



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 January 2014
EMA/HMPC/50290/2014
Committee on Herbal Medicinal Products (HMPC)

Committee on Herbal Medicinal Products (HMPC)

Draft Agenda of the 27-28 January 2014 meeting

27 January 2014, 14:00 – 19:00, room 3A, *plenary*
27 January 2014, 19:00 – 21:30, outside room 3A, *New Year function*
28 January 2014, 09:00 – 13:00, room 3A, *plenary*

Chair: Werner Knöss

- **Health & Safety Information**

In accordance with Agency policy, delegates are to be shown a slide show with health and safety and emergency information and procedures. This is to be displayed at the start of this meeting using the Crestron system as delegates are entering the meeting room. In addition, the meeting secretariat is to draw the delegates' attention to the slideshow and point out the nearest fire exit(s), which are marked where the room has two or more exits. Should there be an evacuation during the meeting staff will guide delegates out of the building via the nearest fire exit.

- **Welcome to new participants**

New AST member in HMPC secretariat
New trainee in HMPC secretariat

- **Transfer of voting rights from members to the alternate members**

From Barbara Razinger to Samo Kreft, from Panayiotis Triantafyllis to Maria Stavrou.

- **Apologies**

Apologies received from Artūras Kažemekaitis, Gert Laekeman and G. Calapai.

- **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 January 2014 HMPC meeting, documenting anticipated restriction on involvement in relation to agenda topics and declarations of interest from members and alternates (EMA/HMPC/14032/2014)

Election of Chair of ORGAM DG

I. Introduction * = Change introduced following last pre-meeting mailing

I.1 Agenda, minutes

I.1.1 Agenda of 27-28 January 2014 HMPC meeting (EMA/HMPC/782373/2013): **for adoption** *Tabled For publication on EMA website*

I.1.2 Time schedule of 27-28 January 2014 HMPC meeting (EMA/HMPC/782372/2013): **for adoption** *Premail 2 – 21 January*

I.1.3 Draft minutes of 11-12 November 2013 HMPC meeting (EMA/HMPC/742564/2013): **for adoption** *Premail 1 – 14 January*
For publication on EMA website

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 *Rapporteurs: O. Pelkonen and J. Wiesner*
Premail 1 – 14 January

- Discussion paper on possible revision public statement (EMEA/HMPC/137212/2005): **for discussion** *Premail 1 – 14 January*

- Presentation by O. Pelkonen given at HMPC informal meeting in Vilnius: **for discussion** *See VI.3.11*

- preliminary draft Reflection paper on assessment of estragole and alkenyl benzenes: **for discussion** *Premail 2 – 21 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.2.1 Coordination on request for eligibility to CP received by CHMP for: **for discussion** *Report by J. Wiesner*

- letter of intent *Premail 1 - 14 January*

- eligibility request *Premail 1 – 14 January*

II.3 Co-ordination with SAWP

II.4 Co-ordination with SWP

II.4.1 Feedback on SWP virtual meeting held on 3 December 2013 *Report by O. Pelkonen*

II.4.2 Report on draft agenda for SWP virtual meeting
scheduled for 28 January 2014 *Report by O. Pelkonen*

II.5 Co-ordination with PDCO

II.6 Co-ordination with PRAC

II.6.1. PRAC recommendation on labelling of efavirenz-
containing medicinal products concerning potential
deleterious pharmacokinetic interaction with Ginkgo biloba
extracts (EMA/PRAC/606660/2013/Adopted): **for
information** *See V.6.1
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/11/WC500153952.pdf*

II.7 Co-ordination with PCWP

II.7.1 PCWP Work plan for 2014 (EMA/552003/2013): **for
adoption** *Presentation on 28 January at 11.30
See also VI.3.16*

II.8 Co-ordination with HCPWP

II.8.1 HCPWP Work plan for 2014 (EMA/549571/2013): **for
adoption** *Presentation on 28 January at 11.45
See also VI.3.16*

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.12.1 HMPC questions WEU and TU provisions: **for
discussion**

- Questions and draft answers (EMA/HMPC/724649/2013) *Premail 1 - 14 January*
 - Discussion on how to improve the genotoxicity data situation
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II.13 Co-ordination with EFSA

II.13.1 Discussion on EFSA scientific opinion related to
hydroxyanthracene derivatives *Premail 1 - 14 January*
<http://www.efsa.europa.eu/en/efsajournal/doc/3412.pdf>

II.13.1.1 Comments from HMPC members

- Comments from H. Neef and W. Vervaet circulated on
13 January 2014
- Comments from L. Anderson and S. Harris circulated on
17 January 2014

II.13.2 Scientific assessment of estragole *See also I.3.1*

III. Organisational matters

III.1 Organisational Matters Drafting Group

III.1.1 ORGAM DG (virtual) meeting to be held on 14 January 2014	<i>Report by ORGAM DG Chair</i>
III.1.1.1 Agenda (EMA/HMPC/739161/2013): for information	<i>Premail 1 – 14 January</i>
III.1.1.2 draft Meeting report (EMA/HMPC/22724/2014): for adoption	<i>Premail 2 – 21 January</i>
III.1.2 Progress on establishment of a draft Q & A on non-European traditional medicines (EMA/HMPC/402684/2013): for discussion	<i>Report by ORGAM DG Chair</i> <i>Adoption scheduled for March 2014</i>
III.1.3 Revised 'HMPC procedure on publication of public statements when no monographs are established' (EMA/HMPC/84530/2010 Rev.2): for adoption	<i>Report by ORGAM DG Chair</i> <i>Premail 1 - 14 January</i>
III.1.4 Revision of guidance on systematic review/revision of monographs and related documents concerning the nature of the changes that trigger a release for public consultation: for discussion	<i>Report by HMPC Chair and MLWP Chair</i>
- proposal from HMPC Chair and MLWP Chair	<i>Premail 1 – 14 January</i>
III.1.5 Progress for the ORGAM DG contribution to the revision of the CTD guideline: for discussion	<i>Report by A. Cunney</i> <i>See II.1.1.2</i>
<u>III.2 Working methodology</u>	
III.2.1 Timetable for the next survey (2013 data) of the 'Uptake of traditional use registration scheme and implementation of the provisions of Directive 2004/24/EC in EU Member States' (EMA/HMPC/28645/2014): for discussion	<i>Report by HMPC</i> <i>Premail 2 – 21 January</i>
III.2.2 Update on support in 2014 to HMPC coordination activities, especially with EDQM: for discussion	<i>See also VI.3.10</i>
*- Presentation	
III.2.3 Meeting of EMA Scientific Coordination Board held on 9 December 2013: for discussion	<i>Report by HMPC Chair</i>
III.2.4 Introduction to MMD: for information	
III.2.4.1 Progress with the establishment of HMPC folders' structure in MMD	<i>Report by HMPC Chair/HMPC secretariat</i>
III.2.4.2 Timetable for next steps in implementation, including training of delegates in March 2014 (EMA/HMPC/28836/2014)	<i>Premail 2 – 21 January</i>
III.2.5 Report on HMPC informal HMPC meeting held in Vilnius in December 2013: for information	<i>Postponed to March 2014</i> <i>See also VI.3.11</i>
III.2.6 Update on organisation of informal HMPC meetings in 2014 during Greek and Italian presidency: for information	<i>Report by I. Chinou and M. Delbò</i>

- Informal HMPC meeting in Rome on 4-5 November 2014	
III.2.7 Meeting dates in 2016-2017-2018: for discussion	<i>Premail 2 – 21 January</i>
III.2.8 Organisation of a training in 2014 for 20 rapporteurs /assessors on the revised assessment report template with instructions on the intended content of the various sections of HMPC ARs (objective 'high quality standards and consistency for monographs, list entries and supporting documents'): for discussion	<i>Rapporteur for AR template revision and Topic Leader for the 'high quality standards and consistency' objective in 2012-2015 HMPC work programme: M. Delbò</i>
III.2.9 Move to new EMA offices in July 2014	
III.2.9.1 Presentation on EMA move to 30 Churchill Place	<i>Premail 2 – 21 January</i>
IV. Quality	
IV.1 Quality Drafting Group	
IV.1.1 Q DG (virtual) meeting to be held on 15 January 2014	<i>Report by Q DG Chair</i>
IV.1.1.1 Agenda (EMA/HMPC/791200/2013)	<i>Premail 1 – 14 January</i>
IV.1.1.2 Draft Meeting report (EMA/HMPC/32635/2014): for adoption	<i>Premail 2 – 21 January</i>
IV.1.2 Quality of essential oils as active substances in herbal medicinal products/traditional herbal medicinal products	<i>Rapporteur: K. Reh Q&A, after adoption, to be added to General quality Q&A for HMP/THMP (EMA/HMPC/41500/2010 Rev.2)</i>
- draft Q&A (EMA/HMPC/462429/2013): for adoption	<i>Premail 2 – 21 January</i>
- final reflection paper (EMA/HMPC/84789/2013): for adoption	<i>Premail 2 – 21 January</i>
IV.1.3 Proposal to establish guidance (e.g. Q&A) regarding HS or HP which are covered by a pharmacopoeia monograph that does not contain an assay: for discussion	<i>Report by R. Länger and Q DG Chair See also VI.3.10</i>
- impact on MRP	
- timelines for guidance drafting	
IV.1.4 Draft 'Reflection paper on microbiological aspects of HMP and THMP' (EMA/HMPC/95714/2013): for adoption	<i>Rapporteurs: K. Hvolby, M. Delbò For release for public consultation until 15 June 2014 <i>Premail 2 – 21 January</i></i>
IV.2 European Pharmacopoeia	
IV.2.1 Update on Pharmacopoeia Commission decisions and publications in Pharmeuropa	<i>Report by M. Bald</i>

IV.2.2 Progress report from Expert Groups 13A, 13B and TCM

- Summary of decisions Extract WP Nov 2013
- Summary of decisions 13B WP Nov 2013
- Summary of decisions TCM WP Nov 2013

Report by M. Bald

Premail 1 – 14 January

See also VI.1.2 and VI.4.2

IV.2.3 EDQM monograph on herbal drug extracts and corresponding information: **for information**

Premail 1 – 14 January

V. Safety & efficacy

V.1 MLWP

The next meeting of the MLWP will be held on 28-30 January 2014 See VI.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

Premail 1 – 14 January

V.1.1.1 Appointment of Rapporteurs/Peer-reviewers

Balsamum peruvianum: P. Claeson/W. Knöss
Calendulae herba: L. Anderson/ P. Claeson
Cinnamomi camphorae (folium/cortex): O. Palomino/B. Huber
Cisti cretici folium/resinum: I. Chinou/J. Wiesner
Cyani flos : J. Wiesner/C. Purdel
Epilobii herba: R. Länger/M. Heroutová
Glycine max, lecithin: P. Claeson/I. Chinou
Helichrysi flos: W. Dymovski/G. Calapai
Juniperi communis summitates: G. Laekeman/O. Palomino
Origami majoranae herba: C. Cavaleiro/ M. Heroutová
Paeoniae radix: J. Wiesner/H. Pinto Ferreira
Pistacia lentiscus, resinum (mastix): I. Chinou/M. Delbò
Polygoni avicularis herba: B. Jansone/J. Viguet-Poupelloz
Ricini oleum: C. Purdel/B. Kroes
Saccharomyces cerevisiae/S. boulardii: J. Wiesner/M. Delbò
Salviae trilobae folium: C. Cavaleiro/I. Chinou
Sideritis herba: B. Kroes/I. Chinou

Other relevant topics

N/A

V.2 Community list entries transmitted to European Commission

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

N/A

V.4 Community herbal monographs (post finalisation)

V.4.1 Corrigendum to monograph on Plantaginis lanceolata folium: **for information** http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000182.jsp&mid=WC0b01ac058001fa1d

V.4.2 Corrigendum to monograph on Origani dictami herba: **for information** http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000182.jsp&mid=WC0b01ac058001fa1d

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

V.5.1 Sambuci fructus

*Rapporteur: G. Fossum
Peer-reviewer: M. Heroutová*

V.5.1.1 Assessment report

Premail 2 – 21 January

V.5.1.1.1 List of references
- available references xx/xx

V.5.1.2 Public statement

V.5.1.3 Overview of comments

V.5.2 Ginseng radix

V.5.2.1 Assessment report

*Rapporteur: R. Länger
Peer-reviewer: W. Knöss*

V.5.2.1.1 List of references
- available references xx/xx

Premail 1 – 14 January

V.5.2.2 Monograph

V.5.2.3 Overview of comments

V.5.3 Curcumae xanthorrhizae rhizoma

*Rapporteurs: E. van Galen/B. Kroes
Peer-reviewer: P. Claeson
No comments received during public consultation*

V.5.3.1 Assessment report
V.5.3.1.1 List of references
- available references xx/xx

Premail 2 – 21 January

V.5.3.2 Monograph

V.5.4 Rubi idaei folium

*Rapporteur: G. Fossum; Peer-reviewer:
P. Claeson
No comments received during public consultation*

V.5.4.1 Assessment report
V.5.4.1.1 List of references
- available references xx/xx

Premail 1- 14 January

V.5.4.2 Monograph

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

V.6.1 Ginkgo folium	<i>Rapporteur: J. Wiesner; Peer-reviewer: O. Palomino; Expert: E.-M. Eibl</i>
V.6.1.1 Assessment report	
V.6.1.1.1 List of references - available references	<i>For release for public consultation until 15 June 2014</i>
V.6.1.2 Monograph	<i>See II.6.1</i> <i>Premail 2 – 21 January</i>

V.7 Community herbal monographs, Community list entries and public statements for discussion

N/A

V.8 Guidelines

V.8.1

VI. Other relevant business

VI.1 Conferences, presentations & research projects

VI.1.1 Report from International Symposium 'Regulation of herbal and traditional medicinal products – European and global strategies' held on 31 September-2 October 2013 in Bonn, Germany: for information	<i>Report by Organising Committee members</i>
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VI.1.2 Report from EDQM Symposium on traditional Chinese medicines held on 14-15 November 2013 in Strasbourg, France: for information - Summary outcome of Symposium	<i>Report by M. Bald and HMPC participants</i> <i>Premail 1 – 14 January</i> <i>See also VI.3.19</i>
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VI.2 International cooperation, collaboration with non-EU regulatory authorities

N/A

VI.3 Documents for information

VI.3.1 HMPC meeting held on 11-12 November 2013	
VI.3.1.1 Table of Decisions (EMA/HMPC/694378/2013)	<i>Premail 1 – 14 January</i>
VI.3.1.2 Meeting report (EMA/HMPC/702025/2013)	<i>http://www.ema.europa.eu/docs/en_GB/document_library/Committee_meeting_report/2013/11/WC500156450.pdf</i>
VI.3.2 Draft agenda of MLWP meeting to be held 28-30 January 2014 (EMA/HMPC/790056/2013)	<i>Premail 2 – 21 January</i>
VI.3.3 MLWP meeting held on 12-14 November 2013	
VI.3.3.1 Table of Conclusions (EMA/HMPC/698330/2013 Ver.2)	<i>Premail 2 – 21 January</i>
VI.3.3.2 Draft Minutes (EMA/HMPC/730474/2013)	<i>Premail 2 – 21 January</i>

VI.3.4 Overview of status of HMPC assessment work – priority list (EMA/HMPC/278067/2006)	Status November 2013 (post-meeting) http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/12/WC500017724.pdf
VI.3.5 Inventory of herbal substances for assessment work – alphabetical order (EMA/HMPC/494079/2007)	Status November 2013 (post-meeting) http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/12/WC500017723.pdf
VI.3.6 Common names of herbal substances in all EU official languages (EMA/HMPC/95087/2011)	Status December 2013 Preamail 1 – 14 January
VI.3.7 HMPC Letter dated 18 December 2013 on BSS and further considerations	Rapporteur: G. Calapai Preamail 1 – 14 January
VI.3.8 Published MLWP 2014 work programme	http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2009/12/WC500020087.pdf
VI.3.9 Published ORGAM DG 2014 work programme	http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2009/12/WC500020090.pdf
VI.3.10 Published Q DG 2014 work programme	http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2009/12/WC500020089.pdf
VI.3.11 Presentations given at informal HMPC meeting held in Vilnius in December 2013	Preamail 2 – 21 January
VI.3.12 Progress with ARSP establishment	Report by HMPC secretariat
VI.3.13 Helmstädter A, Staiger C. Traditional use of medicinal agents: a valid source of evidence. <i>Drug Discovery Today</i> 2014, 19(1):4-7	Circulated to HMPC on 8 January
VI.3.14 Vlachojannis C, Magora F, Chrubasik-Hausmann S. Pro and contra duration restriction of treatment with willow bark extract – letter to the editor. <i>Phytother. Res.</i> 2014, 28:148–149	Circulated to HMPC on 8 January
VI.3.15 Danish Food Agency information rapid alerts on Ayurvedic products sold as food supplements with high levels of toxic heavy metals	Report by S. Bager
VI.3.16 Minutes from the joint PCWP-HCPWP meeting held on 25 September 2013 (EMA/618027/2013)	Preamail 2 – 21 January
VI.3.17 Maggini V, Gallo E, Vannacci A, Gori L, Mugelli A, and Firenzuoli F. e-Phytovigilance for misleading herbal information. <i>Trends in Pharmacological Sciences</i> 2013, 34(11):594-595	Preamail 1 – 14 January

VI.3.18 Pelkonen O, Xu Q, Fan T-P. Why is research on herbal medicinal products important and how can we improve its quality? <i>Journal of Traditional and Complementary Medicine</i> 2014, 4(1):1-7	<i>Circulated to HMPC on 11 January</i>
VI.3.19 Presentations given at the EDQM Symposium on traditional Chinese medicines held on 14-15 November 2013 in Strasbourg, France	Available at http://www.edqm.eu/en/proceedings-international-conference-83.html
VI.3.20 EMA Principles for publication of agendas and minutes of EMA scientific committees	Available at http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/12/WC500158538.pdf
*VI.3.21	<i>Received by NCAs on 17 January 2014</i>
<u>VI.4 Any other information</u>	
VI.4.1 HMPC New Year function on 27 January 2014 at 19.00 in the lobby outside 3A	
VI.4.2 Announced changes in EDQM observers to HMPC	
VI.4.3 Abbreviations in HMPC minutes http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/11/WC500155666.pdf	To be added at next revision: SA = scientific advice PA = protocole assistance