



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 November 2013
EMA/HMPC/704114/2013
Patient Health Protection

Committee on Herbal Medicinal Products (HMPC)

Draft Agenda 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

• 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.

• 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 (Preamble 1 – 29 October 2013)
- HMPC Chair job profile (EMA/HMPC/198377/2010): for information (Preamble 1 – 29 October 2013)
- Candidature for Chair:
Werner Knöss, Germany (letter of candidature with motivation to stand received on 22 October 2013, CV) (Preamble 1 – 29 October 2013)
- 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) (Tabled)



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 Tuesday 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.

- Draft annex to the minutes for the November 2013 HMPC meeting, documenting anticipated restriction on involvement in relation to agenda topics and declarations of interest from members and alternates (EMA/655751/2013)

I. Introduction		<i>* = Change introduced following last pre-meeting mailing</i>
<u>I.1 Agenda, minutes</u>		
I.1.1 Agenda of 11-12 November 2013 HMPC meeting (EMA/HMPC/644886/2013): for adoption	<i>Tabled</i>	
I.1.2 Time schedule of 11-12 November 2013 HMPC meeting (EMA/HMPC/644885/2013): for adoption	<i>Tabled</i>	
I.1.3 Draft minutes of 16-17 September 2013 HMPC meeting (EMA/HMPC/589557/2013): for adoption	<i>Circulated on 23 October 2013</i> <i>For publication on Agency website</i> <i>See also III.2.4</i> <i>Premail 1 – 29 October 2013</i>	
<u>I.2 Legislation and regulatory affairs</u>		
<u>I.3 Questions raised by HMPC members</u>		
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	<i>Rapporteur O. Pelkonen and J. Wiesner</i>	
- Email	<i>Premail 1 – 29 October 2013</i>	
- Public statement on the use of herbal medicinal products containing estragole (EMA/HMPC/137212/2005)	http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2010/04/WC500089960.pdf	
- Discussion paper on possible revision public statement (EMA/HMPC/137212/2005)	<i>Tabled</i>	
I.3.2 BSS validation: for discussion	<i>Rapporteur: G. Calapai</i>	
I.3.2.1 Emails from Z. Biró-Sándor dated 17 September and 5 November 2013	<i>Premail 1 – 29 October 2013</i>	
- Opinion on BSS validity by Z. Szabóné Cserjés dated 17 September 2013	<i>Premail 1 – 29 October 2013</i>	
- Comments on the validation study for the BSS dated 5 November 2013	<i>Premail 2 – 5 November 2013</i>	
- M. Tavakol, R. Dennick. Making sense of Cronbach's alpha. International Journal of Medical Education. 2011; 2:53-55; 2042-6372	<i>Premail 2 – 5 November 2013</i>	
I.3.2.2 Report on the Validity of the BSS – a scale for acute bronchitis by Dr. Lehl dated 14 November 2012	<i>Premail 1 – 29 October 2013</i>	
I.3.2.3 draft comment about Bronchitis symptoms scale (BSS) on behalf of HMPC (EMA/HMPC/280914/2013)	<i>Premail 1 – 29 October 2013</i>	
I.3.2.4 HMPC response letter dated 14 June 2013 (EMA/HMPC/352642/2013): for information	<i>Premail 1 – 29 October 2013</i>	

I.3.2.5 Draft letter dated 12 November 2013 regarding additional data	<i>Tabled</i>
I.3.2.6 Written statements from HMPC members - Email by W. Dymowski dated 31 October 2013 - Email by S. Giroto dated 2 November 2013	<i>Premail 2 – 5 November 2013</i>
<u>I.4 Questions raised by companies</u>	
<u>I.5 Referral procedures</u>	
II. Co-ordination issues	
<u>II.1 General co-ordination issues</u>	
<u>II.2 Co-ordination with CHMP</u>	
<u>II.3 Co-ordination with SAWP</u>	
<u>II.4 Co-ordination with SWP</u>	
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	<i>Report by HMPC Chair /O. Pelkonen</i> http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003412.pdf
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	<i>Premail 1 – 29 October 2013</i>
II.4.1.2 Questions & Answers on ethanol (EMA/507988/2013)	<i>Premail 1 – 29 October 2013</i>
II.4.1.3 Report on Ethanol (EMA/281628/2013)	<i>Premail 1 – 29 October 2013</i>
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	<i>Premail 1 – 29 October 2013</i>
II.4.2 Report on SWP FtF meeting on 1-2 October 2013	<i>Report by O. Pelkonen</i>
<u>II.5 Co-ordination with PDCO</u>	
<u>II.6 Co-ordination with PRAC</u>	

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

Premail 1 – 29 October 2013

Premail 1 – 29 October 2013

Premail 1 – 29 October 2013

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**

In presence of T. Engraff (Eur. Com.)

<http://www.efsa.europa.eu/en/efsajournal/doc/3412.pdf>

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
Premail 1 – 29 October 2013*

III.1.2 draft Q & A on Non-European traditional medicines (EMA/HMPC/402684/2013): **for adoption**

*Report by ORGAM DG Chair
A version with EMA secretariat comments expected to be tabled at the meeting
Premail 2 – 5 November 2013*

- comments from EMA secretariat

Tabled

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

III.1.4 Clarification for implementation of the HMPC procedure on systematic review/revision concerning the release for 3-month public consultation of revised monographs and related documents: for discussion	<p><i>Report by MLWP Chair/HMPC secretariat</i></p> <p><i>See also V.3.3</i></p> <p>http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2011/07/WC500109143.pdf</p>
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	<i>Report by HMPC secretariat</i>
- Email by HMPC secretariat dated 22 October 2013	<i>Tabled</i>
III.2.2 Discussion on international cooperation in the field of herbal medicines: for discussion	<i>Report by HMPC Chair/HMPC secretariat</i>
III.2.2.1 Draft proposal for HMPC international cooperation	<i>To be tabled at meeting.</i>
- Key areas to strengthen the international profile of the EMA in the field of herbal medicines (EMA/HMPC/396677/2013)	
III.2.3 Informal HMPC meeting to be held 10-11 December 2013 in Vilnius, Lithuania: for discussion	<i>Report by A. Kažemekaitis</i>
- Draft agenda	<i>Premail 2 – 5 November 2013</i>
III.2.4 List of acronyms used in HMPC minutes (EMA/HMPC/441838/2013): for discussion	<p><i>Report by HMPC secretariat</i></p> <p><i>For publication on the EMA website, as a permanent annex to HMPC minutes</i></p> <p><i>Premail 2 – 5 November 2013</i></p>
III.2.5 KPIs: for discussion	<i>Presentation</i>
- Report on HMPC deliverables (M, LE, PS, revised M) in EMA 2013 annual report	<i>Tabled</i>
- Confirmation of KPI figures for 2014	
III.2.6 Introduction to MMD: for discussion	
III.2.6.1 Initial presentation to MMD (managing meeting documents)	<i>Report</i>
III.2.6.2 Proposal for HMPC folders' structure in MMD	<i>Premail 2 – 5 November 2013</i>

V. Quality

IV.1 Quality Drafting Group

IV.1.1 Q DG (virtual) meeting held on 16-17 October 2013	<i>Report by Q. DG Chair</i>
IV.1.1.1 Draft Meeting report (EMA/HMPC/634296/2013): for adoption	<i>See also VII.3.9</i> <i>Premail 2 – 5 November 2013</i>
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	<i>Premail 1 – 29 October 2013</i>
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	<i>Rapporteur: L. Anderson</i> <i>For release for public consultation until 15 April 2014</i> <i>Premail 1 – 29 October 2013</i>
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	<i>Rapporteur: K. Reh</i> <i>Q&A after adoption to be added to General quality Q&A for HMP/THMP (EMA/HMPC/41500/2010 Rev.2)</i> <i>Tabled</i>

IV.2 European Pharmacopoeia

IV.2.1 Symposium on traditional Chinese medicines on 14-15 November 2013 in Strasbourg, France: for information - agenda	<i>Report by M. Bald</i> <i>Premail 2 – 5 November 2013</i>
IV.2.2 Appointment of HMPC observers in Pharmacopoeia expert groups 13A, 13B and TCM for 2014	<i>Report by HMPC Chair and Q DG Chair</i>
IV.2.3 Group 13A, the 45th meeting held on 1-2 October 2013 - Summary of decisions	<i>Report by M. Bald and HMPC observer I. Chinou</i> <i>Premail 1 – 29 October 2013</i>

V. Safety & efficacy

V.1 MLWP

<i>The next meeting of the MLWP will be held 12-14 November 2013</i>	<i>See VII.3.2</i>
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	<i>Report by MLWP Chair</i> <i>Status September 2013</i> <i>Premail 2 – 5 November 2013</i>

V.1.1.1 Appointment of Rapporteurs	Transfer of Rapporteurship from D. Csupor to Z. Biró-Sándor for: - Pelargonii radix - Fraxini folium - Chamomillae romanae flos - Colae semen
V.1.1.2 Appointment of Peer-reviewers	Transfer of Peer-review from Z. Biró-Sándor to L. Anderson for Sabalis serrulatae fructus

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	Report by MLWP Chair
V.1.2.1 Draft overview on available genotoxicity data for herbal substances for inclusion into the Community list (EMA/HMPC/283128/2013)	Report by O. Pelkonen/J. Wiesner Preamble 1 – 29 October 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 HMPC secretariat/ L. Anderson
V.1.3 Revised MLWP 2014 work programme (EMA/HMPC/554850/2013): for discussion	Report by HMPC Chair/MLWP Chair
- Feedback from toxicologists/HMPC members on the feasibility and need for a European position (public statement) on HMP containing PAH	Preamble 2 – 5 November 2013
V.1.4 Presentation on WEU provisions in the context of the establishment of monographs: for discussion - PowerPoint presentation	Report by EMA secretariat In presence of T. Engraff (Eur. Com.)
	Tabled

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	Preamble 2 – 5 November 2013
V.3.1.1.1 List of references - available references 139/168	Preamble 2 – 5 November 2013
V.3.1.2 Monograph	Preamble 2 – 5 November 2013

V.3.2 Anisi fructus - Final	
V.3.2.1 Assessment report	Rapporteur: M. Delbò; Peer-reviewer: B. Huber See V.3.1.1
V.3.2.1.1 List of references 139/168	See V.3.1.1.1
V.3.2.2 Monograph	Premail 2 – 5 November 2013
V.3.2.3 List entry	Premail 2 – 5 November 2013
V.3.3 Thymi herba - Public Consultation	
V.3.3.1 Assessment report	Rapporteur: R. Länger; Peer-reviewer: L. Anderson Premail 1 – 29 October 2013
V.3.3.1.1 List of references - available references 81/131	Premail 1 – 29 October 2013
V.3.3.2 Monograph	Premail 2 – 5 November 2013
<u>V.4 Community herbal monographs for adoption (post finalisation)</u>	
<u>V.5 Community herbal monographs, Community list entries and public statements for adoption after public consultation</u>	
<u>V.5.1 Camelliae sinensis non fermentatum folium</u>	
V.5.1.1 Assessment report	Rapporteurs: N. Grigoras/C. Purdel; Peer-reviewer: I. Chinou Premail 1 – 29 October 2013
V.5.1.1.1 List of references 29/171	Premail 1 – 29 October 2013
V.5.1.2 Monograph	Premail 1 – 29 October 2013
V.5.1.3 Overview of comments	Premail 1 – 29 October 2013
<u>V.5.2 Phaseoli fructus (sine semine)</u>	
V.5.2.1 Assessment report	Rapporteur: G. Laekeman; Peer-reviewer: B. Kroes; Experts: B. Bulckaert, P. Vanparys No comments received during the public consultation
V.5.2.1.1 List of references 40/62	Premail 2 – 5 November 2013
V.5.2.2 Monograph	
<u>V.6 Community herbal monographs, Community list entries and public statements for adoption for release for public consultation</u>	
<u>V.6.1 Ginkgo folium</u>	
V.6.1.1 Assessment report	Rapporteur: J. Wiesner; Peer-reviewer: O. Palomino; Expert: E.-M. Eibl Premail 2 – 5 November 2013
V.6.1.1.1 List of references - available references	
V.6.1.2 Monograph	
<u>V.6.2 Sisymbrii officinalis herba</u>	
V.6.2.1 Assessment report	Rapporteur: Z. Biró-Sándor ; Peer-reviewer: B. Kroes Premail 2 – 5 November 2013
V.6.2.1.1 List of references - available references	
V.6.2.2 Monograph	

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)

Rapporteur: A. Cunney

See also III.1.3

Premail 1 – 29 October 2013

V.9.1.1 Draft concept paper (EMA/HMPC/555178/2013):
for adoption

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

Report by J. Wiesner

- Presentations

http://www.bfarm.de/SharedDocs/1_Downloads/DE/BfArM/publ/veranstalt/130930_TradReg/11_Folien.pdf;jsessionid=FED110FBF6DF839781298B65FEA4F62F.1_cid322?_blo b=publicationFile

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)

Premail 1 – 29 October 2013

VII.3.1.2 Meeting report (EMA/HMPC/587804/2013)

Premail 1 – 29 October 2013

VII.3.2 Draft agenda of MLWP meeting to be held 12-14 November 2013 (EMA/HMPC/646389/2013)

Premail 2 – 5 November 2013

VII.3.3 MLWP meeting held 17-19 September 2013

VII.3.3.1 Table of Conclusions (EMA/HMPC/570670/2013)

Premail 1 – 29 October 2013

VII.3.3.2 Minutes (EMA/HMPC/590458/2013)

Premail 2 – 5 November 2013

VII.3.4 Overview of status of HMPC assessment work – priority list (EMA/HMPC/278067/2006)

*Status September 2013 (post-meeting)
Premail 2 – 5 November 2013*

VII.3.5 Inventory of herbal substances for assessment work – alphabetical order (EMA/HMPC/494079/2007)

*Status September 2013 (post-meeting)
Premail 2 – 5 November 2013*

VII.3.6 Common names of herbal substances in all EU official languages (EMA/HMPC/95087/2011)

*Status September 2013
Premail 2 – 5 November 2013*

VII.3.7 Draft ORGAM DG and Q DG meeting dates in 2014 *Premail 1 – 29 October 2013*
(EMA/HMPC/582171/2013)

VII.3.8 Response letters to accepted interested parties *Premail 2 – 5 November 2013*

- 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 *Premail 1 – 29 October 2013*
 - Draft Guideline on Stability Testing for Applications for Variations to a Marketing Authorisation *Premail 1 – 29 October 2013*
 - Concept paper on the need for a reflection paper on quality aspects of medicines for older people *Premail 1 – 29 October 2013*
 - Template for the qualified person's declaration concerning GMP compliance of active substance manufacture and verification of its supply chain "the QP declaration template" *Premail 1 – 29 October 2013*
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VII.3.10 Progress with ARSP establishment *Postponed to January 2014*

VII.4 Any other information
