EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 January 2020
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Inspections, Human Medicines, Pharmacovigilance and Committees Division

Pharmacovigilance Risk Assessment Committee (PRAC): Work Plan 2020

Adopted by the Committee on 31 January 2020

The activities outlined in the work plan for 2020 have been agreed taking into consideration that activities are gradually reinstated following a phase of business continuity.

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1. Evaluation activities for human medicines

1.1. Pre-authorisation activities

1.1.1. Special populations and product guidance

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 2020

PRAC activities to achieve the objectives set for this area:

- Consolidate expert input in the finalisation of GVP P.III – 'Product- or population-specific considerations: pregnancy and breastfeeding' following the public consultation.

PRAC topic leader(s): Ulla Wändel Liminga

Other Committee participants:

Member/alternate/expert	Name	Member State or affiliation
Chair	Sabine Straus	NL
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 the 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 2020

PRAC activities to achieve the objectives set for this area:

- Provide expert input 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 further optimisation of close cooperation with CHMP and CAT as regards RMP assessments, including RMPs for generic medicinal products and RMP requirements for ATMPs.
- Review 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
Alternate	Jana Lukacisinova	CZ
Member	Maia Uusküla	EE
Member	Eva Segovia	ES
Member	Ghania Chamouni	FR
Alternate	Adrien Inoubli	FR
Alternate	Sofia Trantza	GR
Alternate	Željana Margan Koletić	HR
Member	Menno van der Elst	NL
Alternate	Liana Gross-Martirosyan	NL
Member	Ulla Wändel Liminga	SE
Member	Cathalijne van Doorne	Representative of patients' organisations appointed by the EC
Member	Raymond Anderson	Representative of healthcare professionals appointed by the EC
Member	Hedvig Marie Egeland Nordeng	Independent scientific expert appointed by the EC
Member	Birgitta Grundmark	Independent scientific expert appointed by the EC
Member	Daniel Morales	Independent scientific expert appointed by the EC
Member	Antoine Pariente	Independent scientific expert appointed by the EC
Expert	Dennis Lex	DE

1.2. Initial-evaluation activities

See under 1.1.

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.

Activities in 2020

PRAC activities to achieve the objectives set for this area:

- Provide advice on the implementation of the recommendations from the HMA/EMA task force on Big Data.
- Provide advice on the pilot of rapid data analysis for regulatory decision making.
- Provide expert input to the EMA initiative on patient registries and the cross-Committee task force on registries by providing input to the development of guidance on methodological aspects and governance of patient registries.

PRAC topic leader(s): Sabine Straus

Other Committee participants:

Member/alternate/expert	Name	Member State or affiliation
Alternate	Brigitte Keller-Stanislawski	DE
Member	Nikica Mirošević Skvrce	HR
Member	Ulla Wändel Liminga	SE
Alternate	Virginie Hivert	Representative of patients' organisations appointed by the EC
Alternate	Roberto Frontini	Representative of healthcare professionals appointed by the EC
Expert	Dolores Montero Corominas	ES
Expert	Dennis Lex	DE

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 2020

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): Jean-Michel Dogné

Other Committee participants:

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

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 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 2020

PRAC activities to achieve the objectives set for this area, supported by the SMART working group:

- Provide expert input in improving methods and outputs including data analytics and retrieval to ensure continuous improvement of signal management, including piloting the algorithm for detecting unexpected increases in frequency of ADR reporting, and machine learning based on EudraVigilance data.
- Finalise 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
Member	Eva Segovia	ES
Alternate	Maria del Pilar Rayon	ES
Member	Amelia Cupelli	IT

Member/alternate/expert	Name	Member State or affiliation
Alternate	Ilaria Baldelli	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
Expert	Dennis Lex	DE
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 2020

PRAC activities to achieve the objectives set for this area, supported by the PRAC IG:

- Provide expert input in the development of scientific guidance for industry and regulators on impact research methodologies.
- Advise on the conduct of impact research of pharmacovigilance regulatory actions, including updating the available templates and providing training to assessors.
- Increase the involvement of patients and HCPs in measuring the impact of regulatory interventions.

PRAC topic leader(s): Sabine Straus

Other Committee participants:

Member/alternate/expert	Name	Member State or affiliation
Member	Martin Huber	DE
Member	Ghania Chamouni	FR
Alternate	Adrien Inoubli	FR
Member	Nikica Mirošević Skvrce	HR
Member	Amelia Cupelli	IT
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Member	David Benee Olsen	NO
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Member	Daniel Morales	Independent scientific expert appointed by the EC
Member	Antoine Pariente	Independent scientific expert appointed by the EC
Member	Livia Puljak	Independent scientific expert appointed by the EC
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 the EMA regulatory science strategy, to enhance the available regulatory tools to continue supporting the European medicines regulatory network and fulfil its ongoing mission in light of upcoming scientific challenges.

Key objective(s)

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

Activities in 2020

- Provide expert advice regarding pharmacovigilance and RWD aspects in support of the 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 PSUR/PSUSAs and referrals and on benefit-risk communications. For the 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)

- Facilitate early stakeholder engagement with patients and healthcare professionals.
- Strengthen communication tools and coordination of safety information.

Activities in 2020

PRAC activities to achieve the objectives set for this area:

- Develop criteria to assess the timing, procedure type and the most appropriate methodology how to engage with patients and/or healthcare professionals.
- Support early engagement of HCPs and patients in risk minimisation through guidance.
- Review and optimise the content and format of monthly communications of PRAC recommendations.

PRAC topic leader(s): Raymond Anderson

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
Alternate	Roberto Frontini	Representative of healthcare professionals appointed by the EC
Member	Cathalijne van Doorne	Representative of patients' organisations appointed by the EC
Alternate	Virginie Hivert	Representative of patients' organisations appointed by the EC
Expert	Dennis Lex	DE

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 and consistency of PRAC recommendations.

Activities in 2020

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 of pharmacovigilance procedures and assessing impact with a particular focus on supporting capacity building.
- Review and support the implementation of improvements proposed by the GPAG.
- 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.
- Contribute to the development of the pharmacoepidemiology curriculum to enhance the utilisation of RWD in regulatory decision making.

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

Other Committee participants:

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Member	Maia Uusküla	EE
Member	Eva Segovia	ES
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Member	Ulla Wändel Liminga	SE

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

3. List of acronyms and abbreviations

ADR: Adverse Drug reaction

ATMP: Advanced Therapy Medicinal Product

CAT: Committee for Advanced Therapies

CHMP: Committee for Medicinal Products for Human Use

EC: European Commission

EMA: European Medicines Agency ('Agency')

EU: European Union

EU NTC: European Network Training Centre

GPAG: Granularity and Periodicity Advisory Group

GVP: Good Pharmacovigilance Practice

HCP: Healthcare Professional

HMA: Heads of Medicines Agencies

MAH: Marketing Authorisation Holder

PRAC: Pharmacovigilance Risk Assessment Committee

PRAC IG: PRAC Interested Group on Impact

PRIME: Priority Medicines

PSUR: Periodic Safety Update Report

PSUSA: PSUR Single Assessment

RMP: Risk Management Plan

RWD: Real World Data

SciRS: Scientific Committees Regulatory Science Strategy

SMART: Signal Management Review Technical