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SCIENCE MEDICINES HEALTH

24 July 2024
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Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 27-29 May 2024

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

Health and safety information

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

Disclaimers

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

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

Note on access to documents

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1. Introduction

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

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

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

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

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

The Chair welcomed the re-nominated members.

As per provisions in article 2 of the [Rules of Procedure](#), the Vice-Chair deputised for the Chair during the second and the third days of the meeting (28-29 May). Whilst chairing the meeting, the Vice-Chair assigned her voting rights to another delegate (proxy voting).

1.2. Adoption of agenda

HMPC agenda for 27-29 May 2024.

Outcome:

Agenda and time schedule adopted.

1.3. Adoption of the minutes

HMPC minutes for 18-20 March 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 May 2024

Report: HMPC Chair

Action: For discussion

Document tabled: Overview

Outcome:

HMPC noted the status of assessment work.

The HMPC Chair emphasised that only assessments that are almost complete (i.e., with no fundamental comments still to be resolved) should be tabled for adoption, otherwise they should be kept for further discussion. In case of postponement of topics scheduled for the HMPC July 2024 meeting according to the overview, Rapporteurs were asked to inform the Committee secretariat and Chair before the first pre-mail (by 8 July 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

Outcome:

Rapporteurs and Peer-reviewers were appointed.

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

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

Action: For adoption

Documents tabled: PS, AR, LoR, OoC, Reader's Guidance, References 11/155

Outcome:

Final public statement and supporting documents adopted by consensus.

The Rapporteur emphasised that the OoCs has been updated, mainly editorial changes. Moreover, the AR has been updated according to the outcome of the discussion during the March meeting. No changes have been made to the PS since it was previously discussed by the HMPC.

Some HMPC members pointed out that trademarks of medicinal products should be avoided in the AR.

2.2.2. Monograph on *Ginseng radix* and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR, Reader's Guidance, References 34/376

Outcome:

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

Divergent opinions: Ireland, Netherlands, Poland.

The Rapporteur highlighted that AR has been finalised according to the outcome of the discussion during the March meeting, and a short summary of the main changes introduced

in revision 1 was included in the AR chapter 1.3. Moreover, the LoR has been updated and an editorial updating of AR and MO was also performed considering the recently adopted templates.

Some HMPC members emphasised that other components could also be considered as contributing to the pharmacological effects of ginseng, and not only the ginsenoside-metabolites.

2.2.3. Monograph on *Pelargonii radix* and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR, Reader's Guidance, References 8/109

Outcome:

Final revised EU herbal monograph and supporting documents adopted by majority.
Divergent opinions: Finland; Ireland; Italy; Netherlands.

The Rapporteur summarised the OoCs received during public consultation, some of which regarding the in-vitro studies to be considered in the AR. Moreover, the inclusion of the paediatric group 3-5 years into the target populations, based on the broad long-standing safe therapeutic use of pelargonium root, was also emphasised.

The HMPC Chair pointed out the ongoing RWD/RWE pilot study on pelargonium, which results may be analysed when available and conclusions reflected in the EU herbal MO, if found necessary.

Some HMPC members pointed out the comments received during the public consultation about the information on liver disorders that should be replaced by hepatotoxicity in the MO section 4.8 Undesirable effects, which was never included in the monograph.

2.2.4. Monograph on *Rosmarini aetheroleum* and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR, Reader's Guidance, References 6/91

Outcome:

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

The Rapporteur highlighted the deletion in the MO of the liquid preparation as an aid in healing of minor wounds and the inclusion of the contraindication 'do not apply to broken or irritated skin' in section 4.3. Moreover, it was pointed out that the warning included in the MO section 4.4 regarding the use in children and adolescents under 18 years of age is based on the lack of adequate data.

2.2.5. Monograph on *Rosmarini folium* and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR, Reader's Guidance, References 15/91

Outcome:

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

The Rapporteur pointed out that warning in the MO section 4.4 not recommending use as a bath additive in children under 12 years of age because medical advice should be sought, is related to the indication itself as included in the original MO.

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

2.3.1. Monograph on *Urticae herba* and supporting documents

Action: For adoption

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

Outcome:

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

The Rapporteur emphasised that for the indication 1) 'relief of symptoms associated with minor urinary complaints', the preparation a) is for adults/elderly only, but the other preparations are for adolescents as well; the posology was adjusted, as British Herbal Pharmacopoeia has no posology at all, and Bradley (1992) includes a posology only for rheumatic conditions (not as a diuretic). Moreover, and for indication 2) 'relief of minor articular pain', it was proposed to change the warning under the MO section 4.4. justifying the non-recommendation for using in children and adolescents under 18 years of age, i.e., lack of adequate data.

2.3.2. Monograph on *Urticae radix* and supporting documents

Action: For adoption

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

Outcome:

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

The Rapporteur summarised that in the MO the posology for the comminuted herbal substance has been adapted accordingly with the existing posology from products on the EU market. Moreover, the MO section 4.8 'Undesirable effects' has been updated reflecting consistently with the SOC terminology as per recommendations in the EC guideline on SmPC ('adverse reactions descriptions should be based on the most suitable representation within the MedDRA terminology').

2.3.3. Monograph on *Zingiberis rhizoma* and supporting documents

Action: For adoption

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

Outcome:

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

The Rapporteur emphasised that an unpublished study report on ginger extract has been deleted in the AR (similar approach in the past for unpublished studies). Moreover, the LoR have been updated accordingly and no changes have been made in the MO.

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

None

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, Reader's Guidance

Outcome:

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

The Rapporteur summarised that the AR has been revised according to the outcome of the discussion during the March meeting (section about constituents has been shortened; explanatory note under table 4 has been deleted; overall conclusion on clinical pharmacology has been shortened). The MO has not been changed. Moreover, it was clarified that the method of preparation and posology (2-6 g in 200 mL) are based on the product information together with the information in the monograph on tisanes from the French Pharmacopoeia and are in line with the traditional herbal literature.

2.6.2. Monograph on *Tribuli terrestris* herba and supporting documents

Action: For adoption

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

Outcome:

Draft public statement and supporting documents adopted for 3 months public consultation.

The Rapporteur highlighted that the AR and PS have been revised to emphasise that products on the market may not be sufficiently characterised, and information about a long-standing safe medicinal use according to a specific indication, strength and posology is considered insufficient. This also includes the use of *Tribulus terrestris* based on a non-European tradition. Furthermore, data supporting a recognised efficacy are not available as published data.

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

None

4.2. Quality

None

4.3. Regulatory / Procedural

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

Action: For adoption

Documents tabled: Draft revised HMPC best practice guide, Reader's Guidance

Outcome:

Final revised HMPC best practice guide adopted by consensus.

The Rapporteur emphasised that adoption of this revised document will 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). Moreover, it was pointed out that important information has been included on the procedures for establishment of MO/LE, review/revisions, and in the AR/MO templates.

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

Report: HMPC Chair

Action: For discussion

Document tabled: Draft reflection paper

Outcome:

Rapporteurs to review comments received from PDCO and update the draft reflection paper. Next discussion scheduled at the HMPC July 2024 meeting.

The Rapporteur summarised the main points discussed by the PDCO members, mainly regarding the extrapolation question sent by the HMPC.

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 HMPC members noted the ongoing activities of the QDG according to the 3-year plan.

Considering the experience gained in the last years, the QDG agreed to keep the quality topic in the HMPC annual work plan and not as a separate/independent document.

Moreover, the HMPC members were reminded about the call for providing information on the guidance on comparability between preparations.

The HMPC agreed to have a call for nominations of a quality expert to join the QDG replacing a current member that is about to leave the group.

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 2024

Report: HMPC Vice-Chair

Action: For information

Document tabled: Follow-up plan

Outcome:

The HMPC members were informed that the follow-up plan has been updated after the 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

Outcome:

The HMPC members noted a summary of the HMPC-SRLM organised by the Belgian Presidency of the Council of the European Union on 24-25 April 2024 in Louvain-la-Neuve (first day: focus on borderline products (medical devices, food supplements containing herbals, homeopathic medicinal products containing mother tinctures), herbal medicines

and anti-infective activity; second day: focus on HMPC core-business, EU NTC herbal curriculum prioritisations and RWD/RWE in herbal medicines assessment).

Documents tabled: Agenda, Presentations

- Hungarian Presidency meeting

Report: Julia Pallos, Rita Nemeth

Action: For information

Outcome:

The HMPC members were informed that the decision to hold a HMPC SRLM organised by the Hungarian Presidency of the Council of the European Union is waiting for formal approval.

5.1.2. HMPC membership

Report: HMPC Chair

Action: For information

Re-nominated members:

- Romania, Ligia Elena Dutu, (alternate) as of 21 June 2024
- Bulgaria, Iliana Ionkova, (member) as of 01 August 2024
- Luxembourg, Sven Back, (member) as of 06 September 2024

5.1.3. HMPC Co-opted members

- Appointment: Epidemiology - use of herbal medicinal products in children

Report: HMPC Chair

Action: For discussion

Documents tabled: Call for nominations, [Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC](#), Expertise of HMPC members

Outcome:

Appointment postponed (no nominations received).

Some HMPC members pointed out that the area of expertise could be broadened by using a keyword or even changed to another domain.

- Appointment: Clinical Pharmacology

Report: HMPC Chair

Action: For discussion

Documents tabled: Call for nominations, [Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC](#), Expertise of HMPC members

Outcome:

Maria da Graça Ribeiro Campos (Portugal) was appointed as co-opted member in the area of expertise "Clinical Pharmacology" for a 3-year mandate starting on 05 July 2024.

Maria da Graça Ribeiro Campos highlighted her extensive experience with patients in clinical situations involving medicines-herbal products interactions. As co-opted member of HMPC,

Prof. Ribeiro Campos has been involved in the Communication group and is familiar with the ongoing work of the HMPC and believe that her training can contribute to the development of MOs/LEs, and concluded that her experience will be useful in achieving the goal of providing more information to healthcare professionals, as well as patients, about interactions between herbal products and medicines.

5.1.4. Training on the Review procedure including Review Report Template and Peer-reviewer's tasks

Report: HMPC Vice Chair, Nicoleta Carmen Purdel

Action: For information

Document tabled: Presentation

Outcome:

The HMPC members attended the training session on the review procedure, including the rapporteur/peer reviewer's tasks and the review report template.

Because of constant scientific progress and evolution of regulatory frameworks, it was pointed out that MOs should be re-evaluated in a continuous process, and in this regard, the periodic review and, if necessary, the subsequent revision processes are essential to prevent EU herbal monographs from becoming outdated. The applicable main principles were summarised: step I - review of new data; step II - decision on relevance of new data and the need of revision; step III - revision or no revision. Some examples of relevant data that may trigger a revision were also identified: new safety issue (e.g., from literature, EudraVigilance, HMPC PS); new safety data supporting a list entry (e.g., genotoxicity data); new preparations fulfilling TU or WEU, including use in children; harmonisation to other MOs (e.g., ongoing 'diuretic' herbal monographs). The role of the Peer-reviewer as the HMPC gatekeeper when carefully checking the scientific conclusions and quality of the report was also highlighted (decision on the need for revision is taken by the HMPC, based on the peer-reviewed review report). Regarding the Rapporteur role it was highlighted the importance to submit clean (i.e., no track-changes, no comments) peer-reviewed review report to the HMPC plenary meeting(s). Moreover, it was emphasised that no reader's guidance is needed unless if there is a disagreement between Rapporteur and Peer-reviewer, or there is an important issue that needs to be discussed (the Rapporteur should use a reader's guidance and explain what is expected from HMPC members - to save recourses). The review report template, mainly how to use it and FAQs, was thoroughly presented to the HMPC members, highlighting how to populate it. Finally, it was presented how to use the reader's guidance (importantly, the Rapporteur should describe the issue/s for discussion and include a proposal on how to solve the issue).

5.1.5. Interim measures for scientific committees and other groups following the Hopveus appellate judgment

Report: HMPC Chair

Action: For information

Document tabled: Email

Outcome:

The HMPC members noted the interim measures for EMA's scientific committees and other groups that have been taken following the Hopveus appellate judgment.

5.2. EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair/Vice Chair

Action: For information

Documents tabled: Agenda, Minutes

Outcome:

The HMPC Vice-Chair summarised the most relevant topics on the agenda of the SciCoBo meeting held on 6 May.

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

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

Report: HMPC Chair

Action: For information

Outcome:

The HMPC members were reminded of the call for nominations still open for the ESEC position and were asked to identify potential candidates.

5.3.2. Revision of the Pharmaceutical Legislation / Variations Framework

Report: HMPC Chair/Vice Chair

Action: For information

Outcome:

The HMPC members were informed that for the ongoing review of pharmaceutical legislation, the level and the nature of all comments (herbal scope) received on the revision of the variations framework are still unknown (to be further confirmed).

5.4. Cooperation within the EU regulatory network

5.4.1. Coordination with European Pharmacopoeia

- 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 EDQM representative was not present at the meeting and, in this regard, the HMPC members were informed of the documents provided summarising the decisions of the 13B expert group meeting in April 2024 (next meeting in September 2024) and TCM expert group meeting in April 2024 (next meeting in October 2024).

5.5. Cooperation with International Regulators

5.5.1. EU/India Technical Working Group on Ayurveda

Report: HMPC Chair

Action: For information

Outcome:

The HMPC Chair informed the Committee about a request to hold the 3rd meeting of the EU/India Technical Working Group on Ayurveda and, in this regard, members were invited to propose topics of interest for discussion.

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

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

- AESGP hearing report 2023

Report: HMPC Chair

Action: For adoption

Document tabled: Report

Outcome:

AESGP hearing report 2023 adopted by consensus.

- HMPC response to AESGP request on Sennae revision

Report: HMPC Chair

Action: For adoption

Document tabled: Response letter

Outcome:

HMPC response to AESGP request on Sennae revision adopted by consensus.

- AESGP hearing 2024

Report: HMPC Chair

Action: For discussion

Outcome:

The HMPC members emphasised the importance of receiving the topics and presentations in sufficient time for the Committee to prepare the discussion.

Some HMPC members suggested that the Committee may also request feedback from AESGP for topics of interest and also the possibility to hold the meeting as face-to-face in Jan 2025.

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

Documents tabled: Draft paper, Draft paper commented, Reader's Guidance

Outcome:

Rapporteur to finalise the draft paper according to the discussion and possible further comments from HMPC members and EMA's Regulatory Affairs and Legal offices vis-à-vis the next steps, for possible endorsement for consultation at the HMPC July 2024 meeting.

The Rapporteur highlighted that the document has been reviewed by EMA's Regulatory Affairs and Legal offices, and some additional comments from the HMPC Chair. It has been asked to transfer the text into a EMA template, and in addition, changes in accordance with the comments received have been incorporated. Moreover, it was pointed out that the main achievement expected from this document is to highlight the extent and usefulness of the work (ARs, MOs) produced by the Committee.

- (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:

Rapporteur to introduce changes in the draft revised ARSP template according to the discussion and possible further comments from HMPC members.

Next discussion scheduled at the HMPC July 2024 meeting.

The Rapporteur summarised that in this 'proof of concept', the focus for whom the ARSP has been drafted was on patients only as a first step; the content is based on the data adopted and published in the MO and AR; tone and wording adapted to patients, clear, simple, complete and direct: focus on precautions of use and risks; and putting the highlights on some regulatory topics (type of authorisations WEU vs TU: efficacy or long standing use – still be discussed; role of SmPCs and national authorities; exclusion of other borderline products). As topics to be further discussed it was pointed out: the specific information for

healthcare professional's notably herbal-drug interactions – new topic; the format (about photos: even no major objections raised, copyright is concerned; about logos placed near the title, useful for a quick look information but the logos for medicinal products on packaging are not harmonised within the member states (see: NOTICE TO APPLICANTS, GUIDELINE ON THE PACKAGING INFORMATION OF MEDICINAL PRODUCTS FOR HUMAN USE AUTHORISED BY THE UNION - September 2023 - Final revision 14.8)). As the following steps, the Committee needs a general agreement about the key points of the 'proof of concept' presented; the new ARSP template proposal; how to manage the backlog of unpublished monographs.

The HMPC members noted the proposed changes to the current ARSP template for herbal substances in order to 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 the publication of ARSPs to be resumed. 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 to tackle 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 ARPS template.

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

Action: For discussion

Document tabled: Herbal curriculum priorities

Outcome:

The Rapporteur emphasised that the training on contaminants and residues included in the Herbal Curriculum training programme is now available via the EU-NTC LMS (pre-recorded training). Moreover, and following the HMPC-SRLM organised by the Belgian Presidency of the Council of the European Union, new proposals were included in the Herbal Curriculum priorities.

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

Document tabled: List of proposed combinations

Outcome:

Rapporteurs to finalise the draft list of proposed combinations according to the discussion and possible further comments from HMPC members, for possible endorsement at the HMPC July 2024 meeting.

The Rapporteur pointed out that, in the revised list, priority was given to fixed combination products fulfilling the 30-year criteria and including 2 (maximum 3) combined herbal substances.

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

None

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 2nd discussion

Documents tabled: Draft MO, AR, LoR

Outcome:

Rapporteur to introduce changes in the draft revised EU herbal monograph and supporting documents according to the discussion and possible further comments from peer-reviewer and HMPC members.

Next **discussion** scheduled at the **HMPC July 2024** meeting.

The Rapporteur summarised that confirmation is needed for herbal preparation n) if species *C. monogyna* or *C. oxyacantha* leaves and flowers are fully complying with the Ph. Eur. monograph – confirmed; for some products included in the market overview if the active substance is as *folium cum flore* – confirmed. Regarding the reported interaction with antiplatelet agents, information is given on this under the MO section 4.5. 'Interactions with other medicinal products and other forms of interaction' (also kept in the AR).

Some HMPC members pointed out that taking into account the risk of bleeding due to the potential interaction with antiplatelet agents, additional information should be given (e.g., use contraindicated when using with anticoagulant treatments), and in this regard it was agreed that further discussion is needed (contraindication vs warning; potential further action in connection with the EURD list).

6.2.2. Monograph on *Fragariae folium* and supporting documents

Action: For 3rd 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 July 2024** meeting.

The Rapporteur highlighted that wording of indication 1) is now aligned with the recently adopted cross-monographs harmonisation for the so-called 'diuretic herbal monographs'; posology for indications 1) and 2) have been updated to be consistent with the bibliographic data in the AR table 5. Moreover, clarifications were added in the AR table 6 on the herbal tea preparations strength and dosage.

Some HMPC members pointed out that regarding the use in children above 12 years of age for symptomatic treatment of mild diarrhoea (indication 2)), information on the posology (single and daily doses) should be included in the MO; also the special warning in the MO section 4.4. regarding patients with conditions where reduced fluid intake is advised should be shortened and aligned with the other 'diuretic herbal monographs'. Moreover, it was suggested to highlight this monograph to the EDQM for further development of a Ph. Eur. monograph.

6.2.3. [Monograph on Lavandulae aetheroleum and supporting documents](#)

Action: For 14th discussion

Documents tabled: Draft AR, Reader's Guidance

Outcome:

Rapporteur to introduce changes in the draft assessment report according to the discussion and possible further comments from peer-reviewer and HMPC members.

Next **discussion** scheduled at the **HMPC July 2024** meeting.

The Rapporteur summarised that table 17 in the AR chapter 4.1.1. with information on effects on the central nervous system and neuronal activity has been rearranged and shortened, with a summary text with essential information has been introduced as well, hopefully that the combination of both formats – text plus table – helps readability without losing information for in depth information. Moreover, one study was deleted because it was based on conference abstract only and had missing information.

Some HMPC members pointed out that for the aromatherapy topic a summary text would be sufficient (no table needed).

6.2.4. [Monograph on Liquiritiae radix and supporting documents \(postponed\)](#)

6.2.5. [Monograph on Ononidis radix and supporting documents](#)

Action: For 3rd discussion

Documents tabled: Draft MO, AR, LoR

Outcome:

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

Timetable:

Documents to be sent to Peer-reviewer: **21 June 2024**

Peer-review documents to be sent to Rapporteur: **03 July 2024**

Final documents to be included latest in 2nd premail: **15 July 2024**

The Rapporteur highlighted that the MO sections 4.1. 'Therapeutic indications', 4.2. 'posology and method of administration', 4.4 'Special warnings and precautions for use', are in line with the recently adopted cross-monographs harmonisation for the so-called 'diuretic herbal monographs'.

Some HMPC members pointed out that the AR table 1 with the overview of data obtained from marketed medicinal products, should reflect only the products currently on the market.

6.2.6. Monograph on *Plantaginis lanceolatae folium* and supporting documents

Action: For 5th discussion

Documents tabled: Draft MO, AR, LoR

Outcome:

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

Timetable:

Documents to be sent to Peer-reviewer: **21 June 2024**

Peer-review documents to be sent to Rapporteur: **03 July 2024**

Final documents to be included latest in 2nd premail: **15 July 2024**

The Rapporteur highlighted that the main remaining issue is related to the newly proposed therapeutic indication (oral use) and how to distinguish this indication 2) from the indication 1) (oromucosal use), as both are for upper tract respiratory infections.

Some HMPC members suggested the indication 2) to be updated as for the relief of symptoms of common cold associated with cough.

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 4th discussion

Documents tabled: Review report, Reader's Guidance

Outcome:

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

Rapporteur to finalise the review report (already peer-reviewed) for **adoption** at the **HMPC July 2024** meeting.

Final documents to be included latest in 2nd premail: **15 July 2024**

The Rapporteur pointed out that the review report has been updated with information relating to the footnote in the first AR, mentioning some higher percentage in mastic resin for cutaneous use. This footnote was in reference to preparations where mastic was dissolved in organic solvents, which are not nowadays permitted in the medicinal use due to their toxicity and therefore no data to support the inclusion of wider strength in the monograph.

6.3.2. Monograph on Lecithinum ex soya and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

HMPC endorsed the Rapporteur's position that there is relevant new information available that could change the content of the EU herbal monograph and therefore a revision of the complete package is advocated.

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

Timetable:

Documents to be sent to Peer-reviewer: **21 June 2024**

Peer-review documents to be sent to Rapporteur: **03 July 2024**

Final documents to be included latest in 2nd premail: **15 July 2024**

The Rapporteur summarised the PRAC conclusion that the product information of products containing soybean phospholipids (oral use) should be amended, and therefore this is considered relevant for the monograph.

6.3.3. Monograph on Soiae oleum raffinatum and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

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

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

Timetable:

Documents to be sent to Peer-reviewer: **21 June 2024**

Peer-review documents to be sent to Rapporteur: **03 July 2024**

Final documents to be included latest in 2nd premail: **15 July 2024**

The Rapporteur highlighted that despite the Ph. Eur. monograph on soya-bean oil, refined, has been updated in January 2024, the EU herbal monograph on soiae oleum raffinatum uses Ph. Eur. solely as quality standard reference and does not contain standardised preparations referring explicitly to a market in content and posology. Therefore, the updated Ph. Eur. monograph is considered not to trigger a revision of the monograph.

6.3.4. Monograph on Thymi herba and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

Rapporteur to modify the review report according to the discussion and possible additional comments from peer-reviewer and HMPC members.

Next **discussion** scheduled at the **HMPC July 2024** meeting.

The Rapporteur summarised that during the review period two countries have introduced information on possible adverse effects in the labelling of their thyme containing products based on national experiences. Two herbal medicinal products registered as traditional herbal medicinal products can also influence the content of the current monograph on *Thymus vulgaris* L., *T. zygis* L., herba.

Some HMPC members pointed out the need to get additional information regarding the use in children, and also information from EudraVigilance regarding the possible adverse effects.

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 3rd discussion

Outcome:

Postponed.

6.5.2. Monograph on Cisti cretici herba and supporting documents

Action: For 19th discussion

Documents tabled: Draft MO, AR, LoR,

Outcome:

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

Timetable:

Documents to be sent to Peer-reviewer: **21 June 2024**

Peer-review documents to be sent to Rapporteur: **03 July 2024**

Final documents to be included latest in 2nd premail: **15 July 2024**

The Rapporteur pointed out that it is still for confirmation the national common names and the plant part (leaf vs herb).

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

Action: For 9th discussion

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

Outcome:

Postponed.

6.5.4. Monograph on Maydis stigma and supporting documents

Action: For 2nd discussion

Documents tabled: Draft MO, AR

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 July 2024** meeting.

The Rapporteur highlighted the infusion and the decoction to be considered for the MO as information on full posology is available for both administrations.

Some HMPC members pointed out that description of the herbal substance should be done based on EU Pharmacopoeias. Moreover, the duration of use (1 week vs 2 weeks) should be clarified and aligned with the recently adopted cross-monographs harmonisation for the so-called 'diuretic herbal monographs'.

6.5.5. Monograph on Species pectoralis and supporting documents

Action: For 3rd discussion

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

Outcome:

Postponed.

7. Any other business

7.1. Topics for discussion

None

7.2. Documents for information

7.2.1. HMPC

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

- Webex telephone audio to be disabled on Monday 11th of March 2024
- Simultaneous National Scientific Advice (NSA) information and training webinar on 19th of April 2024
- Invitation to participate in EU NTC 10-year Anniversary event
- Joint HMA/EMA Big Data Steering Group Workshop on RWE methods
- [Draft reflection paper on the use of real-world data in non-interventional studies to generate real-world evidence](#)
- A comprehensive review on the hepatotoxicity of herbs used in the Indian (Ayush) systems of alternative medicine

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 27-29 May 2024 meeting, which was held in-person.

An asterisk (*) after the role, in the second column, signals that the member/alternate attended remotely. Additional experts participated in (part of) the meeting, either in-person or remotely.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Emiel Van Galen	Chair	Netherlands	No interests declared	
Astrid Obmann	Member	Austria	No interests declared	
Patricia Bodart	Member	Belgium	No interests declared	
Ivan Kosalec	Member	Croatia	No interests declared	
Darko Trumbetic	Alternate*	Croatia	No interests declared	
Christina Sylvia Chrysostomou	Member	Cyprus	No interests declared	
Markéta Příhodová	Member	Czechia	No restrictions applicable to this meeting	
Marie Heroutova	Alternate*	Czechia	No interests declared	
Nanna Lundgaard Rasmussen	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	
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	
Gabriele Balciunaite Murziene	Member	Lithuania	No interests declared	
Sven Back	Member*	Luxembourg	No interests declared	
Everaldo Attard	Member*	Malta	No interests declared	
Burt H Kroes	Member	Netherlands	No interests declared	
Hilda Kuin	Alternate	Netherlands	No interests declared	
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	
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	
Pierre Duez	Co-opted member	Belgium	No interests declared	
Heidi Foth	Co-opted member	Germany	No interests declared	
Maria Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared	
Maria da Graca Ribeiro Campos	Co-opted member	Portugal	No interests declared	
Peter Sisovsky	Expert	Slovakia	No interests declared	
Kristine Hvolby	Expert	Denmark	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.