10 March 2015
EMA/HMPC/168048/2015
Procedure Management and Business Support Division

Committee on Herbal Medicinal Products (HMPC)

Minutes of the 27-28 January 2015 meeting

27 January 2015, 13:00 – 18:30, room 3E, *plenary*
28 January 2015, 08:30-12:00, room 3E, *plenary*

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 Creston 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.

- **Welcome to new participants**

- **Announcement of new nominations**

Gabriela Duchajová, new HMPC member from Slovakia

- **Election of MLWP Chair**
  See I.1.3

- **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.

- Draft annex to the minutes for the January 2015 HMPC meeting, documenting anticipated restriction on involvement in relation to agenda topics and declarations of interest from members and alternates (EMA/HMPC/58101/2015)

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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).

I. Introduction	
I.1 Agenda, minutes	
I.1.1 Agenda of 27-28 January 2015 HMPC meeting - Timetable, for order of topics *For adoption*	Adopted
I.1.2 Minutes of 24 November 2014 HMPC meeting *For adoption*	Adopted
I.1.3 Election of MLWP Chair - Mandate, objectives and rules of procedure for the HMPC Working Party on European Union Monographs and List (MLWP) - Email 9 January 2015 Candidatures received: Ioanna Chinou *For adoption*	Report: HMPC Chair I. Chinou was re-elected as MLWP Chair for a third 3-year mandate starting 28 January 2015.
I.1.4 Overview of expertise available in the HMPC, MLWP, ORGAM and Q DG	Members who have not yet provided their expertise to send the filled file back to the HMPC secretariat.
I.2 Legislation and regulatory affairs	

I.2.1 Requirement of QP declaration for traditional herbal medicinal products - Memo *For discussion*	Report: Q DG Chair Q DG member. K Reh According to Art. 8 (3) (ha) of Dir. 2001/83/EC an application for authorization of a medicinal product shall be accompanied by a written confirmation that the manufacturer of the medicinal product has verified compliance of the manufacturer of the active substance with principles and guidelines of GMP by conducting audits, in accordance with point (f) of Art. 46. This requirement of a written confirmation was inserted by Dir. 2011/62/EU amending Dir. 2001/83/EC. However, Art. 16c (1)(a) which lists particulars and documents that have to be submitted together with an application for the purpose of a traditional-use registration does not refer to Art. 8(3)(ha). Nevertheless, Art.16g of Dir. refers to Art. 46, which, i.e., lays down the principles of GMP that shall apply by analogy to traditional-use registrations. Eur. Com. representative and EMA Legal Department confirmed that while a written confirmation is difficult to request in the context of a THMP application, verification of compliance with GMP is anyway required by Art. 16g in the context of full GMP requirements (referring to Art. 46) and inspections (Art. 111). The written confirmation of Art. 8(3)(ha) of Dir. 2001/83/EC is different from the one required for active substances imported from non-EU-countries according to Art. 46b(2)(b) of Dir. 2001/83/EC.
I.3 Questions raised by HMPC members	
I.4 Questions raised by companies	
I.5 Referral procedures	
I.6 Co-ordination with Eur. Com.	

I.6.1 Update on NTA review regarding WEU *For information*	Process for Review of NtA as regards to WEU provisions ongoing. After first member states comments collected in January analysis ongoing and after Eur. Com. legal services review results expected for June 2015. For herbal products, few comments received but minor changes expected as regards to reference to herbal monographs. HMPC members noted that HMPC consultation is not foreseen; instead the correct channels should be used at national level.
I.7 Co-ordination with EFSA	
EFSA NDA panel draft opinion on chicory inulin - Email EFSA contact point dated 03 Dec 2014 - Email response EMA dated 08 Dec 2014 *For discussion*	Report: HMPC Chair
Following the presidency meeting in Rome with discussion on laxative assessments and in the context of the MoU between EFSA and EMA, EFSA had informed EMA on "Scientific Opinion on the substantiation of a health claim related to chicory inulin, pursuant to Article 13.5 of Regulation (EC) No 1924/2006". Despite short notice, an answer had been drafted between Chair, Vice Chair and secretariat, distributed between HMPC members and submitted. In contrast to the anthraquinone claim before, no immediate borderline issue, overlap of opinions and safety concern was identified. Overall the opportunity to comment was welcomed and reminded that *vice versa* HMPC may follow and inform EFSA on assessment topics of overlapping interest such as recent public statements on estragole and pulegone.	
I.8 Other external Co-ordination	
II. Safety & efficacy	
II.1 Report on MLWP activities	
II.1.1 Report on progress achieved Overview of status of MLWP assessment work *For information*	Report: MLWP Chair
II.1.2 Clarification on prioritisation of substances before 'calls for submission of scientific data' - Email *For discussion*	For *C. camphora* first a market overview based on information from NCAs to be compiled by the Rapporteur. According to outcome assessment objective to be specified and public call for scientific data to be initiated accordingly.

Cinnamomi camphorae folium/cortex had been put on the HMPC priority list for assessment in January 2014 following the prioritisation exercise in 2013 based on information about products on the market according to NCAs. In order to tailor the assessment for monograph establishment clarification was deemed necessary regarding the herbal substances and derived preparations to be assessed for use in herbal medicinal products/traditional herbal medicinal products. Before a call for scientific data is initiated the Rapporteur should launch a broad request to NCAs comprising all possible herbal substances (Cinnamomum camphora, folium/cortex and eventually other) and derived preparations (e.g. camphor oil and fractions thereof) and their use in mono and combination products.

II.2 European Union list entries transmitted to European Commission

II.3 European Union herbal monographs for public consultation / final adoption after systematic review / revision

II.3.1 Monograph Hederae helicis folium (and supporting documents: AR, LoR; references 162/248) *For adoption for public consultation*	Rapporteur: J. Wiesner Peer-reviewer: I. Chinou Changes introduced in 4.4 of the monograph. Draft revised monograph adopted by consensus for 3 months public consultation until 15 May 2015.

Following the discussions on the validity of the bronchitis severity scale (BSS) the HMPC had asked the MLWP to review relevant monographs. Available data for Hedera preparations have been re-evaluated and the AR adapted accordingly. As a consequence, one herbal preparation had been moved from traditional use to WEU in the Hedera monograph. Furthermore, minor corrections had been introduced by the MLWP and the HMPC to improve the wording as regards to concomitant use with antitussive medicines in section 4.4. of the monograph.

Because of the considerable change after revision, a 3 month public consultation for rev 1 was agreed.

II.3.2 Monograph Thymi herba/Primulae radix (and supporting documents: AR, LoR; references 19/24) *For adoption for public consultation*	Rapporteur: R. Länger Peer-reviewer: L. Anderson Draft revised monograph adopted by consensus for 3 months public consultation until 15 May 2015.

Following the discussions on the validity of the BSS, the HMPC had asked the MLWP to review relevant monographs. Consequently for primula/thyme, 3 extracts were found to have sufficient data to recognise efficacy as 'an expectorant in case of productive cough' and consequently moved to the WEU part of the monograph. For all other preparations the previously granted traditional use indication remained as before. Members discussed the situation of very similar indications between WEU and TU justified only through available data. For two preparations it lead to inclusion in both parts of the monograph with sufficient efficacy and safety data for adults (WEU) and with sufficient safety data but insufficient efficacy data for adolescents and children (TU). With reference to Art. 16a(3) some members expressed concerns as regards to double inclusion of the same preparation with very similar indications. Possibilities for extrapolation from adults to adolescent and children were discussed taking into account a recent EMA concept paper on extrapolation of data under specific circumstances and HMPC principles in this regard (recognition/extrapolation of safety/efficacy clinical data in the WEU part, recognition of safe usage data and possible extrapolation in the TU part).

Because of the considerable change after revision, a 3 month public consultation for rev 1 was agreed.

II.4 European Union herbal monographs (post finalisation)

II.5 European Union herbal monographs, list entries and public statements for adoption after public consultation	
II.5.1 Monograph on Agrimoniae herba (and supporting documents: AR, LoR; references 35/44) *For adoption*	Rapporteur: L. Anderson Peer-reviewer: P. Claeson Final monograph and supporting documents adopted by majority vote (29 out of 30). Norway expressed a favourable position. Divergent opinion: E. v. Galen.
No comments had been received during public consultation. A divergent view was noted as regards to the use of the wording minor inflammations.	
II.5.2 Monograph on Eschscholziae herba cum flore (and supporting documents: AR, OoC, LoR; references 31/39) *For adoption*	Rapporteur: O. Palomino Peer-reviewer: G. Laekeman Final monograph and supporting document adopted by consensus. Norway expressed a favourable position.
Final questions were clarified as regards to content in alkaloids, use in children and common names in all EU languages. Available literature had been provided by the Rapporteur.	
II.5.3 Monograph on Ginkgo folium (and supporting documents: AR, OoC, LoR; references 199/200) - Email dated 21/01/2015 *For adoption*	Rapporteur: J. Wiesner; Peer-reviewer: O. Palomino Final monograph and supporting documents adopted by majority vote (21 out of 30). Norway expressed a favourable position. Divergent opinions: A. Núñez Velázquez, E.S. Leinonen, A. Le, I. Chinou, M. Delbò, U. Mockler, E. v. Galen, P. Claeson, L. Anderson
The committee discussed the existing level of evidence in view of available Cochrane reviews and heterogeneous study outcomes. Several members considered the mixed data situation as not sufficient to grant 'recognised efficacy' in the stated WEU indication. Others pointed to therapeutic alternatives and applicability of existing guidance in this therapeutic area. After public consultation, a few changes had been introduced in the WEU part of the monograph, while some wordings have been changed in the TU part as extrapolations of safety-relevant data from extracts to powders cannot be made in all cases. Proposed new preparations had not been included by MLWP upon proposal by the Rapporteur. Participants were reminded that comments on the draft AR during public consultation (standard disclaimer) are taken into account but not to be presented in the overview of comments as often not strictly related to the content of the draft monograph. In view of traditionally very divergent traditional and authorised indication across MS, national consequences for existing products and new products were shortly discussed.	

II.5.4 Public statement on Picrorhizae kurroae rhizoma (and supporting documents: LoR; references 22/33) *For adoption*	Rapporteur: B. Kroes Peer-reviewer: R. Länger Final public statement and supporting documents adopted by consensus. Norway expressed a favourable position.
II.5.5 Monograph on Pilosellae herba cum flore (and supporting documents: AR, LoR; references 18/21) *For adoption*	Rapporteur: O. Palomino Peer-reviewer: G. Calapai/ M. Delbò Adoption postponed due to ongoing discussions at Ph. Eur. about the correct traditional (Ph. Fr.) and current herbal substance/name of herbal substance. Rapporteur together with HMPC observer at expert group 13B, French member and secretariats to clarify for possible modification and adoption at the HMPC March meeting.
According to information from Ph. Eur. expert group 13B a quality monograph is currently in preparation (Pharmeuropa) and despite the traditional name the roots seem to be a standard part of the item of commerce. As this upcoming Ph. Eur. monograph cannot be referred to yet (expected within 6 months) clarification on the actual substance name and the assessment (traditional use, products on the market in France and Spain, pharmacological data, composition) was still considered useful to be aligned now. After clarification with EDQM and France a final proposal is to be tabled for HMPC adoption in March without additional discussion at MLWP.	
II.6 European Union herbal monographs, list entries and public statements for adoption for release for public consultation	
II.6.1 List entry on Crataegi folium cum flore *For adoption*	Rapporteur: J. Wiesner; Peer-reviewer: R. Länger Draft list entry adopted by majority vote for 3 months public consultation until 15 May 2015.
For one specific extract included in the monograph (within a range of several summarised comparable extracts) sufficient data on genotoxicity are available. According to the decision in September, a list entry had been prepared by the Rapporteur. Several members expressed concerns developing a list entry considering the indication as such as not safe for self-medication. On the other hand it was emphasised that no individual safety data can be requested to make a product based on a monograph 'safer' than that of a list entry; therefore, the safety rationale for both the LE and the monograph should be the same. In any case the reason why for which preparation a LE is proposed or not should be clear in the AR. Some consistency questions with indications in the cardiovascular field for other herbal substances were raised. Due to the exceptional separate public consultation for monograph and LE it was proposed to align the discussions at MLWP/HMPC after closure of the public consultation of the LE.	

II.6.2 Monograph on Myrtilli fructus recens (and supporting documents: AR, LoR) *For adoption*	Rapporteur: E. Widy-Tyszkiewicz Peer-reviewer: G. Calapai; M. Delbò Draft monograph adopted by consensus for 3 months public consultation until 15 May 2015.
Members discussed differences between specific extracts for fructus recens and the herbal substance fructus siccus as regards to standard warnings given but a majority found those differences as proposed by MLWP justified.	
II.6.3 Monograph on Myrtilli fructus siccus (and supporting documents: AR, LoR) *For adoption*	Rapporteur: E. Widy-Tyszkiewicz Peer-reviewer: G. Calapai; M. Delbò Draft monograph adopted by consensus for 3 months public consultation until 15 May 2015. *See II.5.2*
II.7 European Union herbal monographs, list entries and public statements for discussion	
II.8 Guidelines and other guidance documents	
II.8.1 Revision of the Guideline on the use of the CTD format	
- Draft revision 2 of the Guideline on the use of the CTD format *For adoption for public consultation*	Report by ORGAM DG Chair HMPC Rapporteur: A. Cunney, J. Wiesner; ORGAM Rapporteur: S. Bodemann, K. Reh Draft revision 2 adopted for public consultation until 30 June 2015.
According to the concept paper, revision 2 was focused on the presentation and content of Modules 2, 4 and 5 of dossiers for THMPs, to help applicants in their submissions as regards to the non-clinical and the clinical part and the use of monographs in this respect. More detailed clarifications have therefore been introduced mainly in sections 1.5, 2.4, 2.5, 5.3 and 5.4. In addition, minor editorial corrections and amendments have been introduced in other sections. Some points still discussed between Rapporteurs and ORGAM members were considered linguistic/editorial and not requiring further discussion before public consultation. ***Post-meeting note: In view of the upcoming revision 1 remainder Appendix 2 (quality mock up) scheduled for finalisation at Q DG in February and adoption HMPC in March, the document will be released for 3 months public consultation in March containing changes of revision 2 and the new appendix 2.***	
III. Quality	
III.1 Quality Drafting Group	
III.1.1 Meeting report from Q DG meeting held on 10 December 2014 *For adoption*	Report: Q DG Chair Adopted

The HMPC heard a report on the December Q DG meeting (face to face). Main point for discussion was the appendix 2 for the CTD guideline (mock-up) P-part. Other subjects were the quality Q&A revision 5 (see below), the comments received on the draft reflection paper on microbial aspects, a preliminary draft paper on Guidance on the use of new analytical methods, the Q DG work plan 2015 and useful interaction with EDQM in 2015 (preferred TC from September onwards with focus on essential oils). In addition, a clarification on the QP declaration for THMP applications was requested (see I.2.1).	
III.1.2 Revised 'Questions & answers on quality of herbal medicinal products/traditional herbal medicinal products' (rev 5) *For adoption*	Report: Q DG Chair Adoption postponed as different case scenarios should be distinguished according to new Ph. Eur. extract monograph. Q DG to adapt.
The clarity of the Q&A on the general need for benzene specification and applicants to address this issue e.g. for dry extracts was discussed as well as the distinction of cases when the extraction solvent has been removed. For the latter a slight change as regards to oleoresins and soft extracts was requested taking into account the recently changed Ph. Eur. extract definition.	
III.1.3 Draft agenda for the FtF Q DG meeting to be held on 11-12 February 2015 *For information*	Report: Q DG Chair Face to face meeting planned for February to finalise mock-up and progress with RP on microbiological aspects. Meeting (TC) with Ph. Eur. expert group Chairs found more suitable after September following expected developments as regards to essential oils.
III.2 Co-ordination European Pharmacopeia	
III.2.1 EDQM Expert Group 13A meeting held on 2-3 December 2014 - Meeting report *For information*	EDQM: M. Bald, U. Rose HMPC Observer: I. Chinou Ph. Eur. Monograph development for Picrorhiza kurroa as originally proposed by HMPC will be discontinued in view of the adopted public statement and issues with herbal drug availability.
EDQM secretariat announced formation of temporary working party on essential oils in analogy to the extract monograph revision 2 years ago. Nomination of experts in June: representatives of all Ph. Eur. expert groups, industry but also NCAs. Official involvement of HMPC/QDG requested by HMPC but to be confirmed by Ph. Eur. commission.	
III.2.2 EDQM Expert Group 13B meeting held on 21-22 January 2015 - Agenda *For information*	EDQM: M. Bald, U. Rose HMPC Observer: H. Neef EDQM requested support from HMPC on suitable limits for ascaridol from a safety perspective. Rapporteur for Boldo leaf (L. Anderson) appointed as HMPC contact point. If necessary, official recommendation to be requested via HMPC secretariat.

Some recent developments on topics of common interest were discussed: A monograph on Hieracium pilosella is currently under preparation for Pharmeuropa and the standard composition containing parts of the root was noted vis-à-vis the finalised HMPC monograph on leaf/flower pending for adoption (see II.5.5). For Boldo leaf dry extract upper limits from a safety perspective were discussed (essential oil versus ascaridol). The allocation of *Pistacia lentiscus* (mastix) to 13B and a request by the Greek pharmacopoeia group was mentioned as potentially affecting the correct herbal substance to be referred to in HMPC assessment just started.	
III.2.3 EDQM Expert Group TCM meeting to be held on 13-14 January 2015 - Agenda *For information*	EDQM: M. Bald, U. Rose HMPC Observer: R. Länger
HMPC noted current initiative at TCM group to rethink quality concepts and methodological approaches in view of difficulties with conventional assays – in particular availability and costs of reference substances used as marker without link to the actual therapeutic benefit. The value and limits of methods such as HPTLC should be reconsidered. The HMPC Chair pointed to the established principles and equality of substances as regards to quality - independent from their origin. Other members informed that at national pharmacopoeias equally new considerations are given to reasonably measure and specify what is necessary and suitable. The point will be taken up for discussions at the HMPC strategic review and learning meeting in Bonn in June. The HMPC observer also reported the permanent challenge that multiple plant species are used for the same herbal drug and purpose (also according to Ch. Ph.) causing problems to have the correct plant as reference material available for Ph. Eur. monograph development.	
IV. Internal Co-ordination with committee and working parties	
IV.1 Observers at other Committees	
IV.1.1 Overview of HMPC coordination/observers with other committees *For discussion*	Postponed
IV.2 Co-ordination with CHMP	
IV.3 Co-ordination with SWP	
IV.3.1 Coordination with Drafting Group on Excipients - Ethanol as an excipient (after public consultation) *For discussion*	HMPC noted interdisciplinary drafting group under the umbrella of the CHMP. In view of many comments on the ethanol part by herbal companies with reference to the HMPC RP EMA/HMPC/85114/08, involvement of HMPC experts in discussion agreed. Appointed: J. Wiesner, O. Pelkonen, (S. Girotto) Next TC: 26 Feb pm, EMA secretariat to send invites

Draft changes planned for the ‚Guideline on excipients in the label and package leaflet of medicinal products for human use' (CPMP/463/00) had been published last year. The HMPC had been consulted before. For ethanol-related changes many comments had been received from the herbal and also homeopathic industry based on reference to the, Reflection paper on ethanol content in herbal medicinal products and traditional herbal medicinal products used in children' published in 2010. The current Rapporteur for the ethanol part of the multidisciplinary drafting group on excipients had asked for some support from herbal experts in the discussion of available data, the scope and the approach taken for labelling. Two toxicologists and if necessary one pediatrician (Rapporteur for the HMPC RP) were appointed to participate in the discussion on this point. While the excipients guideline is applicable to all MPs, Rapporteurs should check consequences for the HMPC RP and eventual need for adaptations there.	
IV.4 Co-ordination with HCPWP/PCWP	
IV.5 Co-ordination with Working Group on Quality Review of Documents (QRD)	
IV.5.1 Proposal for amendments to QRD template for herbal medicinal products/ THMPs- Annex III, SmPC, labelling and PL - Draft discussion paper on QRD templates for SmPC, Labelling and Patient Leaflet on Mutual-recognition and Decentralised procedures for THMPs - Email *For discussion*	Rapporteurs: E. Svedlund, P. Claeson, R. Länger, E. v. Galen ORGAM had decided to illustrate issues with the general QRD template for THMP in a discussion paper to explore the best way forward instead than starting introducing changes as such. QRD confirmed the possibility for a separate template (as for vet. products) if justified. ORGAM DG to continue developing the paper for further discussion and coordination with QRD in March.
The latest approach as regards to the 'QRD template and its use for THMP' was summarised by the ORGAM DG Chair. A draft discussion paper (with some elements of a Q&A) lists the issues experienced when the standard template is used for THMP. The advantage of such paper is that the amount, scope and extent of eventual alterations become visible. Based on that, the best possible way forward should be decided with the QRD group. So far a future specific template tailored for THMP had not been the objective, however the eventual advantages of a separate template may be considered, if too many herbal exceptions would hinder suitability of the general template for other products. The QRD representative pointed out that relevant documentation should be available by end of February to be able to coordinate at MS level the next planned change. However, after herbal ORGAM discussion in February, a HMPC-approved solution is only possible in March. Members discussed some possible difficulties such as the demarcation between requirements for TU, WEU but also full-mixed and a possible mix up between, monograph, SmPC, herbal declaration guideline and template requirements.	
V. Organisational matters	
V.1 Organisational Matters Drafting Group	
V.1.1 Meeting report from ORGAM DG meeting held on 9 December 2014 *For adoption*	Report: ORGAM DG Chair Adopted.
V.1.2 Revision procedure for Monographs and List entries - Procedure for systematic review of Community herbal monographs and supporting documents *For discussion*	Report: ORGAM DG Chair HMPC adopted three changes in the procedure as regards to list entries. Expected further changes as regards to general revision procedure (HMPC work plan 2015) to be implemented at a later stage.

Three additional paragraphs had been included as regards to the list entry revision, while previous considerations on a major/minor list had been abandoned as an exhaustive presentation of all eventual cases was not deemed possible and some room for individual decisions should be kept. Revision 1 to be published at the agencies website.	
V.1.3 Draft agenda for the ORGAM DG meeting to be held on 10 February 2015 *For information*	Report: ORGAM DG Chair
V.2 Working methodology	
V.2.1 Quality and finalisation of documents transmitted to HMPC for adoption - examples *For discussion*	HMPC noted reason for discussion, examples and general issues.
Triggered by a Rapporteurs request to re-confirm the presentation of an AR by the HMPC before publication, three examples had been distributed and typical pre- and post-adoption changes (editorial, consistancy and content) were presented that make it necessary to go back to the Rapporteur/PR for clarification. The Chair pointed out that -independent from different styles - ideally documents should be ready to be theoretically published the next day and post-adoption clarifications reduced to a minimum, acknowledging that they may occur occasionally as part of the collective approach to get clean and consistent high quality documents on the web. It was proposed that for some assessment parts, Rapporteurs may request on a regular basis support by other colleagues who are experts in this field. Such considerations on a 'specialised peer review' will be taken into account for the revision discussion and the HMPC future discussions (see informal meeting agenda point V.2.3).	
V.2.2 Survey on implementation of Dir. 2004/24/EC (status 2014) - Timetable - List of questions *For adoption*	Timetable adopted. LoQ to be fine-tuned and agreed by HMPC secretariat, HMPC Chair, R. Laenger, W. Dymowski, P. Claeson before sending to national contact points.
The original background and purpose and existing questions and answer structure and resulting issues in data compilation and analysis were presented. It was acknowledged that the survey cannot replace a standard database on herbal products registered/authorised and marketed in Europe. However, some key developments and use of monographs in registrations/authorisations can be substantiated with these data, which was considered still important for 2014. Minor modifications were proposed in view of previous requests to use the survey getting I) an update on use of LEs in applications, II) herbal substance use in children and III) more information on European procedures. Small group to check suitability of questionnaire modifications before sending out to the contact points. A retroactive check of data/answers given in previous years was agreed not to be feasible, but prospectively minor adaptations may be suitable.	
V.2.3 Organisation of a HMPC presidency meeting during Latvian presidency *For discussion*	Report: HMPC Chair The HMPC strategic review and learning meeting (previously called informal meeting) will be hosted 17-19 June at the German agency (BfARM, Bonn). HMPC members noted 3 key areas for discussions planned with 2 of them of strategic importance. Members were invited to contribute via presentations.

Three key areas were announced for the Strategic Review & Learning Meeting co-organised by BfArM and the Latvian Agency 17-19 June in Bonn: 1) *Quo vadis* HMPC, future tasks and work structure for the HMPC, 2) New quality concepts for HMP/THMP (in cooperation with EDQM), 3) Medicinal plant research and experiences with herbal product regulation in Latvia.	
VI. Other relevant business	
VI.1 Conferences, presentations & research projects	
VI.2 International cooperation, collaboration with non-EU regulatory authorities	
VI.2.1 7th annual meeting of IRCH held in Lisbon, Portugal on 2-4 December 2014 *For information*	Report: A-P Martins HMPC Chair HMPC vice Chair HMPC discussed the international cooperation at WHO level and countries involved in IRCH activities. Minutes will be provided once available.
The Portuguese member and the HMPC Chair reported briefly on the organisation of IRCH meeting exceptionally held in Europe at the Portuguese agency. While it was considered as a potentially important platform given the countries and regions represented, some developments as regards key policies and structural challenges (e.g. information sharing) and outcomes still have further to be monitored to determine relevance and EMA involvement in the future.	
VI.3 Documents for information	
VI.3.1 Table of Decisions from HMPC meeting held on 24 November 2014	
VI.3.2 Meeting report from HMPC meeting held on 24 November 2014	http://www.ema.europa.eu/docs/en_GB/document_library/Committee_meeting_report/2014/10/WC500175755.pdf
VI.3.3 Draft agenda of MLWP meeting to be held on 28-30 of January 2015	
VI.3.4 Table of Conclusions from MLWP meeting held on 25-26 of November 2014	
VI.3.5 Draft Minutes from MLWP meeting held on 25-26 of November 2014	
VI.3.6 Overview of status of HMPC assessment work – priority list	http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/12/WC500017724.pdf
VI.3.7 Inventory of herbal substances for assessment work	http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/12/WC500017723.pdf
VI.3.8 Common names of herbal substances in all official EU languages	
VI.3.9 PCWP - Training session for patients and consumers involved in EMA activities (25 November 2014) - Agenda	Observer: S. Bager

VI.3.10 PCWP - Meeting with all eligible organisations (26 November 2014) - Agenda	Observer: S. Bager
VI.3.11 PCWP and HCPWP joint meeting – 16 September (EMA/563152/2014) - Minutes	
VI.3.12 Draft Public statement on the use of herbal medicinal products containing estragole for public consultation	http://www.ema.europa.eu/docs/en_GB/document_library/Public_statement/2014/12/WC500179557.pdf
VI.3.13 Draft Public statement on the use of herbal medicinal products containing pulegone and menthofuran for public consultation	http://www.ema.europa.eu/docs/en_GB/document_library/Public_statement/2014/12/WC500179556.pdf
VI.4 Any other information	
VI.4.1 Abbreviations in HMPC minutes	http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/11/WC500155666.pdf
VI.4.2 Proposal by Kew Gardens to map a plant list - Email from M. Delbò 14 November 2014 - Proposal from Kew Gardens	Report: M. Delbò Postponed.
VI.4.3 Journal of Ethnopharmacology, Vol.158, Part B, Pages 447-518 (2 December 2014) Regulation of herbal and traditional medicinal products – European and global strategies (International Symposium TradReg2013)	http://www.sciencedirect.com/science/journal/03788741/158/part/PB
VI.4.4 The Art and Science of Traditional Medicine Part 1: TCM Today — A Case for Integration, Science 19 Dec. 2014: Vol. 346 no. 6216 p. 1569 Part 2: Multidisciplinary Approaches for Studying Traditional Medicine, Science 16 Jan 2015: Vol. 347 no. 6219 p. 337	http://www.sciencemag.org/content/346/6216/1569.4.summary http://www.sciencemag.org/content/347/6219/337.3.summary

List of participants

Including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 27-28 January 2015 meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Werner Knöss	Chair	Germany	No interests declared	
Reinhard Länger	Member	Austria	No interests declared	
Heidi Neef	Member	Belgium	No interests declared	
Wim Vervaet	Alternate	Belgium	No interests declared	
Elena Mustakerova	Member	Bulgaria	No interests declared	
Ivan Kosalec	Member	Croatia	No restrictions applicable to this meeting	
Maria Stavrou	Member	Cyprus	No interests declared	
Marie Heroutova	Member	Czech Republic	No interests declared	
Steffen Bager	Member	Denmark	No interests declared	
Marje Zernant	Alternate *Replacing HMPC member*	Estonia	No interests declared	
Eeva Sofia Leinonen	Member	Finland	No restrictions applicable to this meeting	
An Le	Member	France	No interests declared	
Jacqueline Viguet Poupelloz	Alternate	France	No interests declared	
Jacqueline Wiesner	Member	Germany	No interests declared	
Ioanna Chinou	Member	Greece	No interests declared	
Zoi Karampourmpouni	Alternate	Greece	No interests declared	
Rita Németh	Alternate *Replacing HMPC member*	Hungary	No restrictions applicable to this meeting	
Una Mockler	Alternate *Replacing HMPC member*	Ireland	No restrictions applicable to this meeting	
Marisa Delbò	Member (Vice-Chair)	Italy	No interests declared	
Dace Kalke	Member	Latvia	No interests declared	
Baiba Jansone	Alternate	Latvia	No restrictions applicable to this meeting	
Artūras Kažemekaitis	Member	Lithuania	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	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Steinar Madsen	Member	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	
Samo Kreft	Alternate *Replacing HMPC member*	Slovenia	No interests declared	
Adele Núñez Velázquez	Member	Spain	No interests declared	
Per Claeson	Member	Sweden	No interests declared	
Linda Anderson	Member	United Kingdom	No interests declared	
Sue Harris	Alternate	United Kingdom	No interests declared	
Gioacchino Calapai	Co-opted member	Italy	No interests declared	
Silvia Girotto	Co-opted member	Italy	No interests declared	
Gert Laekeman	Co-opted member	Belgium	No interests declared	
Olavi Pelkonen	Co-opted member	Finland	No restrictions applicable to this meeting	
Maria Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared	
Melanie Bald	Counseil de l'Europe *via TC*		No interests declared	
Tina-Soon Engraff	EC Representative	European Commission	Full involvement	

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