



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 *Vaccinium macrocarpon* Aiton, 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 20 out of 24 votes a European Union herbal monograph on *Vaccinium macrocarpon* Aiton, fructus 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 and Norway, together with its Annex I and appendix.

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

Amsterdam, 23 November 2022

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Annex I: European Union herbal monograph (EMA/HMPC/49135/2017)

Appendix I: Assessment report (EMA/HMPC/517879/2016)

Appendix II: Divergent positions

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

Cyprus (CY) has a divergent opinion on the HMPC's position on the European Union herbal monograph on *Vaccinium macrocarpon* Aiton, fructus since we are not fully convinced for its efficacy. Just to clarify that we have no objection on its safety or to be perceived as a herbal medicine and not as a food/fruit as it can contribute to the safety monitoring.

Christina Sylvia Chrysostomou, HMPC member from Cyprus

Amsterdam, 23 November 2022

The divergent opinion is based on the lack of data on the tradition of the preparation described and the related lack of data on the substantiation of the indications.

No data are available to meet the requirements of Directive 2001/83/EC (Article 16a(1)(d) in conjunction with Article 16c(1)(c) ["... that the medicinal product in question, or a corresponding product has been in medicinal use throughout a period of at least 30 years preceding the date of the application, including at least 15 years within the Community.."]) with regard to the use in the Community.

There are no products on the European market in which the described preparation has been used medicinally, and only bibliographic data could be provided for the American tradition. This also cannot meet the requirements of Article 16a(1)(e).

While the one indication is not supported by the professional societies, the other is at least not recommended because of the lack of data. Thus, there is the question of the plausibility of the effect as asked for in Article 16a(1)(e) ["... pharmacological effects or efficacy of the medicinal product are plausible on the basis of long-standing use and experience (Article 16a(1)(e))].

Jacqueline Wiesner, HMPC member from Germany

Amsterdam, 23 November 2022

Lithuania (LT) has a divergent opinion on the HMPC's position on the European Union herbal monograph on *Vaccinium macrocarpon* Aiton, fructus as the scientific evidence of the efficacy for the proposed indication is considered insufficient.

Greta Budukeviciute, HMPC member from Lithuania

Amsterdam, 23 November 2022

Vaccinii macrocarpi fructus had not been used in the European medical tradition. In the America, where it was used, the herbal substance have had never the status of being in a medicinal use but

rather of a useful plant. This status has been different to that of herbal medicinal products used in Europe and caused that establishment of accurate traditional medicinal use dosage and posology cannot be established..

Wojciech Dymowski, HMPC member from Poland

Amsterdam, 23 November 2022