EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Division

Pharmacovigilance Risk Assessment Committee (PRAC): Work Plan 2024

Adopted by the Committee on 26 January 2024

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*The activities outlined in the PRAC work plan for 2024 have been agreed taking into consideration the Agency's prioritisation set forth in the EMA multi-annual work programme **2023-2025**.*

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 work topics 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 2024

PRAC activities to achieve the objectives set for this area:

- Finalisation of GVP P. III on 'Product- or population-specific considerations: pregnancy and breastfeeding' following public consultation in 2020.
- Conduct of 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.
- Provide guidance on the use of disease-modifying therapies in women of childbearing potential to propose methods to improve risk management plan (RMP) requirements and to further review pregnancy outcomes intensive monitoring (PRIM) programs for several medicinal products indicated in multiple sclerosis.
- 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'.

PRAC topic leader(s): Ulla Wändel Liminga

Other Committee participants:

Member/alternate/expert	Name	Member State or affiliation
Chair	Sabine Straus	NL
Member	Eva Jirsová	CZ
Member	Tiphaine Vaillant	FR
Alternate	Nathalie Gault	FR
Member	Rhea Fitzgerald	IE
Member	Liana Gross-Martirosyan	NL
Member	Roxana Dondera	RO
Member	Hedvig Marie Egeland Nordeng	Independent scientific expert appointed by the European Commission (EC)

Member/alternate/expert	Name	Member State or affiliation
Member	Tania Schink	Independent scientific expert appointed by the European Commission (EC)
Member	Maria Teresa Herdeiro	Independent scientific expert appointed by the European Commission (EC)

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 2024

PRAC activities to achieve the objectives set for this area:

- Finalise revision 3 of GVP Module XVI on 'Risk minimisation measures: selection of tools and effectiveness indicators' following public consultation in 2021.
- Integrate GVP Module XVI Addendum I on 'Educational materials' in the revision 3 of GVP module XVI.
- Finalise GVP Module XVI Addendum II on 'Risk minimisation measures effectiveness evaluation' following public consultation in 2021.
- Progress with the finalisation of GVP module XVI Addendum III on 'Pregnancy prevention programme' following public consultation in 2022.
- 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).
- Provide expert input for developing a reflection paper on digital tools supporting risk minimisation measures (RMMs).
- Enhance engagement of patients and healthcare professionals (HCPs) by providing input to RMMs, transitioning the working group PRAC Risk Minimisation Alliance (PRISMA) from pilot to its operational phase, for discussing options of effective risk minimisation along the patient journey through healthcare settings and opportunities for implementation of measures in the relevant settings.
- Contribute to the development and regulatory implementation of recommendations for RMMs regarding opioid use disorder (OUD) in the EU.

- Finalise 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

Other Committee participants:

Member/alternate/expert	Name	Member State or affiliation
Chair	Sabine Straus	NL
Member	Jean-Michel Dogne	BE
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Member	Patricia McGettigan	Independent scientific expert appointed by the European Commission (EC)
Expert	Dennis Lex	DE

1.2. 1.1. Post-authorisation activities

See also activities under 1.1.

1.2.1. Information from real-world clinical use of medicines

Activity area

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, their effectiveness and their safety. Use of epidemiological approaches is key and enablers include access to electronic health and insurance records, clear governance, and collaboration across stakeholders including academia. Data and information 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 focussed results of assessment of information from clinical use.

Activities in 2024

PRAC activities to achieve the objectives set for this area:

- Provide expert input in the implementation of the recommendations from the Heads of Medicines Agencies (HMA)/EMA Big Data Steering Group in accordance with the Big Data Workplan deliverables for 2024.
- Provide expert input in 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 in support of 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 in developing a new ICH guideline on 'General principles on planning and designing pharmaco-epidemiological studies that utilise real world data (RWD) for safety assessment of a medicine'.

PRAC topic leader(s): Sabine Straus

Other Committee participants:

Member/alternate/expert	Name	Member State or affiliation
Alternate	Nathalie Gault	FR
Member	Liana Gross-Martirosyan	NL
Member	Annalisa Capuano	Independent scientific expert appointed by the European Commission (EC)

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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

In November 2017 the full functionality of EudraVigilance became operational. This allows 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 2024

PRAC activities to achieve the objectives set for this area:

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

PRAC topic leader(s): Sabine Straus

Other Committee participants:

Member/alternate/expert	Name	Member State or affiliation
Expert	Dennis Lex	DE

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 2024

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 in 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.
- Collaboration with the Clinical Trial Information System (CTIS) Working Group (WG) with regards to signal management activities for clinical trials in line with the Accelerating Clinical Trials in the EU (ACT EU) initiative.
- Provide expert input in 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

Other Committee participants:

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Member	Julia Pallos	HU
Member	Zane Neikena	LV
Member	Liana Gross-Martirosyan	NL
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Expert	Dennis Lex	DE
Expert	Charlotte Backman	SE

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.

Activities in 2024

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 objectives and methodologies, including training to assessors (related to GVP module XVI).
- Oversee and advise on the conduct of impact research of pharmacovigilance regulatory interventions, including prioritisation of research topics.

- Review impact research projects including related processes and provide advice on conduct of impact research through DARWIN EU (in line with the PRAC Impact Group workplan).
- PRISMA feeding into the regulatory impact research (see section 1.1.2 - PRISMA).

PRAC topic leader(s): Liana Gross-Martirosyan

Other Committee participants:

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Chair	Sabine Straus	NL
Member	Martin Huber	DE
Alternate	Nathalie Gault	FR
Member	Amelia Cupelli	IT
Member	Zane Neikena	LV
Member	David Olsen	NO
Member	Ana Sofia Diniz Martins	PT

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 and 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 to engage for the dissemination of an effective pharmacovigilance as well as an interchange 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 2024

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 (see section 1.1.2 - PRISMA).
- Enhance engagement and collaboration between PRAC and WHO pharmacovigilance team.

PRAC topic leader(s): Sabine Straus

Other Committee participants:

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Member	Martin Huber	DE
Member	Sofia Trantza	GR
Member	Hedvig Marie Egeland Nordeng	Independent scientific expert appointed by the European Commission (EC)

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 2024

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 process of implementing the revision of the pharmaceutical legislation affecting PRAC's regulatory decision-making, as needed.
- 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

Other Committee participants:

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