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SCIENCE MEDICINES HEALTH

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Human Medicines Division

Committee on Herbal Medicinal Products (HMPC) Minutes for the meeting on 23-25 January 2023

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

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

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1. Introduction

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

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

In accordance with the Agency's policy on handling of declarations of interests of scientific Committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and 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 23-25 January 2023.

Outcome:

Agenda and time schedule adopted with the remark to link topics 2.1.3./2.1.4. and 4.1.1 with the workplan 2023 discussion.

1.3. Adoption of the minutes

HMPC minutes for 21-23 November 2022.

Outcome:

Minutes adopted with changes introduced prior to the start of and during the meeting (topic on *Lavandulae aetheroleum*).

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 January 2023

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 asked to inform secretariat and Chair before the first pre-mail (by 28 February 2023) to allow best adaptation of agenda and time-schedule.

2.1.2. Appointment of Rapporteurs and Peer-reviewers

New assessments to start in 2023

- Pruni cerasi stipites
- Species pectoralis

Outcome:

Substances were added to the HMPC work plan 2023 (see 5.7.1) but no further substance was identified to start in 2023. Calls for data will be published on the EMA website. Rapporteur assignment postponed to the HMPC March meeting.

Periodic reviews to start in 2023

- Mastix (Mastix, Pistaciae lentisci resina)
- Allii sativi bulbus
- Lecithinum ex soya
- Soiae oleum raffinatum
- Species diureticae
- Fragariae folium
- Malvae sylvestris flos
- Malvae folium
- Silybi mariani fructus

Outcome:

HMPC agreed on Rapporteurs and Peer reviewers for the above periodic reviews to start in 2023.

HMPC secretariat will update the HMPC status overview, Inventory and Priority list and Calls for data will be published on the EMA website.

2.1.3. Pruni cerasi stipites – proposal for assessment

Action: For adoption

Documents: Validated proposal for assessment, references

Outcome:

The HMPC agreed to include Pruni cerasi stipites in Annex I of the HMPC Workplan 2023.

Additional data will be provided including the SmPC of an old product in FR to guarantee availability of essential data (posology) before start of assessment.

HMPC noted the low validation score due to absence of products currently authorised as MPs in the EU. However, due to available information on medicinal use in literature and from marketed products (other product categories) in 5 MSs and the absence of other issues, a monograph establishment was considered possible.
Rapporteur/Peer-Reviewer appointment postponed to the HMPC March meeting.

2.1.4. Species pectoralis – proposal for assessment

Action: For adoption

Documents: Validated proposal for assessment, references

Outcome:

The HMPC agreed to include Species pectoralis in Annex I of the HMPC Workplan 2023.

The Call for data should comprise related traditional tea combination mixtures in the area cough/cold (Sp. expectorantes, Sp. antitussivae) as a possible split could be necessary and proposed during the assessment.

Rapporteur/Peer-Reviewer appointment postponed to the HMPC March meeting.

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

None

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

2.3.1. Monograph on Hippocastani cortex 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 HMPC noted the assessment results (AR overall conclusions) presented by the Rapporteur in a combined format for the two indications together with information on the traditional use.

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

None

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

None

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

2.6.1. Monograph on *Cnici benedicti herba* and supporting documents

Action: For adoption

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

Outcome:

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

The HMPC agreed to split the indication into two indications (MO sections 4.1 Therapeutic indications and 4.2 Posology and method of administration) and to add safety information for doses greater than 5 g per cup of tea (MO section 4.9 Overdose). It was also agreed to remove information about products on the Polish market and to delete the synonym *Centaurea benedicta* in the document titles as long as no Ph. Eur. monograph is available confirming the relevance.

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 (EMA/HMPC/166326/2005)

Action: For discussion

Document tabled: Draft concept paper

Outcome:

Postponed.

4.2. Quality

4.2.1. Guideline on good agricultural and collection practice (GACP) of starting materials of herbal origin (EMA/HMPC/246816/2005) - postponed

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

Action: For adoption

Document tabled: Concept Paper on Revision

Outcome:

Concept paper on revision of the guideline on declaration of herbal substances and herbal preparations adopted by consensus for 3 months public consultation.

The Rapporteur highlighted the grounds justifying the need for guideline revision and pointed out that coordination with the Quality WP, CHMP and CVMP is foreseen once a draft revision is available.

The revision of the declaration guideline (EMA/HMPC/CHMP/CVMP/287539/2005) is reflected in the HMPC workplan 2023. The need and possibility for adapting partially outdated examples was briefly discussed.

Minor changes were proposed for the introduction and the references (addition of relevant Ph. Eur. Chapters that have changed since 2010) before publication.

4.3. Regulatory / Procedural

None

4.4. Report on HMPC Drafting Groups activities

4.4.1. Herbal Quality DG – preparation of Chair and member re-appointment

Report: HMPC Chair, Nicoleta Carmen Purdel

Action: For discussion

Document tabled: [Mandate QDG](#); Proposal, Presentation

Outcome:

Members heard the modalities for the transitional continuation of the herbal Quality DG, based on the current mandate (EMA/HMPC/410043/2008 rev.2, from 12 July 2016) taking into account status before BCP-related hold in 2018 and activities of the *ad hoc* quality group in between. 'Business as usual' will continue until implementation of the new domain structure with a new mandate for a herbal DG (expected 2024).

Participants

HMPC members to confirm DG participation of their respective experienced quality expert being member in QDG and/or active in the *Ad Hoc* Quality Group before. New proposals are possible but limitation to 10 overall will have to be respected.

HMPC members to send confirmations/proposals to the HMPC secretariat by: **28 February 2023**.

Chairperson

After re-appointed QDG composition, the Chairperson (senior quality expert) will be formally confirmed by the HMPC from among the group members during the HMPC March 2023 meeting.

A call for expression of interest to be sent by the HMPC secretariat. Deadline for expressing interest: **28 February 2023**.

Work plan

Not anymore published stand-alone but feeding into annual HMPC work plans (Annex 2) and quality domain multiannual work plans.

Meetings

Already scheduled and to be re-confirmed in March 2023.

4.4.2. [ORGAM DG](#)

None

4.4.3. [Ad-hoc Quality drafting group](#)

Report: Nicoleta Carmen Purdel

Action: For information

Outcome:

See also 4.4.1. HMPC members heard a brief update

5. **Organisational, regulatory and methodological matters**

5.1. **Mandate and organisation of the HMPC**

5.1.1. [Strategic Review and Learning Meetings \(SRLM\)](#)

- HMPC SRLM Follow up plan - status January 2023

Report: HMPC Vice Chair

Action: For information

Document tabled: Follow up plan

Outcome:

The HMPC agreed to review the SRLM follow up plan after the final adoption of the HMPC Workplan 2023, with some topics to be removed if included in the workplan.

- Swedish Presidency meeting – 18-19 April 2023

Report: Karin Erika Svedlund

Action: For discussion

Document tabled: Draft Agenda

Outcome:

The HMPC noted the draft agenda for the HMPC SRLM meeting hosted by the Swedish Presidency of the Council of the European Union to be held on 18-19 April 2023 (virtual meeting).

The HMPC members were invited to send suggestions on topics for discussion during the SRLM meeting. General priorities of the Swedish presidency (e.g. AMR, shortages) were briefly discussed.

5.1.2. [HMPC membership](#)

Report: HMPC Chair

Action: For information

Outcome:

New members:

- Latvia, Inga Sile (member) as of 18 January 2023

Re-nominated members:

- Czechia, Marketa Prihodova (member) as of 10 March 2023
- Czechia, Marie Heroutova (alternate) as of 10 March 2023

End of membership:

- Latvia, Baiba Jansone (member) as of 17 January 2023
- Latvia, Evita Skukaуска (alternate) as of 17 January 2023

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

5.1.3. Election of HMPC Chair

Action: For adoption

Documents tabled: Call for expression of interest, Presentation, [HMPC RoP](#), Candidatures

Outcome:

Elections took place in line with the HMPC Rules of Procedure. Emiel van Galen from the Medicines Evaluation Board (NL) was re-elected as HMPC Chair for a second 3-year mandate starting 02 March 2023.

Achievements and challenges of the past, particularly in view of Covid-related constraints and fundamental changes in meeting organisation but also visions for the next 3 years were reflected on in view of the role herbal products continue to play in health care for EU citizen. See also: [EMA Committee on Herbal Medicinal Products re-elects Emiel van Galen as Chair | European Medicines Agency \(europa.eu\)](#)

5.2. EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair

Action: For information

Document tabled: Presentation

See also 5.8.1

Outcome:

The HMPC Chair summarised briefly relevant topics of the last Scientific Coordination Board (SciCoBo) meetings with focus on work plan, coordination and meeting organisation.

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

Action: For adoption

Document tabled: List of estragole-containing plants

Outcome:

Final version of the document 'List of estragole-containing plants' adopted by consensus for submission to CMDh.

HMPC welcomed the split into 3 lists according to concerns based on estragole levels and the knowledge about it. It was confirmed that the concentration of 1000 ppm was solely to distinguish high vs lower content substances without any specific toxicological meaning, which may be communicated to the CMDh when submitting the list.

Some additional corrections on plants and botanical names were introduced and some improvements for a footnote with regard to the old EFSA-based table in the PS suggested.

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 – postponed

None

5.4.2. Coordination with the European Commission

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

Report: HMPC Chair

Action: For adoption

Documents tabled: Call for data, Questions & Answers

Outcome:

Final versions of the 'Questions & Answers' (by consensus) and the specifically tailored 'Call for data' (by majority) adopted for publication on the EMA website.

One member did not support the Call for data because of the opinion that currently neither a traditional use nor a well-established use for Cannabis flos will be possible to establish. While this concern was acknowledged, the Committee and the EC agreed on the need to initiate the call for data and publish guidance on this topic of high public health interest. Publication is scheduled for mid-February.

5.5. Cooperation with International Regulators

5.5.1. IRCH – WHO 14th annual meeting

Report: HMPC Chair

Action: For information

Documents tabled: Agenda virtual meeting 23-25 November 2022, Presentations

Outcome:

The HMPC noted the agenda of the 14th Annual Meeting of the WHO-International Regulatory Cooperation for Herbal Medicines (IRCH) Network, held online, on 23-25

November 2022. Presentations that were released will be made available to the HMPC members in the MMD as possible.

Brief impressions on the development of the cooperative were exchanged looking at topics discussed at the meeting and the workshops as well as on specific input from China and other members. The next meeting originally scheduled to be organised as face to face again in Latin America has not yet been confirmed.

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 2023**

Report: HMPC Chair

Action: For adoption

Documents tabled: Work plan 2023, Annex 1, Annex 2, Comments

Outcome:

HMPC discussed remaining points and adopted with minor changes the work plan and Annex 1 (herbal monographs) and Annex 2 (herbal guidelines).

HMPC secretariat to circulate the updated clean version for the HMPC members awareness (silent adoption) prior to EMA internal review and publication.

Minor changes were discussed and agreed for work plan, Annex 1 and Annex 2. The HMPC Vice Chair recommended to topic leads and main Rapporteurs to organise kick-off meetings for all projects and guidance-drafting groups early in the year as it was considered useful to get clarity on work distribution and meeting organisation.

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

Action: For discussion

Outcome:

The Rapporteur summarised activities ongoing, mainly the drafting of a discussion paper on data requirements for (T)HMP use in children/adolescents, and the contribution for the HMPC Workplan 2023 (improvement of the HMPC safety assessments for children and collaboration with the PDCO on specific questions).

- Improved use of data sources for HMPC relevant safety assessments

Action: For discussion

Documents tabled: Draft Procedure establishment monographs, Draft revised AR template, EC SmPC guideline, Reader's guidance

Outcome:

The HMPC members were invited to send comments on the changes proposed in draft procedure for preparation of MO/LE and in draft revised AR template for further discussion at the HMPC March 2023 meeting.

The new overarching procedure was briefly presented and the role of Rapporteur, assessor, peer-reviewer and the entire assessment team addressed.

Several modifications in the AR template were briefly introduced and especially the clinical data presentation discussed.

- Training on assessment of applications for herbal medicinal products

Action: For discussion

Documents tabled: Presentation, Course description

Outcome:

The Rapporteur summarised the collaboration with the EDQM in preparation of the next training for herbal medicinal products (EU NTC herbal curriculum); expected date: March/April 2023.

The HMPC members were invited to send comments to the Rapporteur.

5.8. Planning and reporting

5.8.1. HMPC meeting organisation 2023

Report: HMPC Chair

Action: For adoption

Document tabled: Options for F2F/virtual meetings 2023

See also 5.2.1

Outcome:

HMPC Chair summarised the possible arrangements for the HMPC meetings in 2023.

HMPC secretariat to send an email to all HMPC members, inviting them to select 2 meetings which are preferred as virtual-only meetings for 2023 (March, May, July, September, November).

Post-meeting note:

Following the survey, a majority favoured July and November to be held in 2023 as virtual meetings.

5.8.2. Deadline for document submission for 2nd pre-mail

Action: For discussion

Document tabled: Presentation

Outcome:

The HMPC agreed the new deadline for submission of documentation to be included in the 2nd pre-mail (Monday noon, one day before the 2nd premail is sent).

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 *Juniperi pseudo-fructus (galbulus)* and supporting documents

Action: For 1st discussion

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

Outcome:

No comments received during public consultation.

Rapporteur to finalise the draft revised EU herbal monograph and supporting documents for peer review and **adoption** at the **HMPC March 2023** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **15 February 2023**

Peer-review documents to be sent to Rapporteur: **24 February 2023**

Final documents to be included latest in 2nd premail: **06 March 2023**

The HMPC confirmed to remove 'as an adjuvant' from the therapeutic indication ('adjuvant' supposes a defined treatment to which the herbal treatment can be added). The same approach should be discussed at other revision and checked for relevance. Some members expressed a general concern if not clear to what the adjuvant treatment is indicated, other proposed to follow the same approach primarily only for all herbal diuretics. Moreover, it was agreed that the wording in MO section 5.3. Preclinical safety data should be in line with the information given in the AR on toxicological data available (but considered insufficient) or not available at all.

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 *Lavandulae aetheroleum* and supporting documents

Action: For 8th discussion

Documents tabled: Draft MO, AR, LoR, Reader's Guidance, 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 March 2023** meeting.

The HMPC agreed on the proposed traditional use and the Rapporteur was invited to consider whether well-established use is also possible to be established based on conditions of Article 10a of Directive 2001/83/EC and bibliographic clinical studies available in the public domain. Some proposals for changes in MO sections 4.7 and 4.8 based on more

recent clinical safety data and product information were discussed as well as whether recent data could also be considered for the efficacy evaluation.

6.2.3. Monograph on Ginseng radix and supporting documents

Action: For 1st discussion

Documents tabled: Draft MO, AR, LoR, 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 March 2023** meeting.

The Rapporteur briefly summarised changes introduced in the draft MO (sections 2, 3 and 4.2), AR (substantial changes in several chapters including 2.3 overall conclusions on medicinal use, 4.3 overall conclusions on clinical pharmacology and efficacy, 5.1 information from Eudravigilance database) and LoR.

Some HMPC members expressed preference for a brief narrative of the most relevant studies in addition or instead of the entire table 6 in the draft AR.

6.2.4. Monograph on Pelargonii radix and supporting documents

Action: For 5th discussion

Documents tabled: Draft MO, AR, LoR, 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 March 2023** meeting.

The Rapporteur highlighted that AR was amended according to the introduced changes in draft MO and the updated PSUR (2018) conclusions.

The HMPC discussed proposed changes in monograph sections 2, 4.2, 4.4 and 4.8.

Some HMPC members expressed concern about the use of ethanolic preparations in the symptomatic treatment of common cold in children younger than 6 years of age.

6.2.5. Monograph on Plantaginis lanceolatae folium and supporting documents

Action: For 2nd discussion

Documents tabled: Draft MO, AR, LoR

Outcome:

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

Next **discussion** scheduled at the **HMPC March 2023** meeting.

The HMPC agreed with the revised herbal preparations, overviews of products on the market and the evidence for medicinal use, and general conclusions on non-clinical data, as proposed by the Rapporteur. Two new indications (one oral, one cutaneous use) were proposed for the monograph.

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

Action: For 1st discussion

Documents tabled: Draft MO, AR, LoR, 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 March 2023** meeting.

The HMPC agreed to consider conclusions from the clinical interaction study (Thu et al. 2016b) as sufficient for a warning on interactions regarding all drug substances metabolised via CYP2C9 (wording in MO to be defined). Regarding adverse events (AR sections 5.1 and 5.3) the HMPC agreed with the Rapporteur's proposal for a wording to be included in the MO (nervous system disorders and gastrointestinal disorders). Moreover, the HMPC noted proposals for improvement of the indication taking into account other related 'adaptogenic' substances which should be carefully considered and further discussed.

6.2.7. Monograph on *Zingiberis* rhizoma and supporting documents

Action: For 4th discussion

Documents tabled: Draft MO, AR, LoR 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 March 2023** meeting.

Regarding the duration of use in travel sickness to be considered in the WEU MO / revised TU MO, the Rapporteur highlighted that currently only a posology before travel is included without information on additional doses during the travel. The HMPC agreed with the Rapporteur's position to maintain the duration of use in travel sickness as 'single use before travel' only (MO section 4.2).

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

6.3.1. Monograph on *Crataegi folium cum flore* and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

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

Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC March 2023** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **15 February 2023**

Peer-review documents to be sent to Rapporteur: **24 February 2023**

Final documents to be included latest in 2nd premail: **06 March 2023**

The Rapporteur pointed out that there are new clinical safety data (change of adverse effects frequency) and also new information on the use of the comminuted herbal substance available for changes in the monograph. Furthermore, the updated Ph. Eur. monograph excluding now a specific Crataegus species as source plant was mentioned.

6.3.2. Monograph on Ginkgo folium and supporting documents

Action: For 2nd 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 March 2023** meeting.

The Rapporteur highlighted that there are new clinical safety data (additional cardiac adverse effects) and informed that national information from communication with the MAH was useful to put those data into context and adapt as necessary product information (amendments in the wording of different MO sections, e.g. 4.5, 4.6 and 5.3).

HMPC members noted again that Ginkgo is not part of the EURD-list, therefore no harmonised PSUR assessment is foreseen and a specific PRAC procedure following signal detection unlikely to happen – advocating for an HMPC monograph revision without initial interaction with PRAC. The Rapporteur was asked to check what data are publicly available for HMPC assessment and appropriate to finalise the review report before starting the actual revision, which is in principle supported by HMPC.

6.3.3. Monograph on Helichrysi flos and supporting documents

Action: For 2nd discussion

Document tabled: Review report

Outcome:

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

Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC March 2023** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **15 February 2023**

Peer-review documents to be sent to Rapporteur: **24 February 2023**

Final documents to be included latest in 2nd premail: **06 March 2023**

The Rapporteur emphasised that there are no new scientific data/information neither new herbal substances/preparations with 30/15 years of TU nor 10 years of WEU that justify a revision of the MO.

6.3.4. Monograph on *Matricariae flos* and supporting documents

Action: For 1st 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, Reader's guidance

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

Documents 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, Reader's Guidance

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 15th 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 **adoption** for public consultation at the **HMPC March 2023** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **15 February 2023**

Peer-review documents to be sent to Rapporteur: **24 February 2023**

Final documents to be included latest in 2nd premail: **06 March 2023**

The Rapporteur pointed out that draft MO is now based on data from mainly Greek traditional use. Also, PhV data were added in the AR.

6.5.2. Monograph on *Hyperici herba/Cimicifugae rhizoma* and supporting documents - postponed

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

Action: For 3rd discussion

Document tabled: Presentation

Outcome:

Rapporteur to introduce changes in the draft assessment report and consider the comments received for the continuation of the assessment work including the option of a public statement to obtain more data for an EU herbal monograph.

Next **discussion** scheduled at the **HMPC March 2023** meeting.

HMPC Chair and members to check availability of additional information from within and outside the EU.

The Rapporteur presented critical key points regarding (1) a highly refined dry extract, its manufacture and specification in view of suitability for a TU or WEU monograph, (2) the

period of use in the EU mainly based on BG and CZ authorisations/registrations and (3) possible acceptable indications (TU/WEU).

7. Any other business

7.1. Topics for discussion

7.1.1. Summary on national experiences with HMPC monographs during MRP/DCP procedures

Action: For discussion

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

Outcome:

The Rapporteur summarised the latest update of the document and thanked those who provided the information.

Experiences/proposals for specific monographs or guidelines were briefly presented as well as general points as regards ATC Code for THMPs, use of MedDRA terms in MOs, or information on the posology in patients with renal or hepatic impairment.

Members were reminded on the permanent availability of the document in MMD for use by Rapporteurs at start of review/revision procedures ('regulatory practice check').

7.1.2. Pharmacovigilance Conference at Kew Gardens

Action: For discussion

Document tabled: Invitation

Outcome:

HMPC in principle supported the participation of a member.

The HMPC Chair will request further details to better support the HMPC participation at the conference before a small group will specify what exactly will be presented and who is participating on behalf of HMPC.

Post-meeting note:

After feedback from the organiser, the HMPC Vice-Chair proposed to present the Committee activities, experiences of recent years and future visions.

7.1.3. Availability of ESCOP monographs for HMPC assessment work

Action: For discussion

Document tabled: Email communication

Outcome:

Postponed.

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 21-23 November 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

None

7.3. List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 23-25 January 2023 meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Astrid Obmann	Alternate	Austria	No interests declared	
Reinhard Länger	Member	Austria	No interests declared	
Gert Laekeman	Co-opted member	Belgium	No interests declared	
Patricia Bodart	Member	Belgium	No interests declared	
Radina Dimitrova	Alternate	Bulgaria	No interests declared	
Darko Trumbetic	Alternate	Croatia	No interests declared	
Ivan Kosalec	Member	Croatia	No interests declared	
Alexandra Demetriou	Alternate	Cyprus	No interests declared	
Marie Heroutova	Alternate	Czechia	No interests declared	
Markéta Příhodová	Member	Czechia	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
Nanna Lundgaard Rasmussen	Alternate	Denmark	No interests declared	
Maria Paile Hyvarinen	Member	Finland	No interests declared	
Sari Koski	Alternate	Finland	No interests declared	
An Le	Member	France	No interests declared	
Heidi Foth	Co-opted member	Germany	No interests declared	
Jacqueline Wiesner	Member	Germany	No interests declared	
Susanne Flemisch	Alternate	Germany	No interests declared	
Ioanna Chinou	Member	Greece	No interests declared	
Stavroula Mamoucha	Alternate	Greece	No interests declared	
Julia Pallos	Member	Hungary	No restrictions applicable to this meeting	
Rita Nemeth	Alternate	Hungary	No interests declared	
Zsuzsanna Biróné Dr Sándor	Expert*	Hungary	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	
Inga Sile	Member	Latvia	No interests declared	
Sven Back	Member	Luxembourg	No interests declared	
Burt H Kroes	Member	Netherlands	No interests declared	
Emiel Van Galen	Chair	Netherlands	No interests declared	
Hilda Kuin	Alternate	Netherlands	No interests declared	
Gro Anita Fossum	Member	Norway	No interests declared	
Marianne Loiten Dalhus	Alternate	Norway	No interests declared	
Wojciech Dymowski	Member	Poland	No interests declared	
Ana Paula Martins	Member	Portugal	No interests declared	
Maria da Graca Ribeiro Campos	Co-opted member	Portugal	No interests declared	
Maria Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared	
Carmen Purdel	Member	Romania	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Miroslava Horváth Petriková	Member	Slovakia	No interests declared	
Barbara Razinger	Member	Slovenia	No interests declared	
Olga Maria Palomino	Member	Spain	No interests declared	
Olga Teresa Esteban	Alternate	Spain	No interests declared	
Karin Erika Svedlund	Member (Vice-Chair)	Sweden	No interests declared	
A representative from the European Commission attended the meeting				
Meeting run with support from relevant EMA staff				