18 July 2017
EMA/HMPC/461658/2017 Corr.[1]
Inspections, Human Medicines Pharmacovigilance & Committees Division

Committee on Herbal Medicinal Products (HMPC)

Minutes of the meeting on 29-30 May 2017

Chair: Marisa Delbò Vice-Chair: Emiel Van Galen

29 May 2017, 14:00 – 19:00, 2F

30 May 2017, 09:00 – 13:00, 2F

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 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).

[1] Correction in participant list

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1. Introduction

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

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

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

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

New memberships:

Malin Söderberg (Sweden) alternate; start of mandate: 13 May 2017

1.2. Adoption of agenda

HMPC agenda for 29-30 May 2017

Time schedule for 29-30 May 2017

Outcome:
Agenda adopted.

1.3. Adoption of the minutes

HMPC minutes for 27-28 Mar 2017

Outcome:
Minutes adopted. Minor corrections were requested to be introduced in the participant list.

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

2.1.1. Report from the MLWP March 2017 meeting

Report: MLWP Chair
Action: for information
Document: Draft minutes for the MLWP meeting on 28-30 Mar 2017

2.1.2. Appointment of Rapporteurs and Peer-reviewers

- Changes of Rapporteurs for Monograph revision

  Endorsed.

2.1.3. MLWP membership

Report: MLWP Chair
Action: for adoption
Documents: Call for nomination; BE Nomination, CV, motivation letter: P. Duez; List of expertise

Outcome:
HMPC appointed Prof P Duez (BE) as new member of the Monograph and List Working Party.

The BE member confirmed that the nominee would be able to actively support the MLWP work regarding the non-clinical and clinical assessment within substance assessment and toxicological guidance in line with the required expertise as specified in the call for nominations.

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

2.2.1. Monograph on Absinthii herba and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 100/100

Outcome:
Final revised monograph and supporting documents with changes in the monograph (sections 4.2 and 4.4) adopted by consensus.

The committee corrected some parts according to template and discussed the evidence of use as per preparation and appropriate reflection in the AR - in particular vis-à-vis information available from the initial assessment. Furthermore contraindication and warnings were discussed and some adaptations still found necessary in the AR before publication.

2.2.2. Monograph on Echinaceae purpureae radix and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 32/127

Outcome:
Final revised monograph and supporting documents adopted by consensus.

Missing references to be provided as appropriate before publication.

2.2.3. Monograph on Pelargonii radix and supporting documents

Action: for adoption
Documents: MO, AR, LoR, OoC MO, OoC AR; References: 74/104

Outcome:
Adoption postponed, monograph and supporting documents returned to MLWP.
Major unclarified issues highlighted and new modifications proposed during peer review (indication, use in children) requiring new discussion at MLWP before final documents can be adopted at HMPC.

Rapporteur and Peer reviewer explained their views regarding the studies considered including primary and secondary endpoints as regards clinical relevance and relevance for the indication in the monograph. Furthermore the use in children and available data for liquid and dry preparations were scrutinised. In this context general concerns were raised regarding ethanol use as well as the benefit-risk ratio for cough medicines in children.

2.2.4. Monograph and List Entry on Vitis viniferae folium and supporting documents

Action: for adoption
Documents: MO, AR, LoR; References: 0/131
Action: for information
Document: LE

Outcome:
Revised final monograph and supporting documents adopted by majority vote (18 out of 24).
Divergent opinion: A. Assisi, E.S. Leinonen, E. V. Galen, L. Anderson, U. Mockler, W. Dymowski

Missing references to be provided as appropriate before publication.

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

2.4.1. Monograph on Allii sativi bulbus and supporting documents – postponed

Outcome:
Adoption postponed to July 2017 meeting due to late submission.

2.4.2. Monograph on Silybi mariani fructus and supporting documents

Action: for adoption
Documents: MO, AR, LoR, OoC; References: 114/196

Outcome:
No majority could be found for an opinion on the monograph and supporting documents after 2nd public consultation. Follow-up to be discussed at the HMPC July meeting. Proposals regarding indication, split monographs and other options including a public statement were discussed and will be taken into account for follow-up. It was acknowledged that products are on the market (authorised or registered) in many MSs. Persisting doubts by several members on the efficacy not supporting a well-established use indication had

guided MLWP to a proposed monograph with a traditional use indication only. However, also for the traditional indication no majority was found as safety concerns were raised for some MSs. These do not arise from the product as such but solely from the indication and potential misunderstanding when used for self-medication by some groups of the population.

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 – postponed

Outcome:
Adoption postponed to July 2017 meeting due to major issues detected during peer review.

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

2.6.1. Monograph on Salicis cortex and supporting documents

Rapporteur: G. Laekeman; Peer-reviewer: B. Kroes
Action: for adoption
Documents: MO, AR, LoR; Email correspondence; References: 95/132

Outcome:
HMPC noted general information on key points of the editorial review and reasons for delay in publications.

Committee members reflected on consistency of documents and practice regarding procedural steps (peer review, timelines) after MLWP finalisation before HMPC adoption to avoid increased return to MLWP and long post-adoption clarification needs. Some examples were given and the HMPC Chair highlighted that the assessment report template when appropriately used should allow complete transparency of the content of the monograph in all cases.

After final clarification on a key issue detected in Salix documents (contraindications, warnings), HMPC agreed to proposed corrections before publication and final alignments in the assessment report.

2.6.2. Monograph on Salviae officinalis folium and supporting documents

Action: for adoption
Documents: MO, AR, LoR, OoC; Presentations; References: 61/64

Outcome:
HMPC noted clarification on 5 main points detected during the editorial review of Salvia documents and agreed on proposed corrections of inconsistencies in MO and AR before publication. Based on specific examples some general principles were agreed:
(1) Recently registered products in the member states are included in the market overview of the AR. However, inclusion into the monograph should happen only, if sufficient documentation on the 15/30 years is available to the HMPC. Some members highlighted

that individual product data seen at NCAs are considered confidential and cannot be provided for HMPC assessment work.
(2) If changes to preparations are performed in the revised monograph in comparison to the original monograph, a justification needs to be provided in the AR. Concerns were raised on content changes during revision without new safety concerns in view of potential product developments according to existing monographs.
(3, 4 and 5) The AR should provide the relevant specific information on posology as per indication. If extrapolations are made, the justification should be given in the AR (e.g. minor differences in ethanol strength). Also here, concerns were raised on corrections/reductions during revision without imminent safety concerns. It was agreed to generally keep all preparations/indications in revised monographs unless new safety data justifies deletions/ modifications.

2.6.3. Monograph on Pistacia lentiscus (mastix) and supporting documents

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

Outcome:
Postponed to July 2017 meeting.

2.6.4. Monograph on Pruni africanae cortex and supporting documents

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

Outcome:
Postponed to July 2017 meeting.

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:
Postponed to July 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:
Postponed to July 2017 meeting.

4.2. Quality

4.2.1. Planned revision of reflection paper on markers used for quantitative and qualitative analysis of HMP and THMP

Action: for discussion
Documents: Reflection paper; Markers questionnaire

Outcome:
HMPC welcomed short explanation on the questionnaire developed by Q DG and distributed earlier with a **deadline 19 June** as a starting point for the marker concept reconsideration according to Q DG and MLWP work plans.

The Rapporteur explained the background and invited all HMPC members to express their views (from a quality assessors, academic or general regulatory perspective) and national practice in order to allow elaborating a revised concept.

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 (FtF) meeting held on 20 Apr 2017
  Action: for adoption
  Documents: Meeting report; Draft reflection paper on the use of new analytical methods
- Draft agenda for the Q DG meeting to be held on 28 Jun 2017
  Action: for information
  Document: Draft agenda

Outcome:
Meeting report adopted.

The Q DG Chair asked for support with the finalisation of the reflection paper on new analytical methods. HMPC members willing to act as Co-Rapporteur to inform the Q DG Chair (with secretariat in copy). Suggestions of suitable experts to be provided by **19 June 2017**.

QWP guideline on finished dosage forms to be added to QDG agenda for possible endorsement at the HMPC July meeting.

The Q DG Chair highlighted that the revision of the specification guideline will also have priority at the next meeting as well as the development of a draft agenda for an assessors training (see also 5.8.1) since it will be too early to make revised quality, specification and declaration guidelines a main training topic as originally planned.

4.4.2. ORGAM DG

Report: ORGAM DG Chair

- Meeting report
  Action: for adoption
  Document: Meeting report from ORGAM DG meeting held on 4 Apr 2017
- Agenda
  Action: for information
  Document: Draft agenda for the ORGAM DG meeting to be held on 27 Jun 2017

Outcome:
Meeting report adopted.

The new revision procedure will remain the main important topic for ORGAM activities.

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

Report: ORGAM DG Chair
Action: for discussion
Documents: Draft procedure; Template examples; Presentation

See also 6.1.2

Outcome:
HMPC agreed to the main principles for the revised procedure. Open questions were presented and direction given.

One question (consequences of divergent updates MO versus LE) was noted requiring clarification from the Commission on possible additions to a list entry text during national procedures.

ORGAM DG to further develop the procedure taking into account comments from HMPC and MLWP members. Comments to be sent by **19 June 2017** to the ORGAM DG Chair with secretariat in copy.

(1) Although so far no MO has been revised within the 5 year period according to current procedure, a 5 year period for systematic review in the future was suggested if feasible.

(2) Possible double standards were highlighted: e.g. minor polishing of MO but update of the corresponding LE only if safety-relevant. Clarification on the use of LEs in procedures vis-à-vis e.g. the latest SmPC guideline requirements was deemed necessary. It was further noted that if the new proposed revision principle is applied, revision of either MO or LE should happen only in case of justified need; i.e. changes are *per se* major. According to current procedure (e.g. updated monograph with minor adaptations to SmPC guideline) the LE already established (not updated) may not meet the updated SmPC guideline requirements. If the missing parts could be added during the registration procedure, the risk of double standards may become irrelevant. Also the current distinction between voting principles (voting on the changes for LEs, as requested previously by the Commission, instead of voting for the complete modified package for MOs) needs a regulatory check.

(3) It was proposed to add definitions/glossary to the procedure. It was clarified that the new procedure foresees that after systematic review every revision, if agreed necessary, will be a 'full revision'.

(4) No objections were raised against proposed timelines for review and timelines for revision. However, later scrutiny at MLWP for implementation is recommended.

(5) After review only 2 options: revision required (full set of documents), revision not required (Addendum to existing AR; MO, AR not touched). A 'third way' is not possible.

(6) Procedural aspects to be developed by ORGAM DG, the linked 'Best practice guide for revision' (content details) by MLWP

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

- Presidency meeting – Malta, 26-28 Apr 2017 – follow up
  Action: for discussion
  Documents: Agenda; Presentations (8 out of 15); Breakout session groups HMPC July 2016– follow up; Presentation by EMA – Future of HMPC (breakout sessions)

  Outcome:
  Discussion postponed to July 2017 meeting.

  HMPC noted that outcome (presentations, report) from the Malta Strategic Review and Learning Meeting (SRLM) were still incomplete but are planned to be made available to all members.

  The Vice Chair announced to present at the HMPC July 2017 meeting a summary combining the outcome of discussions initiated at the SRLM in Utrecht 2016 and subsequent HMPC 2016 July discussions with essential Malta presentations/outcome.

  The Chair agreed to give these procedural proposals for improvement some discussion time in July.

  The Chair welcomed that Romania has agreed to host a HMPC SRLM during the Estonian Presidency. A date (anticipated in October 2017) will be specified soon. Proposals for agenda points can already be provided to the Romanian HMPC member.

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 from meeting held on 22 Sep 2016, 31 Jan 2017; Agenda: 24 Apr 2017

See also 6.1.4.

Outcome:
HMPC Chair shortly reported on the last Scientific Coordination Board Meeting focused on the impact of the UK's withdrawal from the UK on EMA scientific committees' operations and EMA provided a presentation on Preparedness for UK's withdrawal from the EU (See 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 discussion
Documents: PS; OoC; Letter from HMPC Chair to CHMP Chair, 15 Sep 2015; SWP response, 16 Nov 2016; Presentation

Outcome:
Rationale for changes after public consultation and SWP response, including uncertainty factors and heterogeneous exposure data from food use, were presented. Because the proposed limit is exceeded substantially by the intake from traditional products included in the fennel/anise monographs/list entries, HMPC members understood the consequences for these monographs and LEs, herbal products on national markets and other MPs containing essential oils as excipients.

HMPC adopted after minor amendments the revised public statement. Given the change of the limit value, a second public consultation is foreseen after confirmation of the scientific conclusions by CHMP/SWP. After agreement appropriate information of CMDh (and PRAC) but also EFSA is anticipated.

HMPC secretariat to present the topic to CHMP (ORGAM) for follow-up. The Rapporteurs signalled availability in case of scientific discussion at CHMP plenary or SWP before HMPC July meeting.

5.4. Cooperation within the EU regulatory network

5.4.1. European Commission

- European Union herbal monograph on Saccharomyces cerevisiae CBS 5926
  Action: for adoption
  Document: Draft letter
  Action: for discussion
  Documents: Draft MO, draft AR, draft LoR; draft LE

  Outcome:
  HMPC agreed to the modified draft letter and the one remaining question to seek clarification on the classification of *Saccharomyces* as active substance in medicinal products. HMPC secretariat to edit for signature by HMPC Chair and submit to the Commission. Attachment of the draft AR was not deemed necessary.

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

Outcome:
The update on the status of the submitted List entries for Valerian and Sideritis will be provided in July.

5.4.2. European Pharmacopoeia

- EDQM 13A expert group meeting to be held on 13-14 Jun 2017
  Report: M. Bald (EDQM)
  Action: for information
  Document: Agenda
- EDQM 13B expert group meeting held on 10-11 May 2017
  Report: M. Bald (EDQM)
  Action: for information
  Documents: Agenda; SoD
- EDQM TCM expert group meeting held on 26-27 Apr 2017
  Report: M. Bald (EDQM)
  Action: for information
  Document: Summary of decisions
- EDQM new Pyrrolizidine Alkaloids Working Party (PA)
  Report: M. Bald (EDQM)
  Action: for discussion
  Documents: Nomination form; DoI

Outcome:
HMPC noted update on expert group activities given by the EDQM representative. New monographs under development were highlighted as well as activities regarding essential oils. The HMPC proposal for new monograph developments was received and member interests will be checked before proposing substances for addition to the next work programme.

The HMPC Chair reported that, in a meeting between the secretariat and the HMPC and QDG Chair held in February, it was agreed, in order to optimize resources, that no routine attendance of additional observers is required anymore to 13A, 13B, TCM group meetings on top of anyway present HMPC/QDG members to flag relevant items. However, for important specific topics adequate quality experts should be appointed to guarantee focused coordination as necessary.

HMPC welcomed the formation of the Ph. Eur. working party for PA analytical method development following request by HMPC in 2016. The HMPC agreed to the PA task force's view (work plan 2017, see also agenda items 6.1.3) that the anticipated composition (incl. HMPC and QDG members) does not require an additional observer at present. In case of specific questions this may be reconsidered. Secretariat to inform EDQM accordingly in writing.

5.4.3. Pharmacovigilance – EudraVigilance database and Art.16a registered products

Action: for discussion
Documents: Email correspondence by BPI, 17 Oct 2016; Presentation; Note for clarification: THMP and simplified registrations for homeopathic medicinal products: PhV requirements and EV access

Outcome:
EMA informed that, based on the applicable legal provisions and a previous clarification of the Commission with regard to registered products and the applicability of the Art. 57 database registration obligation, a wording change in the respective FAQ on the EMA website was not advisable. HMPC members expressed concerns that the current information could lead to heterogeneous reporting.

It was indicated that registration holders will need to comply with their PhV reporting obligations, as per the applicable legal provisions, by using the appropriate format provided by the Article 57 database. It was confirmed that there are no fee obligations for registration holders, in light of the pharmacovigilance fees regulation.

5.4.4. Coordination with EFSA

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

  Outcome:
  Postponed to July 2017 meeting.

5.5. Cooperation with International Regulators

5.5.1. WHO – IRCH meetings

- New Delhi, India, 8-10 Nov 2016
  Report: HMPC Chair
  Action: for discussion
  Documents: Agenda; Draft Summary Report
- Bonn, Germany, 14-15 Sep 2017
  Report: HMPC Chair
  Action: for discussion
  Documents: Draft programme; Invitation; Email on focal point appointment

  Outcome:
  According to the usual HMPC practice the HMPC Chair was appointed as new IRCH focal point with the Vice Chair as deputy as necessary. HMPC secretariat will inform WHO secretariat accordingly.

  HMPC noted invitation for the adjacent TradReg Symposium in September in Germany with a scheduled speaker from HMPC. While the topic was welcomed, no speaker was identified yet.

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

5.6.1. AESGP – hearing at MLWP March 2017

Report: MLWP Chair
Action: for information
Document: Draft meeting report

Outcome:
HMPC members noted the report. No comments or objections were made.
The report will be published at the Agency website after MLWP adoption.

5.6.2. EUROCAM request

Report: HMPC Chair
Action: for information
Documents: Letter to HMPC Chair, 13 Feb 2017; The regulation of herbal medicinal products in the EU – by EUROCAM, 13 Feb 2017

Outcome:
Postponed to July 2017 meeting.

5.7. HMPC work plan

5.7.1. HMPC work plan 2017

Report: HMPC Chair
Action: for discussion
Documents: Work plan 2017 – current status; Presentation and proposal I. Chinou on project 2.1.3. Cooperation with Academia

Outcome:
Postponed to July 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:
HMPC agreed to hold an assessors training on 13-14 December at the EMA premises in London. No specific topic was agreed yet. Members were asked to send proposals to the Q DG Chair, the MLWP Vice Chair and the secretariat. A draft agenda will be presented at the HMPC July meeting.

5.9. Legislation and regulatory affairs

5.9.1. Evidence on the period of traditional use

Report: European Commission
Action: for discussion
Documents: Request to EC, 20 Dec 2016; Presentations

Outcome:
Postponed to July 2017 meeting.

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)

Outcome:
Postponed to July 2017 meeting.

6.1.2. Polypodii rhizoma

Action: for discussion
Documents: Revision of MO; Annex

See also 4.4.3

Outcome:
HMPC agreed to keep the review/revision of Polypodii on hold until the new review/revision procedure has been introduced.

6.1.3. 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; Presentation

Outcome:
The HMPC Chair referred the response to the questions to the PA task force that had been appointed as Rapporteurs. Discussion is foreseen for the HMPC July meeting.

A short summary from the PA task force group meeting on 30 May 2017 will be distributed to all HMPC members.

6.1.4. Preparedness for UK's withdrawal from the EU

Action: for discussion
Document: Presentation

See also 5.2.1.

Outcome:
HMPC noted main features of the Agency's preparation for the UK's withdrawal from the EU and subsequent possible impact on committees and substructure operations.

It was acknowledged that HMPC is less affected in terms of Rapporteurship re-distribution needs but more with loss of expertise. Considerations with regard to the UK traditional use acceptance in the future were mentioned as one specific aspect for the HMPC tasks.

Some clarification on surveys to Committee members (Brexit-related but also previous data gathering exercises) was provided with an update scheduled for the HMPC July meeting.

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 27-28 Mar 2017

Overview of expertise of members HMPC and subgroups

Meeting report from HMPC meeting held on 27-28 Mar 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 30-31 May-01 Jun 2017

6.2.3. ARSP

- English template
- English summaries for publication:
  - Aloes
  - Diuretic herbal tea combinations
  - Rose flower
  - Raspberry leaf

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

6.2.4. Other

- Meeting dates for 2019-2021

- User manual on CxMP/WP/SAG members, alternates and experts representing CxMP or EMA officially at external meetings; Documents: User Manual; Approval form; Overview; Presentation

- Herbal substances assessed by HMPC currently without Ph. Eur. Monographs as quality standard

- Survey on uptake of the traditional use registration and implementation of Directive 2004/24/EC in EU Member States, 2016

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 29-30 May 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	
Heidi Neef	Member	Belgium	No interests declared	
Wim Huygh	Alternate	Belgium	No interests declared	
Gert Laekeman	Co-opted member	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	
Maria Stavrou	Member	Cyprus	No interests declared	
Marie Heroutova	Member	Czech Republic	No interests declared	
Markéta Příhodová	Alternate	Czech Republic	No interests declared	
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	
Heidi Foth	Co-opted member	Germany	No interests declared	
Jacqueline Wiesner	Member	Germany	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Ioanna Chinou	Member	Greece	No interests declared	
Zoi 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	
Rachel Cox	Alternate	Ireland	No interests declared	
Alessandro Assisi	Member	Italy	No interests declared	
Baiba Jansone	Alternate	Latvia	No interests declared	
Emiel Van Galen	Member	Netherlands	No interests declared	
Wojciech Dymowski	Member	Poland	No interests declared	
Ana Paula Martins	Member	Portugal	No interests declared	
Miroslava Petrikova	Member	Slovakia	No interests declared	
Barbara Razinger	Alternate	Slovenia	No interests declared	
Cristina Martinez Garcia	Alternate	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	
Sue Harris	Alternate	United Kingdom	No interests declared	
Melanie Bald	Observer (via TC)	EDQM	No interests declared	
Joseph Shafer	Patient Representative	Luxembourg	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
A representative from the European Commission attended the meeting				
Meeting run with support from relevant EMA staff				