28 September 2015
EMA/HMPC/814611/2015
Procedure Management and Committees Support Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 28-29 September 2015

Chair: Werner Knöss – Vice-Chair: Marisa Delbó

28 September 2015 14:00 – 19:00, 3E

29 September 2015 09:00 – 13:00, 3E

Health and safety information

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

Disclaimers

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed.

Of note, this agenda 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 agenda 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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the HMPC plenary session to be held on 28-29 September 2015. See September 2015 HMPC minutes (to be published post November 2015 HMPC meeting).

No new or revised conflict of interests was declared and no restriction in the involvement of members in relation to agenda topics was identified.

New Irish member: Una Mockler and alternate: Annamarie O'Sullivan; Starting date of mandates: 12 September 2015

Resignation: Artūras Kažemekaitis Lithuanian member. No new nomination yet.

1.2. Adoption of agenda

HMPC agenda for 28-29 September 2015.

Outcome:
Adopted

1.3. Adoption of the minutes

HMPC minutes for 6-7 July 2015.

Outcome:
Adopted

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

2.1.1. Report from the MLWP July 2015 meeting

Report: MLWP Chair
Action: for information
Document: Draft minutes for the MLWP meeting on the 7-9 July 2015

2.1.2. New herbal substances proposed for assessment

- *Malva sylvestris* L.
  Report: MLWP Chair
  Action: for adoption
  Document: Email by W. Dymowski 1 July 2015

  Outcome:
  HMPC endorsed the proposal by MLWP to start the assessment of *M. sylvestris* (flos and folium) based on available information from MSs.

HMPC secretariat to update priority list and start a call for scientific data.

MLWP to appoint Rapporteurs.

Traditional medicinal use for more than 30 years for Malvae flos was confirmed for the Polish market; for Malvae folium (as indicated from the 2014 survey among MSs) it was confirmed for the Austrian market.

- *Vaccinium macrocarpon* Aiton
  Report: MLWP Chair
  Action: for adoption
  Documents: HMPC guidance documents: (EMEA/HMPC/328575/2007 Rev.1) and (EMEA/HMPC/107399/2005 Rev. 1), email by EMA 17 December 2014

  See also 5.4.2.

  Outcome:
  HMPC endorsed the proposal by MLWP to start the assessment of *V. macrocarpon* based on preliminary information on the long-standing medicinal use in MSs although marketed in different product categories.

  HMPC secretariat to update priority list and start a call for scientific data.

  MLWP to appoint Rapporteurs.

  ORGAM DG to evaluate need for update of EMEA/HMPC/328575/2007 Rev.1, EMEA/HMPC/107399/2005 Rev. 1, EMEA/HMPC/57137/2007 and related procedural guidance.

  Available information on medicinal use and marketing status as well as assessment of *V. macrocarpon* in product categories outside the medicines framework were discussed. Although no conclusive substantiating data were available, members supported the assessment with likelihood that sufficient data are available to fulfil criteria for establishment of a monograph.

  In addition, definition of criteria for prioritisation for assessment was discussed in view of existing old guidance documents, indicators of market relevance from the annual survey and the important substances of European Phytotherapy already prioritised and mostly assessed (see also 5.7.1).

2.1.3. Prioritisation of monograph revisions

Action: for discussion
Documents: Presentation, draft discussion paper on solutions for revision, draft MLWP revision priority list, draft MLWP work plan 2016, EMA/HMPC/124695/2011 Rev. 1, EMA/HMPC/326440/2007 Rev.2

See also 5.7.1

Outcome:
Proposal agreed for intermediate solution as regards backlog with systematic reviews. From monographs > 5 years a range of substances with higher priority identified for review in 2016 and 2017.

Secretariat to adapt MLWP overview, HMPC priority list, and prepare information for the public meeting report in liaison with HMPC Chair.

MLWP to fine-tune proposal for monograph review/revision and Rapp. appointment before distribution to all HMPC members.

Post meeting note:

According to MLWP discussion 35 substances were prioritised for systematic review and split into intended finalisation in 2016 or 2017 according to priorities confirmed by HMPC, current status of work and resources indicated by Rapporteurs:

For possible finalisation in 2016:

- Absinthii herba
- Aloe
- Althaeae radix
- Equiseti herba
- Foeniculi amari fructus
- Foeniculi amari aetheroleum
- Foeniculi dulcis fructus
- Harpagophyti radix
- Meliloti herba
- Menthae piperitae aetheroleum
- Menthae piperitae folium
- Salicis cortex
- Salviae officinalis folium
- Salviae officinalis aetheroleum
- Sennae folium
- Sennae fructus
- Valerianae radix

For possible finalisation in 2017:

- Agni casti fructus
- Cimicifugae rhizoma
- Curcumae longae rhizoma
- Cynarae folium
- Echinaceae purpureae radix
- Echinaceae pallidae radix
- Frangulae cortex
- Hederae helicis folium
- Hyperici herba
- Hippocastani semen
- Millefolii flos
- Millefolii herba
- Oleae folium
- Rhamni purshianae cortex
- Rhei radix
- Uvae ursi folium
- Valerianae radix/Lupuli flos
- Vitis viniferae folium

2.1.4. Appointment of Rapporteurs and Peer-reviewers

- First Assessment

  See also 2.1.2.

- Revisions
  Rapporteur:
  Herbal substance: Salicis cortex
  Peer-reviewer:
  Herbal substance: Agni casti fructus
  Herbal substance: Cimicifugae racemosae rhizoma
  Herbal substance: Myrrha

  See also 2.1.3.

Outcome:
HMPC endorsed Rapporteur and Peer reviewer as proposed by MLWP.

Proposal to involve for monograph systematic review/revision increasingly HMPC members who were so far not acting as rapporteur in principle agreed. Procedural (such as document EMEA/HMPC/108877/2005 or EMA/HMPC/126542/2005) and practical consequences to be reviewed for the November meeting.

HMPC members to express intentions to act as Rapporteur by 30 October 2015.

First intentions expressed by CR, EE, and FR members.

2.1.5. Cancellation of assessment work for Cinnamomi camphorae cortex/folium

Action: for adoption
Document: Presentation

Outcome:
A majority agreed to the Rapporteur's proposal cancelling the assessment following a request to NCAs on available products but without performing a public call for data because no records for camphor of natural origin in the EU and only combination products, mainly with synthetic camphor, on the market were reported.

Secretariat to adapt tracking documents and inform in the public meeting report.

2.2. Revised EU herbal monographs and list entries for public consultation/final adoption after systematic review/revision

2.2.1. Monograph on Centaurii herba and supporting documents

Action: for adoption
Documents: MO, AR, LoR; references: 41/75

Outcome:
Adoption postponed. Rapporteur to check available data and references for final adjustments in monograph (section 4.2) and AR for possible adoption at the November 2015 meeting. FR to provide relevant literature to the Rapporteur.

Necessary corrections and scope of the revision were discussed vis-à-vis consequences for the use of monographs. Final clarifications on posology and availability of relevant background data as well as alignment between AR and MO will be made by the Rapporteur for the next meeting. The Rapporteur confirmed that no more references were available from the first assessment.

2.2.2. Monograph on Pelargonii radix and supporting documents

Rapporteur: Z. Biró-Sándor; Peer-reviewer: J. Wiesner
Action: for adoption (for public consultation)
Documents: MO unchanged, revised AR, revised LoR; references: 73/105

Outcome:
Draft reviewed monograph (no changes) and supporting documents adopted by majority vote for 3 months public consultation.

Final update of information in the assessment report to be considered after public consultation.

Need for clarification of details on procedural aspects of review/revision procedures (trigger, scope, outcome) to be reviewed by ORGAM and MLWP.

Following the acceptance of the BSS as validated endpoint in 2013 all clinical data had been re-assessed. However, a majority supported the view of rapporteur and MLWP that clinical evidence remains insufficient that would change the content of the existing monograph. A

public consultation with the revised AR was considered useful to give interested parties the opportunity to comment before finalisation of the revision.

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

2.3.1. Monograph on Myrtilli fructus recens and supporting documents

Rapporteur: E. Widy-Tyszkiewicz; Peer-reviewer: G. Calapai, M. Delbò
Action: for adoption
Documents: MO, AR, LoR; references: 150/182

Outcome:
Final monograph and supporting documents adopted by majority vote (23 out of 27). Divergent opinion: S. Bager, P. Claeson, E. v. Galen, E. S. Leinonen. Norway expressed a favourable position.

No comments had been received during public consultation. The suitability of indication 2 was discussed with a majority confirming the proposed wording.

2.3.2. Monograph on Myrtilli fructus siccus and supporting documents

Rapporteur: E. Widy-Tyszkiewicz; Peer-reviewer: G. Calapai, M. Delbò
Action: for adoption
Documents: MO, AR, LoR; references: 150/182

Outcome:
Final monograph and supporting documents adopted by majority vote (25 out of 27). Divergent opinion: E. v. Galen, U. Mockler. Norway expressed a favourable position.

No comments had been received during public consultation. Proposals regarding the content of monograph section 4.6 were made but a majority agreed to the current content of the monograph and supporting documents.

2.3.3. Monograph on Sabalis serrulatae fructus and supporting documents

Action: for adoption
Documents: MO, AR, OoC, LoR; references: 142/142
Documents for information: Email correspondence during peer-review, OoC on AR

Outcome:
Adoption postponed to November 2015 meeting. MLWP to evaluate HMPC comments and perform final adjustments in monograph and AR.

Concerns raised during the peer review were discussed as regards content of monograph sections 4.8 and 4.9 as well as coherence MO/AR and content of some AR sections in relation to appropriate pharmacovigilance and clinical data information according to standard practice in HMPC assessment reports.

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

2.4.1. Monograph on Helichrysi flos and supporting documents

Rapporteur: W. Dymowski; Peer-reviewer: G. Calapai
Action: for adoption
Documents: Draft MO, AR, LoR

Outcome:
Draft monograph and supporting documents with changes in monograph sections 4.2 and 4.4, adopted by consensus for 3 months public consultation.

The HMPC discussed differences in preparations and medicinal tradition according to member state and appropriate wordings in posology and warnings considering available information as regards potential effect on the bile flow in analogy to somewhat comparable substances such as Mentha or Curcuma. Furthermore the pharmacopoeial reference and difficulties with appropriate common name translations were addressed. Some information in the draft AR conclusions regarding ATC code considerations were considered superfluous for a TU indication and requested to be deleted.

2.4.2. Monograph on Origani majoranae herba and supporting documents - postponed

2.4.3. Monograph on Polygoni avicularis herba and supporting documents

Rapporteur: B. Jansone; Peer-reviewer: J. Viguet Poupelloz
Action: for adoption
Documents: Draft MO, AR, LoR

Outcome:
Draft monograph and supporting documents with changes in monograph sections 3 and 4.2, adopted by consensus for 3 months public consultation.

Final corrections regarding common plant name translations were requested. The different importance of listed traditional indications was raised without affecting the content of the draft monograph.

2.4.4. Public statement on Salviae fruticosae folium and supporting documents - 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 pulegone/ menthofuran

Rapporteurs: O. Pelkonen, J. Wiesner
Action: for information
Documents: PS, OoC, letter from HMPC to CHMP 06/2015, SWP response 11/2014

Outcome:
HMPC noted current status of coordination awaiting SWP response.

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

Rapporteurs: O. Pelkonen, J. Wiesner
Action: for information
Documents: PS, OoC, letter from HMPC to CHMP 09/2015, SWP response 04/2014, outcome written procedure

Outcome:
HMPC noted revised documents and letter agreed via written procedure at MLWP and HMPC transmitted for coordination to CHMP/SWP.

The HMPC Chair reminded on the responsiveness of committee members during written procedures for necessary adoptions between meetings to allow progress with important topics.

Further discussion only planned after SWP feedback (discussion just starting).

4.1.3. Concept paper on the revision of the "Guideline on the assessment of clinical S&E in the preparation of Community Herbal Monographs for Well-established and of Community Herbal Monographs/Entries to THMP/Substance/Preparations"

Rapporteurs: P. Claeson, S. Girotto
Action: for adoption
Document: Concept paper

Outcome:
Adopted for publication.

4.2. Quality

None

4.3. Regulatory

4.3.1. Revised public statement on herbal substances containing constituents associated with safety concerns

Rapporteurs: M. Delbò
Action: for adoption
Document: Rev. PS

Outcome:
Adopted for publication.

The committee discussed reasons for revision of the PS and agreed to the proposed minor changes without changing the annexed plant list as such. The change in the title was welcomed to avoid misunderstandings.

4.3.2. Matching patients friendly therapeutic areas for browse search on herbal medicines for human use with TU indications to ATC therapeutic groups (level 2)

Rapporteur: B. Huber, W. Knöss
Action: for adoption
Document: Draft document EMA/568320/2009 Rev. 1

Outcome:
Some changes introduced. Final adjustments to be performed before adoption at the November 2015 meeting.

HMPC Members to provide comments by 30 October 2015.

The committee noted the purpose of the documents i.e. supporting the browse by use function on the website and allowing/explaining the allocation of some newly assessed substances to patient friendly therapeutic areas.

4.4. Report on HMPC Drafting Groups activities

4.4.1. Quality DG

Report: Q DG Chair
Action: for adoption

- Document: Meeting report from Q DG meeting held on 10 September 2015

Outcome:
Adopted.

The DG discussed the follow-up on the reflection paper on microbiological aspects (EMA/HMPC/95714/2013) and draft Q&A in this regard. Because of detailed discussions expected during the HMPC assessors training in December finalisation of the Q&A is only expected in February 2016. The revision 3 of the Guideline on quality of herbal medicinal products/traditional herbal medicinal products was started. Q DG had further discussed the preparation of the 2015 HMPC assessors training on quality as well as status of work 2015 and a first draft of the work plan 2016.

Clarification regarding the QDG discussion on the use of CEP for herbals were given by the Q DG Chair.

Action: for information

- Document: Draft agenda for the Q DG meeting to be held on 15 October 2015

Outcome:
No topics were proposed by HMPC for Q DG.

Action: for adoption

- Document: Draft work plan 2016

Outcome:
Some changes introduced according to feasibility in 2016. Q DG to have a final discussion before adoption in November together with the work plans for HMPC, MLWP and ORGAM DG.

HMPC members to provide comments on quality guidance needed.

4.4.2. ORGAM DG

Report: ORGAM DG Chair
Action: for information

- Document: Draft agenda for the ORGAM DG meeting to be held on 13 October 2015

Outcome:
No topics were proposed by HMPC for ORGAM DG.

The need for face to face meeting was emphasised as well as specified tasks reflected in work plans and agendas to justify such need for face to face meetings.

Action: for discussion

- Document: Draft work plan 2016

Outcome:
ORGAM DG to further develop proposal for discussion and adoption in November together with the work plans for HMPC, MLWP and Q DG.

See also 5.7.1.

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Overview table of expertise of HMPC members and alternates

Action: for discussion
Documents:
Expertise of HMPC members 2014; Briefing note on competence and expertise of HMPC members and alternates; Annex B EMA recommendation on criteria for competence and expertise of new HMPC members and alternates; presentation

Outcome:
Postponed to November 2015 meeting.

5.1.2. Preparation of upcoming co-opted member election

Action: for discussion
Documents: Procedure for nomination/election of co-opted members for HMPC, email by O. Pelkonen 20 July 2015

Outcome:
HMPC confirmed the need for a co-opted member in the area toxicology.

Current co-opted member announced not to candidate again for another term. Secretariat to send out a call for nominations.

HMPC members to nominate candidates and provide to the secretariat by 22 January 2016.

Election of a new co-opted member in November 2015 or February 2016 (new mandate starting after expiry of current co-opted member mandate) according to candidatures received and agreement at the committee.

Post-meeting note: Election scheduled for HMPC February meeting.

5.1.3. Assessors Training, 7-8 December 2015

Report: QDG Chair
Action: for adoption
Document: Draft agenda

Outcome:
Postponed to November 2015 meeting.

5.1.4. Strategic Review and Learning Meeting held in Bonn, 17-19 June 2015

Report: HMPC Chair
Action: for discussion
Document: Minutes

Outcome:
HMPC noted draft minutes which will be sent out for comments.

Some future proposals to be taken up for the HMPC work plan development.

The HMPC Chair summarised briefly some key points from the discussions and presentation in Bonn emphasising the need to reflect appropriate future structure and working methodology in view of changing priorities of the committee and experiences/developments from the last years. He invited members to come forward with proposals for improvement of HMPC member involvement and activities (such as work streams or breakout sessions) beyond the existing substructure of 2 drafting groups and one very closely connected working party. The annual HMPC work plan may be used to develop new ideas not only as regards content of important future projects but also appropriate organisational changes to achieve such goals making best use of available resources.

5.1.5. Strategic Review and Learning Meeting – organisational aspects

Action: for information
Documents:
Principles for organisation of NCA hosted meetings; Responsibilities for confidentiality in NCA hosted meetings

Outcome:
Postponed to November 2015 meeting.

5.2. Coordination with EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting - postponed

5.2.2. Coordination with CHMP: drafting group on excipients: ethanol as an excipient (after public consultation) - postponed

5.2.3. Coordination with CHMP: Public statement on the use of herbal medicinal products containing pulegone/ menthofuran

See also 4.1.1

5.2.4. Coordination with CHMP: Public statement on the use of herbal medicinal products containing estragole

See also 4.1.2

5.2.5. Coordination with PRAC and other Pharmacovigilance topics

PhV/EMA literature monitoring for herbal substances

Action: for information
Document: Presentation

Outcome:
HMPC noted current status of literature monitoring at EMA which will include 100 herbal substance groups.

Outcome vis-à-vis usefulness of data for HMPC to be re-discussed mid 2016 once more experience assembled.

The Monitoring of medical literature and entry of adverse reaction reports into EudraVigilance is a new service by EMA operational since 1 July (and operation for herbal substances since 1 September). Scope, expected benefits, legal background, establishment, working methodology were presented as well as where to find relevant information. The compilation of the list of 100 herbal substances groups was explained as based on substance submissions under Art. 57 of Reg. (EC) No 726/2004, number of MAs and MAHs.

Members agreed that it would be too early now checking whether the outcome of the service might be useful for HMPC (such as updating monographs or triggering revisions due to relevant new safety data), which should be re-assessed in 2016.

5.2.6. Coordination with CMDh: Article 46 assessment work sharing, Paediatric Working Party

Action: for discussion
Document: Email 27 August 2015, presentation

See also 2.2.2.

Outcome:
HMPC noted background information and confirmed to be in principle open for coordination.

Possibility to support the Art. 46 work sharing exercise to be reviewed vis-à-vis the current status of HMPC assessment of Pelargonium within another legal framework. Study in question so far not assessed by HMPC.

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

5.3.1. Coordination with PCWP/HCPWP

Observer: S. Bager
Action: for discussion

Documents:
Minutes of the PCWP plenary meeting held on 3 June 2015
Minutes of the PCWP/HCPWP joint meeting held on 4 June 2015
Minutes of the HCPWP meeting held on 4 June 2015
Agenda from PCWP/HCPWP joint Workshop on risk minimisation measures to be held on 16 September 2015
Draft Agenda from PCWP/HCPWP joint meeting to be held on 17 September 2015

Outcome:
Postponed to November 2015 meeting.

The HMPC observer had given a presentation at PCWP/HCPWP triggering some discussions on the identification and possible involvement of patient/ health care professional organisations in HMPC assessment work. For more detailed considerations, discussion at the HMPC November meeting is foreseen.

5.3.2. Coordination with SWP

Report from SWP meetings
Observer: O. Pelkonen
Action: for information
Document: Oral report

See 4.1.1. and 4.1.2.

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopeia

- EDQM 13A expert group meeting held on 2-3 June 2015
  EDQM: M. Bald, U. Rose; HMPC Observer: I. Chinou
  Action: for information
  Document: Summary of decisions

  Outcome:
  HMPC noted monographs put forward for Pharmeuropa consultation or Ph.Eur. finalisation on substances with potential interest for HMPC such as *Echinacea*, *Vitis* or Menthae aetheroleum as well as current status of the essential oil discussion with 2 Q DG members involved.

  A possibly necessary coordination after finalisation of the HMPC PS on pulegone was agreed.

- EDQM 13B expert group meeting held to be held on 22-23 September 2015
  EDQM: M. Bald, U. Rose; HMPC Observer: B. Kroes (H. Neef)
  Action: for information
  Document: Agenda, Report

  Outcome:
  HMPC noted monographs put forward for Pharmeuropa consultation or Ph.Eur. finalisation on substances with potential interest for HMPC such as Mastix as well as progress with an improved HPTLC methodology (new chapter) applied in several revised Ph. Eur. monographs.

  The HMPC observer flagged as relevant for HMPC monographs/assessment: change of the binomial name for *Passiflora*, use of new *Hypericum* varieties with different chemical profile, use of different *Crataegus* species with diverse chemical profile.

- EDQM TCM expert group meeting held on 5-6 May 2015
  EDQM: M. Bald, U. Rose; HMPC Observer: R. Länger
  Action: for information
  Document: Summary of decisions

- EDQM TCM expert group meeting to be held on 15-16 September 2015
  EDQM: M. Bald, U. Rose; HMPC Observer: R. Länger
  Action: for information
  Document: Agenda

  Outcome:
  HMPC noted ongoing discussion on pyrrolizidine alkaloid analysis and status of TCM monograph development.

  It was agreed to bring the outcome of the ongoing discussion on the need/relevance for assays to the attention of HMPC once a draft document has been agreed by all Ph. Eur. expert groups.

5.4.2. EMA survey on uptake of TUR scheme in EU Member States

Action: for information
Documents: Survey - EMA/HMPC/322570/2011, presentation

Outcome:
HMPC noted the data presented with potential relevance for HMPC work as regards prioritisation of substances and assessment of combination and other products so far not prioritised by HMPC. Data to be considered for the work plan discussion as regards review of current practice and procedures for future needs.

Members exchanged view on prioritisation modalities of substances including combinations. Limits of the survey were mentioned as regards use of monographs (wider use than reflected by registration numbers). Even without specific products on the market monographs may be used (e.g. magisterial preparation in pharmacies or patient information). Also limits of the framework to encompass all traditional products were highlighted in particular as regards combinations containing partially substances of natural origin but not strictly complying with the definition of herbal preparation. The Eur. Com. representative conformed that such minor scope extension requires a major legal expenditure to amend the existing provision and is therefore not on the political agenda.

5.4.3. European Commission - Report: Update on establishment of LE

Action: for information

Outcome:
Postponed to November 2015 meeting.

5.5. Cooperation with International Regulators

5.5.1. Update on status of confidentiality arrangements with DG SANTE and EMA with international partners

Action: for information
Document: Update of confidentiality arrangement

Outcome:
A document was distributed for information of all Committee members as regards two confidentiality arrangements concluded by the Eur. Com. DG SANTE and EMA in July and September 2015 respectively; the first with Swissmedic and the second with the WHO. Both arrangements are concluded for an initial period of 5 years, and may be renewed. Confidentiality agreements were already in place between EMA and the following international partners: USFDA, Japan PMDA/MHLW, Health Canada and TGA Australia.

Under the terms of confidentiality or working arrangements, the parties to the arrangement agree not to disclose non-public information, which means that product related information can be shared between the parties. The arrangements also facilitate ad hoc participation at product related discussions in response to specific requests.

5.5.2. 8th Annual Meeting of IRCH held in Riyadh, Saudi Arabia, 1-3 December 2015

Report: HMPC Chair
Action: for information
Documents: Draft agenda, email by WHO 18 August 2015

Outcome:
Postponed to November 2015 meeting.

5.5.3. HMPC – International representation and cooperation

Report: HMPC Chair
Action: for discussion
Document: Draft proposal HMPC international cooperation

Outcome:
Members to provide comments on the further developed proposal in particular as regards details in Table 1 by 30 October 2015 for finalisation and possible adoption in November 2015.

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

None

5.7. HMPC work plan

5.7.1. Projects on the HMPC work plan 2015

- HMPC work plan 2015
  Action: for information
  Documents: HMPC work plan 2015, presentation, tracking tool

  Outcome:
  Postponed to November 2015 meeting.

- Regulatory guidance for non-European interested parties and harmonisation of assessment practice for herbal substances of non-European origin
  Rapporteur: E. van Galen
  Action: for discussion
  Document: Draft discussion paper on procedure for submission of new proposals / scientific data for the assessment of substances from non-European traditions

  See also 4.4.2

  Outcome:
  HMPC agreed to ORGAM review on relevant existing guidance documents as regards prioritisation of substances for assessment from a perspective of applicants with non-European traditional products/substances.

  Based on feedback of interested parties during conferences a major interest in HMPC guidance as regards TCM and other non-European substances has been noted. In view of the advanced elaboration of TCM monographs at Ph. Eur. (one prerequisite for HMPC monographs allowing to refer to a defined quality), current guidance on prioritisation of substances and requested data should be looked at for suitability. However, in principle no difference should be made between European and non-European substances.

- European collaboration: Coordination with EU bodies concerning different frameworks under which herbal ingredients can be regulated
  Report: HMPC Chair
  Action: for discussion

Document: Email dated 20 July on EFSA 'Draft General scientific guidance for stakeholders on health claim applications' for comments

Outcome:
No need had been identified by HMPC members to comment on EFSA draft guidance documents for stakeholders including the assessment of health claims.

The HMPC Chair reminded that based on the MoU EFSA is informing regularly EMA on documents potentially of relevance for the EMA scientific committees. Given that the need for collaboration with EFSA as regards borderline issues is often emphasised, part of the work plan and that some communication had been re-initiated at the 2014 Italian presidency meeting, the lacking response when official comments are possible on relevant EFSA guidance was surprising and may require identification of new leads for this specific topic.

5.7.2. HMPC work plan 2016

Report: HMPC Chair
Action: for discussion
Document: Draft work plan 2016

Outcome:
HMPC Chair identified topic leads and HMPC members volunteering for participation in activities outlined in the draft work plan.

Activity area	HMPC topic leader	Other committee participants
Monograph and List entry review and revision procedures	M. Delbò	To be identified (tbi)
Forward planning and prioritisation	W. Knöss	R Länger, A Núñez Velázquez
Regulatory guidance for non-European interested parties	E. v Galen	W Knöss, I Chinou
International collaboration	W. Knöss	tbi
European coordination	tbi	EFSA: tbi, I. Kosalec EDQM: B Kroes, R. Länger, I. Chinou, H. Neef MD: A.P. Martins W. Dymowski
Cross committee projects risk/benefit	S. Madsen	(G. Calapai, G. Lakeman)
Cross committee projects patent/HCP involvement	S. Bager	(S. Madsen), (E. Pinto Ferreira) tbi
Coordination with other committees:	tbi	(S. Girotto): PDCO tbi: Safety WP (CHMP) K. Reh: Quality WP (CHMP) S. Bager: PCWP/HCPWP G. Lakeman : J-3R group
Dialogue with main users of EU herbal monographs (hearing, assessors training)	tbi	tbi

HMPC members to provide comments and signal possible active participation in 2016 by 30 October 2015 before finalisation and adoption in November 2015 together with the work plans for MLWP, Q DG and ORGAM DG.

MLWP work plan: MLWP to review proposal for prioritised first assessments and monograph reviews as well as new/ to be revised guidance during Sep/Oct meeting for presentation of a consolidated draft in November.

Q DG work plan: Q DG to double-check listed drafting activities as regards possible realisation in 2016 and specify some topics as regards concrete objectives and activities.

ORGAM work plan: ORGAM DG to discuss proposals for work plan for presentation of a consolidated draft in November.

5.8. Planning and reporting

5.8.1. Meeting dates–– postponed See also 6.2.3.

5.9. Legislation and regulatory affairs

5.9.1. Comments on draft revised monograph on Thymi herba/Primulae radix

Rapporteur: R. Länger
Action: for discussion
Documents: Letter May 2015 and email August 2015, response by EMA 30 July 2015

Outcome:
HMPC noted request for extension. No further questions to the HMPC apart from those already answered by the Rapporteur were raised.

5.9.2. Reflection of divergent opinions on ARSP

Action: for discussion
Document: Letter by E. S. Leinonen 3 September 2015, draft EMA position

Outcome:
Although no legal objections exist for inclusion of links to divergent opinions in the ARSP it was agreed (in analogy to EPAR and EPAR summaries) not to double information already available from the published opinions that are relevant for industry (and available at the same website) in order to not confuse patients within the lay language summary.

5.9.3. Consequences of LEs for legal status of products in member states

Action: for discussion
Document: Letter by E. S. Leinonen 3 September 2015, draft EMA position

Outcome:
HMPC members noted EMA legal view on topic to be clarified nationally: Eur.Com. does not decide, in the decision adopting the list entry, upon whether a HMP should be marketed as OTC or as prescription-only medicine. The decision regarding the legal status of a medicinal product remains a national issue, as per Art. 57 and 73 of Dir. 2001/83/EC. However,

according to Art.16a(1)(a) read together with NtA Vol. 2A chapter 1, Member States should not register as THMP medicinal products which are subject to prescription.

6. Any other business

6.1. Topics for discussion

6.1.1. AYUSH information on Indian medicinal plants assessed at the EMA

Report: HMPC Chair
Action: for discussion
Document: Response letter from HMPC Chair 2 September 2015

See also 5.5

Outcome:
Postponed to November 2015 meeting.

6.1.2. CMDh discussion: Question on potential serious risk to public health during ongoing DCP procedure on THMP

Outcome:
HMPC noted questions as regards inclusion of substances in HMPC monographs during DCP procedure as discussed at CMDh. Some procedural questions were clarified.

The issue of how to deal with preparations not included in an EU monograph (but AR) and subsequent necessary data to be expected in and individual application was discussed.

The use of HMPC specific referrals 16 c(4) and 16c(1)c vis-à-vis referrals to the CMDh at had not been considered by RMS/CMS mostly because of timing reasons (advanced stage of the procedure). Similar scenarios may happen in the future with the increasing use of European procedures for THMPs based on monographs but some limits of monographs regarding SmPC and dossiers of individual products. It was confirmed that for common referral types (Art. 29) at CMDh, if no agreement reached at CMDh for a THMP, cases are transferred to HMPC instead of CHMP.

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 6-7 July 2015

Overview of expertise of members HMPC and subgroups

Meeting report from HMPC meeting held on 6-7 July 2015

Overview of status of HMPC assessment work – priority list

Inventory of herbal substances for assessment work – alphabetical order

Abbreviations in HMPC minutes

6.2.2. MLWP

- Overview of status of MLWP assessment work
- Draft agenda of MLWP meeting to be held on 29 September-1 October 2015

6.2.3. Other

- ARSP (EN); for publication
- ARSP translations in all EU languages; for publication, member states feedback (6 ARSP)
- News story at EMA website, August 2015; Public-friendly information on herbal medicines now available
- Meeting dates: HMPC/MLWP 2016-2018, HMPC drafting groups 2016
- CHMP document on Peer Review Best Practice
- FDA Draft Guidance for Industry: Botanical Drug Development guidance for Industry, 2015
- MMD available for Orgam & Quality Drafting Groups – October 2015
- EFSA Conference on Food Safety 14-16 October 2015
- Draft presentation HMPC Chair at EMA MB 2 October 2015

List of participants

Including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 28-29 September 2015 meeting.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI
Werner Knöss	Chair	Germany	No interests declared
Reinhard Länger	Member	Austria	No interests declared
Kapka Kaneva	Alternate	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
Markéta Příhodová	Alternate	Czech Republic	No restrictions applicable to this meeting
Steffen Bager	Member	Denmark	No restrictions applicable to this meeting
Marje Zernant	Alternate	Estonia	No interests declared
Eeva Sofia Leinonen	Member	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
Una Mockler	Member	Ireland	No restrictions applicable to this meeting
Annamarie O'Sullivan	Alternate	Ireland	No interests declared
Marisa Delbò	Member (Vice-Chair)	Italy	No interests declared
Dace Kalke	Member	Latvia	No interests declared
Baiba Jansone	Alternate	Latvia	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
Nadia Grigoras	Member	Romania	No interests declared
Milan Nagy	Alternate	Slovakia	No interests declared

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI
Samo Kreft	Alternate	Slovenia	No restrictions applicable to this meeting
Adela Núñez Velázquez	Member	Spain	No interests declared
Per Claeson	Member	Sweden	No interests declared
Erika Svedlund	Alternate	Sweden	No interests declared
Sue Harris	Alternate	United Kingdom	No interests declared
Gert Laekeman	Co-opted member	Belgium	No interests declared
Olavi Pelkonen	Co-opted member	Finland	No interests declared
Maria Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared
Melanie Bald	Observer	EDQM	No interests declared
Tina-Soon Engraff	EC Representative	European Commission	Full involvement