EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Inspections, Human Medicines Pharmacovigilance and Committees Division

Pharmacovigilance Risk Assessment Committee (PRAC): Work Plan 2019

Adopted by the Committee on 17 January 2019

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The activities outlined in the PRAC work plan for 2019 have been agreed taking into consideration the Agency's business continuity plans (BCP) due to the preparations for the consequences of the UK's exit from the EU, both in terms of impact on the Agency's operations and the physical relocation of the Agency's premises to the Netherlands.

Temporary scaling back of activities is currently scheduled to last until 30 June 2019, see enclosed link for additional information.

1. Evaluation activities for human medicines

1.1. Pre-authorisation activities

1.1.1. Special populations and product guidances

Certain specific population groups require specific consideration in the conduct of pharmacovigilance. This PRAC work topic channels 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.

Activities in 2019

PRAC activities to achieve the objectives set for this area:

- Consolidate expert input in the drafting of GVP P.III – 'Product- or population-specific considerations: pregnancy and breastfeeding' with a view to initiate the public consultation.

PRAC topic leader(s): Ulla Wändel Liminga

Other Committee participants:

Member/alternate/expert	Name	Member State or affiliation
Chair	Sabine Straus	-
Member	Eva Jirsova	CZ
Member	Ghania Chamouni	FR
Member	Menno van der Elst	NL
Member	Hedvig Marie Egeland Nordeng	Independent scientific expert appointed by the EC

1.1.2. Life-cycle approach to pharmacovigilance and risk management

By ensuring robust, feasible and risk proportionate planning of pharmacovigilance activities including risk minimisation and further collection of data and information, the work of the 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 2019

PRAC activities to achieve the objectives set for this area:

- Provide input in optimising PRAC-SAWP interaction in scientific advice procedures on PASS protocols and in scientific advice procedures involving questions falling under the mandate of the PRAC on pharmacovigilance planning and risk mitigation[1] and further rationalise the cooperation between SAWP and PRAC in order to provide the best possible advice on study design and on risk minimisation.
- Contribute to revision 3 of GVP module XVI on 'Risk minimisation measures: selection of tools and effectiveness indicators' including definitions of the available risk minimisation tools available to PRAC.
- Support the implementation of revision 2 of GVP module V on 'Risk management systems' and further optimisation of RMPs including close cooperation with CHMP in this regard. See also 2.5.

PRAC topic leader(s): Martin Huber

Other Committee participants:

Member/alternate/expert	Name	Member State or affiliation
Alternate	Laurence de Fays	BE
Alternate	Brigitte Keller-Stanislawski	DE
Member	Eva Segovia	ES
Member	Ghania Chamouni	FR
Member	Menno van der Elst	NL
Member	Ulla Wändel Liminga	SE
Expert	Valerie Strassmann	DE

1.2. Initial-evaluation activities

Not applicable

1.3. Post-authorisation activities

1.3.1. Information from real-world clinical use of medicines

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 and will support the PRIME scheme and Adaptive Pathway initiatives.

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.

[1] So called PRAC consultation in scientific advice procedures

Activities in 2019

PRAC activities to achieve the objectives set for this area:

- Consolidate the review of lessons learnt from the pilot regulatory network study involving EMA, Spain and the United Kingdom, as a source of learnings for the regulatory network's support to PRAC using RWD.
- Support the development of a cross-committee approach on how to best collect and use RWD to support regulatory decision-making and to inform the development of PRAC procedures and future study designs.
- Contribute to the EMA initiative on patient registries and the Cross-Committee task force on registries by providing input to the development of a guidance on methodological aspects and governance of patient registries.
- Advise the HMA/EMA task force on big data on priorities and actions to enable big data to support decision-making.

PRAC topic leader(s): Sabine Straus

Other Committee participants:

Member/alternate/expert	Name	Member State or affiliation
Member	Nikica Mirošević Skvrce	HR
Member	Brigitte Keller-Stanislawski	DE
Member	Ulla Wändel Liminga	SE
Alternate	Albert van der Zeijden	Representative of patients' organisations appointed by the EC
Expert	Dolores Montero Corominas	ES
Expert	Nils Feltelius	SE

1.4. Arbitrations and referrals

See under 2.5.

1.5. Pharmacovigilance activities

1.5.1. Optimising management and utility of reported adverse reactions

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 management system (EudraVigilance) to deliver better health protection through simplified reporting, better quality data and better searching, analysis and tracking functionalities. Enhanced detection of new or changing safety issues allows more rapid action to protect public health.

Activities in 2019

PRAC activities to achieve the objectives set for this area:

- Monitor the operations of the new EudraVigilance system functionalities and the experience gained as regards the impacted business processes.

PRAC topic leader(s): Jean-Michel Dogné

Other Committee participants:

Member/alternate/expert	Name	Member State or affiliation
Member	Martin Huber	DE
Expert	Edurne Lázaro	ES

1.5.2. Signal detection and management

Key PRAC tasks include prioritisation, assessment and recommendations on safety signals. This key public health domain has delivered important outputs during PRAC's first six-years of activity 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. Furthermore, as of the end of 2017 through a signal management pilot, MAHs have access to EudraVigilance data and the new processes for managing MAHs' communication of signals raised from EudraVigilance will require review.

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 2019

PRAC activities to achieve the objectives set for this area:

Supported by the SMART working group:

- Review operation of the signal reporting extended pilot by MAHs based on the new EudraVigilance functionality, and provide input in a review of the pilot.
- Provide expert input in improving methods and outputs including data analytics and retrieval to ensure continuous improvement of signal management.
- Consolidate a review of the risk of drug-induced hepatotoxicity in order to improve its management.

PRAC topic leader(s): Menno van der Elst

Other Committee participants:

Member/alternate/expert	Name	Member State or affiliation
Member	Martin Huber	DE
Alternate	Maria del Pilar Rayon	ES
Member	Amelia Cupelli	IT
Member	Zane Neikena	LV
Alternate	Liana Gross-Martirosyan	NL
Member	Birgitta Grundmark	Independent scientific expert appointed by the EC
Member	Stefan Weiler	Independent scientific expert appointed by the EC

Member/alternate/expert	Name	Member State or affiliation
Expert	Charlotte Backman	SE

1.5.3. Measuring the impact of pharmacovigilance activities

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

Key objective(s)

- Improve pharmacovigilance through feedback on impact of regulatory actions.

Activities in 2019

PRAC activities to achieve the objectives set for this area:

Supported by the PRAC IG:

- Develop scientific guidance for industry and regulators on impact research methodologies.
- Embed routine processes to conduct impact research of pharmacovigilance regulatory actions.
- Support early engagement of HCPs and patients in evaluation of risk minimisation activities. See also 2.3.1.
- Support the conduct of independent impact research.

PRAC topic leader(s): Sabine Straus

Other Committee participants:

Member/alternate/expert	Name	Member State or affiliation
Member	Martin Huber	DE
Member	Maia Uusküla	EE
Member	Ghania Chamouni	FR
Member	Nikica Mirošević Skvrce	HR
Member	Amelia Cupelli	IT
Member	Zane Neikena	LV
Alternate	Liana Gross-Martirosyan	NL
Member	David Benee Olsen	NO
Member	Ana Sofia Diniz Martins	PT
Alternate	Márcia Sofia Sanches de Castro Lopes Silva	PT
Member	Julie Williams	UK
Expert	Valerie Strassmann	DE
Expert	Dolores Montero Corominas	ES
Expert	Karl-Mikael Kälkner	SE

1.6. Other specialised areas and activities

1.6.1. Regulatory science

This PRAC work topic channels the Committee's expertise into the development of regulatory science strategies.

Key objective(s)

- Optimise assessment and decision-making at PRAC through better use of regulatory science.

Activities in 2019

- Contribute and provide expert advice regarding pharmacovigilance and RWD aspects in support of the development of EMA's regulatory science strategy.

PRAC topic leader(s): Sabine Straus

Other Committee participants:

Member/alternate/expert	Name	Member State or affiliation
Member	Martin Huber	DE

2. Horizontal activities and other areas

2.1. Committees and working parties

Not applicable

2.2. Inspections and compliance

Not applicable

2.3. Partners and stakeholders

2.3.1. Engage patients and healthcare professionals, communication with stakeholders

The engagement of patients and healthcare professionals is important for effective pharmacovigilance. Patients and healthcare professionals can be involved throughout the process from risk management planning, through reporting of suspected adverse drug reactions, assessments and decision e.g. through PSURs 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 and public hearings.

Key objective(s)

- Strengthen communication tools and coordination of safety information.

Activities in 2019

PRAC activities to achieve the objectives set for this area:

- Support early engagement of HCPs and patients in risk minimisation through guidance. See also 1.5.3.
- Review and improve communications outputs of PRAC meetings: provide input in the current content of the monthly PRAC highlights with a focus on how to communicate on management of a wider spectrum of PRAC's work.

PRAC topic leader(s): Albert van der Zeijden

Other Committee participants:

Member/alternate/expert	Name	Member State or affiliation
Alternate	Laurence de Fays	BE
Member	Martin Huber	DE
Alternate	Sofia Trantza	GR
Member	Julia Pallos	HU
Member	Amelia Cupelli	IT
Member	Raymond Anderson	Representative of healthcare professionals appointed by the EC

2.4. Data-management support

Not applicable

2.5. Process improvements

The 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 the PRAC.
- Increase the efficiency of PRAC plenary discussion.
- Strengthen the quality of PRAC recommendations.

Activities in 2019

PRAC activities to achieve the objectives set for this area:

- Provide input in a training plan as part of the EU Operation of Pharmacovigilance Training curriculum and oversee training activities.
- Support training of assessors in critical appraisal and pharmacovigilance procedures with a particular focus on supporting capacity building in view of Brexit and the transfer of Rapporteurship of products to new Member States.

- Review and support the implementation of improvements proposed by the GPAG as per its work plan 2019.
- Support the implementation of revision 2 of GVP module V on 'Risk management systems' and further optimisation of RMPs including close cooperation with CHMP in this regard. See also 1.1.2.
- Provide expert advice on the optimal role of PRAC for safety related variations.
- 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.

PRAC topic leader(s): Martin Huber; Menno van der Elst

Other Committee participants:

Member/alternate/expert	Name	Member State or affiliation
Alternate	Laurence de Fays	BE
Member	Maia Uusküla	EE
Member	Eva Segovia	ES
Alternate	Maria del Pilar Rayon	ES
Member	Ghania Chamouni	FR
Alternate	Adrien Inoubli	FR
Member	Jolanta Gulbinovič	LT
Member	Ana Sofia Diniz Martins	PT
Alternate	Márcia Sofia Sanches de Castro Lopes Silva	PT
Member	Ulla Wändel Liminga	SE
Member	Julie Williams	UK
Expert	Charlotte Backman	SE

3. List of acronyms and abbreviations

CHMP: Committee for Medicinal Products for Human Use

EC: European Commission

EU: European Union

EMA: European Medicines Agency ('Agency')

EU: European Union

GPAG: Granularity and Periodicity Advisory Group

GVP: Good Pharmacovigilance Practice

HCP: Healthcare Professional

HMA: Heads of Medicines Agencies

MAH: Marketing Authorisation Holder

PASS: Post-Authorisation Safety Study

PRAC: Pharmacovigilance Risk Assessment Committee

PRAC IG: PRAC Interested Group on Impact

PRIME: Priority Medicines

PSUR: Periodic Safety Update Report

RMP: Risk Management Plan

RWD: Real world data

SMART: Signal Management Review Technical