Multi– stakeholder workshop on data quality framework for Adverse Drug Reaction reporting

1 March 2024

Virtual meeting / EMA, Amsterdam

Following the recent publication of the Data quality framework for EU medicine regulation, the European Medicines Regulatory Network (EMRN) is consulting with stakeholders to create chapters for specific domains of medicines regulation. The next chapter will concern human and veterinary Adverse Drug Reactions (ADRs) arising from all sources (e.g. spontaneous reports, medical literature, non– interventional studies and interventional clinical trials).

EMRN is organising a workshop to obtain input from all stakeholders involved in ADR reporting. The aim of this workshop is to bring together experts in the field to build on their extensive experience and knowledge relating to ADR data quality, in order to:

- Familiarise key stakeholders with the published EU Data Quality Framework (DQF):
  - share initial reflections on how to apply the EU DQF metrics/specialisation/maturity levels model to ADR reports;
  - provide an overview of the uses of EudraVigilance data and the current data quality activities performed by EMA on ADR data received in EudraVigilance.
- Collect input from experts in the field and learn from existing experiences:
  - characterise the different ADR reporting routes and use– cases for different stakeholders & the challenges associated regarding the data quality of each route;
  - identify the main actors regarding ADR data quality processes for different stakeholder groups;
  - characterise current practices for improving ADR data quality within different stakeholder groups (e.g. MAHs, regulators, CROs, reporters (patients/HCPs)).
- Discuss important challenges related to measuring, characterising and improving data quality in the context of Adverse Drug Reaction (ADR) data.
- Identify the key topics which should be covered in the Data Quality Framework ADR chapter.

Multi–stakeholder workshop on data quality framework for Adverse Drug Reaction reporting

09:00 Joining and technical checks

09:30 Welcome and opening speeches

Welcome **5'**
Georgy Genov (EMA, Head of PhV Office)

Opening remarks **5'**
Anja van Haren (MEB, co– chair EV EWG and PhV BT)

Opening remarks **5'**
James Mount (SEMPA, Vet PhV WP)

Opening remarks **5'**
Elke Stahl (BfArM, CTCG)

09:50 Session 1: Overview of EU Data Quality Framework

Chair: Paolo Alcini (EMA)

Presentation – Data Quality Framework overview **20'**
Ana Cochino (EMA)

10:10 Session 2: Regulatory ADR Data Quality activities in Europe

Chair: Anja van Haren (MEB)

Presentation – Guidance, standards, EMA Data Quality activities and uses of ADR data (human & veterinary) **20'**
Tom Paternoster– Howe (EMA), Laura Descalzo (EMA)

Presentation – Human NCA Data Quality activities and uses of ADR data **20'**
Elena Rodionova (AGES)

Presentation – Veterinary NCA Data Quality activities and uses of ADR data **20'**
Kathrin Schirmann (BVL)

Questions & Answers **15'**

11:25 Session 3: Stakeholder ADR data quality activities in Europe

Chair: Elke Stahl (BfArM)

Presentation – Human MAH **15'**
Jim Nickas (EUCOPE)

Presentation – CRO **15'**
Zurab Koberidze (EUCROF)

Presentation – Veterinary MAH **15'**
Magali Quetin (AnimalhealthEurope)

Presentation – Non– Commercial Sponsor **15'**
Tuula Ikonen (EORTC)

Questions & Answers **35'**

13:00 Lunch

14:00 Session 4: Panel discussion on high–quality ADR data

Discussion on how to tackle the challenges related to recording, measuring, characterising, analysing and improving ADR data quality.

Chair/moderator: James Mount (SEMPA)

Presentation **10'**
Tom Paternoster– Howe (EMA)

Panel discussion **30'**
Panellists:

Paolo Porcelli (AIFA, Inspector)
Rodrigo Postigo (EMA, PhV Office)
David Lewis (EFPIA)
Magali Quetin (AnimalhealthEurope)
Joop van Gerven (CCMO Committee)
Boukje Raemaekers (WHO-UMC)

Questions & Answers **20'**

15:00 Session 5: Key topics for the development of the ADR chapter of the Data Quality Framework

Discussion **30'**
Moderator: Anne Tobin (HPRA)

15:30 Closing remarks

Wrap– up and next steps **10'**
Paolo Alcini (Head of Healthcare Data, EMA)

Data protection note

Please be aware that personal data will be processed by the EMA in accordance with EMA Privacy statement on organisation of meetings and events (europa.eu). Internally, the Head of Data Analytics and Methods Task Force is appointed to ensure compliance as Internal Controller. Should you have any question on the processing of your personal data, please contact the Internal Controller at datacontroller.analytics@ema.europa.eu

Please consult European Medicines Agency's Data Protection Notice For the Cisco Webex Meetings and Webex Events participants.

Please note this workshop will be broadcast and recorded. The recording will be made public. By attending this meeting, you consent to recording and broadcast. The Agency records or broadcasts a number of meetings, including some virtual meetings. This is part of the Agency's commitment to the principle of transparency as enshrined in the Treaty on the European Union.

At certain points throughout the meeting, participants will be able to ask questions or give their input via the audience interaction tool Slido. Please go to Slido and enter the event code (#1March2024) and passcode (f6w5hz). Interaction via Slido is voluntary, and you may opt to remain anonymous. If you chose to use Slido, you consent to the processing of your personal data as explained in the EMA Data Privacy Statement for Slido

Abbreviations

ADR – Adverse Drug Reaction
AIFA - Italian Medicines Agency
AGES – Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH
AEMPS - Spanish Agency of Medicines and Medical Products
BfArM - Federal Institute for Drugs and Medical Devices
BVL - Federal Office of Consumer Protection and Food Safety
CCMO - Central Committee on Research Involving Human Subjects
CRO - Clinical Research Organisation
CTCG – Clinical Trials Coordination Group
DQF - Data Quality Framework
EFPIA - European Federation of Pharmaceutical Industries and Associations
EMA – European Medicines Agency
EMRN - European Medicines Regulatory Network
EORTC - European Organisation for Research and Treatment of Cancer
EUCOPE - European Confederation of Pharmaceutical Entrepreneurs
EUCROF – European CRO Federation
EV EWG – EudraVigilance Expert Working Group
HCP – Healthcare Professional
HPRA – Health Products Regulatory Authority
MAH – Marketing Authorisation Holder
MEB – Medicines Evaluation Board
NCA – National Competent Authority
PhV BT – Pharmacovigilance Business Team
PhV WP – Pharmacovigilance Working Party
SEMPA – Swedish Medical Products Agency
WHO -UMC - World Health Organization, Uppsala Monitoring Centre