26 September 2014
EMA/HMPC/481453/2014
Procedure Management and Business Support Division

Committee on Herbal Medicinal Products (HMPC)

Agenda of the 29-30 September 2014 meeting

29 September 2014, 14:00 – 19:00, room 3E, *plenary*
30 September 2014, 09:00 – 13:00, room 3E, *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 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.

Delegates are also to be shown an introduction presentation on the new building at 30 Churchill place.

- **Welcome to new participants**

New AD member in the B-CS-SCS
New member in legal support

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

Kapka Kaneva, new Bulgarian alternate
Zoi Karampourmpouni, new Greek alternate
Anna Cunney, now Irish member
Una Mockler, new Irish alternate
Ulrich Rose, new EDQM observer

- **Election of 3 Co-opted members to the HMPC with expertise in:**

- Clinical pharmacology
- Experimental/non-clinical pharmacology
- General and family medicine

See also I.1.3

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- **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 September 2014 HMPC meeting, documenting anticipated restriction on involvement in relation to agenda topics and declarations of interest from members and alternates (EMA/HMPC/564202/2014)

- **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	
I.1 Agenda, minutes	
I.1.1 Agenda of 29-30 September 2014 HMPC meeting Ver.1 - timetable, for order of topics *For adoption*	
I.1.2 Minutes of 30 June-1 July 2014 HMPC meeting *For adoption*	
I.1.3 Election of co-opted members - procedure for nomination/election of co-opted members for HMPC - Overview of expertise available in the HMPC, MLWP, ORGAM, Q DG - Nomination received for Clinical pharmacology - Nomination received for Experimental/non-clinical pharmacology - Nomination received for General and family medicine *For adoption*	Report: HMPC Chair
I.2 Legislation and regulatory affairs	
I.3 Questions raised by HMPC members	
I.3.1 New QRD template for THMPs in mutual recognition and decentralised procedures - email and attachment dated 25 August 2014 *For discussion*	Rapporteurs: E. Svedlund, P. Claeson, R. Laenger, E. v. Galen *See also V.1.1*

I.3.2 Request on mutual recognition procedure (MRP) – for a traditional herbal medicinal product (ART. 16a Directive 2001/83/EC) - email dated 10 September 2014 *For discussion*	Rapporteurs: E. v. Galen
I.3.3 Request on type of extract, acceptable manufacturing steps and defined amounts of key constituents for THMP - email dated 19 September 2014 *For discussion*	Rapporteurs: R. Länger
I.4 Questions raised by companies	
I.5 Referral procedures	
I.6 Co-ordination with Eur. Com.	
I.6.1 Revision procedure for List entries *For discussion*	Report: E van Galen *See also V.1.1* and *V.1.3*
I.7 Co-ordination with EFSA	
I.8 Other external Co-ordination	
II. Safety & efficacy	
II.1 Report on MLWP activities	
II.1.1 Report on progress achieved Overview of status of MLWP assessment work *For discussion*	Report: MLWP Chair
II.1.2 AESGP hearing MLWP May 2014 - report *For endorsement*	
II.2 Community list entries transmitted to European Commission	
II.3 Community herbal monographs for public consultation / final adoption after systematic review / revision	
N/A	
II.4 Community herbal monographs (post finalisation)	
II.5 Community herbal monographs, Community list entries and public statements for adoption after public consultation	
II.5.1 Monograph on Sisymbrii officinalis herba (and supporting documents: AR, LoR) *For adoption*	Rapporteur: Z. Biró-Sándor Peer-reviewer: B. Kroes *References available in MMD 22/22*
II.6 Community herbal monographs, Community list entries and public statements for adoption for release for public consultation	
II.6.1 Monograph on Crataegi folium cum flore (and supporting documents: AR, LoR) *For adoption*	Rapporteur: J. Wiesner Peer-reviewer: R. Länger

II.7 Community herbal monographs, Community list entries and public statements for discussion	
II.8 Guidelines and other guidance documents	
II.8.1 Revision public statement on the use of herbal medicinal products containing estragole - letter by SWP Chair - draft revised public statement *For discussion/adoption*	*See also IV.1.1*
II.8.2 Revision public statement on the use of herbal medicinal products containing pulegone and menthofuran - draft revised public statement *For discussion*	*See also IV.1.2*
II.8.3 Guidance on herbal medicinal products containing polycyclic aromatic hydrocarbons (PAH) - presentation - email dated 29 August 2014 *For discussion*	
III. Quality	
III.1 Quality Drafting Group	
III.1.1 Meeting report from Q DG meeting held on 10 September 2014 *For adoption*	Report: Q DG Chair
III.1.2 Proposal for amendments of 'Questions & answers on quality of herbal medicinal products/traditional herbal medicinal products' - correction of question 1 (microbiological) email dated 3 September 2014 - additional question on (stability), email dated 3 September 2014 *For discussion*	Report: Q DG Chair
III.1.3 draft Q DG work plan 2015 *For discussion*	Report: Q DG Chair *See also V.2.2*
III.2 Co-ordination European Pharmacopeia	
III.2.1 Report from EDQM Expert Group 13B meeting held on 23-24 September 2014 - agenda *For discussion*	EDQM: M. Bald, U. Rose HMPC Observer: H. Neef
III.2.2 Report from EDQM Expert Group TCM meeting held on 16-17 September 2014 - Summary of decisions *For discussion*	EDQM: M. Bald, U. Rose HMPC Observer: R. Länger

IV. Internal Co-ordination with committee and working parties	
IV.1 Co-ordination with SWP	
IV.1.1 Revision public statement on the use of herbal medicinal products containing estragole - *For discussion*	Report: HMPC Chair, HMPC observer at SWP: O. Pelkonen *See also II.8.1*
IV.1.2 Revision public statement on the use of herbal medicinal products containing pulegone and menthofuran - *For discussion*	Report: HMPC Chair *See also II.8.2*
V. Organisational matters	
V.1 Organisational Matters Drafting Group	
V.1.1 Meeting report from ORGAM DG meeting held on 9 September 2014 *For adoption*	Report: ORGAM DG Chair
V.1.2 Revision of HMPC Templates - Community herbal monograph - Community list entry *For adoption*	Report: ORGAM DG Chair Rapporteur: M. Delbó
V.1.3 Revision procedure of List entries *For discussion*	Report: ORGAM DG Chair
V.1.4 Draft ORGAM DG work plan 2015 *For discussion*	*See also V.2.2*
V.2 Working methodology	
V.2.1 Assessors' training 'Community monographs-development and usages' on 25 November 2014 - draft agenda *For adoption*	Report: HMPC Chair Supported by: R. Länger, H. Neef, I. Chinou
V.2.2 HMPC work plan and input for EMA work programme - HMPC work programme 2012-2015 - draft template CXMP (Committee XX) work plan - draft work plans 2015 MLWP, Q DG, ORGAM DG *For discussion*	http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2011/12/WC500119957.pdf *See also III.1.3 and V.1.4*
V.2.3 Informal HMPC meeting to be held in Rome on 4-5 November 2014 - draft agenda *For adoption*	Report: M. Delbó
V.2.4 Quality and finalisation of documents transmitted to HMPC for adoption - examples *For discussion*	

VI. Other relevant business	
VI.1 Conferences, presentations & research projects	
VI.1.1 Paving the way towards a coherent system, AESGP meeting in Brussels 7-8 October 2014 - agenda *For information*	Report: W. Knöss, I. Chinou, M. Delbó EMA: H. Boone http://www.aesgp.eu/media/programmes/AESGP_Conference_October_-_FINAL_4.pdf
VI.2 International cooperation, collaboration with non-EU regulatory authorities	
VI.2.1 7th annual meeting of IRCH to be held in Lisbon, Portugal on 2-4 December 2014 - invitation and draft agenda *For discussion*	Report: HMPC Chair
VI.3 Documents for information	
VI.3.1 Table of Decisions from HMPC meeting held on 30 June – 1 July 2014	
VI.3.2 Meeting report from HMPC meeting held on 30 June – 1 July 2014	http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2014/07/WC500169491.pdf
VI.3.3 Draft agenda of MLWP meeting to be held on 30 September - 2 October 2014	
VI.3.4 Table of Conclusions from MLWP meeting held on 1-3 July 2014	
VI.3.5 Draft Minutes from MLWP meeting held on 1-3 July 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 Overview on the paediatric uses of herbal medicinal products	Rapporteur: S. Girotto
VI.3.10 ARSP for publication (EN) and translations - *Juglans regia* L., folium - *Origanum dictamnus* L., herba - *Marrubium vulgare* L., herba	
VI.3.11 Update from the European Commission's working group on health claims, 16 May 2014	
VI.3.12 PCWP and HCPWP joint meeting (16 September 2014)	Observer: S. Bager
VI.3.13 PCWP and HCPWP workshop (17 September 2014)	
VI.3.14 First HMPC agenda 23-24 September 2004	
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