



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 *Allium sativum* L., bulbus

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 20 out of 26 votes a European Union herbal monograph on *Allium sativum* L., bulbus 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 European Union herbal monograph and assessment report will be published on the European Medicines Agency website.

London, 18 July 2017

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Annex I: European Union herbal monograph (EMA/HMPC/7685/2013)

Appendix I: Assessment report (EMA/HMPC/7686/2013)

Appendix II: Divergent positions

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

I do not support the proposed Union Monograph for *Allium sativum* L., bulb.

The proposed indication is not considered appropriate for self-medication as a traditional use herbal medicinal product:

Traditional herbal medicinal product used as an adjuvant for the prevention of atherosclerosis.

Patients at risk of atherosclerosis require medical intervention to ensure an appropriate risk assessment is undertaken to determine the necessary lifestyle modifications and medications required.

Linda Anderson, HMPC Member from the United Kingdom

London, 18 July 2017

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

The divergent opinion is only related to indication 1.

The suggested indication of an adjuvant treatment for the prevention of atherosclerosis in an otherwise healthy population is not considered medically appropriate or in line with current treatment guidelines. The decision to start or refrain from preventive treatment should be made by a medical doctor based on laboratory tests, physical examination and an individual assessment of total atherosclerotic cardiovascular disease (ASCVD) risk profile. This cannot be self-assessed by the patient. Depending on individual cardiovascular risk profile, the individually recommended treatment can vary substantially, including for instance life-style changes (e.g. concerning smoking, alcohol, weight, physical exercise) with or without medical treatment, antiplatelet treatment, treatment of hypertension, hyperlipidaemia and/or diabetes. Monitoring of this treatment and regular re-assessment of total cardiovascular risk is not possible for the patient to perform on her/his own. Depending on individual cardiovascular risk profile, the self-treatment with garlic products might delay a proper medical diagnosis and the initiation of appropriate treatment, which may put the patient at risk of developing serious cardiovascular conditions. Since diagnosis, initiation and monitoring of therapy require supervision by a medical doctor, the preventive treatment of atherosclerosis is not considered an acceptable indication for a traditional herbal medicinal product.

Indication 2 : Traditional herbal medicinal product THMP used for the relief of the symptoms of cold, exclusively based upon long-standing use" is considered acceptable.

Per Claeson, HMPC Member from Sweden

London, 18 July 2017

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

I do not support the proposed European Union Monograph for *Allium sativum* L., bulb.

The proposed indication is not considered appropriate for self-medication as a traditional use herbal medicinal product:

Traditional herbal medicinal product used as an adjuvant for the prevention of atherosclerosis.

Patients at risk of atherosclerosis require medical intervention to ensure an appropriate risk assessment is undertaken to determine the necessary lifestyle modifications and medications required.

Rachel Cox, HMPC Member from Ireland

London, 18 July 2017

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

The suggested indication of an adjuvant treatment for the prevention of atherosclerosis in an otherwise healthy population is not considered medically appropriate or in line with current treatment guidelines. The decision to start or refrain from preventive treatment should be made by a medical doctor based on laboratory tests, physical examination and an individual assessment of total atherosclerotic cardiovascular disease (ASCVD) risk profile. This cannot be self-assessed by the patient. Depending on individual cardiovascular risk profile, the individually recommended treatment can vary substantially, including for instance life-style changes (e.g. concerning smoking, alcohol, weight, physical exercise) with or without medical treatment, antiplatelet treatment, treatment of hypertension, hyperlipidaemia and/or diabetes. Monitoring of this treatment and regular re-assessment of total cardiovascular risk is not possible for the patient to perform on her/his own. Depending on individual cardiovascular risk profile, the self-treatment with garlic products might delay a proper medical diagnosis and the initiation of appropriate treatment, which may put the patient at risk of developing serious cardiovascular conditions. Since diagnosis, initiation and monitoring of therapy require supervision by a medical doctor, the preventive treatment of atherosclerosis is not considered an acceptable indication for a traditional herbal medicinal product.

The use of a garlic product for the relief of symptoms of common cold is considered an acceptable therapeutic indication for a traditional herbal medicinal product. Thus no objection is raised to Indication 2 of the monograph.

Eeva Sofia Leinonen, HMPC Member from Finland

London, 18 July 2017

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

The divergent opinion is only related to indication 1.

The proposed indication of an adjuvant treatment with a traditional herbal medicinal product for the prevention of atherosclerosis in an otherwise healthy population is not considered medically appropriate or in line with current treatment guidelines. The decision to start or refrain from preventive treatment should be made by a medical doctor based on laboratory tests, physical examination and an individual assessment of total atherosclerotic cardiovascular disease risk profile. This cannot be self-assessed by the patient.

Since diagnosis, initiation and monitoring of therapy require supervision by a medical doctor, the preventive treatment of atherosclerosis is not considered an acceptable indication for a traditional herbal medicinal product, complying with the requirements given in article 16a of Directive 2001/83/EU.

Indication 2: Traditional herbal medicinal product THMP used for the relief of the symptoms of cold, exclusively based upon long-standing use" is considered acceptable.

Emiel Van Galen, HMPC Member from the Netherlands

London, 18 July 2017

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

I cannot accept the actual monograph, on *Allium sativum* for the reason explained below.

It is important to critically evaluate the published data on *Allium sativum* preparations. On this point there exists a discrepancy between the preclinical and the clinical part of the assessment report. Whereas the preclinical part is well-developed, the clinical approach remains too general.

On page 38 of the assessment report a table is depicted. It is extracted from a review made by Ried *et al.* (2013). This table refers to several clinical studies made with garlic preparations wherein alliin was quantified. These studies should be individually analysed with regard to the type of patients, the intervention and the outcomes, before any conclusion can be made about well-established or traditional use.

Furthermore, the possible relation between the content of alliin and clinical outcomes should be more clearly elaborated.

Gert Laekeman, Co-opted member of the HMPC

London, 18 July 2017