23 November 2022
EMA/HMPC/792083/2022
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 19-21 September 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 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

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Table of contents

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 COVID-19 pandemic, and the associated EMA Business Continuity Plan (BCP), the meeting was held in-person with a number of 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 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 19-21 September 2022.

Outcome:

Agenda and time schedule adopted.

1.3. Adoption of the minutes

HMPC minutes for 18-20 July 2022.

Outcome:

Minutes adopted (with minor changes introduced prior to the start of and during the meeting). Missing list of participants will be added.

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 September 2022

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 November meeting according to the overview, Rapporteurs were urgently asked to inform secretariat and Chair before the first pre-mail (by 08 November 2022) to allow best adaptation of agenda and time-schedule.

2.1.2. Appointment of Rapporteurs and Peer-reviewers

Appointment of Peer-reviewers

Outcome:

HMPC agreed on new Peer reviewers for the following periodic reviews started in 2022:

- Helichrysi flos
- Melaleucae aetheroleum
- Ononidis radix
- Origani majoranae herba
- Polygoni avicularis herba
- Rubi idaei folium
- Sisymbrii officinalis herba

HMPC secretariat will update the HMPC status overview.
Members were asked to consider acting as peer reviewer for some remaining reviews started in 2022 (to be appointed at the HMPC November meeting). If required before, previous Rapporteurs (1st assessment) may step in as possible.

Re-appointments according to Hungarian membership change to be confirmed at the HMPC November meeting.

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 Fumariae herba and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR, Readers guidance

Outcome:

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

The Rapporteur confirmed that all appropriate changes requested earlier have been taken into consideration and subsequently changes introduced accordingly in the AR and LoR.
HMPC agreed to keep in the MO information on the single dose of herbal tea as it is in the German product and to update the first paragraph of the overall conclusions in the AR.

2.3.2. Monograph on Rosmarini aetheroleum and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR

Outcome:

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

Timetable:
Documents to be sent to Peer-reviewer: **20 October 2022**
Peer-review documents to be sent to Rapporteur: **03 November 2022**
Final documents to be included latest in 2nd premail: **15 November 2022**

In the MO, it was agreed to consider the "use as a bath additive" as not applicable to the TU therapeutic indications. Moreover, proposal to adapt section 4.8 undesirable effects in accordance with the EC guideline on Summary of Product Characteristics (SmPC) (September 2009) was discussed and agreed upon. In particular, adverse reactions descriptions should be based on the most suitable representation within the MedDRA terminology. This will usually be at the Preferred Term (PT) level and as a general rule, the adverse reactions should be assigned to the most relevant system organ class (SOC) related to the target organ.

HMPC agreed to keep in principle tables 5 and 6 in section 4 of the AR but adapt in relation to the conclusions of clinical studies. The last columns of the table 'Clinical relevance' to be used by the Rapporteur to assess and comment. Other columns may be shortened as possible to improve readability. If necessary, details may be presented in the text.

2.3.3. Monograph on Rosmarini folium and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR

Outcome:

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

Timetable:
Documents to be sent to Peer-reviewer: **20 October 2022**
Peer-review documents to be sent to Rapporteur: **03 November 2022**
Final documents to be included latest in 2nd premail: **15 November 2022**

In the MO, it was agreed to add the preparation 'tincture (1:5), 70% ethanol' and to delete preparations 'extract (DER 1:17.5-18.9), extraction solvent: liqueur wine', 'extract (DER 1:12.5-13.5), extraction solvent: liqueur wine' and 'expressed juice (DER 1:1.8-2.2) from fresh leaf'. Moreover, HMPC agreed to have information on 'Obstruction of bile duct, cholangitis, liver disease, gallstones and any other biliary disorders that require medical supervision" as a special warning and precaution for use (MO section 4.4).

HMPC agreed to adapt MO section 4.8 undesirable effects and tables 5 and 6 in section 4 of the AR (see also 2.3.2).

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

2.4.1. Monograph on Agrimoniae herba and supporting documents

Action: For adoption

Document tabled: Review report

Outcome:

Adoption postponed.
Rapporteur to modify the review report according to the discussion and possible comments from peer-reviewer for **possible adoption** at the **HMPC November** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **20 October 2022**
Peer-review documents to be sent to Rapporteur: **03 November 2022**
Final documents to be included latest in 2nd premail: **15 November 2022**

Rapporteur highlighted that no new authorised/registered herbal medicinal products with Agrimoniae herba were identified in EU countries during the period under review (2016–2022). HMPC agreed to include the newly available toxicological information (resulting from the Ames test), although it may be considered insufficient to trigger a revision of the MO.

2.4.2. Monograph on Epilobii herba and supporting documents

Action: For adoption

Document tabled: Review report

Outcome:

HMPC agreed with Rapporteur's position that no 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 Epilobii herba.
The review report was adopted and will be published as addendum to the existing assessment report on the EMA website.

2.4.3. Monograph on Eschscholziae herba and supporting documents

Action: For adoption

Document tabled: Review report

Outcome:

HMPC agreed with Rapporteur's position that no 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 Eschscholziae herba.

The review report was adopted and will be published as addendum to the existing assessment report on the EMA website.

2.4.4. Monograph on Paulliniae semen and supporting documents

Action: For adoption

Documents tabled: Review report, Readers guidance

Outcome:

Adoption postponed.
Rapporteur to modify the review report according to the discussion and possible comments from peer-reviewer for **possible adoption** at the **HMPC November** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **20 October 2022**
Peer-review documents to be sent to Rapporteur: **03 November 2022**
Final documents to be included latest in 2nd premail: **15 November 2022**

Rapporteur highlighted that the review report has been updated in line with comments received earlier and now includes previously missing EudraVigilance data. Review report to be sent to peer-reviewer for review.

2.4.5. Monograph on Tiliae flos and supporting documents

Action: For adoption

Documents tabled: Review report, Readers guidance

Outcome:

Adoption postponed.
Rapporteur to introduce changes in the review report according to the discussion and possible further comments from peer-reviewer and HMPC members.
Next **discussion / possible adoption** (to confirm later) at the **HMPC November** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **20 October 2022**
Peer-review documents to be sent to Rapporteur: **03 November 2022**
Final documents to be included latest in 2nd premail: **15 November 2022**

HMPC highlighted that causality between exposure to Tilia with the appeared side effects and potential adverse reactions could not be assessed. The relevance of alkaloids should be further evaluated.

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:

Concept paper and supporting documents adopted by consensus for 3 months public consultation.

HMPC highlighted that the current guideline has been available for 15 years and considerable practical experience has been accumulated during that time, in addition to new regulatory guidance available (e.g. ICH) and technical and methodological progress in the field as a whole. Some wordings were polished, and references deleted that may be taken up again during the actual revision.

4.1.2. Guideline on the clinical assessment of fixed combinations of herbal substances / herbal preparations (EMEA/HMPC/166326/2005)

Action: For information

Document tabled: Email communication

Outcome:

Rapporteurs to continue evaluating whether or not to revise the guideline taking into account developments and experience over the last 15 years and new guidance available outside the herbal area.
HMPC members to send comments to the Rapporteur for next **discussion** scheduled for the **HMPC November** meeting.

The Rapporteur reported that, so far, the group has not found a need to revise the guideline EMEA/HMPC/166326/2005. General principles are still applicable and the recent proposal by AESGP to extent the flexible approach for herbal tea combinations to other preparations was given only limited approval (possibly for aqueous extracts only).

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

Document tabled: Email communication

Outcome:

Rapporteurs to draft a first version of the revised GACP incorporating comments received during the public consultation as appropriate, and possible additional comments from the ad-hoc Quality Drafting Group.
Next **discussion** scheduled for the **HMPC November**.

4.3. Regulatory / Procedural

4.3.1. Procedure for the review and revision of EU herbal monographs and EU list entries

Action: For adoption

Documents tabled: Revised procedure (Rev. 3), Revised template

Outcome:

Revised procedure and revised template adopted by consensus.

HMPC agreed on the latest changes made to the *"Review Report template"* and in *"Procedure for the review and revision of European Union herbal monographs and European Union list entries"*.
HMPC secretariat to edit and publish the documents and distribute to all members.
All Rapporteurs were encouraged to use the new template from now on.

4.3.2. Procedure for the Appointment by the HMPC of a rapporteur responsible for a scientific evaluation or the establishment of a Community herbal monograph and/or Community LE (EMEA/HMPC/108877/2005 Rev. 1)

Action: For discussion

Documents tabled: Presentation

Outcome:

HMPC members welcomed in principle new proposals to foster multinational teams and onboarding of junior assessors as necessary.
Rapporteurs to work out details on definition, tasks and procedural consequences for Rapporteurs, newly proposed Co-Rapporteurs, supporting assessors, peer-reviewer and secretariat for discussion at the SRLM Malta meeting.
HMPC members were invited to send further comments to the Rapporteurs (see also 5.7.2).

4.4. Report on HMPC Drafting Groups activities

4.4.1. Quality DG

None

4.4.2. ORGAM DG

None

4.4.3. Ad-hoc Quality drafting group

Report: Nicoleta Carmen Purdel

Action: For information

Document tabled: Ad-hoc Quality Group Minutes September 2022

Outcome:

HMPC noted the progress achieved by the ad-hoc Quality drafting group during the meeting held on 07 September, in particular regarding the document 'Questions & answers on quality of herbal medicinal products / traditional herbal products (EMA/HMPC/41500/2010 Rev.6)'.

- Questions & answers on quality of herbal medicinal products / traditional herbal products (EMA/HMPC/41500/2010 Rev.6)

  Action: For discussion

  Document tabled: Overview of existing quality Q&As

  Outcome:

  HMPC welcomed and endorsed the thorough review of the quality Q&As. For deletion of Q&As now covered in revised guidelines (GLs), revision of remaining GLs and addition of new GLs (e.g. originating from assessors' trainings) it was encouraged to consider a two-step approach to avoid major delays in updating document EMA/HMPC/41500/2010.
  Next **discussion** scheduled for the **HMPC November**.

- Guidance on newly used manufacturing techniques regarding herbal preparations

  Action: For information

  Outcome:

  Rapporteur reported to be in discussion with external experts to allow drafting of a reflection paper or concept paper as appropriate. Quality experts were asked to support the Rapporteur for sketching a first short draft to be further developed in 2023 (main focus CO_2 extracts).
  Additional discussion planned under the QDG.

- Guideline on declaration of herbal substances and herbal preparations (EMA/HMPC/CHMP/CVMP/287539/2005 Rev.1)

  Action: For information

  Outcome:

  The HMPC welcomed that a draft concept paper is planned now after main agreements on the revision of the document 'Questions & answers on quality of herbal medicinal products / traditional herbal products (EMA/HMPC/41500/2010 Rev.6)'.
  Additional discussion planned under the QDG.

- Reflection paper on markers used for quantitative and qualitative analysis of herbal medicinal products and traditional herbal medicinal products (EMEA/HMPC/253629/2007)

Action: For information

Outcome:

The HMPC noted the Rapporteurs report that the reconsideration of general principles would not solely be limited to the reflection paper but affect several documents including some from Ph. Eur. requiring coordination on a wider time frame to allow a thorough analysis. Additional discussion planned under the QDG.

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Strategic Review and Learning Meetings (SRLM)

- French presidency HMPC SRLM Follow up plan - status September 2022

  Report: HMPC Vice Chair

  Action: For information

  Document tabled: Follow up plan

  Outcome:

  The HMPC Vice-Chair confirmed that the follow-up plan is up to date and in line with previous discussions.

- Czech Presidency meeting – 10-11 November 2022 (Hosted by Malta)

  Report: Marketa Prihodova, Everaldo Attard

  Action: For information

  Document tabled: Draft Agenda

  Outcome:

  A preliminary draft agenda for the HMPC SRLM meeting to be hosted by Malta (on behalf of the Czech Republic Presidency of the Council of the European Union) on 10-11 November 2022 was presented.

  HMPC members were invited to send proposals for active participation/ presentation. Invitations to register for the event will be sent to HMPC members in due course.

5.1.2. HMPC membership

Membership update

Report: HMPC Chair

Action: For information

Outcome:

Re-nominated members:

- Portugal, Ana Paula Martins (member) as of 23 September 2022
- Italy, Anna Maria Serrili (alternate) as of 22 August 2022
- France, An Le (member) as of 24 September 2022

Zsuzsanna Bíróne Sándor informed HMPC that this was her last plenary meeting, and that Julia Pallos will be the new Hungarian HMPC member.
HMPC expressed its grateful acknowledgement of all the work done by Zsuzsanna over a period of almost 20 years as the Hungarian HMPC member.

Hungarian rapporteurships will be in principle transferred to the new member (HU PRAC member) taking into account available resources (see also 2.1.2).

5.1.3. General update on RWD/RWE projects at EMA

Action: For discussion

Document tabled: Presentation

Outcome:

HMPC was informed on RWD/RWE projects ongoing at EMA and under the umbrella of the Data Analytics and Real-World Interrogation Network (DARWIN EU®). The three main areas for which RWD analyses can support Committees' decision-making were highlighted: support the planning and validity of applicant studies; understand the clinical context; investigate associations and impact. A process allowing Committees to request for delivering of RWE (email template) is available.

The HMPC Chair emphasised that there should be RWD/RWE for herbal medicines and, in this regard, invited HMPC members to make use of the DARWIN EU® functionalities.

5.2. EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair

Action: For information

Outcome:

The HMPC Chair informed that intermediate reports on Committees' work plans status will be one of the topics for discussion in the next meeting of the Scientific Coordination Board (SciCoBo) to be held on 30 September.
Meeting minutes from the June meeting will be shared once has been approved. Draft agenda for the SciCoBo meeting to be held on 30-09-2022 was added for information during the meeting.

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

Action: For information

Outcome:

The HMPC Chair confirmed that the CMDh is seeking a supporting list with ideally all herbal substances /plants that naturally contain estragole if that is feasible.

Rapporteurs were asked to reconsider the appropriate format and in which way to present best the different knowledge on the actual estragole content.
Final proposal for the list will be scheduled for the **HMPC November 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

None

5.4.2. Coordination with the European Commission

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

Report: HMPC Chair

Action: For discussion

Documents tabled: Draft Questions & Answers, Draft call for data

Outcome:

HMPC endorsed drafts of Q&As and Call for data taking into account peculiarities, challenges, public expectations and limitations when starting the procedure.

Rapporteur to introduce amendments and shortenings according to the discussion and provide the polished papers to all members for **comments by 28 October**.

Next **discussion / possible adoption** at the **HMPC November** meeting.

5.5. Cooperation with International Regulators

None

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

None

5.7. Work plan and related activities

5.7.1. HMPC work plan 2022

Report: HMPC Chair

Action: For information

Documents tabled: HMPC Work plan, Annex 1, Annex 2 – status August 2022

Outcome:

HMPC observed the progress of the HMPC 2022 work plan after a brief update by each topic leader.

Rapporteurs for monographs (WP Annex 1) were asked to signal any updates for the November meeting and focus on new assessments and revisions for the rest of the year.

Rapporteurs for guidelines (WP Annex 2) were asked to liaise with their Co-Rapporteurs and signal to the secretariat if they need any support with documents or meeting organisation.

5.7.2. Improved use of data sources for HMPC relevant safety assessments

Report: Karin Erika Svedlund; Experts: Zsuzsanna Bíróne Sándor, Nicoleta Carmen Purdel, Reinhard Länger, Alessandro Assisi

Action: For discussion

Documents tabled: AR Template, Readers guidance, Procedure for the preparation of Community MO for TU herbal medicinal products, Procedure for the preparation of Community MO for WEU herbal medicinal products, Standard operating procedure on the establishment of EU herbal MO and EU LE and related documents, Procedure for the preparation of an entry to the Community list of herbal substances, preparations and combinations thereof for TU herbal medicinal products'

Outcome:

HMPC agreed to merge three old procedural documents (EMEA/HMPC/182320/2005, EMA/HMPC/182352/2005, EMA/HMPC/57137/2007) into one document, and with the AR, MO and LE templates annexed.
It was also endorsed to incorporate the procedure for the appointment of a rapporteur (EMEA/HMPC/108877/2005) under revision and the document with timelines for the establishment of a EU herbal MO and/or a EU LE (EMA/HMPC/126542/2005).

HMPC members noted many new improvements introduced to the AR template and were invited to send comments for further amendment. A training on the use of the new template once adopted is not foreseen anymore (self-explanatory with instructions and practice when used). Maria Paile Hyvarinen replaces Zsuzsanna Bíróne Sándor in the project group.

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

Report: Miroslava Petriková, Peter Voitl; Experts: Peter Šišovský, Maria Helena Pinto Ferreira

Action: For discussion

Outcome:

Rapporteur reported some progress with the draft discussion paper for principles to be applied for data requirements and possible extrapolations to accept the use in children for TU *vs* WEU.

After analysis of the survey now a meeting is planned involving all group members and presentation of the draft at the **HMPC November meeting**.

5.7.4. Evaluation of a harmonised approach for the use of monographs in procedures for combination products

Report: Olga Maria Palomino; Experts: Reinhard Länger, Wojciech Dymowski, Sarah Kellaghan, Heidi Foth, Maria da Graça Ribeiro Campos, Gert Laekeman

Action: For information

See 4.1.2.

Outcome:

Rapporteur presented first conclusions on the revision of the guideline on the clinical assessment of fixed combinations of herbal substances / herbal preparations (see also 4.1.2).

Rapporteurs and HMPC members were invited to reflect also on explanations on the principles applied for herbal tea combinations in EU monographs, the proposed widening to other preparations by industry (hearing of AESGP held on May 2022) and also the selection and proposal of specific fixed combinations for assessment as appropriate (see template under 5.7.8.)

5.7.5. Collaboration with EC on the feasibility to establish a EU herbal monograph for Cannabis flos

Report: Ana Paula Martins; Experts: Barbara Razinger, Everaldo Attard, Burt Kroes, Ioanna Chinou, Pierre Duez

Action: For information

Outcome:

The HMPC Chair reflected on the various likely steps and coordination with regard to the procedure to start assessment of an EU herbal monograph for Cannabis flos (see also 5.4.2).

5.7.6. Training on assessment of applications for herbal medicinal products

Report: Karin Erika Svedlund; Experts: Reinhard Länger, Nicoleta Carmen Purdel, Burt Kroes

Action: For discussion

Documents tabled: Presentation, Herbal medicinal product applications

Outcome:

Rapporteur highlighted the positive feedback received on the fourth webinar held on 5 July regarding the topic "Herbal medicinal product applications - the CTD-format and the use of EU monographs". As an upcoming training, a webinar on "European Pharmacopoeia: specific chapters for herbal substances, herbal preparations and herbal medicinal products" is being prepared together with the EDQM (foreseen for December 2022).

5.7.7. Implementation of new architecture for WP/DG

Report: HMPC Chair; Experts: Nicoleta Carmen Purdel, Ioanna Chinou, Olga Maria Palomino, Susanne Flemisch, Stefanie Bodemann, Knut Almgren

Action: For discussion

Document tabled: Presentation

Outcome:

The HMPC Chair highlighted that the work of the ad-hoc Quality drafting group will continue for the upcoming months until further developments in implementation of the new architecture for the quality domain will be known.

5.7.8. Preparation of HMPC work plan 2023

Report: HMPC Chair

Action: For discussion

Documents tabled: Draft HMPC 2022 WP report, Template, Template - Proposals for assessment by HMPC

Outcome:

The HMPC secretariat announced contacting Rapporteurs and topic leads regarding details for a centralised report on status of work plan 2022 implementation, validation/need of continuation and preparation of the 2023 work plan.

HMPC topic leaders but also other members are invited to use the standard template to propose continued or new activities/deliverables (realistic and achievable) for the HMPC work plan 2023.

For new substances for assessment to be started in 2023 the specific template should be filled for an informed decision by the HMPC.

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 12th discussion

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

Outcome:

Rapporteur to finalise the draft MO and supporting documents for peer review and **adoption** at the **HMPC November** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **20 October 2022**
Peer-review documents to be sent to Rapporteur: **03 November 2022**
Final documents to be included latest in 2nd premail: **15 November 2022**

The Rapporteur presented changes introduced in the monograph and options to finalise the revision. A majority of HMPC members preferred to keep the dry extract with a low level of

hyperforin within the herbal preparation c) (WEU) but not separate as d) despite the Zahner et al 2019 study and PRAC conclusions.
The Overview of comments will be adapted according to the discussion. Assessment of data *vis-a-vis* the hyperforin content in different extracts and possible consequences for the activity/side effects to be presented in the AR to support national decisions on specific products.

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

6.2.1. Monograph on Foeniculi amari fructus and supporting documents

Action: For 1st discussion

Documents tabled: Draft LE, Reader's Guidance

Outcome:

Rapporteur to introduce changes in the draft LE according to the discussion and possible further comments from peer-reviewer, for **possible adoption** for public consultation at the **HMPC November** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **20 October 2022**
Peer-review documents to be sent to Rapporteur: **03 November 2022**
Final documents to be included latest in 2nd premail: **15 November 2022**

HMPC agreed to take into account carefully the text in the revised MO to have consistent alignment between MO and LE but also by analogy the adopted wording for the peppermint oil revised LE in relation to corresponding MO and the PS on pulegone/menthofuran. Any additional sentence with regard to the genotoxic carcinogenicity of estragole beyond monograph content and reference to the PS should be carefully considered and agreed by all members and appropriately be reflected in the revised AR.

It was confirmed that a draft revised LE will be published for 3 months public consultation, before adoption for transmission to the EC.

6.2.2. Monograph on Foeniculi dulcis fructus and supporting documents

Action: For 1st discussion

Documents tabled: Draft LE, Reader's Guidance

Outcome:

Rapporteur to introduce changes in the draft LE according to the discussion and possible further comments from peer-reviewer, for **possible adoption** for public consultation at the **HMPC November** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **20 October 2022**
Peer-review documents to be sent to Rapporteur: **03 November 2022**
Final documents to be included latest in 2nd premail: **15 November 2022**

See also 6.2.1.

6.2.3. Monograph on Hippocastani cortex and supporting documents

Action: For 2nd discussion

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

Outcome:

Rapporteur to introduce changes in the draft MO and supporting documents according to the discussion and possible further comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC November** meeting.

With regard to the MO, HMPC agreed to: extend the DER range for the second herbal preparation ('Dry extract (DER 5.0-8.5:1), extraction solvent water'); keep the first indication as it is in former MO ('Traditional herbal medicinal product for relief of symptoms of discomfort and heaviness of legs related to minor venous circulatory disturbances'); keep the first sentence in the section 4.7 effects on ability to drive and use machines ('No studies on the effect on the ability to drive and use machines have been performed').
Regarding the AR, HMPC agreed to: keep available information on solubility in water of compounds in section 1.1 even though not in detail checked in other cases; keep esculine as a chemical marker only.

6.2.4. Monograph on Lavandulae aetheroleum and supporting documents

Action: For 6th discussion

Documents tabled: Draft MO, AR, LoR, Presentation

Outcome:

Rapporteur to introduce changes in the draft MO and supporting documents according to the discussion and possible further comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC November** meeting.

HMPC discussed the following sections of the MO: 4.6, 4.7, 4.8.

In the AR sections 5.5.5 fertility, pregnancy and lactation, 5.5.7 effects on ability to drive or operate machinery or impairment of mental ability and 5.5.8 safety in other special situations were updated according to information added in the MO.

6.2.5. Monograph on Pelargonii radix and supporting documents

Action: For 4th discussion

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

Outcome:

Rapporteur to introduce changes in the draft MO and supporting documents according to the discussion and possible further comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC November** meeting.

HMPC agreed to consider children from 4 years of age and with an adequate posology, and also to include the missing information in the current MO on adverse reactions.

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

6.2.7. Monograph on Urticae herba and supporting documents - postponed

6.2.8. Monograph on Zingiberis rhizoma and supporting documents

Action: For 2nd discussion

Documents tabled: Draft AR, Reader's Guidance

Outcome:

Rapporteur to introduce changes in the draft AR and supporting documents according to the discussion and possible further comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC November** meeting.

HMPC emphasised that the HMPC conclusion drafted in 2012 on the risk of bleeding events due to concomitant intake of anticoagulants remains in place and thus no additional warnings/information will be included in the MO.
HMPC agreed with the Rapporteur's position that sufficient (safety) data exist to include the newly available TU indications and preparations.

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 - postponed

6.3.2. Monograph on Crataegi folium cum flore and supporting documents - postponed

6.3.3. Monograph on Ginkgo folium 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 November** meeting.

Rapporteur highlighted the information available in publications on the possible adverse effects associated with the use of Ginkgo biloba. A revision of the EU herbal monograph is considered necessary to include those additional adverse effects.
Although data on potential cardiac side effects are originating from PhV (WHO literature), it may not necessarily trigger PRAC procedures as not considered a new signal (already

included as AE in informative texts in 4 MSs; Ginkgo not part of the EURD-list, therefore no harmonised PSUR-assessment and PRAC tool available).

6.3.4. Monograph on Helichrysi flos and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

Rapporteur to modify the draft review report according to the discussion and possible further comments from Peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC November** meeting.

Rapporteur emphasised that conclusions on the new available data are consistent with the TU and do not influence the content of the current MO.

6.3.5. Monograph on Matricariae flos and supporting documents - postponed

6.3.6. Monograph on Melaleucae aetheroleum and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

Rapporteur to modify the draft review report according to the discussion and possible further comments from Peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC November** meeting.

Rapporteur summarised that there are no new products on the EU market and so far, no clinical studies or new safety concerns related to the use of Melaleucae aetheroleum have been found.
Since side effects such as the skin irritation potential for this essential oil have always been manifold discussed in the literature and at HMPC, any new aspects on these concerns should be briefly presented to confirm that no new data justify any revision.

6.3.7. Monograph on Ononidis radix and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

Rapporteur to modify the draft review report according to the discussion and possible further comments from Peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC November** meeting.

Rapporteur emphasised that no new information was identified that could influence the content of the current herbal MO.

6.3.8. Monograph on Origani majoranae herba and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

Rapporteur to modify the draft review report according to the discussion and possible further comments from Peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC November** meeting.

Rapporteur highlighted that there are no new products on the EU market and so far, no clinical studies or new safety concerns related to the use of Origani majoranae herba have been found.

6.3.9. Monograph on Pilosellae herba cum radice and supporting documents - postponed

6.3.10. Monograph on Polygoni avicularis herba and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

Rapporteur to modify the draft review report according to the discussion and possible further comments from Peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC November** meeting.

Rapporteur noted that no new information was identified that could influence the content of the current herbal MO.

6.3.11. Monograph on Pruni africanae cortex and supporting documents - postponed

6.3.12. Monograph on Rosae flos and supporting documents - postponed

6.3.13. Monograph on Rubi idaei folium and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

Rapporteur to modify the draft review report according to the discussion and possible further comments from Peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC November** meeting.

The Rapporteur emphasised that so far, no new data/findings of relevance to the content of the current herbal MO have been found.

6.3.14. Monograph Sideritis herba and supporting documents - postponed

6.3.15. Monograph on Sisymbrii officinalis herba and supporting documents

Action: For 2nd discussion

Document tabled: Review report

Outcome:

Rapporteur to modify the draft review report according to the discussion and possible further comments from Peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC November** meeting.

Rapporteur summarised that additional information on a stratified posology for the product used orally in children could not be found. Also, there are no new medicinal products on the market containing Sisymbrii officinalis herba.

6.3.16. Monograph on Symphyti radix and supporting documents - postponed

6.4. EU herbal monographs and list entries in preparation for adoption after public consultation

6.4.1. Monograph on Vaccinii macrocarpi fructus and supporting documents

Action: For 4th discussion

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

Outcome:

Rapporteur and peer-reviewer to introduce final changes in the draft MO and supporting documents according to the discussion and to finalise the package for **adoption** at the **HMPC November** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **20 October 2022**
Peer-review documents to be sent to Rapporteur: **03 November 2022**
Final documents to be included latest in 2nd premail: **15 November 2022**

The Rapporteur highlighted that the AR, draft MO and LoR were amended accordingly to comments received from IPs and the respective analysis.
Changes in the AR included clarification on posology and duration of use. The posology has been updated in the draft MO. Various views on an appropriate posology according to strict records of products or according to scientific plausibility and patient understanding were exchanged taking into account other cases (e.g. Tanacetum) and possible questions by IPs. Rapporteur and Peer-reviewer were asked to double check and introduce final amendments also in the AR to improve the understanding for the conclusions reached by the HMPC. Also a reference to product/posology as available from an EFSA health claim evaluation should be kept as evidence if no other original sources are publicly available.

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

Action: For 4th discussion

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

Outcome:

Rapporteur to introduce changes in the draft monograph and supporting documents according to the discussion and possible additional comments from peer-reviewer.
Next **discussion** scheduled at the **HMPC November** meeting.

HMPC agreed to address in the AR the published considerations on the interaction potential based on the chemical composition and bitter properties, but not to include those in the MO interaction section without available studies.

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

On hold

7.2.3. Other

- EMA records management system – update on Sharepoint migration
- Multi-stakeholder workshop: Patient experience data in medicines development and regulatory decision-making

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 19-21 September 2022 meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Astrid Obmann	Alternate	Austria	No interests declared	
Reinhard Länger	Member	Austria	No interests declared	
Gert Laekeman	Co-opted member	Belgium	No interests declared	
Patricia Bodart	Member	Belgium	No interests declared	
Radina Dimitrova	Alternate	Bulgaria	No interests declared	
Darko Trumbetic	Alternate	Croatia	No interests declared	
Ivan Kosalec	Member	Croatia	No interests declared	
Antri Kouroufexi	Member	Cyprus	No interests declared	
Marie Heroutova	Alternate	Czechia	No interests declared	
Markéta Příhodová	Member	Czechia	No restrictions applicable to this meeting	
Kristine Hvolby	Member	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	
Susanne Flemisch	Alternate	Germany	No interests declared	
Ioanna Chinou	Member	Greece	No interests declared	
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	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Alessandro Assisi	Member	Italy	No interests declared	
Anna Maria Serrilli	Alternate	Italy	No interests declared	
Greta Budukeviciute	Member	Lithuania	No interests declared	
Jane Murray	Alternate	Luxembourg	No interests declared	
Sven Back	Member	Luxembourg	No interests declared	
Everaldo Attard	Member	Malta	No interests declared	
Matthew Camilleri	Alternate	Malta	No interests declared	
Burt H Kroes	Member	Netherlands	No interests declared	
Emiel Van Galen	Chair	Netherlands	No interests declared	
Hilda Kuin	Alternate	Netherlands	No interests declared	
Gro Anita Fossum	Member	Norway	No interests declared	
Marianne Loiten Dalhus	Alternate	Norway	No interests declared	
Wojciech Dymowski	Member	Poland	No interests declared	
Ana Paula Martins	Member	Portugal	No interests declared	
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	
Jaroslav Tóth	Alternate	Slovakia	No interests declared	
Miroslava Horváth Petriková	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	
Julia Pallos	Expert	Hungary	No restrictions applicable to this meeting	
Charlotta Lofberg	Expert	Sweden	No restrictions applicable to this meeting	

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