EMA
EUROPEAN MEDICINES AGENCY

# HMPC workplan 2026

## Adopted by the committee on 21 January 2026

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Human Medicines Division

# Contents

# Introduction by the HMPC Chair

Emiel Van Galen

In 2026, the workplan for the Committee on Herbal Medicinal Products (HMPC) reflects three main drivers: to ensure the continuity of all HMPC activities (‘business as usual’); to proceed with topics for which documents were open for public consultation in 2025 (safe use of herbal medicines in children, information related to ‘borderline issues’, improve communication on herbal medicines). Last, but not least: exploring new digital features to strengthen the HMPC work.

*The activities outlined in this workplan have been agreed taking into consideration the Agency’s prioritisation set forth in the EMA multi-annual work programme.*

# Workplan structure

**1**

**Evaluation activities for human medicines:**

- Other specialised areas and activities

**2**

**Horizontal activities and other areas:**

- Committees and working parties
- Partners and stakeholders
- Process improvements

# 1

# Evaluation activities for human medicines

# Other specialised areas and activities

## Explore new initiatives for the use of real-world data (RWD) and opportunities to use digitalisation and artificial intelligence (AI) in support of decisions

Expand the work with the Data Analysis and Real-World Interrogation Network (DARWIN EU) and the joint Heads of Medicines Agencies (HMA) - European Medicine Agency (EMA) Network Data Steering Group (NDSG).

**Key objectives:**

- Explore principles for enhancing the scientific and regulatory use of RWD/AI in the establishment/revision of EU herbal monographs/list entries.
- Continue collaboration with DARWIN EU Coordination Centre.
- Cooperation with the HMA-EMA NDSG.

| Activities in 2026: |
| --- |
| Evaluate additional DARWIN EU studies to be conducted on (traditional) herbal medicinal products ((T)HMPs), focusing on clear research questions, in support of EU herbal monographs. |
| Continue the work of the HMPC/EMA real-world evidence (RWE) liaison group on topics of interest to the Committee related to DARWIN EU studies for (T)HMPs). |
| Explore the new possibilities that digital/AI tools can offer for HMPC assessment work. |

*See Annex for details on the Lead(s)/Contributor(s) and key deliverables*

# Other specialised areas and activities

## HMPC position on the role of European Union herbal monographs and assessment reports in relationship to borderline issues

Enhance guidance for the demarcation between medical devices, food supplements, cosmetics and (traditional) herbal medicinal products, contributing for these products to be marketed under harmonised conditions in the EU.

**Key objectives:**

- Establish a HMPC position on the use of information in EU herbal monographs and assessment reports for borderline issues.
- Expand the work with the HMA-EMA EU-Innovation Network (EU-IN) - Borderline Classification subgroup (BLCG), Heads of Food Safety Agencies (HoA) and European Food Safety Authority (EFSA).

| Activities in 2026: |
| --- |
| Extend collaboration with HMA-EMA EU-IN – BLCG on specific classification issues related to borderline products. |
| Finalise a HMPC reflection paper on the use of information in EU herbal monographs and assessment reports for borderline issues. |
| Explore cooperation with HoA and EFSA on specific safety issues related to herbal products. |

*See Annex for details on the Lead(s)/Contributor(s) and key deliverables*

# 2

# Horizontal activities and other areas

# Committees and working parties

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

Improve signal detection methodology for (T)HMPs, considering their nature, characteristics and the type of product. This is of importance considering that botanical identification and phytochemical characteristics in individual case safety reports and other sources of safety information are sometimes not sufficiently presented.

**Key objectives:**

- Develop guidance on particulars for signal detection for (T)HMPs.
- Continue collaboration with the Pharmacovigilance Risk Assessment Committee (PRAC) on herbal particulars relevant to the signal detection.

| Activities in 2026: | |
|---|---|
| Finalise the reflection paper on particulars for signal detection for (T)HMPs with the contribution of PRAC. | PRAC |
| Centralise available expertise related to safety issues on herbal substances/preparations in a temporary group, supporting HMPC decision-making on safety relevant issues. | |

*See Annex for details on the Lead(s)/Contributor(s) and key deliverables*

# Committees and working parties

## Improve the evaluation of data from paediatric clinical practice for the safe use of herbal substances in children

Develop dedicated criteria/principles for the interpretation of such data, which may support conclusions on most likely therapeutic areas/acceptable indications of (traditional) herbal medicinal products used in children.

**Key objectives:**

- Improve the HMPC assessment for well-established use (WEU) and for traditional use (TU) of (T)HMPs in children to harmonise EU herbal monographs.
- Continue cooperation with the Paediatric Committee (PDCO) on specific questions regarding the paediatric use of marketed (T)HMPs.

| **Activities in 2026:** |
| --- |
| Finalise a reflection paper on data requirements for (T)HMPs used in children. |
| Exchange of views with PDCO for specific questions on the use of (T)HMPs in paediatric population. |

*See Annex for details on the Lead(s)/Contributor(s) and key deliverables*

# Partners and stakeholders

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

Expand the sharing of information in a balanced way, which can contribute to a safer use of (traditional) herbal medicinal products on the EU market.

**Key objectives:**

- Develop principles for enhancing communication on (T)HMPs bringing together similar initiatives already set up by national competent authorities (NCAs).
- Extend collaboration with Patients' and Consumers' Working Party (PCWP) and the Healthcare Professionals' Working Party (HCPWP) on specific communication issues related to (T)HMPs.

| Activities in 2026: |
| --- |
| Establish elements for effective communication initiatives about (T)HMPs focused on the patients and healthcare professionals' needs, and to identify opportunities and limitations for NCAs and EMA/HMPC. |
| Explore EMA initiatives to fight mis-information regarding medicinal products. |
| Explore best practices for communicating (T)HMPs interactions with other medicinal products. |

*See Annex for details on the Lead(s)/Contributor(s) and key deliverables*

# Process improvement

## Improve work-sharing in HMPC activities aiming at sustainability of the European medicines agencies network (EMRN)

Enhance the sharing/transfer of regulatory and scientific knowledge and experience to the next HMPC generation.

**Key objectives:**

- Develop principles for optimising involvement and worksharing among HMPC members in assessment and/or peer-review activities at different levels.
- Raise awareness at the HMA level for an active participation to maintain regulatory/scientific experience.
- Extend the herbal product specific curriculum for NCAs assessors in the framework of the EU Network Training Centre (EU NTC).

| Activities in 2026: |
| --- |
| Establish practical guidance and initiatives to ensure the availability of resources to support HMPC core work, with extended worksharing and increased level of active participation. |
| Review the principles for prioritising the start of the review of existing EU herbal monographs, considering the availability of NCAs assessors to keep current EU herbal monographs scientifically up-to-date. |
| Continue cooperation with the European Directorate for the Quality of Medicines & Healthcare (EDQM) on specific quality key topics. |
| Development and delivery of new EU-NTC LMS training course(s) as contribution to the herbal curriculum. |

*See Annex for details on the Lead(s)/Contributor(s) and key deliverables*

# Annex

# Leads and contributors for the activities

| Activity area | Lead(s) | Contributor(s) |
|---|---|---|
| **Explore new initiatives for the use of real-world data (RWD) and opportunities to use digitalisation and artificial intelligence (AI) in support of decisions** | HMPC (Vice-)Chairs | E. Svedlund, I. Chinou, J. Wiesner, O. Palomino |
| **HMPC position on the role of European Union herbal monographs and assessment reports in relationship to borderline issues** | E. Svedlund | A. Assisi, A. P. Martins, B. Razinger, I. Chinou |
| **Development of guidance on particulars for signal detection for (traditional) herbal medicinal products** | E. Svedlund | H. Kuin, J. Pallos |
| **Improve the evaluation of data from paediatric clinical practice for the safe use of herbal substances in children** | M. H. Pinto Ferreira | I. Chinou, J. Wiesner, P. Šišovský |
| **HMPC communication of information on (traditional) herbal medicinal products to the public and other stakeholders** | A. Lê | B. Razinger, M. Da Graça Campos, O. Palomino, HMPC (Vice-)Chairs |
| **Improve work-sharing in HMPC activities aiming at sustainability of the European medicines agencies network (EMRN)** | HMPC (Vice-)Chairs | E. Svedlund, H. Kuin, I. Chinou, J. Wiesner |

# Main deliverables and achievements of 2025

| Activity area | Deliverables |
|---|---|
| **Establish principles for the role of real-world data in supporting European Union herbal monographs** | • Established a HMPC/EMA RWE liaison group to work on topics of interest to the Committee related to RWD studies for (T)HMPs. |
| **Development of guidance on particulars for signal detection for (traditional) herbal medicinal products** | • Development of HMPC guidance on-going.<br>• Continued collaboration with PRAC on herbal particulars relevant to the signal detection for (T)HMPs. |
| **Improved evaluation of data from paediatric clinical practice for the safe use of herbal substances in children** | • Draft HMPC's reflection paper on data recommendations for (T)HMPs used in children/adolescents published for a 3-month public consultation until 31 August 2025.<br>• Continued expertise exchange with PDCO for specific questions on the use of (T)HMPs in children. |
| **HMPC position on the role of EU herbal monographs and assessment reports in relationship to borderline issues** | • Draft HMPC's reflection paper on the use of information in EU herbal monographs and assessment reports for borderline issues published for a 3-month public consultation until 1 May 2025. |
| **HMPC communication of information on (traditional) herbal medicinal products to the public and stakeholders** | • Preparation of Assessment Report Summaries for the Public (ARSPs) has resumed following review of the specific template. |
| **Improve worksharing in HMPC assessment tasks, supported by new herbal curriculum training courses for assessors** | • Updated overview of decentralised procedure/mutual recognition procedures (DCP/MRP) assessments (up to 2024) for (T)HMPs.<br>• Development and delivery of new EU-NTC training course(s) as contribution to the herbal curriculum.<br>• Established initiatives and common principles to optimise resources, extend worksharing and increase levels of actively participation in the HMPC core work, including trainings for new Committee members, with practical guidance. |
| **Establishment and update of European Union herbal monographs and list entries** | • Herbal monographs, new* = 2<br>• Herbal monographs, reviewed** = 21<br>• Herbal monographs, revised = 4 |

* when the assessment does not lead to the establishment of a monograph, a public statement is prepared
** when after review of new data, no change in monograph/list entry is required, an addendum to the existing assessment report is published

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