EudraVigilance Information Day

7 June 2017

European Medicines Agency, London, United Kingdom

PROGRAMME COMMITTEE

Paolo Alcini, Head of Data Standardisation and Analytics Service, EMA, EU

Sabine Brosch, Principal Scientific Administrator, Pharmacovigilance and Epidemiology Department, EMA, EU

Georgy Genov, Head of Signal and Incident Management Service, EMA, EU

Anja van Haren, EudraVigilance Coordinator, Medicines Evaluation Board (MEB), Netherlands

FACULTY

David Bosque Villaverde, Project Manager of Information Technology, EMA, EU

Gaby Danan, Pharmacovigilance Expert, France

François Domergue, EudraVigilance Auditable Requirement Project Manager, Business Data and Analytics Department, EMA, EU

Julie Durand, Signal Management Lead, Pharmacovigilance and Epidemiology Department, EMA, EU

Michelle Grimes, Executive Director, Drug Safety, Merck Sharp & Dohme, UK

Nick Halsey, Data Scientist, Information Management Division - Data Standardisation and Analytics, EMA, EU

Fatima Saturdine Hergy, Pharm D., Infarmed, PT

Ekaterina Lari, Scientific Administrator, European Medicines Agency (EMA), EU

Subhash Mistry, Manager (Applications Development and Support), GCSP – PV Systems & Agreements, RD Chief Medical Office, GSK, UK

Nils Opitz, Head of PV System Management and Analytics, Bayer, Germany

Rodrigo Postigo, Signal Management Lead, Pharmacovigilance Department, EMA, EU

Adelino Rodrigues, Solution Design & Development, EMA, EU

Mihaela Savastre, Head of Data Modelling and Warehouse – ad interim, EMA, EU

Gilles Touraille, Pharmacovigilance and Risk Management, EMA, EU

Sarah Vaughan, Pharmacovigilance Information Unit Manager, MHRA, UK

Richard Ventham, Senior Manager – Application Development & Support (GPVIMS), Central Safety Department, GSK, UK

Margaret Walters, Deputy Qualified Person for Pharmacovigilance, MSD, UK

NEED FOR THIS EUDRAVIGILANCE INFORMATION DAY

The development of the new and enhanced EudraVigilance functionalities is progressing according to plan with the go life scheduled for November 2017. This EudraVigilance Information Day provides a forum to prepare stakeholders for the implementation and launch of the new EudraVigilance system in the context of the pharmacovigilance legislation and to facilitate change management as part of the Agency's pharmacovigilance programme.

The focus of this Information Day will be on providing a project update and an overview of the Agency's preparations to launch the new EudraVigilance System including various stakeholder support initiatives. The Information Day will also serve as a platform to experts of medicines regulatory authorities and marketing authorisation holders to share their change management planning experience and to raise specific process related or technical questions. Updates of the work of the ICH E2B Implementation Working Group, which is coordinating the implementation of the ICH E2B (R3) ICSR format at international level, will be also provided.

Other topics include the finalisation of the revisions of the Guideline on Good Pharmacovigilance Practices (GVP) Module VI – Management and reporting of adverse reactions to medicinal products and the GVP Module IX – Signal Management.

KEY TOPICS

- EudraVigilance auditable requirements project – achievements to date and next steps
- Change management planning - lessons learned from the perspective of NCAs and MAHs
- ICH E2B Implementation Working Group – what's new?
- Revision of the GVP modules on adverse reaction reporting and signal management
- Preparing for business change – frequently asked questions

TARGET AUDIENCE

- Qualified Persons Responsible for Pharmacovigilance (QPPVs)
- Individuals involved in pharmacovigilance, safety database and information management
- IT system developers and data managers

DETAILS OF THE INFORMATION DAY

Location: European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DIA

08:30 **REGISTRATION**

08:50 **WELCOME NOTE**

Georgy Genov, Head of Signal and Incident Management Service, European Medicines Agency (EMA), EU

09:00 **SESSION 1**

EUDRAVIGILANCE AUDITABLE FUNCTIONALITIES – ACHIEVEMENTS AND NEXT STEPS

Session Co-Chairs:
Sabine Brosch, EMA and Anja van Haren, MEB

This session will give an overview of the latest developments of the project based on the independent audit of the EudraVigilance functionalities, which was performed in the first quarter of 2017. These functionalities, also referred to as auditable functionalities, were adopted by the Pharmacovigilance Risk Assessment Committee (PRAC) and the EMA Management Board in December 2013.

EudraVigilance Project Roadmap: Achievements and Next Steps
François Domergue, EMA

EudraVigilance Go Life Plan – What Stakeholders Need to Know
François Domergue, EMA and David Bosque Villaverde, EMA

EudraVigilance User Registration and Stakeholder Support
Ekaterina Lari, EMA and Francois Domergue, EMA

Panel Discussion/Q&A

Discussants: Mihaela Savastre, EMA; Adelino Rodrigues, EMA; Gaby Danan; Margaret Walters, MSD

10:30 **COFFEE BREAK**

11:00 **SESSION 2**

GUIDANCE IN PHARMACOVIGILANCE

Session Co-Chairs:
Anja van Haren, MEB and Georgy Genov, EMA

This session will provide an overview of the key topics that will be part of revision 2 of GVP Module VI "Management and reporting of adverse reactions to medicinal products" and revision 1 of GVP Module IX "Signal Management", which are planned to be finalised for publication in 3rd quarter 2017. This takes into account the review of the comments received during the public consultation on the two GVP modules in 2016 including the draft reflection paper on the "Collecting and Reporting Information on Off-Label Use in Pharmacovigilance".

Highlights of the Updates to GVP Module IX (Revision 1)
Julie Durand, EMA

Highlights of the Updates to GVP Module VI (Revision 2)
Gilles Touraille, EMA

Panel Discussion/Q&A

Discussants: Sarah Vaughan, MHRA; Margaret Walters, MSD; Gaby Danan, PhV Expert; Rodrigo Postigo, EMA

12:00 **SANDWICH LUNCH**

13:00 **SESSION 3**

HOW TO PREPARE FOR CHANGE

Session Co-Chairs:
Sabine Brosch, EMA and Anja van Haren, MEB

This session will give the opportunity to hear from stakeholders on their approach to prepare for the technical and business process changes that will apply from the launch of the new EudraVigilance system.

Change Management Planning – A Perspective from a Marketing Authorisation Holder
Nils Opitz, Bayer

Change Management Planning – A Perspective from an NCA
Fatima Saturdine Hergy, Infarmed, PT

An MAH Analysis of ICH Backwards and Forwards Conversion (BFC): What Does it Mean for the Data?
Richard Ventham, GSK and Subhash Mistry, GSK

14:30 **COFFEE BREAK**

15:00 **SESSION 4**

HOW TO PREPARE FOR CHANGE (CONTINUED)

Session Co-Chairs:
Anja van Haren, MEB and Georgy Genov, EMA

This session gives an overview of the ongoing work of the ICH E2B Implementation Working Group and how this will impact stakeholders. It will also provide a platform for participants to raise specific technical or business process related questions on the use of the new ICH E2B(R3) format, the simplified reporting of suspected adverse reactions, registration and testing procedures and signal detection and management activities.

*Note: Participants are invited to send their questions by 20 May to **eudravigilance@diaglobal.org** of DIA contact. Alternatively, questions can be raised during the Info Day.*

ICH E2B Implementation Working Group – Use of R3 in Practice
Anja van Haren, MEB and Nick Halsey, EMA

Panel Discussion/Q&As

Discussants: François Domergue, EMA; Nick Halsey, EMA; Rodrigo Postigo, EMA; Julie Durand, EMA; Gilles Touraille, EMA; Sarah Vaughan, MHRA; and Anja van Haren, MEB; Gaby Danan, PhV expert; Fatima Sadurdine Hergy, INFARMED; Michelle Grimes, MSD

16:30 **END OF THE INFORMATION DAY**

REGISTRATION FORM

EudraVigilance Information Day
7 June 2017 | European Medicines Agency, London, United Kingdom

ID #17590

SEND YOUR COMPLETED REGISTRATION FORM TO DIA EUROPE, MIDDLE EAST & AFRICA CONTACT CENTRE TEAM,
E-mail: EMEA@DIAglobal.org Fax: +41 61 225 51 52 For more information please call +41 61 225 51 51

For easy online registration click here

Registration fees*	Fees
Industry	500.00 EUR ❑
Government/Academia/Charitable/Non-Profit (full time)	250.00 EUR ❑

*Registration fee includes: refreshments, sandwich lunch and delegate material

Payment is due 30 days after registration and must be paid in full by commencement of the event.

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Address

Postal Code City

Country

Telephone

Fax

Email*

*(Required for confirmation)

DIA reserves the right to include your name and affiliation on the attendee list.

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

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Payments must be net of all charges and bank charges must be borne by the payer. **If you have not received your confirmation within five working days, please contact DIA EMEA.**

By signing below, I confirm that I agree with DIA EMEA Terms and Conditions of booking. These are available from the office or on http://www.diaglobal.org/EUTerms

Date	Signature

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- Industry (Member/Non-member) € 200.00
- Government/Academia/Charitable/Non-Profit (full time) (Member/Non-member) € 100.00

If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee. DIA EMEA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA EMEA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

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Photography Policy

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The DIA Europe, Middle East & Africa Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.
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