5 May 2014
EMA/HMPC/289059/2014
Procedure Management and Business Support Division

Committee on Herbal Medicinal Products (HMPC)

Minutes of the 24-25 March 2014 meeting

24 March 2014, 14:00 – 19:00, room 3A, *plenary*
25 March 2014, 09:00 – 13:00, room 3A, *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 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.

- **New participants**

Maria Stavrou, nominated as new HMPC member for Cyprus
Erika Svedlund, new HMPC alternate member for Sweden
New EMA RA advisor to the HMPC

- **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 following a request for access to documents under 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

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or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

MMD 1 on 10 March; MMD 2 on 17 March 2014
* = Change introduced following second MMD posting

I. Introduction	
I.1 Agenda, minutes	
I.1.1 Agenda of 24-25 March 2014 HMPC meeting *For adoption* - timetable, for order of topics	Adopted with minor changes.
I.1.2 Minutes of 27-28 January 2014 HMPC meeting (new version 12 March) *For adoption*	Adopted with minor changes. Clarification was provided on required consistency as regards redacting public agenda / minutes according to the main principles and implementation rules. Names of Rapporteurs released first at time of publication of the draft monograph, but confidential before.
Principles for publication of agendas and minutes of EMA scientific committees (EMA/HMPC/73669/2014 Ver. 1) to be followed including commercially confidential information, personal data protection, publication of rapporteur and staff names, or unnecessary public alarm in particular at a stage where the assessment is not completed. The HMPC with its transparent assessment procedure (including public consultation) has been leading in the publication of agendas and minutes including release of rapporteur names since end of 2013. Also according to meanwhile modified implementation rules as adopted by the management board (for product related procedures publication of rapporteur names with final post-committee authorisation only) a more transparent approach has been agreed for non-product-related HMPC procedures (rapporteur names publication with adoption of draft monographs including ARs for public consultation). Consistency between agendas and minutes to be checked before adoption/publication.	
I.2 Legislation and regulatory affairs	
I.2.1 Validation of BSS and feedback received on 24 February 2014 from Dr. Mathes, Schwabe *For information*	Report: HMPC Chair Response expected to be available for discussion at the HMPC May meeting.
I.3 Questions raised by HMPC members	
I.3.1 Following question by R. Länger dated 12 August 2013 on assessment of estragole and alkenyl benzenes - draft reflection paper *For discussion*	Rapporteurs: O. Pelkonen and J. Wiesner See II.4.1, II.13.1 Postponed. After first feedback HMPC secretariat together with Rapporteurs to provide clarification to SWP (next SWP meeting 29/04/14).
Coordination has been initiated and the topic was included in agenda of SWP March 2014. However, more information and specific questions were requested.	

I.3.2 Presentation on Polycyclic Aromatic Hydrocarbons (PAH) - presentation *For discussion*	Rapporteur: A. P. Martins Postponed to HMPC May meeting.
I.3.3 Query on criteria for simplified registration Procedure - email	Rapporteur: E. van Galen Clarification was provided by the EMA legal sector. The legal requirement (Dir. 2001/83/EC Art. 16c(1)(c)) is the use of 30 years including at least 15 years within the Community. For the purpose of this provision "the Community" should be read to include the countries of the EEA. The use in one MS suffices to prove 15 years of use within the Community. HMPC agreed to possible inclusion of the topic into the regulatory Q&A with the next amendment of document EMA/HMPC/345132/2010.

Query: Are herbal products with medicinal use outside the EU throughout a period of at least 30 years eligible for the simplified registration if 15 years use can only be demonstrated for Liechtenstein (LI)?
Aspects raised:

- status of European Economic Area (EEA) countries vis-à-vis EU MS regarding MA and eligibility for MRP in line with Art.2 of Reg. (EC) No 726/2004 and Art. 8 of Dir. 2001/83/EC
- bilateral agreement between Switzerland and LI (Swiss MAs automatically effective in LI). Yet MAs cannot be considered as in accordance with the pharmaceutical *acquis* for the purpose of EU legislation and as a starting point for the purposes of data exclusivity/market protection in the EU
- only since 1st Dec 2010 a treaty between LI and Austria about automatic recognition of the MAs granted via MRP or DCP is operational.
- previous Eur. COM clarification (08/06/2010) on status of marketed products in LI for WEU recognition in the context of monograph establishment by the HMPC (..medicinal use in LI can be considered for the purposes of assessing WEU, whether this use has taken place under the terms of a Community MA, a Swiss MA or no MA at all. In any event,…, systematic and well documented use needs to be proven, taking into account time and extent of use, among other criteria.'

Legal clarification: The legal requirement (Art. 16c(1)(c)) is the use of 30 years including at least 15 years within the Community. For the purpose of this provision "the Community" should be read to include the countries of the EEA. There is no definition in the legislation nor there is a guidance in the NtA as to what should be treated as "the use within the Community". Therefore the literal meaning combined with the purpose of the provision lead to the interpretation that the use in one MS suffices to prove 15 years of use within the Community.
Discussion: Although a view on exposure and safety can unlikely be concluded from the medicinal use in LI alone, the otherwise proven safe use over a period of 30 years outside the EU (such as Switzerland) may allow case by case the formal acceptance of the legal 15/30 period of use requirements if no safety concerns exist. This evaluation for the purpose of eligibility for simplified registration may differ from assessing WEU conditions for eligibility for MA taking into account time and extent of use according to the EU pharmaceutical *acquis*.
It was agreed to consider this topic for inclusion into the Regulatory Q&A with the next revision.

I.4 Questions raised by companies

I.5 Referral procedures

II. Co-ordination issues	
II.1 General co-ordination issues	
II.2 Co-ordination with CHMP	
II.3 Co-ordination with SAWP	
II.4 Co-ordination with SWP	
II.4.1 Scientific assessment of estragole	*See I.3.1*
II.4.2 *Report from SWP activities* *For discussion*	Report: O. Pelkonen Postponed.
II.4.3 Consultation until 24 March 2014 by excipients multidisciplinary group (lead by SWP) - Q&A and report on benzalkonium chloride - Q&A and report on gluten *For discussion*	Report: HMPC Chair Circulated on 7 March 2014, MMD 1 Comments due by 24 March 2014 No specific comments provided by HMPC.
II.4.4 Feedback re meeting of joint CVMP and CHMP 3R's expert group held on 4 March 2014 *For discussion*	Report: J. Wiesner, G. Laekeman Postponed to HMPC May meeting.
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 *For discussion*	Due to difficulties experienced with translations into all EU languages some members expressed preference for English ARSP only while the majority supported available ARSP in their national language as very important information to the public. EMA to continue work/publication for EN ARSP, while modalities for publication in other languages including confirmed need of translation check to be discussed. HMPC secretariat to liaise with medical information sector for options including revised timeframes.

The EMA secretariat reported on difficulties with the translations and delayed feedback from some MS affecting timely publication of ARSP in all EU languages. Comparisons to EPAR standard procedure were made. Options for solution included publication of English ARSP only, translation check in line with procedural deadlines by all MS, publication without additional check by MS, publication with additional MS check as received by the MS.
Members reported from experiences with translations confirming the need for check of the CdT translations as regards plant names and standard terminology of the legislation. No translations were preferred to erroneous translations. The HMPC list of common plant names and experiences from previous translations should be taken into account by the CdT. Some members considered adherence with strict deadlines as not feasible vis-à-vis other priorities. Several members expressed preference for English versions only to save resources and avoid problems. However, a majority considered the availability of ARSP as important and useful considering that many people in their MS do not understand English. It was agreed 1) to maintain the standard procedure and publication for English versions and 2) EMA secretariat to review options for an improved translation/publication process including timelines and reduced involvement of the HMPC secretariat.

II.10 Co-ordination with COMP

II.11 Co-ordination with CMDh

II.12 Co-ordination with Eur. Com.

II.12.1 Letter to the EC in relation to the EFSA scientific opinion related to hydroxyanthracene derivatives - response from EFSA *For information*	Report: HMPC Chair HMPC welcomed response from EFSA as possibility for communication regarding assessment of borderline products under different legislative frameworks. In addition to a contact point in line with the MoU between both agencies the HMPC Chair will act as primary contact in this important matter supported by the previously appointed *ad-hoc* group for this interaction if required.

The Commission representative informed that the decision on the scientific opinion at DG SANCO sister unit is still pending. She also pointed to the possibility for the HMPC to comment on scientific content of EFSA opinions within standard 30 days consultation, acknowledging difficulties with that due to the HMPC meeting frequency. While no response to the letter has been received from the Commission yet, a swift response from EFSA pointed to the different legal frameworks (benefit only vs. benefit risk assessment) and that neither safety considerations nor classification are in the remit of the NDA panel when assessing health claims for food. Further reference was made to a recently published opinion on a Qualified Presumption of Safety (QPS) approach for the safety assessment of botanicals as well as the possibility for MSs to notify to the Eur. COM. substances they consider being of safety concern. Upon decision to forward the request to EFSA, such safety evaluation is under the remit of the ANS Panel and the Food Ingredients and Packaging Unit (recent examples Ephedra and Yohimbe).
EFSA signalled also appreciation to re-establish previous contacts before the request of the Commission (in 2010) to put on hold the evaluation of health claims on botanicals (as reference point for botanicals in EFSA).
The HMPC Chair welcomed the response from EFSA. While the different frameworks are known to the HMPC, the issue addressed in the letter is not only linked to a scientific assessment of a single substance but related in general to risk management and public health. Therefore a Commission response would be important to define modalities of information exchange and cooperation needs in line with the Memorandum of Understanding between both agencies.

II.13 Co-ordination with EFSA	
II.13.1 Scientific assessment of estragole	*See I.3.1, II.4.1*
III. Organisational matters	
III.1 Organisational Matters Drafting Group	
III.1.1 Meeting report from virtual ORGAM DG meeting held on 10 February 2014 *For adoption*	Report: ORGAM DG Chair Adopted.
The ORGAM Chair reported the finalisation of one Q&A (see III.1.2) and two templates (see III.1.3 and III.1.4) during the last ORGAM meeting. The next main topic will be the revision of the CTD guideline as regards the non-clinical/clinical aspects in cooperation with the HMPC Rapporteur.	
III.1.2 Q & A on the EU framework for (traditional) herbal medicinal products, including those from a non-European tradition *For adoption and publication*	Rapporteur: E. van Galen Adopted. Final questions on need for few minor editorial corrections were clarified. HMPC secretariat to publish on the EMA website under Regulatory guidance.
Experiences during the elaboration of the Q&A at ORGAM with input by the EMA (legal, RA, HMPC secretariat) where shared with the committee revealing the specificities of the herbal framework and associated terminology. The ORGAM Chair emphasized the balance between correctness according to the legislation and avoidance of too many details in order to have a Q&A fit for purpose. Questions by the Commission representative and HMPC members were clarified and changes agreed where necessary such as on used abbreviations, procedure types, or the role of monograph vis-à-vis SmPC and labelling. HMPC members welcomed the document as very useful reference for basics of the European framework to facilitate the communication with applicants for products of non-European background. Remaining editorial questions (table of content, links for explanations, key words and linkage of the document on the EMA website) to be clarified between EMA secretariat, Rapporteur and HMPC Chair.	
III.1.3 Template for AR on monographs (Rev.4) *For adoption and publication*	Rapporteur: M. Delbò Adopted without changes. HMPC secretariat to publish at the EMA website.
The template had been modified to improve the structure and clarity for authors and readers; i.e. what exactly and where to place/find necessary and available information to justify the content of a Community herbal monograph/ List entry in line with the legislation and Notice to applicants. Despite general agreement at ORGAM DG and MLWP at this point of time, the rapporteur characterised the template as a living document. Some discussion took place on the complexity of tables, and the conclusions on available data for single ingredients versus the definition of markers. Overall the HMPC welcomed the adapted template as useful for all stakeholders involved. Assessors may simplify case by case if justified, e.g. if insufficient information is available. Rapporteurs now starting the work on new or revised monographs should already use the new template.	
III.1.4 Template for exchange of information on marketed products *For adoption and publication*	Rapporteur: M. Delbò Adopted without changes. HMPC secretariat to publish at the EMA website. Usability test was recommended after about a year's time experience.

The template was adapted to better reflect the information needed for the AR facilitating inclusion of required information. As the template became longer, questions were raised on the practicability. Currently it is not retrievable from the AR, whether no licenced products have been found on the market or no information is available. A general overview (response rate) would be important at the beginning of the assessment (with reasonable expenditure for MS with many products on the market), while missing important information may be added during discussions at MLWP. The Rapporteur considered that only information available should be filled in. No changes were proposed but usability should be re-assessed having more experiences with the modified document.	
III.1.5 Nominations of new ORGAM DG members - nominations received from HMPC members - email from DE 17/03/2014	S. Bodemann (DE) nominated by consensus as new member of ORGAM DG. Members invited to submit further candidatures by 28 April for discussion at the HMPC May meeting.
The HMPC welcomed the candidature of S. Bodemann and noted experiences with monograph and guideline development for the German MLWP and ORGAM members. As another 2 position at ORGAM DG remain open, the HMPC Chair reminded the members to check for possible nominations from their NCAs.	
III.2 Working methodology	
III.2.1 Progress with MMD implementation -email	Members invited to use opportunity during the meeting for direct clarification with IT on experienced problems. HMPC May meeting will run on MMD only (no parallel Eurdralink anymore) with some necessary adjustments such as in naming or version control but keeping standard submission deadlines (week -2, week -1).
Some issues were reported. Direct online work allows via a simple click on agenda points access to the relevant documents, while if documents are downloaded this function is not available. The latter may cause problems with finding documents as naming is reduced (no agenda point number or document number in the title). This may be solved with increasing experience over time. Problems with *msg* files were noted and the secretariat saves relevant emails as word file.	
III.2.2 Report on HMPC informal HMPC meeting held in Vilnius in December 2013 *For discussion*	Report: A. Kažemekaitis Postponed.
III.2.3 Agenda topics for informal HMPC meeting to be held in Rome on 4-5 November 2014 *For discussion*	Report: M. Delbò Members were invited to send in proposals for presentations with main focus on borderline issues.
III.2.4 Meeting dates in 2016-2017-2018 (Revisit time frames by end of the year) *For adoption*	*See also III.2.6* Adopted. HMPC noted that some final adjustment may still be possible to even out meeting capacities across all committees per month.
III.2.5 Organisation of an assessors' training in 2014 for 20 participants *For discussion* - proposals from HMPC members (R. Länger on 3 February)	Report: HMPC Chair Small group (R. Laenger, H. Neef, I. Chinou, W. Knöss) to present first draft programme at HMPC May meeting based on proposals discussed regarding content and format.

Q DG had considered a quality-related topic for the assessors training more appropriate for 2015. Proposals were presented on content and format to foster harmonisation and allow exchange of experiences in applying HMPC monographs / guidance and interpretation of the legislation for specific examples. This was considered important as many assessors have few such opportunities at their NCAs. Pros and cons were discussed for a workshop-like structure to discuss examples experienced by national decision makers versus previous formats, i.e. presentations with subsequent short discussions thereafter. The priority for a training for authors of MLWP ARs was questioned, as the improved template together with the discussions at MLWP allow via 'learning by doing' sufficiently to identify good examples and needs for improvement. The HMPC Chair proposed to combine discussions on the quality of the AR and the use of AR and other HMPC documents during national procedures.	
III.2.6 Update on progress of EMA reorganisation especially the rationalisation of scientific committees secretariats *For discussion*	HMPC members noted main points on as-is analysis, objectives and proposals as presented to the SciCo Board. The rationalisation / centralisation of the secretariat to achieve a harmonised and flexible organisation design was welcomed. However, HMPC Chair and members emphasized the peculiarities of the herbal framework requiring special expertise and long-term experience.
III.2.7 Scientific Coordination Board meeting held on 10 March 2014 *For discussion*	Report: HMPC Chair
III.2.8 Move to new EMA offices in July 2014 III.2.8.1 Presentation on EMA move to 30 Churchill Place	Main features of the new building were presented. HMPC meeting July will be hold at the old building; HMPC meeting September at the new premises.
IV. Quality	
IV.1 Quality Drafting Group	
IV.1.1 Meeting report from FtF Q DG meeting held on 12-13 February 2014 *For adoption*	Report: Q DG Chair Adopted with minor changes.
The Q DG reported positive experience from a 1.5 day face to face meeting discussion. Although no documents finalised, progression with topics of the DG work programme would have been more difficult via virtual meetings. Due to complexity (incl. decision tree) the original Q&A on benzene in extracts is now developed towards a reflection paper. Once finalised, the final format of appropriate guidance may be discussed at HMPC considering the status of a reflection paper according to the Guideline on European guidelines and the importance of the topic vis-à-vis other guidance including existing QWP guidance on benzene impurities. Other topics under discussion/development included appendix 2 for the CTD guideline (module 3 mock up (S-part, P-part still to be finalised), a Q&A on products for which the substance has no assay in the respective Ph. Eur. monograph, comments to Ph. Eur. on fresh herbal drugs, a question on the comparability of herbal preparations, and future topics for an assessors training.	
IV.2 European Pharmacopeia	

IV.2.1 Report from EDQM Expert Group 13A meeting held on 4-5 March 2014 *For discussion* * - report	EDQM: M. Bald HMPC Observer: I. Chinou List for substances requiring a Ph. Eur. quality monograph according to HMPC priorities to be drafted by MLWP for HMPC May meeting in line with minutes of the last 'Chairs meeting' for submission to EDQM by end of May.
The HMPC observer presented the EDQM meeting report and highlighted in particular the work of group 13A on different and the general essential oil monographs. Reference was made to the current work of HMPC Q DG (Reflection paper, Q&A) and possible points of interaction as minuted from the annual Chairs meeting in September. Also the by then agreed interaction regarding monograph development (proposal for which HMPC prioritised substances a missing Ph. Eur. quality standard should be developed) had been taken up and discussed in Strasbourg with approximately 15 HMPC monographs without corresponding Ph. Eur monograph. The EDQM representative informed that the next Ph. Eur. commission meeting will take place in June, therefore a consolidated HMPC proposal should be ideally provided before that. As only a limited number will be possible to include, a ranking would be important. The task was given to MLWP to have a draft available for discussion/decision at the HMPC May meeting. For future reporting see IV.2.3.	
IV.2.2 Invitation to EDQM Expert Group 13B meeting to be held on 8-9 April 2013 *For information*	EDQM: M. Bald HMPC Observer: H. Neef New EDQM representative (U. Rose) at HMPC announced.
For future reporting see IV.2.3.	
IV.2.3 Report from EDQM Expert Group TCM meeting held on 11-12 February 2014 *For discussion*	EDQM: M. Bald HMPC Observer: R. Länger HMPC welcomes in the future concise written reports from observers at Ph. Eur. groups pointing to relevant points and impact for the HMPC (analogy to other observer reports).
The HMPC was informed on finalisation of some Ph. Eur. TCM monographs and general issues such as availability of authenticated material traded in Europe, relevant analytical markers, usefulness of often very expensive reference standards and consideration of reference extracts. Regarding future reporting expectations, the HMPC Chair preferred short written reports for 13A, 13B and TCM pointing to the relevance, impact and need for action for HMPC/Q DG. This would allow an added value for the HMPC from the now re-instated physical attendance of observers (13A, 13B) beyond available EDQM meeting reports and information by the EDQM representative at HMPC/ Q DG.	
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
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 and list entry on Eleutherococci radix (and supporting documents: AR, LoR) Rapporteur: D. Kalke	Rapporteur: D. Kalke Peer-reviewer: G. Calapai Monograph adopted by a majority vote (21 out of 30). Divergent position – A. Cunney (IE), E.S. Leinonen (FI), E. v. Galen (NL), I. Kosalec (HR), M. Delbò (IT), M. Nagy (SK), O. Pelkonen (Coopt. M.), W. Dymowski (PL), Zs. Biróné-Sándor (HU) NO expressed a favourable position. Draft List entry adopted by a majority vote (20 out of 30). Divergent position – A. Cunney (IE), E.S. Leinonen (FI), A. Le (FR), E. v. Galen (NL), I. Kosalec (HR), M. Delbò (IT), M. Nagy (SK), O. Pelkonen (Coopt. M.), W. Dymowski (PL), Zs. Biróné-Sándor (HU) NO expressed a favourable position. HMPC secretariat to publish the documents and transfer Draft LE to Eur. Com.
The MLWP Chair presented the finalised revised documents yet divergent views on the indication as discussed at the MLWP taking into account other adaptogenic drugs but also demarcation to caffeine containing drugs. While several members supported possible slight improvements of the indication wording, a majority agreed to keep the existing traditional indication as no new data support a more substantiated change. Other issues discussed were some old preparations with unusual extraction solvents in the monograph as well as available genotoxicity data. The complete package including the monograph adapted to the new template was agreed by majority vote. Likewise a majority supported that the indication is not changed in the list entry.	
V.3.2 Monograph on Passiflorae herba (and supporting documents: AR, LoR) V.3.2.1 Non-clinical issues	Rapporteur: P. Claeson Peer-reviewer: I. Chinou MMD 2 Adopted by consensus with minor change in monograph section 2. NO expressed a favourable position. HMPC secretariat to publish the documents. HMPC noted DCP procedure for product containing a Passiflora preparation with questions on non-clinical requirements. Amendments in the AR were not considered necessary as monograph/AR in line with Dir. 2001/83/EC and relevant HMPC guidelines for THMP including EMEA/HMPC/32116/05.

A solvent declaration was corrected in monograph section 2.
In view of discussions within a European procedure **raised by one CMS** on necessary pre-clinical (carcinogenicity) data linked with the duration of use (recurrent use beyond 6 months), the need for more clarity in the AR was discussed. A **clear** majority of members confirmed the applicability of specific guidelines for traditionally used substances (> 30 years of safe use) in addition to generally applicable guidance for MP that are tailored to new chemical entities. Moreover no particular pharmacovigilance signals or structural alerts from compounds contained in Passiflora herba preparations have been detected in any MS or during the literature review. If in line with principles of Dir. 2004/24/EC, the AR/MO template, assessment standard procedure and available specific guidance (e.g. herbal specific guidelines EMEA/HMPC/104613/05; EMEA/HMPC/32116/05 or EMEA/HMPC/107079/07) a more detailed justification on the assessment outcome/consequences may not be particularly stated in each AR. The HMPC view on the content of the monograph and the supporting assessment report was confirmed without changes in either document and adopted by consensus.

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 Eucalypti aetheroleum (and supporting documents: AR, LoR, OoC)	Rapporteur: J. Wiesner, Expert: R. Hönow Peer-reviewer: I. Chinou Adopted by consensus. NO expressed a favourable position. HMPC secretariat to publish the documents.
V.5.2 Monograph on Ginseng radix (and supporting documents: AR, LoR, OoC)	Rapporteur: R. Länger Peer-reviewer: W. Knöss Adopted by a majority vote (22 out of 29). Divergent position – A. Cunney (IR), E. v. Galen (NL), G. Calapai (Coopt. M.), M. Delbò (IT), M. Nagy (SK), S. Girotto (Coopt. M.), Zs. Bíróné-Sándor (HU) NO expressed a favourable position. HMPC secretariat to publish the documents.
The package was adopted without further changes. The HMPC was informed on a discussion at MLWP regarding the possibility for a list entry, which was supported by the Rapporteur based on available genotoxicity data but not by a majority at MLWP for reasons not only linked to genotoxicity.	
V.5.3 Monograph on Ononidis radix (and supporting documents: AR, LoR, OoC)	Rapporteur: B. Jansone Peer-reviewer: M. Heroutová Adopted by consensus. NO expressed a favourable position. E. v. Galen (NL) expressed concerns regarding part of the indication (to increase the amount of urine), which in case of application for THMP in the Netherlands, will not be supported. HMPC secretariat to publish the documents.

V.6 Community herbal monographs, Community list entries and public statements for adoption for release for public consultation

V.7 Community herbal monographs, Community list entries and public statements for discussion	
V.7.1 MLWP recommendation to cancel the assessment work on Crataegi fructus (no available information on marketed products with proven 30 years of medicinal use in the EU containing Crataegi fructus as single substance)	Report: MLWP Chair Adopted. HMPC endorsed proposal to discontinue the assessment on Crataegi fructus without publication of a public statement. HMPC secretariat to inform in the public meeting report.
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 27-28 January 2014	
VI.3.2 Meeting report from HMPC meeting held on 27-28 January 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 25-27 March 2014	
VI.3.4 Table of Conclusions from MLWP meeting held on 28-30 January 2014	
VI.3.5 Draft Minutes from MLWP meeting held on 28-30 January 2014	
VI.3.6 Overview of status of HMPC assessment work – priority list	link
VI.3.7 Inventory of herbal substances for assessment work – alphabetical order	link
VI.3.8 Common names of herbal substances in all EU official languages	*Update available at next meeting in May 2014.*
VI.3.9 Rapid alert on 24 February 2014 concerning product Golden Root 450 mg marketed as dietary supplement and found to contain undeclared sildenafil and yohimdina (IT)	

VI.4 Any other information

VI.4.1 New permanent access cards - email	Information circulated on 7 March 2014, MMD 1
VI.4.2 Abbreviations in HMPC minutes	http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/11/WC500155666.pdf

List of participants

Chair of the HMPC	***Apologies***
Werner Knöss	Steffen Bager (DENMARK)
	Evelin Saar (ESTONIA)
	Niamh Curran (IRELAND)
HMPC members	Martina Hudecová (SLOVAKIA)
Reinhard Länger (AUSTRIA)	Arturas Kažemekaitis (LITHUANIA)
Heidi Neef (BELGIUM)	
Elena Mustakerova (BULGARIA)	***HMPC alternate members***
Ivan Kosalec (CROATIA)	Wim Vervaet (BELGIUM)
Maria Stavrou (CYPRUS)	Markéta Příhodová (CZECH REPUBLIC)
Marie Heroutová (CZECH REPUBLIC)	Jacqueline Viguet Poupelloz (FRANCE)
Eeva Sofia Leinonen (FINLAND)	Anna Cunney (IRELAND)
An Lê (FRANCE)	Baiba Jansone (LATVIA)
Jacqueline Wiesner (GERMANY)	Burt Kroes (THE NETHERLANDS)
Ioanna Chinou (GREECE)	Milan Nagy (SLOVAKIA)
Zsuzsanna Biró-Sándor (HUNGARY)	Sue Harris (UNITED KINGDOM)
Marisa Delbó (ITALY)	Nina Dürr (DENMARK)
Dace Kalke (LATVIA)	
Everaldo Attard (MALTA)	**Observer**
Emiel van Galen (THE NETHERLANDS)	Melanie Bald (via teleconference)
Steinar Madsen (NORWAY)	Saša Pilipović (BOSNIA AND HERZEGOVINA)
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)	**European Commission**
Per Claeson (SWEDEN)	Tina Engraff – 24 March 2014
Linda Anderson (UNITED KINGDOM)	
Gioacchino Calapai (CO-OPTED)	**Experts**
Silvia Girotto (CO-OPTED)	Zoi Karampourmpouni
Gert Laekeman (CO-OPTED)	
Olavi Pelkonen (CO-OPTED)	
Maria Helena Pinto Ferreira (CO-OPTED)	
Eeva Sofia Leinonen (FINLAND)	
An Lê (FRANCE)	
Jacqueline Wiesner (GERMANY)	