12 May 2023
EMA/HMPC/238217/2023
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 10-12 May 2023

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

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1. Introduction

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

The Chair opened the meeting by welcoming all participants. The meeting was held in-person with some members connected 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 based 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 member(s) and alternate(s) and thanked the departing members/alternates for their contributions to the Committee.

1.2. Adoption of agenda

HMPC agenda for 10-12 May 2023.

Outcome:

Agenda and time schedule adopted.

1.3. Adoption of the minutes

HMPC minutes for 13-15 March 2023.

Outcome:

Minutes adopted with changes introduced prior to the start of meeting.

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 May 2023

Report: HMPC Chair

Action: For discussion

Document tabled: Overview

Outcome:

HMPC noted the status of assessment work.
In case of postponement of topics scheduled for the HMPC July 2023 meeting according to the overview, Rapporteurs were asked to inform secretariat and Chair before the first pre-mail (by 04 July 2023) to allow best adaptation of agenda and time schedule.

2.1.2. Appointment of Rapporteurs and Peer-reviewers

New assessments starting in 2023

- Pruni cerasi stipites
- Cannabis flos
- Maydis stigma

Outcome:

HMPC agreed on Rapporteurs and Peer reviewers for the above new assessments to start in 2023.
Maydis stigma – new proposal for assessment

Action: For adoption

Documents: Validated proposal for assessment, references

Outcome:

Final proposal for assessment adopted by consensus.

The Rapporteur highlighted that there are other products on the market in EU Member States including information on medicinal use, therapeutic indication and posology but only one is registered as THMP so far (Poland).
The substance will be added to the HMPC priority list, Rapporteur/Peer-reviewer will be appointed (see 2.1.2), a Call for data will be published and tracking documents updated accordingly.

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

2.2.1. Monograph on Fumariae herba and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR

Outcome:

Final revised EU herbal monograph and supporting documents adopted by consensus. The Norwegian delegate expressed a favourable position.

Rapporteur to provide all full text references before publication.

The Rapporteur highlighted that no comments were received during public consultation and therefore no further changes are proposed on the MO, AR and LoR.
For herbal preparation c) it was agreed to change daily dose to "up to 1000 mg".

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

2.3.1. Monograph on Ginseng radix and supporting documents

Action: For adoption

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

Outcome:

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

The Rapporteur summarised the main changes introduced in the AR (chapters 3.1.5 and 3.4.: sentences proposing the possible support of plausibility of traditional use by certain non-clinical data have been deleted as requested; chapter 4.4.: sentence proposing the possible support of plausibility of traditional use in the proposed indication by certain clinical data has been deleted as requested) and in the MO (chapter 4.8: MedDRA-Terminology has been applied to the reported adverse events as requested).
One HMPC member expressed concerns about the possibility of neutropenia that is mentioned in one large study included in the AR. Rapporteur to further comment on this matter after public consultation taking into account the specific preparation used and the clinical setting (co-medication during chemotherapy).

2.3.2. Monograph on Plantaginis lanceolatae folium and supporting documents

Action: For discussion

Documents tabled: MO, email

Outcome:

Adoption postponed.

Rapporteur to introduce changes in the draft monograph and assessment report according to the discussion and to send the package to the peer-reviewer.
HMPC members were invited to send to the Rapporteur any information necessary for the completion of the draft monograph with focus on the wording of the previously agreed indication, while streamlining of the draft AR maybe considered before or after public consultation.
Following agreement between Rapporteur and Peer reviewer draft revised monograph to be tabled for release for public consultation at the **HMPC July 2023 meeting** unless major issues with relevance for the monograph content are detected.

Regarding the inclusion of new preparations it was discussed that products with now 28/29 years on the market will have the required 30 years when the assessment will have been finalised after public consultation, while those with less year may only be mentioned in the AR for now. Also, it was pointed out that indication 2) 'for the relief of symptoms of common cold' may need further discussion. As regards topics raised during peer review, the Chair recommended to distinguish between issues relevant for the content of the revised monograph and those solely for the quality of the AR (e.g. presentation of old, less relevant studies from the first AR version, test results and interpretation of single components). The latter may be of general 'quality of documents' and harmonisation relevance and dealt with after PC and during AR template discussions (see also 5.7.1).

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

2.4.1. Monograph on Ginkgo folium and supporting documents

Action: For adoption

Document tabled: Review report

Outcome:

HMPC agreed with Rapporteur's position to revise the EU herbal monograph because new data were detected that require 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 Ginkgo folium.
The review report was adopted and HMPC tracking documents will be updated.

2.4.2. Monograph on Matricariae flos and supporting documents

Action: For adoption

Document tabled: Review report

Outcome:

HMPC agreed with Rapporteur's position to revise the EU herbal monograph because new data were detected that require 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 Matricariae flos.
The review report was adopted and HMPC tracking documents will be updated.

2.4.3. Monograph on Melaleucae aetheroleum and supporting documents

Action: For adoption

Document tabled: Review report

Outcome:

Adoption postponed.

Rapporteur to modify the review report according to the discussion and comments from peer-reviewer for **possible adoption** at the **HMPC July 2023** meeting.
Relevance of new safety data for the human situation including quotation of appropriate guidance to be reworded with support of peer-reviewer and toxicologists for a final view on the need to update monograph and list entry.

Timetable:
Documents to be sent to Peer-reviewer: **12 June 2023**
Peer-review documents to be sent to Rapporteur: **26 June 2023**
Final documents to be included latest in 2nd premail: **10 July 2023**

Some HMPC members pointed out that additional information on the NOAEL value calculation for the oromucosal use should be included in the review report, in order to confirm the safe use, considering the existence also of an EU list entry. The conversion of animal data to the human situation was calculated based on an FDA guideline for which the availability of a EU equivalent should be double-checked. The Rapporteur highlighted that

the use of tea tree oil during pregnancy and lactation is not recommended (monograph section 4.6. Fertility, pregnancy and lactation) and although the information on oromucosal absorption is not known, it is expected that when used as a gargle, the exposure is lower than from oral use.

2.4.4. Monograph on Myrtilli fructus siccus and supporting documents

Action: For adoption

Document tabled: Review report

Outcome:

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

2.4.5. Monograph on Myrtilli fructus recens and supporting documents

Action: For adoption

Document tabled: Review report

Outcome:

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

2.4.6. Monograph on Ricini oleum and supporting documents

Action: For adoption

Document tabled: Review report

Outcome:

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

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

2.4.8. Monograph on Sisymbrii officinalis herba and supporting documents

Action: For adoption

Document tabled: Review report

Outcome:

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

2.5. 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 Cisti cretici herba and supporting documents

Action: For discussion

Documents tabled: MO, AR

Outcome:

Adoption postponed.

Rapporteur to introduce changes in the draft monograph and assessment report according to the discussion and to send the package to the peer-reviewer. On two issues presented by the Rapporteur, the HMPC gave a clear way forward after discussion.
HMPC members were invited to send to the Rapporteur any information necessary for the completion of the draft monograph acknowledging some data gaps in the posology/TU documentation, while streamlining of the draft AR may be considered before or after PC.

Following agreement between Rapporteur and Peer reviewer, draft monograph to be tabled for release for public consultation at the **HMPC July 2023 meeting** unless major issues with relevance for the monograph content are detected.

Regarding the available data supporting the 30 years of tradition, the Rapporteur emphasised that this MO is exclusively focused on the decoction herbal tea, 10 g, 3 times daily, only for oral use, that is popular and used widely in Greece, even though unambiguous documentation for the posology as in other cases such as on the daily dose is not available and derived indirectly from various sources.
As in previous cases, unpublished toxicological data on specific preparations provided to HMPC for use in the assessment will be quoted accordingly in the LoR when used/mentioned in the AR, in line with the standard policy.

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. Public statement on use of herbal medicinal products containing estragole (EMA/HMPC/137212/2005 Rev 1)

Action: For adoption

Document tabled: Public statement –correction 1

Outcome:

Correction 1 to the public statement (with three additional footnotes in Table 1) adopted by consensus.

The HMPC welcomed and approved the footnotes to Table 1 as correction following feedback that the presented selection of estragole – containing plants based on EFSA publications may be misleading in national procedures when taken out of context.
It was emphasised that there are no changes to the assessment and toxicological conclusion of the HMPC or any modifications in the text of the PS, apart from those necessary clarifications/disclaimers with regard to Table 1.

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

Action: For discussion

Document tabled: Concept paper, OoC, presentation

Outcome:

Rapporteur to prepare a first draft of the revised guideline for the next HMPC meeting and discuss with the Co-Rapporteur.
An additional list of potential issues or work sheet for details maybe provided taking into account to be used as annex to the guideline.
Next **discussion** scheduled at the **HMPC July 2023** meeting.

The Rapporteur summarised her view on comments received and selected points for consideration by HMPC concerning the multicomponent nature, reflections on testing / data interpretation for pharmaceuticals and on limits for genotoxic impurities, as well as strategic approaches by *in silico* tools.
The Co-Rapporteur emphasised the overall relevance of pharmaceutical and ICH standards despite interesting new developments in related areas such as food or environmental toxicology.
In addition, it was reminded that the Concept Paper already foresees that after a draft revised GL is agreed by the HMPC, the Non-Clinical Working Party will be involved.

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 information

Outcome:

A draft revised guideline by the GACP DG has been provided for comments to the Quality DG members. Following further discussions at both groups an agreed draft will be provided to the HMPC for comments and endorsement before further coordination with the Inspectors group.
(See also topic 4.4.2)

4.3. Regulatory / Procedural

4.3.1. Procedure for the preparation of Monographs/List Entries

Action: For discussion

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

Outcome:

The Rapporteur summarised that regarding the procedure no comments were received after HMPC March meeting, and the only change introduced in the meantime is the figure 1, i.e. process flow map of the procedure and anticipated timelines.
HMPC endorsed the extended role of the Peer-reviewer.
Following internal review and completion by the secretariat, **adoption** is foreseen at the **HMPC July 2023** meeting.

4.4. Report on HMPC Drafting Groups activities

4.4.1. ORGAM DG

None

4.4.2. Quality DG

Report: Nicoleta Carmen Purdel

Action: For information

Documents tabled: Minutes, QDG proposal on CEP

Outcome:

HMPC noted the start of the Quality domain implementation with current main focus on QWP (including herbal expertise) and BWP membership and set up, while the implementation of the Herbal DG is scheduled to start earliest in September 2023 (mandate, 3-year work plan etc.).
HMPC endorsed comments on a QWP Q&A for applicants on a question related to herbal CEPs.
A first discussion took place on the GACP guideline currently for comments for further discussion at the QDG June meeting.

HMPC noted that there are several open questions with regard to herbal CEPs such as on determination of substances of concern, that will require further coordination with EDQM and that may also be addressed in the herbal-specific Q&A currently under revision.

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 May 2023

  Report: HMPC Vice Chair

  Action: For information

  Document tabled: Follow-up plan

  Outcome:

  Some topics of the extensive programme at the Swedish SRLM were added to the follow up plan for later pick up for the next HMPC work plan or detailed discussions under the Spanish Presidency of the Council of the European Union.

- Swedish Presidency meeting – 18-19 April 2023

  Report: Karin Erika Svedlund

  Action: For discussion

  Document tabled: Final Agenda, presentations

  Outcome:

  The HMPC Chair emphasised the excellence of the SRLM organised by the Swedish Presidency of the Council of the European Union that was held on 18-19 April 2023.
  Also the HMPC Chair thanked the organisers for the intense and interesting programme and speakers' contributions.
  Members were encouraged to read presentations provided and take into account for future

discussions including the next SRLM under the Spanish Presidency of the Council of the European Union.

- Spanish Presidency meeting – 09-10 October 2023

  Report: Olga Palomino

  Action: For discussion

  Outcome:

  The draft agenda for the next SRLM to be organised by the Spanish Presidency of the Council of the European Union in October 2023 will be presented at the HMPC July 2023 meeting, taking into account some discussions held at the previous SRLM under the SE Presidency and other recent developments relevant for the future of the HMPC.

5.1.2. HMPC membership

Report: HMPC Chair

Action: For information

Outcome:

Re-nominated members:

- Netherlands, Burt Kroes (member) as of 01 May 2023

End of membership:

- Luxemburg, Jane Murray (alternate) as of 03 May 2023

5.1.3. New Experts Management Tool / EMA

Action: For information

Document tabled: Presentation

Outcome:

HMPC was briefed on the updated EMA Policy on the handling of competing interests of scientific committees' members and experts (0044), mainly for implementation of the new Medical Device and in vitro Medical Device Regulations (Regulations (EU) 2017/745 and 2017/746) and of the EMA's Extended Mandate Regulation (Regulation (EU) 2022/123). Also a demo of the new experts management tool was given to the HMPC members.

Several technical questions on experiences were raised and responded to.

5.1.4. HMPC traineeship project: revision of the Q/A document on the EU framework for (T)HMPs

Action: For information

Document tabled: Presentation

Outcome:

HMPC was briefed on the HMPC traineeship project currently ongoing: revision of the Q/A document on the EU framework for (T)HMPs.
The HMPC Chair and two HMPC members volunteered to take part in the review process of this Q/A document.

5.1.5. 100th HMPC meeting celebration

Report: HMPC Chair

Action: For information

Outcome:

The HMPC Chair highlighted key milestones achieved by the Committee since its introduction with Directive 2004/24/EC and acknowledged the contribution of various Chairs as well as some long-serving members being part of the group from the very beginning.

5.2. EMA Scientific Committees or CMDh-v

None

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

None

5.4. Cooperation within the EU regulatory network

5.4.1. Coordination with European Pharmacopoeia

- 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

  Document tabled: SoD

Outcome:

The HMPC noted the summary of decisions from the April 2023 13B group meeting (next meeting in September 2023) with particular emphasis on the new monograph on Cannabis flos that is foreseen to be presented to the Commission in June 2023.
Also the ongoing work following the April 2023 TCM group meeting (next meeting in September 2023) was presented.

HMPC Chair and members enquired further details on some topics including on a wording with regard to quality requirements (heavy metals) for cannabis according to the status/use of the herbal substance that may cause confusion, on a quantified extract of *Dioscorea*

nipponica, and on the intention to possibly add a method for toxic substances of concern (pulegone, estragole, thujone) to the work programme following a survey among MSs which was welcomed.

5.4.2. Coordination with the European Commission

5.5. Cooperation with International Regulators

5.5.1. India — EC/EMA joint technical working group on Ayurveda

Report: HMPC Chair

Action: For information

Document tabled: Agenda meeting held on 29 March 2023

Outcome:

HMPC was briefed on topics on agenda of the 2nd meeting of the INDIA — EC/EMA Joint Technical Working Group on Ayurveda. The report will be distributed for information once available and agreed.

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 2023

Report: HMPC Chair

Action: For discussion

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

Outcome:

The HMPC members noted current status of projects, monographs and guidelines.

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

Action: For discussion

Outcome:

The Rapporteur pointed out that the draft "discussion paper on data requirements for traditional herbal medicinal products and herbal medicinal products used in children and adolescents" is foreseen to be presented for discussion at the HMPC July 2023 meeting following another group meeting.

The HMPC Chair emphasised the long-standing expectations by Interested Parties in this topic and welcomed an early distribution of the draft for a focused discussion of specific questions in July.

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

  Action: For information

  Outcome:

  The Rapporteur presented the main first conclusions on the workshop embedded in the SRLM organised by the Swedish Presidency of the Council of the European Union that was held on 18-19 April 2023.
  (See also topic 5.1.1.).

  The Rapporteur briefly presented the workshop subject and an overview of the group discussions that followed interesting presentations on borderline issues during the HMPC SRLM. Two questions had been discussed: 1) the usefulness of the information in EU herbal MOs and ARs on borderline issues; 2) identify/clarify the role/contribution of HMPC. Written summaries will be provided for the HMPC July meeting.

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

  Action: For discussion

  Outcome:

  The Rapporteur highlighted the successful collaboration with EDQM in hosting the last training for herbal medicinal products (via EU NTC herbal curriculum) that was held on 27 April 2023.
  As next topic for preparation 'Microbiological testing/contaminants' was agreed by the steering group. QDG will discuss who will prepare this training.

- (2.3.1) Implement new working methodology for HMPC – new main procedure and revised template documents

  Action: For discussion

  Documents tabled: Draft revised AR template with comments, Reader's guidance

  Outcome:

  The Rapporteurs reported work in progress with a more mature draft to be provided for the July meeting and after HMPC agreement possibility for using/user-testing the modified AR template.
  The HMPC agreed to keep the possibility for an 'Assessors' comment box' on single items (not summarising chapters) and have some standard wordings for the Eudravigilance check.

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 and supporting documents

Action: For 3rd discussion

Documents tabled: Reader's Guidance, OoC, references, presentation

Outcome:

The HMPC agreed on important questions following comments and suggestions received during public consultation.
Rapporteur to introduce changes accordingly 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 July 2023** meeting.

The Rapporteur highlighted that comments received during the public consultation are related to sections 2, 4.2, 5.3 and 6 of both monographs. The HMPC supported the Rapporteur's opinion for not including "Tolerance values" in section 6 "Pharmaceutical particulars» for various reasons, neither comminuted fruits in section 2 under «herbal preparations». HMPC members also supported the Rapporteur's suggestion to maintain only the lower daily dose of 4.5 g of fruits as a herbal tea for adolescents (12-18y) and adults to keep the estragole intake "as low as practically achievable" in accordance with the HMPC public statement (the same approach is suggested for children). Monograph on Foeniculi dulcis fructus and supporting documents

Action: For 3rd discussion

Documents tabled: Reader's Guidance, OoC, references, presentation

Outcome:

See topic 6.1.1.

6.1.2. Monograph on Foeniculi amari fructus aetheroleum and supporting documents

Action: For 1st discussion

Documents tabled: Reader's Guidance, OoC, references, presentation

Outcome:

Rapporteur to introduce changes in the draft public statement on bitter fennel oil and supporting documents according to the discussion of comments received and possible additional comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC July 2023** meeting.

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

6.2.1. Monograph on Eucalypti aetheroleum and supporting documents - postponed

6.2.2. Monograph on Lavandulae aetheroleum and supporting documents

Action: For 10th discussion

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

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.
A small group was set up to support the Rapporteur in completing the draft revised monograph by 15 June 2023.
As second step, Rapporteur to adapt, reduce and rationalise information in the AR before it goes for peer review.
Next **discussion** scheduled at the **HMPC July 2023** meeting.

The Rapporteur summarised changes introduced in the AR and draft MO, highlighting that the WEU is maintained and supported by clinical evidence. Monograph on Pelargonii radix and supporting documents

Action: For 7th discussion

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

Outcome:

Rapporteur to introduce changes in the draft revised EU herbal monograph and supporting documents according to the discussion and possible further comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC July 2023** meeting.

The HMPC noted the Rapporteur's proposal regarding the wording of the therapeutic indication, and the rationale to include children from 3 years of age. HMPC members discussed the available data for children, old and new therapeutic approaches for the use of expectorants in general, available therapeutic alternatives and diversity in the Member States in this regard. Reference was also made to the ongoing work plan project to rationalise/ harmonise principles for data requirements for children (see 5.7.1).

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

Action: For 3rd discussion

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

Outcome:

Rapporteur to introduce changes in the draft revised EU herbal monograph and supporting documents according to the discussion and possible further comments from peer-reviewer and HMPC member, for **possible adoption** for public consultation at the **HMPC July 2023** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **12 June 2023**
Peer-review documents to be sent to Rapporteur: **26 June 2023**
Final documents to be included latest in 2nd premail: **10 July 2023**

The Rapporteur summarised changes included in the MO (modification of the wording in section 4.5 upon proposal of FI, agreement by Peer-reviewer) and in the AR (addition of publications in the non-clinical pharmacology and deletion of the detailed list of Eudravigilance reports in chapter 5.3.).

6.2.4. Monograph on Urticae herba and supporting documents

Action: For 3rd discussion

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

Outcome:

Rapporteur to introduce changes in the draft revised EU herbal monograph and supporting documents according to the discussion and possible further comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC July 2023** meeting.

The Rapporteur emphasised that changes in the wording of the therapeutic indication, warnings and contraindications are related to the ongoing cross-monographs harmonisation for EU monographs with information on adequate fluid intake.
(See also topic 6.3.4)

6.2.5. Monograph on Urticae radix and supporting documents - postponed

6.2.6. Monograph on Zingiberis rhizoma and supporting documents

Action: For 6th discussion

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

Outcome:

Rapporteur to introduce changes in the draft revised EU herbal monograph and supporting documents according to the discussion and possible further comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC July 2023** meeting.

Regarding the limited quality of studies supporting the WEU therapeutic indication from todays' perspective, the HMPC agreed to include by analogy a statement as used before in the revised AR for the combination herbal product valerian root + hop strobile. On some discrepancies regarding WEU posology versus TU posology for motion sickness, the HMPC noted the Rapporteur position to keep as it was in 2012 despite some detected data gaps yet explain in the AR on what rationale the WEU posology is based on and how a positive benefit-risk assessment can be sustained. Finally, for the newly added TU indications, the Rapporteur asked Member States to provide possible data to support the uptake of three indications (temporary loss of appetite, minor articular pain, symptoms of common cold) into the monograph.

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

6.3.1. Monograph on Capsici fructus and supporting documents

Action: For 2nd discussion

Document tabled: Review report

Outcome:

Rapporteur to eventually modify the review report according to any additional information from HMPC members regarding information available supporting a traditional use and conclude accordingly on the need for revision. HMPC members to provide all information available from marketed products.
Rapporteur to finalise the review report according to data obtained and conclude on 'no revision' or 'revision' and send for peer review before possible **adoption** at the **HMPC July 2023** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **12 June 2023**
Peer-review documents to be sent to Rapporteur: **26 June 2023**
Final documents to be included latest in 2nd premail: **10 July 2023**

The Rapporteur highlighted that even though products with the WEU indication of 'diabetic polyneuropathy' are now available on the EU market (e.g. in Germany), the required data to include this therapeutic indication for concentrations which are not part of clinical trials are not publicly available.
HMPC members were invited to identify possible products with lower Capsicum strength on their markets that may qualify for TU according to the applicable regulatory framework.

6.3.2. Monograph on Ononidis radix and supporting documents

Action: For 3rd discussion

Document tabled: Review report, Reader's guidance

Outcome:

Rapporteur to modify the review report according to the discussion and possible additional comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC July 2023** meeting.

Regarding the revision of MO sections 4.1, 4.3 and 4.4, the Rapporteur and Peer-reviewer were invited to follow the conclusions from the ongoing discussion on the issue of fluid intake restrictions in defined patients groups (with heart insufficiency, kidney injury), for monographs with a diuretic indication.
(See also topic 6.3.4)

6.3.3. Monograph on Origani majoranae herba and supporting documents

Action: For 3rd discussion

Document tabled: Review report

Outcome:

HMPC endorsed the Rapporteur's position that there is no new information available that could change the content of the EU herbal monograph/list entry.
Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC July 2023** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **12 June 2023**
Peer-review documents to be sent to Rapporteur: **26 June 2023**
Final documents to be included latest in 2nd premail: **10 July 2023**

6.3.4. Monograph on Pilosellae herba cum radice and supporting documents

Action: For 2nd discussion

Document tabled: Presentation

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 July 2023** meeting.

The Rapporteur highlighted that rational for eventual revision of this monograph is related to the ongoing harmonisation exercise of the information under MO sections 4.1, 4.3 and 4.4 on the issue of fluid intake restrictions in defined patients groups (with heart insufficiency, kidney injury), for monographs with a diuretic indication.
An additional breakout session with Rapporteurs in charge of monographs with the therapeutic indication "Traditional herbal medicinal product used to increase the amount of urine to achieve flushing of the urinary tract (as an adjuvant) in minor urinary tract complaints" to be organised for preparing a draft proposal for harmonisation of those monographs.

6.3.5. Monograph on Polygoni avicularis herba and supporting documents

Action: For 3rd discussion

Document tabled: Review report

Outcome:

Rapporteur to modify the review report according to the discussion and possible additional comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC July 2023** meeting.

Regarding the revision of MO sections 4.1, 4.3 and 4.4, the Rapporteur and Peer-reviewer were invited to follow the conclusions from the ongoing discussion on the issue of fluid intake restrictions in defined patients groups (with heart insufficiency, kidney injury), for monographs with a diuretic indication.
(See also topic 6.3.4)

6.3.6. Monograph on Pruni africanae cortex and supporting documents

Action: For 1st discussion

Document tabled: Presentation

Outcome:

Rapporteur to prepare a first draft of the review report for discussion at **HMPC July 2023** meeting.

The Rapporteur summarised that there are no new products on the EU market and from the search of literature no relevant new information was founded.
HMPC members were invited to send any additional information if available.

6.3.7. Monograph on Rosae flos and supporting documents

Action: For 1st discussion

Document tabled: Presentation

Outcome:

Rapporteur to prepare a first draft of the review report for discussion at **HMPC July 2023** meeting.

The Rapporteur summarised that there are no new products on the EU market and from the search of literature no relevant new information was founded.
HMPC members were invited to send any additional information if available.

6.3.8. Monograph on Sideritis herba and supporting documents

Action: For 1st discussion

Document tabled: Presentation

Outcome:

Rapporteur to prepare a first draft of the review report for discussion at **HMPC July 2023** meeting.

The Rapporteur summarised that there are no new products on the EU market and from the search of literature no relevant new information was founded.
HMPC members were invited to send any additional information if available.

6.3.9. Monograph on Symphyti radix and supporting documents - 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 Hyperici herba/Cimicifugae rhizoma and supporting documents

Action: For 5th 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.
A majority of members supported the inclusion of a second combination product registered in 11 Member States despite minor gaps in the documentation available to the Rapporteur.
Next **discussion** scheduled at the **HMPC July 2023** meeting.

The Rapporteur highlighted that as regard to warnings, interactions, adverse events according to mono-components MOs/SmPCs, all data is now included in the AR.
Regarding herbal preparations under TU, Rapporteur also to include the preparation b) with a reliable justification based on the regulatory procedures/legislative framework. HMPC members discussed issues arising from the assessment of the combination such as available data for the single substances/preparations and their transferability to the combination in terms of evidence of use, non-clinical data, safety/PhV (both substances on the EURD list), therapeutic indication (specific marketed combi products vs. single substance monographs) as well as posology and regulatory status.

6.5.2. Monograph on Tribuli terrestris herba and supporting documents - postponed

7. Any other business

7.1. Topics for discussion

7.1.1. Feedback - Pharmacovigilance herbal MP conference at Kew Gardens, 13-14 April 2023

Action: For discussion

Documents tabled: Programme, report, presentation

Outcome:

The HMPC Vice-Chair summarised the agenda and main outcomes after her participation in the Pharmacovigilance herbal MP conference at Kew Gardens in representation of the HMPC.

Some interesting aspects from the conference were highlighted. For instance, since case reports for herbal products could potentially be related to an adulterated or falsified product, sufficient information is required for unambiguous identification including but not only linked to the correct scientific botanical name to increase the quality of case reports for herbal products. It was also considered that there is a need for EMA guidance on signal detection for herbal medicinal products, related to the special features for herbal substances/preparations; regulatory requirements, in particular quality requirements (including GMP/GACP). Overall conference participants concluded that the pre-market assessment and pharmacovigilance are very important for the safety of (good quality) herbal products.

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

Action: For discussion

Document tabled: Draft programme

Outcome:

HMPC confirmed support to the Vice-Chair participation in the Society for Medicinal Plant Research (GA) conference Dublin.
The presentation will be based on the presentation given in the Pharmacovigilance herbal MP conference at Kew Gardens. Any comments/corrections should be sent to the Vice Chair.

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 13-15 March 2023

Overview of expertise of members HMPC and subgroups

Inventory of herbal substances for assessment work

Abbreviations in HMPC agendas/minutes

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 – report update

- COMMISSION REGULATION (EU) 2023/648 of 20 March 2023 authorising a health claim made on foods and referring to the reduction of disease risk: a combination containing a standardised artichoke leaf dry extract, monacolin K in red yeast rice, standardised garlic extract and others 'reduces blood LDL-cholesterol concentrations' (based on EFSA assessment Q-2012-00968; https://www.efsa.europa.eu/en/efsajournal/pub/3327).

- ## List of participants

List of participants including any restrictions with respect to involvement of members/ alternates/experts following evaluation of declared interests for the 10-12 May 2023 meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Reinhard Länger	Member	Austria	No interests declared	
Astrid Obmann	Alternate	Austria	No interests declared	
Patricia Bodart	Member	Belgium	No interests declared	
Gert Laekeman	Co-opted member	Belgium	No interests declared	
Iliana Ionkova	Member	Bulgaria	No interests declared	
Radina Dimitrova	Alternate	Bulgaria	No interests declared	
Ivan Kosalec	Member	Croatia	No interests declared	
Darko Trumbetic	Alternate	Croatia	No interests declared	
Christina Sylvia Chrysostomou	Member	Cyprus	No interests declared	
Markéta Příhodová	Member	Czechia	No restrictions applicable to this meeting	
Nanna Lundgaard Rasmussen	Alternate	Denmark	No interests declared	
Maria Paile Hyvarinen	Member	Finland	No interests declared	
Sari Koski	Alternate	Finland	No interests declared	
An Le	Member	France	No interests declared	
Jacqueline Wiesner	Member	Germany	No interests declared	
Susanne Flemisch	Alternate	Germany	No interests declared	
Heidi Foth	Co-opted member	Germany	No interests declared	
Ioanna Chinou	Member	Greece	No interests declared	
Stavroula Mamoucha	Alternate	Greece	No interests declared	
Julia Pallos	Member	Hungary	No restrictions applicable to this meeting	
Rita Nemeth	Alternate	Hungary	No interests declared	
Sarah Kellaghan	Member	Ireland	No interests declared	
Jacqueline Masterson	Alternate	Ireland	No interests declared	
Alessandro Assisi	Member	Italy	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Anna Maria Serrilli	Alternate	Italy	No interests declared	
Inga Sile	Member	Latvia	No interests declared	
Asta Kubiliene	Alternate	Lithuania	No interests declared	
Sven Back	Member	Luxembourg	No interests declared	
Emiel Van Galen	Chair	Netherlands	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	
Wojciech Dymowski	Member	Poland	No interests declared	
Ana Paula Martins	Member	Portugal	No interests declared	
Maria Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared	
Maria da Graca Ribeiro Campos	Co-opted member	Portugal	No interests declared	
Carmen Purdel	Member	Romania	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	
Malin Kyllikki Hobro Soderberg	Alternate	Sweden	No interests declared	
Melanie Bald	Observer	EDQM	No interests declared	
Meeting run with support from relevant EMA staff				