2 March 2018
EMA/CHMP/138933/2018
Inspections, Human Medicines Pharmacovigilance and Committees Division

# Committee for Medicinal Products for Human Use (CHMP): Work Plan 2018

Adopted by the Committee on 22 February 2018

## Table of Contents



*The activities outlined in the CHMP work plan for 2018 have been agreed in view of considering the respective business priorities, as well as the preparation for the Agency's relocation as a result of the UK's exit from the EU and its impact on the Agency's business continuity, and may be subject to further review and reprioritisation in accordance with the business continuity plan of the Agency.*


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 generally serves decision making by different actors. 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. Parallel regulatory/HTA advice has been developed as option to drug developers wishing to construct a drug development programme that is able to address the different needs of regulators and health technology bodies in the most efficient manner possible. Using the experience from this platform, engagement with other stakeholders involved in down-stream decision making should be considered in case beneficial for specific types of medicines developments. This includes payer organisations as well as so-called “switch bodies”.

CHMP topic leader: Robert Hemmings

#### Key objectives

- To monitor the utility of the existing platform for parallel regulatory / HTA discussions to drug developers in terms of providing relevant and robust guidance on drug development.
- To identify opportunities and needs for engagement with other decision makers in multi-stakeholder consultations.
- To engage in other relevant programmes, particularly EUnetHTA Joint Action 3.
- To provide a framework for discussion of proposals for developments using the adaptive pathways concept and contribute through experience to conceptual discussions (particularly IMI ADAPT SMART)

#### Activities in 2018

CHMP activities (through SAWP) to achieve the objectives set for this area:

- To collaborate with EUnetHTA in the further development of frameworks for parallel regulatory/HTA scientific advice / early dialogue
- To monitor MAA submissions and compliance within a clinical trial, which has received parallel SAWP/HTA scientific advice
- Explore the concept of “late dialogues” for post-licensing evidence generation plans
- Engage in discussions between interested parties (HMA, CMDh etc) on systems to provide multi-stakeholder consultation on OTC switch applications involving “switch bodies”.

Other contributors:

| Member/alternate | Name | MS |
|---|---|---|
| Member | Andrea Laslop | AT |
| Chair | Tomas Salmonson | SE |
| Member | Daniela Melchiorri | IT |

| Member/alternate | Name | MS |
|---|---|---|
| Member | Bruno Sepodes | PT |
| Member | Johann Lodewijk Hillege | NL |
| Member | Katarina Vučić | HR |

## *1.2. Initial-evaluation activities*

### 1.2.1. Benefit/Risk methodology

#### Activity areas

Benefit/risk of a medicine requires continuous evaluation throughout the life-cycle. The objective is to balance benefits and risks in a way that is as robust, consistent and transparent as possible.

CHMP topic leader: Johann Lodewijk Hillege

#### Key objectives

- Continued overview of developments in assessing and communicating benefit/risk.
- Continue to work on EPARs to improve the structure and information on benefit/risk, including the effects table and implementation of new templates/guidance.

#### Activities in 2018

CHMP activities to achieve the objectives set for this area:

- Monitoring implementation of benefit-risk template structure and guidance;
- Further explore application of benefit-risk methodologies for decision making and communication (eg output of IMI-PROTECT), including visual displays and value elicitation, in co-ordination with relevant EMA scientific committees (linked to Patients involvement in assessment work topic).
- To produce guidance about contextualising benefit-risk assessment on the basis of available treatment options;
- To explain the rationale for single-arm trials-based approvals to the public and explore the need for wider discussion of such approvals.
- 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, supported by available frameworks, instruments, and data sources (e.g. PROACT-URL, MCDA, patient preference studies). The added value of this approach and the need to develop further training material on regulatory decision-making and structured benefit-risk assessment of medicines for assessors will be evaluated.

Other contributors:

| Member/alternate | Name | MS |
|---|---|---|
| Alternate | Jorge Camarero Jiménez | ES |
| Chair | Tomas Salmonson | SE |
| Co-opted member | Jan Mueller-Berghaus | |
| Vice-Chair | Harald Enzmann | DE |
| Member | Katarina Vučić | HR |

| Member/alternate | Name | MS |
|---|---|---|
| Member | Sinan B. Sarac | DK |
| Member | Kristina Dunder | SE |

### 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.

CHMP topic leader: Harald Enzmann

#### Key objectives

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

#### Activities in 2018

CHMP activities to achieve the objectives set for this area:

- Together with PCWP and based on current experience, explore how to best gather input from the patient community during benefit-risk evaluations, define best practice and issue recommendations.
- Continue to involve patients in oral explanations (as per agreed criteria);
- Whenever feasible, make use of other methodologies for gathering patient input (e.g. written consultations, focus groups); Continue to explore potential value and applicability of elicitation of patient preferences (includes collaboration with IMI PREFER project and also linked to Benefit/Risk methodology topic).
- Report on activities related to patient involvement in CHMP activities to EMA MB (via annual report)

Other contributors:

| Member/alternate | Name | MS |
|---|---|---|
| Chair | Tomas Salmonson | SE |
| Member | Concepcion Prieto Yerro | ES |
| Member | Bruno Sepodes | PT |
| Member | Sinan B. Sarac | DK |
| Member | Katarina Vučić | HR |

### 1.2.3. PRIME (Enhanced early dialogue to foster development and facilitate accelerated assessment)

#### Activity areas

PRIME is a scheme that has been developed to reinforce early dialogue and regulatory support to stimulate innovation, optimise development and enable accelerated assessment of PRIority MEdicines. Further to public consultation and adoption of a reflection paper by the CHMP, the scheme was launched in March 2016. The scheme remains closely monitored.

CHMP topic leader: Tomas Salmonson

#### Key objectives

- Monitoring of the scheme.
- Consider whether modifications or enhancements to the scheme should be proposed

#### Activities in 2018

- Oversight of scheme performance and reporting of activities.
- Update of guidance further to review 1 year of the PRIME scheme.

Other contributors:

| Member/alternate | Name | MS |
|---|---|---|
| Co-opted Member | Rob Hemmings | |
| Member | Bart Van der Schueren | BE |
| Member | Alar Irs | EE |
| Co-opted Member | Jan Mueller-Berghaus | |
| Member | Bruno Sepodes | PT |
| Member | Andrea Laslop | AT |

### 1.2.4. Documenting medicines evaluation – a stakeholder focus on the CHMP AR and the EPAR

#### Activity areas

Review and optimisation of assessment report preparation process. Best use of available resources at CHMP and EMA.

CHMP topic leaders: Kristina Dunder, Harald Enzmann

#### Key objectives

- Review ways to improve the robustness, consistency and soundness of outputs throughout the initial MAA evaluation process. Review of the EPAR with a stakeholder perspective in mind.

#### Activities in 2018

CHMP activities to achieve the objectives set for this area:

- Optimise the preparation of the assessment at national level by providing essential documentation such as scientific advices of “similar” products, raised issues in the assessment process of other comparable products, early input on SmPC on the basis of consistency checks with other products;
- Optimise process flow for generation of output documents during MAA review including identification and role of contributors and check points;
- Optimise the related assessment report templates to best support the process flow;
- Optimise the links between CHMP assessment team and EMA;
- Stimulate discussion of efficacy and safety of sub-goups included in the therapeutic indication;
- Implementation of the reflection paper on therapeutic indication.

| Member/alternate | Name | MS |
|---|---|---|
| Chair | Tomas Salmonson | SE |
| Member | Johann Lodewijk Hillege | NL |
| Member | Outi Maki-Ikola | FI |

### 1.2.5. Liaison with non-EU regulators

#### Activity areas

Confidentiality arrangements, reliance on CHMP assessments.

Article 58 was introduced in the 2004 revision of the Agency's founding regulation, and allows the Agency to give scientific opinions – in collaboration with the World Health Organization – on medicines for use outside of the European Union. The intention of the process is to increase access by low- and middle-income countries (LMICs) to medicines and improve public health.

CHMP topic leader: Tomas Salmonson

#### Key objectives

- Ensure best use of resources through promoting mutual reliance and work-sharing.

#### Activities in 2018

- To continue CHMP involvement in action plan to achieve objectives, improve perception and use of the Article 58 procedure.
- To organise awareness sessions about Article 58.
- Exploring different ways to interact with other regulators.

Other contributors:

| Member/alternate | Name | MS |
|---|---|---|
| Vice-Chair | Harald Enzmann | DE |
| Co-opted member | Sol Ruiz | |
| Member | Fátima Ventura | PT |

## *1.3. Pharmacovigilance activities*

### 1.3.1. Registries – PRAC/CHMP Cross Committee liaison[1]

#### Activity areas

Maximising the potential for use/best practice in relation to drug and/or disease registries for collecting and analysing safety and efficacy data. The project should consider current and potential future use of registries, for example in PAES and adaptive licensing.

CHMP topic leader: Milena Stain

#### Key objectives

- Co-ordinate with any existing EMA initiatives relating to registries; cross-committee collaboration (including PRAC) will be important.
- Understand the pros and cons of using patient registries in different settings and regulatory questions in Europe.
- Test elements of the proposed approach for registries through a Pilot phase.
- Provide a framework for optimising regulatory requests for registries, so that requests are feasible, and study designs are fit for purpose (i.e. capable of answering a specific safety/efficacy question).

#### Activities in 2018

CHMP activities to achieve the objectives set for this area:

- Prepare a report on the patient registries workshop held;
- Engagement with SAWP on the need of specific registries on product level;
- To identify or further develop guideline/guidance on best use of registries (taking into account existing guidance, engagement with patient registries);
- Ongoing work with the Pilot phase (4 candidates selected, 17 pending consideration), evaluation of relevant registries and desired characteristics of a modified/new registry as applicable.
- To collaborate with the Cross-Committee Registry Initiative Task Force to establish a registry platform to support assessors to deal with poor quality data from registries and provide guidance on how to manage requests for registries;
- To contribute to a workshop with PRAC, CHMP and CAT sponsors to propose a smoother assessment process for initial applications.

Other contributors:

| Member/alternate | Name | MS |
|---|---|---|
| Co-opted member | Robert Hemmings | |
| Member | Kristina Dunder | SE |
| Member | Daniela Melchiorri | IT |
| Member | Johann Lodewijk Hillege | NL |
| Chair of the registries task force | Peter Mol | NL |

[1] Cross-Committee topic with PRAC involvement

## *1.4. Other specialised areas and activities*

### 1.4.1. Geriatric medicines strategy

#### Activity areas

The rapid aging of the population worldwide means that sub-population 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.

CHMP topic leader: Katarina Vučić.

#### Key objectives

- Investigation of strategies (e.g. registries, PAES, PASS) to acquire data in the older population, particularly with respect to collection of post-approval data in very old people, with frailty and comorbidities.
- Coordination of geriatric activities across CHMP/PRAC/SAWP/PCWP/HCPWP.

#### Activities in 2018

CHMP activities to achieve the objectives set for this area:

- Development of geriatric GVP module (led by PRAC).
- Continuation of pilot on 10 products with revised geriatric AR (the 10 products have already been included, 5 products have been finalised, 5 are under follow-up until D210).
- Adopt final Reflection paper on physical frailty.
- Preparation of a leaflet providing information on EMA activity in Geriatric Medicines Strategy.
- Monitoring of geriatric medicines strategy.

Other contributors:

| Member/alternate | Name | MS |
|---|---|---|
| Member | Bart Van der Schueren | BE |
| Member | Jorge Camarero Jiménez | ES |
| SAWP | Susan Morgan | UK |
| SAWP | Mario Miguel Rosa | PT |

## 1.4.2. The interface of precision medicines and diagnostics

### Activity areas

The treatment with precision medicines depends to a great extent on the result of a single crucial in vitro test. Usually, the indication (SmPC section 4.1) of a medicine is not restricted to a specific companion diagnostic method or product (CDx) used for the selection of eligible patients in the pivotal trials submitted in the MAA. Rather, the SmPC describes a biomarker the CDx is supposed to detect (e.g. a receptor or mutation). Replacing the CDx used in the pivotal trials with an "in-house" CDx with different performance may result in a different patient population being identified and treated. This can have significant consequences on the overall benefit risk balance for a precision medicine, which may change depending on the CDx used. The importance of the CDx for the selection of eligible patients and its possible impact on the benefit risk balance should be made transparent in assessment reports or SmPC.

CHMP topic leader: Harald Enzmann

### Key objectives

- Develop a CHMP position on how companion diagnostics and related data should be consistently reflected in the SmPCs and European Public Assessment Reports (EPARs).

### Activities in 2018

CHMP activities to achieve the objectives set for this area:

- Explore how characteristics/features of companion diagnostics used in pivotal trials can be made transparent;
- Explore how the dependence of a medicine's benefit-risk balance from the accuracy of the crucial CDx can be described.

Other contributors:

| Member/alternate | Name | MS |
|---|---|---|
| Co-opted member | Sol Ruiz | |
| Co-opted member | Jan Mueller-Berghaus | |
| Co-opted member | Koenraad Norga | |
| Member | Ondřej Slanař | CZ |
| Alternate | Filip Josephson | SE |
| Member | Sinan B. Sarac | DK |

# 2. Horizontal activities and other areas

## *2.1. Collaboration with PDCO to address the needs of the paediatric population*

### Activity areas

Ensure that the needs of the paediatric population are systematically considered in the medicinal products development and assessment of their use.

CHMP topic leader: Koenraad Norga, Agnes Gyurasics

### Key objectives

Reinforce cooperation with the PDCO with a view to supporting the continuity of the paediatric safety and efficacy assessment throughout the lifecycle of medicines.

### Activities in 2018

CHMP activities to achieve the objectives set for this area:

- Further define and implement pilot coordination process with PDCO, with a view to utilising the best available scientific expertise in the network and ensure that paediatric information related to the clinical trial programme are included in the medicine SmPC and labelling.
- At the end of 2018, report on experience gained with revised PDCO-CHMP coordination process for scientific evaluation of medicines of paediatric interest, in order to assess impact and identify opportunities for improvement.

Other contributors:

| Member/alternate | Name | MS |
|---|---|---|
| Vice-Chair | Harald Enzmann | DE |

## 2.2. CHMP preparedness and capacity building

EMA and its scientific committees assess medicines through a network of over 3,700 scientific experts from across the EU from around 50 medicines regulatory authorities from the European Economic Area Member States, the European Commission and EMA. This network is what makes the EU regulatory system unique. The diversity of the experts from across Europe involved in the regulation of medicines in the EU encourages the exchange of knowledge, ideas and best practices between scientists striving for the highest standards for medicines regulation.

CHMP topic leaders: Tomas Salmonson

### Key objectives

- Monitor activity level and discuss mechanisms to address changes in workload pressure and assignment of CHMP roles;

### Activities in 2018

CHMP activities to achieve the objectives set for this area:

- Monitor activity and CHMP role appointment and establish regular feedback to CHMP;
- Explore mechanisms to improve workload distribution;
- Discuss mechanisms to facilitate work-sharing and promote capacity building;
- Draft report with findings and proposals for improvement.

Other contributors:

| Member/alternate | Name | MS |
|---|---|---|
| Vice-Chair | Harald Enzmann | DE |
| Co-opted member | Sol Ruiz | |
| Member | Outi Maki-Ikola | FI |

## *2.3. Referral roadmap*

Multiyear project to analyse, share experience and optimise the preparation and conduct of referral procedures.

CHMP topic leaders: Tomas Salmonson, Harald Enzmann

### Key objectives

- Sharing of experience and better support to the network in preparing a referral.

### Activities in 2018

- Develop a list of points to consider to better support Member States in preparing a potential referral;
- Support any analysis that would be relevant to achieve the above.

Other contributors:

| Member/alternate | Name | MS |
|---|---|---|
| Member | Ewa Balkowiec Iskra | PL |