24 November 2014
EMA/HMPC/624810/2014
Procedure Management and Business Support Division

Committee on Herbal Medicinal Products (HMPC)

Minutes of the 29-30 September 2014 meeting

FINAL

29 September 2014, 14:00 – 19:00, room 3E, *plenary*
30 September 2014, 09:00 – 13:00, 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.

Delegates are also to be shown an introduction presentation on the new building at 30 Churchill place.

- **Welcome to new participants**

- **Announcement of new nominations, changes to composition**

Kapka Kaneva, new Bulgarian alternate
Zoi Karampourmpouni, new Greek alternate
Anna Cunney, new Irish member
Una Mockler, new Irish alternate
Ulrich Rose, new EDQM observer

- **Appointment of 3 Co-opted members to the HMPC with expertise in:**

- Clinical pharmacology
- Experimental/non-clinical pharmacology
- General and family medicine

See also I.1.3

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- **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

I. Introduction	
I.1 Agenda, minutes	
I.1.1 Agenda of 29-30 September 2014 HMPC meeting - timetable, for order of topics *For adoption*	Adopted with minor changes in agenda and timetable.
I.1.2 Minutes of 30 June-1 July 2014 HMPC meeting *For adoption*	Adopted without changes.
Clarification was provided on minutes points I.2.1 (July) and IV.2.2 (May).	
I.1.3 Election of co-opted members - procedure for nomination/election of co-opted members for HMPC - Overview of expertise available in the HMPC, MLWP, ORGAM, Q DG - Nomination received for Clinical pharmacology: G. Calapai - Nomination received for Experimental/non-clinical pharmacology: G. Laekeman - Nomination received for General and family medicine: H. Pinto Ferreira *For adoption*	Report: HMPC Chair Members who have so far not returned the expertise overview to fill in their areas of expertise and submit to HMPC secretariat. HMPC secretariat to complete overview according to answers received for HMPC November meeting. G. Calapai was re-appointed as co-opted member to the HMPC for Clinical pharmacology for a 3 year term starting 24 Nov 2014. G. Laekeman was re-appointed as co-opted member to the HMPC for Experimental/non-clinical pharmacology for a 3 year term starting 24 Nov 2014.

	H. Pinto Ferreira was re-appointed as co-opted member to the HMPC for General and family medicine for a 3 year term starting 24 Nov 2014. HMPC re-confirmed the need for a co-opted member in the competence area paediatric medicine. With termination of the current co-opted membership in this area before the HMPC January 2015 meeting, HMPC Members were asked to send nominations for the new appointment at the HMPC November meeting. HMPC secretariat to send request for nominations to all HMPC members.
I.2 Legislation and regulatory affairs	
I.3 Questions raised by HMPC members	
I.3.1 New QRD template for THMPs in mutual recognition and decentralised procedures - email and attachment dated 25 August 2014 *For discussion*	*See also V.1.1* 1) HMPC agreed to submit first proposal on minor modification to suit THMP specifics (discussed by ORGAM but not modified) to QRD group. 2) HMPC members to submit proposals for more far reaching modifications to Rapporteurs for discussion at next ORGAM meeting and agreement at HMPC Nov meeting before further coordination with QRD.
HMPC noted different intentions by Rapporteurs as regards the nature of changes and agreed on a two-step approach. First to submit minor modifications (simply linked to formal consideration of registrations mentioned in the template) to the QRD group now. Second to collect more advanced proposals from national experiences. The latter will be compiled by the previously allocated Rapporteurs for discussion at ORGAM DG 10 November 2014. Some points to consider were already mentioned such as a) consistency between standards applied in HMPC monographs and standard QRD template not tailored for specificities of THMP in several sections or b) conforming guideline-declaration of HMP/THMP versus standard declarations of strength for other MP.	
I.3.2 Request on mutual recognition procedure (MRP) – for a traditional herbal medicinal product (ART. 16a Directive 2001/83/EC) - email dated 10 September 2014 *For discussion*	Rapporteur: E. v. Galen National experiences with the use of standard assessment templates for THMP in European procedures were exchanged. While direct HMPC initiative or general harmonisation was not found suitable to comprise all specific cases, the topic could be addressed at the upcoming HMPC assessors training.
The HMPC discussed the suitability of standard assessment templates for overview, quality, safety and in particular clinical evaluation (to be replaced with the evidence on safe medicinal use for THMP) used nationally and in communication between RMS and CMS in case of MRP. Practices and experiences were exchanged including the use of additional validation reports amending standard templates taking	

into account particular requirements for THMP. Because of the rather still low amount and heterogeneity of such cases it was agreed that no general harmonisation or template change may be targeted. Agreements between MS could be found case by case without primary involvement of HMPC or CMDh.	
I.3.3 Request on type of extract, acceptable manufacturing steps and defined amounts of key constituents for THMP - email dated 19 September 2014 *For discussion*	Rapporteur: R. Länger Cases for traditionally standardised extracts were discussed regarding current extract definitions, applicable guidelines and suitable procedures. HMPC agreed on further discussion at the upcoming HMPC assessors training. Topics like these could also be suitable for future HMPC presidency meetings.
Members discussed extract definitions, marker distinction and recognition, suitability for registration or authorisation in view of quality standards set historically for certain extracts/products and with reference to Ph. Eur. extract monographs. Several members explained their experiences and signalled inclination for certain flexibility in one or two scenarios. Basic principles of European definitions / guidelines should be maintained alongside recognition of established high quality standards that evolved before harmonisation in Europe such as adjustment to key constituents without recognised clinical evidence. It was acknowledged that this refers to a few examples only and may not require major paradigm change but case by case solutions via agreement between MS in European procedures for instance. Possibilities for national SA and SA by the HMPC and consideration as topic for an assessors training or informal meeting were also discussed.	
I.4 Questions raised by companies	
I.5 Referral procedures	
I.6 Co-ordination with Eur. Com.	
I.6.1 Revision procedure for List entries *For discussion*	Report: E van Galen Eur. Com: Tina Engraff *See also V.1.1* and *V.1.3* HMPC confirmed need for clarification of procedural modalities on the revision of LEs vis-à-vis the revision of monographs. ORGAM to further scrutinise details and check current procedural guidance. The ORGAM proposal of minor modifications not justifying LE revision, in contrast to major changes with emphasis on the safe use was in principle agreed. A list of minor versus major changes was requested to clarify what would trigger a new opinion by the HMPC and submission to Eur. Com. for comitology procedure. Such ORGAM proposal to be discussed at the HMPC Nov meeting.

	EMA legal support was requested to check legal basis for LE revision and report at the HMPC November meeting.
ORGAM Rapporteurs had scrutinised current guidance documents for monographs and their applicability for list entries vis-à-vis legislation and current practice. Possible amendments had been proposed but practical implications require advice by the Eur. Com. In certain analogy to changes triggering the need for a new public consultation during monograph revision, equally for LEs it was proposed to differentiate between minor and/or major changes. Several members saw only really new safety data justifying a revision with subsequent new HMPC opinion, translation into all EU languages, comitology procedure and new publication in the EU official journal. The Eur. Com. representative agreed that minor changes (template/practice adaptations) should indeed not lead to new opinions and resource-consuming comitology procedures. Hence it is important to define minor and major changes. The secretariat reminded that in principle (5 year) renewals as common for individual MA are not specifically addressed by the legislation for LEs, yet monograph revisions had been agreed to keep a high consistent standard across monographs to secure their long term applicability. Two examples in 2014 were mentioned. Minor monograph adaptations not leading to a LE revision (but subsequent minor discrepancies between LE and MO): example Anisi fructus and 'major' monograph revision (removal of a contraindication) leading to a revised LE (Eleutherococcus).	
I.7 Co-ordination with EFSA	
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 discussion*	Report: MLWP Chair
The HMPC noted explanations by the MLWP Chair why some monographs had been postponed and were not considered ready yet for adoption at HMPC (newly available safety data, issues detected during peer review, complete packages including consideration on list entries not finalised at MLWP).	
II.1.2 AESGP hearing MLWP May 2014 - report *For endorsement*	Endorsed.
II.2 Community list entries transmitted to European Commission	
II.3 Community herbal monographs for public consultation / final adoption after systematic review / revision	
II.4 Community herbal monographs (post finalisation)	

II.5 Community herbal monographs, Community list entries and public statements for adoption after public consultation	
II.5.1 Monograph on Sisymbrii officinalis herba (and supporting documents: AR, LoR) *For adoption*	Rapporteur: Z. Biró-Sándor Peer-reviewer: B. Kroes *References available in MMD 22/22* Final monograph with changes in sections 4.1 and 4.4 and supporting documents adopted by consensus. NO expressed a favourable position.
A minor change in the indication was introduced. Newly elected co-opted members not participating in the voting expressed a favourable position.	
II.6 Community herbal monographs, Community list entries and public statements for adoption for release for public consultation	
II.6.1 Monograph on Crataegi folium cum flore (and supporting documents: AR, LoR) *For adoption*	Rapporteur: J. Wiesner Peer-reviewer: R. Länger Draft monograph and supporting documents adopted by a majority vote for release for public consultation until 15 January 2015. A majority of HMPC members agreed giving MLWP the task of developing a list entry for preparations with available data (conforming to guideline) on genotoxicity.
Several members raised concerns regarding indication 1 (linked to cardiac complaints) to be suitable for self-medication. Reference was made to products used for decades on the European market in this indication and previous debates at MLWP. Options were discussed including the cardiologist expert view. An established safety profile for the product was acknowledged. This is supported by many clinical data -usually not available for many herbal substances, although these data were not sufficient to recognise efficacy. Despite general concerns by some members on the suitability of a cardiac indication, a majority agreed to the development of a List entry for indication 1.	
II.7 Community herbal monographs, Community list entries and public statements for discussion	
II.8 Guidelines and other guidance documents	
II.8.1 Revision public statement on the use of herbal medicinal products containing estragole - letter by SWP Chair - draft revised public statement *For discussion/adoption*	After principal agreement by SWP on assessment approach and threshold calculation Rapporteurs in liaison with HMPC Chair to finalise draft PS revision 1 for adoption by written procedure before HMPC November meeting for release for public consultation. *See also IV.1.1*
The history of the old PS, the newly available data that have been compiled and assessed as well as the coordination with SWP before an envisaged revision of the 2005 PS was briefly summarised by the Rapporteur. The relevance of animal data for risk assessment in humans and the classification of estragole as genotoxic carcinogen had been agreed by SWP. The SWP representative considered, however, that following the principle risk assessment and classification of a single substance the consequent	

acceptable limits in multi compound mixtures and risk management in view of possible background intake via food should be carefully assessed by HMPC. No comments were received by HMPC members, and a final review by the Rapporteurs before written procedure was agreed. With publication of the draft revised public statement also information to EFSA is foreseen due to comparable amounts of estragole in foods.	
II.8.2 Revision public statement on the use of herbal medicinal products containing pulegone and menthofuran - draft revised public statement *For discussion*	HMPC received first feedback by SWP, which will be followed by a written answer on questions submitted by HMPC in June. Rapporteurs in liaison with HMPC Chair to modify and amend draft PS rev 1 for adoption via written procedure before the HMPC November meeting for release for public consultation. *See also IV.1.2*
After compilation and evaluation of newly available data, questions had been transferred to SWP as regards the relevance of animal studies and pharmacokinetics for possible extrapolation for human risk assessment. While SWP agreed in principle to International Agency for Research on Cancer (IARC) and HMPC view on the nongenotoxic mode of carcinogenic action for pulegone/menthofuran, essential data gaps (appropriate liver test models) were identified that do not allow excluding a genotoxic action of pulegone metabolites. Some reference was made to the guideline on genotoxic impurities as regards concentrations via natural exposure vis-à-vis concentrations via medicine intake. Yet the difference to concentrations found in some HMP was acknowledged where rather an accumulative approach has to be taken due to co-exposure via food and medicine at comparable level. Exposure duration (short term versus life-long), uncertainty factors, the possibly exhaustible protection via glutathione, accumulation, and possible role of the matrix were discussed. Pulegone thresholds, concentration in Mentha products on the market as well as existing monographs were considered. A final review by the Rapporteurs before written procedure on the draft for release for public consultation was agreed.	
II.8.3 Guidance on herbal medicinal products containing polycyclic aromatic hydrocarbons (PAH) - presentation - email dated 29 August 2014 *For discussion*	HMPC confirmed future importance of the topic for some herbal substances/preparations of European and non-European tradition and agreed to develop a reflection paper to stimulate the discussion and submission of relevant data. Rapporteur to submit a draft in January 2015 to HMPC, MLWP and Q DG Chairs for decision on follow-up and involvement of relevant experts.
The need for guidance as regards PAH was re-discussed as previously included into the MLWP work programme but made dependent on developments and state of knowledge at Ph. Eur. It was acknowledged that overall not many data are available to develop a guideline but for certain herbal substances and derived extracts PAH are an issue that needs to be addressed in individual applications anyway. To develop supporting harmonised European guidance in this respect, a reflection paper was seen as useful first step that beside toxicological considerations may also need input from Q DG and liaison with Ph.Eur. as regards quality aspects.	

III. Quality	
III.1 Quality Drafting Group	
III.1.1 Meeting report from Q DG meeting held on 10 September 2014 *For adoption*	Report: Q DG Chair Adopted.
The main topics were summarised by the QDG Chair: ongoing discussions on a draft reflection paper on benzene in extracts and the herbal CTD guideline Rev2 part 2 (Appendix mock-up), while guidance on new analytical methods, on biopharmaceutical characterisation and on microbial aspects were postponed. A work programme for 2015 was drafted and proposals made for amendment of the quality Q&A. Among minor topics discussed was a request by ORGAM on the ongoing Rev. 3 of the herbal CTD guideline where changes in the clinical/preclinical part have to make reference to the quality part. Q DG suggested that beside the drafting tasks for the HMPC, there is a need to have a European forum where upcoming quality issues arising from assessment can be discussed. The proposal was discussed vis-à-vis the tasks of the HMPC and the drafting group mandate and it was encouraged to specify the proposal in order to identify the right platform and framework going beyond ad-hoc discussions between experts of different member states.	
III.1.2 Proposal for amendments of 'Questions & answers on quality of herbal medicinal products/traditional herbal medicinal products' - correction of question 1 (microbiological) email dated 3 September 2014 - additional question on (stability), email dated 3 September 2014 *For discussion*	Report: Q DG Chair HMPC agreed to modify and amend Q&A EMA/HMPC/41500/2010 Rev.4 as necessary. Q DG to present a revised version for adoption at HMPC November meeting.
III.1.3 draft Q DG work plan 2015 *For discussion*	Report: Q DG Chair *See also V.2.2*
III.2 Co-ordination European Pharmacopeia	
III.2.1 Report from EDQM Expert Group 13B meeting held on 23-24 September 2014 - agenda - report *For discussion*	EDQM: M. Bald, U. Rose HMPC Observer: H. Neef HMPC noted the report and discussed on-going work relevant for the HMPC.
The committee heard reports by the EDQM representatives and the HMPC observer and noted in particular the new Chair of Ph. Eur. expert group 13B and that all herbal substances proposed by HMPC in May have been agreed by the Ph. Eur. commission for the work programme of 13A and 13B. It was encouraged to repeat such exercise in May 2015 in order to further align priorities. Work on new monographs with relevance for HMPC assessment was mentioned such as a possible adjustment of Pilosella herba (HMPC draft monograph) to Pilosella planta tota. The continued cooperation as regards requirements for fresh herbal drugs and essential oils was identified as important for co-ordination. The successful model of a temporary working party at EDQM used for the revision of the Ph. Eur. extract monograph was emphasized.	

III.2.2 Report from EDQM Expert Group TCM meeting held on 16-17 September 2014 - Summary of decisions *For discussion*	EDQM: M. Bald, U. Rose HMPC Observer: R. Länger HMPC noted summary of decisions and monographs currently at different stages of development/publication.
HMPC noted the report summarising the current work on over 40 substances and discussed specific aspects such as herbal substances composed of mainly non-herbal material after processing, and new approaches for assays where the specification of several key compounds and their ratio to each other is more important than the absolute quantification of one single qualitative marker only (no evidence on therapeutic relevance). For the latter the HMPC Chair reminded that overall the same principles of quality assurance have to be applied for European and non-European substances and new approaches may carefully be checked and coordinated.	
IV. Internal Co-ordination with committee and working parties	
IV.1 Co-ordination with SWP	
IV.1.1 Revision public statement on the use of herbal medicinal products containing estragole - *For discussion*	Report: HMPC Chair *See also II.8.1*
IV.1.2 Revision public statement on the use of herbal medicinal products containing pulegone and menthofuran - *For discussion*	Report: HMPC Chair *See also II.8.2*
V. Organisational matters	
V.1 Organisational Matters Drafting Group	
V.1.1 Meeting report from ORGAM DG meeting held on 9 September 2014 *For adoption*	Report: ORGAM DG Chair Adopted.
1) The ORGAM Chair summarised topics discussed: 2) Template revisions: revision monograph and LE template finalised (see V.1.2) and final necessary adjustments for the template for exchange of information on marketed products (published). 3) Revision 3 herbal CTD guideline clinical/non-clinical part: new input mainly regarding sections 2.4 and 4.3 and necessary adjustment with quality requirements (request to Q DG). Finalised by ORGAM and sent to MLWP for review before adoption at HMPC in November. 4) THMP specifics to be considered in new QRD template (see I.3.1) 5) Revision procedure of List entries vis-à-vis monograph revision (see I.6.1) 6) Topics for the 2015 work programme are expected to be identified by HMPC. Face to face meetings every two years are considered necessary.	
V.1.2 Revision of HMPC Templates - Community herbal monograph - Community list entry *For adoption*	Report: ORGAM DG Chair Rapporteur: M. Delbó Adopted with changes by majority vote for publication on EMA website.

The Rapporteur presented agreed changes to the template. An additional proposal on the quality standard footnote was discussed. The quality of a substance should be defined by a pharmacopoeial or other standard in the monograph, as otherwise it is not clear what has been assessed. Reference was made to the common hierarchy (Ph. Eur., other national pharmacopoeias., etc.) and the need for applicants to follow applicable quality guidance anyway. A change is not considered necessary. Different views were expressed on the specific mentioning of aetheroleum in the heading beside herbal substances. It was acknowledged that potentially other specific preparations may need an extra monograph (e.g. distillate, fatty oil) as very different in their characteristics and safety profile to substances and common extracts. For the template the common practice so far is kept, which may be modified for exceptional cases. With reference to the TREATY ON EUROPEAN UNION AND THE TREATY ON THE FUNCTIONING OF THE EUROPEAN UNION (2012/C 326/01) the HMPC agreed to use in future the terms 'European Union herbal monographs' and 'Entry to the European Union List of herbal substances and preparations thereof' replacing 'Community' within the old terms introduced by Directive 2004/24/EC amending, as regards traditional herbal medicinal products, Directive 2001/83/EC and used so far. The term 'EU herbal monographs' as an abbreviation of 'European Union herbal monographs may be used as well. Such change will be introduced prospectively in herbal monographs, list entries, supporting documents and guidelines.	
V.1.3 Revision procedure of List entries *For discussion*	Report: ORGAM DG Chair *Liaise with EC representative to clarify the practical consequences of small changes in LE.* *See also I.6.1*
V.1.4 Draft ORGAM DG work plan 2015 *For discussion*	*See also V.2.2*
V.2 Working methodology	
V.2.1 Assessors' training 'Community monographs- development and usages' on 25 November 2014 - draft agenda *For adoption*	Report: HMPC Chair Supported by: R. Länger, H. Neef, I. Chinou Adopted with minor changes as regards speakers. HMPC secretariat to clarify number of reimbursed invitations according to EMA budget and send out invitations.
Clarification on reimbursed and non-reimbursed participation expected by 10 October by the EMA secretariat. Shift of meeting schedule in November (HMPC start Monday morning, MLWP Wednesday to Friday) to be considered. Members noted online broadcasting and possibility for upfront submission of questions to be discussed in particular in session IV.	
V.2.2 HMPC work plan and input for EMA work programme - HMPC work programme 2012-2015 - draft template CXMP (Committee XX) work plan - draft work plans 2015 MLWP, Q DG, ORGAM DG *For discussion*	http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2011/12/WC500119957.pdf HMPC members to send proposals to ORGAM, QDG and MLWP Chair by 31 Oct 2014 for drafting of work plans 2015 for adoption at HMPC November meeting.

	HMPC advised to consider annual committee work plan in future in line with other scientific committees. From remaining topics of the 2012-2015 work programme extraction of main topics relevant for 2015 for the HMPC to be discussed at HMPC November meeting. *See also III.1.3 and V.1.4*.
First general ideas to align committee work plans across all scientific committees had been presented in July. HMPC specific practice for individual work plans for subgroups (MLWP, Q DG, ORGAM) is intended to change into an annual HMPC work plan. However, first the content for all groups should be agreed and adopted before a new format can be applied. While Q DG had already made a proposal, ORGAM had so far identified only one topic and requested HMPC input. MLWP had no discussion yet. No proposals were made, however it was acknowledged that with upcoming finalisation of the important assessment of single substances and fundamental guidelines new priorities have to be considered. A distinction between a) core business (e.g. monographs), b) guidelines and c) overarching projects should be made. The HMPC Chair referred to the HMPC work programme 2012-2015 and considered the new template/approach previously presented as not specified enough to be fully applied to current HMPC practice. Important overarching projects to be identified for communication to the SciCo board and consideration for the EMA work programme 2015.	
V.2.3 Informal HMPC meeting to be held in Rome on 4-5 November 2014 - draft agenda *For adoption*	Report: M. Delbó HMPC noted interesting programme focused on the borderline between HMP and food supplements and their assessment/ regulation in Europe. All members invited. Proposals for amendment of agenda and presentations still welcome and to be submitted to Italian HMPC member.
V.2.4 Quality and finalisation of documents transmitted to HMPC for adoption - examples *For discussion*	Postponed to November.
VI. Other relevant business	
VI.1 Conferences, presentations & research projects	
VI.1.1 Paving the way towards a coherent system, AESGP meeting in Brussels 7-8 October 2014 - agenda *For information*	Report: W. Knöss, I. Chinou, M. Delbó http://www.aesgp.eu/media/programmes/AESGP_Conference_October_-_FINAL_4.pdf HMPC noted programme focused on borderline products and participation of HMPC/MLWP Chairs and Vice Chair for possible reports at the HMPC November meeting.

VI.2 International cooperation, collaboration with non-EU regulatory authorities	
VI.2.1 7th annual meeting of IRCH to be held in Lisbon, Portugal on 2-4 December 2014 - invitation and draft agenda - programme *For discussion*	Report: HMPC Chair HMPC noted participation of HMPC Chair (HMPC focal point at IRCH) and HMPC secretariat for possible reports at HMPC meeting.
VI.3 Documents for information	
VI.3.1 Table of Decisions from HMPC meeting held on 30 June – 1 July 2014	
VI.3.2 Meeting report from HMPC meeting held on 30 June – 1 July 2014	http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2014/07/WC500169491.pdf
VI.3.3 Final agenda of MLWP meeting held on 30 September - 2 October 2014	
VI.3.4 Final table of Conclusions from MLWP meeting held on 1-3 July 2014	
VI.3.5 Final minutes from MLWP meeting held on 1-3 July 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 EU official languages	
VI.3.9 Overview on the paediatric uses of herbal medicinal products	Rapporteur: S. Girotto
VI.3.10 ARSP for publication (EN) and translations - *Juglans regia* L., folium - *Origanum dictamnus* L., herba - *Marrubium vulgare* L., herba	
VI.3.11 Update from the European Commission's working group on health claims, 16 May 2014	
VI.3.12 PCWP and HCPWP joint meeting (16 September 2014)	Observer: S. Bager
VI.3.13 PCWP and HCPWP workshop (17 September 2014)	
VI.3.14 First HMPC agenda 23-24 September 2004	

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 Relevant publications	
The Chair highlighted an upcoming special issue of the Journal of Ethnopharmacology on regulation of herbal medicinal products worldwide following the TradReg conference in October 2013 as well as other JEP articles regarding EU herbal monographs and TCM.	

The Chair thanked the participants and closed the meeting.

List of participants

Chair of the HMPC	***Apologies***
Werner Knöss	
	Evelin Saar (EE)
HMPC members	Jacqueline Genoux-Hames (LU)
Tina Engraff (European Commission)	Martina Hudecová (SK)
Reinhard Länger (AT)	Barbara Razinger (SL)
Heidi Neef (BE)	
Elena Mustakerova (BG)	
Ivan Kosalec (HR)	***HMPC alternate members***
Maria Stavrou (CY)	Wim Vervaet (BE)
Marie Heroutová (CZ)	Darko Trumbetić (HR)
Steffen Bager (DK)	Markéta Příhodová (CZ)
Eeva Sofia Leinonen (SF)	Marje Zernant (EE)
An Lê (FR)	Zoi Karampourmpouni (GR)
Jacqueline Wiesner (DE)	Jacqueline Viguet Poupelloz (FR)
Ioanna Chinou (GR)	Una Mockler (IE)
Zsuzsanna Biró-Sándor (HU)	Anna Maria Serrilli (IT)
Anna Cunney (IE)	Baiba Jansone (LT)
Marisa Delbó (IT)	Milan Nagy (SK)
Dace Kalke (LV)	Samo Kreft (SL)
Arturas Kažemekaitis (LT)	Burt Kroes (NL)
Everaldo Attard (MT)	Sue Harris (UK)
Emiel van Galen (NL)	
Steinar Madsen (NO)	
Wojciech Dymowski (PL)	**Observer**
Ana Paula Martins (PT)	Melanie Bald (EDQM)
Nadia Grigoras (RO)	Ulrich Rose (EDQM)
Adela Núñez Velázquez (ES)	
Per Claeson (SE)	
Linda Anderson (UK)	
Gioacchino Calapai (co-opted)	
Silvia Girotto (co-opted)	
Gert Laekeman (co-opted)	
Olavi Pelkonen (co-opted)	
Maria Helena Pinto Ferreira (co-opted)	