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Human Medicines Division

Pharmacovigilance Risk Assessment Committee (PRAC): Work Plan 2025

Adopted by the Committee on 12 December 2024

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*The activities outlined in the PRAC 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. Special populations and product guidance

Activity area

Certain population groups may benefit from specific considerations in the conduct of pharmacovigilance. These PRAC activities channel the Committee's expertise into the development of population specific guidance.

Key objective(s)

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

Activities in 2025

PRAC activities to achieve the objectives set for this area:

- Progress with the finalisation of GVP module XVI Addendum I[1] on risk minimisation measures for medicinal products with teratogenic risks following public consultation in 2022.
- Finalise GVP P. III on 'Product- or population-specific considerations: Use of medicinal products in pregnancy and breastfeeding' following public consultation in 2020.
- Conduct peer review activities and/or provision of expert input, as appropriate, into initiatives for strengthening the evidence base for medicine safety in pregnancy and breastfeeding.
- Contribute to further optimise close cooperation with CHMP, by providing expert input on the update of 'CHMP Guideline on risk assessment of medicinal products on human reproduction and lactation: from data to labelling'.
- Revise GVP P. I (revision 1) on 'Product- or population-specific considerations: Vaccines for prophylaxis against infectious diseases'.

PRAC topic leader(s): Ulla Wändel Liminga

Other Committee participants:

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Member	Eva Jirsová	CZ
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[1] GVP Module XVI in its current version revision 3 has, as of 26 July 2024, incorporated guidance on managing materials for additional risk minimisation measures at the level of Member States, which was previously in Addendum I to revision 2 of GVP Module XVI. The Addendum I to revision 3 of GVP Module XVI will refer to risk minimisation measures for medicinal products with teratogenic risks (this draft guidance was previously subject to public consultation with the interim numbering Addendum III).

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1.1.2. Life-cycle approach to pharmacovigilance and risk assessment

Activity area

By ensuring robust, feasible and risk proportionate planning of pharmacovigilance activities including risk minimisation and further collection of data and information as early as possible in the lifecycle of medicines, the work of PRAC supports the protection and promotion of public health. The work of PRAC also underpins innovation throughout the product lifecycle and supports the delivery of new treatments to patients, fulfilling unmet medical needs by optimising their benefit/risk balance.

Key objective(s)

- Strengthen public health promotion and protection.
- Support innovation and the fulfilment of unmet medical needs of patients.

Activities in 2025

PRAC activities to achieve the objectives set for this area:

- Finalise the revision 4 of GVP Module VIII on 'Post-authorisation safety studies' for public consultation and update of the related documents (templates for format and content of PASS protocol and report).
- Contribute to further optimise close cooperation with Committee for Advanced Therapies (CAT), by revising of GVP Module V on 'Risk management system' (revision 3).
- Revise the GVP Modules I on ‘Pharmacovigilance systems and their quality systems’, II on ‘Pharmacovigilance system master file (revision 2)’, III on ‘Pharmacovigilance inspections’, IV on ‘Pharmacovigilance audits (revision 1)’, VI on ‘Collection, management and submission of reports of suspected adverse reactions to medicinal products (Rev. 2)’ and VII on ‘Periodic safety update report’, in line with the revised Implementing Regulation.

- Provide expert input for developing a reflection paper on digital tools supporting risk minimisation measures (RMMs).
- Enhance engagement of patients and healthcare professionals (HCPs) in risk minimisation activities, by operationalising the working group PRAC Risk Minimisation Alliance (PRISMA) to discuss options and factors of effective risk minimisation tools along the patient journey through healthcare settings and opportunities for implementation of measures in the relevant settings.
- Finalise and publish the specific adverse reaction follow-up questionnaires (Specific AR FUQ) guideline and contribute to set-up of the Specific AR FUQ repository as defined in the guideline.

PRAC topic leader(s): Martin Huber

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1.2. Post-authorisation activities

See also activities under 1.1.

1.2.1. Information from real-world clinical use of medicines

Activities in 2025

Collection and analysis of data from the real-world use of medicines is important in supporting assessment and decision-making on how medicines are used in routine clinical care, their effectiveness and their safety in such setting. Use of epidemiological approaches is key, and enablers include access to high-quality data (e.g. electronic health records and insurance claim records, registry data), clear governance, and collaboration across various stakeholders including academia. Data and generated evidence from the real-world use of medicines is a key enabler for access to new treatments.

Key objective(s)

- Strengthen the input of the network and academic research as a source of data and information in PRAC assessments.
- Improve collaboration within the network to deliver robust results of assessment of evidence generated from clinical use.

Activities in 2025

PRAC activities to achieve the objectives set for this area:

- Provide expert input on the implementation of the recommendations from the Heads of Medicines Agencies (HMA)/EMA Joint Network Data Steering Group (NDSG) in accordance with the workplan activities.
- Provide expert input on a pilot project aiming to conduct studies leveraging genetic data linked to real-world data sources to explore any support to PRAC decision-making.
- Provide expert input on strengthening data analysis and routine use of real-world evidence (RWE) to support PRAC decision-making.
- Provide expert input on supporting the development of guidance on use of RWE for regulatory purpose.
- Conduct peer review activities on project deliverables of the EMA commissioned studies, including technical specifications, study protocols and reports.
- Provide expert input on the finalisation of a new ICH guideline (M14) on 'General principles on planning and designing pharmaco-epidemiological studies that utilise real world data (RWD) for safety assessment of a medicine'.
- Provide expert input on a pilot project aiming to explore possibilities for early identification of RWE needs and acceleration of RWE generation in anticipation of the next/upcoming PSUR Single Assessments (PSUSAs).

PRAC topic leader(s): Ulla Wandel Liminga

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1.3. Arbitrations and referrals

See activities under section 2.2.

1.4. Pharmacovigilance activities

1.4.1. Optimising management and utility of reported adverse reactions

Activity area

The establishment and the full functionality of EudraVigilance operations in the previous years allowed simplified reporting, better data access and analysis and greater transparency.

Key objective(s)

- Enhance adverse reaction collection and EudraVigilance management system to deliver better health protection through simplified reporting, better quality data and a more comprehensive assessment within PRAC in order to allow for more rapid actions.

Activities in 2025

PRAC activities to achieve the objectives set for this area:

- Provide expert input on the revision of ICH E2D guideline on 'Post approval safety data management'.

PRAC topic leader(s): Ulla Wandel Liminga

Other Committee participants:

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Member	Petar Mas	HR
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1.4.2. Signal detection and management

Activity area

Key PRAC tasks include prioritisation, assessment and recommendations on safety signals. This key public health domain has delivered important outputs and there is an opportunity to further enhance the effectiveness and efficiency of these activities based on learnings from operation of the processes to date.

Key objective(s)

- Apply evidence-based new methodologies for signal detection.
- Improve signal management processes based on experience.
- Achieve efficient and effective industry input to signal detection and management.

Activities in 2025

PRAC activities to achieve the objectives set for this area:

- Supported by the Signal Management Review Technical (SMART) Working Group aiming to provide expert input on improving methods and outputs for data analytics and retrieval to ensure continuous improvement of signal management process, which includes monitoring and reviewing new developments, together with testing and piloting various methodologies as well as providing relevant guidance for their use.
- Revise GVP Module IX (revision 2) on 'Signal management' in line with the revised Implementing Regulation.
- Provide expert input on the development of further guidance for the Committee on Herbal Medicinal Products (HMPC) on particularities for signal detection for herbal substances/preparations.

PRAC topic leader(s): Martin Huber

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1.4.3. Measuring the impact of pharmacovigilance activities

Activity area

Systematically measuring patient-relevant health outcomes of major regulatory interventions (e.g. post referral procedures) and key pharmacovigilance processes enable the focus of pharmacovigilance on activities and regulatory tools that make a difference in daily healthcare.

Key objective(s)

- Improve pharmacovigilance through measuring impact of regulatory interventions in line with the PRAC Impact Strategy.

Activities in 2025

PRAC activities to achieve the objectives set for this area, supported by the PRAC Interest Group Impact:

- Provide expert input and scientific guidance for industry and regulators on impact research methodologies, including training in line with GVP Module XVI Rev.3 and Addendum II.
- Oversee and advise on the conduct of impact research of pharmacovigilance regulatory interventions, including prioritisation of research topics and regulatory follow-up.
- Provide advice on the conduct of impact research through DARWIN EU and review related European Medicines Regulatory Network (EMRN) processes in line with the PRAC Impact Group (IG) workplan.
- Provide recommendations to facilitate RMM implementation in clinical practice, supported by PRISMA activities (see section 1.1.2. - PRISMA).

PRAC topic leader(s): Liana Martirosyan

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1.5. Digital technologies

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

Activity area

The EMRN, through the HMA/EMA Joint NDSG's oversight, aims to also work towards activities to enable the safe and responsible use of AI in the medicine lifecycle and extract value for public and animal health. In addition, the Network 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.

For PRAC, engagement and provision of pharmacovigilance expert input on the use of new technologies for the undertaking of pharmacovigilance work within the EMRN is considered crucial.

Key objectives

- Continued overview of the HMA/EMA workplan activities on AI, in particular on guidance, policy and product support, change management and experimentation and implementation of AI for the activities related to pharmacovigilance.
- 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 AI applications related to pharmacovigilance and product information, as well as general knowledge mining in regulatory science.

Activities in 2025

- Contribute to the development of knowledge sharing and training material on AI, in particular generative AI, including on ethical and data protection issues, to support assessors.
- Onboard PRAC experts to work with experts on AI to support the committee and interact with the relevant 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.
- Contribute to further optimise close cooperation with CHMP, and its Methodology Working Party, by development of guidance for AI in pharmacovigilance.

PRAC topic leader(s): Ulla Wandel Liminga

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2. Horizontal activities and other areas

2.1. Partners and stakeholders

2.1.1. Engagement with partners, patients and healthcare professionals and communication with stakeholders

Activity area

The engagement of patients and HCPs is important for an effective pharmacovigilance. Patients and HCPs can be involved throughout the process from risk management planning, through reporting of suspected adverse reactions, assessments and decision, e.g. through PSUR/PSUSAs, referrals and on benefit-risk communications. For PRAC, key engagement has included membership of the committee, patients' and HCPs' reporting, involvement in ad-hoc expert groups and scientific advisory groups, stakeholder meetings, public hearings and targeted written consultations.

In addition, the ongoing work on Patient Experience Data (PED) is relevant for the work of PRAC, since data reported directly by patients on their conditions and treatments are essential for adverse reaction reporting and for acceptance of RMMs.

Interaction with partners on an international level, i.e. World Health Organization (WHO), is also considered key for the dissemination of an effective pharmacovigilance as well as an exchange of expertise.

Key objective(s)

- Strengthen communication tools and coordination of safety information.
- Contribute to the improvement of evidence generation in order to result in more meaningful outcomes for patients.

Activities in 2025

PRAC activities to achieve the objectives set for this area:

- Contribute to the elaboration of a reflection paper to provide advice on the best EU approach to generate, collect and analyse PED.
- Enhance engagement of patients and HCPs in PRAC activities including PRISMA (see section 1.1.2.) and activities related to the safety referral roadmap initiative (see section 2.2.).
- Enhance engagement and collaboration between PRAC and WHO pharmacovigilance team.

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2.2. Process improvements

Activity area

PRAC has an important role in continuous improvement of its processes. Key processes through PRAC include risk management plans, post-authorisation study protocols and results, signal management, referrals, periodic safety update reports including single assessment procedures and variations. Observations from running these processes combined with feedback from stakeholders provide opportunities for such improvements.

Key objective(s)

- Strengthen capacity for pharmacovigilance through training.
- Continuously improve processes involving PRAC.
- Strengthen the quality and consistency of PRAC recommendations.

Activities in 2025

PRAC activities to achieve the objectives set for this area:

- Continue to provide input for developing a training plan as part of the EU Operation of Pharmacovigilance Training curriculum and support the delivery of regular trainings/workshops for assessors focusing on critical appraisal of pharmacovigilance procedures and aiming at capacity building.
- Support to the delivery of content of the pharmacoepidemiology curriculum to enhance the utilisation of RWD in regulatory decision making.
- Provide input in the development of points to consider to better support Member States in preparing and conducting a safety referral, in the context of the referral roadmap initiative.
- Review and provide feedback on the amendments of the EURD list proposed by Granularity and Periodicity Advisory Group (GPAG) in response to queries by Member States, marketing authorisation holders or EMA.

PRAC topic leader(s): Martin Huber

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