



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

28 January 2021  
EMA/PRAC/610324/2020  
Human Medicines Division

## Pharmacovigilance Risk Assessment Committee (PRAC): Work Plan 2021

Adopted by the Committee on 28 January 2021

### Table of Content

<b>1. Evaluation activities for human medicines .....</b>	<b>2</b>
1.1. Pre-authorisation activities .....	2
1.2. Initial-evaluation activities .....	3
1.3. Post-authorisation activities .....	4
1.4. Arbitrations and referrals .....	4
1.5. Pharmacovigilance activities .....	5
1.6. Other specialised areas and activities .....	6
<b>2. Horizontal activities and other areas .....</b>	<b>6</b>
2.1. Committees and working parties .....	6
2.2. Inspections and compliance .....	6
2.3. Partners and stakeholders .....	7
2.4. Data-management support .....	8
2.5. Process improvements .....	8
List of acronyms and abbreviations .....	9

***The activities outlined in the work plan for 2021 have been agreed taking into consideration the Agency's prioritisation set forth in the EMA multi-annual work programme 2021-2023.***

# 1. Evaluation activities for human medicines

## 1.1. Pre-authorisation activities

### 1.1.1. Special populations and product guidances

#### Activity area

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 2021

PRAC activities to achieve the objectives set for this area:

- Finalisation of GVP P. III on 'Product- or population-specific considerations: pregnancy and breastfeeding' post-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 Jirsová	CZ
Member	Adrien Inoubli	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 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 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 2021

PRAC activities to achieve the objectives set for this area:

- Initiate the public consultation of revision 3 of GVP module XVI on 'Risk minimisation measures: selection of tools and effectiveness indicators' with addendum II on 'Risk minimisation measures effectiveness evaluation'.
- Finalise revision 3 of GVP module XVI and addendum II post-public consultation, subject to COVID-related work as a priority.
- Finalise GVP module XVI addendum III on 'Pregnancy prevention programme' in view of initiating a public consultation.
- Contribute to further optimise close cooperation with CHMP and CAT as regards RMP assessments, including RMPs for generic medicinal products and RMP requirements for ATMPs.
- 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	-
Member	Eva Jirsová	CZ
Alternate	Jana Lukacisinova	CZ
Alternate	Brigitte Keller-Stanislawski	DE
Member	Maia Uusküla	EE
Member	Eva Segovia	ES
Member	Adrien Inoubli	FR
Alternate	Tiphaine Vaillant	FR
Alternate	Sofia Trantza	GR
Alternate	Željana Margan Koletić	HR
Member	Menno van der Elst	NL
Alternate	Liana Gross-Martirosyan	NL
Member	Ana Sofia Diniz Martins	PT
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**

##### **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 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 2021**

PRAC activities to achieve the objectives set for this area:

- Provide expert input in the implementation of the recommendations from the HMA/EMA Big Data Steering Group.
- Provide expert input to the EMA initiative on patient registries and the cross-Committee task force on registries on the development of guidance on methodological aspects and governance of patient registries: input in the review of the guideline on registry-based studies post public consultation.
- Review of experience gained within the pilot of rapid data analysis: build a checklist based on the experience from actual cases with possible and non-possible data analyses, summarising experience and feedback obtained (including feedback from questionnaire).

PRAC topic leader(s): Sabine Straus

Other Committee participants:

<b>Member / alternate / expert</b>	<b>Name</b>	<b>Member State or affiliation</b>
Alternate	Brigitte Keller-Stanislowski	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. 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. 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 2021

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. This includes methodologies for COVID-19 safety monitoring and input in methodologies to be used during the vaccination campaign.

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
Alternate	Ilaria Baldelli	IT
Member	Zane Neikena	LV
Alternate	Liana Gross-Martirosyan	NL
Member	Birgitta Grundmark	Independent scientific expert appointed by the EC
Expert	Dennis Lex	DE
Expert	Charlotte Backman	SE

### 1.5.2. 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 enables the focus of pharmacovigilance on those activities and regulatory tools that make a difference in daily healthcare.

#### Key objective(s)

- Improve pharmacovigilance through measuring impact of regulatory interventions.

## Activities in 2021

PRAC activities to achieve the objectives set for this area, supported by the PRAC IG 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, see under 1.1.2. ).
- Oversee and advise on the conduct of impact research of pharmacovigilance regulatory interventions, including prioritisation of research topics.
- Enhance engagement of patients and HCPs in measuring the impact of regulatory interventions (see also under 2.3.1. ).

PRAC topic leader(s): Sabine Straus

Other Committee participants:

Member/alternate/expert	Name	Member State or affiliation
Chair	Sabine Straus	-
Member	Martin Huber	DE
Member	Adrien Inoubli	FR
Member	Nikica Mirošević Skvrce	HR
Member	Amelia Cupelli	IT
Member	Zane Neikena	LV
Alternate	Liana Gross-Martirosyan	NL
Member	David Benée Olsen	NO
Member	Ana Sofia Diniz Martins	PT
Member	Cathalijne van Doorne	Representative of patients' organisations 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	Karl-Mikael Kälkner	SE

## 1.6. Other specialised areas and activities

No planned activities

## 2. Horizontal activities and other areas

### 2.1. Committees and working parties

No planned activities

### 2.2. Inspections and compliance

No planned activities

## 2.3. Partners and stakeholders

### 2.3.1. Engage patients and healthcare professionals, communication with stakeholders

#### Activity area

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)

- Strengthen communication tools and coordination of safety information.

#### Activities in 2021

PRAC activities to achieve the objectives set for this area:

- Further review and optimise the content and format of monthly communications of PRAC outcomes, with a specific focus on COVID-19 related activities.
- Enhance engagement of patients and HCPs in measuring the impact of regulatory interventions (see also under 1.5.2. ).
- Provide expert input in the development of risk-type-based points-to-consider for selecting PRAC engagement mechanism: input in a reflection paper (related to 1.5.2. ).

PRAC topic leader(s): Raymond Anderson

Other Committee participants:

Member/alternate/expert	Name	Member State or affiliation
Chair	Sabine Straus	-
Alternate	Laurence de Fays	BE
Member	Martin Huber	DE
Member	Adrien Inoubli	FR
Alternate	Sofia Trantza	GR
Member	Julia Pallos	HU
Member	Amelia Cupelli	IT
Alternate	Roberto Frontini	Representative of healthcare professionals appointed by the EC
Member	Cathelijne van Doorne	Representative of patients' organisations appointed by the EC
Alternate	Virginie Hivert	Representative of patients' organisations 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

## 2.4. Data-management support

No planned activities

## 2.5. Process improvements

### Activity area

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.
- Strengthen the quality and consistency of PRAC recommendations.

### Activities in 2021

PRAC activities to achieve the objectives set for this area:

- Continue to 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, with a specific focus on COVID-19 and other relevant areas.
- 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 by developing further modules.
- Review and support the implementation of improvements proposed by the GPAG, by supporting the development of a best practice guidance based on the experience acquired by GPAG.

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

Other Committee participants:

Member/alternate/expert	Name	Member State or affiliation
Member	Maia Uusküla	EE
Member	Eva Segovia	ES
Alternate	Maria del Pilar Rayon	ES
Member	Adrien Inoubli	FR
Alternate	Tiphaine Vaillant	FR
Member	Ana Sofia Diniz Martins	PT
Alternate	Márcia Sofia Sanches de Castro Lopes Silva	PT
Member	Ulla Wändel Liminga	SE



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

### ***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

COVID-19: Coronavirus disease

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 Interest Group

PRIME: Priority Medicines

PSUR: Periodic safety update report

PSUSA: PSUR single assessment

RMP: Risk management plan

RWD: Real world data

SMART: Signal Management Review Technical