



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 06-08 July 2026

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

Disclaimers

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

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

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1. Introduction

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

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

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

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

The Chair welcomed the new HMPC members and thanked the outgoing members for all their valuable work and contributions.

1.2. Adoption of agenda

HMPC agenda for 06-08 July 2026.

Outcome:

Agenda and time schedule adopted.

1.3. Adoption of the minutes

HMPC minutes for 04-06 May 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 July 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 September 2026 meeting according to the overview, Rapporteurs were asked to inform the Committee secretariat and Chair before the first pre-mail (by 07 September 2026) to allow best adaptation of agenda and time schedule.

2.1.2. Appointment of Rapporteurs and Peer-reviewers

Periodic reviews to start in 2026-2027

Report: HMPC Chair

Action: For discussion

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

Outcome:

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

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

2.2.1. Monograph on Arnicae flos and supporting documents

Action: For adoption

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

Outcome:

Final revised EU herbal monograph on Arnicae flos and supporting documents adopted by consensus.

2.2.2. Monograph on Species diureticae and supporting documents

Action: For adoption

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

Outcome:

Final revised EU herbal monograph on Species diureticae and supporting documents adopted by consensus.

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

None

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

2.4.1. Monograph on Anisi aetheroleum and supporting documents

Action: For adoption

Documents tabled: Review report, Reader's Guidance

Outcome:

HMPC agreed with Rapporteur's position to revise the EU herbal monograph because new data were detected that require an update and changes to the content of the monograph. The HMPC decided by consensus to start the revision procedure and revise the monograph, assessment report and list of references on Anisi aetheroleum. The review report was adopted and HMPC tracking documents will be updated.

The Rapporteur highlighted that the wording of the conclusion on clinical trials was slightly changed, pointing out that the indications studied were different to those included in the EU herbal monograph and that no herbal medicinal product containing anise oil is available for those indications.

2.4.2. Monograph on Anisi fructus and supporting documents

Action: For adoption

Documents tabled: Review report, Reader's Guidance

Outcome:

HMPC agreed with Rapporteur's position to revise the EU herbal monograph because new data were detected that require an update and changes to the content of the monograph. The HMPC decided by consensus to start the revision procedure and revise the monograph, assessment report and list of references on Anisi fructus. The review report was adopted and HMPC tracking documents will be updated.

The Rapporteur emphasised that the summary of EudraVigilance search was shortened and the wording of the conclusion on clinical trials was slightly changed, pointing out that the indications studied were different to those included in the EU herbal monograph and that no herbal medicinal product containing aniseed is available for those indications.

2.4.3. Monograph on Salicis cortex 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 Salicis cortex.

The review report was adopted and after editorial review will be published as addendum to the existing assessment report on the EMA website.

Some HMPC members suggested to have more information, including the drug extract ratio (DER), related to the characterization of the salix alba bark extract mentioned in the genotoxicity and cytotoxicity studies.

2.4.4. Monograph on *Salviae officinalis folium* 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 *Salviae officinalis folium*.

The review report was adopted and after editorial review will be published as addendum to the existing assessment report on the EMA website.

2.4.5. Monograph on *Thymi herba* and supporting documents - postponed

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

2.5.1. Monograph on *Maydis stigma* and supporting documents

Action: For adoption

Document tabled: MO, AR, LoR References

Outcome:

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

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 discussion

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

Outcome:

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

The Rapporteur pointed out that, with regard to some comments received from IPs, there are some unpublished references that will need confirmation of their agreement before publication of AR and OoCs. Furthermore, it was emphasised that patient data from the Eudravigilance database qualifies as personal information and cannot be disclosed to the public, and the OoCs should therefore be amended accordingly (patient personal data must be redacted).

Some HMPC members suggested including more information in AR about the observational study, as well as clearly indicating which points of the clinical trial on climacteric complaints cannot be considered as evidence of WEU efficacy for the fixed combination. With regard to the adverse effects of anxiety, mania and neuropathy, and although different wordings are used among the (mono-) products containing St. John's wort on the EU market, the related information included in their SmPCs should also be considered when evaluating this 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 (EMA/HMPC/107079/2007)

Action: For discussion

Documents tabled: Draft revised Guideline

Outcome:

HMPC members were invited to review and submit any additional comments on the revised guideline, aiming to release a draft version for public consultation by the end of 2026.

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

The Rapporteur summarised the latest changes introduced to the guideline, including the agreement that the Ames test should be kept as the first step in the simplified decision tree on the assessment of genotoxicity of herbal preparations.

4.2. Quality

None

4.3. Regulatory/Procedural

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

Action: For discussion

Documents tabled: Draft Reflection paper, OoC

Outcome:

Draft 'Reflection paper on the use of information in EU herbal monographs and assessment reports for borderline issues' (EMA/HMPC/224438/2024) and the OoC endorsed for further consultation with the EMA Legal and Regulatory offices before a **possible adoption** at the **HMPC September 2026** meeting.

The Rapporteur highlighted the changes introduced, mainly regarding pharmacological action in the definition of medicinal product (in accordance with the text of Directive 2001/83).

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 2026

Outcome:

HMPC members were briefed on the ongoing activities of the QDG, as per the June 2026 meeting, primarily focused on topics 1) comparability between herbal preparations - a first draft of Q&As based on the outcome of the survey and follow-up discussions was presented; 2) guidance supporting the implementation of revised variations framework - new scopes for herbals have been introduced to the variation guidelines (C/2025/5045); and 3) guidance on the classification and role of markers - work already started on the guidance on the classification and role of markers will be continued. The next meeting is scheduled for 22 September 2026 and will be in person.

- Draft Agenda for 22 September 2026 meeting

Report: Astrid Obmann

Action: For information

Document tabled: Draft agenda

Outcome:

HMPC members were informed on the draft agenda for the next QDG (in-person) meeting, scheduled for 22 September 2026.

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

Report: HMPC Chair, Astrid Obmann

Action: For information

Outcome:

HMPC members were briefed on the draft "Mandate, objectives, and rules of procedure for expert groups under the quality, non-clinical, methodology, clinical and veterinary domains".

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 2026

Report: HMPC (Vice-)Chairs

Action: For information

Outcome:

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

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

- Cypriot Presidency meeting June 2026

Report: Christina Sylvia Chrysostomou, Alexandra Demetriou

Action: For information

Document tabled: Agenda, presentations

Outcome:

HMPC members were briefed on the key topics discussed during the HMPC-SRLM, organised by the Cypriot Presidency of the Council of the European Union, 18-19 June 2026, in Paphos. The Cypriot member/alternate were thanked once again for the organization and success of the meeting.

- Irish Presidency meeting 24 November

Action: For information

Outcome:

HMPC members noted the draft agenda for the next HMPC-SRLM, to be organised online by the Irish Presidency of the Council of the European Union on 24 November 2026 and were invited to contribute topics of interest for discussion at the meeting.

5.1.2. HMPC membership

Report: HMPC Chair

Action: For information

New membership:

- SE, Leif Sonny Larsson (alternate), as of 11 May 2026.

Re-nominated members:

- GR, Ioanna Chinou;
- GR, Stavroula Mamoucha;
- IT, Alessandro Assisi;
- MT, Everaldo Attard.

End of membership:

- IE, Jacqueline Masterson (member), as of 2 July 2026;
- LT, Gabriele Balciunaite Murziene (member), as of 20 June 2026;
- SE, Malin Kyllikki Hobro Soderberg (alternate), as of 9 May 2026.

5.1.3. EMA internal guidance on quorum, voting, proxies and divergent positions

Action: For information

Document tabled: Email

Outcome:

HMPC members received practical instructions on how to give and receive proxies relating to voting rights during plenary meetings.

5.1.4. Call for nomination of NCA experts for the Pharmacovigilance group

Action: For discussion

Document tabled: Email, Nominations

Outcome:

HMPC members endorsed the proposal to extend the call for NCA experts for establishing a HMPC pharmacovigilance group until the next plenary meeting in September.

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

Some HMPC members proposed extending the call to other NCA experts who may have experience in pharmacovigilance (HMPC members should distribute the invitation internally within their NCAs).

5.1.5. Call for nomination of herbal and homeopathic expert in the NPL Topic of Annex II

Action: For information

Document tabled: Email

Outcome:

HMPC members were informed that an HMPC member had accepted the HMA's nomination for involvement in the NPL topic of Annex II, as an expert in herbal matters.

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 adoption

Document tabled: Draft Reflection paper

Outcome:

Draft "Reflection paper on particulars for safety signals for (traditional) herbal medicinal products" (EMA/HMPC/PRAC/301178/2025) endorsed for 3-month public consultation.

5.2.2. Request for PRAC advice on Echinacea and the annexed assessment report

Action: For discussion

Documents tabled: PRAC advice on Echinacea, HMPC AR on Echinacea and DILI, Reader's Guidance

Outcome:

Rapporteur to modify the HMPC request for PRAC advice according to the discussion and possible additional comments from the EMA Pharmacovigilance office, for **possible adoption** at the **HMPC September 2026** meeting.

The Rapporteur summarised the draft documents including the HMPC request for PRAC advice, which were prepared from templates used by CHMP and MSs. Furthermore, the questions contained in the draft HMPC request for PRAC advice on Echinaceae were presented (agreed with some suggestions to ensure that information is easily understandable and actionable).

5.2.3. Scientific Coordination Board Meeting

Report: HMPC Chair

Action: For information

Document tabled: Agenda 5 June 2026

Outcome:

HMPC members were briefed on the key agenda points from the last SciCoBo meeting, held on 5 June 2026, primarily focused on strategic planning for the EMRN.

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

Documents tabled: Draft Reflection paper, Reader's guidance

Outcome:

Rapporteur to modify the draft reflection paper according to the discussion and possible additional comments from the ICH M12 implementation group, for **possible adoption** for release for consultation at the **HMPC September 2026** meeting.

The Rapporteur pointed out that the paper has been scrutinised by EMA Legal and Regulatory offices and the main change was the term 'NAS – new active substance' to 'application according to article 8(3)', avoiding terminology as 'full application' - agreed with some suggestions to ensure that information is easily understandable and actionable.

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

- PCWP and HCPWP Work plan for 2025-2028

Action: For information

Document tabled: PCWP/HCPWP Work plan 2025-2028

Outcome:

HMPC members noted the PCWP/HCPWP work plan for 2025-2028, which was adopted during their meeting held from 30 June to 1 July 2026.

- PCWP and HCPWP meeting 30 June - 1 July 2026

Report: HMPC Vice-Chair

Action: For information

Outcome:

HMPC members were briefed on the key agenda points from the last PCWP/HCPWP meeting, held from 30 June to 1 July 2026, which commemorated its 20th anniversary.

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

Outcome:

The EDQM representative summarised the herbal drug monographs adopted at the last session of the European Pharmacopoeia Commission, held on 23–24 June 2026. Further information was provided concerning the texts to be published in *Pharmeuropa* 38.4. With regard to the Ph. Eur. monograph on *Cannabis flos*, it was reported that request for the introduction of *ad hoc* limits for microbial contamination of the herbal drug when administered by vaporisation has since been finalised. A summary of the conclusions from the recent meetings of Expert Groups 13A and 13B, held in May, was also presented.

- Pharmeuropa

Action: For information

Document tabled: *Pharmeuropa* issue 38.2

Outcome:

HMPC members took note of the latest *Pharmeuropa issue 38.2*, with information on texts published for comments, including fennel, bitter (0824); bitter fennel, cut (3254); melissa leaf (1447).

The EDQM representative clarified that since there are some products on the market containing 'bitter fennel, cut', they still justify having a specific Ph. Eur. monograph.

5.4.2. European Food Safety Authority (EFSA)

- EFSA Mandate on the safety assessment of botanicals and botanical preparations - public consultation period open

Report: HMPC Vice-Chair

Action: For information

Document tabled: [Public Consultation](#)

Outcome:

HMPC members were briefed about EFSA's Mandate on the safety assessment of botanicals and botanical preparations, which is now open for public consultation, and were invited to consult the available documentation/information.

5.5. Cooperation with International Regulators

5.5.1. EU/India Technical Working Group on Ayurveda

Report: HMPC Chair

Action: For information

Document tabled: Draft Minutes

Outcome:

HMPC members were briefed on the key agenda points from the 4th meeting of the EU-India EU Technical Working Group (TWG), held on 12 May 2026 and were invited to review the minutes of the corresponding meeting.

5.5.2. Request For Proposal (RFP) for "WHO Global Benchmarking Tool (GBT) for the Evaluation of National regulatory Systems for Herbal Medicines"

Report: HMPC Chair

Action: For information

Document tabled: Email

Outcome:

HMPC members noted the RFP for "WHO Global Benchmarking Tool (GBT) for the Evaluation of National regulatory Systems for Herbal Medicines", primarily intended for contractors with prior experience collaborating with WHO GBT.

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) – preparation for the hearing in November 2026

Report: HMPC Chair

Action: For information

Outcome:

HMPC members were informed that the next hearing with AESGP is scheduled for the November 2026 meeting and were invited to contribute topics of interest for discussion at the meeting.

5.7. Work plan and related activities

5.7.1. Follow-up on HMPC work plan 2026

Report: HMPC Chair

Action: For information

Document tabled: [HMPC work plan 2026](#); HMPC mid-year report

Outcome:

HMPC members were briefed on the current status of activities included in the HMPC work plan 2026 (mid-year report).

- 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 information

Outcome:

HMPC members were invited to report on potential herbal substances/preparations of interest for further DARWIN EU studies (deadline: 4 September 2026). RWE liaison group to review the list of possible candidates in advance for a next **discussion** scheduled at the **HMPC September 2026** meeting.

HMPC members were informed about the ongoing development of an AI tool dedicated to managing the committee's knowledge, based on the minutes of the HMPC meetings. Some HMPC members suggested the possibility of using the AI tool for other committee's tasks (e.g., establishing EU herbal monographs).

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

Action: For information

Outcome:

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

See also 4.3.1.

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

Action: For information

Outcome:

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

See also 5.1.4. and 5.2.1.

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

Action: For information

Document tabled: [Reflection paper \(webpage\)](#)

Outcome:

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

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

Action: For information

Outcome:

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

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

Action: For information

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

Outcome:

HMPC members were informed about the possibility of reassessing the principles for prioritising the start of the review of EU herbal monographs soon, considering NCAs resources (new principles to be integrated into the review/update procedure). Furthermore, a training course on the GACP guideline is being prepared and a preliminary version of the programme will be presented to the steering group (expected in early 2027).

Next **discussion** scheduled at the **HMPC September 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; [Webpage](#)

Outcome:

HMPC members were briefed on the key agenda points for the joint EMA/FDA workshop on the development of herbal-based medicinal products, scheduled for 25 September 2026.

Next **discussion** (preparation for the closed session) scheduled at the **HMPC September 2026** meeting.

5.8.2. Questionnaire on (T)HMPs in the EU market 2026

Action: For discussion

Document tabled: Questionnaire (template)

Outcome:

HMPC group to review the scope (purely NAPs vs MRP/DCPs) to be considered in the questionnaire/survey to collect data on the uptake of the traditional use registration scheme and implementation of the provisions of Directive 2004/24/EC in EU Member States. Next **discussion** scheduled at the **HMPC September 2026** meeting.

Some HMPC members suggested to add information on the procedure number (MA or Registration numbers), also to have two columns (one for herbal(s) substances and another for herbal preparation(s)), and information on the withdrawal date (if it is the status currently). Furthermore, it was proposed that only the RMS to add information for MRP/DCPs.

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 Ribis nigri folium and supporting documents

Action: For 1st discussion

Documents tabled: Draft MO, AR, 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 September 2026** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **07 August 2026**

Peer-review documents to be sent to Rapporteur: **31 August 2026**

Final documents to be included latest in 2nd premail: **14 September 2026**

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

6.2.1. Monograph on Betulae folium and supporting documents

Action: For 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 September 2026** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **07 August 2026**

Peer-review documents to be sent to Rapporteur: **31 August 2026**

Final documents to be included latest in 2nd premail: **14 September 2026**

The Rapporteur summarised that the duration of use is now in accordance with the other so called 'diuretic herbal monographs', keeping a duration of 2 weeks (instead of the previous duration of 2-4 weeks). Furthermore, and regarding children under 12 years, medical advice is always needed and therefore it is not recommended in this population.

Some HMPC members emphasised that its use as a diuretic for cardiac problems cannot be recommended under traditional use (medical advice is always necessary).

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

6.3.1. Monograph on Myrrha and supporting documents

Action: For 6th discussion

Document tabled: Review report

Outcome:

HMPC endorsed the Rapporteur's position that there is no new information available that could change the content of the EU herbal monograph.

Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC September 2026** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **07 August 2026**

Peer-review documents to be sent to Rapporteur: **31 August 2026**

Final documents to be included latest in 2nd premail: **14 September 2026**

The Rapporteur highlighted that no new safety concerns could be detected from the available data and that a summary of the main genotoxicity findings was included.

6.3.2. Monograph on Plantaginis ovatae semen and supporting documents

Action: For 6th discussion

Document tabled: Review report

Outcome:

HMPC endorsed the Rapporteur's position that there is no new information available that could change the content of the EU herbal monograph.

Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC September 2026** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **07 August 2026**

Peer-review documents to be sent to Rapporteur: **31 August 2026**

Final documents to be included latest in 2nd premail: **14 September 2026**

The Rapporteur summarised that from clinical studies in context of the indication constipation it is not clear to distinguish if Ispaghula seed, Ispaghula husk or Psyllium seed was given. However, in the EU herbal monographs, posologies of 8-40 g daily (Ispaghula seed), 7-11 g daily (Ispaghula husk) or 25-40 g daily (Psyllium seed) are described, which are in accordance with van der Schoot et al. (2022) reporting 10-40 g daily, while Gabrielli et al. (2016) describes only 3.5 g day. For such a posology, no products are reported on the EU market. Therefore, a revision of the monograph is not triggered by the newly published clinical studies. Furthermore, paradoxical diarrhoea has been reported, but the reports of diarrhoea are considered not to trigger a revision of the MO section 4.8. Paradoxical diarrhoea is well known in clinical practice but is rather conceived as a phenomenon related to the clinical course of constipation itself and not to the specific treatment.

6.3.3. Monograph on Plantaginis ovatae seminis tegumentum and supporting documents

Action: For 6th discussion

Document tabled: Review report

Outcome:

HMPC endorsed the Rapporteur's position that there is no new information available that could change the content of the EU herbal monograph.

Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC September 2026** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **07 August 2026**

Peer-review documents to be sent to Rapporteur: **31 August 2026**

Final documents to be included latest in 2nd premail: **14 September 2026**

See also 6.3.2..

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 8th discussion

Document tabled: OoC, Pharmaceutical weekly report, Cannabis research Bedrocan

Outcome:

Comments received during public consultation.

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

Timetable:

Documents to be sent to Peer-reviewer: **07 August 2026**

Peer-review documents to be sent to Rapporteur: **31 August 2026**
Final documents to be included latest in 2nd premail: **14 September 2026**

The Rapporteur pointed out that the OoCs, containing the comments received from IPs on the draft PS during the public consultation, was updated in accordance with the discussion held previously, and therefore, HMPC members were invited to review the justifications presented.

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 5th discussion

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

Outcome:

Rapporteur to finalise the draft EU herbal monograph and supporting documents for peer review and **adoption** at the **HMPC September 2026** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **07 August 2026**

Peer-review documents to be sent to Rapporteur: **31 August 2026**

Final documents to be included latest in 2nd premail: **14 September 2026**

The HMPC agreed that no additional information on drug interactions should be included in the MO section 4.5, given that there is no such information derived from non-clinical or clinical studies.

7. Any other business

7.1. Topics for discussion

7.1.1. Pilot – transition to IRIS/SharePoint

Action: For information

Outcome:

HMPC members were informed about the general rules regarding the committee's dedicated library on the IRIS/SharePoint, focusing on the principles of access, naming, uploading, and working with HMPC documents on this platform. In this regard, HMPC members were encouraged to access the platform, as it is expected to contain all documents related to the agenda of the HMPC September 2026 meeting.

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

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 04-06 May 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

- [EMA launches translation tool on its corporate website](#)

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 06-08 July 2026 HMPC meeting, which was held remotely.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Carmen Purdel	Chair	Romania	No restrictions applicable to this meeting	
Astrid Obmann	Member	Austria	No interests declared	
Brigitte Hauser	Alternate	Austria	No interests declared	
Patricia Bodart	Member	Belgium	No restrictions applicable to this meeting	
Daniela Ruseva	Alternate	Belgium	No participation in discussions, final deliberations and voting on:	2.4.5. Monograph on Thymi herba 6.5.1. Monograph on Valerianae radix/Passiflorae herba
Denitsa Momekova	Alternate	Bulgaria	No restrictions applicable to this meeting	
Darko Trumbetic	Alternate	Croatia	No interests declared	
Christina Sylvia Chrysostomou	Member	Cyprus	No interests declared	
Alexandra Demetriou	Alternate	Cyprus	No interests declared	
Markéta Příhodová	Member	Czechia	No restrictions applicable to this meeting	
Kristýna Veselá	Alternate	Czechia	No interests declared	
Nanna Lundgaard Rasmussen	Member	Denmark	No interests declared	
Maria Paile Hyvarinen	Member	Finland	No interests declared	
Sari Koski	Alternate	Finland	No interests declared	
An Le	Member	France	No interests declared	
Helene Ly	Alternate	France	No interests declared	
Jacqueline Wiesner	Member	Germany	No interests declared	
Valerie Niederwieser	Alternate	Germany	No interests declared	
Ioanna Chinou	Member	Greece	No restrictions applicable to this meeting	
Stavroula Mamoucha	Alternate	Greece	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Alessandro Assisi	Member	Italy	No interests declared	
Anna Maria Serrilli	Alternate	Italy	No interests declared	
Inga Sile	Member	Latvia	No restrictions applicable to this meeting	
Jean-Luc Bueb	Member	Luxembourg	No restrictions applicable to this meeting	
Hilda Kuin	Member	Netherlands	No interests declared	
Gro Anita Fossum	Member	Norway	No interests declared	
Marianne Loiten Dalhus	Alternate	Norway	No interests declared	
Wojciech Dymowski	Member	Poland	No interests declared	
Tomasz Stawarski	Alternate	Poland	No restrictions applicable to this meeting	
Miriana Stan	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	
Olga Maria Palomino	Member (Vice Chair)	Spain	No restrictions applicable to this meeting	
Margarita Berrocal Navas	Alternate	Spain	No interests declared	
Karin Erika Svedlund	Member	Sweden	No interests declared	
Sonny Larsson	Alternate	Sweden	No interests declared	
Heidi Foth	Co-opted member	Germany	No interests declared	
Maria Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared	
Kristine Hvolby	Expert	Denmark	No interests declared	
Celine Delerme	Expert	France	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Peter Sisovsky	Expert	Slovakia	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.