08 July 2026
EMA/HMPC/126066/2026
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 04-06 May 2026

Chair: Carmen Purdel, Vice-Chair: Olga Maria Palomino

Disclaimers

Some of the information contained in this set of minutes is considered commercially confidential or sensitive and therefore not disclosed.

Of note, this set of minutes is a working document primarily designed for HMPC members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in this set of minutes cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/729522/2016).

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1. Introduction

1.1. Welcome and declarations of interest of members, alternates and experts

The Chair opened the meeting by welcoming all participants. The meeting was held remotely.

In accordance with the Agency's policy on handling of declarations of interests of scientific Committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and on the topics in the agenda of the meeting, the Committee Secretariat announced the restricted involvement of some Committee members, alternates and experts for the concerned agenda topics. Participants were asked to declare any changes, omissions or errors to their declared interests concerning the matters for discussion. No new or additional competing interests were declared. Restrictions applicable to this meeting are captured in the List of participants included in the minutes.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure. All decisions taken at this meeting were made in the presence of a quorum of members. All decisions, recommendations and advice were agreed by consensus, unless otherwise specified. The members of the EEA-EFTA States agreed with the recommendation of the HMPC, unless otherwise specified.

1.2. Adoption of agenda

HMPC agenda for 04-06 May 2026.

Outcome:

Agenda and time schedule adopted.

1.3. Adoption of the minutes

HMPC minutes for 02-04 March 2026.

Outcome:

Minutes adopted, including amendments suggested by HMPC members.

2. EU herbal monographs and list entries for adoption

2.1. Status of HMPC activities

2.1.1. Overview of HMPC assessment work including the Rapporteurship distribution – Status in May 2026

Report: HMPC Chair

Action: For discussion

Document tabled: Overview

Outcome:

HMPC members noted the status of assessment work.
In case of postponement of topics scheduled for the HMPC July 2026 meeting according to the overview, Rapporteurs were asked to inform the Committee secretariat and Chair before the first pre-mail (by 22 June 2026) to allow best adaptation of agenda and time schedule.

2.1.2. Appointment of Rapporteurs and Peer-reviewers

Periodic reviews to start in 2026-2027

Report: HMPC Chair

Action: For discussion

Document tabled: Overview document to sign-up as Rapporteur/Peer-reviewer

Outcome:

Rapporteurs and/or Peer-reviewers were appointed as needed.

2.1.3. Unscheduled reviews - Primulae radix and combination Primulae radix/Thymi herba

Report: HMPC Chair

Action: For discussion

Document tabled: Draft revised Ph.Eur. monograph on Primula root

Outcome:

HMPC members were briefed about the changes introduced in the draft revised Ph.Eur. monograph on Primula root, mainly related to the addition of new species and synonymous. Considering that the draft revised MO is still under public consultation, the HMPC agreed waiting for the finalisation of the revision process by the EDQM/European Pharmacopoeia Commission (publication in *Pharmeuropa*) before deciding on any action to be taken regarding the EU herbal MOs on Primulae radix and combination Primulae radix/Thymi herba.

2.2. Revised EU herbal monographs and list entries for final adoption

2.2.1. Monograph on Arnicae flos and supporting documents - postponed

2.2.2. Monograph on Fragariae folium and supporting documents

Action: For adoption

Documents tabled: AR, MO, LoR, Reader's Guidance, References 0/0

Outcome:

Final revised EU herbal monograph on Fragariae folium and supporting documents adopted by majority (23 out of 25). Divergent opinion(s): Finland and Germany. The Norwegian delegate expressed a favourable position.

No comments received during public consultation.
The Rapporteur pointed out that, regarding the MO section 4.2. and for indication 2), the posology for adolescents and adults was separated to ensure that information is easily

understandable and actionable. Moreover, it was highlighted that the posology is only based on bibliographic information (no products are available on the EU market).

2.2.3. Monograph on Species diureticae and supporting documents - postponed

2.3. Revised EU herbal monographs and list entries for public consultation

2.3.1. Monograph on Lecithinum ex soya and supporting documents

Action: For adoption

Documents tabled: AR, MO, LoR, Reader's Guidance

Outcome:

Draft revised EU herbal monograph on Lecithinum ex soya and supporting documents adopted by majority for 3-month public consultation.

The Rapporteur summarised the QDG proposal to refer in the lecithin AR to the Ph. Eur. monograph *Phospholipida ex soia ad injectabile* but clearly declaring that this is not the only quality standard that can be used, as this one is explicitly for parenteral use.
Some HMPC members pointed out that the standard QRD template sentence should be followed regarding adverse events not mentioned. In this sense, the MO section 4.8. was revised (not to include the text on other adverse reactions).

2.3.2. Monograph on Matricariae aetheroleum and supporting documents - postponed

2.4. Reviewed EU herbal monographs and list entries for decision on revision

None

2.5. EU herbal monographs, list entries and public statements for final adoption

None

2.6. EU herbal monographs, list entries and public statements for adoption for release for public consultation

None

2.7. EU herbal monographs, list entries and public statements - post finalisation

2.7.1. Monograph on Hyperici herba/Cimicifugae rhizoma and supporting documents

Action: For adoption

Documents tabled: AR, MO, LoR, OoC

Outcome:

Rapporteur to modify the AR and OoC according to the discussion and possible additional comments from peer-reviewer and HMPC members, for possible **re-adoption** at the **HMPC July 2026** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **01 June 2026**
Peer-review documents to be sent to Rapporteur: **15 June 2026**
Final documents to be included latest in 2nd premail: **29 June 2026**

The Rapporteur pointed out the justification for not considering a clinical trial on climacteric complaints, and therefore not taking it into account as evidence of WEU efficacy for the fixed combination.
Some HMPC members emphasised practical issues regarding patient information from the Eudravigilance database, which should not be disclosed to the public, and therefore, the Ooc should be amended accordingly.

3. Referral procedures

None

4. Guidelines and guidance documents

4.1. Non-clinical/clinical safety and efficacy and multidisciplinary

4.1.1. Guideline on the assessment of genotoxicity of herbal substances/preparations (EMEA/HMPC/107079/2007)

Action: For discussion

Outcome:

HMPC members were briefed on the latest discussions, which aimed to finalise a draft for public consultation by the end of 2026. In this sense, the HMPC Chair was appointed as team leader/project facilitator for this guideline revision, while retaining the same rapporteurs and experts.
Rapporteurs and experts to continue the revision of the Guideline on the assessment of genotoxicity of herbal substances/preparations (EMEA/HMPC/107079/2007), according to the discussion and possible additional comments from HMPC members.
Next **discussion** scheduled at the **HMPC July 2026** meeting.

4.2. Quality

None

4.3. Regulatory/Procedural

4.3.1. Reflection paper on data recommendations for herbal medicinal products and traditional herbal medicinal products used in paediatric patients (EMA/HMPC/71333/2023)

Action: For adoption

Documents tabled: Final Reflection paper, OoC

Outcome:

Final 'Reflection paper on data recommendations for herbal medicinal products and traditional herbal medicinal products used in paediatric patients' (EMA/HMPC/71333/2023) and supporting documents adopted by majority (23 out of 24). Divergent opinion(s): Poland. The Norwegian delegate expressed a favourable position.

The Rapporteur summarised the latest comment received from the PDCO, suggesting the use of an alternative wording in the chapter on extrapolation in WEU, to ensure that the information is easily understandable and actionable.

4.3.2. Reflection paper on the use of information in European Union herbal monographs and assessment reports for borderline issues (EMA/HMPC/224438/2024)

Action: For discussion

Documents tabled: Draft Reflection paper, OoC

Outcome:

Rapporteur to modify the draft 'Reflection paper on the use of information in EU herbal monographs and assessment reports for borderline issues' (EMA/HMPC/224438/2024) and the OoC according to the discussion and possible additional comments from EMA Legal and Regulatory offices.
Next **discussion** scheduled at the **HMPC July 2026** meeting.

The Rapporteur summarised the two remaining points for discussion: 1) most appropriate wording to be used ('stakeholders' was agreed); 2) comment on pharmacological action related to the definition of a medicinal product in section 2.1 'Considerations on medicinal products' (the last part of the sentence was agreed to be shortened).

4.4. Report on HMPC Drafting Groups activities

4.4.1. ORGAM DG

- ORGAM in between the plenary meetings

  Report: HMPC (Vice)-Chairs

  Action: For discussion

  Outcome:

  HMPC members were briefed about the proposal to resume the activities of the ORGAM DG between plenary meetings, to particularly advance topics in the committee's work plan. Some HMPC members pointed out practical issues with this proposal, mainly related to members' availability to attend extra meetings, as well as the timeline considering the upcoming new pharma legislation (NPL). Furthermore, it was emphasised that the ORGAM DG would be relevant for the review of HMPC guidance and templates.
  Next **discussion** scheduled at the **HMPC July 2026** meeting.

4.4.2. Quality DG

- QDG April meeting

  Report: Carmen Purdel

Action: For information

Document tabled: Minutes April 2026

Outcome:

HMPC members were briefed on the ongoing activities of the QDG, as per the April 2026 meeting, primarily related to evaluating responses from NCAs to the survey on comparability between herbal preparations. The next meeting is scheduled for 2nd June 2026.

- Draft Agenda for 22 September meeting

  Report: Carmen Purdel

  Action: For information

  Document tabled: Draft agenda

  Outcome:

  HMPC members were informed that an in-person QDG meeting is scheduled for 22 September, and a draft agenda was presented.

- Invitation to EDQM's workshop: Companies' data for CEP applications

  Report: HMPC Vice-Chair

  Action: For information

  Document tabled: Email

  Outcome:

  HMPC members were briefed about the EDQM's workshop: Companies' data for CEP applications, with the proposed changes, appearing to be more general and not having a specific impact on HMPs. It was also highlighted that some reduction in the administrative burden related to Variations is expected for MAHs using a CEP.

- QDG Chair election

  Report: HMPC Chair

  Action: For adoption

  Documents tabled: Mandate QDG, Call, Candidatures

  Outcome:

  The election of the new chairperson took place in accordance with the 'Mandate, objectives and rules of procedure for HMPC temporary working parties and drafting groups'. The nominations received were presented to the Committee. The HMPC elected Astrid Obmann as QDG Chair for a three-year mandate starting on 07 May 2026.

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Strategic Review and Learning Meetings (SRLM)

- HMPC SRLM Follow up plan - status May 2026

Report: HMPC (Vice-)Chairs

Action: For information

Outcome:

HMPC members were invited to regularly consult the follow-up plan with the status of ongoing/new topics/activities proposed after each HMPC-SRLM organised by the Member State holding the rotative Presidency of the Council of the European Union (currently: Cyprus).

- Cypriot Presidency meeting June 2026

  Report: Christina Sylvia Chrysostomou

  Action: For information

  Document tabled: SRLM agenda

  Outcome:

  HMPC members were briefed about the draft agenda for the next HMPC-SRLM, to be organised by the Cypriot Presidency of the Council of the European Union, 18-19 June 2026, in Paphos, and were also invited to register as soon as possible (the email with information for members registration is expected on 6 May).

- Irish Presidency meeting second half 2026

  Report: Jacqueline Masterson

  Action: For information

  Outcome:

  Postponed.

5.1.2. HMPC membership

Report: HMPC Chair

Action: For information

New membership:

- Netherlands, Hilda Kuin (alternate to member), as of 01 May 2026.

5.1.3. HMPC Face-to-Face Meeting Dates for 2027

Action: For information

Document tabled: Draft F2F - HMPC meeting schedule 2027

Outcome:

HMPC members endorsed the proposal for four (4) in-person meetings to be held in 2027: January, May, September and November.

5.1.4. HMPC 22-24 September 2026

Report: HMPC (Vice-)Chairs

Action: For information

Outcome:

HMPC members were informed that the September in-person meeting is scheduled to begin a day later, on 22 September, and end on 24 September. This is due to the joint EMA/FDA workshop on herbal medicines development, which will be held on 25 September, and to which HMPC members have been invited to participate.
See also 5.8.1.

5.2. EMA Scientific Committees or CMDh-v

5.2.1. HMPC/PRAC collaboration on signal detection: safety-assessment for herbal medicinal products

Action: For discussion

Document tabled: Draft Reflection paper

Outcome:

Rapporteur to modify the draft reflection paper according to the discussion and possible additional comments from EMA Legal and Regulatory offices for **possible adoption** at the **HMPC July 2026** meeting.

The Rapporteur summarised comments received from the PRAC (ORGAM), proposing a wider scope ('safety signals' was agreed). Additional changes were endorsed to ensure that information is easily understandable and actionable, including an example of herbal preparation that could cause interactions with other medicinal products.
Some HMPC members pointed out that the committee may consider reviewing the herbal substances/preparations included in the European Union reference dates (EURD) list.
Furthermore, it was proposed to highlight in the conclusions the existence of limited information on the HMPs involved in suspected adverse events/adverse drug reactions.

5.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups

5.3.1. HMPC/Translational Science Office collaboration: requirements for studying the interaction potential of herbal medicinal products

Action: For discussion

Document tabled: Draft Reflection paper

Outcome:

Rapporteur to modify the draft reflection paper according to the discussion and possible additional comments from the ICH M12 implementation group.
Next **discussion** scheduled at the **HMPC July 2026** meeting.

The Rapporteur pointed out that the paper was sent to the ICH M12 implementation group for further consultation, which, in turn, has sent it for discussion in the next meeting of the CP-OEG (MWPs clinical pharmacology operational expert group).

5.3.2. EU Substance Registration System (EU-SRS)

Action: For information

Document tabled: Email

Outcome:

HMPC members took note of the latest progress related to the validation of substances in the EU-SRS (cleansing of herbal substances), based on the EU-SRS guide available on the HMA website.

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopoeia

- EDQM TCM expert group meeting

  Report: Melanie Bald

  Action: For information

  Document tabled: SoD

  Outcome:

  The EDQM representative stated that several herbal drug monographs are scheduled for presentation for adoption at the forthcoming session of the European Pharmacopoeia Commission, to be held on 23–24 June 2026. Further information had been provided concerning the texts published for public consultation in *Pharmeuropa,* including Primula root. A summary of the conclusions of recent expert group meeting of the TCM Expert Group, which held its meeting on 31 March – 01 April 2026, was also presented, and this group is expected to meet again on 29-30 September 2026.

- Feedback on Ginkgo request

  Report: Melanie Bald

  Action: For discussion

  Document tabled: Letter

  Outcome:

  The EDQM representative summarised the letter sent by EDQM group 13A to HMPC regarding a question on the Ph. Eur. monograph on Ginkgo leaves, confirming the group's proposal to maintain the current approach (content in flavonoids to be expressed as flavone glycosides)
  Next **discussion** scheduled at the **QDG June 2026** meeting.

5.4.2. European Food Safety Authority (EFSA)

- Draft opinions on berberine-containing and hydroxycitric acid-containing plant preparations

  Action: For discussion

  Documents tabled: Email, presentations

  Outcome:

  HMPC members were briefed that the draft opinions on berberine-containing and hydroxycitric acid-containing plant preparations are published for public consultation until

11 May, and in this regard, members were invited to submit any comments they deemed relevant, which could be sent by email to EFSA representatives.

Some HMPC members pointed out the chapters referencing the assessments carried out by the EMA/HMPC, particularly the public statement issued due to a negative risk-benefit balance.

5.5. Cooperation with International Regulators

5.5.1. EU/India Technical Working Group on Ayurveda

Report: HMPC Chair

Action: For discussion

Document tabled: Draft agenda

Outcome:

HMPC members were informed on the draft agenda for the 4th meeting of the EU-India EU Technical Working Group (TWG) to be held on 12 May 2026.

5.6. Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee

5.6.1. Association of the European Self-Medication Industry (AESGP) – request for a hearing in November 2026

Report: HMPC Chair

Action: For information

Outcome:

HMPC members were briefed that the next hearing with AESGP is scheduled for the November 2026 meeting.

5.7. Work plan and related activities

5.7.1. Follow-up on HMPC work plan 2026

Report: HMPC Chair

Action: For information

Document tabled: HMPC work plan 2026

- 1) Explore new initiatives for the use of real-world data (RWD) and opportunities to use digitalisation and artificial intelligence (AI) in support of decisions

  Action: For discussion

  Document tabled: Presentation

  Outcome:

  A new topic lead was appointed to coordinate this workplan 2026 topic on RWD/AI. The next meeting of the RWE liaison group will be held in June.
  Next **discussion** scheduled at the **HMPC July 2026** meeting.

HMPC members were informed on previous discussions of the RWE liaison group, regarding a possible list of herbal substances/preparations of interest for the HMPC assessment work and then collect relevant data from the related herbal medicinal products (brand names) on the EU markets. Furthermore, HMPC members were informed about the ongoing development of an AI tool dedicated to managing the committee's knowledge, based on the minutes of plenary meetings (more information is expected at upcoming meetings).
Some HMPC members highlighted the importance of clearly defining the role of real-world data (RWD) and artificial intelligence (AI) in the committee's assessment work.

- 2) HMPC position on the role of European Union herbal monographs and assessment reports in relationship to borderline issues

  Action: For information

  Outcome:

  Next **discussion** scheduled at the **HMPC July 2026** meeting.
  See also 4.3.2.

- 3) Development of guidance on particulars for signal detection for (traditional) herbal medicinal products

  Action: For adoption

  Document tabled: Presentation

  Outcome:

  The HMPC endorsed by consensus the establishment of the HMPC pharmacovigilance group with the main task (on demand, when requested) to compile and assess specific safety data related to EU herbal monographs e.g. EudraVigilance-data. A dedicated call for NCA experts will be launched by the HMPC secretariat.

  The Rapporteur summarised the proposal to establish an HMPC pharmacovigilance group regarding the activity 'Centralise available expertise related to safety issues on herbal substances/preparations in a temporary group, supporting HMPC decision-making on safety relevant issues', which was included in the HMPC work plan 2026.
  Some HMPC members pointed out that, from a practical standpoint, the tasks proposed for this group could, in some ways, surpass the committee's current tasks. In this regard, it was agreed that the main task of this group should be related to the compilation and evaluation of specific safety data (e.g. EudraVigilance data).

- 4) Improve the evaluation of data from paediatric clinical practice for the safe use of herbal substances in children

  Action: For information

  Outcome:

  Next **discussion** scheduled at the **HMPC July 2026** meeting.
  See also 4.3.1.

- 5) HMPC communication of information on (traditional) herbal medicinal products to the public and stakeholders

  Action: For information

  Outcome:

  Next **discussion** scheduled at the **HMPC July 2026** meeting.

- 6) Improve work-sharing in HMPC activities aiming at sustainability of the European medicines agencies network (EMRN)

  Action: For discussion

  Documents tabled: Herbal Curriculum Training Planning 2026-2027, HMPC training curriculum priorities January 2026

  Outcome:

  HMPC members were briefed on the committee's training program, particularly on upcoming training sessions for 2026. Furthermore, the importance of a fair and balanced distribution of HMPC activities among all committee members was emphasized. The importance of raising HMA awareness of the active participation of members and thus maintaining regulatory/scientific expertise was highlighted. Furthermore, a review of the principles was suggested to prioritize the start of the review of EU medicinal plant monographs, considering the availability of NCAs assessors (new principles to be integrated into the review/update procedure).
  Next **discussion** scheduled at the **HMPC July 2026** meeting**.**

5.8. Planning and reporting

5.8.1. EMA/FDA Workshop on herbal medicines development

Report: HMPC Chair

Action: For discussion

Document tabled: Draft programme

Outcome:

HMPC members were briefed on the draft programme for the joint EMA/FDA workshop on the development of herbal-based medicinal products, scheduled for 25th September 2026, and were invited to submit any comments they deemed relevant (draft programme in TEAMs).
Next **discussion** scheduled at the **HMPC July 2026** meeting**.**

5.8.2. Summary on MRP/DCP for herbal medicinal products

Action: For discussion

Document tabled: List EU herbal procedures in CTS

Outcome:

A group with HMPC members was established to prepare a revised questionnaire template for the survey to collect data on the uptake of the traditional use registration scheme and implementation of the provisions of Directive 2004/24/EC in EU Member States.
Next **discussion** scheduled at the **HMPC July 2026** meeting**.**

The Rapporteur summarised the new MRP/DCP for herbal medicines, with a total of 61 successful procedures in the period 2018-2025. Special interest was expressed in procedures finalised without the support of an EU herbal monograph, which could lead to follow-up actions, particularly proposals for new monographs. Some HMPC members pointed out practical issues related to herbal medicines identified as authorised via MRP/DCP (e.g. products on the EU market with different companies and manufacturers). It was proposed

to share this list with the QDG so that they could review the quality issues identified for some of the herbal medicines authorised via MRP/DCP. Furthermore, it was suggested to resume the inquiry to MSs to update the list of national procedures for herbal medicines (last updated: 31 December 2016).

5.9. Legislation and regulatory affairs

None

5.10. Questions from members

None

6. EU herbal monographs and list entries in preparation

6.1. Revision of EU herbal monographs and list entries in preparation for adoption after public consultation

None

6.2. Revision of EU herbal monographs and list entries in preparation for public consultation

6.2.1. Monograph on Betulae folium and supporting documents

Action: For 1st discussion

Documents tabled: Draft AR, MO, LoR

Outcome:

Rapporteur to introduce changes in the draft revised EU herbal monograph and supporting documents according to the discussion and possible further comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC July 2026** meeting.

The Rapporteur pointed out that, regarding the duration of use, the period before contacting a doctor if symptoms persist was still open to discussion: 2 weeks vs 2-4 weeks.
Some HMPC members emphasised that the same agreed-upon duration of use for the other so-called "diuretic herbal monographs" should be followed (i.e. 2 weeks). Moreover, it was proposed to shorten the AR chapter 5.3. adverse events to ensure that the information is easily understandable and actionable.

6.2.2. Monograph on Matricariae flos and supporting documents - postponed

6.3. Review of EU herbal monographs and list entries in preparation for decision on revision

6.3.1. Monograph on Anisi aetheroleum and supporting documents

Action: For 3rd discussion

Documents tabled: Review report, Reader's Guidance

Outcome:

HMPC endorsed the Rapporteur's position that there is relevant new information available that could change the content of the EU herbal monograph and therefore a revision of the complete package is advocated.
Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC July 2026** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **01 June 2026**
Peer-review documents to be sent to Rapporteur: **15 June 2026**
Final documents to be included latest in 2nd premail: **29 June 2026**

The Rapporteur summarised reasons for the revision of the MO: 1) consistency with the revised HMPC's 'Public statement on the use of herbal medicinal products containing estragole' (EMA/HMPC/137212/2005 Rev 1 Corr 1*), due to some risk associated with daily estragole intake when anise oil is used for the indications reported in the MO, according to posologies supported by evidence from traditional use; 2) to update MO section 4.6 to inform patients that *trans*-anethol may be excreted in human breast milk, based on clinical evidence of detectable levels in the milk of lactating women who received 100 mg of *trans*-anethole capsules during a 3-day test. Regarding the EudraVigilance data, reports involving products containing anise seed were highlighted, but none specifically contained anise oil.

6.3.2. Monograph on Anisi fructus and supporting documents

Action: For 3rd discussion

Documents tabled: Review report, Reader's Guidance

Outcome:

HMPC endorsed the Rapporteur's position that there is relevant new information available that could change the content of the EU herbal monograph and therefore a revision of the complete package is advocated.
Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC July 2026** meeting.

Timetable:
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The Rapporteur summarised reasons for the revision of the MO: 1) to reconsider the posology described in the MO with the aim of minimising exposure to estragole, in accordance with the revised HMPC's 'Public statement on the use of herbal medicinal products1 containing estragole' (EMA/HMPC/137212/2005 Rev 1 Corr 1*); 2) to update MO section 4.3 to include hypersensitivity to grass, birch and mugwort pollen, due to cross-reactivity with anise (some studies have shown an increased risk for sensitization to anise among adults and youngsters suffering from birch, mugwort or grass pollinosis as confirmed by skin prick tests); 3) to update MO section 4.6 to inform patients that *trans*-anethol may be excreted in human breast milk, based on clinical evidence of detectable levels in the milk of lactating women who received 100 mg of *trans*-anethole capsules during a 3-day test. Regarding the EudraVigilance data, it was emphasised that a clear causal relationship between aniseed and skin rash, nausea and vomiting, which were the most frequent adverse reactions, could not be identified due to the concomitant intake of several other herbal preparations.

6.3.3. Monograph on Echinaceae angustifoliae radix and supporting documents - postponed

6.3.4. Monograph on Echinaceae pallidae radix and supporting documents - postponed

6.3.5. Monograph on Eleutherococci radix and supporting documents - postponed

6.3.6. Monograph on Myrrha and supporting documents

Action: For 4th discussion

Document tabled: Review report

Outcome:

Rapporteur to modify the review report according to the discussion and possible additional comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC July 2026** meeting.

The Rapporteur highlighted that no new safety issues could be detected from available data. Some HMPC members suggested that a brief summary of the main genotoxicity findings should also be included.

6.3.7. Monograph on Passiflorae herba and supporting documents -postponed

6.3.8. Monograph on Plantaginis ovatae semen and supporting documents - postponed

6.3.9. Monograph on Plantaginis ovatae seminis tegumentum and supporting documents - postponed

6.3.10. Monograph on Psyllii semen and supporting documents - postponed

6.3.11. Monograph on Salicis cortex and supporting documents

Action: For 5th discussion

Document tabled: Review report

Outcome:

HMPC endorsed the Rapporteur's position that there is no new information available that could change the content of the EU herbal monograph.
Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC July 2026** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **01 June 2026**
Peer-review documents to be sent to Rapporteur: **15 June 2026**
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The Rapporteur highlighted that, overall, the data collected over the review period (e.g. few reports of adverse reactions and some new publications on toxicological studies) do not indicate any issue that would require a change in the current MO.

6.3.12. Monograph on Salviae officinalis folium and supporting documents

Action: For 6th discussion

Document tabled: Review report

Outcome:

HMPC endorsed the Rapporteur's position that there is no new information available that could change the content of the EU herbal monograph.
Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC July 2026** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **01 June 2026**
Peer-review documents to be sent to Rapporteur: **15 June 2026**
Final documents to be included latest in 2nd premail: **29 June 2026**

The Rapporteur highlighted that the RR was updated in relation to the reference of an article published on the PubMed website, which listed only the authors' first name (bibliographic reference as presented on the PubMed website).

6.3.13. Monograph on Thymi herba and supporting documents

Action: For 11th discussion

Document tabled: Review report

Outcome:

HMPC endorsed the Rapporteur's position that there is no new information available that could change the content of the EU herbal monograph.
Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC July 2026** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **01 June 2026**
Peer-review documents to be sent to Rapporteur: **15 June 2026**
Final documents to be included latest in 2nd premail: **29 June 2026**

The Rapporteur summarised the pharmacovigilance data found on potential allergic reactions associated with thyme-containing products.
Some HMPC members pointed out that there is a mono-compound thyme-containing product on the EU market reporting adverse reactions that should be considered. An assessment of potential allergic reactions associated with thyme-containing products was also provided (annex 3). Moreover, it was highlighted the difference between the QRD-template standard contraindication in section 4.3 '<Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1 <or {name of the residue(s)}>.' and listed adverse reactions in section 4.8.

6.3.14. Monograph on Valerianae aetheroleum and supporting documents - postponed

6.3.15. Monograph on Valerianae radix and supporting documents - postponed

6.4. EU herbal monographs and list entries in preparation for adoption after public consultation

6.4.1. Monograph on Cannabis flos and supporting documents

Action: For 3rd discussion

Document tabled: OoC

Outcome:

Comments received during public consultation.
Rapporteur to modify the OoC according to the discussion and possible additional comments from peer-reviewer and HMPC members, for possible **adoption** at the **HMPC July 2026** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **01 June 2026**
Peer-review documents to be sent to Rapporteur: **15 June 2026**
Final documents to be included latest in 2nd premail: **29 June 2026**

The Rapporteur summarised that the OoC document, containing the comments received from IPs on the draft PS during the public consultation, was updated in accordance with the discussion held previously. Regarding the specific comment on microbial contamination, reference is made that this is not a specific parameter listed in the EU herbal monograph. Some HMPC members highlighted that the PS and OoC should be reviewed once again by the EMA's Legal and Regulatory offices before their publication.

6.4.2. Monograph on Maydis stigma and supporting documents

Action: For 1st discussion

Document tabled: Draft MO, AR, LoR

Outcome:

No comments received during public consultation.
Rapporteur to finalise the draft EU herbal monograph and supporting documents for peer review and **adoption** at the **HMPC July 2026** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **01 June 2026**
Peer-review documents to be sent to Rapporteur: **15 June 2026**
Final documents to be included latest in 2nd premail: **29 June 2026**

6.5. EU herbal monographs and list entries in preparation for adoption for release for public consultation

6.5.1. Monograph on Valerianae radix/Passiflorae herba and supporting documents

Action: For 4th discussion

Documents tabled: Draft MO, AR, LoR, Reader's Guidance

Outcome:

Rapporteur to introduce changes in the draft EU herbal monograph and supporting documents according to the discussion and possible additional comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC July 2026** meeting.

The Rapporteur highlighted that, as previously required, the information that this combination may increase the effect of other depressants and impair the ability to drive and use machines, so that affected patients should not drive or operate machinery, was included in the MO sections 4.5. and 4.7., respectively.
Some HMPC members pointed out that if no clinical data is available regarding potential interactions, this should be reflected in the MO section 4.5 (the wording should be amended accordingly).

7. Any other business

7.1. Topics for discussion

7.1.1. Pilot – transition to IRIS/SharePoint

Action: For information

Outcome:

A presentation/training session was held on the IRIS/SharePoint, focused on principles of on-line collaboration, how to access HMPC documents in SharePoint, and confirmation if HMPC members have access to the dedicated library, with practical rules/advice for the work to be carried out in this platform. In this regard, HMPC members were informed on the link to the committee's dedicated library in IRIS/SharePoint and were invited to check if they could access it.
Next **discussion** scheduled at the **HMPC July 2026** meeting**.**

7.1.2. Pharmeuropa overview

Action: For discussion

Documents tabled: Overview

Outcome:

HMPC members noted the last issue of the *Pharmeuropa issue 38.1* with information on texts published for comments, including Primula root and Aloes Barbados. It was agreed to have a regular update when *Pharmeuropa* is published.

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 04-06 March 2026

Overview of expertise of members HMPC and subgroups

Inventory of herbal substances for assessment work

List of abbreviations used in EMA human medicines scientific committees & CMDh documents and in relation to EMA's regulatory activities

Common names of herbal substances in all languages

Final Monograph Overview

Best practice guide on using HMPC plenary time efficiently (with annexed Reader's Guidance template)

7.2.2. Assessment Report Summary for the Public (ARSP)

None

7.2.3. Other

- Updated EMA-HMA workplan on data and AI in medicines regulation 2026 to 2028

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/ experts following evaluation of declared interests for the 04-06 May 2025 HMPC meeting, which was held remotely.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Carmen Purdel	Chair	Romania	No restrictions applicable to this meeting	
Astrid Obmann	Member	Austria	No interests declared	
Brigitte Hauser	Alternate	Austria	No interests declared	
Patricia Bodart	Member	Belgium	No restrictions applicable to this meeting	
Daniela Ruseva	Alternate	Belgium	No participation in discussions, final deliberations and voting on:	6.3.13. Monograph on Thymi herba
Denitsa Momekova	Alternate	Bulgaria	No restrictions applicable to this meeting	
Ivan Kosalec	Member	Croatia	No restrictions applicable to this meeting	
Darko Trumbetic	Alternate	Croatia	No interests declared	
Christina Sylvia Chrysostomou	Member	Cyprus	No interests declared	
Alexandra Demetriou	Alternate	Cyprus	No interests declared	
Markéta Příhodová	Member	Czechia	No restrictions applicable to this meeting	
Kristýna Veselá	Alternate	Czechia	No interests declared	
Nanna Lundgaard Rasmussen	Member	Denmark	No interests declared	
Maria Paile Hyvarinen	Member	Finland	No interests declared	
Sari Koski	Alternate	Finland	No interests declared	
An Le	Member	France	No interests declared	
Helene Ly	Alternate	France	No interests declared	
Jacqueline Wiesner	Member	Germany	No interests declared	
Valerie Niederwieser	Alternate	Germany	No interests declared	
Ioanna Chinou	Member	Greece	No restrictions applicable to this meeting	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Stavroula Mamoucha	Alternate	Greece	No interests declared	
Julia Pallos	Member	Hungary	No restrictions applicable to this meeting	
Alessandro Assisi	Member	Italy	No interests declared	
Anna Maria Serrilli	Alternate	Italy	No interests declared	
Inga Sile	Member	Latvia	No restrictions applicable to this meeting	
Jean-Luc Bueb	Member	Luxembourg	No restrictions applicable to this meeting	
Hilda Kuin	Member	Netherlands	No interests declared	
Gro Anita Fossum	Member	Norway	No interests declared	
Marianne Loiten Dalhus	Alternate	Norway	No interests declared	
Wojciech Dymowski	Member	Poland	No interests declared	
Tomasz Stawarski	Alternate	Poland	No restrictions applicable to this meeting	
Ligia Elena Dutu	Alternate	Romania	No restrictions applicable to this meeting	
Dorota Distlerova	Member	Slovakia	No interests declared	
Jaroslav Tóth	Alternate	Slovakia	No restrictions applicable to this meeting	
Barbara Razinger	Member	Slovenia	No interests declared	
Nina Kocevar Glavac	Alternate	Slovenia	No restrictions applicable to this meeting	
Olga Maria Palomino	Member (Vice Chair)	Spain	No restrictions applicable to this meeting	
Margarita Berrocal Navas	Alternate	Spain	No interests declared	
Karin Erika Svedlund	Member	Sweden	No interests declared	
Pierre Duez	Co-opted member	Belgium	No restrictions applicable to this meeting	
Heidi Foth	Co-opted member	Germany	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Maria da Graca Ribeiro Campos	Co-opted member	Portugal	No restrictions applicable to this meeting	
Maria Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared	
Kaatje Smits	Expert	Belgium	No interests declared	
Kristine Hvolby	Expert	Denmark	No interests declared	
Celine Delerme	Expert	France	No interests declared	
Sonny Larsson	Expert	Sweden	No interests declared	
Peter Sisovsky	Expert	Slovakia	No interests declared	
Marie Chantal Zwaan-Baltus	Observer	Netherlands	No interests declared	
Melanie Bald	Observer	EDQM	No interests declared	
An observer from SwissMedic (Switzerland) attended the meeting.				
Meeting run with support from relevant EMA staff.				

Experts' declared interests were evaluated against the agenda topics or activities they participated in.