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Human Medicines

EudraVigilance Expert Working Group (EV-EWG) Work Programme 2025- 2026

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1. Background

1.1. EudraVigilance Expert Working Group Mandate

The EudraVigilance Expert Working Group (EV-EWG) is an advisory group within the pharmacovigilance governance structure in the EU Regulatory Network. The mandate is aligned with deliverables for the pharmacovigilance governance.

The mandate of the EudraVigilance Expert Working Group (EV-EWG) is as follows:

- Elaborate policies and business requirements, draft guidance and co-ordinate aspects related to the practical implementation, operation of and access to EudraVigilance in line with the requirements of the pharmacovigilance and clinical trials legislation in support of the EMA/Member States Pharmacovigilance Business Team and Clinical Trials Coordination Group.
- Provide input on personal data protection activities in relation to pharmacovigilance in accordance with EU data protection legislation.
- Provide input into the international standardisation work in pharmacovigilance and to facilitate a coordinated and harmonised implementation approach in the EU and at international level.
- Elaborate guidelines and good practices related to EudraVigilance including all aspects related to data collection, quality management and data access for the purpose of pharmacovigilance and signal detection.
- Provide input to the development, testing, implementation and validation of analytical and statistical methods and standard reports for data analysis and evaluation.
- Support the on-going maintenance activities of the EudraVigilance system as well as major evolutions as part of the new projects according to the EMA Agile transformation strategy and governance model.
- Facilitate the practical application of the EudraVigilance Access Policy as a consequence of the implementation of ICH the E2B (R3)/ISO IDMP standards and the pharmacovigilance and clinical trials legislation.

1.2. EudraVigilance Expert Working Group Membership

The EV-EWG membership is summarised as follows:

- Eleven members from National Competent Authorities (NCAs) with pharmacovigilance and clinical trial expertise including one member of the Pharmacovigilance Risk Assessment Committee (PRAC) and one member of the Clinical Trials Coordination Group (CTCG).
- Five pharmaceutical industry and commercial sponsor experts (AESGP, EFPIA (2), Medicines for Europe, EuropaBio).
- One non-commercial sponsor organisation member (EORTC).
- The ICH E2B Topic Leaders (EFPIA/EU).
- One observer from Health Canada.
- One observer from Swissmedic.

The co-chairs of the EudraVigilance Expert Working group are Anja van Haren (Medicines Evaluation Board, NL) and Rodrigo Postigo (European Medicines Agency, EU).

Additional experts may be invited at the request of the EV-EWG depending on the specific topic to be addressed.

The names of the members and additional experts of the EV-EWG are listed in Annex A.

1.3. Rules of Participation

Membership of the EV-EWG implies a commitment to participate actively in its work and to attend its meetings regularly. A member may nominate a replacement to participate in those cases where he or she is unable to attend a meeting.

Meeting documentation will be distributed to the EV-EWG members and experts as applicable.

1.4. Organisation of EV-EWG Meetings

- The EV-EWG meetings take place at the premises of the European Medicines Agency (EMA) or remotely. The Secretariat of the EV-EWG is provided by the EMA.
- The meetings will be held and documented in English, without interpretation.
- The draft agenda for each meeting is circulated, together with the relevant documents, by the European Medicines Agency's Secretariat, in consultation with the co-chairs.
- The EV-EWG prepares a work programme for adoption through the pharmacovigilance governance. The work programme could be updated more frequently if required by the topics or the composition of the team.
- Attendance of EV-EWG members and experts via teleconference is facilitated by the EMA.
- Liaison with the Clinical Trials Coordination Group, PRAC, Pharmacovigilance Business Team and other relevant subgroups is also coordinated by the EMA.

2. EudraVigilance Expert Working Group (EV-EWG) meetings schedule 2023 and 2024

2 meetings per year [1]:

- April 2025
- October 2025
- March/April 2026
- October 2026

Additional experts may be invited at the request of the EV-EWG (experts from Member States to be reimbursed by the Agency).

Additional teleconferences/virtual meetings may be organised as necessary.

[1] Number of Experts reimbursed for the face to face meetings if applicable is depending on the available budget of the European Medicines Agency

3. EudraVigilance Expert Working Group Work Programme 2025 – 2026

The activities and deliverables are aligned with the work of the EMA/Member States Pharmacovigilance governance structure for the implementation of the pharmacovigilance legislation and clinical trials legislation.

3.1. Activities associated with Clinical Trials

Provide advice on clinical trial related aspects in liaison with the Clinical Trials Coordination Group, relevant subgroups relating to clinical trials or relevant initiatives such as the Accelerating Clinical Trials in the EU (ACT EU).

Specifically, advice might be provided as relevant for the following two topics:

- Submission of Annual Safety Reports (ASRs) directly to the European Clinical Trials Information System (CTIS) or to a new safety module.
- Submission and analysis of SUSARs submitted to the EV Clinical Trial Module (EVCTM).

3.2. EudraVigilance Data Quality Management

Provide expert advice on best practices related to EudraVigilance data quality management activities described in the Detailed guide regarding the EudraVigilance data management activities by the European Medicines Agency.

- Specifically, advice will be provided as relevant for the implementation of compliance monitoring reports based on reporting timelines.

3.3. Data protection activities

Provide expert advice on best practices related to personal data protection in relation to pharmacovigilance.

3.4. Change management for the project delivered via the EMA Agile transformation strategy and its governance structure.

Provide subject matter expertise as part of the Change Management processes for the projects delivered under the EMA Agile transformation strategy in relation to EudraVigilance in support of major evolution and on-going maintenance activities of the system.

3.5. Signal Management

Contribute to the development of guidelines and good practices in relation to signal management led by the EMA/Member States, SMART groups.

- Specific advice may need to be provided following the update of the Implementing Regulation 520/2012, the monitoring of EudraVigilance by MAHs and the database access provided.

3.6. Medical Literature Monitoring (MLM) service

Provide advice as relevant for the MLM service led by the EMA designed to monitor a number of substances and selected medical literature, in order to identify suspected adverse reactions to medicines authorised in the European Union (EU).

3.7. Support the International Standardisation Activities in Pharmacovigilance

ICH[2]-E2B: Clinical Safety Data Management – Data Elements for Transmission of Individual Case Safety Reports (ICSR) and ISO[3] ICSR

Contribute to the raising implementation issues or questions in relation to the implementation of the ICH E2B(R3) guideline following the mandatory use since 30 June 2022.

Contribute to the raising implementation issues or questions of the ISO terminology on pharmaceutical dose forms and routes of administration following the mandatory use in relation to reporting obligations to EudraVigilance since 30 June 2022.

Provide input for the future review the EU ICSR Implementation Guide for identification of any areas which need updating in line with other activities.

ICH-M1: Medical Dictionary for Drug Regulatory Activities (MedDRA)

The EV-EWG reviews the proposals from MedDRA MSSO for the update of the IME list and then decides and endorses the new versions of the IME list.

Provide input to requests from the MedDRA Management Committee.

Provide input to the work of the ICH M1 Points to Consider Working Group and the Standardised MedDRA Queries (SMQ) development with the aim to maximise data quality in EudraVigilance.

Contribute to the deliverables of the EMA/Member States Pharmacovigilance Business Team in relation to MedDRA.

Other areas of interest aiming to define good practices in light of new methods, research or emerging technologies to better approach future challenges in the area of pharmacovigilance.

ICH-E2D: post-approval safety data management: definitions and standards for expedited reporting.

Contribute and provide input to the Revision 1 of the ICH-E2D guideline including clarification and anticipation of potential implementation issues.

3.8. Artificial Intelligence in pharmacovigilance

Contribute when relevant to the to the integration of AI in pharmacovigilance by providing guidance on regulatory policies, technology frameworks, and change management strategies.

[2] International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
[3] International Organization for Standardization

3.9. Good Vigilance Practice (GVP)

Address practical implementation questions raised by stakeholders with main focus on adverse reaction reporting.

Contribute to the deliverables of the EMA/Member States Pharmacovigilance Business Team in relation to development and updates of GVP modules, particularly in relation to Module VI Management and reporting of ADRs and Module IX Signal Management.

3.10. Communications

The members of the EV-EWG should serve as a vehicle to convey the relevant messages and communications to and within the organisations they belong to and they represent.

The EV-EWG should provide input when relevant to the EudraVigilance information days and other training related activities.

Annex A

EudraVigilance Expert Working Group Members (listed in alphabetical order by family name)

Co-chairs

- Anja van Haren, Medicines Evaluation Board (CBG-MEB), NL
- Rodrigo Postigo (European Medicines Agency)

EMA secretariat

- Victoria Newbould (European Medicines Agency)

Eleven members from National Competent Authorities (NCAs) with pharmacovigilance and clinical trial expertise including one member of the Pharmacovigilance Risk Assessment Committee (PRAC) and one member of the Clinical Trial Facilitation Group (CTFG).

- Member of the L'Agence nationale de sécurité du médicament et des produits de santé (ANSM), FR
- Dieter Cenens - Agence Fédérale des Médicaments et des Produits De Santé (AFMPS), BE
- Maria Luisa Casini - Agenzia Italiana del Farmaco (AIFA), IT
- João Paulo Fernandes - Autoridade Nacional do Medicamento e Produtos de Saúde (INFARMED), PT
- Martin Huber - Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), DE - (PRAC representative)
- Maria Larsson – Läkemedelsverket (MPA), SE
- Lara Quiroga González - Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), ES
- Larissa Kopp Paul Ehrlich Institut (PEI), DE
    - Alternate: Christopher Schulze
- Elke Stahl - Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), DE – (CTCG liaison)
- Stephany Suoth – College Ter Beoordeling van Geneesmiddelen/Medicines Evaluation Board (CBG-MEB), NL
- Kristina Vavrušková - Státní ústavu pro kontrolu léčiv, (SUKL), CZ

Five pharmaceutical industry and commercial sponsor experts (AESGP, EFPIA (2), Medicines for Europe, EuropaBio).

- Aleksandra Bojarczuk - Association of the European Self-Care Industry, (AESGP)
    - Alternate: Jens Illigens
- Thomas Kuckuk, European Federation of Pharmaceutical Industries and Associations (EFPIA)
- Raphael Van Eemeren, European Federation of Pharmaceutical Industries and Associations (EFPIA)

- Attila Oláh, Medicines for Europe
    - Alternate: Augusto Eugénio Pardal Felipe
- Joanne Webbe, EuropaBio
    - Alternate: Michelle Grimes

One non-commercial sponsor organisation member.

- Tuula Ikonen, European Organisation for Research and Treatment of Cancer (EORTC)

The ICH E2B Topic Leaders (EU).

- Tom Paternoster (EMA)

One observer from Health Canada.

- Craig Simon - Health Canada

One observer from Swissmedic

- Thomas Stammschulte - Swissmedic

Additional domain experts

- Alison Durand (Sanofi, FR)
- Martin Henzl (Baxter, AT)
- Andrew Hudson (Roche, UK)
- Andreas Iwanowitsch, (Stada, DE) (Medicines for Europe) - data management
- Claudia Lehmann (Boehringer Ingleheim, DE) EFPIA MedDRA Management Committee representative
- Subhash Mistry (GSK, UK)
- Katharina Weber (Inspectors Working Party, Austrian Medicines and Medical Devices Agency, AT)

Additional experts may be invited at the request of the EV-EWG depending on the specific topic to be addressed).