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EudraVigilance Expert Working Group (EV-EWG) Work Programme 2016

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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 agreement and endorsement procedure depends upon the category of document as listed in Annex B.

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- Elaborate policies and business requirements, draft guidance and co-ordinate aspects related to the practical implementation, operation of and access to EudraVigilance in line with the requirements of the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 project and Maintenance Group 1 structure for the implementation of the pharmacovigilance legislation and the Suspected Unexpected Serious Adverse Reaction (SUSAR) and Annual Safety Reporting project of the Clinical Trial System Expert Group.
- 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 development of business requirements, test and facilitate the implementation of new EudraVigilance system components in line with the auditable requirements of the ADR project.
- Provide input into the update of the EudraVigilance Access Policy as a consequence of the implementation of ICH E2B (R3) and the pharmacovigilance legislation.

1.2 EudraVigilance Expert Working Group Membership

The EV-EWG membership is summarised as follows:

a. 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).

b. Five pharmaceutical industry and commercial sponsor experts (AESGP, EFPIA (2), EGA, EuropaBio).

c. One non-commercial sponsor organisation member (EORTC).

d. The ICH E2B Topic Leaders (EFPIA/EU).

e. One representative from Health Canada.

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

a. The EV-EWG meetings are taking place at the premises of the European Medicines Agency (EMA). The Secretariat of the EV-EWG is provided by the EMA.

b. The meetings will normally be of a two day duration.

c. The meetings will be held and documented in English, without interpretation.

d. 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.

e. The EV-EWG prepares an annual work programme for adoption through the pharmacovigilance governance

f. Attendance of EV-EWG members and experts via teleconference is facilitated by the EMA.

g. Liaison with the SUSAR and Annual Safety Reporting project of the Clinical Trial System Expert Group when necessary concerning specific clinical trial related aspects.

2. EudraVigilance Expert Working Group (EV-EWG) Meetings Schedule 2016

3 meetings each with 12 reimbursed experts[1]:

- 18-19 January
- 19-20 May
- 29-30 September

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.

3. EudraVigilance Expert Working Group Work Programme 2016

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 liasion with the safety subgroup of the Clinical Trial Facilitation Group.

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 and in the context of the IMI WEB-RADR project.

[1] Depending on the available budget of the European Medicines Agency

3.4 Implementation of Pharmacovigilance Legislation

Actions:

- Provide input to the drafting and finalisation of the Pharmacovigilance programme, impact evaluation, training plan, communication plan and business change plan for the projects:
  - ADR project
  - Medical Literature Monitoring (MLM)
  - Article 57 database
- Provide support to the EMA/Member States Pharmacovigilance governance structure in the development of guidance in relation to all EudraVigilance related aspects including the development of user training programmes where applicable.

3.6 Signal Detection and Analysis

Actions:

- Contribute to the drafting of guidelines and good practices in relation to signal detection lead by the EMA/Member States PRAC SMART 2/3 Working Group.

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

Action:

- 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
- Participate in testing backwards forwards conversion between ICH E2B (R2) and (R3)

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

Actions:

- Provide input to requests from the MedDRA Management Board.
- 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 Project and Maintenance group 1 in relation to MedDRA with main focus on medication errors.

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

3.8 Good Vigilance Practice (GVP)

Action:

- 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 Project and Maintenance group 1 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 EudraVigilance Information Days

Action:

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

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 (European Generic Medicines Association (EGA), 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)
- Wendy Huisman (European Generic Medicines Association (EGA), NL)
- Mara Ernst (European Self-Medication Industry, (AESGP), DE)
- 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)
- Victoria Newbould (European Medicines Agency, EU)
- Dierk Petzold (Paul Ehrlich Institut (PEI), DE)
- Elke Stahl (Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), CTFG liaison, DE)
- Phil Tregunno (Medicines and Healthcare Products Regulatory Agency (MHRA), UK)
- Thomas Valkaert (European Organisation for Research and Treatment of Cancer (EORTC), BE)
- Kristina Vavrušková (Státní ústavu pro kontrolu léčiv (SUKL), CZ)
- Margaret Walters (EuropaBio)

Additional domain experts:

- Delphine Bertram (Hospices Civils de Lyon, FR)
- Veronique Demontrond (Sanofi-aventis, FR)
- Diane Farkas (Sanofi-aventis, FR), EFPIA ICH E2B representative
- Alastair Fowkes (AstraZeneca, UK), EFPIA ICH E2B representative
- Andrew Hudson (Roche, UK)
- Denny Lorenz (Bayer, DE), EFPIA ICH E2B representative

- Subhash Mistry (GSK, UK)
- Mary Raphael (Health Canada)

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ANNEX B

3 November 2014
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Pharmacovigilance: coordination of deliverables for operational improvement, system development and system change

Coordination and monitoring of outputs according to this table is conducted by Implementation Group

Category	Type of deliverable from EMA/Member States Project and Maintenance Group	Consultation	EU TMB/IT Directors Executive Committee	Agreement	Endorsement	Adoption
1	Good Vigilance Practice Modules (GVP) • New module or major revision[4]	• Relevant Project and Maintenance Group (PMG) • Formal consultation process with stakeholders	• N/A	• PRAC (CHMP, CMD-h where relevant)	• ERMS-FG on draft documents prior to launch of formal consultation and	• EMA – Executive Director

[4] Reflection paper on maintenance, revision and further development of GVP https://docs.eudra.org/webtop/drl/objectId/090142b282124d2d

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Category	Type of deliverable from EMA/Member States Project and Maintenance Group	Consultation	EU TMB/IT Directors Executive Committee	Agreement	Endorsement	Adoption
					on the revised documents following such formal consultation	
2	Scientific/Technical Guideline (non GVP)	• Relevant Project and Maintenance Group (PMG) • Other relevant technical fora • If appropriate formal consultation process with stakeholders	• N/A	• N/A	• ERMS-FG	• PRAC (CHMP, CMD-h where relevant)
3	Reflection Paper/ Concept paper for new guidance	• Relevant Project and Maintenance Group (PMG) • PRAC (CHMP, CMD-h where relevant) • If appropriate formal consultation with public or selective stakeholders	• N/A	• Relevant Project and Maintenance Group (PMG)	• ERMS-FG	• N/A
4	• New or major revision of business process • Key template change	• Relevant Project and Maintenance Group (PMG) • PRAC (CHMP, CMD-h where relevant)	• N/A	• N/A	• ERMS-FG (if impact on MSs resources)	• EMA – process lead
5	PSUR Repository	• PMG2, PRAG	• Inform	• N/A	• PRAC	• EMA MB

Category	Type of deliverable from EMA/Member States Project and Maintenance Group	Consultation	EU TMB/IT Directors Executive Committee	Agreement	Endorsement	Adoption
	functionalities agreed at Dec 2013 EMA MB • Opinion on functionalities delivered	• ERMS-FG • CMDh				decision
6	EudraVigilance functionalities agreed at Dec 2013 EMA MB • Opinion on functionalities delivered	• PMG1, EV-EWG • EMRS-FG	• Inform	• N/A	• PRAC	• EMA MB decision
7	Non audit IT related documents • Business requirements • Training Plans • Business Change plans • Communication Plans	• Relevant Project and Maintenance Group (PMG) – Eudravigilance, Literature monitoring, Art57, (PMG1) – PSUR Repository (PMG2) – Future Web Portal (PMG3) • Relevant stakeholder Groups (Art57 IWG, EV-EWG, PRAG) • PRAC (CHMP, CMD-h where relevant)	• Inform	• N/A	• N/A	• ERMS-FG (if impact on MSs resources) Or • EMA Programme Management
8	Change requests to existing IT systems in Pharmacovigilance	• Relevant Project and Maintenance Group (PMG) – Eudravigilance, Literature Monitoring, Art57, (PMG1)	• Inform Human CMB only	• N/A	• N/A	• EMA – Executive Director

Category	Type of deliverable from EMA/Member States Project and Maintenance Group	Consultation	EU TMB/IT Directors Executive Committee	Agreement	Endorsement	Adoption
		– PSUR Repository (PMG2) – Future Web Portal (PMG3)				

Abbreviations:

Art57 IWG	Art57 Implementation Working Group
CHMP	Committee on Human Medicinal Products
CMDh	Coordination Group for Mutual Recognition and Decentralised Procedures - Human
EMA	European Medicines Agency
EMA MB	European Medicines Agency Management Board
ERMS-FG	European Risk Management Strategy Facilitation Group
EU TMB	EU Telematics Management Board
EV-EWG	EudraVigilance Expert Working Group
GVP	Good pharmacovigilance practices
Human CMB	Human Change Management Board
PMG	Project and Maintenance Group
PRAC	The Pharmacovigilance Risk Assessment Committee
PRAG	PSUR Repository Advisory Group
PSUR	Periodic Safety Update Report