21 November 2017
EMA/HMPC/767522/2017 - **FINAL**
Inspections, Human Medicines Pharmacovigilance & Committees Division

Committee on Herbal Medicinal Products (HMPC)

MINUTES for the meeting on 18-19 September 2017

Chair: Marisa Delbò Vice-Chair: Emiel Van Galen

18 September 2017, 14:00 – 19:00, 3E

19 September 2017, 09:00 – 13:00, 3E

Health and safety information

In accordance with the Agency's health and safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the meeting.

Disclaimers

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

Of note, this agenda 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 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 18-19 September 2017

Time schedule for 18-19 September 2017

Outcome:
Agenda adopted. Changes were introduced to the Time schedule.

1.3. Adoption of the minutes

HMPC minutes for 17-18 July 2017

Outcome:
Minutes adopted.

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

2.1.1. Report from the MLWP July 2017 meeting

Report: MLWP Chair
Action: for information
Document: Draft minutes for the MLWP meeting on 18-21 July 2017

2.1.2. Appointment of Rapporteurs and Peer-reviewers

Changes of Rapporteurs for Monograph revision

Outcome:

Endorsed.

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

2.2.1. Monograph on Ribis nigri folium and supporting documents

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

Outcome:
Final monograph and supporting documents adopted by majority vote (24 out of 25). The Norwegian delegate expressed a favourable position.

Divergent opinion: E. van Galen.

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

None

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

None

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

None

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

2.6.1. Monograph on Pistacia lentiscus (mastix) and supporting documents - postponed

3. Referral procedures

None

4. Guidelines and guidance documents

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

4.1.1. Reflection paper on Polycyclic aromatic hydrocarbons in HMP/THMP

Action: for discussion
Documents: Presentation; Reflection paper; QDG Draft Discussion Paper on follow up

Outcome:
HMPC agreed to QDG proposal on follow up: (1) Ongoing incorporation into herbal quality guidance currently under revision by QDG. (2) PAH part of assessors training 2017 for

exchange with industry on current situation and future actions including data collection and experiences with 'at risk' herbal ingredients.

HMPC further decided to communicate the outcome/follow-up not only in the public meeting report but also to publish the Overview of comments. **Rapporteur** to compile OoC with the corresponding HMPC response and provide to secretariat by **12 Oct 2017** for discussion by QDG. QDG to review before submission to HMPC for possible adoption in November 2017.

4.1.2. Revision of Guideline on assessment of clinical safety and efficacy (EMA/HMPC/104613/2005) Rev.1

Action: for adoption
Documents: Revised guideline for final adoption, OoC

Outcome:
Revised guideline and OoC adopted with a change in the OoC.

Follow-up topic on data protection will be checked by ORGAM DG in October and EMA secretariat for minor amendments in existing template/ procedures to be presented at the HMPC November meeting.

Minor additions in the OoC were discussed and agreed.

Issues raised during public consultation on data protection were not considered relevant for the scientific guideline as such but rather linked to procedure and template used when the Rapporteur compiles market overview and assessment report. Although only very few cases are probable where data protection could apply in the context of monograph establishment, such check should be reflected in procedural documents.

Secretariat to perform editorial review and publish revised GL and OoC.

4.2. Quality

4.2.1. Concept paper on the development of a Reflection Paper on new analytical methods/technologies in the quality control of herbal substances, herbal preparations and (traditional) herbal medicinal products (EMA/HMPC/541422/2017)

Action: for adoption
Document: Concept Paper

Outcome:
The concept paper was adopted for publication.

HMPC agreed on QDG proposal that after public consultation/ information received, to share the work on the reflection paper between several Co-Rapporteurs including experts from HMPC that are not members of QDG.

Secretariat to perform editorial review and publish the concept paper.

4.3. Regulatory

None

4.4. Report on HMPC Drafting Groups activities

4.4.1. Quality DG

- Meeting report from QDG virtual meeting held on 07 Sep 2017
  Action: for adoption
  Documents: Meeting report; Presentation on outcome survey on Markers
- Draft agenda for the QDG meeting to be held on 19 Oct 2017
  Action: for information
  Document: Draft agenda

Outcome:
Meeting report adopted. As additional topic for the October meeting was proposed the review of the OoC provided by the Rapporteur on the Reflection paper on PAH (see 4.1.1).

The HMPC further noted a report on topics under discussion including revision of the herbal specification guideline, considerations on the concept of markers after consultation of quality assessors across the network, the preparation of an HMPC assessors training in December and the current status and limitations of WHO guidelines in the herbal area.

HMPC agreed to not comment in detail on recent draft WHO guidelines (including quality/processing) but to respond with a letter pointing to general limitations in the applicability for regulators in the European network following GMP and also globally for members of the PIC/S. A draft letter (Chair and secretariat) will be circulated and tabled for HMPC adoption in November (see also 5.5.1).

4.4.2. ORGAM DG

Report: ORGAM DG Chair

- Meeting report
  Action: for adoption
  Document: Meeting report from ORGAM DG meeting held on 05 Sep 2017
- Agenda
  Action: for information
  Document: Draft agenda for the ORGAM DG meeting to be held on 17 Oct 2017

Outcome:
Meeting report adopted. An additional topic for the October meeting a minor follow-up topic on the Clinical guideline revision was given to the DG (see 4.1.2).

The main focus of the last meeting was the overhauled review/revision procedure (see 4.4.3). The committee further heard a report on other drafting group discussions either linked to the new procedure (template adaptations and best practice guidance) or regarding the addition of new substances to the HMPC work programme (template, criteria for prioritisation, call for proposals; see also 5.7.1).

4.4.3. Procedure for the review and revision of European Union herbal monographs and/or European Union list entries (EMA/HMPC/326440/2007)

Report: ORGAM DG Chair
Action: for adoption

Documents: Draft procedure for public consultation; Annex 1 - review template; Addendum – template; Presentation

Outcome:
HMPC agreed to principles and consequences of the streamlined review/revision procedure for monographs and list entries. The draft procedure including template for review outcome/'addendum' was adopted by consensus for public consultation.

Post-meeting note: MLWP agreed to start already using the modified principles/procedure/templates to gather experiences and allow the further fine-tuning before the adoption of the final procedure.

Aim is to streamline the process EU herbal monographs are kept up-to-date as a workable standard for applicants and NCAs taking into account available resources at the HMPC and MLWP. The scope of the procedure has been widened from the periodic review/revision to unscheduled reviews/revisions in line with Reflection paper EMA/HMPC/326440/2007. As a main principle, the revision of monographs and supporting documents will only be started if during the review of newly available data relevant new information has been identified that potentially changes the content of a monograph.

The new principles were agreed by consensus although it was foreseen that some details in the implementation need to be further elaborated to reach the best possible practice based on experiences gathered so far. For such details/examples a best practice guide is currently under development at the MLWP.

4.4.4. Template update – Template on HMPC opinion on list entry or revision of a list entry

Report: ORGAM DG Chair
Action: for discussion
Documents: Draft template; Presentation

Outcome:
Change of opinion template was in principle agreed following previous communication with the Commission in order to reflect that members vote on a necessary change to a LE but not again on the LE as such. In addition it was requested to include a possible wording for a proposed withdrawal of a LE for safety reasons.

EMA to check and present a proposal for ORGAM DG discussion and possible adoption at the HMPC November meeting.

It was acknowledged that for an existing list entry already adopted and published by the Commission, there is no justification to have a second HMPC opinion on a decision already made unless new data and safety concerns exist. In such case the committee has to vote on a proposal for a necessary change or the withdrawal of a LE.

Such specific scope of the opinion will be reflected in the opinion template.

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Strategic Review and Learning Meetings

Report: HMPC Chair, HMPC Vice-chair

Estonia Presidency meeting – Bucharest, 11-12 Oct 2017
Action: for discussion
Documents: Draft Agenda; Discussion paper for the SRLM in Bucharest

Outcome:
Host and HMPC Vice-Chair presented a draft agenda and proposals were made in particular on group discussions linked to the discussion paper.

HMPC members were invited again for comments to the discussion paper and contributions to the SRLM meeting.

Some organisational aspects regarding registration/reservation were clarified.

The discussion paper highlighted main areas for improvement and it was referred to previous proposals made by members during presidency and formal plenary meetings but also asked for new suggestions and ways of implementation. The Chair highlighted that not all members will be present at the SRLM meeting, therefore strategic considerations should be presented to the plenary in November in a condensed form.

5.1.2. Preparation for election of Co-opted members

Report: HMPC Chair
Action: for discussion
Documents: Expertise of HMPC members; Email correspondence from 08 Sep

Outcome:
In view of expiring mandates in November/January and subsequently scheduled (re)election of co-opted members, the specific needs for the HMPC were discussed and 4 areas re-confirmed: Clinical pharmacology, Paediatric medicine, Experimental/non-clinical pharmacology, General and family medicine.

In case no clinical pharmacologist in a strict sense is available it was agreed to widen slightly the scope in order to find appropriate expertise for the clinical assessment/clinical trials. Secretariat to send out the call for nominations.

It was highlighted that also the membership at MLWP will be affected, which should be considered after the nominations/elections of committee co-opted members.

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: 21 Sep 2017; Minutes: 24 Apr 2017

Outcome:
HMPC noted available information and upcoming discussion with Committee chairs of work plans 2018 (see also 5.7.2 and 6.1.4).

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

5.3.1. Coordination with Safety Working Party – Assessment of estragole

Action: for information
Documents: PS; OoC; Presentation at CHMP; CHMP questions to SWP

Outcome:
Members were updated on the communication with CHMP, additional questions to SWP and current state of play. More information is expected at the HMPC November 2017 meeting.

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopoeia

- EDQM 13B expert group meeting held on 20-21 Sep 2017
  Report: M. Bald (EDQM)
  Action: for information
  Document: Agenda
- EDQM TCM expert group meeting held on 27 Apr 2017
  Report: M. Bald (EDQM)
  Action: for information
  Document: SoD
- EDQM TCM expert group meeting held on 19-20 Sep 2017
  Report: M. Bald (EDQM)
  Action: for information
  Document: Agenda
- EDQM Working Group on Pyrrolizidine Alkaloid (PA) analysis
  Report: M. Bald (EDQM)
  Action: for information
  Document: Agenda

Outcome:
HMPC noted agendas and update on the first meeting of the specific WP on PA analysis given by the EDQM representative briefly summarising composition and first discussions as regards existing methods, reference and surrogate substances. No other expert group meetings took place since the last HMPC meeting.

5.4.2. Coordination with EFSA

- Safety assessment of hydroxyanthracene derivatives - update
  Action: for discussion
  Documents: Response from EFSA, 10 Mar 2017; Email correspondence

  No new information was available.

- EFSA new draft statement on PA (see also 6.1.2.)
  Action: for discussion

Document: Draft statement for consultation

Outcome:
HMPC noted document with thresholds close to limits in HMPC Public statement on contamination of herbal medicinal products/traditional herbal medicinal products with pyrrolizidine alkaloids. Underlying methodologies and data were discussed and a further comparison is anticipated at the Assessors training in 2017. It was decided that currently no specific action (comments or other interaction with EFSA) is required.

It was further referred to the upcoming assessors training for which experts from the food area are being invited.

5.5. Cooperation with International Regulators

5.5.1. WHO – IRCH meetings

- Annual IRCH meeting, 11-13 Sep 2017; TradReg symposium, 14-15 Sep 2017 - Bonn, Germany
  Report: HMPC Chair; HMPC Vice-Chair
  Action: for discussion
  Documents: Draft programme; Presentation

  Outcome:
  A short summary by the Vice Chair was noted.

  The Chair highlighted that IRCH is a great opportunity to spread globally the knowledge acquired over 13 years of European harmonisation in the area. Europe has a lot to offer to support a more outcome orientated working methodology which is also envisaged from the new organisational framework within WHO in the future.

  Post meeting note:

  Adopted new terms of references and minutes of the meeting once available to be provided to the HMPC.

- WHO meeting on Herbal Quality Guidance - Hong Kong, China, 4-6 Sep 2017
  Action: for discussion
  Documents: Invitation; Annex 1 guidance on Markers

  Outcome:
  Updated WHO guideline a Good Herbal Processing Practice not yet made available by WHO. HMPC agreed to the QDG proposal to re-send general comments on these limitations.

- WHO draft technical document on clinical research in traditional and complementary medicine
  Action: for discussion
  Documents: Email correspondence; Draft technical document; Table for comments

  Outcome:
  Not discussed.

  Post-meeting note: Based on Rapporteur proposal no specific comments should be sent to WHO but the adopted revised HMPC Safety and efficacy guideline.

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

5.6.1. EUROCAM request to become HMPC interested party

Report: HMPC Chair
Action: for adoption
Documents: Letter to HMPC Chair, 13 Feb 2017; Presentation by EUROCAM, 13 Feb 2017; Letter of application to HMPC, 05 Jul 2017; EUROCAM status; List of interested parties to the HMPC

Outcome:
Endorsed. EUROCAM was accepted as interested party to the HMPC. Limitations of the HMPC activities vis-à-vis homeopathic and anthroposophic products/ practices were highlighted and should also be communicated to the organisation when informing on the acceptance.

HMPC secretariat to inform new IP and update List of IPs as published on the EMA website.

5.7. HMPC work plan

5.7.1. HMPC work plan 2017

- Report: HMPC Chair
  Action: for discussion
  Document: Work plan 2017 – current status

  Outcome:
  The status of projects on the work plan was discussed one by one. New update to be given by the topic leads at the HMPC November meeting in order to conclude on specific activities and necessary follow-up for the HMPC work plan 2018.

  On top of projects listed below, draft documents were announced for the November meeting for discussion of projects 2.1.1 (Summarised discussion with patient representatives for future involvement in HMPC activities) and 2.1.2 (Suitable toxicological models for the safe use of herbal substances in MPs in view of background exposure via food for start in 2018).
- Project 1.3.1. Forward planning and prioritisation
  Report: HMPC Chair; ORGAM Chair
  Action: for adoption
  Documents: Presentation; Draft template on proposals for assessment to HMPC

  Outcome:
  (1) HMPC agreed to publish a call for substances still requiring assessment by HMPC for harmonised European standards.

  Call (incl. combinations, non-European substances) to be published in meeting report, addressed to NCAs and individually to IPs in order to identify final gaps with assessment needs. Number of proposals to be limited and request for basic justification in line with public guidance to be included.

  (2) Template for substance proposals for HMPC assessment was adopted with minor changes. Template intended for internal use (MLWP to HMPC, experts to MLWP or HMPC) to allow clarity on key facts and informed decision by HMPC on start of assessment work.

  (3) Minimum criteria to start assessment work (e.g. MS interest etc.) to be discussed in November.

(4) Proposals by IPs, NCAs and from 2016 survey to be compiled by secretariat one week before HMPC November meeting and discussion with project group 1.3.1. for selection and addition to HMPC/MLWP work plan as feasible.

- Project 1.3.5. European collaboration
  Action: for discussion
  Document: Presentation

  Outcome:
  HMPC discussed proposals by topic lead on feedback from European procedures and PhV data including regular reflection in HMPC agenda, specific rapporteur, and procedural aspects (mandate, standard steps such as market overview as well as the new review/revision procedure). Topic lead together with project participants to draft a specific proposal including questions to RMSs useful for a Rapporteur. Proposal to be discussed at ORGAM DG and after procedural check presentation to HMPC in November.

- Project 2.1.3. Cooperation with Academia
  Report: MLWP Chair
  Action: for discussion
  Documents: Presentation; Proposal

  Outcome:
  Topic lead presented general intention on possible cooperation with academia to raise awareness for HMPC standards in academic teaching activities. It was referred to the EMA framework EMA/125511/2017 and some herbals particulars (benefits and limitations of HMPC assessments/monographs). A more specific proposal to be drafted as a discussion paper by the group in order to obtain clarity on specific goals and proposed ways of implementation for HMPC and EMA. The topic was presented by the lead at the SRLM Malta and will again be presented at the SRLM in Bucharest.

5.7.2. HMPC work plan 2018

- Report: HMPC Chair
  Action: for discussion
  Document: Draft Work plan 2018

  Outcome:
  The preliminary draft was noted. Members were requested to send their proposals within 1 month (**by 23 Oct 2017**) to Chair and secretariat. Work plan will be re-discussed for possible adoption at the HMPC November 2017 meeting.

  Given experience from previous years and also specific cross-network resource challenges for the upcoming years, the HMPC Chair encouraged to concentrate on the most fundamental activities and specific objectives/activities that can be realistically achieved in 2018.

5.8. Planning and reporting

5.8.1. HMPC 2017 assessors training on quality

Action: for discussion
Document: Draft agenda

Outcome:

HMPC endorsed outline of draft agenda and noted status of speaker invitation.

HMPC secretariat to send out calls for nominations for participants and together with QDG Chair to further organise speaker invitation (industry, EFSA, EDQM and HMPC) and agenda development.

5.9. Legislation and regulatory affairs

None

6. Any other business

6.1. Topics for discussion

6.1.1. Question concerning the adjustment of product to HMPC monographs

Report: HMPC Chair
Action: for discussion
Documents: Email correspondence 11 May 2017

Outcome:
HMPC endorsed the draft response.

It was confirmed that there is no mandate/role of the HMPC in an individual national procedure unless e.g. a referral procedure has been initiated.

Comments on the update of monographs and clarity in the assessment report on available data and subsequent monograph content were noted and will be considered - in particular for the ongoing revision of the monograph on Hypericum as confirmed by the Rapporteur.

The difference between information on products on the market in member states and available data for specific substances under assessment was highlighted.

6.1.2. Follow-up questions on Public Statement on Pyrrolizidine alkaloid contaminations (see also 5.4.2.)

Report: HMPC Chair
Action: for discussion
Documents: Draft response; Literature

Outcome:
The status of HMPC responses to NCA questions was confirmed. No Q&A's are foreseen for publication.

HMPC toxicologists to complete in writing final gaps (BE-2 only preliminary response from quality perspective, NL-1) and review/ shorten draft responses for final agreement at HMPC November meeting. Time-schedule: revised responses to secretariat and PA group by HMPC: **7 Nov 2017**. Reviewed document to be provided to HMPC: **14 Nov 2017**.

6.1.3. European Union herbal monograph on Saccharomyces cerevisiae CBS 5926

Action: for information
Documents: Draft letter; Presentation

Outcome:

HMPC Chair requested HMPC members to provide information on status (authorisation of yeast products as herbal medicinal product, biological medicinal products etc.) as per MS within 15 days (deadline **9 Oct 2017;** to be provided to secretariat and to the Chair) in order to support letter modification and discussion at HMPC November meeting.

6.1.4. Preparedness for UK's withdrawal from the EU

Action: for discussion
Document: Presentation

Outcome:

6.1.5. Additional information on data gathering exercise

Action: for discussion
Document: Report on new data gathering

Outcome:
Not discussed.

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 17-18 July 2017

Overview of expertise of members HMPC and subgroups

Meeting report from HMPC meeting held on 17-18 July 2017

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 19-21 Sep 2017

6.2.3. ARSP

- English template
- English summaries for publication:
  - Allii sativi bulbus

No comments/objections were raised on the herbal summary before publication on the EMA website.

6.2.4. Other

- PCWP/HCPWP meetings:
  - Personalised medicines workshop report – 14 March (EMA/185440/2017): For information
  - Draft Agenda AMR workshop - 19 Sept (EMA/765134/2016): For information
  - Draft agenda PCWP-HCPWP - 20 Sept (EMA/370525/2017): For information
- Vaccinii macrocarpi fructus – EC Decision
- Invitation to Conference on Cannabis in Vienna

The Committee agreed that no HMPC representative needs to participate at the conference, as currently not relevant for HMPC activities (monograph and list entry establishment, referrals or guidelines).

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 18-19 September 2017 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	
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	
Markéta Příhodová	Alternate	Czech Republic	No restrictions applicable to this meeting	
Steffen Bager	Member	Denmark	No restrictions applicable to this meeting	
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	
Una Mockler	Member	Ireland	No restrictions applicable to this meeting	
Alessandro Assisi	Member	Italy	No interests declared	
Evita Skukauska	Member	Latvia	No interests declared	
Everaldo Attard	Member	Malta	No interests declared	
Emiel Van Galen	Member	Netherlands	No interests declared	
Burt H Kroes	Alternate	Netherlands	No interests declared	
Steinar Madsen	Member	Norway	No interests declared	
Wojciech Dymowski	Member	Poland	No interests declared	
Ana Paula Martins	Member	Portugal	No interests declared	
Carmen Purdel	Member	Romania	No interests declared	
Milan Nagy	Alternate	Slovakia	No interests declared	
Samo Kreft	Member	Slovenia	No restrictions applicable to this meeting	
Per Claeson	Member	Sweden	No interests declared	
Malin Söderberg	Alternate	Sweden	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	
Heidi Foth	Co-opted member	Germany	No interests declared	
Maria Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared	
Melanie Bald	Observer – via TC	EDQM	No interests declared	