28 January 2014
EMA/HMPC/742564/2013
Committee on Herbal Medicinal Products (HMPC)

Committee on Herbal Medicinal Products (HMPC)

Minutes of the 11-12 November 2013 meeting

11 November 2013, 14:00 – 19:00, room **4B**

12 November 2013, 09:00 – 13:00, room **4B**

Chair: Tony Humphreys (until election of new Chair)

- **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.

* = signals any change introduced after the last pre-meeting mailing

For abbreviations not explained in the minutes, please refer to the published document 'Abbreviations in HMPC minutes'.

- **Election of HMPC Chair and Vice-Chair**
  - Procedure for the election of the HMPC Chair and Vice-Chair to be held on 11 November 2013 (EMA/54923/2010): for information (Premail 1 – 29 October 2013)
  - HMPC Chair job profile (EMA/HMPC/198377/2010): for information (Premail 1 – 29 October 2013)
  - Candidature for Chair:
    Werner Knöss, Germany (letter of candidature with motivation to stand received on 22 October 2013, CV) (pre-meeting mailing)

    *Ioanna Chinou, Greece (letter of candidature with motivation to stand received on 10 November 2013, CV) (Tabled)
  - Candidature for Vice-Chair:
    Marisa Delbò, Italy (letter of candidature with motivation to stand received on 7 November 2013, CV) (pre-meeting mailing)

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7455
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Elections for the positions of Chair and Vice-Chair took place on 11 November 2013, in accordance with the 'Procedure for the election of the HMPC Chair and Vice-Chair' (EMA/54923/2010) based on the HMPC rules of procedure (EMEA/HMPC/139800/2004 Rev 1) and the HMPC Chair job profile (EMA/HMPC/198377/2010).
Werner Knöss was elected as HMPC Chair for a second term
Marisa Delbò was elected as new Vice-Chair
both with a 3-year mandate that started on 11 November 2013.

Chair: the newly elected Chair

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

Dr Markéta Příhodová, new alternate member Czech Republic

Pharm An Lê, new member France

Dr Rita Németh, new member alternate Hungary

Dr Anna Maria Serrilli, new alternate member Italy

Pharm Dr Martina Hudecová, new member Slovakia

- **Transfer of voting right from the following members to the following alternate members:**

From Evelin Saar to Marje Zernant; from Elena Mustakerova to Irina Nikolova; from Martina Hudecová to Milan Nagy; from Linda Anderson to Sue Harris on 12 November 2013.

- **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.

I. Introduction	* = Change introduced following last pre-meeting mailing
I.1 Agenda, minutes	
I.1.1 Agenda of 11-12 November 2013 HMPC meeting (EMA/HMPC/644886/2013 Ver.3): **for adoption**	Adopted with a minor modification to IV.2.3. Agenda to be published on the EMA website. ***Post-meeting note: published on 15 November.***
I.1.2 Time schedule of 11-12 November 2013 HMPC meeting (EMA/HMPC/644885/2013 Ver.1): **for adoption**	Adopted.
I.1.3 Draft minutes of 16-17 September 2013 HMPC meeting (EMA/HMPC/589557/2013): **for adoption**	Adopted. Minutes to be published on the EMA website. ***Post-meeting note: published on 26 November.***
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) - Discussion paper on possible revision public statement (EMEA/HMPC/137212/2005)	*Rapporteur O. Pelkonen and J. Wiesner* *http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2010/04/WC500089960.pdf* Members to consult documents provided by the Rapporteur and check available data at NCA. Discussion postponed until January 2014.
I.3.2 BSS validation: **for discussion** I.3.2.1 Emails from Z. Biró-Sándor dated 17 September and 5 November 2013 - Opinion on BSS validity dated 17 September 2013 - Comments on the validation study for the BSS dated 5 November 2013 - M. Tavakol, R. Dennick. Making sense of Cronbach's alpha. International Journal of Medical Education. 2011; 2:53-55; 2042-6372 I.3.2.2 Report on the Validity of the BSS – a scale for acute bronchitis dated 14 November 2012 I.3.2.3 draft comment about Bronchitis symptoms scale (BSS) on behalf of HMPC (EMA/HMPC/280914/2013) I.3.2.4 HMPC response letter dated 14 June 2013	*Rapporteur: G. Calapai* HMPC members noted statements by the Rapporteur and the HU delegate. Discussion postponed until January 2014.

(EMA/HMPC/352642/2013): **for information** I.3.2.5 Draft letter dated 12 November 2013 regarding additional data 1.3.2.6 Written statements from HMPC members - Email by W. Dymowski dated 31 October 2013 - Email by S. Girotto dated 2 November 2013 Positions regarding medical considerations for validity as well as statistician views were exchanged vis-à-vis published literature and the principle decision made in May in this respect but also implications for specific product applications and European procedures as well as specific monograph revisions based on a particular data sets. It was agreed that Rapporteurs and HMPC Chair draft an attachment to the proposed letter in preparation of the discussion in January.	
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 Excipients review – Ethanol 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** II.4.1.1 Excipients draft for internal comments (SWP, VWP, QWP, BWP, BPWP, CMDh, QRD, PRAC, PDCO and HMPC) – email dated 15 Oct 2013 II.4.1.2 Questions & Answers on ethanol (EMA/507988/2013) II.4.1.3 Report on Ethanol (EMA/281628/2013) ~~II.4.1.4 draft HMPC comments on ethanol Q&A and Report on ethanol (EMA/HMPC/xxxx/2013): **for adoption**~~ II.4.1.5 Concept paper on the need for revision of the guideline on excipients in the label and package leaflet of medicinal products for human use (CPMP/463/00) (EMA/CHMP/SWP/888239/2011): **for information**	*Report by HMPC Chair /O. Pelkonen* *http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003412.pdf* HMPC agreed to recommendation from Rapporteurs / HMPC Chair that no comments are no longer necessary from a herbal perspective. New versions of the ethanol report and Q&A were no longer in conflict with the HMPC reflection paper EMA/HMPC/85114/2008.
II.4.2 Report on SWP FtF meeting on 1-2 October 2013	*Report by O. Pelkonen* HMPC noted the report by the observer pointing in particular to the current status regarding the ICH M7 guideline

	on genotoxic impurities.
II.5 Co-ordination with PDCO	
II.6 Co-ordination with PRAC	
II.6.1. PRAC recommendation: Efavirenz – Interaction with Ginkgo biloba (EMA/PRAC/606660/2013/ADOPTED): **for discussion** - Wiegman et al. 2009: Interaction of Ginkgo biloba with efavirenz. Correspondence. *AIDS* 23:1181–1185 - Naccarato et al. 2012: A Potential Drug–Herbal Interaction between Ginkgo biloba and Efavirenz. *Journal of the International Association of Physicians in AIDS Care* S12-0224, 11:2	*Report (EMA, Signal Management)* *See also V.6.1* HMPC noted the final recommendation by PRAC and confirmed consideration of the interaction for the Ginkgo monograph. Different views were expressed regarding the appropriate wording referring to specific Ginkgo preparations or comprising all possible Ginkgo products in view of limited available data and precautionary considerations. HMPC will feed back to PRAC once the draft monograph for Ginkgo has been adopted.
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.	
II.13 Co-ordination with EFSA	
II.13.1 Scientific opinion on the substantiation of a health claim related to hydroxyanthracene derivatives and improvement of bowel function pursuant to Article 13(5) of Regulation (EC) No 1924/2006, EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), EFSA Journal 2013;11(10):3412: **for discussion**	http://www.efsa.europa.eu/en/efsajournal/doc/3412.pdf HMPC expressed concerns on implications for national markets (borderline issues) and public health. The HMPC agreed to a three-fold follow-up: 1) members communication at national level, 2) consultation of the Eur. Com. and 3) communication between EMA and EFSA based on the memorandum of understanding between the two agencies. For 3) a letter drafted by the HMPC Chair will be distributed to all members for comments by beginning December. For re-discussion at the January meeting.

The HMPC noted the assessment of a health claim for a specific combination product with conclusions on a whole class of active compounds. Members discussed the potential co-existence of products in

different categories that have a pharmacological action and impose some risks for public health via detrimental effects on the intestinal mucosa especially after long term use. The HMPC reiterated the fact that all anthraquinone containing substances are considered as well-established use in HMPC monographs (but not traditional use) and often 'pharmacy only' in the MS, reflecting concerns on uncontrolled self-medication.

A scientific discussion and interaction at early stage at European level was seen preferable to possible follow-up actions at national level. However, it was also noted that EFSA had taken into account all HMPC publications in this regard. The Eur. Com. representative and EMA secretariat drew attention to the wording of the disclaimer in the document, and in particular the fact that the EFSA opinions on substantiation of health claims did not constitute an assessment of safety, nor any decision on whether or not the substance covered by the opinion is or is not classified as a foodstuff.

III. Organisational matters	
III.1 Organisational Matters Drafting Group	
III.1.1 ORGAM DG (virtual) meeting held on 15 October 2013	*Report by ORGAM DG Chair*
III.1.1.1 draft Meeting report (EMA/HMPC/466059/2013): **for adoption**	*Report by ORGAM DG Chair* Adopted.
III.1.2 draft Q & A on Non-European traditional medicines (EMA/HMPC/402684/2013): **for adoption** - comments from EMA secretariat	*Report by ORGAM DG Chair* *A version with EMA secretariat comments was circulated on 8 November.* Adoption postponed. ORGAM DG Chair suggested that the ORGAM DG would further discuss the document at the next meeting, with participation from the RA and Legal colleagues who proposed comments. HMPC endorsed. HMPC secretariat to amend the 2014 ORGAM DG work programme accordingly (for publication on the Agency website at the beginning of January 2014).
III.1.3 ORGAM DG suggestion to cancel the meeting planned for 10 December 2013 and alternative to explore possibility to postpone the meeting in January 2014: **for discussion**	*Report by ORGAM DG Chair* *See III.2.3* The HMPC endorsed the option to postpone the ORGAM DG meeting until mid-January 2014. HMPC secretariat to establish a new meeting date. ***Post-meeting note: the meeting is scheduled for 14 January 2014***
III.1.4 Clarification for implementation of the HMPC procedure on systematic review/revision concerning the release for 3-month public consultation of revised	*Report by MLWP Chair/HMPC secretariat* *See also V.3.3*

monographs and related documents: **for discussion** - *Compilation of changes introduced in section 2 of monographs revised so far (EMA/693890/2013) *http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2011/07/WC500109143.pdf*	HMPC Chair in liaison with MLWP Chair to draft a list of items triggering a release for public consultation, beyond those discussed at the meeting, for further discussion at the next meeting of HMPC.

The HMPC discussed the experience gained in the last years with the revision of monographs and supporting documents, and in particular whether changes introduced during the revision justifies or not the release of the documents for a 3-month public consultation. The committee reviewed past examples of revised monographs, in terms of changes to the HS/HP covered (in section 2), compiled by the HMPC secretariat. The committee could agree on changes that would justify a public consultation (major change to the therapeutic indication(s), deletion of some HP). More examples of changes will be discussed, aiming at making the HMPC approach transparent to the public.

III.2 Working methodology	
III.2.1 Projects under HMPC work programme for 2012-2015 (EMA/HMPC/501139/2011)	*http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2011/12/WC500119957.pdf*
III.2.1.1 Uptake of traditional use registration scheme and implementation of the provisions of Directive 2004/24/EC in EU member states: **for discussion** - Email by HMPC secretariat dated 22 October 2013	*Report by HMPC secretariat* No objections were raised that HMPC secretariat distributes original data (status Dec 2012) received by MSs among national contact points. HMPC confirmed high importance of continued collection and presentation of data on the implementation of Directive 2004/24/EC in the MSs
III.2.2 Discussion on international cooperation in the field of herbal medicines: **for discussion**	*Report by HMPC Chair/HMPC secretariat*
III.2.2.1 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)	Postponed until January 2014.
III.2.3 Informal HMPC meeting to be held 10-11 December 2013 in Vilnius, Lithuania: **for discussion** - Draft agenda	*Report by A. Kažemekaitis* HMPC members were invited to register for the event as soon as possible.
III.2.4 List of abbreviations used in HMPC minutes (EMA/HMPC/441838/2013): **for discussion**	*Report by HMPC secretariat* *For publication on the EMA website, as a permanent annex to HMPC minutes* HMPC noted the changes proposed by the

	HMPC secretariat (additional abbreviations used in September HMPC minutes: see I.1.3). ***Post-meeting note: HMPC secretariat circulated by e-mail on 12 November 20.00 a revised list of abbreviations to HMPC. List was published on 26 November.***
III.2.5 KPIs: **for discussion** - Report on HMPC deliverables (M, LE, PS, revised M) in EMA 2013 annual report - Confirmation of KPI figures for 2014	*Presentation* HMPC noted the maintenance of previous practice regarding the reporting of HMPC deliverables in the EMA annual report and the KPI figures for 2014 (by analogy to 2013). HMPC Chair and MLWP Chair highlighted their wish to be associated in the preparation of the reporting on the HMPC deliverables in the 2013 annual report (opportunity to provide comments on the end-of-year figures, such as long-term effects of having only 5 meetings held in 2012 or the relevance of adopted public statements).

Taking into account adoptions by the HMPC at the meeting, the figures for 2013 are as follows:
- 13 assessment works finalised in 2013 leading to 9 final monographs and 4 final public statements
- 14 draft monographs released for public consultation
- 7 monographs revised and published as final
- 1 list entry released for public consultation.

III.2.6 Introduction to MMD: **for discussion**	
III.2.6.1 Initial presentation to MMD (managing meeting documents)	
III.2.6.2 Proposal for HMPC folders' structure in MMD	HMPC noted the proposal. Revised proposal to be presented in January 2014 for discussion.

The HMPC received a presentation on a new tool allowing delegates' access to documents for a given meeting through a web interface. The system is accessed using an individual sign-on credentials and access is granted by the secretariat for each meeting. Delegates can only see the relevant meetings, which their user log on has access to. This system will replace both pre-meeting and post-meeting mailings by Eudralink. It provides one single document source, with rapid 'posting' of documents by the secretariat and immediate access by the delegates. There are very precise requirements to the user specification and configuration in order to make MMD work; the MMD support team will provide training to all delegates, however IT support should first be sought from the IT department of the NCA. Delegates working outside NCAs (e.g. university) will be provided with a use Connectra token (Citrix key) to achieve connection.
The HMPC noted a proposal to review the agenda structure so that the MMD folders and the agenda sections would match. The proposed new order of topics aims at reflecting the scientific nature of the

work of the HMPC and its key tasks. This proposal is to be further discussed internally at the Agency and with the committee.

V. Quality

IV.1 Quality Drafting Group

IV.1.1 Q DG (virtual) meeting held on 16-17 October 2013	*Report by Q. DG Chair*
IV.1.1.1 Draft Meeting report (EMA/HMPC/634296/2013): **for adoption**	*See also VII.3.9* Adopted.

The drafting group had finalised the first part of the Q&A on quality of essential oils (see IV.1.4). The second set of Q&A and the final reflection paper are anticipated to be ready for adoption in January 2014. According to the annual meeting with the Chairs of expert groups 13A, 13B and TCM (see IV.1.2), close cooperation with EDQM is foreseen as the HMPC reflection paper and Q&A address also on Ph. Eur. quality standards that are currently under discussion such as revisions of monographs on herbal drugs and essential oils. Further discussions took place towards finalisation of guidance on microbiological aspects of herbal medicinal products and on the Q&A regarding benzene as a potential impurity in solvents used in manufacture of herbal preparations. Furthermore work has started regarding the elaboration of a mock-up module 3 as second appendix to the guideline EMEA/HMPC/71049/2007 Rev. 1. Q DG considered also as relevant to inform the HMPC on current QWP topics that are potentially of interest for the Committee (see VII.3.9): regarding the draft guideline on stability testing for applications for variations, a planned reflection paper on quality aspects of medicines for older people and the 'QP declaration template' concerning GMP compliance of active substance manufacture and verification of its supply chain.

IV.1.2 Draft Meeting report Annual meeting HMPC Q DG/Chairs of Eur. Ph. Expert Groups 13A, 13B & TCM (EMA/HMPC/619966/2013): **for adoption**	Adopted. HMPC confirmed the importance of an annual meeting with relevant groups of the Ph. Eur. as quality standards are essential for HMPC monographs and registrations/authorisation of HMPC in the EU.

Q DG and EDQM had no further comments on the report. HMPC noted identified topics requiring close cooperation in 2014 including identification of substances with most urgent need to develop Ph. Eur. quality standards and subsequent information of the EDQM secretariat, requirements for essential oils and regulatory and analytical challenges regarding pyrrolizidine alkaloids.

The HMPC Chair highlighted that all different layers of EMA-EDQM cooperation in the herbal area should be maintained including EDQM observer in HMPC and QDG, HMPC observer in 13A, 13B and TCM and the annual meeting between Q DG and Chairs of EDQM expert groups. This will ensure the adjustment of the standards developed to a system applicable by applicants and authorities.

IV.1.3 Draft Reflection paper on the use of recovered/recycled solvents in the manufacture of herbal preparations for use in herbal medicinal products / traditional herbal medicinal products (EMA/HMPC/453258/2013): **for adoption**	*Rapporteur: L. Anderson* *Proposed for adoption for release for public consultation until 15 April 2014* Adopted as final. Following the previous concept paper a majority agreed that comments from interested parties have

	already been taken into account and no further feedback is expected.
Upon substantial feedback from interested parties on the concept paper EMEA/HMPC/13658/2013 plans to issue a guideline had been cancelled and instead a reflection paper proposed by Q DG. The same critical points as raised in the concept paper have been more elaborated in the reflection paper but no substantial new aspects have been added.	
IV.1.4 Quality of essential oils as active substances in herbal medicinal products/traditional herbal medicinal products - draft Q&A (EMA/HMPC/462429/2013): **for adoption** ~~- final reflection paper (EMA/HMPC/84789/2013): **for adoption**~~	*Rapporteur: K. Reh* *Q&A after adoption to be added to General quality Q&A for HMP/THMP (EMA/HMPC/41500/2010 Rev.2)* Adoption postponed until finalisation of all Q&A on essential oils and the reflection paper. Parallel coordination with EDQM in preparation of the Q DG January meeting, targeting adoption at the HMPC January 2014.
IV.2 European Pharmacopoeia	
IV.2.1 Symposium on traditional Chinese medicines on 14-15 November 2013 in Strasbourg, France: **for information** - agenda	*Report by M. Bald* HMPC noted the agenda and participation of the HMPC Chair. In view of the importance of the topic, EDQM was invited, in their planning of future similar events, to take account of meeting dates for the HMPC and its 3 subgroups, to avoid overlap and therefore allow the participation, in Ph. Eur. conferences & symposia, of national regulators who are members of HMPC, MLWP, ORGAM DG and/or Q DG. HMPC secretariat will transmit to EDQM the meetings dates for the two DGs in 2014 as soon as established and those for 2015-2016-2017 once adopted by the HMPC.
IV.2.2 Appointment of HMPC observers in Pharmacopoeia expert groups 13A, 13B and TCM for 2014	*Report by HMPC Chair and Q DG Chair* The HMPC re-nominated Prof. I Chinou as observer in expert group 'Phytochemistry 13A', Pharm H. Neef as observer in expert group 'Phytochemistry 13B' and confirmed Prof. R. Länger's nomination as observer in expert group 'Traditional Chinese Medicine' (TCM). Observers to provide filled forms to EMA for central communication between EMA

	and EDQM by 20 November 2013. Meeting dates 2014 as usual to be exchanged between HMPC and EDQM secretariat and forwarded to HMPC observers. EDQM representative confirmed that agendas and meeting reports are provided to HMPC observers even if not physically attending. With respect to the importance of the coordination between HMPC and EDQM the HMPC reiterated the considered need for active face-to-face participation of the nominated observers and requested the support of EMA in facilitating such participation.

The HMPC Chair reminded the committee that it had appointed observers in the Expert Groups 13A and 13B since 2009, respectively I. Chinou and H. Neef, whose mandate had been renewed regularly, whilst R. Länger had been recently appointed (March 2013). At the occasion of the re-establishment of the composition of all its Expert Groups (with a new 3-year mandate starting in January 2014), EDQM had contacted the EMA secretariat to seek a central nomination of all EMA experts expected to continue attending Ph. Eur. Expert Groups meetings as observers. The HMPC Chair indicated that he had received correspondence from the EMA secretariat on 8 November, clarifying that the HMPC was invited to confirm their agreement in continuing observership in the 3 Expert Groups, and to formally appoint/re-confirm observers to these groups. Subject to such confirmation, the nominated observers would be asked to complete the relevant documents for transmission to EDQM. The HMPC was informed that the modalities for these observerships were subject to pending clarification of the annual EMA budget for 2014.

IV.2.3 Group 13A, the 45th meeting held on 1-2 October 2013	*Report by M. Bald ~~and~~ ~~HMPC observer I. Chinou~~*
- Summary of decisions	HMPC noted report from EDQM representative on main results of the last group 13A meeting. The latest status on the planned revision of the herbal drug monograph currently under discussion (with consideration of fresh substances) will be communicated to Q DG for discussion at their next meeting (15 January).

The EDQM representative summarised the decisions taken after the last 13A meeting mentioning particularly (revised) monographs ready for publication in Pharmeuropa such as Aloe (hybrids taken out, A. ferox only), Senna (drafts for S. folium, S. fructus acutifoliae and S. fructus angiustifoliae), Salviae officinalis aetheroleum. Furthermore the Committee was updated on the work on Hippocastani semen (plus a standardised extract) and the planned request to remove Hamamelidis aqua from the work programme as no suitable markers could be established to allow establishment of a monograph.

V. Safety & efficacy

V.1 MLWP	
The next meeting of the MLWP will be held 12-14 November 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** V.1.1.1 Appointment of Rapporteurs	*Report by MLWP Chair* *Status September 2013* Transfer of Rapporteurship from D. Csupor to Z. Biró-Sándor for: - Pelargonii radix - Fraxini folium - Chamomillae romanae flos - Colae semen. Endorsed by HMPC.
V.1.1.2 Appointment of Peer-reviewers	Transfer of Peer-review from Z. Biró-Sándor to L. Anderson for Sabalis serrulatae fructus. Endorsed by HMPC.
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**~~ ~~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~~ ~~V.1.2.2 Discussion on options to improve the genotoxicity data situation~~	~~*Report by MLWP Chair*~~ ~~*Report by O. Pelkonen/J. Wiesner Premail 1 – 29 October 2013*~~ ~~*Report by HMPC secretariat/ L. Anderson*~~ Postponed to the HMPC January meeting for discussion with the Eur. Com. representative.
V.1.3 Revised MLWP 2014 work programme (EMA/HMPC/554850/2013): **for discussion** - Feedback from toxicologists/HMPC members on the feasibility and need for a European position (public statement) on HMP containing PAH	*Report by HMPC Chair/MLWP Chair* HMPC agreed to keep the development of appropriate guidance on polycyclic aromatic hydrocarbons in HMP into the 2014 MLWP work programme (already included in 2012 and 2013). Rapporteurs assigned: A-P. Martins and O. Pelkonen. Q DG involvement if necessary. HMPC secretariat to publish the work programme on the Agency website at the beginning of January 2014.
V.1.4 Presentation on WEU provisions in the context of	*Report by EMA secretariat*

the establishment of monographs: **for discussion** - PowerPoint presentation on preliminary conclusions	To be further discussed in January 2014 with input from Eur. Com. representative on questions raised, including the data protection provisions vis-à-vis simplified TU registration and the establishment of monographs on THMP.

The HMPC noted the presentation capturing the issues on which clarification from the Eur. Com.is sought, as they emerged from discussions held in September around three monographs under revision and the data accessible to NCAs in application dossiers. The secretariat presented the positions from the Legal and Regulatory Affairs departments of the Agency. The Eur. Com. representative had been copied on correspondence between the different departments of the Agency and had discussed with the HMPC chair, however given the late circulation of the presentation, it was agreed to postpone the discussion until January.

V.2 Community list entries transmitted to European Commission

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

V.3.1 Anisi aetheroleum - *Final*	Rapporteur: M. Delbò; Peer-reviewer: B. Huber
V.3.1.1 Assessment report	Adopted by consensus.
V.3.1.1.1 List of references - available references 139/168	HMPC secretariat to edit and publish final documents.
V.3.1.2 Monograph	
V.3.2 Anisi fructus - *Final*	Rapporteur: M. Delbò; Peer-reviewer: B. Huber
V.3.2.1 Assessment report	Adopted by consensus.
V.3.2.1.1 List of references 139/168	With a deletion of footnote in 4.2.
V.3.2.2 Monograph	HMPC secretariat to edit and publish final documents.
V.3.2.3 List entry	
V.3.3 Thymi herba - *Final ~~Public Consultation~~*	Rapporteur: R. Länger; Peer-reviewer: L. Anderson
V.3.3.1 Assessment report	HMPC decided that the changes brought to the monograph were considered as 'minor' and did not find necessary to release the documents for public consultation – see general discussion under III.1.4
V.3.3.1.1 List of references - available references 81/131	Adopted by consensus as **final**.
V.3.3.2 Monograph	HMPC secretariat to edit and publish final documents.

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 Camelliae sinensis non fermentatum folium V.5.1.1 Assessment report V.5.1.1.1 List of references 29/171 V.5.1.2 Monograph V.5.1.3 Overview of comments	*Rapporteurs: N. Grigoras/C. Purdel; Peer-reviewer: I. Chinou* Adopted by a majority vote (29 out of 30) without changes to the monograph. Divergent position – N. Curran. NO expressed a favourable position. HMPC secretariat to edit and publish final documents. Rapporteur to provide remaining available references before publication of the final documents.

N. Curran (Ireland) expressed concerns regarding the potential safe use of this herbal substance "for symptoms of fatigue and sensation of weakness" with the view that this indication is not acceptable for a traditional herbal medicinal product in line with Directive 2004/24/EC.

V.5.2 Phaseoli fructus (sine semine) V.5.2.1 Assessment report V.5.2.1.1 List of references 40/62 V.5.2.2 Monograph	*Rapporteur: G. Laekeman; Peer-reviewer: B. Kroes; Experts: B. Bulckaert, P. Vanparys* *No comments received during the public consultation* Adopted by consensus. Three members asked for comments to be minuted. NO expressed a favourable position. HMPC secretariat to edit and publish final documents. Rapporteur to provide remaining available references before publication of the final documents.

P. Claeson (Sweden), B. Razinger (Slovenia) and E. van Galen (The Netherlands) wished to minute their comment that the NCA in their country will discuss with potential applicants the transcription/translation of the wording of the therapeutic indication, especially the wording "to increase the amount of urine".

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

V.6.1 Ginkgo folium V.6.1.1 Assessment report V.6.1.1.1 List of references - available references V.6.1.2 Monograph	*Rapporteur: J. Wiesner; Peer-reviewer: O. Palomino; Expert: E.-M. Eibl* HMPC decided to return the monograph on Ginkgo folium and supporting documents to MLWP for further discussion and input, in order to bring the monograph in line with the HMPC discussion on the PRAC

	recommendations and to consider the outcome of the discussion at the HMPC, especially with respect to alignment of TU sections to those of the WEU part. With a view to adopt the documents for public consultation at HMPC in January 2014.
V.6.2 Sisymbrii officinalis herba V.6.2.1 Assessment report V.6.2.1.1 List of references - available references V.6.2.2 Monograph	*Rapporteur: Z. Biró-Sándor ; Peer-reviewer: B. Kroes* Draft monograph adopted for release for public consultation until 15 April 2014, together with the supporting documents.
Some members proposed slight changes in the wording of the indication. After discussion of the specificities of the traditional medicinal use of Sisymbrium vis-à-vis other cough medicines it was agreed to keep the indication as proposed by MLWP for public consultation.	
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) V.9.1.1 Draft concept paper (EMA/HMPC/555178/2013): **for adoption**	*Rapporteur: A. Cunney* *See also III.1.3* Adopted by consensus. HMPC secretariat to publish at the EMA website for 3 months public consultation.
The scope of the planned revision had been adapted by the Rapporteur from clinical to non-clinical and clinical sections of the dossier according to discussion at the HMPC September meeting.	
VI. Non-clinical assessment/issues	
VII. Other relevant business	
VII.1 Conferences, presentations & research projects	
VII.1.1 International symposium on herbal medicines held on 30 September - 2 October 2013 in Bonn, Germany - Presentations http://www.bfarm.de/SharedDocs/1_Downloads/DE/BfArM/publ/veranstalt/130930_TradReg/11_Folien.pdf;jsessionid=FED110FBF6DF839781298B65FEA4F62F.1_cid322?__blob=publicationFile	*Report by J. Wiesner*
VII.2 International cooperation, collaboration with non-EU regulatory authorities	

VII.3 Documents for information	
VII.3.1 HMPC meeting held 16-17 September 2013 VII.3.1.1 Table of Decisions (EMA/HMPC/568726/2013) VII.3.1.2 Meeting report (EMA/HMPC/587804/2013)	
VII.3.2 Draft agenda of MLWP meeting to be held 12-14 November 2013 (EMA/HMPC/646389/2013)	
VII.3.3 MLWP meeting held 17-19 September 2013 VII.3.3.1 Table of Conclusions (EMA/HMPC/570670/2013) VII.3.3.2 Minutes (EMA/HMPC/590458/2013)	
VII.3.4 Overview of status of HMPC assessment work – priority list (EMA/HMPC/278067/2006)	*Status September 2013 (post-meeting)*
VII.3.5 Inventory of herbal substances for assessment work – alphabetical order (EMA/HMPC/494079/2007)	*Status September 2013 (post-meeting)*
VII.3.6 Common names of herbal substances in all EU official languages (EMA/HMPC/95087/2011)	*Status September 2013*
VII.3.7 Draft ORGAM DG and Q DG meeting dates in 2014 (EMA/HMPC/582171/2013)	
VII.3.8 Response letters to accepted interested parties - EURAMA (EMA/HMPC/642838/2013) - GP-TCM-RA (EMA/HMPC/642837/2013) - EUCOPE (EMA/HMPC/642839/2013) VII.3.8.1 Updated list of interested parties to the HMPC (EMA/HMPC/14070/2013)	
VII.3.9 QWP - Revision of the guideline on stability testing for applications for variations to a marketing authorisation - Draft Guideline on Stability Testing for Applications for Variations to a Marketing Authorisation - Concept paper on the need for a reflection paper on quality aspects of medicines for older people - Template for the qualified person's declaration concerning GMP compliance of active substance manufacture and verification of its supply chain "the QP declaration template"	
VII.3.10 Progress with ARSP establishment	Postponed to January 2014

VII.4 Any other information

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

List of participants

Chair of the HMPC	***Observer***
Werner Knöss	Melanie Bald (via teleconference)
	Saša Pilipović
HMPC members	Merjem Hadjihamza
Reinhard Länger	Jasmina Krlić
Heidi Neef	Dragan Djurovic
Gert Laekeman	
Ivan Kosalec	
Panayiotis Triantafyllis	***European Commission***
Marie Heroutová	
Steffen Bager	
Eeva Sofia Leinonen	***Agency secretariat***
An Lê	
Jacqueline Wiesner	
Ioanna Chinou	
Zsuzsanna Biró-Sándor	
Niamh Curran	
Marisa Delbó	
Dace Kalke	
Arturas Kažemekaitis	
Everaldo Attard	
Emiel van Galen	
Steinar Madsen	
Wojciech Dymowski	
Ana Paula Martins	***Apologies***
Nadia Grigoras	Elena Mustakerova
Adela Núñez Velázquez	Evelin Saar
Barbara Razinger	Silvia Girotto
Per Claeson	Martina Hudecová
Linda Anderson	
Gioacchino Calapai	
Olavi Pelkonen	
Maria Helena Pinto Ferreira	
HMPC alternate members	
Wim Vervaet	
Irina Nikolova	
Darko Trumbetić	
Jacqueline Viguet Poupelloz	
Marje Zernant	
Baiba Jansone	
Anna Maria Serrilli	
Burt Kroes	
Milan Nagy	
Sue Harris	