20 July 2022
EMA/HMPC/563158/2022
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 16-18 May 2022

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

Health and safety information

In accordance with the Agency's health and safety policy, delegates are to be 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

Some documents mentioned in the set of minutes cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/729522/2016).

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1. Introduction

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

The Chair opened the meeting by welcoming all participants. Due to the current coronavirus (COVID-19) pandemic, and the associated EMA Business Continuity Plan (BCP), the meeting was held in-person with some members connected remotely (hybrid setting).

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 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 16-18 May 2022.

Outcome:

Agenda and time scheduled adopted.

1.3. Adoption of the minutes

HMPC minutes for 28-30 March 2022.

Outcome:

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

2. EU herbal monographs and list entries for adoption

2.1. Status of HMPC/MLWP activities

2.1.1. Overview of HMPC/MLWP assessment work including the Rapporteurship distribution – Status in May 2022

- Overview of HMPC/MLWP assessment work

  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 meeting according to the overview, Rapporteurs were asked to inform secretariat and Chair before the first pre-mail (by 05 July 2022) to allow best adaptation of agenda and time-schedule.

- Update on Vaccinii macrocarpi fructus for July meeting

  Report: HMPC Vice-Chair

  Action: For discussion

  Outcome:

  Considering the complexity of this package for Vaccinii macrocarpi fructus, a multi-expert team of experienced assessors was officially established to prepare the draft monograph and supporting documents (assessment report, list of references, overview of comments). First report is expected for the HMPC July meeting.

- Update on Hippocastani cortex

  Report: Wojciech Dymowski

  Action: For discussion

  Outcome:

  Postponed.

2.1.2. Appointment of Rapporteurs and Peer-reviewers

None

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

None

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

2.3.1. Monograph on Foeniculi amari fructus and supporting documents

Action: For adoption

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

Outcome:

Adoption postponed.

Rapporteur and peer-reviewer were invited to have the package ready by 10 June, for circulation to the HMPC, thus giving time to HMPC members to send comments in advance of the **HMPC July** meeting when the package will be presented for possible adoption. Comments from Vice-chair to be sent to the Rapporteur.

2.3.2. Public statement on Foeniculi amari fructus aetheroleum and supporting documents

Action: For adoption

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

Outcome:

Adoption postponed. See 2.3.1

2.3.3. Monograph on Foeniculi dulcis fructus and supporting documents

Action: For adoption

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

Outcome:

Adoption postponed. See 2.3.1

2.3.4. Monograph on Fumariae herba and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR, Readers Guidance

Outcome:

Adoption postponed.

The Rapporteur informed the Committee that:
- use in adolescents is only accepted for the comminuted herbal substance as herbal tea;
- no strong clinical evidence on the influence on bile flow justifies a contraindication, thus the monograph contains a warning that use is not recommended in case of obstruction of the bile duct, cholangitis, liver disease, gallstones and any other biliary diseases.

The Rapporteur presented the cases identified during the searches in EudraVigilance and VigiLyse and subsequently was invited to delete the table and streamline the information in section 5.3 of the AR, as well as to shorten the text in section 5.6 Overall conclusions on clinical safety. The numerous co-medications and/or the long duration of use for some of the cases were noted thus these cases do not relate to the recommended conditions of use of fumitory preparations as laid down in the monograph.

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 July** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **14 June 2021**

Peer-review documents to be sent to Rapporteur: **28 June 2022**

Final documents to be included latest in 2nd premail: **12 July 2022**

2.3.5. Monograph on Juniperi pseudo-fructus and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR, Readers Guidance, Annex, Presentation

Outcome:

Adoption postponed.

HMPC discussed and reached conclusion on a number of discussion points:
- HMPC did not agree to refer to the assessment report of 2009 as the source for the use of the berries (the original source is no longer available and cannot be substituted with the HMPC AR; the historical use of the berries should be described in the AR but taken out of Table 2);
- HMPC endorsed the proposal to delete the word "adjuvant" from the 'urinary tract flushing' indication (justification to be included in the assessment report);
- amend the monograph to make it clear that the digestive indication is only approved for the herbal tea;
- decision to remove the contraindication 'Severe renal disease including infectious interstitial nephritis, pyelitis and pyelonephritis' from section 4.3 of monograph and to have instead a warning under section 4.4 (with adequate justification in the AR based on information available for the HPs in the monograph);
- decision to keep the preparation 'soft extract, extraction solvent water' in the monograph for regulatory consistency (adequate justification to be included in the AR, noting the 'supportive use' rather than 'therapeutic indication' in the evidence of traditional use);
- HMPC agreed not to release the technical document on the weight of juniper berries for public consultation (it was reiterated that, although the scientific work performed is acknowledged, it cannot be part of the AR for it would create a precedent whereby the HMPC could be expected to systematically produce a document on fruits' weight for any monograph covering medicinal use of fruits).

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 July** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **14 June 2021**

Peer-review documents to be sent to Rapporteur: **28 June 2022**

Final documents to be included latest in 2nd premail: **12 July 2022**

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

2.4.1. Monograph on Curcumae xanthorrhizae rhizoma and supporting documents

Action: For adoption

Documents tabled: n/a

Outcome:

Adoption postponed.

HMPC noted that additional products (Hungarian market) still need to be considered in the review report.

Rapporteur to modify the review report with relevant information on these missing products and possible comments from peer-reviewer for **possible adoption** at the **HMPC July** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **14 June 2021**

Peer-review documents to be sent to Rapporteur: **28 June 2022**

Final documents to be included latest in 2nd premail: **12 July 2022**

2.4.2. Monograph on Ginseng radix and supporting documents - postponed

2.4.3. Monograph on Paulliniae semen and supporting documents

Action: For adoption

Document tabled: Review report, Readers Guidance

Outcome:

Adoption postponed.

HMPC noted that results from a search in Eudravigilance database still need to be integrated in the review report. Some of the conclusions under 'Assessor's view' need to capture the comments previously raised by the peer-reviewer. Members were reminded that only findings from interaction studies conducted in humans can lead to a statement in section 4.5 of the monograph. The review report should be re-arranged for greater clarity between phytochemical, non-clinical and clinical investigations; the Rapporteur was also invited to ensure that a conclusion is available for each of these. It was suggested to shorten the paragraph on studies in cancer-related fatigue for this does not correspond to the therapeutic indication approved in the monograph.

Rapporteur to modify the review report according to the discussion, Eudravigilance data, and possible additional comments from peer-reviewer for **possible adoption** at the **HMPC July** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **14 June 2021**

Peer-review documents to be sent to Rapporteur: **28 June 2022**

Final documents to be included latest in 2nd premail: **12 July 2022**

2.4.4. Monograph on Urticae radix and supporting documents

Action: For adoption

Document tabled: Review report

Outcome:

HMPC agreed with the Rapporteur's position to revise the monograph because a new herbal preparation [dry extract (7-9:1), extraction solvent: ethanol 60% V/V] can be added.

The HMPC decided by consensus to start the revision procedure and revise the monograph, assessment report and list of references on Urticae radix. The review report was adopted and HMPC tracking documents will be updated.

During the discussion, the question of the availability of the list of scientific references supporting the proposed revision was raised – see 5.7.3 for conclusion on this matter. In the present case of Urticae radix, the decision to revise the monograph is not based on new data from literature but on the presence of a herbal medicinal product on the German market since May 1992.

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

None

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

None

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

None

3. Referral procedures

None

4. Guidelines and guidance documents

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

4.1.1. Guideline on Assessment of genotoxicity of herbal substances/preparations (EMEA/HMPC/107079/2007) for public consultation

Action: For adoption

Document tabled: Concept paper on the revision of the guideline

Outcome:

Adoption postponed.

HMPC emphasised that a revision of the genotoxicity guideline cannot be justified by the simple fact that new methodologies are available; their validation and suitability for purpose must first be assessed.

Rapporteurs to further work on the draft concept paper according to the discussion, in order to present at the HMPC July meeting a new version for review.

4.2. Quality

None

4.3. Regulatory / Procedural

None

4.4. Report on HMPC Drafting Groups activities

4.4.1. Quality DG

None

4.4.2. ORGAM DG

None

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Strategic Review and Learning Meetings (SRLM)

- SRLM virtual meeting during French EU Council Presidency – 14 April 2022

  Report: An Le

  Action: For information

  Documents tabled: Final agenda, Summary, Presentations, Follow-up plan

  Outcome:

  An Le presented the 4 axes of the SRLM held during the French Presidency: better communication to patients on scientific data and on drug-drug interactions during self-medication and complementary use to conventional treatments; use of real-world data for OTC products; use of pharmaceutical essential oils as alternative therapeutic options to antibiotics (to reduce resistances and misuse); innovative extractions processes, packaging, and protection of species (program for a greener Europe).

  HMPC emphasised that topics on the follow-up plan should be streamlined and adjusted for the current year. Also, and for the time being, no need to link those topics with the approved HMPC work plan.

- SRLM virtual meeting during Czech EU Council Presidency during 2nd half of 2022

  Report: HMPC Chair

  Action: For information

  Document tabled: Overview of meetings scheduled during the CZ presidency

  Outcome:

  HMPC Chair informed the Committee that CZ cannot organise an HMPC SRLM meeting but that Malta is in the process of exploring its capacity to host it.

- SRLM virtual meeting during Swedish EU Council Presidency – 18-19 April 2023

  Report: Karin Erika Svedlund

  Action: For information

Outcome:

HMPC was reminded about the virtual SRLM meeting to be held on 18-19 April 2023.

5.1.2. HMPC membership

Report: HMPC Chair

Action: For information

Outcome:

New members:

- Poland, Ewa Antkiewicz (alternate) as of 31 March 2022
- Denmark, Nanna Lundgaard Rasmussen (alternate) as of 8 April 2022
- EDQM, Bruno Spieldenner (observer) as of 7 May 2022
- Bulgaria, Radina Dimitrova (alternate) as of 13 May 2022

End of membership:

- Poland, Katarzyna Tomaszewska (alternate) as of 30 March 2022
- Denmark, Rahat Nazmi (alternate) as of 7 April 2022

5.1.3. Election of Co-opted member (Non-clinical toxicology)

Report: HMPC Chair

Action: For discussion

Documents: Call for candidatures dated 01 April 2022, Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC, letter of candidature from H. Foth dated 24 April 2022

Outcome:

Heidi Foth was re-elected as HMPC co-opted member in the non-clinical/toxicology domain for a new 3-year mandate starting on 8 July 2022.

5.1.4. Timing of transmission of comments from interested parties received during public consultation

Action: For discussion

Outcome:

HMPC endorsed the HMPC secretariat's proposal to transmit comments from interested parties in individual sets of comments as soon as received at EMA throughout the consultation period, thus giving more time to Rapporteurs to analyse comments (as opposed to current practice to send all comments received in one transmission at the end of the consultation period). It was agreed that the secretariat would send an e-mail to the Rapporteur a few days after the end of the public consultation to signal that no more comments are to be expected.

5.2. EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

None

5.2.2. Coordination with QRD and CMDh – Update on Herbal specifics for QRD template (CMDh/349/2016, Rev.0 - EMA/HMPC/770889/2014)

Action: For discussion

Documents tabled: Addendum to the QRD templates, Responses

Outcome:

HMPC noted the progress achieved in the preparation of the addendum to the QRD templates. The Rapporteur presented a number of discussion points, based on comments received. In particular, agreement was reached on:
- wording for statements on duration of use that are justified either by the constituents (phytochemical composition of the herbal product) or by the therapeutic indication;
- decision to remove in section 4.4. (special warnings) of the monograph's template the standard statement that the use 'has not been established due to the lack of data' when there is no indication for the herbal preparations in some or all subsets of the paediatric population (reason: alignment with recommendation from the SmPC guideline);
- harmonise labelling practice for ethanol when used as an extraction solvent (not as an excipient).

HMPC endorsed some changes after discussion and considered that others were not relevant for the QRD template.
Rapporteur to present a new version at the HMPC July meeting for endorsement prior to transmission to the QRD Working Group for review/comments. HMPC agreed that no public consultation is needed on this addendum intended to assist regulators at NCA level.

5.2.3. Coordination with CMDh - List of estragole-containing plants

Action: For discussion

Documents tabled: List of potential plants containing estragole with a HMPC monograph

Outcome:

HMPC was reminded about the CMDh request and how the previous version of the list had been compiled. The new version contains:
- in red: plants/plant parts for which an HMPC monograph exists and for which estragole intake is likely to be above the guidance value in the HMPC public statement;
- in black: plants/plant parts for which an HMPC monograph exists and for which it is not clear whether estragole intake might be above the guidance value.

The HMPC endorsed the HMPC Chair suggestion to focus on those in red (*Foeniculum vulgare*, *Pimpinella anisum*, *Syzygium aromaticum*) i.e. to initiate an unscheduled review and to let CMDh know once the assessment is finished (review ongoing for *F. vulgare*).
Some Rapporteurs expressed doubts as to why some plants appear in the black category (e.g. *Salvia officinalis, Paullinia cupana*). Rapporteurs were invited to review the list considering as priority the plants/plant parts with expected high levels of estragole as active substance and to present a new version for discussion at the July meeting.

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 13B expert group meeting

  Report: Melanie Bald, Bruno Spieldenner

  Action: For information

  Document tabled: SoD

  Outcome:

  HMPC noted the summary of decisions from the April 2022 meeting of the Group 13B that was highlighted by the EDQM observer, in particular regarding the establishment of a monograph for Cannabis flos (3028). The next meeting of the Group 13B will be held in September 2022.

- EDQM TCM expert group meeting - postponed

5.4.2. Coordination with the European Commission

The HMPC Chair welcomed two members from DG SANTE Unit B4, who will act as liaison until the formal appointment of an EC representative in the HMPC.

- Collaboration with EC on the feasibility to establish an EU herbal monograph for Cannabis flos

  Report: HMPC Chair, Ana Paula Martins

  Action: For discussion

  Documents tabled: Draft Questions & Answers

  Outcome:

  The HMPC Chair reminded participants of the steps that had led to the current ongoing work. DG SANTE had responded positively in February 2020 to the May 2019 HMPC proposal to work on a collection of «*terminology and definitions according to established pharmaceutical quality conventions for specification and standardisation of herbal preparations as a tool for Member States to be able to categorise cannabis-based medicines in their territory*». DG SANTE had noted then that such compilation «*would facilitate comparison of information on distinct products*» and that «[E]*eventually, in justifiable cases, this approach could help MSs to identify certain preparations used for specific indications for which well-established medicinal use within the EU for at least 10 years, with recognised efficacy and an acceptable level of safety based on bibliographic data, is not unlikely and potentially corresponding herbal monographs could be developed*». In its letter, DG SANTE had agreed that «*the registration of cannabis-based medicines (containing relevant amounts of pharmacologically active cannabinoids) as traditional herbal medicines is not likely*».
  During the meeting, DG SANTE pointed to the heterogenicity of cannabis-based products in

the EU, with a great diversity in composition, quality and in legal status (the latter resulting from MSs' capacity to introduce national regulatory provisions for making accessible cannabis-based products to patients). There is a huge interest around cannabis given the potential business opportunities seen by some stakeholders. DG SANTE holds the view that increased harmonisation would be desirable in order to collect safety and efficacy information, to improve patient safety and to protect public health.

Rapporteurs were invited to modify the draft Q&A in accordance with the discussion, in particular:
- cross-references to various documents to be introduced (to the Compilation of terms and definitions for Cannabis-derived medicinal products; to the HMPC guideline on the assessment of clinical safety and efficacy in the preparation of EU herbal monographs for well-established and traditional herbal medicinal products; to the HMPC scientific guidelines on quality);
- comments from EMA Regulatory Affairs Office (additional national requirements due to the nature of the active substance or requirement for agriculture fall outside of the Q/A remit; short description of different existing ways of getting an authorisation to market cannabis-based medicinal products);
- comments from DG SANTE that the document's scope should be clear to avoid any risk of confusion between HMPC monographs and Ph. Eur. monographs.
A clean version will be prepared, which will then be circulated by the secretariat to all HMPC members for review and comments, in advance of another meeting of the group developing the Q&A (to be organised before the HMPC July meeting).

5.4.3. Borderline between medical devices and medicinal products

Action: For discussion

Documents tabled: Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices, Guidance - MDCG endorsed documents and other guidance (europa.eu)

Outcome:

HMPC noted the document and highlighted the need to have a similar guidance document to address borderline issues between food supplements and medicinal products as well. Chair pointed out that HMPC should be kept up-to-date on these borderline issues.

5.5. Cooperation with International Regulators

None

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

5.6.1. Association of the European Self-Medication Industry (AESGP) – hearing on 18 May 2022

- AESGP hearing

  Report: HMPC Chair

  Action: For discussion

Documents tabled: AESGP Proposal on combinations of traditionally used herbal extracts, Draft Agenda (email communication), Article for discussion, List of participants, Presentations

Outcome:

AESGP presented the 2 topics for discussion: 1) Proposal for combinations of traditionally used herbal extracts; 2) RWD-RWE for non-prescription herbal medicines. A hearing report will be drafted separately for publication at the EMA website.

- Post hearing discussion

  Report: HMPC Chair

  Action: For discussion

  Outcome:

  Postponed.

5.7. Work plan and related activities

5.7.1. HMPC work plan 2022

Report: HMPC Chair

Action: For information

Document tabled: HMPC Work plan, Annex 1, Annex 2

Outcome:

HMPC noted the progress with topics on the HMPC work plan 2022. It was highlighted that, for point 2.1.1. 'collaboration with EC on the feasibility to establish an EU herbal monograph for Cannabis flos', HMPC cannot conclude on such feasibility before receiving data from interested parties (thus public consultation on a Questions & Answers document is required).

5.7.2. Quality domain governance and draft multiannual work plan

Report: HMPC Chair, Nicoleta Carmen Purdel; Expert: Kristine Hvolby

Action: For discussion

Document tabled: Ad-hoc Quality Group Minutes 21 April 2022

Outcome:

HMPC noted the progress achieved by the ad-hoc quality group. It was highlighted that further input/collaboration with EMA' s Quality Innovation Group (QIG) may be necessary for example in the context of the development of a draft reflection paper on new analytical methods/technologies in the quality control of herbal medicinal products. I. Chinou offered her expertise with CO2 extraction methods. Next meeting scheduled for 09 June.

5.7.3. Improved use of data source for HMPC relevant safety assessment

Report: HMPC Vice-Chair, Nicoleta Carmen Purdel

Action: For discussion

Documents tabled: Review report template

Outcome:

HMPC agreed that the review report template (version tabled in MMD) can be used from now on by Rapporteurs for any new review to start. More improvements will be brought to the template upon collecting feedback on its use in the coming years. HMPC secretariat was asked to publish the new template. Concerning the number of references needed to be cited in a review report, it was noted that the procedural guidance offers flexibility ('*The list of references may be omitted when the review report's content clearly points to the need for revision'*). It was however acknowledged that for HMPC members to make up their mind before voting on the need for revising a monograph, they should be able to access some key publications, thus justifying that a minimum number of references be included. The suggested number of '10' key references can be exceeded or reduced as long as justified by the Rapporteur.

Maria Paile Hyvarinen will work with Erika Svedlund and Carmen Purdel on the revision of the HMPC AR template for the development of M/LE.

5.7.4. Evaluation of data from paediatric clinical practice for the safe use of herbal substances in children

Report: Miroslava Petriková

Action: For discussion

Documents tabled: Presentation

Outcome:

HMPC noted the progress achieved in the evaluation of data from paediatric clinical practice for the safe use of herbal medicines in children. During the 2 TCs held in April and May, the drafting group discussed the responses received to a questionnaire (24 principles) that had been circulated in December 2021. The group attempts to reach an opinion/agreement on topics that will be addressed in the discussion paper. At this stage, the drafting group would like to receive input from HMPC members. HMPC members are invited to provide:
1) a list or examples of indications for which extrapolation can be done from TU in adults to adolescents + what data should be submitted in order to prove TU in adolescents, and
2) a list or examples of indications and age limits (small children) from which on self (parent) treatment can be accepted.
HMPC noted that the ongoing assessment of Pelargonii radix serves to illustrate the challenges in deriving suitable recommendations for a safe use in the paediatric population from evidence judged incomplete or not sufficiently robust (e.g. conflicting results from small clinical studies, relevance of old literature, tradition of use limited to few countries, etc.).

5.7.5. Development of training on assessment of applications for herbal medicinal products

Report: HMPC Vice-Chair

Action: For discussion

Outcome:

HMPC noted the progress achieved in the development of the training on the CTD format and the use of herbal monographs. The training will be delivered in July 2022 (date to be confirmed). Also, a training will be proposed in collaboration with EDQM, before the end of the current year.

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 Hyperici herba and supporting documents

Action: For 10th discussion

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

Outcome:

The Rapporteur presented the challenges in the assessment, given that the monograph must ensure a match between the marketed products and the information publicly available in scientific publications. Difficulties arise when specifications of a marketed product appear to differ from those described in the literature; as products are not marketed in all MSs, some members do not have access to the products' quality dossiers and specifications. Some members expressed concerns that the TU part of the monograph includes HPs with a daily intake of >1mg hyperforin, given the likelihood of interactions. There was a question if there should be limits also for flavonoids.

Rapporteur to introduce changes in the draft monograph and supporting documents according to the discussion and to send the package to the peer-reviewer. Next **discussion** scheduled at the **HMPC July** meeting.

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

6.2.1. Monograph on Lavandulae aetheroleum and supporting documents

Action: For 4th discussion

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

Outcome:

The Rapporteur enquired about the need to have a separate AR for the essential oil. As a majority of monographs on essential oils are supported by an AR that also supports a monograph on other HPs, HMPC reverted its January 2022 decision to have a distinct AR for Lavandulae aetheroleum (however, paragraphs on the essential oil must be clearly identified). The Rapporteur was invited to revise the tables presenting study results according to the template, aiming to show the critical judgment made for each study of its features and results, as well as the conclusion reached on the studies' relevance. The Rapporteur will ascertain whether studies were conducted on L. flos or L. aetheroleum. The Rapporteur will reintroduce the use as bath additive (the supporting evidence identified at the time of the monograph's preparation still exist and the absence of marketed products is not a reason to remove the use as bath additive). HMPC agreed to keep the statements under section 4.7 Effects on ability to drive and use machines, given the known physiological effects of the inhaled volatile compounds and in view of the approved therapeutic indication.

Rapporteur to introduce changes in the draft monograph and supporting documents according to the discussion and to send the package to the peer-reviewer. Next **discussion** scheduled at the **HMPC July** meeting.

6.2.2. Monograph on Pelargonii radix and supporting documents

Action: For 2nd discussion

Documents tabled: Reader's Guidance

Outcome:

The Rapporteur presented the challenges of using available evidence for HPs that have been on the German market for 15 years under a former national legislative framework to accept a WEU part of the monograph. The HMPC discussed a number of controversial issues:
- the comparability of the different formulations;
- the extrapolation of WEU data to substantiate TU;
- the use of ethanolic preparations in very young children (30 years of medicinal use are confirmed, thus the TU requirement is met; however some members are concerned with safety either in relation to alcoholic extract intake or as they are of the view that administration of medicines to children under a certain age (2 years for some, 4 years for others) should take place after consultation with a physician and not upon parental decision. It was acknowledged that additional information about the German products are required before any decision can be made.

Rapporteur to introduce changes in the draft monograph and supporting documents according to the discussion and to send the package to the peer-reviewer. Next **discussion** scheduled at the **HMPC July** meeting.

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

6.2.4. Monograph on Rosmarini aetheroleum and supporting documents

Action: For 5th discussion

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

Outcome:

HMPC rediscussed the oral use of Rosmarini aetheroleum and invited the Rapporteur to modify the justification as to why this use will be removed from the monograph (with details as to why the supporting references were not correctly interpreted at the time of the monograph's preparation; the justification shall not refer to the absence of products on the market). For the cutaneous use, the limitation to 4 weeks for the duration of use is not modified (a product was approved in 2016 via a DCP with this limit).

Rapporteur to introduce changes in the draft monograph and supporting documents according to the discussion and to send the package to the peer-reviewer. Next **discussion** scheduled at the **HMPC July** meeting.

6.2.5. Monograph on Rosmarini folium and supporting documents

Action: For 5th discussion

Documents tabled: Draft MO, AR

Outcome:

Rapporteur to introduce changes in the draft monograph and supporting documents according to the discussion and to send the package to the peer-reviewer. Next **discussion** scheduled at the **HMPC July** meeting.

6.2.6. Monograph on Urticae herba and supporting documents

Action: For 1st discussion

Document tabled: MO, AR, LoR

Outcome:

HMPC invited the Rapporteur to use the latest monograph template. The HPs corresponding to medicinal products that are no longer marketed in Germany should not be removed from the monograph. Recommendations on fluid intake should be considered (as approved during the HMPC March meeting). The Rapporteur should also amend the monograph as follows:
- as the use of herbal substance is not approved, reference to it should be removed in the relevant sections of the monograph;
- implement the HMPC decision to remove 'as an adjuvant' in the first indication [Traditional herbal medicinal product to increase the amount of urine to achieve flushing of the urinary tract ~~as an adjuvant~~ in minor urinary complaints].

Rapporteur to introduce changes in the draft monograph and supporting documents according to the discussion and to send the package to the peer-reviewer. Next **discussion** scheduled at the **HMPC July** meeting.

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

6.3.1. Monograph on Camelliae sinensis non fermentatum folium and supporting documents

Action: For 4th discussion

Document tabled: Review report, Readers Guidance

Outcome:

The Rapporteur presented the changes brought to the review report since it was last discussed by the Committee. It is essential to highlight the non-relevance of many publications vis-à-vis the HPs included in the monograph. After discussion, the HMPC endorsed the Rapporteur's proposal to amend the review report and not to revise the published AR. The Rapporteur will work towards including an upper limit for (-)-epigallocatechin-3-gallate for the maximum daily dose.

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

Timetable:

Documents to be sent to Peer-reviewer: **14 June 2021**

Peer-review documents to be sent to Rapporteur: **28 June 2022**

Final documents to be included latest in 2nd premail: **12 July 2022**

6.3.2. Monograph on Sisymbrii officinalis herba and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

Postponed.

6.3.3. Monograph on Tiliae flos and supporting documents

Action: For 2nd discussion

Documents tabled: Review report, Readers Guidance

Outcome:

HMPC noted that results from Eudravigilance database still need to be considered in the review report.

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

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

Timetable:

Documents to be sent to Peer-reviewer: **14 June 2021**

Peer-review documents to be sent to Rapporteur: **28 June 2022**

Final documents to be included latest in 2nd premail: **12 July 2022**

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 Cisti cretici herba and supporting documents - postponed

6.5.2. Monograph on Cnici benedicti herba and supporting documents - postponed

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

Action: For 2nd discussion

Documents tabled: Presentation

Outcome:

Postponed.

6.5.4. Monograph on Tribuli terrestris herba and supporting documents

Action: For 1st discussion

Document tabled: Presentation

Outcome:

First results of data and possible way for assessment were presented. Results of first discussion to be taken up by Rapporteurs.

7. Any other business

7.1. Topics for discussion

7.1.1. Filsuvez (birch bark extract)

Action: For discussion

Documents tabled: CHMP opinion on Filsuvez

Outcome:

HMPC noted the CHMP positive opinion for Filsuvez (birch bark extract) for the treatment of epidermolysis bullosa.

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 28-30 March 2022

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)

None

7.2.3. EU herbal monographs, list entries and public statements – on hold

None

7.2.4. Other

- Rai M, Kosalec I, editors. Promising Antimicrobials from Natural Products. Springer 2022
- EDQM – Suspension of a CEP - Flucloxacillin sodium - Sandoz Industrial Products S.A.
- DRAFT Agenda - PCWP-HCPWP Joint meeting - June 2022
- Meeting Summary PCWP HCPWP meeting 2-3 March 2022
- DRAFT PCWP_HCPWP Work plan 2022-2025

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 16-18 May 2022 meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Emiel Van Galen	Chair	Netherlands	No interests declared	
Astrid Obmann	Alternate	Austria	No interests declared	
Reinhard Länger	Member	Austria	No interests declared	
Patricia Bodart	Member	Belgium	No interests declared	
Gert Laekeman	Co-opted member	Belgium	No interests declared	
Radina Dimitrova	Alternate	Bulgaria	No interests declared	
Ivan Kosalec	Member	Croatia	No interests declared	
Darko Trumbetic	Alternate	Croatia	No interests declared	
Antri Kouroufexi	Member	Cyprus	No interests declared	
Maria Yiannitsarou	Alternate	Cyprus	No interests declared	
Marie Heroutova	Alternate	Czechia	No interests declared	
Markéta Příhodová	Member	Czechia	No restrictions applicable to this meeting	
Kristine Hvolby	Expert – via WebEx*	Denmark	No interests declared	
Nanna Lundgaard Rasmussen	Alternate	Denmark	No interests declared	
Steffen Bager	Member	Denmark	No restrictions applicable to this meeting	
Maria Paile Hyvarinen	Member	Finland	No interests declared	
Sari Koski	Alternate	Finland	No interests declared	
An Le	Member	France	No interests declared	
Heidi Foth	Co-opted member	Germany	No interests declared	
Jacqueline Wiesner	Member	Germany	No interests declared	
Susanne Flemisch	Alternate	Germany	No interests declared	
Ioanna Chinou	Member	Greece	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Stavroula Mamoucha	Alternate	Greece	No interests declared	
Zsuzsanna Bíróné Dr Sándor	Member	Hungary	No interests declared	
Jacqueline Masterson	Alternate	Ireland	No interests declared	
Sarah Kellaghan	Member	Ireland	No interests declared	
Alessandro Assisi	Member	Italy	No interests declared	
Anna Maria Serrilli	Alternate	Italy	No interests declared	
Baiba Jansone	Member	Latvia	No interests declared	
Jurate Antanaviciene	Member	Lithuania	No restrictions applicable to this meeting	
Sven Back	Member	Luxembourg	No interests declared	
Everaldo Attard	Member	Malta	No interests declared	
Burt H Kroes	Member	Netherlands	No interests declared	
Hilda Kuin	Alternate	Netherlands	No interests declared	
Gro Anita Fossum	Member	Norway	No interests declared	
Marianne Loiten Dalhus	Alternate	Norway	No interests declared	
Ewa Antkiewicz	Alternate	Poland	No interests declared	
Wojciech Dymowski	Member	Poland	No interests declared	
Ana Paula Martins	Member	Portugal	No interests declared	
Maria da Graca Ribeiro Campos	Co-opted member	Portugal	No interests declared	
Maria Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared	
Carmen Purdel	Member	Romania	No interests declared	
Miroslava Petrikova	Member	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	
Bruno Spieldenner	Observer	EDQM	No interests	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
			declared	
Melanie Bald	Observer	EDQM	No interests declared	
Representatives from the European Commission attended the meeting				
Meeting run with support from relevant EMA staff				

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