30 June 2014
EMA/HMPC/316498/2014
Procedure Management and Business Support Division

Committee on Herbal Medicinal Products (HMPC)

Minutes of the 5-6 May 2014 meeting

5 May 2014, 14:00 – 19:00, room 2A, *plenary*
6 May 2014, 08:30 – 12:30, room 2A, *plenary*
AESGP hearing 13:30-15:30, room 2A

Chair: Werner Knöss

- **Health & Safety Information**

In accordance with Agency policy, delegates are to be shown a slide show with health and safety and emergency information and procedures. This is to be displayed at the start of this meeting using the Crestron system as delegates are entering the meeting room. In addition, the meeting secretariat is to draw the delegates' attention to the slideshow and point out the nearest fire exit(s), which are marked where the room has two or more exits. Should there be an evacuation during the meeting staff will guide delegates out of the building via the nearest fire exit.

- **Declaration of conflict of interests**

In accordance with the Agency's Policy and Procedure on the handling of conflicts of interests, participants in this meeting are asked to declare any conflict of interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests).
Discussions, deliberations and voting will take place in full respect of the restricted involvement of Scientific Committee members and, where relevant, experts attending the plenary meeting, as announced by the Scientific Committee secretariat at the start of the meeting.

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

- **Note on access to documents**

Some documents mentioned in the agenda/minutes cannot be released at present within the framework of Regulation (EC) No 1049/2001 on access to documents because 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).

* = Change introduced after 29/4

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I. Introduction	
I.1 Agenda, minutes	
I.1.1 Agenda of 5-6 May 2014 HMPC meeting - timetable, for order of topics *For adoption*	Adopted
I.1.2 Minutes of 24-25 March 2014 HMPC meeting *For adoption*	Adopted with change in V. 3.1. (see also III.1.1)
Clarification was provided on the level of changes in the Eleutherococcus LE during revision (no change of indication or new preparations added) and the voting outcome at the HMPC March meeting. Clarification on procedural questions was asked from ORGAM DG in view of soon upcoming further finalised revisions for substances with both, MO+LE: adaptation of existing procedures, changes in LE vis-à-vis changes in a monograph triggering the need for LE revision and re-adoption/new opinion/voting, possible scenarios and transfer to the Eur. Com..	
I.2 Legislation and regulatory affairs	
I.2.1 *Validation of BSS and feedback received on 30 April 2014 - email with attachments *For information*	Report: HMPC Chair Rapporteurs to evaluate response provided and prepare position for discussion at the HMPC July meeting.
I.3 Questions raised by HMPC members	
I.3.1 QRD template for THMPs in mutual recognition and decentralised procedures - email *For discussion*	Small group to draft a problem statement with key issues and objectives for HMPC July meeting as basis for coordination with QRD group and potential involvement of HMPC ORGAM DG.
It was noted that current QRD template in some fields is challenging for THMP and may need some adaptations or clarifications how to use for this specific type of MP. Thus for instance patient leaflets for THMP contain often more headings than actual content in some points. It was therefore agreed to contact the QRD group at the Agency to work towards possible solutions. For that, however, specific proposals are needed to clarify the objective with examples for the changes envisaged. While the proposal to give such template work directly to ORGAM was not supported, a small group already familiar with the problem agreed to present a first proposal for further follow-up.	
I.3.2 Presentation on Polycyclic Aromatic Hydrocarbons (PAH) - presentation *For discussion*	HMPC agreed contacting EDQM on current developments at Ph. Eur. and possible necessary coordination. Rapporteur, HMPC Chair and secretariat to draft a letter to be sent to EDQM.
The Rapporteur presented briefly chemical particulars, occurrence and toxicity of PAH as well as current food regulations. Also recent publications on occurrence in products of herbal origin and existing thresholds in some Ph. Eur. monographs (e.g. paraffin) were shown. It was acknowledged that genotoxic/ carcinogenic PAH may occur in some herbal preparations – depending often on the manufacturing process (e.g. some traditional processing methods). Options for the HMPC to prepare guidance were discussed vis-à-vis standard quality requirements set by Ph. Eur. considering maximum limits for specific substances of concern or general limit tests and definitions applicable for all herbal extracts in analogy to heavy metals or aflatoxins. The need for clarification with EDQM was identified for further discussion at the July meeting.	
I.4 Questions raised by companies	

I.5 Referral procedures	
II.Co-ordination issues	
II.1 General co-ordination issues	
II.1.1 ISO identification of medicinal products (IDMP) standards - EU TaskForce - presentation *For discussion*	Nomination of experts HMPC agreed on involvement regarding herbal substances and nominated for expert input: H. Neef, M. Delbo and B. Kroes.
Background information on ISO IDMP was provided aiming for unambiguous identification of substances, products and other terms. One of the previous standards finalised in October 2012 was ISO prEN 11238 ('Data elements and structures for unique identification and exchange of regulated information on substances') where herbal expert input was welcome. Now for the ISO IDMP 11616/5 on pharmaceutical/medicinal product under elaboration equally herbal expertise is needed. A brief outline of involvement via document submission, forms, TCs was provided. Members questioned the eventually doubling of established nomenclature such as standard terms of the Ph. Eur., however, EDQM involvement in the project was confirmed and clarified that despite some overlap the ISO IDMP is only focused on identification of terms in databases but not touching established quality standards.	
II.2 Co-ordination with CHMP	
II.3 Co-ordination with SAWP	
II.4 Co-ordination with SWP	
II.4.1 Assessment of estragole and alkenyl benzenes - draft discussion paper - status report *For discussion*	HMPC noted submission of specific questions to SWP and confirmed need to coordinate with SWP and EFSA. Rapporteurs, HMPC Chair and secretariat to follow-up on coordination (letter plus participation at SWP May virt. meeting) aiming for a SWP feedback for the HMPC July meeting.
II.4.2 Report from SWP activities - report SWP meeting 28 January, 11-12 February 2014 - report SWP meeting 29-30 April 2014 *For discussion*	Report: O. Pelkonen Relevant topics were noted. No need for direct HMPC involvement was identified.
II.4.4 Feedback re meeting of joint CVMP and CHMP 3R's expert group held on 4 March 2014 - agenda *For discussion*	Report: J. Wiesner, G. Laekeman No immediate need for HMPC involvement was identified. Observers to clarify organisational aspects with the responsible secretariat.
II.5 Co-ordination with PDCO	
II.6 Co-ordination with PRAC	
II.7 Co-ordination with PCWP	
II.8 Co-ordination with HCPWP	

II.9 Co-ordination with Medical Writers	
II.9.1 Status report on preparation and publication of ARSP - report *For discussion*	HMPC noted slightly modified proposal in line with EPAR standard procedure and previously agreed specifics for herbal AR summaries. HMPC agreed to proposed *modus operandi* for English ARSP and translations into EU languages regarding generation, review and publication for already adopted documents as well as future standard procedure for newly adopted documents. Review of procedure and translation quality within 1 year. HMPC secretariat to publish finalised English ARSP and further coordinate with medical writers.
Issues and previous agreements from discussions in January, July 2013 and March 2014 were summarised and the currently pending publications for English summaries (EnARSP) as well as available translations presented. Original timelines were set to achieve ARSP publication as part of the whole package for finalised monographs (with final AR). Due to experiences with the quality of translations and in order to allow some flexibility to prioritize workload, new timelines were agreed for a) review by Rapporteur/Co-Rapp (EPAR: 5 working days, new secretariat proposal for herbal EnARSP: 15 working days, HMPC: agreed); and b) check of CdT translations in all EU languages (EPAR: no check, new secretariat proposal: 21 working days, HMPC: 35 working days required). For EnARSP it was agreed to publish the finalised ones and initiate preparation of EnARSP from finalised packages July 2013-May 2014. For ARSP translations EMA to send newly available EnARSP for translation and proceed as agreed with the national assessors check (not more than 4 sent out at the same time). The 11 available first translations (with only partial feedback from the MS) will be kept on hold until the translation procedure has been established.	
II.10 Co-ordination with COMP	
II.11 Co-ordination with CMDh	
II.12 Co-ordination with Eur. Com.	
II.12.1 Response letter from EC in relation to the EFSA scientific opinion related to hydroxyanthracene derivatives *For discussion*	HMPC noted response from Eur. Com.. HMPC concerns will be taken into consideration for upcoming Eur. Com. decision on proposed health claim following consultation of MS representatives. HMPC Chair encouraged HMPC members to liaise at national level with respective colleagues from the food authorities.
Members repeated their public health concern as regards unrestricted use of products containing hydroxyanthracene derivatives currently under discussion in the food area. Some members reported that conditions of use for such products are discussed at the national food authorities, while the health claim as such seems not to be questioned vis-à-vis the pharmacological action and long term detrimental effects known for this compound group as reflected in HMPC documents.	

***** II.12.2 Ongoing Notice to Applicants review regarding well-established use	HMPC noted possible relevance of ongoing review of NtA regard Art. 10a provisions and consider liaising nationally with MS representatives for feedback to NtA group if necessary (before 12 May).
II.13 Co-ordination with EFSA	
III. Organisational matters	
III.1 Organisational Matters Drafting Group	
III.1.1 Virtual ORGAM DG meeting to be held on 13 May 2014 - agenda *For information*	Report: ORGAM DG Chair Postponed from 8 April 2014 New topic to be added to ORGAM agenda following discussion on March HMPC minutes: Necessary clarifications on revision procedure of LE vis-à-vis monograph revision taking into account legislation, current procedure (EMA/HMPC/124695/2011 and EMA/HMPC/326440/2007 Rev.2) and possible scenarios.
III.1.2 Nominations of new ORGAM DG members	No new nominations received.
III.2 Working methodology	
III.2.1 Progress with MMD implementation - email	Members were informed on support opportunities in case of experienced difficulties. HMPC Chair reminded on previous agreement of document upload deadlines in line with established pre-mail policy. HMPC secretariat will inform with a short notice about finalisation of uploading pre-mail 1 and 2. If further changes are necessary after the 2nd pre-mail a short overview will be provided.
III.2.3 Agenda topics for informal HMPC meeting to be held in Rome on 4-5 November 2014 *For discussion*	Report: M. Delbò
Agenda topics will encompass borderline issues in particular with the food area and different assessment approaches as well use of products with herbal ingredients in pregnancy/lactation and children/adolescents. More information on organisational aspects and the draft agenda will be provided at later stage.	

III.2.4 Organisation of an assessors' training in 2014 for 20 participants *For discussion*	Report: HMPC Chair Supported by: R. Laenger, H. Neef, I. Chinou HMPC confirmed as date 25 Nov with consequences for schedule of HMPC meeting (Mon 24 Nov whole day) and MLWP meeting (Wed 26 Nov – Fri 28 Nov). Online participation via AdobeConnect open to the network is foreseen. Members to provide further proposals in writing. Small group to present draft agenda at HMPC July meeting in line with presented overall approach.
The HMPC Chair reported on first exchange between group members on agenda topics aiming for an exchange between those producing HMPC documents and those using them. Some members proposed training via discussion of specific controversial examples at NCAs as well as standard issues experienced in national licensing vis-à-vis the European compromise reflected in HMPC monographs. Industry involvement and choice of examples have still to be looked at in detail.	
III.2.5 Move to new EMA offices in July 2014 - presentation *For information*	
III.2.6 Election of new MLWP Vice-Chair - Mandate, Objectives and Rules of Procedure of MLWP - HMPC Rules of Procedure - Procedure for the election of the MLWP Vice-Chair - Candidatures received from R. Länger, M. Delbò	M. Delbò in the second round elected as MLWP Vice Chair by majority vote for her 2nd 3-year mandate.
III.2.7 Survey 'Uptake of traditional use registration scheme and implementation of the provisions of Directive 2004/24/EC in EU Member States' (2013 data) - status report *For discussion*	Contact points of 5 MS to provide requested data as soon as possible. HMPC secretariat to clarify inconsistencies with respective contact points, compile data and update public summary. Completion and presentation expected for the HMPC July meeting.
A first overview on registrations/ authorisations in 2013 was presented from the responses received so far. Assuming that missing data are provided soon after the meeting, the update of document EMA/327570/2011 will be targeted for mid-June (Revision 4). The secretariat informed on some heterogeneity of responses possibly requiring further clarification in several cases such as MA/TUR dates (first approval vs. first approval after implementation of Dir. 2004/24/EC e.g. with renewal/transition) as well as WEU authorisations vs. all authorisations. It was highlighted that the survey 'Uptake of ...' captures applications and what has been registered/authorised but not what is currently found on the market (e.g. reflection of withdrawal before authorisation/registration only).	
IV. Quality	
IV.1 Quality Drafting Group	

IV.1.1 Meeting report from Q DG meeting held on 10 April 2014 *For adoption*	Report: Q DG Chair Adopted with minor correction.
Topics under discussion at Q DG were presented including revision of the guideline on CTD format, mock-up (appendix 2), Q&As on herbal substances or herbal preparations, which are covered by a pharmacopoeia monograph, but the monograph does not contain an assay (split into herbal substances and preparations, likely to be finalised for the HMPC July meeting), comments on Ph. Eur. draft monograph for fresh herbal drugs as well as preparation of another Q&A on declaration of extracts (DER/solvent) when prepared from fresh herbal drugs. Technical problems during the virtual meeting affected work of O DG. It was reiterated that there is a need for an appropriate balance between virtual and face-to-face meetings.	
IV.1.2 Q&As on herbal preparations, which are covered by a pharmacopoeia monograph, but the monograph does not contain an assay - status report *For information*	Report: Q DG Chair
IV.2 European Pharmacopeia	
IV.2.1 Report from EDQM Expert Group 13B meeting held on 8-9 April 2014 - report *For discussion*	EDQM: M. Bald HMPC Observer: H. Neef HMPC welcomed brief report by EDQM representative and HMPC observer.
Recent progress with monograph development and upcoming Ph. Eur./ Pharmeuropa publications were summarised. The HMPC observer highlighted HMPC-relevant topics such as a new monographs for Camelliae sinensis non fermentata folia (2668), and start of work on monographs for Pilosellae herba and Rhodiolae roseae radix et rhizome, which may trigger need for cooperation with HMPC/MLWP. Revisions are ongoing for Passiflora and Crataegus monographs. As regards HPTLC colour pictures it was clarified that -although published in Pharmeuropa- they will not appear in the respective Ph. Eur. monographs directly but only in the Ph. Eur. knowledge database.	
IV.2.2 Priority of herbal substances with a need of Ph. Eur. Monographs for submission to EDQM - draft priority list *For adoption*	Rapporteur: W. Dymowski, C. Purdel HMPC agreed to presented short-list (p. 7 of the document) but need for further ranking was agreed between HMPC and EDQM. Members to provide comments to Rapporteurs by 16 May. Rapporteurs to finalise proposal in liaison with HMPC / MLWP Chairs and secretariat for official transmission to EDQM by 31 May.
The Rapporteurs had provided the rationale for selection covering legal basis, HMPC prioritised substances without corresponding Ph. Eur monograph, products on the market, HMPC status of work and outcome (e.g. public statements or cancelled assessments) as well as deviating handling of some herbal substances/preparations (e.g. some fatty oils active substance at HMPC, excipient at Ph. Eur.; plant part differences such as herba vs. folium). Consequently a list of 15 substances was proposed for submission to EDQM. The need for further prioritisation was emphasised by the EDQM representative as not all substances can immediately be proposed for potential inclusion into their work programme in June.	

IV.2.3 EDQM conference 6-8 October 2014: 50 years of leadership in the quality of medicines - email *For information*	http://www.edqm.eu/en/Conference-50th-Anniversary-of-the-EDQM-1617.html HMPC noted workshop on herbal substances 7 October 2014.
V. Safety & efficacy	
V.1 Report on MLWP activities	
V.1.1 Report on progress achieved Overview of status of MLWP assessment work *For discussion*	Report: MLWP Chair Overview on status of work on drafts, finals and revisions vis-à-vis KPIs requested for HMPC July meeting. HMPC and MLWP Chairs reminded Rapporteurs and Peer reviewers that finalised documents ready for publication should be transmitted for adoption including literature and clean documents unless open issues or changes need to be visible to be addressed by the HMPC.
An overview on the half-year status of work as regards draft, final and revised monographs and list entries against the 2014 work programme was requested from the secretariat for discussion in July.	
V.1.2 Draft Public statement on plants containing substances associated with general safety concerns *For adoption*	Rapporteur: M. Delbò Adopted with changes (title and text to bring it in line with the modified title) by majority. Agreed necessary final minor corrections to be introduced by Rapporteur. HMPC secretariat to publish document as final.
Final corrections and specifications as regards substance names were requested from the Rapporteur. Changes were introduced in text and title. Despite these changes, some members expressed concerns as the title suggests an assessment outcome which had not been performed in detail; i.e. an *a priori* statement that is not supported by scientific, clinical or post-marketing data. It was clarified that the PS summarises only herbal substances proposed for assessment and found on the market that are currently not prioritised by the HMPC for assessment because constituents with known safety concerns make the possibility for a monograph unlikely. Therefore the use of limited resources is focused on other herbal substances. The statement clarifies further that the possibility for national registration/authorisation remains open if all legal requirements are met.	
V.2 Community list entries transmitted to European Commission	
V.3 Community herbal monographs for public consultation / final adoption after systematic review / revision	

V.3.1 Monograph Lupuli flos (and supporting documents: AR, LoR) *For adoption*	Rapporteur: A. Vlietinck Peer-reviewer: L. Anderson Revised monograph and supporting documents adopted by a majority vote (25 out of 27). NO expressed a favourable position. Divergent position –M. Delbò (IT), G. Calapai (Coopt. M.)
The inclusion of certain traditional preparations with unusual extraction solvents in the monograph was questioned but supported by a majority.	

V.4 Community herbal monographs (post finalisation)

V.5 Community herbal monographs, Community list entries and public statements for adoption after public consultation

V.5.1 Monograph on Arnicae flos (and supporting documents: AR, LoR, OoC) *For adoption*	Rapporteur: J. Wiesner Peer-reviewer: O. Pelkonen; Expert: H. Kairies Final monograph with changes in section 2, 3, 4.2, 4.4 and supporting documents adopted by consensus. NO expressed a favourable position.
V.5.2 Monograph on Fucus vesiculosus (and supporting documents: AR, LoR, OoC) *For adoption*	Rapporteur: G. Laekeman; Peer-reviewer: W. Knöss; Experts: K. Geukens, L. Winjnhoven Final monograph and supporting documents adopted by a majority vote (24 out of 28). NO expressed a favourable position. Divergent position –J. Wiesner (DE), E. Leinonen (FI), E. v. Galen (NL), B. Razinger(SI)
A minority expressed concerns on the appropriateness of the indication and potential effects on TSH levels and thyroid function due to iodine intake according to recommended *Fucus* dosages vis-à-vis authorised iodine medication in thyroid ailments but also baseline consumption via food (e.g. iodinated salt). In particular long-term overdose risks in connection with the indication were not considered appropriate for a safe self-medication foreseen for THMP, yet most members emphasized the need for strictly controlled quality and regulation/pre-authorisation of such products.	
V.6 Community herbal monographs, Community list entries and public statements for adoption for release for public consultation	
V.6.1 Monograph on Agrimoniae herba (and supporting documents: AR, LoR) *For adoption*	Rapporteur: L. Anderson; Peer-reviewer: P. Claeson Draft monograph and supporting documents adopted by consensus for release for public consultation until 31 August 2014.

V.6 2 Monograph on Capsici fructus (and supporting documents: AR, LoR) *For adoption*	No majority found for the draft monograph. HMPC members to reconsider their positions according to the information received during the discussion and provide suggestions to the Rapporteur. Rapporteur to compile comments and present 2 options (1 TU, 1 TU+WEU) for discussion and possible adoption at the HMPC July meeting.
Several members considered some preparations potentially eligible for WEU acceptance based on widespread use and authorisation for more than 10 years and limited clinical data for an acceptable positive benefit-risk assessment. Additional data that are eventually required to demonstrate comparability may be requested when it comes to specific product applications based on the monograph. Others expressed concerns on the foreseeable limitations to use a WEU monograph. The Rapporteur explained details that led to the MLWP proposal including specific challenges for cutaneous pharmaceutical forms for bibliographic applications with reference to other European procedures, the diverse data situation for crèmes and patches (same active substance), the comparability of different preparations and possibilities for distinctive TU and WEU indications.	
V.6.3 Monograph on Lichen islandicus (and supporting documents: AR, LoR) *For adoption*	Rapporteur: M. Heroutová; Peer-reviewer: A. Vlietinck Draft monograph and supporting documents adopted by consensus for release for public consultation until 31 August 2014.
The different nature of compound groups in diverse preparations potentially contributing to the activity and their pharmacological or more mechanic effects as reflected in the AR were discussed in view of medical devices on the market containing the same herbal preparations as included in the draft monograph. However, no changes were considered necessary in the draft AR.	
V.6.6 Monograph on Pilosellae herba cum flore (and supporting documents: AR, LoR) *For adoption*	Monograph and supporting documents returned to MLWP for discussion at their May meeting for final corrections and addition of necessary information.
Some information on the traditional use for a herbal preparation included in the monograph was found missing in the assessment report. If available, it should be added, if not, the herbal preparation should be removed from the draft monograph. After discussion at MLWP and final adjustments by the Rapporteur and Peer-reviewer the package could be tabled for release for public consultation at the HMPC July meeting.	
V.7 Community herbal monographs, Community list entries and public statements for discussion	
V.8 Guidelines	
VI. Other relevant business	
VI.1 Conferences, presentations & research projects	
VI.2 International cooperation, collaboration with non-EU regulatory authorities	
VI.3 Documents for information	

VI.3.1 Table of Decisions from HMPC meeting held on 24-25 March 2014	
VI.3.2 Meeting report from HMPC meeting held on 24-25 March 2014	http://www.ema.europa.eu/docs/en_GB/document_library/Committee_meeting_report/2014/02/WC500161191.pdf
VI.3.3 Draft agenda of MLWP meeting to be held on 6-8 May 2014	
VI.3.4 Table of Conclusions from MLWP meeting held on 25-27 March 2014	
VI.3.5 Draft Minutes from MLWP meeting held on 25-27 March 2014	
VI.3.6 Overview of status of HMPC assessment work – priority list	
VI.3.7 Inventory of herbal substances for assessment work – alphabetical order	
VI.3.8 Common names of herbal substances in all EU official languages	*Update available at next meeting in June/July 2014.*

VI.4 Any other information

VI.4.1 New permanent access cards	Members noted technical information regarding photographs and applications for new permanent passes.
VI.4.2 Abbreviations in HMPC minutes	http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/11/WC500155666.pdf
VI.4.3 Hearing with AESGP - proposed agenda - list of participants	
VI.4.4 Labelling of strength of Herbal medicinal products - email *For discussion*	Members to give feedback to the IT member on national practice of the labelling of THMP according to applicable declaration guideline EMEA/HMPC/CHMP/CVMP/287539/05 and standard requirements of Art. 54a Dir. 2001/83/EC.
The question had been distributed among the EMACOLEX members (The European Medicines Agencies Cooperation on Legal and Legislative Issues, a HMA working group) and in IT forwarded to the herbal assessor. HMPC-delegates should contact their national colleagues to ensure that appropriate answers are given.	
*VI.4.5 Nomination of co-opted members *For information*	Report: HMPC Chair Re-nominations due for 3 co-opted members (Clinical pharmacology, Experimental/non-clinical pharmacology, General and family medicine) who's mandate expires Jul/Sep were announced. Members to consider necessary fields of expertise required for the HMPC and possible nominations in line with Art. 4 HMPC RoP.

List of participants

Chair of the HMPC	***Apologies***
Werner Knöss	Evelin Saar (ESTONIA)
	Arturas Kažemekaitis (LITHUANIA)
HMPC members	Jacqueline Genoux-Hames (LUXEMBOURG)
Reinhard Länger (AUSTRIA)	Martina Hudecová (SLOVAKIA)
Heidi Neef (BELGIUM)	Silvia Girotto (CO-OPTED)
Elena Mustakerova (BULGARIA)	Maria Helena Pinto Ferreira (CO-OPTED)
Ivan Kosalec (CROATIA)	
Maria Stavrou (CYPRUS)	**HMPC alternate members**
Marie Heroutová (CZECH REPUBLIC)	Wim Vervaet (BELGIUM)
Steffen Bager (DENMARK)	Marje Zernant (ESTONIA)
Eeva Sofia Leinonen (FINLAND)	Jacqueline Viguet Poupelloz (FRANCE)
An Lê (FRANCE)	Baiba Jansone (LATVIA)
Jacqueline Wiesner (GERMANY)	Gro Fossum (NORWAY)
Ioanna Chinou (GREECE)	Milan Nagy (SLOVAKIA)
Zsuzsanna Biró-Sándor (HUNGARY)	Erika Svedlund (SWEDEN)
Niamh Curran (IRELAND)	Burt Kroes (THE NETHERLANDS)
Marisa Delbó (ITALY)	Sue Harris (UNITED KINGDOM)
Dace Kalke (LATVIA)	
Everaldo Attard (MALTA)	**Observers**
Emiel van Galen (THE NETHERLANDS)	Saša Pilipović (BOSNIA AND HERZEGOVINA)
Steinar Madsen (NORWAY)	Melanie Bald (Conseil de l'Europe - via teleconference)
Wojciech Dymowski (POLAND)	Arianit Jakupi (KOSOVO)
Ana Paula Martins (PORTUGAL)	Merjem Hadjihamza (MACEDONIA)
Nadia Grigoras (ROMANIA)	Dragan Djurovic (SERBIA)
Barbara Razinger (SLOVENIA)	
Adela Núñez Velázquez (SPAIN) – via teleconference	**European Commission**
Per Claeson (SWEDEN)	Tina Engraff – 24 March 2014
Linda Anderson (UNITED KINGDOM)	
Gioacchino Calapai (CO-OPTED)	
Gert Laekeman (CO-OPTED)	
Olavi Pelkonen (CO-OPTED)	