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SCIENCE MEDICINES HEALTH

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Human Medicines Division

Committee on Herbal Medicinal Products (HMPC) Minutes for the meeting on 19-21 January 2026

Chair: Emiel Van Galen

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.

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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 members of the EEA-EFTA States agreed with the recommendation of the HMPC, unless otherwise specified.

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

1.2. Adoption of agenda

HMPC agenda for 19-21 January 2026.

Outcome:

Agenda and time schedule adopted.

1.3. Adoption of the minutes

HMPC minutes for 17-19 November 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 January 2026

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 March 2026 meeting according to the overview, Rapporteurs were asked to inform the Committee secretariat and Chair before the first pre-mail (by 16 February 2026) to allow best adaptation of agenda and time schedule.

2.1.2. Appointment of Rapporteurs and Peer-reviewers

Periodic reviews to start in 2026-2027

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 as needed.

2.1.3. Re-evaluation of Public Statements

Report: HMPC Chair

Action: For discussion

Document tabled: Overview of THMPs on EU market

Outcome:

A list of herbal substances with HMPC public statements was compiled, indicating which of them currently have products available on EU national markets, and after thorough analysis, the committee agreed not to initiate a review of any of the public statements issued. Some HMPC members emphasised that, although there are HMPs on the EU market for some of the listed herbal substances, they still present safety concerns that will not change the content of the previous public statement.

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

2.2.1. Monograph on Arnicae flos and supporting documents

Action: For adoption

Documents tabled: AR, MO, LoR, OoC, References 0/0

Outcome:

Adoption postponed. Rapporteur to modify the draft revised monograph and assessment report according to the discussion and possible comments from peer-reviewer for **possible adoption** at the **HMPC May 2026** meeting.

Some HMPC members pointed out that some changes are still needed in the AR, mentioning which conclusions should not be drawn in section 4.4.. Moreover, concerns were expressed about the nomenclature used for some of the principal components of the herbal substance.

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

2.3.1. Monograph on Ribis nigri folium and supporting documents

Action: For adoption

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

Outcome:

Draft revised EU herbal monograph and supporting documents adopted by consensus for 3 months public consultation.

The Rapporteur highlighted that, in addition to some editorial changes introduced in the AR/MO, the MO section 4.7 was also updated to reflect the current situation, as no studies are available on the effect on the ability to drive/use machinery. Some HMPC members pointed out that, although the above statement has been previously used in other MOs, it is preferable to follow the wording as proposed in the SmPC guideline/QRD template (agreed). Moreover, it was emphasised that this change may impact the current MO template.

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

2.4.1. Monograph on Betulae folium and supporting documents

Action: For adoption

Documents tabled: Review report, Reader's guidance

Outcome:

HMPC agreed with Rapporteur's position to revise the EU herbal monograph due to the need for consistency with the information included in other so-called 'diuretic herbal monographs', which requires updates and changes to the content of the monograph (sections 4.1., 4.3. and 4.4).

The HMPC decided by consensus to start the revision procedure and revise the monograph, assessment report and list of references on Betulae folium.

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 need to be updated to harmonise with what was agreed upon for the so-called "diuretic herbal monographs".

2.4.2. Monograph on Hamamelidis cortex and supporting documents

Action: For adoption

Documents tabled: Review report

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 Hamamelidis cortex.

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 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.

2.4.3. Monograph on Hamamelidis folium and supporting documents

Action: For adoption

Documents tabled: Review report

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 Hamamelidis folium.

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 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.

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

Action: For adoption

Documents tabled: Review report

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 Hamamelidis folium et cortex aut ramunculus destillatum.

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

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

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

Action: For adoption

Documents tabled: AR, MO, LoR, OoC

Outcome:

Final EU herbal monograph and supporting documents adopted by majority (19 out of 26). Divergent opinions: Finland, Greece, Ireland, Italy, Netherlands, Portugal (member and co-opted member).

The Rapporteur highlighted that the inclusion of an ethanolic extract (i.e., 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 had not been previously agreed upon, and therefore a justification/rationale for this decision is now included in the OoCs and also in the AR (i.e., not fulfilling the 30/15 years criteria). In this regard, it was emphasised again that TU evidence for one herbal preparation (e.g., the ethanolic extract of Cimicifuga) included in a fixed combination will not be sufficient to establish a TU for the 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).

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 (EMA/HMPC/107079/2007)

Action: For discussion

Outcome:

Rapporteurs to continue the revision of the Guideline on the assessment of genotoxicity of herbal substances/preparations (EMA/HMPC/107079/2007), in accordance with the

information and discussions presented.

Next **discussion** scheduled at the **HMPC March 2026** meeting.

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: Draft revised guideline on declarations

Outcome:

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) was endorsed for consultation with the QWP and QRD, CHMP and CVMP.

The Rapporteur summarised some comments received from MSs: 1) 'herbal tea in bag' was kept as a pharmaceutical form, as it is a combined term; furthermore, 'bag' replaced 'sachet' in the example; a similar decision was taken for 'oral herbal material', which is a pharmaceutical dose form according to EDQM standard terms; 2) for the example of essential oil, QDG agreed that the term 'oral drops, liquid' corresponds better to the posology; 3) inserted a new paragraph on combination products in Chapter 5, comparable with the one already included in Chapter 6; 4) in Annex 1, regarding the use of a shortened name for the active substance, QDG agreed to amend the text to address situations where two different parts are used to manufacture the herbal preparation, in order to illustrate that the name should include the plant part, unless otherwise justified; 5) some other editorial changes were made to add more clarity to the text.

As next steps, it was highlighted that the QWP and QRD, CHMPC and CVMP, should be informed before the guideline is released for public consultation.

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 December meeting

Report: Carmen Purdel

Action: For information

Document tabled: Minutes December 2025

Outcome:

HMPC members were briefed on main QDG activities, as per the December 2025 meeting. 1) request received from a Rapporteur regarding *Glycine max* (L.) Merr., lecithinum - QDG agreed that when there is no official quality standard for that preparation, this should be clearly stated in AR; nevertheless, for lecithin, because there is the Ph.Eur. monograph Phospholipida ex soia ad injectabile, this can be mentioned in the AR; 2) revision on the declaration of herbal substances and herbal preparations in (traditional) herbal medicinal products (EMA/HMPC/CHMP/CVMP/287539/2005) - QDG received some comments on the revised draft guideline and discussed them (see also 4.2.1.); 3) NTC- webinar on the revised Variations guideline organised on 11 December by the EMA - QDG agreed on the presentation on the changes with a clear impact on HMPs (the training is available on EU-NTC (course ID: 379015)); 4) QDG 3-year work plan, focused on activities to be finalised and to be started in 2026 (see also below).

The next meeting is scheduled for 05 February 2026. Moreover, it was highlighted that a F2F meeting has been pre-accepted in 2026 for QDG on the margin of the September plenary (draft Agenda to be distributed to the Secretariat to secure the meeting data).

- QDG 3-year work-plan

Report: Carmen Purdel

Action: For discussion

Document tabled: Draft work-plan 2026-28

Outcome:

QDG 3-year work plan 2026-2028 (EMA/HMPC/358650/2025) adopted by consensus.

The next QDG 3-year work plan was presented, focusing on: (A) *Activities to be finalised in 2026* (Guideline on the declaration of herbal substances/preparations in (traditional) herbal medicinal products; Guidance on comparability between herbal preparations); and (B) *Activities to be started in 2026* (Guidance on the classification and the role of markers of medicinal products qualitative analysis of (traditional) herbal medicinal products; Guidance supporting the implementation of the revised Variations framework; Update/revision of the document 'Q&As on quality of (traditional) herbal medicinal products').

Regarding future training, QDG agreed that a training on GACP and related issues could be very beneficial but should be led by the inspectors with some GACP experience. QDG also agreed to investigate whether previous training delivered in 2020-2021 needs to be updated (e.g., training on the types of herbal preparations and their consequences for the control strategy; the choice and role of analytical markers).

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 January 2026

Report: HMPC Chair

Action: For information

Outcome:

HMPC members were invited to regularly consult the follow-up plan with the status of ongoing/new topics/activities proposed after each HMPC-SRLM organised by the Member State holding the rotative Presidency of the Council of the European Union (currently: Cyprus).

- Cypriot Presidency meeting June 2026

Report: Christina Sylvia Chrysostomou

Action: For information

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:

- Germany, Valerie Niederwieser (Alternate), as of 19 December 2025

Re-nominated members:

- Czechia, Marketa Prihodova (Member), as of 10 March 2026

End of membership:

- Germany, Susanne Flemisch (Alternate), as of 18 December 2025

5.1.3. Election of HMPC Chairperson

Action: For adoption

Documents tabled: Call for expression of interest, Presentation, [HMPC RoP](#), Candidatures

Outcome:

The mandate of the HMPC Chair, Emiel Van Galen, will expire on 01 March 2026. The election of the new chair took place in accordance with the HMPC rules of procedure. The nominations received were presented to the Committee. The HMPC elected Carmen Purdel as HMPC Chair for a three-year mandate starting on 02 March 2026. The HMPC and the Agency congratulated Carmen Purdel on her election and wished her all the best in her new role as Chair of the Committee.

See also: [Carmen Purdel elected as new chair of the Committee for Herbal Medicinal Products | European Medicines Agency \(EMA\)](#)

5.1.4. HMPC Vice-Chairperson - upcoming election March 2026

Action: For discussion

Document tabled: Presentation

Outcome:

HMPC members were informed that a call for expressions of interest in the position of HMPC vice-chair would be sent after the current meeting. The deadline for nominations is 25 February 2026 (motivation letter to all HMPC members and EMA). The election is planned for March 2026 with the mandate of the chairperson starting from 05 May 2026.

5.2. EMA Scientific Committees or CMDh-v

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

Action: For discussion

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

Outcome:

Postponed.

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

Action: For information

Outcome:

HMPC members were informed that the draft reflection paper on the investigation of drug interactions of herbal medicinal products has been submitted to the EMA implementation group of the ICH M12 for comments.

Next **discussion** scheduled at the **HMPC March 2026** meeting.

5.3.2. Patient experience data (PED) reflection paper

Report: HMPC (Vice-)Chair(s)

Action: For discussion

Documents tabled: [Reflection Paper on Patient Experience Data \(PED\)](#)

Outcome:

HMPC members agreed not to submit joint comments on the draft reflection on paper patient experience data (PED) during the public consultation until 31 January 2026.

5.4. Cooperation within the EU regulatory network

5.4.1. European Pharmacopoeia

None

5.4.2. European Food Safety Authority (EFSA)

Action: For information

Documents tabled: Draft opinions on berberine-containing plant preparations and on hydroxycitric-acid-containing plant preparations

Outcome:

EFSA representatives summarised the general preliminary conclusions of EFSA's safety assessments, pursuant to Art 8.2. of Reg 1925/2006, relating to 1) berberine-containing plant preparations and to 2) hydroxycitric-acid-containing plant preparations. Moreover, it was pointed out that both draft opinions still need to be endorsed by the EFSA's Panel on Nutrition, Novel Foods and Food Allergens (NDA) before their release for 6-weeks public consultation (end of January), and HMPC members were also invited to send comments.

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

Action: For adoption

Documents tabled: Hearing report 2025

Outcome:

AESGP hearing report 2025 adopted by consensus for publication.

The report from the AESGP hearing held on 19 November 2025, was presented, addressing the two main themes discussed during the meeting: 1) Pharma legislation review; 2) Update on RWD/RWE activities in science/industry.

5.7. Work plan and related activities

5.7.1. Follow-up on HMPC work plan 2025

Report: HMPC Chair

Action: For information

Documents tabled: [HMPC work plan 2025](#)

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

Action: For discussion

Document tabled: Email

Outcome:

HMPC members were invited to send any additional comments or recommendations in relation to issues discussed, focused on a list of products to include in the future DARWIN data mapping assessment projects and what real-world data (RWD) elements about

(T)HMPS would be important for supporting the committee assessments.

Next **discussion** scheduled at the **HMPC March 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. Moreover, it was emphasised the importance to discuss what RWD elements about herbal medicinal products are necessary for HMPC assessments.

- (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 consultation request is being prepared with PRAC for a specific herbal substance and that the group's next meeting is scheduled for February.

Next **discussion** scheduled at the **HMPC 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 RP, OoC

Outcome:

Rapporteurs to finalise the draft 'Reflection paper on data recommendations for herbal medicinal products and traditional herbal medicinal products used in children and adolescents' (EMA/HMPC/71333/2023) and the OoCs according to the discussion for **possible endorsement** at the **HMPC March 2026** meeting for a final consultation with PDCO.

The Rapporteur summarised the main comments received during the public consultation, primarily related to the use of RWD and WEU extrapolation. In this regard, it is proposed to update the related sections of the draft RP (wording agreed).

- (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, Reader's Guidance

Outcome:

Rapporteurs to modify the draft 'Reflection paper on the use of information in EU herbal monographs and assessment reports for borderline issues' (EMA/HMPC/224438/2024) and the OoCs according to the discussion.

Next **discussion** scheduled at the **HMPC March 2026** meeting.

The Rapporteur summarised the main points still for discussion based on the specific comments received from IPs during the 3-month public consultation (all agreed): add a new heading 'Scope'; highlight EU herbal MOs and the annexed ARs could serve as one valuable element supporting the NCAs in their case-by-case decision on classification of individual products (borderline health claims versus therapeutic indications, given 'grey zones' for

some traditional use monographs with therapeutic indications very similar to health claims); revise information related to pharmacological effects to clarify that pharmacological effect is discussed in relation to medical devices, not food supplements.

Some HMPC members pointed out difficulties for having clear 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: Presentation

Outcome:

Rapporteurs to finalise the ongoing drafting of ARSPs for **possible adoption** at the **HMPC March 2026** meeting.

The Rapporteur highlighted the ARSP drafting process is still for discussion: proposal to draft ARSP after the MO final adoption (nomination of a dedicated Rapp), including a comments step by HMPC members and a consultation step with PCWP/HPCWP, before the HMPC final adoption. Moreover, activities are proposed for 2026 to explore best practices for communication on interactions between (T)HMPs and other medicinal products and to improve public communication on safe use of (T)HMPs.

Some HMPC members pointed out that is preferable the ARSP Rapp to be the same one as for the MO itself (nevertheless, there is a ASRP backlog for which Rapps still need to be appointed/confirmed).

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

Action: For information

Documents tabled: Herbal Curriculum Training Planning 2026-2027, HMPC training curriculum priorities January 2026, Overview internal HMPC training on AR and MO templates

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).

Next **discussion** scheduled at the **HMPC March 2026** meeting.

5.7.2. [HMPC work plan 2026](#)

Report: HMPC (Vice-) Chairs

Action: For adoption

Document tabled: HMPC work plan 2026

Outcome:

HMPC work plan 2026 (EMA/HMPC/351681/2025) adopted by consensus.

The HMPC annual work plan was presented, focusing on various topics such as explore new initiatives for the use of RWD and opportunities to use digitalisation and AI in support of

decisions; HMPC position on the role of EU herbal monographs and assessment reports in relationship to borderline issues; development of guidance on particulars for signal detection for (T)HMPs; improve the evaluation of data from paediatric clinical practice for the safe use of herbal substances in children; HMPC communication of information on (T)HMPs to the public and other stakeholders; improve work-sharing in HMPC activities aiming at sustainability of the EMRN. Moreover, it was emphasised that topics in the work plan are highly scrutinised by IPs and, with this in mind, the key objectives and activities planned for 2026 should be realistic.

Some HMPC members pointed out the importance of drawing the attention of IPs to the work developed by the committee (e.g., proposal to create a newsletter). Furthermore, it was suggested to include the MOs figures (new, review, revision) as part of the main deliverables/achievements for 2025.

5.8. Planning and reporting

5.8.1. EMA/FDA Workshop on herbal medicines development

Report: HMPC Chair

Action: For discussion

Document tabled: Draft program, [Botanical Drug Development Guidance for Industry](#)

Outcome:

HMPC members were informed that EMA was contacted by FDA to organise a joint workshop on botanical drug development, to share advanced knowledge/experience and support pharmaceutical developers.

A group of members was established to support EMA/FDA in the organisation of this workshop, starting with the revision of the draft programme.

Next **discussion** scheduled at the **HMPC March 2026** meeting.

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 *Liquiritiae radix* and supporting documents

Action: For 1st discussion

Documents tabled: Draft AR, MO, LoR, OoC

Outcome:

Comments received during public consultation.

Rapporteur to finalise the draft revised EU herbal monograph and supporting documents for peer review and **adoption** at the **HMPC March 2026** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **06 February 2026**

Peer-review documents to be sent to Rapporteur: **13 February 2026**

Final documents to be included latest in 2nd premail: **23 February 2026**

The Rapporteur summarised the remaining issues for discussion, mainly related to the time of CYP induction after treatment with licorice (usually, the maximum induction is observed after 10-14 day with drugs known to be CYP inducers and licorice could be used up to 4 weeks); on the other hand, CYP inhibition occurs rapidly and cannot be ruled out based on available pre-clinical data.

Some HMPC members emphasised that drug-interactions should be reflected in some way in the MO, to make patients aware of the potential risks of concomitant use of CYP substrates and licorice, and in that order, it was agreed to include a sentence in the MO section 4.5. (*'Caution is advised in case of concomitant use of all drug substances the metabolism of which is influenced by CYP3A4'*).

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 - postponed

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 - postponed

6.3.2. Monograph on Anisi fructus and supporting documents - postponed

6.3.3. Monograph on Centaurii herba 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 March 2026** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **06 February 2026**

Peer-review documents to be sent to Rapporteur: **13 February 2026**

Final documents to be included latest in 2nd premail: **23 February 2026**

The Rapporteur highlighted that no relevant adverse events were reported in the Eudravigilance database; the two products identified are already covered in the MO; and the change from the Ph.Eur. monograph revised 07/2024 is already reflected in the name of the herbal substance.

6.3.4. Monograph on Eleutherococci radix and supporting documents

Action: For 1st discussion

Document tabled: Presentation

Outcome:

Rapporteur to prepare first draft of the review report for a next **discussion** scheduled at the **HMPC March 2026** meeting.

The Rapporteur summarised the market overview updated since 2014 (no new products), and the pharmacovigilance data retrieved from Eudravigilance + Vigibase databases (undesirable effects: gastrointestinal complaints – needs further discussion).

6.3.5. Monograph on Myrrha and supporting documents

Action: For 3rd discussion

Document tabled: Review report

Outcome:

Postponed.

6.3.6. Monograph on Plantaginis ovatae 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 May 2026** meeting.

The Rapporteur highlighted that reported cases of paradoxical diarrhoea (which closely resembles common diarrhoea, often occurring suddenly and explosively; it can also cause abdominal pain, cramps, and rectal pain or bleeding; it can be an isolated incident or occur in conjunction with chronic conditions such as irritable bowel syndrome (IBS)) are considered not to trigger a revision of the MO section 4.8. Moreover, some MSs reported that, although no new preparations have appeared on the market, older preparations are still available but are already covered in the current MO/AR.

6.3.7. Monograph on Plantaginis ovatae seminis tegumentum 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 May 2026** meeting.

See also 6.3.6..

6.3.8. Monograph on Psyllii semen 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 May 2026** meeting.

The Rapporteur emphasised that, since no changes have yet been decided regarding adverse events related to Ispaghula husk/seed, changes regarding Psyllii semen should also not be considered.

6.3.9. Monograph on Rusci rhizoma and supporting documents

Action: For 5th 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 March 2026** meeting.

Timetable:

Documents to be sent to Peer-reviewer: **06 February 2026**

Peer-review documents to be sent to Rapporteur: **13 February 2026**

Final documents to be included latest in 2nd premail: **23 February 2026**

The Rapporteur summarised that there are no new safety issues that trigger a revision of the monograph. Overall, there is no new data/findings of relevance for the content of the monograph.

6.3.10. Monograph on Salicis cortex and supporting documents

Action: For 3rd 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 March 2026** meeting.

The Rapporteur highlighted that, overall, data collected over the review period (i.e. few reports on adverse reactions and some new publications on toxicological studies) do not indicate any issue requiring a change in the current MO.

Some HMPC members recommended to improve information included in the review report to ensure that it is easily understandable and actionable.

6.3.11. Monograph on *Salviae officinalis folium* 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 highlighted that one of the articles considered in the review report was published on the PubMed website with only the authors' first name (the article cannot be found with the last names/surnames).

Some HMPC members suggested following the bibliographic reference as presented on the PubMed website. Moreover, it was recommended to shorten the information about the product authorised in Switzerland in 2012 as THMP, but which does not meet the TU 30 years criteria.

6.3.12. Monograph on *Thymi herba* and supporting documents

Action: For 9th discussion

Documents tabled: Review report, Reader's guidance, annex 1, annex 2, annex 3

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 summarised the assessment received from a HMPC member regarding potential allergic reactions associated with thyme-containing products, arguing that a MO revision is recommended. Since new pharmacovigilance data have emerged that need to be assessed, it seems necessary to update the chapter on adverse events in the AR. However, this was not agreed by the Committee.

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

6.4.1. Monograph on *Cannabis flos* and supporting documents

Action: For 1st discussion

Document tabled: OoC

Outcome:

Comments received during public consultation.

Rapporteur to introduce changes in the OoCs received during the public consultation according to the discussion.

Next **discussion** scheduled at the **HMPC March 2026** meeting.

The Rapporteur summarised the main comments received from IPs on the draft PS during the public consultation, mainly related to the eventual existence, in some EU countries (e.g. NL), of *Cannabis sativa* L. flos preparations, as a single herbal substance present in

products manufactured according to GMP, standardised in terms of cannabinoid content, released with official batch certificates, and distributed exclusively as medicinal products. Some HMPC members pointed out again that requirements for the establishment of an EU herbal monograph (TU/WEU) on *Cannabis sativa* L., flos, were found not to be fulfilled at present, and that it was not possible to draft a complete assessment report at this moment.

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 2nd discussion

Documents tabled: Draft MO, AR, LoR

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 March 2026** meeting.

The Rapporteur pointed out that, regarding drug interactions, it is recommended to include information that these herbal substances may increase the effect of other depressants, as indicated in the SmPC of the combination product (agreed). In this sense, this combination may impair the ability to drive and use machines, so affected patients should not drive or operate machinery (agreed).

Some HMPC members emphasised that regarding the MO overdose section, the statement that 'supportive treatment should be given if symptoms appear' should not be included.

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 19-21 November 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)

None

7.2.3. Other

- Invitation European Herbal Health Products Summit 2026 (email)

List of participants

List of participants including any restrictions with respect to involvement of members/alternates/experts following evaluation of declared interests for the 19-21 January 2026 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	
Brigitte Hauser	Alternate	Austria	No interests declared	
Patricia Bodart	Member	Belgium	No restrictions applicable to this meeting	
Iliana Ionkova	Member	Bulgaria	No restrictions applicable to this meeting	
Ivan Kosalec	Member	Croatia	No restrictions applicable to this meeting	
Alexandra Demetriou	Alternate	Cyprus	No interests declared	
Markéta Přihodová	Member	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	
Valerie Niederwieser	Alternate	Germany	No interests declared	
Ioanna Chinou	Member	Greece	No restrictions applicable to this meeting	
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	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Inga Sile	Member	Latvia	No restrictions applicable to this meeting	
Jean-Luc Bueb	Member	Luxembourg	No interests declared	
Everaldo Attard	Member	Malta	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 interests declared	
Ana Paula Martins	Member	Portugal	No interests declared	
Carmen Purdel	Member	Romania	No restrictions applicable to this meeting	
Jaroslav Tóth	Alternate	Slovakia	No restrictions applicable to this meeting	
Barbara Razinger	Member	Slovenia	No interests declared	
Nina Kocevar Glavac	Alternate*	Slovenia	No interests declared	
Olga Maria Palomino	Member	Spain	No restrictions applicable to this meeting	
Margarita Berrocal Navas	Alternate*	Spain	No interests declared	
Malin Kyllikki Hobro Soderberg	Alternate	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	
Maria da Graca Ribeiro Campos	Co-opted member*	Portugal	No restrictions applicable to this meeting	
Marie Chantal Zwaan-Baltus	Expert - in person	Netherlands	No interests declared	
Peter Sisovsky	Expert - remotely	Slovakia	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of DoI	Topics on agenda for which restrictions apply
Charlotta Lofberg	Expert - remotely	Sweden	No interests declared	
Sonny Larsson	Expert - remotely	Sweden	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.