24 September 2025
EMA/HMPC/244166/2025
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 7-9 July 2025

Chair: Emiel Van Galen, Vice-Chair: Karin Erika Svedlund

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).

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

Table of contents

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 Chair welcomed the re-nominated HMPC members and thanked the member (alternate) who was leaving the Committee for all her valuable work and contributions to the HMPC.

1.2. Adoption of agenda

HMPC agenda for 7-9 July 2025.

Outcome:

Agenda and time schedule adopted.

1.3. Adoption of the minutes

HMPC minutes for 5-7 May 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 July 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 September 2025 meeting according to the overview, Rapporteurs were asked to inform the Committee secretariat and Chair before the first pre-mail (by 8 September 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

Outcome:

Proposal ('ranking list') of herbal substances with public statements for possible revision to be drafted for **discussion** at the **HMPC September 2025** meeting.

A proposal for a possible review of the adopted public statements was presented, as reasons for an initial PS in the past may no longer be applicable (e.g. 30/15 years criteria). Some HMPC members pointed out that the first criterion for this review exercise should be to check whether there are products available on the EU market (and before launching a public call for scientific data).

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

2.2.1. Monograph on Plantaginis lanceolatae folium and supporting documents

Action: For adoption

Documents tabled: Draft MO, AR, OoC, LoR, Reader's guidance

Outcome:

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

The Rapporteur highlighted that the information on herb-related preparations complying the current Ph. Eur. definition, with an additional explanatory note on the botanical material(s) considered, has been updated in the AR.

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

2.3.1. Monograph on Fragariae folium and supporting documents

Action: For adoption

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

Outcome:

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

The Rapporteur emphasised that the only remaining issue was concerning the wording used in the MO sections 4.2. and 4.4., which state that use in children under 12 years of age is not recommended as it has not been established due to lack of adequate data.
Some HMPC members pointed out that the wording regarding the non-recommended use in children under 12 years of age should be aligned with the QRD template. Moreover, it was highlighted that the AR should be updated accordingly, including the agreed age range.

2.3.2. Monograph on Liquiritiae radix and supporting documents

Action: For adoption

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

Outcome:

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

The Rapporteur highlighted that the MO section 4.6 has been updated to align with the standard text for pregnancy and lactation reported in the Appendix 3 of the EMA scientific guideline 'Risk assessment of medicinal products on human reproduction and lactation: from data to labelling' (EMEA/CHMP/203927/2005). Consequently, changes were made to the Assessor's comment in the AR section 5.5.5 'Fertility, pregnancy and lactation' to reword the text in line with that of the MO.
Some HMPC members emphasised that, in relation to drug-interactions, the signal magnitude should be clearly stated in the AR.

2.3.3. Monograph on Species diureticae and supporting documents

Action: For adoption

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

Outcome:

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

The Rapporteur summarised the latest editorial changes introduced in the MO/AR, mainly related to the names and synonyms of some herbal substances included in this combination, and in accordance with the existing individual monographs.

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

2.4.1. Monograph on Calendulae flos 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 not to revise the monograph, assessment report and list of references on Calendulae flos.
The review report was adopted and after editorial review will be published as addendum to the existing assessment report on the EMA website.

In the absence of the Rapporteur, the Peer-reviewer emphasised that the Ph. Eur. monograph has been updated, with the identification method changing from TLC to HPTLC, but this will be reflected when there is a need to revise the EU herbal monograph.
Some HMPC members suggested including a reference/footnote to the change of the identification method in the Ph. Eur. monograph.

2.4.2. Monograph on Cimicifugae rhizoma and supporting documents - postponed

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

2.5.1. Monograph on Species pectorales and supporting documents

Action: For adoption

Documents tabled: Draft AR, LoR, MO

Outcome:

Final EU herbal monograph and supporting documents adopted by majority (25 out of 26). Divergent opinion: Ireland. The Norwegian delegate expressed a favourable position.

The Rapporteur highlighted that no comments were received during public consultation, and therefore, no changes have been made to the draft AR/MO.
Some HMPC members pointed out that reference to individual herbal substances should be accordingly with the names used in the individual monographs.

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

2.6.1. Monograph on Cannabis flos and supporting documents

Action: For adoption

Document tabled: Draft PS

Outcome:

Draft public statement adopted for 3 months public consultation.

The Rapporteur pointed out that requirements for the establishment of an EU herbal monograph (TU/WEU) on *Cannabis sativa* L., flos, were found not to be fulfilled at present, and that it was not possible to draft a complete assessment report at this moment. Therefore, it has been proposed to discontinue the assessment procedure.

2.6.2. Monograph on Maydis stigma and supporting documents

Action: For adoption

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

Outcome:

Adoption postponed.
Rapporteur to modify the draft monograph and assessment report according to the discussion and possible comments from peer-reviewer for **possible adoption** for public consultation at the **HMPC September 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **04 August 2025**
Peer-review documents to be sent to Rapporteur: **01 September 2025**
Final documents to be included latest in 2nd premail: **15 September 2025**

The Rapporteur summarised the changes made to the AR (e.g. information related to content/quantity when measured in tablespoons).
Some HMPC members pointed out that information on the period-of-time after which a doctor or qualified health professional should be consulted needs be harmonised in the AR sections 4.2. and 4.4. (2 weeks agreed). It was also emphasised that the therapeutic indication should follow the harmonised wording agreed upon for the so-called "diuretic monographs". Moreover, information related to serious medical conditions that are not easily perceived by patients/consumers (e.g. swelling due to heart or kidney insufficiency) should not be included in the AR/MO.

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)

Action: For discussion

Document tabled: Draft revised guideline

Outcome:

Rapporteurs to update the draft revised guideline (including flow chart) according to the discussion and any additional comments of the break-out session to be organised.
Next **discussion** scheduled at the **HMPC September 2025** meeting.

The Rapporteur highlighted the comments received from HMPC members, mainly related to the simplification of the flowchart where a positive AMES test was assessed, which will need further discussion (in a breakout session). This discussion is linked to the ICH guideline S2 (R1) on genotoxicity testing and data interpretation for pharmaceuticals intended for human use (EMA/CHMP/ICH//126642/ 2008) and the use of the AMES test as a screening tool (in case of a test positive result, it will be double checked with additional confirmatory tests). Some HMPC members emphasised that regarding additional confirmatory tests where a positive AMES test, it has been commonly accepted a single mammalian test with two endpoints.

4.2. Quality

4.2.1. Guideline on good agricultural and collection practice (GACP) of starting materials of herbal origin (EMA/HMPC/246816/2005)

Action: For adoption

Document tabled: Revised guideline, OoC

Outcome:

Final revised 'Guideline on good agricultural and collection practice (GACP) of starting materials of herbal origin' (EMA/HMPC/246816/2005) and supporting documents adopted by consensus. The Norwegian delegate expressed a favourable position.

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 June meeting

  Report: Astrid Obmann

  Action: For information

  Document tabled: Minutes June 2025

  Outcome:

  HMPC members noted the QDG activities accordingly to the June meeting, in particular: 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; 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). The next meeting is scheduled for September 2025.
Some HMPC members suggested that there should be some national flexibility in how an extract is declared, giving Member States the possibility to deviate from the two options mentioned in the guideline.

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 July 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 (next: 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

Re-nominated members:

- Croatia, Ivan Kosalec (Member), as of 01 July 2025
- Croatia, Darko Trumbetic (Alternate), as of 01 July 2025
- Cyprus, Christina Sylvia Chrysostomou (Member), as of 14 September 2025
- Germany, Heidi Foth (Co-opted member), as of 08 July 2025
- Hungary, Julia Pallos (Member), as of 22 September 2025
- Italy, Anna Maria Serrilli (Alternate), as of 22 August 2025
- Portugal, Ana Paula Martins (Member), as of 23 September 2025

End of membership:

- Portugal, Eva Mendes (Alternate), as of 21 June 2025

5.1.3. HMPC meetings in 2026

- Meetings 'in-person' *vs* 'remotely'

Report: HMPC Chair

Action: For information

Outcome:

HMPC members were informed of the four 'face-to-face' meetings planned for 2026: January, March, September and November.

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: Presentation

Outcome:

HMPC members were briefed about the drafting of a reflection paper on the safety-assessment of herbal medicinal products, relating to the HMPC/PRAC collaboration on signal detection.
Some HMPC members emphasised that it is not only important to search the EudraVigilance database, but also to carry out a proper assessment of the retrieved safety data.
Next **discussion** scheduled at the **HMPC September 2025** meeting.

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 noted the planned working meeting to review requirements for studying the interaction potential of herbal medicinal products.
Next **discussion** scheduled at the **HMPC September 2025** meeting.

5.2.3. Scientific Coordination Board Meeting

Report: HMPC Chair

Action: For information

Documents tabled: Agenda 27 June 2025

Outcome:

HMPC members were briefed on the main topics discussed during the SciCoBO meeting held in June.

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 information

  Document tabled: Email

  Outcome:

  HMPC members were informed of the call for the HMPC nomination of representatives to the PCWP and HCPWP.

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopoeia

- EDQM 13A, 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 summarised the last meeting of the Ph. Eur. Commission, which took place in June 2025. Regarding the study on methodologies for determining estragole (toxic component) in herbal essential oils (e.g. from bitter fennel fructus), the draft text on estragole's monograph is now released for consultation. Moreover, the HMPC members were informed on the summary of decisions from the 13A expert group meeting in May 2025 (next meeting in October 2025), 13B expert group meeting in May 2025 (next meeting in September 2025), and TCM expert group meeting in in May 2025 (next meeting in October 2025).

5.4.2. European Food Safety Authority (EFSA)

- EFSA opinion on fennel Article 8(2)

Action: For information

Document tabled: Draft opinion

Outcome:

The EFSA representative highlighted that the initial draft opinion on fennel Art. 8(2) of Reg. 1925/2006 was slightly changed following consultation with the EFSA Scientific Committee, but not changing the main conclusions. As the next steps, it was highlighted that the public consultation on the draft opinion on fennel Art. 8(2) of Reg. 1925/2006 will be launched on 14 July and is planned to remain open until 15 September.

- EFSA Compendium of botanicals

  Report: HMPC (Vice-)Chairs

  Action: For information

  Document tabled: Compendium of botanicals | EFSA

  Outcome:

  HMPC members noted the EFSA Compendium of botanicals that was published online in May 2025, and some of them suggested a greater exchange of information between EMA/HMPC and EFSA on the common grounds taken into account in the preparation of the compendium.

5.4.3. 'Pharma package' - Pharmaceutical Legislation Reform

Report: HMPC Chair

Action: For information

Document tabled: proposal for revised Regulation; proposal for revised Directive

Outcome:

HMPC members have been briefed on proposals for a Regulation and Directive setting out the principles relating to medicinal products for human use, after the Council of the European Union agreed its position on new pharmaceutical legislation.

5.4.4. Exchange of views with European Commission on Pharmaceutical Legislation Reform

EC representatives: Olga Solomon, Florian Schmidt

Action: For discussion

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

Document tabled: Invitation; Concept note; Provisional programme

Outcome:

HMPC members were informed of the invitation to the WHO-IRCH workshops WG 1 (Safety and Regulation of Herbal Medicines) and WG 3 (Efficacy and Intended use of Herbal Medicines), planned for August 2025 in India, and some of them confirmed that they will attend.

- WHO Traditional, Complementary and Integrative medicine (TCI)

  Report: HMPC Vice-Chair

  Action: For information

  Document tabled: Traditional, complementary and integrative medicine (TCI); WHO Traditional Medicine Strategy 2025–2034

  Outcome:

  HMPC members noted the 'WHO traditional medicine strategy 2025-2034', which has been made available online, with strategic objectives focused on evidence, regulation, integration and collaboration.

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. HMPC work plan 2025

Report: HMPC Chair

Action: For information

Document tabled: HMPC work plan 2025; Progress report

Outcome:

HMPC members were informed 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

  Document tabled: HMPC RWE Liaison Group Meeting 20_05_2025

  Outcome:

  HMPC/RWE liaison group to continue activities in line with the HMPC work plan 2025. Next **discussion** scheduled at the **HMPC September 2025** meeting.

  The HMPC Chair highlighted the RWE liaison group, as foreseen in the Committee's work plan 2025, and in this context the possibility of selecting additional herbal substances for DARWIN-EU studies. The invitation to attend the 73rd International Congress and Annual Meeting of the Society for Medicinal Plants and Natural Product Research (GA), in Naples -

Italy, from August 31 to September 3, 2026, was also highlighted.
Some HMPC members emphasised the potential interest of RWD/RWE in filling knowledge gaps regarding the use of herbal substances, specifically in certain target populations (e.g. paediatrics).

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

  Action: For discussion

  Document tabled: 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 September 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 continue activities in line with the HMPC work plan 2025.
  Next **discussion** scheduled at the **HMPC September 2025** meeting.

  As a note, the draft 'Reflection paper on data recommendations for traditional herbal medicinal products and herbal medicinal products used in children and adolescents' (EMA/HMPC/187311/2025) has currently been out for 3-month public consultation.

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

  Action: For information

  Document tabled: Draft Reflection paper, OoO, Reader's guidance

  Outcome:

  Rapporteurs will present an overview of comments received on the draft reflection paper.
  Next **discussion** scheduled at the **HMPC September 2025** meeting.

  Comments were received on the draft 'Reflection paper on the use of information in EU herbal monographs and assessment reports for borderline issues (EMA/HMPC/224438/2024) after a 3-month public consultation.

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

  Action: For discussion

  Document tabled: draft revised ARSP

  Outcome:

  Rapporteurs to finalise the draft revised ARSP template according to the discussion and comments received from the EMA's medical writers for **possible adoption** at the **HMPC September 2025** meeting.

  PCWP/HCPWP members and EMA's medical writers were consulted on the draft revision of the ARSP templates, and comments have been received. Based on the post-meeting

version, more examples for ARSPs will be drafted to be discussed at the September meeting.

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

  Action: For information

  Document tabled: Overview internal HMPC training on AR and MO templates, Herbal Curriculum Training Planning 2024-2025

  Outcome:

  Rapporteurs to continue activities in line with the HMPC work plan 2025.
  Next **discussion** scheduled at the **HMPC September 2025** meeting**.**

  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).

5.7.2. HMPC work plan 2026 - cross-committee topics

Report: HMPC Chair

Action: For discussion

Outcome:

HMPC members were informed about the start of discussion on committees' work plans for 2026, scheduled for the SciCoBo meeting in September, with a special emphasis on cross-committee topics.

5.8. Planning and reporting

5.8.1. EMA/HMPC scientific conference/event

- EMA's 30th anniversary scientific conference

  Report: HMPC Chair

  Action: For information

  Document tabled: Agenda

  Outcome:

  HMPC members were briefed on the EMA's 30th anniversary scientific conference held on 25 June.

- HMPC scientific event

  Report: HMPC Chair

  Action: For discussion

  Document tabled: Draft programme

  Outcome:

HMPC members endorsed the draft programme for the scientific event focusing on the committee's work, scheduled for 24 September 2025, as part of the ongoing celebrations of the EMA's 30th anniversary.

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 Lavandulae aetheroleum and supporting documents

Action: For 20th discussion

Documents tabled: 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 September 2025** meeting.

The Rapporteur highlighted published clinical studies on oral lavandula oil (meta-analyses of clinical studies are available) and products on the EU market (marketing authorisations through national or mutual recognition / decentralised procedures).
Some HMPC members suggested an assessment team to particularly draft the AR chapter 4 (breakout session to be scheduled). Examples of issues encountered in relation to published studies were emphasised.

6.2.2. Monograph on Lecithinum ex soya and supporting documents

Action: For 1st 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 September 2025** meeting.

The Rapporteur emphasised the new safety information relevant for the MO section 4.8 (undesirable effects) but no published data to support revision of the MO section 4.5 (needs further discussion).

6.2.3. Monograph on Matricariae aetheroleum and supporting documents

Action: For 2nd discussion

Documents tabled: Draft MO, AR, 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, for **possible adoption** for public consultation at the **HMPC September 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **04 August 2025**
Peer-review documents to be sent to Rapporteur: **01 September 2025**
Final documents to be included latest in 2nd premail: **15 September 2025**

The Rapporteur highlighted that hypersensitivity reactions, including severe allergic reactions to flowers, are now also considered for the essential oleum.
Some HMPC members agreed that, even in the absence of adverse events, references to potential safety concerns (e.g. hypersensitivity reactions) should be kept in the AR/MO.

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

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

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

6.3.3. Monograph on Plantaginis ovatae semen and supporting documents

Action: For 3rd discussion

Document tabled: Review report

Outcome:

Rapporteur to modify the review report according to the discussion and possible further comments from Peer-reviewer and HMPC members.

The Rapporteur emphasised the proposed amendment to the MO section 4.8., mentioning cases with diarrhoea in patients with constipation, and adding symptoms of oesophageal obstruction (needs further discussion).

6.3.4. Monograph on Plantaginis ovatae seminis tegumentum and supporting documents

Action: For 3rd discussion

Document tabled: Review report

Outcome:

Rapporteur to modify the review report according to the discussion and possible further comments from Peer-reviewer and HMPC members.

See also 6.3.3..

6.3.5. Monograph on Primulae flos 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 September 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **04 August 2025**
Peer-review documents to be sent to Rapporteur: **01 September 2025**
Final documents to be included latest in 2nd premail: **15 September 2025**

The Rapporteur highlighted that, to date, there is no Ph. Eur. monograph for Primula flos, and none of the case reports registered in Eudravigilance could be related to the intake of Primula flower and therefore this information does not trigger a revision of the monograph.

6.3.6. Monograph on Primulae 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 September 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **04 August 2025**
Peer-review documents to be sent to Rapporteur: **01 September 2025**
Final documents to be included latest in 2nd premail: **15 September 2025**

The Rapporteur emphasised that the Ph. Eur. monograph for Primula radix has been updated and none of the case reports registered in Eudravigilance could be related to the intake of Primula root and therefore this information does not trigger a revision of the monograph.

6.3.7. Monograph on Rusci rhizoma 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 September 2025** meeting.

The Rapporteur highlighted that, based on safety data from the EudraVigilance database, there are reported cases of adverse reactions involving this herbal substance.
Some HMPC members pointed out that the reported cases of adverse reactions were related to a combination product. Moreover, it was suggested to improve the summary on hypersensitivity reactions, to ensure that this information in the review report is easily understandable and actionable.

6.3.8. Monograph on Salviae officinalis folium 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 September 2025** meeting.

The Rapporteur emphasised the published study relating to a product that was authorised in Switzerland as a THMP, and also recognised by Lichtenstein, which may qualify this substance as a medicinal product in the EU.
Some HMPC members highlighted that the guidance provided in the 'regulatory questions and answers on herbal medicinal products' should be followed. Moreover, the Swiss representative to the HMPC was invited to provide information on this specific herbal product (e.g. whether the required time period was met).

6.3.9. Monograph on Thymi herba and supporting documents

Action: For 7th 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 September 2025** meeting.

The Rapporteur summarised that some EU member states have included information on possible adverse reactions in the labelling of (combination) products containing thyme preparations, but to date there are no data on similar adverse reactions with mono-component products containing only thyme.

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 1st discussion

Documents tabled: OoC

Outcome:

Rapporteur to introduce changes in the draft EU herbal monograph/list entry and supporting documents according to the discussion and to send the package to the peer-reviewer.
Next **discussion** scheduled at the **HMPC September 2025** meeting.

The Rapporteur summarised the main comments received during the PC, which were advocating the inclusion of the ethanol extract (fixed combination containing the dry extract from Hyperici (DER 3.5-6:1), extraction solvent ethanol 60% V/V and dry extract from Cimificugae (DER 4.5-8.5:1), extraction solvent ethanol 60% V/V) in the MO. In this regard, it was pointed out that TU evidence for the single active substance (i.e. the ethanolic extract of Cimicifuga) of a fixed combination will not be sufficient to establish a TU for a combination product (as per the Guideline on the assessment of clinical safety and efficacy in the preparation of EU herbal monographs for well-established and traditional herbal medicinal products, EMA/HMPC/104613/2005).
Some HMPC members emphasised that the rationale for not considering the ethanol extract should be improved to ensure that the information in the AR is easily understandable and actionable (and not based on confidential information).

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

7.1.1. Study on the use of traditional herbal products to treat animals – stakeholder consultation

Report: HMPC Chair

Action: For discussion

Document tabled: Letter

Outcome:

The HMPC members were briefed on the ongoing stakeholder consultation regarding a study from EC aiming to collect views on the possibility to make a legislative proposal to introduce a simplified system for the registration of traditional herbal products used to treat animals. Some HMPC members highlighted that individual NCAs were also consulted on this study. Furthermore, it was highlighted that the use of herbal products in the treatment of animals does not fall within the scope of the HMPC and the information on EU herbal monographs is not established for the use in animals.

7.1.2. EMA's Methodology Working Party (MWP) temporary drafting group - Assessment of SmPC section 5.1: A Guide for Assessors of Centralised Applications

Report: HMPC (Vice-)Chairs

Action: For information

Document tabled: draft version; Guide on assessment of SmPC section 5.1

Outcome:

The HMPC members noted the draft version of the guide for assessment of SmPC section 5.1.

7.1.3. GP-TCM Annual Meeting - London 24-27 July 2025

Report: HMPC Chair

Action: For information

Document tabled: Agenda

Outcome:

HMPC members were informed about the draft programme for the annual GP-TCM conference, which will be attended by the HMPC Chair and an HMPC Co-opted member.

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 5-7 May 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

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/ experts following evaluation of declared interests for the 7-9 July 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
Emiel Van Galen	Chair	Netherlands	No interests declared	
Astrid Obmann	Member	Austria	No interests declared	
Brigitte Hauser	Alternate	Austria	No interests declared	
Patricia Bodart	Member	Belgium	No interests declared	
Daniela Ruseva	Alternate	Belgium	No participation in discussions, final deliberations and voting on:	6.3.9 Monograph on Thymi herba
Iliana Ionkova	Member	Bulgaria	No interests declared	
Denitsa Momekova	Alternate	Bulgaria	No interests declared	
Ivan Kosalec	Member	Croatia	No interests declared	
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	
Ioanna Chinou	Member	Greece	No interests declared	
Stavroula Mamoucha	Alternate	Greece	No interests declared	
Rita Nemeth	Alternate	Hungary	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
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 interests declared	
Sven Back	Member	Luxembourg	No interests declared	
Everaldo Attard	Member	Malta	No interests declared	
Matthew Camilleri	Alternate	Malta	No interests declared	
Hilda Kuin	Alternate	Netherlands	No interests declared	
Gro Anita Fossum	Member	Norway	No interests declared	
Wojciech Dymowski	Member	Poland	No interests declared	
Ana Paula Martins	Member	Portugal	No interests declared	
Ligia Elena Dutu	Alternate	Romania	No interests declared	
Jaroslav Tóth	Alternate	Slovakia	No interests declared	
Barbara Razinger	Member	Slovenia	No interests declared	
Olga Maria Palomino	Member	Spain	No interests declared	
Margarita Berrocal Navas	Alternate	Spain	No interests declared	
Karin Erika Svedlund	Member (Vice-Chair)	Sweden	No interests declared	
Malin Kyllikki Hobro Soderberg	Alternate	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 Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared	
Maria da Graca Ribeiro Campos	Co-opted member	Portugal	No interests declared	
Melanie Bald	Observer	EDQM	No interests declared	
Marie Zwaan	Expert	Netherlands	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.