1st Information Day on Periodic Safety Update Reports – ICH E2C(R2) Periodic Benefit-Risk Evaluation Reports (PBRERs)

Event #13576
19 June 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

Almath Spooner
Pharmacovigilance and Risk Management Lead, PRAC Vice-chair; Irish Medicines Board (IMB), IE

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 Information Day on Periodic Safety Update Reports

The new ICH E2C(R2) Periodic Benefit-Risk Evaluation Report (PBRER) is intended to become the new standard for periodic benefit-risk evaluation reporting on medicinal products.

This PSUR Information Day provides a forum to hear the latest news from regulators running the assessment process and pharmaceutical industry experts from the ICH E2C Expert Working Group. The discussions will focus on how to ensure high quality of PSURs and assessment for public health and on greater emphasis on meaningful evaluation of important new risk information in the context of a medicinal product's benefits.

This PSUR Information Day will highlight the revised scope, the benefits as well as the risks, the new ICH E2C(R2) format, content and submission process, EU regional requirements and how EU PSUR assessment results in direct and binding product information updates.

Key Topics

- Revised PSUR scope (PBRER)
- Benefit/risk evaluation
- New ICH E2C(R2) format and content
- EU regional requirements
- Direct and binding product information updates

Who Will Attend

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

- Pharmacovigilance
- Clinical Development
- Information Management
- Safety databases

EUROPEAN MEDICINES AGENCY
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08:15 **Registration**

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

09:00 **Session 1**

NEW PHARMACOVIGILANCE SYSTEM AND THE NEW SCOPE, FORMAT AND CONTENT OF THE PERIODIC SAFETY UPDATE REPORTS (PSURS).

Session Co-chairs:
Sabine Brosch, EMA, EU
Almath Spooner, PRAC Vice-chair; IMB, IE

This session will present the changes to periodic reporting in the wider context of the new EU system for pharmacovigilance and risk management. Moreover, the session will present an overview of the scope, format and content of the new 'PSUR' and provide insight into approaches to the assessment of the risk-benefit balance as introduced by the new pharmacovigilance legislation and the new ICH-E2C(R2) guideline on the Periodic Benefit Risk Evaluation Report (PBRER).

Wider scope of the PSURs and their role within the new EU system for pharmacovigilance and risk management
Rodrigo Postigo, EMA, EU

Format and content of the PSURs: from EU law to international consensus
Valerie E. Simmons, EU Qualified Person for Pharmacovigilance, Global Product Safety, Eli Lilly and Company Ltd., UK

10:00 **COFFEE BREAK**

10:30 **Session 2**

ASSESSMENT OF PSURS IN THE EU REGULATORY NETWORK

Session Co-chairs:
Enrica Alteri, EMA, EU
Julie Williams, PRAC Member; MHRA, UK

This session will give a unique insight of the assessment of PSURs in the EU taking into account the role of the Pharmacovigilance Risk Assessment Committee (PRAC) and the establishment of the EU single assessment procedure. The session will also explain the role of the EU Reference Date list and the opportunity it presents for harmonisation beyond the EU.

EU PSUR Single Assessment Procedure
Heidi Janssen, EMA, EU

List of EU reference dates and frequency of submission of PSURs
Kelly Plueschke, EMA, EU

PSUR assessment under the mandate of the PRAC and PRAC recommendations
Julie Williams, PRAC Member; MHRA, UK

12:00 **LUNCH BREAK**

13:00 **Session 3**

PSUR DECISION MAKING, TRANSPARENCY AND THE ROLE OF EUDRAVIGILANCE

Session Co-chairs:
Heidi Janssen, EMA, EU
Michael Richardson, BMS, UK

This session will provide clarity on the regulatory outcomes following the assessment of the PSURs and the different possible scenarios together with tips on how to optimise the PSUR drafting, submission, assessment and consultation to deliver robust regulatory action for public health. Moreover the publication of documents relating to PSURs and PSURs assessment procedures will be outlined as part for the transparency provisions established in the EU legislation and the role of EudraVigilance data will be explored.

Regulatory outcomes of the PSUR assessment
Zaide Frias, EMA, EU

Publication of the outcome of PRAC assessments of PSURs in the European Medicines web-portal
Juan Garcia Burgos, EMA, EU

How EudraVigilance data are used in the context of the PSUR assessment
Francois Domergue, EMA, EU

14:30 **COFFEE BREAK**

15:00 **Session 4**

EXPERIENCES ON THE PREPARATION AND ASSESSMENT OF PSURS

Session chair:
Peter Arlett, EMA, EU

This session will integrate the experiences from the perspective of the pharmaceutical industry and EU regulators on the preparation and assessment of PSURs following the implementation of the pharmacovigilance legislation and the transitional period for the new content of PSURs. This session will provide an opportunity for questions and debate and will highlight the key changes, challenges and lessons learnt from PSURs preparation and assessment focusing on the importance of the reassessment of the risk-benefit balance from the perspective of patient safety and public health and the strengthening of the link between assessment and regulatory action.

Industry perspective on the PSUR preparation and assessment process
Omer de Mol, Genzyme, NL

EU Regulatory network perspective on the PSUR assessment process
Almath Spooner, PRAC Vice-chair; IMB, IE

Questions, discussion and debate
Peter Arlett, Almath Spooner, Valerie E. Simmons, Omer de Mol

16.30 **END OF THIS INFORMATION DAY**

HOTEL INFORMATION

Attendees have to make their own reservation. Recommended hotel close to the EMA:

Hilton London Docklands Riverside
265 Rotherhithe Street,
London , SE16 5HW, United Kingdom
Telephone: +44 (0)20 7231 1001
Fax: +44 (0)20 7231 0599
Email: reservations.docklands@hilton.com

Britannia International
Marsh Wall,
London, E14 9SJ,
United Kingdom
Telephone: +44 (0)871 222 0042
Fax: +44 (0) 871 222 7712

DIA EUROPE TRAINING PROGRAMME 2013/2014

Chemistry, Manufacturing and Controls (CMC) / Quality

- **Global CTD Dossier – Regulatory aspects and focus on quality documentation including concepts of Quality by Design**
  1-3 December 2013 | Dubai, United Arab Emirates | ID 13562
- **Quality by Design for Chemical and Biotech Products – A hands-on course for the pharmaceutical industry and regulators**
  11-13 September 2013 | Vienna, Austria | ID 13559

Clinical Research

- **Advanced GCP Study Monitoring**
  Next recurrence of this course to be announced
- **Clinical Aspects of Quality Risk Management and Quality by Design**
  19-20 September 2013 | Basel, Switzerland | ID 13560
- **Clinical Project Management – Part I**
  18-20 September 2013 | Basel, Switzerland | ID 13572
- **Clinical Project Management – Part II**
  25-27 November 2013 | Zurich, Switzerland | ID 13501
- **Clinical Statistics for Non-Statisticians**
  24-25 October 2013 | London, United Kingdom | ID 13551
- **Essentials of Clinical Study Management**
  20-22 November 2013 | Paris, France | ID 13554
- **Practical GCP Compliance Auditing of Trials and Systems**
  23-25 October 2013 | London, United Kingdom | ID 13548

Non-Clinical Safety Sciences

- **Non-Clinical Safety Sciences and Their Regulatory Aspects**
  24-28 February 2014| Lisbon, Portugal

Regulatory Affairs

- **Authorisation of Biopharmaceuticals, Biosimilars and Advanced Therapies in Europe**
  18-20 September 2013 | Basel, Switzerland | ID 13546
- **European Regulatory Affairs: In-depth review of current registration procedures in the European Union**
  6-7 June 2013 | Basel, Switzerland | ID 13550
  21-22 November 2013 | Paris, France | ID 13553
- **Good Management of Medical Devices including In Vitro Diagnostics and Companion Diagnostics: Legal and practical aspects of devices**
  10-12 June 2013 | Amsterdam, the Netherlands | ID 13547
- **Health Authority Interactions – Preparation, consultation and implementation**
  15-16 October 2013 | Vienna, Austria | ID 13575
- **Health Technology Assessment (HTA)**
  26-27 November 2013 | Zurich, Switzerland | ID 13561
- **Paediatric Investigation Plans (PIP)**
  Next recurrence of this course to be announced
- **The Impact of Regulatory Affairs on Chemistry, Manufacturing & Controls (CMC)**
  2-4 October 2013 | Basel, Switzerland | ID 13532
- **US Regulatory Affairs: A comprehensive review of regulatory procedures for INDs and NDAs in the US**
  6-8 November 2013 | Paris, France | ID 13552

Safety and Pharmacovigilance

- **Benefit/Risk Management**
  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**
  Next recurrence of this course to be announced
- **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**
  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
- **1st Information Day on Periodic Safety Update Reports – ICH E2C(R2) Periodic Benefit-Risk Evaluation Reports (PBRERs)**
  19 June 2013 | London, United Kingdom | ID 13576
- **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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The DIA Tailored Training programmes in Europe make the most of a selection of world-class expert faculty who are experienced professionals in the pharmaceutical and related industries.

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REGISTRATION FORM

1st Information Day on Periodic Safety Update Reports
19 June 2013 | European Medicines Agency, London, United Kingdom

DIA www.diahome.org
ID #13576

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	❑

TOTAL AMOUNT DUE: _____

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.

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 #13576 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.