31 January 2024
EMA/HMPC/566870/2023
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 20-22 November 2023

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

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 remotely.

In accordance with the Agency's policy on handling of declarations of interests of scientific Committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and on the topics in the agenda of the meeting, the Committee Secretariat announced that no restriction in the involvement of meeting participants for agenda topics was identified (see list of participants).

Participants were asked to declare any changes, omissions or errors to their declared interests concerning the matters for discussion. No new or additional competing interests were declared.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure. All decisions taken at this meeting were made in the presence of a quorum of members. All decisions, recommendations and advice were agreed by consensus, unless otherwise specified.

The Chair welcomed the new and re-nominated members and thanked Gert Laekeman (Belgium), who was leaving the Committee as co-opted member, for all his valuable work and contributions to the HMPC for the last years.

1.2. Adoption of agenda

HMPC agenda for 20-22 November 2023.

Outcome:

Agenda and time schedule adopted.

1.3. Adoption of the minutes

HMPC minutes for 18-20 September 2023.

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 November 2023

Report: HMPC Chair

Action: For discussion

Document tabled: Overview

HMPC noted the status of assessment work.
In case of postponement of topics scheduled for the HMPC January 2024 meeting according to the overview, Rapporteurs were asked to inform secretariat and Chair before the first pre-mail (by 16 January 2024) to allow best adaptation of agenda and time schedule.

2.1.2. Appointment of Rapporteurs and Peer-reviewers

New Rapporteur

Re-appointments according to HMPC co-opted membership change for ongoing assessment procedures:

- Lavandulae aetheroleum (Revison Draft)

Outcome:

A new Rapporteur for Lavandulae aetheroleum has been appointed by the HMPC.
Secretariat to update the HMPC status overview in accordance.

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, Report (EN)

Outcome:

The HMPC members noted the report (EN) provided by the AESGP, which addresses the possible establishment of a correlation factor between the values obtained with the spectrophotometric method used in the previous versions and with the new HPLC method used in the current versions of the Ph. Eur. monographs on Sennae folium and Sennae fructus.
Given the significant variability found among the results reported, which makes it not possible to establish with sufficient certainty a general correlation factor between the values obtained by the two analytical methods identified above, the HMPC pointed out that unscheduled reviews on Sennae folium and Sennae fructus are not fully justified.

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

2.2.1. Monograph on Hippocastani cortex and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR

Outcome:

Final revised EU herbal monograph and supporting documents adopted by consensus.

The Rapporteur highlighted that some changes have been made to the AR (local tolerance; clinical efficacy; adverse events, serious adverse events and deaths; drug interactions and other forms of interaction; overdose; effects on ability to drive or operate machinery or impairment of mental ability) mainly related to the content of esculin in the horse-chestnut bark preparations. Some HMPC members emphasised that references to the cream

tradenames used for haemorrhoids should not be included in the AR.
No changes were introduced in the EU herbal MO.

2.2.2. Monograph on Rosmarini aetheroleum and supporting documents - postponed

2.2.3. Monograph on Rosmarini folium and supporting documents - postponed

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

2.3.1. Monograph on Lavandulae aetheroleum and supporting documents

Action: For adoption

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

Outcome:

Adoption postponed because a new Rapporteur has been appointed.
Rapporteur to introduce changes in the draft 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 new Rapporteur any information in relation to issues discussed.
Next **discussion** scheduled at the **HMPC January 2024** meeting.

2.3.2. Monograph on Urticae herba and supporting documents

Action: For adoption

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

Outcome:

Adoption postponed.
Rapporteur to modify the draft EU herbal monograph and assessment report according to the discussion and possible comments from peer-reviewer for **possible adoption** for public consultation at the **HMPC January 2024** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **18 December 2023**
Peer-review documents to be sent to Rapporteur: **08 January 2024**
Final documents to be included latest in 2nd premail: **22 January 2024**

The Rapporteur summarised the MO changes made to the wording of the indication 1) in accordance with the recently adopted cross-monographs harmonisation for EU herbal monographs with a diuretic indication. Moreover the MO's sections of contraindications and warnings were amended to be in line with the other monographs in the same therapeutic area (information that adequate fluid intake is required during treatment and related warning or contraindication concerning the use in patients under a reduced fluid intake).

It was highlighted that medicinal products included in the AR market overview would need to be confirmed.

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

2.4.1. Monograph on Fragariae folium and supporting documents

Action: For adoption

Document tabled: Review report; References 0/20

Outcome:

HMPC agreed with Rapporteur's position to revise the EU herbal monograph because of the adopted harmonised "diuretic" indication that requires 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 Fragariae folium.
The review report was adopted and HMPC tracking documents will be updated.

The Rapporteur emphasised that in order to achieve consistency with the recently adopted cross-monographs harmonisation for EU herbal monographs with a diuretic indication, a revision of this MO is considered advisable. This harmonisation included changes in the wording of several sections of the MO, such as the indication, contraindications and warnings (information that adequate fluid intake is required during treatment and related warning or contraindication concerning the use in patients under a reduced fluid intake).

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

None

2.7. EU herbal monographs, list entries and public statements - post finalisation

None

3. Referral procedures

None

4. Guidelines and guidance documents

4.1. Non-clinical/clinical safety and efficacy and multidisciplinary

4.1.1. Guideline on the assessment of genotoxicity of herbal substances/preparations (EMEA/HMPC/107079/2007)

Action: For discussion

Document tabled: Concept paper

Outcome:

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

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 a second review after the initial comments. Given the boundary issues between GACPs and GMPs, the draft revised GACP guideline should be sent to the Quality Working Party (QWP) and GMP/GDP Inspectors Working Group (GMDP IWG) in advance of the public consultation.
Next **discussion** and **possible adoption** scheduled at the **HMPC January 2024** meeting.

Timetable:
Comments from QDG until 06 December;
Comments from HMPC members until 22 December;
GACP group to review comments until 12 January;
Clean consolidated draft version to be provided for HMPC January 2024 plenary meeting for endorsement and further coordination with QWP and GMDP 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:

Final Q&A on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/41500/2010) adopted by consensus.

The Rapporteur pointed out that some Q&As were considered old and outdated by the herbal QDG and were therefore deleted. On the other hand, two new Q&As have been added.

Post-adoption: An editorial change in terminology from "herbal drugs" to herbal "substances" was suggested.

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, Reader's Guidance

Outcome:

The Rapporteur pointed out that editorial changes have been implemented in accordance with comments received from EMA. Further clarification is still needed on the general publication policy of EMA (transparency of unpublished references).
Draft procedure to be modified for **possible adoption** at the **HMPC January 2024** 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 draft reflection paper on data recommendations for (T)HMPs used in children and adolescents has been updated in line with previous comments. HMPC members were invited to submit written comments by 22 December and before the document be ready to be sent to the PDCO for further analysis.

Some remarks were made about the RWD applicability to the establishment of MOs for the traditional use of HMPs. Moreover, it was emphasised that RWD can be useful during the assessment process to establish EU herbal MOs in support to clinical trials.
HMPC agreed to keep the reference to RWD in the draft document.

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, Reader's Guidance

Outcome:

The Rapporteur pointed out that editorial changes have been implemented in accordance with comments received from EMA. Further clarification is still needed on the general publication policy of EMA (transparency of unpublished references).
Draft revised AR template (including the MO template) to be modified for **possible adoption** at the **HMPC January 2024** 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:

Final revised "Questions & Answers on the EU framework for (traditional) herbal medicinal products, including those from a 'non-European' tradition" adopted by consensus.

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, QDG Work plan 2024-2026

Outcome:

The QDG activities were reported, with emphasis on the adopted three-year work plan that will be reviewed in the context of other ongoing work in the Quality domain to check for synergies and overlaps. Other QDG activities such as the new EU-NTC training on contaminants, microbiological testing, impurities (Q1/2024); the OoC related to the draft revised GACP guideline; and the new Q/A on quality of HMPs were also highlighted.
The QDG Chair highlighted the importance of the group to hold a face-to-face (F2F) meeting in 2024 after a long time without having this possibility and a draft agenda justifying a F2F meeting will be prepared in advance.

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 November 2023

Report: HMPC Vice-Chair

Action: For information

Document tabled: Follow-up plan

Outcome:

The HMPC Vice-Chair emphasised the main updates to the topics included in the follow-up plan after the Spanish SRLM.

- Spanish Presidency meeting – 09-10 October 2023

  Report: Olga Palomino

  Action: For discussion

  Documents tabled: Agenda; Presentations

  Outcome:

  The HMPC Chair highlighted the excellence of the SRLM organised by the Spanish Presidency of the Council of the European Union on 9-10 October 2023.
  It was pointed out that the meeting presentations have been provided.

- Belgian Presidency meeting – 24-25 April 2024

  Report: Patricia Bodart

  Action: For discussion

  Document tabled: Agenda

  Outcome:

  The next SRLM organised by the Belgian Presidency of the Council of the European Union will be held (face-to-face) on 24-25 April 2024 in Louvain la Neuve and a first draft agenda will be presented at the HMPC January 2024 meeting.
  HMPC members were invited to propose topics that they would like to have for discussion during the next SRLM.

- Improved collaboration between HMPC and European Pharmacopoeia herbal groups

  Report: HMPC Chair

  Action: For discussion

  Document tabled: SRLM Report on European Pharmacopoeia topic

  Outcome:

  The HMPC Chair highlighted that during the SRLM organised by the Spanish Presidency of the Council of the European Union some possible ways of improving the collaboration between the HMPC and EDQM were discussed.
  In addition to extend EDQM participation in HMPC meetings, the HMPC endorsed that topics that herbal QDG will work on for the next three years will be shared with EDQM, with reference to the overall work plan of the Quality Working Party.

5.1.2. HMPC membership

Report: HMPC Chair

Action: For information

Outcome:

New membership:

- France, Helene Ly, (alternate) as of 16 November 2023

Re-nominated members:

- Italy, Alessandro Assisi, (member) as of 13 August 2023
- Denmark, Nanna Lundgaard Rasmussen, (member) as of 1 January 2024

End of membership:

- Belgium, Gert Laekeman, (co-opted member) as of 23 November 2023
- Austria, Peter Voitl, (co-opted member) as of 3 November 2023 (resignation letter)

5.1.3. HMPC Co-opted members

- Appointment of experts: 1) Clinical – General medical practice; 2) Clinical – Clinical trials methodology and statistics

  Report: HMPC Chair

  Action: For adoption

  Document tabled: Call for nominations dated 06 October 2023, Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC, Candidatures

  Outcome:

  Maria Helena Pinto Ferreira (Portugal) was re-appointed as co-opted member in the area of expertise "General medical practice" for a three-year mandate starting on 24 November 2023. As the only nominee for this area of expertise, Maria Helena Pinto Ferreira highlighted her vast experience as a general practitioner and family doctor, and as a HMPC member.

  The appointment of a co-opted member in the area of expertise "Clinical trials methodology and statistics" was postponed to the HMPC January 2024 meeting.

  Appointment of expert took place in accordance with the procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC.

- Call for nomination of experts: Paediatrics - Paediatric medicine

  Report: HMPC Chair

  Action: For discussion

  Documents tabled: PV resignation email; Expertise of HMPC members

  Outcome:

  HMPC noted the resignation letter of the current co-opted member in the area of expertise "paediatrics".
  A call for nomination of experts in "Paediatrics" as candidates for HMPC co-opted member will be launched among Member States and the appointment will take place at the HMPC January 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. RWD/RWE pilot project for HMPC

Report: HMPC Chair

Action: For discussion

Document tabled: Proposed research questions

Outcome:

HMPC endorsed two proposals for pilot RWD/RWE research projects with specific emphasis on herbal medicinal products.
Both research projects will be developed in collaboration with the EMA's Data Analytics and Methods Taskforce - Real World Evidence workstream.

5.4. Cooperation within the EU regulatory network

5.4.1. Coordination with European Pharmacopoeia

- EDQM 13A expert group meeting

  Report: Melanie Bald

  Action: For information

  Document tabled: SoD

- EDQM 13B expert group meeting

  Report: Melanie Bald

  Action: For information

  Document tabled: SoD

- EDQM TCM expert group meeting

  Report: Melanie Bald

  Action: For information

  Outcome:

  The HMPC noted the summary of decisions from the October 2023 13A group meeting (next meeting in February 2024), September 2023 13B expert group meeting (next meeting in January 2024) and September 2023 TCM expert group meeting (next meeting in February 2024).
  The EDQM representative highlighted that a webinar was being organised to provide users insights into the new Ph. Eur. monograph on cannabis flower (3028) recently adopted. This new monograph will be published in Ph. Eur. Supplement 11.5 in January 2024 and will become the legally binding standard in Europe for cannabis flower on 01 July 2024. Moreover, the ongoing discussions on the Ph. Eur. cranberry monograph (expressed juice versus refined dry extract) were also highlighted.

- EDQM Webinar on the new Ph. Eur. Cannabis flower monograph

  Report: HMPC Chair

  Action: For information

  Document tabled: Email

  Outcome:

  The HMPC Chair emphasised that the new cannabis flower monograph adopted by the Ph. Eur. Commission in June 2023 has been made available for information and that a EDQM webinar will be held in this context (14 December 2023).

5.4.2. Coordination with European Commission

- Herbal matters in the new proposals for Regulation and Directive

  Report: HMPC Vice Chair

  Action: For discussion

  Document tabled: Presentation

  Outcome:

  The HMPC Vice-Chair summarised changes that were introduced in the new proposals of pharmaceutical legislation (Directive and Regulation) particularly with regard to herbal medicinal products.

5.5. Cooperation with International Regulators

5.5.1. Coordination with Swiss Agency for Therapeutic Products (Swissmedic)

- Swissmedic observer to HMPC

  Report: HMPC Chair

  Action: For information

  Document tabled: Confidentiality arrangement with Swissmedic; HMPC Roles of Procedure

  Outcome:

  HMPC endorsed the Swissmedic request to join the Committee as an observer.
  The Swissmedic representative will be invited to take part in the HMPC January 2024 meeting.

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) – hearing on November 2023

- AESGP hearing

  Report: AESGP members

  Action: For discussion

  Document tabled: Agenda, List of participants, Presentations

  Outcome:

  AESGP presented the four topics for discussion: 1) RWD-RWE (update on ongoing work in AESGP); 2) EU monographs on Sennae (explanation on the AESGP request for a change related to analytical methods); 3) Extract combination (request for an update from the HMPC); 4) Review of the variation legislation (changes needed for the variation classification of herbal medicinal products).
  A hearing report will be drafted separately for publication at the EMA website.

- Post hearing discussion

  Report: HMPC Chair

Action: For discussion

Outcome:

Committee's views to be shared with the AESGP before the hearing report is published.

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 the final status of projects, monographs and guidelines developed under the Committee work plan 2023.

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

  Outcome:

  HMPC noted the reflection paper on data recommendations for (T)HMPs used in children and adolescents to be submitted to the PDCO for further analysis.
  See also topic 4.3.2.

  Action: For discussion

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

  Action: For discussion

  Document tabled: Survey results

  Outcome:

  HMPC noted the preliminary analysis of the survey results on combination products and a first list of a few justified candidates for evaluation by the Committee was proposed.
  Next discussion scheduled at the HMPC January 2024 meeting.

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

  Action: For discussion

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

  Outcome:

  The Rapporteur emphasised that the aim of this document is to provide guidance on the information available in EU herbal monographs and assessment reports.
  HMPC members were invited to submit written comments by 12 January 2024.

- (2.2.1) Prepare a new Communication Initiative for HMPC stakeholders on herbal products

  Action: For discussion

  Document tabled: Presentation on survey results

Outcome:

The HMPC noted the main findings of the survey on Member States' communication initiatives related to herbal medicinal products and endorsed the list of main recommendations.

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

  Action: For discussion

  Outcome:

  The Rapporteur emphasised that the HMPC training steering group had been invited to a meeting of the EU Network Training Centre (EU-NTC). It was also pointed out the ongoing planning of a new training on contaminants, microbiological testing, impurities (Q1/2024).

- (2.3.1) Implement new working methodology for HMPC following reorganisation of EMA WPs/DGs

  Action: For discussion

  Documents tabled: Template for a European Union herbal monograph, Reader's Guidance

  Outcome:

  HMPC noted the new procedure for the preparation of MOs/LEs ((EMA/HMPC/887331/2022), the revised template for AR for the development of MOs/LEs (EMA/HMPC/418902/2005) and the revised MO template.
  See also topics 4.3.1 and 4.3.3.

5.7.2. HMPC work plan 2024

Report: HMPC Chair

Action: For discussion

Documents tabled: Draft Work plan 2024, Annex 1, Annex 2

Outcome:

HMPC members noted the draft HMPC work plan for 2024 (including two new topics and four topics carried over from 2023) and were invited to submit written comments by 12 January 2024.
The HMPC Chair pointed out that a first glance of this work plan was presented during the SciCoBo meeting in September and that a second, but more detailed presentation, is planned for the SciCoBo meeting in December.

5.8. Planning and reporting

None

5.9. Legislation and regulatory affairs

None

5.10. Questions from members

None

6. EU herbal monographs and list entries in preparation

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

6.1.1. Monograph and List Entry on Foeniculi amari fructus and supporting documents

Action: For 4th discussion

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

Outcome:

Rapporteur to finalise the draft revised EU herbal monograph, list entry and supporting documents for peer review and **adoption** at the **HMPC January 2024** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **18 December 2023**
Peer-review documents to be sent to Rapporteur: **08 January 2024**
Final documents to be included latest in 2nd premail: **22 January 2024**

The Rapporteur highlighted that the AR and the OoCs have been slightly modified according to the suggestions from HMPC members during the discussion held at the September meeting. As a result, only reference to the revised HMPC "Public statement on the use of herbal medicinal products containing estragole" has been kept supporting the need to minimise exposure to estragole.

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

Action: For 4th discussion

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

Outcome:

Rapporteur to finalise the draft revised EU herbal monograph, list entry and supporting documents for peer review and **adoption** at the **HMPC January 2024** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **18 December 2023**
Peer-review documents to be sent to Rapporteur: **08 January 2024**
Final documents to be included latest in 2nd premail: **22 January 2024**

See also topic 6.1.1.

6.1.3. Monograph on Foeniculi amari fructus aetheroleum and supporting documents - postponed

6.1.4. Monograph on Rhodiolae roseae rhizoma et radix and supporting documents

Action: For 1st discussion

Document tabled: OoC

Outcome:

Rapporteur to introduce changes in the draft revised 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 January 2024** meeting.

The Rapporteur summarised the main comments received during the public consultation. Regarding the interactions with other medicinal products and the possibility that Rhodiola rosea may decrease the activity of CYP2C9, the Rapporteur pointed out that according to available data the decrease is only modest. Moreover, related to undesirable effects, the Rapporteur emphasised that data from Eudravigilance and data from the studies suggest gastrointestinal or nervous system ADR, although some data may be duplicates.

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 Pilosellae herba cum radice and supporting documents

Action: For 1st discussion

Documents tabled: Draft MO, AR

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 January 2024** meeting.

The Rapporteur emphasised that this MO's revision is proposed in accordance with the recently adopted cross-monographs harmonisation for EU herbal monographs with a diuretic indication. Moreover, a recommendation requiring an adequate fluid intake during treatment to ensure an increase of the amount of urine, is included.
It was pointed out that the recommendation not to be used by patients with conditions in which a reduced fluid intake is advised should be better supported.

6.2.3. Monograph on Urticae radix and supporting documents

Action: For 2nd discussion

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

Outcome:

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

Timetable:
Documents to be sent to Peer-reviewer: **18 December 2023**
Peer-review documents to be sent to Rapporteur: **08 January 2024**
Final documents to be included latest in 2nd premail: **22 January 2024**

The Rapporteur emphasised that the MO has been updated with the inclusion of 2 new herbal preparations: f) dry extract (7-9:1), extraction solvent ethanol 60% (V/V); g) dry extract (5.4-6.6:1), extraction solvent ethanol 20% (V/V). In the AR, the preclinical/clinical data has been updated and new data regarding the effect of nettle root agglutinin on cell proliferation according to BPH was included.
It was highlighted the possibility of merging herbal preparations c) and g) (to be confirmed by Rapporteur and Peer-reviewer).

6.2.4. Monograph on Zingiberis rhizoma and supporting documents

Action: For 8th discussion

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

Outcome:

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

Timetable:
Documents to be sent to Peer-reviewer: **18 December 2023**
Peer-review documents to be sent to Rapporteur: **08 January 2024**
Final documents to be included latest in 2nd premail: **22 January 2024**

The Rapporteur highlighted that in the TU monograph the posology and duration of use for indication 1) (i.e., "relief of motion sickness") have been updated in accordance with AT and DE products. The preparations and posologies included in the initial WEU and TU monographs are kept and explanations in the AR were added (in particular AR sections 2.3, 4.4 and 6 has been updated), to explain the deviations between data and monographs.
The rational for the restrictions on the maximum daily dose was emphasised, not because of safety concerns, but because of information from HMPs.

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

6.3.1. Monograph on Allii sativi bulbus and supporting documents

Action: For 1st discussion

Documents tabled: Review report, presentation

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 January 2024** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **18 December 2023**
Peer-review documents to be sent to Rapporteur: **08 January 2024**
Final documents to be included latest in 2nd premail: **22 January 2024**

The Rapporteur highlighted that, and in support of this five years' review, there are new references provided by IPs during the call for data; and an updated Ph. Eur. monograph was published. Moreover, several new mono-products were reported from the MSs; and new products/posology need to be included in the EU herbal MO/AR.

6.3.2. Monograph on Lecithinum ex soya and supporting documents

Action: For 1st discussion

Document tabled: Presentation

Outcome:

Rapporteur to prepare a first draft review report according to the discussion and possible additional comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC January 2024** meeting.

The Rapporteur summarised that no data or comments were provided by IPs during the call for data; and a few products were reported from the MSs but corresponding to products included in market overview in the first version of the AR. Moreover, new safety information has been provided by the PRAC Assessment Report on the PSUR(s) for soybean phospholipids (oral use). Taking into account the PSUSA outcome, amendments are proposed to be included in the relevant sections of the EU herbal MO/AR.

6.3.3. Monograph on Malvae sylvestris flos and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

Postponed.

6.3.4. Monograph on Malvae folium and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

Postponed.

6.3.5. Monograph on Mastic (Mastix, Pistaciae lentisci resina) and supporting documents

Action: For 1st discussion

Document tabled: Presentation

Outcome:

Rapporteur to prepare a first draft review report according to the discussion and possible additional comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC January 2024** meeting.

The Rapporteur highlighted that no data or comments were provided by IPs during the call for data; and no new products in the market overview were reported from the MSs. Moreover, only one clinical study was identified but out of scope of the MO and review procedure (essential oil of mastic gum); and safety data (EudraVigilance) still to be included.

6.3.6. Monograph on Matricariae aetheroleum 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 January 2024** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **18 December 2023**
Peer-review documents to be sent to Rapporteur: **08 January 2024**
Final documents to be included latest in 2nd premail: **22 January 2024**

The Rapporteur emphasised that the MO revision is recommended because the indication should be adapted to the traditional uses of marketed herbal preparations. In addition, the posology should be corrected.

6.3.7. Monograph on Silybi mariani fructus and supporting documents

Action: For 1st discussion

Documents tabled: Review report, presentation

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 January 2024** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **18 December 2023**
Peer-review documents to be sent to Rapporteur: **08 January 2024**
Final documents to be included latest in 2nd premail: **22 January 2024**

The Rapporteur highlighted that no new references were provided by IPs during the call for data; an updated Ph. Eur. monograph was published (HPLC method, but already included in the MO/AR); and several new mono-products were reported from the MSs but equivalent to the existing ones in the MO. Moreover, no new information on side-effects or pre-clinical

studies relevant for the approved indications; and no new clinical trials justifying the inclusion of WEU indications.

6.3.8. Monograph on Soiae oleum raffinatum and supporting documents

Action: For 1st discussion

Document tabled: Presentation

Outcome:

Rapporteur to prepare a first draft review report according to the discussion and possible additional comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC January 2024** meeting.

The Rapporteur summarised that no data or comments were provided by IPs during the call for data and that a few products were reported from the MSs but already included in the MO (therapeutic indication and posology).

6.3.9. Monograph on Species diureticae and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

HMPC endorsed the Rapporteur's position that there is the adopted harmonised "diuretic" indication that requires update and changes to 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 January 2024** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **18 December 2023**
Peer-review documents to be sent to Rapporteur: **08 January 2024**
Final documents to be included latest in 2nd premail: **22 January 2024**

The Rapporteur pointed out that since finalisation of EU herbal MO on Species diureticae a new monograph for a herbal substance in this indication, Herniariae herba, has been published. Moreover, the discussions on the wording of the indication in this therapeutic area should be considered as well as revisions of EU herbal MOs in this therapeutic area. Therefore the MO/AR have to be revised in order to take combinations with Herniariae herba and the decisions on the recently adopted cross-monographs harmonisation for EU herbal monographs with a diuretic indication into consideration.

6.3.10. Monograph on Symphyti radix and supporting documents

Action: For 2nd discussion

Document tabled: Review report

Outcome:

HMPC endorsed the Rapporteur's position that there is no new information available that could change the content of the EU herbal monograph.

Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC January 2024** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **18 December 2023**
Peer-review documents to be sent to Rapporteur: **08 January 2024**
Final documents to be included latest in 2nd premail: **22 January 2024**

The Rapporteur emphasised that only a correction is suggested to include the recommended PA limit in line with the revised HMPC "Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) including recommendations regarding contamination of herbal medicinal products with PAs" (EMA/HMPC/893108/2011 Rev. 1) in the MO sections 5.3 and 6.

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 - postponed

6.5.2. Monograph on Cisti cretici herba and supporting documents - postponed

6.5.3. Monograph on Hyperici herba/Cimicifugae rhizoma and supporting documents

Action: For 7th discussion

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

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 January 2024** meeting.

The Rapporteur emphasised that the rationale to include both preparations a) and b) under TU has been extended. It was pointed out that products identified on the market have different extract solvents for the cimicifugae part (propanol extract versus ethanol extract) and cannot be considered equivalents, even more because daily doses are different.

6.5.4. Monograph on Maydis stigma and supporting documents

Action: For 1st discussion

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

Outcome:

Postponed.

6.5.5. Monograph on Pruni cerasi stipites and supporting documents

Action: For 2nd discussion

Documents tabled: Draft MO, AR, LoR

Outcome:

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

Timetable:
Documents to be sent to Peer-reviewer: **18 December 2023**
Peer-review documents to be sent to Rapporteur: **08 January 2024**
Final documents to be included latest in 2nd premail: **22 January 2024**

The Rapporteur pointed out that only one product (tea) has proven TU for more than 30/15 years on the market (firstly as HMP and secondly as food supplement), thus fulfilling the requirement to qualify as a THMP. As a consequence, the name of the EU herbal MO is changed to *Prunus avium* (L.), peduncle. Moreover, the draft MO was updated in accordance with the recently adopted cross-monographs harmonisation for EU herbal monographs with a diuretic indication. This harmonisation included changes in the wording of several sections of the MO, such as the indication, contraindications and warnings (information that adequate fluid intake is required during treatment and related warning or contraindication concerning the use in patients under a reduced fluid intake).
It was emphasised that references to food supplements should refer to health claims (instead of to therapeutic indications).

6.5.6. Monograph on Species pectoralis and supporting documents

Action: For 1st discussion

Document tabled: Presentation

Outcome:

Rapporteur to prepare a first 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 January 2024** meeting.

The Rapporteur summarised that there is a EU herbal monograph for almost all the herbal substances included in the combinations on the market; and also Ph. Eur. monographs for several components of the combinations. Moreover, products are on the market for more than 30 years; and a possible therapeutic indication was pointed out.

7. Any other business

7.1. Topics for discussion

7.1.1. Update common names list

Action: For discussion

Document tabled: Oral presentation

Outcome:

HMPC noted the missing data to conclude the updating of the list of common names.

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 18-20 September 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

- Draft Agenda – PCWP/HCPWP and all eligible organisations meetings
- EMA corporate website relaunch: what you need to know (email)
- Variation for a medicinal product with valerian root - received in Ireland

Outcome:

HMPC noted the ongoing IE national variation for a THMP with the herbal substance valerian root. HMPC to be informed as soon as further developments on this matter become available.

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 November 2023 meeting, which was held 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	
Reinhard Länger	Member	Austria	No interests declared	
Astrid Obmann	Alternate	Austria	No interests declared	
Patricia Bodart	Member	Belgium	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	
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	
Sarah Kellaghan	Member	Ireland	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	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	
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	
Gert Laekeman	Co-opted member	Belgium	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	
Melanie Bald	Observer	EDQM	No interests declared	
Kristine Hvolby	Expert	Denmark	No interests declared	
Peter Sisovsky	Expert	Slovakia	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Meeting run with support from relevant EMA staff				

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