6th European Forum for Qualified Person for Pharmacovigilance (QPPV)

Event #12104
24-26 April 2012
Hilton London Docklands Riverside Hotel, London, UK

Conference Co-Chairs

Vicki Edwards
Senior Director, European Pharmacovigilance
Abbott Laboratories, UK

Michael Richardson
Vice President GPV&E and EU QPPV
Bristol-Myers Squibb Pharmaceuticals Ltd., UK

Programme Committee

Barbara De Bernardi
Qualified Person Deputy, Pfizer Italy, Italy

Peter De Veene
EU QPPV, F. Hoffmann-La Roche Ltd., UK

Brian Edwards
Principal Consultant, Pharmacovigilance and Drug Safety, NDA Regulatory Science Ltd., UK

Elspeth McIntosh
Director, Castle Pharmacovigilance Limited, UK

Margaret Walters
Director & Deputy EU QPPV, Merck Sharp & Dohme Ltd., UK

EU QPPV
Pre-conference Workshop
Tuesday, 24 April 2012
13:00 - 18:00

Overview

This year's conference's focuses on the new EU pharmacovigilance legislation and on its potential impact on the EU QPPV. The opening session will explore the practical challenges of implementation, some legal aspects and explain how the new Committees and Procedures will impact how we work.

The sessions that follow include:

- **QUALITY MATTERS**
  QPPVs will receive the latest information on the development of PSMFs, some practical advice on implementing quality systems in PV and an update on findings of interest from recent inspections.

- **MANAGING THE 'HOUSE OF CARDS': HOW TO COPE WITH GLOBALISATION AND TECHNOLOGY**
  Hear the latest tips and share experiences.

- **CURRENT TRENDS**
  This session will explore the challenges posed and opportunities presented for pharmacovigilance by new technologies such as social media.

- **EU LEGISLATION: STRONGER, MORE EFFICIENT AND MORE TRANSPARENT? BUT WHERE DOES THE QPPV FIT IN?**
  Put your questions to an expert panel.

- **MOVING FROM SAFETY REPORTING TO BENEFIT: RISK EVALUATION**
  An overview of the main changes in and insights on benefit/ risk and signal detection activities.

- **BENEFIT/RISK MANAGEMENT**
  Regulators and industry reveal how the science of post-authorisation effectiveness measurement has progressed and its impact on the QPPV's oversight of the pharmacovigilance system.

- **CHALLENGES OF CHANGING LEGISLATION ON OVERSIGHT ROLE OF THE QPPV**
  - Receive specific examples of current divergence in expectation at the national level
  - Discuss how a QPPV can best monitor for and address any varying expectations as the upcoming implementation progresses
  - Explore whether or not the QPPV will need new skills/training in the new world.

Who Will Attend

- European Qualified Persons for Pharmacovigilance
- Deputy Qualified Persons
- Senior pharmacovigilance regulators and inspectors
- CRO and consultants providing QPPV services
- National responsible persons for pharmacovigilance

Continuing Education

DIA meetings are generally approved by the SwAPP (Swiss Association of Pharmaceutical Professionals), Commission for Professional Development (CPD) and SGPM (Swiss Society of Pharmaceutical Medicine) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for these credits and certificates are available on request from the registration desk.

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TUESDAY | 24 APRIL 2012

EU QPPV PRE-CONFERENCE WORKSHOP

Workshop Co-Chairs:
Janet Hormbrey
Executive Director, EU QPPV, For Risk Management & Pharmacovigilance, Merck Sharp & Dohme Inc., Belgium
Elspeth McIntosh
Director, Castle Pharmacovigilance Ltd., UK

This workshop is aimed to those EU QPPVs who are new to the role, those who support the QPPV and those who are thinking of taking on a QPPV role. The session will focus on providing an understanding of the QPPV role, the practical issues facing QPPVs in a range of company sizes and types, what skills and knowledge you need for the role, and legal considerations for QPPVs.

12:30 REGISTRATION AND WELCOME COFFEE / SANDWICH LUNCH

13:00 **Session 1**

Overview of the QPPV Role
Elspeth McIntosh, Director, Castle Pharmacovigilance Ltd., UK

Practicalities of Life as a Big Company QPPV (tips on QPPV oversight)
Janet Hormbrey, Executive Director, EU QPPV, For Risk Management & Pharmacovigilance, Merck Sharp & Dohme Inc., Belgium

Practicalities of Life as a Small company QPPV (meeting the same standards with less)
Jeff Guillon, Pharmacovigilance Manager and EU QPPV, Alliance Pharmaceuticals, UK

14:30 COFFEE BREAK

14:45 **Session 2**

Special Considerations for a QPPV in a Non-EU Company
Karen Pattenden, Senior Director Drug Safety & Public Health/EU QPPV, Gilead, UK

Special Considerations for Contract QPPVs
Deirdre McCarthy, Director, Customer Delivery Europe, Lifecycle Safety & Infrastructure Management, Quintiles, Ireland

Skills and Technical Training for the QPPV Role
Elspeth McIntosh, Director, Castle Pharmacovigilance Ltd., UK

16:15 COFFEE BREAK

16:30 **Session 3**

QPPV Legal Issues - Contracts, indemnity, the impact of new legislation on QPPVs
Chris Foreman, Director, Legal Affairs, Scandinavian Region, MSD, Belgium

Panel Discussion
With all session speakers

18:00 END OF WORKSHOP

WEDNESDAY | 25 APRIL 2012

START OF QPPV CONFERENCE

08:00 REGISTRATION AND WELCOME COFFEE

08:45 **Session 1**

OVERVIEW OF CHALLENGES OF THE NEW LEGISLATION
Session Chairperson:
Vicki Edwards, Senior Director, European Pharmacovigilance, Abbott Laboratories, UK

The new EU pharmacovigilance legislation represents the biggest change in this area since 1995. This legislation will significantly alter the way we monitor safety of medicines as we consider safety in the context of benefit. The theme of this conference is to look at the new legislation and focus on the potential impact this will have on the EU QPPV.

This first session will explore the practical challenges of implementation, some legal aspects and explain how the new Committees and Procedures will impact how we work.

Welcome and Introduction
Vicki Edwards, Senior Director, European Pharmacovigilance, Abbott Laboratories, UK

Overview of Challenges of the New Legislation / Transition Measures / Practical Implications
Government representative invited

Implications of Terminology for Implementation of New Legislation
Christine Bendall, Consultant, Arnold & Porter (UK) LLP Solicitors, UK

Potential Impact of New Committees and Procedures
Anthony Humphreys, Head of Regulatory, Procedural and Committee Support, European Medicines Agency, EU

Panel Discussion
With session chair and session speakers

10:30 COFFEE BREAK

11:00 **Session 2**

QUALITY MATTERS
Session Chairperson:
Elspeth McIntosh, Director, Castle Pharmacovigilance Limited, UK

Pharmacovigilance Systems Master Files, being introduced to replace the DDPS, and the introduction of formal PV Quality Systems, are intended to strengthen oversight and improve compliance in all areas of PV. This session will provide QPPVs with the latest information on the development of PSMFs, some practical input around the implementation of quality systems in PV and an update on finding of interest from recent inspections.

Pharmacovigilance System Master File
Joanna Harper, Pharmacovigilance Inspector, IE&S Division, Medicines and Healthcare products Regulatory Agency (MHRA), UK

Quality Management System
Monika Pietrek, Managing Director, Pietrek Associates GmbH, Germany

Inspections – Recent findings and impact of new legislation
Joanna Harper, Pharmacovigilance Inspector, IE&S Division, Medicines and Healthcare products Regulatory Agency (MHRA), UK

Panel Discussion
With session chair and session speakers

12:30 LUNCH BREAK

14:00 **Session 3**

MANAGING THE 'HOUSE OF CARDS': HOW TO COPE WITH GLOBALISATION AND TECHNOLOGY

Session Chairperson:
Brian Edwards, Principal Consultant, Pharmacovigilance and Drug Safety, NDA Regulatory Science Ltd., UK

By 2 July 2012, all MAHs must have submitted information to the EMA electronically on all medicinal products for human use authorised or registered in the EU.

Find out why this matters to public safety and should thus concern the QPPV. For many products authorised in the EU the system is truly global. Key PV activities and pivotal studies are often placed outside the EU. Changes in regulations throughout the world impact how product risk is managed. What is the latest thinking about how the QPPV can cope in this changing environment? Come and find out what tips can be learnt and experiences shared.

ISO Standards: Art 57 – What does the QPPV need to be aware of?
Joerg Seebeck, Parexel International, Germany

Safety Technology: What does the QPPV need to know?
Barry Burnstead, Consultant, SelectCRO, UK

Global: How to maintain the PV system in diverging regulatory environments?
Laurent Auclert, EU QPPV, Sanofi, France

15:30 COFFEE BREAK

16:00 **Session 4**

CURRENT TRENDS

Session Chairperson:
Vicki Edwards, Senior Director, European Pharmacovigilance, Abbott Laboratories, UK

New technologies have brought us into the world of social media where news travels fast. From a pharmacovigilance perspective this presents us with challenges as legislation struggles to keep up with the impact of these current technologies but is it all bad news? Does this new era actually present opportunities for pharmacovigilance? This session will explore these opportunities and the involvement of the QPPV.

Social Media-listening – Are there opportunities?
Additional presenter invited

Patient Support Programmes/ Market Research – How involved should the QPPV be?
Sally Okun, Health Data Integrity & Patient Safety, PatientsLikeMe Inc., USA

Internet-initiated Research
Additional presenter invited

17:30 RECEPTION

18:30 END OF DAY 1

THURSDAY | 26 APRIL 2012

08:00 REGISTRATION AND WELCOME COFFEE

08:45 **Session 5**

EU LEGISLATION: STRONGER, MORE EFFICIENT AND MORE TRANSPARENT? BUT WHERE DOES THE QPPV FIT IN?

Session Chairperson:
Peter De Veene, EU QPPV, F. Hoffmann-La Roche Ltd., UK

The implementation of the new EU PV legislation is in full preparation promising to making PV stronger and more efficient and at the same time increasing transparency.

Learn from regulators and industry how the new provisions, with more focus on evaluating benefit/risk throughout the lifecycle of the products, will change the face of Pharmacovigilance and what the key impact is for you as QPPV. This session will also provide you the opportunity to ask your questions to an expert panel.

Introduction to the Day
Michael Richardson, International Head of GPV&E and EU QPPV, Bristol-Myers Squibb Pharmaceuticals Ltd., UK

Setting the Scene
Peter Arlett, Head of Pharmacovigilance and Risk Management, European Medicines Agency, EU

EU Legislation goes beyond Safety Risk Management
Peter De Veene, EU QPPV, F. Hoffmann-La Roche Ltd., UK

Impact assessment – View from a generics company
Balwant Heer, EU QPPV, Mylan, UK

Panel Discussion
With session chair and session speakers

10:30 COFFEE BREAK

11:00 **Session 6**

MOVING FROM SAFETY REPORTING TO BENEFIT: RISK EVALUATION

Session Chairperson:
Barbara De Bernardi, Qualified Person Deputy, Pfizer Italy, Italy

The New Legislation has significantly changed the requirements for PSURs and has shifted their main focus on the benefit risk evaluation. This section will provide an overview of the main changes and also insights on benefit/ risk and signal detection activities.

Overview of ICH E2C(R)
Valerie Simmons, EU QPPV Executive, Global Patient Safety, Eli Lilly and Company Ltd., UK

Challenges in Benefit/Risk Management
Patrizia Cavazzoni, Senior Vice President, Worldwide Safety Strategy, Pfizer Inc., USA

12:30 LUNCH BREAK

13:30 **Session 7**

BENEFIT/RISK MANAGEMENT

Session Chairperson:
Michael Richardson, International Head of GPV&E and EU QPPV, Bristol-Myers Squibb Pharmaceuticals Ltd., UK

Benefit/Risk management has moved centre stage to ensure ongoing evaluation of medicines throughout their lifecycle.
The science of post authorisation effectiveness measurement has made big strides and balancing this with risk minimisation effectiveness has brought significant requirements for managing the B/R profile. Hear from Regulators and Industry how this has progressed and its impact on the QPPV's oversight of the pharmacovigilance system.

Risk Management Plans – Is there a significant change?
Michael Richardson, International Head of GPV&E and EU QPPV, Bristol-Myers Squibb Pharmaceuticals Ltd., UK

Real World Data – Effectiveness
Sally Okun, Health Data Integrity & Patient Safety, PatientsLikeMe Inc., USA

Measuring Effectiveness of Risk Minimisation
Swapu Banerjee, Board Member and Head of Development, Pope Woodhead & Associates Ltd., UK

15:00 COFFEE BREAK

15:30 **Session 8**

CHALLENGES OF CHANGING LEGISLATION ON OVERSIGHT ROLE OF THE QPPV

Session Chairperson:
Margaret Walters, Director & Deputy EU QPPV, Merck Sharp & Dohme Ltd., UK

The draft GVP Modules currently states that the QPPV is a 'natural person', and that this individual must have oversight of the MAHs Pharmacovigilance System. In order to effectively fill the role of this natural person we must seek to understand the physiology i.e. how much does the QPPV needs to be a hands-on person, what should he/she delegate or not delegate, where to rely on the MAH, where does the QPPV fit in an organisation (small, medium, big), within PV outside PV, what is oversight (signing off on everything?), what phenotype does the new B/R QPPV need to have. This final session will aim explore this and to bring together the various topics presented from the QPPV perspective over the two days.

An Individual Company View on QPPV Oversight
Maria Wishart, Deputy QPPV, Physician Director Safety Governance, GlaxoSmithKline, UK

Feedback from an In-Meeting Survey on Current QPPV Oversight
Margaret Walters, Director & Deputy EU QPPV, Merck Sharp & Dohme Ltd., UK

Panel Discussion: In the new world does the QPPV need new/ different skills?
With session chair and session speakers

Closing Remarks
Vicki Edwards, Senior Director, European Pharmacovigilance, Abbott Laboratories, UK

17:00 WRAP UP AND END OF CONFERENCE

About DIA

The DIA is a global association of approximately 18,000 members who are involved in the discovery, development, regulation, surveillance or marketing of pharmaceuticals or related products. The DIA is committed to the broad dissemination of information on the development of new medicines or generics, biosimilars, medical devices and combination products with continuously improved professional practice as the goal.

The DIA is an independent non-profit organisation. The voluntary efforts of DIA members and speakers allow the DIA to organise conferences, workshops and training courses and provide publications at a reasonable, competitive cost.

DIA's headquarters are in Horsham, PA, USA, with the European office in Basel, Switzerland, and other regional offices in Tokyo, Japan, Mumbai, India, and Beijing, China.

For more information, visit www.diahome.org or call DIA Europe +41 61 225 51 51.

TRAVEL INFORMATION

London Gatwick Airport / Stansted Airport
Please use this link to get directions to the Hilton London Docklands Riverside Hotel: http://www1.hilton.com/en_US/hi/hotel/LONNDHI-Hilton-London-Docklands-Riverside/directions.do#localairports

London City Airport
Take the DLR train to Bank DLR Station, change platform at Poplar DLR Station towards Lewisham DLR Station or change to the Underground Jubilee Line towards Stanmore at Canning Town. Leave at Canary Wharf Station and walk to the Canary Wharf Pier. Take the complimentary ferry service (for hotel guests only) to cross the river Thames to arrive at the Hilton London Docklands Riverside Hotel.
The hotel is no longer allowed to operate the courtesy bus service to Canada Water. If you wish to use Canada Water Station, please use the C10 public bus service that stops outside the hotel. The stop is displayed and announced as the Hilton London Docklands Riverside.

For more details please visit: www.tfl.gov.uk

HOTEL INFORMATION

The DIA has blocked a number of rooms at the:

Hilton London Docklands Riverside Hotel
265 Rotherhithe Street
London SE16 5HW, UK
http://www1.hilton.com/en_US/hi/hotel/LONNDHI-Hilton-London-Docklands-Riverside/index.do

at the special rate of:
£ 170.00 for room only, exclusive of VAT
Breakfast vouchers available at £15.00

Group Name: Drug Information Association European Office
Group Code: GDIAA

To make your reservation please use this link: http://www.hilton.com/en/hi/groups/personalized/L/LONNDHI-GDIAA-20120423/index.jhtml?WT.mc_id=POG

Or call the reservation team:+44 (0) 207 2311001

Important: Please complete your reservations by 26 March 2012 at the latest. Reservations received after this date will be subject to hotel availability and room rate may vary.

In case of cancellation:
Cancellation of the hotel booking must be made in writing directly to the hotel 48 hours prior to the arrival date. Cancellations made at least 48 hours prior to arrival will not incur any cancellation charges. Any cancellation made less than 48 hours prior to arrival will be subject to the first night being charged at the full agreed rate. All no shows will be billed for the entire stay.

REGISTRATION FORM

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24-26 April 2012 | Hilton London Docklands Riverside Hotel, London, UK

ID # 12104

DIA www.diahome.org

If DIA Europe cannot verify your membership upon receipt of the registration form, you will be charged the non-member fee. Registration fees are inclusive of lunch and coffee breaks and other catering services to the amount of € 125.00.

CATEGORY	Member (after 13 March 2012)	FEE
Industry		€ 1'365.00 ❑
Academia /Government /Non-profit (Full-Time)		€ 683.00 ❑
I wish to attend the EU QPPV Pre-Conference Workshop		€ 300.00 ❑

Non-Member	FEE
Industry	€ 1'480.00 ❑
Academia /Government /Non-profit (Full-Time)	€ 798.00 ❑

A one-year membership to DIA is available to those paying a non-member registration. If paying a non-member fee, please indicate if you do, or do not wish to become a member: YES___ NO___

TOTAL AMOUNT DUE: €_____ **NOTE: PAYMENT IS DUE 30 DAYS AFTER REGISTRATION AND MUST BE PAID IN FULL BY COMMENCEMENT OF THE EVENT**

STUDENT, GROUP DISCOUNTS AND SME RATES ARE AVAILABLE! PLEASE CONTACT DIA EUROPE FOR MORE INFORMATION. 12104DIAWEB

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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DIA Europe, Kuechengasse 16, Postfach, 4002 Basel, Switzerland

❑ Bank transfers: When DIA Europe 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# 12104 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.

CANCELLATION POLICY: All cancellations must be in writing and received with DIA Europe by 17:00 CET on 16 April 2012.

Cancellations are subject to an administrative fee:

Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00. Academia/Government/Non-profit (Member/non-member) = € 100.00. Tutorial cancellation: € 50.00. If you do not cancel by the date above 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 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 DIA Europe office of any such substitutions as soon as possible.

IMPORTANT: Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA Europe. If you have not received your confirmation within five working days, please contact DIA Europe.

HOW TO REGISTER

The DIA Europe Customer Services Team will be pleased to assist you with your registration. Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET.

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