EMA
EUROPEAN MEDICINES AGENCY

CHMP workplan 2026

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Human Medicines Division

Contents

Introduction by the CHMP Chair

Bruno Sepodes

In 2026, the CHMP will focus on its core scientific and regulatory responsibilities, ensuring high-quality, timely and consistent benefit–risk assessments of human medicines while further improving the efficiency and clarity of its evaluation processes.

The Committee will advance key activities across pre-authorisation and initial evaluations, specialised areas and horizontal initiatives.

This means that the CHMP will also advance work in specialised areas ensuring that regulatory decisions adequately reflect evolving scientific, demographic and clinical realities, with continued emphasis on patient and healthcare professional involvement and close collaboration with other EMA Committees and Working Parties. This will be a critical year for preparing the network for the implementation of the new pharmaceutical legislation, with the CHMP contributing its expertise to support regulatory readiness and a smooth transition to the new framework.

CHMP has several established groups to which it has delegated specific tasks (see: CHMP: Working parties and other groups of interest).

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:

- Pre-authorisation activities
- Initial-evaluation activities
- Other Specialised areas and activities

2

Horizontal activities and other areas:

- Committees and working parties

1

Evaluation activities for human medicines

Evaluation activities for human medicines

Pre-authorisation activities

CAT

Scientific consultations involving other decision makers to facilitate optimisation of clinical evidence generation in drug development programmes

Clinical evidence generated during drug development is intended to serve different decision making. It is therefore desirable that evidence requirements do address regulatory needs as well as those of other down-stream decision makers.

Key objective:

- To engage with other decision makers in multi-stakeholder consultations on evidence generation planning.
- To prospectively identify post-licensing evidence needs considering the expected evidence available at time of initial decision making by regulators and HTAs, respectively.

Activities in 2026:

Collaborate with the Member State Coordination Group on HTA (HTACG) on evidence requirements and management of uncertainties for different types of developments, to inform prospective evidence planning for development programmes.
Engage with the HTACG on opportunities for collaboration on scientific and methodological guidelines.
Explore with healthcare payers' opportunities for sharing views on prospective evidence planning, focusing on post-licensing evidence needs.

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

Evaluation activities for human medicines

Initial-evaluation activities

CAT

Patient and Healthcare Professional involvement in assessment work

The objective is to facilitate engagement of patients and healthcare professionals in benefit/risk evaluation and related activities and reflect their input in CHMP assessments.

In addition, to facilitate the collection and use of patient experience data, so their perspectives and preferences can be considered in benefit/risk evaluations and related activities, along the medicine regulatory lifecycle.

Key objective:

- Maintain current and explore additional processes to capture and include patient experience data within CHMP benefit/risk evaluations.
- Maintain current and explore additional processes to capture and include patient and healthcare professionals' views within CHMP benefit/risk evaluations and reflect this input in assessment reports.

Activities in 2026:
Monitor and improve methodologies to capture input to CHMP procedures (including participation in oral explanations, written consultations, and engaging with patient and healthcare professional organisations at start of Marketing Authorisation Applications).
Contribute to the public consultation and finalisation of the patient experience data Reflection Paper.
Continue to explore how best to reflect in the assessment reports the way that patient and healthcare professional input and patient experience data is assessed and the rationale for acceptance/exclusion for benefit/risk decision-making, linked with the assessment report templates optimization.
Participate in drafting of new ICH guidance on patient experience data and patient preference elicitation.

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

Initial-evaluation activities

Documenting medicines evaluation – an efficiency and stakeholder focus on the CHMP AR and the EPAR

Continue to optimise the evaluation assessment report with the aim to simplify, avoid replication of work and consider stakeholders' expectations. Ensure the best use of available resources at CHMP and EMA to achieve this goal.

Key objective:

- Review ways to improve the efficiency, robustness, consistency and soundness of outputs throughout the initial MAA (iMAA) evaluation process.

Activities in 2026:
Evaluate the outcomes from the pilot where companies pre-fill the D80 templates and decide on future implementation; publish a report.
Enhance, integrate and align templates with the overview template across various types of applications (e.g. extension of indication, generic/hybrid).
Identify and implement optimised templates and assessment processes using available technologies.
Continue trainings on the updated reports and processes as and when needed.

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

Evaluation activities for human medicines

Initial-evaluation activities

CAT

Strengthening the assessment of companion diagnostics (CDx)

CDx is essential for defining patients' eligibility for specific treatment with a medicinal product. As part of the conformity assessment of a CDx, the notified body shall seek a scientific opinion on the suitability of the CDx with the concerned medicinal product(s) from the competent authorities before issuing an EU technical documentation assessment certificate or an EU type-examination certificate, or a supplement to them for the CDx. The CHMP seeks to strengthen the assessment process.

Key objective:

- Collaborate in the framework for identification of overarching issues in the assessment of CDx consultation procedures.
- Continued identification of general principles that can be later used for training assessment teams and to update the procedural guidance or assessment templates.
- Ensure lessons learnt are in place leading to harmonisation and efficiency gain.

Activities 2026
Collaborate with the CDx expert group to consolidate the evaluation of consultation procedures across CHMP members.
Monitor assessments to capture input in CHMP procedures.
Collaborate with MWP on the guideline on biomarker development.

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

Other specialised areas and activities

Geriatric medicines strategy

The rapid aging of the population worldwide means that people over 80 years are the fastest growing subpopulation group. The EMA geriatric medicines strategy aims to ensure that the benefit/risk balance of medicines is researched and evaluated with respect to the epidemiology of the disease, and that findings are adequately reflected in the CHMP assessment documents.

Key objective:

- Ensure that the geriatric population is addressed in CHMP assessment reports and product information.

Activities in 2026:
Perform an ex-post control on recently approved initial marketing authorisations to monitor for geriatric information presentation in assessment reports.
Review selected scientific advice and Day 120 initial marketing authorisation assessment reports to monitor for geriatric information intake.
In the context of the CHMP pilot on RWD studies, investigate the feasibility to generate RWE on disease epidemiology, frailty and standard of care in older patients to support the committee decision-making
Reinstate collaborative working with geriatric experts

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

2

Horizontal activities and other areas

Horizontal activities and other areas

Committees and working parties

PRAC

Special populations and product guidance

Certain specific population groups require consideration in the conduct of assessment. This topic channels the Committee's expertise into the development of population specific guidance in terms of risk assessment of medicinal products on human reproduction and lactation in collaboration with PRAC committee.

Key objective:

- Strengthen assessment by industry and regulators through dedicated guidance on specific populations.
- Strengthen systematic generation of information on the benefits and risks of medicines in pregnancy and breastfeeding.

Activities in 2026:

Update of 'CHMP Guideline on risk assessment of medicinal products on human reproduction and lactation: from data to labelling'. Prepare the guideline for the public consultation phase.

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

Horizontal activities and other areas

Committees and working parties

Review the assessment of indirect treatment comparisons

Indirect comparisons are sometimes utilized to support regulatory claims and decision-making. Strengthening reporting standards to deliver reliable, interpretable evidence would reduce review burden and enable faster, more informed regulatory decisions across key assessments.

Key objectives:

- To maintain and ensure evidence standards for claims using indirect comparisons in view of methods used to support significant benefit claims.

Activities in 2026:	
Collaborate with the Committee for Orphan Medicinal Products (COMP) and Methodology Working Party (MWP) to develop guidance for applicants for reporting on indirect comparisons in submissions.	COMP
Collaborate with the MWP to review the potential impact of the new pharmaceutical legislation on the guidance.	

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

Annex

Leads and contributors for the activities

Activity	Lead(s)	Contributor(s)
Scientific consultations involving other decision makers to facilitate optimisation of clinical evidence generation in drug development programmes	Bruno Sepodes	Carla Torre, Paolo Foggi, Peter Mol, Robert Porszasz, Christian Gartner
Patient and Healthcare Professional involvement in assessment work	Fátima Ventura	Bruno Sepodes, Edward Laane, Carla Torre
Documenting medicines evaluation – an efficiency and stakeholder focus on the CHMP AR and the EPAR	Daniela Philadelphy	Kristina Dunder, Janet Koenig, Patrick Vrijlandt, Margareta Bego, Maria Grazia Evandri, Finbarr Leacy
Strengthening the assessment of Companion Diagnostics (CDx)	Patrick Vrijlandt	Fátima Ventura, Martin Mengel, Filip Josephson, Ingrid Wang
Geriatric medicines strategy	Ewa Balkowiec Iskra	Bruno Sepodes, Martine Trauffle, Sabine Mayrhofer, Carla Torre, Edward Laane, Lyubina Racheva Todorova, Mario Miguel Rosa, Elina Rönnemaa
Special populations and product guidance	Jan Mueller Berghaus	Ewa Balkowiec Iskra, Maria Grazia Evandri
Review the assessment of indirect treatment comparisons	Johanna Lähteenvuo	Christian Gartner, Elita Poplavska

Main deliverables and achievements of 2025 (1/3)

Activity	Deliverables
Scientific consultations involving other decision makers to facilitate optimisation of clinical evidence generation in drug development programs	• Contribution to the Implementing Regulation on the procedures for joint scientific consultations on medicinal products for human use at Union level and the Briefing document template for Parallel HTA Coordination Group (HTACG)/European Medicines Agency (EMA) Joint Scientific Consultation (JSC) for Medicinal Products (MP). • From July 2025, conducted of the first parallel Joint Scientific Consultations under the HTA Regulation. • Publication of the Joint HTAb-regulatory perspectives on understanding evidence challenges, managing uncertainties and exploring potential solutions as outcome of a workshop series between HTA bodies and regulators. • Webinar with MEDEV/ESIP on biosimilar developments and related evidence requirements. • Regular engagement at MEDEV/ESIP meetings on recent medicines approvals.
Contributing to Accelerating Clinical Trials in the EU (ACT EU)	• Completion of ten SAWP/CTCG pilot procedures for consolidated advice under the ACT EU initiative, an outcome report will be published in 2026. • For more details, see the ACT EU website
Benefit/Risk methodology and communication	• Key principles for documenting key (un)favourable effects in the effects table were agreed and incorporated into the new overview template.
Patients and Healthcare Professional involvement in assessment work	• Reflection paper on Patient Experience Data published for consultation in Sep 2025 • Multiple meetings with PCWP/HCPWP to discuss how best reflect in the AR the patient and HCP input and patient experience data. • Review and publication of the ICH E22 Guideline on general considerations for patient preference studies - Step 2b • A focus group with CHMP, SAWP members and assessors was created to support the finalisation of the ICH E22 guideline in 2026 • Study protocol developed and analysis completed for the study - Patient Experience Data in regulatory decision-making: An analysis of non-interventional studies in marketing authorization applications submitted to the EMA in 2018-2023
Documenting medicines evaluation – an efficiency and stakeholder focus on the CHMP AR and the EPAR	• Completed the Revamp Pilot, where applicants pre-fill the D80 assessment report templates with factual data (11 products in pilot) • Launched new overview/assessment report (AR) template and co-authoring process. • Updated the D80 clinical and non-clinical templates in line with the overview. • Launched the new D80 quality templates (1 for chemicals, 1 for biologicals). • Launched the new Line Extension AR template, aligned with the new overview/report

Main deliverables and achievements of 2025 (2/3)

Activity	Deliverables
Digital Technologies	• Ongoing work of the Drafting group to update Digital Technologies Q&A • Presentation and discussion of Qualification requests concerning digital methodologies at CHMP plenaries
Enabling the safe and responsible use of Artificial Intelligence in the medicine lifecycle	• Updates on AI literacy, including available resources in the EU-NTC learning management system (LMS), EMA strategy and future plans to address AI literacy needs. An AI literacy campaign has been agreed and is being prepared to roll-out across the network considering specific personas (different roles in the agencies and network) • Supporting product specific AI topic discussions: A gap analysis on AI specific product support needs was conducted, a proposed framework was developed, and a pilot is ongoing until mid-2026. • AI experimentation: two Knowledge Mining workshops were conducted in late 2025 which included representation from multiple agencies and committee members. A high-level roadmap has been endorsed at the NDSG under the Data and AI workplan and will initiate with a pilot phase focusing on a Knowledge Mining stream and another stream of work to define different prompts to enable different use cases. • First Qualification Opinion of an AI-related methodology published in March 2025: AIM-NASH • EMA and FDA set common principles for AI in medicine development.
Contribution of real-word data (RWD) to evidence generation	• Five study requests from SAWP resulted in three studies focused on Acute Myeloid Leukemia (AML) and paediatric use of sartans. Six study requests from CHMP led to three studies addressing Alzheimer's disease and acute Graft-versus-Host Disease (GvHD). The remaining, unfeasible, requests were due to lack of data granularity. • Conducted screening of upcoming MAA to identify gaps where RWE generation could add value. • CHMP experts engaged with known databases within their network to encourage their participation in the DARWIN network. • Updated the data strategy of DARWIN EU based on feedback from SAWP and CHMP. • SAWP and CHMP experts contributed to studies in the areas of AML, Duchenne Muscular Dystrophy and Alzheimer Disease to gain familiarity with existing data networks in these diseases and provide feedback on regulatory data needs. • Published the roadmap of RWE guidances
Contribution of individual patient data to evidence generation	• New pilot procedures onboarded in 2025 • Follow-up surveys on pilot learnings run throughout 2025 • Network Community on Raw Data membership expanded to include contact points from more NCAs • Network Advisory Group on Raw Data membership expanded to include CAT, PDCO and NDSG members • Change management intensified (several presentations to EMA/EMRN and public fora, Industry Group focusing on Clinical Study Data and Network Advisory Group on Raw Data meetings held) over the course of 2025 • Collection of business requirements to support IT development ahead of implementation has been endorsed by EMRN Portofolio Board in July 2025 and is currently underway
Strengthening the assessment of Companion Diagnostics	• Formalisation of Mandate of the CDx expert group (adopted in August 2025) • Supporting CDx specific topic discussions at CHMP • Update of section 6.3.4 "In vitro biomarker test for patient selection for efficacy" of the CHMP-CAT overview assessment report

Main deliverables and achievements of 2025 (3/3)

Activity	Deliverables
Provision of information to support Joint Clinical Assessment	• Development of guidance on the exchange of information between EMA and the HTA secretariat in the context of Joint Clinical Assessments (JCA) for medicinal products under Regulation (EU) 2021/2282, in collaboration with the HTA secretariat (SANTE C2) as well as the JCA subgroup. • Since July 2025, provision of relevant and necessary information from ongoing centralised procedures to the HTA Secretariat. • Communication on the guidance at the Industry Standing Group in June 2025
Geriatric medicines strategy	• Reviewed selected Day 120 initial marketing authorisation assessment reports to monitor the inclusion of geriatric information. Conducted an analysis of the Day 120 assessment reports and drafting the corresponding report ongoing. • Three finalised RWE studies in the area of geriatric populations: 1) Antipsychotic prescribing in people with dementia in Europe: a descriptive analysis of trends and patient characteristics. 2) DUS Characterising STOPP criteria medication use in people with recurrent falls. 3) Antipsychotic prescribing in the general population in Europe: a descriptive analysis of trends and patient characteristics. • Two finalised publications on the area of osteoporosis and osteoarthritis: "Treatment of osteoporosis and Osteoarthritis in the oldest old" and "executive summary: treatment of osteoporosis and osteoarthritis in the oldest old"
Special populations and product guidance	• The concept paper comments were addressed by the multistakeholders group during the drafting process. • Concept paper on revision of the Guideline on Risk 6 Assessment of Medicinal Products on Human 7 Reproduction and Lactation: from Data to Label
International Regulatory Science Cooperation	• The scope of EMA's OPEN Framework has been expanded to include all medicines that target unmet medical needs and advanced therapy medicines products (ATMPs). • The use of the OPEN framework is also extended to post-authorisation procedures.

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