09 July 2025
EMA/HMPC/187311/2025
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 5-7 May 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 and thanked the member who was leaving the Committee for all her valuable work and contributions to the HMPC.

1.2. Adoption of agenda

HMPC agenda for 5-7 May 2025.

Outcome:

Agenda and time schedule adopted.

1.3. Adoption of the minutes

HMPC minutes for 17-19 March 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 May 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 July 2025 meeting according to the overview, Rapporteurs were asked to inform the Committee secretariat and Chair before the first pre-mail (by 24 June 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.

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

2.2.1. Monograph on Zingiberis rhizoma and supporting documents

Action: For adoption

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

Outcome:

Final revised EU herbal monograph and supporting documents adopted by majority (19 out of 25). Divergent opinions: DE, EL, FI, IE, IT, NL. The Norwegian delegate expressed a favourable position.

The rapporteur highlighted that the MO section 5.3. has been updated with additional information on chronic toxicity studies (target organs), based on the data available in the AR. Moreover, the AR chapter 4.2.2. on clinical studies has been revised.
Some HMPC members pointed out the 'pros and cons' of clinical studies carried out outside the EU to possibly support the MO's therapeutic indications in the light of the 'Reflection paper on the extrapolation of results from clinical studies conducted outside the European Union (EU) to the EU population' (EMEA/CHMP/EWP/692702/2008), emphasising that it should be decided 'on a case-by-case basis', taking into account, in particular, the quality of the studies.

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:

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

Timetable:
Documents to be sent to Peer-reviewer: **2 June 2025**
Peer-review documents to be sent to Rapporteur: **16 June 2025**
Final documents to be included latest in 2nd premail: **30 June 2025**

The Rapporteur summarised some bibliographic sources that support the use of wild strawberry leaves as an astringent in mild diarrhoea (indication 2)) in children, although the available data is not sufficient for dosage adjustments in children under 12 years of age (i.e. only for adolescents).
Some HMPC members pointed out that, given the lack of solid data supporting the use of Fragariae folium in the symptomatic treatment of mild diarrhoea in young children, the age limit should be limited to over 12 years old.

2.3.2. Monograph on Ononidis radix and supporting documents

Action: For adoption

Documents tabled: Draft MO, AR, LoR

Outcome:

Draft revised EU herbal monograph and supporting documents adopted by consensus for 3-month public consultation.

The Rapporteur highlighted that the single dose range has been amended to 2-4 g, with a maximum daily dose of 12 g.

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

2.4.1. Monograph on Melissae folium and supporting documents

Action: For adoption

Document tabled: Review report

Outcome:

HMPC agreed with Rapporteur's position to revise the EU herbal monograph because new data were detected that require 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 Melissae folium.
The review report was adopted and HMPC tracking documents will be updated.

The Rapporteur summarised that there are new products on the EU market (the preparation soft extract (2.3-3:1), aqueous, fulfils the 30/15 years criteria of TU). In addition, new safety information from products on the market are available (to be assessed).
Some HMPC members emphasised that if there is new relevant non-clinical data, it should be part of the assessment report.

2.4.2. Monograph on Ribis nigri folium and supporting documents

Action: For adoption

Document tabled: Review report

Outcome:

HMPC agreed with Rapporteur's position to revise the EU herbal monograph because new data were detected that require 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 Ribis nigri folium.
The review report was adopted and HMPC tracking documents will be updated.

The Rapporteur highlighted that, to ensure consistency with the information included in the other so-called 'diuretic herbal monographs', the MO revision is advisable.

2.4.3. Monograph on Vitis viniferae folium and supporting documents

Action: For adoption

Documents tabled: Review report, Reader's guidance

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 Vitis viniferae folium.
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 pointed out a request to include the dry extract (DER 4-6:1), extraction solvent water, for oral use under TU, which had already been discussed during the previous assessment in 2018 (this herbal preparation is not a new product and has since been withdrawn from the EU market).

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: 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 July 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **2 June 2025**
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The Rapporteur highlighted that single doses have been extended from 2-4 g to 2-8 g and daily doses from 4-12 g to 4-24 g, based on a TU herbal preparation from the British Herbal Pharmacopoeia. Moreover, the use in children under 12 years age is not recommended. Some HMPC members point out the differences in content/quantity when measured in tablespoons (agreed to express it only as tablespoons in the AR table 1, as the original market overview data, and not to convert it to mass units). Moreover, it was requested not to include information in AR/MO related to serious medical conditions not easily perceived by patients/consumers (e.g. swelling due to heart or kidney insufficiency).

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 possible additional comments from HMPC members.
Next **discussion** scheduled at the **HMPC July 2025** meeting.

The Rapporteur summarised the proposals put forward by some members, mainly related to simplify the flowchart, where a positive result of the AMES test was assessed. This 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). Moreover, the use of the AMES test as a screening tool was emphasised (i.e. in case of a positive result, it will be double checked with additional confirmatory tests).
Some HMPC members pointed out that some individual herbal compounds may influence the outcome of the AMES test. Moreover, the 'pros & cons' of referencing the ICH guideline S2 (R1) were highlighted.

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 (internal consultation)

Document tabled: Draft revised guideline, OoC

Outcome:

The HMPC endorsed by consensus the draft revised 'Guideline on good agricultural and collection practice (GACP) of starting materials of herbal origin' (EMA/HMPC/246816/2005) for a second consultation with the GMP/GDP Inspectors Working Group (GMDP IWP) and Quality Working Party (QWP) prior its final adoption.

The Rapporteurs pointed out that the OoCs and the draft revised GACP guideline were updated accordingly to the comments received from the QDG.

4.3. Regulatory / Procedural

4.3.1. Reflection paper on data recommendations for traditional herbal medicinal products and herbal medicinal products used in children and adolescents (EMA/HMPC/187311/2025)

Action: For adoption (public consultation)

Document tabled: Draft RP on data recommendations for THMP used in children/adolescents

Outcome:

The HMPC endorsed by consensus 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) for 3-month public consultation.

4.4. Report on HMPC Drafting Groups activities

4.4.1. ORGAM DG

None

4.4.2. Quality DG

- QDG April meeting

  Report: Carmen Purdel

  Action: For information

  Document tabled: Minutes April 2025

  Outcome:

  HMPC members noted the QDG activities accordingly to the April meeting, in particular: 1) revision of the guideline on Good Agricultural and Collection Practice (GACP) of starting materials of herbal origin (EMEA/HMPC/246816/2005, mainly regarding the finetuning of definitions and terminology; 2) revision on the declaration of herbal substances and herbal

preparations in herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/CHMP/CVMP/287539/2005). mainly focused on the declaration "as dry extract" although the extract used was soft or liquid.

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Strategic Review and Learning Meetings (SRLM)

- HMPC SRLM Follow up plan - status May 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 one: Poland).

- Polish Presidency meeting 13-14 May

  Report: Wojciech Dymowski

  Action: For information

  Document tabled: Draft agenda

  Outcome:

  HMPC members were informed on the draft agenda for the next HMPC-SRLM organised by the Polish Presidency of the Council of the European Union, 13-14 May 2025, focused on: 1) regulatory issues related to some herbal products; 2) safety issues posed by specific herbal compounds; 3) University activity & research in the herbal field; 4) strategic discussions on future activities of the HMPC.

5.1.2. HMPC membership

Report: HMPC Chair

Action: For information

New membership:

- Bulgaria, Denitsa Momekova (alternate), as of 01 May 2025

Re-nominated members:

- Belgium, Patricia Bodart (member), as of 08 April 2025
- Slovakia, Toth Jaroslav (alternate), as of 08 April 2025
- Slovenia, Barbara Razinger (member), as of 28 June 2025

End of membership:

- Bulgaria, Radina Dimitrova (alternate), as of 30 April 2025

5.1.3. HMPC Co-opted members

- Appointment of Co-opted member:

  1) Non-clinical toxicology (Exp: 07 July 2025)

  Report: HMPC Chair

  Action: For adoption

  Document tabled: Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC; Appointment of Co-opted member to HMPC_2025May

  Outcome:

  Heidi Foth (DE) was appointed as HMPC co-opted member in the area of expertise 'Non-clinical toxicology' for a 3-year mandate starting on 08 July 2025.

  Heidi Foth highlighted her extensive scientific expertise and experience in procedures to evaluate toxicological risks. As a co-opted member of HMPC, Prof. Foth has been contributing to the committee work as a rapporteur and supporting other rapporteurs as a peer reviewer.

5.1.4. Health & Safety induction

Action: For information

Document tabled: Video

Outcome:

HMPC members were briefed on health, safety and emergency information and procedures according to the of the Agency's health and safety policy.

5.2. EMA Scientific Committees or CMDh-v

5.2.1. HMPC/PRAC collaboration on signal detection for herbal medicinal products

Action: For information

Document tabled: Presentation 'EudraVigilance and safety signal management process'

Outcome:

A presentation was given on 'EudraVigilance and safety signal management process', which focused mainly on practical information for rapporteurs on collecting and analysing data from the EudraVigilance (EV) database and managing potential safety signals detected.

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

None

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopoeia

None

5.4.2. European Food Safety Authority (EFSA)

Action: For information

Document tabled: Draft opinion fennel Art 8(2); HMPC comments on the EFSA draft opinion

Outcome:

The HMPC endorsed by consensus the proposed comments on the EFSA's draft opinion on fennel Art. 8(2) of Reg. 1925/2006.

The EFSA representative emphasised that the public consultation of the draft opinion on fennel is expected to start within 1 month, following the endorsement of the EFSA scientific committee, and will last 6 weeks.

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

Action: For discussion

Outcome:

Postponed.

5.5. Cooperation with International Regulators

None

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

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

  Report: HMPC Chair

  Action: For discussion

  Documents tabled: Reflection paper on use of real-world data in non-interventional studies to generate real-world evidence for regulatory purposes; Email 'Participation of HMPC delegates on the 73rd International Congress and Annual Meeting of the Society for Medicinal Plants and Natural Product Research (GA)'

  Outcome:

Rapporteurs to hold a preparatory meeting with the RWE liaison group to plan the next activities in line with the HMPC work plan 2025.
Next **discussion** scheduled at the **HMPC July 2025** meeting.

The HMPC Chair pointed out the RWE liaison group, as established in the Committee's work plan for 2025, and in this context the possibility of selecting additional herbal substances for DARWIN-EU studies. An 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 31st August to 3rd September 2026, was also highlighted. Moreover, the recently published 'Reflection paper on use of real-world data in non-interventional studies to generate real-world evidence for regulatory purposes' (EMA/99865/2025) was emphasised.
Some HMPC members summarised the potential interest of RWD/RWE in filling knowledge gaps on the use of herbal substances, specifically in certain target populations (e.g. paediatrics), but at the same time an internal debate is recommended on the acceptance criteria of RWD/RWE to support the assessments drawn up by the Committee, and this based on previous experience gained from the 2 pilot studies carried out in 2024 and possible additional studies to be initiated during the current year.

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

  Action: For information

  Outcome:

  Next **discussion** scheduled at the **HMPC July 2025** meeting**.**

  The Rapporteur informed the Committee on the next steps regarding the ongoing work on particulars for signal detection for THMPs (in collaboration with PRAC and EMA colleagues).

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

  Action: For information

  Outcome:

  Rapporteurs to update the draft revised ARSP template according to any comments to be received from PCWP/HCPWP members and EMA medical writers.
  Next **discussion** scheduled at the **HMPC July 2025** meeting**.**

  The Rapporteur pointed out that the PCWP/HCPWP members were informed during their meeting in April, about the activities developed by the HMPC related to the communication domain, including updating the ARSP template. As next steps, it was advised to consult the EMA medical writers for comments on the draft revised ARSP template, together with an example of 'proof of concept'.

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

  Report: HMPC Chair

  Action: For information

  Document tabled: 'Assessment report template chapters 1 and 2 and corresponding sections in the monograph template (including revisions)'

  Outcome:

A presentation/training session was given on 'Assessment report template chapters 1 and 2 and corresponding sections in the monograph template (including revisions)', which focused mainly on the practical rules/advice for rapporteurs when filling in the first two paragraphs of the AR.

5.8. Planning and reporting

5.8.1. EU-NTC LMS domain for International regulators

Report: HMPC Vice-Chair

Action: For discussion

Document tabled: Presentation

Outcome:

The HMPC endorsed by consensus the proposal that the audience for the so-called 'herbal curriculum' on the EU-NTC LMS should be limited to EU NCAs assessors.

The Rapporteur pointed out that the HMPC herbal curriculum (HC) steering group was of the opinion that the courses included in the HC were developed for herbal assessors in the NCAs, and in this regard, the preference is to limit them to audiences within the EU. Instead, the steering group proposes that HMPC starts a work plan topic in 2026 to develop new courses to academia (or part of the communication work plan topic) in collaboration with academia.
Some HMPC members emphasised the importance of consulting with academia to better understand in advance what their topics of interest would be related to herbal substances.

5.8.2. EU-NTC LMS 'welcome pack' for new committee members

Action: For information

Documents tabled: Enhancing the Onboarding Experience, HMPC-specific presentation

Outcome:

HMPC members were informed about the so-called 'welcome pack', which aims to improve the onboarding experience for new members/alternates of the scientific committees as they begin their journey at the EMA. The presentation on the HMPC specific topic, together with the 5 presentations on cross-committee topics, are available in the EU-NTC LMS as training materials.

5.8.3. HMPC scientific conference

Report: HMPC Chair

Action: For discussion

Document tabled: Draft programme

Outcome:

HMPC members were briefed on the preliminary programme of the scientific event specifically related to the Committee's work and, in this regard, were invited to contribute to refining the topics proposed for a next **discussion** scheduled at the **HMPC July 2025**

meeting.
The HMPC has agreed to September 2025 as the preferred date for this scientific event.

Some HMPC members pointed out that any examples of herbal substances to be presented should relate to the finalised assessments, and not only limited to positive outcomes, but also to the challenges experienced by the Committee. Moreover, the possible misuse of chemical substances (e.g. antidepressants) in comparison with herbal substances in nervous/psychiatric conditions may be relevant to be mentioned.

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 Plantaginis lanceolatae folium and supporting documents

Action: For 2nd discussion

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

Outcome:

Comments received during public consultation. Rapporteur to finalise the draft revised EU herbal monograph and supporting documents for **adoption** at the **HMPC July 2025** meeting.

The Rapporteur summarised the remaining issues for discussion, mainly related to the botanical material(s) to be considered in the name of the MO, i.e. leaf and/or herb. It was confirmed that the herb-related preparations included in the AR/MO comply with the current Ph. Eur. definition.
Some HMPC members pointed out that references to herb-related preparations should be cited in the AR, with an additional explanatory note on the botanical material(s) considered, and not change the name of 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 19th discussion

Documents tabled: Draft AR, MO, 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 July 2025** meeting.

The Rapporteur emphasised that the list of references has been updated, including a fine correspondence with the references mentioned in the AR.
Some HMPC members pointed out that the AR/MO should only reflect the previously agreed TU (WEU should not be considered). It was also highlighted that the related PSUSA should also be considered in the AR.

6.2.2. Monograph on Liquiritiae radix and supporting documents

Action: For 5th discussion

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

Timetable:
Documents to be sent to Peer-reviewer: **2 June 2025**
Peer-review documents to be sent to Rapporteur: **16 June 2025**
Final documents to be included latest in 2nd premail: **30 June 2025**

The Rapporteur pointed out 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.

6.2.3. Monograph on Matricariae aetheroleum and supporting documents

Action: For 1st 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.
Next **discussion** scheduled at the **HMPC July 2025** meeting.

The Rapporteur emphasised the remaining issue related to essential oleum constituents *versus* flowers constituents (it was questioned whether hypersensitivity reactions, including severe allergic reaction from flowers, should also be considered for the essential oleum).
Some HMPC members pointed out that, even in the absence of adverse events, references to potential safety concerns (e.g. hypersensitivity reactions) should be kept in the AR/MO.

6.2.4. Monograph on Species diureticae and supporting documents

Action: For 2nd discussion

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

Timetable:
Documents to be sent to Peer-reviewer: **2 June 2025**
Peer-review documents to be sent to Rapporteur: **16 June 2025**
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The Rapporteur summarised the remaining issues for discussion, mainly related to incomplete data in the AR tables (no indication given or posology/SD/DD incomplete, e.g. combination Levistici radix with Ononidis radix – agreed to be deleted). Regarding the new MO on Herniariae herba, it was proposed 6-26% as the range in a combination (agreed). For the ongoing assessment on Maydis stigmata, it was suggested to be removed to avoid misunderstanding (agreed). As per in the initial MO, it was proposed to keep the approach that 'Herbal substances mentioned in brackets are considered as excipient (no plausible contribution to the traditional indication)', as dosages in the teas are far below the recommendations in the single MOs and do not raise any concern (agreed).
Some HMPC members emphasised that for combination MOs it may be relevant to consider them for revision at periods shorter than 5 years, as individual MOs may have been revised in the meantime.

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

6.3.1. Monograph on Calendulae flos and supporting documents

Action: For 2nd discussion

Document tabled: Review report

Outcome:

HMPC endorsed the Rapporteur's position that there is no new information available that could change the content of the EU herbal monograph.
Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC July 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **2 June 2025**
Peer-review documents to be sent to Rapporteur: **16 June 2025**
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The Rapporteur emphasised that new references were identified but not changing the content of the current MO. Moreover, from the EudraVigilance search reports were found on erythema, pruritus, papule and burning sensation, but these adverse reactions are

considered covered by the skin sensitization already listed in the MO section 4.8 Undesirable effects.

6.3.2. Monograph on Cimicifugae rhizoma and supporting documents

Action: For 2nd discussion

Document tabled: Review report, Reader's Guidance

Outcome:

HMPC endorsed the Rapporteur's position that there is no new information available that could change the content of the EU herbal monograph.
Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC July 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **2 June 2025**
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The Rapporteur highlighted that a meta-analysis by Castelo-Branco et al. (2021) and a full reference to the new herbal medicinal product reported in AT have been included, but neither changed the content of the current MO.

6.3.3. Monograph on Curcumae longae rhizome and supporting documents

Action: For 3rd discussion

Documents tabled: Review report

Outcome:

Rapporteur to modify the review report according to the discussion and possible additional comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC July 2025** meeting.

The Rapporteur summarised that, so far, no liver toxicity and no drug interaction have been reported with posologies listed in the current MO. Moreover, none of the reported cases retrieved from the EudraVigilance database triggers a MO revision because there was concomitant use of other drugs/supplements and/or details of the preparations used were missing (e.g. dose/ type of extract are not included in the case reports.)
Some HMPC members emphasised the difficulties in establishing a DD limit for curcumin content, beyond which the intake of curcumin-containing products could trigger drug-interactions/hepatotoxicity, and this should be clearly reflected in the AR/MO. Moreover, it was suggested that this review report should be shared with EDQM and EFSA.

6.3.4. Monograph on Echinaceae angustifoliae radix 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 July 2025** meeting.

The Rapporteur emphasised that reported liver-related adverse reactions (e.g. hyperbilirubinaemia, hepatitis, hepatic enzyme increased) were subjected to further investigation, concluding that, so far, it is not possible to associate a causality link between the echinaceae intake and hepatoxicity.
Some HMPC members suggested updating the review report to include relevant information from the first addendum to the AR.

6.3.5. Monograph on Echinaceae pallidae radix and supporting documents

Action: For 3rd discussion

Document tabled: Review report

Outcome:

Rapporteur to modify the review report according to the discussion and possible additional comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC July 2025** meeting.

The Rapporteur highlighted that for the Echinaceae pallidae radix extract (DER 1:3.5-6.5), extraction solvent: ethanol 96% (V/V)/liquor vine (1:1.15), the concentration of ethanol (45-50 %) is similar to the ethanol concentration in the herbal preparation b) (50 %). Moreover, liquor wine is not a Ph. Eur. substance and in most of the EU member states it is not used as an extraction solvent in herbal preparations.
Some HMPC members suggested a single review report for both echinaceaes (angustifoliae and pallidae).

See also 6.3.4.

6.3.6. Monograph on Plantaginis ovatae semen 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 July 2025** meeting.

The Rapporteur summarised an overview with the new clinical studies published related to the MO indications, highlighted their strengths and weaknesses. Differences on the WEU posology versus TU posology were also emphasised (3x higher for TU). Moreover, and based on new Pharmacovigilance data, it was suggested to amend the MO section 4.8. with more complete information on adverse events/clinical safety data (adding symptoms of oesophageal obstruction and mentioning cases with diarrhoea in patients with constipation).
Some HMPC members highlighted that posology differences may have already been addressed in previous assessments.

6.3.7. Monograph on Plantaginis ovatae seminis tegumentum 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 July 2025** meeting.

See also 6.3.6.

6.3.8. Monograph on Rusci rhizoma 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 July 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **2 June 2025**
Peer-review documents to be sent to Rapporteur: **16 June 2025**
Final documents to be included latest in 2nd premail: **30 June 2025**

The Rapporteur highlighted that no new products with butcher's broom as the sole herbal substance have been registered/authorised since the last revision in 2018. Moreover, reported cases of possible interactions and adverse reactions involving this herbal substance have not triggered a change in the current MO.
Some HMPC members made suggestions (mainly editorial) to ensure that the information in the review report is easily understandable and actionable.

6.3.9. Monograph on Thymi herba and supporting documents

Action: For 6th discussion

Document tabled: Review report

Outcome:

Rapporteur to modify the review report according to the discussion and possible additional comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC July 2025** meeting.

The Rapporteur summarised that during the review period, two EU member states have included information on possible adverse reactions in the labelling of combination products containing thyme preparations, but to date, there is no data on similar adverse reactions with mono-component products only containing thyme.
Some HMPC members suggested the potential effect related to excipients as constituents of

thyme-containing products, and in this regard, members were invited to identify their national mono-component products only containing thyme.

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

6.4.1. Monograph on Species pectorales and supporting documents

Action: For 1st discussion

Documents tabled: Draft AR, LoR, MO

Outcome:

Rapporteur to finalise the draft EU herbal monograph and supporting documents for peer review and **adoption** at the **HMPC July 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **2 June 2025**
Peer-review documents to be sent to Rapporteur: **16 June 2025**
Final documents to be included latest in 2nd premail: **30 June 2025**

The Rapporteur highlighted that no comments were received during public consultation, and therefore, no changes have been made to the draft AR/MO.

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

6.5.1. Monograph on Cannabis flos and supporting documents

Action: For 7th discussion

Document tabled: Draft PS

Outcome:

Rapporteurs to finalise the draft public statement for **adoption** for public consultation at the **HMPC July 2025** meeting.

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 therefore, it is proposed to discontinue the assessment procedure.

7. Any other business

7.1. Topics for discussion

7.1.1. New HMPC guideline on the requirements to study the interaction potential of herbal medicinal products

Rapporteur: HMPC Vice-Chair

Action: For discussion

Documents tabled: ICH M12 Guideline on drug interaction studies; EU guideline on the investigation of drug interactions

Outcome:

The HMPC endorsed by consensus the proposal to draw up a regulatory document on the requirements for studying the interaction potential of herbal medicinal products.

The Rapporteur summarised that a new ICH guideline on drug interactions has recently come into force (ICH M12), and in this regard, it is proposed the HMPC to take the responsibility for publishing a regulatory document regarding the requirements to study the interaction potential of herbal medicinal products, and this in close collaboration with the EMA temporary drafting group for the implementation of ICH M12.

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 17-19 March 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

- EFSA Evaluation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 of a powder obtained from cranberries, and defence against bacterial pathogens in the lower urinary tract

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/ experts following evaluation of declared interests for the 05-07 May 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 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	
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	
Karoline Holm Felding	Alternate*	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	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Jacqueline Wiesner	Member	Germany	No interests declared	
Susanne Flemisch	Alternate	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	
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	
Burt H Kroes	Member	Netherlands	No interests declared	
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	
Ana Paula Martins	Member	Portugal	No interests declared	
Carmen Purdel	Member	Romania	No interests declared	
Dorota Distlerova	Member	Slovakia	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	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
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 Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared	
Maria da Graca Ribeiro Campos	Co-opted member	Portugal	No interests declared	
Leif Sonny Larsson	Expert	Sweden	No interests declared	
Peter Sisovsky	Expert*	Slovakia	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.