Joint EMA/DIA Information Day on Risk Management Planning

30 June 2015
European Medicines Agency
30 Churchill Place, Canary Wharf, London E14 5EU, UK

NEED FOR THIS RISK MANAGEMENT PLANS (RMPS) INFORMATION DAY

The Pharmacovigilance Risk Assessment Committee (PRAC) has been operational since the implementation of the Pharmacovigilance Legislation in July 2012. Pharmacovigilance guidelines are in place specific for the area of risk management. Three years on, this Information Day is aimed primarily at providing marketing authorisation holders (MAHs) and marketing authorisation applicants (MAAs) with insights and learnings from PRAC regarding key factors contributing to successful risk management.

The day's focus will be on quality aspects of risk management planning to meet the requirements for risk management plans both for the benefit of European public health and in terms of the regulatory aspects. Practical examples will be used to illustrate the matters highlighted.

Additionally, experience with the evaluation of RMPs and Post authorisation safety studies (PASS) protocols, both for innovative and for generic products, has led to the recognised need to fine tune some of the guidance and processes. This information day will inform participants about changes to come.

KEY TOPICS

- Develop risk management plans of high quality
- Post authorisation safety studies (PASS): submitting a successful study protocol
- Plan risk minimisation in a European environment with different health care systems, languages and cultures
- Revision of "Good Pharmacovigilance Guideline (GPV) V – Risk Management"

TARGET AUDIENCE

Professionals working in the area of:

- Qualified Persons responsible for Pharmacovigilance (QPPVs)
- Assessors at National Competent Authorities (NCAs)
- Individuals involved in risk management planning, risk minimisation development and post authorisation safety studies at small to medium enterprises (SMEs), MAAs/ MAHs for generic products, MAAs/MAHs for innovator products and Contract Research Organisations

1995 2015 EMA

EUROPEAN MEDICINES AGENCY
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DIA DEVELOP INNOVATE ADVANCE

PROGRAMME COMMITTEE

Enrica Alteri
Head, Human Medicines Evaluation Division, EMA, EU

Peter Arlett
Head, Pharmacovigilance Department, EMA, EU

Almath Spooner
Vice Chair of the EMA's Pharmacovigilance Risk Assessment Committee (PRAC)
Pharmacovigilance and Risk Management Lead, Health Products Regulatory Authority (HPRA), IE

Sabine Straus
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Medicines Evaluation Board (MEB), NL

FACULTY

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Dr. Reddy's Laboratories Ltd., UK

Julie Beynon
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Kora Doorduyn-van der Stoep
CMDh member (EU-representative) / Policy adviser; Medicines Evaluation Board (MEB), NL

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Senior Director, Regulatory Policy and Intelligence, AbbVie, UK

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QPPV and Head of Affiliate Vigilance Excellence, AbbVie, UK

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LOCATION

European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom

Capacity: The event is limited to 110 participants.

HOTEL INFORMATION

Attendees are kindly requested to make their own hotel reservation.

Recommended hotel:
Hilton London Docklands Riverside
265 Rotherhithe Street
London SE16 5HW
Tel: +44 20 7231 1001
Fax: +44 20 7231 0599
Email: reservations.docklands@hilton.com

08:30 **REGISTRATION**

08:45 **WELCOME NOTE**

Enrica Alteri, Head, Human Medicines Evaluation Division, EMA, EU

09:00 **SESSION 1**

RISK MANAGEMENT PLANS: GETTING IT RIGHT

Co-chairs: **Julie Beynon,** MHRA and **Corinne de Vries,** EMA

In this session, experience with Risk Management Plan development and assessment since the implementation of the PhV legislation in July 2012 will be presented with a focus on learnings on good risk management planning both for innovative and generic medicines, plus some recent developments to help facilitate the development and implementation of RMPs for generic products.

Lessons learned from PRAC experience with Risk Management Plans
Almath Spooner, HPRA, IE

Reflections on risk management for generic products
Kora Doorduyn -van der Stoep, MEB, NL

Risk management for generic products – a perspective from industry
John Barber, Dr. Reddy's Laboratories Ltd., UK

10:30 **COFFEE BREAK**

11:00 **SESSION 2**

SUCCESS FACTORS FOR RISK MINIMISATION IN EUROPE

Co-chairs: **John Barber,** Dr. Reddy's Laboratories Ltd and **Luis Prieto,** EMA

This session will focus on the considerations and challenges when considering the implementation of additional risk minimisation measures in a European context of multiple languages and different health care systems, with specific learnings regarding the management of risks associated with medication errors. The session will use practical examples to illustrate some of the learnings and opportunities

Managing risks associated with medication errors: insulins as an example
Julie Beynon, MHRA, UK

Considerations regarding additional risk minimisation activities in a European context - regulatory perspective
Corinne de Vries, EMA, EU

Considerations regarding additional risk minimisation activities in a European context - industry perspective
Vicki Edwards, AbbVie, UK

12:30 **SANDWICH LUNCH**

13:30 **SESSION 3**

KEYS TO SUCCESS FOR POST AUTHORISATION STUDY PROTOCOLS

Co-chairs: **Almath Spooner,** HPRA, and **Giampiero Mazzaglia,** EMA

Speakers in this session will present highlights regarding what makes for a successful study protocol for PASS and opportunities for studying drug utilisation and drug safety for the purposes of Risk Management in a European context. In addition, challenges with some study objectives will be presented as examples, plus suggestions regarding alternative approaches to address questions when traditional approaches may not be feasible.

Lessons learned from PRAC experience with PASS protocols
Valerie Strassmann, BfArM, DE

Experience with EU research networks for PASS
Xavier Kurz, EMA, EU

Evaluating medicine safety in the context of Risk Management – industry perspective
David Gillen, Celgene Europe Ltd, UK

15:00 **COFFEE BREAK**

15:30 **SESSION 4**

GVP V REVISION FOR PUBLIC CONSULTATION

Co-chairs: **Peter Arlett,** EMA, and **Emma Du Four,** AbbVie

Having had the experience of developing, assessing and implementing RMPs with the GVP V over the past three years, lessons have been learned and opportunities recognised regarding how to improve the Guidance. Input from stakeholders has been used to work on a major revision of the GVP V, which will go out for public consultation. This session provides an overview of the eight areas of focus for the revision, with a more in-depth discussion of three of these areas, and a panel discussion at the end of the session.

Overview of eight major areas of focus in the GVP V update based on PRAC and industry feedback – Sneak preview of guidance update for three of the major topic areas
Emil Cochino, EMA, EU

Reflections from PRAC
Almath Spooner, HPRA, IE

Panel discussion

17:00 **END OF THIS INFORMATION DAY**

REGISTRATION FORM

Joint EMA/DIA Information Day on Risk Management Planning
30 June 2015, European Medicines Agency, London, United Kingdom

ID#15523

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
Online Registration Available at www.DIAglobal.org. Go to Meetings and Events

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.

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

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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.
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