



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 June 2014
EMA/HMPC/355484/2014
Procedure Management and Business Support Division

Committee on Herbal Medicinal Products (HMPC)

Agenda of the 30 June-1 July 2014 meeting

30 June 2014, 14:00 – 19:00, room 3A, *plenary*
1 July 2014, 08:30 – 12:30, room 3A, *plenary*
(Visit to 30 Churchill place on 1 July 2014, 19:00)

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 June/July 2014 HMPC meeting, documenting anticipated restriction on involvement in relation to agenda topics and declarations of interest from members and alternates (EMA/HMPC/382257/2014)

- **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).



* = Change introduced after 23/6

I. Introduction	
<u>I.1 Agenda, minutes</u>	
I.1.1 Agenda of 30 June-1 July 2014 HMPC meeting - timetable, for order of topics <i>For adoption</i>	Tabled
I.1.2 Minutes of 5-6 May 2014 HMPC meeting <i>For adoption</i>	Tabled
<u>I.2 Legislation and regulatory affairs</u>	
I.2.1 Validation of the BSS - assessment of reliability and implications for specific monographs - draft assessment report - letter dated 18 Dec 2013 - response with attachments received on 30 April 2014 - list of additional data/literature - positions from Rapporteurs <i>For discussion</i>	Report: HMPC Chair Tabled
<u>I.3 Questions raised by HMPC members</u>	
I.3.1 New QRD template for THMPs in mutual recognition and decentralised procedures - email <i>For discussion</i>	Report: P. Claeson Tabled
<u>I.4 Questions raised by companies</u>	
<u>I.5 Referral procedures</u>	
II.Co-ordination issues	
<u>II.1 General co-ordination issues</u>	
<u>II.2 Co-ordination with CHMP</u>	
<u>II.3 Co-ordination with SAWP</u>	
<u>II.4 Co-ordination with SWP</u>	
II.4.1 Assessment of estragole and alkenyl benzenes - draft discussion paper - status report - presentation - letter to SWP Chair - HMPC PS on the use of HMPC cont estragole <i>For discussion</i>	Tabled

<p>II.4.2 Revision on Public Statement on the use of herbal medicinal products containing pulegone and menthofuran</p> <ul style="list-style-type: none"> - discussion paper toxicological assessment - comments received during May written procedure - draft revised public statement - letter to SWP Chair - presentation - menthae piperitae aetheroleum - monograph <p><i>For discussion</i></p>	Tabled
<u>II.5 Co-ordination with PDCO</u>	
<u>II.6 Co-ordination with PRAC</u>	
<u>II.7 Co-ordination with PCWP</u>	
<u>II.8 Co-ordination with HCPWP</u>	
<u>II.9 Co-ordination with Medical Writers</u>	
<u>II.10 Co-ordination with COMP</u>	
<u>II.11 Co-ordination with CMDh</u>	
<u>II.12 Co-ordination with Eur. Com.</u>	
<u>II.13 Co-ordination with EFSA</u>	
III. Organisational matters	
<u>III.1 Organisational Matters Drafting Group</u>	
<p>III.1.1 Virtual ORGAM DG meeting to be held on 13 May 2014</p> <ul style="list-style-type: none"> - meeting report <p><i>For information</i></p>	<p>Report: ORGAM DG Chair</p> <p>Meeting 10 June postponed</p> <p>Tabled</p>
<u>III.2 Working methodology</u>	
<p>III.2.2 Nomination of co-opted members</p> <ul style="list-style-type: none"> - procedure for nomination co-opted members for HMPC, 12 Nov 04 - Overview of expertise available in the HMPC <p><i>For discussion</i></p>	<p>Report: HMPC Chair</p> <p>Tabled</p>
<p>III.2.3 Organisation of an assessors' training in 2014 for 20 participants</p> <ul style="list-style-type: none"> - agenda <p><i>For discussion</i></p>	<p>Report: HMPC Chair</p> <p>Supported by: R. Länger, H. Neef, I. Chinou</p>
<p>III.2.4 Move to new EMA offices in July 2014</p> <ul style="list-style-type: none"> - presentation <p><i>For information</i></p>	

<p>III.2.5 Survey 'Uptake of traditional use registration scheme and implementation of the provisions of Directive 2004/24/EC in EU Member States' (2013 data)</p> <p>- status report</p> <p><i>For discussion</i></p>	<p>Tabled</p>
<p>III.2.6 HMPC work plan and input for EMA work programme 2015</p> <p>- presentation</p> <p>- current work programmes HMPC, MLWP, Q DG, ORGAM DG</p> <p><i>For discussion</i></p>	<p>EMA: Roberto De Lisa</p> <p>Tabled</p>
<p><u>IV. Quality</u></p>	
<p><u>IV.1 Quality Drafting Group</u></p>	
<p>IV.1.1 Meeting report from Q DG meeting held on 18 June 2014</p> <p><i>For adoption</i></p>	<p>Report: Q DG Chair</p> <p>Tabled</p>
<p>IV.1.2 Q&A on herbal substances that do not contain an assay in the Ph.Eur. monograph.</p> <p><i>For adoption</i></p>	<p>For inclusion into Quality Q and A document (EMA/HMPC/41500/2010)</p> <p>Tabled</p>
<p>IV.1.3 Q&A on herbal preparation that do not contain an assay in the Ph.Eur. monograph.</p> <p><i>For adoption</i></p>	<p>For inclusion into Quality Q and A document (EMA/HMPC/41500/2010)</p> <p>Tabled</p>
<p>IV.1.4 Q&A on declaration of DER and extraction solvent in case of fresh herbal substances</p> <p><i>For adoption</i></p>	<p>For inclusion into Quality Q and A document (EMA/HMPC/41500/2010)</p> <p>Tabled</p>
<p>IV.1.5 Q DG comments on EDQM monograph on fresh herbal drugs</p> <p><i>For adoption</i></p>	<p>Tabled</p>
<p><u>IV.2 European Pharmacopeia</u></p>	
<p>IV.2.1 Report from EDQM Expert Group 13A meeting held on 2-3 June 2014</p> <p>- group 13A summary of decisions</p> <p><i>For discussion</i></p>	<p>EDQM: M. Bald HMPC Observer: I. Chinou</p> <p>Tabled</p>
<p>IV.2.2 Report from EDQM Expert Group TCM meeting held on 5-6 June 2014</p> <p>- group TCM summary of decisions</p> <p><i>For discussion</i></p>	<p>EDQM: M. Bald HMPC Observer: R. Länger</p> <p>Tabled</p>
<p>IV.2.3 Priority of herbal substances with a need of Ph. Eur. Monographs for submission to EDQM</p> <p>- priority list (EMA/HMPC/328288/2014) submitted 28/05/14</p> <p><i>For information</i></p>	<p>Tabled</p>

IV.2.4 Request by EDQM on isomenthone <i>For discussion</i>	Tabled	
<u>V. Safety & efficacy</u>		
<u>V.1 Report on MLWP activities</u>		
V.1.1 Report on progress achieved Overview of status of MLWP assessment work <i>For discussion</i>	Report: MLWP Chair	
V.1.2 Appointment for Rapporteurs and Peer-reviewer		
Herbal substance	Rapporteur	Peer-reviewer
Arctii radix (M)		
Boldi folium (M)		
Caryophyllii flos (PS)		
Caryophyllii floris aetheroleum (M)		
Centaurii herba (M)		
Curcumae longae rhizoma (M)		
Equiseti herba (M)		
Hamamelidis folium et cortex aut ramunculus destillatum (M+LE)		
Hamamelidis cortex (M)		
Hamamelidis folium (M)		
Harpagophyti radix (M)		
Hippocastani cortex (M)		
Hippocastani semen (M)		
Orthosiphonis folium (M)		
Leonuri cardiaca herba (M)		
Mate folium (M)		
Polypodii rhizoma (M)		
Salicis cortex (M)		
Sideritis herba		
Taraxaci radix cum herba (M)		
Taraxaci folium (M)		
Thymi aetheroleum (M + LE)		
Trigonellae foenugraeci semen (M)		
Vitis viniferae folium (M + LE)		
Myrtilli fructus, myrtilli recens, myrtilli fructus siccus (M)		
V.2 Community list entries transmitted to European Commission		
V.3 Community herbal monographs for public consultation/final adoption after systematic review/revision		
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 Rosae flos (and supporting documents: AR, LoR, references 0/32) <i>For adoption</i>	Tabled	
V.6 Community herbal monographs, Community list entries and public statements for adoption for release for public consultation		

V.6.1 Monograph on Capsici fructus (and supporting documents: AR, LoR, OoC) <i>For adoption/discussion</i>	Tabled
V.6.2 Monograph on Eschscholziae herba cum flore (and supporting documents: AR, LoR) <i>For adoption</i>	Tabled
V.6.3 Monograph on Matricariae aetheroleum (and supporting documents: AR, LoR) <i>For adoption</i>	Tabled
V.6.4 Monograph on Matricariae flos (and supporting documents: AR, LoR) <i>For adoption</i>	Tabled
V.6.5 Monograph on Picrorhizae kurroae rhizoma (and supporting documents: LoR, PS) <i>For adoption</i>	Tabled
V.6.6 *Monograph on Pilosellae herba cum flore (and supporting documents: AR, LoR) <i>For adoption</i>	Tabled
<u>V.7 Community herbal monographs, Community list entries and public statements for discussion</u>	
<u>V.8 Guidelines</u>	
<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>	
<u>VI.3 Documents for information</u>	
VI.3.1 Table of Decisions from HMPC meeting held on 5-6 May 2014	Tabled
VI.3.2 Meeting report from HMPC meeting held on 5-6 May 2014	http://www.ema.europa.eu/docs/en_GB/document_library/Committee_meeting_report/2014/05/WC500167583.pdf Tabled
VI.3.3 Draft agenda of MLWP meeting to be held on 2-3 July 2014	
VI.3.4 Table of Conclusions from MLWP meeting held on 6-8 May 2014	Tabled
VI.3.5 Draft Minutes from MLWP meeting held on 6-8 May 2014	Tabled
VI.3.6 Overview of status of HMPC assessment work – priority list	

VI.3.7 Inventory of herbal substances for assessment work – alphabetical order	
VI.3.8 Common names of herbal substances in all EU official languages	Tabled
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