19 November 2025
EMA/HMPC/336824/2025
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 22-24 September 2025

Chair: Emiel Van Galen, 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 Chair welcomed the new and re-nominated HMPC members/alternates.

1.2. Adoption of agenda

HMPC agenda for 22-24 September 2025.

Outcome:

Agenda and time schedule adopted.

1.3. Adoption of the minutes

HMPC minutes for 7-9 July 2025.

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 September 2025

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 November 2025 meeting according to the overview, Rapporteurs were asked to inform the Committee secretariat and Chair before the first pre-mail (by 03 November 2025) to allow best adaptation of agenda and time schedule.

2.1.2. Appointment of Rapporteurs and Peer-reviewers

Periodic reviews to start in 2025-2026

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 accordingly.

2.1.3. Re-evaluation of Public Statements

Report: HMPC Chair

Action: For discussion

Document tabled: Proposal for a possible review of established Public Statements, Annex, Presentation

Outcome:

HMPC members to confirm which herbal substances with public statements currently have products available in their national markets for a next **discussion** at the **HMPC November 2025** meeting.

A second proposal to review the adopted public statements was presented, as the reasons that led to an initial PS in the past may no longer be applicable (e.g. new THMP registered or expected to fulfil the 30/15 years criteria; broad scientific interest or recent scientific publications; new information on adverse events retrieved from Eudravigilance or concerning interactions).
Some HMPC members emphasised that the first criterion for reviewing the public statements should be to check whether products are available on the EU market (and before deciding to launch a public call for scientific data).

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

None

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

2.3.1. Monograph on Matricariae aetheroleum and supporting documents - postponed

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

2.4.1. Monograph on Cimicifugae rhizoma and supporting documents

Action: For adoption

Documents tabled: Review report, References 00/00

Outcome:

Postponed.

2.4.2. Monograph on Primulae flos and supporting documents

Action: For adoption

Documents tabled: Review report, References 00/00

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 not to revise the monograph, assessment report and list of references on Primulae flos.
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, to date, there is no Ph. Eur. monograph for Primulae flos, no new products on the EU market, and none of the case reports registered in Eudravigilance could be related to the intake of Primula flos.

2.4.3. Monograph on Primulae radix and supporting documents

Action: For adoption

Documents tabled: Review report, References 00/00

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 not to revise the monograph, assessment report and list of references on Primulae radix.
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 Ph. Eur. monograph for Primulae radix has been updated (but changes do not trigger the MO revision), no new products on the EU market,

and none of the case reports registered in Eudravigilance could be related to the intake of Primulae root.

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

2.6.1. Monograph on Maydis stigma and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR, Reader's guidance, References 87/92

Outcome:

Draft EU herbal monograph and supporting documents adopted for 3 months public consultation.

The Rapporteur summarised the main changes introduced in the AR/MO, including separate posology for decoctions and infusions.
Some HMPC members pointed out to further update to improve the MO sections 4.1, 4.4. and 5.3. and emphasised that the maximum duration of use (i.e., the period-of-time after which a doctor or qualified health professional should be consulted) was previously agreed to be 2 weeks. Moreover, it was emphasised that the NOEL of 500 mg/kg should be further clarified.

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

None

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) - postponed

4.2. Quality

None

4.3. Regulatory / Procedural

4.3.1. Assessment report summary for the public (ARSP)

Action: For adoption

Document tabled: Revised template

Outcome:

Final revised template 'Assessment report summary for the public (ARSP)' adopted by consensus.

The Rapporteur summarised the main changes introduced in the revised ARSP template, which were validated by EMA medical writers.
Minor editorial/linguistic changes were also proposed by some Member States (agreed).

4.4. Report on HMPC Drafting Groups activities

4.4.1. ORGAM DG

None

4.4.2. Quality DG

- QDG September meeting

  Report: Carmen Purdel

  Action: For information

  Document tabled: Minutes September 2025

  Outcome:

  HMPC members were briefed on QDG activities as per the September meeting: 1) revision on the declaration of herbal substances and herbal preparations in (traditional) herbal medicinal products (EMA/HMPC/CHMP/CVMP/287539/2005, focused on how to declare an extract, i.e., giving the DER or stating the equivalent amount of herbal substance (HMPC members' preference to declare the extract in both ways); 2) guidance on comparability between herbal preparations, focused on the considerations that should be taken into account when comparing two manufacturing processes, e.g., type of manufacturing process, process parameters, conditions (a questionnaire to be circulated among the HMPC members); 3) herbal curriculum training, this time focused on understanding how CEPs are developed in order to have a harmonised approach (EDQM templates seem not to be aligned with the eCTD structure). The next meeting is scheduled for October 2025.
  Some HMPC members highlighted advantages of having a CEP (e.g., harmonisation of decisions; saving time in assessments), but its applicability to herbal substances may pose challenges.

- Questionnaire on comparability between herbal preparations

  Report: Carmen Purdel

  Action: For information

  Document tabled: Questionnaire

Outcome:

HMPC members were informed about the questionnaire on the comparability of herbal preparations, which will be distributed to gather practical examples based on national experience, e.g., when dealing with variations. HMPC members were invited to submit their responses by 05 December 2025.

- QDG membership

  Report: Carmen Purdel

  Action: For information

  Outcome:

  HMPC members were informed of two vacancies that are about to become available and accordingly a call for nominations (secretariat) will be issued for the possible appointment of new members to the QDG at the November HMPC meeting.

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 September 2025

  Report: HMPC Vice-Chair

  Action: For information

  Document tabled: Follow-up plan

  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: Denmark).

- Danish Presidency meeting 8-10 October

  Report: Nanna Lundgaard Rasmussen

  Action: For information

  Document tabled: Draft agenda

  Outcome:

  HMPC members were informed on the draft agenda for the next HMPC-SRLM organised by the Dannish Presidency of the Council of the European Union, 08-10 October 2025.

5.1.2. HMPC membership

Report: HMPC Chair

Action: For information

New membership:

- Poland, Tomasz Stawarski (Alternate), as of 30 March 2025

Re-nominated members:

- Cyprus, Alexandra Demetriou (Alternate), as of 14 September 2025
- Finland, Sari Koski (Alternate), as of 24 September 2025

5.1.3. HMPC Chairperson - upcoming election 2026

Report: HMPC Chair

Action: For discussion

Outcome:

The HMPC secretariat informed the Committee members about the upcoming election of HMPC Chairperson in January 2026. A call for candidates will be sent out after the November meeting. Further details and timelines will be communicated in due course.

5.2. EMA Scientific Committees or CMDh-v

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

Report: HMPC Vice-Chair

Action: For discussion

Document tabled: Draft Reflection paper

Outcome:

Rapporteur to introduce changes in the draft reflection paper on particulars for signal detection for herbal medicinal products according to the discussion, and comments from the EMA Regulatory Affairs.
Next **discussion** scheduled at the **HMPC November 2025** meeting.

HMPC members were briefed about the ongoing discussion on the best process for HMPC/PRAC interaction in signal detection for (T)HMPs.
Some HMPC members emphasised that, from a practical perspective, it is important to have a clear understanding of the HMPC/PRAC interaction process when safety concerns arise following a search of the EudraVigilance database.

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

Report: HMPC Vice-Chair

Action: For information

Document tabled: ICH M12 guideline on drug interaction studies

Outcome:

HMPC members were informed about the draft document on requirements for studying the interaction potential of herbal medicinal products.
Next **discussion** scheduled at the **HMPC November 2025** meeting.

5.2.3. Scientific Coordination Board Meeting

Report: HMPC Chair

Action: For information

Document tabled: Agenda 19 September 2025

Outcome:

HMPC members were briefed about the main topics discussed during the SciCoBO meeting held in September.

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

5.3.1. Patients and Consumers Working Party (PCWP) and the Healthcare Professionals Working Party (HCPWP)

- Nomination of a representative (and alternate)

  Report: HMPC Chair

  Action: For adoption

  Document tabled: Email PCWP/HCPWP

  Outcome:

  The HMPC re-nominated Olga Palomino (ES) and An Lê (FR) as HMPC observers in the Healthcare Professionals Working Party (HCPWP) and the Patients and Consumers Working Party (PCWP).

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopoeia

None

5.4.2. European Food Safety Authority (EFSA)

- Exchange on safety topics of common interest

  Action: For information

  Outcome:

  Postponed.

5.5. Cooperation with International Regulators

5.5.1. WHO International Regulatory Co-operation for Herbal Medicines (IRCH)

- WHO-IRCH workshops WG 1 (Safety and Regulation of Herbal Medicines) & WG 3 (Efficacy and Intended use of Herbal Medicines) – 6-8 August 2025, Delhi - India

  Report: HMPC Chair

Action: For information

Documents tabled: Safety dossier, WHO–IRCH workshop presentation

Outcome:

HMPC members were briefed on the key topics discussed during the WHO-IRCH workshops WG 1 (Safety and Regulation of Herbal Medicines) and WG 3 (Efficacy and Intended use of Herbal Medicines), held in August 2025.

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)

- AESGP hearing 2025

  Report: HMPC Chair

  Action: For information

  Document tabled: Email AESGP

  Outcome:

  HMPC members were informed on the main topics for the next AESGP hearing, which is scheduled for November 2025.

5.7. Work plan and related activities

5.7.1. HMPC work plan 2025

Report: HMPC Chair.

Action: For information

Documents tabled: HMPC work plan 2025, Progress report

Outcome:

HMPC members were briefed about the progress of the committee work plan for 2025.

- (1.3.1) Establish principles for the role of real-world data in supporting European Union herbal monographs

  Action: For discussion

  Outcome:

  The HMPC Chair summarised the latest RWE liaison group meeting, which focused on the possibility of conducting additional DARWIN-EU studies for herbal substances. Next **discussion** scheduled at the **HMPC November 2025** meeting.

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

  Action: For discussion

  Document tabled: Draft Reflection paper, presentation

  Outcome:

Rapporteurs to continue activities in line with the HMPC work plan 2025. See also 5.2.1..
Next **discussion** scheduled at the **HMPC November 2025** meeting.

- (1.3.3) Improved evaluation of data from paediatric clinical practice for the safe use of herbal substances in children

  Action: For information

  Outcome:

  Rapporteurs to prepare the OoCs based on the comments received from IPs during the 3-month public consultation.
  Next **discussion** scheduled at the **HMPC November 2025** meeting.

- (2.1.1) HMPC position on the role of EU herbal monographs and assessment reports in relationship to borderline issues

  Action: For discussion

  Documents tabled: Draft Reflection paper, OoC, Presentation

  Outcome:

  Rapporteurs to introduce changes in the draft 'Reflection paper on the use of information in EU herbal monographs and assessment reports for borderline issues' (EMA/HMPC/224438/2024) according to the discussion and comments received from IPs during the 3-month public consultation.
  Next **discussion** scheduled at the **HMPC November 2025** meeting.

  Comments were received that reflect the main issue (the lack of a harmonised way to classify different product categories in the EU). Moreover, the comments emphasised the need for guidance and a common EU best practice for the classification of borderline products.

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

  Action: For discussion

  Document tabled: ARSP examples

  Outcome:

  Five EU herbal monographs were presented as 'proof of concept' to test the revised ARSP template, which was formally adopted during the current meeting. See also 4.3.1..
  Next **discussion** scheduled at the **HMPC November 2025** meeting.

- (2.3.1) Improve work-sharing in HMPC assessment tasks, supported by new herbal curriculum training courses for assessors

  Action: For information

  Documents tabled: Overview internal HMPC training on AR and MO templates, Herbal Curriculum Training Planning 2024-2025, Training 'Assessment report template chapter 3 and corresponding sections in the monograph template (including revisions)'

  Outcome:

  The HMPC members noted the progress of the training programme planned for 2025, targeting committee assessors (assessment report template and corresponding sections in the monograph template) and NCAs (EU-NTC herbal curriculum). A presentation/training

session was given on 'assessment report template chapter 3 and corresponding sections in the monograph template (including revisions)', which focused mainly on the practical rules/advice for rapporteurs when filling in the third chapter of the AR.
Next **discussion** scheduled at the **HMPC November 2025** meeting**.**

5.7.2. HMPC work plan 2026 - cross-committee topics

Report: HMPC Chair

Action: For information

Outcome:

HMPC members were informed about the start of discussions on the committees' work plans for 2026, including the workshop held at the SciCoBo September meeting, with special emphasis on cross-committee topics. HMPC members have been invited to submit proposals for consideration in the HMPC work plan 2026.

5.8. Planning and reporting

None

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 Arnicae flos and supporting documents

Action: For 1st discussion

Documents tabled: Draft AR, MO, LoR, OoC

Outcome:

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 November 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **20 October 2025**
Peer-review documents to be sent to Rapporteur: **31 October 2025**
Final documents to be included latest in 2nd premail: **10 November 2025**

The Rapporteur highlighted a comment received from an IP regarding a specific preparation (tincture) to be considered in the MO.
Some HMPC members emphasised the 30/15 years criterion for considering a preparation for inclusion (or not) in the MO.

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

6.2.1. Monograph on Lavandulae aetheroleum and supporting documents

Action: For 21st discussion

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

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 November 2025** meeting.

The Rapporteur summarised that an introductory description of the products on the EU market, including therapeutic indications and dosages, was inserted in the AR chapter 2.3, and that the AR chapter 6 on the general conclusion was also updated with a compilation of sentences from the respective parts of the AR.
Some HMPC members pointed out that the duration of maximum use (if symptoms persist or worsen) should be stated in the MO and based on the product information on the market.

6.2.2. Monograph on Lecithinum ex soya and supporting documents

Action: For 2nd discussion

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

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, for **possible adoption** for public consultation at the **HMPC November 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **20 October 2025**
Peer-review documents to be sent to Rapporteur: **31 October 2025**
Final documents to be included latest in 2nd premail: **10 November 2025**

The Rapporteur highlighted that a range for the daily dose is proposed in the MO section 4.2. and based on the single dose of the products on the EU market (agreed); no published data related to interactions with anticoagulants that could support revision of the MO section 4.5 (agreed); information on the soya-bean lecithin which is proposed in the MO section 4.7 (agreed).

6.2.3. Monograph on Matricariae flos and supporting documents

Action: For 1st discussion

Document tabled: Reader's Guidance

Outcome:

Rapporteur to prepare a first draft of the 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 November 2025** meeting.

The Rapporteur summarised proposals still for discussion: to delete the preparation d) and to update the AR with information that it is an old declaration of preparation b), as preparations d) and b) are the same extracts (agreed); to delete preparation n) as it was only used in a combination product (combination from dry extract and Matricaria essential oil) and has never been as single ingredient product on the market (agreed); to keep studies from combination products Matricaria extracts and Matricaria essential oil ("Kamillosan Konzentrat" and "Kamillosan Salbe") for the safety assessment only (agreed); to update the indication 5) as "Traditional herbal medicinal product used for the treatment of minor inflammation of the skin (such as sunburn), superficial wounds and small boils (furuncles)" (agreed); to include haemorrhoids as single indication (agreed).

6.2.4. Monograph on Ribis nigri 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 November 2025** meeting.

The Rapporteur highlighted that the MO sections 4.1., 4.3. and 4.4. have been updated. Some HMPC members pointed out that the wording of therapeutic indication 2) should be harmonised upon agreed for the so-called "diuretic herbal monographs".

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

6.3.1. Monograph on Althaeae radix and supporting documents

Action: For 1st 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 November 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **20 October 2025**
Peer-review documents to be sent to Rapporteur: **31 October 2025**
Final documents to be included latest in 2nd premail: **10 November 2025**

The Rapporteur emphasised that there are no new single-component products on the EU market, and in none of the case reports registered in Eudravigilance is there certainty as to the relationship between the ingestion of althaea radix and the adverse reactions observed.

6.3.2. Monograph on Carvi aetheroleum and supporting documents

Action: For 1st 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 November 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **20 October 2025**
Peer-review documents to be sent to Rapporteur: **31 October 2025**
Final documents to be included latest in 2nd premail: **10 November 2025**

The Rapporteur highlighted a minor inconsistency in the therapeutic indication when comparing with Melissa officinalis, Pimpinella anisum and other herbs for gastrointestinal disorders, which is not considered sufficient to trigger a MO revision.

6.3.3. Monograph on Carvi fructus and supporting documents

Action: For 1st 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 November 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **20 October 2025**
Peer-review documents to be sent to Rapporteur: **31 October 2025**
Final documents to be included latest in 2nd premail: **10 November 2025**

See also 6.3.2.

6.3.4. Monograph on Curcumae longae rhizome and supporting documents

Action: For 4th 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 November 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **20 October 2025**
Peer-review documents to be sent to Rapporteur: **31 October 2025**
Final documents to be included latest in 2nd premail: **10 November 2025**

The Rapporteur emphasised that none of the reported liver toxicity cases retrieved from the EudraVigilance database triggers a MO revision because there was concomitant use of other drugs/supplements. Moreover, some data was gathered to calculate a DD limit for curcumin content, beyond which the intake of curcumin-containing products could trigger drug-interactions/hepatotoxicity, which is much higher to what was established in the MO.
Some HMPC members proposed additional information to be considered whenever there is a concomitant intake of enhancer substances which may increase the bioavailability of curcumin content (to be taken into consideration in future revisions).

6.3.5. Monograph on Echinaceae angustifoliae radix and supporting documents

Action: For 3rd discussion

Document tabled: Review report, references

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 November 2025** meeting.

The Rapporteur summarised the literature and EudraVigilance finds on liver injury/ hepatobiliary disorders, and the conclusion is that, overall, no new safety data was identified that could trigger a MO revision. Current E. angustifolia monograph is considered for the intended use consistent with the other Echinaceae monographs. There are no new data/findings of relevance for the content of the monograph.

6.3.6. Monograph on Echinaceae pallidae radix and supporting documents

Action: For 4th discussion

Document tabled: Review report, references

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 November 2025** meeting.

The Rapporteur summarised the literature and EudraVigilance finds on liver injury/ hepatobiliary disorders, and the conclusion is that, overall, no new safety data was identified that could trigger a MO revision. There is very little new literature data and none of it was considered relevant for the MO. Moreover, the indication "short-term prevention of colds" based on a new product (DE) was also highlighted.
Some HMPC members emphasised that herbal substances with therapeutic indications related to the immune system (i.e., "prevention") have great implications in public health and therefore a higher standard of proof (i.e., WEU) is recommended.

6.3.7. Monograph on Equiseti herba and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

HMPC endorsed the Rapporteur's position that the required consistency with the information included in other so-called 'diuretic herbal monographs' 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 November 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **20 October 2025**
Peer-review documents to be sent to Rapporteur: **31 October 2025**
Final documents to be included latest in 2nd premail: **10 November 2025**

The Rapporteur emphasised that the MO sections 4.1., 4.3. and 4.4. have to be updated in order to be harmonised upon agreed for the so-called "diuretic herbal monographs".

6.3.8. Monograph on Myrrha and supporting documents

Action: For 1st discussion

Document tabled: Presentation

Outcome:

Rapporteur to prepare a first draft of the review report for a next **discussion** at the **HMPC November 2025** meeting.

The Rapporteur presented a summary report of search for new information, focused on the pharmacology and biological activities, concluding that no new data on safety concern were published; ethanol intake during use may be relevant for safety concern, but, the ethanol warning is already given in the MO. In summary none of the new published information is suitable to trigger a revision of the monograph for the myrrha tincture in TU (oral and cutaneous) applications.

6.3.9. Monograph on Oenotherae oleum and supporting documents

Action: For 1st 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 November 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **20 October 2025**
Peer-review documents to be sent to Rapporteur: **31 October 2025**
Final documents to be included latest in 2nd premail: **10 November 2025**

The Rapporteur highlighted that the Ph.Eur monograph (Oenotherae oleum raffinatum 01/2020:2104) was updated (reference to this can be done when there is a need to revise the EU herbal MO); several trials investigated the clinical efficacy of evening primrose oil, but only a few used only oenothera oleum (more data are necessary to support some potential benefits for the psychological symptoms (e.g. anxiety, depressive mood, irritability) of postmenopausal women assessed using the menopause rating scale (MRS) quality of life questionnaire).

6.3.10. Monograph on Psyllii semen and supporting documents

Action: For 1st 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** to be scheduled after HMPC has decided on the Ispaghula review.

The Rapporteur highlighted that the Ph. Eur. monograph was updated (changes do not trigger a MO revision). However, it was emphasised that if changes for Ispaghula husk/seed are decided, then these changes (adverse events) should also be considered for Psyllii semen (agreed).

6.3.11. Monograph on Rusci rhizoma and supporting documents

Action: For 3rd 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 November 2025** meeting.

The Rapporteur emphasised that the relationship between the reported adverse events, the use of Ruscus aculeatus rhizome containing products and the influence of other variables like disproportionality in reporting, pre-existing conditions or duration of use, are now also addressed.
Some HMPC members proposed additional changes to improve the summary on the hypersensitivity reactions and to ensure that this information in the review report is easily understandable and actionable.

6.3.12. Monograph on Salicis cortex and supporting documents

Action: For 1st 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 November 2025** meeting.

The Rapporteur pointed out that there is no new medicinal products with Salicis cortex reported as introduced on the EU market; a few reports on adverse reactions were found but they do not influence the current safety profile. Moreover, some new publications on toxicological studies were published and may be added as annex to the current AR.
Some HMPC members higlighted that if safety information is already reflected in the MO, there is no need to include it again in the review report.

6.3.13. Monograph on Salviae officinalis folium and supporting documents

Action: For 2nd 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 November 2025** meeting.

The Rapporteur emphasised that the published study with a product authorised in Switzerland as THMP has limitations including a limited number of participants and a short observation period of only 4 weeks.
Some HMPC members proposed additional changes to improve the assessor's comments on identified clinical studies and to ensure that this information in the review report is easily understandable and actionable.

6.3.14. Monograph on Thymi herba and supporting documents

Action: For 8th 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** to be scheduled after HMPC has decided on the safety assessment of any allergic reactions associated with thyme-containing products.

The Rapporteur summarised that some EU member states (e.g. AT, DE, IE, SE) have included information on possible adverse reactions in the labelling of (combination) thyme-containing products, but to date there are no data on similar adverse reactions with mono-component products containing only thyme. Thus, there is a need for assessment of the information to be considered for single compound products vs combination products.
Some HMPC members pointed out that there are thyme single compound and thyme combination products on the EU market, though information on possible adverse reactions were more often for the combination products. Moreover, it should not be excluded the potential effect related to excipients as constituents of thyme-containing products. The HMPC members were invited to gather any additional data on the eventual allergic reactions reported in their national mono-component products only containing thyme.
An HMPC member state will prepare an assessment on the eventual allergic reactions associated with thyme-containing products.

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

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

Action: For 2nd discussion

Documents tabled: Draft AR, MO, OoC

Outcome:

Postponed.

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

None

7. Any other business

7.1. Topics for discussion

None

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 7-9 July 2025

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)

On hold

7.2.3. Other

- New EMA Code of Conduct to be tabled to scientific committees meetings

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/ experts following evaluation of declared interests for the 22-24 September 2025 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
Emiel Van Galen	Chair	Netherlands	No interests declared	
Astrid Obmann	Member	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:	6.3.14. Monograph on Thymi herba
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	
Markéta Příhodová	Member	Czechia	No restrictions applicable to this meeting	
Kristýna Veselá	Alternate*	Czechia	No restrictions applicable to this meeting	
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	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
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	
Anna Maria Serrilli	Alternate*	Italy	No interests declared	
Inga Sile	Member	Latvia	No restrictions applicable to this meeting	
Sven Back	Member*	Luxembourg	No interests declared	
Everaldo Attard	Member	Malta	No restrictions applicable to this meeting	
Burt H Kroes	Member	Netherlands	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 restrictions applicable to this meeting	
Ana Paula Martins	Member	Portugal	No interests declared	
Carmen Purdel	Member	Romania	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	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
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	
Pierre Duez	Co-opted member	Belgium	No restrictions applicable to this meeting	
Heidi Foth	Co-opted member	Germany	No interests declared	
Maria da Graca Ribeiro Campos	Co-opted member	Portugal	No restrictions applicable to this meeting	
Kristine Hvolby	Expert *	Danish Medicines Agency	No interests declared	
Charlotta Lofberg	Expert*	Sweden	No interests declared	
Melanie Bald	Observer*	EDQM	No interests declared	
A representative from the European Commission attended the meeting.				
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.