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Inspections, Human Medicines Pharmacovigilance and Committees Division

Committee for Medicinal Products for Human Use (CHMP): Work Plan 2021

Adopted by the Committee on 28 January 2021

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The activities outlined in the CHMP work plan for 2021 have been agreed taking into consideration the Agency's prioritisation set forth in the EMA multi-annual work programme 2021-2023.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

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.
- To explore activities of common interest to decision-makers for reinforcing patient relevance in clinical evidence generation.

Activities in 2021

CHMP activities to achieve the objectives set for this area:

- To work with EU stakeholders facilitating the increased involvement of patients and health care professionals in ICH Guidelines Work. For Europe, PCWP and HCWP appear as the natural partners.

CHMP topic leader: Bruno Sepodes

Other contributors:

Member/alternate	Name	MS
Member	Andrea Laslop	AT
Member	Johann Lodewijk Hillege	NL
SAWP Chair	Anja Schiel	NO

1.2. Initial-evaluation activities

1.2.1. Benefit/Risk methodology and communication

Activity areas

Benefits and risks require continuous evaluation throughout the life-cycle 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 2021

CHMP activities to achieve the objectives set for this area:

- To produce an internal reflection paper describing the experience with and rationale for single-arm trials-based approvals with focus on oncology and explore the need for wider discussion to other therapeutic areas of such approvals and producing external guidance for public consultation;
- To produce guidance about contextualising benefit-risk assessment on the basis of available treatment options;
- To explore the feasibility of using a more explicit approach in describing value-judgments in the current benefit risk assessment framework/template. This will be achieved by means of case-study based focus groups with assessors, including a number of problem-based exercises in which the CHMP will become more familiar with quantitative Benefit / Risk assessment, supported by available frameworks, instruments, and data sources (e.g., PROACT-URL, MCDA, patient preference studies and RWD). The added value of this approach and the need to develop further training material on regulatory decision-making and structured benefit-risk assessment in the life cycle of medicines for clinical and pharmacovigilance assessors will be evaluated. In this training, the decision-support tooling developed within the framework of the IMI GetReal initiative (www.imi-getreal.eu), and the results and experiences from IMI PREFER (www.imi-prefer.eu) will be explored (see also 1.1.1).

CHMP topic leader: Johann Lodewijk Hillege

Other contributors:

Member/alternate	Name	MS
Chair	Harald Enzmann	DE
Alternate	Filip Josephson	SE
Co-opted member	Jan Mueller-Berghaus	DE
Vice-Chair	Bruno Sepodes	PT
Member	Sinan B. Sarac	DK
Member	Kristina Dunder	SE
Member	Armando Genazzani	IT

1.2.2. Patients involvement in assessment work

Activity areas

The objective is to facilitate participation of patients and consumers in benefit/risk evaluation and related activities, to capture patient's values and preferences and obtain information on the current use of medicines and their therapeutic environment, all along the lifecycle of the medicines, from early development throughout evaluation and post-marketing surveillance.

Key objectives

- Incorporate additional and regular processes to capture and include patient views and preferences within CHMP benefit / risk evaluations.

Activities in 2021

CHMP activities to achieve the objectives set for this area:

- Explore additional methodologies to capture input to CHMP procedures (including setting up standardised written consultation, process for involvement of patient organisations at start of Marketing Authorisation Applications focus group)

- Recommendations how to elicit patients' values and preferences in medicines evaluation.

CHMP topic leaders: Fátima Ventura and Concepcion Prieto Yerro

Other contributors:

Member/alternate	Name	MS
Vice-Chair	Bruno Sepodes	PT
Member	Sinan B. Sarac	DK
Alternate	Edward Lane	EE

1.2.3. 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 2021

- Qualification of digital Technologies: discuss all digital qualification procedures from Scientific Advice (SA) in CHMP by development of a Digital Technology framework; monitor marketing authorisation applications (MAA)/extensions with digital aspects in general and as to discussions having taken place in SA.
- Expand EMA expert base in the areas of digital, biomechanics and devices, to provide support to different activities, including evaluation and scientific advice.
- Collaborate in developing additional frameworks with Notified Bodies for products with integral Medical Devices and digital technologies.

CHMP topic leaders: Bruno Sepodes

Other contributors:

Member/alternate	Name	MS
Chair	Harald Enzmann	DE
Alternate	Fátima Ventura	PT
Member	Ewa Balkowiec Iskra	PL
Member	Martina Weise	DE
Expert	Sabine Mayrhofer	DE

1.2.4. 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 randomized 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 product.

Key objectives

- Explore use cases and possible processes for including real world evidence data to support decision making in regulatory submissions.
- 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 Individual Patient Data (IPD) from clinical trials to support assessment of initial marketing authorisation applications.

Activities in 2021

- Initiate a pilot of rapid real-world data analysis in Scientific Advice (SA) and identify use cases.
- Review initial Marketing Authorisation Applications (MAA) from 2018 and 2019 for inclusion of RWE and extraction of learnings.
- Establish a group of experts to advise CHMP on Real World Evidence in regulatory submissions.
- Proceed with pre-pilot of analysis and visualisation of IPD from a marketing authorisation dossier to support the assessment and learn of the practicalities and benefits of such an approach.

CHMP topic leaders: Alar Irs

Other contributors:

Member/alternate	Name	MS
Co-opted member	Christian Gartner	AT
Co-opted member	Carla Torre	PT
Member	Bjorg Bolstad	NO
Expert	Fabrice Eroukhmanoff	NO

1.2.5. CHMP external engagement and communication

Activity areas

Decision-making on the safe and effective use of medicinal product 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.

Communication and outreach efforts will be channelled via national regulators. Initially, an analysis and discussion across interested CHMP members will be prioritised to map existing outreach communication activities at national level. In the second stage, this initiative to enhance CHMP external engagement will be expanded to academia/universities.

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 2021

- 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.
- Identify a group of people ready to act as spokespersons as national level.
- Implement selected communication activities at national level sponsored by CHMP members.

CHMP topic leaders: Harald Enzmann

Other contributors:

Member / alternate	Name	MS
Vice-Chair	Bruno Sepodes	PT
Member	Maria Concepcion Prieto Yerro	ES
Member	Andrea Laslop	AT
Member	Armando Genazzani	IT
Member	Konstantinos Markopoulos	EL
Member	Ilko Getov	ES
Member	Elita Poplavska	LV
Member	Margareta Bego	HR

1.2.6. Supplementary Urgency Procedures for Regulatory Assessment

Activity area

The COVID 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.

Activities in 2021

- Identify situations that will be considered emergency situations requiring rapid action by the Committee.
- Analyse weaknesses and opportunities of the current operational setup, including but not limited to experience gained during the COVID pandemic.
    - Identify potential for improvements within the current legal framework.
    - Flag opportunities for improvement that might possibly be addressed by adaptations of the legal framework, making use of dedicated interactions and advise from both EMA and EC.
- Design supplementary urgency procedural tools to be used in situations where standard regulatory assessment procedures are insufficient to meet the urgency.
- Ensure compatibility of the proposed scheme with the current legal framework.

CHMP topic leaders: Bruno Sepodes

Other contributors:

Member/alternate	Name	MS
Co-opted Member	Sol Ruiz	ES
Member	Johann Lodewijk Hillege	NL
Chair	Harald Enzmann	DE
Member	Kristina Dunder	SE
Member	Sinan Sarac	DK

1.3. Post-authorisation activities

No planned activities

1.4. Arbitration and referrals

No planned activities

1.5. Pharmacovigilance activities

No planned activities

1.6. Other specialised areas and activities

1.6.1. 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 2021

- 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.

CHMP topic leader: Andrea Laslop

Other contributors:

Member/alternate	Name	MS
SAWP	Mario Miguel Rosa	PT
SAWP	Elina Rönnemaa	SE
Vice-Chair	Bruno Sepodes	PT
Member	Martine Trauffler	LU
Expert	Sabine Mayrhofer	DE

2. Horizontal activities and other areas

2.1. Committees and Working Parties

2.1.1. Comprehensiveness of clinical data in marketing authorisations

Activity area

CHMP and CAT have each a distinct remit in the evaluation of advance therapy medicinal products (ATMPs). In that sense there is a need for coherence between the CHMP and CAT assessments in respect to assessing comprehensiveness of clinical data. Scientific collaboration between the CHMP and CAT through early exchange of information would ensure that each committee reaches a common approach to benefit risk of advance medicine medicinal products.

Key objectives

- Reinforce, if necessary, update, the common understanding of the comprehensiveness of data in CAT and CHMP.

Activities in 2021

CAT/CHMP inter-committee ad hoc group on comprehensiveness will:

- Identify key issues and collect different views.
- Develop consensus positions or clearly outline alternative positions.
- Report to CAT/CHMP for discussion and adoption.

CHMP topic leader: Harald Enzmann

Other contributors:

Member / alternate	Name	MS
CAT topic leader	Martina Schüssler-Lenz	DE
Member	Jan Mueller-Berghaus	DE
CAT Member	Maura O'Donovan	IE
Member	Romaldas Mačiulaitis	LT
CAT Member	Carla Herberts	NL
CAT Member	Rune Kjeken	NO
Member	Sol Ruiz	ES