29 May 2024
EMA/HMPC/152252/2024
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 18-20 March 2024

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).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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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 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 18-20 March 2024.

Outcome:

Agenda and time schedule adopted.

1.3. Adoption of the minutes

HMPC minutes for 29-31 January 2024.

Outcome:

Minutes adopted.

2. EU herbal monographs and list entries for adoption

2.1. Status of HMPC activities

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

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 May 2024 meeting according to the overview, Rapporteurs were asked to inform the Committee Secretariat and Chair before the first pre-mail (by 13 May 2024) to allow best adaptation of agenda and time schedule.

2.1.2. Appointment of Rapporteurs and Peer-reviewers

- Periodic reviews to start in 2024-2025

  Report: HMPC Chair

  Action: For information

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

- New Rapporteurs (re-appointments according to Austrian membership change)

  Rhodiolae roseae rhizoma et radix (revision pre-final)

  Species diureticae (revision draft) New Peer-reviewer

  Crataegi folium cum flore (revision draft)

  Outcome:

  Rapporteurs and Peer-reviewers were appointed.

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

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

Action: For adoption

Documents tabled: MO, AR, OoC, LoR, References 30/122

Outcome:

Final revised EU herbal monograph and supporting documents adopted by majority.
Divergent opinion: Ireland

HMPC members pointed out some inconsistencies between the botanical name and synonyms for the herbal substance and in this regard the Committee agreed to follow the same terminology as per the Ph. Eur. monograph published in Pharmeuropa.

2.2.2. Monograph on Rosmarini aetheroleum and supporting documents

Action: For discussion

Documents tabled: Draft MO, AR, OoC, LoR, References 15/92

Outcome:

Adoption postponed.
Rapporteur to modify the draft revised monograph and assessment report according to the discussion and possible comments from peer-reviewer for **possible adoption** at the **HMPC May 2024** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **19 April 2024**
Peer-review documents to be sent to Rapporteur: **03 May 2024**
Final documents to be included latest in 1st premail: **13 May 2024**

The Rapporteur highlighted the deletion of the liquid preparation as an aid in healing of minor wounds (not apply to 'broken or irritated skin'). Moreover, the MO section 4.8 'Undesirable effects' was updated in accordance with the EC guideline on SmPC ('adverse reactions descriptions should be based on the most suitable representation within the MedDRA terminology').
Some HMPC members pointed out that the AR section 5.3. 'Adverse events, serious adverse events and deaths' should be complemented in accordance with the MO section 4.8 'Undesirable effects'.

2.2.3. Monograph on Rosmarini folium and supporting documents

Action: For discussion

Documents tabled: Draft MO, AR, LoR, References 15/92

Outcome:

Adoption postponed.
Rapporteur to modify the draft revised monograph and assessment report according to the discussion and possible comments from peer-reviewer for **possible adoption** at the **HMPC May 2024** meeting.

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The Rapporteur pointed out the different age limit for leaf *vs* essential oil (12 *vs* 18 years). See also topic 2.2.2..

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

2.3.1. Monograph on Eucalypti aetheroleum and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR

Outcome:

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

The Rapporteur summarised the remaining comments (in the AR table 3 with the overview of evidence, and specifically for the cutaneous use, to specify how many drops are considered as 'few' for rubbering on the skin of chest or back – not possible to be specified; if results of the clinical study with a combination product containing also 1,8 cineole should be kept – not agreed; reference to a product brand name containing 1,8 cineole – not agreed; in the AR section 5.5.6 'Overdose' reference to 'may progress to coma' related to

the 'central nervous depression or loss of consciousness' – not agreed (MO section 4.9 'Overdose' updated accordingly)).

2.3.2. Monograph on Pilosellae herba cum radice 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-month public consultation.

The Rapporteur highlighted that the botanical name in the MO was updated to *Pilosella officinarum* Vall. (syn *Hieracium pilosella* L.), herba cum radice. Moreover, the posologies of products on the EU market were combined in one posology only (i.e., 'single dose: 200-520 mg, 2-4 times daily; daily dose: 560 mg up to 1300 mg').

2.3.3. 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 revised 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 May 2024** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **19 April 2024**
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The Rapporteur emphasised that for the indication 1 ('relief of symptoms associated with minor urinary complaints') the target population 'adolescents over 12 years of age' is kept. Some HMPC members pointed out that the use by adolescents over 12 years of age for the relief of symptoms associated with minor urinary complaints should be justified in the AR (based on nettle products in the EU market – HMPC members to inform the Rapporteur accordingly). Moreover, duration of use should be in accordance with other MOs for the same therapeutic areas. Finally, in the MO section 4.4 'Special warnings and precautions for use', the additional advice for 'adequate fluid intake' is already included in the therapeutic indication.

2.3.4. Monograph on Urticae radix and supporting documents

Action: For adoption

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

Outcome:

Adoption postponed.
Rapporteur to modify the draft revised 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 May 2024** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **19 April 2024**
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The Rapporteur summarised that two new herbal preparations (two different dry extracts fulfilling the 30 years' criteria at the moment of the revision) were included in the MO. Some HMPC members highlighted that in the AR section 4.4 'Overall conclusions on clinical pharmacology and efficacy' it would be preferable to reflect only the clinical studies for which all information is available, without references to the EAU guidelines. Moreover, consistent SOC terminology should be used in the MO section 4.8 'Undesirable effects' and in the AR, in accordance with the EC guideline on SmPC ('adverse reactions descriptions should be based on the most suitable representation within the MedDRA terminology').

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

2.4.1. Monograph on Malvae sylvestris flos and supporting documents

Action: For adoption

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

2.4.2. Monograph on Malvae folium and supporting documents

Action: For adoption

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

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 Prunus avium peduncle and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR

Outcome:

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

Timetable:
Documents to be sent to Peer-reviewer: **19 April 2024**
Peer-review documents to be sent to Rapporteur: **03 May 2024**
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The Rapporteur summarised the remaining comments in the AR (constituents list to include only a very short overview on the main compounds – not agreed; in table 4 with the overview of evidence, references highlighted with an asterisk (*) to be included in the column 'period of use' – agreed; in section 4.4 with overall conclusions on clinical pharmacology and efficacy, plausibility for traditional use should not be included in this section on clinical data- agreed) and in the MO (the botanical name comprising both *Prunus avium* L., peduncle and *Prunus cerasus* L., peduncle - agreed).

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

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 adoption

Document tabled: Draft revised GACP guideline

Outcome:

Draft revised "Guideline on good agricultural and collection practice (GACP) of starting materials of herbal origin" (EMA/HMPC/246816/2005) adopted by consensus for 3-month public consultation.

The HMPC noted comments received from the GMDP IWP and no comments were received from the QWP.

4.3. Regulatory / Procedural

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

Action: For adoption

Document tabled: Draft revised AR template

Outcome:

Draft revised "Template for Assessment report for the development of EU herbal monographs and EU list entries" (EMA/HMPC/418902/2005) adopted by consensus for 3-month public consultation.

The Rapporteur pointed out that this draft revised AR template (together with the draft revised MO template) is part of the draft 'Procedure for the preparation of EU herbal monographs and EU list entries and appointment of HMPC rapporteurs and peer-reviewers' (EMA/HMPC/887331/2022) already released for public consultation.

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

Action: For adoption

Documents tabled: Draft revised MO template, Addendum to QRD templates

Outcome:

Draft revised "Template for a EU herbal monograph" (EMEA/HMPC/107436/2005) adopted by consensus for 3-month public consultation.

The Rapporteur pointed out that this draft revised MO template (together with the draft revised AR template) is part of the draft 'Procedure for the preparation of EU herbal monographs and EU list entries and appointment of HMPC rapporteurs and peer-reviewers' (EMA/HMPC/887331/2022) already released for public consultation.

4.3.3. Reflection paper on data recommendations for (T)HMPs used in children and adolescents (EMA/HMPC/71333/2023)

Action: For adoption

Document tabled: Draft reflection paper

Outcome:

Draft procedure "Reflection paper on data recommendations for (T)HMPs used in children and adolescents" (EMA/HMPC/71333/2023) adopted by consensus to be transferred to the Paediatric Committee (PDCO) for comments.

The Rapporteur summarised the main remaining points (regarding extrapolation in WEU, focus on safety concerns was added based on the group discussion; for the topic on THMP, the requirement for consumption data was harmonised based on a MS comment).
In order to agile the consultation with PDCO, some questions on the main topics identified by HMPC to be prepared in advance and sent together with the RP.

4.3.4. Best practice guide on using HMPC plenary time efficiently (EMA/HMPC/601160/2020)

Action: For discussion

Document tabled: Draft revised HMPC best practice guide

Outcome:

Draft revised HMPC best practice guide to be modified according to the discussion for **adoption** at the **HMPC May 2024** meeting.

The Rapporteur summarised that this BPG is an internal document aimed at providing hands on guidance to HMPC members/alternates/experts participating at the plenary meetings. Due to new working methodologies, the cut-off date to include new topics on the draft HMPC agenda has been changed from Tuesday to Monday 12pm of the week before the HMPC plenary and references to MLWP have been deleted. Moreover, the 'Check-list for Rapporteurs and Peer-reviewers' currently included in the internal HMPC document 'Guide to Rapporteurs and Peer-reviewers for the establishment of monographs, list entries, public statements and related documents' was proposed to be added as annex 2 in the HMPC best practice guide. Finally, it was proposed to supersede the internal HMPC documents 'Guide to Rapporteurs and Peer-reviewers for the establishment of monographs, list entries, public statements and related documents' including the 'Check-list for Rapporteurs and Peer-reviewers' (EMA/HMPC/287394/2009 Rev. 4) and the 'Best practice guide for review and revision of EU-monographs/list entries' (EMA/HMPC/433002/2017). Important information has been included in the procedures for establishment of MO and LE and review/revisions, and/or in the AR and MO templates and/or in the HMPC best practice guide.
The HMPC agreed on the changes proposed by the Rapporteur.

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 related activities were reported, with emphasis on the adopted mandates and ongoing call for nominations for the Biological and Chemical Quality's European Specialised Expert Community (ESEC); the draft revised GACP guideline that was presented to QWP in February with the deadline for comments on 12 March; the revision of Guideline on the chemistry of active substances (a new subchapter on starting material from herbal origin is proposed) for which the QDG agreed to align the wording with the Q&A on starting materials of herbal origin. Moreover, as the topic of guidance on comparability between preparations is added to the HMPC workplan 2024, it was agreed a collection of examples from NCAs, that could indicate the actual status and if a harmonized approach and appropriate criteria are used; also the new EU-NTC training on contaminants and residues in HMPs was updated and it was agreed that the training is addressed to beginners (training to be delivered in small recordings); and for the ongoing revision of the pharmaceutical legislation, the main principles were presented, especially the need to streamline the variation framework by decreasing, downgrading and simplifying the various categories of variations.

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Strategic Review and Learning Meetings (SRLM)

- HMPC SRLM Follow up plan - status March 2024

  Report: HMPC Vice-Chair

  Action: For information

  Document tabled: Follow-up plan

  Outcome:

  Follow-up plan to be updated after the next HMPC SRLM organised by the Belgian Presidency of the Council of the European Union.

- Belgian Presidency meeting – 24-25 April 2024

  Report: Patricia Bodart

  Action: For discussion

  Document tabled: Draft Agenda

  Outcome:

  The next HMPC SRLM organised by the Belgian Presidency of the Council of the European Union will be held in person on 24-25 April 2024 in Louvain la Neuve and the draft agenda was presented. HMPC members were invited to propose any additional topic that they would like to have for discussion.

5.1.2. HMPC membership

Report: HMPC Chair

Action: For information

New membership:

- Belgium, Pierre Duez (Co-opted member) as of 1 February 2024

Re-nominated members:

- Spain, Olga Maria Palomino (Member) as of 21 February 2024

End of membership:

- Lithuania, Asta Kubiliene (Alternate) as of 03 March 2024

5.1.3. HMPC Co-opted members

- Appointment of expert: Paediatrics - Paediatric medicine

  Report: HMPC Chair

  Action: For discussion

  Documents tabled: Call for nominations dated 11 December 2023, Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC, Expertise of HMPC members

  Outcome:

  Appointment postponed.
  Some HMPC members pointed that an expert with knowledge in epidemiology and practical experience in the clinical use of herbal medicinal products in children (e.g., a family doctor) should be considered.

- Call for nomination of experts: Clinical Pharmacology

  Report: HMPC Chair

  Action: For discussion

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

  Outcome:

  A call for nomination of experts in "Clinical Pharmacology" as candidates for HMPC co-opted member will be launched among Member States and the appointment will take place at the HMPC May 2024 meeting.

5.1.4. Assessment Report Summary for the Public (ARSP)

Report: HMPC Chair

Action: For discussion

Document tabled: Presentation

Outcome:

HMPC members noted the current situation regarding the delay in publishing ARSPs for herbal substances (ARSP backlog) and the possible options for resuming the preparation

(and publication) of these summaries for the public. Moreover, it was highlighted that, according to the HMPC's work plan for 2024, the ARSP template is due to be revised, in addition to resume the publication of ARSPs.
Some HMPC members emphasised that resuming the ARSP publication for the new/revised herbal MOs entails an additional task for the Rapporteur/Peer-review team, and that the ARSP backlog (to be handled separately) requires further discussion in the Committee. It was also pointed out that the ARSP preparation (and publication) is always depending on the availability of a new/revised template that is much easier to use for an ARSP.

5.2. EMA Scientific Committees or CMDh-v

None

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

5.3.1. EMA/CMDh Drafting Group on the revision of the Variations Framework

Action: For information

Outcome:

HMPC members noted the information on the revision of the variations framework made available by the European Commission on their website.

5.3.2. Call for nominations for the Biological and Chemical Quality European Specialised Expert Community (ESEC)

Action: For information

Document tabled: Presentation

Outcome:

HMPC members noted the ongoing call for nominations for the Biological and Chemical Quality's European Specialised Expert Community (ESEC) and were invited to send their expressions of interest to take part in ESECs for possible endorsement at the HMPC May 2024 meeting.
In this regard, it was emphasised that as a pool of expertise for DGs, OEGs and future WP members (integration of experts and expertise identification), ESECs allow for the broadest possible participation of NCA experts with an interest to contribute to EMRN (capacity and knowledge building), facilitating dissemination of information/knowledge through the NCA network, access to WP documents and learnings (knowledge sharing). Moreover, it was pointed out that a nomination from a Committee member with a brief summary of their expertise should be send when applying for the open positions, together with a detailed CV to demonstrate the relevant expertise and up-to-date eDoI should accompany the submission via the survey tool, as per the tabled call for nominations document.

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:

  HMPC members noted the summary of decisions from the 13A expert group meeting in February 2024 (next meeting in May 2024), 13B expert group meeting in January 2024 (next meeting in April 2024) and TCM expert group meeting in February 2024 (next meeting in April 2024).

5.4.2. Coordination with European Commission

- Technical comments on proposals for revision of pharmaceutical legislation

  Report: HMPC Chair/Vice-Chair

  Action: For information

  Document: Herbal issues of technical nature identified in the Revision proposals for Regulation and Directive

  Outcome:

  The HMPC Chair highlighted that the EC was informed about the herbal issues of a technical nature identified in the Revision proposals for Regulation and Directive.

5.4.3. Coordination with European Food Safety Authority (EFSA)

- HMPC observer to EFSA

  Report: HMPC Chair/Vice-Chair

  Action: For information

  Outcome:

  The HMPC Chair highlighted that EFSA issued a draft scientific opinion on additional scientific data related to the safety of some herbal preparations for which the publication is expected.

5.5. Cooperation with International Regulators

None

5.6. Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee

None

5.7. Work plan and related activities

5.7.1. HMPC work plan 2024

Report: HMPC Chair

Action: For information

Document tabled: HMPC work plan 2024 (europa.eu)

- (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 issues"

  Outcome:

  The Rapporteur emphasised that, as foreseen in the HMPC work plans for 2023 and 2024, the Committee will establish a common position on the role of EU herbal monographs and assessment reports in relationship to borderline issues.
  Draft document first to be reviewed by EMA's Regulatory Affairs and Legal offices for a next discussion scheduled at the HMPC May 2024 meeting.

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

  Action: For discussion

  Document tabled: Draft revised ARSP template

  Outcome:

  HMPC members noted the first "proof of concept" related to the revision of the ARSP template. As for the herbal identification, it was pointed out the link to the table containing the common names of herbal substances in all MSs and also the visual representation of the plant part described in the EU herbal monograph. Regarding the risks associated with the use of a herbal substance, it was emphasised to have sections on drug-herbal interactions with specific information for doctors/pharmacists highlighted in a different colour.
  Some HMPC members pointed out that content & format of the image representing or identifying the part of the herbal substance should be further discussed. Moreover, it was emphasised that information included in ARSPs is part of a group of documents (MOs, ARs, LoRs, Opinion) published on a specific herbal substance.
  HMPC members were invited to send comments for a next discussion scheduled at the HMPC May 2024 meeting.

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

  Action: For discussion

Documents tabled: Course description EU NTC LMS Contaminants and impurities, Herbal curriculum – contaminants and residues, Herbal curriculum priorities, Draft presentation on Contaminants and residues in Herbal Medicinal Products

Outcome:

The Rapporteur emphasised that the upcoming training on contaminants and residues included in the Herbal Curriculum training programme will be delivered in the end of April/beginning of May via the EU-NTC LMS (the training will be pre-recorded, i.e., no live session).
Moreover, as the next Herbal Curriculum priorities, it was emphasised the planned training on development of EU herbal monographs (procedure, standards, limitations, experience) for possible delivery at the HMPC May 2024 meeting (face-to-face training).

5.7.2. Follow up on HMPC work plan 2023

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

Action: For discussion

Outcome:

The Rapporteur pointed out that, at this stage, priority will only be given to fixed combination products fulfilling the 30-year criteria and including 2 (maximum 3) combined herbal substances.
A revised list of fixed combinations products on the EU market for prioritisation will be presented at the HMPC May 2024 meeting.

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 on Foeniculi amari fructus aetheroleum and supporting documents

Action: For 3rd discussion

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

Outcome:

Comments were received during public consultation. Rapporteur to finalise the draft public statement and supporting documents for peer review and **possible adoption** at the **HMPC May 2024** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **19 April 2024**
Peer-review documents to be sent to Rapporteur: **03 May 2024**
Final documents to be included latest in 2nd premail: **20 May 2024**

The Rapporteur summarised that the OoCs, AR and draft PS have been updated mainly to highlight the lack of adequate data on genotoxicity of bitter fennel oil and the absence of carcinogenicity data; this change is in agreement with the bitter and sweet fennel fruits). Moreover, reference to the revised HMPC 'Public statement on the use of herbal medicinal products containing estragole' (EMA/HMPC/137212/2005 Rev 1) is kept supporting the need to minimise exposure to estragole.

6.1.2. Monograph on Ginseng radix and supporting documents

Action: For 1st discussion

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

Outcome:

No comments received during public consultation. Rapporteur to finalise the draft revised EU herbal monograph and supporting documents for peer review and **possible adoption** at the **HMPC May 2024** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **19 April 2024**
Peer-review documents to be sent to Rapporteur: **03 May 2024**
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The Rapporteur highlighted that concerns were expressed about the possibility of neutropenia mentioned in one large clinical study included in the AR.
HMPC agreed with the Rapporteur position that, taking into account the data currently available, a modification of the MO section 4.5 'Interactions with other medicinal products and other forms of interaction' is not considered necessary (however, the topic should be monitored and, if necessary, re-evaluated).

6.1.3. Monograph on Pelargonii radix and supporting documents

Action: For 1st discussion

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

Outcome:

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

Timetable:
Documents to be sent to Peer-reviewer: **19 April 2024**
Peer-review documents to be sent to Rapporteur: **03 May 2024**
Final documents to be included latest in 2nd premail: **20 May 2024**

The Rapporteur summarised the OoCs mostly related to the inclusion of the paediatric group (children with 3-5 years) into the target populations, based on the broad long-standing safe therapeutic use of pelargonium root. It was emphasised that the wording used in the MO section 4.8 'Undesirable effects' should be updated according to the EC guideline on SmPC ('adverse reactions descriptions should be based on the most suitable representation within the MedDRA terminology') and that the outcome of the last PSUSA on pelargonium should be reflected in the AR as well.
Some HMPC members pointed out that, as soon as they become available, results (data and information) of the ongoing RWD/RWE pilot project on pelargonium should be analysed and conclusions reflected in the EU herbal MO, if applicable.

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

6.2.1. Monograph on Crataegi folium cum flore and supporting documents

Action: For 1st discussion

Document tabled: AR

Outcome:

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

The Rapporteur pointed out that for some products included in the market overview the active substance needs to be confirmed as folium cum flore; if the 'soft extract (2.8-5.3:1), extraction solvent: ethanol 45% m/m' is to be kept as a single monograph extract - agreed; if published preclinical results can be seen as supportive of indication 1 (i.e., 'relieve symptoms of temporary nervous cardiac complaints (e.g. palpitations, perceived extra heart beat due to mild anxiety)') – not agreed; if interaction with antiplatelet agents should be kept as a safety signal (no case reports are available from the Eudravigilance database) – to be confirmed; if reference for a short-term use is to be kept for the indication 2 ('relief of mild symptoms of mental stress and to aid sleep')– agreed; if a LE should be considered – requires further discussion in the Committee.

6.2.2. Monograph on Fragariae folium 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 members.
Next **discussion** scheduled at the **HMPC May 2024** meeting.

The Rapporteur highlighted changes introduced in the MO section 4.4. 'Special warnings and precautions for use' regarding patients with conditions where reduced fluid intake is advised.

Some HMPC members pointed out that the wording 'flushing therapy' should not be used in the MO section 4.4. 'Special warnings and precautions for use', and that the warning regarding fluid restrictions in patients should be aligned with the recently adopted cross-monographs harmonisation for the so-called 'diuretic herbal monographs'. Any deviations to the previous agreed wording should be further justified in the AR (e.g., additional data).

6.2.3. Monograph on Lavandulae aetheroleum and supporting documents

Action: For 14th discussion

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

Outcome:

Postponed.

6.2.4. Monograph on Liquiritiae radix and supporting documents

Action: For 1st discussion

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

Outcome:

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

The Rapporteur summarised that it is proposed to widen the posology for indication 2 'expectorant in cough associated with cold' based on the DE product – agreed; additional sentences on the clinically relevant PK interactions with drugs metabolised by CYP3A4 (i.e., midazolam, omeprazole) are also proposed to be included in the MO's sections 4.4 'Special warnings and precautions for use', and 4.5 'interactions with other medicinal products and other forms of interaction' – agreed. Still on the PK interactions, the Rapporteur proposal for a warning on potential interaction with MTX to be included in the MO requires further discussion in the Committee. Given the large number of clinical efficacy studies available, the Rapporteur proposed including in a table only PD studies with powdered/comminuted root and water extracts.
Some HMPC members pointed out that the use of liquorice consumption with intakes of glycyrrhizin during pregnancy and lactation is not recommended.

6.2.5. Monograph on Ononidis 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 members.
Next **discussion** scheduled at the **HMPC May 2024** meeting.

The Rapporteur highlighted that changes in the MO sections 4.1. 'Therapeutic indications', and 4.2. 'posology and method of administration' are in line with the recently adopted cross-monographs harmonisation for the so-called 'diuretic herbal monographs'; however, a slightly different wording is proposed in the MO section 4.4 'Special warnings and precautions for use', considering publications on the effectiveness of fluid restrictions. Some HMPC members pointed out that the warning regarding fluid restrictions in patients should be aligned with the recently adopted cross-monographs harmonisation for the so-called 'diuretic herbal monographs'. Any deviations to the previous agreed wording should be further justified in the AR (e.g., additional data).

6.2.6. Monograph on Zingiberis rhizoma and supporting documents

Action: For 10th discussion

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

Outcome:

Rapporteur to finalise 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 May 2024** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **19 April 2024**
Peer-review documents to be sent to Rapporteur: **03 May 2024**
Final documents to be included latest in 2nd premail: **20 May 2024**

The Rapporteur pointed out that overall, the AR has been shortened; changes in the MO section 5.3 'Preclinical safety data' and corresponding sections in AR have been agreed; and no changes regarding indications have been introduced (i.e., 'cough' not considered for the TU indication for 'relief of symptoms of common cold').

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

6.3.1. Monograph on Mastic (Mastix, Pistaciae lentisci resina) 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 May 2024** meeting.

The Rapporteur highlighted that it is proposed to include in the review report information linked with the footnote in the first AR mentioning some higher percentage in mastic resin for cutaneous use (from older references) to be reconsidered with the next systematic revision of the MO.

6.3.2. Monograph on Thymi herba and supporting documents

Action: For 1st discussion

Documents tabled: Review report, references

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 2nd discussion

Document tabled: Presentation

Outcome:

Rapporteur (together with the multidisciplinary assessment team) to prepare the first draft assessment report according to the discussion and possible additional comments from peer-reviewer and HMPC members.

6.5.2. Monograph on Cisti cretici herba and supporting documents

Action: For 18th discussion

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

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 May 2024** meeting.

The Rapporteur emphasised that this MO is exclusively focused on the Greek tradition for oral use of the herbal substance as a decoction, for which there is bibliographic evidence supporting the posology.
On the posology-related issue, the majority of the HMPC members supported the Rapporteur position.

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

Action: For 8th discussion

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

Outcome:

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

Timetable:
Documents to be sent to Peer-reviewer: **19 April 2024**

Peer-review documents to be sent to Rapporteur: **03 May 2024**
Final documents to be included latest in 2nd premail: **20 May 2024**

The Rapporteur pointed out the remaining point regarding the preparation b) (i.e., fixed combination containing the dry extract from Hyperici (DER 3.5-6:1), extraction solvent ethanol 60% V/V and dry extract from Cimificugae (DER 4.5-8.5:1), extraction solvent ethanol 60% V/V).
It was requested not to consider the preparation b) in the TU for the relief of mild climacteric complaints like hot flushes and sweating when associated with slightly depressed mood, and, in addition, it was requested that any relevant information in the NTP technical report for this combination should be included in the AR.

6.5.4. Monograph on Maydis stigma and supporting documents

Action: For 1st discussion

Documents tabled: Draft MO, AR, Reader's Guidance, 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 May 2024** meeting.

The Rapporteur highlighted that the single dose of corn silk decoction has been one tablespoon for one glass of water, but given the wide range of weights measured with different tablespoons over the years and in order to be consistent with the tradition, it is proposed to include the single dose as 2-4 g in the MO. Moreover, the therapeutic indication is now aligned with the recently adopted cross-monographs harmonisation for the so-called 'diuretic herbal monographs'.
Some HMPC members pointed out that pharmaceutical form should be consistent with products on the market (i.e., herbal tea *vs* decoction (preferred option)). Moreover, and regarding the age limit for which the use is not recommended without medical practitioner, 12 years old was agreed to be kept.

6.5.5. Monograph on Tribuli terrestris herba and supporting documents

Action: For 6th discussion

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

Outcome:

Rapporteur to finalise the draft public statement and supporting documents for peer review and **possible adoption** for public consultation at the **HMPC May 2024** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **19 April 2024**
Peer-review documents to be sent to Rapporteur: **03 May 2024**
Final documents to be included latest in 2nd premail: **20 May 2024**

The Rapporteur highlighted the main reasons (lack of/limited data) why it is not currently possible to establish an herbal MO. Furthermore, data supporting a recognised efficacy are not available as published data.

7. Any other business

7.1. Topics for discussion

7.1.1. EU NTC Engagement Event, 5 December 2023

Action: For information

Outcome:

The Rapporteur emphasised some details from the last EU NTC engagement event, held in December 2023, including the measures taken to identify the training needs of the EU network in accordance with the allocated budget. Specifically regarding the herbal domain, it was pointed out that the Herbal Curriculum Steering Group is working to prioritise a training on the review and revision procedure, including the review report template and the peer-reviewer's tasks.

7.1.2. Proxy vote – training

Action: For information

Document tabled: Presentation

Outcome:

HMPC members noted the procedure and template needed to be followed in case a member is transferring his/her proxy vote to another member.

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 29-31 January 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

- PCWP/HCPWP, 27 - 28 February 2024 (Draft agenda)

- PCWP/HCPWP, 14-15 November 2023 (Meeting summary)
- Draft guidance on scientific principles and data requirements for the safety and relative bioavailability assessment of substances proposed as new micronutrient sources (LINK)
- Draft guidance on the scientific requirements for an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283 (LINK)
- Draft guidance on the scientific requirements for a notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283 (LINK)
- Tetra-national congress Phytotherapy 2024 (LINK)
- Society of Medicinal Plant and Natural Product Research GA – European Herbal Health Products Summit, 20 February 2024, Brussels (Final program; Presentation)
- RIVM Risk assessment of herbal preparations containing Withania somnifera (Ashwagandha) (Report; LINK)
- Enhancing security of EMA Webex meetings
- Pharmaceuticals – changes to marketing authorisations (review of EU rules) (LINK)
- SNSA Webinar for NCA representatives

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 March 2024 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	
Astrid Obmann	Member	Austria	No interests declared	
Brigitte Hauser	Alternate	Austria	No interests declared	
Patricia Bodart	Member	Belgium	No interests declared	
Radina Dimitrova	Alternate	Bulgaria	No interests declared	
Darko Trumbetic	Alternate	Croatia	No interests declared	
Christina Sylvia Chrysostomou	Member	Cyprus	No interests declared	
Alexandra Demetriou	Alternate	Cyprus	No interests declared	
Markéta Příhodová	Member	Czechia	No restrictions applicable to this meeting	
Marie Heroutova	Alternate	Czechia	No interests declared	
Nanna Lundgaard Rasmussen	Member	Denmark	No interests declared	
Maria Paile Hyvarinen	Member	Finland	No interests declared	
Sari Koski	Alternate	Finland	No interests declared	
An Le	Member	France	No interests declared	
Helene Ly	Alternate	France	No interests declared	
Jacqueline Wiesner	Member	Germany	No interests declared	
Susanne Flemisch	Alternate	Germany	No interests declared	
Ioanna Chinou	Member	Greece	No interests declared	
Stavroula Mamoucha	Alternate	Greece	No interests declared	
Julia Pallos	Member	Hungary	No restrictions applicable to this meeting	
Rita Nemeth	Alternate	Hungary	No interests declared	
Jacqueline Masterson	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
Alessandro Assisi	Member	Italy	No interests declared	
Anna Maria Serrilli	Alternate	Italy	No interests declared	
Jaqueline Masterson	Member	Ireland	No interests declared	
Inga Sile	Member	Latvia	No interests declared	
Gabriele Balciunaite Murziene	Member	Lithuania	No interests declared	
Burt H Kroes	Member	Netherlands	No interests declared	
Hilda Kuin	Alternate	Netherlands	No interests declared	
Marianne Loiten Dalhus	Alternate	Norway	No interests declared	
Wojciech Dymowski	Member	Poland	No interests declared	
Ana Paula Martins	Member	Portugal	No interests declared	
Carmen Purdel	Member	Romania	No interests declared	
Dorota Distlerova	Member	Slovakia	No interests declared	
Jaroslav Tóth	Alternate	Slovakia	No interests declared	
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	
Pierre Duez	Co-opted member	Belgium	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	Member	Denmark	No interests declared	
Knut Almgren	Expert	Sweden	No interests declared	
Peter Sisovsky	Expert	Slovakia	No interests declared	
Reinhard Länger	Expert	Austria	No interests declared	
An observer from SwissMedic (Switzerland) attended the meeting.				
Meeting run with support from relevant EMA staff				

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