16 December 2021
Human Medicines Division

Committee for Medicinal Products for Human Use (CHMP): Work Plan 2022

Adopted by the Committee on 16 December 2021

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The activities outlined in the CHMP work plan for 2022 have been agreed taking into consideration the Agency's prioritisation set forth in the EMA multi-annual work programme 2022-2024.

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1. Evaluation activities for human medicines

1.1. Pre-authorisation activities

1.1.1. Multi-stakeholder consultations to facilitate optimisation of clinical evidence generation in drug development programmes

Activity areas

Clinical evidence generated during drug development is intended to serve different decision making. Whilst scientific advice on evidence requirements for regulatory purpose is well established, in recent years the opportunities for engagement with additional stakeholders during such discussions have been increasingly recognised.

Key objectives

- To identify opportunities and needs for engagement with other decision makers in multi-stakeholder consultations.

Activities in 2022

CHMP activities to achieve the objectives set for this area:

- Collaborate with HTA bodies on prospective evidence planning for development programmes through provisions of parallel EMA/HTA scientific advice until the new HTA Regulation is in operation. Within this framework, extend collaboration to refine with HTA bodies the objectives of and tools for post-licensing evidence generation (PLEG).
- Explore with healthcare payers opportunities for sharing views on prospective evidence planning, focusing on post-licensing evidence needs.

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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 benefits and risks in a way that is as robust, consistent and transparent as possible.

Key objectives

- Continued overview of developments in assessing and communicating benefits and risks.

Activities in 2022

CHMP activities to achieve the objectives set for this area:

- To produce a reflection paper describing the experience with and rationale for single-arm trials-based approvals across therapeutic areas and publish it for public consultation.

CHMP topic leader: Johann Lodewijk Hillege

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1.2.2. Patients involvement in assessment work

Activity areas

The objective is 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.

Activities in 2021

CHMP activities to achieve the objectives set for this area:

- Monitor and improve methodologies to capture input to CHMP procedures (including participation in OEs, written consultations, and full implementation of process for engaging with patient organisations at start of Marketing Authorisation Applications).
- Participate in drafting of new ICH guidance on patient experience data and patient preference elicitation.

CHMP topic leaders: Fátima Ventura and Concepcion Prieto Yerro

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

Activity areas

Improve/optimise the initial evaluations assessment report with the aim to simplify, avoid replication of work and meet/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 evaluation process.

Activities in 2022

CHMP activities to achieve the objectives set for this area:

- Optimise the related assessment report templates (e.g. benefit-risk section, efficacy section of overview template) to avoid duplication of information while facilitating inclusion of all relevant information (e.g. explanation of the therapeutic indication, efficacy and safety in subgroups and outcomes of SAG meetings and oral explanations).

CHMP topic leaders: Johann Lodewijk Hillege

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1.2.4. Enhanced communication with down-stream decision makers about regulatory assessment

Activity areas

Recognising that the regulatory outcome is only one step along the path for access to patients, it is important that there is mutual understanding and appropriate knowledge sharing between decision makers. This would need to respect the various remits of the individual parties. It is expected that fostering exchanges between regulators and down-stream decision makers on product specific matters will enhance the access of innovative medicines for patients.

Key objectives

- Continuously improve output documents as reference for down-stream decision makers.

Activities in 2022

CHMP activities to achieve the objectives set for this area:

- Provide updated guidance for key regulatory outputs (assessment reports, labelling) to enhance usefulness for down-stream decision makers.

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1.2.5. 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.
- Explore enhanced cooperation with Notified Bodies.

Activities in 2022

- 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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1.2.6. Contribution of real-word data and individual patient data to evidence generation

Activity areas

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 control trials.
Real-world evidence, as well as analysis of individual patient data from clinical trials have the potential to enhance decision-making through the lifecycle of medicinal products.

Key objectives

- Implement real-world evidence use cases to support evidence generation in Scientific Advice (SA).
- Review past experience and develop recommendations regarding the evidentiary value of real-world evidence.
- Ensure expert advice on real-world evidence is available to support CHMP decision-making.
- Explore the analysis of raw data from MA dossiers to support assessment of initial marketing authorisation applications.

Activities in 2022

- Complete the pilot initiated on RWE studies to support SA decision making.
- Follow-up on the review of the initial Marketing Authorisation Applications (MAA) 2018-19 project, to characterise the contribution of real-world evidence to the B/R evaluation, and identify lessons learned to be discussed with CHMP.
- Identify use cases of RWE and establish processes in order to start a pilot on RWE studies to support CHMP decision-making (including the feasibility to provide RWE on disease epidemiology and standard of care in the elderly).
- Establish a group of experts to advise CHMP on RWE in regulatory submissions.
- Proceed with proof-of-concept pilots of analysis and visualisation of raw data from marketing authorisation dossiers to support the assessment and learn of the practicalities and benefits of such an approach. Organise a workshop on the submission of raw data in marketing authorisation dossiers.

CHMP topic leaders: Alar Irs

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1.2.7. CHMP external engagement and communication

Activity areas

Decision-making on the safe and effective use of medicinal products is one of the main objectives of the CHMP and the EU medicines' regulatory system. Given the implications of these decisions in public health, there is a need to contribute more to explain the scientific rationale of regulatory decisions and increase the visibility of such decisions to the general public and professional stakeholders. Tools and channels are in place at EU-level, largely in English as working language of the Agency. However, it has been identified that further outreach and dissemination is needed at national level and in local languages. In addition, it is considered important to identify scientific spokespersons at national level who can communicate with the public on behalf of EMA and its committees on key regulatory decisions. This initiative aims to enhance CHMP's external engagement and communication to ensure that CHMP key decisions and opinions reach further nationally and locally to interested and key stakeholders, and ultimately increase trust in the regulatory system, contributing to a better and safer use of medicines.

Key objectives

- Promote and strengthen the visibility of CHMP and the EU Regulatory Network to increase trust in the regulatory system and support better and safer use of medicines.
- Promote that CHMP key decisions and opinions reach further nationally and locally to interested and key stakeholders (e.g. professional audiences and the general public).
- Ensure selection of appropriate channels for effective communication at national level, including national regulatory agencies, academia and special interest communities.

Activities in 2022

- Analysis to map existing channels and tools at national level (e.g. via NCA webpage, EMA CHMP highlights, re-use communication materials for translation at national level) and identify what is missing/needed.
- Expand group of members ready to act as spokespersons at national level.
- Expand and implement selected communication activities at national level sponsored by CHMP members with the aim to target different groups (patients, experts communities, etc.).

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1.2.8. Supplementary Urgency Procedures for Regulatory Assessment

Activity area

The COVID-19 pandemic gave an opportunity to address some of the limitations of the currently used procedural architecture. While any major overhaul or modernisation of the centralised procedure would require the adaptation of the legal framework by the European Commission, CHMP may provide supplementary support to the existing system with additional procedural tools to be used when the existing procedures are insufficient in the context of an urgency (SUPRA).

Key objectives

- Improve CHMP preparedness for urgency situations.
- Enhance efficiency in managing applications in emergency situations.
- Ensure compatibility of the proposed scheme with the current legal framework.

Activities in 2022

- Drawing lessons from COVID-19 evaluations: review procedural tools for the evaluation of marketing authorisation in emergency situations (rolling-reviews, Article 5(3) referral procedures).

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1.3. Other specialised areas and activities

1.3.1. Geriatric medicines strategy

Activity areas

The rapid aging of the population worldwide means that the subpopulation over 80 years are the fastest growing 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 2022

- Perform an ex-post control on (post-pilot) recently approved initial marketing authorisations to monitor for geriatric information presentation in assessment reports.
- Review selected scientific advice and D-120 initial marketing authorisation 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 RWE studies, investigate the feasibility to provide RWE on disease epidemiology and standard of care in the elderly to support the committee decision-making.

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2. Horizontal activities and other areas

2.1. Partners and stakeholders

2.1.1. International Regulatory Science Cooperation

Activity areas

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, and 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. A pilot **O**pening our **P**rocedures at **E**MA to **N**on-EU authorities (OPEN) was initiated in 2020 aiming to share scientific expertise to tackle common challenges on COVID-19 vaccines and therapeutics while enhancing transparency on regulatory decisions and promoting EU Regulatory System. The benefits and experience gathered during this pilot can form the basis of future recommendations that could possibly be implemented in the post-COVID era, including the extension of OPEN to antimicrobial products.

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 2022

- Perform a lessons-learned from the current OPEN pilot.
- Put forward proposals for a future model and its intended use, including possible considerations related to the EC's Pharma Strategy if relevant.

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