EudraVigilance Information Day

8 November 2016
European Medicines Agency, London, United Kingdom

PROGRAMME COMMITTEE

Peter Arlett, Head of Pharmacovigilance and Epidemiology Department, European Medicines Agency (EMA), EU

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

Margaret Walters, Deputy EU Qualified Person for Pharmacovigilance, MSD, UK
Member of the EudraVigilance Expert Working Group (EV-EWG)

FACULTY

Gianmario Candore, Scientific Administrator, EMA, EU

Ana-Silvia Cochino, Scientific Administrator, EMA, EU

Gaby Danan, Pharmacovigilance Expert, FR

Peter De Veene, QPPV, Grünenthal GmbH, DE

Francois Domergue, EV Auditable Requirement Project Manager, Business Data and Analytics Department, EMA, EU

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

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

Wendy Huisman, EU Qualified Person for Pharmacovigilance, Teva Pharmaceuticals Europe B.V., The Netherlands
Member of the EudraVigilance Expert Working Group (EV-EWG)

Nicole Lang, Doctor of Medicine, Ratiopharm GmbH, DE

Ekaterina Lari, Scientific Administrator, EMA, EU

Steven Le Meur, Scientific Administrator, EMA

David Lewis, Global Head of Pharmacovigilance, Senior Visiting Fellow, Univ. of Hertfordshire, Novartis Pharma AG, CH

Tom Paternoster-Howe, Scientific Administrator, EMA, EU

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

Michael Richardson, VP International GPV&E and EU QPPV, Bristol-Myers Squibb, UK

Gilles Touraille, Pharmacovigilance and Risk Management, EMA, EU

Sarah Vaughan, Pharmacovigilance Information Unit Manager, MHRA, UK

NEED FOR THIS EUDRAVIGILANCE INFORMATION DAY

This EudraVigilance Information Day provides a forum to prepare stakeholders for the implementation and launch of the new and enhanced EudraVigilance functionalities in the context of the pharmacovigilance legislation. It further aims to facilitate change management as part of the Agency's pharmacovigilance programme and the planning of modifications to business processes by medicines regulatory authorities and pharmaceutical companies.

The focus of this Information Day will be on the achievements including a walk-through of the different business processes supported by EudraVigilance and a demonstration of some of the key functionalities for use by medicines regulatory authorities and marketing authorisation holders in the EEA.

Other topics include 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 and the next steps.

KEY TOPICS

- Revision of the GVP modules on adverse reaction reporting and signal management
- Preparing for business change – frequently asked questions from a pharmaceutical industry perspective
- EudraVigilance auditable requirements project – achievements to date and next steps
- Pharmacovigilance business processes supported by EudraVigilance and demonstration of key functionalities for use by medicines regulatory authorities and pharmaceutical companies

TARGET AUDIENCE

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

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DIA

08:30 REGISTRATION

08:50 WELCOME NOTE

Peter Arlett, EMA

09:00 SESSION 1

GUIDANCE IN PHARMACOVIGILANCE

Session Chairs: Sabine Brosch, EMA, EU, and Georgy Genov, EMA

This session will provide an overview of the key changes introduced as part of the revision of GVP Module VI "Management and reporting of adverse reactions to medicinal products" and GVP Module IX "Signal Management". The feedback received as part of the public consultation on the two GVP modules and on the draft reflection paper on the "Collecting and Reporting Information on Off-Label Use in Pharmacovigilance" will be presented from an industry perspective including the next steps for finalisation.

Summary of the key changes of GVP Module VI (draft revision 2) and the principles set out in the discussion paper on collecting and reporting information on off-label use in pharmacovigilance
Gilles Touraille, EMA

Comments on revision 2 of GVP module VI from an industry perspective
Peter DeVeene, Grünenthal

Comments on the reflection paper on off label use from an industry perspective
Michael Richardson, BMS

Summary of the key changes of GVP Module IX (draft revision 1) related to signal management and increased EudraVigilance access
Julie Durand, EMA

Comments on revision 1 of GVP IX from an industry perspective
Nicole Lang, Ratiopharm, and Dave Lewis, Novartis

Panel Discussion/Q&A
Discussants: Wendy Huisman, TEVA, Margaret Walters, MSD, Sarah Vaughan, MHRA, and Gaby Danan, PhV expert

10:45 COFFEE BREAK

11:15 SESSION 2

EUDRAVIGILANCE AUDITABLE REQUIREMENTS PROJECT – CHANGE MANAGEMENT PLANNING

Session Chairs: Sabine Brosch, EMA, EU, and Paolo Alcini, EMA

This session will update on the status of the EudraVigilance auditable requirements project with a summary of the most recent change management activities including the new EudraVigilance webpage and the training support provided by the Agency. It will also provide a platform to share experience and raise questions with regard to the changes to come.

EudraVigilance auditable requirements project – latest developments
Francois Domergue, EMA

Change management planning – a perspective from a marketing authorisation holder
Michelle Grimes, MSD

Panel Discussion/Q&A

Discussants: Wendy Huisman, TEVA, Margaret Walters, MSD, Sarah Vaughan, MHRA, and Gaby Danan, PhV expert

12:15 SANDWICH LUNCH

13:15 SESSION 3

PHARMACOVIGILANCE BUSINESS PROCESSES AND THE NEW EUDRAVIGILANCE SYSTEM. PART I

Session Chairs: Sabine Brosch, EMA, EU , and Paolo Alcini, EMA

This session will focus on the pharmacovigilance business processes supported by the new EudraVigilance system and address the registration process of MAH users to access EVDAS for the purpose of signal detection, the reporting of ICSRs in the new ICH E2B(R3) format, the recoding of medicinal product information in ICSRs and the duplicate detection. A demonstration of new or enhanced EudraVigilance functionalities will be also provided.

EudraVigilance registration including EVDAS access for marketing authorisation holders
Ekaterina Lari, EMA

ICSR reporting in E2B(R3) format using EVWEB and re-routing of ICSRs to EEA Member States
Tom Paternoster-Howe, EMA

ICSRs – use of product information based on Article 57 data in XEVMPD
Ana Cochino, EMA, and Steven Le Meur, EMA

Duplicate management and EudraVigilance
Gianmario Candore, EMA, and Tom Paternoster-Howe, EMA

Panel Discussion/Q&A
Discussants: Wendy Huisman, TEVA, Margaret Walters, MSD, Sarah Vaughan, MHRA, and Gaby Danan, PhV expert

15:00 COFFEE BREAK

15:30 SESSION 4

PHARMACOVIGILANCE BUSINESS PROCESSES AND THE NEW EUDRAVIGILANCE SYSTEM. PART II

Session Chairs: Sabine Brosch, EMA, EU, and Paolo Alcini, EMA

This session will explain how marketing authorisation holders obtain EudraVigilance access to reports of suspected adverse reactions that occurred in the EEA in relation to medicinal products for which they hold a marketing authorisation. It will also address the access by marketing authorisation holders to EVDAS and the functionalities that can be used for signal detection. A demonstration of the available functionalities will be also provided.

Access to EudraVigilance for MAHs – ICSR download in E2B(R3) format
Tom Paternoster-Howe, EMA

Access to EVDAS by MAHs
Rodrigo Postigo, EMA

Panel Discussion/Q&A
Discussants: Wendy Huisman, TEVA, Margaret Walters, MSD, Francois Domergue, EMA, Sarah Vaughan, MHRA, and Gaby Danan, PhV expert

17:00 END OF THE INFORMATION DAY

DETAILS OF THE INFORMATION DAY

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

Capacity: The event is limited to 110 participants

REGISTRATION FORM

EudraVigilance Information Day
8 November 2016 European Medicines Agency, London, United Kingdom

ID #16523

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

Please register online at www.diaglobal.org/evinfoday

Registration fees*	Fees
Industry	400.00 EUR ❑
Government/Academia/Charitable/Non-Profit (full time)	200.00 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.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

Card N°

Exp. Date /

Cardholder's Name

❑ **Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." Please include your name, company, Event ID #16523 as well as the invoice number to ensure correct allocation of your payment.

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

Cancellation Policy

All cancellations must be made in writing and be received at the DIA EMEA office four weeks prior to the event start date. Cancellations are subject to an administrative fee:

- 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.

Transfer Policy

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA EMEA office of any such substitutions as soon as possible.

Photography Policy

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA EMEA in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

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.
Tel. :+41 61 225 51 51 Fax: +41 61 225 51 52
Email: EMEA@DIAglobal.org Mail: DIA Europe, Middle East & Africa, Küchengasse 16, 4051 Basel, Switzerland Web: www.DIAglobal.org