23 April 2019
EMA/HMPC/269869/2018 – corr.1
Inspections, Human Medicines Pharmacovigilance & Committees Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 26-27 March 2018

Chair: Marisa Delbò Vice-Chair: Emiel Van Galen

26 March 2018, 14:00 – 19:00, 2F

27 March 2018, 09:00 – 13:00, 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).

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Table of contents

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).

1.2. Adoption of agenda

HMPC agenda for 26-27 March 2018

Time schedule for 26-27 March 2018

Outcome:
Agenda adopted.

1.3. Adoption of the minutes

HMPC minutes for 29-30 January 2018

Outcome:
Minutes adopted with minor amendments.

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

2.1.1. Appointment of Rapporteurs and Peer-reviewers

Changes of Rapporteurs and Peer-reviewers

New assessments

Allii sativi bulbus – Rapporteur
Species sedativae - Rapporteur

Monograph revision

Species amarae - Rapporteur
Hippocastani cortex - Peer-review

Polypodii rhizoma - Peer-review

Outcome:
Endorsed.
The change of Rapporteur for Allium and remaining tasks were discussed.

2.1.2. Report from the MLWP January 2018 meeting

Report: MLWP Vice Chair
Action: for information
Document: Draft minutes for the MLWP meeting on 30 January - 01 February 2018

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

2.2.1. Monograph on Agni casti fructus and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 00/98

Outcome:

Final revised monograph and supporting documents adopted by majority vote (18 out of 23). The Norwegian delegate expressed a favourable position.

Divergent opinions: Alessandro Assisi, Eeva Sofia Leinonen, Emiel van Galen, Linda Anderson, Rachel Cox

Because of only minor changes compared to the original monograph the HMPC considered that a public consultation is not necessary.

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

Minor changes with regard to the posology were discussed in alignment with other recent revisions. Divergent opinions referred to the quality of studies to support a recognised efficacy according to Article 10a and the Annex of Directive 2001/83/EC.

2.2.2. Monograph on Calendulae flos and supporting documents

Action: for adoption
Documents: MO, AR, LoR, LE; References: 01/93

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

Because of only minor changes compared to the original monograph the HMPC considered that a public consultation is not necessary.

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

Changes in the monograph were considered not relevant for preparations included in the existing list entry. No new opinion was adopted for the list entry.

2.2.3. Monograph on Cimicifugae rhizoma

Action: for adoption
Documents: MO, AR, LoR, OoC; References: 49/145

Outcome:

Final revised monograph and supporting documents adopted by majority vote (20 out of 25). The Norwegian delegate expressed a favourable position.

Divergent opinions: Alessandro Assisi, Eeva Sofia Leinonen, Emiel van Galen, Linda Anderson, Rachel Cox

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

HMPC agreed to add in future a list of specific abbreviations to all AR (no standard abbreviations or those already explained on the EMA website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000193.jsp&mid=WC0b01ac0580028e96

List of acronyms and abbreviations commonly used in HMPC agendas and minutes.)

HMPC secretariat will adapt the AR template accordingly with the next revision.

Divergent opinions referred mostly to insufficient data to recognise efficacy for the well-established-use indication as well as some safety concerns.

2.2.4. Monograph on Cynarae folium and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 00/115

Outcome:
Final revised monograph adopted by consensus. The Norwegian delegate expressed a favourable position.

Because of only minor changes compared to the original monograph the HMPC considered that a public consultation is not necessary.

Issues were detected in the assessment report. Before publication Rapporteur together with Peer reviewer, SE member and secretariat to make sure that changes agreed at MLWP are reflected in the AR. Final edited assessment report to be distributed to all HMPC for endorsement before publication.

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

2.2.5. Monograph on Sambuci flos and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 03/31

Outcome:
Final revised monograph with changes in sections 2, 3 and 4.2 and supporting documents adopted by consensus. The Norwegian delegate expressed a favourable position.

Because of only minor changes compared to the original monograph the HMPC considered that a public consultation is not necessary.

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

Questions with regard to the herbal substance (comminuted/fragmented) and the respective posology were clarified.

2.2.6. Monograph on Verbasci flos and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 04/44

Outcome:
Final revised monograph with changes in sections 2, 3 and 4.2 and supporting documents with changes in the AR adopted by consensus. The Norwegian delegate expressed a favourable position.

Because of only minor changes compared to the original monograph the HMPC considered that a public consultation is not necessary.

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

Questions with regard to the herbal substance (comminuted/fragmented) and the respective posology were clarified.

Some final amendments were requested with regard to the evidence of the traditional use as presented in the tables of the assessment report.

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

2.3.1. Monograph on Gentianae radix and supporting documents

Action: for adoption
Documents: Draft MO, AR, LoR; References: 08/47

Outcome:
Draft revised monograph and supporting documents with minor modifications in the AR adopted by consensus for 3 months public consultation.

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

2.4.1. Silybi mariani fructus and supporting documents

Action: for discussion
Documents: MO, AR, LoR, OoC; Email correspondence dated 18 July 2017, 10 Aug 2017 and 21 Mar 2018; Previous voting results

Outcome:
HMPC noted a summary by the Chair regarding draft monographs and divergent opinions with main focus on the indication. HMPC members were asked to prepare for the discussion at the HMPC June meeting.

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

2.5.1. Monograph on Fragariae folium and supporting documents

Action: for adoption
Documents: Draft MO, AR, LoR; References: 18/124

Outcome:
Draft monograph and supporting documents adopted by consensus for 3 months public consultation.

2.5.2. Monograph on Malvae folium and supporting documents

Action: for adoption
Documents: Draft MO, AR, LoR; References: 00/119

Outcome:
Adoption postponed and documents returned to MLWP.
Issues were detected in monograph (section 4.2) and assessment report requiring clarification before release for public consultation.

The safe preparation of herbal teas based on the documented traditional use was found not to be sufficiently justified in the assessment report and reflected in the posology of the draft monograph.

2.5.3. Monograph on Malvae sylvestris flos and supporting documents

Action: for adoption
Documents: Draft MO, AR, LoR; References: 00/119

Outcome:
Adoption postponed and documents returned to MLWP.

Issues were detected in monograph (section 4.2) and assessment report requiring clarification before release for public consultation.
See 2.5.2.

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

2.6.1. Monograph on Avenae fructus and supporting documents

Action: for adoption
Documents: Review outcome; References: 00/63

Action: for information
Documents: MO, AR, LoR

Outcome:
HMPC agreed with Rapporteur opinion 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 not to revise the monograph, assessment report and list of references on Avenae fructus. The Norwegian delegate expressed a favourable position.

The review summary as provided by the Rapporteur together with the HMPC position will be published on the EMA website as Addendum to the existing assessment report in line with the revised procedure EMA/HMPC/124695/2011 Rev. 2 once adopted as final (scheduled for June 2018).

HMPC secretariat to update tracking documents accordingly.

HMPC agreed that in future new key references should be provided to HMPC and secretariat to facilitate the next periodic review.

Experiences with the new review template were discussed. It was highlighted that for some traditional substances no authorised medicinal products exist although substances are used in pharmacies etc. Therefore the check for standard PhV databases may not add relevant information for the review that is focused on newly available safety data.

2.6.2. Monograph on Avenae herba and supporting documents

Action: for adoption
Documents: Review outcome; References: 00/63

Action: for information
Documents: MO, AR, LoR

Outcome:
HMPC agreed with Rapporteur opinion 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 not to revise the monograph, assessment report and list of references on Avenae herba. The Norwegian delegate expressed a favourable position.

The review summary as provided by the Rapporteur together with the HMPC position will be published on the EMA website as Addendum to the existing assessment report in line with the revised procedure EMA/HMPC/124695/2011 Rev. 2 once adopted as final (scheduled for June 2018).

HMPC secretariat to update tracking documents accordingly.

HMPC agreed that in future new key references should be provided to HMPC and secretariat to facilitate the next periodic review.

3. Referral procedures

None

4. Guidelines and guidance documents

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

None

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 – postponed for June 2018

Report: QDG Chair

4.2.2. Guideline on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/201116/2005) Rev. 3 – postponed for June 2018

Report: QDG Chair

4.2.3. Guideline on quality of water for pharmaceutical use (EMA/150605/2018)

Action: for discussion
Documents: Guideline; Presentation; Concept paper

Outcome:
HMPC noted presentation by QWP member.
For herbal specifics HMPC members to send comments to QDG Chair **by 12 April** for discussion at next QDG meeting 19 April.
Consolidated QDG comments, if any, to be provided to QWP latest by 30 April.

HMPC noted status of revision, parties involved and the nature of changes introduced. Most changes were not considered specifically relevant for the HMPC. QDG was asked to have a more detailed check and provide comments to QWP if necessary.

4.3. Regulatory / Scientific

4.3.1. Procedure for calls for scientific data for use in HMPC assessment works (EMA/HMPC/1004/2006 Rev. 4)

Report: ORGAM Chair
Action: for adoption
Document: Procedure

Outcome:
Revision 4 of the procedure was adopted with minor modifications regarding use of unpublished data as agreed at the January HMPC meeting as well as adaptations to the revised monograph revision procedure EMA/HMPC/124695/2011 Rev. 2.

4.4. Report on HMPC Drafting Groups activities

4.4.1. Quality DG

Report: Q DG Chair

- Meeting report from Q DG face to face meeting held on 22 Feb 2018
  Action: for adoption
  Document: Meeting report
- Draft agenda for the Q DG virtual meeting to be held 19 Apr 2018

Action: for information
Document: Draft agenda

Outcome:
Meeting report was adopted. HMPC secretariat to distribute to all HMPC members a QDG draft position on AESGP proposals regarding variation simplifications for herbal products.

One topic will be added to the forthcoming meeting in April (see 4.2.3. Revised Guideline on quality of water for pharmaceutical use).

The committee was informed that despite major progress with the revision of the two fundamental herbal quality guidelines one final round for harmonisation and amendment was considered necessary. Draft revisions will be distributed to all HMPC members for comments after the next QDG meeting in order to prepare adoption for further coordination with CHMP and CVMP (via QWP) before public consultation.

- Nomination for new observers at QDG
  Action: for adoption
  Documents: Nomination from PL; Nomination from SE; QDG mandate

  Outcome:
  HMPC endorsed as observers to QDG Ewa Backhaus (PL) and Robert Burman (SE).

  The high number of observers to a drafting group was noted but considered useful for harmonisation and information across the network. It was reminded that observers represent also a pool of senior experts for contributions in the area of expertise related to and beyond drafting activities of QDG.

4.4.2. ORGAM DG

Report: ORGAM DG Chair

- Meeting report from ORGAM virtual meeting held on 14 Mar 2018
  Action: for adoption
  Document: Meeting report
- Agenda ORGAM DG meeting to be held on 23 Apr 2018
  Action: for information
  Document: Draft agenda

  Outcome:
  Meeting report was adopted. Updates were given by the ORGAM Chair on the forthcoming virtual meeting in April.

  Because of increasing resource issues, secretariat to send out a new call to all HMPC and MLWP members for DG membership as well as Rapporteurship on specific procedural guidance relevant for HMPC operations.

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Election of Co-opted member

Report: HMPC Chair
Action: for adoption

Documents: Expertise of HMPC members; Call for nominations from 28 Feb 2018; Candidature (Clinical expert)

Outcome:
HMPC elected by majority Ewa Balkowiec Iskra as new co-opted member with Clinical pharmacology as area of expertise for a 3-year mandate starting 4 June 2018.

HMPC also appointed Ewa Balkowiec Iskra as new member of the MLWP.

5.1.2. Timing of Chair elections

Action: for discussion
Document: Presentation

Outcome:
HMPC noted minor changes in practice regarding the timing of Chair/Vice Chair elections applied across all scientific committees.

5.1.3. Strategic Review and Learning Meetings

Report: HMPC Chair, HMPC Vice-chair
Austria Presidency meeting – Vienna, 15-17 Oct 2018
Action: for discussion
Document: Draft Agenda

Outcome:
A first draft agenda was presented and members invited to propose topics and contributions.

Members were also informed on planned satellite stakeholder meetings organised independently from the HMPC Strategic Review and Learning Meeting by AESGP (herbal products) and ECHAMP (homeopathic products).

5.1.4. Organisation of HMPC-MLWP during 2018-2019

Action: for discussion
Document: Presentation

Outcome:
The Committee was informed on EMA decision regarding MLWP meetings during the BCP period 2018-2019. Following discussions with HMPC, it has been agreed to reduce MLWP face-to-face meetings in 2018 from 6 to 4 and in 2019 from 6 to 3 meetings. Maintained are 2-day face-to-face meetings in 2018 in June and September and in 2019 in January, May and September.
For 2019, a prolonged HMPC plenary time (starting Monday lunch time and finishing Tuesday end of the day) is foreseen for those three meeting months without MLWP.

The use of TCs for small groups and specific topics complementing MLWP plenaries to prepare HMPC meetings during the BCP period as well as the prospects after the BCP period were discussed. The HMPC Chair, on behalf of the Committee members, recommended to reconsider the HMPC and MLWP meetings forward planning once the BCP period 2018-2019 will end and usual business will restart.

Post-meeting note:

During the following MLWP meeting it was agreed that a small group will collect proposals and draft a document how to adapt to the new situation for discussion at the next MLWP meeting.

5.2. Coordination with EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting

Report: HMPC Chair
Action: for information
Documents: Minutes 11 Dec 2017; Agenda 12 Mar 2018; Minutes 12 March 2018

Outcome:
Updates were given by HMPC Chair on the discussions of the last SciCoBo meeting held in March 2018.

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

None

5.4. Cooperation within the EU regulatory network

5.4.1. Coordination with European Pharmacopoeia

- EDQM 13A expert group meeting to be held on 6-7 March 2018
  Report: M Bald (EDQM)
  Action: for information
  Document: Agenda, SoD

- EDQM 13B expert group meeting held on 23-24 Jan 2018
  Report: M Bald (EDQM)
  Action: for information
  Document: SoD

- EDQM TCM expert group meeting to be held on 24-25 January 2018
  Report: M Bald (EDQM)
  Action: for information
  Document: SoD

- EDQM PA working party
  Report: M Bald (EDQM)

Outcome:
HMPC noted summary of decisions and updates on 13A, 13B, and TCM expert group activities given by the EDQM representative.

5.4.2. Coordination with EFSA

None

5.5. Cooperation with International Regulators

5.5.1. EU – India/AYUSH communication

Action: for discussion
Document: Information from AYUSH dated 16 March 2018; Letter dated 16 March 2018

Outcome:
HMPC noted update given on the communication between EMA and India/AYUSH. The committee endorsed the letter and the invitation of Indian experts to the June HMPC/MLWP meeting in view of the start of the review procedure for 4 Indian plants previously assessed with the outcome 'public statement'.

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

5.6.1. Requests by Interested Parties

- Requests for hearing by EUROCAM
  Report: HMPC Chair
  Action: for information
  Document: email communication

- Request for IP status by ECHAMP
  Report: HMPC Chair
  Action: for information
  Document: Request dated 18 Jan 2018

  Outcome:
  EUROCAM was informed that no general hearing is planned in 2018, however no proposal on specific hearing topic was received so far.

  ECHAMP had been informed on the requirements to become interested party and the limitations in the scope of HMPC activities regarding homeopathic products and practitioner regulation.

  HMPC agreed that without additional information no further action will be taken.

5.6.2. Question on HMPC assessment and national monograph use

Report: HMPC Chair
Action: for discussion
Document: Draft letter; Hederae helicis folium MO, AR, LoR; Email correspondence; Literature

Outcome:
HMPC agreed that letter by HMPC Chair should contain as regards question 4 the wording as in the Hedera AR. No additional justification will be added in the AR but references to support the rationale (PhV decisions in FR, IT and if available PhV-WP).

HMPC noted that several other stakeholders contacted EMA regarding the justification of a contraindication in the Hedera monograph. It was decided not to re-open the discussion at

present. Any new data will be taken into account for a future revision of the monograph according to procedure EMA/HMPC/124695/2011 Rev. 2.

5.7. Work plan

5.7.1. HMPC work plan 2018

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

Postponed.

5.8. Planning and reporting

None

5.9. Legislation and regulatory affairs

None

6. Any other business

6.1. Topics for discussion

6.1.1. Questions from NCAs on Public statement on pyrrolizidine alkaloid contaminations

Action: for discussion
Documents: Response to questions; HMPC response; Literature

Outcome:
Draft responses were in principle agreed but found not yet sufficiently clear to facilitate regulatory practice at NCAs.

An additional summarising paragraph will be added on the response to question 1.

Scheduled for adoption at the HMPC June meeting.

The Committee discussed different approaches in risk assessment such as the use of potency factors. The HMPC and QDG Chairs pointed out that useful toxicological considerations should also be linked with practicalities of medicinal product regulation linked to diverse, variable and often unknown content of individual alkaloids, batch to batch inconsistencies and so far no harmonised analytical method/reference substances. Useful direction to requesting NCAs should be given for case by case decision at national level.

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 29-30 January 2018

Overview of expertise of members HMPC and subgroups

Meeting report from HMPC meeting held on 29-30 January 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
- Draft agenda of MLWP meeting to be held on 27-28 March 2018

6.2.3. ARSP

- English template
- English summaries for publication:
  - Uvae Ursi folium

No objections were raised on the Herbal summary before publication.

6.2.4. Other

- PCWP/HCPWP meetings:
  - Draft Agenda of the PCWP/HCPWP joint meeting – 17-18 April 2018
  - Draft PCWP/HCPWP Work Plan for 2018-2019
- HMPC comments on Ethanol used as an excipient in medicinal products for human use submitted on 23 Feb 2018
- HMPC comments on EFSA Safety assessment of green tea submitted on 23 Feb 2018
- HMPC request to EC on Clarification on classification on Saccharomyces cerevisiae CBS 5926 submitted on 30 Jan 2018
- EFSA opinion on: Human acute exposure assessment to tropane alkaloids
- Proposed Q&A from EC for NTA on traditional 15 years of use
- Critical evaluation of causality assessment of herb–drug interactions in patients
- EU herbal monographs, list entries and public statements post adoption
  - Remaining publication delays:
    - Allii sativi bulbus
    - Pistacia lentiscus (mastix)

6.2.5. Feedback on national experiences with HMPC monographs and guidelines

- draft template
- summary feedback, examples feedback received

After a first experience the collection of feedback and their practical integration into review/revision procedures for monographs and guidelines will be discussed at the HMPC June meeting.

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 26-27 March 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	
Wim Huygh	Alternate	Belgium	No interests declared	
Elena Mustakerova	Member	Bulgaria	No interests declared	
Ivan Kosalec	Member	Croatia	No restrictions applicable to this meeting	
Darko Trumbetic	Alternate	Croatia	No interests declared	
Marie Heroutova	Member	Czech Republic	No interests declared	
Magdalena Zakova	Expert	Czech Republic	No interests declared	
Steffen Bager	Member	Denmark	No restrictions applicable to this meeting	
Eeva Sofia Leinonen	Member	Finland	No interests declared	
Jacqueline Wiesner	Member	Germany	No interests declared	
Zoi(Zoe) Karampourmpouni	Alternate	Greece	No interests declared	
Rachel Cox	Alternate	Ireland	No interests declared	
Alessandro Assisi	Member	Italy	No interests declared	
Baiba Jansone	Alternate	Latvia	No interests declared	
Audronis Lukosius	Alternate	Lithuania	No interests declared	
Marcel Bruch	Member	Luxembourg	No interests declared	
Emiel Van Galen	Member	Netherlands	No interests declared	
Burt H Kroes	Alternate	Netherlands	No interests declared	
Steinar Madsen	Member	Norway	No interests declared	
Wojciech Dymowski	Member	Poland	No interests declared	
Ana Paula Martins	Member	Portugal	No interests declared	
Milan Nagy	Alternate	Slovakia	No interests declared	
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	
Malin Kyllikki Hobro Soderberg	Alternate	Sweden	No interests declared	
Linda Anderson	Member	United Kingdom	No interests declared	
Sue Harris	Alternate	United Kingdom	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	
Melanie Bald	Observer	EDQM	No interests declared	