14th EudraVigilance Information Day

Adverse drug reaction reporting in the EU and highlights of the new pharmacovigilance legislation

Event #13529
23 May 2013
European Medicines Agency, London, United Kingdom

Programme Committee

Peter Arlett
Head, Pharmacovigilance and Risk Management, European Medicines Agency (EMA), EU

Sabine Brosch
Business Lead EudraVigilance and International Standardisation in Pharmacovigilance, European Medicines Agency (EMA), EU

Gaby Danan
Pharmacovigilance Expert, France

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

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

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.

For more information, visit www.diahome.org or call DIA Europe +41 61 225 51 51.

Need for this EudraVigilance Information Day

EudraVigilance Information Days provide a forum to update stakeholders about the achievements and latest developments with regard to the implementation of the new pharmacovigilance legislation. It will provide important technical and operational details that need to be taken into account by marketing authorisation holders in their daily application of the new legislation in the broader context of EudraVigilance and adverse reaction reporting in the EU.

This EudraVigilance Information Day will highlight the latest developments in applying data privacy legislation and the impact on adverse drug reaction data exchange between stakeholders. A dedicated questions and answers session will focus on expected updates of the Good Pharmacovigilance Practice (GVP) Module VI, relating to the management and reporting of adverse reactions to medicinal products. Other topics will include highlights of the work of the new Pharmacovigilance and Risk Assessment Committee (PRAC), including experience on signal management related to electronic reaction monitoring reports (eRMRs) and based on EudraVigilance data, practical experience with the new Pharmacovigilance System Master File (PSMF) and updates on the Risk Management Plan, including the latest information on Post-Authorisation Safety Studies (PASS) and Post-Authorisation Efficacy Studies (PAES).

A look at the pharmacovigilance activities of the Croatian Medicines Agency (HALMED) in preparation for EU accession on 1 July 2013 will conclude this Information Day.

Key Topics

- Latest developments on applying data privacy legislation and its impact on the adverse drug reaction data exchange between stakeholders
- Update of GVP Module VI – detailed questions and answers session
- Medicinal products subject to additional monitoring
- The work of the PRAC
- Experience of signal management based on EudraVigilance data
- Implementation experience with the new PSMF
- Risk Management Planning including the latest information on PASS and PAES
- EU accession of Croatia

Who Will Attend

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

- Pharmacovigilance
- Clinical Development
- Information Management
- Safety databases

EudraVigilance

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08:15 **Registration**

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

09:00 **Session 1**

THE WORK OF THE PHARMACOVIGILANCE RISK ASSESSMENT COMMITTEE (PRAC) AND SIGNAL MANAGEMENT EXPERIENCE BASED ON EUDRAVIGILANCE DATA

This session will provide an important overview of the composition, the mandate and the output of the PRAC. In addition, the experience on signal management based on the Guideline on good pharmacovigilance practices (GVP), module IX "Signal management" as well as the use of the electronic reaction monitoring reports (eRMRs) generated from EudraVigilance data will be presented from a Member State and EMA perspective.

The work of Pharmacovigilance Risk Assessment Committee (PRAC): Assessment and monitoring of safety issues
Almath Spooner, Vice-chair, Irish Medicines Board (IMB), IRL

Signal management activities by the Medicines Evaluation Board (MEB)
Sabine Straus, PRAC member of the MEB, NL

Signal management activities by the EMA
Georgy Genov, Head, Signal Detection and Data Analysis, EMA, EU

10:30 **COFFEE BREAK**

11:00 **Session 2**

EU ACCESSION OF CROATIA

In preparation of the EU accession on 1 July 2013, this session will give a unique insight of the pharmacovigilance activities of the Croatian Agency for Medicinal Products and Medical Devices (Agencija za lijekove i medicinske proizvode, HALMED). More specifically, aspects of electronic adverse reaction reporting and the plans for electronic submission of information on medicines will be addressed

Viola Macolić-Šarinić, Head of Agency, HALMED, CR
Nenad Čajko, Associate for IT Affairs, HALMED, CR

11:40 **Session 3**

IMPLEMENTATION EXPERIENCE WITH THE NEW PHARMACOVIGILANCE SYSTEM MASTER FILE (PSMF)

The legal requirement for marketing authorisation holders to maintain and make available upon request a Pharmacovigilance System Master File (PSMF) was introduced to harmonise and strengthen the conduct of pharmacovigilance activities in the EU. This session will provide the opportunity to hear from the Federal Institute for Drugs and Medical Devices (BfArM) Pharmacovigilance Inspectorate about the initial implementation experience and to discuss frequently asked questions in the context of the PSMF.

Experience with the PSMF from a pharmacovigilance inspection perspective
Kimberley Sherwood, Pharmacovigilance Inspectorate, BfArM, DE

Frequently asked questions and answers related to the PSMF
Sophia Mylona, Clinical and Non-Clinical Compliance Section, EMA, EU

12:30 **SANDWICH LUNCH**

13:30 **Session 4**

GUIDELINE ON GOOD PHARMACOVIGILANCE PRACTICES: UPDATE OF MODULE VI – MANAGEMENT AND REPORTING OF ADVERSE REACTIONS, DATA PRIVACY AND CODING WITH MEDDRA

This session will provide an update on the requirements on adverse reaction reporting applicable to post-authorisation studies and will allow for the discussion of frequently asked questions in relation to the practical application of GVP module VI. Furthermore, highlights of the EU data privacy legislation in the context of adverse reaction reporting and EudraVigilance will be presented. In addition, an update on MedDRA coding aspects related to the new pharmacovigilance legislation will be provided.

Updated requirements on reporting for post-authorisation studies and questions and answers
Mick Foy, Group Manager - Vigilance Intelligence and Research Group, Vigilance and Risk Management of Medicines, MHRA, UK
Gilles Touraille, Signal Detection and Data Analysis Section, EMA, EU

Data privacy legislation and impact on the adverse drug reaction data exchange between stakeholders and EudraVigilance
Alessandro Spina, Data Protection Officer, EMA, EU

MedDRA Term Selection: Latest activities of the Points to Consider Working Group
Patrick Revelle, Director MedDRA MSSO

15:00 **COFFEE BREAK**

15:30 **Session 5**

RISK MANAGEMENT PLAN INCLUDING THE LATEST INFORMATION ON POST-AUTHORISATION SAFETY STUDIES (PASS) AND POST-AUTHORISATION EFFICACY STUDIES (PAES) AND LATEST DEVELOPMENTS ON MEDICINAL PRODUCTS SUBJECT TO ADDITIONAL MONITORING

This session will give insight on the handling of risk management plans and the conduct of PASSs and PAEs. Early experiences with review of PASS protocols and lessons learned will also be addressed. The activities related to the publication of the list of medicinal products, which are subject to additional monitoring will be discussed.

Risk Management Plan including the latest information on Post-Authorisation Safety Studies (PASS) and Post-Authorisation Efficacy Studies (PAES)
Xavier Kurz, Business Coordination and Scientific Projects Section, EMA, EU

Latest developments on medicinal products subject to additional monitoring
Ana Hidalgo-Simon, Head, Risk Management Section, EMA, EU

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

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HOTEL INFORMATION

Recommended Hotel:

Hilton London Docklands Riverside

265 Rotherhithe Street, London , SE16 5HW, UK

Telephone: +44 (0)20 7231 1001

Fax: +44 (0)20 7231 0599

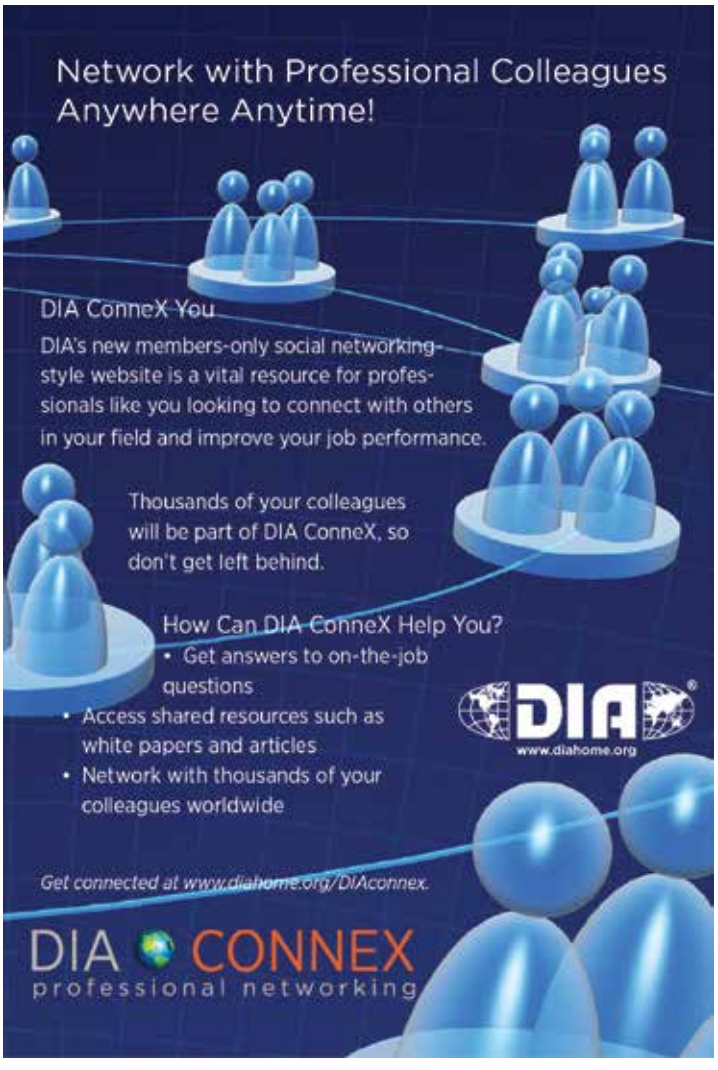
Email: reservations.docklands@hilton.com

DIA was able to negotiate a special rate for participants of the Information Day:

Room rate is **GBP 174** per room including VAT and buffet breakfast.

To book a room, **click here**. Please fill in corporate account number: 481223696.

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**
  13-14 May 2013 | Zurich, Switzerland | ID 13523
  26-27 September 2013 | Prague, Czech Republic | ID 13524
- **Diagnosis and Management of Drug-Induced Liver Injury (DILI)**
  19-20 September 2013 | Paris, France | ID 13563
- **How to Prepare for Pharmacovigilance Audits and Inspections**
  11-12 June 2013 | Nice, France | ID 13555
  7–8 November 2013 | Paris, France | ID 13556
- **Pre-Marketing Clinical Safety**
  18-19 April 2013 | Vienna, Austria | ID 13526
- **Signal Management in Pharmacovigilance**
  10-11 June 2013 | Nice, France | ID 13557
  6–7 November 2013 | Paris, France | ID 13558

European Medicines Agency Information Days and Courses

- **EudraVigilance Information Day**
  19 June 2013 | London, United Kingdom | ID 13529
  22 October 2013 | London, United Kingdom | ID 13530
- **Excellence in Pharmacovigilance: Clinical trials and post-marketing**
  18-22 November 2013 | London, United Kingdom | ID 13522
- **IDMP International Standards ICH M5/M2 and the Implementation of eSubmission of MPIs in the EU, Article 57(2) Information Day**
  10 December 2013 | London, United Kingdom | ID 13531
- **EudraVigilance courses:**
  - EudraVigilance – Electronic reporting of ICSRs in the EEA
  - eXtended EudraVigilance Medicinal Product Dictionary
  - Introduction to Pharmacovigilance and Electronic Transmission of Individual Case Safety Reports (ICSR) for the Use of Eudravigilance at the European Medicines Agency

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

For course details on EV, please visit www.diahome.org > Training > EudraVigilance > Click on > Related Courses.

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REGISTRATION FORM

14th EudraVigilance Information Day

23 May 2013 | European Medicines Agency, London, United Kingdom

ID #13529

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	€ 150.00	❑

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 #13529 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

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