EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Division

Committee for Medicinal Products for Human Use (CHMP): Work Plan 2025

Adopted by the Committee on 02 December 2024

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[1] Correction on page 2

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The activities outlined in the CHMP work plan for 2025 have been agreed taking into consideration the Agency's prioritisation set forth in the EMA multi-annual work programme 2024-2026

1. Evaluation activities for human medicines

1.1. Pre-authorisation activities

1.1.1. 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 objectives

- 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 2025

CHMP activities to achieve the objectives set for this area:

- Collaborate with the Member State Coordination Group on HTA (HTACG) on prospective evidence planning for development programmes through provision of parallel joint scientific consultation under the new HTA Regulation.
- Review experience with evidence at time of regulatory and HTA decision making, respectively, to inform prospective guidance on future developments
- Explore with healthcare payers opportunities for sharing views on prospective evidence planning, focusing on post-licensing evidence needs.

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Member	Peter Mol	NL
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1.1.2. Contributing to Accelerating Clinical Trials in the EU (ACT EU)

In accordance with the CHMP mandate, CHMP provides advice for undertakings on the conduct of the various tests and trials necessary to demonstrate the quality, safety and efficacy of medicinal products particularly regarding the development of new therapies.

Clinical Trial applications are in the remit of the member state where the application has been submitted.

Given the complex nature of medicines development, advice on closely related aspects of clinical trials being given by different regulatory actors, and the importance of building a consensus regulatory view in an efficient way, the objective is to develop a consolidated scientific advice process.

Key objectives

- Optimise European scientific advice through provision of consolidated scientific advice, bringing advice for clinical trial authorisation and for evidence to support marketing authorisation together, respecting roles and remits.
- As a first focus for consolidated advices and strengthening of scientific advice, to deliver the best evidence for decision making, in particular, for unmet medical needs, rare diseases, and on vaccines and therapeutics for public health crises and pandemics, with an emphasis on multinational clinical trials, where appropriate.

Activities in 2025

CHMP activities to achieve the objectives set for this area:

- As part of ACT EU priority action on consolidated advice on clinical trials, contribute to an increase in the quality of clinical trials and marketing authorisation applications, bringing together applicants, SAWP and CTCG for an early dialogue.
- Provide input to the implementation of best practices in guidance development and in CTCG/ HTA methodology subgroup/ Methodology Working Party (MWP) information exchange in collaboration with ACT EU priority action on clinical trials methodologies and the MWP.

CHMP topic leader: Ewa Balkowiec Iskra

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1.2. Initial-evaluation activities

1.2.1. Benefit/Risk methodology and communication

Activity areas

Benefits and risks require continuous evaluation throughout the lifecycle of a medicine. The objective is to balance and document benefits and risks in a way that is as robust, consistent and transparent as possible.

Key objectives

- Continue to enhance consistency in the assessment and communication of benefit-risk in the European Public Assessment Report.

Activities in 2025

CHMP activities to achieve the objectives set for this area:

- Develop knowledge sharing and training material for the EMRN to implement the reflection paper on single-arm trials that are submitted as pivotal evidence in marketing authorisation dossiers across therapeutic areas.
- Promote development and implementation of best practices for the assessment and communication of the benefit-risk in the new optimised assessment report template (see 1.2.3).

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1.2.2. 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 objectives

- 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 2025

CHMP activities to achieve the objectives set for this area:

- 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 optimisation (see 1.2.1 and 1.2.3).
- Participate in drafting of new ICH guidance on patient experience data and patient preference elicitation.

CHMP topic leaders: Fátima Ventura and Jayne Crowe

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

Activity areas

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

Key objectives

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

Activities in 2025

CHMP activities to achieve the objectives set for this area:

- Launch the new Overview template in January 2025.
- Update the D80 clinical and non-clinical templates based on alignment with the Overview and following feedback from their first year of use. Update the template for Line Extensions in line with the iMAA Overview template
- Finalise the D80 quality templates and the D80 clinical template for biosimilars
- Take stock of the outcomes from the pilot where companies pre-fill the D80 templates and decide on future implementation
- Start work on a separate Overview template for biosimilars

CHMP topic leader: Daniela Philadelphy

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1.2.4. Digital technologies

Activity areas

Meet the challenge of assessing the benefit/risk of the increasing number of medicines and outcome measures utilising digital technologies. This activity will foster expertise growth and cross-agency cooperation in a fast-developing field while respecting the remit of different stakeholders.

Key objectives

- Ensure coordination and dissemination of learnings from cases (advices, qualifications, MAAs) across EMA activities.
- Continued enhanced cooperation in the area of medical devices.

Activities in 2025

CHMP activities to achieve the objectives set for this area:

- Qualification of digital technologies: discuss all digital qualification procedures (with additional focus on procedures with AI elements) from Scientific Advice (SA) in CHMP by development of a Digital Technology framework; monitor marketing authorisation applications (MAAs)/extensions with digital aspects (including applications with AI elements) in general and discussions from SA. Feed learnings into discussions on possible future guidance development.
- Expand EMA expert base in the areas of digital, biomechanics and devices, to provide support to different activities, including evaluation and scientific advice.

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1.2.5. Enabling the safe and responsible use of Artificial Intelligence (AI) in the medicine lifecycle

The European Medicines Regulatory Network (EMRN), through the Big Data Steering Group's oversight, developed a multi-annual workplan on AI to enable the safe and responsible use of AI in the medicine lifecycle and extract value for public and animal health. In addition, the EMRN strategy to 2028 reflects on the need to focus on improving decision-making, optimising processes and increasing efficiency through the use of data, digitalisation and AI.

Key objectives

- Continued overview of the developments in the multi-annual AI workplan, in particular on guidance, policy and product support, change management and experimentation and implementation of AI
- Ensure coordination of change management activities, including information and training needs on AI, in particular generative AI solutions
- Build assessors knowledge and experience by sharing of case studies of applications of AI across the medicine's lifecycle, in particular, non-clinical, clinical, safety, quality, product information and general knowledge mining in regulatory science.

Activities in 2025

CHMP activities to achieve the objectives set for this area:

- Develop knowledge sharing and training material on AI, in particular generative AI, including on ethical and data protection issues, to support assessors.
- Onboard a group of experts on AI at CHMP to support the committee, and interact with working parties, on regulatory science topics related to AI.
- Establish a procedure to strengthen the EMA support on product-specific AI topic discussions.
- Establish and maintain a cooperation on AI experimentation to improve efficiency and quality of decision-making.

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1.2.6. Contribution of real-word data (RWD) to evidence generation

Enhanced analysis of data from the development and real-world use of medicinal products has the potential to further support regulatory decision-making. In this area, real-world evidence (RWE) offers the possibility to provide an additional perspective on the use and performance of medicines in everyday clinical use, complementing the evidence obtained from randomised controlled trials.

Real-world evidence has the potential to enhance decision-making through the lifecycle of medicinal products.

Key objectives

- Identify and test real-world evidence use cases to support evidence generation in Scientific Advice (SA) and CHMP decision-making.
- Ensure expert advice and guidance on real-world evidence (RWE) is available to support CHMP decision-making.

Activities in 2025

CHMP activities to achieve the objectives set for this area:

- Continue the collaboration initiated on RWD studies to support the provision of SA on the generation of robust RWE.
- Continue the conduct of RWD studies to support CHMP decision-making (including provision of RWE on disease epidemiology and standard of care in the elderly, and assessment of use and performance of medicinal products in special populations such as pregnant individuals).

- Provide expert input to the yearly review of the experience gained with RWE studies conducted across the regulatory network to support regulatory decision making and to potential related publications.
- Expand the existing group of experts on RWE to broaden the support to CHMP and their associated working parties in regulatory activities through the Methodology ESEC.
- Develop a roadmap of RWE guidance to support high-quality RWE generation and continue strengthening the use of RWE for regulatory decision-making. Provide expert input in support to the development of guidance on use of RWE for regulatory purpose, including in the field of pharmacogenomic data linked to real-world data sources (e.g. biobanks).

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1.2.7. Contribution of individual patient data to evidence generation

Enhanced access to clinical study data from the marketing authorisation (MA) dossier has the potential to further support regulatory decision-making. Targeted analysis and visualisation of 'raw data', i.e. individual patient data from clinical studies in an electronic structured format, will be piloted to understand its impact on benefit-risk assessment and regulatory decision-making through the lifecycle of medicinal products.

Key objectives

- Explore the analysis of raw data from MA dossiers to support the assessment of initial marketing authorisation applications and selected post-authorisation procedures.

Activities in 2025

CHMP activities to achieve the objectives set for this area:

- Continue the proof-of-concept pilots of analysis and visualisation of raw data from marketing authorisation dossiers to learn of the practicalities and benefits of such an approach, taking into account the learnings and recommendations of the pilots' interim report.
- Expand Network Community on Raw Data to regularly share developments on the raw data proof-of-concept pilots and foster close collaboration across the Network into using raw data for regulatory decision-making.

CHMP topic leader: Christian Gartner

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1.2.8. Strengthening the assessment of Companion Diagnostics

Activity areas

As per the Regulation (EU) 2017/746, a companion diagnostic (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 in accordance with Directive 2001/83/EC 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 objectives

- 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.
- Collaborate with MWP on the guideline on biomarker development.

Activities in 2025

CHMP activities to achieve the objectives set for this area:

- Collaborate with the CDx expert group to consolidate the evaluation of consultation procedures across CHMP members.
- Monitor assessments to capture input in CHMP procedures at iMAAs.

CHMP topic lead: Patrick Vrijlandt

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1.2.9. Provision of information to support Joint Clinical Assessment

Activity areas

The Regulation on Heath Technology Assessment (Regulation EU 2021/2282) will come into application in January 2025. One of the areas for regulatory/HTA collaboration under this Regulation concerns the provision of information from the regulatory assessment of an application for marketing authorisation or extension of indication for medicinal products to inform the respective Joint Clinical Assessment (JCA) for this technology performed by the Member State Coordination Group on HTA (HTACG) and its subgroups. The reason being that the assessment scope for JCA is based on the therapeutic indication of the medicinal product. Therefore, while preserving the separation of the respective remits of the Coordination Group and the European Medicines Agency, information shall be provided via the

respective secretariats. The Implementing Regulation on JCA for medicinal products (Commission Implementing Regulation (EU) 2024/1381) specifies further the type of information provided.

Key objectives

- To provide relevant and necessary information from the regulatory assessment to support the preparation of Joint Clinical Assessments led by the HTACG.

Activities in 2025

CHMP activities to achieve the objectives set for this area:

- Development of guidance on provision of information on substantial questions or outstanding issues from the CHMP review that might impact the JCA assessment scope, in collaboration with the HTA secretariat and the JCA Subgroup.

CHMP topic lead: Margareta Bego

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1.3. Other specialised areas and activities

1.3.1. 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 objectives

- Make sure the geriatric population is addressed in CHMP assessment reports and product information.

Activities in 2025

CHMP activities to achieve the objectives set for this area:

- 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.
- Propose amendments to assessment reports and guidance following CHMP review of recently approved and ongoing initial marketing authorisation applications.

- 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 (see 1.2.5).
- Reinstate collaborative working with geriatric experts, identified through a public call for expression of interest in 2023.

CHMP topic leader: Ewa Balkowiec Iskra

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2. Horizontal activities and other areas

2.1. Committees and working parties

2.1.1. 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 objectives

- 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 2025

CHMP activities to achieve the objectives set for this area:

- Update of 'CHMP Guideline on risk assessment of medicinal products on human reproduction and lactation: from data to labelling'.
- Revision of the Guideline's text and preparation for the public consultation phase

CHMP topic leader: Jan Mueller Berghaus

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2.2. Partners and stakeholders

2.2.1. International Regulatory Science Cooperation

Given the increasing complexity of global developments in the pharmaceutical sector there is a drive to achieve greater harmonisation, building a convergence of regulatory tools and standards worldwide to ensure that safe, effective and high-quality medicines are developed, registered and maintained in the most resource efficient manner whilst meeting high standards.

This cooperation is mandated by the globalisation of medicine: in its supply chains, its research and development and its expertise. Reliance, where an authority relies on work done by another authority but retains its full power of decision, is supported by EMA. OPEN (**O**pening our **P**rocedures at **E**MA to **N**on-EU authorities) was established by EMA in 2020 as a framework to increase international collaboration and share scientific expertise on the evaluation of COVID-19 vaccines and therapeutics, initially as a pilot. The benefits and experience gathered during this pilot highlighted the advantages of collaboration across regulatory agencies. Following the success of the pilot, the OPEN scope has been extended to include marketing authorisation applications for: medicines targeting AMR; medicines supported through EMA's PRIority MEdicines (PRIME) scheme, but currently not including advanced therapy medicinal products (ATMPs); other products that address a high unmet medical need; and medicines responding to health threats or public health emergencies. Guidance is also available for applicants on how to request the review of their products under the OPEN framework.

Key objectives

- Facilitate the assessment of the same data by multiple authorities.
- Continue to develop a solid and agile framework that strengthens the collective scientific assessment.

Activities in 2025

CHMP activities to achieve the objectives set for this area:

- Consolidate OPEN scheme process with selected international collaborators.

CHMP topic leader: Sol Ruiz

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