Information Day on Medication Errors

20 October 2016
European Medicines Agency, London, United Kingdom

PROGRAMME COMMITTEE

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Jamie Wilkinson
Pharmaceutical Group of the European Union (PGEU), Belgium

Christina Winter
Safety Evaluation and Risk Management, GlaxoSmithKline (GSK), United Kingdom

WHY AN INFORMATION DAY ON MEDICATION ERRORS?

Medication errors are a major public health burden and error prevention is a shared responsibility between patients, healthcare professionals, regulators and pharmaceutical industry at all levels of healthcare delivery. This information day is an opportunity for pharmaceutical industry, regulatory agencies as well as health care providers to exchange experience with the new EU good practice guide on medication errors published by the EU regulatory network in 2015. The objective is to raise awareness of the EU pharmacovigilance obligations for medication errors and to discuss operational aspects and good practice recommendations with regard to medication error reporting, evaluation and prevention with insight into the current regulatory thinking on how to tackle medication errors within health care delivery systems for the benefit of patient safety.

KEY TOPICS

- Recording medication errors with and without adverse reaction(s)
- Classification of medication errors and key MedDRA coding principles
- EU reporting requirements for medication errors
- Assessment of medication error reports and aspects of root cause analysis
- Public health impact of risk minimisation and prevention strategies for medication errors

TARGET AUDIENCE

This program has been developed for scientists in pharmaceutical industry, regulatory agencies as well as health care providers involved in the recording, reporting, evaluation and prevention of medication errors in the context of product life-cycle risk management and benefit-risk assessment of medicines.

Professionals working in the area of:

- Drug Safety/Pharmacovigilance
- Patient Safety
- Risk Management/REMS
- Periodic Safety Update Reporting (PSUR)
- Regulatory Affairs
- Medical Affairs
- Post-marketing activities
- Quality Assurance/Compliance

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DIA DEVELOP INNOVATE ADVANCE

08:00 REGISTRATION

08:45 WELCOME NOTE

Peter Arlett, EMA

08:50 - 10:45 SESSION 1

PHARMACOVIGILANCE OF MEDICATION ERRORS – REGULATORY AND INDUSTRY PERSPECTIVE

Co-chairs: Claudia Kayser, BfArM, DE and Margaret Walters, MSD, UK

This session will provide an overview of the new good practice recommendations for managing medication error reports for EU pharmacovigilance purposes with an opportunity to discuss stakeholder experience.

08:50 **PRAC experience with regulatory tools for medication errors**
June Raine, MHRA, UK

09:30 **Overview of key principles of the EU Good Practice Guide on medication errors**
Thomas Goedecke, EMA, EU

10:00 **Implementing good practice – industry experience with medication errors**
Joanne Emmott, MSD, UK

10:30 **Panel discussion**
Joined by Kathryn Ord, MHRA, UK

10:45 - 11:00 COFFEE BREAK

11:00 - 12:45 SESSION 2

GETTING IT RIGHT: GOOD CODING PRACTICE FOR DATA RETRIEVAL AND ANALYSIS

Co-chairs: Christina Winter, GSK, UK, and Victoria Newbould, EMA, EU

This session looks at important MedDRA coding concepts relevant for medication error reporting and data retrieval in the EU, including the new Standardised MedDRA Query for medication errors. Coding examples based on EudraVigilance data will be discussed.

11:00 **Preview of new MedDRA hierarchy for medication errors - coding and retrieval considerations**
Judy Harrison, MedDRA MSSO, US

11:30 **Data retrieval using the new SMQ for medication errors**
Christina Winter, GSK, UK

12:00 **Data analysis based on overview of EudraVigilance data**
Victoria Newbould, EMA, EU

12:30 **Panel discussion**
Joined by Anja van Haren, MEB, NL, and remotely joined by Sonja Brajovic, FDA, US

12:45 - 13:30 SANDWICH LUNCH

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

13:30 - 14:45 SESSION 3

LEARNING FROM MEDICATION ERRORS FROM A PATIENT SAFETY AND PHARMACOVIGILANCE PERSPECTIVE

Co-chairs: Thomas Goedecke, EMA and Claudia Kayser, BfArM, DE

This session focuses on the benefits of learning from errors throughout the product life cycle and will introduce tried and tested, as well as new methods for the evaluation of the risk of medication errors, including root cause analysis and related methodologies from both a patient safety and pharmacovigilance perspective.

13:30 **Safe medication practice – what can we learn from root cause analysis and related methods?**
David Gerrett, NHS Improvement, UK

14:00 **Medication errors as a challenge for pharmacovigilance – BfArM experience**
Claudia Kayser, BfArM, DE

14:30 **Panel discussion**
Joined by Joanne Emmott, MSD, UK, Ciara Kirke, HSE, IE, and Roberto Frontini, Centre for Patient Safety Leipzig, DE

14:45 - 15:00 COFFEE BREAK

15:00 - 16:45 SESSION 4

PATIENT AND HEALTHCARE PROFESSIONAL ENGAGEMENT IN ERROR PREVENTION STRATEGIES

Co-chairs: June Raine, MHRA, UK and Jamie Wilkinson, PGEU, BE

This session will provide an overview of regulatory tools for risk minimisation and prevention of medication errors based on real life examples with a focus on how to better engage patient and healthcare professionals in error prevention strategies.

15:00 **Life-cycle approach to error prevention – an overview**
Kathryn Ord, MHRA, UK

15:30 **Implementation of risk minimisation measures in clinical practice – challenges and opportunities**
Jamie Wilkinson, PGEU, BE

16:00 **Communication on medication errors – patient perspective**
Rob Camp, EURORDIS, FR

16:30 **Panel discussion**
Joined by Margaret Walters, MSD, UK, Annemarie Hellebek, Danish Society for Patient Safety, Denmark, Maria Karga, Patras University Hospital, GR, and Ciara Kirke, HSE, IE

16:45 CLOSING REMARKS

June Raine, MHRA, UK and Peter Arlett, EMA, EU

17:00 END OF THE INFORMATION DAY

REGISTRATION FORM

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20 October 2016 | European Medicines Agency, London, United Kingdom

ID #16522

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.

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 #16522 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

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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

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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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