



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 May 2021
EMA/HMPC/177648/2021
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 1-3 March 2021

Chair: E van Galen, Vice-Chair: E Svedlund

1 March 2021, 10:00 – 17:00, virtual meeting

2 March 2021, 09:00 – 17:00, virtual meeting

3 March 2021, 09:00 – 16:00, virtual 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 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/127362/2006).

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1. Introduction

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

The Chairperson opened the meeting by welcoming all participants. Due to the current coronavirus (COVID-19) outbreak, and the associated EMA Business Continuity Plan (BCP), the meeting was held remotely.

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 current meeting, the Committee Secretariat announced that no restriction in the involvement of meeting participants in upcoming discussions was identified.

Participants in this meeting were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. No new or additional interests or restrictions were declared with regard to topics on the agenda.

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 and as included in the list of participants.

1.2. Adoption of agenda

HMPC agenda for 1-3 March 2021.

Time schedule for 1-3 March 2021.

Outcome:

Agenda adopted.

Time schedule endorsed.

1.3. Adoption of the minutes

HMPC minutes for 11-13 January 2021.

Outcome:

Minutes adopted.

2. EU herbal monographs and list entries for adoption

2.1. Status of HMPC/MLWP activities

2.1.1. Overview of HMPC/MLWP assessment work including the Rapporteurship distribution – Status in March 2021

Report: HMPC Chair

Action: for discussion

Document: Overview

Outcome:

HMPC noted status of assessment work.

In case of postponement of topics scheduled for the HMPC May meeting according to the overview, Rapporteurs were asked to inform secretariat and Chair before the first pre-mail (by 19 April 2021) to allow best adaptation of agenda and time-schedule.

2.1.2. Appointment of Rapporteurs and Peer-reviewers

Report: HMPC Chair

Action: for adoption

New Rapporteur and Peer-Reviewer:

Reappointments

- Aloysiae citriodoraefolium
- Hyperici herba
- Mate folium
- Rosmarini aetheroleum
- Rosmarini folium
- Solidaginis virgaureae herba
- Trigonellae foenugraeci semen

New assessments to start in 2021

- Cnici benedicti herba
- Cimicifugae rhizoma/ Hyperici herba

New substance for decision on prioritisation

- Tribulus terrestris herba

Documents: Proposal (CZ), Summary of proposals

Periodic reviews to start in 2021

- Cucurbitae semen
- Levistici radix
- Juglandis folium

Outcome:

HMPC agreed on re-appointments and on new Rapporteurs and Peer reviewers according to adopted workplan 2021. HMPC secretariat will update the HMPC status overview. Remaining Rapp. /PRs to be appointed at **HMPC May meeting**.

Decision on Tribulus terrestris herba (appropriateness of indication) as well as Rapp./PR appointment postponed to the **HMPC May meeting**, after submission of a more detailed proposal for assessment.

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 Hyperici herba and supporting documents

Action: for adoption

Documents: MO, AR, LoR, Reader's Guidance; References: 03/822

Outcome:

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

The Rapporteur presented adaptations in MO sections 4.1, 4.2, 4.6 and 5.3 mainly aiming for updating/ correcting the WEU part as well as aligning the respective AR content taking into account comments from members and information from the PSUSA assessment. Final adjustments were performed in MO section 5.1 and some information deleted for possible discussion after consultation to reflect best useful information for the clinical situation.

Some members signalled to not support the monograph regarding either WEU or TU in line with previous divergent opinions for the initial assessment.

2.3.2. Monograph on Trigonellae foenugraeci semen and supporting documents

Action: for adoption

Documents: MO, AR, LoR, Readers Guidance; References: 67/126

Outcome:

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

Major changes had been introduced after peer review.

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

2.4.1. Monograph on Cinnamomi corticis aetheroleum and supporting documents

Action: for adoption

Document: Review report, Readers Guidance, Vigilyze overview; References: 00/02

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 *Cinnamomi corticis aetheroleum*.

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

2.4.2. Monograph on *Cinnamomi cortex* and supporting documents

Action: for adoption

Document: Review report, Readers guidance, Vigilyze overview; References: 00/12

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 *Cinnamomi cortex*.

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

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. Public statement on *Saccharomyces cerevisiae* CBS 5926 and supporting documents

Action: for information

Document: PS

Outcome:

HMPC Chair informed the Committee on the current status. Updated draft PS as well as supporting AR and LoR to be finalised in cooperation with EMA and to be presented at the **HMPC May** meeting for possible adoption for public consultation.

2.6.2. Monograph on *Species digestivae* and supporting documents

Action: for adoption

Documents: MO, AR, LoR, email communication; References: 00/21

Outcome:

Adoption postponed.

Rapporteur to modify the draft MO and AR according to the discussion. Considerations regarding estragole and comments from peer-reviewer and AT on calculations and inclusion of substances to be taken into account for discussion at the **HMPC May** meeting.

Members discussed inclusion and exclusion of comminuted substances according to manifold use and their separation into possible active substances or consideration as excipients and subsequent calculations on adapted absolute/relative proportions and posologies.

2.6.3. Monograph on Taraxaci officinalis radix and supporting documents – postponed

2.6.4. Monograph on Vaccinii macrocarpi fructus and supporting documents

Action: for adoption

Documents: Presentation, MO, AR, LoR; References: 459/249

Outcome:

Adoption postponed.

Rapporteur supported by Peer-reviewer and HMPC Vice Chair to finalise the draft MO and AR according to the discussion and circulate the final version to members for comments **by 31 March 2021**. Members to provide final comments by 19 April 2021. Final **adoption for public consultation** scheduled for **HMPC May** meeting.

Rapporteur/Peer reviewer/HMPC vice Chair to signal in advance to HMPC secretariat whether a preparatory meeting for finalisation is required. The use in men versus women and subsequent warnings were discussed vis-a-vis other herbal substances in comparable indications. Changes were introduced in various MO sections and the AR.

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. Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) including recommendations regarding contamination with PAs (EMA/HMPC/893108/2011 Rev. 1)

Action: for discussion

Documents: [Draft PS](#), OoC

Outcome:

Rapporteurs to finalise OoC responses to questions from Interested Parties according to the discussion and modify PS if necessary.

Following receipt of announced SWP comments small preparatory meeting to be organised between Rapporteurs and HMPC Chair/Vice-Chair as appropriate. The adoption is scheduled for **HMPC May** meeting (end of transition period).

Comments were discussed such as proposed exceptional provisions for essential oils.

4.2. Quality

4.2.1. Guideline on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/201116/2005 Rev. 3)

Action: for information

Documents: [Draft Guideline](#), OoC

Outcome:

See 4.2.2.

4.2.2. Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/162241/2005 Rev. 3)

Action: for information

Document: [Draft Guideline](#), OoC

Outcome:

HMPC welcomed update on status of finalisation and progress on OoC for the specification GL by quality experts in drafting meeting. Except 3 final items still to be clarified it is now possible to modify both, quality and specification GLs.

As necessary small preparatory meeting to be organised. Aim to present drafts for discussion/ comments **at the HMPC May meeting**.

Few remaining items were reported to the committee such as the issue of quantified extracts and analytical markers, the diverse national handling when some Ph. Eur. monographs contain ranges but not single values, and finally minor language problems.

4.2.3. Nitrosamines and Herbal MPs

Action: for discussion

Documents: CMDh practical guidance for Marketing Authorisation Holders

Outcome:

HMPC discussed the Rapporteur's draft proposal. While several members considered current guidance as applicable and sufficient for herbal MPs, others advocated for additional guidance taking into account risks applicable to all MPs but also herbal specifics.

Members are invited to send their comments and specific information to the Rapporteur **by 31 March 2021** and next discussion at **HMPC May** meeting.

4.2.4. Change of assay methods in Ph. Eur. monographs

Action: for discussion

Outcome:

HMPC welcomed the Rapporteur's draft proposal. Members (including EDQM observer) are invited to send comments to the Rapp **by 31 March 2021**. Updated proposal to be presented for second discussion at **HMPC May** meeting.

Limitations for the HMPC monographs were discussed acknowledging that one generally applicable conversion factor cannot always be made available to simply adapt. Regulatory and practical solutions at various levels were considered to give best possible but also flexible advice for individual solutions in nationally authorised products.

4.3. Regulatory / Procedural

4.3.1. Regulatory Q&A on herbal medicinal products

Action: for discussion

Documents: Proposals for Q&A; [Regulatory Q&A on herbal medicinal products](#), [Q&A on the EU framework for \(T\)HMP, including those from a 'non-European' tradition](#)

Outcome:

Members to send comments till **31st March 2021**. Rapporteurs and secretariat to update proposals to be presented for possible adoption at **HMPC May** meeting.

The Q&A are intended to explain some specifics of herbal tea combination monographs, that could be useful as reference point for future assessments and questions (OoC) in this regard. Aim is to avoid misunderstandings on complexity and conventions applied that were raised on previous combination monographs.

4.4. Report on HMPC Drafting Groups activities

4.4.1. Quality DG

None

4.4.2. ORGAM DG

None

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Strategic Review and Learning Meetings

Portugal Presidency virtual meeting – 17-18 March 2021

Report: A P Martins

Action: for information

Document: Draft agenda

Outcome:

HMPC noted the invitation and information by the Portuguese delegate on the SRLM under the PT presidency which will be organised 17-18th March via video conference. A draft agenda was discussed.

5.1.2. HMPC membership

New membership:

- Ireland, Jacqueline Masterson (alternate) as of 14 January 2021
- Luxembourg, Jane Murray (alternate) as of 17 February 2021
- Spain, Olga Maria Palomino (member) as of 21 February 2021

End of membership:

- Spain, Adela Nunez Velazquez (member) as of 22 February 2021
- Lithuania, Audronis Lukosius (alternate) as of 1 March 2021

5.1.3. Election of Co-opted member (paediatrics)

Report: HMPC Chair

Action: for adoption

Documents: Call for nominations dated 21 January 2021, [Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC](#), Candidature

Outcome:

Election took place in line with the HMPC Rules of procedure.

The Committee elected as new co-opted member with expertise in paediatric medicine Dr. Peter Voitl (AT) for a 3-year mandate starting 3 May 2021.

5.1.4. Preparation of Election of Co-opted member (Clinical pharmacology)

Report: HMPC Chair

Action: for discussion

Documents: Expertise of HMPC members

Outcome:

HMPC discussed the expiry of the mandate of the current co-opted member in clinical pharmacology and confirmed the continued need for additional expertise in this area.

A Call for nomination of candidates for co-opted membership will be sent out to HMPC members with the election scheduled at the **HMPC May meeting**.

5.1.5. HMPC meeting dates 2022-2024

Action: for adoption

Document: Meeting dates

Outcome:

HMPC meeting dates adopted.

5.2. EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair

Action: for information

Documents: Draft Minutes 14 December 2020, Minutes 1 February 2021

Outcome:

HMPC noted topics discussed at the SciCo Board.

5.2.2. Update on PSUSA *Menthae piperitae aetheroleum*

Action: for discussion

Documents: Presentation, MO, Email communication, [Menthae piperitae aetheroleum](#)

Outcome:

Rapporteur of *Menthae piperitae aetheroleum* monograph updated the HMPC on the finalised PSUSA procedure. HMPC endorsed Rapporteur's position that no additional warning is needed in the monograph and therefore no review to be scheduled.

During HMPC assessment no clinical data were available to conclude on warnings regarding sideburns from application of the essential oil. However, HMPC welcomed initiated dialogue to feedback to HMPC any signals detected with regard to *Mentha* preparations in the context of the PSUSA procedure; for instance, if there are specific new safety data for the oil preparation beyond theoretical considerations from the menthol content.

It was suggested that for all herbal substances on the EURD list (very few) PRAC Rapporteurs inform HMPC to check whether alignment with previous assessment and existing monographs is required.

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

5.3.1. Public statement on the use of herbal medicinal products containing estragole

Action: for adoption

Documents: Questions to SWP, Final PS, OoC

Outcome:

Question adopted by consensus. HMPC secretariat to coordinate the communication before final publication.

The proposed questions to SWP/CHMP on the scientific conclusions following previous rounds and advice from SWP were agreed. No objections were raised to clarify the handling of adolescents in the PS conclusions, not specifically addressed in the draft version so far.

Beside appliance in HMPC monographs (see also 6.2.1 - 6.2.3.) also the practical implementation for nationally authorised herbal products as well as for the rare cases of excipients in non-herbal products will require further coordination with CHMP and CMDh.

5.4. Cooperation within the EU regulatory network

5.4.1. Coordination with European Pharmacopoeia

- EDQM 13B expert group meeting

Report: M Bald

Action: for information

Document: SoD

- EDQM TCM expert group meeting

Report: M Bald

Action: for information

Document: SoD

Outcome:

HMPC noted summaries of decisions for 13B and TCM meetings highlighted by the EDQM observer.

Relevant items under preparation, discussion or for adoption were emphasised including monographs on Juglans, Cannabis, Pulsatilla, Senna standardised dry extract, Dioscera refined extract and the general chapter on essential oils. Also the issue of method changes and conversion factors was discussed (see also 4.2.4).

5.4.2. Coordination with the European Commission

- Cannabis for medicinal use

Report: HMPC Chair

Action: for adoption

- New draft EC Regulation amending Annex III of Reg 1925/2006 regarding HADs

Action: for information

Documents: Draft regulation; Email correspondence, [EP ENVI agenda January 2021](#)

Outcome:

HMPC noted current status as updated by EC. EC will inform HMPC secretariat once the regulation comes into force.

5.5. Cooperation with International Regulators

5.5.1. IRCH – WHO 12th annual virtual meeting

Report: HMPC Chair

Action: for information

Documents: Report, Agenda, Participants list

Outcome:

HMPC noted the report from IRCH – WHO annual meeting.

EMA secretariat to re-establish coordination with WHO regarding EMA contact points, Mednet use and appropriate information flow.

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

5.6.1. AESGP

Report: HMPC Chair

Action: for adoption

Document: AESGP hearing report held on 18 November 2020

Outcome:

Modified hearing report adopted for publication at EMA website.

5.6.2. EUCOPE

- Hearing to be held in May 2021

Report: HMPC Chair

Action: for discussion

Document: Draft Agenda, Request for hearing

Outcome:

HMPC agreed to the draft Agenda for hearing to be held at **HMPC May** meeting. No modifications or additional topics were proposed.

'Paediatric group' according to work plan project (see 5.7.1) to discuss preparatory meeting and involvement of PDCO members as possible.

- Digital Conference on the European Health Economy

Report: HMPC Chair

Action: for information

Documents: Questions on BW Event Session on Health claims; List of participants

Outcome:

HMPC noted the short report by the HMPC Chair who participated at the digital conference on the European Health Economy.

5.7. Work plan

5.7.1. HMPC work plan 2021

Report: HMPC Chair, HMPC Vice Chair

Action: for information

Documents: Work plan 2021, Annex 1, Annex 2

Outcome:

Adjustments in Annex 2 (guidelines) including appointments of Rapporteurs were agreed:

- PS on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs)

- GL on quality of HMPs/ GL on specifications: test procedures and acceptance criteria

- GL on Good Agricultural and Collection Practice (GACP)
- Update/revision of Q&A on quality of herbal medicinal products
- GL on Assessment of genotoxicity of herbal substances/preparations
- Addendum to the Quality Review of Documents templates
- Update Review and Revision Best Practice Guides, Assessment Report and Review Report templates

Items postponed to 2022:

- Guidance on newly used manufacturing techniques regarding herbal preparations;
 - Guidance on the use of new analytical methods for the quality control of herbal MPs
- PhV data and experiences in national assessments
Report: R Laenger, HMPC Vice Chair
Action: for discussion
Document: Updated summary on national experiences with HMPC monographs and during MRP/DCP procedures; References: 29/29
Outcome:
HMPC welcomed the updated summary on national experiences with HMPC monographs during MRP/DCP procedures. Rapporteur to prepare a proposal for possible regular consideration in assessments.
 - Forward planning and prioritisation
Report: HMPC Vice Chair
Action: for adoption
Documents: Draft New Template
Outcome:
Draft new template for proposals to HMPC for assessment to establish EU herbal monograph/list entry adopted by consensus. Members are invited to reconsider submission of their previous proposals using new template.
 - Use of real-world data and requirements for the safe use of herbal substances in children
Report: HMPC Vice Chair, H Pinto Ferreira, M Petrikova
Action: for information
Document: Presentation
Outcome:
HMPC noted the current status of development of the discussion paper. Newly elected co-opted member for paediatrics to be contacted by HMPC topic lead to support and join this group. Next discussion is scheduled at **HMPC May** meeting.
 - Development of training on assessment of applications for herbal medicinal products
Report: HMPC Vice Chair, C Purdel

Action: for information

Documents: Course description template

Outcome:

HMPC welcomed the update on the training 'Introduction to herbal medicinal product application' that took place via EU NTC.

Also the second training session will be available online.

5.8. Planning and reporting

5.8.1. Big Data Training Signpost

Action: for discussion

Document: Presentation

Outcome:

HMPC noted the presentation and suggestion to join training on big data.

Training opportunities by external providers were confirmed to be available for the whole network (incl. co-opted members) at different levels; for more information a specific contact email was provided in the presentation.

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 *Foeniculi amari fructus* and supporting documents

Action: for discussion

Document: See 6.2.3; References: 00/00

Outcome:

See 6.2.3

6.2.2. Monograph on *Foeniculi amari fructus aetheroleum* and supporting documents

Action: for discussion

Document: See 6.2.3.; References: 00/00

Outcome:

See 6.2.3

6.2.3. Monograph on *Foeniculi dulcis fructus* and supporting documents

Action: for discussion

Document: Presentation; References: 00/00

Outcome:

Rapporteur to introduce changes in the monograph/AR considering the majority opinion to follow the proposed most 'conservative approach' in calculations of estragole content and intake for a **5th discussion** at the **HMPC May** meeting.

6.2.4. Monograph on *Juniperi pseudo-fructus* and supporting documents - postponed

6.2.5. Monograph on *Lavandulae aetheroleum* and supporting documents

Action: for discussion

Documents: Reader's Guidance

Outcome:

Rapporteur to introduce changes in the monograph/AR according to the discussion for a **2nd discussion** at the **HMPC May** meeting.

The Rapporteur presented newly available studies on aromatherapy and their relevance for the assessment. While the inhalation route is in principle possible for THMPs, it was referred to the generally applicable criteria for acceptance of TU and WEU which will be easier to discuss for the committee once new data are added to the revised AR and subsequent conclusions are drawn.

6.2.6. Monograph on *Pelargonii radix* and supporting documents - postponed

6.2.7. Monograph on *Agropyri repentis rhizoma* and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR, Readers Guidance; References: 74/67

Outcome:

HMPC did not endorse the Rapporteur's position regarding the indication. A clarification regarding the posology of the German product and usage in adolescents is needed.

Rapporteur to introduce changes in the monograph/AR according to the discussion for a **2nd discussion** at the **HMPC May** meeting.

Members should send their comments on the AR to the Rapporteur. For the clinical part and the indication discussion the peer-reviewer should be involved.

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

6.3.1. Monograph on Colae semen and supporting documents

Action: for discussion

Documents: Review report; References: 164/53

Outcome:

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

Rapporteur to adjust the review report regarding toxicological data that should be reduced to relevant summarising information and shortly commented by the Rapporteur with support of a toxicologist. Rapporteur to finalise it for peer review and **adoption** at the **HMPC May** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **30 March 2021**

Peer-review documents to be sent to Rapporteur: **13 April 2021**

Final documents to be included latest in 2nd premail: **27 April 2021**

Non-clinical data on reproductive toxicity showing some effects on the endocrine system were not considered relevant for the human situation.

6.3.2. Monograph on Fucus vesiculosus and supporting documents - postponed

6.3.3. Monograph on Fumariae herba and supporting documents

Action: for discussion

Documents: Review report, Reader's guidance; References: 00/16

Outcome:

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

Rapporteur to finalise the review report for peer review and **adoption** at the **HMPC May** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **30 March 2021**

Peer-review documents to be sent to Rapporteur: **13 April 2021**

Final documents to be included latest in 2nd premail: **27 April 2021**

6.3.4. Monograph on Mate folium and supporting documents

Action: for discussion

Documents: Review report, email correspondence; References: 00/34

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 for peer review and **adoption** at the **HMPC May** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **30 March 2021**

Peer-review documents to be sent to Rapporteur: **13 April 2021**

Final documents to be included latest in 2nd premail: **27 April 2021**

6.3.5. Monograph on Plantaginis lanceolatae folium and supporting documents

Action: for discussion

Document: Review report; References: 00/09

Outcome:

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

Rapporteur to finalise the review report according to the discussion for peer review and for **a 2nd discussion** or possible **adoption** at the **HMPC May** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **30 March 2021**

Peer-review documents to be sent to Rapporteur: **13 April 2021**

Final documents to be included latest in 2nd premail: **27 April 2021**

The Rapporteur proposed a revision for several minor reasons beside identified new preparations to be added to the monograph.

6.3.6. Monograph on Rosmarini aetheroleum and supporting documents

Action: for discussion

Documents: Review report, Presentation; References: 05/05

Outcome:

Rapporteur to introduce changes in the review report according to the discussion considering that a majority of the committee is in favour of the revision for a **3rd discussion** at the **HMPC May** meeting.

Newly available scientific data as well as information from market overview and experience from European procedures were presented and after consideration of various aspects the

relevance for changes to R. aetheroleum and R. folium monographs should be re-discussed at the HMPC May meeting.

6.3.7. Monograph on Rosmarini folium and supporting documents

Action: for discussion

Documents: Review report, Presentation; References: 08/08

Outcome:

See 6.3.6

6.3.8. Monograph on Sabalis serrulatae fructus and supporting documents

Action: for discussion

Document: Review report; References 52/37

Outcome:

Rapporteur to introduce changes in the review report according to the discussion for a **8th discussion** at the **HMPC May** meeting.

Newly available data for different types of extracts according to solvent were discussed and whether these would change the content of the monograph as agreed during the initial assessment.

6.3.9. Monograph on Solidaginis virgaureae herba and supporting documents - postponed

6.3.10. Monograph on Urticae folium and supporting documents

Action: for discussion

Document: Review report; References: 28/11

Outcome:

Rapporteur to introduce changes in the review report according to the discussion (clear proposal) for a **3rd discussion** at the **HMPC May** meeting.

Newly available clinical safety data were discussed and reasons for new warnings in some products' SmPCs as well as applicability of data for herb versus leaf. The Rapporteur was asked for a reduced and consistent presentation of relevant data incl. short assessment of relevance for the monograph for committee decision.

6.3.11. Monograph on Urticae herba and supporting documents

Action: for discussion

Document: Review report; References: 28/06

Outcome:

See 6.3.10

6.3.12. Monograph on *Violae tricoloris herba* and supporting documents

Action: for discussion

Documents: Review report, email correspondence; References: 28/25

Outcome:

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

Rapporteur to adjust/shorten the review report regarding PhV data and finalise it for peer review and **adoption** at the **HMPC May** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **30 March 2021**

Peer-review documents to be sent to Rapporteur: **13 April 2021**

Final documents to be included latest in 2nd premail: **27 April 2021**

Like in previous cases a minor change in the botanical description of source plants alone such as subspecies synonyms (definition in Ph. Eur. monograph) should not trigger a monograph revision but instead be mentioned in the review report for possible consideration in national product procedures and modification with the next revision as necessary.

6.3.13. Monograph on *Zingiberis rhizoma* and supporting documents

Action: for discussion

Document: Readers Guidance, Presentation; References: 137/25

Outcome:

Rapporteur to prepare the review report according to the discussion for a **4th discussion** at the **HMPC May** meeting.

HMPC discussed the new market overview, new studies available, warnings issued by food agencies in some MSs, and a proposed new indication. Some members offered to re-check national products' information. Toxicologists did not see major concerns regarding embryotoxicity and use during pregnancy.

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

6.4.1. Monograph on *Menyanthes trifoliata folium* and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 77/73

Outcome:

No comments received during public consultation. Rapporteur to finalise the draft documents for peer review and **adoption** at the **HMPC May** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **30 March 2021**

Peer-review documents to be sent to Rapporteur: **13 April 2021**

Final documents to be included latest in 2nd premail: **27 April 2021**

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

6.5.1. Monograph on *Andrographidis paniculatae folium* and supporting documents – postponed

6.5.2. Monograph on *Centellae asiaticae herba* and supporting documents – postponed

6.5.3. Monograph on *Cisti cretici folium* and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR, Readers Guidance, Presentation; References: 00/86

Outcome:

Rapporteur to introduce changes in the MO and AR according to the discussion for a **11th discussion** at the **HMPC May** meeting. Rapporteur to organise a meeting with PR to discuss all the outstanding issues if needed.

7. Any other business

7.1. Topics for discussion

7.1.1. Overview of WebEx - new virtual meetings platform

Action: for discussion

Document: Presentation

Outcome:

HMPC welcomed the presentation on new virtual meetings platform. Members are invited to sign up for trainings as presented.

The HMPC May meeting will be based on WebEx and early login check is recommended when using it for the first time.

7.1.2. Update on HMPC Opinion for *Allii sativi bulbus*

Action: for discussion

Documents: Presentation, Opinion, [HMPC RoP](#)

Outcome:

HMPC endorsed the modification and publication of the Opinion for *Allii sativi bulbus*, that was postponed due to missing Norwegian divergent position which could not be clarified

with the Norwegian Member, Alternate and Agency. While the Norwegian position as reflected in the HMPC minutes from July 2017 (divergent opinion S. Madsen) has to be considered invalid, the majority opinion of the committee remains unchanged.

The Committee was reminded on the Rules of procedure regarding voting and provision of divergent positions as well as consequences for the validity of the vote if members do not provide the divergent position in time.

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 11-13 January 2021

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)

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

None

7.2.4. Other

- Draft Agenda for the PCWP/HCPWP Joint meeting on 2-3 March 2021
- [Guideline on good pharmacovigilance practices \(GVP\)](#)
Public consultation on revision 3 of GVP Module XVI on risk minimisation measures and on its new Addendum II from 3 February 2021
Documents: 26 GVP Introductory Cover Note - M XVI Rev 3 with ADD II for public consultation, 2-01 GVP Module XVI Addendum II - Evaluation, 09 GVP Module Risk Minimisation Measures Rev 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 1-3 March 2021 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	
Reinhard Länger	Member	Austria	No interests declared	
Patricia Bodart	Member	Belgium	No interests declared	
Darko Trumbetic	Alternate	Croatia	No interests declared	
Maria Yiannitsarou	Alternate	Cyprus	No interests declared	
Markéta Příhodová	Member	Czech Republic	No restrictions applicable to this meeting	
Marie Heroutova	Alternate	Czech Republic	No interests declared	
Steffen Bager	Member	Denmark	No restrictions applicable to this meeting	
Rahat Nazmi	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	
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	
Zsuzsanna Biróné Dr Sándor	Member	Hungary	No interests declared	
Sarah Kellaghan	Member	Ireland	No interests declared	
Jacqueline Masterson	Alternate	Ireland	No restrictions applicable to this meeting	
Alessandro Assisi	Member	Italy	No interests declared	
Clemence Varret	Member	Luxembourg	No interests declared	
Everaldo Attard	Member	Malta	No interests declared	
Burt H Kroes	Member	Netherlands	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Hilda Kuin	Alternate	Netherlands	No interests declared	
Gro Anita Fossum	Alternate	Norway	No interests declared	
Wojciech Dymowski	Member	Poland	No interests declared	
Ana Paula Martins	Member	Portugal	No interests declared	
Carmen Purdel	Member	Romania	No interests declared	
Miroslava Petrikova	Member	Slovakia	No interests declared	
Milan Nagy	Alternate	Slovakia	No interests declared	
Barbara Razinger	Member	Slovenia	No interests declared	
Olga Palomino	Member	Spain	No interests declared	
Cristina Martinez Garcia	Alternate	Spain	No interests declared	
Karin Erika Svedlund	Member (Vice-Chair)	Sweden	No interests declared	
Gert Laekeman	Co-opted member	Belgium	No interests declared	
Heidi Foth	Co-opted member	Germany	No interests declared	
Maria Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared	
Melanie Bald	Observer	EDQM	No interests declared	
Barbara Toth	Expert	Hungary	No interests declared	
Kristine Hvolby	Expert	Denmark	No interests declared	
Friederike Stolte	Expert	Germany	No interests declared	
Knut Almgren	Expert	Sweden	No interests declared	
Guðrún Stefánsdóttir	Expert	Iceland	No restrictions applicable to this meeting	
Peter Voitl	Expert	Austria	No interests declared	
Meeting run with the help of EMA staff				