EudraVigilance Information Day

21 June 2016
European Medicines Agency, London, United Kingdom

PROGRAMME COMMITTEE

Peter Richard Arlett
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FACULTY

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Francois Domergue, Scientific Administrator, Data Standardisation and Analytics
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Julie Durand, Scientific administrator, Signal Management Service, Pharmacovigilance Department
EMA, EU

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Martin Henzl, Director PV Technology, Global Patient Safety
Baxter Medical Products GmbH, AT

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GSK, UK

Victoria Newbould, Scientific Officer
EMA, EU

Tom Paternoster-Howe, Scientific Administrator
EMA, EU

Gilles Touraille, Pharmacovigilance and Risk Management
EMA, EU

Christina Winter, Medical director, Safety Evaluation and Risk Management
GSK, UK

NEED FOR THIS EUDRAVIGILANCE INFORMATION DAY

This EudraVigilance Information Day provides a forum to update stakeholders about latest developments with regard to EudraVigilance in the context of the implementation 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 pharmaceutical companies.

Other topics to be addressed include the revision of the Guideline on Good Pharmacovigilance Practices (GVP) Module VI – Management and reporting of adverse reactions to medicinal products with main focus on the transition to the ISO/ICH E2B(R3) format, GVP IX revision on signal management, as well as a summary of the first year of the operation of the medical literature monitoring and ICSR reporting.

The Information Day will conclude with an interactive session on challenging MedDRA coding examples.

KEY TOPICS

- Adverse reaction reporting and analysis, EudraVigilance system changes to come
- Definitions, principles, processes and reporting of ICSRs in R3 format: what will change with the revision of GVP Module VI?
- Preparing for business change from a pharmaceutical industry perspective
- One year of medical literature monitoring performed by the Agency – achievements and lessons learned
- MedDRA – an interactive session on challenging MedDRA coding examples

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

Capacity: The event is limited to 110 participants

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DIA DEVELOP INNOVATE ADVANCE

08:30 **REGISTRATION**

08:45 **KEY NOTE**

PHARMACOVIGILANCE HIGHLIGHTS

Sabine Brosch, EMA, EU

09:15 **SESSION 1**

NEW AND REVISED GUIDANCE IN PHARMACOVIGILANCE

Session Chairs: Anja van Haren, MEB, NL and Sabine Brosch, EMA, EU

This session will provide a summary of the highlights of revision 2 of the Guideline on good pharmacovigilance practices (GVP) Module VI – Management and reporting of adverse reactions to medicinal products and the draft reflection paper on Collecting and Reporting Information on Off-Label Use in Pharmacovigilance, which will be both subject to public consultation.

Draft GVP Module VI – Revision 2 – ICSR Management
Gilles Touraille, EMA, EU

Draft GVP Module VI – Revision 2 – Pharmacovigilance business processes
Sabine Brosch, EMA, EU

Collecting and Reporting Information on Off-Label Use in Pharmacovigilance
Gilles Touraille, EMA, EU

Draft GVP Module IX – Revision 1 – Signal management with increased EudraVigilance access
Julie Durand, EMA, EU

Panel Discussion/Q&A

Discussants: Wendy Huisman, Teva Pharmaceuticals, NL, Anja van Haren, MEB, NL, and Gaby Danan, PhV expert, FR

10:45 COFFEE BREAK

11:15 **SESSION 2**

THE AGENCY'S MEDICAL LITERATURE MONITORING SERVICE – ACHIEVEMENTS AND LESSONS LEARNED

Session Chairs: Anja van Haren, MEB, NL, and Sabine Brosch, EMA, EU

Following almost 12 months of operation of the medical literature monitoring (MLM) service by the Agency in accordance with Article 27 of Regulation (EC) 726/2004, in this session the achievements, the outcome of the latest customer survey and the independent audit will be presented. Enhancements to functionalities to be expected as a result of the EudraVigilance auditable requirements project will be also discussed.

The Agency's MLM service – current achievements and audit feedback
Tom Paternoster-Howe, EMA, EU

MLM Stakeholder survey outcome and lessons learned
Corina Hrehoret, Actavis, RO, and Tom Paternoster-Howe, EMA, EU

EudraVigilance system enhancements – what will change for the MLM service
Nick Halsey, EMA, EU

Panel Discussion/Q&A

Discussant: Margaret Walters, MSD, UK, and Gaby Danan, PhV expert, FR

12:45 SANDWICH LUNCH

13:45 **SESSION 3**

EUDRAVIGILANCE AUDITABLE REQUIREMENTS PROJECT – CHANGE MANAGEMENT PLANNING

Session Chairs: Anja van Haren, MEB, NL and Sabine Brosch, EMA, EU

This session will update on the EudraVigilance auditable requirements project including the new EudraVigilance webpage and the training support provided by the Agency. It will also provide participants with the opportunity to learn about the approach towards change management planning from the perspective of a pharmaceutical company in the EEA.

EudraVigilance Change Management Planning – latest update, new webpage and training support
Francois Domergue, EMA, EU

EudraVigilance Change Management Planning – a perspective of a marketing authorisation holder
Martin Henzl, Baxter Medical Products, AT, and Subhash Mistry, GSK, UK

Panel Discussion/Q&A

Discussants: Margaret Walters, MSD, UK, Wendy Huisman, Teva Pharmaceuticals, NL, and Gaby Danan, PhV expert, FR

15:15 COFFEE BREAK

15:45 **SESSION 4**

MEDDRA – ICSR REPORTING AND CHALLENGING CODING EXAMPLES

Session Chairs: Anja van Haren, MEB, NL, and Sabine Brosch, EMA, EU

This interactive session is designed to allow participants to engage with the speakers and discuss real life coding examples in the context of ICSR reporting.

Real life coding examples
Christina Winter, GSK, UK, and Victoria Newbould, EMA, EU

Panel Discussion/Q&A

Discussants: Gaby Danan, PhV Expert, FR, and Margaret Walters, MSD, UK

16:45 **END OF THE INFORMATION DAY**

REGISTRATION FORM

EudraVigilance Information Day
21 June 2016 European Medicines Agency, London, United Kingdom

ID #16524

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

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.

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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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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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