18 November 2020
EMA/HMPC/539421/2020
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Final Minutes for the meeting on 21-23 September 2020

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

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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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Table of contents

1. Introduction 5

1.1. Welcome and declarations of interest of members, alternates and experts 5

1.2. Adoption of agenda 5

1.3. Adoption of the minutes 5

2. EU herbal monographs and list entries for adoption 6

2.1. Status of HMPC / MLWP activities 6

2.1.1. Overview of HMPC/MLWP assessment work including the Rapporteurship distribution – Status in September 2020 6

2.1.2. Appointment of Rapporteurs and Peer-reviewers 6

2.2. Revised EU herbal monographs and list entries for final adoption 6

2.2.1. Monograph on Millefolii herba and supporting documents 6

2.3. Revised EU herbal monographs and list entries for public consultation 7

2.4. Reviewed EU herbal monographs and list entries for decision on revision 7

2.4.1. Monograph on Juniperi aetheroleum and supporting documents 7

2.4.2. Monograph on Juniperi pseudo-fructus and supporting documents 7

2.5. EU herbal monographs, list entries and public statements for final adoption 8

2.6. EU herbal monographs, list entries and public statements for adoption for release for public consultation 8

2.6.1. Monograph on Menyanthes trifoliata folium and supporting documents 8

2.6.2. Monograph on Saccharomyces cerevisiae CBS 5926 and supporting documents 8

2.7. EU herbal monographs, list entries and public statements - post finalisation 8

3. Referral procedures 8

4. Guidelines and guidance documents 9

4.1. Non-clinical / clinical safety and efficacy and multidisciplinary 9

4.1.1. Public statement on the use of herbal medicinal products containing estragole 9

4.2. Quality 9

4.2.1. Guideline on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/201116/2005 Rev. 3) 9

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) - postponed 9

4.3. Regulatory / Procedural 10

4.4. Report on HMPC Drafting Groups activities 10

4.4.1. Quality DG 10

4.4.2. ORGAM DG 10

5. Organisational, regulatory and methodological matters 10

5.1. Mandate and organisation of the HMPC 10

5.1.1. Strategic Review and Learning Meetings 10

5.1.2. Election of Co-opted member (paediatrics) 10
5.1.3. Preparation of election Co-opted members (Experimental/non-clinical pharmacology and General and family medicine) 11
5.1.4. Proxy form for HMPC 11
5.1.5. Organisation of November 2020 HMPC meeting 11
5.1.6. HMPC meeting dates 2022-2024 11
5.2. EMA Scientific Committees or CMDh-v 12
5.2.1. Scientific Coordination Board Meeting 12
5.2.2. Coordination with PDCO and PRAC 12
5.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups 12
5.3.1. Coordination with SAWP 12
5.4. Cooperation within the EU regulatory network 12
5.4.1. Coordination with European Pharmacopoeia 12
5.4.2. Coordination with the European Commission 12
5.5. Cooperation with International Regulators 13
5.6. Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee 13
5.6.1. Comments on use of HMPC Reflection Papers in National Procedures 13
5.7. Work plan 13
5.7.1. HMPC work plan 2020 13
5.8. Planning and reporting 14
5.9. Legislation and regulatory affairs 14
5.10. Questions from members 14
6. EU herbal monographs and list entries in preparation 14
6.1. Revision of EU herbal monographs and list entries in preparation for adoption after public consultation 14
6.1.1. Monograph on Hyperici herba and supporting documents 14
6.2. Revision of EU herbal monographs and list entries in preparation for public consultation 15
6.2.1. Monograph on Orthosiphonis folium and supporting documents 15
6.2.2. Monograph on Trigonellae foenugraeci semen and supporting documents 15
6.3. Review of EU herbal monographs and list entries in preparation for decision on revision 16
6.3.1. Monograph on Agropyri repentis rhizoma and supporting documents 16
6.3.2. Monograph on Carvi aetheroleum and supporting documents 16
6.3.3. Monograph on Carvi fructus and supporting documents 16
6.3.4. Monograph on Caryophylii floris aetheroleum and supporting documents 17
6.3.5. Monograph on Chamomillae romanae flos and supporting documents 17
6.3.6. Monograph on Cinnamomi corticis aetheroleum and supporting documents - postponed ... 18
6.3.7. Monograph on Cinnamomi cortex and supporting documents - postponed 18

6.3.8. Monograph on Colae semen and supporting documents 18
6.3.9. Monograph on Fucus vesiculosus and supporting documents - postponed 18
6.3.10. Monograph on Fumariae herba and supporting documents - postponed 18
6.3.11. Monograph on Lavandulae aetheroleum and supporting documents 18
6.3.12. Monograph on Lavandulae flos and supporting documents 19
6.3.13. Monograph on Mate folium and supporting documents 19
6.3.14. Monograph on Plantaginis lanceolatae folium and supporting documents - postponed..... 20
6.3.15. Monograph on Rosmarini aetheroleum and supporting documents - postponed..... 20
6.3.16. Monograph on Rosmarini folium and supporting documents - postponed 20
6.3.17. Monograph on Solani dulcamarae stipites and supporting documents 20
6.3.18. Monograph on Solidaginis virgaureae herba and supporting documents - postponed 21
6.3.19. Monograph on Urticae folium and supporting documents 21
6.3.20. Monograph on Urticae herba and supporting documents 21
6.3.21. Monograph on Violae tricoloris herba and supporting documents 21
6.4. EU herbal monographs and list entries in preparation for adoption after public consultation 21
6.4.1. Monograph on Aloysiae citriodorae folium and supporting documents - postponed 21
6.4.2. Monograph on Species amarae and supporting documents..... 22
6.4.3. Monograph on Species sedativae and supporting documents 22
6.5. EU herbal monographs and list entries in preparation for adoption for release for public consultation 23
6.5.1. Monograph on Andrographidis paniculatae folium and supporting documents - postponed 23
6.5.2. Monograph on Centellae asiaticae herba and supporting documents..... 23
6.5.3. Monograph on Salviae miltiorrhizae radix et rhizoma and supporting documents 23
6.5.4. Monograph on Species digestivae or species stomachicae and supporting documents - postponed 23
6.5.5. Monograph on Taraxaci officinalis radix and supporting documents 23
6.5.6. Monograph on Vaccinii macrocarpi fructus and supporting documents 24
6.5.7. Monograph on Cisti cretici folium and supporting documents - postponed 24
7. Any other business 24
7.1. Topics for discussion 24
7.2. Documents for information 24
7.2.1. HMPC 24
7.2.2. ARSP..... 24
7.2.3. EU herbal monographs, list entries and public statements – on hold..... 24
7.2.4. Other 25
List of participants 26

1. Introduction

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

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 table of decisions 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 line with the relevant provisions of the Rules of Procedure.

New membership:

- Italy, Alessandro Assisi (member) as of 13 August 2020
- Greece, Stavroula Mamoucha (alternate) as of 6 September 2020
- Finland, Maria Paile Hyvarinen (member) as of 17 September 2020

End of membership:

- France, Michele Brum (alternate) as of 13 July 2020
- Ireland, Sheena Kennedy (member) as of 21 July 2020
- Denmark, Karoline Holm Felding (alternate) as of 7 August 2020
- Greece, Zoi Karampourpouni (alternate) as of 5 September 2020
- Luxembourg, Marcel Bruch (member) as of 10 September 2020
- Finland, Eeva Sofia Leinonen (member) as of 16 September 2020

1.2. Adoption of agenda

The agenda for 21-23 September 2020 was adopted.

Time schedule for 21-23 September 2020 was endorsed with minor modifications.

1.3. Adoption of the minutes

HMPC minutes for 6-8 July 2020 were adopted and will be published on the EMA website.

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 September 2020

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 November meeting according to the overview, Rapporteurs were asked to inform the secretariat and Chair before the first pre-mail (by 2 November 2020) to allow best adaptation of agenda and time-schedule.

2.1.2. Appointment of Rapporteurs and Peer-reviewers

New assessments
Centellae asiaticae herba - New Peer Reviewer
Cisti cretici folium - New Rapporteur
Menyanthes trifoliata folium - New Peer Reviewer

Reviews
Absinthii herba - New Peer Reviewer
Cinnamomi corticis aetheroleum - New Peer Reviewer
Cinnamomi cortex - New Peer Reviewer
Colae semen - New Peer Reviewer
Fumariae herba - New Rapporteur
Plantaginis lanceolatae folium - New Peer Reviewer

Outcome:

HMPC endorsed re-appointment of Rapporteurs and Peer-reviewers subsequent to HMPC composition changes.

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

2.2.1. Monograph on Millefolii herba and supporting documents

Action: for adoption

Documents: MO, LE, AR, LoR, Reader's guidance; References: 81/94

Outcome:

Final revised EU herbal monograph and supporting documents adopted by consensus. The Norwegian delegate expressed a favourable position.

New EU list entry adopted by majority vote (24 out of 25). The Norwegian delegate expressed a favourable position.

Divergent opinion: Wojciech Dymowski

HMPC secretariat to initiate translation process and transfer to the European Commission.

Beside final clarifications regarding posology, the thujone content was the main point of discussion taking into account reliability of literature sources, possible variation according to plant provenance, and Ph. Eur. requirements currently not having an upper limit. It was agreed that overall levels of usual provenances are not in a range of major concern. The subject is discussed in the Assessment report but no warning, limit or reference to the HMPC thujone PS is included in the monograph. That way assessors and companies are made aware of the issue while a mandatory routine testing on thujone appears not justified.

The divergent opinion on the List entry referred to the necessary assurance that no high-thujone provenances are used in EU medicinal products.

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

None

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

2.4.1. Monograph on Juniperi aetheroleum and supporting documents

Action: for adoption

Documents: Review report, Reader's guidance; References: 9/0

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 Juniperi aetheroleum.

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

New data that needs to be taken into consideration during next revision (consistency with Juniperi pseudo-fructus AR) will be mentioned in the addendum.

2.4.2. Monograph on Juniperi pseudo-fructus and supporting documents

Action: for adoption

Documents: Review report, Reader's guidance; References: 10/2

Outcome:

HMPC agreed with Rapporteur's position to revise the monograph because new data were detected that require update and changes to the content of the monograph.

The HMPC decided by consensus to start the revision procedure and revise the monograph, assessment report and list of references on Juniperi pseudo-fructus.

The review report was adopted and HMPC tracking documents will be updated.

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 Menyanthes trifoliata folium and supporting documents

Action: for adoption

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

Outcome:

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

Final inconsistencies were corrected in the posology section in line with information given in the assessment report.

The method of administration and the maximum daily dose were aligned in monograph according to AR information before the adoption.

2.6.2. Monograph on Saccharomyces cerevisiae CBS 5926 and supporting documents

Action: for discussion

Documents: Draft PS, AR, LoR; References: 2/214

Outcome:

Adoption postponed.

Several members expressed their opinion, that in case the AR will be published, it needs specific amendments in line with the assessment outcome and majority opinion of the HMPC. However, no specific changes were yet agreed for the PS and the AR.

EMA secretariat to look into procedural options including publication of supporting documents in preparation for decision making scheduled for the **HMPC November meeting**.

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 estragole

Action: for discussion

Documents: Draft revised PS, OoC

Outcome:

HMPC discussed comments received by Interested Parties.
HMPC endorsed the Rapporteurs' position that comments and new data received during public consultation do not lead to substantial changes in the draft PS and overall conclusions.

Rapporteur to finalise the draft document for **adoption** at the **HMPC November** meeting before coordination with CHMP/SWP and CMDh and final publication.

Some members questioned the availability of a strong data basis to support the conclusions of the PS for natural plant mixtures used for decades in medicines and in foods. The relation to food exposure, products and standards versus medicinal product standards was re-discussed. A majority of members agreed with the Rapporteurs and considered the statement as adequately addressing the risks without setting strict limits - in line with comparable approaches and also the feedback from SWP.

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 revised Guideline, OoC

Outcome:

HMPC welcomed the Rapporteur's update on status of finalisation. The OoC is largely agreed on by the small expert group and accordingly minor changes will be introduced into the revised GL.

For clarification of few remaining specifically challenging details quality experts will liaise before discussion at the **HMPC November** meeting.

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) - postponed

Outcome:

Postponed.

4.3. Regulatory / Procedural

None

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

Germany Presidency meeting – September 2020
Action: for information

Documents: Final agenda, presentations

Outcome:

HMPC acknowledged the successful organisation of the first virtual HMPC SRLM under the German presidency that took place in September. The Chair thanked for arranging all the valuable presentations, that were possible to be presented via video conference.

A short summary by the DE presidency for HMPC decisions on follow-up actions was announced for the HMPC November meeting. Particularly the interaction with other Committees should be further progressed.

For the Portuguese presidency first half 2021 it was announced that only a virtual meeting will be organised; and a date tentatively set for 17/18 March 2021.

5.1.2. Election of Co-opted member (paediatrics)

Report: HMPC Chair

Action: for adoption

Documents: Call for nominations, Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC, Expertise of HMPC members
Outcome:

Election postponed. No candidates were nominated by HMPC members.

The need for a paediatric expert was re-confirmed. Members were asked to check in the regulatory, scientific and medical community of their MSs to find additional expertise for the committee. A repeated call will be sent by the secretariat in preparation of election at the HMPC November meeting.

5.1.3. Preparation of election Co-opted members (Experimental/non-clinical pharmacology and General and family medicine)

Report: HMPC Chair

Action: for discussion

Documents: Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC, Expertise of HMPC members

Outcome:

HMPC discussed the expiry of mandates of two current co-opted members in November and confirmed the continued need for additional expertise in

- 'experimental/non-clinical pharmacology' and
- 'general and family medicine'

Call for nominations of candidates for election at the HMPC November meeting will be sent out to HMPC members.

5.1.4. Proxy form for HMPC

Action: for information

Documents: Template, HMPC rules of procedure

Outcome:

HMPC noted information on the possibilities of using proxy during the plenary meetings in line with the changed RoP as adopted during the July meeting. The proxy template and principles how to communicate and use the proxy were presented. Practical questions on the use were clarified.

5.1.5. Organisation of November 2020 HMPC meeting

Action: for information

Document: Information from EMA website

Outcome:

HMPC noted that the November (and likely also the January) meeting will be virtual and that all current arrangements in terms of remote versus F2F meetings apply until the end of 2020.

5.1.6. HMPC meeting dates 2022-2024

Action: for information

Document: Meeting dates

Outcome:

HMPC noted the meeting dates for 2022-2024.

Meeting dates were planned according to logistical requirements for procedures and committee coordination for the main EMA operational business. No objections were raised with regard to the pre-scheduled HMPC meeting weeks. A separate table solely for HMPC dates was asked to be made available.

5.2. EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

None

5.2.2. Coordination with PDCO and PRAC

- PDCO response to HMPC on Hedera Helix
  Action: for discussion

  Documents: PDCO response to HMPC dated 24 July 2020, Data for contraindication in children, Discussion paper for contraindication for use in children, Presentation

  Outcome:

  HMPC welcomed and discussed feedback by PDCO on specific questions regarding extrapolation of data and a contraindication for children for Hedera helix.
  HMPC secretariat to organise a meeting of project participants under topic 2.1.3 of the workplan to draft a proposal for follow-up. Members willing to support are invited to contact HMPC secretariat for possible involvement. The proposal will be discussed at the **HMPC November** meeting.

  The committee discussed the view of the PDCO that available data are not considered sufficient for a contraindication for Ivy specifically, pointing at the same time to the limited need/efficacy for these products in this indication and age group as well as the final responsibility of MSs and PRAC on specific contraindications. The project group intends for the specific case Hedera to discuss whether to consult the PRAC before drawing consequences of the HMPC monograph

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

5.3.1. Coordination with SAWP

- Scientific Advice and Protocol Assistance **Action:** for information
  Document: Email correspondence dated 10 September 2020

5.4. Cooperation within the EU regulatory network

5.4.1. Coordination with European Pharmacopoeia

None

5.4.2. Coordination with the European Commission

- Cannabis for medicinal use
  Report: HMPC Chair

  Action: for discussion

  Document: Letter from EC

5.5. Cooperation with International Regulators

None

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

5.6.1. Comments on use of HMPC Reflection Papers in National Procedures

Report: HMPC Chair

Action: for adoption

Documents: BPI request, Draft HMPC response

Outcome:

The draft response to the comments on use of HMPC Reflection papers in national procedures was presented and agreed by the HMPC.

HMPC members were reminded on the necessary transparency in guidance establishment and the right choice of document according to purpose - in particular reflection papers that are not meant to replace GLs. However, the main issue raised i.e. the actual use of HMPC guidance documents in national procedures was not seen to be the responsibility of the HMPC.

5.7. Work plan

5.7.1. HMPC work plan 2020

Report: HMPC Chair, HMPC Vice Chair
Action: for discussion
Document: Work plan 2020, Annex 1, Annex 2 – current status September 2020

Outcome:

HMPC discussed status of HMPC activities planned for 2020.

- Activity area 1-3-1: Implementation of a modified procedure for EU herbal monograph establishment and maintenance
  Report: HMPC Vice Chair, HMPC Chair
  Action: for discussion
  Document: Reader's Guidance template

  Outcome:

  HMPC noted the usefulness of a reader's guidance and endorsed in principle the proposed template as an annex to the best practice guide. Project lead and participants to check possibility for other updates of the best practice guide for possible adoption at the **HMPC November** meeting.

  In addition, a new summary of experiences from European procedures with consequences for monograph revisions was announced for the November meeting.

- Activity area 1-3-2: Forward planning and prioritisation
  Report: HMPC Vice Chair, HMPC Chair
  Action: for discussion

Document: Presentation

Outcome:

HMPC discussed a proposal how to identify herbal substances, preparations and combinations in medicinal use by European citizens for which monographs are useful as basis for national assessments.

HMPC secretariat will circulate a call (including template to be used) to MSs to propose new substances/combinations for which they consider EU harmonised opinions useful taking into account recent experiences in national registrations/authorisations.

A summary of validated proposals for discussion and informed decision on prioritisation will be scheduled for the **HMPC November meeting**.

HMPC discussed already few potential candidates including substances for which previously the assessment ended without a monograph. Some concerns regarding available data and assessment outcomes were raised confirming the need for informed prioritization based on transparent overviews and justifications (template use).

- Activity area 2-2-1: Development of training on assessment of applications for herbal medicinal products
  Report: HMPC Vice Chair
  Action: for discussion
  Document: Presentation

  Outcome:

  HMPC welcomed presentation by the steering group on the development of training, very positive feedback on the first training, and next trainings in preparation.

  Plans and priorities for 2021 were presented and members asked to give feedback to the steering group in case any particular training needs are identified.

5.8. Planning and reporting

None

5.9. Legislation and regulatory affairs

None

5.10. Questions from members

None

6. EU herbal monographs and list entries in preparation

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

6.1.1. Monograph on Hyperici herba and supporting documents

Action: for discussion (see also 6.5.7)

Documents: MO-TU, AR, LoR, OoC, Reader's guidance; References: 03/822

Outcome:

Rapporteur to introduce changes in the monograph according to the discussion for **a fifth discussion at the HMPC November** meeting.

HMPC endorsed changes introduced in AR and MO according to the last discussion and keep the monograph on a general level without listing each specific new interaction which can be updated to the latest status in national procedures for specific SmPCs. Several members proposed a slight rewording of indication 4 and the Rapporteur was asked to consider adjustments taking into account other monographs.

Members discussed conclusions that can be made from the PSUSA procedure – also highlighted by AESGP-, while not leading to fundamental issues as regards PhV procedures at PRAC–some information might be useful to facilitate the alignment of SmPCs via monographs.

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

6.2.1. Monograph on Orthosiphonis folium and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR, Reader's guidance; References: 00/55

Outcome:

HMPC endorsed the Rapporteur's position regarding single/daily dose and propose to align the posology into grams instead of milligrams.

Rapporteur to introduce changes in the monograph according to the discussion for **a third discussion at the HMPC November** meeting.

Members discussed and agreed minor changes in monograph section 4.2. The indication was kept although new preparations added may have had slightly differently worded traditional uses. Despite a meanwhile available Ames test, there was the view that it is incomplete to accept minimum requirements from a genotoxicity perspective and allow a list entry. The consistency as regards contraindication and warnings should be double-checked also vis-a-vis other diuretics before public consultation.

6.2.2. Monograph on Trigonellae foenugraeci semen and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 05/99

Outcome:

HMPC endorsed the Rapporteur's position that Trigonellae foenugraeci semen is not recommended for pregnant and lactating women.

Rapporteur to introduce changes according to the discussion for **a third discussion at the HMPC November** meeting.

HMPC members heard a summary of new information added to the AR. More conclusions were requested on the new clinical data particular as regards safety in view of monograph

sections 4.6 and 5.3. The use during pregnancy and lactation was discussed from a safety perspective. No relevant new PhV data were identified. It was also noted that several new clinical data refer to indications so far not included in the monograph. Furthermore, more details on a specific preparation used in Poland will be added.

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

6.3.1. Monograph on Agropyri repentis rhizoma and supporting documents

Action: for discussion

Documents: Review report; References: 67/02

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 November** meeting.

Timetable:

Documents to be sent to peer-reviewer: **13 October 2020**

Peer-review documents to be sent to Rapporteur: **27 October 2020**

Final documents to be included latest in 2nd premail: **10 November 2020**

6.3.2. Monograph on Carvi aetheroleum and supporting documents

Action: for discussion

Documents: Review report, Reader's guidance; References: 17/17

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 November** meeting.

Timetable:

Documents to be sent to peer-reviewer: **13 October 2020**

Peer-review documents to be sent to Rapporteur: **27 October 2020**

Final documents to be included latest in 2nd premail: **10 November 2020**

Although a number of new clinical safety data had been identified related to the monograph sections 4.5, 4.6 and 4.8; the Rapporteur had changed the conclusion according to feedback during the HMPC July meeting and does not anymore recommend the revision.

6.3.3. Monograph on Carvi fructus and supporting documents

Action: for discussion

Documents: Review report, Reader's guidance; References: 17/17

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 November** meeting.

Timetable:

Documents to be sent to peer-reviewer: **13 October 2020**

Peer-review documents to be sent to Rapporteur: **27 October 2020**

Final documents to be included latest in 2nd premail: **10 November 2020**

6.3.4. Monograph on Caryophylii floris aetheroleum and supporting documents

Action: for discussion

Documents: Review report; References: 05/05

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 November** meeting.

Timetable:

Documents to be sent to peer-reviewer: **13 October 2020**

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Final documents to be included latest in 2nd premail: **10 November 2020**

Few new entries in Eudravigilance had been found, but those were either already reflected in the previous assessment or found for combination products, not products with clove oil as single substance.

6.3.5. Monograph on Chamomillae romanae flos and supporting documents

Action: for discussion

Documents: Review report; References: 31/21

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 November** meeting.

Timetable:

Documents to be sent to peer-reviewer: **13 October 2020**

Peer-review documents to be sent to Rapporteur: **27 October 2020**

Final documents to be included latest in 2nd premail: **10 November 2020**

6.3.6. Monograph on Cinnamomi corticis aetheroleum and supporting documents - postponed

Outcome:

Postponed.

6.3.7. Monograph on Cinnamomi cortex and supporting documents - postponed

Outcome:

Postponed.

6.3.8. Monograph on Colae semen and supporting documents

Action: for discussion

Documents: Review report; References: 53/53

Outcome:

Rapporteur to introduce changes in the review report for **a third discussion at the HMPC November** meeting.

The Rapporteur was asked to focus on the relevant new findings and the discussion assessment of those as regards the monograph content. Conclusions on new toxicological data found should be presented and the number of listed references reduced to those relevant.

6.3.9. Monograph on Fucus vesiculosus and supporting documents - postponed

Outcome:

Postponed.

6.3.10. Monograph on Fumariae herba and supporting documents - postponed

Outcome:

Postponed.

6.3.11. Monograph on Lavandulae aetheroleum and supporting documents

Action: for discussion

Documents: Review report, Readers guidance; References: 43/197

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 adjust the review report regarding PhV data and clean/finalise it for peer review and **adoption** at the **HMPC November** meeting.

Timetable:

Documents to be sent to peer-reviewer: **13 October 2020**

Peer-review documents to be sent to Rapporteur: **27 October 2020**

Final documents to be included latest in 2nd premail: **10 November 2020**

New clinical and safety data are made available and specification of preparations in the existing monographs maybe scrutinised vis-a-vis new market developments.

The Rapporteur was asked to remove unnecessary details e.g. regarding PhV data from the review report and replace with a summary.

6.3.12. Monograph on Lavandulae flos and supporting documents

Action: for discussion

Documents: Review report; References: 00/00

Outcome:

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

However, Rapporteur to consider start of the revision procedure for Lavandulae flos because of the joint AR with Lavandulae aetheroleum (proposed for revision).

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

Timetable:

Documents to be sent to peer-reviewer: **13 October 2020**

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Final documents to be included latest in 2nd premail: **10 November 2020**

The Rapporteur was asked to focus in review report on what is new and not to include information already in the AR to which the Addendum will be annexed. For consistency and to ease substance-specific assessment and revision in future, the Committee will decide to either revise /update both monographs/packages or to keep all old supporting documents (AR, LOR) for the unchanged flos monograph and to limit for the revised aetheroleum monograph the AR/LoR on aetheroleum only.

6.3.13. Monograph on Mate folium and supporting documents

Action: for discussion

Document: Presentation; References: 00/00

Outcome:

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

The issue of polycyclic aromatic hydrocarbons (PAHs) was considered a general quality issue not requiring in-depth re-discussion in the Assessment report for Mate folium.

Rapporteur to draft the review report for **a second discussion at the HMPC November** meeting.

HMPC to reflect on the urgency to address the PAH issue with general guidance for work plans of the next years.

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

Outcome:

Postponed.

6.3.15. Monograph on Rosmarini aetheroleum and supporting documents - postponed

Outcome:

Postponed.

6.3.16. Monograph on Rosmarini folium and supporting documents - postponed

Outcome:

Postponed.

6.3.17. Monograph on Solani dulcamarae stipites and supporting documents

Action: for discussion

Documents: Review report; References: 00/00

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 November** meeting.

Timetable:

Documents to be sent to peer-reviewer: **13 October 2020**

Peer-review documents to be sent to Rapporteur: **27 October 2020**

Final documents to be included latest in 2nd premail: **10 November 2020**

Preparations on the DE market mentioned in the existing AR have meanwhile 30 years and could justify the revision of the monograph adding new preparations for cutaneous use.

However, it was noted that these have meanwhile been withdrawn from the market as a medicine and maybe marketed otherwise. The Rapporteur will check from more information from DE for final conclusion.

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

Outcome:

Postponed.

6.3.19. Monograph on Urticae folium and supporting documents

Action: for discussion

Documents: Review report; References: 28/28

Outcome:

Rapporteur to introduce changes in the review report for **a second discussion at the HMPC November** meeting.

No relevant new data that could change the content of the monograph were identified.

6.3.20. Monograph on Urticae herba and supporting documents

Action: for discussion

Documents: Review report; References: 28/28

Outcome:

Rapporteur to introduce changes in the review report for **a second discussion at the HMPC November** meeting.

A number of new references relevant for the assessment were identified but none to change the content of the monograph. However, for an expressed juice a diverse posology (> 30 years traditional use) compared to the one in the existing monograph was identified and thus revision of the monograph proposed. It was suggested to remove less relevant references from the review report.

6.3.21. Monograph on Violae tricoloris herba and supporting documents

Action: for discussion

Documents: Review report; References: 00/29

Outcome:

Postponed.

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

6.4.1. Monograph on Aloysiae citriodorae folium and supporting documents - postponed

Outcome:

Postponed.

6.4.2. Monograph on Species amarae and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR, OoC; References: 10/21

Outcome:

HMPC discussed comments received during public consultation and endorsed Rapporteur's view that no substantial changes will be included in the draft monograph.

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

Timetable:

Documents to be sent to peer-reviewer: **13 October 2020**

Peer-review documents to be sent to Rapporteur: **27 October 2020**

Final documents to be included latest in 2nd premail: **10 November 2020**

Members discussed the comments referring to the concept of combination monographs as well as on the indication. It was confirmed that naturally combination monographs may not exhaustively reflect 1:1 each single combination or substance in a common herbal indication that had once been on the market. However, even if not explicitly mentioned this may not reduce opportunities for companies for their individual products in national procedures. The relationship between combination- and mono- monographs and what it practically means may be clarified in the OoC but potentially also a general Q&A (see also 6.4.3).

6.4.3. Monograph on Species sedativae and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR, OoC; References: 35/23

Outcome:

HMPC discussed comments received during public consultation and endorsed Rapporteur's view that no substantial changes will be included in the draft monograph.

Some points on the general concept of combination monographs may be adjusted with response to comments on other monographs (see 6.4.2) and the issue may be considered to be reflected in a general Q&A to avoid misunderstandings.

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

Timetable:

Documents to be sent to peer-reviewer: **13 October 2020**

Peer-review documents to be sent to Rapporteur: **27 October 2020**

Final documents to be included latest in 2nd premail: **10 November 2020**

The HMPC discussed comments received as regards the concept of combination monographs as well as the indication. It referred to inclusion of plants potentially without an HMPC mono monograph or the maximum number of combination partners. It was acknowledged that

some aspects of the combination MOs maybe misunderstood and should be clarified in the OoC but potentially also the HMPC Regulatory Q&A such as a question how to use EU herbal monographs on combinations.

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

Outcome:

Postponed.

6.5.2. Monograph on Centellae asiaticae herba and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 0/216

Outcome:

Postponed.

6.5.3. Monograph on Salviae miltiorrhizae radix et rhizoma and supporting documents

Action: for discussion

Documents: Draft PS, AR, LoR; References: 00/90

Outcome:

Postponed.

6.5.4. Monograph on Species digestivae or species stomachicae and supporting documents - postponed

Outcome:

Postponed.

6.5.5. Monograph on Taraxaci officinalis radix and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR, Reader's guidance; References: 00/99

Outcome:

Rapporteur to introduce changes according to the discussion for **a second discussion at the HMPC November** meeting.

The Rapporteur presented the first draft AR going through what is common and specific for radix vis-a-vis the already existing other Taraxacum monographs.

Committee members welcomed the proposal and suggested for the next discussion the use of the Readers guidance to point to specific items in AR and MO and necessary clarification with the committee.

6.5.6. Monograph on Vaccinii macrocarpi fructus and supporting documents

Action: for discussion

Documents: Draft MO, AR, LoR; References: 459/260

Outcome:

Postponed.

6.5.7. Monograph on Cisti cretici folium and supporting documents - postponed

Outcome:

Postponed.

7. Any other business

7.1. Topics for discussion

None

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 6-8 July 2020

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

7.2.2. ARSP

- English template
- English summaries for publication
    - Herniariae herba
    - Thymi aetheroleum
    - Tanaceti parthenii herba

No objections were raised against the publication of three summaries for the public.

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

None

7.2.4. Other

- Meeting report PCWP HCPWP meeting 2 June
- Meeting report PCWP HCPWP meeting (ICH) 3 June
- Meeting report PCWP HCPWP meeting (PhV) 24 June
- Draft Agenda Workshop on the application of the General Data Protection Regulation (GDPR) in the area of health and Secondary Use of Data for Medicines and Public Health Purposes - 23/09/2020
- Draft Agenda Workshop on benefit-risk of medicines used during pregnancy and breastfeeding - 22/09/2020
- Nitrosamines Impurities in medicinal products - CHMP outcome

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 September 2020 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	
Ivan Kosalec	Member	Croatia	No restrictions applicable to this meeting	
Darko Trumbetic	Alternate	Croatia	No interests declared	
Antri Kouroufexi	Member	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	
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	
Ioanna Chinou	Member	Greece	No interests declared	
Stavroula Mamoucha	Alternate	Greece	No interests declared	
Zsuzsanna Bíróné Dr Sándor	Member	Hungary	No interests declared	
Alessandro Assisi	Member	Italy	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Baiba Jansone	Member	Latvia	No interests declared	
Everaldo Attard	Member	Malta	No interests declared	
Burt H Kroes	Member	Netherlands	No interests declared	
Steinar Madsen	Member	Norway	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	
Adela Núñez Velázquez	Member	Spain	No interests declared	
Karin Erika Svedlund	Member (Vice-Chair)	Sweden	No interests declared	
Ewa Balkowiec Iskra	Co-opted member	Poland	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	
Olga Palomino	Expert - via Adobe*	Spain	No interests declared	
Pierre Duez	Expert - via Adobe*	Belgium	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Friederike Stolte	Expert - via Adobe*	Germany	No interests declared	
A representative from the European Commission attended the meeting				
Meeting run with support from relevant EMA staff				

* Experts were only evaluated against the agenda topics or activities they participated in.