21 January 2026
EMA/HMPC/377649/2025
Human Medicines Division

Committee on Herbal Medicinal Products (HMPC)

Minutes for the meeting on 17-19 November 2025

Chair: Emiel Van Galen, Vice-Chair: Karin Erika Svedlund

Health and safety information

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

Disclaimers

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

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 set of 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/729522/2016).

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1. Introduction

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

The Chair opened the meeting by welcoming all participants. The meeting was held in person.

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 on the topics in the agenda of the meeting, the Committee Secretariat announced the restricted involvement of some Committee members, alternates and experts for the concerned agenda topics. Participants were asked to declare any changes, omissions or errors to their declared interests concerning the matters for discussion. No new or additional competing interests were declared. Restrictions applicable to this meeting are captured in the List of participants included in the minutes.

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. All decisions taken at this meeting were made in the presence of a quorum of members. All decisions, recommendations and advice were agreed by consensus, unless otherwise specified.

The Chair welcomed the new and re-nominated HMPC members and thanked the HMPC members who left the Committee for all their valuable work and contributions to the HMPC.

1.2. Adoption of agenda

HMPC agenda for 17-19 November 2025.

Outcome:

Agenda and time schedule adopted.

1.3. Adoption of the minutes

HMPC minutes for 22-24 September 2025.

Outcome:

Minutes adopted including amendments suggested by HMPC members.

2. EU herbal monographs and list entries for adoption

2.1. Status of HMPC activities

2.1.1. Overview of HMPC assessment work including the Rapporteurship distribution – Status in November 2025

Report: HMPC Chair

Action: For discussion

Document tabled: Overview

Outcome:

HMPC members noted the status of assessment work.
In case of postponement of topics scheduled for the HMPC January 2026 meeting according to the overview, Rapporteurs were asked to inform the Committee secretariat and Chair before the first pre-mail (by 05 January 2026) to allow best adaptation of agenda and time schedule.

2.1.2. Appointment of Rapporteurs and Peer-reviewers

Periodic reviews to start in 2025-2026

Report: HMPC Chair

Action: For discussion

Document tabled: Overview document to sign-up as Rapporteur/Peer-reviewer

Outcome:

Rapporteurs and/or Peer-reviewers were appointed accordingly.

2.1.3. Re-evaluation of Public Statements

Report: HMPC Chair

Action: For discussion

Document tabled: Overview of THMPs on EU market

Outcome:

HMPC members to complete the list of herbal substances with public statements that currently have products available in their national markets for a next **discussion** at the **HMPC January 2026** meeting.

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

2.2.1. Monograph on Arnicae flos and supporting documents - postponed

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 Althaeae radix and supporting documents

Action: For adoption

Documents tabled: Review report, References 04/04

Outcome:

HMPC agreed with Rapporteur's position that no EU herbal 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 Althaeae radix.
The review report was adopted and after editorial review will be published as addendum to the existing assessment report on the EMA website.

The Rapporteur emphasised that there are no new single-component products on the EU market, and in none of the case reports registered in Eudravigilance is there certainty as to the relationship between the ingestion of althaea radix and the adverse reactions observed.

2.4.2. Monograph on Carvi aetheroleum and supporting documents

Action: For adoption

Documents tabled: Review report, References 00/00

Outcome:

HMPC agreed with Rapporteur's position that no EU herbal 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 Carvi aetheroleum.
The review report was adopted and after editorial review will be published as addendum to the existing assessment report on the EMA website.

The Rapporteur highlighted that the minor inconsistency in the therapeutic indication when comparing with Melissa officinalis, Pimpinella anisum and other herbs for gastrointestinal disorders was not considered sufficient to trigger a MO revision.

2.4.3. Monograph on Carvi fructus and supporting documents

Action: For adoption

Documents tabled: Review report, References 00/00

Outcome:

HMPC agreed with Rapporteur's position that no EU herbal 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 Carvi fructus.
The review report was adopted and after editorial review will be published as addendum to the existing assessment report on the EMA website.

See also 2.4.2..

2.4.4. Monograph on Cimicifugae rhizoma and supporting documents

Action: For adoption

Documents tabled: Review report, Reader's Guidance, References 00/07

Outcome:

HMPC agreed with Rapporteur's position that no EU herbal 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 Cimicifugae rhizoma.
The review report was adopted and after editorial review will be published as addendum to the existing assessment report on the EMA website.

The Rapporteur highlighted that the potential risk of hepatotoxicity was already addressed, and no changes of the monograph resulted from the PSUSA-procedure.

2.4.5. Monograph on Curcumae longae rhizome and supporting documents

Action: For adoption

Documents tabled: Review report, References 00/15

Outcome:

HMPC agreed with Rapporteur's position that no EU herbal 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 Curcumae longae rhizome.
The review report was adopted and after editorial review will be published as addendum to the existing assessment report on the EMA website.

The Rapporteur emphasised that data was gathered to calculate a DD limit for curcumin content, beyond which the intake of curcumin-containing products could trigger drug-interactions/hepatotoxicity, but it was much higher to what is established in the MO. Moreover, it was considered not necessary to include additional information about whenever there is a concomitant intake of enhancer substances which may increase the bioavailability of curcumin content (to be taken into consideration in future revisions).
It was suggested to share the review report with EFSA as an example for increasing collaboration in the assessment of herbal substances used as medicinal products and food supplements.

2.4.6. Monograph on Equiseti herba and supporting documents

Action: For adoption

Documents tabled: Review report, References 00/02

Outcome:

HMPC agreed with Rapporteur's position to revise the EU herbal monograph due to inconsistencies with information included in other so-called 'diuretic herbal monographs' that require update and changes to the content of the monograph.
The HMPC decided by consensus to start the revision procedure and revise the monograph, assessment report and list of references on Equiseti herba.
The review report was adopted and HMPC tracking documents will be updated.

The Rapporteur emphasised that the MO sections 4.1., 4.3. and 4.4. have to be updated in order to be harmonised upon agreed for the so-called "diuretic herbal monographs".

2.4.7. Monograph on Oenotherae oleum and supporting documents

Action: For adoption

Documents tabled: Review report, References 00/02

Outcome:

HMPC agreed with Rapporteur's position that no EU herbal 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 Oenotherae oleum.
The review report was adopted and after editorial review will be published as addendum to the existing assessment report on the EMA website.

The Rapporteur highlighted that the Ph.Eur monograph (Oenotherae oleum raffinatum 01/2020:2104) was updated (reference to this can be done when there is a need to revise the EU herbal MO); several trials investigated the clinical efficacy of evening primrose oil, but only a few used only oenothera oleum (more data are necessary to support some potential benefits for the psychological symptoms (e.g. anxiety, depressive mood, irritability) of postmenopausal women assessed using the menopause rating scale (MRS) quality of life questionnaire).

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. Guideline on the assessment of genotoxicity of herbal substances/preparations (EMEA/HMPC/107079/2007) - postponed

4.2. Quality

4.2.1. Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products' (EMA/HMPC/CHMP/CVMP/287539/2005)

Report: Carmen Purdel

Action: For discussion

Documents tabled: Guideline on Declarations outcome QDG meeting, Proposals for revision of HMPC declaration

Outcome:

HMPC members were invited to send comments on the draft revised Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products' (EMA/HMPC/CHMP/CVMP/287539/2005) for consideration in the QDG December meeting (deadline: 05 December 2025), with a next **discussion** scheduled at the **HMPC January 2026** meeting.

The Rapporteur summarised the grounds for reviewing the GL: mainly chapters 5 and 6 have been updated to elaborate the guidance on declaration of herbal substances and herbal preparations, most notably regarding naming of herbal substances, and declaration of fresh and frozen herbal substances, extraction solvents, excipients, and combination products.

4.3. Regulatory / Procedural

None

4.4. Report on HMPC Drafting Groups activities

4.4.1. ORGAM DG

None

4.4.2. Quality DG

- QDG October meeting

  Report: Carmen Purdel

  Action: For information

  Document tabled: Minutes October 2025

  Outcome:

HMPC members were briefed on main QDG activities as per the October meeting: 1) interested parties' collaboration and query received via askEMA; 2) revision of the declaration of herbal substances and herbal preparations in (traditional) herbal medicinal products (EMA/HMPC/CHMP/CVMP/287539/2005; 3) QDG 3-year work plan, focused on activities to be finalised and to be started in 2026; 4) EDQM collaboration. The next meeting is scheduled for 09 December 2025.

- QDG membership – appointment of member(s)

  Report: HMPC Chair; Carmen Purdel

  Action: For adoption

  Documents tabled: Mandate HMPC DG, Call, Nominations

  Document tabled: Draft revised guideline

  Outcome:

  HMPC members were informed of the two nominations received for the open positions in the QDG membership: 1) Mirna Galović from Croatian Agency (HALMED); 2) Stefanie Bodemann from Germany Agency (BfArM).
  Mirna Galović (HALMED, Croatia) and Stefanie Bodemann (BfArM, German) were appointed members of the HMPC-QDG by consensus.

- QDG 3-year work-plan

  Report: Carmen Purdel

  Action: For discussion

  Document tabled: Draft work-plan 2026-28

  Outcome:

  Postponed.

5. Organisational, regulatory and methodological matters

5.1. Mandate and organisation of the HMPC

5.1.1. Strategic Review and Learning Meetings (SRLM)

- HMPC SRLM Follow up plan - status November 2025

  Report: HMPC Chair

  Action: For information

  Outcome:

  Postponed.

- Danish Presidency meeting 8-10 October 2025

  Report: Nanna Lundgaard Rasmussen

  Action: For information

  Documents tabled: 'Danish carousel' outcome; Presentations

  Outcome:

HMPC members were briefed about the main outcomes of the HMPC-SRLM organised by the Dannish Presidency of the Council of the European Union, 08-10 October 2025, which will be reflected in the SRLM follow-up plan for the HMPC meeting in January 2026.

- Cypriot Presidency meeting June 2026

  Report: Christina Sylvia Chrysostomou

  Action: For information

  Document tabled: Presentation

  Outcome:

  HMPC members were informed on the next HMPC-SRLM to be organised by the Cypriot Presidency of the Council of the European Union, 18-19 June 2026, in Paphos, and were invited to propose additional topics for discussion.

5.1.2. HMPC membership

Report: HMPC Chair

Action: For information

New membership:

- Luxembourg, Jean-Luc Bueb (Member), as of 1 October 2025
- Slovenia, Nina Kočevar Glavač (Alternate), as of 22 August 2025

Re-nominated members:

- France, An Le (Member), as of 24 September 2025
- Germany, Jacqueline Wiesner (Member), as of 19 December 2025
- Latvia, Inga Sile (Member), as of 18 January 2026
- Malta, Matthew Camilleri (Alternate), as of 9 October 2025

End of membership:

- Hungary, Rita Nemeth (Alternate), as of 15 July 2025
- Luxembourg, Sven Back (Member), as of 1 October 2025
- Netherlands, Burt Kroes (Member), as of 1 November 2025

5.1.3. HMPC Chairperson - upcoming election 2026

Report: HMPC Chair

Action: For discussion

Document tabled: Presentation

Outcome:

HMPC members were informed that a call for expressions of interest in the position of HMPC chairperson would be sent after the current meeting. The deadline for nominations is 14 January 2026 (motivation letter to all HMPC members and EMA). The election is planned for January 2026 with the mandate of the chairperson starting from 02 March 2026.
In addition, the election for the HMPC Vice-chair position is planned for the meeting in March 2026 (start date of next mandate: 05 May 2026). A call for candidates will be sent out after the January 2026 meeting. Further details and timelines will be communicated in due course.

5.1.4. Fight against disinformation

Action: For information

Document tabled: Presentation

Outcome:

HMPC members were briefed on EMA's misinformation framework and current activities, focused on three main pillars: 1) insights to drive misinformation management; 2) collaborate to share best practices, information and possibly campaigns; 3) build trust in EMA's public health activities. Moreover, some suggestions were made to enhance the public awareness about the HMPC role in public health field (e.g. podcast).
Some HMPC members highlighted that the scientific work from EMA is sometimes misused to promote products not related to public health.

5.1.5. Code of conduct of the European Medicines Agency – provisions for members and experts of scientific committees

Action: For information

Document tabled: Presentation

Outcome:

The EMA presented the updated code of conduct of the EMA, including provisions for members and experts of scientific committees. It was clarified that parts of the code of conduct (common ethical principles) are applicable to all visitors of the EMA: impartiality, integrity and independence; objectivity; confidentiality; respect; non-discrimination; prevention of harassment. Moreover, it was emphasised that specific provisions for handling declarations of interest and confidentiality undertakings as defined in the current 'EMA policy on the handling of competing interests of scientific committees' members and experts (Policy 0044) are also applicable.

5.1.6. Meeting with civil society representatives in EMA scientific committees and management board

Report: HMPC Chair

Action: For information

Documents tabled: Report

Outcome:

The HMPC Chair highlighted the Committee related topics included in the summary report, such as the use of (traditional) herbal medicinal products in children's age groups, the use of HMPC assessments for borderline products and improved communication with the public; the possibility of an EU herbal monograph for cannabis flos for medicinal use.

5.2. EMA Scientific Committees or CMDh-v

5.2.1. HMPC/PRAC collaboration on signal detection: safety-assessment for herbal medicinal products

Report: HMPC (Vice-)Chair(s)

Action: For discussion

Document tabled: Draft "Mandate, Objectives and Rules of Procedure of the HMPC Safety Drafting Group"

Outcome:

Rapporteur to introduce changes in the draft tSDG mandate according to the discussion and HMPC members were invited to send to the Rapporteur any additional comments or recommendations in relation to issues discussed.
Next **discussion** scheduled at the **HMPC January/March 2026** meeting.

HMPC members were briefed about the draft mandate for a HMPC temporary drafting group on safety issues (tSDG), after a gap has been identified by some members regarding the gathering and assessment of pharmacovigilance data for (T)HMPs when it comes to establishing or reviewing EU herbal monographs.
Some HMPC members pointed out that, from a practical perspective, it is fundamental to have a clear understanding of what is expected (tasks/activities) from this tSDG, and which will be the temporal horizon for its mandate. In this regard, it was emphasised that the scope of the group should be reduced and focused on the pharmacovigilance of (T)HMPs), even considering a "proof of concept"/pilot phase period, for example, through the creation of small ad hoc groups dedicated to evaluating pharmacovigilance data related to specific herbal substances under evaluation by the HMPC.

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

5.3.1. HMPC/Translational Science Office collaboration: requirements for studying the interaction potential of herbal medicinal products

Report: HMPC Vice-Chair

Action: For discussion

Document tabled: Draft Reflection paper

Outcome:

HMPC members endorsed to send the draft reflection paper on the investigation of drug interactions of herbal medicinal products to the EMA implementation group of the ICH M12.
Next **discussion** scheduled at the **HMPC January/March 2026** meeting.

The Rapporteur summarised that this RP's purpose is to provide recommendations on how drug interaction issues can be investigated and reported for (T)HMPs applications. In this regard, a section is included with basic information about DDI mechanisms, structured on what to consider regarding applications under the different legal bases (WEU, TU, NAS) - data collection, recommendations on different kind of applications, product information; further guidance regarding assessment of in vitro and in vivo animal studies; further guidance on how interpretation of data should be done and how it should be expressed in the product information (in line with the ARSP template).

5.3.2. HMA Substance Validation Group (SVG)

Action: For information

Document tabled: Presentation

Outcome:

HMPC members were informed on work progress related to the validation of herbal substances in the EU-SRS, mainly focused on the naming rules/hierarchy and on the herbals user guide which is published in the dedicated webpage of the HMA SVG. As a specific problem, it was pointed out that systematic botanical names can change very frequently, and in this sense, how to deal with and monitor these changes.
Some HMPC members emphasised that the standard rule is to follow the names from the Ph. Eur.. Furthermore, it was suggested that the HMPC be involved when SVG questions arose regarding the specific naming of herbal substances.

5.3.3. Patient experience data (PED) reflection paper

Action: For information

Documents tabled: Presentation; Reflection Paper on Patient Experience Data (PED)

Outcome:

HMPC members were invited to send comments on the draft Patient experience data (PED) reflection paper (RP) for a next **discussion** scheduled at the **HMPC January 2026** meeting.

HMPC members were briefed on possible ways for the committee to contribute to the draft RP, which is published for public consultation until 31 January 2026. This paper discusses types and sources of PED, general principles and elaborates on the use and value of PED across the medicine lifecycle; PED can inform medicine development and regulatory submissions, by providing patient insights that can be valuable for the assessment of marketing authorisation applications, as well as in the post-marketing setting; principles outlined in the reflection paper were designed for 'traditional' medicinal product development, but they can also apply to herbal medicines. Moreover, it was clarified that initial thoughts were related to consider medicinal products with the standard development pathway (that is why HMPC was no included in the first consultation with EMA scientific committees).

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopoeia

- EDQM 13A expert group meeting

  Report: Melanie Bald

  Action: For information

  Document tabled: SoD

- EDQM 13B expert group meeting

  Report: Melanie Bald

  Action: For information

  Document tabled: SoD

- EDQM TCM expert group meeting

  Report: Melanie Bald

Action: For information

Document tabled: SoD

Outcome:

The EDQM representative highlighted that the meeting of the Ph. Eur. Commission, which took place on 18 November 2025, and summarised the decisions of the 13A expert group meeting in October 2025 (next meeting in February 2026), 13B expert group meeting in September 2025 (next meeting in February 2026), and TCM expert group meeting in October 2025 (next meeting in January 2026).

5.4.2. European Food Safety Authority (EFSA)

- EFSA botanicals database

Action: For information

Document tabled: Presentation

Outcome:

HMPC members were briefed on the areas of application of the EFSA Compendium of Botanicals as part of the EFSA's toolkit for assessing botanicals and plant-derived substances of concern. It was highlighted that this is an open-source database to facilitate the hazard identification of botanicals and botanical preparations, but an exclusion of a botanical/plant-derived substances from the Compendium of Botanicals does not mean it is safe. Moreover, assessment approaches should be tailored to the characteristics of the regulatory framework and assessment question.
Some HMPC members emphasised the learning/training sets of the different QSAR platforms used/integrated in the compendium and highlighted the importance of having oversight of the cutoff date related to the last update of data. Moreover, it was clarified that focus is on plants used as food/food supplement.

5.5. Cooperation with International Regulators

None

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

5.6.1. Association of the European Self-Medication Industry (AESGP)

- AESGP hearing 2025

Report: HMPC Chair; AESGP

Action: For discussion

Documents tabled: Preparatory paper; Presentations

Outcome:

The AESGP presented the two topics for discussion: 1) Pharma legislation review; 2) Update on RWD/RWE activities in Science/Industry.
A hearing report will be drafted separately for publication at the EMA/HMPC website.

5.7. Work plan and related activities

5.7.1. HMPC work plan 2025

Report: HMPC Chair

Action: For information

Documents tabled: HMPC work plan 2025, Progress report

Outcome:

HMPC members were informed about the progress of the committee work plan for 2025.

- (1.3.1) Establish principles for the role of real-world data in supporting European Union herbal monographs

  Action: For discussion

  Document tabled: Last meeting email

  Outcome:

  HMPC members were invited to send any additional comments or recommendations in relation to issues discussed, focused on what data (RWD) elements about (T)HMPS would be important for supporting the committee assessments.
  Next **discussion** scheduled at the **HMPC January 2026** meeting.

  HMPC were informed about the latest RWE liaison group meeting, mainly focused on the possibility of the committee to provide an extended list of herbal substances to include in the future DARWIN EU data mapping assessment project.
  Some HMPC members suggested that each time a new MO or revision is initiated, the research question(s) to be fulfilled by RWD (DARWIN-EU studies) should be identified.

- (1.3.2) Development of guidance on particulars for signal detection for (traditional) herbal medicinal products

  Action: For information

  Outcome:

  HMPC members were informed that a "proof of concept"/pilot request for consultation with PRAC is being prepared for a specific herbal substance. See also 5.2.1..
  Next **discussion** scheduled at the **HMPC January/March 2026** meeting.

- (1.3.3) Improved evaluation of data from paediatric clinical practice for the safe use of herbal substances in children

  Action: For discussion

  Documents tabled: Draft Reflection paper, Extrapolation in WEU herbal products, OoC

  Outcome:

  Rapporteurs to prepare the OoCs based on the comments received from the IPs during the 3-month public consultation.
  Next **discussion** scheduled at the **HMPC January 2026** meeting.

  The Rapporteur summarised the main points to be discussed, primarily related to the use of RWD and WEU extrapolation.
  Some HMPC members emphasised that RWD is not meant to replace interventional clinical

data (RCTs) on safety and efficacy of medicinal products but recognised the challenges of conducting them for HMPs although they should follow the same regulatory/scientific standards as for other medicinal products. Moreover, it was suggested to also involve CMDh in the WEU discussion and that questions should be firstly addressed by the HMPC/RWE liaison group.

- (2.1.1) HMPC position on the role of EU herbal monographs and assessment reports in relationship to borderline issues

  Action: For discussion

  Documents tabled: Draft Reflection paper, OoC

  Outcome:

  Rapporteurs to compile the OoCs and eventually introduce changes in the draft 'Reflection paper on the use of information in EU herbal monographs and assessment reports for borderline issues' (EMA/HMPC/224438/2024) according to the discussion.
  Next **discussion** scheduled at the **HMPC January/March 2026** meeting.

  The Rapporteur summarised the general comments received from IPs during the 3-month public consultation emphasising the need for guidance and a common best practice for the classification of borderline products given the lack of a harmonised way to classify different product categories across the EU.

- (2.2.1) HMPC communication of information on (traditional) herbal medicinal products to the public and stakeholders

  Action: For adoption

  Document tabled: ARSPs for Cnici benedicti herba; Ginseng radix; Pilosellae herba cum radice; Rosmarini aetheroleum; Rosmarini folium; Taraxaci officinalis radix; Trigonellae foenugraeci semen; Valerianae radix; Zingiberis rhizoma

  Outcome:

  HMPC members endorsed nine ARSPs (Cnici benedicti herba; Ginseng radix; Pilosellae herba cum radice; Rosmarini aetheroleum; Rosmarini folium; Taraxaci officinalis radix; Trigonellae foenugraeci semen; Valerianae radix; Zingiberis rhizoma) for publication. Moreover, the identified ARSPs will be shared with the PCWP.

  ARSPs for nine EU herbal monographs were presented using the revised template adopted during the HMPC September meeting.
  Some HMPC members suggested minor editorial changes to specific ARSPs.

- (2.3.1) Improve work-sharing in HMPC assessment tasks, supported by new herbal curriculum training courses for assessors

  Action: For information

  Documents tabled: Overview internal HMPC training on AR and MO templates, Herbal Curriculum Training Planning 2024-2025; Training 'Assessment report template chapters 4-5-6

  Outcome:

  HMPC members noted the progress of the training programme planned for 2025, targeting committee assessors (assessment report template and corresponding sections in the monograph template) and NCAs (EU-NTC herbal curriculum). A presentation/training

session was given on 'assessment report template chapters 4-5-6 and corresponding sections in the monograph template (including revisions)', which focused mainly on the practical rules/advice for rapporteurs when filling in these 3 chapters of the AR.
Next **discussion** scheduled at the **HMPC January/March 2026** meeting**.**

5.7.2. HMPC work plan 2026

Report: HMPC (Vice-)Chairs

Action: For discussion

Document tabled: Draft workplan

Outcome:

HMPC members were invited to send comments and suggestions on the draft HMPC work plan 2026 for **adoption** at the **HMPC January 2026** meeting.

HMPC members were informed about the draft work plan for 2026, including objectives and activities related to the 6 main topics. Furthermore, the new template (a PowerPoint presentation), which includes a mid-year report, was highlighted.

5.8. Planning and reporting

None

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 Lavandulae aetheroleum and supporting documents

Action: For 22nd discussion

Documents tabled: Draft AR, MO, LoR, Reader's Guidance

Outcome:

Rapporteur to introduce changes in the draft revised EU herbal monograph and supporting documents according to the discussion and possible further comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC January 2026** meeting.

The Rapporteur summarised that the AR chapter 2.3 was cleared from names of member states and the last sentence with interpretation was erased; references were checked for consistency and therefore several short paragraphs were shortened/erased; and chapter on genotoxicity was rearranged and shortened (no new text inserted). However, the 'clinical relevance/significance' resulting from some of the identified clinical studies is still open for adjustments. Moreover, the MO has been updated, mainly the duration of use for TU: the wording "If the symptoms persist after two weeks use of the product, a doctor or a qualified health care practitioner should be consulted" seems appropriate; concerning the age limit: in paragraph 4.3 and 5.5.3 information about data of use in children are given and according to these chapters an age limit of 12 year is well supported.
Some HMPC members pointed out challenges in including meta-analysis in the AR, given that its connection to the products of interest for evaluation may be subject to discussion, and therefore not totally supporting WEU. Moreover, it was again emphasised that the committee has previously agreed to only include TU in MO. AR chapter 4 to be amended with rationale justifying the above conclusions.

6.2.2. Monograph on Lecithinum ex soya and supporting documents

Action: For adoption

Documents tabled: AR, MO, LoR, Reader's Guidance

Outcome:

Rapporteur to introduce changes in the draft revised EU herbal monograph and supporting documents according to the discussion and possible further comments from peer-reviewer and HMPC member, for **possible adoption** for public consultation at the **HMPC March 2026** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **26 January 2026**
Peer-review documents to be sent to Rapporteur: **09 February 2026**
Final documents to be included latest in 2nd premail: **23 February 2026**

The Rapporteur pointed out issues still for discussion: 1) include a TU indication in line with Silybi mariani fructus i.e. 'traditional herbal medicinal product for the symptomatic relief of digestive disorders, sensation of fullness and indigestion and to support the liver function, after serious conditions have been excluded by a medical doctor' (requires further discussion); 2) include a TU indication in line with Allii sativi bulbus i.e. 'traditional herbal medicinal product used as an adjuvant for the prevention of atherosclerosis' (requires further discussion).
Some HMPC members highlighted this MO is for lecithin as a mixture fraction coming from soya-beans (not an isolated compound). Moreover, it was emphasised that MO should be aligned as much as possible to the products on the market.

6.2.3. Monograph on Matricariae flos and supporting documents – postponed

6.2.4. Monograph on Ribis nigri folium and supporting documents

Action: For 2nd discussion

Documents tabled: Draft AR, MO, LoR, Reader's guidance

Outcome:

Rapporteur to introduce changes in the draft revised EU herbal monograph and supporting documents according to the discussion and possible further comments from peer-reviewer and HMPC member, for **possible adoption** for public consultation at the **HMPC January 2026** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **15 December 2025**
Peer-review documents to be sent to Rapporteur: **31 December 2025**
Final documents to be included latest in 2nd premail: **12 January 2026**

The Rapporteur pointed out the remaining issue for discussion related to including a therapeutic indication relating to digestive function for *Ribes nigrum,* taking as reference a product authorised in FR, but although, the period of traditional use was fulfilled, the AR, since the first version adopted in 2017, stated that "the HMPC could not find a suitable indication for the traditional use to support digestive elimination"; thus, this use was not included in the MO.
Some HMPC members proposed additional changes to improve AR/MO and to ensure that information is easily understandable and actionable.

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

6.3.1. Monograph on Anisi aetheroleum and supporting documents

Action: For 1st discussion

Document tabled: Presentation

Outcome:

Rapporteur to prepare the first draft of the review report for discussion at the **HMPC January 2026** meeting.

The Rapporteur summarised that no authorised (T)HMPs containing essential oil from seed of *Pimpinella anisum* as the only active substance are on the EU market, and that a number of new references concerning *in vitro*/*in vivo* non-clinical studies on primary and secondary PD were found but mostly carried out outside EU. Also, it was highlighted that assessment of Eudravigilance data and literature case-reports is ongoing. Regarding the estragole content, it was pointed out that estimated exposure of estragole for anise oil based on the posology reported in the MO (daily intake), is well above the guidance value of 0,05 mg/person per day mentioned in the HMPC's 'Public statement on the use of herbal medicinal products containing estragole' (EMA/HMPC/137212/2005).
Some HMPC members pointed out that the same procedure as done for bitter fennel fruit oil should be followed.

6.3.2. Monograph on Anisi fructus and supporting documents

Action: For 1st discussion

Document tabled: Presentation

Outcome:

Rapporteur to prepare the first draft of the review report for discussion at the **HMPC January 2026** meeting.

The Rapporteur summarised that MO revision is proposed to update sections 4.3 (use in patients with known hypersensitivity to birch and mugwort pollen) and 4.6 (excretion of *trans*-anethol in milk). Regarding the estragole content, it was pointed out that estimated exposure of estragole for aniseed in adults and adolescents, based on the posology reported in the MO (daily intake), is well above the guidance value of 0,05 mg/person per day mentioned in the HMPC's 'Public statement on the use of herbal medicinal products containing estragole' (EMA/HMPC/137212/2005).
Some HMPC members pointed out that the same approach as fennel should be followed, i.e. only the lowest dose of the posology to be kept in the MO.

6.3.3. Monograph on Betulae folium and supporting documents

Action: For 1st discussion

Documents tabled: Review report, presentation

Outcome:

HMPC endorsed the Rapporteur's position that the required consistency with the information included in other so-called 'diuretic herbal monographs' could change the content of the EU herbal monograph and therefore a revision of the complete package is advocated.
Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC January 2026** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **15 December 2025**
Peer-review documents to be sent to Rapporteur: **31 December 2025**
Final documents to be included latest in 2nd premail: **12 January 2026**

The Rapporteur emphasised that the MO sections 4.1., 4.3. and 4.4. have to be updated in order to be harmonised upon agreed for the so-called "diuretic herbal monographs".

6.3.4. Monograph on Echinaceae angustifoliae radix and supporting documents

Action: For 4th discussion

Document tabled: Review report

Outcome:

Rapporteur to modify the review report according to the discussion and possible additional comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC March 2026** meeting.

The Rapporteur pointed out that no new data or safety concerns of relevance were identified for MO content. Moreover, it was highlighted that E. angustifolia is considered for the intended use consistent with the other Echinaceae monographs and thus proposed to prepare the review report for final decision pending PRAC advice.
Some HMPC members discussed whether to retain a comparative table of Echinacea MOs, ultimately agreeing to remove it and rely on the conclusion that the current MO remains consistent. Moreover, it was proposed to wait for the PRAC advice and completion of reviews for all Echinacea species before making a final decision.

6.3.5. Monograph on Echinaceae pallidae radix and supporting documents

Action: For 5th discussion

Document tabled: Review report

Outcome:

Rapporteur to modify the review report according to the discussion and possible additional comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC March 2026** meeting.

The Rapporteur emphasised a new German product registered in 2018 which uses a liquor wine and ethanol extraction and is indicated for 'short-term prevention of colds', while the current MO only covers 'treatment of common cold'.
Some HMPC members discussed whether the new product's indication and extraction method are sufficiently different to require a MO revision (are effects similar?; are there regulatory/consistency implications?). Moreover, it was considered whether to harmonise indications across all Echinacea species, noting that phytochemical similarities might justify consistent indications if prevention is added for one species. Finally, it was proposed to wait for the PRAC advice and completion of reviews for all Echinacea species before making a final decision.

6.3.6. Monograph on Hamamelidis cortex and supporting documents

Action: For 1st discussion

Document tabled: Review report, References 01/01

Outcome:

HMPC endorsed the Rapporteur's position that there is no new information available that could change the content of the EU herbal monograph.
Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC January 2026** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **15 December 2025**
Peer-review documents to be sent to Rapporteur: **31 December 2025**
Final documents to be included latest in 2nd premail: **12 January 2026**

The Rapporteur emphasised that no new data regarding chemical composition or pharmacological properties of hamamelis bark were identified and there are no new herbal substances/preparations with 30/15 years of TU or 10 years of WEU.

6.3.7. Monograph on Hamamelidis folium and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

HMPC endorsed the Rapporteur's position that there is no new information available that could change the content of the EU herbal monograph.
Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC January 2026** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **15 December 2025**
Peer-review documents to be sent to Rapporteur: **31 December 2025**
Final documents to be included latest in 2nd premail: **12 January 2026**

The Rapporteur highlighted that no new data regarding chemical composition or pharmacological properties of hamamelis leaf were identified and there are no new herbal substances/preparations with 30/15 years of TU or 10 years of WEU.

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

Action: For 1st discussion

Document tabled: Review report

Outcome:

HMPC endorsed the Rapporteur's position that there is no new information available that could change the content of the EU herbal monograph.
Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC January 2026** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **15 December 2025**
Peer-review documents to be sent to Rapporteur: **31 December 2025**
Final documents to be included latest in 2nd premail: **12 January 2026**

The Rapporteur emphasised that the case reports in Eudravigilance did not differentiate between "folium" and "folium et cortex aut ranunculus destillatum" and in no case, the relationship between the use of witch hazel and the observed adverse reactions was established. Moreover, there are no new herbal substances/preparations with 30/15 years of TU or 10 years of WEU.

6.3.9. Monograph on Myrrha and supporting documents

Action: For 2nd discussion

Document tabled: Review report

Outcome:

Rapporteur to modify the review report according to the discussion and possible additional comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC January 2026** meeting.

The Rapporteur presented a summary report of search for new information, focused on the pharmacology and biological activities, concluding that no new data on safety concern were published; ethanol intake during use may be relevant for safety concern, but the ethanol warning is already given in the MO. In summary none of the new published information is suitable to trigger a revision of the monograph for the myrrha tincture in TU (oral and cutaneous) applications.

6.3.10. Monograph on Passiflorae herba and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

HMPC endorsed the Rapporteur's position that there is relevant new information available that could change the content of the EU herbal monograph and therefore a revision of the complete package is advocated.
Rapporteur to finalise the review report and send for peer review before **adoption** at the **HMPC January/March 2026** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **15 December 2025**
Peer-review documents to be sent to Rapporteur: **31 December 2025**
Final documents to be included latest in 2nd premail: **12 January 2026**

The Rapporteur summarised that as compared to other MOs in the section on qualitative and quantitative composition liquid extracts are described. However, for dried extracts the only information given is: "Dried extracts corresponding to the tea and liquid extracts above." Dry extracts eligible for TU should be described in a more detailed way, as by now many EU countries have registered dry extracts for TU and furthermore, also already for the original MO and the 1st revision, specified dry extracts have been reported (with 30 years of usage).
Some HMPC members pointed out that the concept of describing liquids extracts and only referring to dry extracts has not been consistently followed for other MOs.

6.3.11. Monograph on Plantaginis ovatae semen and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

Rapporteur to modify the review report according to the discussion and possible additional comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC January/March 2026** meeting.

The Rapporteur emphasised that, according to the SmPC guideline, it would be preferable to include reports on abdominal pain, nausea, vomiting and diarrhoea in the MO chapter 4.8 (requires further discussion, as these symptoms/signals are common to so-called laxatives).

6.3.12. Monograph on Plantaginis ovatae seminis tegumentum and supporting documents

Action: For 1st discussion

Document tabled: Review report

Outcome:

Rapporteur to modify the review report according to the discussion and possible additional comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC January/March 2026** meeting.

See also 6.3.11..

6.3.13. Monograph on Psyllii semen and supporting documents

Action: For 2nd discussion

Document tabled: Review report

Outcome:

Rapporteur to modify the review report according to the discussion and possible additional comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC January/March 2026** meeting.

The Rapporteur emphasised that no changes in adverse events for Ispaghula husk/seed were decided so far, then these changes should not also be considered for Psyllii semen.

6.3.14. Monograph on Rusci rhizoma and supporting documents

Action: For 4th discussion

Document tabled: Review report

Outcome:

Rapporteur to modify the review report according to the discussion and possible additional comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC January 2026** meeting.

The Rapporteur emphasised that the relationship between the reported adverse events, the use of Ruscus aculeatus rhizome containing products and the influence of other variables like disproportionality in reporting, pre-existing conditions or duration of use, are now also addressed.
Some HMPC members proposed to use the standard sentence about EudraVigilance when no relevant data was founded and thus shortening the related information in the review report.

6.3.15. Monograph on Salicis cortex and supporting documents

Action: For 2nd discussion

Document tabled: Review report, Reader's guidance

Outcome:

Rapporteur to modify the review report according to the discussion and possible additional comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC January 2026** meeting.

The Rapporteur pointed out that there are no new medicinal products with Salicis cortex reported as introduced on the EU market; a few reports on adverse reactions were found but they do not influence the current safety profile. Moreover, some new publications on toxicological studies were published and may be added as annex to the current AR.
Some HMPC members highlighted that if safety information is already reflected in the MO, there is no need to include it again in the review report. Moreover, it was proposed to shorten information included in the review report should be improved to ensure that it is easily understandable and actionable.

6.3.16. Monograph on Salviae officinalis folium and supporting documents

Action: For 3rd discussion

Document tabled: Review report

Outcome:

Rapporteur to modify the review report according to the discussion and possible additional comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC January 2026** meeting.

The Rapporteur emphasised that the published study with a product authorised in Switzerland in 2012 as THMP does not fulfil the TU period of 30 years.
Some HMPC members suggested to delete references to trade names of THMPs.

6.3.17. Monograph on Thymi herba and supporting documents - postponed

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

6.4.1. Monograph on Hyperici herba/Cimicifugae rhizoma and supporting documents

Action: For 2nd discussion

Documents tabled: Draft AR, MO, LoR, OoC

Outcome:

Comments received during public consultation. Rapporteur to finalise the draft EU herbal monograph/list entry and supporting documents for peer review and **adoption** at the **HMPC January 2026** meeting.

Timetable:
Documents to be sent to Peer-reviewer: **15 December 2025**
Peer-review documents to be sent to Rapporteur: **31 December 2025**
Final documents to be included latest in 2nd premail: **12 January 2026**

The Rapporteur highlighted that the inclusion of an ethanolic extract (fixed combination containing the dry extract from Hyperici (DER 3.5-6:1), extraction solvent ethanol 60% V/V and dry extract from Cimicifugae (DER 4.5-8.5:1), extraction solvent ethanol 60% V/V) in the MO was previously not agreed, and thus the rationale for this justification was updated in the OoCs. In this regard, it was emphasised that TU evidence for the single active substance (i.e. the ethanolic extract of Cimicifuga) of a fixed combination will not be sufficient to establish a TU for a combination product (as per the Guideline on the assessment of clinical safety and efficacy in the preparation of EU herbal monographs for well-established and traditional herbal medicinal products, EMA/HMPC/104613/2005).
Some HMPC members emphasised that the rationale for not considering the ethanol extract should be improved to ensure that the information in the AR is easily understandable and actionable (and not based on confidential information).

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

6.5.1. Monograph on Valerianae radix/Passiflorae herba and supporting documents

Action: For 1st discussion

Documents tabled: Draft MO

Outcome:

Rapporteur to introduce changes in the draft EU herbal monograph and supporting documents according to the discussion and possible additional comments from peer-reviewer and HMPC members.
Next **discussion** scheduled at the **HMPC January 2026** meeting.

The Rapporteur highlighted that there is at least one TU combination product currently on the ES market, and also some products that despite fulfilling the 30/15years criteria are not any longer on the DE market (need further discussion before being included in the MO). Moreover, it was proposed to split the proposed indication in two indications (agreed). Some HMPC members stressed that it would be helpful to know the reasons why the products were withdrawn from the DE market. It was also pointed out that for the AT products the 30/15years criteria is almost achieved.

7. Any other business

7.1. Topics for discussion

None

7.2. Documents for information

7.2.1. HMPC

Table of Decisions from HMPC meeting held on 22-24 September 2025

Overview of expertise of members HMPC and subgroups

Inventory of herbal substances for assessment work

List of abbreviations used in EMA human medicines scientific committees & CMDh documents and in relation to EMA's regulatory activities

Common names of herbal substances in all languages

Final Monograph Overview

Best practice guide on using HMPC plenary time efficiently (with annexed Reader's Guidance template)

7.2.2. Assessment Report Summary for the Public (ARSP)

- Cnici benedicti herba
- Ginseng radix
- Pilosellae herba cum radice

- Rosmarini aetheroleum
- Rosmarini folium
- Taraxaci officinalis radix
- Trigonellae foenugraeci semen
- Valerianae radix
- Zingiberis rhizoma

7.2.3. Other

- Invitation to Participate and Publicize the WHO Health Heritage Innovations Open Call (H2I)
- Mandate, objectives and rules of procedure for EMA working parties under the domains published
- WHO Global Traditional Medicine Strategy for 2025-2034
- Fact sheet on reference limits for contaminants in HMs

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/ experts following evaluation of declared interests for the 17-19 November 2025 HMPC meeting, which was held in-person.
An asterisk (*) after the role, in the second column, signals that the member/alternate attended remotely. Additional experts participated in (part of) the meeting, either in person or remotely.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Emiel Van Galen	Chair	Netherlands	No interests declared	
Astrid Obmann	Member	Austria	No interests declared	
Patricia Bodart	Member	Belgium	No restrictions applicable to this meeting	
Daniela Ruseva	Alternate*	Belgium	No participation in discussions, final deliberations and voting on:	6.3.10. Monograph on Passiflorae herba
Iliana Ionkova	Member	Bulgaria	No restrictions applicable to this meeting	
Denitsa Momekova	Alternate*	Bulgaria	No restrictions applicable to this meeting	
Ivan Kosalec	Member	Croatia	No restrictions applicable to this meeting	
Darko Trumbetic	Alternate*	Croatia	No interests declared	
Alexandra Demetriou	Alternate	Cyprus	No interests declared	
Markéta Příhodová	Member	Czechia	No restrictions applicable to this meeting	
Kristýna Veselá	Alternate*	Czechia	No restrictions applicable to this meeting	
Nanna Lundgaard Rasmussen	Member	Denmark	No interests declared	
Maria Paile Hyvarinen	Member	Finland	No interests declared	
Sari Koski	Alternate*	Finland	No interests declared	
An Le	Member	France	No interests declared	
Helene Ly	Alternate*	France	No interests declared	
Jacqueline Wiesner	Member	Germany	No interests declared	
Ioanna Chinou	Member	Greece	No restrictions applicable to this meeting	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Julia Pallos	Member	Hungary	No restrictions applicable to this meeting	
Jacqueline Masterson	Member	Ireland	No interests declared	
Alessandro Assisi	Member	Italy	No interests declared	
Anna Maria Serrilli	Alternate*	Italy	No interests declared	
Inga Sile	Member	Latvia	No restrictions applicable to this meeting	
Hilda Kuin	Alternate	Netherlands	No interests declared	
Gro Anita Fossum	Member	Norway	No interests declared	
Marianne Loiten Dalhus	Alternate	Norway	No interests declared	
Wojciech Dymowski	Member	Poland	No interests declared	
Tomasz Stawarski	Alternate*	Poland	No restrictions applicable to this meeting	
Ana Paula Martins	Member	Portugal	No interests declared	
Carmen Purdel	Member	Romania	No restrictions applicable to this meeting	
Dorota Distlerova	Member	Slovakia	No interests declared	
Jaroslav Tóth	Alternate*	Slovakia	No restrictions applicable to this meeting	
Barbara Razinger	Member	Slovenia	No interests declared	
Nina Kocevar Glavac	Alternate	Slovenia	No restrictions applicable to this meeting	
Olga Maria Palomino	Member	Spain	No restrictions applicable to this meeting	
Margarita Berrocal Navas	Alternate*	Spain	No interests declared	
Karin Erika Svedlund	Member (Vice-Chair)	Sweden	No interests declared	
Pierre Duez	Co-opted member*	Belgium	No restrictions applicable to this meeting	
Heidi Foth	Co-opted member	Germany	No interests declared	
Maria Helena Pinto Ferreira	Co-opted member	Portugal	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Maria da Graca Ribeiro Campos	Co-opted member	Portugal	No restrictions applicable to this meeting	
Kristine Hvolby	Expert*	Denmark	No interests declared	
Valerie Niederwieser	Expert*	Germany	No interests declared	
Edyta Burda-Daghish	Expert*	Germany	No interests declared	
Marie Chantal Zwaan-Baltus	Expert	Netherlands	No interests declared	
Ciska Matai	Expert	Netherlands	No interests declared	
Peter Sisovsky	Expert*	Slovakia	No interests declared	
Charlotta Lofberg	Expert*	Sweden	No interests declared	
Melanie Bald	Observer*	EDQM	No interests declared	
An observer from SwissMedic (Switzerland) attended the meeting.				
Meeting run with support from relevant EMA staff.				

Experts' declared interests were evaluated against the agenda topics or activities they participated in.