06 May 2026
EMA/HMPC/62790/2026
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 02-04 March 2026

Chair: Carmen Purdel, Vice-Chair: Karin Erika Svedlund

Health and safety information

In accordance with the Agency's health and safety policy, delegates were briefed on health, safety and emergency information and procedures prior to the start of the meeting.

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 the 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 in person.

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.

The Chair thanked the HMPC members who left the Committee for all their valuable work and contributions.

1.2. Adoption of agenda

HMPC agenda for 02-04 March 2026.

Outcome:

Agenda and time schedule adopted.

1.3. Adoption of the minutes

HMPC minutes for 19-21 January 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 March 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 May 2026 meeting according to the overview, Rapporteurs were asked to inform the Committee secretariat and Chair before the first pre-mail (by 20 April 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

Documents tabled: Overview document to sign-up as Rapporteur/Peer-reviewer; Review/revision procedure

Outcome:

Rapporteurs and/or Peer-reviewers were appointed as needed. A first set of "call for data" will be released for 3 months.

Some HMPC members pointed out that, and according to the 'Procedure for the review and revision of European Union herbal monographs and European Union list entries' EMA/HMPC/124695/2011), the need for revision will be considered after every 5 years since publication date of the first version (or last revised version, if applicable) of the MO or the publication date of the last addendum to the AR (in case a review has been previously performed not leading to a revision) in order to ensure that EU herbal monographs/EU list entries are up to date (scientific state of the art). Moreover, the importance of verifying whether new (T)HMPs are on the EU market before initiating the review/revision process was highlighted, and, in this sense, the regular updating of the MRP/DCP list for herbal substances may be relevant.

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

2.2.1. Monograph on Liquiritiae radix and supporting documents

Action: For adoption

Documents tabled: AR, MO, LoR, Reader's Guidance, References 0/335

Outcome:

Final revised EU herbal monograph on Liquiritiae radix and supporting documents adopted by majority (25 out of 26). Divergent opinion(s): Poland. The Norwegian delegate expressed a favourable position.

The Rapporteur highlighted that the AR/MO was updated in accordance with the last discussion, reflecting the recommendation for caution in case of concomitant use of all drug substances whose metabolism is influenced by CYP3A4. Moreover, it was emphasised that both indications are based on products available on the EU market, including their use as expectorants for cough associated with cold.

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

2.3.1. Monograph on Lecithinum ex soya and supporting documents - postponed

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

2.4.1. Monograph on Centaurii herba and supporting documents

Action: For adoption

Document tabled: Review report

Outcome:

HMPC agreed with Rapporteur's position that no EU herbal monograph revision is needed because no new data of relevance were detected that would change the content of the monograph.
The HMPC decided by consensus vote not to revise the monograph, assessment report and list of references on Centaurii herba.
The review report was adopted and after editorial review will be published as addendum to the existing assessment report on the EMA website.

The Rapporteur highlighted that no relevant adverse events were reported in the Eudravigilance database; the two identified products are already covered by the MO; and the change in relation to the Ph. Eur. monograph, revised 07/2024, is already reflected in the name of the herbal substance.

2.4.2. Monograph on Rusci rhizoma and supporting documents

Action: For adoption

Document tabled: Review report

Outcome:

HMPC agreed with Rapporteur's position that no EU herbal monograph revision is needed because no new data of relevance were detected that would change the content of the monograph.
The HMPC decided by consensus vote not to revise the monograph, assessment report and list of references on Rusci rhizoma.
The review report was adopted and after editorial review will be published as addendum to the existing assessment report on the EMA website.

The Rapporteur emphasised that the reported adverse events do not justify the MO revision.

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

Document tabled: OoC

Outcome:

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

Timetable:
Documents to be sent to Peer-reviewer: **27 March 2026**
Peer-review documents to be sent to Rapporteur: **13 April 2026**
Final documents to be included latest in 2nd premail: **27 April 2026**

The Rapporteur pointed out that the OoC and AR were updated, reflecting the assessment of other comments received during the public consultation. It was highlighted that, as a precautionary safety measure, the adverse effects listed in section 4.8 derive from the individual MOs on Hyperici herba and Cimicifugae rhizoma and their preparations, included in products on the EU market. Moreover, rational was given for not considering a clinical trial on climacteric complaints, including reference to the 'Guideline on clinical investigations for Hormone Replacement Therapy of oestrogen deficiency symptoms in postmenopausal women' (EMEA/CHMP/021/97 Rev. 1), and therefore not taken into consideration as evidence of WEU efficacy for the fixed combination.

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

Document tabled: EFSA email

Outcome:

Rapporteurs to continue the revision of the Guideline on the assessment of genotoxicity of herbal substances/preparations (EMEA/HMPC/107079/2007), in accordance with the

information and discussions presented.
Next **discussion** scheduled at the **HMPC May 2026** meeting.

An overview of genotoxicity guidelines for medicines was presented, focusing on the two main guidelines for genotoxicity testing in human/veterinary products: 1) 'ICH guideline S2 (R1) on genotoxicity testing and data interpretation for pharmaceuticals intended for human use'; and 2) 'VICH GL23: Studies to evaluate the safety of residues of veterinary drugs in human food: genotoxicity testing'. Both documents provide standard battery of tests that can be used for predicting potential human risks of new 'small molecule' drug substances being developed as human pharmaceuticals (ICH S2(R1)), and for the evaluation of the genotoxicity of veterinary drug residues (VICH GL23). Regarding the use of 'threshold of toxicological concern' (TTC) approach for herbal substances, some difficulties related to the particularities of this type of substance were highlighted.

4.2. Quality

4.2.1. Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products' (EMA/HMPC/CHMP/CVMP/287539/2005)

Report: Carmen Purdel

Action: For discussion

Document tabled: Draft revised guideline on declarations

Outcome:

Draft revised 'Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products' (EMA/HMPC/CHMP/CVMP/287539/2005) endorsed for 3-month public consultation.

The Rapporteur summarised the comments received from the QRD members, which resulted in some changes introduced in the draft revised guideline.

4.3. Regulatory/Procedural

None

4.4. Report on HMPC Drafting Groups activities

4.4.1. ORGAM DG

None

4.4.2. Quality DG

- QDG February meeting

  Report: Carmen Purdel

  Action: For information

  Document tabled: Minutes February 2026

  Outcome:

HMPC members were briefed on the main QDG activities, as per the February 2026 meeting: 1) revised Variations guideline: QDG is planning to prepare a Q&A document to clarify new requirements; 2) query on DNA: QDG agreed to add this topic to the open list for discussion with EDQM, together with pesticides and their acceptance limits for the inhalator route; 3) comparability between preparations – survey: responses were compiled into a single document for further discussion in the April meeting. The next meeting is scheduled for 7th April 2026.

- QDG Chairperson election May 2026

  Report: Carmen Purdel

  Action: For information

  Outcome:

  HMPC members were informed that a call for expressions of interest in the position of QDG Chairperson would be sent after the current meeting. The deadline for nominations is 04 May 2026 (motivation letter to all HMPC members and EMA). The election is planned for May 2026 with the mandate of the chairperson starting from 07 May 2026.

- Draft "Mandate, objectives, and rules of procedure for expert groups under the quality, non-clinical, methodology, clinical and veterinary domains"

  Report: Carmen Purdel

  Action: For information

  Document tabled: Draft mandate

  Outcome:

  HMPC members were briefed that the draft 'Mandate, objectives, and rules of procedure for expert groups under the quality, non-clinical, methodology, clinical and veterinary domains' relating to OEGs, tDGs and ESECs, was open for comments until 13 March, and, in that regard, they were invited to submit any comments they have.

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 March 2026

  Report: HMPC Vice-chair

  Action: For information

  Outcome:

  The Vice-chair informed that the HMPC SRLM Follow up plan was updated with inputs from the HMPC-SRLM organised by the Danish Presidency of the Council of the European Union held in October 2025.
  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 draft agenda

  Outcome:

  HMPC members were briefed on 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 invited to propose additional topics for discussion.

- Irish Presidency meeting second half 2026

  Report: Jacqueline Masterson

  Action: For information

  Outcome:

  HMPC members were informed that the HMPC-SRLM to be organised by the Irish Presidency of the Council of the European Union, second half of 2026, will be held online only (details still to be confirmed).

5.1.2. HMPC membership

Report: HMPC Chair

Action: For information

End of membership:

- Netherlands, Burt H Kroes (Member), as of 19 January 2026;
- Netherlands, Emiel Van Galen (Chair), as of 1 March 2026.

5.1.3. Election of HMPC Vice-Chairperson

Action: For adoption

Documents tabled: Call for expression of interest, Presentation, HMPC RoP, Candidatures

Outcome:

The mandate of the HMPC Vice-Chair, Erika Svedlund, will expire on 04 May 2026. The election of the new vice-chair took place in accordance with the HMPC rules of procedure. The nominations received were presented to the Committee. The HMPC elected Olga Palomino as HMPC Vice-Chair for a three-year mandate starting on 05 May 2026. The HMPC and the Agency congratulated Olga Palomino on her election and wished her all the best in her new role as Vice-Chair of the Committee.

5.1.4. HMPC - desired areas of expertise

Report: HMPC Chair

Action: For adoption

Documents tabled: HMPC areas of expertise, Email

Outcome:

HMPC members were asked to confirm whether each member/alternate's area of expertise was still valid or to update it if necessary, considering the committee's upcoming activities (deadline: end of the current meeting).

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:

"Reflection paper on particulars for signal detection for (traditional) herbal medicinal products" (EMA/HMPC/PRAC/301178/2025) endorsed for consultation with PRAC.
Next **discussion** or possible **adoption** scheduled at the **HMPC May 2026** meeting.

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:

'Reflection paper on the investigation of drug interactions of herbal medicinal products' (EMA/HMPC/30298/2026) endorsed for further consultation with the ICH M12 implementation group.
Next **discussion** scheduled at the **HMPC May 2026** meeting.

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopoeia

- EDQM 13A expert group meeting

  Report: Melanie Bald

  Action: For information

  Document tabled: SoD

- EDQM 13B expert group meeting

  Report: Melanie Bald

  Action: For information

  Document tabled: SoD

- EDQM TCM expert group meeting

  Report: Melanie Bald

Action: For information

Document tabled: SoD

Outcome:

The EDQM representative stated that a number of herbal drug monographs were scheduled for presentation for adoption at the forthcoming sessions of the European Pharmacopoeia Commission, to be held on 10–11 March 2026 and 3–24 June 2026. Further information had been provided concerning the texts intended for publication for public consultation in *Pharmeuropa*.
The representative additionally presented a summary of the conclusions of recent expert group meetings, namely: the 13A Expert Group, which convened in February 2026, with its subsequent meeting planned for May 2026; the 13B Expert Group, which likewise met in February 2026 and was also scheduled to reconvene in May 2026; and the TCM Expert Group, which held its meeting in January 2026 and was expected to meet again in March 2026.
Regarding the Ph. Eur. monograph on *Cannabis flos*, it was reported that a request had been received for the introduction of *ad hoc* limits for microbial contamination for the herbal drug when administered by vaporisation. The representative noted that, once the request for revision had been formally endorsed by the European Pharmacopoeia Commission, the revised monograph would be published in *Pharmeuropa* for public consultation.

5.4.2. European Food Safety Authority (EFSA)

Action: For information

Outcome:

HMPC members were briefed that the draft opinions on berberine-containing and hydroxycitric acid-containing plant preparations were planned to be published for public consultation on 02 March 2026. The public consultation will stay open for 2 months. Furthermore, HMPC members were informed that both documents were under embargo and should not be distributed until they were officially published on the EFSA website. In addition, HMPC members were invited to provide comments on both documents, which can be sent by email to EFSA representatives.

5.5. Cooperation with International Regulators

5.5.1. EU/India Technical Working Group on Ayurveda

Report: HMPC Chair

Action: For discussion

Document tabled: Minutes September 2024

Outcome:

HMPC members were informed on the draft programme 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

None

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: Email

  Outcome:

  HMPC members were invited to submit additional recommendations, focusing on a list of products to be included in future DARWIN data mapping assessment projects and which real-world data (RWD) elements on (T)HMPS would be important to support the committee's assessments. Next meeting of the RWE liaison group to be held in April.
  Next **discussion** scheduled at the **HMPC May 2026** meeting.

  HMPC members were informed on previous discussions of the RWE liaison group, mainly focused on the possibility of the committee to provide an extended list of herbal substances to include in the future DARWIN EU data mapping assessment project. Moreover, it was emphasised the importance to discuss which RWD elements for herbal medicinal products are necessary for HMPC assessments. Some herbal substances of potential interest for conducting DARWIN studies were also discussed.

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

  Action: For discussion

  Documents tabled: Draft Reflection paper, OoC, Reader's Guidance

  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 OoCs according to the discussion and possible additional comments from HMPC members.
  Next **discussion** scheduled at the **HMPC May 2026** meeting.

  The Rapporteur summarised that the RP was updated based on comments received from IPs during the 3-month public consultation.

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

  Action: For discussion

  Document tabled: Presentation

  Outcome:

  Rapporteur to modify the proposal to bring together the available expertise on safety issues relating to herbal substances/preparations into a temporary group, according to the

discussion and possible additional comments from HMPC members.
Next **discussion** scheduled at the **HMPC May 2026** meeting.

The Rapporteur summarised that some points still require further discussion 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' included in the HMPC work plan 2026: 1) task to compile and assess specific safety data related to EU herbal monographs when requested by HMPC (e.g. EV-data) in collaboration with PRAC/EMA colleagues?; 2) name 'HMPC (temporary) pharmacovigilance group'?; 3) call for experts including a group leader?; 4) meetings on a case-by-case basis?.
Some HMPC members pointed out that, from a practical standpoint, this group will operate on an 'ad hoc' basis (as needed), and that NCAs experts with knowledge in pharmacovigilance could also be involved in the group.

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

  Action: For discussion

  Documents tabled: Draft RP, OoC

  Outcome:

  'Reflection paper on data recommendations for herbal medicinal products and traditional herbal medicinal products used in children and adolescents' (EMA/HMPC/71333/2023) endorsed for final consultation with PDCO.
  Next **discussion** or possible **adoption** scheduled at the **HMPC May 2026** meeting.

  The Rapporteur highlighted that the RP was updated based on feedback received from the EMA's Regulatory, Legal and RWE offices, primarily regarding the use of RWD and WEU extrapolation. As lessons learnt, extrapolation in WEU is possible; however, if new data is needed to be generated, it is no longer WEU, and this conclusion does not depend on the availability of authorised products. Moreover, the use of the terminology 'paediatric patients' (instead of 'children and adolescents') was agreed.

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

  Action: For adoption

  Documents tabled: Summaries for the public on Hyperici herba, Pelargonii radix, Foeniculi amari fructus, Foeniculi dulcis fructus

  Outcome:

  Rapporteurs to modify the draft ARSPs according to the discussion and possible additional comments from HMPC members.
  Next **discussion** or possible **adoption** scheduled at the **HMPC May 2026** meeting.

  ARSPs for 4 additional EU herbal MOs were presented using the revised template adopted during the HMPC September 2025 meeting: bitter fennel; sweet fennel; hypericum; pelargonium.
  Some HMPC members pointed out that, for some ARSP sections (e.g. adverse reactions, interactions), resources may already be available on the best lay language to use (e.g. guidance from the EMA's medical writers).

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

  Action: For discussion

  Document tabled: Presentation

  Outcome:

  A presentation/training session was held on the 'Tasks of the Peer-reviewers', including the 'HMPC plenary best practice guide' (in particular Annex II 'Check-list for Rapporteurs and Peer-reviews'), with practical rules/advice for the work to be carried out, mainly related to the Procedure for the preparation of EU herbal MOs and LEs including appointment of Rapporteurs and Peer-Reviewers and the Procedure for the review and revision of EU herbal MOs and LEs.
  Some HMPC members emphasised the importance of having an internal folder (unpublished and linked to the MMD for each meeting) with all the training material developed, especially relevant for new committee members. Furthermore, the importance of the readers' guidance to streamline discussions during plenary meetings was also highlighted.
  Next **discussion** scheduled at the **HMPC May 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, Botanical Drug Development Guidance for Industry

Outcome:

HMPC members were briefed on the draft programme for the joint workshop planned by the EMA/FDA on the drug development of herbal-based medicinal products, with a preparatory meeting to be held next week.
Next **discussion** scheduled at the **HMPC May 2026** meeting**.**

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

6.1.1. Monograph on Fragariae folium and supporting documents

Action: For 1st discussion

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

Outcome:

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

Timetable:
Documents to be sent to Peer-reviewer: **27 March 2026**
Peer-review documents to be sent to Rapporteur: **13 April 2026**
Final documents to be included latest in 2nd premail: **27 April 2026**

The Rapporteur pointed out that, with regard to posology, and for indication 1), the amount of water should be 300-400 ml and the decoction should be divided into 2/3 doses to be drunk daily (agreed).

6.1.2. Monograph on Species diureticae and supporting documents

Action: For 1st discussion

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

Outcome:

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

Timetable:
Documents to be sent to Peer-reviewer: **27 March 2026**
Peer-review documents to be sent to Rapporteur: **13 April 2026**
Final documents to be included latest in 2nd premail: **27 April 2026**

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

None

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 2nd discussion

Document tabled: Review report, Reader's Guidance

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 May 2026** meeting.

The Rapporteur presented the first draft RR, summarising the 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) updating 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. Furthermore, it was highlighted that EudraVigilance search and signal assessment is ongoing.

6.3.2. Monograph on Anisi fructus and supporting documents

Action: For 2nd discussion

Document tabled: Review report, Reader's Guidance

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 May 2026** meeting.

The Rapporteur presented the first draft RR, summarising the 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. Furthermore, it was highlighted that EudraVigilance search and signal assessment is ongoing.

6.3.3. Monograph on Echinaceae angustifoliae radix and supporting documents

Action: For 5th discussion

Document tabled: Review report

Outcome:

Rapporteur to modify the review report according to the discussion and possible comments or recommendations expected from the PRAC.
Next **discussion** to be scheduled at the **HMPC 2026** meeting, after the PRAC advice has been issued.

The Rapporteur highlighted that no new data or safety concerns relevant to the MO content were identified. Moreover, it was noted that E. angustifolia is considered suitable for its intended use, consistent with other Echinaceae MOs, and therefore, the proposal is to update the RR for final decision, pending only the PRAC advice.
Some HMPC members proposed not including the information that the MO on E. purpurea, herba does not have a TU indication for oral use (agreed).

6.3.4. Monograph on Eleutherococci radix and supporting documents - postponed

6.3.5. Monograph on Myrrha and supporting documents

Action: For 3rd 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 May 2026** meeting.

The Rapporteur highlighted that the RR was updated in accordance with the latest discussion and is therefore now subject to peer-reviewing.

6.3.6. Monograph on Salicis cortex 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 May 2026** meeting.

The Rapporteur highlighted that, overall, the data collected over the review period (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.
Some HMPC members recommended improving the information included in the RR, particularly regarding the review of adverse reactions reports and publications on toxicological studies, to ensure that it is easily understandable and actionable.

6.3.7. Monograph on Salviae officinalis folium and supporting documents

Action: For 5th 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 May 2026** meeting.

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

6.3.8. Monograph on Thymi herba and supporting documents

Action: For 10th 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 May 2026** meeting.

The Rapporteur summarised the pharmacovigilance data found on potential allergic reactions associated with thyme-containing products.
Some HMPC members pointed out that an assessment of potential allergic reactions associated with thyme-containing products was provided (annex 3). It was also noted that there are mono-compound thyme-containing products on the EU market. Furthermore, recommendations were made to improve the information included in the RR to ensure that it is easily understandable and actionable.

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 2nd 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.
Next **discussion** scheduled at the **HMPC May 2026** meeting.

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 microbiological contamination, the ongoing revision of the Ph. Eur. monograph on Cannabis flos (EDQM 13B expert group) was highlighted.
Some HMPC members suggested clarifying that 'permission to use' and 'marketing authorisation' are not synonymous from a regulatory standpoint. Furthermore, it was pointed out that the PS and OoC should be reviewed again by the EMA's Legal and Regulatory offices before their adoption.

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 3rd 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 May 2026** meeting.

The Rapporteur emphasised that all preparations fulfilling the 30 years criteria were included in the AR/MO. Moreover, the information that this combination may increase the effect of other depressants and may impair the ability to drive and use machines, so that affected patients should not drive or operate machinery, was now included in the MO sections 4.5. and 4.7., respectively.

Some HMPC members pointed out that it should be verified whether all identified herbal-based preparations (extracts) were considered in the ARs/MOs of the mono-compounds.

7. Any other business

7.1. Topics for discussion

7.1.1. Herbal Summit 2026, 25 February, Brussels

Action: For information

Document tabled: Summit webpage

Outcome:

HMPC members were briefed on the programme of the Herbal Summit 2026, held on 25 February in Brussels, focused on the key points 1) Economic footprint of herbal medicines: a model for the European economy; and 2) Importance of herbal medicines for patients: medical, consumer and regulatory perspectives.

7.1.2. Pilot – transition to IRIS/SharePoint

Action: For information

Outcome:

HMPC members were informed of the planned transition to IRIS/SharePoint for HMPC meetings during 2026. Further details will be released as they become available.

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 19-21 January 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

- Annual update of EMA DoI

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/ experts following evaluation of declared interests for the 02-04 March 2026 HMPC meeting, which was held in-person.
An asterisk (*) after the role, in the second column, signals that the member/alternate attended remotely. Additional experts participated in (part of) the meeting, either in person or 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:	6.3.8. Monograph on Thymi herba and supporting documents
Iliana Ionkova	Member	Bulgaria	No restrictions applicable to this meeting	
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 restrictions applicable to this meeting	
Kristine Hvolby	Member*	Denmark	No interests declared	
Nanna Lundgaard Rasmussen	Member*	Denmark	No interests declared	
Sari Koski	Alternate*	Finland	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Maria Paile Hyvarinen	Member	Finland	No interests declared	
An Le	Member	France	No interests declared	
Helene Ly	Alternate*	France	No interests declared	
Valerie Niederwieser	Alternate	Germany	No interests declared	
Ioanna Chinou	Member	Greece	No restrictions applicable to this meeting	
Stavroula Mamoucha	Alternate*	Greece	No interests declared	
Julia Pallos	Member	Hungary	No restrictions applicable to this meeting	
Jacqueline Masterson	Member	Ireland	No interests declared	
Alessandro Assisi	Member	Italy	No interests declared	
Inga Sile	Member	Latvia	No restrictions applicable to this meeting	
Jean-Luc Bueb	Member	Luxembourg		
Everaldo Attard	Member	Malta	No restrictions applicable to this meeting	
Hilda Kuin	Alternate	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 interests declared	
Ana Paula Martins	Member	Portugal	No interests declared	
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 interests declared	
Olga Maria Palomino	Member	Spain	No restrictions applicable to this meeting	
Margarita Berrocal Navas	Alternate*	Spain	No interests declared	
Karin Erika Svedlund	Member (Vice-Chair)	Sweden	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Pierre Duez	Co-opted member	Belgium	No restrictions applicable to this meeting	
Heidi Foth	Co-opted member	Germany	No interests declared	
Maria Helena Pinto Ferreira	Co-opted member*	Portugal	No interests declared	
Marie Chantal Zwaan-Baltus	Expert - in person	Netherlands	No interests declared	
Peter Sisovsky	Expert - remotely*	Slovakia	No interests declared	
Sonny Larsson	Expert - remotely*	Sweden	No interests declared	
Charlotta Lofberg	Expert - remotely*	Sweden	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.