19 March 2025
EMA/HMPC/60660/2025
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 20-22 January 2025

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

Health and safety information

In accordance with the Agency's health and safety policy, delegates were briefed on health, safety and emergency information and procedures prior to the start of the meeting.

Disclaimers

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

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

Note on access to documents

Some documents mentioned in the set of minutes cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/729522/2016).

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1. Introduction

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

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

In accordance with the Agency's policy on handling of declarations of interests of scientific Committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and on the topics in the agenda of the meeting, the Committee secretariat announced 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 and thanked the member who was leaving the Committee for all her valuable work and contributions to the HMPC.

1.2. Adoption of agenda

HMPC agenda for 20-22 January 2025.

Outcome:

Agenda and time schedule adopted.

1.3. Adoption of the minutes

HMPC minutes for 18-20 November 2024.

Outcome:

Minutes adopted including amendments suggested by 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 January 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 March 2025 meeting according to the overview, Rapporteurs were asked to inform the Committee secretariat and Chair before the first pre-mail (by 03 March 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 to be appointed at the next HMPC meetings.

2.1.3. New assessment 2025 - Valeriana + Passiflora

Action: For adoption

Documents: Validated proposal for assessment

Outcome:

Adoption postponed.
Rapporteur to complete the market overview with Valeriana + Passiflora products on the EU national markets for possible **endorsement** at the **HMPC March 2025** meeting.

The Rapporteur highlighted that there are products on the EU market for the combination of Valeriana with Passiflora, including at least one product fulfilling the 15/30 years (ES).
Some HMPC members pointed out that a complete overview of products on the EU market would be useful.

2.1.4. New assessment 2025 - Plantago ovata semen and tegumentum

Action: For adoption

Documents: Validated proposal for assessment

Outcome:

The HMPC decided by consensus not to start a new assessment for the combination Plantago ovata semen and tegumentum.

The Rapporteur presented the proposal for a new assessment of the combination Plantago ovata semen and tegumentum, detailing the EU market overview and available Ph. Eur. monographs.
Some HMPC members pointed out that the combination products presented as available on the EU market are potentially from the same pharmaceutical company and therefore do not differ from each other.

2.1.5. Cinainu ad hoc Expert meeting (re-examination)

Report: HMPC Chair

Action: For discussion

Documents: Call for herbal quality expert nominations (email)

Outcome:

HMPC members noted the call for nominations of herbal quality experts for the cinainu's re-examination and were invited to share this call with their national experts (important to note that experts should not be staff members of NCAs nor members of any EMA committees/working parties or must be retired for at least 3 years). In addition, the EMA Quality Specialist supporting the cinainu's re-examination reinforced the importance of this expert's call.

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

2.2.1. Monograph on Urticae herba and supporting documents

Action: For adoption

Documents tabled: Draft MO, AR, LoR

Outcome:

Final revised EU herbal monograph and supporting documents adopted by majority (23 out of 24). Divergent opinion: Ireland. The Norwegian delegate expressed a favourable position.

The Rapporteur highlighted that despite no comments were received during the public consultation, some amendments (mainly editorial) were made to the AR in order to improve the readability's quality.

2.2.2. Monograph on Urticae radix and supporting documents

Action: For adoption

Documents tabled: Draft MO, AR, LoR

Outcome:

Final revised EU herbal monograph and supporting documents adopted by majority (23 out of 24). Divergent opinion: Cyprus. The Norwegian delegate expressed a favourable position.

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

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

2.3.1. Monograph on Fragariae folium and supporting documents

Action: For adoption

Documents tabled: MO, AR, Reader's guidance

Outcome:

Adoption postponed.
Rapporteur to introduce changes in the draft revised EU herbal monograph and assessment report according to the discussion and to send the package to the peer-reviewer.
HMPC members were invited to send to the Rapporteur any information in relation to issues discussed.
Next **discussion** scheduled at the **HMPC March 2025** meeting.

The Rapporteur emphasised that comments were received mentioned that strawberry leaf may have a weak evidence for the diuretic effect (indication 1 supported by only 3 bibliographic references). Moreover, it was confirmed that no products with this herbal substance are present on the EU market.
Some HMPC members pointed out that both indications ('relief of symptoms associated with minor urinary tract complaints' and 'symptomatic treatment of mild diarrhoea') have exactly the same posology (i.e., 5 g of comminuted herbal substance in 250 ml of water), despite this approach has been followed in the past for other herbal substances.
Additional suggestions were made to the AR in order to ensure that the information is easily understandable and actionable (as it is in the template).

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

2.4.1. Monograph on Avenae fructus and supporting documents

Action: For adoption

Documents tabled: Review report, Reader's guidance

Outcome:

HMPC agreed with Rapporteur's position that no EU herbal monograph revision is needed because no new data of relevance were detected that would change the content of the monograph.
The HMPC decided by consensus not to revise the monograph, assessment report and list of references on Avenae fructus.
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 detailed assessment of the pharmacovigilance data showed no new safety issues related to Avena sativa herba or fruit. It was pointed out that the pharmaceutical form in the MO on Avena sativa fructus is not according to the EDQM's standard terms. Moreover, several new studies were highlighted that support the use of Avena sativa fructus in minor inflammatory skin reactions (e.g., sunburn) and wound healing, the indication in the current MO.
Some HMPC members emphasised that the clinical studies identified cannot be used to support traditional use, which should be reflected in the review report.

2.4.2. Monograph on Avenae herba and supporting documents

Action: For adoption

Documents tabled: Review report, Reader's guidance

Outcome:

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

See also 2.4.1.

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

The Rapporteur pointed out that the search in pharmacovigilance databases (EudraVigilance) revealed no new safety issues with artichoke leaf extracts.

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

The Rapporteur pointed out that the search in pharmacovigilance databases (EudraVigilance) revealed no new safety issues with olive leaf.

2.4.5. Monograph on Uvae ursi folium and supporting documents

Action: For adoption

Documents tabled: Review report, Reader's guidance

Outcome:

Adoption postponed.
Rapporteur to modify the review report according to the discussion and possible comments from peer-reviewer for **possible adoption** at the **HMPC March 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **12 February 2025**
Peer-review documents to be sent to Rapporteur: **21 February 2025**
Final documents to be included latest in 2nd premail: **3 March 2025**

The Rapporteur summarised two clinical studies with bearberry leaf in uncomplicated urinary tract infections, but results cannot influence the current MO, which is based on TU. Some HMPC members pointed out that Uvae ursi folium is not included in the EURD list and information in the review report should reflect this fact. It was also suggested that texts under the sections 'inconsistency that could trigger a revision of the monograph' and 'revision needed' in the 'rapporteur's proposal on revision' should be deleted. Moreover, it was emphasised that if complete information is not yet available, clinical studies should not be mentioned.

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:

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

The rapporteur summarised that, on the basis of previous discussions, the wording of the special warnings, contraindications and adverse reactions now reflects both the information on SmPCs of combination products on the EU market and that on MOs of mono-components.
Some HMPC members pointed out that a warning may be necessary, given the long duration (6 weeks), before consulting a qualified health professional if symptoms do not improve or worsen. Regarding the warning that 'during the treatment intense UV-exposure should be avoided' this should be further clarified (also in the AR).

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) – postponed

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:

The Rapporteur informed that the OoC, based on the comments received from the IPs, and the draft revised GACP guideline are now being reviewed by the QDG.
Next **discussion** scheduled at the **HMPC March 2025** meeting.

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 December meeting

  Report: Nicoleta Carmen Purdel

  Action: For information

  Document tabled: Minutes December 2024

  Outcome:

  HMPC members noted the QDG activities accordingly to the December meeting, in particular: 1) revision on the declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products; 2) revision of the Guideline on Good Agricultural and Collection Practice (GACP) of starting materials of herbal origin (the revised document was sent to QDG for further discussion in February); 3) guidance on comparability between herbal preparations.

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 January 2025

  Report: HMPC Vice-Chair

  Action: For information

  Document tabled: Follow-up plan

  Outcome:

  The Rapporteur confirmed that the follow up plan is updated after the HMPC-SRLM held by the Hungarian Presidency in December 2024 (e.g., climate changes and possible impact on quality of herbal substances and preparations; HMPC clinical safety assessment (AR chapter 5) and resources).
  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

  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 and were invited to propose additional topics for discussion.

5.1.2. HMPC membership

Report: HMPC Chair

Action: For information

Outcome:

New membership:

- Czechia, Kristýna Veselá (Alternate) as of 1 January 2025

Re-nominated members:

- Romania, Carmen Purdel, (Member) as of 26 February 2025

End of mandate:

- Czechia, Marie Heroutova (Alternate) as of 31 December 2024

5.1.3. HMPC Co-opted member

- Call for a Co-opted member:

  Report: HMPC Chair

  Action: For discussion

  Document tabled: Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC

  Outcome:

  Postponed.

5.2. EMA Scientific Committees or CMDh-v

None

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

5.3.1. RWD studies on Pelargonii radix and Cannabis flos

Report: HMPC Chair

Action: For discussion

Document tabled: DARWIN EU study reports; Reader's guidance

Outcome:

HMPC members noted the final reports received relating to the RWD studies on Pelargonii radix and Cannabis flos, and taking into account the practical experience gained in 2024, a HMPC/TDA-RWE liaison group was agreed.

A proposal was put forward to create a HMPC/TDA-RWE liaison group, whose expertise could help identify future opportunities to fill knowledge gaps related to HMPC work, which the DARWIN EU studies could address.
Different points of view were expressed related to what extent have the two study reports answered the initial research questions; for what kind of questions from HMPC, DARWIN RWD studies can offer any additional value, despite the current limitations in the searchable databases; proposals to be submitted for DARWIN EU studies in 2025; basic principles on the scientific and regulatory use of RWD in the establishment/revision of EU herbal MOs.
Some HMPC members pointed out that, in practice, no new information was added with the two DARWIN pilot studies carried out in 2024 but only confirmed what was already in the HMPC's assessments. On the other hand, the limitations of EU databases with data on HMPs (OTCs vs prescription products) were highlighted and, in this regard, it is advisable to have more different and searchable databases.

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopoeia

None

5.4.2. European Food Safety Authority (EFSA)

- EFSA working group meeting on substances other than vitamins and minerals (Art. 8(2) of Regulation (EC) No 1925/2006)

  Action: For discussion

  Documents tabled: Minutes; Draft opinion on monacolins from red yeast rice; Previous scientific opinion on the safety of monacolins in red yeast rice; Commission Regulation (EU) 2022/860 - monacolins from red yeast rice

  Outcome:

  HMPC members noted the draft EFSA's opinion on monacolins from red yeast rice and were invited to submit any comments by 24 January.

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

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

- AESGP hearing 2024

  Report: HMPC Chair

  Action: For adoption

  Document tabled: Hearing report

  Outcome:

  Hearing report 2024 adopted by consensus for publication.

5.7. Work plan and related activities

5.7.1. HMPC work plan 2025

Report: HMPC Chair

Action: For adoption

Document tabled: HMPC work plan 2025

Outcome:

HMPC work plan 2025 (EMA/HMPC/60660/2025) adopted by consensus.

The HMPC work plan for 2025 was presented, focusing on various topics such as real-world data (importance of establishing principles for the role of RWD in supporting herbal MOs); collaboration with PRAC, improving public communication (importance of clear communication with patients and healthcare professionals); and increasing training and worksharing (importance of internal training and collaboration initiatives to support new assessors/experts).
Some HMPC members pointed out that the topics in the work plan are highly scrutinised by IPs and, with this in mind, the key objectives and activities planned for 2025 should be

realistic. Moreover, the Committee agreed to maintain a specific topic related to the paediatric use of herbal medicinal products.

5.7.2. Follow-up on 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 information

  Outcome:

  HMPC members were informed that the draft 'reflection paper on data recommendations for traditional herbal medicinal products and herbal medicinal products used in children and adolescents" has been sent to the PDCO for comments/review prior to public consultation.

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

  Action: For discussion

  Outcome:

  The Rapporteur informed the Committee that at the second meeting with some PRAC members, they were asked to provide examples of herbal medicines whose eventual adverse reactions might be of interest for further research.

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

  Action: For information

  Document tabled: Draft paper

  Outcome:

  HMPC members agreed on the editorial changes proposed by the EMA on the Draft 'Reflection paper on the use of information in EU herbal monographs and assessment reports for borderline issues' before its publication on the EMA webpage for public consultation.

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

  Action: For adoption

  Document tabled: Draft revised ARSP template

  Outcome:

  Rapporteur to introduce changes in the draft revised ARSP template according to the discussion and additional comments from HMPC members for possible **endorsement** for consultation with the Patients' and Consumers' Working Party (PCWP) at the **HMPC March 2025** meeting.

  The Rapporteur summarised the main changes made to the ARSP template, incorporating feedback from members with the aim of providing the general public with easily understandable and actionable information. In addition, a 'proof of concept' using an MO on a specific herbal substance was also presented.

Some HMPC members pointed out that information about the possibility that HMPs based on ethanol extracts may still contain alcohol traces should be clearer. Moreover, and with regard to the efficacy's plausibility based on long-standing use and experience, the preference to not include non-clinical (animal) data, except for negative effects, but to focus on clinical data, was emphasised.
HMPC members were invited to send additional suggestions, as this iterative process ensures that the ARSP template remains relevant and effective.

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

  Action: For information

  Document tabled: Presentation 'Training on the Procedure for the preparation of European Union herbal monographs and European Union list entries and annexed AR template chapter 1'

  Outcome:

  A presentation was given on the HMPC's procedure for the preparation of EU herbal monographs/list entries, highlighting responsibilities of the HMPC rapporteurs/assessors/ peer-reviewers, the main principles (step I - appointment of rapporteur and peer-reviewer; step II - assessment of data and drafting of documents for public consultation; step III - discussion on comments from interested parties and adoption of finalised documents). Moreover, the tasks of the HMPC Secretariat for the procedure were also presented.

5.8. Planning and reporting

5.8.1. Summary on MRP/DCP for herbal medicinal products

Action: For discussion

Document tabled: List EU herbal procedures in CTS

Outcome:

Rapporteur to add the recommendations of the previous rapporteur into the document with the exhaustive list of MRP/DCP herbal medicines approved in the last 5 years. Document to be revised in 2 years.

5.8.2. 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:

HMPC members were informed on the interest of International Regulators (with primary focus on candidate countries) to attend training courses available in the EU-NTC LMS. In this regard, it has identified the recent herbal training on 'contaminants and residues in herbal medicinal products' as a possible course for inclusion in a separate domain of the EU-NTC LMS for International Regulators.
Additional clarifications to be provided by the EU-NTC LMS managers at the **HMPC March 2025** meeting.

5.8.3. EMA's 30th anniversary: events and activities in 2025

Report: HMPC Chair

Action: For information

Outcome:

HMPC members were informed about the events and activities underway to celebrate the EMA's 30th anniversary and, in this regard, were invited to identify topics related to the committee's work that could be covered by an EMA scientific conference.

5.9. Legislation and regulatory affairs

5.9.1. EU legislation concerning homeopathic and herbal medicinal products

Report: HMPC Chair

Action: For information

Documents tabled: Revised texts (proposal); Herbal issues in the Revision Proposals for Regulation and Directive_28feb 2024

Outcome:

HMPC members were informed about the revised (proposal) EU legislation on homeopathic and herbal medicinal products and, in this regard, were invited to send any additional comments or suggestions to their national representatives in the EU legislation revision process.

5.10. Questions from members

None

6. EU herbal monographs and list entries in preparation

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

6.1.1. Monograph on Plantaginis lanceolatae folium and supporting documents

Action: For 1st discussion

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

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 March 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **12 February 2025**
Peer-review documents to be sent to Rapporteur: **21 February 2025**
Final documents to be included latest in 2nd premail: **3 March 2025**

The Rapporteur summarised the OoC addressing comments received from the IPs during the public consultation. In this regard, it was highlighted the missing information (volume vs weight) for preparation k); changes in AR especially in chapter 6; preparation b) (lozenge; registered for 'traditionally used for the strengthening of the respiratory tract') in MO for indication 'Traditional herbal medicinal product as a demulcent for the symptomatic treatment of oral or pharyngeal irritations and associated dry cough' for oral use?/oromucosal use?/both? (needs further discussion); the duration of use in skin conditions (1 week?) (needs further discussion).

6.1.2. Monograph on Zingiberis rhizoma and supporting documents

Action: For 2nd discussion

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

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 March 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **12 February 2025**
Peer-review documents to be sent to Rapporteur: **21 February 2025**
Final documents to be included latest in 2nd premail: **3 March 2025**

The Rapporteur highlighted that comments were primarily on the use of ginger in pregnancy-induced nausea and vomiting but emphasised that studies to substantiate efficacy and safety are considered insufficient in relation to the current requirements. Moreover, the published WEU studies on motion sickness were not up to the standards currently expected and, in this regard, it was explained in the AR that, for reasons of regulatory consistency and since there are no new safety issues for this indication, the preparation and posology of the WEU monograph remain unchanged during this revision.

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

Action: For 3rd 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 March 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **12 February 2025**
Peer-review documents to be sent to Rapporteur: **21 February 2025**
Final documents to be included latest in 2nd premail: **3 March 2025**

The Rapporteur highlighted that the AR and MO were updated (e.g., table with clinical studies; adverse effects). Several clinical studies have been identified but they are not fulfilling the current requirements for a WEU to be established. Regarding the indication 1) and for the powdered herbal substance, the posology was updated to 'single dose: 100 mg to 750 mg, 2 to 5 times daily'.

6.2.2. Monograph on Arnicae flos and supporting documents

Action: For 3rd 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 member, for **possible adoption** for public consultation at the **HMPC March 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **12 February 2025**
Peer-review documents to be sent to Rapporteur: **21 February 2025**
Final documents to be included latest in 2nd premail: **3 March 2025**

The Rapporteur confirmed that the AR and MO had been updated in line with the previous discussion.
Some HMPC members pointed out that, with regard to use in children and adolescents, information should be presented in an easily understandable and actionable way.

6.2.3. Monograph on Crataegi folium cum flore and supporting documents

Action: For 5th 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 member, for **possible adoption** for public consultation at the **HMPC March 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **12 February 2025**
Peer-review documents to be sent to Rapporteur: **21 February 2025**
Final documents to be included latest in 2nd premail: **3 March 2025**

The Rapporteur summarised the changes made to the AR and MO, particularly with regard to the new herbal preparations and respective posologies.
Some HMPC members have drawn attention to the indication 1) to relieve symptoms of temporary nervous cardiac complaints, as this can encompass dangerous (even life-threatening) situations if not monitored regularly by a medical doctor, especially those related to heart rhythm.

6.2.4. Monograph on Ginkgo folium and supporting documents - postponed

6.2.5. Monograph on Lavandulae aetheroleum and supporting documents - postponed

6.2.6. Monograph on Liquiritiae radix and supporting documents

Action: For 4th discussion

Documents tabled: Draft MO, AR, LoR

Outcome:

Postponed.

6.2.7. Monograph on Ononidis radix and supporting documents

Action: For 7th 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 March 2025** meeting.

The Rapporteur highlighted that the AR had been updated, in particular the overview of the two DE standard marketing authorisations (Standardzulassung, 1986 and 2004). Moreover, it was pointed out that despite the aim of harmonisation with the other so-called 'diuretic herbal monographs, it is also relevant to keep the historical bibliographic data in order not to omit the entire EU tradition over 30 years and the only source remains the German Commission E.
Some HMPC members pointed out that the information (therapeutic indications, posologies, etc.) in the former Standardzulassung 1986 had been completely replaced by the newer one Standardzulassung 2004, which should be reflected in the AR.

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

6.3.1. Monograph on Calendulae flos and supporting documents

Action: For 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 March 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **12 February 2025**
Peer-review documents to be sent to Rapporteur: **21 February 2025**
Final documents to be included latest in 2nd premail: **3 March 2025**

The Rapporteur summarised that from the EudraVigilance search, reports were found on erythema, pruritus, papule and burning sensation, but these adverse reactions are considered covered by the skin sensitization already listed in the MO section 4.8 Undesirable effects.

6.3.2. Monograph on Cimicifugae rhizoma and supporting documents

Action: For 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 March 2025** meeting.

The Rapporteur summarised the (non-)clinical studies that were published during the review period, but none of the study results trigger the MO revision. A new herbal medicinal product was reported (AT) but already included in the MO as herbal preparation b); however indication and posology deviate from the current ones, but study data are not publicly available. Moreover, the risk of hepatotoxicity is already addressed in the MO and no changes result from the PSUSA procedure.
Some HMPC members pointed out that a complete reference to the new HMP reported (AT) should be included in the market overview table.

6.3.3. Monograph on Curcumae longae rhizome and supporting documents

Action: For 2nd discussion

Document tabled: TBC

Outcome:

Postponed.

6.3.4. Monograph on Echinaceae angustifoliae radix 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 March/May 2025** meeting.

The Rapporteur highlighted that no new scientific data were found in the literature. However, and in regard to reported liver reactions (e.g., hyperbilirubinaemia, hepatitis, hepatic enzyme increased) this needs to be the subject of further investigation.
Some HMPC members suggested setting up an expert group to support the Rapporteur in

assessing reported liver reactions associated with echinaceae spp, possibly in collaboration with PRAC colleagues.

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

6.3.6. Monograph on Gentianae radix and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

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

Timetable:
Documents to be sent to Peer-reviewer: **12 February 2025**
Peer-review documents to be sent to Rapporteur: **21 February 2025**
Final documents to be included latest in 2nd premail: **3 March 2025**

The Rapporteur summarised that no new HMPs with gentiana lutea root extracts as the sole active substance have been registered/authorised since the last revision in 2017 and also no relevant safety issues were reported. Several in vitro studies have been identified studying the cytotoxic and genotoxic effect of gentiana lutea extract, but these studies are not relevant at the moment, because they do not change the conclusion about safety.

6.3.7. Monograph on Lupuli 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 March 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **12 February 2025**
Peer-review documents to be sent to Rapporteur: **21 February 2025**
Final documents to be included latest in 2nd premail: **3 March 2025**

The Rapporteur pointed out a new study that included healthy young adults who reported depression (self-diagnosis) but the dosage used was not given and the population was also too small to be conclusive.

6.3.8. Monograph on Meliloti herba and supporting documents

Action: For 3rd 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 March 2025** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **12 February 2025**
Peer-review documents to be sent to Rapporteur: **21 February 2025**
Final documents to be included latest in 2nd premail: **3 March 2025**

The Rapporteur emphasised that the review report had been updated in line with the previous discussion, with the aim of presenting information in an easily understandable and actionable way.

6.3.9. Monograph on Melissae folium and supporting documents

Action: For 2nd discussion

Documents tabled: Review report, Reader's guidance

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 March 2025** meeting.

The Rapporteur summarised the remaining issue for discussion, i.e., if preparation 'soft extract (2.3-3:1) aqueous' (DE product fulfilling the 30/15 years criteria of TU) is covered (or not) by preparation e) 'dried water or ethanol (45-53% V/V) extracts corresponding to the tea, liquid extract and tincture above' (needs further discussion). In addition, any adverse reactions identified for products on the EU market are requested from the Member States.

6.3.10. Monograph on Plantaginis ovatae semen 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 March 2025** meeting.

The Rapporteur pointed out two clinical studies that were published during the review period, but for the posology mentioned in one of the studies (only 3.5 g day, i.e., below the posology in the current MO) there are no products reported on the EU market (needs further discussion). Cases of diarrhoea have been reported in patients with constipation

and, as the causality of the event 'diarrhoea' was assessed as possibly related, it was suggested that this information be included (needs further discussion).

6.3.11. Monograph on Plantaginis ovatae seminis tegumentum 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 March 2025** meeting.

See also 6.3.10.

6.3.12. Monograph on Ribis nigri folium and supporting documents

Action: For 1st discussion

Document tabled: Review report, Reader's guidance

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 March 2025** meeting.

The Rapporteur summarised that new references were published during the review period, most of them referring to the chemical composition and non-clinical studies investigating the anti-oxidant and anti-microbial activities of blackcurrant leaf, but no new clinical studies were available. Moreover, literature data and EudraVigilance search did not identify any new safety concern, and no new herbal substances/preparations with 30/15 years of TU or 10 years of WEU are available. However, there is the need to update information reported in the MO sections 4.1, 4.3 and 4.4 to harmonise the content with the other so-called 'diuretic herbal monographs'. In addition, there are references with evidence of TU as a diuretic for the comminuted blackcurrant leaf as a herbal tea with the same posology reported in the MO for the relief of minor articular pain, but there are no products on the EU market (needs further discussion).

6.3.13. Monograph on Thymi herba and supporting documents

Action: For 4th discussion

Documents tabled: Review report, Reader's guidance

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 March 2025** meeting.

The Rapporteur and HMPC members agreed that the new registered AT product 'liquid extract (DER 1:4.5), extraction solvent: ammonia solution 10% (m/m):glycerol 85%

(m/m):ethanol 96% (V/V):water (1:10:70:109)' is already covered by the current preparation c) in the MO.

6.3.14. Monograph on Vitis viniferae folium and supporting documents

Action: For 3rd discussion

Documents tabled: Review report, Reader's guidance

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 March 2025** meeting.

The Rapporteur highlighted that further data were received on the Ph. Eur. monograph 2025:2667 Grapevine Leaf (Vitis viniferae folium), which will be published in April 2025, where an HPLC assay is used instead of the spectrophotometric assay mentioned in the French Pharmacopoeia's monograph, which has been used before, and this change may be relevant regarding the expression of total flavonols and anthocyanosides content (agreed to be addressed in the review report). Moreover, it was emphasised an after the deadline request to consider the preparation *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).

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

6.4.1. Monograph on Cisti cretici herba and supporting documents

Action: For 1st discussion

Documents tabled: Draft MO, AR, LoR, OoC

Outcome:

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

Timetable:
Documents to be sent to Peer-reviewer: **12 February 2025**
Peer-review documents to be sent to Rapporteur: **21 February 2025**
Final documents to be included latest in 2nd premail: **3 March 2025**

The Rapporteur summarised the OoC addressing all the comments received from the IPs during the public consultation, emphasising that no substantial changes were proposed to the draft MO.

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

6.5.1. Monograph on Cannabis flos and supporting documents - postponed

6.5.2. Monograph on Maydis stigma and supporting documents

Action: For 5th discussion

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

Outcome:

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

Timetable:
Documents to be sent to Peer-reviewer: **12 February 2025**
Peer-review documents to be sent to Rapporteur: **21 February 2025**
Final documents to be included latest in 2nd premail: **3 March 2025**

The Rapporteur highlighted that the AR had been updated (e.g., since the active constituents are not known, all the main constituents of the aqueous extracts are mentioned). It was also pointed out the tablespoon content issue (real value vs theoretical value), which needs further discussion. Moreover, a clarification was added in the AR section 5.3 about a case notified as myositis.

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 18-20 November 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

- Special report 23/2024: Food labelling in the EU | European Court of Auditors
- European Herbal Health Products Summit – Which way forward

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/ experts following evaluation of declared interests for the 20-22 January 2025 HMPC meeting, which was held in-person.
An asterisk (*) after the role, in the second column, signals that the member/alternate attended remotely. Additional experts participated in (part of) the meeting, either in person or remotely.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Emiel Van Galen	Chair	Netherlands	No interests declared	
Astrid Obmann	Member	Austria	No interests declared	
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	
Christina Sylvia Chrysostomou	Member	Cyprus	No interests declared	
Markéta Příhodová	Member	Czechia	No restrictions applicable to this meeting	
Nanna Lundgaard Rasmussen	Member	Denmark	No interests declared	
Karoline Holm Felding	Alternate*	Denmark	No interests declared	
Maria Paile Hyvarinen	Member	Finland	No interests declared	
Sari Koski	Alternate*	Finland	No interests declared	
An Le	Member	France	No interests declared	
Helene Ly	Alternate*	France	No interests declared	
Jacqueline Wiesner	Member	Germany	No interests declared	
Susanne Flemisch	Alternate*	Germany	No interests declared	
Ioanna Chinou	Member	Greece	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Stavroula Mamoucha	Alternate*	Greece	No interests declared	
Julia Pallos	Member	Hungary	No restrictions applicable to this meeting	
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	
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	
Ewa Antkiewicz	Alternate*	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	
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	
Maria Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared	
Maria da Graca Ribeiro Campos	Co-opted member	Portugal	No interests declared	
Kristine Hvolby	Expert*	Denmark	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Peter Sisovsky	Expert*	Slovakia	No interests declared	
Melanie Bald	Observer	EDQM	No interests declared	
A representative from the European Commission attended the meeting.				
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.