25 January 2023
EMA/HMPC/917662/2022
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 21-23 November 2022

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

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 21-23 November 2022.

Outcome:

Agenda and time schedule adopted.

1.3. Adoption of the minutes

HMPC minutes for 19-21 September 2022.

Outcome:

Minutes adopted (with minor changes introduced prior to the start of and some changes 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 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 January 2023 meeting according to the overview, Rapporteurs were urgently asked to inform secretariat and Chair before the first pre-mail (by 10 January 2023) to allow best adaptation of agenda and time-schedule.

2.1.2. Appointment of Rapporteurs and Peer-reviewers

New Peer Reviewer

Reviews started 2022:

- Agrimoniae herba
- Capsici fructus
- Crataegi folium cum flore
- Ginkgo folium
- Matricariae flos
- Myrtilli fructus siccus
- Myrtilli fructus recens
- Pilosellae herba cum radice
- Pruni africanae cortex
- Ricini oleum
- Rosae flos
- Sideritis herba

New Rapporteur

Re-appointments according to membership change for ongoing assessment procedures:

- Sisymbrii officinalis herba (Review – D)
- Symphyti radix (Review – D)
- Urticae herba (Revision – D)
- Urticae radix (Revision – D)
- Vaccinii macrocarpi fructus (1st assessment PF)

Outcome:

HMPC agreed on new Peer reviewers for the above periodic reviews started in 2022.
Also re-appointments of new Rapporteurs according to membership change for the above ongoing assessment procedures were agreed.
HMPC secretariat will update the HMPC status overview.

2.1.3. Prunus cerasus – proposal for assessment

Action: For discussion

Documents: Proposal for assessment, references, presentation

Outcome:

HMPC noted and discussed limited available information and references on different substances/preparations.
Members were invited to send information on products with *Prunus cerasus* substances that might be available on their national markets to the Rapporteur for update of the proposal **by 16 December 2022.**
Rapporteur to send extended proposal to the HMPC secretariat by **10 January 2023** for validation and committee decision at the January HMPC plenary.

It was acknowledged that information on traditional use from various EU MSs is limited and partially derived from bibliographic references and product categories other than authorised MPs. Some members considered that assessment work should only be started for substances that are already formally on the market as MP. Others referred to the legislation and the need for data on 'medicinal use', independent of the product category / source it is derived from as also made transparent in the template.

2.1.4. Species pectoralis – proposal for assessment

Action: For discussion

Documents: Proposal for assessment, references

Outcome:

HMPC noted and discussed available information and references on products and magisterial tea combinations.
Members were invited to send information on products/ tea combinations labelled as Species pectoralis, expectorans, antitussivae or related that might be available on their national markets to the Rapporteur for update of the proposal **by 16 December 2022.**
Rapporteur to send extended proposal to the HMPC secretariat by **10 January 2023** for validation and committee decision at the **January HMPC plenary**.

Members were also invited sending other proposals for assessment by 10 January 2023 using the same template (see also 5.7.2).

For tea combinations in the area cough and cold, some members foresaw some difficulties when applying the established principles, e.g. on herbal substances with documented use in combinations but no established HMPC mono-monograph, or with regard to the demarcation of closely related therapeutic indications. However, it was recommended to leave single problems to the assessment as such, and first decide on the general possibility and usefulness to establish a monograph. For comparable questions previously solutions have been found e.g. Species digestivae.

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

2.2.1. Monograph on Hyperici herba and supporting documents

Action: For adoption

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

Outcome:

Final revised EU herbal monograph and supporting documents adopted by majority (19 out of 28). Divergent opinions: Cyprus, Finland, Greece, Hungary, Italy, Netherlands, Portugal, Republic of Ireland. The Norwegian delegate expressed a favourable position.

The Rapporteur presented changes introduced in AR and MO (no changes in LoR and OoC). Three final questions were discussed: (1) HMPC agreed to maintain the particular high posology of 1800 mg (posology: 300-600 mg/1-3 times daily) as the maximum daily dose for the herbal preparation a (WEU). (2) Pharmacokinetic interactions: HMPC agreed to keep the list of examples in 4.5 as a compromise as agreed before public consultation. A footnote referring to the corresponding AR section and to national procedures gives flexibility for concrete product information without trying to be exhaustive and up to date in the MO. (3) Pharmacodynamic interactions TU: Warnings were widened from dry extracts to all preparations to align with the WEU part although there are no case reports indicating pharmacodynamics interactions with any TU preparations (duration of use < 2 weeks). The Rapporteur highlighted that the inclusion (acknowledging pharmacodynamic interactions) means practically that at least some clinical activity would be assumed without recognition of therapeutic efficacy.

Divergent opinions referred mainly to concerns on the proof of efficacy (WEU) and on safety, particularly the interaction potential and appropriateness for self-medication for TU.

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

2.3.1. List entry on Foeniculi amari fructus and supporting documents

Action: For adoption

Document tabled: Revised LE, Reader's Guidance

Outcome:

Draft revised list entry adopted for 3 months public consultation.

The Rapporteur informed that the revised draft LE was modified in the section "Pharmaceutical particulars" following the approach taken in the revised LE for peppermint oil. Subsequently the LE text is not exactly the same as in the corresponding section of the monograph.

HMPC members agreed to the proposal to delete in Special warnings and precautions for use (Indications 1 and 3) the qualifier: '…, unless justified by a risk assessment based on adequate safety data' regarding the use in children between 4 and 12 years of age (not recommended if estragole exceeds the guidance value of 1.0 µg/kg bw per day). Rationale: applications based on a list entry should not require any additional data by the applicant.

It was agreed that the rationale for LE revision will be added in the final ARs. Draft ARs published already with the draft revised MOs did not yet cover the LE revision specifically.

2.3.2. List entry on Foeniculi dulcis fructus and supporting documents

Action: For adoption

Document tabled: Revised LE, Reader's Guidance

Outcome:

Draft revised list entry adopted for 3 months public consultation.

See 2.3.1

2.3.3. Monograph on Rosmarini aetheroleum and supporting documents

Action: For adoption

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

Outcome:

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

HMPC agreed to remove the new herbal substance synonym from the MO title (not yet confirmed in Ph. Eur. MOs) in line with previously agreed conventions.

The omission of the essential oil use as bath additive in comparison to the first monograph was confirmed.

In section 4.8. Undesirable effects the wording was adapted to MedDRA terminology, a new proposal also intended to be changed in the AR template in general.

2.3.4. Monograph on Rosmarini folium and supporting documents

Action: For adoption

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

Outcome:

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

The Rapporteur highlighted the rewording of posology for use as bath additive (indication 2 preparation a) but also some adaptions in the oral use posology according to critical evaluation of the information presented in the AR. Some data gaps and possible inaccuracies in traditional dosage information (level of comminution, 'leaves vs. twigs', bulk volume and teaspoon sizes) were acknowledged but not considered highly relevant.

Moreover, the HMPC agreed to remove the new herbal substance synonym from the MO title (not yet confirmed in Ph. Eur. MOs) in line with previously agreed conventions.

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:

HMPC agreed with Rapporteur's position that no EU herbal monograph revision is needed because no new data of relevance were detected that would change the content of the monograph.

The Rapporteur emphasised that the newly available toxicological information (mainly resulting from the Ames test) was considered insufficient to trigger a revision of the MO, and also no new medicinal products were found available on the market.

The HMPC decided by consensus not to revise the monograph, assessment report and list of references on Agrimoniae herba.
The review report was adopted and after editorial review will be published as addendum to the existing assessment report on the EMA website.

2.4.2. Monograph on Paulliniae semen and supporting documents

Action: For adoption

Document tabled: Review report, Reader's Guidance

Outcome:

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

2.4.3. Monograph on Tiliae flos and supporting documents

Action: For adoption

Document tabled: Review report, Reader's Guidance

Outcome:

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

The HMPC agreed to simplify the information included in the section 'New regulatory practice that could trigger a revision of the monograph' according to the new review report template. Moreover, and based on the Rapporteur comments, it was agreed to include additional information under the section 'New information not considered to trigger a revision at present but that could be relevant for the next review'.

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

2.5.1. Monograph on Vaccinii macrocarpi fructus and supporting documents

Action: For adoption

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

Outcome:

Final EU herbal monograph and supporting documents adopted by majority (20 out of 24). Divergent opinion: Cyprus, Germany, Lithuania, Poland. The Norwegian delegate expressed a favourable position.

Following the HMPC September discussion, footnotes had been added to table's 3a) and 3b) in the AR, to clarify the DER and rounding up of the posology in the MO.

For the prevention of urinary tract infections (UTIs), the original source of an EFSA reference regarding the posology of 63 ml twice daily was investigated by the Peer-Reviewer, who found no earlier reference for the posology in the 2009 EFSA opinion based on a claim submitted by the applicant that does not explicitly mention the use in the EU.

Subsequently Rapporteur / Peer-Reviewer proposed to delete the EFSA reference from AR table 3b as well as the posology of 60 (63) ml twice daily from the MO, because documentation is missing for 30/15 years of use. The deletion also solved the problem of "the gap" between two traditional posologies for the prevention of UTI. Also, the dose and frequency of use for the prevention will no longer be in the same range as in the posology for the treatment of UTI. A majority of members supported this view. A minority preferred to keep ranges as established for the draft MO considering the overall level of inaccuracy in traditional uses not justifying too strict dosages of juice quantities.

Divergent opinions referred mainly to missing data for a 15 years' tradition in the EU.

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

Action: For discussion

Document tabled: Draft concept paper

Outcome:

The HMPC discussed the draft CP for GL revision and current relevance in national procedures, MRPs/DCPs, as well as monograph establishment.
Several members did not support the revision and considered the GL as not used / obsolete.

It was proposed to add useful combination elements to the general herbal clinical GL (EMA/HMPC/104613/2005 – Rev. 1) with the next revision but not starting a revision of EMEA/HMPC/166326/2005.
The need for revision or withdrawal of the herbal fixed combination GL should be embedded in the overall approach taken on the combination project on the 2023 HMPC work plan (see 5.7.2).
Members to send comments to the Rapporteur for next **discussion** scheduled for the **HMPC January 2023** meeting.

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 discussion

Document tabled: Comments on Concept Paper, OoC

Outcome:

HMPC noted update by the Rapporteur and discussed some general aspects of the revision. Presentation of the first draft revised GL for **discussion** scheduled for the **HMPC January 2023** meeting.

Members discussed some aspects that currently draw specific interest to this GL such as the need to distinguish indoor and outdoor cultivation in view of different levels of possible control, consequences for different fumigation provisions in and outside the EU, the overlap of GMP and GACP (Annex 7), the status of EU/ HMPC guidance vis-à-vis WHO guidance and the general risk to focus too much on current requests related to cannabis cultivation.

4.3. Regulatory / Procedural

4.3.1. 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

See 5.7.1.

Outcome:

Rapporteur pointed to the previously endorsed merger of this procedure for the appointment of a Rapporteur (EMEA/HMPC/108877/2005) with three old procedural documents (EMEA/HMPC/182320/2005, EMA/HMPC/182352/2005, EMA/HMPC/57137/2007) into a single document (see also 5.7.1).
New proposals on e.g. assessment teams will be directly incorporated and discussed there.

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 November 2022

Outcome:

The HMPC noted the topics that were discussed during the QDG meeting held on 02 November, in particular regarding the document 'Questions & answers on quality of herbal medicinal products / traditional herbal products (EMA/HMPC/41500/2010 Rev.6)'.

Ongoing and planned items were highlighted with a need to update the work plan as regards quality guidance. It was emphasized that early scheduled meeting dates for the first half of 2023 will improve availability of members for discussion (see also 4.4.4).

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

  Action: For discussion

  Document tabled: Quality documentation for medicinal products when used with a medical device

  Outcome:

  The Rapporteur summarised latest discussions including a request for a separated document with the "old Q/As" deleted taken to the GLs, which was clarified to be difficult for occasionally updated Q/A documents.
  For a pragmatic approach it was agreed to cluster changes in EMA/HMPC/41500/2010 for not delaying agreed updates further but also not to revise and re-publish the Q&A with single item changes too often.
  Additional discussion planned at the ad-hoc QDG before tabling Revision 7 for adoption at HMPC.

- Guidance on newly used manufacturing techniques regarding herbal preparations

  Action: For discussion

  Document tabled: Draft concept paper

  Outcome:

  Rapporteur summarised the first draft CP.
  A majority agreed in principle to publish first a concept paper in 2023 to invite for feedback/ data from IPs before stimulating the discussion with a reflection paper (not a direct guidance document). Rapporteur to reflect comments/discussion e.g. on relevance of single methodologies or benefits for industry.
  Additional discussion planned at the ad-hoc QDG before presentation at the HMPC.

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

Action: For discussion

Document tabled: Draft concept paper

Outcome:

Rapporteur summarised the first draft CP.
Accumulated experience with marketing authorisation/registration procedures of HMPs/THMPs in connection with Ph. Eur. updates after 2010 and revised related HMPC guidelines require the revision of the GL.
HMPC members, in particular quality assessors, were invited for sending comments on the CP to the Rapporteurs before **possible adoption** at the **HMPC January 2023** meeting.

- 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 discussion

Document tabled: Discussion paper

Outcome:

The Rapporteur invited quality assessors for comments on the discussion paper to primarily agree on aspects that need improvement. Plan is to draft a roadmap how to reflect that best vis-a-vis the existing RP on markers, other already updated HMPC guidance and at which point to involve EDQM (no intention to change Ph. Eur. definitions).
HMPC members to send comments to the Rapporteurs for discussion planned at the ad-hoc QDG.

4.4.4. Update on Quality domain

Action: For discussion

Document tabled: Presentation

Outcome:

HMPC heard a presentation on the Working party Operational Model (WOM) - Quality Domain covering priorities, architecture, and operational model.
Difficulties with the non-recognition of a herbal specialised expert community, neither fitting into the chemical nor the biological ESEC (specific legislation) and subsequent organisational issues (e.g. DG status, governance) were discussed. The HMPC Chair emphasised the need for a permanent 'home platform' for a loyal group of active quality assessors feeding into the HMPC, and that clear and updated Guidance on Quality issues remains crucial for a harmonised quality assessment by national competent authorities.
It was confirmed that due to delays with the implementation in the quality domain, HMPC QDG should continue in 2023 its work as done previously ('business as usual') according to current mandate (members, Chair, meeting organisation).
A plan to structure according to 'business as usual' will be presented at next meeting.

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 November 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. Moreover, it was agreed to change the designation 'Multi Expert Assessment Team (MEAT) to 'Multi-Disciplinary Expert Team (MDET)'.

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

  Report: Marketa Prihodova, Everaldo Attard

  Action: For information

  Document tabled: Agenda, Presentations

  Outcome:

  The HMPC noted the final agenda and presentations adopted for the HMPC SRLM meeting hosted by Malta (on behalf of the Czech Republic Presidency of the Council of the European Union) on 10-11 November 2022.
  Results of group discussions on the HMPC communication and interactions were presented. Furthermore, the HMPC Chair summarised the "pros and cons" of options for meeting organisation and member participation in 2023 (virtual, hybrid, and face-to-face meetings) and presented two proposals.

5.1.2. HMPC membership

Report: HMPC Chair

Action: For information

Outcome:

New memberships:

- Hungary, Jullia Pallos (member) as of 22 September 2022
- Cyprus, Christina Sylvia Chrysostomou (member) as of 22 September 2022
- Cyprus, Alexandra Demetriou (alternate) as of 22 September 2022

End of membership:

- Denmark, Steffen Bager (member) as of 21 September 2022)
- Cyprus, Antri Kouroufexi (member) as of 21 September 2022
- Cyprus, Maria Yiannitsarou (alternate) as of 21 September 2022

Re-nominated members:

- Germany, Jacqueline Wiesner (member) as of 13 October 2022
- Germany, Susanne Flemisch (alternate) as of 13 October 2022

The HMPC Chair welcomed the new/re-nominated members and thanked all members who terminated their membership.

5.1.3. Preparation for election of HMPC Chair

Action: For discussion

Documents tabled: HMPC RoP, Presentation

Outcome:

The HMPC was reminded on the provisions of article 3 of the RoP applicable to the election of the HMPC Chair and Vice-Chair as well as practical implementation and timelines.
Elections are due to take place during the HMPC January 2023 meeting and the HMPC March 2023, respectively, using the EU survey tool instead of a ballot box.
HMPC members were invited to submit in writing their candidatures for the HMPC Chair by 13 January 2023 and for the HMPC Vice-Chair by 03 March 2023. Calls for candidatures will also be sent out.

5.1.4. Document collaborative platform – Teams integration

Action: For discussion

Document tabled: Presentation

Outcome:

The HMPC was briefed about Teams (a Microsoft tool) as a possible document collaborative platform to be used in the future for editing documents online.
Topics (channels) relevant to HMPC work are to be defined before creating them in Teams.
Dedicated IT support is expected to be present at one of the next meetings to assist HMPC members in configuring Teams on their computers.

5.2. EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair

Action: For information

Document tabled: TBC

Outcome:

The HMPC Chair gave a short view on relevant topics of the last Scientific Coordination Board (SciCoBo) meetings.
The next SciCoBo meeting will be held on 02 December 2022 where for instance the next year's scientific committees' meetings organisation and also committee work plans will be discussed.

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

Action: For adoption

Document tabled: List of estragole-containing plants

Outcome:

The Rapporteurs presented 2 lists, one with estragole-containing herbal substances/essential oils of higher concern (content >1000 ppm), and another for which the amounts of estragole are not specified, not confirmed and/or relatively low.
Some HMPC members asked for a review/correction of the botanical names.
Rapporteurs to facilitate the understanding of each list in a short qualifier vis-à-vis the HMPC PS to enable national assessors without herbal background to largely understand differences in total amounts and knowledge on estragole contents in different herbal substances when searching in their national databases.
Adoption of the finalised document is scheduled for the **HMPC January 2023 meeting** before submission to CMDh.

Some members questioned the practical usability of the 2 lists by national assessors without 'instructions for use' on 'high-alert' plants vs. 'low-alert plants'. Also difficulties in procedures were mentioned vis-à-vis the list contained in the PS as such (copied from an EFSA reference) e.g. when for a plant listed no references are available to confirm specific contents in estragole. The Rapporteurs highlighted the difficulties to find reliable references for estragole contents specific for defined herbal substances.

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, Bruno Spieldenner

  Action: For information

  Document tabled: SoD

- EDQM 13B expert group meeting

  Report: Melanie Bald, Bruno Spieldenner

  Action: For information

  Document tabled: SoD

- EDQM TCM expert group meeting

  Report: Melanie Bald, Bruno Spieldenner

  Action: For information

  Document tabled: SoD

- Draft *Cannabis flos* monograph published in Pharmeuropa

Report: Melanie Bald, Bruno Spieldenner

Action: For information

Document tabled: *Cannabis flos* draft monograph Pharmeuropa

Outcome:

HMPC noted the summary of decisions from the October 2022 13A group meeting, September 2022 13B group meeting and the October 2022 TCM group meeting as presented by the EDQM observer.
HMPC members enquired briefly about the current status of Ph. Eur monograph development for Vaccinium macrocarpon, Indian plants previously suggest by HMPC such as Withania somnifera, Aesculus hippocastanum, Cannabis-derived substances and also proposed having an annual meeting with the Chairs' of groups 13A, 13B and TCM.

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 adoption

Outcome:

Adoption postponed.
Rapporteur presented the latest proposal after discussion of several comments received from members and the Agency's Legal and Regulatory Affairs office.
While no new changes were introduced, some sensitive sections (e.g. Call for data introduction, Q&A on eligible / excluded therapeutic indications) were discussed from a perspective of regulatory correctness but also understanding of stakeholders outside established pharmaceutical regulation and the overall purpose to manage expectations.
Rapporteur to introduce final changes in draft documents Q&A and Call for data in accordance with discussion and possible final comments from the Agency's Legal and Regulatory Affairs offices, for **adoption** at the **HMPC January 2023** meeting.

5.5. Cooperation with International Regulators

5.5.1. IRCH – WHO 14th annual meeting

Report: HMPC Chair

Action: For information

Documents tabled: Communication EMA/HMPC representation, Draft Agenda virtual meeting 23-25 November 2022

Outcome:

Members endorsed participation of the two focal points representing EMA (HMPC Chair, HMPC scientific lead). Several members will also attend as national representatives.
Some organisational difficulties as already experienced the last two years were mentioned (overlap with HMPC meeting in November, zoom online setting with technical problems).

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 November 2022

Outcome:

HMPC noted the status of execution of work plan 2022 after a brief update by the HMPC secretariat.

- Improved use of data sources for HMPC relevant safety assessments

  Report: Karin Erika Svedlund

  Action: For discussion

  Documents tabled: Reader's guidance, Draft Procedure for the preparation of European Union herbal monographs and European Union list entries and appointment of HMPC rapporteurs and peer-reviewers, Draft AR Template

  Outcome:

  The approach taken to merge several old procedures including appointment of Rapporteurs was presented and in principle agreed.
  New proposals for an improved AR template were presented and particularly changes to the clinical data table discussed from a practical and scientific point of view. Rapporteurs will take suggestions into account and continue in 2023.

  A first draft of a combined modernised procedural document largely following the structure of the more recent review/revision procedure was presented and still controversially discussed issues highlighted.

  Among several improvements and additional instructions that had been introduced, the content of the clinical overview table was of highest interest and several proposals were made e.g. on necessary columns, table vs text, content expected, discussion of study limitations and clinical relevance.

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

  Report: Miroslava Horváth Petriková, Peter Voitl

  Action: For information

  Outcome:

  Postponed.

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

Report: Olga Maria Palomino

Action: For information

Outcome:

While the herbal fixed combination GL is currently not considered requiring update (see also 4.1.1.), the other actions planned for 2022 will be carried over to 2023.

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

  Report: Ana Paula Martins

  Action: For information

  Outcome:

  See 5.4.2.

- Training on assessment of applications for herbal medicinal products

  Report: Karin Erika Svedlund

  Action: For information

  Outcome:

  Following successful two new trainings in 2022 and positive feedback, the ongoing preparation of the next training for the herbal curriculum was presented: a webinar on "European Pharmacopoeia: specific chapters for herbal substances, herbal preparations and herbal medicinal products" which is being prepared together with the EDQM (expected to be delivered in March/April 2023).

- Implementation of new architecture for WP/DG

  Report: HMPC Chair

  Action: For information

  Outcome:

  The HMPC Chair referred mainly to the extended transitional period for the quality domain (see 4.4.4), while herbal subgroups and experts are not considered for other domains. In 2023, the main focus will also be on the herbal Quality DG as well as adapting HMPC procedures for MO establishment without MLWP.

- PhV data and experiences in national assessments (National experiences)

  Report: HMPC Vice Chair, Reinhard Länger

  Action: For discussion

  Documents: Proposed action for HMPC, Updated summary on national experiences with HMPC monographs during MRP/DCP procedures

  Outcome:

  The document available in MMD for use by Rapporteurs at start of review procedures was updated with new information from MRP/DCP. The discussion was postponed to the January meeting.

5.7.2. 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, Draft WP 2023, Draft Annex 1 (monographs), Draft Annex 2 (guidance), Presentation

Outcome:

The HMPC noted the status of preparation of work plan 2023 after a brief update by the scientific lead on 8 projects currently proposed by the Chairs (new or carried over from 2022).
HMPC (Vice-)Chairs and topic leads were invited to check open questions for clarity on actions/ deliverables in 2023. Further discussions and finetuning will be done in small groups in advance of the HMPC January 2023 meeting as necessary.
HMPC members were invited to send further comments and suggestions on the work plan 2023 but also on Annex 1 (monographs) and Annex 2 (guidelines).
Specific proposals on new substances or substance combinations should be submitted in the uploaded template to the secretariat by **10 January 2023** for validation allowing informed decision by the committee on additions to the work plan 2023.

5.8. Planning and reporting

None

5.9. Legislation and regulatory affairs

None

5.10. Questions from members

None

6. EU herbal monographs and list entries in preparation

6.1. Revision of EU herbal monographs and list entries in preparation for adoption after public consultation

None

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

6.2.1. Monograph on Eucalypti aetheroleum and supporting documents - postponed

6.2.2. Monograph on Hippocastani cortex and supporting documents

Action: For 3rd discussion

Documents tabled: Draft MO, AR, LoR

Outcome:

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

Timetable:
Documents to be sent to Peer-reviewer: **23 December 2022**
Peer-review documents to be sent to Rapporteur: **06 January 2023**
Final documents to be included latest in 2nd premail: **17 January 2023**

The Rapporteur highlighted changes introduced in the draft MO: update of the DER for the dry extract (7.0-8.5:1); maintenance of the indication 1) as it is in the current MO; update of the posology for the dry extract (single dose: 200 mg/2 times daily; daily dose: 400 mg). Some HMPC members pointed out that both herbal preparations should be considered for the two indications and that esculine should be kept as a chemical marker only (AR).

6.2.3. Monograph on Lavandulae aetheroleum and supporting documents

Action: For 7th discussion

Documents tabled: Draft MO, AR, LoR, Presentation

Outcome:

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

The Rapporteur summarised changes in the draft MO, mainly in section 4.6 fertility, pregnancy and lactation and regarding the safety data from use as an inhalation during labour and delivery and other periods of pregnancy and during lactation.
Several other comments referred to necessary deletions and changes required mainly in MO sections 4.7 and 4.8 taking for instance into consideration what applies to which use exactly (e.g. use as bath additive vs. oral use vs. inhalation).
Safety data in the AR were taken from an oral preparation with *Lavandula* essential oil and from inhaled *Lavandula* essential oil and have to be further considered.

6.2.4. Monograph on Pelargonii radix and supporting documents

Action: For 5th discussion

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

Outcome:

Postponed

6.2.5. Monograph on Plantaginis lanceolatae folium and supporting documents

Action: For 1st discussion

Documents tabled: Draft MO, AR, LoR

Outcome:

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

The Rapporteur highlighted the main changes introduced in the draft MO.
Some HMPC members point out the 'cough associated with cold' to be added as a third indication in MO section 4.1 therapeutic indications (and not mentioned in indication 1 as it is now).

6.2.6. Monograph on Rhodiolae roseae rhizoma et radix and supporting documents - postponed

6.2.7. Monograph on Zingiberis rhizoma and supporting documents

Action: For 3rd discussion

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

Outcome:

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

The HMPC discussed the Rapporteur's proposals regarding the duration of use in prevention of symptoms associated with motion sickness (single use before travel) and advised the rapporteur to consider the duration of use for products on the market. The HMPC did not agree to present adverse reactions in a table under the section 4.8. undesirable effects, nor to include data on oral administration of the ginger phenolics included in the section 5.2 Pharmacokinetic (WEU).

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

Action: For 1st discussion

Document tabled: Review report

Outcome:

Postponed.

6.3.3. Monograph on Ginkgo folium and supporting documents

Action: For 2nd discussion

Document tabled: Review report

Outcome:

Postponed.

6.3.4. Monograph on Helichrysi flos and supporting documents

Action: For 2nd discussion

Document tabled: Review report

Outcome:

Postponed.

6.3.5. Monograph on Myrtilli fructus siccus and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

Postponed.

6.3.6. Monograph on Myrtilli fructus recens and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

Postponed.

6.3.7. Monograph on Ononidis radix and supporting documents

Action: For 2nd discussion

Document tabled: Review report

Outcome:

Postponed.

6.3.8. Monograph on Pilosellae herba cum radice and supporting documents

Action: For 1st discussion

Document tabled: Presentation

Outcome:

Postponed.

6.3.9. Monograph on Polygoni avicularis herba and supporting documents

Action: For 2nd discussion

Document tabled: Review report

Outcome:

Postponed.

6.3.10. Monograph on Pruni africanae cortex and supporting documents

Action: For 1st discussion

Document tabled: Presentation

Outcome:

Postponed.

6.3.11. Monograph on Ricini oleum and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

Postponed.

6.3.12. Monograph on Rosae flos and supporting documents

Action: For 1st discussion

Document tabled: Presentation

Outcome:

Postponed.

6.3.13. Monograph on Rubi idaei folium and supporting documents

Action: For 2nd discussion

Document tabled: Review report, Reader's guidance

Outcome:

Postponed.

6.3.14. Monograph Sideritis herba and supporting documents

Action: For 1st discussion

Document tabled: Presentation

Outcome:

Postponed.

6.3.15. Monograph on Sisymbrii officinalis herba and supporting documents

Action: For 3rd discussion

Document tabled: Review report

Outcome:

Postponed.

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

None

6.5. EU herbal monographs and list entries in preparation for adoption for release for public consultation

6.5.1. Monograph on Cisti cretici herba and supporting documents

Action: For 14th discussion

Documents tabled: Draft MO, AR, LoR

Outcome:

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

The Rapporteur emphasised that draft MO, AR and LoR are mainly based on the information and products from the Greek tradition. It was highlighted that table in AR with the polyphenols list needs to be reviewed. Moreover, missing pharmacovigilance data should also be considered.

6.5.2. Monograph on Cnici benedicti herba and supporting documents

Action: For 5th discussion

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

Outcome:

Rapporteur to finalise the draft EU herbal monograph and supporting documents for peer review and possible **adoption** for public consultation at the **HMPC January 2023** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **23 December 2022**
Peer-review documents to be sent to Rapporteur: **06 January 2023**
Final documents to be included latest in 2nd premail: **17 January 2023**

HMPC agreed to address the warning 'when taken at high doses (greater than 5g per cup of tea) may cause stomach irritation and vomiting' in the MO section 4.9 overdose.

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

Action: For 3rd discussion

Documents tabled: Draft MO

Outcome:

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

The Rapporteur summarised the first draft MO for the fixed herbal combination Hyperici herba/Cimificugae rhizoma (TU).
HMPC noted the wording proposed for the therapeutic indication as mild climacteric complaints like hot flushes, sweating and slightly depressed mood. Some HMPC members pointed out the possibility to include information from Hyperici herba and Cimificugae rhizoma as individual herbal substances.

Problems regarding missing data for a 30 years' tradition in the EU were discussed for one specific combination.
The Rapporteur was asked to verify the posology b) and prepare the first draft AR.

6.5.4. Monograph on Tribuli terrestris herba and supporting documents

Action: For 2nd discussion

Documents tabled: Draft AR

Outcome:

HMPC noted several issues regarding available data and with respect to the indication presented by the Rapporteur in the draft AR. Rapporteur to introduce changes in the AR according to initial feedback received and draft a first EU herbal monograph as currently possible. Next **discussion** scheduled at the **HMPC January 2023** meeting.

The Rapporteur presented various challenges in the first draft AR for Tribuli terrestris herba such as data on traditional uses and scientific publications coming from various sources e.g. from Bulgaria but also different plant parts.

As already discussed in 2021 (but agreed by a majority to go ahead) when adding the substance to the HMPC work plan, the therapeutic indication is unprecedented in the HMPC TU area and should be carefully drafted. The HMPC Chair pointed out that the wording should be revised. He will send a proposal to the Rapporteur for consideration and further discussion. Furthermore, the unusual DER (for an (unprocessed) "other extract") was discussed and should be verified. A draft monograph with possible first solutions for all the challenges presented in the draft AR should facilitate the discussion at the next meeting.

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 19-21 September 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

- DRAFT Agenda - Annual PCWP-HCPWP meeting with all eligible organisation - 15 November 22
- Meeting Summary - PCWP meeting - 22 September 2022
- Meeting Summary - HCPWP meeting - 22 September 2022
- Meeting Summary - PCWP HCPWP meeting - 22 September 2022
- Recording and presentations from the "Multi-stakeholder workshop Patient experience data in medicines development and regulatory decision-making" on 21 September 2022
- Addendum to the Quality Review of Documents templates "adopted by QRD without changes and agreed by CMDh"
- Launch of a public consultation on the "EU Data Quality Framework for medicines regulation" on 18 October 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 21-23 November 2022 meeting.

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	
An Le	Member	France	No interests declared	
Ana Paula Martins	Member	Portugal	No interests declared	
Anna Maria Serrilli	Alternate	Italy	No interests declared	
Astrid Obmann	Alternate	Austria	No interests declared	
Barbara Razinger	Member	Slovenia	No interests declared	
Burt H Kroes	Member	Netherlands	No interests declared	
Carmen Purdel	Member	Romania	No interests declared	
Christina Sylvia Chrysostomou	Member	Cyprus	No interests declared	
Darko Trumbetic	Alternate	Croatia	No interests declared	
Emiel Van Galen	Chair	Netherlands	No interests declared	
Everaldo Attard	Member	Malta	No interests declared	
Ewa Antkiewicz	Alternate	Poland	No interests declared	
Gert Laekeman	Co-opted member	Belgium	No interests declared	
Greta Budukeviciute	Member	Lithuania	No interests declared	
Gro Anita Fossum	Member	Norway	No interests declared	
Heidi Foth	Co-opted member	Germany	No interests declared	
Hilda Kuin	Alternate	Netherlands	No interests declared	
Ioanna Chinou	Member	Greece	No interests declared	
Ivan Kosalec	Member	Croatia	No interests declared	
Jacqueline Wiesner	Member	Germany	No interests declared	
Jacqueline Masterson	Alternate	Ireland	No interests declared	
Jaroslav Tóth	Alternate	Slovakia	No interests declared	
Julia Pallos	Member	Hungary	No restrictions applicable to	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
			this meeting	
Karin Erika Svedlund	Member (Vice-Chair)	Sweden	No interests declared	
Maria Paile Hyvarinen	Member	Finland	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	
Marianne Loiten Dalhus	Alternate	Norway	No interests declared	
Marie Heroutova	Alternate	Czechia	No interests declared	
Markéta Příhodová	Member	Czechia	No restrictions applicable to this meeting	
Matthew Camilleri	Alternate	Malta	No interests declared	
Melanie Bald	Observer	EDQM	No interests declared	
Miroslava Horváth Petriková	Member	Slovakia	No interests declared	
Nanna Lundgaard Rasmussen	Alternate	Denmark	No interests declared	
Olga Maria Palomino	Member	Spain	No interests declared	
Olga Teresa Esteban	Alternate	Spain	No interests declared	
Patricia Bodart	Member	Belgium	No interests declared	
Radina Dimitrova	Alternate	Bulgaria	No interests declared	
Reinhard Länger	Member	Austria	No interests declared	
Rita Nemeth	Alternate	Hungary	No interests declared	
Sarah Kellaghan	Member	Ireland	No interests declared	
Sari Koski	Alternate	Finland	No interests declared	
Stavroula Mamoucha	Alternate	Greece	No interests declared	
Susanne Flemisch	Alternate	Germany	No interests declared	
Sven Back	Member	Luxembourg	No interests declared	
Wojciech Dymowski	Member	Poland	No interests declared	
Zsuzsanna Bíróné Dr Sándor	Member	Hungary	No interests declared	
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
A representative 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.