17 June 2019
EMA/HMPC/403891/2019
Inspections, Human Medicines Pharmacovigilance & Committees Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 13-15 May 2019

Chair: Marisa Delbò Vice-Chair: Emiel van Galen

13 May 2019, 14:00 – 19:00, 0C

14 May 2019, 09:00 – 19:00, 0C

15 May 2019, 09:00 – 16:00, 0C

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 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. All decisions taken at this meeting were made in the presence of a quorum of members (i.e. 22 or more members were present in the room).

1.2. Adoption of agenda

HMPC agenda for 13-15 May 2019

Time schedule for 13-15 May 2019

Outcome:
Agenda adopted.

Time schedule endorsed with minor changes.

1.3. Adoption of the minutes

HMPC minutes for 14-16 January 2019

Outcome:
Minutes adopted with a minor change.

Before adoption, the January minutes were discussed with regard to points 2.1.2/2.1.3 (Rapporteurship transfer from UK rapporteurs; all monographs under preparation discussed at HMPC), 2.7.1 (deadline for member comments not clear), and 6.1.3 (granularity of HMPC minutes on discussions for ongoing assessments without final HMPC decisions; Readers guidance).

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 May 2019

Report: HMPC Chair, MLWP Chair
Action: For discussion
Document: Overview

Outcome:
For postponed topics Rapporteurs present informed whether documents can be provided for the July meeting.

HMPC re-confirmed the submission deadline Tuesday week -1 to allow preparation of members. Topics (monograph/ guidelines) without documents provided by Tuesday lunchtime should be postponed (except presentations / first time discussions).

The transfer of UK rapporteurships as adopted in January was confirmed (see also 7.1.7).

The discussion of all assessments at the extended HMPC plenary time was confirmed, including all those under preparation (section 6) and those with current Rapporteurs not being HMPC members. Under current BCP provisions it appears not appropriate to wait for MLWP input.

For Allium finalisation the Rapporteur should be contacted again for confirmation of finalisation and if necessary a new Rapporteur to be appointed in July 2019.

For Calendulae herba (prioritised for first assessment 28/01/2014) the old and new Rapporteur stated that insufficient data and marketing information for specific products suggest the assessment may be discontinued. The rationale will be provided in writing for HMPC decision at the July plenary.

2.1.2. Appointment of Rapporteurs and Peer-reviewers

Start of assessment after review of available data

- Andrographidis paniculatae folium

Start of unscheduled review of newly available data

- Zingiberis rhizoma

Outcome:
Rapporteurs/ PRs were appointed.

Rapporteur transfer after change in Romanian membership to be confirmed in July 2019.

2.1.3. Andrographidis paniculatae folium and supporting documents – possibility for monograph establishment

Action: for adoption
Documents: Review report, Presentation; References: 15/11

Outcome:

Rapportuer presented after review of available data minimum information to allow development of a monograph.

HMPC agreed by majority to Rapporteur's proposal for start of assessment of Andrographidis paniculatae folium towards monograph establishment (possible outcome TU monograph).

For the combination Andrographidis paniculate herba / Eleutheroccoci radix (possible outcome WEU monograph) the Rapportuer was asked to double-check and present available data using the corresponding template for discussion and decision at the HMPC July meeting.

Some members raised doubts about the availability of sufficient data on traditional use as well as the need for a monograph for one specific combination (if only one marketed product is known).

2.1.4. Monograph on Zingiberis rhizoma and supporting documents

Action: for discussion
Documents: Review report template; Email correspondence; New references received from AESGP: 137

Outcome:
New scientific data were provided for revision of the monograph.

Since the previous Rapporteur declined, a new Rapporteur was appointed (see 2.1.2). Following the review of data using the review report template discussion and decision on revision is scheduled for September 2019.

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

2.2.1. Monograph on Menthae piperitae folium and supporting documents (see also 2.3.2.)

Action: for adoption
Documents: MO, AR, LoR; References: 109/205

Outcome:

HMPC agreed by consensus to the content of the monograph.

Due to the shared assessment report formal adoption will take place together with M. piperitae aetheroleum (see also 2.3.2) to allow publication of complete opinion and document package.

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

Action: for adoption
Documents: MO, AR, LoR, OoC, Presentation, DE comments on AR, References: 11/35

Outcome:
Adoption postponed. Changes were introduced in the MO and AR. Rapporteur to implement further changes according to the discussion.

Documents to be transmitted for peer-review prior to possible **final adoption** in July 2019.

Because the Rapporteur will not be able to attend the July meeting, comments by members to be provided in writing to allow Rapporteur the inclusion before submission for adoption in July, if possible, or in September in case of major issues.

Timetable:
Documents to be sent to peer-reviewer: **31 May 2019**
Peer-review documents to be sent to Rapporteur: **20 June 2019**
Documents to be sent to all HMPC for comments in writing: **30 June 2019**

Final documents to be included latest in 2nd premail: **2 July 2019**

HMPC acknowledged weak clinical evidence from RCTs for specific combinations – however, no new data are available to justify changed conclusions for the MO. A proposed shift from WEU to TU of some combinations with substantially lower posology compared to the Valerian mono-monograph was not agreed due to (a) regulatory consistency, (b) difficulties with the 30 years documentation despite no safety concerns and (c) possible but unknown contributing effect of *H. lupulus.* Instead an appropriate wording in the clinical and overall conclusions of the AR should be introduced. It was further agreed to delete major parts in section 5.1 of the monograph and to rationalise the information in AR tables on clinical relevance.

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

2.3.1. Monograph on Hippocastani semen and supporting documents

Action: for adoption
Documents: MO, AR, LoR, Readers guidance, Presentation; References: 00/80

Outcome:
Draft revised monograph and supporting documents with minor modifications in the MO and AR were adopted by consensus for 3 months public consultation.

Based on the Readers guidance main changes in the revised monographs and previous discussions were summarised. Members discussed the way preparations and posologies were presented in the MO including the introduced footnote regarding the new Ph. Eur. method for aescin determination and the subsequent conversion factor from the old declarations. Furthermore the addition of new preparations and possible overlaps between TU and WEU were scrutinised. Finally, standardisation versus quantification for aescin, use in children (contraindication vs 'not relevant') and the additional information available from a PhV data check (pilot project for separate discussion see 7.1.1) were addressed.

2.3.2. Monograph on Menthae piperitae aetheroleum and supporting documents

Action: for adoption
Documents: MO, AR, LoR, LE; References: 109/205

Outcome:
Draft revised MO, draft revised LE and supporting documents with modifications in the MO, LE and AR were adopted by majority for 3 months public consultation.

Remaining issues were discussed and corrected as necessary with regard to content of monograph section 5.3 (toxicity/pulegone–specific content in SmPC vs monograph) as well as sections 4.2. and 4.4 for the posology/warnings for use in children specific for Indication

1 and 2 and oral/oromucosal use versus cutaneous use. Also the intake (minimum period) before meals was discussed which came up during DCP procedures and reconsidered with a view on the pharmaceutical form.

The list entry was put into the latest template and final adjustments in line with the revised monograph were performed where relevant.

2.3.3. Monograph on Rhamni purshianae cortex and supporting documents - postponed

2.3.4. Monograph on Tanaceti parthenii herba and supporting documents

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

Outcome:
Changes were introduced in the MO. Rapporteur to implement further changes in MO and AR according to the discussion.

Documents to be transmitted for peer-review prior to final discussion and possible **adoption for public consultation** in July 2019.

Timetable:
Documents to be sent to peer-reviewer: **31 May 2019**
Peer-review documents to be sent to Rapporteur: **15 June 2019**
Final documents to be included latest in 2nd premail: **2 July 2019**

Members scrutinized and discussed with the Rapporteur and Peer reviewer the available documentation and information from literature, from MPs in EU Member states and Switzerland/Liechtenstein, as well as from food supplements. The safety and degree of medicinal use of a substantially higher posology compared to the current version of the monograph was discussed to agree on the subsequent content of the tables in AR section 2 and in the monograph section 4.2. Also considerations for specific populations (e.g. pregnant women) were made.

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

2.4.1. Monograph on Hamamelidis cortex and supporting documents - postponed

2.4.2. Monograph on Hamamelidis folium and supporting documents - postponed

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

2.4.4. Monograph on Millefolii herba and supporting documents

Action: for adoption
Documents: Review report; References: 10/06

Outcome:
Relevant new data were identified that would change the content of the monograph and allow establishment of a list entry. The HMPC agreed with the Rapporteur's position and decided to revise the monograph, assessment report and list of references on Millefolii herba.

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

None

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

2.7.1. Monograph on Pistacia lentiscus, resinum (mastix) and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 101/78

Outcome:
Postponed

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

Outcome:
The Rapporteur presented the state of play and possible options for a way forward. Members were asked to use the summary of the discussion and two presentations by the Rapporteurs to prepare for the discussion at the July 2019 meeting.

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 – April 2019
  Report: HMPC Chair
  Action: for discussion
  Documents: Presentations
- Finnish Presidency meeting – Czech Republic, Prague – November 2019
  Action: for discussion
  Document: Invitation

  Outcome:
  HMPC noted the report and presentations of the Romanian SRLM.

  The Czech member confirmed that the Czech agency hosts the HMPC SRLM meeting (5-6 November in Prague) and invited all members. The Finnish delegate welcomed the proposal and signalled support in preparation of agenda/meeting.

  For the first half of 2020, Croatia announced not to organise an HMPC SRLM meeting and to request at HMA whether other MSs have the opportunity to take over.

  For the second half of 2020, Germany pre-announced that the meeting will likely take place in the week 31 Aug - 4 Sep.

5.1.2. Election of Co-opted member

Report: HMPC Chair
Action: for adoption
Documents: Call for nomination, Candidature; HMPC rules of procedure; Procedure for the nomination and appointment of co-opted members

Outcome:
The previous co-opted member for toxicology, Heidi Foth, was re-elected for a 3-year mandate starting on 8 July 2019.

5.1.3. Election of QDG Chair

Report: HMPC Chair
Action: for adoption
Documents: Call for nomination; QDG mandate

Outcome:
Election postponed for the July 2019 meeting due to the lack of candidatures. A reminder call will be sent out by the secretariat.

The committee thanked the previous Chair for her long term contribution to the QDG as a member and the dedicated and successful Chairmanship since 2016. The particular importance of appropriate quality guidance in the regulation of complex herbal medicinal products was emphasised.

5.1.4. Rapporteurs at HMPC

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

Outcome:
HMPC noted the presentation and background information to align with principles applied at other Committees (Committee vs WP, Chair role).
A proposal for implementation is scheduled for the HMPC July meeting.

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 Agenda 2 May 2019

Outcome:
Some specific items considered relevant for the HMPC were highlighted by the Chair such as challenges for composition of Committees and subgroups in terms of activity and expertise.

5.2.2. Coordination with PDCO/PRAC

- Discussion paper of age limitation of use of cough and cold herbal medicinal products in children
  Action: for discussion
  Documents: Draft discussion paper, OoC, Summary of age limitations, Table of products for children

  Outcome:
  Postponed

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

5.3.1. Nomination of Scientific Committees' representatives at the HCPWP and PCWP

Action: for discussion
Documents: HCPWP mandate, PCWP mandate, PCWP and HCPWP rules of procedure; Email correspondence

Outcome:
Based on information from previous HMPC members at PCWP/HCPWP, HMPC endorsed the candidature of the Co-opted member for non-clinical pharmacology and the French delegate as alternate, provided that the previous representative confirms not to be available anymore.
It was recapped that beyond patients commenting on herbal summaries and also draft monographs, the Committee could use opportunities to invite patients' views on specific topics discussed at HMPC. This may be supportive in particular when certain wordings for products for self-medication (e.g. indications/warnings) are discussed controversially in terms of safety and patients' perceptions.

Post-meeting note:
Post-meeting agreement that the Danish delegate takes the role as HMPC representative at PCWP/HCPWP for linkage and regular reporting, while the Co-opted member for non-clinical pharmacology and French delegate back up as alternates.

5.4. Cooperation within the EU regulatory network

5.4.1. Coordination with the European Commission

- *Cannabis* for medicinal use
  Action: for discussion
  Documents: EMCDDA report, EP resolution, Presentation

  Outcome:
  HMPC noted presentation and request by Commission representative as regards developments with *Cannabis* derived substances intended for medicinal use.

  The importance of correct terminology/scope according to definitions and standard provisions for single active substances as well as herbal substances/preparations was emphasised as essential prerequisite for any follow-up requests, discussions or questionnaires. The Commission welcomed the discussion for follow-up including discussion at the HMPC July meeting.

5.4.2. Coordination with European Pharmacopoeia

- EDQM 13A expert group meetings
  Report: M Bald (EDQM)
  Action: for information
  Document: SoD
- EDQM 13B expert group meetings

Report: M Bald (EDQM)
Action: for information
Document: SoD

- EDQM TCM expert group meetings
  Report: M Bald (EDQM)
  Action: for information
  Document: SoD

- EDQM PA working party meetings
  Report: M Bald (EDQM)
  Action: for information
  Document: SoD

Outcome:
HMPC noted updates on 13A, 13B, TCM expert group activities as well as the PA working party and monographs adopted or in preparation at the Ph. Eur. commission.

For the Committee mainly the status of the PA method development was of interest.

5.4.3. Understanding the training needs of NCA assessors involved in the work of the HMPC: Priority needs and plans for training 2019 – 2020

Action: for discussion
Document: Presentation

Outcome:
Four members, HMPC Chair and Vice Chair had responded to the call after the January meeting. HMPC noted the presentation on next steps as regards steering group, provision of available training material, identification of training needs and possible curriculum format.

The HMPC noted the proposal to involve 4 members with expertise in Quality, Clinical, Pre-clinical /Toxicology, Pharmacovigilance, in the Steering group. Next steps include the organisation of discussions, with a view to begin work on preparation of a draft curriculum (design), including proposals for training topics – for further discussion and finalisation at Committee level. Members were also reminded to provide information on training available / provided to new assessors in NCAs on assessment of Herbal Medicinal Products in MAAs, on the assessment of substances in monographs, and on the use of monographs and guidelines in national procedures.

5.4.4. International Collaboration Program (ICP) – possibility for training on herbal medicinal products

Report: HMPC Vice-Chair
Action: for discussion
Document: Email correspondence

Outcome:
HMPC noted information by HMPC Vice-Chair on the planned training on herbal medicinal products by the Dutch agency in the framework of the ICP and considerations to open such training across the network including all HMPC members.
The initiative was generally welcomed. Extension to participants from other countries than those 10 designated ICP-EU countries (as well as speakers) has to be.

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

None

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 May 2019

Outcome:

HMPC noted current status of planned activities 2019.

5.8. Planning and reporting

None

5.9. Legislation and regulatory affairs

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 (traditional use) and supporting documents - postponed

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 - postponed

6.2.2. Monograph on Thymi aetheroleum and supporting documents - postponed

6.2.3. Monograph on Trigonellae foenugraeci semen and supporting documents - postponed

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

6.3.1. Monograph on Centellae asiaticae herba and supporting documents - postponed

6.3.2. Monograph on Filipendulae ulmariae flos and supporting documents - postponed

6.3.3. Monograph on Filipendulae ulmariae herba and supporting documents - postponed

6.3.4. Monograph on Quercus cortex and supporting documents - postponed

6.3.5. Monograph on Solidaginis virgaureae herba 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 - postponed

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

6.5.3. Monograph on Herniariae herba and supporting documents

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

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 July 2019**.

Timetable:
Documents to be sent to peer-reviewer: **31 May 2019**
Peer-review documents to be sent to Rapporteur: **15 June 2019**
Final documents to be included latest in 2nd premail: **2 July 2019**

Using a Reader's guidance, changes following the last discussion and remaining questions were presented. Members discussed mainly (i) the suitability of the Ames test data and (ii) the sufficiency of documentation for the single substance.

According to one toxicologist not using the pre-incubation method was given as main reason not to accept data as in accordance with the OECD guideline. Others pointed out that OECD

471 allows both, the pre-incubation method as well as the plate incorporation method. In other cases such specific requirement had not been considered essential – nor is it outlined in HMPC guidance in this respect (EMEA/HMPC/107079/2007 and EMA/HMPC/32116/2005 Rev.1).
As regards the proof of traditional use it was highlighted that there is no real product on the market and that the substance seems to be used only in combinations. It was referred to magisterial preparations and the legislation not requiring authorised MPs but medicinal use in specified conditions.

6.5.4. Monograph on Menyanthes trifoliata folium and supporting documents

Action: for discussion
Documents: Draft MO, AR, LoR, Presentation; References: 66/71

Outcome:
Rapporteur to introduce changes in the MO and AR according to the discussion for **a fourth discussion in HMPC July 2019**.

A presentation was given on the traditional dosage descriptions including some background information on the function of bitter drugs. While some members raised concerns with the wide range of posologies and partially insufficient documentation, the Rapporteur pointed to the tradition to be covered. Also the way bitter drugs work would not require limiting artificially posologies for the monograph. Besides, the relevance for use in children was discussed.

6.5.5. Monograph on Saccharomyces cerevisiae CBS 5926 and supporting documents

Action: for discussion
Documents: Draft MO, Draft LE, Draft AR, Draft LOR; EMA letter to EC, EC response; References: 02/188

Outcome:
Postponed

6.5.6. Monograph on Salviae mitiorrhizae radix et rhizoma and supporting documents - postponed

6.5.7. Monograph on Species amarae and supporting documents

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

Outcome:
Rapporteur to introduce changes in the MO and AR according to the discussion for **a fourth discussion in HMPC July 2019**.

The Rapporteur presented changes to the AR including addition of *Menyanthes* given that the mono-monograph will be established. It was noted that in contrast to Species digestivae no major estragole-containing substances are traditionally used. The Committee discussed the rationale for limitation to maximum four combination partners and the role of various substances including those intentionally mitigating the strong bitter taste. Furthermore

members looked at the minimum content of a substances and rationale of transfer of warnings from the mono-monographs at a given strength/dosage to be taken up in the combination.

6.5.8. Monograph on Vaccinii macrocarpi fructus and supporting documents - 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:
Postponed

7.1.2. PSUSA procedure for Pelargonii radix

Action: for discussion
Documents: MO, Presentation

Outcome:
Postponed

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

Report: HMPC Vice-Chair
Action: for discussion
Document: Feedback report

Outcome:
Postponed

7.1.4. Handling of confidential information within the EU network

Action: for discussion
Document: Presentation

Outcome:
HMPC noted the presentation on the handling of confidential information within the EU network.

7.1.5. Updated Welcome Pack for new Committee members and CoIs (Conflicts of Interests)

Action: for discussion
Documents: Updated welcome pack; Introduction presentations

Outcome:
HMPC noted the presentations on the member and delegates welcome pack as well as the reminder on provisions and procedures as regards competing interests.

Changes to the welcome pack refer to the new information for Amsterdam and the Spark building. It was also reminded that the welcome pack contains beside the presentation an annex with links to information/documents on all HMPC relevant activities.

The EMA Secretariat reminded the Committee of the principles on handling competing interests for Scientific Committees' members and experts as detailed in the corresponding EMA Policy on handling competing interests for Scientific Committees' members and experts (EMA/626261/2014, Rev. 1). In particular, the presentation detailed the types of interests to be declared in the electronic declaration of interests (eDoI) by a member or an expert, the corresponding restrictions in EMA activities if an interest is declared, the requirement to inform the EMA of any intention to become an employee in a pharmaceutical company and the breach of trust procedure in case an interest is not declared intentionally or through gross negligence. In case of any doubt, members and experts are advised to contact EMA for advice before agreeing on any involvement in non-EMA/non-NCAs activities that potentially could be considered as a competing interest and incompatible with involvement in EMA activities.

7.1.6. Induction training for HMPC members at SPARK building

Action: for discussion
Documents: Presentations

Outcome:
HMPC noted the presentations on the introduction for HMPC members at the SPARK building including all relevant health and safety instructions.

7.1.7. BREXIT: Extension of the period under 'Article 50

Action: for discussion
Document: Presentation

Outcome:
HMPC noted the presentation on the status and general handling of the current Brexit situation and consequences for UK involvement in different activities.

It was acknowledged that for HMPC without product-specific procedures there are less transition issues than for other committees. For HMPC the Rapporteur and PR transfer for ongoing assessments has been agreed in January and is gradually implemented, while no new Rapporteur or Chair roles are allocated to UK delegates that continue to participate as long as the Art. 50 withdrawal has not been implemented.

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 14-16 January 2019

Overview of expertise of members HMPC and subgroups

Meeting report from HMPC meeting held on 14-16 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

HMPC meeting dates 2019-2021

7.2.2. ARSP

- English template
- English summaries for publication:
  - Oat grain
  - Oat herb
  - Myrrh
  - Shepherd's purse
  - Polypodi rhizoma
  - Motherwort
  - Yarrow flower
  - Green bean pod
  - Tormentil

No objections were raised on new assessment reports for the public to be published on the EMA website.

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

- Monograph on Allii sativi bulbus and supporting documents
  Documents: MO, AR, LoR, OoC, email correspondence
- Foeniculi amari fructus and supporting documents – on hold due to Estragole PS
- Foeniculi amari fructus aetheroleum and supporting documents – on hold due to Estragole PS
- Foeniculi dulcis fructus and supporting documents – on hold due to Estragole PS
- Species digestivae or species stomachicae and supporting documents - on hold due to Estragole PS

7.2.4. Other

- Literature provided as potentially relevant for HMPC assessments: Bovee TFH *et al*.: Are effects of common ragwort in the Ames test caused by pyrrolizidine alkaloids? Mutation Research 778 (2015) 1–10

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 13-15 May 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	
Iliana Ionkova	Member	Bulgaria	No interests declared	
Ivan Kosalec	Member	Croatia	No restrictions applicable to this meeting	
Darko Trumbetic	Alternate	Croatia	No interests declared	
Maria Stavrou	Member	Cyprus	No interests declared	
Marie Heroutova	Member	Czech Republic	No interests declared	
Eeva Sofia Leinonen	Member	Finland	No interests declared	
Sari Koski	Alternate – via TC	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 Bíróné Dr Sándor	Member	Hungary	No interests declared	
Alessandro Assisi	Member	Italy	No interests declared	
Audronis Lukosius	Alternate	Lithuania	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	
Milan Nagy	Alternate	Slovakia	No interests declared	
Samo Kreft	Member	Slovenia	No restrictions applicable to this meeting	
Karin Erika Svedlund	Member	Sweden	No interests declared	
Anna Wannberg	Expert	Sweden	No interests declared	
Linda Anderson	Member	United Kingdom	No interests declared	
Silvia Girotto	Co-opted member	Italy	No interests declared	
Gert Laekeman	Co-opted member	Belgium	No interests declared	
Maria Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared	
Melanie Bald	Observer – via TC	EDQM	No interests declared	
Hilda Kuin	Expert - in person	NL	No interests declared	