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SCIENCE MEDICINES HEALTH

15 January 2020  
EMA/HMPC/32208/2020  
Inspections, Human Medicines Pharmacovigilance & Committees Division

## Committee on Herbal Medicinal Products (HMPC)

### Minutes for the meeting on 18-20 November 2019

Chair: Marisa Delbò                      Vice-Chair: Emiel van Galen

18 November 2019, 14:00 – 19:00, 1C

19 November 2019, 09:00 – 19:00, 1C

*(AESGP hearing: 19 November 2019, 14.00 – 16.00, 1C)*

20 November 2019, 09:00 – 16:00, 1C

*(HMPC Chair elections: 20 November 2019, 15.15 – 16.00, 1C)*

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

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Some documents mentioned in the minutes 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).

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## Table of contents

<b>1.</b>	<b>Introduction</b>	<b>5</b>
1.1.	Welcome and declarations of interest of members, alternates and experts .....	5
1.2.	Adoption of agenda.....	5
1.3.	Adoption of the minutes .....	5
<b>2.</b>	<b>EU herbal monographs and list entries for adoption</b>	<b>6</b>
2.1.	Status of HMPC/MLWP activities .....	6
2.1.1.	Overview of HMPC/MLWP assessment work including the Rapporteurship distribution – Status in November 2019 .....	6
2.1.2.	Appointment of Rapporteurs and Peer-reviewers .....	6
2.2.	Revised EU herbal monographs and list entries for final adoption .....	7
2.3.	Revised EU herbal monographs and list entries for public consultation .....	7
2.3.1.	Monograph on Millefolii herba and supporting documents.....	7
2.4.	Reviewed EU herbal monographs and list entries for decision on revision.....	7
2.4.1.	Monograph on Arctii radix and supporting documents.....	7
2.4.2.	Monograph on Orthosiphonis folium and supporting documents .....	7
2.4.3.	Monograph on Taraxaci folium and supporting documents .....	7
2.4.4.	Monograph on Taraxaci radix cum herba and supporting documents .....	8
2.4.5.	Monograph on Quercus cortex and supporting documents.....	8
2.5.	EU herbal monographs, list entries and public statements for final adoption .....	8
2.6.	EU herbal monographs, list entries and public statements for adoption for release for public consultation .....	9
2.6.1.	Monograph on Calendulae herba and supporting documents .....	9
2.6.2.	Monograph on Herniariae herba and supporting documents .....	9
2.7.	EU herbal monographs, list entries and public statements - post finalisation .....	9
<b>3.</b>	<b>Referral procedures</b>	<b>9</b>
<b>4.</b>	<b>Guidelines and guidance documents</b>	<b>10</b>
4.1.	Non-clinical/clinical safety and efficacy and multidisciplinary .....	10
4.1.1.	Public statement on the use of herbal medicinal products containing estragole .....	10
4.1.2.	Public statement on the contamination of herbal medicinal products/traditional herbal medicinal products with pyrrolizidine alkaloids (EMA/HMPC/328782/2016).....	10
4.1.3.	Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) (EMA/HMPC/893108/2011) .....	10
4.2.	Quality .....	11
4.3.	Regulatory / Procedural .....	11
4.3.1.	Update on procedures for monograph and list entry establishment - postponed .....	11
4.4.	Report on HMPC Drafting Groups activities .....	11
4.4.1.	Quality DG .....	11
4.4.2.	ORGAM DG .....	11

<b>5.</b>	<b>Organisational, regulatory and methodological matters</b>	<b>11</b>
<b>5.1.</b>	<b>Mandate and organisation of the HMPC</b>	<b>11</b>
5.1.1.	Strategic Review and Learning Meetings	11
5.1.2.	Election of HMPC Chair	11
5.1.3.	Preparation of upcoming elections	12
<b>5.2.</b>	<b>Coordination with EMA Scientific Committees or CMDh-v</b>	<b>12</b>
5.2.1.	Scientific Coordination Board Meeting	12
5.2.2.	Coordination with PDCO/PRAC	12
<b>5.3.</b>	<b>Coordination with EMA Working Parties/Working Groups/Drafting Groups</b>	<b>13</b>
<b>5.4.</b>	<b>Cooperation within the EU regulatory network</b>	<b>13</b>
5.4.1.	Coordination with European Pharmacopoeia	13
5.4.2.	Herbal EU NTC curriculum: Draft principles and priorities for training	13
<b>5.5.</b>	<b>Cooperation with International Regulators</b>	<b>14</b>
5.5.1.	11th WHO IRCH meeting in Budapest 5-7 December	14
<b>5.6.</b>	<b>Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee</b>	<b>14</b>
5.6.1.	AESGP – hearing	14
5.6.2.	Comments on use of HMPC Reflection Papers in National Procedures	14
<b>5.7.</b>	<b>Work plan</b>	<b>14</b>
5.7.1.	HMPC work plan 2019	14
5.7.2.	Draft HMPC work plan 2020	15
<b>5.8.</b>	<b>Planning and reporting</b>	<b>15</b>
5.8.1.	Move to EMA building – timelines and practical arrangements	15
5.8.2.	EMA future proofing	15
<b>5.9.</b>	<b>Legislation and regulatory affairs</b>	<b>16</b>
<b>5.10.</b>	<b>Questions from members</b>	<b>16</b>
<b>6.</b>	<b>EU herbal monographs and list entries in preparation</b>	<b>16</b>
<b>6.1.</b>	<b>Revision of EU herbal monographs and list entries in preparation for adoption after public consultation</b>	<b>16</b>
6.1.1.	Monograph on Hippocastani semen and supporting documents	16
6.1.2.	Monograph on Hyperici herba and supporting documents - postponed	16
6.1.3.	Monograph on Menthae piperitae aetheroleum and supporting documents (see also 7.2.3.)	16
<b>6.2.</b>	<b>Revision of EU herbal monographs and list entries in preparation for public consultation</b>	<b>17</b>
6.2.1.	Monograph on Trigonellae foenugraeci semen and supporting documents - postponed	17
<b>6.3.</b>	<b>Review of EU herbal monographs and list entries in preparation for decision on revision</b>	<b>17</b>
6.3.1.	Monograph on Filipendulae ulmariae flos and supporting documents - postponed	17
6.3.2.	Monograph on Filipendulae ulmariae herba and supporting documents	17

6.3.3.	Monograph on Juniperi aetheroleum and supporting documents - postponed.....	17
6.3.4.	Monograph on Juniperi pseudo-fructus and supporting documents - postponed .....	17
6.3.5.	Monograph on Sabalis serrulatae fructus and supporting documents – request for unscheduled revision.....	17
6.3.6.	Monograph on Rosmarini aetheroleum and supporting documents - postponed.....	18
6.3.7.	Monograph on Rosmarini folium and supporting documents - postponed .....	18
6.3.8.	Monograph on Solidaginis virgaureae herba and supporting documents .....	18
6.3.9.	Monograph on Zingiberis rhizoma and supporting documents – request for unscheduled revision .....	18
<b>6.4.</b>	<b>EU herbal monographs and list entries in preparation for adoption after public consultation.....</b>	<b>18</b>
<b>6.5.</b>	<b>EU herbal monographs and list entries in preparation for adoption for release for public consultation .....</b>	<b>18</b>
6.5.1.	Monograph on Cisti cretici folium and supporting documents - postponed .....	18
6.5.2.	Monograph on Menyanthes trifoliata folium and supporting documents.....	18
6.5.3.	Monograph on Saccharomyces cerevisiae CBS 5926 and supporting documents.....	18
6.5.4.	Monograph on Salviae mitiorrhizae radix et rhizoma and supporting documents .....	19
6.5.5.	Monograph on Species amarae and supporting documents.....	19
6.5.6.	Monograph on Species sedativae and supporting documents - postponed .....	19
6.5.7.	Monograph on Vaccinii macrocarpi fructus and supporting documents .....	19
6.5.8.	Monograph on Verbenae citriodorae folium and supporting documents - postponed .....	19
6.5.9.	Monograph on Andrographidis paniculatae folium and supporting documents - postponed	19
6.5.10.	Monograph on Centellae asiaticae herba and supporting documents - postponed.....	19
<b>7.</b>	<b>Any other business</b>	<b>19</b>
<b>7.1.</b>	<b>Topics for discussion .....</b>	<b>19</b>
7.1.1.	Develop a strategy for use of PhV data/tools in HMPC assessment .....	19
7.1.2.	PSUSA procedure for Pelargonii radix .....	20
<b>7.2.</b>	<b>Documents for information.....</b>	<b>20</b>
7.2.1.	HMPC .....	20
7.2.2.	ARSP.....	20
7.2.3.	EU herbal monographs, list entries and public statements – on hold.....	21
7.2.4.	Other .....	21
	<b>List of participants</b>	<b>22</b>

## 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, except for G. Laekeman who declared a competing interest for himself related to a food supplement and voluntarily excluded himself from participation in the discussion on agenda point 6.3.9.

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.

New nomination membership:

- MT, Matthew Camilleri (alternate) as of 11 October 2019

End of membership:

- MT, Andre Mangani (alternate) as of 10 October 2019

### 1.2. Adoption of agenda

HMPC agenda for 18-20 November 2019

Time schedule for 18-20 November 2019

**Outcome:**

Agenda adopted.

Time schedule endorsed.

### 1.3. Adoption of the minutes

HMPC minutes for 23-25 September 2019

**Outcome:**

Minutes adopted.

## 2. EU herbal monographs and list entries for adoption

### 2.1. Status of HMPC/MLWP activities

#### 2.1.1. Overview of HMPC/MLWP assessment work including the Rapporteurship distribution – Status in November 2019

---

Report: HMPC Chair

**Action:** for discussion

Document: Overview

**Outcome:**

HMPC noted status of assessment work.

For substances on the work programme Rapporteurs informed on the likely availability of documents for the next meetings.

For the follow-up on Andrographis it was referred to the HMPC May minutes for 'Andrographidis paniculatae folium' and to the HMPC September minutes for 'Andrographidis paniculatae herba in combination'.

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

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Report: HMPC Chair

**Action:** for adoption

**Documents:** Call for Rapporteurs/Peer Reviewers, List B with volunteers

**Outcome:**

HMPC agreed to transfer of Rapporteurs and peer reviewers from MLWP members to HMPC members. For assessments already started the current Rapporteur finalises the current procedure (new assessment, review or revision) and a new Rapporteur will be appointed with start of a new procedure (review or revision).

*New assessments*

Salviae mitiorrhizae radix et rhizoma      New Rapporteur

*Reviews*

Filipendulae ulmariae flos      New Peer-Reviewer

Filipendulae ulmariae herba      New Peer-Reviewer

Mate folium      New Rapporteur, New Peer-Reviewer

Rosmarini aetheroleum      New Rapporteur

Rosmarini folium      New Rapporteur

Quercus cortex      New Peer-Reviewer

*Revisions*

Thymi aetheroleum      New Peer-Reviewer

The proposed Rapporteur transfer for Trigonellae foenugraeci semen should only be decided when the current Rapporteur confirms that he does not want to finalise the current revision procedure.

**Post-meeting note:**

*The current Rapporteur for Trigonella agreed with the immediate transfer.*

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

None

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

### 2.3.1. Monograph on Millefolii herba and supporting documents

---

**Action:** for adoption

Documents: MO, LE, AR, LoR; References: 00/69

**Outcome:**

Minor changes were introduced in the MO, AR and LE. Draft revised monograph, the new list entry and supporting documents adopted by consensus for public consultation.

## 2.4. Reviewed EU herbal monographs and list entries for decision on revision

### 2.4.1. Monograph on Arctii radix and supporting documents

---

**Action:** for adoption

Document: Review report; References: 59/33

**Outcome:**

Decision postponed to the January meeting.

As highlighted by the peer-reviewer, some new data regarding marketed products still have to be checked as well as editorial improvements to be performed.

### 2.4.2. Monograph on Orthosiphonis folium and supporting documents

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**Action:** for adoption

Documents: Review report; References: 05/04

**Outcome:**

HMPC agreed with Rapporteur's position that a monograph revision is needed because new data of relevance were detected that would change the content of the monograph.

The HMPC decided by consensus to revise the monograph, assessment report and list of references on Orthosiphonis folium.

### 2.4.3. Monograph on Taraxaci folium and supporting documents

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**Action:** for adoption

Document: Review report; References: 17/16

**Outcome:**

HMPC agreed with Rapporteur's position that no monograph revision is needed because no new data of relevance were detected that would change the content of the monograph.

The HMPC decided by consensus not to revise the monograph, assessment report and list of references on Taraxaci folium.

The review report was adopted and will be published as addendum to the existing assessment report on the EMA website.

#### 2.4.4. Monograph on Taraxaci radix cum herba and supporting documents

---

**Action:** for adoption

Document: Review report; References: 39/14

**Outcome:**

HMPC agreed with Rapporteur's position that no monograph revision is needed because no new data of relevance were detected that would change the content of the monograph.

The HMPC decided by consensus not to revise the monograph, assessment report and list of references on Taraxaci radix cum herba.

The review report was adopted and will be published as addendum to the existing assessment report on the EMA website.

A reference to the newly established Ph. Eur. monograph on 'Taraxaci herba cum radice' will be introduced in the existing monograph as a correction (footnote section 2).

In the context of the work plan 2020 preparation (see agenda point 5.7.2) it was noted that for Taraxaci radix alone (existing Ph. Eur. monograph) some market relevance was detected and it could be proposed for monograph development.

#### 2.4.5. Monograph on Quercus cortex and supporting documents

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**Action:** for adoption

Document: Review report; References: 18/10

**Outcome:**

HMPC agreed with Rapporteur's position that no monograph revision is needed because no new data of relevance were detected that would change the content of the monograph.

The HMPC decided by consensus not to revise the monograph, assessment report and list of references on Quercus cortex.

The review report was adopted and will be published as addendum to the existing assessment report on the EMA website.

The Committee discussed the relevance of some information in the review report e.g. with regard to non-clinical information. Also the reference to data for pure pyrogallol which is not present as such in the herbal substance should be followed by a statement on relevance. Amendments were agreed.

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

None



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

### 2.6.1. Monograph on Calendulae herba and supporting documents

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**Action:** for discussion

Documents: PS, AR, LoR, discussion letter, discussion material; References: 15/16

**Outcome:**

HMPC decided that the assessment will be discontinued in line with procedure EMA/HMPC/84530/2010 Rev.2 due to insufficient data available in the public domain for the only preparation marketed in different ways in EU member states. No EU herbal monograph will be established at present.

The cancellation of assessment will be communicated in the November HMPC meeting report and the public Overview of assessment work – Priority list (EMA/HMPC/278067/2006).

The HMPC Chair asked to follow-up with the Commission to clarify some principle questions regarding the regulation of anthroposophic herbal products taking into account provision for homeopathic MPs, traditional herbal MPs as well as some specific national regulations.

### 2.6.2. Monograph on Herniariae herba and supporting documents

---

**Action:** for discussion

Document: MO, AR, LoR, Readers guidance; References: 35/22

**Outcome:**

Draft monograph and supporting documents with modifications in the AR adopted by majority for 3 months public consultation.

Members discussed available toxicity data and additional sentences on their evaluation were added in the AR. It was clarified that most data on traditional use refer to the use in combination with other diuretic herbal substances, while for the use as single substance only limited information is available. It was agreed to keep the MO and AR on the use of the substance alone including relevant additional information in the AR on the use in combinations. For the use as combination the existing 'Species diureticae' monograph will be updated once the Herniaria monograph is finalised.

## 2.7. EU herbal monographs, list entries and public statements - post finalisation

None

## 3. Referral procedures

None

## 4. Guidelines and guidance documents

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

#### 4.1.1. Public statement on the use of herbal medicinal products containing estragole

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**Action:** for discussion

Documents: Draft revised PS; OoC; Questions for finalisation, Summary of recommendations

**Outcome:**

Draft revised Public statement (revision 1 – second version) and Overview of comments adopted by majority for another 3 months public consultation.

Due to substantial changes in the draft revised public statement compared to the draft published in 2014, the HMPC decided to exceptionally allow a second public consultation for transparency.

Members discussed appropriate conclusions and principles to be followed in view of limited available data and the long-standing use in several countries considering also the background intake via food as well as the protection of vulnerable patient groups. After public consultation it is foreseen to coordinate with CMDh and CHMP in view of the occasional use of estragole containing excipients in non-herbal products.

#### 4.1.2. Public statement on the contamination of herbal medicinal products/traditional herbal medicinal products with pyrrolizidine alkaloids (EMA/HMPC/328782/2016)

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**Action:** for discussion

Document: Presentation (see also 4.1.3.); [PS](#)

**Outcome:**

HMPC noted the Rapporteur's presentation giving an overview of developments and new information available including data received upon the Call for data that finished in August 2019.

During the call for data some new information was received. However, no real new toxicity study data are available, while the model use and calculation from existing data is meanwhile differently approached than in the past e.g. by some expert groups at EMA or also EFSA. It was also informed on efforts to create a body of data to support the use of potency factors for a differentiated evaluation of various PAs.

In addition selected data from the BPI (German Industry) database has been made available. A discussion on specific next steps is foreseen for the January meeting.

#### 4.1.3. Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) (EMA/HMPC/893108/2011)

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**Action:** for discussion

Document: Presentation (see also 4.1.2.); [PS](#)

**Outcome:**

Please see 4.1.2

## 4.2. Quality

None

## 4.3. Regulatory / Procedural

### 4.3.1. Update on procedures for monograph and list entry establishment - postponed

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## 4.4. Report on HMPC Drafting Groups activities

### 4.4.1. Quality DG

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None

### 4.4.2. ORGAM DG

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None

## 5. Organisational, regulatory and methodological matters

### 5.1. Mandate and organisation of the HMPC

#### 5.1.1. Strategic Review and Learning Meetings

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Finnish Presidency meeting – Czech Republic, Prague – 5-6 November 2019

**Action:** for discussion

Documents: Presentations, Summary of discussions groups

**Outcome:**

The Chair thanked the Czech agency for the warm welcome and excellent organisation of the meeting hosted during the Finnish Presidency. Presentations were distributed and a summary outcome of group discussions was read to the Committee for discussion at the HMPC January meeting.

#### 5.1.2. Election of HMPC Chair

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**Action:** for adoption

Documents: Call for candidates, [HMPC RoP](#), Candidatures

**Outcome**

Elections took place in line with the HMPC Rules of procedure. The outcome was inconclusive.

A new, independent election will be held at the beginning of the next meeting with a new call for interest to be sent out in due course.

As the mandate of the current Chair ended 20 November 2019, the current Vice-Chair will take the Chairperson responsibilities/tasks till the next election during the January 2020 HMPC meeting.

The Vice Chair election previously planned for the HMPC January 2020 meeting will be postponed.

### 5.1.3. Preparation of upcoming elections

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**Action:** for discussion  
Document: Presentation

**Outcome:**

HMPC noted the presentation given on mandate expiries and elections pending and due for 2020.

HMPC elections will be held according to Rules of Procedure and expiry of mandates. However, in line with practice for other Committees' subgroups that are suspended during BCP, pending elections for subgroups will be held only with reactivation of these groups.

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

### 5.2.1. Scientific Coordination Board Meeting

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Report: HMPC Chair

**Action:** for information  
Document: Draft Minutes dated 25 September 2019

**Outcome:**

HMPC noted the information given by the Chair with regards to the Scientific Coordination Board Meeting.

The Chair pointed to the overlap between SciCoBoard and HMPC meetings and emphasized the rather strong impact of the BCP measures regarding suspension of subgroups and GL developments for the HMPC operation. Any information on the reactivation would therefore be welcome.

### 5.2.2. Coordination with PDCO/PRAC

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- Discussion paper of age limitation of use of cough and cold herbal medicinal products in children  
**Action:** for discussion  
Documents: Draft discussion paper, OoC, Summary of age limitations, Table of products for children

**Outcome:**

Rapporteur to finalise the agreed discussion paper according to the discussion for possible adoption at the HMPC January meeting and further coordination with (a) PRAC and (b) PDCO.

Rapporteur to re-word the question; DE, SE and HU member to support with available clinical and PhV data for Hedera to be annexed to the question.

The members discussed with the Rapporteur the best approach to find solutions for a harmonised assessment for HMPC monographs to streamline future decisions. Pros and cons to raise the general issue and the specific Hedera case including data available/ not available were discussed as well as the best way for coordination.

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

None

### 5.4. Cooperation within the EU regulatory network

#### 5.4.1. Coordination with European Pharmacopoeia

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- EDQM 13A expert group meetings  
Report: M Bald (EDQM)  
**Action:** for information  
Document: SoD
- EDQM TCM expert group meetings  
Report: M Bald (EDQM)  
**Action:** for information  
Document: SoD
- Certification procedure - Steering Committee interaction with HMPC  
**Action:** for information  
Document: email communication

**Outcome:**

HMPC noted the information with regards to the 13A and TCM summary of decisions as well as the communication regarding the appropriate coordination between EMA and EDQM on various items of importance including issues of relevance for the herbal CEP procedure at EDQM vis-a-vis EMA guidance establishment.

In view of the ongoing revision of the HMPC PS on contamination with PA, the HMPC was particularly interested in the new analytical method for PA largely finalised at EDQM. The EDQM secretariat did not consider the sharing or coordinating with HMPC before publication in Pharmeuropa.

#### 5.4.2. Herbal EU NTC curriculum: Draft principles and priorities for training

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**Action:** for adoption

Documents: Draft Herbal EU NTC curriculum, Draft curriculum priorities

Document for information: Draft curriculum principles, Presentation

**Outcome:**

Herbal EU NTC curriculum and curriculum priorities were adopted by consensus.

HMPC noted a presentation on the activities since the September meeting. Few comments were received and considered in training document development leading to some changes.

Among the next steps for next year is the delivery of 3 priority courses (Q3 – Q4 2020) and the review of training topics and curriculum by HMPC and priorities for 2021 (Q4 2020).

The Committee discussed some questions regarding diverse levels (beginner, medium, advanced) and the acknowledgement/ certification when participating at these courses (including online Webinars) taking into account approaches taken and planned at other groups.

## 5.5. Cooperation with International Regulators

### 5.5.1. 11th WHO IRCH meeting in Budapest 5-7 December

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**Action:** for information

Documents: Draft programme

**Outcome:**

HMPC noted the information given with regard to the 11<sup>th</sup> WHO IRCH meeting.

It was confirmed that some European MS will participate including HU, DE and NL (HMPC Vice-Chair) to flag European interests and report back at the HMPC January meeting.

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

### 5.6.1. AESGP – hearing

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Report: HMPC Chair

**Action:** for discussion

Documents: Draft Agenda, List of participants, Presentations

**Outcome:**

AESGP discussed with HMPC 7 topics of relevance. A hearing report will be drafted separately for publication at the EMA website.

The Committee received some new information and answered questions on key topics in the herbal area. Updates were given and views exchanged with regard to HMPC guidance development concerning herbal products containing pyrrolizidine alkaloids (2 presentations by AESGP), estragole and polycyclic aromatic hydrocarbons; the alignment of EU herbal monographs with Ph. Eur. monographs as regards declaration of the active substance; the publication of HMPC meeting outcomes; the increase in European procedures for herbal medicinal products including use of EU herbal monographs (1 presentation by AESGP); and the possible impact of the Medical Device Regulation for products containing herbal ingredients.

### 5.6.2. Comments on use of HMPC Reflection Papers in National Procedures

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Report: HMPC Chair

**Action:** for discussion

Documents: BPI comments dated 31 October 2019; [Procedure for EU guidelines \(EMA/P/24143/2004 Rev. 1 corr\)](#)

**Outcome:**

HMPC noted and discussed the issues raised. A reply will be drafted by EMA and circulated to the members for comments before the January meeting.

## 5.7. Work plan

### 5.7.1. HMPC work plan 2019

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Report: HMPC Chair

**Action:** for discussion

Documents: Work plan 2019, Annex 1, Annex 2 – current status November 2019

**Outcome:**

HMPC noted current status of planned activities 2019.

Items not started or finalised in 2019 will be reconsidered for the work plan 2020 (see 5.7.2).

### 5.7.2. Draft HMPC work plan 2020

---

Report: HMPC Chair

**Action:** for discussion

Document: Draft Work plan 2020, Annex 1, Annex 2

**Outcome:**

HMPC discussed and agreed on draft work plan items. After modifications according to the discussion the plan will be circulated again for comments and identification of topic leaders and project contributors before final adoption at the HMPC January meeting.

HMPC acknowledged that the plan was drafted in view of limited resources available. Only items are reflected that are essential to finalise or necessary for the functioning /streamlining of HMPC core business. For some topics a further amendment of the wording of activities/realistic deliverables in 2020 will be necessary as well as identification of topic leads and contributing members. For Annex 1 (monographs) and Annex 2 (GLs) a first selection was performed that should be double checked again before final decision and adoption at the HMPC January meeting.

## 5.8. Planning and reporting

### 5.8.1. Move to EMA building – timelines and practical arrangements

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**Action:** for discussion

Documents: Presentations

**Outcome:**

HMPC noted the information given with regard to the move to the EMA building.

HMPC noted adapted timelines for first and second pre-mail and submission of documents for the January meeting.

All members should check before travel all relevant information relevant for access to the new building on the EMA website and as distributed with the invitations.

### 5.8.2. EMA future proofing

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**Action:** for discussion

Document: Presentation

**Outcome:**

The presentation was noted and questions relevant for future operations of the HMPC such as re-activation of subgroup activities and guideline development discussed.

The main elements of the re-organisation including the reasons, the four task-forces and next steps to be expected were briefly introduced.

## 5.9. Legislation and regulatory affairs

None

## 5.10. Questions from members

None

# 6. EU herbal monographs and list entries in preparation

## 6.1. Revision of EU herbal monographs and list entries in preparation for adoption after public consultation

### 6.1.1. Monograph on Hippocastani semen and supporting documents

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**Action:** for discussion

Documens: MO, AR, LoR; References: 75/72

**Outcome:**

Draft documents to be modified according to the discussion and transmitted for peer-review prior to possible **final adoption in January 2020**.

Timetable:

Documents to be sent to peer-reviewer: **30 November 2019**

Peer-review documents to be sent to Rapporteur: **9 December 2019**

Final documents to be included latest in 2nd premail: **8 January 2020**

The Committee discussed mainly 2 issues raised during public consultation: (1) the presentation of the conversion factor old/new method (range?) and (2) the relevant use in adolescents. For (1) it was acknowledged that the monograph cannot serve as a blueprint for all individual products as regards declaration and no ideal solution is available. Sometimes the (old) aescin strength was even part of the product name. As substance/preparations remain practically the same as well as HMPC conclusions on their efficacy and safety, the matter of declaration should be solved in national procedures including possible variations. A footnote in the monograph reflecting also the old standardisation may be useful for that. For (2) the wording in the monograph was adapted and differentiated between adolescents and children.

### 6.1.2. Monograph on Hyperici herba and supporting documents - postponed

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### 6.1.3. Monograph on Menthae piperitae aetheroleum and supporting documents (see also 7.2.3.)

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**Action:** for discussion

Documents: LE, MO, AR, LoR (document for information: Menthae piperitae folium – MO);

References: 109/205

**Outcome:**

Draft documents to be finalised and cleaned for peer-review prior to possible **final adoption in January 2020**.



Timetable:

Documents to be sent to peer-reviewer: **30 November 2019**

Peer-review documents to be sent to Rapporteur: **9 December 2019**

Final documents to be included latest in 2nd premail: **8 January 2020**

No comments were received on the revised *Menthae aetheroleum* package. Because of the shared assessment report with *Menthae folium*, members were asked to send any remaining comments to the Rapporteur before adoption of both revised monographs, the revised list entry for *aetheroleum* and supporting documents at the HMPC January meeting.

## 6.2. Revision of EU herbal monographs and list entries in preparation for public consultation

6.2.1. Monograph on *Trigonellae foenugraeci semen* and supporting documents - postponed

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## 6.3. Review of EU herbal monographs and list entries in preparation for decision on revision

6.3.1. Monograph on *Filipendulae ulmariae flos* and supporting documents - postponed

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6.3.2. Monograph on *Filipendulae ulmariae herba* and supporting documents

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**Action:** for discussion

Documents: Review report; References: 15/15

**Outcome:**

Postponed

6.3.3. Monograph on *Juniperi aetheroleum* and supporting documents - postponed

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6.3.4. Monograph on *Juniperi pseudo-fructus* and supporting documents - postponed

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6.3.5. Monograph on *Sabalidis serrulatae fructus* and supporting documents – request for unscheduled revision

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**Action:** for discussion

Documents: Review report; References: 05/05

**Outcome:**

HMPC agreed that the unscheduled monograph revision based on newly submitted data is only feasible if

1) the specific data made available for a CO<sub>2</sub> extract are accepted as comparable to the hexane extract included in the monograph and

2) in general the chemical comparability allows extrapolation of clinical data from one preparation to another for inclusion into the monograph.

Members were asked to provide comments to the Rapporteur for re-discussion at the January meeting.

The Rapporteur had suggested the revision of the monograph, however, several members raised concerns with regard to the general principle but also the specific case such as applicability of data for one CO2 extract for other CO2 extracts and how to be reflected in the monograph.

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6.3.6. **Monograph on Rosmarini aetheroleum and supporting documents - postponed**

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6.3.7. **Monograph on Rosmarini folium and supporting documents - postponed**

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6.3.8. **Monograph on Solidaginis virgaureae herba and supporting documents**

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**Action:** for discussion

Document: Review report; References: 21/19

**Outcome:**

Postponed

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6.3.9. **Monograph on Zingiberis rhizoma and supporting documents – request for unscheduled revision**

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**Action:** for discussion

Document: Review report; Readers guidance, References: 137/25

**Outcome:**

Postponed

6.4. **EU herbal monographs and list entries in preparation for adoption after public consultation**

None

6.5. **EU herbal monographs and list entries in preparation for adoption for release for public consultation**

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6.5.1. **Monograph on Cisti cretici folium and supporting documents - postponed**

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6.5.2. **Monograph on Menyanthes trifoliata folium and supporting documents**

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**Action:** for discussion

Documents: Draft MO, AR, LoR; References: 69/73

**Outcome:**

Postponed

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6.5.3. **Monograph on Saccharomyces cerevisiae CBS 5926 and supporting documents**

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**Action:** for discussion

Documents: Draft MO, Draft LE, Draft AR, Draft LoR, EMA letter to EC, EC response;

References: 02/188

**Outcome:**

Postponed

#### 6.5.4. Monograph on *Salviae mitiorrhizae radix et rhizoma* and supporting documents

**Action:** for discussion

Documents: Draft MO, AR, LoR, Additional information NL; References: 00/32

**Outcome:**

Postponed

#### 6.5.5. Monograph on *Species amarae* and supporting documents

**Action:** for discussion

Documents: Draft MO, AR, LoR; References: 00/16

**Outcome:**

Postponed

#### 6.5.6. Monograph on *Species sedativae* and supporting documents - postponed

#### 6.5.7. Monograph on *Vaccinii macrocarpi fructus* and supporting documents

**Action:** for discussion

Documents: Draft MO, AR, LoR; References: 00/18

**Outcome:**

Postponed

#### 6.5.8. Monograph on *Verbenae citriodoraе folium* and supporting documents - postponed

#### 6.5.9. Monograph on *Andrographidis paniculatae folium* and supporting documents - postponed

#### 6.5.10. Monograph on *Centellae asiaticae herba* and supporting documents - postponed

## 7. Any other business

### 7.1. Topics for discussion

#### 7.1.1. Develop a strategy for use of PhV data/tools in HMPC assessment

**Action:** for discussion

Documents: Presentation

**Outcome:**

HMPC members endorsed the pilot strategy.

HMPC agreed by majority to consider 3 PhV data sources for HMPC assessment to obtain safety relevant data with slight changes in data collection and AR template (pilot project in 2020, see also 5.7.2). More details will be discussed at the HMPC January meeting.

Following sources should be tested in a pilot for future incorporation when checking safety relevant data for HMPC assessment: (1) Signal detection in EudraVigilance (2) PSUR single assessment (PSUSA) and (3) Medical Literature Monitoring (MLM).

Some members raised concerns that HMPC should not interfere with PhV standard procedures – if something serious is detected such information should reach the HMPC. However, it was reminded that PhV data were already part of the standard market overview request at the beginning of each assessment and appear usually under AR point 5.3 (adverse events). As PhV data compilation has tremendously changed over the last 5 years it was encouraged to adapt to these safety data sources for HMPC assessment. Access to these sources and interaction with PhV colleagues/ resources will be tested in 2020 for some cases.

### 7.1.2. PSUSA procedure for *Pelargonii radix*

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**Action:** for discussion

Documents: MO, Presentation

**Outcome:**

HMPC noted proposed changes in the monograph based on data obtained during the PSUSA evaluation.

Rapporteur to provide a Review report for the January 2020 HMPC meeting.

Proposals are founded on newly available data/regulatory practice; i.e. information from products on the market as collected during the PSUSA procedure. A review report will be prepared for the HMPC January meeting.

The Rapporteur had proposed changes in monograph sections 4.2, 4.4 and 4.8. In view of the recent revision (adopted in June 2018), the need for start of the revision procedure should therefore be considered carefully and decided in January 2020.

## 7.2. Documents for information

### 7.2.1. HMPC

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Table of Decisions from HMPC meeting held on 23-25 September 2019

Overview of expertise of members HMPC and subgroups

[Meeting report from HMPC meeting held on 23-25 July 2019](#)

[Overview of status of HMPC assessment work – priority list](#)

[Inventory of herbal substances for assessment work](#)

[Abbreviations in HMPC agendas/minutes](#)

Common names of herbal substances in all languages

Final Monograph Overview

### 7.2.2. ARSP

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- English template
- English summaries for publication

- Frangula bark
- Valerian root and hop strobili

No objections were raised against publication of the herbal summaries.

### 7.2.3. EU herbal monographs, list entries and public statements – on hold

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- Monograph on *Allii sativi bulbus* and supporting documents – unsolved post-adoption issues
- Monograph on *Foeniculi amari fructus* and supporting documents – awaiting Estragole PS finalisation
- Monograph on *Foeniculi amari fructus aetheroleum* and supporting documents – awaiting Estragole PS finalisation
- Monograph on *Foeniculi dulcis fructus* and supporting documents – awaiting Estragole PS finalisation
- Monograph on *Species digestivae* or *species stomachicae* and supporting documents - awaiting Estragole PS finalisation
- Monograph on *Menthae piperitae folium* and supporting documents - awaiting *Menthae piperitae aetheroleum* finalisation

### 7.2.4. Other

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- PCWP/HCPWP meetings:
  - Meeting Summary PCWP Plenary Meeting 24 Sep 2019
  - Meeting Summary HCPWP Plenary Meeting 24 Sep 2019
  - Meeting Summary PCWP/HCPWP Joint Meeting 25 Sep 2019
  - Draft Agenda for the Annual PCWP/HCPWP meeting with all eligible organisations, 20 November
- Traditional Chinese Medicine: A Statement by EASAC and FEAM

## List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 18-20 November 2019 meeting.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Marisa Delbò	Chair	Italy	No interests declared	
Reinhard Länger	Member	Austria	No interests declared	
Patricia Bodart	Member	Belgium	No interests declared	
Iliana Ionkova	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	
Sari Koski	Alternate – via Adobe	Finland	No interests declared	
An Le	Member	France	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 Biróné Dr Sándor	Member	Hungary	No interests declared	
Sheena Kennedy	Member	Ireland	No restrictions applicable to this meeting	
Alessandro Assisi	Member	Italy	No interests declared	
Evita Skukaуска	Member	Latvia	No interests declared	
Audronis Lukosius	Alternate	Lithuania	No interests declared	
Clemence Varret	Alternate	Luxembourg	No interests declared	
Everaldo Attard	Member	Malta	No interests declared	
Emiel Van Galen	Member	Netherlands	No interests declared	
Wojciech Dymowski	Member	Poland	No interests declared	
Ewa Widy Tyszkiewicz	Expert	Poland	No interests declared	
Ana Paula Martins	Member	Portugal	No interests declared	
Carmen Purdel	Member	Romania	No interests declared	
Milan Nagy	Alternate	Slovakia	No interests declared	
Barbara Razinger	Member	Slovenia	No interests declared	
Karin Erika Svedlund	Member	Sweden	No interests declared	
Malin Kyllikki Hobro Soderberg	Alternate	Sweden	No interests declared	
Anna Wannberg	Expert – via Adobe	Sweden	No interests declared	
Silvia Giroto	Co-opted member	Italy	No interests declared	
Gert Laekeman	Co-opted member	Belgium	On a voluntary basis no participation in	agenda point 6.3.9

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
			discussions, final deliberations and voting on	
Heidi Foth	Co-opted member	Germany	No interests declared	
Maria Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared	
Melanie Bald	Observer – via Adobe	EDQM	No interests declared	