological plausible activity would be considered as beneficial for the cardiovascular system (function). Safety concerns were raised towards the demarcation between mild functional complaints and organic symptoms. Since an exclusion of serious conditions by a medical doctor would be possible, it is not agreed that a long tradition of such products in the field of “cardiovascular system” can be precluded.

It is to point out, that in a different monograph (*Leonurus cardiaca*) an indication “Traditional herbal medicinal product used to relieve symptoms of nervous cardiac complaints such as palpitations, after serious conditions have been excluded by a medical doctor”. Even here demarcation between nervous cardiac complaints and cardiac complaints could not be easily done by laypersons.

Furthermore also for other herbal substances e.g. *Visci albi herba* the indication “to support cardiovascular system” is used in a lot of countries within the EU.

Even though I agree with the indication given so far in the monograph I disagree with the exclusion of the indication “traditionally used to support cardiovascular system”.

London, 22 November 2011
One member of the HMPC did not agree with the HMPC's opinion on *Olea europaea* L., folium for following reason:

The proposed therapeutic indication for *Olea europaea* 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 Swedish 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. heart failure, kidney diseases, chronic lung diseases, liver diseases, diabetes, arthritis, leg thrombosis etc. None of these conditions/diseases are suitable for self-medication. These conditions will be excluded in the required examination by the medical doctor.

Which cases of water retention are then included in the therapeutic indication? No such cases/conditions have been identified in the monograph. Neither are any such cases/conditions documented by 30 years of traditional use, according to the assessment report.

If no valid therapeutic indication within the scope of a traditional use registration has been given in a proposed monograph, it should be rejected. The wording "to promote renal elimination of water" is a lay description of the pharmacological effect of a diuretic. The monograph, with the proposed wording of the therapeutic indication without identification of the conditions/cases considered appropriate to be treated with *Olea europaea* L., folium, is considered to encourage use of products containing olive leaf as a diuretic medicinal product in high risk therapeutic areas like hypertension and heart failure.

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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. heart failure, kidney diseases, chronic lung diseases, liver diseases, diabetes, arthritis, leg thrombosis etc. None of these conditions/diseases are suitable for self-medication. These conditions will be excluded in the required examination by the medical doctor.

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

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Water retention (edema) can be caused by a number of serious conditions and diseases, e.g. cardiovascular conditions which can not 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.

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This indication cannot be accepted as a 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.

London, 22 November 2011