4 May 2015
EMA/HMPC/465862/2015
Scientific Committee Support

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 4-5 May 2015

Chair: Werner Knöss – Vice-Chair: Marisa Delbó

4 May 2015, 14:00 – 19:00, room 2F

5 May 2015, 08:30 – 12:30, room 2F

(AESGP hearing at MLWP: 5 May 2015, 13.30 – 15.30, room 2F)

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 minutes is considered commercially confidential or sensitive and therefore not disclosed.

Of note, these minutes are a working document primarily designed for HMPC members and the work the Committee undertakes.

Note on access to documents

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

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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 4-5 May 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.

- Changes to membership, new participants:

Marcel Bruch, new member for Luxembourg,

Alternate position for Belgium remains currently vacant.

1.2. Adoption of agenda of the meeting

- HMPC agenda for 4-5 May 2015

Adopted

- Time schedule

Minor changes

1.3. Adoption of the minutes

- HMPC minutes for 9-10 March 2015

Adopted

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

2.1.1. Report from the MLWP March meeting

Report: MLWP Chair
Action: for information
Documents: Draft minutes for the MLWP meeting on the 10-12 March 2015
Overview of status of MLWP assessment work
Common names of herbal substances in all EU official languages

Outcome:

Updated list with plant names in all languages available after repeated consultation. Response from some MS still missing. If MS don't provide names, monographs with be published without name in relevant languages.

Rapporteurs and HMPC secretariat to use this list as basis for monographs/ List entries before publication.

2.1.2. Prioritisation/cancellation of substances for assessment – Appointment of Rapporteurs/Peer reviewers

Report: MLWP Chair
Action: for adoption

First assessment (to be added to HMPC inventory and priority list):

- Valerianae aetheroleum

Outcome: Agreed by HMPC
During revision of the Valerianae radix monograph the split of the monograph was decided in line with established practise for other substances. Revised monographs will be published for Valerianae radix and Valerianae aetheroleum.

- Piperis methystici rhizoma proposed for HMPC assessment (proposal DE)

Document: e-mail dated 22/04/2015

Outcome: Agreed by HMPC
Without prior discussion at MLWP, DE requested adding the substance to the HMPC priority list as announced at the HMPC March meeting. Following the outcome of a legal case, the need for a harmonised European assessment was supported by a majority of members.

MLWP to propose Rapporteur and Peer reviewer.

Subsequently modification of the Public statement on herbal substances containing constituents associated with safety concerns (EMA/HMPC/682247/2013) proposed.

In view of safety concerns and previous pharmacovigilance action in European MSs the HMPC earlier included the substance among those currently not prioritised for assessment as expressed in PS EMA/HMPC/682247/2013. Pros and cons for a HMPC assessment following the outcome of a court case were discussed from a legal, regulatory and scientific perspective. Implications in MS, eventually newly available data, need for quality scrutiny linked to published data as well as the role of HMPC documents vis-à-vis other regulatory tools were taken into account. Given the known history of the substance used in MPs no major questions were raised regarding a 30 years period of medicinal use. However, it was agreed that major safety concerns would require a thorough benefit risk assessment according to requirements of Art. 16a and 10a of Dir. 2001/83/EC aiming for a harmonised European view.

Revision:

New Rapporteur for Frangulae cortex, Rhamni purshianae cortex, Rhei radix

Outcome: Agreed by HMPC

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

None

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

2.3.1. Monograph on Capsici fructus and supporting documents

Rapporteur: R. Länger; Peer-reviewed: M. Heroutová
Action: for adoption
Documents: MO, AR, LoR, OoC; references 178/206

Outcome:
Final monograph and supporting documents adopted by majority vote. Norway expressed a favourable position.

Divergent opinion: M. Delbò, G. Calapai

It was agreed that due to lack of clinical data the use in adolescents is not supported.

Some specifics in the monograph (WEU) vis-à-vis existing products on the market with a heterogeneous data situation according to preparation, route of administration and age group were highlighted. Possible extrapolations suitable for the generic monograph versus individual product applications were discussed. Thus, although originally partially included in the draft monograph, the HMPC majority followed the MLWP proposal not accepting the use in adolescents for the monograph. Some concerns regarding the overall conclusions, the level of evidence and the wording of the indication were raised.

Additional information (e.g. the market overview) and final polishing in the AR was requested.

2.3.2. Monograph on Pilosellae herba cum radice and supporting documents

Rapporteur: O. Palomino, Peer-reviewer: G. Calapai/M. Delbò
Action: adoption
Documents: MO, AR, LoR; references 18/21, OoC

Documents for information: e-mails dated 02-03/02/2015, 26/03/2015, list A of Ph.Fr. 10th éd. 01/96

Outcome:
Final monograph with changed substance name, corrected posology and supporting documents adopted by majority vote (28 out of 29).
Norway expressed a favourable position.

Divergent opinion: E. v. Galen

Rapporteur in liaison with peer reviewer and HMPC secretariat to clean documents to allow publication.

The substance name had been changed according to discussions at the previous meeting and in writing thereafter in line with views from Ph. Eur., Ph. Fr. and French authorities. No new documents by the Rapporteur had been distributed before the meeting, but posology corrections and other minor changes aligning AR and monograph had been provided by the Peer reviewer. Upon request by members, the Chair reminded that all documents including the AR should be available for adoption in final clean version for publication. A divergent view referred to the appropriateness of the wording for a traditional indication.

2.3.3. Monograph on Symphyti radix and supporting documents

Rapporteur: Z. Biró-Sándor; Peer-reviewer: J. Wiesner
Action: for adoption
Documents: MO, AR, LoR, OoC; references 48/70

Outcome:
Final monograph (with changes in sections 4.1, 4.4 and 5.3) and supporting documents adopted by consensus.

Norway expressed a favourable position.

Following the finalisation of the public statement on PA, the monograph that had been on hold for a longer period (end of public consultation November 2011) has now been finalised with minor modification and reference to the conclusions of document EMA/HMPC/893108/2011.

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

2.4.1. Monograph on Ricini oleum and supporting documents

Action: for adoption for public consultation
Documents: MO, AR, LoR (drafts)

Outcome:
Adoption postponed.

A majority did not agree on proposed indication 2.

Returned to MLWP for final adjustment of monograph and supporting documents for possible adoption for release for publication by HMPC in July 2015.

Following recommendation of the MLWP but a split view on indications, the Committee discussed in detail available data and posologies for two indications (laxative and purgative) taking into account the medicinal practice in different MSs. A majority did not consider a purgative bowel cleaning action as appropriate due to diverse reasons: insufficient data, reservations towards a well-established efficacy vis-à-vis available alternatives and considerations about obsolete versus up-to-date clinical practice. In this direction Rapporteur and MLWP were asked to adapt the documents for a possible release for public consultation by the HMPC.

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

Action: for discussion/adoption
Documents: revised public statement, overview of comments, comments from Sweden

Outcome:
HMPC noted response received from interested parties during public consultation and view of the Rapporteurs.

Due to the wider importance beyond HMP, escalated coordination among EMA scientific committees and the EU network agreed before finalisation of revised public statement.

MLWP to update and polish documents in response to comments/ data received before transfer to CHMP/ SWP.

The Rapporteur summarised briefly the interest by industry and comments received including confidential data as well as intentions to perform additional tests and submit new data. Six main areas/directions of repeating comments were outlined and a general direction discussed before giving the detailed finalisation of the overview of comments and the PS to MLWP. NCA views were taken into consideration and the need for further coordination confirmed.

Some members highlighted the importance of the assessment for products outside the mandate of the HMPC i.e. the use of pulegone containing substances in HMP/THMP as basis for individual benefit/risk assessments in HMPC monographs. Members were therefore asked to check their respective markets beyond HMP/THMP such as use of peppermint oil as excipients making a pure safety assessment necessary within the whole network according to strength, posology and duration of use.

Post-meeting note: Following break out session at MLWP more substantial changes to PS considered necessary. Rapporteurs, HMPC Chair, SE Member and HMPC secretariat to prepare revised PS, OoC, and List of questions (letter) by 28 May 2015 for written procedure among MLWP and HMPC members followed by transfer to SWP/CHMP.

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

Action: for discussion/adoption
Documents: overview of comments, draft reflection paper

Outcome:
HMPC noted comments received and view of Rapporteur. Further comments expected from SE.
MLWP to discuss and finalise documents updated by the Rapporteurs.

Main comments received and directions of adaptation of the PS were shortly presented.

4.2. Quality

4.2.1. Planned Revision 3 of the 'Guideline on quality of herbal medicinal products/traditional herbal medicinal products' (EMEA/HMPC/CHMP/CVMP/214869/2006)

Report: Q DG Chair
Action: for adoption
Document: concept paper

Outcome: Adopted
HMPC secretariat to check necessary coordination with CHMP/QWP and CVMP before publication.

The HMPC raised no objections on the planned revision following explanations by the Q DG Chair.

4.2.2. Planned Revision 3 of the 'Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and HMP/THMPs' (EMA/CPMP/QWP/2820/00 Rev. 2, EMA/CVMP/815/00 Rev. 2, EMA/HMPC/162241/2005 Rev. 2)

Report: Q DG Chair
Action: for adoption
Document: concept paper

Outcome: Adopted
HMPC secretariat to check necessary coordination with CHMP/QWP and CVMP before publication.

The HMPC raised no objections on the planned revision following explanations by the Q DG Chair.

4.2.3. Reflection paper on microbiological aspects of HMP/THMP

Report: Q DG Chair
Action: for adoption
Documents: final reflection paper, final reflection paper (track changes), overview of comments

Outcome: Adopted
Final reflection paper and overview of comments to be published at EMA website.

Q DG to develop specific guidance in form of Q&A.

HMPC noted divergent concerns by interested parties and regulators regarding the status of the document vis-à-vis existing guidelines and Ph. Eur. Standards.

The HMPC noted that the RP had triggered some response and misperceptions as regards scope and aim (i.e. reflection paper to trigger the discussion, highlight possible gaps and list general points to consider linked to the topic). This led to comments asking not to create additional requirements (requested by IPs), or to generate more specific guidance if possible aiming for clarity (requested by regulators). It was confirmed that the revised finalised RP does not represent new guidance as such but is useful to summarise key points on all aspects linked to this important herbal-specific topic.

Specific guidance, where possible, will be given in the Q&A format to be developed by Q DG in 2015.

4.3. Regulatory

None

4.4. Report on HMPC Drafting Groups activities

4.4.1. Quality DG

Report: Q DG Chair

- Meeting report from Q DG meeting held on 26 March 2015

Action: for adoption

Outcome: Adopted

HMPC members noted the report by the Q DG Chair briefly summarising the ongoing work of the drafting group. Beside the finalised documents for HMPC adoption (see 4.2.1, 4.2.2, and 4.2.3) the group had also reviewed the need for revision of the Guideline on quality of combination herbal medicinal products. No complete revision but only minor updates were found necessary. Furthermore a draft for a reflection paper on the use of new analytical methods is under development.

The HMPC Chair emphasised the need to check regularly the 2015 HMPC/ Q DG work plan and signal to the Committee the progress and necessary modifications.

- Draft agenda for the Q DG meeting to be held on 21 May 2015

Action: for information

4.4.2. ORGAM DG

Report: ORGAM DG Chair

- Meeting report from the ORGAM DG meeting held on 24 March 2015

Action: for adoption

Outcome: Adopted

The ORGAM DG is currently working exclusively on the finalisation of a discussion paper regarding the use of the QRD template as regards SmPC, package leaflet and labelling (see 5.3.3). Finalisation is expected for the HMPC July meeting. No further questions were raised by HMPC members.

- Draft agenda for the ORGAM DG meeting to be held on 19 May 2015

Action: for information

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Strategic Review & Learning Meetings

Strategic Review & Learning HMPC-Meeting under the Latvian Presidency (co-hosted by BfArM) 18-19 June 2015
Report: HMPC Chair

Action: for information
Document: draft agenda

Outcome:
HMPC members invited to participate in strategically important meeting as regards functioning and future of the HMPC assessment work and essential quality questions.

Currently no Strategic Review & Learning Meeting planned for HMPC during Luxemburg presidency.

5.1.2. Assessors Training 2015

Report: HMPC Chair

Action: for discussion
Document: draft agenda

Outcome:
HMPC agreed on quality-related topic for assessors training comprising current key issues for discussion within the network including EDQM.
First draft by Q DG Chair, HMPC Chair and secretariat to be further developed by Q DG for presentation at the HMPC July meeting.

HMPC secretariat to propose and pre-book date/room (preference December linked to HMPC DG dates).

5.2. Coordination with EMA Scientific Committees or CMDh-v

5.2.1. General coordination

- Scientific Coordination Board Meeting 30 March 2015

Report: HMPC Chair
Action: information
Document: agenda

Outcome: Adopted
HMPC Chair highlighted relevant topics for the HMPC including EU Medicines Agencies Network Strategy to 2020, committee work plans, cross-committee initiatives, international activities and coordination on the safety assessment for pulegone.

- HMPC Observers at other Committees and Working Parties

Action: discussion
Presentation

Outcome:
Current HMPC observers and their status at other groups re-confirmed:

PCWP/HCPWP: S Bager (member/ attendance), QWP: K Reh (member/attendance), SWP: O Pelkonen (observer/ mailing monitoring and TC attendance if required), PDCO: S. Girotto (observer/ mailing monitoring and attendance if required), JEG 3R: G. Lakeman (observer/ attendance),

No current need for observers at other groups identified. Review of coordination needs and modalities after 1 year.

Observers requested to report regularly at HMPC meetings in writing (based on agendas/minutes) to shortly flag relevance of topics for HMPC.

Cross-agency emphasis on appropriate coordination between committees, the specific role of HMPC and historical development were reflected in order to re-define need, role and activities of observers vis-à-vis the coordinating function of the committees' secretariats. Existing observers were re-confirmed; no current need for additional observers (such as PRAC) deemed necessary.

The secretariat confirmed that herbal-specific topics are usually well identified and signalled by other secretariats. However general topics having also some relevance for the herbal sector are better identified via observers given that peculiarities of herbal products and scope of the HMPC work are usually not in the main focus for other committees.

- EMA benefit-risk methodology project and activities

Action: discussion, appointment of member for steering group

Outcome:
HMPC appointed S. Madsen (Norway).

One candidate with a long track record in benefit-risk assessment and major interest in new methodologies was appointed for active participation in the steering group and reporting regularly to the HMPC on relevance for the Committee and subgroups (e.g. ORGAM as regards AR templates) as regards WEU and eventually also TU assessment.

5.2.2. Coordination with CHMP

Drafting group on excipients: ethanol as an excipient (after public consultation)

Action: for information

Ethanol topic currently postponed until June with involvement of HMPC Rapporteurs.

HMPC discussion foreseen in July including relevance for the HMPC reflection paper EMA/HMPC/85114/2008 and monograph practice.

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

5.3.1. Interaction with PCWP - Revised framework of interaction with patients and consumers and their organisations

Proposal for future option for patient involvement in HMPC work

Rapporteur: S. Bager
Action: for discussion
Document: presentation

Outcome:
HMPC noted practice at other committees and considerations on possible future options for HMPC.

As first step patient and consumer organisations with an interest in herbal medicines to be identified in order to find appropriate modalities fitting into the current HMPC/ MLWP structure.

The progress with patient involvement in EMA activities was presented. Some modalities as practised in other Committees with legally based official representatives could be clarified. While more involvement in herbal specific topics was welcomed in general, precise aims and practicality need to be carefully checked. More considerations should be given to the current HMPC mandate and structure (actual assessment at MLWP, HMPC non- binding European view on substances but not specific products) and expected benefit for HMPC adoption. Members emphasised specific national situations particular for this area, need for experiences with widely used self-medication OTC products, and targeted selection of appropriate representatives/ organisations.
Currently one consumer organisation (BEUC) is found on the list of official interested parties to the HMPC.

5.3.2. Coordination with Joint CVMP/CHMP ad hoc expert group on 3Rs

Action: for discussion
Document: meeting report March 2015

Outcome:
The report was noted.
A brief summary following the public consultation of the draft Guideline on regulatory acceptance of 3R testing approaches was provided. With the main focus of the group on key CHMP working parties and the centralised procedure, no direct relevance for HMPC/MLWP work was detected. However, in view of often limited data in the herbal area the observer recommended further monitoring given that animal data may not always be necessary. The HMPC Chair confirmed that current European developments have to be followed as regards relevance for data requirements in the specific herbal framework.

5.3.3. Coordination with QRD group

QRD template for THMPs in mutual recognition and decentralised procedures

Report: ORGAM Chair
Action: for discussion
Document: draft discussion paper on QRD templates for SmPC, Labelling and Patient Leaflet on Mutual-recognition and Decentralised procedures for THMPs

Outcome:
HMPC members to send comments to ORGAM Chair.

ORGAM to finalise document for possible adoption at HMPC July meeting as basis for discussion with QRD group.

The ORGAM Chair summarised the scope, aim and structure of the comprehensive discussion paper under development. Following the legal basis, difficulties for (traditional) herbal products with the standard template structure and possible solutions are presented in detail. Some particular issues were highlighted and members raised questions such as use /status of monograph standard wordings versus SmPC / general guidelines standards, the content of SmPC section 5.1, wordings regarding use in pregnancy/ lactation, or appropriate wordings in cases when for THMP no data are known or required.

Main issues should be highlighted now by HMPC members to allow adoption at HMPC in July.

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopeia

- EDQM 13B expert group meeting held on 21-22 April 2015

EDQM: M. Bald, U. Rose; HMPC Observer: H. Neef
Action: for information
Document: agenda, summary of decisions

HMPC noted progress in Ph. Eur. monograph development including some with relevance for HMPC assessment (e.g. Pilosella, Uncaria).

- EDQM TCM expert group meeting to be held on 5 - 6 May 2015

EDQM: M. Bald, U. Rose; HMPC Observer: R. Laenger
Action: for information
Document: agenda

Some topics with regulatory/HMPC relevance were highlighted requiring future coordination:

A draft document discussing criteria to decide on the need of an assay is currently under preparation and will also be shared with groups 13A and 13B.

TCM substances containing pyrrolizidine alkaloids are currently on hold as an appropriate method for PA determination needs to be developed (yet conclusions of the HMPC PS on PA generally considered at NCAs).

Setting limits for alkaloids in Aconitum species (quality versus toxicology considerations) are of interest in particular as they may be influenced by specific TCM processing methods (substance versus preparation).

- EDQM 13A expert group meeting held on 2-3 June 2015

EDQM: M. Bald, U. Rose; HMPC Observer: I. Chinou
Action: for information
The HMPC observer was not able to participate at the last meeting and will unlikely be able to participate at the June meeting. For the specific working group on essential oils (integrated in group 13A) representatives from Industry, manufacturers and regulators have been invited.

Monographs on Withania and Adhatoda still on the work programme but slow progress due to difficulties with appropriate reference material (see also 5.5.2).

5.4.2. EFSA

Public consultation on draft Guidance on the scientific requirements for health claims related to the gastro-intestinal tract, the immune system, and defence against pathogenic microorganisms.

Rapporteurs: G. Calapai, H. Pinto-Ferreira, I. Kosalec
Action: for information
Document: comments by HMPC, Gastroenterology DG, EMA`s anti-infectives & vaccines service, submitted 23/03/2015

5.4.3. EU Network Training Centre

Action: for information
Document: presentation

HMPC noted goal and opportunities as well as access to more information via web link given.

HMPC members to explore whether herbal-specific topics are available or could be offered.

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

Action: for information
Document: presentation, draft status report

Outcome:
More detailed information with relevance for the HMPC assessment work and prioritisation to be presented at the July meeting.

Response from all contact points had been received and main data shortly summarised. Despite further increase in applications and registrations, a decrease in registrations per year (total 125 registrations in 2014) with diverse distribution across MS can be noted.

Document EMA/HMPC/322570/2011 Rev. 5 had been updated and will be published at the EMA website after final check of data.

A proposal was discussed to check the reasons why monographs are not used or deviated from in national procedures in order to draw conclusions for HMPC assessment. However, limitations of the data set were acknowledged due to many registrations done before respective monographs have been finalised, insufficient knowledge about reasons in each case, or known national deviations (WEU acceptance, use in children, indication wordings) often already expressed in divergent opinions by HMPC Members.

5.5. Cooperation with International Regulators

5.5.1. Response by AYUSH, India on data request for five Indian plants

Report: HMPC Chair
Action: for discussion
Documents: e-mail dated 24/04/2015, Ayurvedic medicinal plants PCIM AYUSH input, HMPC letter to Indian authorities March 2013 on data requirements for 5 Indian plants

Outcome:
HMPC agreed on need for further improved communication as regards information required from India to be suitable for HMPC assessment work.

HMPC Chair in liaison with E. V Galen and secretariat to draft response to be distributed among HMPC members and sent out before HMPC July meeting.

The secretariat summarised previous interaction with AYUSH. Acknowledgment of Indian herbal traditions is a regular point raised by Indian authorities such as during the EU-India Joint WG 29/4 – 2/5. Since 2011 EMA had received input on 17 calls for scientific data, but never comments during public consultations. Submitted monographs completed from an Ayurvedic perspective with references listed (but no references/ data as such) had so far not been useful for Rapporteurs and had therefore no impact on assessment outcomes. Also the new response received did not provide new data (e.g. requested safety data for

Adhatoda). Members agreed to more precisely communicate what exactly is needed (e.g. via AR template) and to consider the invitation of a representative in order to foster the understanding for the HMPC assessment. The HMPC Chair informed that structural changes (AYUSH as ministry itself) may contribute to new communication opportunities.

5.5.2. HMPC – International representation and cooperation

Report: HMPC Chair
Action: for discussion
Documents: draft proposal HMPC international cooperation

Outcome:
Draft document to be further developed by HMPC Chair and secretariat and distributed among HMPC members for comments before communication with EMA international liaison officer.

Members to send comments by 31 May 2015.

A draft from 2013 had been revised and attuned to the EU network strategy as regards global regulatory contributions. Further details have to be elaborated. The international recognition and use of EU herbal monographs may be reflected by active promotion, representation and cooperation with a defined EMA role. Chair and Vice Chair reported that participation and eventually lead in the appropriate international organisation have further to be monitored given that some organisations may comprise the right representatives but have not found efficient working structures yet.

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

5.6.1. Hearing with AESGP at MLWP

Action: for discussion
Documents: draft agenda, participants list, presentation

Outcome:
Interaction with interested parties and hearing practice to be reviewed in 2016.

The HMPC welcomed the annual hearing with AESGP at MLWP and noted the agenda topics. It was agreed that the focus for discussion should remain on real issues for HMPC/MLWP assessment while points on the overall system as such including decision making practice at NCAs or single AESGP member issues should keep an ancillary information character only. History and current hearing practice were discussed for reconsideration in view of the list of participants vis-à-vis the existing list of Interested parties. Recognised IPs may be reminded on their possibility to ask for a hearing if considered useful for specific purposes.

5.6.2. Requirements for essential oils - Request for revision of HMPC Quality Q&A

Action: for discussion
Documents: e-mails dated 24/11/2014, 16/04/2015 by C. Valder, Frey + Lau GmbH, comments

Outcome:
Current Q&A was considered as valid view of the HMPC without need to change before further coordination with Ph. Eur. and new outcomes as regards requirements for essential oils.

Q DG Chair in liaison with HMPC Chair and secretariat to respond to the requesting company.

The HMPC did not object to the view of the Q DG Chair that issues addressed were not necessarily caused by or even found in the existing HMPC Q&A as regards essential oils. A revision or removal was therefore not found appropriate at this point in time.

5.7. HMPC work plan

5.7.1. HMPC work programme 2012 – 2015

Action: for information

5.7.2. HMPC work plan 2015

Action: for discussion

- Monograph and List entry systematic revision – long term strategy

Report: I. Chinou (W. Knöss, M. Delbo)

- Forward planning and prioritisation – identification of herbal substances requiring European standards as basis for national assessments

Report: B. Kroes (W. Dymowski, I. Chinou, H. Neef, R. Länger)

- Regulatory guidance for non-European interested parties and harmonisation of assessment practice for herbal substances of non-European origin

Report: W. Knöss (E. v. Galen)

- European and International collaboration

Report: W. Knöss (E. v. Galen, S. Bager, M. Delbo, A.P. Martins, H. Neef)

Outcome:
HMPC noted status of implementation of work plan topics and monitoring by EMA.

The HMPC Chair went shortly through topics of the adopted public HMPC work plan 2015 as regards current progress. Given the half year status (3 out of 6 meetings) the regular monitoring at HMPC and subgroup meetings was recommended in view of the EMA internal reporting and preparation of future work plans.

Project leaders and members involved to send comments/ updates if available to the HMPC secretariat in preparation of the next HMPC agenda.

5.8. Planning and reporting

5.8.1. EU Medicines Agencies Network Strategy 2020

Report: HMPC Chair
Action: for discussion
Documents: EU Medicines Agencies Network Strategy 2020, (EMA/MB/151414/2015), EMA press release 31/03/2015, HMPC Chair comments dated 24/02/2015

Outcome:
HMPC welcomed introduction of the strategy and opportunity for comments.

Further comment to be submitted to the HMPC secretariat by 15 June 2015 using the published template.

HMPC secretariat in liaison with HMPC Chair to collect comments and submit before end of June.

Following an introduction including approach and document history, key features and focus of the four themes (human health, animal health and human health in relation to veterinary medicines, optimising the operation of the network and global regulatory environment) were presented. The HMPC was informed on the next steps and invited to comment. The HMPC Chair welcomed the opportunity previously given to the Chairs and now to the Committees to comment in parallel with the public consultation. Although herbal medicines play only a minor role within the overall system, the importance of the international collaboration (theme 4) was highlighted in view of the globally leading EU standards in the herbal medicines area. Questions were answered as regards key performance indicators (to be defined more in detail vis-à-vis specific actions reflected in multiannual work programmes) and the importance of specific borderline issues such as with food supplements (appropriateness to include in a high level medicines strategy paper to be scrutinised).

5.9. Legislation and regulatory affairs

None

6. Any other business

6.1. Topics for discussion

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 9-10 March 2015

Overview of expertise of members HMPC and subgroups

Meeting report from HMPC meeting held on 9-10 March 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

TOC of MLWP meeting held on 10-12 March meeting 2015

Draft agenda of MLWP meeting to be held on 5-7 May 2015

6.2.3. Other

Rapid Alert - Type I - W.-W. Les Herbes Pures J.B. Ltée

Coordination with Kew Gardens: e-mail W. Dymowski dated 10/04/2015

List of participants

Including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 4-5 May 2015 meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Werner Knöss	Chair	Germany	No interests declared	
Reinhard Länger	Member	Austria	No interests declared	
Heidi Neef	Member	Belgium	No interests declared	
Elena Mustakerova	Member	Bulgaria	No interests declared	
Ivan Kosalec	Member	Croatia	No restrictions applicable to this meeting	
Maria Stavrou	Member	Cyprus	No interests declared	
Marie Heroutova	Member	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 Le	Member	France	No interests declared	
Jacqueline Wiesner	Member	Germany	No interests declared	
Ioanna Chinou	Member	Greece	No interests declared	
Zsuzsanna Bíróné Sándor	Member	Hungary	No interests declared	
Marisa Delbò	Member (Vice-Chair)	Italy	No interests declared	
Baiba Jansone	Alternate *Replacing HMPC member*	Latvia	No interests declared	
Artūras Kažemekaitis	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	
Gro Anita Fossum	Alternate	Norway	No interests declared	
Wojciech Dymowski	Member	Poland	No interests declared	
Ana Paula Martins	Member	Portugal	No interests declared	
Carmen Purdel	Alternate *Replacing HMPC member*	Romania	No interests declared	
Gabriela Duchajová	Member	Slovakia	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Barbara Razinger	Member	Slovenia	No interests declared	
Adela Núñez Velázquez	Member	Spain	No interests declared	
Per Claeson	Member	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	
Olavi Pelkonen	Co-opted member	Finland	No restrictions applicable to this meeting	
Maria Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared	
Melanie Bald	Counseil de l'Europe *via TC*		No interests declared	

* Experts were only evaluated against the topic(s) they have been invited to talk about.