23 September 2019
EMA/HMPC/530624/2019 **FINAL**
Inspections, Human Medicines Pharmacovigilance & Committees Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 8-10 July 2019

Chair: Marisa Delbò Vice-Chair: Emiel van Galen

08 July 2019, 14:00 – 19:00, 2D

09 July 2019, 09:00 – 19:00, 2D

10 July 2019, 09:00 – 16:00, 2D

Health and safety information

In accordance with the Agency's health and safety policy, delegates were briefed on health, safety and emergency information and procedures prior to the start of the meeting.

Disclaimers

Some of the information contained in this 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 this set of minutes cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

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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 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.

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.

Due to several apologies, the quorum required for the adoption of scientific opinions or recommendations by the Committee according to Article 7 of the HMPC Rules of procedure had not reached the required two thirds of the total members of the Committee eligible to vote (22).

New nomination membership (BE): Patricia Bodart (member) as of 21 May 2019

End of membership (BE): Heidi Neef (member) as of 20 May 2019

End of membership (SI): Samo Kreft (member) as of 27 June 2019

Swap of roles membership (SI): Barbara Razinger (from alternate to member) as of 27 June 2019

No competing interest with regard to the agenda topics was declared.

1.2. Adoption of agenda

HMPC agenda for 08-10 July 2019

Time schedule for 08-10 July 2019

Outcome:
Agenda adopted.

Time schedule endorsed.

1.3. Adoption of the minutes

HMPC minutes for 13-15 May 2019

Outcome:
Minutes adopted with a change in point 2.2.2. and in the List of participants.

2. EU herbal monographs and list entries for adoption

2.1. Status of HMPC/MLWP activities

2.1.1. Overview of status of HMPC and MLWP assessment work including the Rapporteurship distribution – Status in July 2019

Report: HMPC Chair
Action: For discussion
Document: Overview

Outcome:

The status of first assessments, reviews and revision procedures was determined. Rapporteurs confirmed whether documents for ongoing procedures will be made available for discussion at the HMPC September meeting. The availability of documents for Quercus, Solidagus, Arctium and Juniperus needs still to be checked with the Rapporteurs.

2.1.2. Appointment of Rapporteurs and Peer-reviewers

Report: HMPC Chair

Action: for adoption

Rapporteur transfer following end of membership of R Iavorszky

Orthosiphonis folium – New Rapporteur

Species amarae – New Rapporteur

Peer-Reviewer transfer following end of membership of R Iavorszky

Polypodii rhizoma – New PR

Hippocastani cortex – New PR

Outcome:
HMPC endorsed re-appointments according to change in RO membership. Polypodii rhizoma PR change currently not relevant (recently finalised review with outcome 'no revision').

2.1.3. Andrographidis paniculatae folium in combination and supporting documents - request for unscheduled monograph revision - postponed

2.1.4. Monograph on Sabalis serrulatae fructus and supporting documents - request for for unscheduled monograph revision - postponed

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

2.2.1. Monograph on Valerianae radix/Lupuli flos and supporting documents

Action: for adoption

Documents: MO, AR, LoR, OoC, Readers guidance dated 15 May 2019, DE comments on AR dated 07 January 2019, SE comments on AR dated 01 July 2019; References: 11/35

Outcome:
Changes were introduced in the MO and AR. Adoption postponed for the September 2019 meeting due to lack of quorum of HMPC members.

Documents to be transmitted for possible **final adoption** in September 2019.

Timetable:
Comments from all members to be sent to Rapporteur by: **6 September 2019**
Final clean documents to be included latest in 2nd premail: **17 September 2019**

Corrections were performed in several sections of the monograph and the assessment report. Mainly statements with regard to the value of clinical studies and the justification of the well-established use were scrutinised and should be aligned and cleaned for final adoption.

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

2.3.1. Monograph on Rhamni purshianae cortex and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 27/38

Outcome:
Draft documents to be finalised according to the discussion and transmitted for peer-review prior to possible **adoption for release for public consultation in September 2019**.

Timetable:
Documents to be sent to peer-reviewer: **31 July 2019**
Peer-review documents to be sent to Rapporteur: **6 September 2019**
Final clean documents to be included latest in 2nd premail: **17 September 2019**

Members discussed the non-availability of specific clinical studies for well-established use recognition as well as the way preparations should be presented in section 2 of the monograph. It was decided to follow the general approach (standardised preparations in general with a specified posology according to hydroxyanthracene derivative (HAD) content in section 4.2) in line with Senna but not the specific listing of preparations as applied for Aloe (see also 6.1.1 and 6.2.1).

2.3.2. Monograph on Tanaceti parthenii herba and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 00/104

Outcome:
Changes were introduced in the MO. Draft documents to be finalised according to the discussion and transmitted for peer-review prior to possible **adoption for release for public consultation in September 2019**.

FR and SP delegates to provide clarifying data on nationally registered products to the Rapporteur.

Documents to be sent to peer-reviewer: **31 July 2019**
Peer-review documents to be sent to Rapporteur: **6 September 2019**
Final clean documents to be included latest in 2nd premail: **17 September 2019**

Members were asked to provide written comments to the Rapporteur by **6 September 2019** to facilitate the discussion and finalisation for public consultation at the HMPC September meeting.

The Rapporteur presented changes in assessment report and new proposals for monograph sections 4.2, 4.6 and 5.3. The discussion focused on the best presentation of the posology according to marketed products (old lower daily dose versus new higher daily dose as well as the need for bridging) and further on corresponding appropriate warnings/contraindications particularly during pregnancy and lactation. The provision of complete information from marketed products in Spain and France was considered essential.

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

2.4.1. Monograph on Hamamelidis cortex and supporting documents

Action: for adoption
Document: Review report; References: 00/02

Outcome:
Changes were introduced in the review report. Rapporteur to provide a finalised clean document (specific for the active substance) including relevant full text references for possible adoption in **September 2019**.

HMPC endorsed the view not to start the revision procedure for any of the Hamamelis substances (shared AR), because no relevant new data were detected that would change the content of the monographs.

To reflect a newly available Ph. Eur. monograph (including assay method) as relevant quality standard, a correction will be introduced in the existing monograph on Hamamelis cortex (footnote section 2), which should also be reflected in the Addendum to the AR.

The HMPC discussed the relevance of safety data (NTP study on pyrogallol) and appropriate reflection in the Addendum to the AR. The Rapporteur was also asked to reflect on the specificity of data mentioned in review reports for the 3 different Hamamelis substances. In view of few new data and unlikely relevant change in the monographs, the start of the revision procedure was currently not considered useful although documents from 2010 require adaption to recent templates with the next revision.

2.4.2. Monograph on Hamamelidis folium and supporting documents

Action: for adoption
Document: Review report; References: 00/00

Outcome:
Rapporteur to provide a finalised clean document (specific for the active substance) including relevant full text references for possible adoption in **September 2019**.

2.4.3. Monograph on Hamamelidis folium et cortex aut ramunculus destillatum and supporting documents

Action: for adoption
Document: Review report; References: 00/00

Outcome:
Rapporteur to provide finalised clean document (specific for the active substance) including relevant full text references for possible adoption in **September 2019**.

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 Herniariae herba and supporting documents

Action: for adoption
Documents: MO, AR, LoR, Readers guidance; References: 34/31

Outcome:
Adoption postponed. Draft documents to be finalised according to the discussion and transmitted for peer-review prior to possible **adoption for release for public consultation in September 2019**.

Rapporteur to adapt AR after check with toxicologists in order to allow conclusions on the safe use and the possibility for monograph establishment.

Rapporteur to check possibilities for a 'mono-monograph' versus a combination monograph according to available data.

Documents to be sent to peer-reviewer: **31 July 2019**
Peer-review documents to be sent to Rapporteur: **6 September 2019**
Final documents to be included latest in 2nd premail: **17 September 2019**

Concerns were raised with regard to non-clinical safety data and their relevance discussed comparing dosages used in animal studies and human dosages according to traditional use.

The use of traditional posologies from combination products for the conclusion on the use of the substance alone was questioned. The Rapporteur will consider the option of a combination monograph only.

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; Comments from SE; SWP subgroup comments; Presentations from H Foth and J Wiesner

Outcome:
HMPC members noted Rapporteurs' opinions. Via a 'tour de table' preference for 3 options to finalise the PS were checked.

Rapporteur to adapt PS according to the discussion and provide specific questions to be circulated in advance to the members in order to prepare for clear positions and a repeated 'tour de table' for decision by the **HMPC in September 2019**.

Limits and acceptable safety factors were discussed in view of traditional dosages for medicinal products, estimated food exposure as well as insufficient data in order to come to final conclusions.

4.2. Quality

None

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

- Follow up on Romania Presidency meeting – 4-5 April 2019
  Action: for discussion
  Documents: BPG PRAC plenary, HMPC Readers Guidance template
- Finnish Presidency meeting – Czech Republic, Prague – 5-6 November 2019
  Action: for discussion

Document: Draft programme proposal

Outcome:
HMPC noted reader's guidance template and PRAC best practice guide. A follow up discussion is considered for the HMPC SRLM in November.

HMPC discussed draft outline for the SRLM programme in November. The CZ delegate invited members to provide topics and titles of presentations latest by mid-September.

Some additional topics were proposed such as the relevance of the
Ames test for herbal substances/preparations or the impact of Rapporteur re-assignments for working methodology/role of MLWP (see also 5.1.3).

5.1.2. Election of QDG Chair

Report: HMPC Chair
Action: for adoption
Documents: 2nd Call for nomination dated 18 June 2019; QDG mandate

Outcome:
Election postponed.

5.1.3. Rapporteurs at HMPC

Action: for discussion
Documents: Presentation, HMPC rules of procedure, MLWP mandate

Outcome:
HMPC was informed on principles for the stepwise transfer of Rapporteurships/PRs to HMPC members/ alternates to align with other EMA scientific committees. Some reservations were expressed given the previous leading role of MLWP in MO/LE establishment and differences to other committees. Details for practical implementation were clarified and subsequent adaptations in HMPC-MLWP working methodology discussed.

Next steps:

Lists for necessary transfers distributed by **19 July 2019**.

HMPC members/alternates to signal interest by latest **13 September 2019** to the secretariat.

Secretariat to compile information for agenda and first wave of reappointment at **HMPC September 2019 meeting**.

After initial transfer from Chairs to HMPC members/alternates in September 2019 the transfer from MLWP to HMPC will be started in November 2019.

The future role of MLWP Rapporteurs was discussed and some possibilities and consequences for the transfer (e.g. meeting participation as alternate/expert, transfer preferable to HMPC member of the same MS etc.). Questions were raised on working methodology adaptations: main discussion/responsibility at the committee and clarification of specific questions or initial drafting at the working party. It was also proposed to discuss details at the next Strategic Review and Learning Meeting (see 5.1.1).

5.2. Coordination with EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair
Action: for information
Document: Draft Minutes dated 2 May 2019

Outcome:
HMPC noted draft minutes.

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 the European Commission - postponed

- Cannabis for medicinal use

5.4.2. Coordination with European Pharmacopoeia

- EDQM 13A expert group meetings
  Action: for information
  Document: SoD 13A
- Certification procedure - Steering Committee meeting held on 28 May 2019
  Report: HMPC Chair
  Action: for discussion
  Document: Agenda

  Outcome:
  HMPC noted the information given on the 13A SoD.

  The HMPC Chair highlighted that the Steering Committee meeting advocated an improved information exchange between the DCEP (Certification Department) by sharing documents/meeting minutes with DCEP and providing regular feedback on decisions which directly impact the CEP procedures. An observer from the DCEP at the HMPC-QDG could be beneficial (currently only an observer from European Pharmacopoeia Department participates to the HMPC/QDG) and the EMA secretariat should check possibilities in coordination with EDQM.

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. AESGP – possible hearing in November 2019

Report: HMPC Chair

Action: for information
Document: email correspondence dated 12-20 June 2019

Outcome:

HMPC agreed to the AESGP proposal to postpone the annual hearing originally planned for September 2019 at MLWP to the HMPC November meeting. A reasonable timing should be agreed given time constraints under the specific BCP circumstances.

5.7. Work plan

5.7.1. HMPC work plan 2019

Report: HMPC Chair
Action: for information
Document: Work plan 2019, Annex 1, Annex 2 – current status July 2019

Outcome:
HMPC noted current status of planned activities 2019.

5.8. Planning and reporting

5.8.1. Update on BCP and HMPC meeting dates

Action: for information
Document: Oral report

Outcome:
HMPC noted the information provided with reference to the Management board meeting June.

Despite uncertainties with regard to BCP it was confirmed that currently the meeting weeks 2019-2021 have not changed and should be taken as basis for planning.

5.9. Legislation and regulatory affairs

None

5.10. Questions from members

5.10.1. QRD Template

Action: for discussion
Document: Proposals for template improvement, Addendum to the Quality Review of Documents templates for SmPC for THMPs

Outcome:
HMPC discussed the proposal to initiate adaptations in document CMDh/349/2016, Rev.0 (EMA/HMPC/770889/2014) from July 2016 to adapt to recent changes in the QRD template for further coordination with QRD and CMDh.

The decision to start such initiative in 2019 or 2020 will be taken at the **HMPC September meeting**.

According to experiences from European procedures recent changes in the generally applicable QRD template are not yet reflected in the HMPC-created Addendum for THMP as published on the CMDh website. Proposed adaptations were already summarised to initiate the coordination with QRD and CMDh. The HMPC Chair considered the topic as not urgent, and proposed consideration for the HMPC 2020 work plan referring also to the BCP related temporary suspension of drafting group activities including the HMPC ORGAM DG.

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 Frangulae cortex and supporting documents

Action: for discussion
Document: Draft MO, AR, LoR, OoC; References: 42/43

Outcome:
Draft documents to be modified according to the discussion and transmitted for peer-review prior to possible **final adoption in September 2019**.

Timetable:
Documents to be sent to peer-reviewer: **31 July 2019**
Peer-review documents to be sent to Rapporteur: **3 September 2019**
Final documents to be included latest in 2nd premail: **17 September 2019**

The committee discussed comments received during public consultation.

Regarding the way preparations should be presented in section 2 of the monograph it was decided to follow the general approach (standardised preparations in general with a specified posology according to hydroxyanthracene derivative (HAD) content in section 4.2) in line with Senna but not the specific listing of preparations as applied for Aloe.

6.1.2. Monograph on Hyperici herba (traditional use) and supporting documents

Action: for discussion
Documents: Draft MO (TU), MO (WEU), AR, LoR, Readers guidance; References: 02/557

Outcome:
Draft documents to be modified according to orientation given on main 4 questions of the Readers's guidance and other discussion points for a 3rd discussion **in September 2019** or **November 2019**.

Members discussed the proposed specific extension of safety/interaction information considering the length and need for updates of the resulting sections. Subsequently also the information in the WEU monograph would have to be aligned although in January 2018 it was decided not to revise the WEU monograph. Alternatively it was proposed to keep the more general approach which can be updated at time of national decisions for the SmPCs of specific products. Furthermore a slight change of the traditional indication and the update of the AR were discussed.

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

6.2.1. Monograph on Rhei radix and supporting documents

Action: for discussion
Documents: MO, AR, LoR; References: 55/57

Outcome:
Draft documents to be modified according to the discussion and transmitted for peer-review prior to possible **adoption for release for public consultation in September 2019**.

Timetable:
Documents to be sent to peer-reviewer: **31 July 2019**
Peer-review documents to be sent to Rapporteur: **3 September 2019**
Final documents to be included latest in 2nd premail: **17 September 2019**

Regarding the way preparations should be presented in section 2 of the monograph it was decided to follow the general approach (standardised preparations in general with a specified posology according to hydroxyanthracene derivative (HAD) content in section 4.2) in line with Senna but not the specific listing of preparations as applied for Aloe.

6.2.2. Monograph on Thymi aetheroleum and supporting documents

Action: for discussion
Documents: Draft MO, AR, LoR; References: 121/138

Outcome:
Draft documents to be modified according to the discussion and transmitted for peer-review prior to possible **adoption for release for public consultation in September 2019**.

Timetable:
Documents to be sent to peer-reviewer: **31 July 2019**
Peer-review documents to be sent to Rapporteur: **6 September 2019**
Final documents to be included latest in 2nd premail: **17 September 2019**

Members were asked to provide written comments to the Rapporteur latest by **12 September 2019** to facilitate the discussion and finalisation for public consultation at the HMPC September meeting.

Changes to AR and monograph were presented. Monograph sections 2 (including reference to Ph. Eur monograph with changed name), 4.2 (alignment drops and ml), 5.3 (appropriate information in reflection of available non-clinical data) and some sections in the assessment report mainly linked to the update of wordings from the old AR version were discussed. Also new PhV data -often linked to skin irritation- are being checked.

6.2.3. Monograph on Trigonellae foenugraeci semen and supporting documents

Action: for discussion
Documents: Draft MO, AR, LoR, Review report; References: 00/98

Outcome:
Changes were introduced in the MO. Draft documents to be modified according to the discussion for **a second discussion in HMPC September 2019**.

The Rapporteur presented the first version of revised documents and changes in comparison to the current AR and MO in line with new data (often on use in glycemia and interaction with antidiabetics) and new templates. Changes in monograph sections 4.2, 4.6 and 5.3 were introduced. Members commented on the available information from marketed products and literature on medicinal use and derived posologies as reflected in AR tables 2 and 3. Members were asked to provide comments and any available information on marketed products for revision and re-discussion in September.

6.2.4. Monograph on Millefolii herba and supporting documents

Action: for discussion
Documents: Draft MO, LE, AR; New References: 08/08

Outcome:
Changes were introduced in the AR. Draft documents to be modified according to the discussion for **a second discussion in HMPC September 2019**.

The Rapporteur presented the first version of revised documents and changes in comparison to the current AR and MO in line with new data and new templates.

Members discussed the appropriateness of information provided under historical data in the AR such as listing several references quoting each other for the same facts or mentioning monographs in national Pharmacopoeias - some of them including posologies.

The applicability and relevance of new genotoxicity data (Ames test) were discussed in view of which preparations can be included in the new draft list entry (aqueous extract - herbal teas - expressed juice with reference to HMPC guideline EMA/HMPC/67644/2009).

Additional information on medicinal use of products/preparations was requested from PL.

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

6.3.1. Public statement on Centellae asiaticae herba and supporting documents – possibility for monograph establishment

Action: for discussion
Document: Review report; References: 00/22

Outcome:
A majority of present members supported the start of monograph establishment based on available data.

The Rapporteur was asked to finalise the review report according to the discussion for **adoption at the HMPC September 2019 meeting**.

Data including those made available during public consultation of the first PS (OoC Annex) were scrutinised. For some preparation the 30 years period seems now to be fulfilled, while for other products the problem remains that they were not considered herbal preparations.

In acknowledgement that *C. asiatica* is one of the widely used non-European traditional plants for medicinal purposes - although not registered/authorised as (T)HMP so far - a majority supported finalisation of the review with the recommendation to start monograph establishment.

6.3.2. Monograph on Taraxaci folium and supporting documents - postponed

6.3.3. Monograph on Taraxaci radix cum herba and supporting documents - postponed

6.3.4. Monograph on Rosmarini aetheroleum and supporting documents - postponed

6.3.5. Monograph on Rosmarini folium and supporting documents - 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 Calendulae herba and supporting documents

Action: for discussion
Documents: Discussion paper, Draft preliminary MO, Uptake of the traditional use registration; References: 00/00

Outcome:

Rapporteur to update the discussion paper and to prepare a public statement according to the discussion for possible adoption **in September 2019**.

The Rapporteur presented the rationale why a monograph for Calendulae herba may not be established with reference to marketed products/ recent national experiences, the anthroposophic background and traditional manufacturing according to the homeopathic pharmacopoeia of some preparations in question. It was requested to double–check the validity of the legal and regulatory basis given that anthroposophic medicines *per se* are not excluded from the scope of Art. 16a. Also previously reported traditional use registrations in 3 MSs were noted and should be considered for the justification.

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

6.5.3. Monograph on Menyanthes trifoliata folium and supporting documents

Action: for discussion
Documents: Draft MO, AR, LoR; References: 68/73

Outcome:
Postponed

6.5.4. Monograph on Saccharomyces cerevisiae CBS 5926 and supporting documents

Action: for discussion
Documents: Draft MO, Draft LE, Draft AR, Draft LoR; References: 02/188

Outcome:
HMPC discussed the options to finalise the assessment and consequences of a monograph or public statement for national decisions.

Members were asked to be prepared and if required consult within their Agencies for 7th discussion and final decision at **the September meeting.**

The rationale was repeated why live-biotherapeutic products may not be considered as herbal substances/preparations and therefore not in the scope of definitions according to Directive 2001/83/EC. Likewise the position was reiterated that the definition allows *fungi* in a broad sense and that there are no major safety concerns for *S. cerevisiae* acknowledging the widespread use in food. While the nature of the active substance as living organism is clearly different to other herbal MPs, and for quality aspects guidelines for biological products and specific Ph. Eur. requirements have to be considered, some members are of the view that an herbal monograph may be useful.

6.5.5. Monograph on Species amarae and supporting documents

Action: for discussion
Documents: Draft MO, AR, LoR; References: 00/16

Outcome:
Postponed

6.5.6. Monograph on Vaccinii macrocarpi fructus and supporting documents - postponed

6.5.7. Monograph on Verbenae citriodorae folium and supporting documents

Action: for discussion
Documents: Draft MO, AR, LoR; References: 00/22

Outcome:
Postponed

7. Any other business

7.1. Topics for discussion

7.1.1. Develop a strategy for use of PhV data/tools in HMPC assessment

Action: for discussion
Documents: Presentations

Outcome:
The five main PhV elements were presented as well as a practical test how available data/assessments may be useful for HMPC assessment.

HMPC agreed on a strategy to start with 1-3 easy features, acquire the necessary knowledge via small trainings sessions, while more complex elements may not be used in the first wave.

In line with the HMPC work plan, PhV activities were introduced that could potentially support the HMPC task to keep herbal monographs up to date: signal detection in EudraVigilance, PSUR single assessment (PSUSA), Medical Literature Monitoring (MLM), as well as Risk Management Plans (RMPs) and the Art. 57 database for MPs on the EU market. Experiences from the national perspective e.g. during revision of the monograph on Hippocastani semen were explained.

A further practical test with four benchmark substances in terms of data situation was presented to demonstrate whether there are relevant safety data not detected otherwise (literature search, market overview, call for data), what is the expenditure to retrieve these data and whether there are specific data access limitations. Recommendations were given to adapt the PhV part of the HMPC standard assessment with the immensely changed development in PhV data collection/availability.

Rapporteurs to present at **HMPC in September** a proposal for implementation how to use available data from (1) literature monitoring, (2) PSUSAs for herbal substances and (3) relevant cases from signal detection (availability check with national PhV colleagues/PRAC members).

7.1.2. PSUSA procedure for Pelargonii radix - postponed

7.1.3. 2019 International Forum on Traditional Chinese Medicine (TCM) and Botanical Medicine held in Shenzhen from April 25th to 26th, 2019

Action: for discussion
Document: Feedback report

Outcome:
HMPC noted the information provided by the HMPC Vice-Chair.

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 13-15 May 2019

Overview of expertise of members HMPC and subgroups

Meeting report from HMPC meeting held on 13-15 January 2019

Overview of status of HMPC assessment work – priority list

Inventory of herbal substances for assessment work

Abbreviations in HMPC agendas/minutes

Common names of herbal substances in all languages

Overview of status of HMPC/MLWP assessment work

Final Monograph Overview

7.2.2. ARSP

- English template
- English summaries for publication:
  None

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

- Monograph on Allii sativi bulbus and supporting documents – unsolved post-adoption issues
  Documents: MO, AR, LoR, OoC, email correspondence dated 18 June 2019
- Monograph on Foeniculi amari fructus and supporting documents – awaiting Estragole PS finalisation
- Monograph on Foeniculi amari fructus aetheroleum and supporting documents – awaiting Estragole PS finalisation
- Monograph on Foeniculi dulcis fructus and supporting documents – awaiting Estragole PS finalisation
- Monograph on Menthae piperitae folium and supporting documents – awaiting finalisation shared AR with Menthae aetheroleum for final adoption
  Documents: MO, AR, LoR
- Monograph on Pistacia lentiscus, resinum (mastic) and supporting documents – unsolved post-adoption issues
  Documents: MO (version 1.42), AR (Version 1.64), LoR (Version 1.29) (all dated 14/05/19 distributed to HMPC 24/06/19); Comments received on package from 14/05/19: RO, PL, AT; SE; new documents all dated 30/06/19 provided by Rapp. 01/07/2019 (not distributed to all HMPC): AR (dated 30-06 - not clean), AR (dated 30-06 - clean), LoR (dated 30-06), New reference: Paraschos *et al*. 2012
- Monograph on Species digestivae or species stomachicae and supporting documents - awaiting Estragole PS finalisation

7.2.4. Other

- The European Herb Growers Association (EUROPAM) position on drying (dehydration) factors for medicinal and aromatic plants (MAPs)

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 08-10 July 2019 meeting.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Marisa Delbò	Chair	Italy	No interests declared	
Reinhard Länger	Member	Austria	No interests declared	
Patricia Bodart	Member	Belgium	No interests declared	
Iliana Ionkova	Member	Bulgaria	No interests declared	
Ivan Kosalec	Member	Croatia	No restrictions applicable to this meeting	
Marie Heroutova	Member	Czech Republic	No interests declared	
Markéta Příhodová	Alternate	Czech Republic	No restrictions applicable to this meeting	
Steffen Bager	Member	Denmark	No restrictions applicable to this meeting	
Sari Koski	Alternate – via adobe	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	
Zoi(Zoe) Karampourmpouni	Alternate	Greece	No interests declared	
Zsuzsanna Biróné Dr Sándor	Member	Hungary	No interests declared	
Barbara Toth	Expert – via Adobe	Hungary	No interests declared	
Una Mockler	Member – via Adobe	Ireland	No interests declared	
Alessandro Assisi	Member	Italy	No interests declared	
Everaldo Attard	Member	Malta	No interests declared	
Emiel Van Galen	Member	Netherlands	No interests declared	
Burt H Kroes	Alternate	Netherlands	No interests declared	
Steinar Madsen	Member	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	
Adela Núñez Velázquez	Member	Spain	No interests declared	
Olga Palomino	Expert	Spain	No interests declared	
Karin Erika Svedlund	Member	Sweden	No interests declared	
Malin Kyllikki Hobro Soderberg	Alternate	Sweden	No interests declared	
Ewa Balkowiec Iskra	Co-opted member – via Adobe	Poland	No interests declared	
Heidi Foth	Co-opted member	Germany	No interests declared	
Maria Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared	
Carlos Cavaleiro	Expert – via Adobe	Portugal	No interests declared	
Melanie Bald	Observer – via Adobe	EDQM	No interests declared	