

2nd Periodic Safety Update Report Information Day

Event ID 14504

29 April 2014, European Medicines Agency (EMA), London, UK



Programme Committee

Peter Richard Arlett

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Pharmacovigilance and Risk Management Lead, PRAC Vice-chair, Irish Medicines Board (IMB), IE
Details of the

Faculty

Enrica Alteri

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QPPV, Sanofi-Aventis R&D, FR, EFPIA representative

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State Medicines Control Agency, PRAC member, LT

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Kristiina Puusaari

Human Medicines Evaluation, EMA, EU

Irene Rager

Head of Evaluation Procedures (PSURs, PSUSAs, PASS), EMA, EU

Yoshihiko Sano

WHLA/PMDA liaison officer at EMA

Valerie Simmons

EU QPPV Executive at Eli Lilly & co, UK

Chris Turner

Pharmacovigilance, EMA/Health Canada

Menno van der Elst

Alternate PRAC Member, MEB, NL

Ana Zanoletty

Procedure Management Department, EMA, EU

Overview

This Information Day provides a forum to discuss the implementation experience with PSURs under the new pharmacovigilance legislation from an EU, international regulators' as well as pharmaceutical industries' perspective. This will include the first practical experience with the recently started single PSUR assessment for centrally and nationally authorised medicinal products.

Specific aspects of the quality of PSURs in terms of assessment for public health and greater emphasis on meaningful evaluation of important new risk information in the context of a medicinal product's benefits will be addressed.

Practical aspects in relation to the December 2013 updates of GVP module VII will be presented. Furthermore, an exchange on the ICH E2C(R2) guideline on the "Periodic Benefit- Risk Evaluation Report (PBRER)" will occur, where ICH experts will present highlights in relation to the supplemental E2C Q&A document.

Key functionalities of the new PSUR Repository to be audited will be outlined.

Key Topics

- Implementation experience and questions based on the ICH E2C (R2) format and content
- Benefit/risk evaluation in the context of PSUR assessments
- Updates to GVP Module VII
- Application of the EU reference date list for PSUR submissions
- Submission requirements and procedural aspects of the PSUR single assessment procedure
- PSUR Repository functionalities to be audited
- 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
- Regulatory Affairs
- Information Management
- Safety Databases

Details of this Information Day

Location : **European Medicines Agency**

7 Westferry Circus

Canary Wharf, London E14 4HB, UK

Capacity: The event is limited to 130 participants.

| | |
|-------|---|
| 08:00 | Registration |
| 08:30 | Welcome Note Peter Arlett, Head, Pharmacovigilance and Risk Management, EMA, EU |
| 08:45 | Session 1 - part 1 TECHNICAL AND PROCEDURAL ASPECTS OF PSUR SUBMISSIONS AND THE PSUR SINGLE ASSESSMENT Session co-chairs: Heidi Janssen and Irene Rager, EMA, EU This session will provide a detailed update on the technical and procedural aspects in relation to PSUR submissions and the PSUR single assessment. It will start with an overview of the PSUR/PSUSA assessed so far including statistics, type of outcome and challenges encountered. Other key areas addressed will include procedural aspects related to periodicity, submissions and the maintenance of EURD list. The PSUR Repository functionalities to be audited will be also summarised. An overview of the PSUR/PSUSA assessment experience so far Maria Boulos, EMA, EU Application of the EU reference date list for PSUR submissions Katerina-Christina Deli, EMA, EU Submission requirements and procedural aspects of the PSUR single assessment procedure Ana Zanoletty, EMA, EU |
| 10:15 | COFFEE BREAK |
| 10:40 | Session 1 - part 2 PSURs for Nationally Authorised Products - Transitional and Future arrangements Anne Ambrose, MHRA, UK PSURs Repository and functionalities to be audited Kristiina Puusaari, EMA, EU |
| 11:40 | Session 2 - part 1 PRACTICAL IMPLEMENTATION EXPERIENCE WITH THE PBRER IN THE EU Session chair: Almath Spooner, IMB, IE This session will focus on the experience of the implementation and operation of the ICH E2C(R2) guideline on the “Periodic Benefit-Risk Evaluation Report (PBRER)” from a regulators’ and industry perspective. Experience with operation of the new PSUR assessment procedure at the PRAC Jolanta Gulbinovic, VVKT, LT Experience with operation of the new PSUR assessment procedure at Health Canada Chris Turner, EMA/Health Canada |
| 12:30 | SANDWICH LUNCH |

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|-------|---|
| 13:15 | Session 2 - part 2 Experience with operation of the new PSUR assessment procedure at PMDA Yoshihiko Sano, PMDA representative Reflections from a pharmaceutical industry perspective on the implementation and operation of the new PBRER format Laurent Auclert, EFPIA representative |
| 14:00 | Session 3 - part 1 PERIODIC BENEFIT RISK EVALUATION REPORTING IN PRACTISE Session chair: Enrica Alteri, EMA, EU This session will focus on the main objectives of the PBRER with regard to the optimisation and effective use of medicines and will provide an overview of the expectations of the PRAC as regards the presentation of signals and the risk assessment. Practical suggestions on content optimisation will be highlighted from an industry perspective. Periodic Benefit Risk Evaluation Report -has it achieved what it set out to do? Almath Spooner, IMB, IE Presenting signal evaluations and presenting risk assessments in the PBRER - interdependencies with signal management Menno van der Elst, MEB, NL Practical suggestions to optimize content: an industry perspective Valerie Simmons, Eli Lilly, UK |
| 15:30 | COFFEE BREAK |
| 16:00 | Session 3 - part 2 Periodic Benefit Risk Evaluation Reporting - an industry perspective Klaudija Marijanovic Barac, EGA representative Exposure, off-label use, benefit evaluation - what is expected by the PRAC MHRA speaker invited, UK |
| 16:45 | END OF INFORMATION DAY |

REGISTRATION FORM

2nd Periodic Safety Update Report Information Day
29 April 2014, European Medicines Agency (EMA), London, UK



ID #14504

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

FEES

| | | |
|---|----------|--------------------------|
| Standard fee | € 365.00 | <input type="checkbox"/> |
| Reduced fee for Academia/Non-profit (Full-time) | € 180.00 | <input type="checkbox"/> |
| Reduced fee for Government | € 180.00 | <input type="checkbox"/> |

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

TOTAL AMOUNT DUE: _____

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

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First Name

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Address

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Signature

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

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DIA EUROPE MIDDLE EAST & AFRICA TRAINING COURSES

Chemistry, Manufacturing and Controls (CMC) / Quality

- **Quality by Design - New concepts for chemical and biotech product development and optimisation**
22-24 September 2014 | Vienna, Austria | ID 14543
- **Global CTD Dossier - Regulatory aspects and focus on quality documentation including concepts of Quality by Design**
November 2014 | Location to be confirmed | ID 14553

Clinical Research

- **Clinical Project Management - Part I**
22-24 September 2014 | Paris, France | ID 14542
- **Practical GCP Compliance Auditing of Trials and Systems**
22-24 October 2014 | London, United Kingdom | ID 14531
- **Clinical Statistics for Non-Statisticians**
23-24 October 2014 | London, United Kingdom | ID 14532
- **Essentials of Clinical Study Management**
5-7 November 2014 | London, United Kingdom | ID 14557
- **Clinical Project Management - Part II**
10-12 November 2014 | Barcelona, Spain | ID 14555

Non-Clinical Safety Sciences

- **Non-Clinical Safety Sciences and Their Regulatory Aspects**
Date and location to be confirmed

Regulatory Affairs

- **Paediatric Investigation Plans (PIP)**
13-14 May 2014 | London, United Kingdom | ID 14552
- **Essentials of European Regulatory Affairs** **NEW OFFERING!**
23-24 June 2014 | Amsterdam, The Netherlands | ID 14541
3-4 November 2014 | Paris, France | ID 14556
- **Good Management of Medical Devices**
23-25 June 2014 | Amsterdam, The Netherlands | ID 14536
- **EU Regulation of In Vitro Diagnostics (IVDs)** **NEW OFFERING!**
26 June 2014 | Amsterdam, The Netherlands | ID 14538
- **Health Technology Assessment (HTA)**
13-14 October 2014 | Paris, France | ID 14551
- **How to Prepare for your Meeting with Health Authorities**
14-15 October 2014 | Paris, France | ID 14546
- **Authorisation of Biopharmaceuticals, Biosimilars and Advanced Therapies in Europe**
22-24 October 2014 | London, United Kingdom | ID 14545
- **US Regulatory Affairs: A comprehensive review of regulatory procedures for INDs and NDAs in the US**
5-7 November 2014 | London, United Kingdom | ID 14554
- **Approval of generic medicines in the EU. Focus on CMC requirements and bioequivalence**
Date and location to be confirmed

Safety and Pharmacovigilance

- **Benefit/Risk Management**
19-20 May 2014 | Prague, Czech Republic | ID 14533
10-11 November 2014 | Barcelona, Spain | ID 14547
- **Signal Management in Pharmacovigilance**
21-22 May 2014 | Prague, Czech Republic | ID 14534
November 2014 | Paris, France | ID 14549
- **Pre-Marketing Clinical Safety**
16-17 June 2014 | Amsterdam, The Netherlands | ID 14539
- **Post-Authorisation Safety Studies (PASS)** **NEW OFFERING!**
18-19 June 2014 | Amsterdam, The Netherlands | ID 14535
- **Medical Approach in Diagnosis and Management of ADRs**
22-23 September 2014 | Paris, France | ID 14540
- **Diagnosis and Management of Drug-Induced Liver Injury (DILI)**
23-24 September 2014 | Paris, France | ID 14544
- **ICH Endorsed Pharmacovigilance**
21 October 2014 | Dakar, Senegal | ID 14559
November 2014 | Algiers, Algeria | ID 14560
- **How to Prepare for Pharmacovigilance Audits and Inspections**
November 2014 | Paris, France | ID 14550

European Medicines Agency Information Days and Courses

- **PSUR Information Day**
29 April 2014 | London, United Kingdom | ID 14504
- **ICSR Information Day**
13 May 2014 | London, United Kingdom | ID 14502
- **Excellence in Pharmacovigilance: Clinical trials and post-marketing**
13-17 October 2014 | London, United Kingdom | ID 14548
- **MedDRA Information Day**
November 2014 | London, United Kingdom
- **EnCePP Information Day**
Autumn 2014 | London, United Kingdom | ID 14503

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

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