



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 September 2023
EMA/HMPC/452624/2023
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 18-20 September 2023

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

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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 re-nominated members and thanked Wieland Peschel, who was leaving the Agency, for all his valuable work and contributions to the Committee for the last 15 years. In addition, the Chair remembered Noël Wathion, who recently passed away, for his enormous work in the service of the European medicines regulatory network and, in particular, in relation to the HMPC as a Scientific Committee.

1.2. Adoption of agenda

HMPC agenda for 18-20 September 2023.

Action: For adoption

Outcome:

Agenda and time schedule adopted with few adjustments.

1.3. Adoption of the minutes

HMPC minutes for 17-19 July 2023.

Action: For adoption

Outcome:

Minutes adopted without changes proposed.

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 2023

Report: HMPC Chair

Action: For discussion

Document tabled: Overview

Outcome:

HMPC noted the status of assessment work.

In case of postponement of topics scheduled for the HMPC November 2023 meeting according to the overview, Rapporteurs were asked to inform secretariat and Chair before the first pre-mail (by 07 November 2023) to allow best adaptation of agenda and time-schedule.

2.1.2. Appointment of Rapporteurs and Peer-reviewers

None

2.1.3. Request for unscheduled review on Sennae folium and Sennae fructus

Rapporteur: HMPC Chair

Action: For discussion

Documents tabled: Email; Request for revision

Outcome:

HMPC noted the grounds pointed out by the requester for this unscheduled review (possible implications for dosage recommendations following assay changes in European Pharmacopoeia monographs).

Requester to provide a English version of the report in support of this request for an unscheduled review on Sennae folium and Sennae fructus.

Next **discussion** scheduled at the **HMPC November 2023** meeting.

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

None

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

2.3.1. Monograph on Plantaginis lanceolatae folium and supporting documents - postponed

2.3.2. Monograph on Pelargonii radix and supporting documents

Action: For adoption

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

Outcome:

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

The Rapporteur emphasised that the limit of 3 years of age is proposed to be kept for the three herbal preparations, as there are products on the market for more than 30 years with traditional use without concerns have been identified in the safety reports.

Reviewed EU herbal monographs and list entries for decision on revision

2.3.3. Monograph on Ononidis radix and supporting documents

Action: For adoption

Documents tabled: Review report; References 42/12

Outcome:

HMPC agreed with Rapporteur's position to revise the EU herbal monograph because new wording for the therapeutic indication was adopted that requires an update and changes to the content of the monograph.

The HMPC decided by consensus to start the revision procedure and revise the monograph, assessment report and list of references on Ononidis radix.

The review report was adopted and HMPC tracking documents will be updated.

The Rapporteur emphasised that this MO's revision is proposed mainly to include the recently discussed diuretic indication: "Traditional herbal medicinal product used for the relief of symptoms associated with minor urinary tract complaints in addition to the general recommendation of a sufficient fluid intake to increase the amount of urine".

2.3.4. Monograph on Pilosellae herba cum radice and supporting documents

Action: For adoption

Documents tabled: Review report; References 0/0

Outcome:

HMPC agreed with Rapporteur's position to revise the EU herbal monograph because new wording for the therapeutic indication was adopted that requires an update and changes to the content of the monograph.

The HMPC decided by consensus to start the revision procedure and revise the monograph, assessment report and list of references on Pilosellae herba cum radice.

The review report was adopted and HMPC tracking documents will be updated.

The Rapporteur emphasised that this MO's revision is proposed mainly to include a recommendation to ensure adequate fluid intake during the use of the product and the recently discussed diuretic indication: "Traditional herbal medicinal product used for the relief of symptoms associated with minor urinary tract complaints in addition to the general recommendation of a sufficient fluid intake to increase the amount of urine".

2.3.5. Monograph on Polygoni avicularis herba and supporting documents

Action: For adoption

Documents tabled: Review report; References 05/05

Outcome:

HMPC agreed with Rapporteur's position to revise the EU herbal monograph because a new wording for the therapeutic indication was adopted that requires an update and changes to the content of the monograph.

The HMPC decided by consensus to start the revision procedure and revise the monograph, assessment report and list of references on *Polygoni avicularis herba*.

The review report was adopted and HMPC tracking documents will be updated.

The Rapporteur emphasised that this MO's revision is proposed mainly to include the recently discussed diuretic indication: "Traditional herbal medicinal product used for the relief of symptoms associated with minor urinary tract complaints in addition to the general recommendation of a sufficient fluid intake to increase the amount of urine".

2.3.6. [Monograph on *Pruni africanae cortex* and supporting documents](#)

Action: For adoption

Documents tabled: Review report, Reader's Guidance, References 02/02

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 Rapporteur summarised that there are no new herbal substances/preparations with 30/15 years of TU or 10 years of WEU. EudraVigilance outcome was added (no new data).

The HMPC decided by consensus not to revise the monograph, assessment report and list of references on *Pruni africanae cortex*.

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

2.3.7. [Monograph on *Rosae flos* and supporting documents](#)

Action: For adoption

Document tabled: Review report, Reader's Guidance, References 04/03

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 Rapporteur pointed out that there are no new products on the EU market and from the search of literature no relevant new information was founded. EudraVigilance outcome was added (no new data).

The HMPC decided by consensus not to revise the monograph, assessment report and list of references on *Rosae flos*.

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

2.3.8. Monograph on Sideritis herba and supporting documents

Action: For adoption

Documents tabled: Review report, Reader's Guidance, References 03/03

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 Rapporteur emphasised that there are no new herbal substances/preparations with 30/15 years of TU or 10 years of WEU. EudraVigilance outcome was added (no new data). The HMPC decided by consensus not to revise the monograph, assessment report and list of references on Sideritis herba.

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

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

2.4.1. Monograph on Cnici benedicti herba and supporting documents

Action: For adoption

Documents tabled: Draft MO, AR, LoR

Outcome:

Final EU herbal monograph and supporting documents adopted by majority. Divergent opinion: Ireland. The Norwegian delegate expressed a favourable position.

The Rapporteur pointed out that no comments were received during public consultation. Some wording changes were introduced in the MO section 5.3. Preclinical safety data and "decoction" was added in the MO section 4.2 Posology and method of administration.

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

2.5.1. Monograph on Cisti cretici herba and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR, References xx

Outcome:

Postponed.

2.6. 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 (EMA/HMPC/107079/2007)

Action: For discussion

Document tabled: [Concept paper](#), Oral report

Outcome:

The Rapporteur highlighted the ongoing topics for updating the guidance on genotoxicity (e.g. carcinogenotoxicity endpoints). It was also emphasised that any additional requirements should be carefully discussed, taking into account the regulatory practice. Some HMPC members pointed out difficulties related to the applicability and interpretation of *in-vitro* screening tests for genotoxicity when applied to herbal substances/preparations. Next **discussion** scheduled at the **HMPC November 2023** meeting.

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: Draft revised guideline, OoC

Outcome:

The Rapporteur emphasised that the draft revised guideline and the OoC had been sent to the herbal QDG for further analysis. It was also noted that after endorsement by the HMPC and taking into account the boundary issues between GACPs and GMPs, the revised guideline should be sent to the Inspectors Working Group (IWG)) as first step. Next **discussion** and **possible adoption** scheduled at the **HMPC November 2023** meeting.

Timetable:

Discussion at QDG on 16 October (GACP group to attend this meeting);

Clean consolidated draft version to be provided for November HMPC plenary meeting for endorsement and further coordination with IWG before public consultation.

4.2.2. Q&A on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/41500/2010)

Action: For adoption

Document tabled: Draft revised Q&A (Rev.7)

Outcome:

Postponed.

4.3. Regulatory / Procedural

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

Action: For discussion

Document tabled: Draft Procedure for the preparation of MO and LE

Outcome:

The Rapporteur emphasised that the procedure for the preparation of MO and LE was drafted and ready to be submitted to the EMA's Regulatory and Legal offices (by the secretariat) for review. No comments were received from HMPC Members.

Next **discussion** and **possible adoption** for public consultation at the **HMPC November 2023** meeting.

4.3.2. Reflection paper on data recommendations for (T)HMPs used in children and adolescents

Action: For discussion

Documents tabled: Draft reflection paper; Draft Annex: 'Therapeutic areas for adolescents and children for traditional use (TU)'

Outcome:

The Rapporteurs emphasised that the reflection paper and its annex were drafted and ready to be submitted to the PDCO for further analysis.

HMPC members were invited to send any additional comments in order to prepare a mature draft version for possible endorsement at the November HMPC before stepping into coordination with PDCO.

Next **discussion** and **possible adoption** scheduled at the **HMPC November 2023** meeting.

4.3.3. 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:

The Rapporteur highlighted that the revised AR template for the development of EU MO/LE was drafted and ready to be submitted to the EMA's Regulatory and Legal offices (by the secretariat) for review. No comments were received from HMPC Members.

Next **discussion** and **possible adoption** for public consultation at the **HMPC November 2023** meeting.

4.3.4. Questions & Answers on the EU framework for (traditional) herbal medicinal products, including those from a 'non-European' tradition (EMA/HMPC/402684/2013)

Report: HMPC Chair

Action: For adoption

Document tabled: Draft revised Q&A (Rev.1)

Outcome:

HMPC noted the main changes made to the Q/A document after the July meeting. Some members requested for "Traditional African Medicine (TAM)" to be included (Q&A #3) and for the reference to the SmPC to be clarified (Q&A #25).

Secretariat to finalise draft revised Q&A (Rev.1) for **adoption** at the **HMPC November 2023** meeting.

4.4. Report on HMPC Drafting Groups activities

4.4.1. ORGAM DG

None

4.4.2. Quality DG - report

Report: Nicoleta Carmen Purdel

Action: For information

Document tabled: Minutes

Outcome:

The QDG activities were reported, with emphasis on the herbal QDG three-year work plan, which is proposed for integration into the Quality domain (QWP).

4.4.3. Quality DG – 3-year work plan

Action: For adoption

Document tabled: Draft work plan

Outcome:

Herbal QDG three-year work plan adopted by consensus.

HMPC heard about the proposed strategic, tactical (activities/projects to deliver the strategic goals) and operational (medicinal product-specific activities) goals, and expertise for herbal QDG in its role to provide support to the HMPC in the area of quality of (T)HMPs (e.g., updating and developing guidance addressing specific quality issues in herbals).

HMPC members welcomed the harmonisation for the quality aspects of herbals that is envisaged with this QDG three-work work plan (e.g., new guidelines/guidance and training 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 September 2023

Report: HMPC Vice-Chair

Action: For information

Document tabled: Follow-up plan

Outcome:

The HMPC Vice-Chair emphasised that no new topics had been included in the follow-up plan (planned for after the Spanish SRLM). The HMPC Chair confirmed that there are no plans for the immediate future relating to the veterinary use of (T)HMPS. Antimicrobial resistance (AMR) was suggested for further development in connection with the EMA's regulatory science strategy to 2025.

- Spanish Presidency meeting – 09-10 October 2023

Report: Olga Palomino

Action: For discussion

Document tabled: Draft agenda

Outcome:

The latest draft agenda for the next SRLM organised by the Spanish Presidency of the Council of the European Union on 9-10 October 2023 was presented. It was pointed out that the first day is reserved for internal delegates only and that, on the second day, some external speakers and participants have also been invited to attend the meeting as well .

5.1.2. HMPC membership

Report: HMPC Chair

Action: For information

Outcome:

Re-nominated members:

- Malta, Everaldo Attard, (member) as of 11 September 2023
- Netherlands, Hilda Kuin, (alternate) as of 16 November 2023

5.1.3. Preparation of nomination and appointment of Co-opted members

Report: HMPC Chair

Action: For discussion

Document tabled: [Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC](#), presentation

Outcome:

HMPC noted the next steps regarding the nomination and appointment of co-opted members, taking into account that two mandates are about to expire on 23/11/2023. The HMPC agreed to move towards more clinical expertise and therefore seek co-opted members with experience in clinical assessment of HMPs (and eventually with general medical practice).

5.1.4. General update on RWD/RWE projects at EMA

Action: For discussion

Document tabled: Presentation

Outcome:

HMPC was informed on the [report on the experience gained with regulatory-led RWE studies](#) to support EU regulatory decision-making. In addition, an update on [DARWIN EU®](#) was provided. Furthermore, the Committee was reminded of the process for any Committee/NCA of a Member State to request RWE studies (email template). EMA also informed HMPC of a recently established RWE folder (in DREAM/MMD), which contains useful information on processes and guidance, DARWIN EU® data partners, as well as details on the studies conducted to support regulatory decisions.

HMPC members suggested a few topics and a small working group was proposed to discuss first proposals for possible RWE pilot studies on HMPs.

5.2. EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair

Action: For information

Documents tabled: Agenda 15 September 2023, Minutes 26 June 2023

Outcome:

The HMPC Chair summarised the relevant topics on the agenda of the Scientific Coordination Board (SciCoBo) meeting held on 15 September with focus on the Committees 'work plans for 2024. The HMPC workplan 2023 topics on paediatric use of (T)HMPs, borderline issues, communication strategy and training programme were proposed to continue in 2024 and, as a new topic, guidance on safety signal detection for herbal substances/preparations was also proposed.

As the next steps, HMPC (Chair, Vice-Chair and secretariat) to prepare a first draft version of workplan 2024 for presentation during the Committee meeting in November and in advance of the SciCoBo meeting in December.

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

None

5.4. Cooperation within the EU regulatory network

5.4.1. Coordination with European Pharmacopoeia

None

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) – request for a hearing in November 2023

Report: HMPC Chair

Action: For discussion

Document tabled: Email

Outcome:

HMPC noted that the AESGP hearing will be held during the next plenary meeting in November.

List of AESGP speakers and topics for discussion to be provided in advance to HMPC members (secretariat).

5.7. Work plan and related activities

5.7.1. HMPC work plan 2023

Report: HMPC Chair

Action: For discussion

Documents tabled: Work plan 2023, Annex 1, Annex 2 – current status

Outcome:

The HMPC members noted status of projects, monographs and guidelines (next report during the Committee meeting in November).

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

Document tabled: Draft survey

Action: For discussion

Outcome:

HMPC agreed to the proposed survey on combination products with the aim of establishing a short list of few justified candidates for evaluation by the Committee.

The possible high amount of combination products in some Member States was highlighted again. It was clarified that Member States should only identify authorised/registered

(T)HMPCs and with products on the market.

Survey on combination products to be sent to Member States (secretariat).

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

Document tabled: Draft-The role of MO and AR in relationship to borderline issues

Action: For discussion

Outcome:

HMPC noted the first draft document relating to the role of MO/AR in relationship to borderline issues.

HMPC members were invited to submit comments to the Rapporteurs over the next 2/3 weeks in order to prepare a second draft.

Next **discussion** scheduled at the **HMPC November 2023** meeting.

5.8. Planning and reporting

5.8.1. HMPC meeting organisation 2024

Report: HMPC Chair

Action: For information

Document tabled: Email

Outcome:

HMPC was informed that, for the year 2024, all Committees should follow the 50% principle for meetings held in person.

HMPC meetings in 2024: January, May and September will be in person; March, July and November will be held virtually.

5.9. Legislation and regulatory affairs

None

5.10. Questions from members

5.10.1. Query from Slovenia NCA - THMP with vitamins/minerals

Report:

Action: For discussion

Documents tabled: Email, presentation

Outcome:

The HMPC was informed of the outcome of the request for consultation sent to the Member States on the applicability of the 30/15 year criteria for proof of TU in a combination of herbal substances/preparations with vitamins.

It was emphasised that, in this regard, Member States should base themselves on the requirements applied in their own countries.

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 and List Entry on *Foeniculi amari fructus* and supporting documents

Action: For 3rd discussion

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

Outcome:

Rapporteur to introduce changes in the draft revised EU herbal monograph/list entry and supporting documents according to the discussion and possible additional comments from Peer-reviewer and HMPC members.

Peer-reviewer to double-check coherence of the content of revised MO/LE and substantiated justification in AR and OoC.

Next **discussion** scheduled at the **HMPC November 2023** meeting.

6.1.2. Monograph and List Entry on *Foeniculi dulcis fructus* and supporting documents

Action: For 3rd discussion

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

Outcome:

Rapporteur to introduce changes in the draft revised EU herbal monograph/list entry and supporting documents according to the discussion and possible additional comments from Peer-reviewer and HMPC members.

Peer-reviewer to double-check coherence of the content of revised MO/LE and substantiated justification in AR and OoC.

Next **discussion** scheduled at the **HMPC November 2023** meeting.

See also topic 6.1.1..

6.1.3. Monograph on *Foeniculi amari fructus aetheroleum* and supporting documents

Action: For 3rd discussion

Documents tabled: Draft PS, AR, LoR, OoC, Reader's Guidance

Outcome:

Postponed.

6.1.4. Monograph on *Hippocastani cortex* and supporting documents

Action: For 1st discussion

Documents tabled: Draft MO, AR, LoR, Reference

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 2023** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **18 October 2023**

Peer-review documents to be sent to Rapporteur: **31 October 2023**

Final documents to be included latest in 2nd premail: **13 November 2023**

The Rapporteur highlighted that no changes had been proposed to the MO and that only minor changes had been made to the AR.

It was clarified that ES and FR products have been registered for a long time at national level (30/15 year criteria for TU).

6.1.5. Monograph on Rosmarini aetheroleum and supporting documents

Action: For 2nd discussion

Documents tabled: Draft MO, AR, OoC

Outcome:

No comments received during public consultation.

Rapporteur to finalise the draft revised EU herbal monograph and supporting documents for peer-review and **possible adoption** at the **HMPC November 2023** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **18 October 2023**

Peer-review documents to be sent to Rapporteur: **31 October 2023**

Final documents to be included latest in 2nd premail: **13 November 2023**

The Rapporteur summarised that comments received during public consultation were mainly related to the liquid dosage form for cutaneous use (no products available on the market as such). However, it was pointed out that some references (e.g., from ESCOP) have included solutions of the essential oil for wound healing.

Taking into account other MOs with a similar therapeutic indication, the HMPC agreed to keep the liquid dosage form for the symptomatic treatment of minor inflammations of the skin and as an aid in healing of minor wounds (without mentioning the eventual antiseptic effect). Also, the HMPC agreed to delete the contraindication "Do not apply to broken or irritated skin".

6.1.6. Monograph on Rosmarini folium and supporting documents

Action: For 2nd discussion

Documents tabled: Draft MO, AR

Outcome:

No comments received during public consultation.

Rapporteur to finalise the draft revised EU herbal monograph and supporting documents for peer-review and **possible adoption** at the **HMPC November 2023** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **18 October 2023**

Peer-review documents to be sent to Rapporteur: **31 October 2023**
Final documents to be included latest in 2nd premail: **13 November 2023**

See also topic 6.1.5..

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

6.2.1. Monograph on Eucalypti aetheroleum and supporting documents - postponed

6.2.2. Monograph on Lavandulae aetheroleum and supporting documents

Action: For 12th discussion

Documents tabled: Draft MO, AR, LoR, Reader's Guidance, General comments, 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 2023** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **18 October 2023**

Peer-review documents to be sent to Rapporteur: **31 October 2023**

Final documents to be included latest in 2nd premail: **13 November 2023**

6.2.3. Monograph on Urticae herba 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, for **possible adoption** for public consultation at the **HMPC November 2023** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **18 October 2023**

Peer-review documents to be sent to Rapporteur: **31 October 2023**

Final documents to be included latest in 2nd premail: **13 November 2023**

The Rapporteur emphasised that the changes to the MO are proposed mainly because of the recently discussed diuretic indication: "Traditional herbal medicinal product used for the relief of symptoms associated with minor urinary tract complaints in addition to the general recommendation of a sufficient fluid intake to increase the amount of urine".

6.2.4. Monograph on Urticae radix and supporting documents

Action: For 2nd discussion

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

Outcome:

Postponed.

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

6.3.1. Monograph on *Fragariae folium* and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

HMPC endorsed the Rapporteur's position that the adopted harmonised therapeutic indication for the (traditional) use of the so-called EU "diuretic" monographs 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 2023** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **18 October 2023**

Peer-review documents to be sent to Rapporteur: **31 October 2023**

Final documents to be included latest in 2nd premail: **13 November 2023**

The Rapporteur emphasised that this MO's revision is proposed mainly to include the recently discussed diuretic indication: "Traditional herbal medicinal product used for the relief of symptoms associated with minor urinary tract complaints in addition to the general recommendation of a sufficient fluid intake to increase the amount of urine". The AR should be updated regarding the new diuretic indication.

No new products on the market were identified and no new pharmacovigilance data was available.

6.3.2. Monograph on *Malvae sylvestris flos* and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

Postponed.

6.3.3. Monograph on *Malvae folium* and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

Postponed.

6.3.4. Monograph on *Matricariae aetheroleum* and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

Postponed.

6.3.5. Monograph on *Symphyti radix* and supporting documents

Action: For 2nd discussion

Document tabled: Review report

Outcome:

Postponed.

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 1st discussion

Document tabled: Presentation

Outcome:

HMPC welcomed this first discussion on the possibility of establishing an EU herbal monograph on *Cannabis flos*.

The HMPC members were invited to provide additional information taking into account their national context regarding the use of medicinal cannabis.

Next **discussion** scheduled at the **HMPC November 2023** meeting.

6.5.2. Monograph on *Hyperici herba/Cimicifugae rhizoma* and supporting documents

Action: For 7th discussion

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

Outcome:

Postponed.

6.5.3. Monograph on *Pruni cerasi stipites* and supporting documents

Action: For 1st discussion

Documents tabled: Draft MO, AR, LoR

Outcome:

Rapporteur 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 2023** meeting.

The Rapporteur confirmed that the correct scientific name should be "*Prunus cerasus* (L.), *Prunus avium* (L.), peduncle" (and not stipites) and that there are products on the market that have proven TU for more than 30/15 years, thus fulfilling the requirement to qualify as a THMP. In addition, it was noted that the draft MO will be updated to include the recently discussed diuretic indication: "Traditional herbal medicinal product used for the relief of symptoms associated with minor urinary tract complaints in addition to the general recommendation of a sufficient fluid intake to increase the amount of urine".

Some members of the HMPC emphasised that references to websites (hyperlinks) should not be included in the AR (to be deleted).

6.5.4. [Monograph on Species pectoralis and supporting documents](#)

Action: For 1st discussion

Document tabled: Presentation

Outcome:

Postponed.

6.5.5. [Public Statement on Tribuli terrestris herba and supporting documents](#)

Action: For 5th discussion

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

Outcome:

Rapporteur to introduce changes in the draft public statement and supporting documents according to the discussion and possible additional comments from Peer-reviewer and HMPC members.

Next **discussion** scheduled at the **HMPC November 2023** meeting.

The HMPC members noted the explanatory reasons (mainly due to lack of/limited data) why it is not currently possible to establish an EU herbal MO for Tribuli terrestris herba, despite the products on the EU market. The HMPC agreed with the Rapporteur's proposal on the definition of the herbal substance (to be implemented in PS/AR).

7. Any other business

7.1. Topics for discussion

7.1.1. [Workshop on RWD/RWE for HMPs in children, Bonn, 19 June 2023](#)

Report: HMPC Chair

Action: For discussion

Document tabled: Oral report

Outcome:

The HMPC Chair pointed out that a draft report is still under discussion after the workshop on RWD/RWE for HMPs in children, Bonn (a public version will be distributed as soon as it becomes available).

7.1.2. [Society for Medicinal Plant Research \(GA\) conference Dublin, 03-05 July 2023](#)

Report: HMPC Vice-Chair

Action: For discussion

Document tabled: Oral report, presentation

Outcome:

The HMPC Vice-Chair summarised the presentations following her and the HMPC Greek Member's participation in the Society for Medicinal Plant Research (GA) conference: "Regulatory perspective on safety of herbal medicinal products" and "Regulatory perspective on botanical safety issues".

7.1.3. [Update common names list](#)

Action: For discussion

Document tabled: Oral presentation

Outcome:

HMPC noted the status and steps needed to update the list of common names (via TEAMS channel).

7.2. **Documents for information**

7.2.1. [HMPC](#)

Table of Decisions from HMPC meeting held on 17-19 July 2023

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

HMPC plenary Best Practice Guide with annexed Reader's Guidance template

7.2.2. [Assessment Report Summary for the Public \(ARSP\)](#)

On hold

7.2.3. [Other](#)

- Meeting Summary – PCWP and HCPWP - 27 and 28 June 2023

- Draft Agenda – PCWP and HCPWP Joint meeting - 19 and 20 September 2023
- [European Parliamentary Research Service \(EPRS\) Study: “Health claims made on foods: Findings on the implementation and application of Regulation \(EC\) No 1924/2006”](#)
- New process to submit requests for MWP input
- New voting system – Test voting

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 18-20 September 2023 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	Alternate	Austria	No interests declared	
Patricia Bodart	Member	Belgium	No interests declared	
Gert Laekeman	Co-opted member	Belgium	No interests declared	
Iliana Ionkova	Member	Bulgaria	No interests declared	
Radina Dimitrova	Alternate	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	
Marie Heroutova	Alternate	Czechia	No interests declared	
Nanna Lundgaard Rasmussen	Alternate	Denmark	No interests declared	
Maria Paile Hyvarinen	Member	Finland	No interests declared	
Sari Koski	Alternate*	Finland	No interests declared	
An Le	Member*	France	No interests declared	
Jacqueline Wiesner	Member	Germany	No interests declared	
Susanne Flemisch	Alternate*	Germany	No interests declared	
Heidi Foth	Co-opted member	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	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Rita Nemeth	Alternate*	Hungary	No interests declared	
Sarah Kellaghan	Member	Ireland	No interests declared	
Jacqueline Masterson	Alternate*	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	
Gabriele Balciunaite Murziene	Member	Lithuania	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	
Maria Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared	
Carmen Purdel	Member	Romania	No interests declared	
Miroslava Horváth Petriková	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	
Olga Teresa Esteban	Alternate	Spain	No interests declared	
Karin Erika Svedlund	Member (Vice-Chair)	Sweden	No interests declared	
Kristine Hvolby	Expert*	Denmark	No interests declared	
Meeting run with support from relevant EMA staff				

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