20 November 2018
EMA/HMPC/813680/2018 Corr.[1]
Inspections, Human Medicines Pharmacovigilance & Committees Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 24-25 September 2018

Chair: Marisa Delbò Vice-Chair: Emiel Van Galen

24 September 2018, 14:00 – 19:00, 2F

25 September 2018, 09:00 – 13:00, 2F

(AESGP hearing at MLWP: 25 September 2018, 14.00 – 16.00, 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 the minutes is considered commercially confidential or sensitive and therefore not disclosed.

Of note, the 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).

[1] Correction in participant list

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1. Introduction

1.1. Welcome and declarations of interest of members, alternates and experts

In accordance with the Agency's policy on handling of declarations of interests of scientific committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and based on the topics in the agenda of the current meeting, the Committee Secretariat announced that no restriction in the involvement of meeting participants in upcoming discussions was identified.

Participants in this meeting were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. No new or additional interests or restrictions were declared.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure and as included in the list of participants. All decisions taken at this meeting were made in the presence of a quorum of members (i.e. 22 or more members were present in the room).

End of membership (IE): Rachel Cox (alternate); End of mandate: 03 August 2018

The Chair welcomed two participating experts (Dr. Nesari, Dr Joshi) from the Indian ministry of AYUSH (Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy).

1.2. Adoption of agenda

HMPC agenda for 24-25 September 2018

Time schedule for 24-25 September 2018

Outcome:
Agenda adopted.

Time schedule endorsed.

1.3. Adoption of the minutes

HMPC minutes for 23-24 July 2018

Outcome:
Minutes adopted.

It was clarified that individual presence during voting for monographs/ list entries is always recorded but not reflected in detail in the minutes.

Standard policy for all Committees regarding voting, publication of opinions and divergent positions as well as information given in the minutes will be continued without changes.

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

2.1.1. Report from the MLWP June 2018 meeting

Report: MLWP Chair/MLWP Vice-Chair
Action: for information
Document: Draft minutes for the MLWP meeting on 05-07 June 2018

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

2.2.1. Monograph on Curcumae longae rhizoma and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 00/132

Outcome:
Final revised monograph with changes in section 2.3 and supporting documents adopted by consensus. The Norwegian delegate was not present during the meeting.

Before publication Rapporteur to provide the set of full text references supporting the revised assessment in line with the LoR.

Final changes were presented and additional changed introduced in section 2 of the assessment report.

2.2.2. Monograph on Sennae folium and supporting documents

Action: for adoption
Documents: MO, AR, LoR, OoC; References: 173/217

Outcome:
Final revised monograph and supporting documents adopted by consensus. The Norwegian delegate was not present during the meeting.

Before publication Rapporteur to provide the set of full text references supporting the revised assessment in line with the LoR.

2.2.3. Monograph on Sennae fructus and supporting documents

Action: for adoption
Documents: MO, AR, LoR, OoC; References: 173/217

Outcome:
Final revised monograph and supporting documents adopted by consensus. The Norwegian delegate was not present during the meeting.

Before publication Rapporteur to provide the set of full text references supporting the revised assessment in line with the LoR.

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

None

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

None

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

None

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

None

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

2.7.1. Monograph on Cynarae folium and supporting documents

Action: for adoption
Documents: MO, AR, LoR; Email correspondence

Outcome:
Adoption postponed.

It was agreed that final inconsistencies between assessment report and monograph sections 2/4.2 need to be clarified and endorsed at the next meeting before publication.

3. Referral procedures

None

4. Guidelines and guidance documents

4.1. Non-clinical/clinical safety and efficacy and multidisciplinary

4.1.1. Guideline on non-clinical documentation in applications for marketing authorisation/registration of well-established and traditional herbal medicinal products (EMEA/HMPC/32116/2005 Rev.1)

Action: for adoption
Documents: Revised Guideline, OoC

Outcome:
Final revised guideline was adopted by consensus.

No comments had been received from CMDh and the document had been agreed by the Safety Working Party.

The secretariat will publish the final revised guideline and the overview of comments received during public consultation on the EMA website.

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

Action: for adoption
Documents: Draft revised PS, OoC; Comments from SE; SWP subgroup comments; Presentation

Outcome:

Postponed to the HMPC November meeting.

4.2. Quality

4.2.1. Q&A on elemental impurities - evaluation in herbal medicinal products

Report: HMPC Chair
Action: for adoption
Document: Draft Q&A

Outcome:
After discussion the need for some amendments was agreed before inclusion to HMPC quality Q&A document EMA/HMPC/41500/2010. HMPC agreed on a transitory clarification via Q&A before the topic can be reflected in herbal quality and specification guidelines that are currently under revision.

HMPC Chair will modify Q&A and provide to the secretariat for adoption by written procedure by **31 October 2018**.

HMPC discussed the scope of the ICH Q3D guideline and consequences and measures for products excluded such as veterinary products and herbal products. It was emphasised to distinguish between requirements for risk assessment based on GMP principles and dossier requirements for specific products such as (traditional) herbal MPs. The transitional Q&A should clarify expectations because of the safety relevance before it can be considered in the quality guidelines under revision.

4.3. Regulatory / Procedural

4.3.1. Template for information exchange for the preparation of the assessment report supporting the establishment of European Union monographs and European Union list entries (EMA/HMPC/137093/2006 rev.2)

Report: ORGAM DG Chair
Action: for adoption
Document: Draft revised template

Outcome:

Draft revised template was adopted by consensus.

HMPC noted the scope for single active substances, while ORGAM DG intends to develop a second template specifically applicable for combinations.

In the revision of the template a clarification was added regarding appropriate information to the Rapporteur on applicable data protection for relevant products when data for use in monograph and list entry establishment are provided.

The secretariat will publish the revised template on the EMA website for use by Rapporteurs for new assessments and monograph reviews/revisions.

4.4. Report on HMPC Drafting Groups activities

4.4.1. Quality DG

Report: HMPC Chair

- Meeting report from Q DG virtual meeting held on 06 Sep 2018
  Action: for adoption
  Document: Meeting report

Outcome:
Meeting report was adopted.

The progress with drafting activities (see also 4.2.1, 5.3.2 and 5.4.1) was reported including items in coordination with the European Commission, EDQM and also with the Quality WP such as herbal-specific comments on a planned Q&A 'How to use a CEP'.

HMPC noted that because of the Agency's move no Q DG meetings will take place during BCP phase 3 and development of guidelines is temporarily suspended. Temporary suspensions and scaling back of activities is currently scheduled to last until 30 June 2019. EMA will review this in April 2019, once it has moved to its temporary building in Amsterdam.

4.4.2. ORGAM DG

Report: ORGAM DG Chair

- Meeting report from ORGAM DG virtual meeting held on 04 Sep 2018
  Action: for adoption
  Document: Meeting report

Outcome:
Meeting report was adopted.

The ORGAM DG Chair reported on the progress with regard to three procedural topics (see also 4.3.1) including a revision of the 'Procedure on management of proposals submitted by interested parties' (EMA/HMPC/328575/2007).

HMPC noted that because of the Agency's move no ORGAM DG meetings will take place during BCP phase 3 and development of guidance is temporarily suspended. Temporary suspensions and scaling back of activities is currently scheduled to last until 30 June 2019. EMA will review this in April 2019, once it has moved to its temporary building in Amsterdam.

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Strategic Review and Learning Meetings

- Austria Presidency meeting – Vienna, 15-17 Oct 2018
  Action: for discussion
  Document: Revised Draft Agenda; Invitation; Practical information
- SRLM meetings in 2019
  Action: for discussion
  Document: Email correspondence

  Outcome:
  HMPC noted updates on content and practical information given by the Austrian member and welcomed selection of important topics for the SRLM.

  For 2019, it was announced that the meeting under the Romanian presidency is scheduled for 4/5 April 2019, while the Finnish Agency decided not to organise a SRLM for the HMPC during the second half of 2019 and will inquire for a voluntary host at HMA.

5.2. Coordination with EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair
Action: for information
Documents: Agenda 10 September 2018

Outcome:
HMPC noted information given by HMPC Chair with major emphasis on the BCP phase 3 impact for all working parties /groups (see 5.8.1) and Committee work plans (see 5.7.2) as well as the Regulatory Science Engagement Plan to 2025 (see 6.1.4).

The impact of BCP phase 3 measures, i.e. temporary suspension and scaling back of activities in six areas (including guideline development, working party operations) - currently scheduled to last until 30 June 2019 - was discussed with a view on HMPC and subgroup activities and meeting schedules. EMA will review this in April 2019, once it has moved to its temporary building in Amsterdam. It was referred to the SRLM meeting agenda in October to discuss possible adaptations in order to maintain core operations of the Committee according to legal mandate without input of subgroups during that period.

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

5.3.1. Coordination with PDCO/PRAC

- Discussion paper on necessary data for contraindication for use in children
  Action: for discussion
  Document: Draft Discussion paper

Outcome:
HMPC discussed background, title, scope, intention and given examples of the first draft document. Rapporteur to modify the document according to the discussion.

Members to provide comments to the Rapporteur by **30 November 2018** for re-discussion at the HMPC January 2019 meeting.

The Rapporteur had started from the most common area 'cough and cold' listing relevant monographs and assessments outcomes according to data availability and safety considerations. Given the previous debates and interaction with interested parties (Hedera) as well as the safety working party (estragole, PAs) members discussed the best possible approach choosing either a specific area or a general scope on consistent principles to be applied. The necessary distinction between well-established and traditional use, of safety vs efficacy considerations as well as the relevance of usage data was emphasised in view of the specific herbal legislation and data situation with usually insufficient data available. It was agreed that in the initial phase the discussion paper will cover the age limitation of use of cough and cold herbal medicinal products in children.

5.3.2. Coordination with QWP

- Herbal specific addition to Q&A ' How to use a CEP'
  Action: for adoption
  Document: Comment on Draft Q&A

Outcome:
Herbal specific addition to the QWP Q&A was endorsed by the HMPC.

HMPC noted background of the intended QWP Q&A on 'How to use a CEP' complementing an EDQM document 'How to read a CEP' as well as prolonged timelines due to temporary suspension of guidance document development during BCP phase 3.

5.3.3. Information for the package leaflet regarding ethanol used as an excipient in medicinal products for human use

Action: for discussion
Document: Report (Annex to excipient guideline EMA/CHMP/43486/2018)

Outcome:
HMPC noted changes in the document and anticipated timelines for final adoption, publication and coming into effect. Clarifications were provided on specific questions relevant for herbal products.

HMPC noted also relevance for monographs (section 4.4 - reference to excipients guideline for herbal preparations containing ethanol) and specific products' active substances (e.g. tinctures/liquid extracts).

The history and main steps of the Annex to the EC GL on 'Excipients in the labelling and package leaflet of medicinal products for human use' were presented as well as main format/content changes regarding ethanol between draft and final version. Some examples were shown. Members discussed more stringent policies in some MSs (e.g. level zero policy for pregnant women in France), difficulties for products with only trace amounts of solvent residues (such as some homeopathics) and most understandable units and calculation for health care professionals and patients. HMPC noted that after the next steps (CHMP

adoption, NTA endorsement, QRD translations before publication) a transition period for implementation of 3 years from the date of publication of the revised Annex will be given to MAHs.

5.4. Cooperation within the EU regulatory network

5.4.1. Coordination with the European Commission

- Clarification of classification on Saccharomyces cerevisiae CBS 5926
  Report: HMPC Chair
  Action: for discussion
  Documents: EMA letter to EC, EC response, Draft MO, draft LE, draft AR, draft LOR

  Outcome:
  Postponed to the November HMPC meeting

- AESGP proposal on the simplification of variations specific to herbal medicinal product
  Report: HMPC Chair
  Action: for discussion
  Document: AESGP proposal on the simplification of variations specific to herbal medicinal product

  Outcome:
  Partially modified QDG view on four items was endorsed for submission to the European Commission.

5.4.2. Coordination with European Pharmacopoeia

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

  Outcome:
  HMPC noted updates given by the EDQM representative on 13B and PA expert group activities and monographs adopted or in preparation at the Ph. Eur. commission.

  No immediate impact for HMPC monographs (such as Crataegus) was detected.

  In view of the necessary update of guidance on PAs (see 5.7.1) HMPC inquired about the progress with analytical method development and emphasised the importance of the availability of such method for MAHs and NCAs.

5.4.3. Understanding the training needs of NCA assessors involved in the work of the HMPC: Priority needs and plans for training 2018 – 2020

Action: for discussion
Document: Presentation

Outcome:
HMPC noted the presentation given.

It was agreed to discuss the topic first at the October HMPC SRLM in Vienna, before coming back to identify specific sponsors, training needs, potential curriculum format and next steps to be taken.

The HMPC got an introduction with information on the EU Network Training Centre, training activities 2015 – 2018, types of courses available at the EU NTC Learning Management System (LMS), EU NTC curricula, key roles to support the development of curricula, the Committee role as well as considerations in identification of training needs. Different examples form other Committees and WPs were presented. With the support of 2-3 Committee members next an action plan should be set up in order to develop and deliver training in identified priority areas and to focus on the development of reusable training material.

5.5. Cooperation with International Regulators

5.5.1. AYUSH information on Indian medicinal plants

Report: M Nesari, V K Joshi
Action: for discussion
Document: Presentation

Outcome:
HMPC welcomed the experts as a good opportunity to foster mutual understanding and noted the presentation given by the AYUSH delegates including proposals for future collaboration. It was recommended to primarily focus on specific discussions at MLWP (4 Indian substances) on data requirements for monographs establishment.

The HMPC heard a presentation on 'Quality standards of Ayurvedic Medicines- Integration of Ayurvedic principles with modern science and regulatory provisions'. The presentation elaborated on history, experience and rationale of plants used, principles of drug action in traditional Indian systems of medicine, the holistic approach of Ayurveda, factors affecting the quality, plant raw material controls, the Ayurvedic Pharmacopoeia of India, drug regulations as well as nomenclature and categories of medicines according to dosage forms.

AYUSH activities with individual EU countries and with the EC were presented and proposals made for a continued dialogue. The HMPC Chair welcomed the information and proposals long term, referring to specific challenges in 2019 due to the EMA relocation. She acknowledged quality control as essential for herbal medicines advocating the interaction with the Ph. Eur. In contrast, for the HMPC with its focus on safety and plausible traditional use other data are usually missing in order to establish monographs such as on specified strength/posology of products used in the EU.

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

5.6.1. AESGP – hearing at MLWP September 2018

Report: MLWP Chair
Action: for discussion
Document: Draft Agenda with List of participants

Outcome:

HMPC noted draft agenda and the HMPC Chairs' view reporting also the recommendations from the QDG Chair with regard to topics proposed.

5.7. Work plan

5.7.1. HMPC work plan 2018

Report: HMPC Chair
Action: for information
Document: Work plan 2018 – current status September 2018

- 1.3.3. Activity area: Coordination on safety assessments of herbal constituents
  - Public statement on Contamination of herbal medicinal products/traditional herbal medicinal products with pyrrolizidine alkaloids (PAs) (EMA/HMPC/328782/2016)

Action: for discussion
Documents: Presentation

Outcome:

Postponed to the HMPC November meeting

5.7.2. HMPC work plan 2019

Report: HMPC Chair
Action: for discussion
Document: Draft Work plan 2019; Email correspondence

Outcome:
HMPC noted impact of BCP phase 3 on working parties/groups and guideline development.

Topics on the HMPC work plan were limited to core business of the Committee and few safety relevant guidelines. HMPC subgroup meetings and guideline development are during BCP phase 3 temporarily suspended until June 2019 (see also 5.8.1).

Draft work plan (incl. Annex 1 - monographs and Annex 2 - guidance) will be distributed for comments and Rapporteur confirmation for activities in 2019 for possible adoption in November 2019.

5.8. Planning and reporting

5.8.1. HMPC meeting dates 2019 – BCP phase 3 impact

Report: HMPC Chair
Action: for discussion
Document: Presentation

Outcome:
HMPC noted information given.

HMPC subgroup activities are temporarily suspended until June 2019. Exact meeting dates will be provided to the members in the coming weeks.

HMPC heard a report on the business continuity measures taken including objective, categorisation of activities, phases and the specific challenges during the 1st and 2nd half of 2019 in view of the double relocation. Temporary suspensions and scaling back of activities is currently scheduled to last until 30 June 2019. EMA will review this in April 2019, once it has moved to its temporary building in Amsterdam. Thereafter it is aimed for gradual restoration of previously suspended activities.

HMPC noted that as a consequence, in addition to previously announced changes in the HMPC/MLWP meeting schedule, during phase 3 and upcoming phase 4 no meetings will take place for MLWP, Quality DG and ORGAM DG. Instead HMPC meetings will be prolonged from 1 to 2.5 days when no MLWP takes place in order to uphold the core business of monograph/list entry development according to HMPC mandate. The HMPC meeting beginning of March cannot take place because of the move week without available facilities neither in London nor Amsterdam.

Post meeting note:
As HMPC meeting schedule 2019 was confirmed: 14-16 Jan (Mon 2pm – Wed 4pm; ***London****), 13-15 May (Mon 2pm– Wed 4pm,* ***Amsterdam Spark building****), 8-10 Jul (Mon 2 – Wed 4pm), 23-24 Sep 2019 (Mon 2pm – Tue 1pm;* ***MLWP 24-26 Sep - Tue 2pm - Thu 1pm****); 18-20 Nov (Mon 2pm – Wed 4pm)*

5.9. Legislation and regulatory affairs

5.9.1. WEU/Bibliographic application regarding Art. 10a Dir. 2001/83/EC for HMPs – Reference to other products

Report: HMPC Chair
Action: for discussion
Documents: Comments by EUCOPE; Draft response to EUCOPE; Guideline on the assessment of clinical safety and efficacy; Regulatory Q&A

Outcome:

One remaining issue in the modified answer by the Rapporteur was detected. EMA RA/legal support to suggest minor addition for finalisation at the HMPC November meeting.

One part of the request was considered not yet sufficiently addressed in the draft response.

6. Any other business

6.1. Topics for discussion

6.1.1. Management of references for the review and revision of EU herbal monographs and EU List entries

Action: for discussion
Document: Presentation

Outcome:
HMPC noted agreed practice and specific issues for monograph reviews/revisions. Detailed discussion and agreement was given to the MLWP to be reported at the November HMPC meeting.

6.1.2. EU Telematics strategy 2020-2025

Action: for discussion
Documents: Presentation; Concept Paper

Outcome:
HMPC noted the presentation on background, roadmap and consultation regarding the Telematics strategy 2020-2025.
HMPC members to provide comments on the concept paper from a herbal perspective with particular focus on the tables describing how network business activities will need to change and improve with support of Telematics.

6.1.3. New PhV information on herbal substances relevant for HMPC assessment

Action: for discussion
Document: Presentation

Outcome:
Postponed

6.1.4. Regulatory Science Engagement Plan to 2025

Action: for discussion
Document: Presentation

Outcome:
HMPC noted the presentation regarding the Regulatory Science Engagement Plan and the planned workshop in October.

The Committee was informed on previous steps, fiches, baseline report, structure of the strategy, main vision, priority areas, strategic goals and core recommendations. Next steps were indicated including the stakeholder outreach starting with a workshop on 24 October.

It was acknowledged that the traditional herbal area is usually not associated with innovations and noted that no herbal specific topics are currently included in the human strategy while in comparison the veterinary area had developed its own strategy. Some examples of innovative developments in the herbal area were discussed such as modern analytical methods, where so far industry did not want to engage. Another example was the interaction with health care professionals and universities that do incorporate complementary medicines into innovative clinical approaches, although not linked with modern pharmaceutical product development. The HMPC was encouraged to rethink their vision and identify most important research questions and areas where herbal regulators should be prepared for but also stimulate proactively the discussion.

6.1.5. Workshop on Pyrrolizidine Alkaloids (PAs)

Action: for discussion
Document: Agenda

Outcome:
Postponed

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 23-24 July 2018

Overview of expertise of members HMPC and subgroups

Meeting report from HMPC meeting held on 23-24 July 2018

Overview of status of HMPC assessment work – priority list

Inventory of herbal substances for assessment work

Abbreviations in HMPC agendas/minutes

Common names of herbal substances in all languages

6.2.2. MLWP

- Overview of status of HMPC/MLWP assessment work

6.2.3. ARSP

- English template

6.2.4. Other

- Article on NICE guideline; draft NICE guideline- Cough (acute): antimicrobial prescribing
- EU herbal monographs, list entries and public statements post adoption
  - Allii sativi bulbus: Scientific literature compilation and open questions; post adoption delays (MO, AR, LoR, OoC, email correspondence)
  - Pistacia lentiscus, resinum (mastic) (MO, AR, LoR, email correspondence)

6.2.5. Feedback on national experiences with HMPC monographs and guidelines

- draft template
- summary feedback

6.2.6. Annual Meeting of International Regulatory Cooperation for Herbal Medicines (IRCH), WHO, 07-09 December 2018

Report: HMPC Chair
Document: Email correspondence

6.2.7. CZ request regarding classification of a product containing β-glucan isolated from *Pleurotus ostreatus*

Document: Email correspondence

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 25-25 September 2018 meeting.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Marisa Delbò	Chair	Italy	No interests declared	
Reinhard Länger	Member	Austria	No interests declared	
Iliana Ionkova	Member	Bulgaria	No interests declared	
Ivan Kosalec	Member	Croatia	No restrictions applicable to this meeting	
Darko Trumbetic	Alternate	Croatia	No interests declared	
Maria Stavrou	Member	Cyprus	No interests declared	
Marie Heroutova	Member	Czech Republic	No interests declared	
Martina Holenkova	Alternate	Czech Republic	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	
Alessandro Assisi	Member	Italy	No interests declared	
Evita Skukauska	Member	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	
Els Ensink	Expert	Netherlands	No interests declared	
Wojciech Dymowski	Member	Poland	No interests declared	
Ana Paula Martins	Member	Portugal	No interests declared	
Raluca Iavorszky	Member	Romania	No interests declared	
Miroslava Petrikova	Member	Slovakia	No interests declared	
Samo Kreft	Member	Slovenia	No restrictions applicable to this meeting	
Adela Núñez Velázquez	Member	Spain	No interests declared	
Karin Erika Svedlund	Member	Sweden	No interests declared	
Ewa Balkowiec Iskra	Co-opted member	Poland	No interests declared	
Silvia Girotto	Co-opted member	Italy	No interests declared	
Gert Laekeman	Co-opted member	Belgium	No interests declared	
Heidi Foth	Co-opted member	Germany	No interests declared	

Maria Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared	
Klaus Reh	QWP chair - via Adobe TC	Germany	No interests declared	
Vinod Kumar Joshi	Expert	India	No interests declared	
Manoj Nesari	Expert	India	No interests declared	
Meeting run with support from relevant EMA staff				

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