



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 January 2015
EMA/HMPC/21023/2015
Procedure Management and Business Support Division

Committee on Herbal Medicinal Products (HMPC)

Agenda of the 27-28 January 2015 meeting

27 January 2015, 13:00 – 18:30, room 3E, *plenary*
28 January 2015, 08:30-12:00, room 3E, *plenary*
(New Year's party on 27 January, 18:30-22:00, restaurant)

Chair: Werner Knöss

- **Health & Safety Information**

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

- **Announcement of new nominations**

Gabriela Duchajová, new HMPC member from Slovakia

- **Election of MLWP Chair**

See I.1.3

- **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 2015 HMPC meeting, documenting anticipated restriction on involvement in relation to agenda topics and declarations of interest from members and alternates (EMA/HMPC/58101/2015)



- **Note on access to documents**

Some documents mentioned in the agenda/minutes cannot be released at present within the framework of Regulation (EC) No 1049/2001 on access to documents because they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents .

* = Change introduced after

I. Introduction	
<u>I.1 Agenda, minutes</u>	
I.1.1 Agenda of 27-28 January 2015 HMPC meeting - Timetable, for order of topics <i>For adoption</i>	
I.1.2 Minutes of 24 November 2014 HMPC meeting <i>For adoption</i>	
I.1.3 Election of MLWP Chair - Mandate, objectives and rules of procedure for the HMPC Working Party on European Union Monographs and List (MLWP) - Email 9 January 2015 Candidatures received: Ioanna Chinou <i>For adoption</i>	Report: HMPC Chair
I.1.4 Overview of expertise available in the HMPC, MLWP, ORGAM and Q DG	
<u>I.2 Legislation and regulatory affairs</u>	
I.2.1 Requirement of QP declaration for traditional herbal medicinal products - Memo <i>For discussion</i>	Report: Q DG Chair Q DG member. K Reh
<u>I.3 Questions raised by HMPC members</u>	
<u>I.4 Questions raised by companies</u>	
<u>I.5 Referral procedures</u>	
<u>I.6 Co-ordination with Eur. Com.</u>	
I.6.1 Update on NTA review regarding WEU <i>For information</i>	
<u>I.7 Co-ordination with EFSA</u>	
EFSA NDA panel draft opinion on chicory inulin - Email dated 03 Dec 2014 - Email dated 08 Dec 2014 <i>For discussion</i>	Report: HMPC Chair

<u>I.8 Other external Co-ordination</u>	
<u>II. Safety & efficacy</u>	
<u>II.1 Report on MLWP activities</u>	
II.1.1 Report on progress achieved Overview of status of MLWP assessment work <i>For information</i>	Report: MLWP Chair
II.1.2 Clarification on prioritisation of substances before 'calls for submission of scientific data' - Email <i>For discussion</i>	
<u>II.2 European Union list entries transmitted to European Commission</u>	
<u>II.3 European Union herbal monographs for public consultation/final adoption after systematic review/revision</u>	
II.3.1 Monograph Hederae heliis folium (and supporting documents: AR, LoR; references 162/248) <i>For adoption</i>	
II.3.2 Monograph Thymi herba/Primulae radix (and supporting documents: AR, LoR; references 19/24) <i>For adoption</i>	
<u>II.4 European Union herbal monographs (post finalisation)</u>	
<u>II.5 European Union herbal monographs, list entries and public statements for adoption after public consultation</u>	
II.5.1 Monograph on Agrimoniae herba (and supporting documents: AR, LoR; references 35/44) <i>For adoption</i>	
II.5.2 Monograph on Eschscholziae herba cum flore (and supporting documents: AR, OoC, LoR; references 00/39) <i>For adoption</i>	
II.5.3 Monograph on Ginkgo folium (and supporting documents: AR, OoC, LoR; references 199/200) - Email dated 21/01/2015 <i>For adoption</i>	
II.5.4 Public statement on Picrorhizae kurroae rhizoma (and supporting documents: LoR; references 22/33) <i>For adoption</i>	

II.5.5 Monograph on Pilosellae herba cum flore (and supporting documents: AR, LoR; references 00/21) <i>For adoption</i>	
<u>II.6 European Union herbal monographs, list entries and public statements for adoption for release for public consultation</u>	
II.6.1 List entry on Crataegi folium cum flore <i>For adoption</i>	
II.6.2 Monograph on Myrtilli fructus recens (and supporting documents: AR, LoR) <i>For adoption</i>	
II.6.3 Monograph on Myrtilli fructus siccus (and supporting documents: AR, LoR) <i>For adoption</i>	See II.5.2
<u>II.7 European Union herbal monographs, list entries and public statements for discussion</u>	
<u>II.8 Guidelines and other guidance documents</u>	
<u>II.8.1 Revision of the Guideline on the use of the CTD format</u>	
- Draft revision 2 of the Guideline on the use of the CTD format <i>For adoption for public consultation</i>	Report by ORGAM DG Chair
<u>III. Quality</u>	
<u>III.1 Quality Drafting Group</u>	
III.1.1 Meeting report from Q DG meeting held on 10 December 2014 <i>For adoption</i>	Report: Q DG Chair
III.1.2 Revised 'Questions & answers on quality of herbal medicinal products/traditional herbal medicinal products' (rev 5) <i>For adoption</i>	Report: Q DG Chair
III.1.3 Draft agenda for the FtF Q DG meeting to be held on 11-12 February 2015 <i>For information</i>	Report: Q DG Chair
<u>III.2 Co-ordination European Pharmacopeia</u>	
III.2.1 EDQM Expert Group 13A meeting held on 2-3 December 2014 - Meeting report <i>For information</i>	EDQM: M. Bald, U. Rose HMPC Observer: I. Chinou
III.2.2 EDQM Expert Group 13B meeting held on 21-22 January 2015 - Agenda <i>For information</i>	EDQM: M. Bald, U. Rose HMPC Observer: H. Neef

III.2.3 EDQM Expert Group TCM meeting to be held on 13-14 January 2015 - Agenda <i>For information</i>	EDQM: M. Bald, U. Rose HMPC Observer: R. Länger
<u>IV. Internal Co-ordination with committee and working parties</u>	
<u>IV.1 Observers at other Committees</u>	
IV.1.1 Overview of HMPC coordination/observers with other committees <i>For discussion</i>	
<u>IV.2 Co-ordination with CHMP</u>	
- Email - Presentation - Rapporteur AR on the NAS claim - Co-Rapporteur AR on the NAS claim <i>For discussion</i>	
<i>For discussion</i>	
<u>IV.3 Co-ordination with SWP</u>	
IV.3.1 Coordination with Drafting Group on Excipients - Ethanol as an excipient (after public consultation) <i>For discussion</i>	
<u>IV.4 Co-ordination with HCPWP/PCWP</u>	
<u>IV.5 Co-ordination with Working Group on Quality Review of Documents (QRD)</u>	
IV.5.1 Proposal for amendments to QRD template for herbal medicinal products/ THMPs- Annex III, SmPC, labelling and PL - Draft discussion paper on QRD templates for SmPC, Labelling and Patient Leaflet on Mutual-recognition and Decentralised procedures for THMPs - Email <i>For discussion</i>	Rapporteurs: E. Svedlund, P. Claeson, R. Länger, E. v. Galen
<u>V. Organisational matters</u>	
<u>V.1 Organisational Matters Drafting Group</u>	
V.1.1 Meeting report from ORGAM DG meeting held on 9 December 2014 <i>For adoption</i>	Report: ORGAM DG Chair

V.1.2 Revision procedure for Monographs and List entries - Procedure for systematic review of Community herbal monographs and supporting documents <i>For discussion</i>	Report: ORGAM DG Chair
V.1.3 Draft agenda for the ORGAM DG meeting to be held on 10 February 2015 <i>For information</i>	Report: ORGAM DG Chair
V.2 Working methodology	
V.2.1 Quality and finalisation of documents transmitted to HMPC for adoption - examples <i>For discussion</i>	
V.2.2 Survey on implementation of Dir. 2004/24/EC (status 2014) - Timetable - List of questions <i>For adoption</i>	
V.2.3 Organisation of a HMPC presidency meeting during Latvian presidency <i>For discussion</i>	Report: HMPC Chair
<u>VI. Other relevant business</u>	
<u>VI.1 Conferences, presentations & research projects</u>	
<u>VI.2 International cooperation, collaboration with non-EU regulatory authorities</u>	
VI.2.1 7th annual meeting of IRCH held in Lisbon, Portugal on 2-4 December 2014 - Presentations <i>For information</i>	Report: A-P Martins HMPC Chair HMPC vice Chair
<u>VI.3 Documents for information</u>	
VI.3.1 Table of Decisions from HMPC meeting held on 24 November 2014	
VI.3.2 Meeting report from HMPC meeting held on 24 November 2014	http://www.ema.europa.eu/docs/en_GB/document_library/Committee_meeting_report/2014/10/WC500175755.pdf
VI.3.3 Draft agenda of MLWP meeting to be held on 28-30 of January 2015	
VI.3.4 Table of Conclusions from MLWP meeting held on 25-26 of November 2014	
VI.3.5 Draft Minutes from MLWP meeting held on 25-26 of November 2014	
VI.3.6 Overview of status of HMPC assessment work – priority list	http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/12/WC500017724.pdf
VI.3.7 Inventory of herbal substances for assessment work	http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/12/WC500017723.pdf

VI.3.8 Common names of herbal substances in all official EU languages	
VI.3.9 PCWP - Training session for patients and consumers involved in EMA activities (25 November 2014) - Agenda	Observer: S. Bager
VI.3.10 PCWP - Meeting with all eligible organisations (26 November 2014) - Agenda	Observer: S. Bager
VI.3.11 PCWP and HCPWP joint meeting – 16 September (EMA/563152/2014) - Minutes	
VI.3.12 Draft Public statement on the use of herbal medicinal products containing estragole for public consultation	http://www.ema.europa.eu/docs/en_GB/document_library/Public_statement/2014/12/WC500179557.pdf
VI.3.13 Draft Public statement on the use of herbal medicinal products containing pulegone and menthofuran for public consultation	http://www.ema.europa.eu/docs/en_GB/document_library/Public_statement/2014/12/WC500179556.pdf
VI.4 Any other information	
VI.4.1 Abbreviations in HMPC minutes	http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/11/WC500155666.pdf
VI.4.2 Proposal by Kew Gardens to map a plant list - Email from M. Delbò 14 November 2014 - Proposal from Kew Gardens	Report: M. Delbò
VI.4.3 Journal of Ethnopharmacology, Vol.158, Part B, Pages 447-518 (2 December 2014) Regulation of herbal and traditional medicinal products – European and global strategies (International Symposium TradReg2013)	http://www.sciencedirect.com/science/journal/03788741/158/part/PB
VI.4.4 The Art and Science of Traditional Medicine Part 1: TCM Today – A Case for Integration, Science 19 Dec. 2014: Vol. 346 no. 6216 p. 1569 Part 2: Multidisciplinary Approaches for Studying Traditional Medicine, Science 16 Jan 2015: Vol. 347 no. 6219 p. 337	http://www.sciencemaq.org/content/346/6216/1569.4.summary http://www.sciencemaq.org/content/347/6219/337.3.summary