07 May 2025
EMA/HMPC/125295/2025
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 17-19 March 2025

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

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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

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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 that no restriction in the involvement of meeting participants for agenda topics was identified (see list of participants).

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.

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 (alternate).

1.2. Adoption of agenda

HMPC agenda for 17-19 March 2025.

Outcome:

Agenda and time schedule adopted.

1.3. Adoption of the minutes

HMPC minutes for 20-22 January 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 March 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 May 2025 meeting according to the overview, Rapporteurs were asked to inform the Committee secretariat and Chair before the first pre-mail (by 21 April 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.
Some HMPC members suggested that priority should be given to review monographs in view of the existence of herbal medicinal products on the EU market.

2.1.3. New assessment 2025 - Valeriana + Passiflora

Action: For adoption

Document tabled: Validated proposal for assessment, Updated table with market overview

Outcome:

The HMPC endorsed by consensus to start a new assessment for the EU herbal combination of Valeriana with Passiflora and a call for data will be launched.

The Rapporteur highlighted that there are products on the EU market for the combination of Valeriana with Passiflora fulfilling the 30/15 years criteria.

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

None

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

2.3.1. Monograph on Allii sativi bulbus 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 release for public consultation.

The Rapporteur summarised that several clinical studies with garlic bulb had been identified for the treatment of metabolic syndrome, cardiovascular disease risk factors or atherosclerotic process, but it was considered that they did not fulfil the current requirements for a WEU to be granted.

2.3.2. Monograph on Arnicae flos and supporting documents

Action: For adoption

Documents tabled: Draft MO, AR, LoR

Outcome:

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

The Rapporteur emphasised that only the tincture's preparation with arnica is defined in the Ph. Eur..

2.3.3. Monograph on Crataegi folium cum flore and supporting documents

Action: For adoption

Documents tabled: Draft MO, AR, LoR

Outcome:

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

2.3.4. Monograph on Fragariae folium and supporting documents

Action: For adoption

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

Outcome:

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

Timetable:
Documents to be sent to Peer-reviewer: **7 April 2025**
Peer-review documents to be sent to Rapporteur: **16 April 2025**
Final documents to be included latest in 2nd premail: **28 April 2025**

The Rapporteur summarised the changes introduced in the AR: 1) the herbal tea (infusion), was included under the chapter 1.1 herbal preparations, (agreed); 2) argumentation regarding use in children above 12 years of age was included in chapter 5.4.1 (the strength in children is exactly the same as in adults but the quantity of infusion is smaller (100 ml) which corresponds to the single dose (1.5-3.0 g of herbal substance) (agreed).
Some HMPC members pointed out that posologies for both indications are the same (i.e. 5 g of comminuted herbal substance in 250 ml of water). Also, for both indications, the age limit for children/adolescents should be stated as above 12 years old. As there are no products on the EU market, it was emphasised that it is not possible to conclude on the safety profile based on the absence of reports from Eudravigilance.

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

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

The Rapporteur pointed out that data from EudraVigilance/VigiBase do not trigger a revision since they were related to combination products or concomitant medications; no new HMPs with gentiana lutea root extracts as the sole active substance have been registered/authorised on the EU market since the last revision in 2017. Moreover, other in vitro studies had been identified studying the cytotoxic and genotoxic effect of gentiana lutea extract, but these studies were not considered relevant as they do not change the conclusion about the herbal substance safety.

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

The Rapporteur highlighted two studies on young adults using hop strobile preparations that had been published over the review period, but both were considered as out of the scope for the revision of the clinical safety data.
Some HMPC members proposed that the study's information on young adults not yet finished to be considered as 'new information not considered to trigger a revision at present but that could be relevant for the next review'.

2.4.3. Monograph on Meliloti herba and supporting documents

Action: For adoption

Document tabled: Review report

Outcome:

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

The Rapporteur summarised that no new herbal substances/preparations with 30/15 years of TU or 10 years of WEU were identified by the EU member states in the review period. Moreover, reports from EudraVigilance/VigiBase have not changed the safety profile of the single melilot preparations.

2.4.4. Monograph on Uvae ursi 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 Uvae ursi 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 highlighted that results from two new clinical studies in uncomplicated UTIs in woman have been published but were considered not to influence the current MO, which is based on TU.

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

2.5.1. Monograph on Cisti cretici herba and supporting documents

Action: For adoption

Documents tabled: Draft MO, AR, LoR, OoC

Outcome:

Final EU herbal monograph and supporting documents adopted by majority (24 out of 25). Divergent opinion: Germany. The Norwegian delegate expressed a favourable position.

The Rapporteur emphasised that a full set of genotoxicity studies have been identified but are not considered in the AR as they were not performed with the preparation described in the MO. Moreover, it was considered not to merge the decoction's preparation with a dry extract's preparation as proposed during the public consultation.

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 May 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **7 April 2025**
Peer-review documents to be sent to Rapporteur: **16 April 2025**
Final documents to be included latest in 2nd premail: **28 April 2025**

The Rapporteur highlighted that it was proposed to extend the posology from 2-4 g to 2-8 g and daily doses from 4-12 g to 4-24 g, after considering the inclusion of a TU preparation from the British Herbal Pharmacopoeia.
Some HMPC members pointed out that warnings under the MO section 4.4 would need further discussion give some of them are related to serious medical conditions not easily perceived by patients/consumers (e.g., swelling due to heart or kidney insufficiency).
Moreover, it was suggested to double-check duration of use stated in the MO sections 4.2. *vs* 4.4.

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 according to the discussion and possible additional comments from HMPC members.
Next **discussion** scheduled at the **HMPC May 2025** meeting.

The Rapporteur summarised that interpretation of mutagenicity, after a positive Ames test, needs confirmation in mammalian cell-based systems, and in this regard, the guideline on genotoxicity testing should in principle contain several accepted mammalian cell based assays. As for the next steps, changes need to be made to the draft revised guideline on the basis of comments received from member states.

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 discussion

Document tabled: OoC, Draft revised guideline

Outcome:

Rapporteurs to modify the draft revised guideline according to the discussion and possible additional comments from QDG for **possible adoption** at the **HMPC May 2025** meeting.

The Rapporteur pointed out that the OoCs and the draft revised GACP guideline were reviewed by the QDG, and in this regard, it had been proposed not to mix the terms 'medicinal plant' and 'herbal substance' (definition of 'medicinal plant' was added and used throughout the guideline instead of 'herbal substance'). The term 'plant production' was also added to be in the definitions.

4.3. Regulatory / Procedural

None

4.4. Report on HMPC Drafting Groups activities

4.4.1. ORGAM DG

None

4.4.2. Quality DG

- QDG February meeting

  Report: Carmen Purdel

  Action: For information

  Document tabled: Minutes February 2025

  Outcome:

  HMPC members noted the QDG activities accordingly to the February meeting, in particular: 1) Revision on the declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/CHMP/CVMP/287539/2005). Where the same herbal starting material undergoes two consecutive extractions by

different solvents, and then the fractions are combined, it was agreed that both extraction solvents should be considered for the declaration. Also, QDG investigated the possibility of replacing the term 'tincture' with the general term "liquid extracts". Although liquid extracts also cover tinctures, QDG has also considered that for 'tincture' there is a specific monograph in Ph. Eur., different from the liquid extracts. 2) Revision of the Guideline on Good Agricultural and Collection Practice (GACP) of starting materials of herbal origin (EMEA/HMPC/246816/2005). It was agreed that the term 'plant production' should be defined and also not to mix the terms 'medicinal plant' and 'herbal substance' (definition of 'medicinal plant' was added for more clarity). GACP topic will be on agenda for the next QDG meeting in April.
Regarding the possibility of replacing the term 'tincture' with the general term 'liquid extracts', some HMPC members emphasised that both terms should be kept separate, as they are now in the Ph. Eur.. As an additional remark, the EDQM representative pointed out that both terms are often co-existing in the same monograph but with different meanings.

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Strategic Review and Learning Meetings (SRLM)

- HMPC SRLM Follow up plan - status March 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.

- Polish Presidency meeting 13-14 May

  Report: Wojciech Dymowski

  Action: For information

  Document tabled: Draft agenda

  Outcome:

  HMPC members were informed on the first draft agenda for the next HMPC-SRLM to be organised by the Polish Presidency of the Council of the European Union, 13-14 May 2025: 1) regulatory issues; 2) safety issues; 3) University activity & research; 4) strategic discussions on future activities. Moreover, HMPC members were informed that official invitations will be sent during the next days/week.

5.1.2. HMPC membership

Report: HMPC Chair

Action: For information

New membership:

- Spain, Margarita Berrocal Navas (Alternate) as of 24 January 2025
- Belgium, Daniela Ruseva (Alternate) as of 14 February 2025

Re-nominated members:

- Hungary, Rita Nemeth (Alternate) as of 05 April 2025

5.1.3. HMPC Co-opted members

- Calls for a Co-opted member:

  Report: HMPC Chair

  Action: For information

  Document tabled: Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC; Call for Co-opted members to HMPC_2025-Mar

  Outcome:

  Call for nomination of candidates with expertise in non-clinical toxicology to be launched and HMPC members to send eventual candidatures till 5 May 2025 for **possible appointment of a co-opted member** at the **HMPC May 2025** meeting.

  HMPC members were informed that a fifth co-opted member has not yet been appointed for some time and that the mandate of the expert in non-clinical toxicology is about to expire (07 July 2025), and in this regard, a call for nomination of candidates will be started.

5.1.4. Committee meeting dates 2027-2028

- Proposed committee meeting dates for the period of 2027-2028

  Action: For information

  Document tabled: Draft - Committee meeting dates - 2027-2028

  Outcome:

  HMPC members noted the proposed dates for the Committee's meetings scheduled for 2027-2028, which will be published on the EMA/HMPC website.

5.1.5. Implementation of revised policy 0044 on handling of competing interests

Action: For information

Outcome:

HMPC members were informed on the implementation of revised Policy 0044 on handling of competing interests, which will be effective from 1 May 2025. In this regard, all members and experts were requested to submit a Declaration of Interests (DoI) in the new format via the Experts Management Tool (EMT) by 1 May 2025. If no DoI is received by 1 May 2025, the member/expert cannot be involved in an EMA activity/meeting falling under Policy 0044 after 1 May 2025 until a new DoI is submitted.

5.2. EMA Scientific Committees or CMDh-v

None

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

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

- Mandates and Rules of Procedure for PCWP and HCPWP

  Action: For adoption

  Documents tabled: EMA HCPWP Mandate and composition update proposal Feb 2025, EMA PCWP and HCPWP Rules of procedure update proposal Feb 2025, EMA PCWP Mandate and composition_update proposal Feb 2025, Proposal for PCWP and HCPWP membership enlargement

  Outcome:

  The HMPC endorsed by consensus the proposals to update the mandate, objectives, composition, and rules of procedure of the PCWP and HCPWP.

  HMPC members noted the proposal to enlarge PCWP/HCPWP to 25 member organisations, to reflect increase in number of eligible organisations over the years, aligns with recent restructuring of EMA WPs and to accommodate constant number of membership applications from PCOs and reduces gap for HCPOs applications. This enlargement considers the new role and responsibility of PCWP/HCPWP (e.g. to allow PCWP/HCPWP oversight of discussion fora such as the Cancer Medicines Forum) and therefore requires changes in the mandate, objectives, composition, and rules of procedure of 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:

  HMPC members were informed on the summary of decisions from the 13A expert group meeting in February 2025 (next meeting in May 2025), 13B expert group meeting in January 2025 (next meeting in May 2025), and TCM expert group meeting in February 2025 (next meeting in May 2025).

5.4.2. European Food Safety Authority (EFSA)

Action: For information

Document tabled: 19th WG Draft Agenda 2025-03-03, Draft opinion fennel Art 8(2)

Outcome:

HMPC members noted the draft EFSA's opinion on fennel Art 8(2) of Reg 1925/2006 and were invited to provide comments till the endorsement of the opinion for public consultation.

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

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

  Action: For information

  Outcome:

  Next **discussion** scheduled at the **HMPC May 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).

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

  Action: For discussion

  Document tabled: draft RP on data recommendations for THMPs used in children and adolescents

  Outcome:

  Rapporteur to finalise the reflection paper according to the discussion for **possible adoption** for public consultation at the **HMPC May 2025** meeting.

  The Rapporteur emphasised that, after receiving comments from the PDCO, the draft document had been updated. In particular, it was pointed out the published clinical trials of sufficient quality in the relevant age groups as the only proof substantiating the indication of an HMP in children/adolescents and that requirements for WEU (e.g. scientific literature

establishing that the active substances of the medicinal products has been in well-established medicinal use within the EU for at least ten years, with recognised efficacy and an acceptable level of safety) are fulfilled in the respective age group.

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

  Action: For discussion

  Documents tabled: Draft revised ARSP template, Herbal summaries, Presentation

  Outcome:

  HMPC members agreed to consult the PCWP/HCPWP (next meeting in April) the draft revised ARSP template together with an example of 'proof of concept'.
  Next **discussion** scheduled at the **HMPC May 2025** meeting, after receiving feedback from PCWP/HCPWP.

  A presentation was given highlighting the possible alternative options to be considered in the revision of the ARSP template, giving comments received from HMPC members with the aim of providing the public in general with easily understandable and actionable information. Moreover, 'proofs of concept' using MOs on specific herbal substances were also made available.

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

  Report: HMPC Chair

  Action: For information

  Outcome:

  HMPC members noted that a presentation/training on 'Assessment report template chapters 1 and 2 and corresponding sections in the monograph template (including revisions)' is planned to be given at the **HMPC May 2025** meeting.

5.8. Planning and reporting

5.8.1. EU NTC LMS domain for International regulators

Report: HMPC Vice-Chair

Action: For information

Document tabled: Request to include training on contaminants/residues in HMPs (email)

Outcome:

Next **discussion** on possible suitable formats for dissemination of the herbal training courses scheduled at the **HMPC May 2025** meeting.

HMPC members were informed on the possible alternative tools for communicating the training courses (herbal curriculum) already available on the EU-NTC LMS to wider audiences (e.g., via the YouTube channel).
Some HMPC members expressed pros & cons of a wider distribution of scientific and regulatory work (including training courses) produced by the Committee.

5.8.2. HMPC scientific conference

Report: HMPC Chair/Vice-Chair

Action: For information

Outcome:

HMPC members were briefed that there is the possibility of organising a scientific conference specifically related to the work of the Committee, and, in this regard, they were invited to suggest topics of interest for a next **discussion** at the **HMPC May 2025** meeting.

5.9. Legislation and regulatory affairs

None

5.10. Questions from members

None

6. EU herbal monographs and list entries in preparation

6.1. Revision of EU herbal monographs and list entries in preparation for adoption after public consultation

6.1.1. Monograph on Zingiberis rhizoma and supporting documents

Action: For 3rd discussion

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

Outcome:

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

Timetable:
Documents to be sent to Peer-reviewer: **7 April 2025**
Peer-review documents to be sent to Rapporteur: **16 April 2025**
Final documents to be included latest in 2nd premail: **28 April 2025**

The rapporteur pointed out the issues still for discussion: 1) MO section 5.3 to be revised adding information from the chronic toxicity studies, e.g. target organs (needs further discussion, since it is not certain that it will be possible to obtain this information); 2) statement in the AR chapter 4.2.2 'Studies comparing ginger to vitamin B6 or dimenhydrinate is considered questionable due to the uncertain efficacy of vitamin B6 and dimenhydrinate and have been excluded' (needs further discussion, since active comparators were used (i.e. not placebo-controlled studies)); 3) Committee views on 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) in the treatment of nausea and vomiting in pregnancy (needs further discussion).

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 18th 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 May 2025** meeting.

The Rapporteur summarised the remaining issues: 1) AR table 2.1.1. lists two herbal substance preparations (flos) for tea in PL national registration but not mentioned in MO (both preparations should be kept out of MO as it focusses on Lavender oil preparations only - agreed); 2) AR table 2.1.1. contains a product from BG with a preparation of lavender oil in ethanol/water for external use in skin and a preparation of essential Lavender oil in ethanol for external use on is also registered in PL (both preparations should be kept out of MO as not fulfilling the 30/15years criteria – agreed); 3) AR table 2.1.1. lists a preparation of Lavender oil in combination with other plant oils (clove, peppermint, thyme and rosemary) in TU in FR is also kept out of MO; it is a liquid dosage form for inhalation with the target region epithelium of the nose (and likely also upper respiratory tract); the reasons to keep it out of MO are that posology of Lavender oil is unclear and it is a combination product (agreed).

6.2.2. Monograph on Liquiritiae radix and supporting documents

Action: For 4th 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 members.
Next **discussion** scheduled at the **HMPC May 2025** meeting.

The Rapporteur emphasised the remaining issues still open for discussion: 1) proposal to include the maximum daily dose of 160 mg for the preparation b), i.e. the soft extract (DER 1:0.4-0.5), under section 4.9 rather than in section 4.2, since it is much higher than the recommended daily dose (64 – 96 mg, corresponding to the single dose of 32 mg taken 2-3 times daily) - according to the market overview, the maximum daily dose of 160 mg derives from a HMP authorised in DE from 1976 to 2012 (agreed; 2) sections 4.4 and 4.5 have been reworded to extend the warning on potential interaction to all drugs metabolised by CYP 3A4 instead of limiting it only to midazolam and omeprazole (needs further discussion). Some HMPC members pointed out concerns about herbal-drug interactions impacting CYP enzymes, debating whether to list specific drug substances or just the impact on CYP enzymes, as an exhaustive listing can be misleading (to be further clarified in the MO sections 4.4. and 4.5.).

6.2.3. Monograph on Ononidis radix and supporting documents

Action: For 8th 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 May 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **7 April 2025**
Peer-review documents to be sent to Rapporteur: **16 April 2025**
Final documents to be included latest in 2nd premail: **28 April 2025**

The Rapporteur highlighted that the indication was aligned with the information included in the other so-called 'diuretic herbal monographs'.
Some HMPC members proposed not to declare the total number of products under the AR table 1. overview. Moreover, it was pointed out that the age range should be amended (i.e., '> 12 years' instead of '< 12 years')

6.2.4. Monograph on Species diureticae and supporting documents

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

The Rapporteur highlighted the main changes introduced with this revision: 1) new monograph on Herniariae herba (Herniariae herba has been added to the AR and all related tables have been updated); 2) new indication - the indication has been aligned with the information included in the other so-called 'diuretic herbal monographs' and considering the recommendations on fluid intake; 3) calculation or rounding errors (which do not have any outcomes on the conclusion).
Some HMPC members emphasised that the table in the AR with information from individual published EU herbal monographs may be quicky outdated. Moreover, it was pointed the missing information in the MO section 4.4. that this herbal substance is not recommended for patients with conditions where reduced fluid intake is advised.

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

6.3.1. Monograph on Cimicifugae rhizoma and supporting documents

Action: For 2nd discussion

Document tabled: Review report, Reader's Guidance

Outcome:

Postponed.

6.3.2. Monograph on Curcumae longae rhizome and supporting documents

Action: For 2nd discussion

Documents tabled: Presentation, Review report

Outcome:

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

The Rapporteur summarised the pharmacovigilance details that were collected on the reported interactions and side effects (relevance for the monograph), and the literature search conducted for the reported side effects and for possible drug interactions.
Some HMPC members pointed out that it may be difficult to establish a (over)dose that could trigger a liver injury (hepatotoxicity) and therefore to have a related statement in the MO section 4.9. Moreover, it has suggested to share this assessment report with EFSA.

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

6.3.4. Monograph on Echinaceae pallidae radix and supporting documents

Action: For 2nd discussion

Document tabled: Review report

Outcome:

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

The Rapporteur highlighted that an expert group has settled to support assessing reported liver reactions associated with echinaceae spp, and the final conclusion will be included in the review report. Moreover, it was pointed out one possible new preparation to be considered, an extract from Echinaceae pallidae radix (1:3.5-6.5), extraction solvent: ethanol 96% (V/V)/liquor vine (1:1.15) - the ethanol concentration in the herbal preparation is 45-50% (V/V) - which might be already covered by the current herbal preparation b) in the MO.
Some HMPC members emphasised the pros & cons of considering herbal preparations that contain liquor wine (needs further discussion), and in this regard, the review report to be updated accordingly.

6.3.5. Monograph on Melissae folium and supporting documents

Action: For 3rd discussion

Document tabled: Review report

Outcome:

HMPC endorsed the Rapporteur's position that there is relevant new information available that could change the content of the EU herbal monograph and therefore a revision of the complete package is advocated.
Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC May 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **7 April 2025**
Peer-review documents to be sent to Rapporteur: **16 April 2025**
Final documents to be included latest in 2nd premail: **28 April 2025**

The Rapporteur pointed out that there are new products on the EU market (e.g, 'soft extract (2.3-3:1) aqueous' - fulfilling the 30/15 years criteria of TU). In addition, no new safety issues have been identified.

6.3.6. Monograph on Ribis nigri folium and supporting documents

Action: For 2nd discussion

Document tabled: Review report, Reader's guidance

Outcome:

HMPC endorsed the Rapporteur's position that harmonisation with other MOs in the same therapeutic area could change the content of the EU herbal monograph and therefore a revision of the complete package is advocated.
Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC May 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **7 April 2025**
Peer-review documents to be sent to Rapporteur: **16 April 2025**
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The Rapporteur summarised that in order to achieve consistency with the information included in the other so-called 'diuretic herbal monographs', a revision is advisable. Furthermore, changes to the MO sections 4.3 and 4.4 according to the harmonised approach, will be also implemented.

6.3.7. Monograph on Thymi herba and supporting documents

Action: For 5th discussion

Document tabled: Review report

Outcome:

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

The Rapporteur highlighted that a new herbal preparation 'liquid extract (DER 1:1), extraction solvent: ethanol 22% V/V' (BE) has been identified, but it is not fulfilling the 30/15 years criteria.

Some HMPC members pointed out that the new herbal preparation identified on the BE market is very close to preparation a) in current MO ('liquid extract (DER 1:1), extraction solvent ethanol 24% (V/V)'). It was also suggested to strength the ethanol range to 24% (eventually during the next revision). Moreover, additional information will be provided by some HMPC members to be considered in the review report.

6.3.8. Monograph on Vitis viniferae folium and supporting documents

Action: For 4th discussion

Documents 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 May 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **7 April 2025**
Peer-review documents to be sent to Rapporteur: **16 April 2025**
Final documents to be included latest in 2nd premail: **28 April 2025**

The Rapporteur pointed out considerations whether to include or not the preparation of Vitis vinifera 'dry extract (DER 4-6:1) extraction solvent water, in TU with the different indication 'symptomatic relief of itching and burning associated with haemorrhoids, after serious conditions have been excluded by medical doctor' (agreed to be addressed in the review report but not included in the MO).

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

None

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 6th discussion

Documents tabled: Draft PS, Reader's Guidance, Call for data with Annex

Outcome:

Rapporteur to update the draft public statement, according to the discussion and possible additional comments from HMPC member and the EMA Regulatory Affairs/Legal offices.
Next **discussion** scheduled at the **HMPC May 2025** meeting.

The Rapporteur summarised that no conclusions could be drawn due to the absence of medicinal products with single herbal preparations from *Cannabis sativa* L., flos on the EU market. Therefore, requirements for the establishment of an EU herbal monograph on TU/WEU herbal medicinal products containing *Cannabis sativa* L., flos were not fulfilled. Some HMPC members pointed out that there are cannabis-derived medicinal products used in the EU countries, but they are not sufficiently declared.

7. Any other business

7.1. Topics for discussion

None

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 20-22 January 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

- Meeting Summary PCWP-HCPWP 20 Nov 2024
- DRAFT Agenda - PCWP-HCPWP meeting - 1-2 April 2025_1

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/ experts following evaluation of declared interests for the 17-19 March 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 interests declared	
Ivan Kosalec	Member	Croatia	No interests declared	
Christina Sylvia Chrysostomou	Member	Cyprus	No interests declared	
Markéta Příhodová	Member	Czechia	No restrictions applicable to this meeting	
Kristýna Veselá	Alternate	Czechia	No 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	
Jacqueline Wiesner	Member	Germany	No interests declared	
Susanne Flemisch	Alternate	Germany	No interests declared	
Ioanna Chinou	Member	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	

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