



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Inspections & Human Medicines Pharmacovigilance

EudraVigilance Expert Working Group (EV-EWG) Work Programme 2018

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1. Background

1.1. EudraVigilance Expert Working Group Mandate

The EudraVigilance Expert Working Group (EV-EWG) will work in an advisory capacity within the streamlined pharmacovigilance governance structure. 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- Elaborate policies and business requirements, draft guidance and co-ordinate aspects related to the practical implementation, operation of and access to EudraVigilance in line with the requirements of the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 relevant subgroups relating to Clinical Trials.
- Co-ordinate 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 implementation of the new EudraVigilance system as well as major evolutions and on-going maintenance activities of the system as part of the change management governance for EU Telematics systems.
- 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:

- Nine 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).
- 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 Sabine Brosch (European Medicines Agency, EU) and Anja van Haren (Medicines Evaluation Board, NL).

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). The Secretariat of the EV-EWG is provided by the EMA.
- The meetings will normally be of a two day duration.
- 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 an annual work programme for adoption through the pharmacovigilance governance
- Attendance of EV-EWG members and experts via teleconference is facilitated by the EMA.
- Liaison with the Clinical Trial Facilitation Group and relevant subgroups concerning specific clinical trial related aspects.

2. EudraVigilance Expert Working Group (EV-EWG) meetings schedule 2018

3 meetings each with 12 reimbursed experts¹:

- 22-23 Feb
- 13-14 June
- 27-28 Sep

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 Depending on the available budget of the European Medicines Agency

3. EudraVigilance Expert Working Group Work Programme 2018

The specific timetable for the activities and deliverables outlined is aligned with the work of the EMA/Member States Pharmacovigilance governance structure for the implementation of the pharmacovigilance legislation.

3.1. Activities associated with Clinical Trials

Action:

- Provide advice on clinical trial related aspects in liaison with the Clinical Trial Facilitation Group and relevant subgroups relating to clinical trials.

3.2. EudraVigilance Data Quality Management

Action:

- Provide expert advice on best practices related to EudraVigilance data quality management activities.

3.3. Data protection activities

Action:

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

3.4. Change management for EU Telematics systems

Actions:

- Provide input to the Pharmacovigilance programme, impact evaluation, training plan, communication plan and business change plan for projects as applicable.
- Provide subject matter expertise as part of the Change Management governance for EU Telematics systems in relation to EudraVigilance in support of major evolution and on-going maintenance activities of the system.

3.5. Signal Detection and Analysis

Action:

- Contribute to the development of guidelines and good practices in relation to signal detection lead by the EMA/Member States SMART Methods group.

3.6. Support the International Standardisation Activities in Pharmacovigilance

ICH²-E2B: Clinical Safety Data Management – Data Elements for Transmission of Individual Case Safety Reports (ICSR) and ISO³ ICSR

Actions:

- Contribute to the development of implementation questions in relation to the implementation of the new ICH E2B(R3) guideline.
- Review the EU Implementation Guide for identification of any areas which need updating in line with other activities.

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

Actions:

- Provide input to requests from the MedDRA Management Committee.
- Support the maintenance of the of Important Medical Events (IME) List.
- 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.

3.7. Good Vigilance Practice (GVP)

Actions:

- Address practical implementation questions raised by stakeholders with main focus on adverse reaction reporting and prepare Questions and Answers (Q&As) as necessary.
- 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.

3.8. EudraVigilance Information Days

Action:

- Communicate the activities of the EV-EWG to stakeholders and provide input on the development of the programmes.

² International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

³ International Organization for Standardization

Annex A

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

- Pascal Auriche (L'Agence nationale de sécurité du médicament et des produits de santé (ANSM), FR)
- Sabine Brosch (European Medicines Agency (EMA), EU)*
- Maria Luisa Casini (Agenzia Italiana del Farmaco (AIFA), IT)
- Augusto Eugénio Pardal Felipe (Medicines for Europe (MFE), PT)
- Nick Halsey (European Medicines Agency (EMA), EU)
- Anja van Haren (Medicines Evaluation Board (CBG-MEB), NL)*
- Fatima Herji (Autoridade Nacional do Medicamento e Produtos de Saúde (INFARMED), PT)
- Tuula Ikonen (European Organisation for Research and Treatment of Cancer (EORTC), BE)
- Christoph Kueng (Swissmedic, CH) Observer
- Maria Larsson (Läkemedelsverket, SE)
- Edurne Lazaro (Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), ES)
- David Lewis (European Federation of Pharmaceutical Industries and Associations (EFPIA))
- Hervé le-Louet (Hôpital Henri Mondor, FR)
- Dierk Mentzer (Paul Ehrlich Institut (PEI), DE)
- Victoria Newbould (European Medicines Agency (EMA), EU)
- Mary Raphael (Health Canada)
- Martina Schaeublin (Swissmedic, CH) Alternate observer
- Elke Stahl (Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), CTFG liaison, DE)
- Phil Tregunno (Medicines and Healthcare Products Regulatory Agency (MHRA), UK)
- Kristina Vavrušková (Státní ústavu pro kontrolu léčiv (SUKL), CZ)
- Margaret Walters (EuropaBio, UK)
- Leonie Zimmerman (European Self-Medication Industry, (AESGP), DE)

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

- Veronique Demontrond (Sanofi-aventis, FR) alternate
- Diane Farkas (Sanofi-aventis, FR), EFPIA ICH E2B representative

- Martin Henzl (Baxter, AT)
- Andrew Hudson (Roche, UK)
- Claudia Lehmann (Boehringer Ingelheim, DE) EFPIA MedDRA Management Committee representative
- Denny Lorenz (Bayer, DE), EFPIA ICH E2B representative
- Subhash Mistry (GSK, UK)
- Paolo Porcelli (Inspectors Working Party, AIFA, IT)