24 March 2014
EMA/HMPC/174259/2014
Procedure Management and Business Support Division

Committee on Herbal Medicinal Products (HMPC)

Agenda of the 24-25 March 2014 meeting

24 March 2014, 14:00 – 19:00, room 3A, *plenary*
25 March 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.

- **New participants**

Maria Stavrou, nominated as new HMPC member for Cyprus
Erika Svedlund, new HMPC alternate member for Sweden

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 March 2014 HMPC meeting, documenting anticipated restriction on involvement in relation to agenda topics and declarations of interest from members and alternates (EMA/HMPC/138648/2014)

- **Note on access to documents**

Some documents mentioned in the agenda/minutes cannot be released at present following a request for access to documents under Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7455
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

I. Introduction

I.1 Agenda, minutes

I.1.1 Agenda of 24-25 March 2014 HMPC meeting *For adoption* - timetable, for order of topics	Tabled

I.1.2 Minutes of 27-28 January 2014 HMPC meeting (new version 12 March) *For adoption*	Circulated on 7 February 2014, MMD 2

I.2 Legislation and regulatory affairs

I.2.1 Validation of BSS and feedback received on 24 February 2014 from Dr. Mathes, Schwabe *For information*	Report: HMPC Chair

I.3 Questions raised by HMPC members

I.3.1 Following question by R. Länger dated 12 August 2013 on assessment of estragole and alkenyl benzenes - draft reflection paper *For discussion*	Rapporteurs: O. Pelkonen and J. Wiesner *See II.4.1, II.13.1* Tabled

I.3.2 Presentation on Polycyclic Aromatic Hydrocarbons (PAH) - presentation *For discussion*	Rapporteur: A. P. Martins MMD 1

I.3.3 Query on criteria for simplified registration procedure - email *For discussion*	Rapporteur: E. van Galen Tabled

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.3 Co-ordination with SAWP

II.4 Co-ordination with SWP

II.4.1 Scientific assessment of estragole	*Awaiting feedback from SWP (topic on the agenda of SWP meeting to be held on 20 March)*

II.4.2 Report from SWP activities *For discussion*	Report: O. Pelkonen MMD 2

II.4.3 Consultation until 24 March 2014 by excipients multidisciplinary group (lead by SWP) - Q&A and report on benzalkonium chloride - Q&A and report on gluten *For discussion*	Report: HMPC Chair Circulated on 7 March 2014, MMD 1 Comments due by 24 March 2014

II.4.4 Feedback re meeting of joint CVMP and CHMP 3R's expert group held on 4 March 2014 *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 *For discussion*	MMD 2

II.10 Co-ordination with COMP

II.11 Co-ordination with CMDh

II.12 Co-ordination with Eur. Com.

II.12.1 Letter to the EC in relation to the EFSA scientific opinion related to hydroxyanthracene derivatives *- response from EFSA *For information*	Report: HMPC Chair MMD 2

II.13 Co-ordination with EFSA

II.13.1 Scientific assessment of estragole	*See I.3.1, II.4.1*

III. Organisational matters

III.1 Organisational Matters Drafting Group

III.1.1 Meeting report from virtual ORGAM DG meeting held on 10 February 2014	Report: ORGAM DG Chair

For adoption	MMD 1

III.1.2 Q & A on the EU framework for (traditional) herbal medicinal products, including those from a non-European tradition *For adoption and publication*	Rapporteur: E. van Galen MMD 1

III.1.3 Template for AR on monographs (Rev.4) *For adoption and publication*	Rapporteur: M. Delbò Tabled

III.1.4 Template for exchange of information on marketed products *For adoption and publication*	Rapporteur: M. Delbò Tabled

III.1.5 Nominations of new ORGAM DG members - nominations received from HMPC members - email from DE 17/03/2014	MMD 2

III.2 Working methodology

III.2.1 Progress with MMD implementation - email	

III.2.2 Report on HMPC informal HMPC meeting held in Vilnius in December 2013 *For discussion*	Report: A. Kažemekaitis

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 Meeting dates in 2016-2017-2018 (Revisit time frames by end of the year) *For adoption*	 *See also III.2.6* MMD 1

III.2.5 Organisation of an assessors' training in 2014 for 20 participants *For discussion* - proposals from HMPC members (R. Länger on 3 February)	Report: HMPC Chair MMD 1

III.2.6 Update on progress of EMA reorganisation, especially the rationalisation of scientific committees secretariats *For discussion*	

III.2.7 Scientific Coordination Board meeting held on 10 March 2014 *For discussion*	Report: HMPC Chair

III.2.8 Move to new EMA offices in July 2014 III.2.8.1 Presentation on EMA move to 30 Churchill Place	MMD 2

IV. Quality

IV.1 Quality Drafting Group

IV.1.1 Meeting report from FtF Q DG meeting held on 12-13 February 2014 *For adoption*	Report: Q DG Chair MMD 2

IV.2 European Pharmacopoeia

IV.2.1 Report from EDQM Expert Group 13A meeting held on 4-5 March 2014 *For discussion* - report	EDQM: M. Bald HMPC Observer: I. Chinou Tabled

IV.2.2 Invitation to EDQM Expert Group 13B meeting to be held on 8-9 April 2013 *For information*	EDQM: M. Bald HMPC Observer: H. Neef

IV.2.3 Report from EDQM Expert Group TCM meeting held on 11-12 February 2014 *For discussion*	EDQM: M. Bald HMPC Observer: R. Länger

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

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 and list entry on Eleutherococci radix (and supporting documents: AR, LoR)	Rapporteur: D. Kalke Peer-reviewer: G. Calapai MMD 2

V.3.2 Monograph on Passiflorae herba (and supporting documents: AR, LoR) V.3.2.1 Non-clinical issues	Rapporteur: P. Claeson Peer-reviewer: I. Chinou MMD 2 Tabled

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 Eucalypti aetheroleum (and supporting documents: AR, LoR, OoC)	Rapporteur: J. Wiesner, Expert: R. Hönow Peer-reviewer: I. Chinou MMD 2

V.5.2 Monograph on Ginseng radix (and supporting documents: AR, LoR, OoC)	Rapporteur: R. Länger Peer-reviewer: W. Knöss MMD 2

V.5.3 Monograph on Ononidis radix (and supporting documents: AR, LoR, OoC)	Rapporteur: B. Jansone Peer-reviewer: M. Heroutová MMD 2

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

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

V.7.1 MLWP recommendation to cancel the assessment work on Crataegi fructus (no available information on marketed products with proven 30 years of medicinal use in the EU containing Crataegi fructus as single substance)	Report: MLWP Chair

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 27-28 January 2014	MMD 1
VI.3.2 Meeting report from HMPC meeting held on 27-28 January 2014	http://www.ema.europa.eu/docs/en_GB/document_library/Committee_meeting_report/2014/02/WC500161191.pdf
VI.3.3 Draft agenda of MLWP meeting to be held on 25-27 March 2014	Tabled

VI.3.4 Table of Conclusions from MLWP meeting held on 28-30 January 2014	MMD 1
VI.3.5 Draft Minutes from MLWP meeting held on 28-30 January 2014	MMD 1
VI.3.6 Overview of status of HMPC assessment work – priority list	link
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.3.9 Rapid alert on 24 February 2014 concerning product Golden Root 450 mg marketed as dietary supplement and found to contain undeclared sildenafil and yohimdina (IT)	MMD 2

VI.4 Any other information

VI.4.1 New permanent access cards - email	Information circulated on 7 March 2014, MMD 1

VI.4.2 Abbreviations in HMPC minutes	http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/11/WC500155666.pdf