12 November 2013
EMA/HMPC/708071/2013
Patient Health Protection

Committee on Herbal Medicinal Products (HMPC)

Minutes of the 16-17 September 2013 meeting

Chair: Werner Knöss

16 September 2013, 14:00 – 19:00, room 4A

17 September 2013, 8:30 – 12:00, room 4A

- **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.

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

The HMPC welcomed Tina Engraff, European Commission representative at HMPC (Unit D-6)

The HMPC noted the change to the HMPC secretariat composition and wished the best in her future career.

- **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 restriction on the involvement of members and alternate members in relation to agenda topics and the interests declared.

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I. Introduction	* = Change introduced following last pre-meeting mailing
I.1 Agenda, minutes	
I.1.1 Agenda of 16-17 September 2013 HMPC meeting (EMA/HMPC/437612/2013 Vers.2): **for adoption**	Adopted. Redacted version published on the EMA website on 16 September 2013. See III.2.6.
I.1.2 Time schedule of 16-17 September 2013 HMPC meeting (EMA/HMPC/538032/2013 Vers.1): **for adoption**	Adopted.
I.1.3 Draft minutes of 8-9 July 2013 HMPC meeting (EMA/HMPC/453569/2013): **for adoption**	*Circulated on 5 August 2013* Adopted.
I.2 Legislation and regulatory affairs	
I.3 Questions raised by HMPC members	
I.3.1 Question by R. Länger dated 12 August 2013 in relation to estragole amounts in herbal extracts and average intake of estragole by food: **for discussion** - Email - *Public statement on the use of herbal medicinal products containing estragole (EMEA/HMPC/137212/2005)	*Report by R. Länger* *Coordination with EFSA* *http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2010/04/WC500089960.pdf* Rapporteurs assigned: O. Pelkonen, J. Wiesner HMPC members to liaise with toxicologists at NCA and provide available data/assessments to Rapporteurs. Rapporteurs to present data situation (in particular since 2005) for discussion on possible revision of PS EMEA/HMPC/137212/2005 at HMPC November meeting. Rapporteurs/ HMPC secretariat to double- check with EFSA current status in the food area.

Common estragole contents in plants and associated risks as regards human exposure due to intake via food and medicine were discussed. Several members confirmed similar on-going discussions with toxicologists at NCAs on the basis of the HMPC PS (EMEA/HMPC/137212/2005). It was agreed that Rapporteurs check whether new data including recent concepts on risk calculation are available that could trigger a revision of the PS from 2005. In case a revision is agreed in November, coordination with EFSA is foreseen.

I.4 Questions raised by companies	
I.4.1 Registration of combination herbal medicinal products in relation to the marketing authorisations for medicinal products	*Report by HMPC Chair and HMPC secretariat* *In the presence of T. Engraff (Eur. Com.)*
I.4.1.1 Letter from dated 22 July 2013 I.4.1.2 Draft response letter to dated 16 September 2013 (EMA/560660/2013): **for adoption**	Adopted. HMPC secretariat to transmit the dated and signed letter.
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 SWP comments on draft public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) (EMA/HMPC/893108/2011): **for discussion** II.4.1.1 Public statement (EMA/HMPC/893108/2011) II.4.1.1.1 Overview of comments (EMA/HMPC/280542/2013) II.4.1.2 SWP comments dated 22 July and 1 August 2013 II.4.1.3 HMPC Rapporteurs response to SWP comments	*Rapporteurs: J. Wiesner/O. Pelkonen* *Outcome written procedure at SWP* HMPC agreed to report and response by Rapporteurs to SWP comments. No further changes introduced in PS. HMPC secretariat to submit documents to SWP and in case of agreement after next SWP meeting (1-2 October) to publish documents on the EMA website for public consultation.
HMPC accepted the response by the Rapporteurs on the three points brought forward by SWP (reference to ICH M7, threshold and consideration of accepted and common limits in food, wording as regards specific population groups such as pregnant /lactating women). After follow-up with SWP, it is anticipated to publish the second draft with the proposed changes for public consultation in October. HMPC noted that due to conferences HMPC rapporteurs are not available for eventual TC discussion on that point during the next SWP meeting. Minor remaining issues to be sorted via written procedure.	
~~II.4.2 HMPC comments on ethanol report (EMA/281628/2013) within planned revision of the Guideline on excipients in the label and package leaflet of medicinal products for human use (CPMP/463/00): **for discussion**~~	~~*Report by HMPC Chair /O. Pelkonen*~~ *Postponed to November 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 MIS	
II.10 Co-ordination with COMP	
II.11 Co-ordination with CMDh	
II.12 Co-ordination with Eur. Com.	
III. Organisational matters	
III.1 Organisational Matters Drafting Group	
III.1.1 ORGAM DG (virtual) meeting to be held on 15 October 2013	*Report by ORGAM DG Chair*
III.1.1.1 Draft agenda (EMA/HMPC/466059/2013): **for adoption**	Adopted.
III.1.2 Draft ORGAM DG 2014 work programme (EMA/HMPC/544796/2013): **for adoption**	*Report by ORGAM DG Chair* *See also V.9.1* Adopted with one amendment (planning of at least one face-to-face meeting every 2 years). HMPC secretariat to make proposals for dates in 2014 for the virtual meetings. Such dates should appear on the 2014 work programme when published at the beginning of January 2014. The release of the Rapporteurs' names in the work programme was confirmed.
III.2 Working methodology	
III.2.1 Appointment of new members in MLWP	*Report by HMPC Chair/MLWP Chair*
III.2.1.1 Procedural aspects for the appointment of new members in the MLWP: **for information**	HMPC noted the procedural advice reflecting on the cross-Agency practice at Working Party level, in particular the advisory function of the Committee chair and the concerned working party chair.

III.2.1.2 Nominations received from HMPC members with CV: **for discussion** - Nomination of Prof C. Cavaleiro by A. P. Martins and H. Pinto Ferreira dated 31 July 2013 - Nomination of Dr C. Purdel by N. Grigoras dated 30 August 2013 - Nomination of by Z. Biró-Sándor dated 30 August 2013	On the advice from the HMPC and MLWP Chairs and after a trend vote, the HMPC appointed by consensus two new members of the MLWP in replacement of the last 2 members who had resigned: - Prof. C. Cavaleiro - Dr C. Purdel. The HMPC welcomed the nomination of who is invited to contribute to the MLWP work via support to Z. Biró-Sándor; such contribution will enhance her experience with the MLWP assessment practice. HMPC secretariat to update EMA databases and for the Website information to be modified accordingly.
III.2.2 Projects under HMPC work programme for 2012-2015 (EMA/HMPC/501139/2011) III.2.2.1 Forward planning & prioritisation – herbal substances, preparations and combinations for which a monograph should be established in the next years - Preparation of a public statement for substances associated with basic safety concerns and not suited to the traditional use system: **for discussion**	*http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2011/12/WC500119957.pdf* *Appointment of Rapporteurs* Appointment of O. Pelkonen as Co-Rapporteur and transfer to MLWP for appointment of Rapporteurs. ***Post-meeting note:*** ***MLWP discussed scope and objective of such document vis-à-vis requests from NCA and IP for assessment, the HMPC inventory and the HMPC 'PS on CPMP list of herbal drugs with serious risks, dated 1992' (EMEA/HMPC/246736/2005).*** ***Rapporteur assigned: M. Delbò supported by I. Chinou, G. Laekeman*** ***Consolidated proposal for options to be presented at MLWP November meeting.***
III.2.3 Discussion on international cooperation in the field of herbal medicines: **for discussion** III.2.3.1 Draft proposal for HMPC international cooperation - Key areas to strengthen the international profile of the EMA in the field of herbal medicines (EMA/HMPC/396677/2013)	*Report by HMPC Chair/HMPC secretariat* HMPC agreed to main features and further development of the paper for presentation and discussion at the HMPC November meeting. HMPC secretariat together with HMPC Chair

	to amend and distribute new version by 20 October 2013 to all members to give another opportunity for feedback.
Past and current contacts/activities with a) European institutions b) international regulatory organisations c) international organisations under the WHO umbrella and non-EU regulatory bodies were discussed as regards prioritisation of key activities and specification of objectives. The coordination within Europe (EDQM, EFSA) was confirmed as main priority to allow the functioning of the system established for HMP/THMP in Europe since 2004. In view of the international recognition of HMPC monographs and guidelines but current underrepresentation of EMA/HMPC in this field at the global level a reconsideration of the role such as within IRCH was proposed. Members who did not respond during the first consultation in May/June were welcomed to contribute now.	
III.2.4 Informal HMPC meeting to be held 9-11 December 2013 in Vilnius, Lithuania: **for discussion** - Draft agenda	A. Kažemekaitis reported on the status of organisation of the informal meeting (invitations sent on 13 September). HMPC members noted the preliminary draft agenda and were invited to contact A. Kažemekaitis with proposals for more presentations. The presidency in 2014 will be shared by Greece (1st half) and Italy (2nd half). I. Chinou reported on preparatory steps however the organisation of an informal HMPC meeting during the Greek presidency cannot be confirmed at this stage. M. Delbò informed the HMPC that the informal HMPC meeting in Italy will take place during the period between 4 and 9 November 2014. ***Post-meeting note: the meeting will take place on 4-5 November 2014.***
*III.2.5 Presentation on the restructuring of the Agency organisational: **for discussion** - PowerPoint presentation	HMPC welcomed the introductory presentation Head of the Division in charge of the HMPC & HMPC secretariat. Regular contacts will be established for an efficient dialogue on challenges faced by the HMPC in the conduct of its tasks as laid down in Directive 2004/24/EC and in the context of the 'rationalisation of CXMP secretariats' exercise as part of the Agency restructuration.
III.2.6 Measures to implement EMA policy on publication of agendas and minutes of scientific committees: **for discussion** - PowerPoint presentation	HMPC welcomed the presentation on the rationale, timelines and principles guiding the Agency's phased publication of all CXMP agendas and minutes. HMPC noted the release of its public agenda on 16 September in which some information was redacted (deleted) because

	of one or more of the possible justifications: 1) for the sake of personal data protection (PDP) e.g. initials and names of Agency staff. The HMPC noted the release of CXMP and WP members' names (which are in the public domain already) who act as Rapporteurs, Co-Rapporteurs or Peer-reviewers when appointed to lead the different assessment works on behalf of either a Committee or a WP 2) data which are commercially confidential information (CCI) 3) Consideration given to sensitive issues (criteria will be developed in this regard). Experience will be gained over the months in applying these principles to the HMPC agendas and minutes. It was confirmed that there is no expectation to create another type of document to record some aspects of a discussion. Building on the experience already obtained by the PRAC, the HMPC secretariat will highlight in yellow the different texts which appear to require redaction in the minutes before they are published on the Agency website. The scope and release of HMPC public meeting reports might be reconsidered in the light of cross-committee harmonisation of practices and given that minutes will become public. Respective timelines and content for ToD/Public meeting report/Minutes will be reflected upon.
III.2.7 List of acronyms used in HMPC minutes (EMA/HMPC/441838/2013): **for discussion**	HMPC members to send comments. For adoption in November together with the September HMPC minutes, for publication on the EMA website as a permanent annex (as done by PRAC).
III.2.8 Election of HMPC Chair and Vice-Chair - Procedure for the election of the HMPC Chair and HMPC Vice-Chair on 11 November (EMA/544790/2013): **for adoption**	*Report by HMPC secretariat* HMPC noted that the procedural steps were identical to that followed in 2010 and adopted the procedure. EMA secretariat to circulate a dedicated message to the HMPC (with HMPC chair job profile circulated in 2010, the adopted procedure, an overview of past elections, a

	reminder about the deadline and an invitation for possible candidates to contact EMA management for any questions in advance of the elections.
*III.2.9 Information about reflections on the management of declarations of interests and conflicts of interests: **for discussion** - PowerPoint presentation	*Report* HMPC noted the deadline for submission of eCV and guidance received in relation to expected level of information concerning professional education, employment and work experience. Additional information (publications, membership in organisations, involvement in projects) will facilitate ex-post control on the handling of conflicts of interests of experts, including correctness of completion of DoIs.
III.3 Interaction with interested parties	
III.3.1 Applications for IP to the HMPC: **for adoption** III.3.1.1 GP-TCM Research Association dated 12 August 2013 - Interested parties to the HMPC, in particular for the field of non-European Traditional Herbal Medicine (EMA/HMPC/150135/2013) III.3.1.2 EUCOPE dated 2 August 2013 - Request EUCOPE as Interested Party of HMPC - International Non Profit Association Articles of Association - EUCOPE International Non Profit Association By-laws	*Report by HMPC secretariat* Accepted following information by HMPC secretariat on validity and completeness of the data provided vis-à-vis the different criteria. HMPC secretariat to update the 'List of interested parties to the HMPC' and draft response letters to accepted IPs for signature by the HMPC Chair.
HMPC agreed to accept both IPs according to available information on legitimacy, mission/objectives, activities, representativity, structure, accountability/ consultation modalities and available contact point. GP-TCM RA had applied previously following a HMPC call focused on IPs in the area non-European traditional medicines (postponed in May due to pending registration in a EU MS), while EUCOPE had applied on their own initiative.	
IV. Quality	
IV.1 Quality Drafting Group	
Annual meeting of HMPC Q DG/Chairs of Eur. Ph. Expert Groups 13A, 13B & TCM: 17 September 2013, 13:00 – 16:00 (room 2G) See IV.1.2	
IV.1.1 Q DG (virtual) meeting held on 25 July 2013 IV.1.1.1 Meeting report (EMA/HMPC/488194/2013): **for adoption**	*Report by H. Neef*

HMPC noted the report on the progress achieved by Q DG during their July meeting on following topics: Q&A on essential oils, Q&A on benzene in solvents used in the manufacture of HMP/THMP (closed to finalisation, possible adoption by HMPC anticipated for November), and reflection paper on the use of recovered/ recycled solvents. Furthermore the meeting with Ph.Eur. expert group Chairs was prepared (see IV.1.2) and the work programme 2014 (see IV.1.4) has been drafted vis-à-vis the status of the work 2013.

IV.1.2 Annual meeting HMPC Q DG/Chairs of Eur. Ph. Expert Groups 13A, 13B & TCM IV.1.2.1 Draft agenda (EMA/HMPC/394564/2013): **for adoption**	*To be held during the meeting of the MLWP Tuesday, 17 September 2013 13:00 – 16:00 (room 2G)* Endorsed. No further changes introduced.

HMPC members were invited to join the mutual information and discussions on ongoing topics between Q DG, MLWP and EDQM at start of the MLWP meeting.

~~IV.1.3 Draft Q&A on benzene in extracts (EMA/HMPC/462947/2013): **for adoption**~~	~~*Rapporteur: K. Reh*~~ ~~*Report by H. Neef*~~ *Postponed to November meeting*
IV.1.4 Draft Q DG work programme 2014 (EMA/HMPC/473889/2013): **for adoption**	Adopted without changes. Meeting dates still to be specified depending on confirmation of available budget by EMA management (requested two face to face meetings). Q DG Chair pointed to difficulties in discussing and drafting according to the work programme without face to face meetings.

The Q DG Chair explained that most topics taken were taken over from the 2013 work programme for finalisation in 2014 plus one new topic (Reflection paper on the use of recovered solvents). No further proposals made by HMPC. HMPC noted the possible need for revision of older guidance in order to update according to recent developments such as the upcoming revised Ph.Eur. monograph on extracts. According to the Q DG mandate to draft/revise guidance as considered necessary by the HMPC, HMPC members were invited to come up with proposals according to needs detected at NCAs as regards quality issues. Programme to be published after confirmation of meeting dates at the EMA website beginning 2014.

IV.2 European Pharmacopoeia

Annual meeting of HMPC Q DG/Chairs of Eur. Ph. Expert Groups 13A, 13B & TCM: 17 September 2013, 13:00 – 16:00 (room 2G) See IV.1.2

V. Safety & efficacy

V.1 MLWP

The next meeting of the MLWP will be held 17-19 September 2013	*See VII.3.2*

Status on Community herbal monographs, Community list entries, public statements, appointment of new Rapporteurs and Peer-reviewers	
V.1.1 Overview of status of MLWP assessment work (EMA/HMPC/519580/2007): **for discussion**	*Report by MLWP Chair* *Status July 2013*
V.1.1.1 Appointment of Rapporteurs	N/A
V.1.1.2 Appointment of Peer-reviewers	N/A
Other relevant topics	
V.1.2 List entry adoption – consistency and transparency in the assessment of available data and options to improve data availability: **for discussion** *(WP)*	*Report by MLWP Chair* HMPC members to reflect discussion and documents presented for planned finalisation in November and tour-de-table among members as regards
V.1.2.1 Draft overview on available genotoxicity data for herbal substances for inclusion into the Community list (EMA/HMPC/283128/2013) - Draft evaluation of genotoxicity data for herbal substances including list of questions on possible revision of the assessment approach - Presentation by O. Pelkonen	*Report by O. Pelkonen/J. Wiesner* 1) evaluation of available genotoxicity data (examples Ginseng, Orthosiphon, Melaleuca) including list of questions on possible revision of the assessment approach.
V.1.2.2 Discussion on options to improve the genotoxicity data situation	*Report by HMPC secretariat/ L. Anderson* 2) options to improve the availability of genotoxicity data taking into account legal framework, previous initiatives, necessary safety data and availability of data at industry and NCAs.

The output of ~120 finalised monographs versus only 10 LEs is usually founded on lack of genotoxicity data. Given the legal task of the HMPC producing list entries to facilitate national applications even more than it is the case for monographs, HMPC secretariat and Rapporteurs had looked into (1) the consistency in evaluation of available genotoxicity data, currently set standards and risk-based room for manoeuvre in case of minor deviations and (2) if there are any opportunities to improve access to existing data.

(1) It was agreed not to discuss examples from before establishment of OECD based guidelines by the HMPC. Members were invited to reflect only on recent cases vis-à-vis existing guidance and the list of points to consider compiled by the Rapporteurs for final discussion in November.

(2) The discrepancy between existing data and data available to the HMPC was noted in view of ~1000 registrations in the EU acc. to Dir. 2004/24/EC covering ~130 substances (in mono-products) plus ~500 WEU authorisations. The difference between 'no data available' as stated in HMPC monographs and ARs and 'no concern' because existing data (available at industry and NCAs) confirm no genotoxicity risks for

specific preparations, is currently not solvable because data are not published. However, the non-existence of LEs was not seen as compromising the ease for applicants to achieve registrations. Contrary it was seen as a trigger to generate missing safety data with the common practice in MSs to request Ames data which are not expensive and usually provided without difficulties. Several members expressed that over time the knowledge on 'no concerns as regards genotoxicity' should also be put into the public domain for public health reasons. For long-term solutions, the committee discussed the previously reflected voluntary release of available data by industry groups, the future consideration of marketed registered products with negative genotoxicity results and no risk signals for HMPC assessments, the sharing of knowledge between MSs, the avoidance of unnecessary multiple testing taking into account the bracketing /matrixing principle as established by EMEA/HMPC/67644/09, and opportunities to fill the gap via EU funded research projects.

V.1.3 Timelines for revision of monographs due to new scientifically relevant data (validation BSS): **for discussion** - Reflection paper on the reasons and timelines for revision of final Community herbal monographs and Community list entries (EMA/HMPC/326440/2007 Rev.2)	HMPC noted the timelines proposed by Rapporteurs: R. Länger: proposal on MLWP September agenda for Thyme/Primula. Z. Biró-Sándor and J. Wiesner will provide feedback in November respectively for Pelargonii radix and Hederae helicis folium. *http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/12/WC500017022.pdf*

Rapporteurs reported to the HMPC briefly on possible consequences for the assessment of three substances as currently discussed at MLWP with detailed evaluations starting either in September or November. The MLWP was requested to fit the revisions immediately into the ongoing work without specification of a timetable for finalisation.

*V.1.4 Draft MLWP 2014 work programme (EMA/HMPC/554850/2013): **for adoption**	*Report by HMPC Chair/MLWP Chair* Adopted. Adjustments to be made: - to reflect progress for Camelliae sinensis non fermentatum folium and Sisymbrii officinalis herba after the November meetings - if the need for a PS on polycyclic aromatic hydrocarbons (PAH) is confirmed - to be completed with the additional new guidance documents (PS on HS associated with safety concerns + guidance on use of mono-monographs for combination products' application/assessment). See III.2.2.1

V.2 Community list entries transmitted to European Commission

V.3 Community herbal monographs for adoption after systematic review/revision

V.4 Community herbal monographs for adoption (post finalisation)

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

V.5.1 Andrographidis paniculatae folium V.5.1.1 Assessment report V.5.1.1.1 List of references - available references 120/150 V.5.1.2 Public statement	*Rapporteur: Z. Biró-Sándor; Peer-reviewer: B. Kroes* *No comments received during public consultation* Adopted by consensus. HMPC secretariat to edit and publish final documents.
Following proposals by the peer-reviewer (postponed adoption in July) modifications had been introduced in the AR. Subsequently the list of references cited in the AR was reduced. No changes were introduced by MLWP or HMPC in the public statement.	
V.6 Community herbal monographs, Community list entries and public statements for adoption for release for public consultation	
V.6.1 Rosae flos V.6.1.1 Assessment report V.6.1.1.1 List of references V.6.1.2 Monograph	*Rapporteur: I. Chinou; Peer-reviewer: H. Pinto Ferreira* Adopted with changes in the monograph (sections 2, 3 and 4.2). One member pointed to a concern over the second therapeutic indication's wording that might lead to a possible divergent position at the time of adoption of the final monograph and supporting documents. Adopted for release for public consultation until 15 January 2014.
V.7 Community herbal monographs, Community list entries and public statements for discussion	
V.8 Reference documents for the preparation of Community herbal monographs, Community list entries, public statements and related documents	
V.9 Guidelines	
V.9.1 Revision of the guideline on the use of the CTD format in the preparation of a registration application for traditional herbal medicinal products (EMA/HMPC/71049/2007 Rev. 1): **for discussion** V.9.1.1 Draft concept paper (EMA/HMPC/555178/2013)	*Rapporteur: A. Cunney* *Appointment of a Co-Rapporteur and involvement of ORGAM DG* J. Wiesner appointed as Co- Rapporteur. Minor changes to be introduced (extension of scope to pre-clinical part) for adoption at the HMPC November meeting. Potential future involvement for guideline revision by new MLWP members.
Following the improvement of the guideline as regards quality requirements (last revision lead by Q DG) it was agreed that further clarifications should be introduced vis-à-vis non-quality related parts of the dossier. This became apparent from comments received by IPs during the last revision and discussions at	

ORGAM DG and HMPC meetings as well as the informal meeting in Dublin. With the focus on the use of monographs and the expected content of the dossier sections 2.5 and 2.7 (Clinical overview and summaries) but also 2.4 and 2.6 (Non-clinical overviews and summaries) plus diverse practice as regards sections 4 and 5, clarity and harmonisation on requirements according to data situation is targeted to facilitate applications at national level. The pending parallel finalisation of a 'mock-up on module 3' (amending the previously introduced best practice guide) as confirmed for the work programme of Q DG was noted.	
VI. Non-clinical assessment/issues	
VII. Other relevant business	
VII.1 Conferences, presentations & research projects	
VII.1.1 Organisation of international symposium on herbal medicines by BfArM to be held on 30 September - 2 October 2013 in Bonn, Germany - Programme	HMPC noted the latest programme and the announced participation (around 150 participants from almost 20 different countries, 2/3 from industry and 1/3 from regulatory authorities).
VII.2 International cooperation, collaboration with non-EU regulatory authorities	
VII.3 Documents for information	
VII.3.1 HMPC meeting held 8-9 July 2013 VII.3.1.1 Table of Decisions (EMA/HMPC/419290/2013) VII.3.1.2 Meeting report (EMA/HMPC/428663/2013)	
VII.3.2 Draft agenda of MLWP meeting to be held 17-19 September 2013 (EMA/HMPC/430303/2013)	
VII.3.3 MLWP meeting held 9-11 July 2013 VII.3.3.1 Table of Conclusions (EMA/HMPC/422555/2013) VII.3.3.2 Minutes (EMA/HMPC/441130/2013)	
VII.3.4 Overview of status of HMPC assessment work – priority list (EMA/HMPC/278067/2006) *(PC)*	*Status July 2013 (post-meeting)*
VII.3.5 Inventory of herbal substances for assessment work – alphabetical order (EMA/HMPC/494079/2007) *(PC)*	*Status July 2013 (post-meeting)*
VII.3.6 Common names of herbal substances in all EU official languages (EMA/HMPC/95087/2011)	*Status July 2013*
VII.3.7 EMA decision P/0156/2013 of 5 July 2013, agreement of a paediatric investigation plan and on the granting of a deferral for dry extract from Betulae cortex (EMA/346350/2013)	http://www.ema.europa.eu/docs/en_GB/document_library/PIP_decision/WC500147624.pdf
*VII.3.8 EMA decision P/0184/2013 of 31 July 2013 on a product specific waiver for capsici acris extractum spissum normatum (EMA/418994/2013)	http://www.ema.europa.eu/docs/en_GB/document_library/PIP_decision/WC500148524.pdf

VII.3.9 Meeting report of the MLWP-AESGP hearing held on 14 May 2013 (EMA/HMPC/413550/2013) *(EC)*	http://www.ema.europa.eu/docs/en_GB/document_library/Report/2013/07/WC500146577.pdf
VII.3.10 Assessment report summaries for the public (ARSP) from July 2013 - Walnut Leaf - summary for the public (EMA/432131/2013) - Dittany of Crete herb - summary for the public (EMA/441263/2013) - White horehound - summary for the public (EMA/446032/2013)	
VII.3.11 Assessment report summaries for the public (ARSP) translation phase - Psyllium seed – summary for the public (EMA/322933/2013) - Melissa leaf – summary for the public (EMA/HMPC/310761/2013) - Ispaghula husk –summary for the public (EMA/313600/2013) - Ispaghula seed –summary for the public (EMA/313692/2013) - Eucalyptus leaf – summary for the public (EMA/300235/2013) - Chicory root – summary for the public (EMA/HMPC/286842/2013) - Woody nightshade – summary for the public (EMA/261736/2013) - Guarana seed – summary for the public (EMA/284498/2013) - *Ginger – summary for the public (EMA/296580/2012) - *Lavender oil – summary for the public (EMA/530968/2012) - *Arctic root - summary for the public (EMA/289537/2012)	*After translation by CdT followed by review by HMPC members from 23 August to 13 September* HMPC to rediscuss in November proposals to be received from EMA secretariat in relation to the concerns expressed by HMPC members on the receipt of linguistic versions to be checked, for 11 ARSP.
The HMPC expressed the following concerns: - too short timelines - too many ARSP received at the same time - the translators did not have access to the Excel table with the common names - the ARSP template with too few standard sentences & lack of knowledge of the specific terminology in	

the field of herbal medicines
- risk of confusion for readers vis-à-vis the coexistence of linguistic versions of ARSP (on EMA website) that might differ from product information for marketed products (on a national level) as well as the English text of the HMPC monograph.

The HMPC secretariat pointed to potential solutions to the concerns raised:
- realistic timetables that take into account the 'seasonal' period of the year such as the summer period
- not more than 3 ARSP submitted at a given time for checking by HMPC members
- Excel table to be made available to the CdT/translators
- ARSP template to be expanded with more standard texts
- publication with a short disclaimer that clarifies the levels of responsibility for such linguistic versions of ARSP.

VII.3.12 Draft agenda PCWP/HCPWP joint meeting 25 September 2013 (EMA/448547/2013)

VII.3.13 Draft agenda workshop on patient's voice in the evaluation of medicines 26 September 2013 (EMA/437597/2013)

VII.4 Any other information

The HMPC Chair thanked all participants (see list in annex 1) and closed the meeting.

A list of abbreviations (annex 2) used in HMPC minutes can be found on the EMA website.

Annex 1: List of participants

Chair of the HMPC	***Observer***
Werner Knöss	Melanie Bald
HMPC members	***European Commission***
Reinhard Länger	Tina Engraff
Heidi Neef	
Elena Mustakerova	***Agency secretariat***
Ivan Kosalec	
Panayiotis Triantafyllis	
Marie Heroutová	
Evelin Saar	
Eeva Sofia Leinonen	
Jacqueline Wiesner	
Ioanna Chinou	
Zsuzsanna Biró-Sándor	
Niamh Curran	
Marisa Delbó	
Arturas Kažemekaitis	***Apologies***
Everaldo Attard	Steffen Bager
Emiel van Galen	Antoine Sawaya
Steinar Madsen	Dace Kalke
Wojciech Dymowski	Ján Slúka
Ana Paula Martins	Barbara Razinger
Nadia Grigoras	Adela Núñez Velázquez
Per Claeson	Gert Laekeman
Linda Anderson	
Gioacchino Calapai	
Silvia Girotto	
Olavi Pelkonen	
Maria Helena Pinto Ferreira	
HMPC alternate members	
Wim Vervaet	
Darko Trumbetić	
Nina Dürr	
Jacqueline Viguet Poupelloz	
Anna Cunney	
Baiba Jansone	
Burt Kroes	
Milan Nagy	
Samo Kreft	
Sue Harris	