31 May 2016
EMA/HMPC/385080/2016
Procedure Management and Committees Support Division

# Committee on Herbal Medicinal Products (HMPC)

## Minutes of the meeting on 4-5 April 2016

Chair: Werner Knöss – Vice-Chair: Marisa Delbò

4 April 2016 14:00 – 19:00, 3E

5 April 2016 08:30 – 12:30, 3E

(AESGP hearing at MLWP: 5 April 2016 13:30 – 15:30, Room 3E)

**Health and safety information**

In accordance with the Agency's health and safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the meeting.

**Disclaimers**

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed.

Of note, this agenda is a working document primarily designed for HMPC members and the work the Committee undertakes.

**Note on access to documents**

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of 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 or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
**Send a question via our website** www.ema.europa.eu/contact

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# 1. Introduction

## 1.1. Welcome and declarations of interest of members, alternates and experts

In accordance with the Agency's policy on handling of declarations of interests of scientific committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and based on the topics in the agenda of the current meeting, the Committee Secretariat announced that no restriction in the involvement of meeting participants in upcoming discussions was identified.

Participants in this meeting were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. No new or additional interests or restrictions were declared.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure and as included in the list of participants. All decisions taken at this meeting were made in the presence of a quorum of members (i.e. 22 or more members were present in the room).

New Co-opted member (toxicology): Heidi Foth; Starting date of mandate: 4 April 2016

## 1.2. Adoption of agenda

HMPC agenda for 4-5 April 2016; Time schedule

**Outcome:**
Adopted

Minor changes in time schedule were agreed according to importance of topics.

## 1.3. Adoption of the minutes

HMPC minutes for 1-2 February 2016

**Outcome:**
Adopted

# 2. European Union herbal monographs and list entries

## 2.1. Report on MLWP activities

### 2.1.1. Report from the MLWP February 2016 meeting

Report: MLWP Chair
**Action:** for information
Document: Draft minutes for the MLWP meeting on the 3-4 February 2016

### 2.1.2. Calls for scientific data

- Monograph systematic review

Report: MLWP Chair
**Action:** for adoption

Avenae fructus; Avenae herba; Calendulae flos; Myrrha (Commiphora molmol); Oenotherae biennis oleum; Polypodii rhizome; Rusci aculeati rhizome; Sambuci flos; Tanaceti parthenii herba; Thymi aetheroleum; Trigonellae foenugraeci semen; Verbasci flos

**Outcome:**
Although not prioritised for review in the work plan 2016/2017, the committee agreed to initiate the call for data for start of the systematic review procedure for 12 monographs. A proposal by the secretariat was agreed to split in 3 waves to avoid overload with simultaneous calls for interested parties.

### 2.1.3. Appointment of Rapporteurs and Peer-reviewers

- Monograph systematic review

**Herbal substance**
Avenae fructus
Avenae herba
Calendulae flos
Rusci aculeati rhizoma
Trigonellae foenugraeci semen
Valerianae radix/Lupuli flos
Ribis nigri folium

- Appointment of Rapporteur (none MLWP members)

**Outcome:**
New Rapporteurs for systematic review were endorsed.

The HMPC Chair welcomed new volunteers for Rapporteurship but reminded that it does neither sort the accumulated backlog nor allows a systematic review of all monographs every 5 years. Therefore a modification of the current review/revision procedure should still be pursued as foreseen in the 2016 HMPC work plan.

### 2.1.4. Change in membership of MLWP

Report: MLWP Chair
**Action**: for discussion
Document: Resignation of a MLWP member, Beate Huber, 7 March 2016

**Outcome:**
The HMPC confirmed the need for experience from medical practice ideally with paediatric expertise in the working party. A second choice might be a medical doctor with expertise in non-European traditional medicines such as TCM or Ayurveda.

HMPC secretariat to send out a call for nominations to all HMPC members for candidates to be proposed for possible nomination at the HMPC May meeting.

The HMPC further reflected on possibilities to establish a closer link with PDCO and strengthening the input from medical doctors regarding medical practice acknowledging that the data situation for traditional herbal products is usually scarce requiring pragmatic approaches (see also extrapolation topic in point 5.2.2. of HMPC February meeting).

## 2.2. Revised EU herbal monographs and list entries for final adoption

### 2.2.1. Monograph on Thymi herba and Primulae radix and supporting documents

**Action**: for adoption
Documents: MO, AR, LoR, references: 22/22

**Outcome:**
Final revised monograph and supporting documents with minor changes in monograph adopted by majority vote (23 out of 26). Norway expressed a favourable position.
Divergent opinion: E. van Galen, L. Anderson, M. Delbò

The revision was initiated by new scientific data with regard to the validity and use of the Bronchitis Severity Score (BSS).
The correct name of the monograph was discussed and modified ('and/or' as regards possible source species) taking into account Ph. Eur. definitions.
Divergent opinions referred to doubts in the recognised efficacy to fulfil WEU criteria and the use in children for the TU indication.

## 2.3. Revised EU herbal monographs and list entries for public consultation

None

## 2.4. EU herbal monographs, list entries and public statements for final adoption

### 2.4.1. List Entry and Monograph on Crataegi folium cum flore

Rapporteur: J. Wiesner; Peer-reviewer: R. Länger
**Action**: for adoption
Documents: MO, LE, AR, LoR, OoC, references: 86/89

**Outcome:**
Final monograph and supporting documents with changes in monograph adopted by majority vote (17 out of 26). Norway expressed a favourable position.
Divergent opinion: E. van Galen, G. Calapai, I. Chinou, L. Anderson, M.H.P. Ferreira, M. Delbò, U. Mockler, W. Dymowski, Z. Biro-Sandor

Due to the high number of divergent opinions based on safety concerns with regard to indication 1 (relieve symptoms of temporary nervous cardiac complaints after serious conditions have been excluded by a medical doctor) founded in diverse therapeutic traditions and practice in the MSs, the Committee raised no objections on the Chairs proposal not to vote but to discontinue the development of a list entry.

Several members expressed their divergent position because in their view any cardiac indication is not considered suitable for self-medication in their MS. Differences in medical

approach, health care customs and patient self-management in the EU were noted and therefore it was agreed not to propose to the Eur. Com. a binding list entry. Although genotoxicity data are available for one preparation, it was specified that safety concerns don't refer to the herbal substance as such but the indication and use in general. The Rapporteur was asked to adapt the AR accordingly.

Further discussion points referred to the tradition, the duration of use (change for indication 1), concerns regarding adolescents and the use of DER instead of drug solvent ratio for tinctures.

### 2.4.2. Monograph on Helichrysi flos

Rapporteur: W. Dymowski; Peer-reviewer: G. Calapai
**Action**: for adoption
Documents: MO, AR, LoR, references: 46/49

**Outcome:**
Final monograph and supporting documents with minor changes in the monograph (section 4.2) adopted by consensus. Norway expressed a favourable position.

No comments had been received during public consultation.

### 2.4.3. Monograph on Polygoni avicularis herba

Rapporteur: B. Jansone; Peer-reviewer: J. Viguet-Poupelloz
**Action**: for adoption
Documents: MO, AR, LoR, references: 79/79

**Outcome:**
Final monograph and supporting documents adopted by majority vote (25 out of 26). Norway expressed a favourable position.
Divergent opinion: E. van Galen
No comments had been received during public consultation.
The divergent view referred to the wording of the traditional indications 2 and 3.

### 2.4.4. Monograph on Silybi mariani fructus

Rapporteur: O. Palomino; Peer-reviewer: W. Knöss
**Action**: for adoption
Documents: MO, AR - TU, MO, AR - WEU/TU, LoR, OoC, SE comments; references: 114/195

**Outcome:**
Vote on TU/WEU monograph (largely according to published draft monograph): 7 positive (out of 25); Norway expressed a non-favourable position.
Divergent position: B. Razinger, E. S. Leinonen, E. v. Galen, E. Attard, G. Calapai, H. Foth, I. Chinou, I. Kosalec, J. Wiesner, L. Anderson, M.H.P. Ferreira, Marie Heroutová, M. Delbò, M. Nagy, P. Claeson, S. Bager, S. Madsen, U. Mockler, Z. Biro-Sandor

Vote on TU only monograph: 7 positive (out of 25). Norway expressed a non-favourable position.

Divergent position: Adela Núñez Velázquez, A.P. Martins, B. Razinger, D. Kalke, E. Attard, G. Laekeman, G. Calapai, H. Foth, I. Chinou, I. Kosalec, J. Wiesner, L. Anderson, M.H.P. Ferreira, Marie Heroutová, M. Delbò, M. Nagy, R. Länger, S. Madsen, W. Dymowski

Vote on TU only monograph with introduced modified indication (wording includes hepatic disorders): 15 positive (out of 25).

As no simple majority could be reached (17 out of 33 committee members), the Chair decided not to pursue further proposed modifications in the monograph (e.g. removal of a specific preparation). Chair, Rapporteur, Vice Chair, MLWP Chair and EMA secretariat to discuss follow-up including considerations to close the assessment and communicate in a public statement the reasons why a monograph cannot be established.

While old authorisations of one product in most MSs were acknowledged, there was no majority to support a recognised efficacy for the proposed indication based on available clinical evidence for the WEU part of the monograph. The specific use and pharmacological evidence with respect to the liver was recognised by many, but no majority supported a traditional use indication either mentioning hepatic disorders (safety concerns with regard to alcohol abuse and self-medication) or not mentioning hepatic disorders (not reflecting traditional use and plausibility).

## 2.5. EU herbal monographs, list entries and public statements for adoption for release for public consultation

### 2.5.1. Monograph on Cisti cretici folium and supporting documents – postponed

**Outcome:**
Adoption postponed to May 2016 meeting.

# 3. Referral procedures

None

# 4. Guidelines and guidance documents

## 4.1. Non-clinical / clinical safety and efficacy and multidisciplinary

### 4.1.1. Reflection paper on herbal medicinal products containing polycyclic aromatic hydrocarbons (PAH)

**Action:** for discussion
Document: Draft reflection paper

**Outcome:**
Late comments received by the Rapporteur before and during the meeting to be taken into account for modification of the paper. Members invited to provide additional comments by **22 April** 2016.

Rapporteur to submit improved and cleaned version by **30 April** to the secretariat for agreement by all HMPC members.

HMPC members recognised that the PAH regulation is more advanced in the food area. Risks in the medicines area are less widespread and limited to some specific herbal substances. Furthermore it was emphasised that coordination is needed with EDQM as regards testing and the final aim of the reflection paper (primarily asking for data) should be made clear to stakeholders. The UK member and Co-opted member toxicology were asked to support the Rapporteur in finalisation of the RP.

## 4.2. Quality

### 4.2.1. Reflection paper on the use of new analytical methods in the quality control of herbal substances, herbal preparations and (traditional) herbal medicinal products – postponed

Report: QDG Chair

**Outcome:**
Postponed to May 2016 meeting.

## 4.3. Regulatory

### 4.3.1. Revised guideline on the use of the CTD format for registration applications

Report: QDG Chair, ORGAM DG Chair
**Action**: for adoption
Documents: Revised CTD guideline (EMA/HMPC/71049/2007, Rev.2); OoC main text; OoC Appendix 2; Comments SE and DE

**Outcome:**
Adopted by consensus.

No further modifications were requested. HMPC members noted that final comments had been discussed in an extra TC. Some compromises had to be found such as in keeping the balance between clear messages and simple reference to other existing guidelines as justified. HMPC secretariat to publish the revised documents on the EMA website.

## 4.4. Report on HMPC Drafting Groups activities

### 4.4.1. Quality DG

Report: Q DG Chair
**Action:** for adoption
Document: Meeting report from Q DG meeting held on 11 Feb 2016

**Outcome:**
Adopted

The DG had finalised the quality part for the revised herbal CTD guideline, mainly as regards comments received on the new Appendix 2 ‘mock-up module 3’ (see above). The group had further discussed the revision of the ‘Guideline on quality of herbal medicinal products/ traditional herbal medicinal products’ and some topics in coordination with EDQM such as herbal specific issues in relation to Certificates of suitability (CEPs). The EDQM representative emphasised the urgency to get a response regarding the CEP request.

**Action:** for information
Document: Draft agenda for the Q DG meeting to be held on 4 May 2016

**Outcome:**
Pyrrolizidine alkaloid topic (see also 6.1.1) to be added to the May agenda.

### 4.4.2. ORGAM DG

Report: ORGAM DG Chair

**Action:** for adoption
Documents: Meeting reports from ORGAM DG meeting held on 9 Feb and 16 March 2016

**Outcome:**
Adopted

**Action:** for information
Documents: Draft agenda for the ORGAM DG meeting to be held on 3 May 2016; Addendum to the QRD templates for SmPC, Labelling and Patient Leaflet on Mutual-recognition and Decentralised procedures for THMPs (EMA/HMPC/770889/2014)

**Outcome:**
No further topics proposed by HMPC for ORGAM DG.

# 5. Organisational, regulatory and methodological matters

## 5.1. Mandate and organisation of the HMPC

### 5.1.1. Mandate of Quality DG

**Action:** for discussion
Documents: Current QDG mandate; QDG waiting list; Croatian nomination of observer in HMPC and QDG; Candidature received: Dr Friederike Stolte

**Outcome:**
Only one expression of interest received.
Members to confirm current Q DG members or express interest in new memberships for the HMPC May meeting (active member, observer) for reconsideration by HMPC on Q DG membership in line with upcoming mandate modifications.
Call for expression of interest to be sent out by secretariat by 15 April 2016.

### 5.1.2. Assessors Training December 2015 – follow up

Report: QDG Chair
**Action:** for information
Documents: Summary outcome of group discussions

**Outcome:**
Once missing summary is available, distribution to all participants of the training and consideration by Q DG for follow-up regarding Q&A, guidelines and coordination with EDQM.

### 5.1.3. Assessors Training 2016

Report: S. Bager
**Action:** for discussion
Document: Draft Agenda

**Outcome:**
HMPC secretariat to contact CMDh Chair, set a date and inform members on specified date end of 2016 (Nov/Dec outside HMPC meeting weeks).
HMPC members were invited to send proposals by **6 May** 2016.
Topic lead to narrow title and agenda topics for a more concrete proposal and agreement at HMPC May meeting.

Several proposals collected were welcomed but it was encouraged to focus the training on a specific type of assessment and assessor due to limitations in participation.

### 5.1.4. Strategic Review and Learning Meetings – organisational aspects

Report: E. van Galen
**Action:** for discussion
Document: Draft agenda, meeting 12-13 April 2016, Netherlands

**Outcome:**
HMPC noted 3 main parts of the agenda (food supplements and PhV; medicinal cannabis, future visions for HMPC) and were invited to contribute in particular to the last topic via short presentations.
No new information was available as regards an HMPC meeting during the upcoming the Slovakian presidency (no strategic meeting planned).

## 5.2. Coordination with EMA Scientific Committees or CMDh-v

### 5.2.1. Coordination with CHMP/SWP - Public statement on the use of herbal medicinal products containing pulegone/menthofuran

Rapporteur: J. Wiesner
**Action:** for discussion
Documents: New data, provided December 2015; SWP/CHMP preliminary feedback from Oct 2015 and Mar 2016; Overview pulegone development; Draft revised PS; Draft OoC

**Outcome:**
Rapporteur to modify document according to SWP recommendations for agreement in May 2016.
Rapporteur for the Mentha monographs review to continue with revision according to PS recommendations.
HMPC secretariat to further coordinate with CHMP the follow-up for final publication.

The evolution of threshold calculations was presented and discussed vis-à-vis duration and pattern of use of peppermint oil products taking into account uncertainty factors and safety margins. Rapporteurs should complete the public statement from a herbal perspective and continue with the Mentha monograph revisions based on SWP response. However, before publication overall coordination under lead of CHMP should be awaited in order to align

assessment and measures proposed between HMPs with peppermint oil as active substance and MPs that contain peppermint oil as excipient.

### 5.2.2. Report from Scientific Coordination Board – 18 March 2016

Report: HMPC Chair
**Action:** for information
Document: Agenda

**Outcome:**
HMPC noted highlighted agenda topics including cross committee projects and considerations on options for joint meetings (CMDh, PDCO) for future presidency meetings.

## 5.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups

### 5.3.1. Coordination with PCWP/HCPWP

Observer: S. Bager

- EMA PCWP/HCPWP session on communication and information on medicines, 8 March 2016

**Action:** for information
Document: Agenda

- EMA PCWP/HCPWP joint meeting, 9 March 2016

**Action:** for information
Document: Agenda

- Patient involvement within EMA/HMPC

**Action:** for adoption
Document: Patient involvement within EMA/HMPC

**Outcome:**
Patient involvement in HMPC activities in principle welcome but adoption postponed. HMPC noted that 5 patient organisations with interest in herbal medicines have been identified. As a training participation of 2-3 per meeting at next meetings agreed.

Specific modalities of involvement to be checked against standard procedures.

HMPC members to send comments by **30 April** 2016.

For adoption at HMPC May meeting.

HMPC reflected as important to foster among patients and consumers the knowledge about HMPC activities and about OTC use in general. The practical implications and limitations (timing) of proposed patient representative activities in standard HMPC (and MLWP) procedures may be checked and eventually more specified.

### 5.3.2. European Union reference date (EURD) list – update for herbal substances

Report: Z. Biróné Dr Sándor
**Action:** for discussion
Documents: Email communication; Presentation

**Outcome:**
HMPC endorsed request to add peppermint oil to EURD list (5 year frequency). Exceptional extension to non-authorised products (e.g. Art. 16a registered) currently not recommended but to be checked again after finalisation of HMPC PS on pulegone/menthofurane and revision of the Mentha monographs.

General issues with inclusion of herbal substances in EURD list (e.g. registered products not in Art. 57 database) were noted. With more experience gained the topic should be re-discussed. It was acknowledged that PSUR alignment and harmonised submission dates and assessment are not in the mandate of HMPC. However, the pros and cons of exceptional inclusion of herbal substances (registered HMP by default excluded) and subsequent scope and frequency decisions may require some feedback from HMPC in some cases.

## 5.4. Cooperation within the EU regulatory network

### 5.4.1. European Pharmacopeia

- EDQM 13A expert group meeting to be held on 23-25 February 2016
  EDQM: M. Bald, U. Rose; HMPC Observer: I. Chinou
  **Action:** for information
  Documents: Summary of discussion; Report by I. Chinou; Information on Grindelia
- EDQM 13B expert group meeting to be held on 19-20 April 2016
  EDQM: M. Bald, U. Rose; HMPC Observer: H. Neef
  **Action:** for information
  Document: Agenda

  **Outcome:**
  HMPC noted progress regarding a Ph. Eur. discussion paper on assay requirements potentially available for comments in May, while the survey on essential oils among manufacturers did not bring the expected information.
  Changes in botanical names (Senna to be implemented during current revision, Grindelia to be implemented once progressed at Ph. Eur.) with relevance for HMPC monographs were highlighted.
  HMPC decided to continue with Saccharomyces monograph, while EDQM may comment during public consultation.

### 5.4.2. HMPC comments to EDQM on CEPs for herbal active ingredients - postponed

Report: QDG Chair

**Outcome:**
Postponed to May 2016 meeting.

The EDQM representative highlighted the need to get a response soon. Q DG Rapporteur to draft response for Q DG agreement and submission to EDQM.

### 5.4.3. EFSA – Guidance on traditional foods from third countries and Novel Food - consultations

Report: HMPC Chair; Rapporteurs: G. Calapai; I. Kosalec; H. Pinto Ferreira
**Action:** for discussion
Document: Email distributed to HMPC, 23 Feb 2016

**Outcome:**
No need for HMPC comments was identified.

### 5.4.4. European Commission – Update on establishment of List entries (Melaleuca)

Report: HMPC Chair, M. Delbò
**Action:** for discussion
Documents: Draft LE; Ph. Eur. Monograph; Letter from Eu. Com. dated 21 March 2016

**Outcome:**
Compliance with Ph. Eur. monograph description was supported, although the wide definition allowing inclusion of any Melaleuca species was questionable in this specific case. The possible reduction to the substance (preparation) name 'Melaleucae aetheroleum' instead of a complete Ph. Eur. definition regarding species in the title of the LE was discussed. The importance of the actual specification of the substance was emphasised while the inclusion of species was of less relevance.
Rapporteur in liaison with HMPC Chair and secretariat to draft an answer for transmission to the Eur. Com. by **30 April** 2016.

The Rapporteur referred the original Australian ISO standard but also the difficulties to exclude species without a method in the Ph. Eur. monograph allowing such demarcation to other species. Any substance complying with the Ph. Eur. monograph for Melaleucae aetheroleum would be acceptable for medicinal use - independent from which Melaleuca species obtained. The wide definition regarding source plants was considered unfortunate (e.g. vis-à-vis *M. leucadendra or M. quinquenervia)* because representing source plants for other essential oils (Cajuput or Niaouli), however, standard procedure and naming according to Ph. Eur. standard was preferred.

### 5.4.5. Survey on uptake of the traditional use registration and implementation of Directive 2004/24/EC in EU Member States, 2015 - Preliminary outcome

**Action:** for discussion
Document: Presentation

**Outcome:**
HMPC noted first summary. PL still to provide data for update of the report EMA/HMPC/322570/2011 (Rev. 6) on the Agency website and more detailed presentation to the HMPC in May.

HMPC took note of a comparable number of registrations/authorisation in the EU in 2014 and 2015. An increase in MRP and DCP procedures for herbal products was shown. Substances assessed by the HMPC but not marketed in EU MSs as medicines and substances marketed but not assessed by the HMPC were listed.

## 5.5. Cooperation with International Regulators

### 5.5.1. 8th Annual Meeting of IRCH held in Riyadh, Saudi Arabia, 1-3 December 2015

Report: HMPC Chair, HMPC Vice-Chair
**Action:** for information
Documents: Summary Report; Presentations

**Outcome:**
Postponed to May 2016 meeting.

### 5.5.2. HMPC – International representation and cooperation

Report: HMPC Chair
**Action:** for adoption
Document: Draft proposal HMPC international cooperation

**Outcome:**
Postponed to May 2016 meeting.

## 5.6. Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee

### 5.6.1. Hearings with interested parties in 2016

**Action**: for discussion
Documents: AESGP hearing draft Agenda; Participants list; Presentations

**Outcome:**
No additional agenda topics were proposed, neither another hearing with other IPs on a specific topic in 2016. It was proposed to hold the established hearing with AESGP at HMPC directly.

HMPC members recognised that many agenda points proposed by AESGP for the hearing with MLWP were not directly linked to monograph establishment but to specific guidance development - mostly still ongoing.

## 5.7. HMPC work plan

### 5.7.1. Projects on the HMPC work plan 2016

**Action:** for discussion
Documents: Work plan 2016 – current status, HMPC work plan tracking tool 2016

**Outcome:**
Postponed to May 2016 meeting.

- Cross committee risk/benefit project
  Report: S. Madsen
  **Action:** for discussion
  Document: Presentation

The aim and composition of the benefit/risk steering group was presented focusing on risk perspectives, old substances and the reasons for their re-evaluation as well as efficacy tables as a tool. Possible improvements for the HMPC assessment methodology (WEU) were discussed addressing future challenges in terms of update, data to be considered and how to be best communicated in particular for drugs with marginal clinical effects. A new update on possible elements of the project for HMPC usage should to be given second half of 2016.

- Harmonisation of assessment practice for herbal substances of non-European origin
  Report: E. van Galen
  Action: for discussion
  Document: Draft list of Ayurvedic herbs

  **Outcome:**
  Postponed to May 2016 meeting.

## 5.8. Planning and reporting

None

## 5.9. Legislation and regulatory affairs

None

# 6. Any other business

## 6.1. Topics for discussion

### 6.1.1. Occurrence of pyrrolizidine alkaloids – issues on national markets and follow up

Report: HMPC Chair, L. Anderson
**Action:** for discussion
Documents: Information received from UK, DE, AT; Published articles; Request from NL

**Outcome:**
HMPC members noted measures taken in UK, DE, AT and SE as well as incoherent data situation. In view of quality issues linked to safety concerns that are not limited to single markets only, the need for coordinated European measures was emphasised. EDQM and European Commission were informed.

HMPC members agreed to

1) Communicate to EDQM accelerated need for development of a validated Ph. Eur. method for PA analysis.

2) Recommend short term temporary measures for national implementation based on harmonised information status. (A task force including regulatory competence and scientific expertise was established to deliver a draft document within 3-4 weeks. Composition: topic leader P. Claeson; members L. Anderson, J. Wiesner, B. Kroes, R. Länger, H. Foth, I. Chinou)

3) To reconsider long term testing requirements and other measures. Initiate accordingly the revision of relevant guidelines as required (quality, specification, GACP; led by Q DG)

4) To inform relevant groups at EMA.

The HMPC agreed as a general direction to improve and harmonise the data situation (in particular which herbal substances affected) in order to define the extent of the problem and concentrate first line on the most imminent ones. It was acknowledged that findings are not limited to substances used in medicines, while recommendations will remain in the scope of MPs. New analytical opportunities that partially led to findings are not homogenously available across all MSs and capacities limited. The content of PS EMA/HMPC/893108/2011 was re-confirmed as well as the intention to keep PA in medicinal products as low as practically achievable. However, transitory measures for risk management will encompass elements of manufacture and GACP, testing requirements and toxicological considerations.

## 6.2. Documents for information

### 6.2.1. HMPC

Table of Decisions from HMPC meeting held on 1-2 February 2016

Overview of expertise of members HMPC and subgroups

Meeting report from HMPC meeting held on 1-2 February 2016

Overview of status of HMPC assessment work – priority list

Inventory of herbal substances for assessment work – alphabetical order

Abbreviations in HMPC agendas/minutes

Common names of herbal substances in all languages

### 6.2.2. MLWP

- Overview of status of MLWP assessment work
- Draft agenda of MLWP meeting to be held on 6-7 April 2016

### 6.2.3. ARSP

- English summaries for publication
  Documents: Castor oil; Ironwort; Horsetail herb; Valerian root; Valerian essential oil
- English template

### 6.2.4. Other

- New internal guidance on management of confidentiality and declarations of interests for observers participating in EMA scientific meetings;
  Documents: Observers summary for Committees and WPs; Observers at EMA Meetings; Letter to Swissmedic, 23 March 2016

### 6.2.5. Update on availability of herbal hand books at the Agency library

- Overview of status of availability of herbal hand books at the Agency library - March 2016

## List of participants

Including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 4-5 April 2016 meeting.

| Name | Role | Member State or affiliation | Outcome restriction following evaluation of e-DoI | Topics on agenda for which restrictions apply |
|---|---|---|---|---|
| Werner Knöss | Chair | Germany | No interests declared | |
| Reinhard Länger | Member | Austria | No interests declared | |
| Elena Mustakerova | Member | Bulgaria | No interests declared | |
| Ivan Kosalec | Member | Croatia | No restrictions applicable to this meeting | |
| Darko Trumbetic | Alternate | Croatia | No interests declared | |
| Maria Stavrou | Member | Cyprus | No interests declared | |
| Marie Heroutova | Member | Czech Republic | No interests declared | |
| Steffen Bager | Member | Denmark | No restrictions applicable to this meeting | |
| Eeva Sofia Leinonen | Member | Finland | No interests declared | |
| Jacqueline Wiesner | Member | Germany | No interests declared | |
| Ioanna Chinou | Member | Greece | No interests declared | |
| Zoi(Zoe) Karampourmpouni | Alternate | Greece | No interests declared | |
| Zsuzsanna Bíróné Dr Sándor | Member | Hungary | No interests declared | |
| Una Mockler | Member | Ireland | No restrictions applicable to this meeting | |
| Annamarie O'Sullivan | Alternate | Ireland | No interests declared | |
| Marisa Delbò | Member (Vice-Chair) | Italy | No interests declared | |
| Anna Maria Serrilli | Alternate | Italy | No interests declared | |
| Dace Kalke | Member | Latvia | No interests declared | |
| Baiba Jansone | Alternate | Latvia | No interests declared | |
| Everaldo Attard | Member | Malta | No interests declared | |
| Emiel Van Galen | Member | Netherlands | No interests declared | |
| Steinar Madsen | Member | Norway | No interests declared | |
| Wojciech Dymowski | Member | Poland | No interests declared | |
| Ana Paula Martins | Member | Portugal | No interests declared | |
| Milan Nagy | Alternate | Slovakia | No interests declared | |
| Barbara Razinger | Member | Slovenia | No interests declared | |

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| Adela Núñez Velázquez | Member | Spain | No interests declared | |
| Cristina Martinez Garcia | Alternate | Spain | No interests declared | |
| Per Claeson | Member | Sweden | No interests declared | |
| Erika Svedlund | Alternate | Sweden | No interests declared | |
| Linda Anderson | Member | United Kingdom | No interests declared | |
| Sue Harris | Alternate | United Kingdom | No interests declared | |
| Gioacchino Calapai | Co-opted member | Italy | No interests declared | |
| Gert Laekeman | Co-opted member | Belgium | No interests declared | |
| Heidi Foth | Co-opted member | Germany | No interests declared | |
| Maria Helena Pinto Ferreira | Co-opted member | Portugal | No interests declared | |
| Martina Holenková | Expert | Czech Republic | No interests declared | |
| Olga Maria Palomino | MLWP member | Spain | No interests declared | |
| Melanie Bald | Observer (via TC) | EDQM | No interests declared | |
| Tina-Soon Engraff | EC Representative | European Commission | Full involvement | |