DIA Pharmacovigilance Conference

10-11 May 2017

Chelsea Harbour Hotel, London, UK

PROGRAMME COMMITTEE

Gaby Danan
Pharmacovigilance Expert, France

Maarten Lagendijk
Pharmacovigilance Coordinator, Medicines Evaluation Board (MEB), Netherlands

Stephanie Millican
Senior Scientific Assessor, Medicines & Healthcare Products Regulatory Agency (MHRA), UK

Margaret Walters
Deputy EU Qualified Person for Pharmacovigilance, MSD, UK

OVERVIEW

Changes in pharmacovigilance activities in and outside Europe have prompted new challenges for all stakeholders. Methodologies used in risk management are evolving and becoming increasingly accurate in addressing potential and identified risks.

Join the Pharmacovigilance Conference to discuss paths forward and formulate answers to **key questions**:

1. **Benefit-risk assessment** - What and how to do in practice?
2. What are the **key pharmacovigilance inspection trends**, plus options for improving organisation and processes - including the role of the EU QPPV and the Pharmacovigilance System Master File (PSMF)?
3. What progress and insights have been made within new EU project **WEB-RADR on pharmacovigilance and social media**?
4. What are the current regulatory and practical challenges of the **Risk Management Plan** and can potential improvements be identified?
5. How do the latest **Pharmacoepidemiological** approaches support risk management?

The conference format is designed to **stimulate dialogue** and **generate solutions** through a series of **interactive sessions and workshops** conducted in an informal setting allowing for in-depth discussion in smaller groups.

Day 1: **Workshops** dedicated to collaboration with experts and colleagues on benefit-risk assessment and differing approaches to the implementation of the regulation changes

Day 2 Morning: **Interactive Presentations** on Risk Management and Pharmacovigilance Plans

Day 2 Afternoon: **Workshop on Risk Minimisation Measures**, with several experts from industry, academia and regulatory authorities convening to discuss the current issues and propose different approaches

WHAT YOU WILL LEARN

- How to assess benefit-risk in practice
- How to implement the new EV rules
- How to improve inspection outcomes
- How to manage signals with access to EV and, in the future, to social media
- Which pharmacoepidemiological methods are appropriate for supporting risk management
- How to evaluate the effectiveness of risk minimisation measures

WHO SHOULD ATTEND?

Established professionals who are seeking to improve practical skills in key areas in pharmacovigilance, including:

- Signal management
- Pharmacoepidemiology
- Risk Management Plan
- Benefit-risk assessment
- Quality assurance

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DAY ONE I WEDNESDAY, 10 MAY

08:00 REGISTRATION AND WELCOME COFFEE

WORKSHOPS ON BENEFIT-RISK ASSESSMENT IN PRACTICE

Choose one of these Parallel Workshops

09:00 SESSION 1A

WORKSHOP ON BENEFIT-RISK ASSESSMENT IN PSUR: DISCUSSION ON PRACTICES

Co-Leaders:
Sarah Morgan, Benefit-Risk Management, Group Manager, MHRA, UK
Doris Stenver, PRAC Member, Chief Medical Officer, Danish Medicines Agency, Denmark

In the PSUR it is expected to provide a practical evaluation of the benefit-risk of the medicinal product. This evaluation is frequently given in general terms. How could we improve and present this assessment taking into consideration a competent authority and PRAC expectations?

SESSION 1B

WORKSHOP ON BENEFIT-RISK KEY DRIVERS

Co-Leaders:
Shahrul Mt-Isa, Associate Principal Scientist, Biostatistics, MSD, UK
Kaatje Bollaerts, Biostatistician, IMI Coordinator, P-95, Belgium

Depending on the medicinal product what would be the best key drivers to assess the benefit-risk and how should this assessment should be updated over time?

10:30 COFFEE BREAK

WORKSHOPS ON EV ACCESS IMPLEMENTATION AND PSMF CHALLENGES

Choose one of these Parallel Workshops

11:00 SESSION 2A

WORKSHOP ON IMPLEMENTATION EXPERIENCE AND CHALLENGES AS EV ACCESS IS GAINED

Co-Leaders:
Margaret Walters, Deputy EU Qualified Person for Pharmacovigilance, MSD, UK
Sabine Brosch, Principal Scientific Administrator, European Medicines Agency (EMA), EU

Based on examples of EudraVigilance (EV) readiness preparation to date, participants will take part in an interactive session aimed at identifying best practices and sharing potential solutions to practical challenges.

SESSION 2B

WORKSHOP ON HOW TO OPTIMISE HAVING MULTIPLE PSMFS

Co-Leaders:
Maria Wishart, Deputy EU Qualified Person for Pharmacovigilance, AstraZeneca, UK
Dionne Usher, Senior Specialist, EU QPPV Office, MSD, UK

EU, non-EU, License Partner... just to name a few pharmacovigilance system master files (PSMFs) that we need to align, produce and track. How are companies approaching the increasing demand for PSMFs?

12:30 LUNCH

14:00 SESSION 3

WORKSHOPS WRAP-UP FOR DAY 1

Leader:
Margaret Walters, Deputy EU Qualified Person for Pharmacovigilance, MSD, UK

Leaders, discussants and attendees from all 4 workshops will convene in one group to review, compare and discuss key learnings from the workshops.

- Benefit-Risk Assessment in PSUR: Discussion on Practices
- Benefit-Risk Key Drivers
- Implementation Experience and Challenges as EV Access is Gained
- How to Optimise Having Multiple PSMFs

15:30 COFFEE BREAK

16:00 SESSION 4

PHARMACOVIGILANCE AND SOCIAL MEDIA

Co-Chairs:
Phil Tregunno, Signal Management Unit Manager, Medicines & Healthcare products Regulatory Agency (MHRA), UK
Sabine Brosch, Principal Scientific Administrator, European Medicines Agency (EMA), EU

The session will discuss how social media can be used for pharmacovigilance system - what are the points to consider from a regulator perspective and what best practices have been identified until now?

17:30 END OF DAY 1

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DAY TWO | THURSDAY, 11 MAY

09:00 SESSION 5

RISK MANAGEMENT PLAN: CHALLENGES AND OPPORTUNITIES

Co-chairs:
Doris Stenver, PRAC Member, Chief Medical Officer, Danish Medicines Agency, Denmark
Jan Petracek, CEO European Pharminvent Services, Czech Republic

The guidelines for risk management plans (RMPs) evolved over time but there are still some questions on the content and how to develop it. What are the expectations of the PRAC? How it is assessed by the authorities? What are the main weaknesses of the RMPs provided by the license holders and how to improve them?

RMP Experiences – A PRAC Perspective
Doris Stenver, PRAC Member, Chief Medical Officer, Danish Medicines Agency, Denmark

Lessons Learned from 100 EU-RMPs Submitted 2013-2017 - Will the New EU GVP Module V Help?
Jan Petracek, CEO European Pharminvent Services, Czech Republic

Practical Aspects of EU RMP for Generics
Olga Mariscal, EU QPPV, Cinfa, Spain

10:30 COFFEE BREAK

11:00 SESSION 6

PHARMACOEPIDEMIOLOGICAL STUDIES FOR PHARMACOVIGILANCE PLAN

Co-Chairs:
Katherine Donegan, Pharmacoepidemiology Research & Intelligence Unit Manager, Medicines & Healthcare products Regulatory Agency (MHRA), UK
Steve Hobbiger, Vice President and QPPV, R&D, GSK, UK

Studies proposed in a pharmacovigilance plan aim to characterise the main adverse drug reactions (ADRs) to be followed in the life cycle of medicinal products. With some examples, pros and cons of the methods to be used in pharmacovigilance plans will be presented.

Marianne Cunnington, Senior Director and Therapy Area Lead, GSK, UK

12:30 LUNCH

14:00 SESSION 7

WORKSHOP ON RISK MINIMISATION MEASURES AND EFFECTIVENESS EVALUATION

Co-Leaders:
Maarten Lagendijk, Pharmacovigilance Coordinator, Medicines Evaluation Board (MEB), Netherlands
Inge M. Zomerdijk, Pharmacovigilance Assessor, Medicines Evaluation Board (MEB), Netherlands

The 3-hour intensive workshop will look into detailed practices in risk minimisation and give insights to effectiveness evaluation from both regulator and industry perspective.

17:30 END OF CONFERENCE

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.

Conference Venue

Chelsea Harbour Hotel
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United Kingdom

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E: events.chelseaharbour@millenniumhotels.co.uk

Exhibition Opportunities

The Pharmacovigilance Workshop Series Conference & Exhibition offers the possibility to a limited number of company exhibition opportunities at this event. Showcase your product or service to a truly global audience of qualified professionals, from entry level to expert, in the pharmaceutical, biotechnology, devices and related healthcare industries, government, academia and healthcare delivery.

Exhibit Booths put you and your products directly in front of decision makers who are or can become your customers. For more information, or to sign up, contact: EMEA.Exhibition@DIAglobal.org

REGISTRATION FORM | ID# 17108

Pharmacovigilance Conference | 10-11 May 2017 | Chelsea Harbour Hotel, London, UK

DIA

Early-bird discount available for members: Register by 11 April 2017

To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above.

Early-bird fee applies to industry members only. **€ 1'230.00** ❑

CATEGORY	Member *	Non-Member*
Industry	€ 1'430.00 ❑	€ 1'585.00 ❑
Government/Charitable/Non-profit/Academia (Full-Time)	€ 715.00 ❑	€ 870.00 ❑
TUTORIAL: Introduction to the role of the QPPV - 09 May 2017	€ 400.00 ❑	€ 400.00 ❑

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee . Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to avaibility. Please contact DIA EMEA for more information.
Registration fee includes: refreshments, lunches, reception and meeting materials.

*All fees are subject to the applicable VAT. Payment 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 MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE ATTENDEE'S BUSINESS CARD HERE

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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, Middle East and Africa.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or online by clicking **here.**

Date	Signature

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All cancellations must be made in writing and be received at the DIA Europe, Middle East and Africa office four weeks prior to the event start date. Cancellations are subject to an administrative fee:

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

For cancellations after this date, or if the delegate fails to attend the meeting, no refund of fees will be given and 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, 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 and Video 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 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 Center will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.

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