5 May 2014
EMA/HMPC/273396/2014 Corr. *
Procedure Management and Business Support Division

Committee on Herbal Medicinal Products (HMPC)

Agenda of the 5-6 May 2014 meeting

5 May 2014, 14:00 – 19:00, room 2A, *plenary*
6 May 2014, 08:30 – 12:30, room 2A, *plenary*
AESGP hearing 13:30-15:30, room 2A

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.

- **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 May 2014 HMPC meeting, documenting anticipated restriction on involvement in relation to agenda topics and declarations of interest from members and alternates (EMA/HMPC/220901/2014)

- **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 (EMA/127362/2006).

* Validation of BSS and feedback received on 30 April 2014 on page 2

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* = Change introduced after 29/4

I. Introduction	
I.1 Agenda, minutes	
I.1.1 Agenda of 5-6 May 2014 HMPC meeting - timetable, for order of topics *For adoption*	
I.1.2 Minutes of 24-25 March 2014 HMPC meeting *For adoption*	
I.2 Legislation and regulatory affairs	
I.2.1 *Validation of BSS and feedback received on 30 April 2014 - email with attachments *For information*	Report: HMPC Chair
I.3 Questions raised by HMPC members	
I.3.1 New QRD template for THMPs in mutual recognition and decentralised procedures - email *For discussion*	Report: P. Claeson
I.3.2 Presentation on Polycyclic Aromatic Hydrocarbons (PAH) - presentation *For discussion*	Rapporteur: A. P. Martins
I.4 Questions raised by companies	
I.5 Referral procedures	
II.Co-ordination issues	
II.1 General co-ordination issues	
II.1.1 ISO identification of medicinal products (IDMP) standards - EU TaskForce - presentation *For discussion*	Nomination of experts
II.2 Co-ordination with CHMP	
II.3 Co-ordination with SAWP	
II.4 Co-ordination with SWP	
II.4.1 Assessment of estragole and alkenyl benzenes - draft discussion paper - status report *For discussion*	

II.4.2 Report from SWP activities - report SWP meeting 28 January, 11-12 February 2014 - report SWP meeting 29-30 April 2014 *For discussion*	Report: O. Pelkonen To be tabled
II.4.4 Feedback re meeting of joint CVMP and CHMP 3R's expert group held on 4 March 2014 - agenda *For discussion*	Report: J. Wiesner, G. Laekeman
II.5 Co-ordination with PDCO	
II.6 Co-ordination with PRAC	
II.7 Co-ordination with PCWP	
II.8 Co-ordination with HCPWP	
II.9 Co-ordination with Medical Writers	
II.9.1 Status report on preparation and publication of ARSP - report *For discussion*	To be tabled
II.10 Co-ordination with COMP	
II.11 Co-ordination with CMDh	
II.12 Co-ordination with Eur. Com.	
II.12.1 Response letter from EC in relation to the EFSA scientific opinion related to hydroxyanthracene derivatives *For discussion*	
II.13 Co-ordination with EFSA	
III. Organisational matters	
III.1 Organisational Matters Drafting Group	
III.1.1 Virtual ORGAM DG meeting to be held on 13 May 2014 - agenda *For information*	Report: ORGAM DG Chair Postponed from 8 April 2014 To be tabled
III.1.5 Nominations of new ORGAM DG members	
III.2 Working methodology	
III.2.1 Progress with MMD implementation - email	
III.2.3 Agenda topics for informal HMPC meeting to be held in Rome on 4-5 November 2014 *For discussion*	Report: M. Delbò

III.2.4 Organisation of an assessors' training in 2014 for 20 participants *For discussion*	Report: HMPC Chair Supported by: R. Laenger, H. Neef, I. Chinou
III.2.5 Move to new EMA offices in July 2014 - presentation *For information*	To be tabled
III.2.6 Election of new MLWP Vice-Chair - Mandate, Objectives and Rules of Procedure of MLWP - HMPC Rules of Procedure - Procedure for the election of the MLWP Vice-Chair - Candidatures received from R. Länger, M. Delbò	
III.2.7 Survey 'Uptake of traditional use registration scheme and implementation of the provisions of Directive 2004/24/EC in EU Member States' (2013 data) - status report *For discussion*	
IV. Quality	
IV.1 Quality Drafting Group	
IV.1.1 Meeting report from Q DG meeting held on 10 April 2014 *For adoption*	Report: Q DG Chair
IV.1.2 Q&As on herbal preparations, which are covered by a pharmacopoeia monograph, but the monograph does not contain an assay - status report *For information*	
IV.2 European Pharmacopeia	
IV.2.1 Report from EDQM Expert Group 13B meeting held on 8-9 April 2014 - report *For discussion*	EDQM: M. Bald HMPC Observer: H. Neef
IV.2.2 Priority of herbal substances with a need of Ph. Eur. Monographs for submission to EDQM - draft priority list *For adoption*	
IV.2.3 EDQM conference 6-8 October 2014: 50 years of leadership in the quality of medicines - email *For information*	http://www.edqm.eu/en/Conference-50th-Anniversary-of-the-EDQM-1617.html
V. Safety & efficacy	
V.1 Report on MLWP activities	

V.1.1 Report on progress achieved Overview of status of MLWP assessment work *For discussion*	Report: MLWP Chair Tabled 2/5
V.1.2 Draft Public statement on plants containing substances associated with general safety concerns *For adoption*	

V.2 Community list entries transmitted to European Commission

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

V.3.1 Monograph Lupuli flos (and supporting documents: AR, LoR) *For adoption*	Rapporteur: A. Vlietinck Peer-reviewer: L. Anderson

V.4 Community herbal monographs (post finalisation)

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

V.5.1 Monograph on Arnicae flos (and supporting documents: AR, LoR, OoC) *For adoption*	Rapporteur: J. Wiesner Peer-reviewer: O. Pelkonen; Expert: H. Kairies
V.5.2 Monograph on Fucus vesiculosus (and supporting documents: AR, LoR, OoC) *For adoption*	Rapporteur: G. Laekeman; Peer-reviewer: W. Knöss; Experts: K. Geukens, L. Winjnhoven

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

V.6.1 Monograph on Agrimoniae herba (and supporting documents: AR, LoR) *For adoption*	Rapporteur: L. Anderson; Peer-reviewer: P. Claeson
V.6 2 Monograph on Capsici fructus (and supporting documents: AR, LoR) *For adoption*	Rapporteur: R. Länger; Peer-reviewer: M. Heroutová
V.6.3 Monograph on Lichen islandicus (and supporting documents: AR, LoR) *For adoption*	Rapporteur: M. Heroutová; Peer-reviewer: A. Vlietinck
V.6.6 Monograph on Pilosellae herba cum flore (and supporting documents: AR, LoR) *For adoption*	Rapporteur: O. Palomino; Peer-reviewer: G. Calapai

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

V.8 Guidelines

VI. Other relevant business

VI.1 Conferences, presentations & research projects	
VI.2 International cooperation, collaboration with non-EU regulatory authorities	
VI.3 Documents for information	
VI.3.1 Table of Decisions from HMPC meeting held on 24-25 March 2014	
VI.3.2 Meeting report from HMPC meeting held on 24-25 March 2014	http://www.ema.europa.eu/docs/en_GB/document_library/Committee_meeting_report/2014/04/WC500164759.pdf
VI.3.3 Draft agenda of MLWP meeting to be held on 6-8 May 2014	
VI.3.4 Table of Conclusions from MLWP meeting held on 25-27 March 2014	
VI.3.5 Draft Minutes from MLWP meeting held on 25-27 March 2014	To be tabled
VI.3.6 Overview of status of HMPC assessment work – priority list	Tabled 2/5
VI.3.7 Inventory of herbal substances for assessment work – alphabetical order	link
VI.3.8 Common names of herbal substances in all EU official languages	*Update available at next meeting in May 2014.*

VI.4 Any other information

VI.4.1 New permanent access cards	
VI.4.2 Abbreviations in HMPC minutes	http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/11/WC500155666.pdf
VI.4.3 Hearing with AESGP - proposed agenda - list of participants	Report: HMPC Chair, MLWP Chair
VI.4.4 Labelling of strength of Herbal medicinal products - email *For discussion*	Report: M. Delbo, HMPC Chair