7th European Forum for Qualified Person for Pharmacovigilance (QPPV)

Event #13104
17-18 April 2013
Hotel Holiday Inn Bloomsbury, London, UK
16 April 2013 - Pre-Conference Workshop

Programme Co-Chairs

Vicki Edwards
QPPV and Head of Affiliate Vigilance Excellence, Global Pharmacovigilance and Global Medical Services, AbbVie, UK

Michael Richardson
International Head of 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, Switzerland

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Maarten A.C. Lagendijk
Pharmacovigilance Coordinator, Pharmacovigilance Department, Medicines Evaluation Board (MEB), the Netherlands

Elspeth McIntosh
Director, Castle Pharmacovigilance Limited, UK

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

EU QPPV
Pre-Conference Workshop
Tuesday, 16 April 2013
13:00 - 18:00
Register for only € 300

Overview

In an ever changing regulatory environment it is vital to remain abreast of any changes likely to impact on the QPPV's essential role. Such changes may arise from updates to European requirements or those of the regulatory authorities outside of the EEA (e.g. FDA) or from cross-regional initiatives such as ICH. The 2013 meeting aims to inform QPPVs about any challenges relating to the ongoing release of the new PV legislation by the EMA and provide recommendations on incorporating those changes into the daily life of the QPPV.

Objectives

- To explore early experience and challenges of implementation of the new Pharmacovigilance legislation
- To identify and understand the specific impact of the changes on the QPPV role
- To address issues arising for QPPVs in working with partners
- To provide some practical guidance on how to work with the new Pharmacovigilance System Master File
- To determine if the QPPV now needs new skills
- To understand the role of the QPPV in the world of ongoing benefit/risk evaluation

Who Will Attend

- EEA Qualified Persons for Pharmacovigilance
- Deputy Qualified Persons for Pharmacovigilance
- Senior Pharmacovigilance Regulators and Inspectors
- CRO and Consultants providing QPPV Services
- National Responsible Persons for Pharmacovigilance
- Quality Management
- Heads of Pharmacovigilance

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TUESDAY | 16 APRIL 2013

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

As a result of positive feedback from previous years we are repeating this informative workshop. It is intended for 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 workshop 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

13:00 Session 1

Welcome and Introduction
Elspeth McIntosh, Director, Castle Pharmacovigilance Ltd, UK

The Impact of the 2012 Legislation on the QPPV Role – Key Changes and New Responsibilities (including local QPs/RPs)
Deirdre McCarthy, Director, Customer Delivery Europe, Lifecycle Safety & Infrastructure Management, Quintiles, Ireland

Key Definitions and Terms in the QPPV World
Elspeth McIntosh, Director, Castle Pharmacovigilance Ltd, UK

The QPPV role - panel discussion, hints and tips, different ways of working, training etc.
Elspeth McIntosh, Director, Castle Pharmacovigilance Ltd., UK
Deirdre McCarthy, Director, Customer Delivery Europe, Lifecycle Safety & Infrastructure Management, Quintiles, Ireland
Janet Hormbrey, Executive Director, EU QPPV, For Risk Management & Pharmacovigilance, Merck Sharp & Dohme Inc., Belgium

14:30 COFFEE BREAK

14:45 Session 2

Crisis, What Crisis? – Issues management for the QPPV
Janet Hormbrey, Executive Director, EU QPPV, For Risk Management & Pharmacovigilance, Merck Sharp & Dohme Inc., Belgium

Discussion and experiences from the audience

Quality Systems and the QPPV - Interfaces with Quality and the PV QMS
Monika Pietrek, Managing Director, Pietrek Associates GmbH, Germany

16:15 COFFEE BREAK

16:30 Session 3

Legal Considerations for the QPPV – New developments
Chris Foreman, Director, Legal Affairs, Scandinavian Region, MSD, Belgium

Panel Discussion
With all session speakers

18:00 END OF WORKSHOP

WEDNESDAY | 17 APRIL 2013

08:00 REGISTRATION AND WELCOME COFFEE

08:45 WELCOME AND INTRODUCTION
Michael Richardson, International Head of GPV&E and EU QPPV, Bristol-Myers Squibb Pharmaceuticals Ltd, UK

Jytte Lyngvig, European Director, DIA Europe, Switzerland

09:00 Session 1

REFLECTIONS ON THE NEW LEGISLATION; IS IT MEETING THE OBJECTIVES?

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

The focus of this year's conference is implementation of the new EU pharmacovigilance legislation and on its impact on the EU QPPV. The opening session will hear views from stakeholders, industry and patients on whether the new safety legislation is achieving its objectives.

Are Patients Better Protected? – A industry view
Thomas Loenngren, Strategic Advisor, NDA Group, UK

Was the Pain Worth the Gain?
Barry Arnold, EU Qualified Person for Pharmacovigilance, AstraZeneca, UK

And what do patients think?
David H.-U. Haerry, European Aids Treatment Group (EATG), Belgium

Panel Discussion

10:30 COFFEE BREAK

11:00 Session 2

PHARMACOVIGILANCE RISK ASSESSMENT COMMITTEE AND THE QPPV

Session Chairperson:
Maarten A.C. Lagendijk, Pharmacovigilance Coordinator,
Pharmacovigilance Department, Medicines Evaluation Board (MEB), the Netherlands

With the new legislation, pharmacovigilance in the EU saw many changes. Among other things a new committee was created, the Pharmacovigilance Risk Assessment Committee (PRAC). The PRAC deals with all aspects of the risk management of medicinal products, including the detection, assessment, minimisation and communication relating to the risk of adverse reactions, the design and evaluation of post-authorisation safety studies and pharmacovigilance audits.
This session will focus on the role and responsibilities of the PRAC, those of the QPPV and will handle the interaction and communication between them. In addition, the session will also focus specifically on one of the new tasks of the PRAC under the new legislation: the detection and management of safety signals.
In this session the experience of PRAC so far will be discussed, and the expectations of this Committee in the ever changing pharmacovigilance environment. The experience of industry will also be shared, accompanied by practical examples, to highlight the challenges that are faced by industry in general and people in pharmacovigilance in particular. Finally, it will also provide insight into the process surrounding signal management: from data collection and the signal detection process to the methodology used and the communication of the outcome.

PRAC: Experiences to date
Almath Spooner, Vigilance Assessment Manager, Irish Medicines Board, Ireland

Signal Detection under the New Legislation
Anja Van Haren, EudraVigilance Coordinator, Medicines Evaluation Board, the Netherlands

PRAC/Industry Communication Challenges
Peter de Veene, EU QPPV, F. Hoffmann-La Roche Ltd, Switzerland

Panel Discussion

12:30 LUNCH BREAK

14:00 Session 3

EU LEGISLATION IMPACT ON GLOBAL REQUIREMENTS & QPPV OVERSIGHT

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

For a QPPV working in company with EU authorised products marketed internationally, there are interesting challenges with global implementation of the new EU standards arising out of the latest legislation.
This session will examine how a QPPV can practically have oversight and influence the quality of global processes impacting EU authorised products. Topics to discuss include adverse event management, risk management, post-marketing study conduct, differing regulatory interpretations of ICH, use of technology and affiliate training and performance. Speakers will give a first-hand account of their experiences with advice about how to cope.

Personal Perspectives on Practicality of Being a QPPV in a Global System
Sue Rees, Head of Pharmacovigilance & Medical Information and EU QPPV, Eisai Europe Limited, UK
Anne-Ruth Van Troostenburg de Bruyn, QPPV, Takeda R & D (Europe) Ltd, UK

Benefit/Risk for the PBRER of Mature Products - Is this a waste of our time or an opportunity?
Anne-Ruth van Troostenburg de Bruyn, QPPV, EBD London, UK

Risk Management: Company standards versus local requirements
Michael Richardson, International Head of GPV&E and EU QPPV, Bristol-Myers Squibb Pharmaceuticals Ltd, UK

15:30 COFFEE BREAK

16:00 Session 4

CONTRACTS AND AGREEMENTS: HOW CAN THE QPPV ACHIEVE OVERSIGHT?

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

There is clearly an increasing focus at inspection on QPPV oversight of contracts and agreements. Now more than ever it is essential to ensure mutual understanding, update and implementation to comply with new requirements and expectations i.e. with respect to training, reconciliation, data collection (i.e. from social media), awareness of PSPs, access to applicable PSMFs etc. This session will seek to aid awareness of potential pitfalls and explore future possibilities.

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License Partner Oversight - Towards a comprehensive approach
Philip J. Weatherill, Vice President Global Pharmacovigilance, Ipsen Biopharm Ltd, UK

Challenges with Updating Agreements through Product Lifecycles and with Changing Expectations
Gro Laier, Deputy QPPV, Novo Nordisk A/S, Denmark

Auditing for Compliance and/or Sharing PSMF and Inspection Data – The future?
Pam Bones, Head, GRQ-PV Audit, Allergan, UK

THURSDAY | 18 APRIL 2013

08:00 WELCOME COFFEE

08:30 INTRODUCTION TO DAY 2
Vicki Edwards, QPPV and Head of Affiliate Vigilance Excellence, Global Pharmacovigilance and Global Medical Services, AbbVie, UK

08:45 Session 5

FROM SAFETY SIGNAL TO B/R ASSESSMENT: IMPACTS ON PSURS/ PBRERS AND RMPS

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

New European Legislation: Is it time for a new era of safety science? Requirements for many pharmacovigilance activities have been significantly amended. What is its impact, especially on PSURs / PBRERs, RMPs and PASSs? What are the difficulties associated with its implementation? What are the experiences gained and the lessons learned until now?

Information presented in the different sections will be enriched by a final interactive discussion.

Signal Management
- **Signal detection, validation/evaluation**
- **Risk determination for New EU-RMPs**

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

From PSURs to PBRERs
- **Focus on special challenges (e.g. off label use, effectiveness, transparency)**
- **PRAC Interactions/experiences**

Valerie E. Simmons, EU QPPV, Global Patient Safety, Eli Lilly and Company Ltd, UK

PASS and ENCePP Register
Susana Perez-Gutthann, Vice President, Global Head Epidemiology, RTI Health Solutions, Spain

Discussion

10:45 COFFEE BREAK

11:15 Session 6

NEW SKILLS FOR THE QPPV

Session Chair:
Elspeth McIntosh, Director, Castle Pharmacovigilance Limited, UK

The new pharmacovigilance legislation poses new challenges for, and requires new skills from, QPPVs. This session will increase awareness of some key issues which may be new to QPPVs.

Technical Challenges – What's next for EVMPD and E2B
Adrian Maynier, PV Business Systems Specialist, Genzyme, the Netherlands

External Communications – New skills and challenges arising from increased transparency
Peter Coë, Executive Director, Tudor-Reilly, UK

12:30 LUNCH BREAK

13:30 Session 7

ARE THERE DIFFERENT EXPECTATIONS OF THE QPPV AT INSPECTIONS UNDER THE NEW LEGISLATION?
Session Chairperson:
Vicki Edwards, QPPV and Head of Affiliate Vigilance Excellence, Global Pharmacovigilance and Global Medical Services, AbbVie, UK

This session will explore early inspection experiences following implementation of the new legislation. It will look at whether or not the approach to inspection has changed and if there are different expectations of the QPPV. It will identify any common findings noted by inspectors.

My First PV Inspection under the New Legislation
Vicki Edwards, QPPV and Head of Affiliate Vigilance Excellence, Global Pharmacovigilance and Global Medical Services, AbbVie, UK

Inspection under the New Legislation – How is the industry doing?
Anya Sookoo, Expert Inspector, GCP & Pharmacovigilance, MHRA, UK

14:30 COFFEE BREAK

15:00 Session 8

PSMF – CREATION, MAINTENANCE AND QPPV INVOLVEMENT
Session Chairperson:
Peter de Veene, EU QPPV, F. Hoffmann-La Roche Ltd, Switzerland

This session will look at the challenges for the industry in implementation of the PSMF requirements. It will look at different company approaches and provide practical guidance on how to establish and maintain a PSMF and explore if and how QPPVs are using it as a tool for system oversight. Delegates will be invited to complete a questionnaire on Day 1 on their experience with compilation and use of the PSMF. The session will consist of a brief overview to set the scene and will then open into a panel discussion and Q&A driven by the results of the questionnaire.

Setting the Scene – The need for a PSMF
Wendy Huisman, EU Qualified Person for Pharmacovigilance, Teva Pharmaceuticals Europe B.V., the Netherlands

Questionnaire Feedback and Panel Discussion
Peter de Veene, EU QPPV, F. Hoffmann-La Roche Ltd, Switzerland
Anya Sookoo, Expert Inspector, GCP & Pharmacovigilance, MHRA, UK
Margaret Walters, Director & Deputy EU QPPV, Merck Sharp & Dohme Ltd, UK
Elspeth McIntosh, Director, Castle Pharmacovigilance Limited, UK
Wendy Huisman, EU Qualified Person for Pharmacovigilance, Teva Pharmaceuticals Europe B.V., the Netherlands

Closing Remarks
Vicki Edwards, QPPV and Head of Affiliate Vigilance Excellence, Global Pharmacovigilance and Global Medical Services, AbbVie, UK

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

17:00 WRAP UP AND END OF CONFERENCE

Glossary

CRO	Contract Research Organisation
E2B	electronic reporting of adverse events
EEA	European Economic Area
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
EVMPD	EudraVigilance Medicinal Product Dictionary
GPV&E	Global Pharmacovigilance and Epidemiology
ICH	International Conference of Harmonisation
PASS	Post-authorisation Safety Studie
PBRER	Periodic Benefit-Risk Evaluation Report
PRAC	Pharmacovigilance Risk Assessment Committee
PSMF	Pharmacovigilance System Master File
PSP	Product Safety Profile
PSUR	Periodic Safety Update Report
PV	Pharmacovigilance
QA	Quality Assurance
QMS	Quality Management System
QP	Qualified Person
QPPV	Qualified Persons for Pharmacovigilance
R&D	Research and Development
RMP	Risk Management Plan
RP	Responsible Person

REGISTRATION FORM

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I wish to attend the EU QPPV Pre-Conference Workshop 16 April 2013 € 300.00 ❑

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