08 July 2020
EMA/HMPC/290980/2020
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 4-6 May 2020

Chair: E. van Galen, Vice-Chair: E. Svedlund

4 May 2020, 10:00 – 17:00, Remote virtual meeting

5 May 2020, 09:00 – 17:00, Remote virtual meeting

6 May 2020, 09:00 – 15:00, Remote virtual meeting

Disclaimers

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

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

Note on access to documents

Some documents mentioned in 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

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 table of decisions 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 with regard to topics on the agenda.

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.

New nomination:

Swap of roles:

- CZ, Marketa Prihodova (member) as of 10 March 2020
- CZ, Marie Heroutova (alternate) as of 10 March 2020
- NL, Burt Kroes (member) as of 29 April 2020

End of membership:

- IT, Alessandro Assisi (member) as of 8 March 2020

1.2. Adoption of agenda

The agenda for 4-6 May 2020 was adopted with no amendments.

Time schedule for 4-6 May 2020 was endorsed.

1.3. Adoption of the minutes

The minutes for 2-4 March 2020 were adopted with minor changes in sections 5.4.2 and 6.5.4. and will be published on the EMA website.

2. EU herbal monographs and list entries for adoption

2.1. Status of HMPC/MLWP activities

2.1.1. Overview of HMPC/MLWP assessment work including the Rapporteurship distribution – Status in May 2020

Report: HMPC Chair
Action: for discussion

Document: Overview

Outcome:
HMPC noted status of assessment work.

For substances on the work programme Rapporteurs informed on the likely availability of documents for the next meetings.

In case of postponement of topics scheduled for the HMPC July meeting Rapporteurs were asked to inform secretariat and Chair before the first pre-mail (by 22 June 2020) to allow best adaptation of agenda and time-schedule.

2.1.2. Appointment of Rapporteurs and Peer-reviewers

New assessments
Salviae mitiorrhizae radix et rhizoma – New Peer reviewer

Reviews
Centaurii herba – New Rapporteur
Curcumae longae rhizoma – New Rapporteur
Curcumae xanthorrhizae rhizoma – New Rapporteur

Revisions
Bursae pastoris herba – New Peer reviewer

Outcome:
HMPC endorsed re-appointments according to change in NL membership.

Rapporteurs /peer reviewers were invited to reconsider activities/workload for this year and possibly offer some assessments such as reviews to new members/alternates to make best possible use of resources and spread the Rapporteur distributions wider across EU member states.

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

2.2.1. Monograph on Rhamni purshianae cortex and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 51/41

Outcome:
Final revised EU herbal monograph and supporting documents adopted by majority vote (23 out of 24). The Norwegian delegate expressed a favourable position.

Divergent opinion: Wojciech Dymowski

Consistency and differences in the posology section between various hydroxyanthracene laxatives (HAD) were discussed (specified maximum HAD levels for herbal tea preparations). Also the diverse spectrum in the HAD composition and subsequent possible limitations in comparability of clinical effects was raised.

The divergent position referred to the limited bibliographic clinical evidence specifically available for Cascara alone in view of requirements for well-established medicinal use according to Art. 10, (a), (ii) of Directive 2001/83/EU.

2.2.2. Monograph on Rhei radix and supporting documents

Action: for adoption
Documents: MO, AR, LoR, OoC; References: 55/62

Outcome:
Final revised EU herbal monograph and supporting documents adopted by majority vote (23 out of 24). The Norwegian delegate expressed a favourable position.

Divergent opinion: Wojciech Dymowski

Rapporteur to provide missing references before publication of the package.

Members discussed comments received and background information regarding a combination product for external use and modified slightly corresponding information in AR and Overview of comments without direct impact on the monograph.

The divergent opinion referred to the limited clinical evidence specifically available for Rhei radix and possible limitations in analogies to other laxatives referred to (Senna, Aloe) since composition and types of HAD are different.

2.2.3. Monograph on Tanaceti parthenii herba and supporting documents

Action: for discussion
Documents: MO, AR, LoR; References: 0/108; Question to patient representatives, comments from patients

Outcome:
Adoption postponed.

HMPC discussed patient representative comments on specific question by HMPC regarding the posology.

Clarification regarding Rapporteur and final wording of the monograph before final adoption expected for the HMPC July meeting.

When discussing patients' comments for clarity of the posology and possible bridging of the old lower posology with the new higher posology several members confirmed their concerns regarding the higher posology as included in the published draft monograph.

2.2.4. Monograph on Thymi aetheroleum and supporting documents - postponed

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

2.4.1. Monograph on Filipendulae ulmariae herba and supporting documents

Action: for adoption
Documents: Review report; References: 15/15

Outcome:
HMPC agreed with Rapporteur's position that no monograph revision is needed because no new data of relevance were detected that would change the content of the monograph.

The HMPC decided by consensus not to revise the monograph, assessment report and list of references on Filipendulae ulmariae herba.

The review report was adopted and will be published as addendum to the existing assessment report on the EMA website.

HMPC noted limited new data, some positive experience from the check for PhV data and agreed to focus the final review report to what is new compared to the first assessment without copying information from the already existing published assessment report.

2.4.2. Monograph on Filipendulae ulmariae flos and supporting documents

Action: for adoption
Documents: Review report; References: 0/3

Outcome:
HMPC agreed with Rapporteur's position that no monograph revision is needed because no new data of relevance were detected that would change the content of the monograph.

The HMPC decided by consensus not to revise the monograph, assessment report and list of references on Filipendulae ulmariae flos.

The review report was adopted and will be published as addendum to the existing assessment report on the EMA website.
Rapporteur to provide missing references before publication of the package.

HMPC noted limited new data, some positive experience from the check for PhV data and agreed to focus the final review report to what is new compared to the first assessment without copying information from the already existing published assessment report.

2.4.3. Monograph on Pelargonii radix and supporting documents

Action: for adoption
Documents: Review report; References: 0/6

Outcome:
HMPC agreed with the Rapporteur's position that there is new information available that could change the content of the monograph. In addition, the previous revision focused solely on re-evaluation of clinical data vis-a-vis the bronchitis severity score but did not include all new data available since the first assessment.

The review report -still requiring editorial amendments- was adopted and the revision is being initiated with a Call for data and new market overview.

New data include clinical safety, clinical data with children and new information on some inconsistencies in the declaration of the active substance as well as other monograph sections compared to marketed products partially revealed during the PSUSA assessment and by Eudravigilance database entries.

2.4.4. Monograph on Sabalis serrulatae fructus and supporting documents

Action: for adoption
Documents: Review report, Readers guidance; References: 15/1

Outcome:
The HMPC decided not to revise the monograph, assessment report and list of references on Sabalis serrulatae fructus at present because a more comprehensive overview of newly available public data is necessary before a decision on revision can be made.

Considering that the first assessment was finalised in 2015, HMPC decided to start the periodic review procedure, publish a Call for data and initiate a new market overview.

A decision on the revision will be taken based on all new information complementing those specifically submitted regarding CO2 extracts.

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

2.6.1. Monograph on Menyanthes trifoliata folium and supporting documents

Action: for adoption
Documents: MO, AR, LoR, Readers guidance; References: 46/74

Outcome:
Adoption postponed.

Changes introduced in the monograph and AR. Further changes requested with regard to the posology in monograph section 4.2 and the corresponding alignment with the information given in the AR.

Czech, Greek and Romanian members volunteered to support the Rapporteur finalising the documents for possible adoption for release for public consultation at the HMPC July meeting.

Parts of the posology section were re-discussed in terms of plausibility and practical usage as well as in terms of presentation in the monograph using footnotes for details under discussion. Simplification was advocated so that companies can make use of the monograph.

2.6.2. Monograph on Aloysiae folium and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 0/31

Outcome:
Draft EU herbal monograph and supporting documents adopted with several changes by consensus for 3 months public consultation.

Adaptations were performed in the monograph to align with the evidence for use presented in the AR. Changes were made in preparations included, regarding use in children/adolescents and in the posology.

2.6.3. Monograph on Species amarae and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 10/21

Outcome:
Draft EU herbal monograph and supporting documents adopted by majority for 3 months public consultation.

HMPC endorsed the release for public consultation, although not all substances do have a single substance monograph already published as reference (see 2.6.1). The draft monograph on Menyanthes is in preparation and expected to be published in July 2020.

Some members raised concerns about the classification, title and choice of substance preparations included in the monograph because not 100% matching the pharmacognostic concept of bitter substances as appetite stimulants. Mentioned were different compositions and possibly function in mixtures with overlaps between Species amararae, Species aromaticae and Species digestivae. A majority however considered some simplification and flexibility acceptable since all substances included are traditionally used in the same therapeutic indication - single or combined.

2.6.4. Monograph on Species sedativae and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 36/22

Outcome:
Draft EU herbal monograph and supporting documents adopted by majority for 3 months public consultation.

The presentation of possible combinations in the monograph (generally possible combination partners versus specific figures for portions in combinations) was discussed and may be adapted to previous combination monographs (specific numbers in AR only). A majority agreed to allow certain flexibility within reasonable ranges even though not each quantitatively slightly deviating combination may have an individual documented evidence.

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

None

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 contamination of herbal medicinal products/traditional herbal medicinal products with pyrrolizidine alkaloids (EMA/HMPC/328782/2016)

Action: for discussion
Document: see 4.1.2.

Outcome:
See 4.1.2.

4.1.2. Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) (EMA/HMPC/893108/2011)

Action: for discussion
Document: Revised combined public statement

Outcome:
The HMPC agreed to merge public statement EMA/HMPC/328782/2016 and EMA/HMPC/893108/2011 into one document. Relevant aspects of the more recent contamination issue are being included into the overarching PS EMA/HMPC/893108/2011.

Members were requested to submit their comments to the Rapporteur before 26 June 2020 to allow the Rapporteur to finalise the document for possible adoption for public consultation at the HMPC July meeting.

Toxicologists' views were discussed and should be considered. Independent from the model use it was considered paramount to agree on limit values from a safety and practicality perspective that are useful as general guidance for industry. However, some details, e.g. number of decimals after the comma that are of practically limited relevance were considered useful from a toxicology perspective.

4.2. Quality

4.2.1. Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/162241/2005 Rev. 3)

Action: for discussion
Documents: Revised Guideline, OoC

Outcome:
Postponed.

4.2.2. Guideline on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/201116/2005 Rev. 3)

Action: for discussion
Documents: Revised Guideline, OoC

Outcome:
HMPC and invited experts discussed comments received during public consultation. The Rapporteur was asked to modify the OoC according to the discussion and start implementation in the guideline for possible discussion at the HMPC July meeting.

For clarification of specifically challenging details quality experts may liaise before the HMPC July meeting.

For the majority of questions the direction of response was agreed as starting point to finalise the GL. Remaining questions and more controversial items will be discussed in the next phase.

4.3. Regulatory / Procedural

None

4.4. Report on HMPC Drafting Groups activities

4.4.1. Quality DG

None

4.4.2. ORGAM DG

None

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Revised CxMP Rules of Procedure for emergency situations

Action: for adoption
Documents: Revised Rules of Procedure, Comparative table

Outcome:
The revised HMPC rules of procedures as proposed and adopted by the EMA Management Board (MB) were adopted by consensus.

The MB at its meeting on 19 March 2020 adopted amendments to the existing Rules of Procedure of EMA's scientific committees and MB. These amendments are required to enable those bodies to continue their workings in a virtual emergency setting, as well as to ensure the validity of the various output decisions that each committee will adopt during remote meetings. A change is also introduced in the quorum required for adoption of scientific opinions or recommendations in case of an emergency situation. To add flexibility to the system, irrespective of an emergency situation, the possibility is introduced to give a proxy vote to another member or to the alternate of a member who is present at the relevant meeting of the body concerned.

5.1.2. Election of HMPC Vice-Chair

Action: for adoption
Documents: Call for candidates, HMPC RoP, Candidatures

Outcome:
Election took place in line with the HMPC Rules of procedure.

Erika Svedlund was elected in the second voting round as new HMPC Vice-chair with a 3-year mandate starting 05 May 2020.

5.2. EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair
Action: for information
Document: Agenda dated 17 April 2020, Draft agenda for 07 May 2020

Outcome:
HMPC noted topic discussed at the Scientific Coordination Board in April and the agenda for the upcoming May meeting.

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

5.3.1. QRD Template – update of Addendum for THMP

Action: for discussion
Document: Proposal for Update of the Addendum, Addendum to the Quality Review of Documents templates for SmPC for THMPs

Outcome:
Postponed

5.4. Cooperation within the EU regulatory network

5.4.1. Coordination with European Pharmacopoeia

- EDQM 13A expert group meeting
  Report: M Bald
  Action: for information
  Document: SoD March 2020

  Outcome:
  HMPC noted summaries of decisions for the latest Group 13A meeting an topics highlighted by the EDQM observer.
- EDQM PA working party meetings

  Action: for adoption
  Documents: Draft method for determination of Pyrrolizidine Alkaloids published in Pharmeuropa; draft comments

  Outcome:
  No comments from HMPC members were received by the Rapporteur.

  HMPC adopted comments drafted by the Rapporteur for submission to EDQM.

Comments focused largely on the scope of the method proposed in line with the discussion during the HMPC March meeting.

5.4.2. Herbal EU NTC curriculum

Action: for information
Document: Course description template

Outcome:

HMPC welcomed the successful introduction of the first herbal-specific course within the NTC programme 'Types of herbal preparations and consequences for the control strategy', that took place on 30th of April 2020 via EU NTC.

The course is available online and further trainings are in preparation.

5.4.3. Coordination with the European Commission

- Planned COMMISSION REGULATION (EU) amending Annex III to Regulation (EC) No 1925/2006 as regards botanical species containing hydroxyanthracene derivatives
  Report: HMPC Chair
  Action: for discussion
  Documents: draft HMPC comments

  Outcome:
  HMPC agreed sending comments on the planned amendment to Regulation (EC) 1925/2006 regarding hydroxyanthracene derivatives (HADs) in foods and noted information on timelines.

- Cannabis for medicinal use
  Action: for discussion

5.5. Cooperation with International Regulators

None

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

None

5.7. Work plan

5.7.1. HMPC work plan 2020

Report: HMPC Chair
Action: for discussion
Document: Work plan 2020, Annex 1, Annex 2 – current status May 2020

Outcome:
HMPC noted status of activities planned for 2020.

5.8. Planning and reporting

5.8.1. Future-proofing - Human Medicines – Committees - postponed

5.9. Legislation and regulatory affairs

5.9.1. Impact of Brexit on traditional and well-established use evidence

Action: for discussion
Documents: Email correspondence dated 10 February 2020, market overview template

Outcome:
Data from the UK market can be taken into account during the transition period as per the normal practice. Any information that is required from UK authorities in this respect can be requested by Rapporteurs from the UK in writing.

HMPC secretariat will contact MHRA to announce and confirm continued practice regarding market overview at the beginning of assessment procedures for monograph establishment/revision.

5.10. Questions from members

None

6. EU herbal monographs and list entries in preparation

6.1. Revision of EU herbal monographs and list entries in preparation for adoption after public consultation

6.1.1. Monograph on Millefolii herba and supporting documents - postponed

6.2. Revision of EU herbal monographs and list entries in preparation for public consultation

6.2.1. Monograph on Orthosiphonis folium and supporting documents – postponed

6.2.2. Monograph on Trigonellae foenugraeci semen and supporting documents

Action: for discussion
Documents: Draft MO, AR, LoR, References 0/98

Outcome:
Postponed.

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

6.3.1. Monograph on Juniperi aetheroleum and supporting documents

Action: for discussion
Documents: Review report; References: 7/6

Outcome:
Postponed.

6.3.2. Monograph on Juniperi pseudo-fructus and supporting documents

Action: for discussion
Documents: Review report; References: 10/10

Outcome:
Postponed.

6.3.3. Monograph on Solidaginis virgaureae herba and supporting documents - postponed

6.4. EU herbal monographs and list entries in preparation for adoption after public consultation

6.4.1. Monograph on Herniariae herba and supporting documents

Action: for discussion
Documents: Draft MO, AR, LoR, OoC, Readers guidance; References: 35/24

Outcome:
No relevant comments were received during public consultation leading to any changes in the draft monograph.

Draft documents to finalised according to the discussion and transmitted for peer-review prior to possible final adoption in July 2020.

Timetable:
Documents to be sent to peer-reviewer: 15 May 2020
Peer-review documents to be sent to Rapporteur: 8 June 2020
Final documents to be included latest in 2nd premail: 30 June 2020

During public consultation several amendments of the monograph were proposed including additional herbal preparations, indication, and posologies. Unfortunately, although several references were submitted, no information was provided that justifies the proposed changes and it was agreed not to change the monograph.

6.5. EU herbal monographs and list entries in preparation for adoption for release for public consultation

6.5.1. Monograph on Centellae asiaticae herba and supporting documents – postponed

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

6.5.3. Monograph on Salviae miltiorrhizae radix et rhizoma and supporting documents – postponed

6.5.4. Monograph on Vaccinii macrocarpi fructus and supporting documents

Action: for discussion
Documents: Draft MO, AR, LoR; References: 51/234

Outcome:
The Rapporteur presented available/missing information for the description of the active substance. For both, the expressed (and concentrated/dried) juice as well as a refined extract some key data are missing to allow the standard format using conventional DER and extraction solvent. Options for reference to the original herbal substance (corresponding to a certain amount of cranberries) or to a certain amount of procyanidins as well as comparable previous cases (such as Symphytum, Ginkgo, Ginger, Arctostaphylos) and their shortcomings were discussed.

7. Any other business

7.1. Topics for discussion

None

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 2-4 March 2020

Overview of expertise of members HMPC and subgroups

Meeting report from HMPC meeting held on 2-4 March 2020

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

Final Monograph Overview

7.2.2. ARSP

- English template
- English summaries for publication
  - none

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

- Monograph on Allii sativi bulbus and supporting documents
  Documents: MO, AR, LoR

  HMPC noted finalisation of documents by the Rapporteur and secretariat pending only

  completion of the HMPC opinion according to voting outcome in July 2017 (missing divergent position from Norway).

- Monograph on Foeniculi amari fructus and supporting documents – awaiting Estragole PS finalisation
- Monograph on Foeniculi amari fructus aetheroleum and supporting documents – awaiting Estragole PS finalisation
- Monograph on Foeniculi dulcis fructus and supporting documents – awaiting Estragole PS finalisation
- Monograph on Species digestivae or species stomachicae and supporting documents - awaiting Estragole PS finalisation

7.2.4. Other

- CMDh practical guidance for Marketing Authorisation Holders of nationally authorised products (incl. MRP/DCP) in relation to the Art. 5(3) Referral on Nitrosamines (March 2020, CMDh/412/2019, Rev.4; Q&A 1.5 regarding THMPs)
- https://www.afro.who.int/news/who-supports-scientifically-proven-traditional-medicine

List of participants

List of participants including any restrictions with respect to involvement of members / alternates/experts following evaluation of declared interests for the 4-6 May 2020 meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Emiel Van Galen	Chair	Netherlands	No interests declared	
Reinhard Länger	Member	Austria	No interests declared	
Patricia Bodart	Member	Belgium	No interests declared	
Antri Kouroufexi	Member	Cyprus	No interests declared	
Darko Trumbetic	Alternate	Croatia	No interests declared	
Markéta Příhodová	Member	Czech Republic	No restrictions applicable to this meeting	
Marie Heroutova	Alternate	Czech Republic	No interests declared	
Steffen Bager	Member	Denmark	No restrictions applicable to this meeting	
Karoline Holm Felding	Alternate	Denmark	No restrictions applicable to this meeting	
Eeva Sofia Leinonen	Member	Finland	No interests declared	
Sari Koski	Alternate	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 Dr Sándor	Member	Hungary	No interests declared	
Sheena Kennedy	Member	Ireland	No restrictions applicable to this meeting	
Evita Skukauska	Alternate	Latvia	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Everaldo Attard	Member	Malta	No interests declared	
Burt H Kroes	Alternate	Netherlands	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	Member	Romania	No interests declared	
Miroslava Petrikova	Member	Slovakia	No interests declared	
Barbara Razinger	Member	Slovenia	No interests declared	
Adela Núñez Velázquez	Member	Spain	No interests declared	
Karin Erika Svedlund	Member (Vice-Chair)	Sweden	No interests declared	
Gert Laekeman	Co-opted member	Belgium	No interests declared	
Heidi Foth	Co-opted member	Germany	No interests declared	
Silvia Girotto	Co-opted member	Italy	No interests declared	
Ewa Balkowiec Iskra	Co-opted member	Poland	No interests declared	
Maria Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared	
Pierre Duez	Expert*	Belgium	No restrictions applicable to this meeting	
Klaus Reh	Expert*	Germany	No interests declared	
Olga Palomino	Expert*	Spain	No interests declared	
Friederike Stolte	Expert*	Germany	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Kristine Hvolby	Expert*	Denmark	No interests declared	
Melanie Bald	Observer	EDQM	No interests declared	
Meeting run with support from relevant EMA staff				

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