21 September 2022
EMA/HMPC/662996/2022
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 18-20 July 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 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 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 18-20 July 2022.

Outcome:

Agenda and time schedule adopted.

1.3. Adoption of the minutes

HMPC minutes for 16-18 May 2022.

Outcome:

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

2. EU herbal monographs and list entries for adoption

2.1. Status of HMPC activities

2.1.1. Overview of HMPC assessment work including the Rapporteurship distribution – Status in July 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 September meeting according to the overview, Rapporteurs were urgently asked to inform secretariat and Chair before the first pre-mail (by 06 September 2022) to allow best adaptation of agenda and time-schedule.

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:

Draft revised EU herbal monograph and supporting documents adopted by majority vote for 3 months public consultation. Rapporteur to present consequences for the corresponding List entry at the **HMPC September** meeting.

HMPC agreed on changes introduced in MO sections 4.2, 4.4, 5.3 and 6 as well as in some parts of the AR.

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:

Draft revised public statement and supporting documents adopted by consensus for 3 months public consultation.
HMPC agreed that due to new safety concerns an EU herbal monograph cannot be supported anymore and proposed the withdrawal of monograph EMEA/HMPC/263292/2006.

HMPC agreed on various improvements in the wording of the PS, e.g. to remove the direct explicit reference to "high doses of estragole" (to be according to the AR), concluding that there are safety concerns with this use of bitter fennel oil due to risks of genotoxicity and carcinogenicity in humans with reference to details in the "Public statement on the use of herbal medicinal products containing estragole" (EMA/HMPC/137212/2005 Rev 1). It was

acknowledged that it is the first time that a previous HMPC opinion on a monograph is revised, and monograph withdrawal concluded due to safety concerns, which is not yet foreseen by template and procedure so far.

2.3.3. Monograph on Foeniculi dulcis fructus and supporting documents

Action: For adoption

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

Outcome:

Draft revised EU herbal monograph and supporting documents adopted by majority vote for 3 months public consultation.
Rapporteur to present consequences for the corresponding List entry at the **HMPC September** meeting.

See also: 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.
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 September** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **16 August 2022**
Peer-review documents to be sent to Rapporteur: **30 August 2022**
Final documents to be included latest in 2nd premail: **13 September 2022**

Because of unforeseen absence of the Rapporteur, the package was presented by the Peer-reviewer.
HMPC agreed to remove the sentence *"Single dose 1.6 g/150ml as herbal infusion"* from section 4.2 in the MO, and additional amendments were introduced in the AR.

2.3.5. Monograph on Juniperi pseudo-fructus and supporting documents

Action: For adoption

Documents tabled: MO, AR, LoR, Presentation

Outcome:

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

The HMPC agreed that the original wording of the therapeutic indication should be maintained as regards *"to increase the amount of urine to achieve flushing of the urinary tract in minor urinary tract complaints"* but *'as an adjuvant'* is deleted. 'Adjuvant' supposes a defined treatment to which the herbal treatment can be added. As there is no clear

instruction in that way, the therapeutic indication is reduced. A corresponding explanation is added in section 2 of the AR.
The wording in section 4.4 special warnings of the MO was changed to *"not recommended"* as regards use in severe renal diseases, in order to avoid being similar to a wording of a contraindication (section 4.3) without clinical evidence.
Finally, HMPC noted that clinical data is not strong enough for justifying allergic skin reactions, but an explanatory note should be included in the AR.

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

2.4.1. Monograph on Camelliae sinensis non fermentatum folium 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 Camelliae sinensis non fermentatum folium.
The review report was adopted and will be published as addendum to the existing assessment report on the EMA website.

The HMPC discussed the content of epigallocatechin-3-gallate and respective posology in green tea preparations included in the EU herbal monograph for the relevance of European Food Safety Authority guidance and warnings above certain levels resulting from food consumption and agreed to the Rapporteur assessment in this regard.

2.4.2. Monograph on Curcumae xanthorrhizae rhizoma 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 Curcumae xanthorrhizae rhizoma.
The review report was adopted and will be published as addendum to the existing assessment report on the EMA website.

HMPC noted that information on the two additional combination products from the Hungarian market still do not justify the need to revise the monograph.

2.4.3. Monograph on Ginseng radix and supporting documents

Action: For adoption

Document tabled: Review report

Outcome:

HMPC agreed with Rapporteur's position to revise the monograph because new data were detected that require update and changes to the content of the monograph.
The HMPC decided by consensus to start the revision procedure and revise the monograph, assessment report and list of references on Ginseng radix.
The review report was adopted and HMPC tracking documents will be updated.

HMPC endorsed that a revision of the monograph is deemed necessary given the new market overview and some other information obtained: a herbal preparation not yet included in the monograph (TU since 1976), four herbal preparations that require an update as regards posology or extraction solvent, and more precise information made available on the starting material of several herbal preparations (white or red ginseng) which should be addressed in the AR.

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

HMPC endorsed that from a clinical efficacy/safety point of view no revision is deemed necessary as medicinal products corresponding to the therapeutic indications described in clinical studies are not reported to be on the EU market (WEU criteria are not fulfilled) and no causal link could be established between any adverse events and herbal medicinal products containing Juglandis folium.

2.4.5. Monograph on Paulliniae semen and supporting documents - Postponed

2.4.6. Monograph on Tiliae flos and supporting documents – Postponed

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.

Rapporteur to modify the concept paper (CP) according to the discussion and comments from the second Rapporteur and EMA secretariat for **adoption** for publication at the **HMPC September** meeting.

Timetable:
Document to be sent to Rapporteur II: **31 July 2022**
Comments/corrections to be sent to Rapporteur I: **16 August 2022**
Pre-final document to be sent to HMPC secretariat: **30 August 2022**
Final documents to be included latest in 2nd premail: **13 September 2022**

HMPC noted that chapters 1 to 3 (introduction, problem statement, discussion (on the problem statement)) have been revised to better reflect that the CP is fit for purpose. Only main reasons for a required guideline (GL) revision are to be announced in the CP in analogy with other CPs of HMPC or other EMA groups: i.e. time elapsed since the first version (more than 10 years ago), change of the ICH framework, and experience gathered from applying the current GL.

4.2. Quality

None

4.3. Regulatory / Procedural

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

Action: For discussion

Document tabled: Draft revised procedure (Rev. 3), Draft revised template

Outcome:

HMPC noted new changes in the *"Review Report template"* that is part of the *"Procedure for the review and revision of European Union herbal monographs and European Union list entries"*.
HMPC members were invited to send comments to the Rapporteurs (in particular on topic 3), in order to finalise the revision for possible adoption at the **HMPC September meeting**.

Rapporteurs highlighted that the procedure in principle does not change (no need for public consultation) and updates reflect only minor changes in current practice (e.g. MLWP tasks taken by HMPC).

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

Action: For information

Document tabled: Ad-hoc Quality Group Minutes June 2022

Outcome:

HMPC noted the progress achieved by the ad-hoc Quality Group. It was highlighted that the selection process of core members for the EMA's Quality Innovation Group (QIG) is ongoing. A preliminary discussion on the reflection paper on newly used manufacturing techniques regarding herbal preparations and extracts was carried out with an invited expert. In addition, first steps were given towards the update/revision of questions & answers on quality of herbal medicinal products (EMA/HMPC/41500/2010).
Next meeting scheduled for 07 September.

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 July 2022

  Report: HMPC Vice Chair

  Action: For information

  Document tabled: Follow up plan

  Outcome:

HMPC Vice Chair to modify the follow-up list according to the discussion in terms of priorities with a view which topics are relevant for the HMPC work plan 2023 and which topics to be taken up / further developed at the next SRLM meetings.

HMPC noted that topics on the follow-up plan should be streamlined and adjusted for the current year. While not all topics are (yet) to be considered for the HMPC annual work plan, future vision/ideas should be kept and further developed as appropriate. In particular, the Chair emphasised the role of Multi Expert Assessment Teams in future (Rapporteur and Peer-reviewer), which was scheduled to be established in 2022. Additionally, and in regard to the future role of ARSP in HMPC communication, it was noted that there are ongoing discussions within the Patients' and Consumers' Working Party (PCWP).

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

  Report: Marketa Prihodova, Everaldo Attard

  Action: For information

  Outcome:

  The Chair announced the start of the Czech Republic Presidency of the Council of the European Union. HMPC noted that the next SRLM will be hosted by Malta on 9-11 November 2022.

5.1.2. HMPC membership

Membership update

Report: HMPC Chair

Action: For information

Outcome:

New members:

- Slovakia, Jaroslav Toth (alternate) as of 11 July 2022
- Lithuania, Greta Budukeviciute (member) as of 01 July 2022

Re-nominated members:

- Austria, Reinhard Länger (member) as of 22 September 2022
- Germany, Heidi Foth (co-opted member) as of 8 July 2022
- Malta, Matthew Camilleri (alternate) as of 9 October 2022
- Finland, Sari Koski (alternate) as of 24 September 2022

End of membership:

- Lithuania, Jurate Antanaviciene (member) as of 30 June 2022

5.1.3. EMA records management system – update on Sharepoint migration

Action: For discussion

Document tabled: Presentation

Outcome:

HMPC was informed about the EMA's plan for switching from DREAM to SharePoint as the new Agency's document management system, with a gradual migration foreseen for between July and September.

The scientific cabinets relevant to the Committees' members are foreseen to be migrated in August and several training dates are available in EU NTC for Committees' members to attend (strongly encouraged to do so).

Post-meeting note: After the meeting, HMPC was informed that the migration from DREAM/MMD to SharePoint will not take place over the summer as initially planned. An updated plan will be shared with HMPC members as soon as possible.

5.1.4. Hybrid meetings Q3-Q4 2022

Action: For discussion

Document tabled: Presentation

Outcome:

HMPC was informed about EMA's plan on Committees' face-to-face meetings scheduled from September to December 2022. Dates already defined for Committee meetings in 2022 are unchanged and in general there is a monthly alternance of remote and face-to-face/hybrid meetings. As HMPC meets every two months, the remaining two meetings of the year (to be held in September and November) will be face-to-face/hybrid.

5.2. EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair

Action: For information

Document tabled: Agenda 27 June 2022

Outcome:

HMPC noted topics discussed in June and on agenda for discussion in September at the Scientific Coordination Board.
The HMPC Chair highlighted that migration to Sharepoint and implementation of the new WP architecture were addressed during the last meeting.

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 adoption

Documents tabled: Addendum to the QRD templates, Readers Guidance

Outcome:

Updated herbal addendum to the QRD templates adopted by consensus.
Secretariat to send the updated addendum to the QRD for comments/endorsement before transfer to CMDh.

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

Action: For discussion

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

Outcome:

HMPC noted that the list of estragole-containing herbal substances requested by CMDh to complement the HMPC PS 'on the use of herbal MPs containing estragole' had been reduced to those three with available EU herbal monographs and available information on strength and posology - being also those of highest concern.
Rapporteurs to add an explanatory note with the rationale and will contact the CMDh Chair before the next meeting.

The understanding/handling of substances with lower or non-confirmed estragole content should be briefly indicated before the list is sent to the CMDh. To be considered: substances listed in the table included in the HMPC PS, substances potentially part of excipients or new active substances with or without an EU herbal monograph, availability of Ph. Eur. monographs.

5.2.4. Outcome PSUSA/00010707/202110 soybean phospholipids (oral use)

Action: For discussion

Document tabled: Report from the CMDh meeting held on 21-22 June 2022

Outcome:

HMPC noted the CMDh decision on the variation of the marketing authorisations of medicinal products containing soybean phospholipids (oral use) as active substance. This decision was taken having considered the PSURs on the basis of the PRAC recommendations and the PRAC assessment reports.
HMPC agreed to add to the 2023 work plan the lecithin herbal monograph from 2018 for review and check of necessary revision.

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

None

5.4. Cooperation within the EU regulatory network

5.4.1. Coordination with European Pharmacopoeia

- EDQM 13A expert group meeting

  Report: Melanie Bald

  Action: For information

  Document tabled: SoD

- EDQM TCM expert group meeting

  Report: Melanie Bald

  Action: For information

  Document tabled: SoD

  Outcome:

HMPC noted the summaries of decisions from the June 2022 13A group meeting and the May 2022 TCM group meeting and highlights presented by the EDQM observer.

Regarding the 13A group, it was highlighted that the following monographs will be published in Pharmeuropa:

- Anisi aetheroleum;
- Rosmarini folium;
- Viola herba cum flore.

The next meeting of the 13A group will be held in October 2022.

In the context of TCM group, it was highlighted that the following monographs will be published in Pharmeuropa:

- Amomi fructus;
- Amomi fructus rotundus;
- Polygoni multiflora caulis.

The next meeting of the TCM group will be held in October 2022.

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

Document tabled: Draft Questions & Answers

See also: 7.2.4.

Outcome:

HMPC noted progress on the draft Q/A document regarding cannabis-derived herbal products. According to the HMPC work plan 2022 a specifically tailored Call for data will be established under cross reference to general information in the Q/A document.
An improved version of the draft Q/A together with a draft Call for data will be prepared in advance to the HMPC September meeting.

5.5. Cooperation with International Regulators

5.5.1. India — EC/EMA Joint Technical Working Group Ayurveda

Report: HMPC Chair

Action: For information

Outcome:

HMPC noted short feedback from a first meeting with the Indian counterpart and challenges coming from mutual understanding and a summary of actions.
The agreed meeting report will be circulated in advance of a 2nd meeting with Indian authorities.

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

Post-hearing discussion / follow-up

Report: HMPC Chair

Action: For adoption

Document tabled: Report on the AESGP hearing at HMPC meeting, May 2022

Outcome:

HMPC adopted the report on the AESGP hearing that was held during the HMPC meeting in May.
The hearing report will be published on the EMA website.

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 July 2022

Outcome:

HMPC noted the progress with topics on the HMPC work plan 2022.
The Chair announced that all work plan topics will be put on the HMPC September agenda for a short update by the topic lead.
All topic leads were invited to flag when there is a need for organisation of a group meeting and if they need the support of the secretariat.

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

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

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 11th discussion

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

Outcome:

Rapporteur to introduce changes agreed in the draft monograph and to adapt the assessment report according to the discussion and to send the package to the peer-reviewer.
Next **discussion** scheduled for the **HMPC September** meeting aiming for finalisation and adoption at the HMPC November meeting.

Rapporteur presented all the changes introduced in the MO and highlighted that in the WEU part sections 4.3 and 4.5 depend on the actual herbal preparation, the limit regarding hyperforin is mentioned in section 2 only for herbal preparation d). In the TU part the differentiation based on the daily intake of hyperforin is kept as in the published version of the MO. Rationale for this is that the duration of use is limited to 1 week (indications 2 and 3) or 2 weeks (indications 1 and 4).

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

6.2.1. Monograph on Hippocastani cortex and supporting documents

Action: For 1st 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 further comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC September** meeting.

The HMPC agreed to accept as TU the French product, which means at least 15 years on the European market. The AR should reflect the review of those last 15 years of the product on the French market.

6.2.2. Monograph on Lavandulae aetheroleum and supporting documents

Action: For 5th discussion

Documents tabled: Draft MO, AR, LoR, Presentation

Outcome:

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

Some HMPC members emphasised that a decision for revision of the MO was adopted in November 2020 due to new scientific data and therefore section 5.3 (adverse events) in the AR should be updated to reflect available data.

6.2.3. Monograph on Pelargonii radix and supporting documents

Action: For 3rd 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 further comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC September** meeting.

Rapporteur highlighted all the changes added in the draft MO: inclusion of children from 4 years of age in order to be in line with other MOs in the same therapeutic area, i.e., Tilia flos, Primula radix; inclusion of the missing adverse reactions in the current MO; correction of the determination of the active substance in the solid pharmaceutical form. Regarding section 2 qualitative and quantitative composition for herbal preparation b) HMPC agreed to express it as *"dry extract corresponding to preparation a)"*. In addition, HMPC agreed not to merge the liquid and dry extract preparations. AR to be adapted accordingly.

6.2.4. Monograph on Plantaginis lanceolatae folium and supporting documents

6.2.5. Monograph on Rosmarini aetheroleum and supporting documents

Action: For 6th 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 further comments from peer-reviewer and HMPC member, for **possible adoption** for public consultation at the **HMPC September** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **16 August 2022**
Peer-review documents to be sent to Rapporteur: **30 August 2022**
Final documents to be included latest in 2nd premail: **13 September 2022**

Rapporteur highlighted that oral use of the essential oil was removed from the current draft MO as supporting references were not correctly interpreted or not in use (British Herbal Pharmacopoeia, French Pharmacopoeia) and there are not or have not been any products

on the market. The rational for this withdrawal has been included in the AR, together with some changes suggested by the peer-reviewer.

6.2.6. Monograph on Rosmarini folium and supporting documents

Action: For 6th 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 further comments from peer-reviewer and HMPC member, for **possible adoption** for public consultation at the **HMPC September** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **16 August 2022**
Peer-review documents to be sent to Rapporteur: **30 August 2022**
Final documents to be included latest in 2nd premail: **13 September 2022**

Some HMPC members noted that the wording in MO section 4.4 special warnings and precautions for use should be updated in accordance with previously adopted similar herbal products.

6.2.7. Monograph on Urticae herba and supporting documents

Action: For 2nd discussion

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

Outcome:

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

As the term 'adjuvant' supposes a defined treatment to which the herbal treatment can be added, and there is no clear instruction in that way, the therapeutic indication is reduced not mentioning the use 'as an adjuvant'. The herbal preparation d*) 'Expressed juice (1:1) from fresh herb, stabilized and adjusted with ethanol 96% (V/V), 20-25% ethanol content in final product'* should be confirmed. For indication a), and in section 4.4. special warnings and precautions for use, further inputs should be considered for children (<12 years) and even for adolescents (<18 years).

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

6.3.1. Monograph on Agrimoniae herba 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 monograph.
Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC September** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **16 August 2022**
Peer-review documents to be sent to Rapporteur: **30 August 2022**
Final documents to be included latest in 2nd premail: **13 September 2022**

Rapporteur highlighted that there are no new authorised/registered herbal medicinal products in the EU countries influencing the content of the MO on Agrimoniae herba that could trigger a revision of the monograph.

6.3.2. Monograph on Epilobii herba and supporting documents

Action: For 1st discussion

Documents tabled: Review report, Reader's Guidance, Reference

Outcome:

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 September** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **16 August 2022**
Peer-review documents to be sent to Rapporteur: **30 August 2022**
Final documents to be included latest in 2nd premail: **13 September 2022**

Rapporteur highlighted that there is no new medicinal product containing Epilobii herba (as the only active ingredient) on the market and no data was submitted during the call for scientific data. Some HMPC members noted that there is a new clinical study, and even though this one was done with a product classified as food supplement, it was agreed to consider the study in the review report.

6.3.3. Monograph on Eschscholziae herba 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 monograph.
Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC September** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **16 August 2022**
Peer-review documents to be sent to Rapporteur: **30 August 2022**
Final documents to be included latest in 2nd premail: **13 September 2022**

Rapporteur highlighted that no new references were provided by Interested Parties during the call for data, no new mono-products were reported from the Member States and no new relevant scientific data is available.

6.3.4. Monograph on Sisymbrii officinalis 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 September** meeting.

Rapporteur highlighted that revision is recommended because a new more detailed posology was provided (stratified posology for the orally used product in children). HMPC requested additional information about TU of this stratified posology for the orally used product in children and a justification for not having been considered in previous assessments (to be confirmed for the Belgian product).

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 3rd discussion

Documents tabled: OoC, Reader's Guidance

Outcome:

Rapporteurs to introduce changes in the overview of comments and start the revision of assessment report according to the discussion and to send the package to the peer-reviewer.
Controversial remaining points discussed at the small group were summarised by the Vice Chair one by one in a Reader's guidance, discussed and agreed including via trend votes to have clear direction for finalisation of OoC, AR and MO without need for re-discussion.
Next **discussion** scheduled at the **HMPC September** meeting aiming for finalisation and adoption at the HMPC November meeting.

Regarding the overall conclusions on TU in the AR section 2.3, HMPC endorsed the Rapporteurs proposal to keep the juice in the monograph as "*expressed juice from the fresh fruit (DER 1:0.6-0.9)"*.
Regarding the OoC, HMPC endorsed the Rapporteurs position that information about the refinement step is considered insufficient in the public domain, and the herbal preparation will not be included in the monograph. HMPC members to confirm their availability to revise information on market overview to be included in the assessment report. Netherlands confirmed that the original information should be kept in the assessment report (Spain to confirm their position on this matter). HMPC agreed to update the information regarding the UK registration in accordance with the latest SmPC on the MHRA webpage. Also, HMPC agreed to delete brand names of food supplements and medical devices in the assessment report and to shorten the information to include relevant information on medicinal use only.

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

6.5.2. Monograph on Cnici benedicti herba and supporting documents

Action: For 3rd discussion

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

Outcome:

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

HMPC agreed to remove *"5.0-10.0 g of herbal substance or comminuted herbal substance as a tea preparation in 150-200ml of boiling water, before meals"* from the MO and to add an explanatory note in the AR identifying the reasons for this preparation not to be considered. Also, HMPC agreed to keep the liquid forms in the MO for the time being.

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

Action: For 2nd discussion

Document tabled: Presentation

Outcome:

Rapporteur to prepare first draft of the monograph for discussion at **HMPC September** meeting.

HMPC agreed with the Rapporteur's proposal to develop a TU monograph for the herbal combination *"3.75 mg dry extract from Cimificugae rhizoma DER 6-11:1, extraction solvent propan-2-ol 40% V/V + 70 mg dry extract from Hyperici herba, DER 3.5-6:1, extraction solvent ethanol 60% V/V"*.

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 16-18 May 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

- EDQM certification of suitability (CEP) procedure – actions taken on CEP/CEP applications
- Cannabidiol novel food evaluations on hold pending new data
- Draft Agenda - PCWP and HCPWP meeting - 22 September 2022
- Meeting minutes - PCWP and HCPWP meeting – 01-02 June 2022

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 18-20 July 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	
Gert Laekeman	Co-opted member	Belgium	No interests declared	
Patricia Bodart	Member	Belgium	No interests declared	
Ivan Kosalec	Member	Croatia	No interests declared	
Antri Kouroufexi	Member	Cyprus	No interests declared	
Markéta Příhodová	Member	Czechia	No restrictions applicable to this meeting	
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	
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	
Sven Back	Member	Luxembourg	No interests declared	

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