



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 November 2014
EMA/HMPC/638812/2014
Procedure Management and Business Support Division

Committee on Herbal Medicinal Products (HMPC)

Agenda of the 24 November 2014 meeting

24 November 2014, 09:00 – 19:00, room 3E, *plenary*
(Assessors training on 25 November 2014, 09:00-17:00, 3E)

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.

- **Welcome to new participants**

new trainee at the B-CS-SCS

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

Resignation of Mariette Backes-Lies (LU member)

- **Election of Co-opted member to the HMPC with expertise in:**

- Paediatric medicine

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 November 2014 HMPC meeting, documenting anticipated restriction on involvement in relation to agenda topics and declarations of interest from members and alternates (EMA/HMPC/639151/2014)

- **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 24 November 2014 HMPC meeting - timetable, for order of topics <i>For adoption</i>	
I.1.2 Minutes of 29-30 September HMPC meeting <i>For adoption</i>	
I.1.3 Election of co-opted member - procedure for nomination/election of co-opted members for HMPC - Overview of expertise available in the HMPC, MLWP, ORGAM, Q DG - Nomination received for Paediatric medicine <i>For adoption</i>	Report: HMPC Chair
<u>I.2 Legislation and regulatory affairs</u>	
I.2.1 Revision procedure for List entries - email from legal department 7 November 2014 - draft list of minor/major changes <i>For discussion</i>	<i>See also I.6 and V.1.3</i>
I.2.2 New terminology for herbal monographs and list entries - email from legal department 8 October 2014 <i>For information</i>	
<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 Revision procedure for List entries <i>For discussion</i>	Report: E. van Galen <i>See I.2.1 and V.1.3</i>
<u>I.7 Co-ordination with EFSA</u>	

I.7.1 Report from 'HMPC strategic presidency meeting' held in Rome on 4-5 November 2014 - agenda - presentations <i>For information</i>	Report: M. Delbó, 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 MLWP work plan 2015 <i>For adoption</i>	Report: MLWP Chair See V.2.1
<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 on Echinaceae purpureae herba (and supporting documents: AR, LoR) <i>For adoption</i>	<i>MLWP proposed no changes to the existing LE.</i>
II.3.2 Monograph Betulae folium (and supporting documents: AR, LoR) <i>For adoption</i>	Rapporteur: Peer-reviewer:
<u>II.4 European Union herbal monographs (post finalisation)</u>	
<u>II.5 European Union herbal monographs, European Union list entries and public statements for adoption after public consultation</u>	
II.5.1 Monograph and list entry on Melaleucaea alternifoliae aetheroleum (and supporting documents: AR, LoR, OoC) <i>For adoption</i>	Rapporteur: M. Delbó Peer-reviewer: J. Viguet-Poupelloz
II.5.1 Monograph on Lichen islandicus (and supporting documents: AR, LoR, OoC) <i>For adoption</i>	Rapporteur: M. Heroutová Peer-reviewer: A. Vlietinck
<u>II.6 European Union herbal monographs, European Union list entries and public statements for adoption for release for public consultation</u>	
II.6.1 Monograph on Carvi aetheroleum (and supporting documents: AR, LoR) <i>For adoption</i>	
II.6.2 Monograph on Carvi fructus (and supporting documents: AR, LoR) <i>For adoption</i>	<i>See II.6.1</i>

II.6.3 Monograph on <i>Sabalisa serrulatae fructus</i> (and supporting documents: AR, LoR) For adoption	
<u>II.7 European Union herbal monographs, European Union list entries and public statements for discussion</u>	
II.7.1 MLWP recommendation to cancel the assessment work on <i>Cyani flos</i> (and supporting documents: presentation) <i>For adoption</i>	
II.7.2 MLWP recommendation to cancel the assessment work on <i>Myrtilli folium</i> (and supporting documents: Mo and AR) <i>For adoption</i>	
<u>II.8 Guidelines and other guidance documents</u>	
II.8.1 Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) - final public statement - overview of comments <i>For adoption</i>	<i>For final adoption.</i>
II.8.2 Public statement on the use of herbal medicinal products containing estragole - letter by SWP Chair - draft revised public statement <i>For adoption</i>	<i>Draft adoption for public consultation.</i>
II.8.3 Public statement on the use of herbal medicinal products containing pulegone and menthofuran - letter by SWP Chair - draft revised public statement <i>For adoption</i>	<i>Draft adoption for public consultation. See also IV.3.1</i>
<u>III. Quality</u>	
<u>III.1 Quality Drafting Group</u>	
III.1.1 Meeting report from Q DG meeting held on 12 November 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 <i>Postponed to January 2015</i>
III.1.3 Reflection paper on Benzene (class 1 solvent) as a potential impurity in solvents used for the manufacture of herbal preparations <i>For adoption</i>	Report: Q DG Chair

III.1.5 Q DG work plan 2015 <i>For adoption</i>	Report: Q DG Chair See V.2.1
<u>III.2 Co-ordination European Pharmacopeia</u>	
III.2.1 EDQM Expert Group 13A meeting to be held on 2-3 December 2014 - agenda <i>For information</i>	EDQM: M. Bald, U. Rose HMPC Observer: I. Chinou
III.2.2 EDQM: 50 years of leadership in the quality of medicines – paving the way for the future meeting held on 6-8 October 2014 - presentations <i>For information</i>	EDQM: M. Bald, U. Rose
III.2.3 HMPC observers at Ph. Eur. Expert groups 13A, 13B and TCM -email <i>For discussion</i>	
<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>	
<u>IV.3 Co-ordination with SWP</u>	
IV.3.1 Revision public statement on the use of herbal medicinal products containing pulegone and menthofuran <i>For discussion</i>	See II.8.3
<u>IV.4 Co-ordination with HCPWP/PCWP</u>	
IV.4.1 Draft Work plan for the European Medicines Agency Human Scientific Committees' Working Party with Healthcare Professionals' Organisations (HCPWP) - presentation <i>For adoption</i>	HMPC observer: S. Bager
IV.4.2 Draft Work plan for the European Medicines Agency Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) 2015 - presentation <i>For adoption</i>	HMPC observer: S. Bager

<u>IV.5 Co-ordination with Working Group on Quality Review of Documents (QRD)</u>	
IV.5.1 QRD template modifications tailored for THMPs - Annex III, SmPC, labelling and PL - <i>with minor changes submitted to QRD</i> - <i>email</i> - Annex III, SmPC, labelling and PL - <i>with further proposed changes by ORGAM</i> <i>For discussion/adoption</i>	Rapporteurs: E. Svedlund, P. Claeson, R. Laenger, E. v. Galen <i>See also V.1.2</i>
<u>V. Organisational matters</u>	
<u>V.1 Organisational Matters Drafting Group</u>	
V.1.1 Meeting report from ORGAM DG meeting held on 10 November 2014 <i>For adoption</i>	Report: ORGAM DG Chair
V.1.2 QRD template modifications tailored for THMP <i>For discussion/adoption</i>	Rapporteurs: E. Svedlund, P. Claeson, R. Laenger, E. v. Galen <i>See IV.5.1</i>
V.1.3 Revision procedure of List entries <i>For discussion</i>	Report: ORGAM DG Chair <i>See I.2.1</i>
V.1.4 ORGAM DG work plan 2015 <i>For adoption</i>	<i>See V.2.2</i>
<u>V.2 Working methodology</u>	
V.2.1 HMPC work plan 2015 and input for EMA work programme - HMPC work programme 2012-2015, current status - HMPC work plan 2015 - work plan 2015 MLWP - work plan 2015 Q DG - work plan 2015 ORGAM DG Add as per discussion <i>For adoption</i>	<i>See also II.1.2, III.1.3 and V.1.4</i>
V.2.2 '2015 EMA policy on the handling of declarations of interests of scientific committees' members and experts' - presentation <i>For information</i>	
V.2.3 Election of MLWP Chair in January 2015 - Mandate, objectives and rules of procedure for the HMPC Working Party on European Union Monographs and European Union List (MLWP) (EMEA/HMPC/379153/2005 Rev.2) <i>For information</i>	

V.2.4 Assessors' training 'European Union monographs- development and usages' on 25 November 2014 - agenda <i>For information</i>	Report: HMPC Chair Supported by: R. Länger, H. Neef, I. Chinou
V.2.5 Quality and finalisation of documents transmitted to HMPC for adoption - examples <i>For discussion</i>	
V.2.6 Survey on implementation of Dir. 2004/24/EC (status 2014) - Timetable - List of questions <i>For discussion</i>	
V.2.7 Minor change of time schedule for January 2015 meeting - email dated 18 November 2014 <i>For discussion</i>	
<u>VI. Other relevant business</u>	
<u>VI.1 Conferences, presentations & research projects</u>	
VI.1.1 Paving the way towards a coherent system, AESGP meeting in Brussels 7-8 October 2014 - report <i>For information</i>	Report: W. Knöss, I. Chinou, M. Delbó http://www.aesgp.eu/media/reports/London_report.pdf
<u>VI.2 International cooperation, collaboration with non-EU regulatory authorities</u>	
VI.2.1 7th annual meeting of IRCH to be held in Lisbon, Portugal on 2-4 December 2014 - draft agenda - programme <i>For information</i>	Report: HMPC Chair
<u>VI.3 Documents for information</u>	
VI.3.1 Table of Decisions from HMPC meeting held on 29-30 September 2014	
VI.3.2 Meeting report from HMPC meeting held on 29-30 September 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 26 - 28 November 2014	
VI.3.4 Table of Conclusions from MLWP meeting held on 30 September – 2 October 2014	
VI.3.5 Draft Minutes from MLWP meeting held on 30 September – 2 October 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 EU official languages	
VI.3.9 PCWP - Training session for patients and consumers involved in EMA activities (25 November 2014) - draft agenda	Observer: S. Bager
VI.3.10 PCWP - EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) meeting with all eligible organisations (26 November 2014) - draft agenda	Observer: S. Bager
VI.3.11 News item on 10 th anniversary HMPC at the EMA website	http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/11/news_detail_002211.jsp&mid=WC0b01ac058004d5c1
VI.3.12 NTP project: Report on Carcinogens (RoC) Concept: Goldenseal Root Powder	
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 Non-European traditional herbal medicines in Europe: A community herbal monograph perspective. L. Que <i>et al.</i> , <i>Journal of Ethnopharmacology</i> 156(2014) 107–114	