EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 January 2023
EMA/PRAC/45172/2023
Human Medicines Division

Pharmacovigilance Risk Assessment Committee (PRAC): Work Plan 2023

Adopted by the Committee on 23 January 2023

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*The activities outlined in the PRAC work plan for 2023 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 specific population groups require specific consideration 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 by industry and regulators through dedicated guidance on specific populations.
- Strengthen systematic generation of information on the benefits and risks of medicines in pregnancy and breastfeeding.

Activities in 2023

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 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	Anette Kirstine Stark	DK
Member	Tiphaine Vaillant	FR
Alternate	Nathalie Gault	FR
Member	Menno van der Elst	NL
Alternate	Liana Gross-Martirosyan	NL
Member	Roxana Dondera	RO
Alternate	Alexandra-Maria Spurni	RO
Member	Hedvig Marie Egeland Nordeng	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, the work of PRAC supports the protection and promotion of public health. The work of PRAC also underpins innovation throughout the product lifecycle thereby and supporting the delivery of new treatments to patients, fulfilling unmet medical needs.

Key objective(s)

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

Activities in 2023

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.
- Finalise GVP module XVI addendum I on 'Educational materials' following public consultation in 2021.
- Finalise GVP module XVI addendum II on 'Risk minimisation measures effectiveness evaluation' following public consultation in 2021.
- Finalise GVP module XVI addendum III on 'Pregnancy prevention programme' following public consultation in 2022.
- Provide expert input to the revision of GVP Module VIII on 'Post-authorisation safety studies' (revision 4) and update of the related documents.
- Contribute to further optimise close cooperation with CAT, by providing expert input to the revision of GVP Module V on 'Risk management system' (revision 3).
- Provide expert input for developing a concept paper on digital tools supporting risk minimisation measures.
- Provide expert input on the review of the risks of dependence and addiction associated with use of medicines containing opioids – development of recommendations for risk minimisation measures on opioid use disorder (OUD) in the EU.
- Consolidate the review on the use and utility of specific adverse reaction follow-up questionnaires as a routine pharmacovigilance activity.

PRAC topic leader(s): Martin Huber

Other Committee participants:

Member/alternate/expert	Name	Member State or affiliation
Chair	Sabine Straus	NL
Member	Eva Jirsová	CZ
Alternate	Jana Lukacisinova	CZ
Member	Anette Kirstine Stark	DK
Member	Maia Uusküla	EE
Member	Maria del Pilar Rayon	ES

Member/alternate/expert	Name	Member State or affiliation
Alternate	Mónica Martínez Redondo	ES
Member	Tiphaine Vaillant	FR
Alternate	Nathalie Gault	FR
Member	Sofia Trantza	GR
Member	Nikica Mirošević Skvrce	HR
Alternate	Željana Margan Koletić	HR
Member	Rhea Fitzgerald	IE
Member	Amelia Cupelli	IT
Member	Menno van der Elst	NL
Alternate	Liana Gross-Martirosyan	NL
Member	Ana Sofia Diniz Martins	PT
Member	Roxana Dondera	RO
Alternate	Alexandra-Maria Spurni	RO
Member	Ulla Wändel Liminga	SE
Alternate	Mari Thörn	SE
Member	Roberto Frontini	Representative of healthcare professionals appointed by the European Commission (EC)
Alternate	Salvatore Antonio Giuseppe Messana	Representative of healthcare professionals appointed by the European Commission (EC)
Member	Declan Noone	Representative of patients' organisations appointed by the European Commission (EC)
Alternate	Marko Korenjak	Representative of patients' organisations appointed by the European Commission (EC)
Member	Hedvig Marie Egeland Nordeng	Independent scientific expert appointed by the European Commission (EC)
Member	Patricia McGettigan	Independent scientific expert appointed by the European Commission (EC)
Expert	Dennis Lex	DE

1.2. Initial-evaluation activities

See activities under section 1.1.

1.3. Post-authorisation activities

See also activities under 1.1.

1.3.1. 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 2023

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 2023.
- 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	Nikica Mirošević Skvrce	HR
Alternate	Liana Gross-Martirosyan	NL
Member	Annalisa Capuano	Independent scientific expert appointed by the European Commission (EC)

1.4. Arbitrations and referrals

See under 2.2.

1.5. Pharmacovigilance activities

1.5.1. 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 2023

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
Alternate	Željana Margan Koletić	HR
Expert	Dennis Lex	DE

1.5.2. 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 2023

PRAC activities to achieve the objectives set for this area, supported by the Signal Management Review Technical (SMART) working group:

- 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.

PRAC topic leader(s): Menno van der Elst

Other Committee participants:

Member/alternate/expert	Name	Member State or affiliation
Member	Jean-Michel Dogné	BE
Member	Martin Huber	DE
Member	Maria del Pilar Rayon	ES
Member	Zane Neikena	LV
Alternate	Liana Gross-Martirosyan	NL

Member/alternate/expert	Name	Member State or affiliation
Member	Milou-Daniel Drici	Independent scientific expert appointed by the European Commission (EC)
Expert	Dennis Lex	DE
Expert	Charlotte Backman	SE

1.5.3. 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 2023

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).
- Enhance engagement of patients and healthcare professionals (HCPs) in measuring the impact of regulatory interventions and in providing input to risk minimisation measures, supported by the piloting phase of PRAC points-to-consider for selecting PRAC engagement mechanism (PRAC Risk Minimisation Alliance (PRISMA)).

PRAC topic leader(s): Liana Gross-Martirosyan

Other Committee participants:

Member/alternate/expert	Name	Member State or affiliation
Chair	Sabine Straus	NL
Member	Martin Huber	DE
Alternate	Nathalie Gault	FR
Member	Nikica Mirošević Skvrce	HR
Member	Amelia Cupelli	IT
Member	Zane Neikena	LV
Member	David Benee Olsen	NO
Member	Ana Sofia Diniz Martins	PT
Member	Roberto Frontini	Representative of healthcare professionals appointed by the European Commission (EC)

2. Horizontal activities and other areas

2.1. Partners and stakeholders

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

Activity area

The engagement of patients and HCPs is important for effective pharmacovigilance. Patients and HCPs can be involved throughout the process from risk management planning, through reporting of suspected adverse drug 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 healthcare professionals' reporting, involvement in ad-hoc expert groups and scientific advisory groups, public hearings and targeted written consultations.

Key objective(s)

- Strengthen communication tools and coordination of safety information.

Activities in 2023

PRAC activities to achieve the objectives set for this area:

- Provide expert input for developing a position paper to reflect on the best EU approach to generate and collect patient experience data (PED).
- Enhance engagement of patients and HCPs (see section 1.5.3 - PRISMA).

PRAC topic leader(s): Sabine Straus

Other Committee participants:

Member/alternate/expert	Name	Member State or affiliation
Member	Sofia Trantza	GR

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 2023

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 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 support the implementation of improvements proposed by the granularity and periodicity advisory group (GPAG), by supporting the development of a best practice guidance based on the experience acquired by GPAG.
- Revise the principles of the 'Best Practice Guide on using PRAC plenary time efficiently and effectively' dedicated to the improvement of the functioning of the Committee and further propose. This activity is supported by the 'PRAC working group on efficiency and effectiveness for PRAC plenary meetings'.

PRAC topic leader(s): Martin Huber

Other Committee participants:

Member/alternate/expert	Name	Member State or affiliation
Member	Maria del Pilar Rayon	ES
Member	Tiphaine Vaillant	FR
Alternate	Nathalie Gault	FR
Member	Sofia Trantza	GR
Alternate	Željana Margan Koletić	HR
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