Periodic Safety Update Report Information Day

28 October 2016
European Medicines Agency, London, United Kingdom

PROGRAMME COMMITTEE

Jolanta Gulbinovic
PRAC Member
Chief expert, Drug safety evaluation, safety surveillance, risk assessment and management, State Medicines Control Agency, Lithuania

Evdokia Korakianiti
Head of Procedure Management department, European Medicines Agency (EMA), EU

Anabela Luis de Lima Marcal
Head of Compliance and Inspections department, European Medicines Agency (EMA), EU

Klaudija Marijanovic Barac
Director, Director, Global Group Leader Risk Management, PLIVA Croatia Ltd., Croatia

June Raine
Pharmacovigilance Risk Assessment Committee (PRAC) Chair
Director of Vigilance and Risk Management of Medicines, Medicines and Healthcare products Regulatory Agency (MHRA), UK

Michael Richardson
VP International GPV&E and EU QPPV, Bristol-Myers Squibb, UK

Menno van der Elst
Alternate PRAC Member
Medicines Evaluation Board, The Netherlands

FACULTY

Kora H Doorduyn-van der Stoep
CMDh member (EU-representative)/Policy adviser, Medicines Evaluation Board, The Netherlands

Margarida Guimarães
PRAC Member
Directorate of Risk Management for Medicines, INFARMED, PT

Jean-Louis Hottart
Senior Specialist, Regulatory Affairs, Merck & Co., Inc., Belgium

David Lewis
Head of Pharmacovigilance, Novartis Pharma AG, Switzerland

Irene Rager
Head of Service E, Procedure Management Department, EMA, EU

Robin Ruepp
Procedure Management Department, EMA, EU

Craig Hartford
VP, Safety Surv & Risk Management, Worldwide Safety & Regulatory, W R&D., Pfizer, UK

Sue Rees
EU QPPV, Executive Director, Global Patient Safety, Amgen Ltd, UK

Ernesto Vera-Sanchez
Pharmacovigilance Inspector, AEMPS, Spain

Ana Zanoletty
Procedure Management Department, EMA, EU

OVERVIEW

This Information Day provides a forum between the EU Regulators and Industry to launch discussions on the PSUR Roadmap; a tool which is envisaged to progress the understanding of the PSUR as a key element in the medicinal product lifecycle, and its central role in the protection of public health. Understanding how to deliver the benefits achieved as a consequence of the re-focused PSUR to patients and healthcare professionals will also be tackled during the day in a session focusing on the implementation of PSUR outcomes.

The information day will provide a space to further understand the tools that Industry and regulators have available to deliver these benefits, such as the PSUR Repository and the EURD list. There will be two interactive sessions on the PSUR Repository during the lunch break where users of the PSUR Repository will be able to raise their questions and concerns with experts on the system from the EMA.

To close the loop on all aspects of the PSUR, the Information Day will have a session on the role of PSURs in Pharmacovigilance Inspections. During this session, a Pharmacovigilance inspector will share his experience with regards to how an inspection is conducted, as well as practical experience of the most common issues found - providing insight into how these can be avoided.

The Information day is therefore the coalescence of different initiatives, aiming to bring together different aspects of the PSUR, from its inception and creation, through its assessment and implementation of its outcomes, and the tools that we have at hand to support these processes, with the key object to align understanding of all these aspects.

KEY TOPICS

- Launch the PSUR Roadmap
- Share experiences on the preparation, assessment and follow up of PSURs:
  - o the refocused PSUR content and what the assessor expects
  - o the central role of critical appraisal
  - o understand the challenges faced when implementing the outcomes and optimising solutions to deliver key information to healthcare professionals and patients
- Share information on the practical tools which help deliver the benefits of the PSUR Roadmap:
  - o the main challenges using the PSUR Repository and how can these be resolved
  - o understand how the EURD list works and why it is key to the single assessment
- The industry and inspectors' expectations of a Pharmacovigilance inspection in relation to PSURs – experience and common issues

TARGET AUDIENCE

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

- Pharmacovigilance
- Clinical Development
- Regulatory Affairs
- Information Management
- Safety Databases

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DIA DEVELOP INNOVATE ADVANCE

08:00 **REGISTRATION**

08:40 **WELCOME AND INTRODUCTION**

Evdokia Korakianiti, EMA

08:45-09:25 **PHARMACOVIGILANCE THROUGH THE PRODUCT LIFECYCLE AND THE CRITICAL ROLE OF THE PSUR – HOW TO REACH A SHARED UNDERSTANDING AND SOLVING COMMON CHALLENGES**

08:45-09:05 **June Raine, MHRA**

09:05-09:25 **Michael Richardson, Bristol-Myers Squibb**

09:25-11:10 **SESSION 1**

PSUR ROADMAP – OPTIMISING THE SINGLE ASSESSMENT PROCEDURE FOR PSURS

Session chair:
Craig Hartford, Pfizer

09:25-09:40 **Introduction and background**
Irene Rager, EMA

09:40-10:10 **What is an ideal PSUR? – A new focus based on aligned expectations**
Margarida Guimarães, INFARMED

10:10-10:40 **The refocussed PSUR and a new approach to assessment**
Menno van der Elst, MEB

10:40-11:00 **How Industry can improve PSURs and achieve alignment of expectations**
David Lewis, Novartis

11:00-11:10 **Questions and panel discussion**

11:10-11:30 COFFEE BREAK

11:30-12:20 **SESSION 1 CONTINUED**

PSUR ROADMAP – OPTIMISING THE SINGLE ASSESSMENT PROCEDURE FOR PSURS

11:30-11:50 **Delivering the benefits of the new PSUR for healthcare professionals and patients – efficient and effective implementation – An Industry perspective**
Klaudija Marijanovic Barac, PLIVA

11:50-12:10 **Delivering the benefits of the new PSUR for healthcare professionals and patients – efficient and effective implementation – A Regulator's perspective**
Kora Doorduyn - van der Stoep, CMDh member, MEB

12:10-12:20 **Questions and panel discussion**

12:20-13:20 SANDWICH LUNCH

12:20-13:20 **PSUR REPOSITORY INTERACTIVE SESSION**

13:20-15:00 **SESSION 2**

TOOLS TO DELIVER THE BENEFITS OF THE NEW PSUR

Session co-chairs:
Klaudija Marijanovic-Barac, PLIVA
and **Irene Rager**, EMA

13:20-13:40 **Making best use of the PSUR Repository**
Ana Zanoletty, EMA

13:40-14:00 **Making best use of the PSUR Repository**
Jean Louis Hottart, MSD

14:00-14:20 **Optimising the use of the EURD list – the key to the single assessment**
Menno van der Elst, MEB

14:20-14:40 **Optimising the use of the EURD list – the key to the single assessment**
Robin Ruepp, EMA

14:40-14:50 **Questions and panel discussion**

14:50-15:10 COFFEE BREAK

15:10-16:20 **SESSION 3**

THE ROLE OF PSURS IN PHARMACOVIGILANCE INSPECTIONS – GETTING IT RIGHT AND PRACTICAL EXPERIENCE

Session Chair:
Anabela Luis de Lima Marçal, EMA

15:10-15:40 **The Inspector's experience**
Ernesto Vera-Sanchez, AEMPS

15:40-16:10 **The Industry experience**
Sue Rees, Amgen

16:10-16:20 **Questions and panel discussion**

16:20-16:30 **CLOSING REMARKS**
Evdokia Korakianiti, EMA

16:30 **END OF INFORMATION DAY**

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

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.

REGISTRATION FORM

Periodic Safety Update Report Information Day
28 October 2016 | European Medicines Agency, London, United Kingdom

ID #16598

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 #16598 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

Cancellation Policy

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

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 EMEA 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 EMEA in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

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.
Tel. :+41 61 225 51 51 Fax: +41 61 225 51 52
Email: EMEA@DIAglobal.org Mail: DIA Europe, Middle East & Africa, Küchengasse 16, 4051 Basel, Switzerland Web: www.DIAglobal.org

© DIA 2016