6 July 2015
EMA/HMPC/645800/2015
Scientific Committee Support

Committee on Herbal Medicinal Products (HMPC)

Minutes of the meeting on 6-7 July 2015

Vice-Chair: Marisa Delbó, replacing HMPC Chair

6 July 2015 14:00 – 19:00, 2F

7 July 2015 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 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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1. Introduction

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

- Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the HMPC plenary session to be held on 6-7 July 2015.

Outcome:
No new or revised conflict of interests was declared and no restriction in the involvement of members in relation to agenda topics was identified.

- Adoption of agenda

HMPC agenda for 6-7 July 2015

Outcome:
Adopted

- Time schedule

Outcome:
Minor changes

1.2. Adoption of the minutes

- HMPC minutes for 4-5 May 2015

Outcome:
Adopted

2. European Union herbal monographs and list entries

2.1. Report on MLWP activities

2.1.1. Report from the MLWP May meeting

Report: MLWP Chair
Action: for information
Documents: draft minutes for the MLWP meeting on the 5-7 May 2015
draft meeting report of the AESGP/MLWP hearing held on 5 May 2015

Outcome:
No further HMPC comments made on the hearing report. After editing and final agreement at the MLWP July meeting to be published on the EMA website.

2.1.2. Appointment of Rapporteurs and Peer-reviewers

Herbal substance:
Piper methysticum G. Forst., rhizoma

Outcome:
HMPC endorsed Rapporteur and Peer reviewer as proposed by MLWP.

2.1.3. Cancellation of assessment work for Juniperi communis summitates

Rapporteur: G. Laekeman; Peer-review: O. Palomino
Action: for adoption
Document: presentation

Outcome:
The HMPC endorsed the proposal by Rapporteur and MLWP to cancel the assessment work based on insufficient data on medicinal use of the substance (medicines market overview and some textbooks) which makes the possibility for establishing a monograph unlikely.

Some limited heterogeneous data for *J. communis* or *J. sabina* (obsolete internal use and external use with irritant properties) are available suggesting that establishment of 30 years safe use will not be possible.

2.2. Revised EU herbal monographs and list entries for public consultation/final adoption after systematic review/revision

2.2.1. Monograph on Equiseti herba and supporting documents

Rapporteur: J. Wiesner; Peer-review: P. Claeson
Action: for adoption for release for public consultation
Documents: draft MO, AR, LoR; references: 92/127

Outcome:
Draft revised monograph and supporting documents with changes in monograph sections 4.2, 4.4, 4.6 and 4.8 adopted by consensus for 3 months public consultation.

HMPC agreed to keep the comminuted herbal substance in solid dosage form (tablet) with subsequent modifications in monograph sections 3 and 4.2 and in the AR before publication.

Available data for preparations on the market in mono and combination products were discussed and additional information from Spain provided. Several sections were adapted according to recent template, established practice and cross check with comparable other monographs.

2.2.2. Monograph on Valerianae aetheroleum and supporting documents

Rapporteur: J. Wiesner; Peer-review: S. Girotto
Action: for adoption for release for public consultation
Documents: draft MO, AR, LoR; references 88/96

Outcome:
Draft revised monograph and supporting documents adopted by consensus for 3 months public consultation.
Valerianae aetheroleum had previously been included in the monograph Valerianae radix (EMEA/HMPC/340719/2005) but according to meanwhile established practice the essential oil is now covered by an extra monograph.

2.2.3. List entry and monograph on Valerianae radix and supporting documents

Rapporteur: J. Wiesner; Peer-review: S. Girotto
Action: for adoption for release for public consultation
Documents: draft LE, draft MO, AR, LoR; references 88/96

Outcome:
Draft list entry, draft revised monograph and supporting documents adopted by consensus for 3 months public consultation.

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

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

Rapporteur: I. Chinou; Peer-reviewer: M. Delbó
Action: for adoption
Documents: draft MO, AR, LoR

Outcome:
Draft monograph and supporting documents with changes in monograph sections 4.2 and 4.4 adopted by consensus for 3 months public consultation.

2.3.2. Monograph on Ricini oleum and supporting documents

Rapporteur: C. Purdel; Peer-reviewer: B. Kroes
Action: for adoption
Documents: draft MO, AR, LoR

Outcome:
Draft monograph and supporting documents with changes in monograph sections 2, 3 and 4.3 adopted by consensus for 3 months public consultation.
The frequency of use was discussed vis-à-vis other laxatives in view of the misuse potential and an additional sentence for limitation agreed.
The proposed contraindication in pregnancy and lactation was kept following considerations regarding the balance between need for clinical evidence, guideline conformity, other products on the market and overdose risks as known from historical illicit abuse and some pharmacological data.

2.3.3. List entry and monograph on Sideritis herba and supporting documents

Rapporteur: I. Chinou; Peer-reviewer: B. Kroes
Action: for adoption
Documents: draft LE, draft MO, AR, LoR

Outcome:
Draft list entry with changes in 'Indications' and 'Posology', draft monograph with changes in monograph sections 4.1 and 4.2 and supporting documents adopted by consensus for 3 months public consultation.
A more specific indication regarding gastrointestinal discomfort was considered necessary.
The committee accepted the discrepancy between draft LE and draft MO as regards species included in view of genotoxicity data only available for one species and no licensed medicinal products -subject to PhV on the market- that could further substantiate the safe use without need for eventually additional data in an application.

2.3.4. Monograph on Silybi mariani fructus and supporting documents

Rapporteur: O. Palomino; Peer-reviewer: W. Knöss
Action: for adoption
Documents: draft MO, AR, LoR

Outcome:
Draft monograph and supporting documents with a minor change in monograph section 2 adopted by majority vote for 3 months public consultation.
The evidence for recognised efficacy in the proposed WEU indication was discussed as well as the possible misuse of these products and the sufficiency of safeguards in the monograph as basis for SmPC, labelling and patient information.
Different views were also expressed on the proposed TU indication considering related substances and indications, the state of knowledge on the mechanism of action and diverse traditional use in the MSs.

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

2.4.1. Monograph on Carvi aetheroleum and supporting documents

Rapporteur: P. Claeson; Peer-reviewer: M. Delbó; Expert: E. Svedlund
Action: for adoption
Documents: MO, AR, LoR; references: 54/55

Outcome:
Final monograph and supporting documents adopted by majority vote (27 out of 28).
Norway expressed a favourable position.
Divergent opinion: E. v. Galen.

2.4.2. Monograph on Carvi fructus and supporting documents

Rapporteur: P. Claeson; Peer-reviewer: M. Delbó; Expert: E. Svedlund
Action: for adoption
Documents: MO, AR, LoR, OoC; references: 54/55

Outcome:
Final monograph and supporting documents adopted by consensus.
Norway expressed a favourable position.

2.4.3. Monograph on Matricariae aetheroleum and supporting documents

Rapporteur: W. Knöss; Peer-reviewer: R. Länger; Expert: C. Werner
Action: for adoption
Documents: MO, AR, LoR, OoC; references: 115/127
Documents for information: email from W. Knöss dated 25/06/2015
email from W. Dymowski dated 02/07/2015

Outcome:
Final monograph and supporting documents adopted by majority vote (26 out of 28).
Norway expressed a favourable position.
Divergent opinion: E. v. Galen, L. Anderson

2.4.4. Monograph on Matricariae flos and supporting documents

Rapporteur: W. Knöss; Peer-reviewer: R. Länger; Expert: C. Werner
Action: for adoption
Documents: MO, AR, LoR, OoC; references: 115/127
Documents for information: email from W. Knöss dated 25/06/2015
email from W. Dymowski dated 02/07/2015

Outcome:
Final monograph and supporting documents with changes in monograph section 4.2 adopted by majority vote (26 out of 28).
Norway expressed a favourable position.
Divergent opinion: E. v. Galen, L. Anderson

Remaining minor issues from the peer review were clarified keeping the Rapporteurs proposal for practical reasons (high number and diversity of preparations, forms and posology) in the monograph. A proposed clarification regarding dosage and application form in the interaction section was not followed in view of the diversity of products captured in the MO and available clarifying information in the AR. Decisions on appropriate information on interaction for a specific product can be made at the national level within an application.

Supplementary information on marketed products in PL were provided to be considered for the supporting documents.

3. Referral procedures

None

4. Guidelines and guidance documents

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

4.1.1. Public statement on the use of herbal medicinal products containing pulegone/ menthofuran

Rapporteurs: O. Pelkonen; J. Wiesner
Action: for information
Documents: PS, OoC, letter from HMPC to CHMP 06/2015, SWP response 11/2014

Outcome:
The outcome of the MLWP discussion in May and the follow up by Rapporteurs, HMPC Chair and secretariat was reported. The modified documents had been endorsed by a majority of MLWP and HMPC members and transferred to CHMP for further coordination. A first feedback from the CHMP meeting in June was provided and with envisaged SWP, CHMP but eventually also CMDh and further EFSA consultation.

4.2. Quality

None

4.3. Regulatory

4.3.1. Public statement on herbal substances containing constituents associated with safety concerns

Rapporteur: Marisa Delbò
Action: for discussion
Document: public statement

Outcome:
Document transferred to MLWP for minor revision according to recent developments regarding prioritisation.
Following the recent addition of *Piper methysticum* to the HMPC priority list the content of the PS on the prioritisation of substances for HMPC assessment was discussed and minor revision proposed. It was emphasised that the outcome of an assessment cannot be predicted. Until then the existing concerns towards the herbal substances listed in the PS remain. However, the opportunity should be used to improve some wordings in the PS in order to avoid some misconceptions such as understanding it as a definitive 'negative list' without detailed benefit risk assessment case by case.

4.4. Report on HMPC Drafting Groups activities

4.4.1. Quality DG

Report: Q DG Chair

- Meeting report from Q DG meeting held on 21 May 2015

Action: for adoption

Outcome:
Adopted

Beside a check of the work plan implementation status, the DG had a first discussion on specific Q&A following the finalisation of the reflection paper on microbiological aspects (EMA/HMPC/95714/2013) and further progressed with a reflection paper on new analytical methods (presentation to HMPC envisaged for December). A first draft for an assessors training on quality topics to be held at the EMA in December was elaborated for discussion/agreement by HMPC. Current topics experienced at national level were discussed for a harmonised view vis-à-vis applicable guidelines and Ph. Eur. requirements such as use of certificates of suitability (CEP) in applications or the need for tests for uniformity of mass for multidose containers. Q DG confirmed the HMPC view on a company request that the Q&A on essential oils should be maintained until further progress at EDQM.

- Draft agenda for the Q DG meeting to be held on 10 September 2015

Action: for information

Outcome:
No additional topics were proposed by HMPC for Q DG. The further development of the assessors training agenda should be progressed already in July to allow organisation (see 5.1.2).

4.4.2. ORGAM DG

Report: ORGAM DG Chair

- Meeting report from the ORGAM DG meeting held on 19 May 2015

Action: for adoption

Outcome:
Adopted

- Draft agenda for the ORGAM DG meeting to be held on 8 September 2015

Action: for information

Outcome:
No work for ORGAM DG was identified by HMPC. The proposal from the ORGAM DG Chair to cancel the next meeting was endorsed.

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Strategic Review & Learning Meetings

Strategic Review & Learning HMPC-Meeting under the Latvian Presidency (co-hosted by BfArM) held on 18-19 June 2015
Report: HMPC Vice-Chair
Action: for information
Documents: presentations, agenda

Outcome:
The three main blocks discussed in Bonn were briefly presented. In particular the strategic discussion was emphasised to reflect and rethink some structural and procedural provisions in order to shape the HMPC for future challenges.

It was proposed to improve the communication and visibility of the HMPC work, to involve all HMPC members (not only MLWP members) in the activities including the core task of monograph/list entry establishment and to find possible new temporary subgroup structures to engage more members efficiently on defined topics. The practicality vis-à-vis the current system and standard procedures (MLWP feeding into HMPC) and potentially procedural changes have further to be explored.

Some members expressed their availability of volunteering to become Rapporteur for the revision of monographs/list entries in collaboration with a MLWP peer-reviewer, in order to reduce the backlog. During the September meeting the Secretariat will present the list of monographs not yet assigned for revision to the HMPC Members for their consideration.

Discussion on proposals to be held at the September meeting based on the minutes of the Strategic meeting in June.

A first announcement was made on the next HMPC Strategic Review & Learning Meeting under the Dutch Presidency: scheduled for 12-13 April 2016. No meeting planned under the current Luxembourg presidency.

5.1.2. Assessors Training December 2015

Report: QDG Chair
Action: for discussion
Documents: draft agenda, draft agenda with breakout session

Outcome:
A majority of HMPC members endorsed a draft agenda on herbal quality topics including breakout sessions.

Following a fine-tuned proposal by HMPC secretariat and Q DG Chair, Q DG to agree on topics, speakers and modalities of breakout sessions for HMPC endorsement by 31 July in order to allow room booking, budget check, coordination with EDQM and invitations.

An alternative option to be kept for discussion at the September meeting in case breakout sessions cannot be realised. EDQM involvement and potential additional topics (e.g. essential oils) depending on status at Ph. Eur. expert group work were discussed.

5.2. Coordination with EMA Scientific Committees or CMDh-v

5.2.1. Coordination with CHMP: drafting group on excipients: ethanol as an excipient (after public consultation)

Rapporteurs: J. Wiesner, O. Pelkonen, S. Girotto
Action: for information

Outcome:
Following many comments from herbal and homeopathic manufactures the Q&A and overview of comments regarding ethanol are under revision. Currently a graduated system with 3 thresholds according to ethanol dosage is defined as regards labelling needs under consideration of age groups. Different administration forms have still to be considered.

Once the draft is finished by the DG (anticipated in July) it will be provided to the HMPC secretariat to allow HMPC Rapporteurs to draft comments for endorsement by HMPC. In particular the effect on current standard wordings in EU herbal monographs and the HMPC RP on ethanol used in herbal medicines in children (EMA/HMPC/85114/2008) will be scrutinised.

5.2.2. Coordination with CHMP: Public statement on the use of herbal medicinal products containing pulegone/ menthofuran

See also 4.1.1

5.2.3. Coordination with PRAC and other Pharmacovigilance topics

PhV/EMA literature monitoring for herbal substances

Action: for information
Document: presentation

Outcome:
Postponed to September 2015 meeting.

5.2.4. Coordination with PDCO

Report from PDCO meeting held on 17-19 June 2015

Observer: S. Girotto
Action: for information
Document: presentation

Outcome:
Postponed to September 2015 meeting.

5.2.5. Scientific Coordination Board Meeting held on 29 June 2015

Report: HMPC Vice-Chair
Action: for information
Document: agenda

Outcome:
Main points were shortly presented with a perspective of potential relevance for the HMPC, e.g. organisation of strategic presidency meetings or committee work plan development/tracking.

The discussion on potential committee interests in some cross committee projects (blue ribbon projects) was mentioned. Some projects driven by other committees could be of interest for the HMPC without being part of the HMPC core-task or mandate nor foreseeing specific activities by HMPC members such as ' post–authorisation studies' or 'extrapolation'.

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

5.3.1. Coordination with PCWP/HCPWP

Report from PCWP/HCPWP joint meetings held on 3-4 June 2015

Observer: S. Bager
Action: for information

Outcome:
The observer, when next participating at PCWP, will give a presentation on the HMPC activities in order to allow identification of patient groups with an interest in HMPC work. This will then help to explore possible modalities of patient representatives' involvement in HMPC assessment. A feedback will be given at the HMPC September meeting.

5.3.2. Coordination with SWP

Report from SWP meetings

Observer: O. Pelkonen
Action: for information
Document: report

Outcome:
Current topics under SWP lead with potential interest for the HMPC and its assessment work were identified: the ICH M7 Guideline on Genotoxic Impurities (elements already used in connection with pulegone and estragole as well as other carcinogens evaluation), ICH Q3C Topic on Residual Solvents (equation for the calculation of permissible limits have been used in connection with both pulegone and estragole), ICH Q3D Topic on heavy metal impurities (may be of interest regarding some traditional medicines e.g. from non-European tradition such as TCM). No specific follow-up by the HMPC was concluded.

Continued interaction is expected for pulegone and estragole public statements and will be reported at the September meeting.

The observer will participate at the next meetings (TCs) and if not available seek replacement with another HMPC member via the secretariat to follow the discussion.

5.3.3. Coordination with QRD group

QRD template for THMPs in mutual recognition and decentralised procedures

Report: ORGAM Chair
Action: for discussion

Documents: draft discussion paper on QRD templates for SmPC, Labelling and Patient Leaflet on Mutual-recognition and Decentralised procedures for THMPs

Outcome:
Adopted with changes for transfer to QRD group and further coordination
Remaining open comments were discussed and agreed in SmPC part 4.3, 4.6, 4.7, 4.8, 5.1, 5.2, labelling/packaging part 2 and 5, as well as minor points in the patient leaflet part. HMPC secretariat after final editorial check to transmit to QRD group. No current HMPC preference for an extra template or minor adaptation of the existing ones to address particularities of THMP for use for European procedures.

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopeia

- EDQM 13B expert group meeting held to be held on 22-23 September 2015

EDQM: M. Bald, U. Rose; HMPC Observer: H. Neef
Action: for information

Outcome:
Postponed to September 2015 meeting.

- EDQM TCM expert group meeting held on 5-6 May 2015

EDQM: M. Bald, U. Rose; HMPC Observer: R. Länger
Action: for information
Document: summary of decisions

Outcome:
Postponed to September 2015 meeting.

- EDQM 13A expert group meeting held on 2-3 June 2015

EDQM: M. Bald, U. Rose; HMPC Observer: I. Chinou
Action: for information
Document: summary of decisions

Outcome:
Postponed to September 2015 meeting.

5.4.2. EU survey on uptake of TUR scheme in EU Member States

Action: for information
Documents: survey - EMA/HMPC/322570/2011, presentation

Outcome:
Postponed to September 2015 meeting.

5.5. Cooperation with International Regulators

5.5.1. HMPC – International representation and cooperation - *postponed*

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

None

5.7. HMPC work plan

5.7.1. HMPC work plan 2015 and preparation for 2016

Action: for information
Documents: HMPC work plan 2015, presentations, tracking tool

Outcome:
The rationale and principles for the new harmonised approach of committee work plan development and tracking was presented. Format and periods covered were aligned between committees allowing a better link to the agency work programmes, identification of cross committee relevance and subsequent coordination. The newly developed tool will help to track status of projects in a given year, recording activities against objectives and help to start drafting work plans mid-year to achieve adjustment between committee's and EMA plans by December.
Some clarification was given on cross-committee activities driven by other committees that could be of potential interest for the HMPC. While information in some project would be useful, specific activities by HMPC members are unlikely because HMPC tasks/mandate are outside most initiatives (see also 5.2.5). Further follow up to be led by HMPC Chair in liaison with the secretariat and to be based on status of implementation of the 2015 work plan. HMPC secretariat to distribute by 20 July work plan presentation to the members for feedback on implementation and changes/proposals for 2016.

5.8. Planning and reporting

5.8.1. EMA Annual report 2014

Action: for information
Document: EMA Annual report 2014

5.8.2. Meeting dates

Action: for information
Documents: HMPC/MLWP 2016-2018, HMPC drafting groups 2016

Outcome:
The rationale behind some changes in the meeting dates was explained with considerations to achieve a more even distribution per month whilst maintaining the procedure-determined order of committees and taking account of holiday periods. Changes refer mainly to CVMP, COMP and HMPC.
Members expressed concern regarding the late announcement vis-à-vis planning of other activities first half of 2016 and the re-scheduled July 2016 meeting (last week). Comments will be taken on board and the committee informed on final decision (anticipated in July).

5.9. Legislation and regulatory affairs

5.9.1. Comments on draft revised monograph on Thymi herba/Primulae radix

Rapporteur: R. Länger
Action: for discussion
Document: letter dated 15 May 2015

Outcome:
Draft response and draft list of questions by legal department / RA in liaison with HMPC secretariat to be sent to Rapporteur and HMPC Chair by 20 July for preparation of the response to the comments received.
The comments received regarding inclusion of a specific preparation in the monograph WEU were discussed considering legislation, standard practice of monograph establishment and available clinical and quality data. Legal provisions versus scientific evaluation in respect of extrapolation, similarity and the wording of the indication were balanced. It was agreed that assessment as well as the wording in AR and the monograph are in line with established practice and not deviating from other substances. For a more detailed consideration more data will be asked from the commenting party.

6. Any other business

6.1. Topics for discussion

Taiwanese regulatory system for traditional medicinal products

Affiliation: Department of Chinese Medicine and Pharmacy, Ministry of Health and Welfare, Taiwan
Action: for discussion
Documents: presentation, CV's of the representatives

Outcome:
Regulation, control but also health care system, tradition, experience and investigation with TCM in Taiwan were presented. Committee members welcomed the presentation and got clarifications on the national database helping to extract useful data, on specific traditional formulations, fixed versus patient-customised combinations, the standard/pharmacopoeial basis for quality control, and the tandem education in traditional and Western medicine.

6.2. Documents for information

6.2.1. HMPC

Table of Decisions from HMPC meeting held on 4-5 May 2015

Overview of expertise of members HMPC and subgroups

Meeting report from HMPC meeting held on 5-7 May 2015

Overview of status of HMPC assessment work – priority list

Inventory of herbal substances for assessment work – alphabetical order

Abbreviations in HMPC minutes

Articles:
Detection of pyrrolizide alkaloids in German licensed herbal medicinal teas. *Phytomedicine* 2015 22(6):648–656

Herbal hepatotoxicity in traditional and modern medicine: actual key issues and new encouraging steps. *Front Pharmacol* 2015 6:72

Safety assessment of botanicals and botanical preparations used as ingredients in food supplements: testing a European Food Safety Authority-tiered approach. *Mol Nutr Food Res* 2010 54(2):175-185

6.2.2. MLWP

Overview of status of MLWP assessment work
Common names of herbal substances in all EU official languages
Draft agenda of MLWP meeting to be held on 7-9 July 2015

6.2.3. Other

ARSP:
- Medical writers restarted the work on ARSP's
- Translations in all EU languages are to be published

List of participants

Including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 6-7 July 2015 meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Heidi Neef	Member	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	
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	
Marje Zernant	Alternate	Estonia	No interests declared	
Eeva Sofia Leinonen	Member	Finland	No interests declared	
An Le	Member	France	No interests declared	
Jaqcueline Viguet Poupelloz	Alternate	France	No restrictions applicable to this meeting	
Birgit Merz	Alternate *Replacing HMPC member*	Germany	No interests declared	
Ioanna Chinou	Member	Greece	No interests declared	
Zoi Karmapourmpouni	Alternate	Greece	No interests declared	
Zsuzsanna Bíróné Sándor	Member	Hungary	No interests declared	
Anna Cunney	Member	Ireland	No interests declared	
Marisa Delbò	(Vice-Chair, replacing Chair)	Italy	No interests declared	
Dace Kalke	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	
Burt H Kroes	Alternate	Netherlands	No interests declared	
Steinar Madsen	Member	Norway	No interests declared	
Gro Anita Fossum	Alternate	Norway	No interests declared	
Wojciech Dymowski	Member	Poland	No interests declared	
Ana Paula Martins	Member	Portugal	No interests declared	
Nadia Grigoras	Member	Romania	No interests declared	
Milan Nagy	Alternate	Slovakia	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Samo Kreft	Alternate	Slovenia	No interests declared	
Adela Núñez Velázquez	Member	Spain	No interests declared	
Per Claeson	Member	Sweden	No interests declared	
Erika Svedlund	Alternate (Via TC)	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	
Olavi Pelkonen	Co-opted member	Finland	No restrictions applicable to this meeting	
Maria Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared	

* Experts were only evaluated against the product(s) they have been invited to talk about.