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SCIENCE MEDICINES HEALTH

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Inspections, Human Medicines Pharmacovigilance & Committees Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 13-15 January 2020

Chair: vacant Vice-Chair: Emiel van Galen

13 January 2020, 12:00 – 19:00, 1C

(HMPC Chair elections: 13 January 2020, 16.00 – 17.00, 1C)

14 January 2020, 09:00 – 18:00, 1C

15 January 2020, 09:00 – 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.

Note on access to documents

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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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, 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:

- DE, Susanne Flemisch (alternate) as of 19 December 2019
- FR, Michele Brum (alternate) as of 01 January 2020

End of membership:

- DE, Birgit Merz (alternate) as of 18 December 2019

1.2. Adoption of agenda

HMPC agenda for 13-15 January 2020

Time schedule for 13-15 January 2020

Outcome:

Agenda adopted.

Time schedule endorsed.

1.3. Adoption of the minutes

HMPC minutes for 18-20 November 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 January 2020

Report: HMPC Vice-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 Allium it was noted that a corrected assessment report has just been provided to address post-adoption issues, which will be discussed at the HMPC March meeting.

2.1.2. Appointment of Rapporteurs and Peer-reviewers

Report: HMPC Vice-Chair

Action: for adoption

Outcome:

HMPC confirmed the Rapporteurs and Peer-reviewers on new procedures in line with the work plan 2020 (see 5.7.1).

New assessments to start in 2020

- Taraxaci radix

Periodic reviews to be started in 2020

- Agropyri repentis rhizoma
- Caryophylli floris aetheroleum
- Carvi aetheroleum
- Carvi fructus
- Chamomillae romanae flos
- Cinnamomi cortex
- Cinnamomi corticis aetheroleum
- Colae semen
- Fucus vesiculosus
- Fumariae herba
- Lavandulae aetheroleum
- Lavandulae flos
- Mate folium
- Plantaginis lanceolatae folium
- Solani dulcamarae stipites
- Urticae herba
- Urticae folium
- Viola tricoloris herba

- Zingiberis rhizoma

Revision to be started in 2020

- Pelargonii radix

Other changes:

Absinthi herba: New Rapporteur

Sabalis serrulatae fructus: New Peer-reviewer

HMPC secretariat will update the HMPC status overview, announce the start of procedures in the public meeting report and publish Calls for data (in several waves to ease the response by interested parties).

2.1.3. Absinthii herba and supporting documents - request for unscheduled monograph revision

Action: for discussion

Documents: Request from AESGP, Review Report

Outcome:

HMPC agreed with the Rapporteur's position that the wording in monograph section 4.7. should be corrected.

Rapporteur to finalise the review report with the recommendation for correction of the current monograph for **adoption at the HMPC March meeting**.

Timetable:

Documents to be sent to Peer-reviewer: **07 February 2020**

Peer-review documents to be sent to Rapporteur: **14 February 2020**

Final documents to be included latest in 2nd premail: **25 February 2020**

Alignment in consistency with the PS on the use of HMPs containing thujone and the monograph on *Salviae officinalis folium* was endorsed. Because the monograph was recently revised and no new data were provided, a need to start a new revision procedure could not be established.

HMPC agreed to correct the oversight during the revision following the rationale provided in the AR for the revised *Salvia* monograph. It was further proposed to discuss at the HMPC March meeting the alignment in the interpretation of Dettling (2004) data in the PS on the use of HMPs containing thujone (EMA/HMPC/732886/2010 Rev.1).

2.1.4. Taraxaci radix and supporting documents - possible monograph development

Action: for adoption

Documents: Proposal for assessment; see also 5.7.1.

Outcome:

HMPC agreed to the Rapporteur's proposal that there seem to be sufficient data for a monograph establishment.

The substance will be added to the HMPC work programme and a Call for data will be published.

The proposal is based on mono and combination products reported to be on the market in some MSs, available Ph. Eur. monograph and other supporting scientific information.

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

2.2.1. Monograph on Hippocastani semen and supporting documents

Action: for adoption

Documents: MO, AR, LoR, Reader's guidance; References: 75/72

Outcome:

Final revised monograph and supporting documents adopted by majority vote (25 out of 26). The Norwegian delegate expressed a favourable position.

Divergent opinion: Wojciech Dymowski

The footnote in the monograph regarding the old Ph. Eur. monograph has been updated in accordance with the HMPC November discussions. A reference to the rationale on correlation factors in the OoC has been introduced in the AR. A majority agreed that beyond that the issue of analytical conversion factors and adapted specification/declaration of Hippocastani preparations may be solved in national procedures for specific products.

The divergent position referred to the one conversion factor used for the monograph emphasizing that individual products may have slightly deviating conversion factors based on specific analytical data.

2.2.2. Monograph on Menthae piperitae aetheroleum and supporting documents

Action: for adoption

Documents: LE, MO, AR, LoR ; References: 109/205

Outcome:

Final revised monograph and supporting documents adopted by majority vote (24 out of 26). The Norwegian delegate expressed a favourable position.

Divergent opinions: Alessandro Assisi, Sheena Kennedy

Rapporteur to provide missing references before publication of the package.

Changes to EU list entry adopted by consensus. The Norwegian delegate expressed a favourable position. HMPC secretariat to initiate translation process and transfer to the European Commission.

Divergent opinions on the monograph referred to the acceptance of well-established use of the indication already included in the first version of the monograph but not to any changes included during the revision.

2.2.3. Monograph on Menthae piperitae folium and supporting documents

Action: for adoption

Documents: MO, AR, LoR; References: 109/205

Outcome:

Final revised monograph and supporting documents adopted by consensus. The Norwegian delegate expressed a favourable position.

Rapporteur to provide missing references before publication of the package.

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

None

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: 58/33

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 *Arctii radix*.

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

A minor discrepancy between the posology in the monograph and a registered product on the market in one MS was discussed. However, as the information was already available during the first assessment no change in the monograph was requested.

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

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 contamination of herbal medicinal products/traditional herbal medicinal products with pyrrolizidine alkaloids (EMA/HMPC/328782/2016)

Action: for discussion

Document: Draft revised PS

Outcome:

HMPC noted the first draft revision by the Rapporteurs according to new data made available and discussed toxicological models and other factors relevant for limit calculation.

Rapporteurs to modify according to the discussion for re-discussion at the HMPC March meeting and possible adoption for coordination with SWP before release for public consultation in conjunction with the PS on the use of HMPs containing PA.

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

4.4. Report on HMPC Drafting Groups activities

4.4.1. Quality DG

None

4.4.2. ORGAM DG

None

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Strategic Review and Learning Meetings

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

Action: for discussion

Document: Summary of group discussions

Outcome:

HMPC noted the feedback given from the group topic leaders.

Regarding future SRLM meetings, no new information was provided for a possible SRLM under the Croatian presidency (no HMPC meeting scheduled), while the date for the SRLM under the German presidency was announced: 2-4 September 2020.

5.1.2. Election of HMPC Chair

Action: for adoption

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

Outcome:

The election 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.

The current Vice-Chair and then the EMA secretariat will take the Chairperson responsibilities/tasks till the next election during the March 2020 HMPC meeting.

The Vice-Chair election previously planned for the HMPC January 2020 meeting (mandate ending 29 January 2019) will be held at the meeting following successful Chair election.

5.2. Coordination with EMA Scientific Committees or CMDh-v

5.2.1. Coordination with PDCO/PRAC

- Discussion paper on age limitation for use of cough and cold herbal medicinal products in children

Action: for discussion

Documents: Draft discussion paper, Annex to draft discussion paper

Outcome:

HMPC agreed to the question and 2 Annexes with some modifications for submission to PDCO/PRAC.

Co-opted member for paediatrics with the help of the HMPC scientific lead to introduce the topic at PDCO as required.

Modifications were endorsed and a deletion of an annexed table was proposed. A final editing was considered necessary before submission to the PDCO for an introduction into the topic.

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

Report: HMPC Vice-Chair

Action: for discussion

Document: [Draft method for determination of Pyrrolizidine Alkaloids published in Pharmeuropa](#)

Outcome:

HMPC welcomed publication of the PA LC-MS or MS method principle and validation criteria in Pharmeuropa and noted scheduled times for comments and finalisation.

Further discussion was postponed to the HMPC March meeting with potentially an EDQM representative available.

It was clarified that it is not a specific method but rather a frame for method development and validation to allow some flexibility. It was encouraged that national quality experts look into the details within the Pharmeuropa time limits for comments. Some questions regarding method accuracy, choice of reference substances and implications for ongoing revision of HMPC public statements (see 4.1) may be discussed at the HMPC March meeting.

5.5. Cooperation with International Regulators

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

Action: for information

Document: Report from Vice-Chair

Outcome:

HMPC noted a brief meeting summary and developments at IRCH under new WHO management. The meeting report will be distributed once available.

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

5.6.1. AESGP – hearing

Action: for adoption

Document: Draft report

Outcome:

Adoption postponed. HMPC welcomed draft hearing summary but asked for slight modifications to reflect better AESGP and HMPC positions. Members present at the hearing were re-invited to send comments. HMPC secretariat to implement and distribute before adoption at the HMPC March meeting.

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

5.7. Work plan

5.7.1. Draft HMPC work plan 2020

Action: for adoption

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

Outcome:

HMPC work plan including Annex 1 and Annex 2 adopted with minor modifications and added project leads and participants.

5.8. Planning and reporting

5.8.1. EMA building – Health & Safety induction (compulsory for all members)

Action: for information

Document: Presentation

Outcome:

All participants attended the introduction to the new building, health/safety and fire instructions and signed in the respective participant list.

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 Hyperici herba and supporting documents - postponed

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

6.2.1. Monograph on Orthosiphonis folium and supporting documents - postponed

6.2.2. Monograph on Trigonellae foenugraeci semen and supporting documents - postponed

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

6.3.2. Monograph on Filipendulae ulmariae herba and supporting documents

Action: for discussion

Documents: Review report; References: 15/15

Outcome:

HMPC endorsed the Rapporteur's position that no new data seem to be available that require the revision of the current monograph.

The Rapporteur was asked to finalise the review report according to the discussion including check of PhV data for **adoption** at the **HMPC March 2020 meeting**.

Timetable:

Documents to be sent to peer-reviewer: **07 February 2020**

Peer-review documents to be sent to Rapporteur: **14 February 2020**

Final documents to be included latest in 2nd premail: **25 February 2020**

6.3.3. [Monograph on Juniperi aetheroleum and supporting documents](#)

Action: for discussion

Documents: Review report; References: 00/58

Outcome:

Rapporteur to modify the review report including check of PhV data (support by the IE delegate), reduction of references to those relevant for safety/efficacy and provision of those as full texts for **2nd discussion at the HMPC March 2020 meeting**.

HMPC endorsed Rapporteur's preliminary position that no new data seem to be available that require the revision of the current monograph.

6.3.4. [Monograph on Juniperi pseudo-fructus and supporting documents](#)

Action: for discussion

Documents: Review report; References: 00/38

Outcome:

Rapporteur to modify the review report including check of PhV data, (support by the IE delegate) reduction of references to those relevant for safety/efficacy and provision of those as full texts for **2nd discussion at the HMPC March 2020 meeting**.

HMPC endorsed Rapporteurs preliminary position that no new data seem to be available that require the revision of the current monograph.

HMPC noted the name change in the corresponding Ph. Eur. monograph (plant part). Such update can be given in an addendum to the AR but does not justify alone to revise the complete package.

6.3.5. [Monograph on Pelargonii radix and supporting documents - request for unscheduled monograph revision](#)

Action: for discussion

Documents: Review report, MO; References: 00/07

Outcome:

The Rapporteur was asked to finalise the review report according to the discussion for **adoption** together with relevant key references at the **HMPC March 2020 meeting**.

Timetable:

Documents to be sent to peer-reviewer: **07 February 2020**

Peer-review documents to be sent to Rapporteur: **14 February 2020**
Final documents to be included latest in 2nd premail: **25 February 2020**

HMPC endorsed the Rapporteur's position that there is new information available that could change the content of the monograph. In addition, the last revision focused solely on re-evaluation of clinical data vis-a-vis the bronchitis severity score but did not include all new data available since the first assessment. A complete update of the package appears indicated in view of time elapsed since the first assessment (2012).

The substance was therefore added for start of revision to the HMPC workplan 2020 and a Call for new data will be published.

6.3.6. [Monograph on Rosmarini aetheroleum and supporting documents - postponed](#)

6.3.7. [Monograph on Rosmarini folium and supporting documents - postponed](#)

6.3.8. [Monograph on Sabalis serrulatae fructus and supporting documents – request for unscheduled revision](#)

Action: for discussion

Documents: Review report; References: 05/05

Outcome:

HMPC noted an update by the French delegate on the national situation in France.

A majority raised concerns regarding comparability and extrapolation in view of established general principles as well as specific complicating factors such as CO₂ extracts' characteristics and the lack of a recognised active constituent for Sabal.

Rapporteurs to update the report according to the discussion **for possible adoption at the HMPC March meeting**.

Timetable:

Documents to be sent to peer-reviewer: **07 February 2020**

Peer-review documents to be sent to Rapporteur: **14 February 2020**

Final documents to be included latest in 2nd premail: **25 February 2020**

The general question on comparability as well as handling of CO₂ extracts is to be re-considered at the HMPC March meeting e.g. for Q&A development by quality experts.

Scientific, regulatory and legal aspects of the request were discussed including principles for biosimilars and analogies/differences to herbal MPs. There was agreement to (1) differentiate between the specific data situation of the Sabal request and (2) general questions on principles applied (comparability, extrapolation, data transfer, specification of CO₂ extracts for possible inclusion into monographs). While (1) the unscheduled review procedure should be finalised in March (members have the opportunity to give their divergent positions in the review report), the general questions (2) will need further discussions. It should include a check of coverage by existing HMPC Q&A/ guidance and need for useful amendments.

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

Action: for discussion

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

Outcome:

HMPC noted the Rapporteur's view that data provided are not sufficient alone to decide on the need for monograph revision and additionally a new market overview is required.

In view of the time elapsed since the first assessment (adoption of the first monograph 2012) it was agreed to check for all new data available to decide on the need for monograph update.

HMPC agreed to include the substance under 'Periodic reviews to be started' on the work plan 2020 and publish a Call for data.

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 Menyanthes trifoliata folium and supporting documents

Action: for discussion

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

Outcome:

Rapporteur to introduce changes in the MO and AR according to the discussion for **a fifth discussion in HMPC March 2020**.

The Rapporteur gave a short update on key issues and the latest status of the documents. Some members raised remaining inconsistencies as previous comments had not been sufficiently reflected in MO and AR. Critical points were discussed one by one. The Vice-Chair advised that the Rapporteur after introducing the changes liaises first with commenting members before providing an updated version for the next plenary. Changes and open points should be summarised in a Readers' guidance to facilitate the discussion and finalisation.

6.5.2. Monograph on Saccharomyces cerevisiae CBS 5926 and supporting documents

Action: for discussion

Documents: Draft MO, Draft LE, Draft AR, Draft LoR, EMA letter to EC, EC response; References: 02/188

Outcome:

HMPC discussed (a) the scientific background and definition of HMPs vis-a-vis the uniqueness of living yeasts and (b) benefits/disadvantages of a monograph plus the potential content of a PS in view of authorised products.

The Vice-Chair encouraged to continue the mutual understanding (general agreement on point a) for the eighth discussion at the HMPC March meeting with a focus on point b) for regulatory pragmatic solutions to facilitate NCAs and to finalise the HMPC procedure.

6.5.3. Monograph on Species amarae and supporting documents

Action: for discussion

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

Outcome:

Rapporteur to modify the documents according to the discussion for possible **adoption for public consultation at the HMPC March meeting.**

Timetable:

Documents to be sent to peer-reviewer: **07 February 2020**

Peer-review documents to be sent to Rapporteur: **14 February 2020**

Final documents to be included latest in 2nd premail: **25 February 2020**

HMPC noted the link to the Menyanthes 'mono-monograph' (see 6.5.1), for which the draft may not be published later than this combination monograph that refers to it.

The Rapporteur showed the last changes in the AR and the topics still to be clarified. Details of the complex Tables 2 and 3 in section 2 of the assessment report were discussed requiring e.g. some clarifications on original information for Artemisia in some traditionally used combinations to re-confirm the calculations performed.

6.5.4. Monograph on Species sedativae and supporting documents - postponed

6.5.5. Monograph on Vaccinii macrocarpi fructus and supporting documents

Action: for discussion

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

Outcome:

Rapporteur to introduce changes in the MO and AR according to the discussion for **a sixth discussion in HMPC March 2020.**

The latest status of the documents and challenges in the assessment were presented. Several comments were made and partially changes introduced, while a more detailed check and amendments will be required for the next discussion: (1) concerns to support the traditional use from information derived from clinical trials; (2) the preparation specification in monograph section 2 and comparability of extracts/data with reference to national registrations (refinement steps of the extract); (3) the summary of the clinical evidence and the distinction of treatment and prevention; (4) the contraindications in the monographs not supported by information in the AR and parallels to antibiotics used in the same indication; (5) interactions and undesirable effects; (6) available genotoxicity data, and (7) the use in men vis-à-vis women and comparability with other substances such as Uvae ursi folium in this respect.

6.5.6. Monograph on Verbenae citriodora folium and supporting documents - postponed

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

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

6.5.9. Monograph on *Salviae miltiorrhizae radix et rhizoma* and supporting documents

Action: for discussion

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

Outcome:

Rapporteur to modify AR and LoR according to the discussion and reconsider the possibility for monograph establishment for the herbal substance.

Members were asked to provide comments and relevant supporting information to the Rapporteur for **a second discussion in HMPC March 2020**.

The Rapporteur presented draft documents and data available including the distinction of various substances and preparations described in pharmacopoeias, products and literature. Some members did not agree with the proposed public statement, because for a herbal substance the totality of data usually accepted may allow a monograph. Members discussed the value/contribution of some literature sources, of information from products outside MP legislation and from sales data for safety conclusions.

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

Document: Presentation

Outcome:

HMPC noted presentation and examples (*Pelargonium*, *Hypericum*, *Cimicifuga*, *Hedera*) on check of data from the Eudravigilance database for incorporation into review and assessment reports.

Positive test examples were noted as well as obstacles such as no resources by PhV colleagues for support in some MSs, lacking access for non-NCA members, correct selection of search terms and confidentiality of data.

A first proposal was made how to practically test the use of available PhV data to improve the corresponding information in HMPC ARs. Reference was also made to available training courses within the EU-NTC network. Some challenges were presented that require cooperation between a herbal and a PhV expert. The approach and result was illustrated with an example (*Hedera*, see 5.2.1).

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 18-20 November 2019

Overview of expertise of members HMPC and subgroups

[Meeting report from HMPC meeting held on 18-20 November 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

- English template
- English summaries for publication

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

- Monograph on *Allii sativi bulbos* 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

7.2.4. Other

None

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 13-15 January 2020 meeting.

| Name | Role | Member State or affiliation | Outcome restriction following evaluation of e-DoI | Topics on agenda for which restrictions apply |
|----------------------------|-----------------------|-----------------------------|---|---|
| Emiel van Galen | Vice Chair | Netherlands | 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 – via Adobe | Czech Republic | No interests declared | |
| Markéta Příhodová | Alternate | Czech Republic | No restrictions applicable to this meeting | |
| Steffen Bager | Member | Denmark | No restrictions applicable to this meeting | |
| Karoline Holm Felding | Alternate – via Adobe | Denmark | No restrictions applicable to this meeting | |
| Eeva Sofia Leinonen | Member | Finland | No interests declared | |
| An Le | Member | France | No interests declared | |
| Michele Brum | Alternate – via TC | 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 | |
| Everaldo Attard | Member | Malta | No interests declared | |
| Burt H Kroes | Alternate | Netherlands | No interests declared | |
| Hilda Kuin | Expert | Netherlands | No interests declared | |
| Steinar Madsen | Member | Norway | No interests declared | |
| Gro Fossum | Alternate – via Adobe | Norway | No interests declared | |
| Wojciech Dymowski | Member | Poland | No interests declared | |
| Ana Paula Martins | Member | Portugal | No interests declared | |
| Carmen Purdel | Member | Romania | No interests declared | |
| Miroslava Petrikova | Member | Slovakia | No interests declared | |
| Barbara Razinger | Member | Slovenia | No interests declared | |
| Adela Núñez | Member | Spain | No interests declared | |

| | | | | |
|-----------------------------|-----------------------|----------|---|-------|
| Velázquez | | | | |
| Karin Erika Svedlund | Member | Sweden | No interests declared | |
| Malin Soderberg | Alternate – via Adobe | Sweden | No interests declared | |
| Gert Laekeman | Co-opted member | Belgium | On a voluntary basis no participation in discussions, final deliberations and voting on | 6.3.9 |
| Heidi Foth | Co-opted member | Germany | No interests declared | |
| Maria Helena Pinto Ferreira | Co-opted member | Portugal | No interests declared | |
| Olga Palomino | Expert | Spain | No interests declared | |