EMA/HMPC/169170/2025
EMA/HMPC/M/H/0277
Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a European Union herbal monograph on *Zingiber officinale* Roscoe, rhizoma

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 19 out of 25 votes a revised European Union herbal monograph on *Zingiber officinale* Roscoe, rhizoma 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 appendices.

The revised European Union herbal monograph and assessment report will be published on the European Medicines Agency website. They replace those adopted on 27 March 2012.

Amsterdam, 07 May 2025.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Annex I: European Union herbal monograph (EMA/HMPC/885789/2022)

Appendix I: Assessment report (EMA/HMPC/765220/2022)

Appendix II: Divergent positions

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

Finland does not agree on the WEU part of the ginger monograph.

The quality of available studies in motion sickness and the clinical relevance of the results from these studies to substantiate efficacy in motion sickness are considered low in relation to current requirements ('Guideline on the assessment of clinical safety and efficacy in the preparation of EU herbal monographs for well-established and traditional herbal medicinal products' (EMA/HMPC/104613/2005–Rev. 1). For example, in the two old studies by Grøntved et al. (1988) and Schmid et al. (1994) motion sickness was not an inclusion criteria and subjects with no motion sickness could have been included. Furthermore, there is no information available if the tools used to measure motion sickness had been validated and there is no specification of which group difference should be classified as clinically relevant and thus no calculation of the required sample size is possible. This makes the interpretation of the results of the studies difficult and a conclusion on WEU in prevention of motion sickness cannot be made.

Maria Paile-Hyvärinen, HMPC member from Finland

Amsterdam, 07 May 2025.

Germany do not agree with the AR and monograph on *Zingiber officinale* Roscoe, rhizoma.

Reason:

The divergent opinion is based on the lack of data on well-established use and on the lack of data on traditional use for indications 3, 4 and 5.

There are no data available to meet the requirements of Directive 2001/83/EC on well-established use (Article 10a). Neither products on the market nor clinical studies are public available which support the indication and posology of the well-established use.

For indications 3,4 and 5, there are no data 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."]). There are no products on the European market in which the described preparations have been used for medicinal purposes for 30 years. Bibliographic data cannot be used to meet the requirements of Article 16a(1).

Jacqueline Wiesner, HMPC member from Germany

Amsterdam, 07 May 2025.

Greece do not agree with the AR and monograph on *Zingiber officinale* Roscoe, rhizoma.

Reason:

The divergent opinion is based on the lack of data on well-established use as well as on the lack of data on the tradition of the described preparation and the related lack of data to substantiate the indication (indications 3, 4 and 5 of traditional use- three more indications have been further added).

There are no adequate data available to meet the requirements of Directive 2001/83/EC on well-established use (Article 10a). Neither products on the market nor clinical studies are public available which support the indication and posology of the well-established use.

Moreover, there are no data 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 for the indications and posologies (indications 3, 4 and 5 of traditional use) based uniquely on literature data from Bradley (1992). There are no products on the European market in which the described preparations have been used for medicinal purposes for 30 years. Literature data cannot be used to support new indications and to meet the requirements of Article 16a(1).

Ioanna Chinou, HMPC member from Greece

Amsterdam, 07 May 2025.

Ireland do not support the proposed European Union Monograph for Zingiberis rhizoma. We do not support the inclusion of children under 12 years of age for indication 1. In addition, we have concerns regarding the potential safe use of this herbal substance "for the temporary loss of appetite", therefore, in our view, this indication is not acceptable for a traditional herbal medicinal product in line with Directive 2004/24/EC.

Jackie Masterson, HMPC member from Ireland

Amsterdam, 07 May 2025.

Italy do not agree with the HMPC's opinion on a well-established use (WEU) for *Zingiber officinale* Roscoe rhizoma for the following reason:

The data available since the first version of the monograph were insufficient to support a WEU indication for Zingiber officinale Roscoe rhizoma as a "Herbal medicinal product for the prevention of nausea and vomiting in motion sickness"; indeed, clinical studies were not of adequate quality and their clinical relevance was low. No new clinical studies to substantiate efficacy in the WEU indication were found during the revision process, therefore the evidence available remains insufficient to fulfil the requirements of the article 10a and Annex 1 of Directive 2001/83/EC, as amended.

Alessandro Assisi, HMPC member from Italy

Amsterdam, 07 May 2025.

The Netherlands do not agree with the HMPC's opinion on *Zingiber officinale* Roscoe, rhizoma for the following reasons:

The data provided is insufficient to support a well-established use indication for Zingiber officinale Roscoe, rhizoma as a "Herbal medicinal product for the prevention of nausea and vomiting in motion sickness".

The clinical trials presented are of inadequate quality and Zingiber officinale Roscoe has not been scientifically proven to have recognized efficacy in accordance with the requirements of Article 10a and Annex 1 Directive 2001/83/EC, as amended.

Burt Kroes, HMPC member from the Netherlands

Amsterdam, 07 May 2025.