2 February 2016
EMA/HMPC/85759/2016 Corr.[1]
Procedure Management and Committees Support Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 23-24 November 2015

Chair: Werner Knöss – Vice-Chair: Marisa Delbó

23 November 2015 14:00 – 19:00, 3E

24 November 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 document is considered commercially confidential or sensitive and therefore not disclosed.

Of note, this is a working document primarily designed for HMPC members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned below 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).

[1] Correction in participant list

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Table of contents

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 23-24 November 2015.

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 Spanish alternate: Cristina Martinez Garcia; Starting date of mandate: 06 October 2015.
New Lithuanian member: Rugile Pilviniene; Starting date of mandate: 14 October 2015.

Observers: Dr. Manoj Nesari, Ministry of AYUSH and Prof. Vinod Kumar Joshi, Banaras Hindu University, India

1.2. Adoption of agenda

HMPC agenda for 23-24 November 2015.

Outcome:
Adopted with one change (added point 6.1.3.).

1.3. Adoption of the minutes

HMPC minutes for 28-29 September 2015.

Outcome:
Adopted.

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

2.1.1. Report from the MLWP September 2015 meeting

Report: MLWP Chair
Action: for information
Document: Draft minutes for the MLWP meeting on the 29 Sept – 1 Oct 2015

Outcome:
HMPC agreed to MLWP proposal starting a pilot project on a combination monograph (herbal tea, diuretics), while previous plans to develop a reflection paper on the use of mono monographs for combination products will not be further pursued.

HMPC secretariat to publish a call for scientific data exceptionally on herbal tea combinations for a specific indication instead of a specific herbal substance. The new pilot approach to be announced and explained in the public meeting report. MLWP Rapporteurs (R. Länger, W. Knöss) to support with the wording of the call.

2.1.2. Monographs – proposals for minor corrections

- Vitis viniferae folium

Rapporteur: I. Chinou; Peer-reviewer: B. Kroes; Report: MLWP Chair
Action: for adoption
Documents: MO; AR; e-mail 21 Aug 2015

Outcome:
Adopted. HMPC endorsed correction of the ATC code. HMPC secretariat to publish corrected document.

Proposals for other amendments of the monograph to be taken into account for the upcoming systematic review/revision.

- Echinacea purpurea herba

Rapporteur: S. Kreft, B. Razinger; Peer-reviewer: J. Wiesner
Action: for discussion
Documents: Letter 24 Sept 2015; Echinaceae purpureae herba MO posology

Outcome:
Adopted. HMPC endorsed minor correction of posology of the monograph. HMPC secretariat to publish corrected document.

The more precise posology in the revised monograph had been based on the available overview of marketed products. However, no new data are available and the summarised posology in the old monograph was confirmed taking into account dosages used in clinical trials. The correction had been triggered by a company. Now the reference to the revised - not only superseded- monograph is possible and can be used to facilitate national authorisations.

2.1.3. Appointment of Rapporteurs and Peer-reviewers

- First assessment

Herbal substance: Vaccinium macrocarpon Aiton, fructus
Herbal substance: Malva sylvestris L., folium and flos

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

- Current Rapporteur Distribution

Document: Presentation

Outcome:
HMPC noted uneven Rapporteur distribution presented for first assessments and revisions (assignments and finalised assessments). Volunteering HMPC members (from MSs partially not represented at MLWP) were so far not taken into account during MLWP discussions. Rapporteur distribution (part of MLWP overview) to be re-introduced into the public Overview of HMPC assessment work.

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

2.2.1. Monograph on Althaeae radix and supporting documents

Action: for public consultation
Documents: MO; AR; LoR; references: 71/73

Outcome:
Draft revised monograph and supporting documents adopted by consensus for 3 months public consultation.
HMPC noted some controversial discussion as regards use in children and adolescents.
Changes to the monograph were considered as major so that public consultation was considered necessary.

2.2.2. Monograph on Centaurii herba and supporting documents

Action: for final adoption
Documents: MO; AR; LoR; references: 41/78

Outcome:
Final revised monograph and supporting documents adopted by consensus. Norway expressed a favourable position.

Because of only minor changes in the monograph a public consultation was not considered necessary.

Additional references had been provided by AT to the Rapporteur. Polish member to provide data to the Rapporteur for final amendments in the AR.

2.2.3. Monograph on Hederae helicis folium and supporting documents

Action: for final adoption
Documents: MO; AR; OoC; LoR; references: 164/164

Outcome:
Final revised monograph and supporting documents adopted by majority vote (24 out of 29). Norway expressed a favourable position.
Divergent opinion: L. Anderson, M. Delbò, W. Dymowski, G. Laekeman. E S. Leinonen
Some peculiarities such as use in children, correct terminology and applicability of pharmaceutical form/ route of administration or the sufficiency of data to support WEU from comparative studies and other minor issues were re-discussed. However, it was confirmed that the revision was not based on a systematic review but a specific trigger (acceptance BSS as valid tool in this indication) which limits the scope. A systematic review of new data to update the monograph and supporting documents is scheduled for 2017.

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

2.3.1. Monograph on Epilobii herba and supporting documents

Rapporteur: R. Länger; Peer-reviewer: M. Heroutová; Expert: A. Obmann
Action: for adoption
Documents: MO; AR; LoR; references: 54/56

Outcome:
Final monograph and supporting documents adopted by consensus. Norway expressed a favourable position.
No comments were received during public consultation.

2.3.2. Monograph on Sabalis serrulatae fructus and supporting documents

Rapporteur: G. Laekeman/A. Vlietinck; Peer-reviewer: L. Anderson
Action: for adoption
Documents: MO; AR; OoC; LoR; references: 142/142

Outcome:
Final monograph and supporting documents adopted by majority vote (25 out of 29). Norway expressed a favourable position.

Divergent opinions: L. Anderson, Zs. Birone-Sandor, E. v. Galen, A. O'Sullivan.

Final amendments in the AR to be performed before publication.

Some members expressed their concern towards selective presentation in the AR, e.g. lack of comments on clinical summaries without analysis of single studies before 2000. With agreement between Rapporteur and Peer reviewers on the monograph content, a majority supported, however, the package for finalisation, while some wordings in the AR are to be clarified before publication.

Divergent views were expressed claiming insufficient evidence to support well-established use in particular a consistent proof of efficacy.

2.3.3. Public statement on Uncariae tomentosae cortex and supporting documents

Rapporteur: Z. Biró-Sándor; Peer-reviewer: R. Länger
Action: for adoption
Documents: PS; AR; LoR; references: 131/143

Outcome:
Final public statement and supporting documents adopted by consensus. Norway expressed a favourable position.

No new data had been received during public consultation. The HMPC maintained therefore the view that no monograph can be established despite 15 years of medicinal use in the EU lacking specific sufficient evidence regarding the medicinal use outside the EU for more than 30 years regarding the plant part used, the herbal preparation, the indication and the posology.

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

2.4.1. Public statement on Balsamum peruvianum and supporting documents

Action: for adoption
Documents: Draft PS; AR; LoR

Outcome:
Draft public statement and supporting documents adopted by majority vote for 3 months public consultation.

The Rapporteur had incorporated new information from France and Spain into the assessment, however, maintained the safety concerns (high allergenic potential vis-à-vis available alternatives in this indication), despite some combination products on the market without worrying signals from Pharmacovigilance. Some members made reference to cosmetics and the possibility to test allergic reactions before use, inclined to acknowledge the long standing use of the substance. Two members signalled a divergent view on the PS.

2.4.2. Monograph on Pruni africanae cortex and supporting documents

Action: for adoption
Documents: Draft MO; AR; LoR

Outcome:
Draft monograph with changes in title and sections 2 and 4.2, as well as supporting documents adopted by consensus for release for public consultation.

Rapporteur to perform polishing of the AR before publication. Data provided by Poland to be considered.
A second preparation suggested by the Rapporteur due to new information provided was not accepted as fulfilling criteria for 30 years TU.

2.4.3. Public statement on Salviae fruticosae folium and supporting documents

Action: for adoption
Documents: Draft PS; AR; LoR

Outcome:
Draft public statement and supporting documents adopted by consensus for 3 months public consultation.
Despite some data on traditional use and a Ph. Eur. monograph, overall information was considered inconsistent and not specific enough to draft a monograph. Interested parties are given the chance for additional information during public consultation to allow continuation of the assessment.

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 discussion
Documents: PS; OoC; letter from HMPC to CHMP June 2015; SWP response Oct 2015; presentation

Outcome:
HMPC noted current status of discussion at SWP and CHMP. Rapporteurs had reviewed PS according to current proposal discussing final open points such as the genotoxic potential. While complete information on one existing study (Comet assay) is still missing, no further news on studies announced by industry had been received. Further discussion is foreseen after final feedback from CHMP/SWP (5 HMPC questions plus 2 CHMP questions).

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 Sept 2015; SWP response April 2014

Outcome:
HMPC noted ongoing discussion at SWP. Further discussion is foreseen only after final feedback from CHMP/SWP.

4.2. Quality

4.2.1. Reflection paper on the use of new analytical methods in the quality control of herbal substances, herbal preparations and (traditional) herbal medicinal products

Rapporteurs: K. Reh, W. Kubelka
Action: for adoption for public consultation
Document: Draft reflection paper

Outcome:
Postponed to February 2016 meeting.

4.3. Regulatory

4.3.1. 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:
HMPC members to send comments by 8 December 2015. Rapporteurs in liaison with secretariat to compile comments and finalise the document for adoption by written procedure.
Some members agreed with the Rapporteur's draft revision and proposed other ATC codes second level to be included, others confirmed their general reservations linking traditional use indications with ATC codes, even though ATC codes are not allocated to individual substances anywhere on the HMPC website except within adopted HMPC documents (e.g. WEU monographs). The Chair invited to send comments including on title and text of the document, but finalisation should be targeted to allow consistent publication of monographs and use of search functions for all herbal substances at the EMA website.

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 15 October 2015

Outcome:
Meeting report adopted.

The HMPC noted the report by the Chair on discussions and deliverables. The draft reflection paper 'new methods' (see 4.2.1.) was in principle finalised but amendments were necessary so that the Rapporteur could not provide the document for HMPC.
For the draft work plan 2016 (see 5.7.2.), the certificates of suitability (CEPs) topic was kept as separate point. It was identified as important to coordinate with EDQM as herbal CEPs application increased and can be expected gradually more within individual national applications.

Action: for information
Document: Draft agenda for the Q DG meeting to be held on 9 December 2015

Outcome:
No further topics requested by HMPC from Q DG. Given the importance of the revised CTD guideline and near completion from ORGAM side, priority should be given to finalise the CTD guideline (primarily mock-up) during an additional face to face meeting 8-9 Dec.

4.4.2. ORGAM DG

Report: ORGAM DG Chair
Action: for adoption
Document: Meeting report from ORGAM DG meeting held on 13 October 2015

Outcome:
Adopted.

The meeting was primarily dedicated to the CTD guideline revision beside a first discussion on the implementation status of the 2015 work plan and the draft 2016 work plan.

Action: for information
Document: Draft agenda for the ORGAM DG meeting to be held on 10 December 2015

Outcome:
No further topics were requested by HMPC from ORGAM DG. Final distribution of work to be decided for 2016 work plan (see also 5.7.2.) according to ORGAM mandate before publication.

Action: for discussion
Documents: CTD guideline (EMA/HMPC/71049/2007); draft OoC (clinical and pre-clinical part)

Outcome:
Orientation was given for an open point in the pre-clinical/clinical part.

Final revised CTD guideline and Overview of comments to be tabled for HMPC adoption after input from Q DG (mainly appendix 2 'mock up').

The need to demonstrate in several dossier sections that a product contains a HS/HP which corresponds to a HS/HP of a MO/LE was discussed. IPs proposed to include the 'need to demonstrate' only once in the dossier – being essential for several aspects of the dossier, while otherwise it can be referred to it. The HMPC agreed to the Rapporteurs preference keeping the need 'to demonstrate' in each section (e.g. 2.4, 2.5) in order to facilitate the work for assessors of single dossier parts. It was not specified so far in the CTD guideline, in which part the correspondence with a MO/LE (as clarified in a Regulatory Q&A 7 and 8) is to be included.

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

Outcome:
HMPC noted new approach in recommendations of EMA to NCAs when nominating members for EMA scientific committees. Current overview on HMPC-specific expertise is based on 2008 and 2014 consultation in analogy to other committee's structure. Members to provide comments by 15 December 2015 to the HMPC secretariat. EMA secretariat to review for endorsement at the HMPC 2016 February meeting. In case of changes to the existing structure, all members of HMPC, MLWP, QDG and ORGAM to newly fill the expertise overview.

HMPC Chair emphasised that beside suitable expertise the possibility to dedicate work to the HMPC is another decisive prerequisite for national representatives.

5.1.2. Preparation of upcoming elections

- Co-opted member, toxicology
- QDG Chair

Action: for discussion
Documents: Request for nomination email 22 Oct 2015; Procedure for nomination co-opted members for HMPC

Outcome:
The request for nomination of co-opted member candidates was sent out on 22 Oct 2015. Deadline for nominations is 22 January 2016. Depending on candidatures a new co-opted member in toxicology will be elected at the HMPC February meeting.

The current 3-year mandate of the QDG Chair expires in March 2016. A new appointment is scheduled for the HMPC February meeting. QDG to discuss and HMPC members to nominate possible candidates by 22 January 2016 for election at the HMPC February meeting.

5.1.3. Assessors Training, 7-8 December 2015

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

Outcome:
Adopted by consensus. Final adjustments to be performed as one speaker not available anymore. QDG in liaison with the secretariat to further organise the break-out sessions (cases studies to be discussed, expectations to be defined).

5.1.4. Strategic Review and Learning Meeting – organisational aspects

Action: for information
Documents: Organisation of strategic review and learning meetings under European Presidency; Principles for organisation of NCA hosted meetings; Responsibilities for confidentiality in NCA hosted meetings

Outcome:
HMPC noted principles proposed for all committees. No further questions were raised. Confidentiality issues for external speakers were seen less relevant for HMPC due to the almost complete transparency of HMPC. The aligned possibility for EMA reimbursed participation of some not NCA affiliated members (e.g. co-opted members) was welcomed.

5.2. Coordination with EMA Scientific Committees or CMDh-v

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

Action: for information

Outcome:
HMPC noted update by HMPC Rapporteur. Documents still under development. Coordination with HMPC foreseen according to progress at excipients DG.

With reference to the current state of discussion the Rapporteur considered neither the HMPC reflection paper 'ethanol/use in children' nor the HMPC monograph template affected. However, planned labelling requirements at lower thresholds are new and not toxicologically justified from existing EMA guidance documents. If HMPC maintains the standard reference to the (revised) excipients guideline, companies and NCAs will have to follow these new requirements.

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

See 4.1.1

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

See 4.1.2

5.2.4. Coordination with CMDh: Article 46 assessment work sharing, Working Party on Paediatric Regulation

Action: for information
Documents: Email 27 Aug 2015; email communication 12-16 Oct 2015

Outcome:
For specific case according to diverse status in MSs it was agreed that the Art. 46 assessment is to be performed by a MS with available authorised products. HMPC to be informed via Peer-reviewer and Rapporteur for consideration during finalisation of the monograph revision.

5.2.5. Coordination with PDCO

- Expert support for herbal combination product

Report: W. Knöss, A. P. Martins, L. Anderson
Action: for information

- Report on relevant topics from PDCO meetings

Report: S. Girotto (observer)
Action: for information
Document: Presentation

Outcome:
Postponed to February 2016 meeting.

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

5.3.1. Coordination with PCWP/HCPWP

Observer: S. Bager

- Work plan for the EMA PCWP 2016

Action: for adoption

Document: Work plan

- Work plan for the EMA HCPWP 2016

Action: for adoption
Document: Work plan

Outcome:
Work plans adopted without comments.

- Draft Agenda - Training session for patients and consumers interested in EMA activities, 25 Nov 2015

Action: for information
Document: Draft agenda

- Draft Agenda - EMA PCWP meeting with all eligible organisations, 26 Nov 2015

Action: for information
Document: Draft agenda

Outcome:
HMPC noted ongoing discussion with patients and health care professionals on possible involvement in HMPC activities. A proposal by the observer will be provided at the HMPC February meeting.

5.3.2. Coordination with QRD group

QRD templates for THMPs in mutual recognition and decentralised procedures

Report: ORGAM Chair
Action: for discussion
Documents: Comments received by QRD Group; presentation

Outcome:
HMPC welcomed comments from QRD group. ORGAM DG to finalise document according to comments received.

Follow-up and necessary coordination (QRD, CMDh) to be discussed at HMPC February meeting.

Comments from 15 MS had been received and compiled. A standalone document was preferred by a QRD majority due to herbal specifics (analogy to e.g. vet. products). The ownership of a standalone document as well as publication and consultation provisions have still to be clarified. The HMPC Chair stated that the risk of a divergent development of two standalone documents has to be considered.

5.4. Cooperation within the EU regulatory network

5.4.1. HMPC Chair presentation at 89th EMA MB meeting, 2 October 2015

Report: HMPC Chair
Action: for information
Documents: Presentation; press release

Outcome:
HMPC noted EMA MB positive feedback and welcomed EMA press release.

5.4.2. European Pharmacopoeia

- EDQM 13A expert group meeting held on 3-4 November 2015
  EDQM: M. Bald, U. Rose; HMPC Observer: I. Chinou
  Action: for information
  Documents: Agenda; EDQM monographs on Hippocastani semen and Hippocastani seminis extractum siccum normatum; Report

  Outcome:
  HMPC noted topics of potential relevance highlighted by the EDQM representative such as planned next steps in the essential oil discussion and assay change in the *Hippocastanum* Ph. Eur. monographs.

  Given that the triterpene glycosides/aescin content is part of the herbal preparation description in the EMA monograph Hippocastani semen, national assessors should be aware of the new thresholds due to change from a photometric to a LC assay and their comparability in national procedures. HMPC should adapt ARs and monographs on Hippocastani semen and cortex. The HMPC Chair preferred not to step into a revision for specific reason but consider the change during the systematic review scheduled for 2017. It was informed that the new Ph. Eur. monographs will be published in July 2016 and come into force in January 2017.

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

  Outcome:
  HMPC noted topics of potential relevance highlighted by the EDQM representative such as the changed botanical name for *Pistacia lentiscus* (Ph. Eur. mastix monograph) or HPTLC method changes and the linked knowledge database.

  It was clarified that the HPLTC methodology is not bound to a single company's equipment but still possible manually, although resolution of a modern semiautomatic apparatus gives better results.

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

  Outcome:
  HMPC noted topics of potential relevance highlighted by the EDQM representative such as progress on the assay discussion and deletion of three pyrrolizidine alkaloid (PA) containing TCM substances from the work programme. A substantial extension of the already extensive TCM group work programme is not expected.

- Appointment of HMPC observers and meeting dates 2016
  Action: for discussion
  Document: DG dates for 2016

Outcome:
HMPC confirmed the need having HMPC observers attending EDQM meetings which was regarded to be more efficient towards continuous coordination than having an annual meeting between QDG and Chairs of expert groups 13A, 13B and TCM.

I. Chinou, H. Neef and R. Länger were reconfirmed as observers for 13A, 13B and TCM, respectively.

Agendas, meeting reports and oral reports provided by the EDQM observer at QDG and HMPC were regarded to be an important part of the coordination presenting the EDQM perspective but could not substitute the above mentioned observerships. Meeting dates 2016 have been adjusted as far as possible to avoid overlaps. Observers may not be able to participate at each meeting.

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

Action: for adoption
Documents: Timetable; list of questions

Outcome:
Timetable and list of questions without changes adopted.

HMPC members to indicate any changes to contact points to the secretariat by 14 Dec 2015.

No change of questions, answer structure or timetable (submission of new data by 15 February) was proposed.

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

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

Action: for information
Document: Presentation

Outcome:
HMPC noted concerns by the Eur. Com. representative regarding divergent opinions on revised and newly submitted list entries (Eleutherococcus, Melaleuca) vis-à-vis procedural aspects at Commission level for list entry adoption. Re-consideration of the HMPC revision procedure (voting on proposed change but not the whole unchanged LE content without new data) as well as the careful wording of divergent opinions by HMPC members vis-à-vis the existing legislation and linked regulatory, procedural and scientific standards was advised. Further information on the follow-up will be given at the HMPC February 2016 meeting.

5.5. Cooperation with International Regulators

5.5.1. AYUSH information on Indian medicinal plants

Report: M. Nesari, V.K. Joshi
Action: for discussion
Documents: Response letter from HMPC Chair 2 Sept 2015; Letter 5 Nov 2015; presentation

Outcome:
HMPC welcomed observers from AYUSH and the information on the ministry, regulation of traditional medicines in India and main historical features and the holistic concept of traditional medicines in India. Previous contacts with EMA and EU MSs were reiterated and proposals for exchange of information and cooperation discussed.

HMPC members mentioned typical issues hampering the establishment of EU herbal monographs for Indian plants despite a long tradition of use: lacking specific information on strength and posology, clinical data vis-à-vis often many –non-clinical data, uncertainty about traditionally diverse preparations and combinations, or the European limitation to indications suitable for self-medication of minor disorders without need for medical consultation – often not in line with traditional Ayurvedic uses for more severe diseases. The observers offered to provide upon request information where possible including from the Ayurvedic Pharmacopoeia but also emphasised the diversity of traditions on the Indian sub-continent and the differences between single constituents and traditional preparations as a whole.

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 Aug 2015

HMPC Chair for EMA and HMPC Vice-Chair for Italy will attend the meeting and report at the next HMPC meeting.

5.5.3. HMPC – International representation and cooperation

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

Outcome:
No comments by HMPC members have been received. Draft document endorsed for transfer to EMA international affairs department for feedback and possible further discussion anticipated for the HMPC February meeting.

The document was still considered a draft but before finalisation a communication with the EMA international affairs department was considered beneficial. The reflection of the network strategy 2020 as regards global importance of EMA standards was emphasised, even though in the herbal area the leading international platforms justifying active EMA contribution still have to crystalize long term.

5.5.4. 2nd Annual Complementary/Herbal Medicines Workshop in the margins of the 10th International Summit of Heads of Medicines Regulatory Agencies (ICMRA), Mexico City, 10 November 2015

Report: HMPC Chair
Action: for information

Outcome:
Feedback from international affairs department and national representatives to be discussed at the HMPC February meeting. It was clarified that organisation and agenda items (such as EMA herbal summaries for the public) were chosen by the organisers but not EMA.

5.6. Contacts of the CXMP 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 status; presentation; tracking tool; MLWP work plan 2015 status; Q DG work plan 2015 status; ORGAM DG work plan 2015 status

  Outcome:
  HMPC noted implementation status of activities scheduled for 2015 and EMA cross-committee approach in planning / tracking of committee activities. Experiences from 2015 to be considered for the 2016 HMPC and subgroup work plans and planned activities.

- Monograph and List entry systematic revision
  Action: for discussion
  Document: Presentation

  Outcome:
  Postponed.

5.7.2. HMPC draft work plan 2016

Report: HMPC Chair
Action: for adoption
Documents: HMPC draft work plan 2016; MLWP draft work plan 2016; Q DG draft work plan 2016; ORGAM DG draft work plan 2016

Outcome:
HMPC, MLWP, QDG and ORGAM draft work plans 2016 were adopted by consensus with minor changes in HMPC, MLWP and ORGAM DG draft work plans 2016.

Final polishing of wordings and Rapporteur appointments to be clarified between HMPC, MLWP, QDG and ORGAM Chairs, topic leaders and HMPC secretariat before publication.

5.8. Planning and reporting

5.8.1. Meeting dates

Action: for information
Document: HMPC/MLWP 2016 to 2018

Outcome:
Agreed. The HMPC Chair emphasised that future changes should be preferably performed at least 1 year in advance to allow scheduling of other appointments around HMPC meetings.

After cross committee consultation meeting dates were slightly changed (e.g. July meetings). No objections were raised by the members.

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 15 May 2015; Response Oct 2015; Annex conclusion

Outcome:
HMPC agreed to Rapporteurs view that details of the manufacturing process may be relevant for individual applications but not for inclusion into an EU herbal monograph. No purification or specific treatment in this case would justify derogation from standard practice by the Committee (DER, solvent and posology specification). MLWP to finalise the revised monograph for HMPC adoption.

EMA regulatory and legal department in liaison with HMPC Chair and Rapporteur to draft response letter for adoption by written procedure.

6. Any other business

6.1. Topics for discussion

6.1.1. ADAPT-SMART – presentation

Action: for discussion

Outcome:
HMPC noted main features of the ADAPT-SMART project and invitation to contribute on some aspects if applicable for herbal medicinal products.

6.1.2. Herbal assessment report summary for the public

Action: for discussion
Document: Presentation

Outcome:
Members were reminded of the standard English template and the procedure for ARSP generation both for the English original and the translations. Because of experiences with partially misleading translations HMPC members were invited to support the generation of a translated template (including standard phrases) in all EU languages to avoid unnecessary repeating errors, expenditure and delays for all parties involved.

Members should be aware that the English summary has been agreed by Rapporteur, Peer reviewer and medical writers and seen by HMPC before documents are sent for official translation into all EU languages. Thereafter members should refrain from commenting on

the English summary and only comment on the correctness of the translation vis-à-vis the English original because otherwise the whole process starts again.

It was announced to potentially involve in addition patient representatives in checking ARSP in the future.

6.1.3. Update from the European Commission's Working Group meeting on health claims, 9th November 2015

Report: L. Anderson
Action: for discussion
Document: e-mail dated 23 Nov 2015,
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/477291/Commission_Working_Group_on_health_claims_9_Nov_15.pdf

Outcome:
The current developments at the Commission regarding the adoption of health claims for food supplements containing hydroxyanthracene derivatives (HAD) were discussed (MS consultation on 2 options by 30 November).

HMPC members were encouraged for follow-up at national level. HMPC Chair to contact the Eur. Com. representative with reference to previously expressed concerns sent on 14 March 2014. Concerns for public health referred to (1) the misleading wording of the health claim vis-à-vis population groups and the pharmacological action of HAD, (2) the general unlimited use supplementing food in a healthy population for such purpose in view of more healthy alternative options, and (3) mostly to safety concerns linked to indication (abuse and overdose potential) and the toxicological properties (habituation/addiction, intestine modification, genotoxicity).

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 28-29 September 2015

Overview of expertise of members HMPC and subgroups

Meeting report from HMPC meeting held on 28-29 September 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 24-26 November 2015

6.2.3. ARSP

- English summaries for publication
- ARSP translations in all EU languages; for publication, member states feedback

6.2.4. Other

- Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Commission work programme 2016 'No time for business as usual', Strasbourg, 27.10.2015 com(2015) 610 final; Annex II: REFIT Initiatives
- Article 57: Information by Pharmacovigilance Department; Documents: Article 57 Publication Dashboard Report to NCAs; Article 57 Publication Dashboard Report to EMA Committees; Pharmacovigilance programme update, Oct 2015
- EFSA CEF Panel: Scientific Opinion on Flavouring Group Evaluation 208 Revision 1 (FGE.208Rev1): Consideration of genotoxicity data on representatives for 10 alicyclic aldehydes EFSA Journal 2015;13(7):4173
- IARC monographs on the evaluation of carcinogenic risks to humans. Some drugs and herbal products. Volume 108. International Agency for Research on Cancer. WHO, Lyon 2015. (includes Ginkgo, Kava-Kava, pulegone, Aloe)
- Rethinking traditional Chinese medicines for cancer. Editorial. The Lancet Oncology. Vol 16, Nov. 2015
- The Nobel Prize in Physiology or Medicine 2015: William C. Campbell, Satoshi Ōmura, Youyou Tu (for artemisinin isolation from TCM for treatment of malaria). Press release
- Episalvan (previously known as Oleogel) – final positive CHMP opinion and assessment report on product from herbal origin on 19 November 2015 meeting

List of participants

Including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 23-24 November 2015 meeting.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restriction s apply
Werner Knöss	Chair	Germany	No interests declared	
Reinhard Länger	Member	Austria	No interests declared	
Kapka Kaneva	Alternate	Bulgaria	No interests declared	
Darko Trumbetic	Member	Croatia	No restrictions applicable to this meeting	
Maria Stavrou	Member	Cyprus	No interests declared	
Marie Heroutova	Member	Czech Republic	No interests declared	
Martina Holenkova	Expert	Czech Republic	No interests declared	
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 Lê	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	
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	
Rugile Pilviniene	Member	Lithuania	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	
Milan Nagy	Alternate	Slovakia	No interests declared	
Barbara Razinger	Member	Slovenia	No interests declared	
Adela Núñez Velázquez	Member	Spain	No interests declared	
Cristina Martinez Garcia	Alternate	Spain	No interests declared	
Per Claeson	Member	Sweden	No interests declared	
Erika Svedlund	Alternate	Sweden	No interests declared	
Linda Anderson	Member	United Kingdom	No interests declared	
Sue Harris	Alternate	United Kingdom	No interests declared	

Gioacchino Calapai	Co-opted member	Italy	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	
Vinod Kumar Joshi	Observer	Banaras Hindu University	N/A	
Manoj Nesari	Observer	Ministry of AYUSH	N/A	
A representative from the European Commission attended the meeting				
Meeting run with support from relevant EMA staff				

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