21 January 2026
EMA/HMPC/358650/2025
Human Medicines Division

Three-year work plan for the Quality Drafting Group of the Committee on Herbal Medicinal Products

Name of drafting group:	**Quality Drafting Group of the Committee on Herbal Medicinal Products (HMPC-QDG)**
Chairperson:	Carmen Purdel

Work plan period: January 2026 – December 2028

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Table of contents

1. Strategic goals

While herbal medicinal products (HMPs) are not particularly mentioned in the European medicines agencies network strategy to 2028, some topics are relevant for HMPs with their emphasis on quality assessment and control.

1.1. *Short-term strategic goals*

- Provide support to HMPC on all Quality aspects for medicinal products containing herbal active substances[1].
- Provide scientific and regulatory expertise under supervision of HMPC to particular questions on chemistry and analysis of herbal substances/preparations for medicinal use to EU network and support the understanding for control of complex natural compound mixtures and their relevance for safety and efficacy of HMPs (incl. for SA, MDs etc.); ensure a common interpretation of EU guidelines related to Quality aspects.
- Sustain and extend harmonization between MSs by amending the harmonized framework of quality standards applicable for HMPs in the EU.
- Progress development of EU and international guidelines and identify/initiate new guidance topics as relevant. Consolidate learnings from new manufacturing technologies (e.g. supercritical CO_2 extracts, nanotechnology) and new analytical methods (e.g. quantitative NMR and near-IR spec.) for HMPs and provide support to training activities on implementation of priority guidelines.
- In collaboration with other parties in the European medicines regulatory network, advance international regulators and stakeholder interactions: academia, interested parties (IPs), etc.
- Support the establishment of a subgroup of European specialised experts for products containing herbal active substances as part of the Quality European Specialised Expert Community (ESEC).

1.2. *Long-term strategic goals*

The long-term strategic priorities for the HMPC-QDG are as follows:

- Ensure the quality, in relation to the safety and efficacy, of marketed medicines.
- Reinforce scientific and regulatory capacity, resilience and capability of the network and improve the scientific quality of assessments.
- Ensure dedicated collaboration with European regulatory authorities, organisations and industry to promote further development of herbal quality standards including in response to EP, EC on new market trends such as cannabis-derived medicines.
- In collaboration with HMPC, enhance collaboration with academic group.
- Improve the assessment and classification of complex borderline products.
- Maintain appropriate regulatory science knowledge management as a resource to assist the network; in close collaboration with ESECs and other WPs of the Quality domain, develop training and tools to increase mutual understanding and streamline assessment processes.

[1] herbal active substance defined according to Directive 2004/24/EC

2. Tactical goals: activities/projects to deliver the strategic goals

In contrast to most other groups at the EMA, the main customer of HMPC-QDG services and documents are, via HMPC, the NCAs and industry because fundamental and specific standards are mainly used in national procedures. To a minor extent direct input into EMA procedures is required. The below guidelines activities (new guidelines/revisions) reflect the strategic goals listed above.

Guidance activities include review of existing HMPC-QDG guidance and identification of published guidance that may benefit from revision.

Further guidance activities (new guidance/revisions) may be necessary in relation to the implementation of new/revised pharmaceutical legislation.

2.1. *Guideline activities*

2.2. *Work plan period: January 2026 – December 2028*

2.2.1. Guideline activities:

(A) Activities to be finalised in 2026

EU Guidance documents, Revision:

- **Guideline on the declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products**

Rationale: New practices and experiences have already been identified for an update of this guideline; publication of revised guideline.

EU Guidance documents, New:

- **Guidance on comparability between herbal preparations**

Rationale: The absence of guidance causes difficulties at the national level in different procedures. Investigate the possibility to identify appropriate criteria and publish adequate guidance.

(B) Activities to be started in 2026

EU Guidance documents, New/Revision:

- **Guidance on the classification and the role of markers of medicinal products qualitative analysis of herbal medicinal products and traditional herbal medicinal products**

Rationale: Markers are used for quantitative and qualitative analytical control purposes of herbal MPs and for the classification of herbal extracts. However, it is not always clear which constituents are characteristic and/or if the characteristic constituents are suitable to ensure the quality of herbal MPs. In the view of the specific and complex nature, guidance is needed on the selection and use of markers.

- **Guidance supporting the implementation of the revised variations framework**

Rationale: Recent revision of the variations framework for human medicines, through changes in legislation and guidelines, will trigger the need for further clarifications, especially for the new herbal scopes. A possible Q&A document to clarify new requirements is foreseen.

- **Update/revision of the document "Questions & answers on quality of herbal medicinal products/traditional herbal medicinal products"**

Rationale: Remove Q&A now addressed in new revised guidelines.

(C) Activities to be started in 2027-2028

HMPC-QDG will consider the following:

- **Revision of guideline on the quality of combinations of herbal medicinal products**

Rationale: About a third of all herbal authorisations and registrations are combination products. The guideline is more than 10 years old and requires updates considering new European Pharmacopoeia (Ph. Eur.) standards and advanced experiences in the MSs.

- **Guidance on the contamination of herbal medicinal products with polycyclic aromatic hydrocarbons (PAHs)**

Rationale: Following signals mainly from the food and environmental sector, the HMPC had issued a reflection paper and organised a training together with industry to inform more about the topic. Several data were provided by pharmaceutical industry. The form of appropriate guidance and possible testing needs for a group of substances according to specific intrinsic (e.g. mate tea) or extrinsic risks (drying practices for herbal substances in some countries of origin) needs to be evaluated and decided.

- **Guidance on the use of new analytical methods for the quality control of herbal medicinal products**

Rationale: A range of new analytical methods/technologies, e.g. DNA-based technologies, nuclear magnetic resonance spectroscopy, chemometric approaches (including Multivariate analysis) and principal component analysis and biosensors, etc, are being developed and are sometimes already applied in the quality control of herbal substances, herbal preparations and (traditional) HMPs. Guidance is needed to clarify the place of new analytical methods/technologies in the overall quality control system of HMPs.

2.3. *Training activities*

Continue training of quality assessors on a regular basis and building on the Herbal curriculum in the EU network training centre (EU-NTC) under the supervision of HMPC.

*Training under discussion for **2026-2028:***

- Revision/update quality training materials delivered on EU-NTC and included in 'Herbal Curriculum'.

2.4. *Communication and Stakeholder activities*

2.4.1. European level

Continue to engage effectively with industry through specific hearing with IPs on a regular basis (i.e. yearly) to gain external perspective on regulatory science needs. Strategic direction is aligned with Agency priorities (work plan development).

Extent the coordination with EDQM and provide input on the development and review of Ph. Eur. monographs and general chapters, methods and notices. Increase the dialogue on other topics such as

evaluation criteria used in the EDQM certification of herbal active substances and the need for harmonisation with the ones used in the authorisation and registration procedures for (traditional) HMPs in order to ensure consistency with regulatory procedures.

2.4.2. International level

Contribute, comment on international developments and support representation of HMPC and EMA in herbal quality questions, in liaison with International affairs to WHO, mainly IRCH (International Regulatory Cooperation on Herbal medicines) or ICDRA (International Conference of Drug Regulatory Authorities).

2.5. *Multidisciplinary collaboration*

Maintain, or strengthen as relevant, the ongoing collaboration with other working parties and groups, e.g., QWP, GMDP-IWG as well as CMDh, NcWP. Continue to liaise and collaborate on quality-related matters with EDQM. Scientific input for the elaboration and revision of Ph. Eur. monographs, general chapters and notices, and to the EDQM certification of herbal active substances in view of authorisation and registration procedures for (traditional) HMPs.

Collaborate with the NcWP for activities related to the evaluation of potentially toxic components naturally occurring in the herbal drug / herbal preparation (e.g. pulegone, menthofuran, estragole).

3. Operational goals: medicinal product-specific activities

In contrast to most other groups at the EMA, the main customer of HMPC-QDG services and documents is, via HMPC, the NCAs and industry because fundamental and specific standards are mainly used in national procedures. To a minor extent, direct input into EMA procedures is required. Tactical and operational goals can be allocated to four main areas:

1. **Support for HMPC/NCAs**

- By drafting answers to questions of members or IPs;
- By responding to quality issues arising from HMPC assessments in the context of monograph development and mainly safety-relevant guidance;
- Harmonization between NCAs.

2. **Support for other groups within EMA**

- By responding to specific herbal quality questions to HMPC by other groups such as SAWP, CHMP, PDCO or CVMP, e.g. for HMPs based on cannabinoids or other natural products for SA or regarding eligibility.

3. **Support of the wider EU regulatory network**

- Upon request of the European Commission or other EU agencies (e.g. EFSA, EUDA) provide herbal quality expert advice (e.g. on cannabis distinction of products, substances and preparations);
- Maintain and improve close coordination with EDQM, in particular Ph. Eur. expert groups 13A, 13B and TCM;
- Support for EMA internationally not to lose the leading global position of European standards: the set of guidelines on the quality of HMPs are used/recognised globally as reference in international contacts (e.g. with FDA, SFDA, AYUSH, TGA and WHO).

3.1. *Pre-submission activities*

The HMPC-QDG can provide input on quality questions for HMPs and other containing herbal substances, preparations or isolates (such as in combinations) in the framework of HMPC coordination with other EMA committees/working parties, as required by request:

- SAWP (e.g. SA procedures);
- CHMP, PDCO, COMP (e.g. eligibility, quality and composition issues);
- External requests by IPs and AskEMA;
- European Commission.

3.2. *Evaluation and supervision activities*

HMPC-QDG can provide input on quality questions for herbal and other MPs containing herbal substances, preparations or isolates (such as in combinations) in the framework of HMPC coordination with other EMA committees/working parties, as required by upon request:

- PRAC, CMDh (e.g. PhV issues, PSUSA and EURD for herbals);
- External requests by IPs and AskEMA;
- European Commission (e.g. approached by non-EU governmental bodies on specific herbal products).