20 November 2024
EMA/HMPC/478382/2024
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 23-25 September 2024

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 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 thanked the member (alternate) who was leaving the Committee for all her valuable work and contributions to the HMPC.

1.2. Adoption of agenda

HMPC agenda for 23-25 September 2024.

Outcome:

Agenda and time schedule adopted.

1.3. Adoption of the minutes

HMPC minutes for 22-24 July 2024.

Outcome:

Minutes adopted.

2. EU herbal monographs and list entries for adoption

2.1. Status of HMPC activities

2.1.1. Overview of HMPC assessment work including the Rapporteurship distribution – Status in September 2024

Report: HMPC Chair

Action: For discussion

Document tabled: Overview

Outcome:

The HMPC members noted the status of assessment work.
In case of postponement of topics scheduled for the HMPC November 2024 meeting according to the overview, Rapporteurs were asked to inform the Committee secretariat and Chair before the first pre-mail (by 04 November 2024) to allow best adaptation of agenda and time schedule.

2.1.2. Appointment of Rapporteurs and Peer-reviewers

- Periodic reviews to start in 2024-2025

Report: HMPC Chair

Action: For information

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

Outcome:

Rapporteurs and/or Peer-reviewers were appointed.

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

None

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

2.4.1. Monograph on Boldi folium and supporting documents

Action: For adoption

Document tabled: Review report, References 0/0

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 Boldi 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 there are no new products on the EU market and also no new scientific clinical or safety data justifying a revision of the monograph. However, it was noted that spontaneous case reports have been published regarding hepatotoxicity or liver injury and the use of boldo preparations which seems to be relevant to assess the possibility of new case reports in the future.

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 Hyperici herba/Cimicifugae rhizoma and supporting documents

Action: For adoption

Documents tabled: 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 November 2024** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **16 October 2024**
Peer-review documents to be sent to Rapporteur: **28 October 2024**
Final documents to be included latest in 1st premail: **04 November 2024**

The Rapporteur emphasised that adverse reactions and interactions are based on the SmPCs of the combination products on the market, but also on the mono components' MOs. In this regard, the AR was updated with a rationale justifying which adverse events should be considered in the safety profile of this fixed combination.
Some HMPC members pointed out that adverse reactions listed in the monograph could be supported with data from clinical trials and also from the EudraVigilance database. Moreover, a summary of the adverse events reported in the SmPCs of the combination products should also be considered in the AR section 5.3.

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

Documents tabled: Draft revised guideline, Presentation

Outcome:

Rapporteur to modify the draft revised guideline according to the discussion and possible additional comments from HMPC members.
Next **discussion** scheduled at the **HMPC November 2024** meeting.

The Rapporteur summarised the changes introduced in the draft revised guideline, with particular emphasis on the step-by-step testing strategy (also presented in the form of a decision tree). Moreover, the progress made in recent years in genotoxicity tests was emphasised, putting them at the forefront as predictable tests (Ames test is the starting point), avoiding waiting for the evidence provided by the carcinogenic tests.

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

Documents tabled: OoC, Draft revised GACP guideline

Outcome:

Rapporteurs to complete the OoC on the basis of comments received from IPs and eventually begin to update the draft revised GACP guideline accordingly.
Next **discussion** scheduled at the **HMPC November 2024/January 2025** meeting.

The HMPC noted the extensive list of comments received from IPs during the public consultation. As a general comment, the request for information on the indoor cultivation to be included as a specific chapter or annex was emphasised. The documents will also be discussed with QDG before new discussion at the HMPC November 2024/January 2025 meeting.

4.3. Regulatory / Procedural

4.3.1. Procedure for the preparation of Monographs/List Entries (EMA/HMPC/887331/2022)

Action: For adoption

Documents tabled: Draft Procedure for the preparation of MO and LE, Reader's Guidance

Outcome:

'Procedure for the preparation of European Union herbal monographs and European Union list entries and appointment of HMPC rapporteurs and peer-reviewers' (EMA/HMPC/887331/2022) adopted by consensus.

The Rapporteur pointed out that no comments were received during the public consultation and therefore no changes have been introduced.

4.3.2. Template for Assessment report for the development of EU herbal monographs and EU list entries (EMA/HMPC/418902/2005)

Action: For discussion

Document tabled: Draft revised AR template

Outcome:

Rapporteur to modify the drafted revised AR template according to the discussion and possible additional comments from HMPC members for possible **adoption** at the **HMPC November 2024** meeting.

The Rapporteur summarised that although no comments were received during the public consultation, the working group has proposals for discussion: in section 1.2, to delete the search performed in a previous assessment (agreed), as in the Review Report template to have information on data received from IPs during the calls for data (not agreed); in section 1.3 to briefly summarise the main changes under this section (agreed); in section 2.3, to merge information from other tables in the AR to avoid a very long table here (agreed); in sections 3.1.5 and 3.4, to include examples of optional standard sentences derived from a previous assessment report (agreed, but the 'yellow part' to be deleted); in section 5.5.8, to include a sentence about the lack of pharmacokinetic data making it impossible to do a dose recommendation in specific patient groups (agreed). Moreover, it was emphasised that it is not intended to change the headings of the main topics included in the AR.

4.3.3. Template for a European Union herbal monograph (EMEA/HMPC/107436/2005)

Action: For discussion

Document tabled: Draft revised MO template

Outcome:

Rapporteur to modify the drafted revised MO template according to the discussion and possible additional comments from HMPC members for possible **adoption** at the **HMPC November 2024** meeting.

The Rapporteur highlighted that no comments were received during the public consultation, but the working group has proposals for discussion: in section 4.2, to add some more comprehensible information to the rapporteur (agreed); in section 4.4., to add the standard sentence '<No known precautions for use.>' if there are no warnings or precautions for use (agreed).

4.3.4. Declaration of ethanol used as extraction solvent - Addendum to the QRD templates for SmPC, Labelling and Patient Leaflet on MRP/DCP specific for (T)HMPs (EMA/HMPC/770889/2014; CMDh/349/2016, Rev.1)

Action: For discussion

Document tabled: Email, Addendum to QRD templates

Outcome:

HMPC did not agree to propose changes in the addendum to the QRD template for product information of (T)HMPs in the specific case of dry extracts that use ethanol as extraction solvent (declaration 'free of ethanol'.

4.4. Report on HMPC Drafting Groups activities

4.4.1. ORGAM DG

None

4.4.2. Quality DG

- QDG September meeting

  Report: Nicoleta Carmen Purdel

  Action: For information

  Outcome:

  The HMPC members noted the ongoing activities of the QDG according to the three-year plan 2024-2026 and were informed of the main topics of the September meeting held in person by this herbal drafting group: EMA/CMDh joint paper for EC on the revision of the Variations Guidelines; Revision of the GACP guideline; EU-NTC training for 2025 in collaboration with EDQM (European Pharmacopoeia and certificates of suitability (CEP) (herbal substance/preparation); reference standards for herbals in the European Pharmacopoeia); QDG three-year workplan (2025-2027).

- Publication of the QDG three-year work plan

  Report: Nicoleta Carmen Purdel

  Action: For discussion

  Document tabled: Work plan 2024-2026

  Outcome:

  HMPC agreed to publish the QDG three-year plan as a separate document at the dedicated webpage of this herbal drafting group, and also to keep the annual quality topics/activities as Annex 2 of the HMPC work plan.

- Call for a new QDG member

  Report: Nicoleta Carmen Purdel

  Action: For discussion

  Document tabled: Call for nominations

  Outcome:

  HMPC was informed that the first call for nominations of a quality expert to the QDG has so far been unsuccessful.
  Some HMPC members emphasised the possibility of additional experts to join the QDG (in addition to the current nine planned members).

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Strategic Review and Learning Meetings (SRLM)

- HMPC SRLM Follow up plan - status September 2024

  Report: HMPC Vice-Chair

  Action: For information

  Document tabled: Follow-up plan

Outcome:

The 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.

- Hungarian Presidency meeting – 02-04 December 2024

  Report: Julia Pallos, Rita Nemeth

  Action: For information

  Documents tabled: Draft agenda, Presentation

  Outcome:

  The HMPC members were informed on the draft agenda for the next HMPC-SRLM organised by the Hungarian Presidency of the Council of the European Union, 3-4 December 2024. Moreover, it was confirmed that an invitation letter will be send shortly to the HMPC members and the deadline of the registration is 15th November 2024. Applications for performing presentations are still welcome.

5.1.2. HMPC membership

Report: HMPC Chair

Action: For information

Outcome:

End of mandate:

- Spain, Olga Teresa Esteban, (alternate) as of September 2024.

5.1.3. HMPC Co-opted members

- Call for a new Co-opted member: Epidemiology - use of herbal medicinal products in children

  Report: HMPC Chair

  Action: For discussion

  Documents tabled: Call for nominations, Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC, Expertise of HMPC members

  Outcome:

  The HMPC Chair pointed out that a fifth co-opted member of the HMPC has still to be appointed. In this regard, Committee members were asked to consider whether they would recommend strengthening the HMPC with broader expertise in areas such as epidemiology and/or RWD/RWE.
  Next **discussion** scheduled at the HMPC **November 2024** meeting.

  Some HMPC members emphasised the lack of NCAs experts with sufficient experience to contribute to the HMPC's core business.

5.1.4. Summary on MRP/DCP for herbal medicinal products

Action: For discussion

Document tabled: Overview herbal procedures in CTS

Outcome:

The Rapporteur summarised the procedure for collecting and reporting MRP/DCP data for HMPs (articles article 10a WEU and 16a TU) from CTS and informed the Committee that, given the extensive retrieved, an order of priorities should be established to manage the expected workload.
Next **discussion** scheduled at the HMPC **November 2024** meeting.

Some HMPC members pointed out that focus should be on the MRP/DCP approved in recent years (e.g., from the last 5 years) and then the questionnaire form should be sent to the related RMSs for getting only the main relevant issues during the assessment. Moreover, the HMPC Chair highlighted the possibility of including this subject on the MRP/DCP for HMPs as a topic in the HMPC's work plan 2025.

5.1.5. Committee meetings in Microsoft Teams and new tool for voting

Action: For information

Document tabled: Presentation

Outcome:

The HMPC members were informed about the new tool for voting 'Decisions' (an add-on app for Microsoft Teams), since Webex polls (Webex meetings) is to be discontinued on 30th September. The main change is that members will need to use Microsoft Teams app (or Teams in browser) to join the meeting online, instead of Webex, with the possibility to log in with their NCA account. As the next steps, a follow up written communication will be sent to the members with training invites and further info, and the next HMPC meeting/voting in November (online) will already be held via Teams/Decisions.

5.1.6. Work plan for Herbal Curriculum Steering Group

Report: HMPC Vice-Chair

Action: For discussion

Documents tabled: Herbal curriculum 2024-2025, Herbal curriculum priorities, Email

Outcome:

The HMPC Vice-Chair summarised the planned courses in the area of herbal medicinal products assessment (herbal curriculum) for 2024–2025 via the EU Network Training Centre (EU-NTC): Development of EU herbal monographs / Tasks of HMPC; European Pharmacopoeia and certificates of suitability (CEP) (herbal substance/preparation).

5.1.7. EU-NTC promo at Scientific Committee meetings - postponed

5.1.8. New Fee Regulation (NFR) (Regulation (EU) 2024/568)

Action: For information

Documents tabled: Guidance scientific support/advice THMPs, Regulation (EU) 2024/568

Outcome:

The HMPC members were informed that a new fees regulation is coming into force on 1st of January 2025 (Regulation (EU) 2024/568). In this regard, the Q/As document with information on the fees applicable to herbal medicinal products (Guidance scientific support/advice THMPs) need to be updated.
Secretariat to review the Q/As document for possible **adoption** at the **HMPC November 2024** meeting.

5.2. EMA Scientific Committees or CMDh-v

None

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

5.3.1. European Substance Registration System (EU-SRS)

Report: HMPC Chair

Action: For information

Outcome:

The HMPC members were informed about the ongoing work of the Substance Validation Group (SVG) and in particular of the role of the European Substance Registration System (EU-SRS) as an important tool in the substances lifecycle in EU. In regard to the herbal records, it was pointed out that the preferred term should be the name most accurately describing the herbal substance at a given time, and a hierarchy of four levels is proposed in EU-SRS. As per the next steps for the herbal records in EU-SRS: agree on naming rules; finalization of herbal guide (2024); cleanse records in EU-SRS especially remove duplicates (2025); build substances with hierarchy in EU-SRS joining forces with pharmaceutical industry & UMC to make this work and possibility to create EU-set of records for global use (2025 onwards).

5.3.2. Revision of the Variations framework

Report: HMPC Chair

Action: For information

Documents tabled: HMPC/QDG letter, Response EMA/CMDh Drafting Group

Outcome:

The HMPC Chair summarised the response received to the letter sent earlier by the Committee suggesting that THMPs are covered in the Variations framework. In this regard, it was pointed out that the amended Variations Regulation (Commission Delegated Regulation (EU) 2024/1701 of 11 March 2024) has not changed the regulatory framework related to THMPs. As per the next steps, the HMPC was informed of the next planned phase of the ongoing revision of the Variations Guidelines.

5.3.3. Granularity and Periodicity Advisory Group (GPAG) – procedure for herbal substances in European Union Reference Dates (EURD) list

Report: HMPC Vice-Chair

Action: For information

Outcome:

The HMPC Vice-Chair pointed out that the GPAG is planning to review the procedure for including herbal substances on the EURD list (e.g. with an impact on the PSUR submission) and in this regard the Committee will be invited soon to provide input.
Next **discussion** scheduled at the HMPC **November 2024/January 2025** meeting.

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopoeia

None

5.4.2. European Food Safety Authority (EFSA)

- HMPC observer to EFSA

Report: HMPC Vice-Chair

Action: For information

Documents tabled: EFSA Minutes May 16, EFSA Agenda September 05, EFSA Agenda September 11

Outcome:

The HMPC Vice-Chair highlighted the minutes from the EFSA's Working Group on substances other than vitamins and minerals (Art. 8(2) of Regulation (EC) No 1925/2006) under the scientific panel on Nutrition, novel foods and food allergens.

5.5. Cooperation with International Regulators

5.5.1. EU/India Technical Working Group on Ayurveda

Report: HMPC Chair

Action: For information

Documents tabled: Agenda, Minutes

Outcome:

The HMPC Chair briefed the Committee on the main outcomes of the 3rd meeting of the EU/India Technical Working Group on Ayurveda. Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee

5.5.2. Association of the European Self-Medication Industry (AESGP)

- AESGP hearing 2024

Report: HMPC Chair

Action: For discussion

Documents tabled: Agenda, List of participants, Presentations

Outcome:

The AESGP presented the two topics for discussion: 1) RWE/RWD for herbal medicinal products; 2) Revision of the Variations classification guideline.
A hearing report will be drafted separately for publication at the EMA/HMPC website.

- Pre/Post hearing discussion

  Report: HMPC Chair

  Action: For discussion

  Outcome:

  The HMPC Chair summarised the AESGP's questions in support of the hearing and, in this regard, the Committee's responses will be included in the hearing report (to be shared with the AESGP before the hearing report is published).

5.6. Work plan and related activities

5.6.1. HMPC work plan 2024

Report: HMPC Chair

Action: For information

Document tabled: HMPC work plan 2024 (current status - September)

Outcome:

The HMPC members noted the current status of the HMPC work plan 2024.

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

  Report: HMPC Chair

  Action: For discussion

  Document tabled: Draft reflection paper

  Outcome:

  Rapporteurs to modify the draft reflection paper according to the discussion and possible additional comments from HMPC members.
  Next **discussion** scheduled at the **HMPC November 2024** meeting.

  The Rapporteur summarised that, following the PDCO comments, the drafting group decided not to include references to the concept of extrapolation as provided in the reflection paper on the use of extrapolation in the development of medicines for paediatrics (there is a general lack of PK/PD data for herbal medicinal products).

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

  Action: For information

  Document tabled: Draft guidance

Outcome:

Rapporteurs to modify the draft guidance according to the discussion and possible additional comments from PRAC members (informal views' exchange).
Next **discussion** scheduled at the **HMPC November 2024** meeting.

The Rapporteur highlighted the changes introduced and confirmed that an informal exchange of views had begun with some PRAC members. Some HMPC members pointed out challenges faced by a herbal assessor in detecting and evaluating safety signals related to HMPs, which should be taken into account.

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

  Action: For information

  Documents tabled: Draft paper, Reader's guidance

  Outcome:

  Rapporteurs to modify the draft paper according to the discussion and comments received from the consultation with relevant stakeholders of the European medicines regulatory network.
  Next **discussion** scheduled at the **HMPC November 2024** meeting.

  The Rapporteur emphasised that the draft paper was sent for consultation and comments were already received from the EU-Innovation Network (EU-IN) Borderline Classification Group (BLCG). Moreover, updated paper for possible endorsement at the HMPC November 2024 for release for three months public consultation.

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

  Action: For discussion

  Document tabled: Draft revised ARSP template

  Outcome:

  Rapporteurs to complement the draft revised ARSP template with an example of a herbal substance for possible **endorsement** for consultation with the Patients' and Consumers' Working Party (PCWP) at the **HMPC November 2024** meeting.

  The Rapporteur summarised the changes made to the draft revised ARSP template, in line with the previous discussions and the comments from a HMPC member (mainly wording adjustments). Some HMPC members expressed concern about that the ARSP is written only in English and is not translated into the 24 official EU languages.

- (2.2.2) Training on assessment of applications for herbal medicinal products

  Action: For information

  Document tabled: Draft Development of EU herbal monographs September 2024

  Outcome:

  Training to herbal assessor's at NCAs under the proposed course on 'Development of EU herbal monographs (procedure, standards, limitations, experience)' endorsed by consensus to be sent to the EU Network Training Centre (EU NTC).

The Rapporteur summarised the planned training within the EU-NTC herbal curriculum: HMPC – who we are and what we do (including HMPC Rules of procedure, work plan and guidelines in quality, non-clinical and clinical area).

- (2.3.1) Enable better worksharing and facilitate broader participation of members in assessment tasks

  Action: For information

  Document tabled: Draft Development of EU herbal monographs September 2024

  Outcome:

  Trainings to HMPC under the proposed course on 'Development of EU herbal monographs (procedure, standards, limitations, experience)' endorsed by consensus.

  The Rapporteur summarised the planned trainings not within the EU-NTC herbal curriculum but included in the HMPC work plans 2024-2025: Procedure for the preparation of European Union herbal monographs and European Union list entries; AR template and corresponding sections in the MO template; HMPC Plenary Best Practice Guide including the Reader's Guidance (annex I). Moreover, it was highlighted that the training on review and revision procedure was already delivered in 2024 to HMPC.

5.6.2. Follow up on HMPC work plan 2023

- (1.3.2) Harmonise the approach for the use of EU herbal monographs in the assessment of combination products

  Action: For discussion

  Document tabled: List of proposed combinations

  Outcome:

  Rapporteurs to complement the first proposed combination with the validation form 'Proposal to HMPC for assessment to establish EU herbal monograph / list entry' and to further substantiate the second proposed combination for possible **endorsement** at the **HMPC November 2024** meeting.

5.6.3. HMPC work plan 2025

Report: HMPC Chair

Action: For discussion

Document tabled: Draft HMPC work plan 2025

Outcome:

The HMPC Chair summarised the first draft HMPC work plan for 2025 and HMPC members were invited to send any comments or suggestions in relation to topics proposed.
Next **discussion** scheduled at the **HMPC November 2024** meeting.

5.7. Planning and reporting

None

5.8. Legislation and regulatory affairs

None

5.9. Questions from members

5.9.1. Search of Eudravigilance data

Action: For discussion

Document tabled: Email

Outcome:

HMPC Chairs and secretariat to draw up a proposal to facilitate the collection and analysis of Eudravigilance (EV) data in support of the rapporteurs' assessment of new/revision of EU herbal monographs.
Next **discussion** scheduled at the **HMPC November 2024/January 2025** meeting.

The challenges of searching the Eudravigilance (EV) database in terms of collecting and evaluating the data retrieved were emphasised. In this regard, it was suggested that the Committee appoints a small group of HMPC members with access to the EV database and carry out this search for all the herbal substances listed in the HMPC's work plan. Moreover, the possibility of appointing a co-opted member with expertise and experience in pharmacovigilance was suggested.

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 Eucalypti aetheroleum and supporting documents

Action: For discussion

Documents tabled: Draft MO, AR, LoR, OoC

Outcome:

Comments were received during public consultation.
Rapporteur to finalise the draft revised EU herbal monograph and supporting documents for peer review and **adoption** at the **HMPC November 2024** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **16 October 2024**
Peer-review documents to be sent to Rapporteur: **28 October 2024**
Final documents to be included latest in 2nd premail: **11 November 2024**

The Rapporteur summarised the remaining comment regarding the MO section 4.9 overdose for the insertion of two headings on cutaneous use and oral use, but not on inhalation use (agreed).

6.1.2. Monograph on Pilosellae herba cum radice and supporting documents

Action: For 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 November 2024** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **16 October 2024**
Peer-review documents to be sent to Rapporteur: **28 October 2024**
Final documents to be included latest in 2nd premail: **11 November 2024**

The Rapporteur pointed out that no comments were received on the draft revised monograph, assessment report and list of references.

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

6.2.1. Monograph on Allii sativi bulbus and supporting documents - postponed

6.2.2. Monograph on Arnicae flos and supporting documents

Action: For 1st discussion

Documents tabled: AR, Reader's guidance

Outcome:

Rapporteur to introduce changes in the draft revised EU herbal monograph and supporting documents according to the discussion and possible further comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC November 2024** meeting.

The Rapporteur summarised the remaining issues regarding the 4 herbal preparations included in the MO: a) for the tincture (DER 1:10), extraction solvent: ethanol 70% (V/V), agreed to follow the ointment strength of 5-25% tinctures (ESCOP), 2-3 times daily; b) for the tincture (DER 1:10), extraction solvent: ethanol 60% (V/V), agreed to keep the liquid dosage form (2.5 ml as an impregnated dressing) to apply on the affected area; c) for the tincture (DER 1:5), extraction solvent: ethanol 60% (V/V), agreed to exchange it to liquid extract (DER 1:1), extraction solvent: ethanol 60% (V/V), with 4% liquid extract in base; d) for the liquid extract of fresh flowers (DER 1:20), extraction solvent: ethanol 50% (m/m), agreed to keep this preparation (rationale to be included). Regarding the new preparations/new dosage forms for the MO: a) for the tincture (DER 1:10), extraction solvent: ethanol 70% (V/V), agreed that the use by children under 3 years of age is not recommended, to dilute the tincture before use for insect bites, and to include the DE product (1996).

6.2.3. Monograph on Crataegi folium cum flore and supporting documents

Action: For 4th 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 November 2024** meeting.

The Rapporteur highlighted the amendments made to the AR, with particular emphasis on the risk of bleeding after surgery following the intake of hawthorn preparations. Moreover, it was recommended not to include in the MO section 4.4 a warning that heart symptoms must have regular medical advice, as this is already mentioned in the indication 1) ('…after serious conditions have been excluded by a medical doctor'). Some HMPC members pointed out that heart symptoms can be really dangerous (even life-threatening) if not monitored regularly by a medical doctor, especially those related with the cardiac rhythm.

6.2.4. Monograph on Fragariae folium and supporting documents

Action: For 5th discussion

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

Outcome:

Rapporteur to introduce changes in the draft revised EU herbal monograph and supporting documents according to the discussion and possible further comments from peer-reviewer and HMPC members, for **possible adoption** for public consultation at the **HMPC November 2024** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **16 October 2024**
Peer-review documents to be sent to Rapporteur: **28 October 2024**
Final documents to be included latest in 2nd premail: **11 November 2024**

The Rapporteur proposed some changes to the wording of the MO section 4.4 for indication 1), which were not agreed, as this special warning regarding patients with conditions where reduced fluid intake is advised should be shortened and aligned with that included in the other so-called 'diuretic herbal monographs'.

6.2.5. Monograph on Ginkgo folium and supporting documents - postponed

6.2.6. Monograph on Lavandulae aetheroleum and supporting documents

Action: For 16th discussion

Documents tabled: AR, Reader's guidance

Outcome:

Rapporteur to introduce changes in the AR and draft the revised EU herbal monograph according to the discussion and possible further comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC November 2024** meeting.

The Rapporteur summarised that regarding the AR chapter 5, all paragraphs concerning the suspected endocrine effects in children in conjunction with "supportive" in vitro data were erased as the reasoning for this statement is very ambiguous and needs many more and precise data. Moreover, the paragraphs dealing with the question of addiction were cut down to short lines because this health risk is not supported by early warnings to be relevant (one key study on the topic is worked out in chapter 5.5.8). Finally, the paragraphs on cell culture-based experiments with lavender oil with the endpoints endocrine effect and tumour cell growth were erased because of high experimental concentration and missing data on specificity and sound mechanistic evaluation.
Some HMPC members pointed out that, although there are herbal products based on the WEU/full application, the data supporting these products is not in the public domain and, as such, the MO should be for traditional use only.

6.2.7. Monograph on Liquiritiae radix and supporting documents - postponed

6.2.8. Monograph on Ononidis radix and supporting documents

Action: For 5th discussion

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

Outcome:

Rapporteur to introduce changes in the draft revised EU herbal monograph and supporting documents according to the discussion and possible further comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC November 2024** meeting.

The HMPC Chair highlighted that comments were received from a Member State for improvements on the AR.

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

6.3.1. Monograph on Avenae fructus and supporting documents

Action: For 1st 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 November 2024** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **16 October 2024**
Peer-review documents to be sent to Rapporteur: **28 October 2024**
Final documents to be included latest in 2nd premail: **11 November 2024**

The Rapporteur summarised that there are studies that support the TU in minor inflammatory skin reactions (such as sunburn) and wound healing – to be further assessed. It is also suggested to add atopic dermatitis to the indication, because this is also an example of minor inflammatory skin reaction and apparently relevant for the real-world use. Furthermore it was pointed out there are side effects reported in Vigibase, which support the skin reactions in atopic patients that is already mentioned in the MO section 4.8 of Avena sativa, fructus; however, it was proposed to describe these side effects more precisely, in accordance with the reported skin reactions in Vigibase.
Some HMPC members suggested to have two separate ARs, one for Avenae fructus and the other for Avenae herba.

6.3.2. Monograph on Avenae herba and supporting documents

Action: For 1st 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 November 2024** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **16 October 2024**
Peer-review documents to be sent to Rapporteur: **28 October 2024**
Final documents to be included latest in 2nd premail: **11 November 2024**

See also 6.3.2..

6.3.3. Monograph on Cynarae folium and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

HMPC endorsed the Rapporteur's position that there is no new information available that could change the content of the EU herbal monograph.
Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC November 2024** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **16 October 2024**
Peer-review documents to be sent to Rapporteur: **28 October 2024**
Final documents to be included latest in 2nd premail: **11 November 2024**

The Rapporteur emphasised that no new indications, herbal preparations and dosages were identified, towards the existing therapeutic indication in the adopted MO (EudraVigilance data to be included). Moreover, there are no new products on the market and no new scientific data related to non-clinical and clinical safety or clinical efficacy which could trigger a revision.

6.3.4. Monograph on Lini semen and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

HMPC endorsed the Rapporteur's position that there is no new information available that could change the content of the EU herbal monograph.
Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC November 2024** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **16 October 2024**
Peer-review documents to be sent to Rapporteur: **28 October 2024**
Final documents to be included latest in 2nd premail: **11 November 2024**

The Rapporteur highlighted that no revision is considered required because there are no new products on the market and no new scientific data related to non-clinical and clinical safety or clinical efficacy which could trigger a revision.

6.3.5. Monograph on Meliloti herba and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

Rapporteur to modify the review report according to the discussion and possible additional comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC November 2024** meeting.

The Rapporteur emphasised that there are no EudraVigilance/VigiLyze reports on single component products containing *Melilotus officinalis* L., herba, or its extracts (no change to the safety profile). Also, no new herbal substances/preparations with 30/15 years of TU or 10 years of WEU were declared from the EU member countries in the review period.
Some HMPC members suggested not including references to combination products or food supplements.

6.3.6. Monograph on Oleae folium and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

HMPC endorsed the Rapporteur's position that there is no new information available that could change the content of the EU herbal monograph.
Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC November 2024** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **16 October 2024**

Peer-review documents to be sent to Rapporteur: **28 October 2024**
Final documents to be included latest in 2nd premail: **11 November 2024**

The Rapporteur summarised that no new indications, herbal preparations and dosages were identified, towards the existing therapeutic indication in the adopted MO (EudraVigilance data to be included). Moreover, there are no new products on the market and no new scientific data related to non-clinical and clinical safety or clinical efficacy which could trigger a revision.

6.3.7. Monograph on Plantaginis ovatae semen and supporting documents - postponed

6.3.8. Monograph on Plantaginis ovatae seminis tegumentum and supporting documents - postponed

6.3.9. Monograph on Polypodii 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 November 2024** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **16 October 2024**
Peer-review documents to be sent to Rapporteur: **28 October 2024**
Final documents to be included latest in 2nd premail: **11 November 2024**

The Rapporteur highlighted that no references were provided by IPs during the call for data, and there are no new safety issues detected from the EudraVigilance/Vigibase database.

6.3.10. Monograph on Sambuci flos and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

HMPC endorsed the Rapporteur's position that there is no new information available that could change the content of the EU herbal monograph.
Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC November 2024** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **16 October 2024**
Peer-review documents to be sent to Rapporteur: **28 October 2024**
Final documents to be included latest in 2nd premail: **11 November 2024**

The Rapporteur emphasised that no references were provided by IPs during the call for data, and there are no new safety issues detected from the EudraVigilance/Vigibase database.

6.3.11. Monograph on Thymi herba and supporting documents - postponed

6.3.12. Monograph on Uvae ursi folium and supporting documents

Action: For 2nd 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 November 2024** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **16 October 2024**
Peer-review documents to be sent to Rapporteur: **28 October 2024**
Final documents to be included latest in 2nd premail: **11 November 2024**

The Rapporteur pointed out a product mentioned in the previous AR but not included in the current MO. Moreover, it was clarified that another product intended for MRP has firstly to undergo some variations to the terms of the initial marketing authorisation, but this product is already included in the current MO.
Some HMPC members suggested that more information should be obtained on the strength/dosage of the product intended for MRP.

6.3.13. Monograph on Verbasci flos and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

HMPC endorsed the Rapporteur's position that there is no new information available that could change the content of the EU herbal monograph.
Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC November 2024** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **16 October 2024**
Peer-review documents to be sent to Rapporteur: **28 October 2024**
Final documents to be included latest in 2nd premail: **11 November 2024**

The Rapporteur highlighted that no references were provided by IPs during the call for data, and there are no new safety issues detected from the EudraVigilance/Vigibase database.

6.3.14. Monograph on Vitis viniferae folium and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

Rapporteur to modify the review report according to the discussion (and eventual EudraVigilance data) and possible additional comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC November 2024** meeting.

The Rapporteur summarised that no new indications, herbal preparations and dosages were identified, towards the existing therapeutic indication in the adopted MO (EudraVigilance data to be included). Moreover, there are no new products on the market and no new scientific data related to non-clinical and clinical safety or clinical efficacy which could trigger a revision.

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 4th discussion

Document tabled: Presentation

Outcome:

Rapporteurs to introduce changes in the draft EU herbal monograph and supporting documents according to the discussion and possible additional comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC November 2024** meeting.

The Rapporteur highlighted that regarding the non-clinical characteristics of cannabis and its constituents, there are indications of harmful effects that are of relevance to the clinical use, but several aspects complicate the interpretation and comparisons of the results from the published studies. Therefore, this should be further studied in a product specific setting and taken into consideration in the development of any potential medicinal product containing Cannabis flos or its active constituents.
Some HMPC members pointed out that, although there are cannabis products used in the EU countries, they may not qualify as medicinal products, as it is foreseen in the pharmaceutical legislation (WEU - article 10a of the Directive 2001/83/EC of the European Parliament and of the Council).

6.5.2. Monograph on Maydis stigma and supporting documents

Action: For 4th discussion

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

Outcome:

Postponed.

6.5.3. Monograph on Species pectorales and supporting documents

Action: For 4th discussion

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

Outcome:

Rapporteur to finalise the draft EU herbal monograph and supporting documents for peer review and **adoption** at the **HMPC November 2024** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **16 October 2024**
Peer-review documents to be sent to Rapporteur: **28 October 2024**
Final documents to be included latest in 2nd premail: **11 November 2024**

The Rapporteur summarised the remaining issues: 1) for the duration of use, it is proposed to harmonise with the other MOs in the same therapeutic area, i.e., 1 week (agreed); 2) for the range of Tiliae flos in the combination, it is proposed to present as 2-60% (agreed). Some HMPC members pointed out that, although the range of Salicis cortex 20-60% is too high, it reflects the products on the market.

7. Any other business

7.1. Topics for discussion

7.1.1. Working Group Food Supplements of Heads of Food Safety Agencies

Report: HMPC Chair/Vice-Chair

Action: For information

Document tabled: Heads of Food Safety Agencies working group Food Supplements (HoA WG FS) first report; Press release 'Same rules for food supplements in Europe – European food safety authorities present list of critical substances'; FAQ for report by HoA working group 'Food Supplements'

Outcome:

Postponed.

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 22-24 July 2024

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

- EDQM certification of suitability (CEP) procedure – actions taken on CEP/CEP applications
- PCWP/HCPWP, 27-28 February 2024 (Meeting summary report)
- PCWP/HCPWP, 02-03 July 2024 (Final agenda)
- PCWP/HCPWP, 02-03 July 2024 (Meeting summary report)
- Robyn Langham’s visit from TGA to EMA/ HMPC Chair presentation TGA – CMO

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/ experts following evaluation of declared interests for the 23-25 September 2024 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 e-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	
Iliana Ionkova	Member	Bulgaria	No interests declared	
Ivan Kosalec	Member	Croatia	No interests declared	
Darko Trumbetic	Alternate*	Croatia	No interests declared	
Alexandra Demetriou	Alternate	Cyprus	No interests declared	
Markéta Příhodová	Member	Czechia	No restrictions applicable to this meeting	
Marie Heroutova	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	
Susanne Flemisch	Alternate*	Germany	No interests declared	
Ioanna Chinou	Member	Greece	No interests declared	
Stavroula Mamoucha	Alternate*	Greece	No interests declared	
Julia Pallos	Member*	Hungary	No restrictions applicable to this meeting	
Rita Nemeth	Alternate	Hungary	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Jacqueline Masterson	Member	Ireland	No interests declared	
Alessandro Assisi	Member	Italy	No interests declared	
Anna Maria Serrilli	Alternate*	Italy	No interests declared	
Inga Sile	Member	Latvia	No interests declared	
Sven Back	Member*	Luxembourg	No interests declared	
Everaldo Attard	Member*	Malta	No interests declared	
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	
Karin Erika Svedlund	Member (Vice-Chair)	Sweden	No interests declared	
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	
Peter Sisovsky	Expert*	Slovakia	No interests declared	
An observer from SwissMedic (Switzerland) attended the meeting.				
Meeting run with support from relevant EMA staff				

Experts were evaluated against the agenda topics or activities they participated in.