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SCIENCE MEDICINES HEALTH

20 November 2019  
EMA/HMPC/563130/2019 **FINAL**  
Inspections, Human Medicines Pharmacovigilance & Committees Division

## Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 23-25 September 2019

Chair: Marisa Delbò Vice-Chair: Emiel van Galen

23 September 2019, 14:00 – 19:00, 2D

24 September 2019, 09:00 – 19:00, 2D

25 September 2019, 09:00 – 16:00, 2D

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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 ongoing 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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## 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 table of decisions 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 with regard to the agenda topics, 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 6.3.13.

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:

- IE, Sheena Kennedy (member) as of 01 September 2019
- LU, Clémence Varret (alternate) as of 06 August 2019
- DK, Karoline Holm Felding (alternate) as of 22 September 2019

End of membership:

- IE, Una Mockler (alternate) as of 30 July 2019
- LU, Jacqueline Genoux-Hames (alternate) as of 02 August 2019
- DK, Nina Durr (alternate) as of 21 September 2019

### 1.2. Adoption of agenda

HMPC agenda for 23-25 September 2019

Time schedule for 23-25 September 2019

**Outcome:**

Agenda adopted.

Time schedule endorsed.

### 1.3. Adoption of the minutes

HMPC minutes for 08-10 July 2019

**Outcome:**

Minutes adopted with changes in agenda points 5.1.3 and 7.1.1.

## 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 September 2019

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Report: HMPC Chair

**Action:** for discussion

Document: Overview

**Outcome:**

HMPC noted status of assessment work.

Status and progress for the assessment of individual substances were discussed in the context of the HMPC work plan (see 5.7.1) and the rapporteur re-appointment (2.1.2). HMPC secretariat will update the overview according to meeting outcome.

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

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Report: HMPC Chair

**Action:** for adoption

**Documents:** Presentation, Call for Rapporteurs/Peer Reviewers 2019-07-22, List A with volunteers

Calendulae herba - new Peer-Reviewer

**Rapporteur/PR transfer following new policy (step A Chairs to members/alternates):**

**Outcome:**

Cisti cretici folium - new Rapporteur

Menyanthidis trifoliatae folium - new Peer-Reviewer

Saccharomyces cerevisiae CBS 5926 - new Peer-Reviewer

Allii sativi bulbus - new Peer-Reviewer

Pistacia lentiscus, resina (mastic) - new Rapporteur; new Peer-Reviewer

Species digestivae or species stomachicae - new Peer-Reviewer

Centellae asiaticae herba - new Peer-Reviewer

Hamamelidis cortex - new Peer-Reviewer

Hamamelidis folium - new Peer-Reviewer

Hamamelidis destillatum - new Peer-Reviewer

Orthosiphonis folium - new Peer-Reviewer

Frangulae cortex - new Peer-Reviewer

Hippocastani semen - new Peer-Reviewer

Menthae piperitae aetheroleum - new Peer-Reviewer

Menthae piperitae folium - new Peer-Reviewer

Rhamni purshianae cortex - new Peer-Reviewer

Rhei radix - new Peer-Reviewer

Foeniculi amari fructus - new Rapporteur

Foeniculi amari fructus aetheroleum - new Rapporteur

Foeniculi dulcis fructus - new Rapporteur

Public statement on contamination of HMP/THMP with pyrrolizidine alkaloids (PAs) (EMA/HMPC/328782/2016) - new 3rd Rapporteur (chemical part)

It was further clarified that Chairs of HMPC Drafting Groups can act as Rapporteurs for Monograph/ LE assessments as undertaken by HMPC/MLWP.

It was agreed that changes of Rapporteurs become effective after the end of the meeting. It was also confirmed that expert work is acknowledged and experts or previous Rapporteurs who contributed to the HMPC assessment work will appear on assessment reports as (lead) assessor (or 'drafting Rapporteur'), while the responsibility and presentation of the package is with the HMPC Rapporteur.

### 2.1.3. [Andrographidis paniculatae herba in combination - possibility for monograph establishment](#)

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**Action:** for adoption

Documents: Proposal to HMPC for assessment; References: 00/09

**Outcome:**

HMPC agreed by majority to the Rapporteurs proposal that there are currently insufficient data that make a monograph of *Andrographidis paniculatae herba in combination* likely.

HMPC will not start a new assessment and the substance will not be added to the HMPC work programme.

The Rapporteur presented available information. There was general agreement that the available clinical data appear not be sufficient for the well-established use. There were also doubts about the 30 years of traditional use (variable specific combinations in different MS and inconsistent data for posology, indication etc.).

### 2.1.4. [Public statement on Centellae asiaticae herba and supporting documents – possibility for monograph establishment](#)

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**Action:** for adoption

Document: Review report; References: 00/22

**Outcome:**

HMPC agreed by majority to the Rapporteurs proposal that there seem to be sufficient data for monograph establishment.

HMPC will start a new assessment and the substance will be added to the HMPC work programme.

The possibility for a monograph was mainly linked to the meanwhile elapsed 30 years period on safe medicinal use for a specific preparation, while the situation for specific Centella-derived authorised products (not considered as herbal substance/preparation) has not changed (see also previous PS). Some concerns were raised with regard to genotoxicity/carcinogenicity as well as other safety considerations which will be addressed in detail in the assessment report.

#### 2.1.5. Monograph on *Sabalisa serrulatae fructus* and supporting documents - request for unscheduled monograph revision

---

**Action:** for adoption

Documents: Briefing document, Presentation, References

**Outcome:**

HMPC was informed on the background of the application. The Rapporteur will provide a review report for the HMPC November meeting for Committee decision whether the data provided justify triggering the revision procedure; i.e. will lead to changes in the current monograph.

HMPC noted also the time of adoption of the initial assessment and the possible start of the periodic review in 2020.

The Committee heard reports from the national situation in France and other MSs and discussed the specific request but also the general approach how to deal with supercritical CO<sub>2</sub> extracts vis-à-vis other classic solvent extracts for monograph development. The difficulties in the herbal area with 'chemo-equivalence', 'phyto-equivalence' or 'bio-similarity' are well known and it should be considered whether national case by case decisions for specific products are easier than trying to solve the issue via an EU herbal monograph in view of limited publicly available data.

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

### 2.2.1. Monograph on *Frangulae cortex* and supporting documents

---

**Action:** for adoption

Document: Draft MO, AR, LoR, OoC; References: 42/43

**Outcome:**

Final revised monograph and supporting documents adopted by majority vote (24 out of 25). The Norwegian delegate expressed a favourable position.

Divergent opinion: Wojciech Dymowski

Comments received during public consultation were endorsed.

The Committee discussed again the available evidence for well-established use recognition.

The divergent opinion referred to insufficient data from clinical trials and shortcomings in the extrapolation from other hydroxyanthracene derivatives (HADs) such as Senna or Aloe because Rhamnus contains a HAD fraction that may differ in the safety and efficacy profile - not sufficiently explained in the AR.

HMPC agreed on a higher level ATC code for contact laxatives (A06AB) unless specific codes are available for specific substances such as senna or cascara.



### 2.2.2. Monograph on Valerianae radix/Lupuli flos and supporting documents

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**Action:** for adoption

Documents: MO, AR, LoR, OoC, Readers guidance dated 06 September 2019; References: 11/35

**Outcome:**

Changes were introduced in the MO and AR. Final revised monograph and supporting documents adopted by majority vote (21 out of 24). The Norwegian delegate expressed a favourable position.

Divergent opinions: Alessandro Assisi, Emiel van Galen, Sheena Kennedy

Rapporteur to provide missing references before publication of the package.

The Committee discussed comments mainly on monograph section 4.2 and AR sections 2.3, 3.1 and 6 for final agreement. Divergent positions referred to the insufficient evidence for a well-established use indication already expressed for the first version of the monograph but not linked to the changes introduced in the monograph and AR.

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

### 2.3.1. Monograph on Rhamni purshianae cortex and supporting documents

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**Action:** for adoption

Documents: MO, AR, LoR; References: 51/38

**Outcome:**

Draft revised monograph with minor changes and supporting documents adopted by majority for public consultation.

HMPC agreed on a higher level ATC code for contact laxatives (A06AB) unless specific codes are available for specific substances such as senna or cascara (here A06AB07).

### 2.3.2. Monograph on Rhei radix and supporting documents

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**Action:** for adoption

Documents: MO, AR, LoR; References: 55/57

**Outcome:**

Draft revised monograph with minor changes and supporting documents adopted by consensus for public consultation.

HMPC agreed on a higher level ATC code for contact laxatives (A06AB) unless specific codes are available for specific substances such as senna or cascara.

### 2.3.3. Monograph on Tanacetii parthenii herba and supporting documents

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**Action:** for adoption

Documents: MO, AR, LoR; References: 00/104

**Outcome:**

Draft revised monograph with minor changes and supporting documents adopted by majority for public consultation.

The Rapporteur (in liaison with the HMPC representative at PCWP/ HCP WP) was asked to formulate specific questions in preparation of possible patient contribution during HMPC discussion after public consultation.

The Rapporteur presented changes in MO and AR and members discussed safety data as well as the posology in line with traditional use and products on the market. Some concerns were raised as regards 'titration of an effective dose' for a TU substance without efficacy data behind. Some interaction information originating from PhV were proposed to include in the AR but were considered insufficient for inclusion into the monograph section 4.5.

#### 2.3.4. Monograph on Thymi aetheroleum and supporting documents

**Action:** for adoption

Documents: Draft MO, AR, LoR; References: 122/138

**Outcome:**

Draft revised monograph with minor changes and supporting documents adopted by consensus for public consultation.

Minor changes such as alignment from drops to ml in the posology were presented.

**Post meeting note:**

***The Committee agreed with the Rapporteur's position that there is no need for the revision of the corresponding list entry (cutaneous use).***

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

#### 2.4.1. Monograph on Hamamelidis cortex and supporting documents

**Action:** for adoption

Document: Review report, Corrected MO; References: 00/02

**Outcome:**

HMPC agreed with Rapporteurs 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 majority not to revise the monograph, assessment report and list of references on Hamamelidis cortex.

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

HMPC agreed to a correction in the current monograph (footnote for reference to the new Ph. Eur. monograph).

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

**Action:** for adoption

Document: Review report; References: 00/00

**Outcome:**

HMPC agreed with Rapporteurs 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 majority not to revise the monograph, assessment report and list of references on Hamamelidis folium.

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

#### 2.4.3. Monograph on Hamamelidis folium et cortex aut ramunculus destillatum and supporting documents

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**Action:** for adoption

Document: Review report; References: 00/00

**Outcome:**

HMPC agreed with Rapporteurs 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 majority not to revise the monograph, assessment report and list of references on Hamamelidis folium et cortex aut ramunculus destillatum.

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

#### 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

None

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

##### 2.7.1. Monograph on Pistacia lentiscus, resinum (mastic) and supporting documents

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**Action:** for adoption

Documents: MO, AR; presentation; References: 102/79

**Outcome:**

HMPC agreed by majority to post-adoption corrections in monograph and assessment report as well as new references to allow publication of the documents.

Corrections referred to substance name (all documents), posology (MO section 4.2), changes in the AR (sections 2, 3, 4 and 6) and newly added references to the LoR. The discussion focused on the evidence for the indication / posology for the cutaneous use and members heard a presentation by the Rapporteur. It was agreed to keep the cutaneous indication and its posology as previously adopted with reference to historic evidence presented. While newly added references may point to a wider possible strength, this should be reconsidered with the next systematic revision of the package. It was agreed to not formally re-adopt the package. The AT member expressed support for the recent post-adoption corrections in MO and AR as they addressed one major reason of his previous divergent opinion.

**Post-meeting note:**

**The MT member confirmed to agree with the post-adoption corrections in MO and AR as well as the new references to allow for publication of the documents as evidence for the traditional use had been presented now.**

### 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

**Action:** for discussion

Documents: Draft revised PS; OoC; Presentations/recommendations from Rapporteurs; Questions for finalisation

**Outcome:**

HMPC discussed specific questions and agreed on the way forward for questions 2-6.

For question 1, a final proposal should be provided within the revised PS for agreement at the **HMPC November** meeting.

HMPC further agreed on specific wordings to be introduced in the PS by the Rapporteur. Rapporteur and members discussed limits for intake, recommendations for sensitive groups and adolescents, the use in excipients, the duration of use/understanding of 'short term use'. Once agreed on the specific wording of the PS (scheduled for November) first considerations were made on the publication of the revised PS and overview of comments from the public consultation.

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

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

#### 4.2. Quality

None

#### 4.3. Regulatory / Procedural

##### 4.3.1. Procedure on management of proposals submitted by interested parties for EU List Entries or EU Herbal Monographs (EMA/HMPC/328575/2007 Rev.2)

Report: ORGAM DG Chair

**Action:** for adoption

Documents: Draft revised procedure, OoC, email correspondence

**Outcome:**

Adopted with minor changes in the revised procedure and the OoC.

Minor changes with regard to feedback mechanism to proposing interested parties (rationale for not accepting a substance for assessment) as well as titles of EMA/ HMPC tracking documents were discussed and agreed.

## 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

Document: Draft Agenda, Registration form, Practical information, Invitation letter

**Outcome:**

HMPC noted agenda and practical information.

Speakers were asked to provide presentations via email ideally 1 week before the meeting.

HMPC Chair thanked the Czech host for stepping in during the Finnish presidency and compilation of an interesting agenda. Members were encouraged to participate and to register and book as soon as possible.

#### 5.1.2. Preparation for election of HMPC Chair

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**Action:** for discussion

Documents: [HMPC RoP](#), Presentation

**Outcome:**

HMPC noted presentation on the procedure for the scheduled elections (Chair at the end of the November 2019 meeting and the Vice Chair at the January 2020 meeting).

Call for candidates and procedural information will be sent in writing.

## 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 Agenda dated 25 September 2019

**Outcome:**

HMPC noted draft agenda.

### 5.2.2. Coordination with PDCO/PRAC - postponed

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

### 5.3.1. QRD Template – update of Addendum for THMP

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**Action:** for discussion

Document: Proposals for template improvement, [Addendum to the Quality Review of Documents templates for SmPC](#) for THMPs

**Outcome:**

HMPC agreed to include the topic into the HMPC work plan 2020.

### 5.3.2. Coordination with PCWP/ HCPWP

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**Action:** for adoption

Document: PCWP HCPWP Work plan 2019-2022

**Outcome:**

Adopted.

To further foster patient involvement in HMPC work after the pilot exposure in 2018 (beside standard involvement in herbal summaries and possibility for comments on draft monographs), it was reminded on the possibility to invite patient representatives helping with specific questions. As an example was mentioned the possible involvement in the discussion on Tanacetum for use in migraine (see also 6.3.8) for which patients perceptions of posologies/recommendations will be re-discussed after public consultation.

## 5.4. Cooperation within the EU regulatory network

### 5.4.1. Coordination with European Pharmacopoeia

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- EDQM 13B expert group meetings

Report: M Bald (EDQM)

**Action:** for information

Document: SoD

**Outcome:**

HMPC noted the information with regard to the 13B summary of decisions.

The species change in the updated Ph. Eur. monograph on *Crataegi folium cum flore* was highlighted. Also some specific challenges for the development of *Cannabis* monographs (e.g. inclusion of preparations, sample availability) were discussed.

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

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**Action:** for discussion

Documents: Draft Herbal EU NTC curriculum, Draft curriculum principles, Draft curriculum priorities, Presentation

**Outcome:**

HMPC noted first draft documents and comments by the HMPC Chair.

Members to provide comments by 24 October.

Three documents from the steering group were shortly introduced (draft herbal curriculum, principles and priorities) and first comments by the Chair regarding target audience, course owners and review of material noted. After the meeting, documents will be sent out to all members for a closer look and comments. Further developed documents will then be presented at the HMPC November meeting.

### 5.5. Cooperation with International Regulators

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

None

### 5.7. Work plan

#### 5.7.1. HMPC work plan 2019

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Report: HMPC Chair

**Action:** for information

Document: Work plan 2019, Annex 1, Annex 2 – current status September 2019

**Outcome:**

HMPC noted current status of planned activities 2019.

Most monograph assessments were noted as ongoing, while for those not yet started the likely first discussion at HMPC was indicated. Juniperus reviews were announced for November, Filipendula reviews for January, and for Rosmarini reviews a new Rapporteur will first have to be appointed in November.

### 5.8. Planning and reporting

#### 5.8.1. Move to EMA building, deadlines and meeting dates until Jan 2020

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**Action:** for discussion

Document: Presentation

**Outcome:**

HMPC noted the information provided with reference to the new EMA building as well as the meeting dates until Jan 2020.

The schedule for the gradual move of the agency to the new EMA building was provided.

## 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

None

## 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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### 6.2.2. Monograph on *Millefolii herba* and supporting documents

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**Action:** for discussion

Documents: Draft MO, LE, AR, LoR; New References: 08/08

**Outcome:**

Draft documents to be modified according to the discussion and transmitted for peer-review prior to possible **adoption for release for public consultation in November 2019**.

Timetable:

Documents to be sent to peer-reviewer: **18 October 2019**

Peer-review documents to be sent to Rapporteur: **8 November 2019**

Final documents to be included latest in 2nd premail: **12 November 2019**

Members were asked to provide written comments to the Rapporteur latest by **12 November 2019** to facilitate the discussion and finalisation for public consultation at the HMPC November meeting.

Members discussed changes in the AR and available information from products on the market. For the new draft list entry the relevance of genotoxicity data for all aqueous preparations should be discussed and agreed before release for public consultation scheduled for November 2019.

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

### 6.3.1. Monograph on *Arctii radix* and supporting documents

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**Action:** for discussion

Document: Review report; References: 58/33



**Outcome:**

The Rapporteur was asked to finalise and clean/shorten the review report according to the discussion for **adoption** together with relevant key references **at the HMPC November 2019 meeting**.

Members agreed largely with the Rapporteurs view that no new relevant data are available that would make the monograph revision necessary. Details of low relevance should be removed from the review report and references reduced to key references i.e. to those relevant for the assessment and monograph content as regards safety and efficacy/plausibility.

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**6.3.2. Monograph on Filipendulae ulmariae flos and supporting documents – postponed**

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**6.3.3. Monograph on Filipendulae ulmariae herba and supporting documents – postponed**

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**6.3.4. Monograph on Juniperi aetheroleum and supporting documents – postponed**

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

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**6.3.6. Monograph on Orthosiphonis folium and supporting documents**

**Action:** for discussion

Documents: Review report, supporting documents; References: 05/04

**Outcome:**

The Rapporteur was asked to finalise the review report according to the discussion for **adoption** together with relevant key references **at the HMPC November 2019 meeting**.

The revision of the monograph was advocated because of new safety and toxicological data (incl. on genotoxicity/mutagenicity), new preparations possible to include into the monograph, and the definition change (botanical name, standardisation) of the updated Ph. Eur. monograph. While new limited data may still not allow the preparation of a list entry (to be double checked with new peer-reviewer), the start of the revision was considered useful.

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**6.3.7. Monograph on Taraxaci folium and supporting documents**

**Action:** for discussion

Document: Review report; References: 00/16

**Outcome:**

The Rapporteur was asked to finalise the review report according to the discussion for **adoption** together with relevant key references at the **HMPC November 2019 meeting**.

Some new clinical and safety data were detected, however, not considered changing the content of the monograph because of major shortcomings in the information available.

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**6.3.8. Monograph on Taraxaci radix cum herba and supporting documents**

**Action:** for discussion

Document: Review report; References: 00/14

**Outcome:**

The Rapporteur was asked to finalise the review report according to the discussion for **adoption** together with relevant key references at the **HMPC November 2019 meeting**.

Additionally a correction of the current monograph for reference to the Ph. Eur. was proposed, which can also be mentioned in the addendum without revising the complete package.

The new Ph. Eur. monograph 'Taraxaci officinalis herba cum radice' was not yet available at the time of the first assessment.

No new relevant data were identified to change the content of the monograph. A general comment regarding the use in children/adolescents was taken into consideration but not agreed without new data.

### 6.3.9. Monograph on *Quercus cortex* and supporting documents

**Action:** for discussion

Document: Review report; References: 18/10

**Outcome:**

The Rapporteur was asked to clean/shorten and finalise the review report according to the discussion (only relevant information) for **adoption** together with relevant key references at the **HMPC November 2019 meeting**.

Members discussed safety relevance of new data detected including toxicological and pharmacovigilance data. For instance the relevance of allergic reactions including to pollen from *Quercus* may be double-checked whether leading to changes in the monograph before deciding on the start of the revision procedure.

### 6.3.10. Monograph on *Rosmarini aetheroleum* and supporting documents – postponed

### 6.3.11. Monograph on *Rosmarini folium* and supporting documents – postponed

### 6.3.12. Monograph on *Solidaginis virgaureae herba* and supporting documents

**Action:** for discussion

Document: Review report; References: 21/19

**Outcome:**

Rapporteur to introduce changes in the review report for **a third discussion at the HMPC November 2019**.

Based on new non-clinical/clinical data as well as some changes of the marketing status in some MSs the Rapporteur suggested a revision of the monograph. However, some members asked the Rapporteur to double-check whether the content of the monograph would change and to present a modified review report for the next meeting.

### 6.3.13. Monograph on Zingiberis rhizoma and supporting documents – request for unscheduled revision

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**Action:** for discussion

Document: Review report; 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

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

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**Action:** for discussion

Documents: Draft PS, Draft AR, email communication, Draft preliminary MO, Comments from SE, [Uptake of the traditional use registration](#); References: 00/00

**Outcome:**

The Rapporteur was asked to check and finalise documents according to the discussion including relevant information on the method of manufacture of products on the market for further discussion and possible adoption at the **HMPC November 2019 meeting**.

Members discussed options to develop a monograph, issue a public statement (incl. AR and LoR) or discontinue the assessment because of insufficient data. National experiences with classification were discussed noting different approaches (declaration as homeopathic or as herbal preparation) linked to the manufacturing method or also to the indication. Previous national decisions including clarification sought from the Commission and related court cases with regard to Anthroposophic products were reported as well as specific legislation in some MSs.

Given the borderline to homeopathic products it was agreed to change the peer-reviewer (see 2.1.2).

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

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#### 6.5.3. Monograph on Menyanthes trifoliata folium and supporting documents

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**Action:** for discussion

Documents: Draft MO, AR, LoR; References: 59/73

**Outcome:**

Postponed

#### 6.5.4. 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; References: 02/188

**Outcome:**

Postponed

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

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**Action:** for discussion

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

**Outcome:**

Postponed

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6.5.6. **Monograph on *Species amarae* and supporting documents**

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**Action:** for discussion

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

**Outcome:**

Postponed

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6.5.7. **Monograph on *Species sedativae* and supporting documents**

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**Action:** for discussion

Documents: Draft MO, AR, LoR; References: 35/44

**Outcome:**

Postponed

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6.5.8. **Monograph on *Vaccinii macrocarpi fructus* and supporting documents**

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**Action:** for discussion

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

**Outcome:**

Postponed

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6.5.9. **Monograph on *Verbenae citriodoraе folium* and supporting documents**

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**Action:** for discussion

Documents: Draft MO, AR, LoR; References: 00/22

**Outcome:**

Rapporteur to introduce changes in the MO and AR according to the discussion for **a third discussion in HMPC November 2019**.

First draft versions of AR and MO were presented and critical points highlighted requiring further data check in particular with regard to preparations, age limitation, and interpretation of toxicological data.

## 7. Any other business

### 7.1. Topics for discussion

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

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**Action:** for discussion  
Documents: Presentation

**Outcome:**  
Postponed

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

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**Action:** for discussion  
Documents: MO, Presentation

**Outcome:**  
Postponed

### 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 08-10 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

Overview of status of HMPC/MLWP assessment work

Final Monograph Overview

#### 7.2.2. ARSP

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- English template
- English summaries for publication

#### 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 *Menthae piperitae folium* and supporting documents – awaiting finalisation shared AR with *Menthae aetheroleum* for final adoption  
Documents: MO, AR, LoR
- Monograph on *Species digestivae* or *species stomachicae* and supporting documents - awaiting Estragole PS finalisation

#### 7.2.4. Other

- Draft programme: Borderline Products Workshop, 22–23 October 2019, Uppsala, Sweden
- PCWP/HCPWP meetings:
  - PCWP - Meeting Summary PCWP Plenary Meeting 24 Sep 2019
  - PCWP/HCPWP - Meeting Summary PCWP/HCPWP Joint Meeting 25 Sep 2019
  - HCPWP - Meeting Summary for the HCPWP Plenary Meeting 24 Sep 2019

### List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 23-25 September 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	
Martina Holenkova	Expert	Czech Republic	No interests declared	
Steffen Bager	Member	Denmark	No restrictions applicable to this meeting	
Eeva Sofia Leinonen	Member	Finland	No interests declared	
An Le	Member	France	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	
Baiba Jansone	Alternate	Latvia	No interests declared	
Audronis Lukosius	Alternate	Lithuania	No interests declared	
Everaldo Attard	Member	Malta	No interests declared	
Emiel Van Galen	Member	Netherlands	No interests declared	

Burt H Kroes	Alternate	Netherlands	No interests declared	
Els Ensink	Expert	Netherlands	No interests declared	
Hilda Kuin	Expert	Netherlands	No interests declared	
Gro Anita Fossum	Alternate	Norway	No interests declared	
Wojciech Dymowski	Member	Poland	No interests declared	
Ewa Widy Tyszkiewicz	Expert	Poland	No interests declared	
Carmen Purdel	Member	Romania	No interests declared	
Milan Nagy	Alternate	Slovakia	No interests declared	
Barbara Razinger	Member	Slovenia	No interests declared	
Adela Núñez Velázquez	Member	Spain	No interests declared	
Karin Erika Svedlund	Member	Sweden	No interests declared	
Anna Wannberg	Expert	Sweden	No interests declared	
Ewa Balkowiec Iskra	Co-opted member	Poland	No interests declared	
Gert Laekeman	Co-opted member	Belgium	On a voluntary basis no participation in discussions, final deliberations and voting on	agenda point 6.3.13
Heidi Foth	Co-opted member	Germany	No interests declared	
Melanie Bald	Observer	EDQM	No interests declared	