EMA
EUROPEAN MEDICINES AGENCY

PRAC workplan 2026

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Human Medicines Division

Contents

Introduction by the PRAC Chair

Ulla Wändel Liminga

In 2026, the PRAC will focus on core business activities, including revision of Good Vigilance Practices (GVPs) and other guidance documents related to pharmacovigilance. The PRAC will continue its collaboration with other committees, namely CHMP, CAT and HMPC via specific deliverables. The Committee will also provide continued expert input to further develop the use of artificial intelligence and real-world evidence in regulatory pharmacovigilance activities, as well as strengthen the capacity of the network through training.

PRAC has several established groups to which it has delegated specific tasks (see: PRAC: Working parties and other groups of interest).
In addition, for specific activities, PRAC collaborates with several partners, such as the World Health Organisation and the Heads of Medicines Agencies (HMA)/EMA Joint Network Data Steering Group (NDSG).

The activities outlined in this workplan have been agreed taking into consideration the Agency's prioritisation set forth in the EMA multi-annual work programme.

Workplan structure

1

Evaluation activities for human medicines:

- Pre-authorisation activities
- Post-Authorisation activities
- Pharmacovigilance activities
- Other specialised areas and activities

2

Horizontal activities and other areas:

- Partners and stakeholders
- Process improvements

1

Evaluation activities for human medicines

Pre-authorisation activities

Special populations and product guidance

Certain populations or product groups benefit from specific considerations in the conduct of pharmacovigilance. These PRAC activities channel the Committee's expertise into the development of population or product specific guidance.

Key objective(s)

- Strengthen pharmacovigilance activities performed by industry and regulators concerning specific product groups through dedicated guidance.
- Strengthen systematic generation of information on the benefits and risks of medicines in pregnancy and breastfeeding.

Activities in 2026	
Strengthen cooperation with Committee for Medicinal Products for Human Use (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'.	CHMP
Revise the GVP P. I (rev.1) on 'Product- or population-specific considerations: Vaccines for prophylaxis against infectious diseases'.	

See Annex for details on the Lead(s)/Contributor(s) and key deliverables

Evaluation activities for human medicines

Pre-authorisation activities

Life-cycle approach to pharmacovigilance and risk assessment

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.

Key objective(s)

- Strengthen public health promotion and protection.
- Support innovation throughout the product lifecycle.

Activities in 2026	
Strengthen close cooperation with Committee for Advanced Therapies (CAT) by revising of GVP Module V on 'Risk management system' (revision 3).	CAT
Revise GVP Modules II on 'Pharmacovigilance system master file (rev 2)', IV on 'Pharmacovigilance audits (rev 1)', and VI on 'Collection, management and submission of reports of suspected adverse reactions to medicinal products (rev 2)', in line with the revised Implementing Regulation (EU) 520/2012.	
Provide expert input for developing a reflection paper on digital tools supporting risk minimisation measures (RMMs).	
Contribute to set-up of the specific adverse reaction follow-up questionnaires (Specific AR FUQ) repository as defined in the respective guideline.	
Finalise the revision 4 of GVP Module VIII on 'Post-authorisation safety studies' and update of the related documents.	

See Annex for details on the Lead(s)/Contributor(s) and key deliverables

Post-authorisation activities*

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 in routine clinical care, their effectiveness and safety in such setting. Use of epidemiological approaches is key, and enablers include access to high-quality data, clear governance, and collaboration across various stakeholders including academia. Data and generated evidence from the real-world use of medicines is important 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.
- Strengthen collaboration within the network to deliver robust assessments of evidence generated from clinical use.

Activities in 2026
Provide expert input on strengthening (real-world) data analysis via the different pathways available for evidence generation and routine use of real-world evidence (RWE) to support PRAC decision-making.
Provide expert input on supporting the development of guidance on use of RWE for regulatory purpose in collaboration with Methodology Working Party (MWP).

See Annex for details on the Lead(s)/Contributor(s) and key deliverables

**Please refer also to the 'Pre-authorisation activities' as some of them are also relevant to the post-authorisation setting.*

Evaluation activities for human medicines

Pharmacovigilance activities

Signal detection and management

Key PRAC tasks include prioritisation, assessment and recommendations on safety signals, based on signal detection undertaken by EMA and the national competent authorities. This has delivered important outputs during the past years. There is a continuous 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.

Activities in 2026	
Revise GVP Module IX (rev 2) on 'Signal management' in line with the revised Implementing Regulation (EU) 520/2012.	
Contribute to the finalisation of the Committee on Herbal Medicinal Products (HMPC) reflection paper on particulars for signal detection for (traditional) herbal medicinal products.	HMPC

See Annex for details on the Lead(s)/Contributor(s) and key deliverables

Other specialised areas and activities

Enabling the safe and responsible use of Artificial Intelligence (AI) in the medicine lifecycle

The EMRN, through the HMA/EMA Joint NDSG's oversight, aims to work towards activities to enable the safe and responsible use of AI in the medicine lifecycle and extract value for public and animal health. In addition, the Network strategy to 2028 reflects on the need to focus on improving decision-making, optimising processes and increasing efficiency through the use of data, digitalisation and AI. For PRAC, engagement and provision of pharmacovigilance expert input on the use of new technologies within the EMRN is considered crucial.

Key objective(s)

- Continued overview of the HMA/EMA workplan activities on AI, in particular on guidance, policy and product support, change management and experimentation and implementation of AI for pharmacovigilance related activities.

Activities in 2026

Provide expert input to the development of guidance on the use of AI in pharmacovigilance, in collaboration with the Methodology Working Party (MWP).

See Annex for details on the Lead(s)/Contributor(s) and key deliverables

2

Horizontal activities and other areas

Partners and stakeholders

Engagement with patients and healthcare professionals (HCPs) and communication with stakeholders

The engagement of patients and HCPs is important for effective pharmacovigilance, and they can be involved throughout different steps in the process. For PRAC, key engagement means membership in 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 work on Patient Experience Data (PED) is relevant for PRAC, as data reported directly by patients on their conditions and treatments are valuable in suspected adverse reaction reporting and for acceptance of RMMs.

Key objective(s)

- Strengthen communication tools and coordination of safety information.
- Contribute to the improvement of evidence generation with respect to PED.

Activities in 2026

Contribute to the implementation of the comments received from the public consultation of the EU reflection paper on PED.

See Annex for details on the Lead(s)/Contributor(s) and key deliverables

Process improvements

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.

Experience from running these processes together 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 2026
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.
Based on case studies, provide input in the development of procedural/assessment recommendations and supportive guidance material to better support Member States in preparing and conducting a safety referral, in the context of the referral roadmap initiative.

See Annex for details on the Lead(s)/Contributor(s) and key deliverables

Annex

Leads and contributors for the activities (1/2)

Activity	Lead(s)	Contributor(s)
Special populations and product guidance	**Ulla Wändel Liminga**	
GVP P. I (rev.1) on 'Product- or population-specific considerations: Vaccines for prophylaxis against infectious diseases': revision.		Jean-Michel Dogné, Marie Louise Schougaard Christiansen, Maria de Pilar Rayon, Amelia Cupelli, Maria Teresa Herdeiro, Milou-Daniel Drici, Anette Kirstine Stark
Strengthen cooperation with Committee for Medicinal Products for Human Use (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'.		Eva Jirsová, Rhea Fitzerald, Hedvig Marie Egeland Nordeng, Maria Teresa Herdeiro
Life-cycle approach to pharmacovigilance and risk assessment	**Liana Martirosyan**	
Strengthen close cooperation with Committee for Advanced Therapies (CAT) by revising of GVP Module V on 'Risk management system' (revision 3).		Ulla Wändel Liminga, Bianca Mulder, Roberto Frontini
Finalise the revision 4 of GVP Module VIII on 'Post-authorisation safety studies' and update of the related documents.		Maria del Pilar Rayon, Patricia McGettigan
GVP Modules II on 'Pharmacovigilance system master file (rev 2)', IV on 'Pharmacovigilance audits (rev 1)', and VI on 'Collection, management and submission of reports of suspected adverse reactions to medicinal products (rev 2)', in line with the revised Implementing Regulation (EU) 520/2012 revision.		Dennis Lex (expert) (GVP IV)
Provide expert input for developing a reflection paper on digital tools supporting risk minimisation measures (RMMs).		Maria del Pilar Rayon, Barbara Kovacic Bytyqi, Mari Thörn, Roberto Frontini
Contribute to set-up of the specific adverse reaction follow-up questionnaires (Specific AR FUQ) repository as defined in the respective guideline.		Eva Jirsová, Tiphaine Vaillant, Petar Mas, Amelia Cupelli, Ana Sofia Diniz Martins, Dennis Lex (expert)
Information from real-world clinical use of medicines	**Ulla Wändel Liminga**	
Provide expert input on strengthening (real-world) data analysis via the different pathways available for evidence generation and routine use of real-world evidence (RWE) to support PRAC decision-making.		Petar Mas, Rhea Fitzerald, Liana Martirosyan, Maria Teresa Herdeiro, Patricia McGettigan
Provide expert input on supporting the development of guidance on use of RWE for regulatory purpose in collaboration with Methodology Working Party (MWP).		Carla Torre, Anette Kirstine Stark, Patricia McGettigan

Leads and contributors for the activities (2/2)

Activity	Lead(s)	Contributor(s)
Signal detection and management	**Liana Martirosyan**	
Revise GVP Module IX (rev 2) on 'Signal management' in line with the revised Implementing Regulation (EU) 520/2012. Contribute to the finalisation of the Committee on Herbal Medicinal Products (HMPC) reflection paper on particulars for signal detection for (traditional) herbal medicinal products.		Karin Erneholm, Maria del Pilar Rayon, Dennis Lex (expert), Charlotte Backman (expert) Maria del Pilar Rayon, Julia Pallos, Zane Neikena, Dennis Lex (expert)
Enabling the safe and responsible use of Artificial Intelligence (AI) in the medicine lifecycle	**Ulla Wändel Liminga**	
Provide expert input to the development of guidance on the use of AI in pharmacovigilance, in collaboration with the Methodology Working Party (MWP).		Jean-Michel Dogné, Milou Daniel Drici
Engagement with patients and healthcare professionals (HCPs), and communication with stakeholders	**Ulla Wändel Liminga**	
Contribute to the implementation of the comments received from the public consultation of the EU reflection paper on PED.		Ana Sofia Diniz Martins, Anette Kirstine Stark, Hedvig Marie Egeland Nordeng
Process improvements	**Liana Martirosyan**	
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. Provide input in the development of points to consider to better support Member States in preparing and conducting a safety referral.		Ana Sofia Diniz Martins Maria del Pilar Rayon, Tiphaine Vaillant, Barbara Kovacic Bytyqi, Charlotte Backman (expert)

Main deliverables and achievements of 2025 (1/2)

Activity	Deliverables
Special populations and product guidance	• ADEPT project: protocols agreed (objective 1, objective 2) • DARWIN EU® – Utilisation of commonly used benzodiazepines during pregnancy and the incidence of pregnancy losses – protocol approved • Concept paper on revision of the Guideline on Risk 6 Assessment of Medicinal Products on Human 7 Reproduction and Lactation: from Data to Label: address of comments received and work on the draft of the guideline started • GVP Module XVI Addendum I – Risk minimisation measures for medicinal products with embryo-fetal risks • GVP P. III on 'Product- or population-specific considerations: pregnancy and breastfeeding' (adopted, pending publication) • GVP P.I on 'Product- or population-specific considerations: Vaccines for prophylaxis against infectious diseases': revision 1 started
Life-cycle approach to pharmacovigilance and risk assessment	• GVPs updates related to the implementing regulation (M I, II, III, IV, VI, VIII): ongoing • GVP V: revision 3 ready for Committees consultation, along with an updated RMP template, before the public consultation • GVP VIII: finalisation of revision following publication of ICH M14 • GVP Module VI Addendum II - Masking of personal data in individual case safety reports submitted to EudraVigilance • Guideline on specific adverse reaction follow-up questionnaires (Specific AR FUQ) • PRISMA: Risk Minimisation Measures (RMMs) webpage created; work continues to describe the EU Landscape of RMMs integration in dispensing and prescribing software, and related topics as background to the development of a concept paper on digital tools supporting RMMs.
Information from real-world clinical use of medicines	• Collaboration with the Heads of Medicines Agencies (HMA)/EMA Joint Network Data Steering Group (NDSG) continues, as well as through the established PRAC RWE Liaison group. • 18 DARWIN EU PRAC-related studies started in 2025. 13 DARWIN EU PRAC-related studies finalised in 2025, some of which have started in 2024. • ICH M14 guideline on general principles on planning, designing, analysing and reporting of non-interventional studies that utilize real-world data for safety assessment of medicines • DARWIN EU® - Association between genetic polymorphisms of interest and risk of myopathy among statin users – along with the published study report • Pilot aiming to explore possibilities for early identification of RWE needs and acceleration of RWE generation in anticipation of the next/upcoming PSUR Single Assessments (PSUSAs), is now completed.
Optimising management and utility of reported adverse reactions	• ICH E2D post-approval safety data management - scientific guideline
Signal detection and management	• SMART Processes and Methods: ongoing activity with meetings discussing improvements related to signal management (e.g. enhancement of the signal management process for class signals, AI models in predictive safety monitoring, integration of pharmacogenomic data in ICSRs and results from DARWIN studying adverse events of special interest, progress and implementation of tools developed to support signal detection under the framework of the Health Data Lab). • GVP Module IX Signal management: Questions and Answers on Implementing Regulation (EU) 2025/1466: Amendment of Regulation (EU) No 520/2012 and Conclusion of the Signal Detection in EudraVigilance Pilot by MAHs; GVP revision is ongoing. • Guidance document is under development on the specific aspects that should be taken into account when detecting safety signals for (T)HMPs.

Main deliverables and achievements of 2025 (2/2)

Activity	Deliverables
Measuring the impact of pharmacovigilance activities	• Commissioned impact study (SC01/EMA/2020/46/TDA/L4.01) on dissemination of additional RMMs for patients and healthcare professionals in EU/EEA countries (ongoing). • Two collaborating expert projects launched, one on discontinuation of additional RMM tools for CAPs (protocol endorsed, data extraction ongoing) and one on mapping clinical practice guideline issuing organisations in EU (outline endorsed); Review of feasibility assessments conducted in DARWIN EU (protocol endorsed, data extraction ongoing). • DARWIN EU pilot impact study on NOMAC/CMA use following RMM for meningioma completed with regulatory follow-up on results in October 2025. • Literature review on use of digital tools and AI for RMM effectiveness evaluation completed, informing the ongoing development of a reflection paper on digital support tools.
Enabling the safe and responsible use of Artificial Intelligence (AI) in the medicine lifecycle	• Updates on AI literacy, including available resources in the EU-NTC learning management system (LMS), EMA strategy and future plans to address AI literacy needs. An AI literacy campaign has been agreed and is being prepared to roll-out across the network considering specific personas (different roles in the agencies and network). • Preparatory discussions on the development of guidance on AI in pharmacovigilance in collaboration with MWP. • Update on knowledge mining initiative and regulatory AI use cases. Two Knowledge Mining workshops were conducted in late 2025 which included representation from multiple agencies and committee members. A high-level roadmap has been endorsed at the NDSG under the Data and AI workplan, and will initiate with a pilot phase focusing on a Knowledge Mining stream and another stream of work to define different prompts to enable different use cases. • EMA and FDA set common principles for AI in medicine development.
Engagement with partners, patients and healthcare professionals and communication with stakeholders	• Patient experience data (PED) reflection paper: released for public consultation • Presentation of WHO in the PRAC Strategic Review and Learning meeting of November in Copenhagen organised under the Danish presidency, about the maternal safety in the use of medicines. • Ongoing activities of M4All - Art 58 with the active involvement of PRAC and concerned WHO member states in the assessment of pre-authorisation RMPs. Feedback on the process was requested to the Rapporteurs.
Process improvements	• Two assessors' trainings on PSUR/PSUSA and on the effectiveness of RMMs including examples of impact research conducted under the remit of the PRAC Impact Strategy. • Pharmacoepidemiology Curriculum: last two modules are finished. The full curriculum is now available to the European medicines regulatory network. • Internal EMA review of stakeholders' engagement in the context of referral procedures with a view to making recommendations, to be continued in 2026. • GPAG: work continues in bimonthly meeting basis followed by the adoption of the outcomes at PRAC plenaries.

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