15th EudraVigilance Information Day

Event ID 14501
12 March 2014
European Medicines Agency, London, United Kingdom

Programme Committee

Paolo Alcini
Head Data Collection and Management, EMA, EU

Peter Arlett
Head of Pharmacovigilance Department, EMA, EU

Sabine Brosch
Monitoring and Incident Management, Pharmacovigilance, European Medicines Agency (EMA), EU

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Pharmacovigilance Expert, France

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EudraVigilance Coordinator, Medicines Evaluation Board (MEB), The Netherlands

Faculty

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Scientific Administrator, European Medicines Agency (EMA), EU

Tom Paternoster
Scientific Administrator, European Medicines Agency (EMA), EU

Kelly Plueschke
Scientific Administrator, European Medicines Agency (EMA), EU

Izabela Skibicka
Scientific Administrator, European Medicines Agency (EMA), EU

Sabine Straus
Head of Pharmacovigilance, Medicines Evaluation Board (MEB), NL

Need for this EudraVigilance Information Day

EudraVigilance Information Days provide a forum to update stakeholders about the achievements and latest developments with regard to EudraVigilance in the broader context of implementation of the pharmacovigilance legislation.

A dedicated session on EudraVigilance will provide a summary of the EudraVigilance functionalities, which are, according to Article 24 of Regulation 726/2004, subject to an independent audit. A progress update on the preparation for literature monitoring services by the Agency as well as on the finalisation of the EU ICSR Implementation Guide will be also provided.

This Information Day will also provide an insight into the three year EU-wide pharmacovigilance project coordinated by MHRA and referenced as "Strengthening Collaboration for Operating Pharmacovigilance in Europe" (SCOPE). This Joint Action aims to further strengthen pharmacovigilance with main focus on operation at Member States level.

Other topics addressed will include the communication and follow up of safety signals, frequently raised implementation questions related to GVP module VI and commonly encountered data quality issues in relation to ICSR reporting.

Key Topics

- Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE)
- EudraVigilance functionalities to be audited
- Monitoring of medical literature by the Agency and the entry of relevant information into EudraVigilance
- EudraVigilance data quality
- Experience following publication of PRAC recommendations based on safety signals
- GVP Module VI – questions and answers session
- Notification process on withdrawn products

Who Will Attend

This programme will benefit Qualified Persons Responsible for Pharmacovigilance (QPPVs) and individuals involved in:

- Pharmacovigilance
- Clinical Development
- Information Management
- Safety databases

Details of the Information Day

Location: European Medicines Agency
7 Westferry Circus
Canary Wharf
London E14 4HB, UK

Capacity: The event is limited to 120 participants

EudraVigilance

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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08:15 **Registration**

08:45 **Welcome Note**
Peter Arlett, Head, Pharmacovigilance and Risk Management, EMA, EU

Session chairs for the 15th EudraVigilance Information Day:
Anja van Haren and **Sabine Brosch**

09:00 **Session 1**

EUDRAVIGILANCE

This session gives insight into the EudraVigilance functionalities to be audited in accordance with Article 24 of Regulation (EC) 726/2004 and a status update on the preparations for the literature monitoring activities by the Agency in line with Article 27 of the Regulation.

EudraVigilance functionalities to be audited
Sabine Brosch and Nick Halsey, EMA, EU

Status update on the monitoring of medical literature and the entry of relevant information into EudraVigilance
Sabine Brosch, EMA, EU and Steven Le Meur, EMA, EU

09:45 **Session 2**

EU ICSR IMPLEMENTATION GUIDE UPDATE

The audience will be updated on the finalisation of the EU ICSR Implementation Guide, which is key to the preparation for the implementation of the ISO ICSR standard.

ICH E2B (R3) – EU ICSR Implementation Guide
Nick Halsey, EMA, EU

10:15 **COFFEE BREAK**

10:45 **Session 2 (continued)**

EUDRAVIGILANCE

Aspects related to expedited compliance monitoring and frequently encountered data quality issues related to Individual Case Safety Reports (ICSRs) submitted to EudraVigilance will be addressed.

The duplicate detection algorithm in EudraVigilance
Gianmario Candore, EMA, EU

Data quality management – expedited reporting compliance and frequently encountered data quality issues in ICSRs
Tom Paternoster, EMA, EU

12:00 **SANDWICH LUNCH**

About DIA

DIA is a neutral, global, professional, member-driven association of nearly 18,000 professionals involved in the discovery, development, and life cycle management of pharmaceuticals, biotechnology, medical devices and related health care products. Through our international educational offerings and myriad networking opportunities, DIA provides a global forum for knowledge exchange that fosters the innovation of products, technologies and services to improve health and well being worldwide. Headquarters are in Horsham, Pa., USA, with offices in Basel, Switzerland, Tokyo, Japan, Mumbai, India and Beijing, China.

13:00 **Session 3**

SIGNAL MANAGEMENT

As of September 2013, PRAC recommendations on signals are published on a monthly basis. This session provides an overview of signals related activities from a regulators' and pharmaceutical industry's perspective.

Management of signals from an EU regulator's perspective
Sabine Straus, MEB, NL

Management of signals from an EMA perspective
Georgy Genov, EMA, EU

Experience with PRAC signals (follow-up and communication) from an industry perspective
Laurent Auclert, QPPV Sanofi, Chairman EFPIA PV Committee, France

14:30 **COFFEE BREAK**

15:00 **Session 4**

PHARMACOVIGILANCE LEGISLATION IMPLEMENTATION

GVP Module VI – questions and answers
Izabela Skibicka, EMA, EU, Gilles Touraille, EMA, EU and Gaby Danan, France

Notification process of withdrawn products
Kelly Plueschke, EMA, EU

16:15 **Session 5**

SCOPE

This session will provide an overview of the key objective of SCOPE aiming to enable national Competent Authorities in Member States to further progress from implementation of the pharmacovigilance legislation to the operation of the legal requirements to the highest possible standards against agreed benchmarks and best practices.

Mick Foy, MHRA, UK

17:00 **END OF INFORMATION DAY**

HOTEL INFORMATION

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Recommended Hotel:
Hilton London Docklands Riverside
265 Rotherhithe Street, London, SE16 5HW, UK
Telephone: +44 20 7231 1001
Email: reservations.docklands@hilton.com

DIA has blocked a limited number of rooms at the rate of GBP 139.00 single and GBP 149.00 double room/night including breakfast and VAT. To make your booking please visit the DIA event website.

The hotel is situated opposite of Canary Wharf, conveniently connected by a shuttle boat. The landing stage is in walking distance to the European Medicines Agency (2 min). The ferry ticket is included in the room rate. Please make sure you receive it when checking in.
For further information, please go to http://www1.hilton.com/en_US/hi/hotel/LONNDHI-Hilton-London-Docklands-hotel/index.do

DIA 2013 Training Courses in Safety and Pharmacovigilance

- **Benefit/Risk Management**
  19-20 May 2014 | Prague, Czech Republic | ID 14533
  October 2014 | Location to be confirmed I ID 14547
- **Medical Approach in Diagnosis and Management of ADRs**
  22-23 September 2014 | Paris, France I
- **Diagnosis and Management of Drug-Induced Liver Injury (DILI)**
  23-24 September 2014 | Paris, France I ID 14544
- **How to Prepare for Pharmacovigilance Audits and Inspections**
  November 2014 | Location to be confirmed I ID 14550
- **ICH Endorsed Pharmacovigilance**
  21 October 2014 | Dakar, Senegal I ID 14559
  November 2014 | Algiers, Algeria I ID 14560
- **Medical Approach in Diagnosis and Management of ADRs**
  22-23 September 2014 | Paris, France
- **Pre-Marketing Clinical Safety**
  16-17 June 2014 | Location to be confirmed | ID 14539
- **Post-Authorisation Safety Studies (PASS)** *new offering!*
  18-19 June 2014 | Location to be confirmed | ID 14535
- **Signal Management in Pharmacovigilance**
  21-22 May 2014 | Prague, Czech Republic | ID 14534
  November 2014 | Location to be confirmed I ID 14549

European Medicines Agency Information Days and Courses

- **Excellence in Pharmacovigilance: Clinical trials and post-marketing**
  17-21 February 2014 | London, United Kingdom | ID 14500
  13-17 October 2014 | London, United Kingdom I ID 14548
- **EnCePP Information Day**
  6 June 2014 | London, United Kingdom | ID 14503
- **EudraVigilance Information Day**
  12 March 2014 | London, United Kingdom | ID 14501
- **ICSR Information Day**
  13 May 2014 | London, United Kingdom | ID 14502
- **MedDRA Information Day**
  November 2014 | London, United Kingdom
- **PSUR Information Day**
  Date to be confirmed| London, United Kingdom

EudraVigilance courses:

- EudraVigilance – Electronic reporting of ICSRs in the EEA
- eXtended EudraVigilance Medicinal Product Dictionary
- Introduction to Pharmacovigilance and Rules for Expedited Reporting of Individual Case Safety Reports (ICSRs) in Europe

Courses throughout the year | European Medicines Agency, London, United Kingdom and selected European cities.

For information on EudraVigilance courses, please visit www.diahome.org > Meetings & Training > About Meetings & Training > In-Person Instruction > EudraVigilance > EudraVigilance Courses.

REGISTRATION FORM

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12 March 2014 | European Medicines Agency, London, United Kingdom

ID #14501

FAX YOUR COMPLETED REGISTRATION FORM TO: +41 61 225 51 52 or email to: diaeurope@diaeurope.org

FEES

Standard fee	€ 365.00	❑
Reduced fee for Academia/Non-profit (Full-time)	€ 180.00	❑
Reduced fee for Government	€ 180.00	❑

The registration fee includes meeting material, sandwich lunch and refreshments.

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

TOTAL AMOUNT DUE: _____

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 #14501 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 Europe.**

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

Date	Signature

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe office five working days prior to the event start date. Cancellations are subject to an administrative fee:

- Industry € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) € 100.00

If you do not cancel five working days prior to the event start date and do not attend, you will be responsible for the full registration fee. DIA Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA Europe 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 Europe 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 Europe in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.