19 September 2017
EMA/HMPC/630124/2017 **FINAL**
Inspections, Human Medicines Pharmacovigilance & Committees Division

Committee on Herbal Medicinal Products (HMPC)

Minutes of the meeting on 17-18 July 2017

Chair: Marisa Delbò Vice-Chair: Emiel van Galen

17 July 2017, 14:00 – 19:00, 3F

18 July 2017, 09:00 – 13:00, 3F

Health and safety information

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

Disclaimers

Some of the information contained in this agenda 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 agenda 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).

As patient representative Dominique Hamerlijnck (EFA - European Federation of Allergy and Airways Diseases Patients' Associations) was welcomed.

In line with the HMPC work plan it was found important that after first training participation of different patient representatives, experiences should be summarised and proposals for long term input should be made by the topic lead. EMA to check additional participation of representatives with an interest in HMPC work is foreseen in 2017.

1.2. Adoption of agenda

HMPC agenda for 17-18 July 2017

Time schedule for 17-18 July 2017

Outcome:
Agenda adopted.

Some changes to the time schedule were agreed.

1.3. Adoption of the minutes

HMPC minutes for 29-30 May 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 May 2017 meeting

Report: MLWP Chair
Action: for information
Document: Draft minutes for the MLWP meeting on 30 May-01 Jun 2017

HMPC noted report based on the draft minutes.

2.1.2. Appointment of Rapporteurs and Peer-reviewers

- Changes of Rapporteurs for Monograph revision

Endorsed.

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

2.2.1. Monograph on Pelargonii radix and supporting documents

Action: for discussion
Documents: MO, AR, LoR, OoC MO, OoC AR; References: 98/98

Outcome:
Adoption postponed. Although finalised by MLWP in May and transferred to HMPC for final adoption, the HMPC agreed to a proposal by the Rapporteur to discuss the indication again at the MLWP before final adoption in September.

2.2.2. Monograph on Cimicifugae rhizoma and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 49/159

Outcome:
Final adoption postponed. HMPC decided on the need for public consultation before finalising the revision mainly due to changes in monograph section 4.2.
Draft revised monograph adopted by majority vote for release for 3 months public consultation.
Members discussed the posology from the perspective of what has been marketed/used, what has been applied in clinical trials and how to interpret the summarising posology for all three preparations in the current monograph. Safety as well as efficacy aspects and possible extrapolations according to quality of studies were taken into account but also the regulatory impact (necessary variations, European procedures) if the posology is not according to market overview. A majority agreed to follow the proposal of the Rapporteur as agreed by MLWP. HMPC opted for public consultation due to the nature of changes in the revised monograph. Concerns by few members were noted regarding hepatotoxicity and the benefit-risk ratio but not found related to the specific posology question.

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

2.3.1. Monograph on Menthae piperitae aetheroleum and supporting documents

Action: for adoption
Documents: MO, AR, LE, LoR; References: 104/205

Outcome:
Adoption postponed. Changes were introduced in the MO. MO and supporting documents will be re-discussed at the July 2017 MLWP meeting for possible HMPC adoption for release for public consultation in September. Rapporteur, peer reviewer and MLWP were asked to transfer completely finalised and cleaned documents for HMPC adoption.

MO and supporting documents as agreed by MLWP were not considered ready for adoption for release for public consultation. Changes were introduced in MO sections 2, 4.2, 4.8, 5.2 and 5.3. Further changes in the MO but also in the in the AR were requested.

Members discussed mainly the use in children and age limits in view of the current MO content, the PS on pulegone, other safety considerations generally linked to the terpene content and PhV actions for other terpene containing products/ administration forms.

It was agreed that the use in children as well as presentation of clinical data in the AR should be solved at MLWP and final clean documents made available to HMPC in September.

2.3.2. Monograph on Sennae folium and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 173/224

Outcome:
Draft revised monograph and supporting documents adopted by consensus for release for public consultation.
The changed botanical name of the plant affecting the monograph title and eventually website search functions was highlighted and a footnote on the monograph title page for clarification was endorsed.

The Rapporteur pointed to the different approach to Aloe as adopted in 2016 when preparations/posologies have been specified during the revision. For Senna monographs it was at the MLWP May meeting decided to keep general substance specification/posology according to the content of sennosides as done during the early monographs in 2006.

In addition, the new analytical method to be introduced in Ph. Eur. monographs was discussed (change from photometric to HPLC assay) but clarified that the current standard is still valid and the new method/revised Ph. Eur. MO is only likely to be adopted in 1.5-2 years' time. A conversion/correction factor is not yet established and values in the EU herbal monographs should therefore not be changed at present.

2.3.3. Monograph on Sennae fructus and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 173/224

Outcome:
Draft revised monograph and supporting documents adopted by consensus for release for public consultation.
The changed botanical name of the plant affecting the monograph title and eventually website search functions was highlighted and a footnote on the monograph title page for clarification was endorsed.
See also 2.3.2

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

2.4.1. Monograph on Allii sativi bulbus and supporting documents

Action: for adoption
Documents: MO, AR, LoR, OoC; References: 52/244

Outcome:
Changes were introduced in the AR. Final monograph and supporting documents adopted by majority vote (20 out of 26). The Norwegian delegate expressed a divergent position. Divergent opinions: E. S. Leinonen, E. van Galen, G. Laekeman, L. Anderson, R. Cox, P. Claeson, S. Madsen.

Missing references to be provided before publication.

HMPC noted explanations for delays with finalising the documents and requested several changes in the AR.

Divergent opinions referred mostly to indication 1 (adjuvant for the prevention of atherosclerosis) because it was considered that patients at risk of atherosclerosis require medical intervention to ensure an appropriate risk assessment is undertaken to determine the necessary lifestyle modifications and medications required. Since medical supervision (diagnosis, initiation and monitoring of therapy) were considered necessary, some members did not support a traditional indication for self-medication. One member expressed concerns regarding the clinical assessment requiring a more differentiated analysis according to clinical outcomes for well-defined preparations.

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

Action: for discussion
Documents: MO, AR, LoR; References: 65/65

Outcome:
Postponed to HMPC September 2017 meeting.
Rapporteur to respond on questions after editorial review. In case of remaining major issues to be clarified at HMPC in September in analogy to Salvia and Salix in May 2017.

2.6.2. Monograph on Pruni africanae cortex and supporting documents

Action: for discussion
Documents: MO, AR, LoR, OoC, Opinion; References: 70/61

Outcome:
Rapporteur response received after editorial review. Only in case of major remaining issues to be clarified at HMPC in September in analogy to Salvia and Salix in May 2017.

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: Reflection paper; Presentation

Outcome:
Discussion postponed to HMPC September 2017 meeting.

4.1.2. Revision of "Guideline on non-clinical documentation for herbal medicinal products in applications for marketing authorisation (bibliographical and mixed applications) and in applications for simplified registration" (EMEA/HMPC/32116/2005)

Action: for adoption
Document: Draft revised guideline for public consultation

Outcome:
Draft revised guideline with changes adopted for release for public consultation.

Some regulatory details on data requirements and possible misinterpretations as regards bibliographic versus mixed applications were discussed and wordings modified accordingly.

4.1.3. Revision of 'Guideline on assessment of clinical safety and efficacy in the preparation of Community herbal monographs for well-established and of Community herbal monographs/entries to the Community list for traditional herbal medicinal products/substances/preparations (EMA/HMPC/104613/2005)

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

Outcome:
Adoption postponed to HMPC September 2017 meeting.

4.2. Quality

4.2.1. Guideline on Manufacture of the Finished Dosage Form

Report: Q DG Chair
Action: for adoption
Documents: QWP guideline, OoC, Presentation

Outcome:
The guideline was adopted.

The history and scope of the guideline as well as main changes (such as new applicability to biotech products) were shortly presented. It was clarified that the Quality DG had no comments from a herbal perspective.

4.3. Regulatory

None

4.4. Report on HMPC Drafting Groups activities

4.4.1. Quality DG

Report: Q DG Chair

- Meeting report from Q DG virtual meeting held on 28 Jun 2017
  Action: for adoption
  Document: Meeting report
- Draft agenda for the Q DG meeting to be held on 07 Sep 2017
  Action: for information
  Document: Draft agenda

Outcome:
Meeting report adopted. No additional topics were proposed for the upcoming meeting.

The Q DG Chair highlighted items discussed and announced that the DG is finalising the review of the specification guideline. As regards future guidance on the use of new analytical methods it was agreed to publish first a concept paper. Members agreed on main topics of an assessors training on contaminants in herbal medicinal products to be held in December (see also 5.8.1) and discussed coordination topics with Quality WP, EDQM and WHO.

4.4.2. ORGAM DG

Report: ORGAM DG Chair

- Meeting report
  Action: for adoption
  Document: Meeting report from ORGAM DG meeting held on 27 Jun 2017
- Agenda
  Action: for information
  Document: Draft agenda for the ORGAM DG meeting to be held on 05 Sep 2017

Outcome:
Meeting report adopted. No additional topics were proposed for the upcoming meeting.

The main topic of the meeting was the revision procedure (see 4.4.3). In addition, necessary changes for the procedure for call for data linked to revision of monographs had been discussed but kept on hold until the revision procedure as such is agreed. ORGAM DG had first discussions on a proposal for a Q&A on the scope of monographs (originating from a template change proposal and later disclaimer for the website) and the current external and internal documentation for proposing and accepting herbal substances for HMPC assessment.

4.4.3. Proposal for the revision procedure of the EU monographs/List entries

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

Outcome:
HMPC noted questions on the principles raised by ORGAM and gave direction for finalisation of the procedure. ORGAM to present a modified detailed procedure at the HMPC September meeting for possible release for public consultation. Involvement of EMA legal department / RA requested for clarification on questions regarding update MO vs LE.

Main questions from the current procedure/ practice were:

Members discussed pros and cons in view of the backlog and impossibility to follow the current procedure on a 5 year systematic review due to lack of resources. It was asked to clarify the regulatory/legal value of planned addenda for pathway A.

The HMPC Chair considered all points as already clarified from HMPC side. ORGAM was encouraged to finalise the draft and involve EMA regarding potential issues with use of revised monographs/ non-revised LEs for minor modernisations in national procedures.

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

- Malta Presidency meeting – Malta, 26-28 Apr 2017 – follow up
  Action: for discussion
  Documents: Discussion paper on follow-up and need for improvement; Presentation on need for improvement; Additional presentations from Malta meeting

  Outcome:
  Based on previous discussions at the last presidency meetings and at HMPC, the Vice Chair presented 4 key issues and possible solutions to improve the functioning of the HMPC.

Members to send comments to the Vice Chair with secretariat and Chair in copy. Accordingly, a further updated proposal is planned to be presented at the SRLM meeting in Bucharest.

The Maltese member highlighted that remaining presentations from the Malta meeting previously not available from the website have now been completed and made available in MMD.

- Estonia Presidency meeting – Bucharest, 11-12 Oct 2017
  Action: for information
  Documents: Email correspondence from 6 July 2017; Email correspondence from 26 June 2017

  Outcome:
  The Romanian delegate invited all members to the SRLM. A website has been set up and members can register.

  Members to send proposals for the agenda to support compilation of a draft agenda and discussion at the HMPC September meeting.

5.2. Coordination with EMA Scientific Committees or CMDh-v

5.2.1. Scientific Coordination Board Meeting - postponed

Report: HMPC Chair
Outcome:
Discussion postponed to HMPC September 2017 meeting.

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

5.3.1. Coordination with Safety Working Party – Assessment of estragole

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

Outcome:
Discussion postponed to HMPC September 2017 meeting.

5.4. Cooperation within the EU regulatory network

5.4.1. European Commission - postponed

- Update on List Entries
  Action: for information
  Document: List of herbal substances, preparations and combinations thereof for use in THMP

  Outcome:
  Discussion postponed to HMPC September 2017 meeting.

5.4.2. European Pharmacopoeia

- EDQM 13A expert group meeting held on 13-14 Jun 2017
  Report: M. Bald (EDQM)
  Action: for information
  Documents: Agenda; SoD
- EDQM 13B expert group meeting held on 10-11 May 2017
  Report: M. Bald (EDQM)
  Action: for information
  Documents: Agenda; SoD

  Outcome:
  HMPC noted update on expert group activities as well as the specific WP on pyrrolizidine alkaloid analysis.

  The information included addition of substances to the work programme (e.g. Senna fruit extract and dry extract, Cannabis extracts) as well as deletions (e.g. *Polypodium*– no producer found). For the pyrrolizidine assay working party the consolidated composition and a first meeting scheduled for September was announced.

  From the substances with HMPC monographs but no Ph. Eur. monographs as communicated by HMPC, *Eschscholtzia* and *Helichrysum* were proposed for addition to the work programme while for *Symphytum* (PA method required) and *Vaccinium macrocarpon* (HMPC monograph indicating specific preparations) some prerequisites were considered by EDQM as still missing. Regarding the new assay in Senna monographs, the current status was clarified (in preparation for Pharmeuropa) and timelines when the Ph. Eur. will be finally revised (see 2.3.2).

  The HMPC Chair also informed that she joined the Ph. Eur. steering committee.

5.4.3. Coordination with EFSA

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

  Outcome:
  Discussion on follow up postponed to HMPC September 2017 meeting.

  The HMPC representative that attended a working group meeting 13/14 July at EFSA briefly highlighted the usefulness to explain the HMPC assessment approach and toxicological data and models but could not report on the final outcome of the safety assessment at the ANS panel (Panel on Food Additives and Nutrient Sources Added to Food).

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; Invitation

Outcome:
HMPC agreed to Chairs proposal that HMPC Vice-Chair will participate to the IRCH meeting as well as to the TradReg symposium (presentation according to proposal by the host) on behalf of the HMPC.

HMPC noted that WHO agreed to EMA proposal having exceptionally two focal points from EMA as well as HMPC secretariat involved for all communication (see also 6.2.4).

- WHO meeting on Herbal Quality Guidance - Hong Kong, China, 4-6 Sep 2017
  Report: HMPC Chair; QD G Chair
  Action: for discussion
  Documents: Invitation; 2nd Draft guideline on Good Herbal Processing Practice

  Outcome:
  Not discussed.

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

5.6.1. EUROCAM request

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 statuses; List of interested parties to the HMPC

Outcome:
Postponed to HMPC September 2017 meeting.

5.7. HMPC work plan

5.7.1. HMPC work plan 2017

- Report: HMPC Chair
  Action: for discussion
  Document: Work plan 2017 – current status
- Project 1.3.1. Forward planning and prioritisation
  Report: HMPC Chair; ORGAM Chair
  Action: for discussion
  Documents: Presentation; Draft template on proposals for assessment to HMPC
- Project 2.1.3. Cooperation with Academia
  Report: MLWP Chair
  Action: for discussion
  Documents: Presentation; Proposal

  Outcome:
  Discussion postponed to HMPC September 2017 meeting.

5.8. Planning and reporting

5.8.1. HMPC 2017 assessors training on quality

Report: Q DG Chair
Action: for discussion
Document: Draft agenda

Outcome:
Topic will be re-discussed at the HMPC September 2017 meeting.

HMPC agreed to main topics and draft outline for training on contaminants in particular pyrrolizidine alkaloids and furthermore polycyclic aromatic hydrocarbons and bioburden.

Members to send proposals for speakers by **31 July** in order to allow further development of the agenda and sending first invitations to external speakers before September. An advanced draft will be presented at the HMPC September meeting for adoption.

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; Call for submission (PL); Request (PL); Draft response

Outcome:
Discussion postponed to HMPC September 2017 meeting.

6.1.2. Follow up on Public Statement on Pyrrolizidine alkaloid contaminations

Report: HMPC Chair
Action: for discussion
Documents: BE Herbal Board questions on PA public statement; NL questions on PA; Meeting report from breakout session May 2017; BE additional question July 2017; Draft response.

Outcome:
HMPC noted outcome of the PA group meeting on 30 May.
Draft responses on BE questions were discussed. HMPC agreed to compile all into one Q&A document for internal use, add missing responses and distribute among all HMPC members for comments before adoption at the HMPC September meeting.

The toxicological basis of the HMPC public statement and the practical implementation in the MSs were debated. While some emphasised that a harmonised European approach is preferable, others highlighted that national markets/situations may differ and the

responsibility is with the NCA. Some experiences with most or least affected substances, possibilities for skip testing and resources for analysis as well as choice of marker substances were shared.

The complete set of BE and NL questions will be compiled by the secretariat and the PA group to provide the remaining draft answers.

6.1.3. DG SANTE study on Regulation (EC) No 1924/2006 with regard to health claims made on plants and their preparations and the general regulatory framework for their use in foods

Report: HMPC Chair
Action: for discussion

Documents: Letter of introduction; Email correspondence; List of questions

Outcome:
HMPC noted consultation of stakeholders following the EC REFIT initiative and upcoming interview by the HMPC Chair. The List of Questions was discussed and general concerns raised on the overlapping frameworks and partly unjustified extrapolations from the medicines to the food area.

Background information for the initiative and subsequent consultation were given as well as for some specific items of the legal/regulatory framework for food.

6.1.4. European Union herbal monograph on Saccharomyces cerevisiae CBS 5926

Action: for discussion
Documents: Amended draft letter; Presentation

Outcome:
HMPC Chair reported on a meeting between the HMPC and MLWP Chairs, HMPC Vice Chair and the EMA. EMA will send some suggestion for clarification of the letter adopted by HMPC during the May meeting. The amended letter will be circulated to HMPC before submission to the Commission.

6.1.5. Preparedness for UK's withdrawal from the EU; New data gathering exercise

Action: for discussion
Documents: Presentations; Report on new data gathering, Agenda Working Group of preparedness

Outcome:
Discussion postponed to HMPC September 2017 meeting.

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 29-30 May 2017

Overview of expertise of members HMPC and subgroups

Meeting report from HMPC meeting held on 29-30 May 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 18-20 Jul 2017

6.2.3. ARSP

- English template
- English summaries for publication:
  - Wormword herb
  - Purple coneflower root
  - Grapevine leaf

No comments/objections were raised on newly finalised herbal summaries for publication.

6.2.4. Other

- PCWP/HCPWP meetings:
  - Draft Agenda of the PCWP/HCPWP joint meeting – 27/28 June (EMA/213892/2017): For information
  - Minutes PCWP/HCPWP joint meeting – 15 March (EMA/182189/2017): For information
- Pharmacovigilance – EudraVigilance database and Art.16a registered products
- WHO - IRCH focal point
- Notification to the CMDh Chair, Referral under Article 29(1) of Directive 2001/83/EC

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 17-18 July 2017 meeting.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Reinhard Länger	Member	Austria	No interests declared	
Wim Huygh	Alternate	Belgium	No interests declared	
Elena Mustakerova	Member	Bulgaria	No interests declared	
Iliana Ionkova	Alternate	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	
Martina Holenkova	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	
Ioanna Chinou	Member	Greece	No interests declared	
Zoi (Zoe) Karampourmpouni	Alternate	Greece	No interests declared	
Zsuzsanna Bíróné Dr Sándor	Member	Hungary	No interests declared	
Rachel Cox	Alternate	Ireland	No interests declared	
Marisa Delbò	Chair	Italy	No interests declared	
Alessandro Assisi	Member	Italy	No interests declared	
Evita Skukauska	Member	Latvia	No interests declared	
Baiba Jansone	Alternate	Latvia	No interests declared	
Everaldo Attard	Member	Malta	No interests declared	
Emiel Van Galen	Member	Netherlands	No interests declared	
Hilda Kuin	Expert	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	
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	
Per Claeson	Member	Sweden	No interests declared	
Malin Söderberg	Alternate	Sweden	No interests declared	
Linda Anderson	Member	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 (via TC)	EDQM	No interests declared	
Dominique Hamerlijnck	Patient Representative	EFA	No interests declared	