



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

16 September 2013  
EMA/HMPC/566094/2013  
Committee on Herbal Medicinal Products (HMPC)

## Committee on Herbal Medicinal Products (HMPC)

### Draft Agenda of the 16-17 September 2013 meeting

Chair: Werner Knöss

16 September 2013, 14:00 – 19:00, room **4A**

17 September 2013, 8:30 – 12:00, room **4A**

- **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.

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

Tina Engraff, European Commission representative at HMPC (Unit D-6)

- **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 2013 HMPC meeting, documenting anticipated restriction on involvement in relation to agenda topics and declarations of interest from members and alternates (EMA/564107/2013)



<b>I. Introduction</b>		* = Change introduced following last pre-meeting mailing
<b><u>I.1 Agenda, minutes</u></b>		
I.1.1 Agenda of 16-17 September 2013 HMPC meeting (EMA/HMPC/566094/2013): <b>for adoption</b>	To be tabled at meeting	
I.1.2 Time schedule of 16-17 September 2013 HMPC meeting (EMA/HMPC/538032/2013 Vers.1): <b>for adoption</b>	To be tabled at meeting	
I.1.3 Draft minutes of 8-9 July 2013 HMPC meeting (EMA/HMPC/453569/2013): <b>for adoption</b>	Circulated on 5 August 2013 Premail 2 – 10 September 2013	
<b><u>I.2 Legislation and regulatory affairs</u></b>		
<b><u>I.3 Questions raised by HMPC members</u></b>		
I.3.1 Question by R. Länger dated 12 August 2013 in relation to estragole amounts in herbal extracts and average intake of estragole by food: <b>for discussion</b>	Report by R. Länger Premail 1 – 2 September 2013	
- Email		
- *Public statement on the use of herbal medicinal products containing estragole (EMEA/HMPC/137212/2005)	<a href="http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2010/04/WC500089960.pdf">http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2010/04/WC500089960.pdf</a>	
<b><u>I.4 Questions raised by companies</u></b>		
I.4.1 Registration of combination herbal medicinal products in relation to the marketing authorisations for medicinal products	Report by /HMPC Chair In the presence of T. Engraff (Eur Com) In the presence of	
I.4.1.1 Letter from dated 22 July 2013	Premail 1 – 2 September 2013	
I.4.1.2 Draft response letter to dated 16 September 2013 (EMA/560660/2013): <b>for adoption</b>	To be tabled at meeting	
<b><u>I.5 Referral procedures</u></b>		
<b>II. Co-ordination issues</b>		
<b><u>II.1 General co-ordination issues</u></b>		
<b><u>II.2 Co-ordination with CHMP</u></b>		
<b><u>II.3 Co-ordination with SAWP</u></b>		

<b><u>II.4 Co-ordination with SWP</u></b>		
II.4.1 SWP comments on draft public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) (EMA/HMPC/893108/2011): <b>for discussion</b>		<i>Rapporteurs: J. Wiesner/O. Pelkonen</i> <i>Outcome written procedure at SWP</i>
II.4.1.1 Public statement (EMA/HMPC/893108/2011)		Premail 2 – 10 September 2013
II.4.1.1.1 Overview of comments (EMA/HMPC/280542/2013)		Premail 2 – 10 September 2013
II.4.1.2 SWP comments dated 22 July and 1 August 2013		Premail 2 – 10 September 2013
II.4.1.3 HMPC Rapporteurs response to SWP comments		Premail 2 – 10 September 2013
<del>II.4.2 HMPC comments on ethanol report (EMA/281628/2013) within planned revision of the Guideline on excipients in the label and package leaflet of medicinal products for human use (CPMP/463/00): <b>for discussion</b></del>		<del><i>Report by HMPC Chair /O. Pelkonen</i></del>  <i>Postponed to November meeting</i>
<b><u>II.5 Co-ordination with PDCO</u></b>		
<b><u>II.6 Co-ordination with PRAC</u></b>		
<b><u>II.7 Co-ordination with PCWP</u></b>		
<b><u>II.8 Co-ordination with HCPWP</u></b>		
<b><u>II.9 Co-ordination with MIS</u></b>		
<b><u>II.10 Co-ordination with COMP</u></b>		
<b><u>II.11 Co-ordination with CMDh</u></b>		
<b><u>II.12 Co-ordination with Eur. Com.</u></b>		
<b>III. Organisational matters</b>		
<b><u>III.1 Organisational Matters Drafting Group</u></b>		
III.1.1 ORGAM DG (virtual) meeting to be held on 15 October 2013		<i>Report by ORGAM DG Chair</i>
III.1.1.1 Draft agenda (EMA/HMPC/466059/2013): <b>for adoption</b>		Premail 2 – 10 September 2013
III.1.2 Draft ORGAM DG 2014 work programme (EMA/HMPC/544796/2013): <b>for adoption</b>		<i>Report by ORGAM DG Chair</i>  Premail 2 – 10 September 2013
<b><u>III.2 Working methodology</u></b>		
III.2.1 Appointment of new members in MLWP		<i>Report by HMPC Chair/MLWP Chair</i>
III.2.1.1 Procedural aspects for the appointment of new members in the MLWP: <b>for information</b>		

III.2.1.2 Nominations received from HMPC members with CV: <b>for discussion</b>	
- Nomination of by A. P. Martins and H. Pinto Ferreira dated 31 July 2013	Premail 1 – 2 September 2013
- Nomination of by N. Grigoras dated 30 August 2013	Premail 1 – 2 September 2013
- Nomination of by Z. Biró-Sándor dated 30 August 2013	Premail 1 – 2 September 2013
III.2.2 Projects under HMPC work programme for 2012-2015 (EMA/HMPC/501139/2011)	
<a href="http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2011/12/WC500119957.pdf">http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2011/12/WC500119957.pdf</a>	
III.2.2.1 Forward planning & prioritisation – herbal substances, preparations and combinations for which a monograph should be established in the next years	
- Preparation of a public statement for substances associated with basic safety concerns and not suited to the traditional use system: <b>for discussion</b>	<i>Appointment of Rapporteurs</i>
III.2.3 Discussion on international cooperation in the field of herbal medicines: <b>for discussion</b>	
<i>Report by HMPC Chair/HMPC secretariat</i>	
III.2.3.1 Draft proposal for HMPC international cooperation	To be tabled at meeting
- Key areas to strengthen the international profile of the EMA in the field of herbal medicine (EMA/HMPC/396677/2013)	
III.2.4 Informal HMPC meeting to be held 10-11 December 2013 in Vilnius, Lithuania: <b>for discussion</b>	
<i>Report by A. Kažemekaitis</i>	
- Draft agenda	To be tabled at meeting
*III.2.5 Presentation on the restructuring of the Agency organisational: <b>for discussion</b>	
<i>Report by</i>	
III.2.6 Measures to implement EMA policy on publication of agendas and minutes of scientific committees: <b>for discussion</b>	
<i>Report by</i>	
III.2.7 List of acronyms used in HMPC minutes (EMA/HMPC/441838/2013): <b>for discussion</b>	
<i>Report by HMPC secretariat</i>	
Premail 2 – 10 September 2013	
III.2.8 Election of HMPC Chair and Vice-Chair	
<i>Report by HMPC secretariat</i>	
- Procedure for the election of the HMPC Chair and HMPC Vice-Chair on 11 November (EMA/544790/2013): <b>for adoption</b>	Premail 2 – 10 September 2013
*III.2.9 Information about reflections on the management of declarations of interests and conflicts of interests: <b>for discussion</b>	
<i>Report by</i>	

---

### **III.3 Interaction with interested parties**

---

III.3.1 Applications for IP to the HMPC: <b>for adoption</b>	<i>Report by HMPC secretariat</i>
III.3.1.1 GP-TCM Research Association dated 12 August 2013	Premail 1 – 2 September 2013 Premail 2 – 10 September 2013
- Interested parties to the HMPC, in particular for the field of non-European Traditional Herbal Medicine (EMA/HMPC/150135/2013)	Premail 1 – 2 September 2013
III.3.1.2 EUCOPE dated 2 August 2013	Premail 1 – 2 September 2013
- Request EUCOPE as Interested Party of HMPC	Premail 1 – 2 September 2013
- International Non Profit Association Articles of Association	Premail 1 – 2 September 2013
- EUCOPE International Non Profit Association By-laws	

---

### **IV. Quality**

---

#### **IV.1 Quality Drafting Group**

---

*Annual meeting of HMPC Q DG/Chairs of Eur. Ph. Expert Groups 13A, 13B & TCM: 17 September 2013, 13:00 – 16:00 (room 2G) See IV.1.2*

---

IV.1.1 Q DG (virtual) meeting held on 25 July 2013	<i>Report by H. Neef</i>
IV.1.1.1 Meeting report (EMA/HMPC/488194/2013): <b>for adoption</b>	Premail 2 – 10 September 2013
IV.1.2 Annual meeting HMPC Q DG/Chairs of Eur. Ph. Expert Groups 13A, 13B & TCM	<i>To be held during the meeting of the MLWP Tuesday, 17 September 2013 13:00 – 16:00 (room 2G)</i>
IV.1.2.1 Draft agenda (EMA/HMPC/394564/2013): <b>for adoption</b>	Premail 2 – 10 September 2013
<del>IV.1.3 Draft Q&amp;A on benzene in extracts (EMA/HMPC/462947/2013): <b>for adoption</b></del>	<del><i>Rapporteur: K. Reh</i></del> <i>Report by H. Neef</i> <i>Postponed to November meeting</i>
IV.1.4 Draft Q DG work programme 2014 (EMA/HMPC/473889/2013): <b>for adoption</b>	Premail 2 – 10 September 2013

---

#### **IV.2 European Pharmacopoeia**

---

*Annual meeting of HMPC Q DG/Chairs of Eur. Ph. Expert Groups 13A, 13B & TCM: 17 September 2013, 13:00 – 16:00 (room 2G) See IV.1.2*

---

---

## V. Safety & efficacy

---

### V.1 MLWP

---

*The next meeting of the MLWP will be held 17-19 September 2013*

*See VII.3.2*

---

### **Status on Community herbal monographs, Community list entries, public statements, appointment of new Rapporteurs and Peer-reviewers**

---

V.1.1 Overview of status of MLWP assessment work (EMA/HMPC/519580/2007): **for discussion**

*Report by MLWP Chair  
Status July 2013  
Preamble 2 – 10 September 2013*

V.1.1.1 Appointment of Rapporteurs

N/A

V.1.1.2 Appointment of Peer-reviewers

N/A

---

### **Other relevant topics**

---

V.1.2 List entry adoption – consistency and transparency in the assessment of available data and options to improve data availability: **for discussion**

*Report by MLWP Chair*

V.1.2.1 Draft overview on available genotoxicity data for herbal substances for inclusion into the Community list (EMA/HMPC/283128/2013)

*Report by O. Pelkonen/J. Wiesner  
Preamble 1 – 2 September 2013*

- Draft evaluation of genotoxicity data for herbal substances including list of questions on possible revision of the assessment approach

To be tabled at meeting

- Presentation by O. Pelkonen

To be included in the post-meeting mailing

V.1.2.2 Discussion on options to improve the genotoxicity data situation

*Report by HMPC secretariat/  
L. Anderson*

---

V.1.3 Timelines for revision of monographs due to new scientifically relevant data (validation BSS): **for discussion**

*Report by HMPC Chair/MLWP Chair*

- Reflection paper on the reasons and timelines for revision of final Community herbal monographs and Community list entries (EMA/HMPC/326440/2007 Rev.2)

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Other/2009/12/WC500017022.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/12/WC500017022.pdf)

---

\*V.1.4 Draft MLWP 2014 work programme (EMA/HMPC/554850/2013): **for adoption**

*Report by HMPC Chair/MLWP Chair  
To be tabled at meeting*

---

### **V.2 Community list entries transmitted to European Commission**

---

### **V.3 Community herbal monographs for adoption after systematic review/revision**

---

### **V.4 Community herbal monographs for adoption (post finalisation)**

---

---

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

---

**V.5.1 Andrographidis paniculatae folium**

*Rapporteur: Z. Biró-Sándor; Peer-reviewer: B. Kroes*

*No comments received during public consultation*

V.5.1.1 Assessment report

Premail 2 – 10 September 2013

V.5.1.1.1 List of references

- available references 120/150

Premail 2 – 10 September 2013

V.5.1.2 Public statement

Premail 2 – 10 September 2013

---

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

---

**V.6.1 Rosae flos**

*Rapporteur: I. Chinou; Peer-reviewer: H. Pinto Ferreira*

V.6.1.1 Assessment report

Premail 2 – 10 September 2013

V.6.1.1.1 List of references

Premail 2 – 10 September 2013

V.6.1.2 Monograph

Premail 2 – 10 September 2013

---

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

---

---

**V.8 Reference documents for the preparation of Community herbal monographs, Community list entries, public statements and related documents**

---

**V.9 Guidelines**

V.9.1 Revision of the guideline on the use of the CTD format in the preparation of a registration application for traditional herbal medicinal products (EMA/HMPC/71049/2007 Rev. 1): **for discussion**

*Rapporteur: A. Cunney*

*Appointment of a Co-Rapporteur and involvement of ORGAM DG*

V.9.1.1 Draft concept paper (EMA/HMPC/555178/2013)

Premail 2 – 10 September 2013

---

**VI. Non-clinical assessment/issues**

---

---

**VII. Other relevant business**

---

**VII.1 Conferences, presentations & research projects**

---

VII.1.1 Organisation of international symposium on herbal medicines by BfArM to be held on 30 September - 2 October 2013 in Bonn, Germany

*Report by J. Wiesner*

- Programme

Premail 2 – 10 September 2013

---

**VII.2 International cooperation, collaboration with non-EU regulatory authorities**

---

---

### **VII.3 Documents for information**

---

#### VII.3.1 HMPC meeting held 8-9 July 2013

VII.3.1.1 Table of Decisions (EMA/HMPC/419290/2013)      Preamail 1 – 2 September 2013

VII.3.1.2 Meeting report (EMA/HMPC/428663/2013)      Preamail 1 – 2 September 2013

---

VII.3.2 Draft agenda of MLWP meeting to be held 17-19 September 2013 (EMA/HMPC/430303/2013)      Preamail 1 – 2 September 2013

---

#### VII.3.3 MLWP meeting held 9-11 July 2013

VII.3.3.1 Table of Conclusions (EMA/HMPC/422555/2013)      Preamail 1 – 2 September 2013

VII.3.3.2 Minutes (EMA/HMPC/441130/2013)      Preamail 1 – 2 September 2013

---

VII.3.4 Overview of status of HMPC assessment work – priority list (EMA/HMPC/278067/2006)      *Status July 2013 (post-meeting)*  
Preamail 2 – 10 September 2013

---

VII.3.5 Inventory of herbal substances for assessment work – alphabetical order (EMA/HMPC/494079/2007)      *Status July 2013 (post-meeting)*  
Preamail 2 – 10 September 2013

---

VII.3.6 Common names of herbal substances in all EU official languages (EMA/HMPC/95087/2011)      *Status July 2013*  
Preamail 1 – 2 September 2013

---

VII.3.7 EMA decision P/0156/2013 of 5 July 2013, agreement of a paediatric investigation plan and on the granting of a deferral for dry extract from *Betulae cortex* (EMA/346350/2013)      [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/PIP\\_decision/WC500147624.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/PIP_decision/WC500147624.pdf)

---

\*VII.3.8 EMA decision P/0184/2013 of 31 July 2013 on a product specific waiver for *capsici acris extractum spissum normatum* (EMA/418994/2013)      [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/PIP\\_decision/WC500148524.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/PIP_decision/WC500148524.pdf)

---

VII.3.9 Meeting report of the MLWP-AESGP hearing held on 14 May 2013 (EMA/HMPC/413550/2013)      [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Report/2013/07/WC500146577.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Report/2013/07/WC500146577.pdf)

---

#### VII.3.10 Assessment report summaries for the public (ARSP) from July 2013

- Walnut Leaf - summary for the public (EMA/432131/2013)      To be tabled at meeting

- Dittany of Crete herb - summary for the public (EMA/441263/2013)      To be tabled at meeting

- White horehound - summary for the public (EMA/446032/2013)      To be tabled at meeting

---

VII.3.11 Assessment report summaries for the public (ARSP)      *After translation by CdT followed by review by HMPC members from 23 August to 13 September*

- Psyllium seed – summary for the public (EMA/322933/2013)      Preamail 2 – 10 September 2013

---



- Melissa leaf – summary for the public (EMA/HMPC/310761/2013)	Premail 2 – 10 September 2013
- Ispaghula husk –summary for the public (EMA/313600/2013)	Premail 2 – 10 September 2013
- Ispaghula seed –summary for the public (EMA/313692/2013)	Premail 2 – 10 September 2013
- Eucalyptus leaf – summary for the public (EMA/300235/2013)	Premail 2 – 10 September 2013
- Chicory root – summary for the public (EMA/HMPC/286842/2013)	Premail 2 – 10 September 2013
- Woody nightshade – summary for the public (EMA/261736/2013)	Premail 2 – 10 September 2013
- Guarana seed – summary for the public (EMA/284498/2013)	Premail 2 – 10 September 2013
- *Ginger – summary for the public (EMA/296580/2012)	To be included in the post-meeting mailing
- *Lavender oil – summary for the public (EMA/530968/2012)	To be included in the post-meeting mailing
- *Arctic root - summary for the public (EMA/289537/2012)	To be included in the post-meeting mailing
VII.3.12 Draft agenda PCWP/HCPWP joint meeting 25 September 2013 (EMA/448547/2013)	Premail 2 – 10 September 2013
VII.3.13 Draft agenda workshop on patient's voice in the evaluation of medicines 26 September 2013 (EMA/437597/2013)	Premail 2 – 10 September 2013
<b><u>VII.4 Any other information</u></b>	