Impact of the New Pharmacovigilance Legislation on Regulatory Affairs

Event ID #13117
4-5 June 2013
Hotel NH Harrington Hall, London, UK

Programme Chair

Anu M. Tummavuori-Liemann
Switzerland

Programme Committee

Peter Bachmann
CMDh Chair, European and International Affairs, Federal Institute for Drugs and Medical Devices (BfArM), Germany – confirmed

Emma L. Du Four
Senior Director, Regulatory Policy and Intelligence Regulatory Affairs, AbbVie Ltd, UK

Zaide Frias
Head of Regulatory Affairs, European Medicine Agency, European Union

Katrin Rupalla
Vice-President, Regulatory Affairs, Bristol-Myers Squibb Pharmaceuticals Ltd, France

Continuing Education

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

Overview

This two day conference will focus on the impact of the new pharmacovigilance legislation on regulatory affairs, from various perspectives. The changes in legislation will affect the way product assessment is carried out in both pre- and post-authorisation phases, introduce new obligations to Marketing Authorisation Holders (MAH), and bring in continuous benefit risk assessment. This important conference will also be looking at the impact of the newly founded Pharmacovigilance Risk Assessment Committee (PRAC) on the life-cycle management of products and the PRAC's interactions with other committees.

Key Topics

The conference will provide

- An update on the implementation of the new pharmacovigilance legislation with a particular emphasis on the regulatory aspects. Information will be provided on the operation of the PRAC and the new Periodic Safety Update Report/Periodic Benefit-Risk Evaluation Report (PSUR/PBRER) and Risk Management Plan (RMP) requirements will be explored including how assessments will be handled by PRAC
- An overview of the key elements for Post-authorisation Safety Studies (PASS) and Post-authorisation Efficacy Studies (PAES) and sessions will review how the new pharmacovigilance legislation is impacting regulatory affairs and drug development more broadly.

Sessions will include

- Fundamentals – The role of PRAC & CMD(h)
- New features of the pharmacovigilance legislation and their impact on regulatory activities
- New pharmacovigilance legislation and how it is impacting drug development
- Involvement of two sets of rapporteurs in the procedures and impact on regulatory affairs
- Referrals, opinions and conditions
- New pharmacovigilance legislation and the opportunities for regulatory affairs
- Panel discussion on impact on drug development and approval

Objectives

- To provide insight into the regulatory requirements, scientific and operational challenges associated with the implementation of the new pharmacovigilance legislation
- Attendance will offer opportunities to exchange experiences and hear from the regulators directly about how different aspects of the new legislation will be implemented

Who Will Attend

This conference is aimed at intermediate and experienced professionals from

- Regulatory agencies
- The pharmaceutical industry and service providers
- Academic institutions

including

- Regulatory affairs personnel
- Pharmacovigilance staff
- Quality assurance personnel for pharmacovigilance and pharmacovigilance inspectors
- Clinical and medical personnel
- Project managers in drug development

This conference is currently in development. Please visit www.diahome.org for regular programme updates or contact the Event Manager on Michael.Hediger@diaeurope.org

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TUESDAY I 4 JUNE 2013

08:30 REGISTRATION AND WELCOME COFFEE

09:30 Session 1

FUNDAMENTALS – THE ROLE OF PRAC & CMD(h)

Session Chairperson:
Emma L. Du Four, Senior Director, Regulatory Policy and Intelligence Regulatory Affairs, AbbVie Ltd, UK

This session will cover overview of the PRAC including remit, membership and interaction with CMD(h).

PRAC – General overview including membership, working procedures and transparency
Government representative invited

How Will CMD(h) Interact with the PRAC
Peter Bachmann, CMDh Chair, European and International Affairs, Federal Institute for Drugs and Medical Devices (BfArM), Germany

11:00 COFFEE BREAK

11:30 Session 2

NEW FEATURES OF THE PHARMACOVIGILANCE LEGISLATION AND THEIR IMPACT ON REGULATORY ACTIVITIES

Session Chairperson:
Angelika Joos, Head Regulatory Policy EU & Most of World, Merck Sharp & Dohme (Europe) Inc., Belgium

This session will cover an overview of the key elements for PASS, PAES and annual review of conditions.

Requirements for PASS Including Article 22 Joint Protocols and Registries
Government representative invited

PAES, Annual Re-assessment and Renewals
Government representative invited

Monitoring (Black Symbol) and Change in Scope of Drugs
Government representative invited

13:00 LUNCH

14:00 Session 3

NEW PV LEGISLATION AND HOW IT IS IMPACTING DRUG DEVELOPMENT

Session Chairperson:
Katrin Rupalla, Vice-President, Regulatory Affairs, Bristol-Myers Squibb Pharmaceuticals Ltd, UK

This session will discuss the impact of the new PV legislation on the drug development and pre-approval phase from various perspectives.

How Does the New PV Legislation Impact the Drug Development and Pre-Approval Phase from the EMA Perspective?
Andrea Laslop, Head of Unit, AGES PharmMed, Austria

How Does the New PV Legislation Impact the Drug Development and Pre-Approval Phase from the Industry Perspective?
Katrin Rupalla, Vice-President, Regulatory Affairs, Bristol-Myers Squibb Pharmaceuticals Ltd, UK

How Do these Elements Impact the Approval and Post-Approval-Phase from the Industry Perspective
Angelika Joos, Head Regulatory Policy EU & Most of World, Merck Sharp & Dohme (Europe) Inc., Belgium

15:30 COFFEE BREAK

16:00 Session 4

WHAT IS NEXT IN 2013?

Session Chairperson:
Zaide Frias, Head of Regulatory Affairs, European Medicine Agency, European Union

Industry Experience with Amendments to the PV Legislation and Position on PV Fees

Anne-Marie de Ferran, QPPV Office Manager, QQPV Office and Pharmacovigilance Policy, Global Pharmacovigilance & Epidemiology, Sanofi-Aventis R&D, France

XEVMPD and Future of Art 57 (2)
John Kiser, Senior Director, Regulatory Operations, Abbvie Ltd., USA

17:00 DRINKS RECEPTION

18:00 END OF DAY ONE

WEDNESDAY I 5 JUNE 2013

08:30 Session 5

INVOLVEMENT OF TWO SETS OF RAPPORTEURS IN THE PROCEDURES AND IMPACT ON REGULATORY AFFAIRS

Session Chairperson:
Peter Bachmann, CMDh Chair, European and International Affairs, Federal Institute for Drugs and Medical Devices (BfArM), Germany

This session will discuss procedural aspects involving two sets of rapporteurs.

Marketing Authorisation Application and post-approval phase - Working with two sets of rapporteurs from the EMA perspective
Government representative invited

Marketing Authorisation Application and post-approval phase - Working with two sets of rapporteurs from the CHMP perspective
Kristina Dunder, Clinical Assessor, Senior Expert, Alternate CHMP Member, Medical Products Agency, Sweden

Industry Experience - Working with two sets of rapporteurs
Industry representative invited

10:00 COFFEE BREAK

10:30 Session 6

NEW PV LEGISLATION AND THE OPPORTUNITIES FOR REGULATORY AFFAIRS

Session Chairperson:
Isabelle Clamou, Director, EFPIA, Belgium

This session will discuss the opportunities the new PV legislation provides and initiatives and status around adaptive licensing.

Adaptive Licensing: Overview of initiatives and status
Government representative invited

Data Elements around Adaptive Licensing and Which Tools of the New PV Legislation Could be Used
Andrea Laslop, Head of Unit, AGES PharmMed, Austria

Progressive Marketing Authorization (Adaptive Licensing): How could pilot programs look like taking the new EU PV legislation into account?
Anton Hoos, Senior Vice President, European Medical Affairs, GlaxoSmithKline, UK

12:00 **LUNCH**

13:00 **Session 7**

REFERRALS, OPINIONS AND CONDITIONS

Session Chairperson:
Anu M. Tummavuori-Liemann, Switzerland

Referral Procedures: Art 20, 31 and UUP (107i), public hearings from the EMA perspective
Government representative invited

Referral Procedures: Art 20, 31 and UUP (107i), public hearings from the PRAC perspective
Sabine Straus, Head of Pharmacovigilance, Medicines Evaluation Board, the Netherlands

Referral Procedures from the CMDh Perspective
Peter Bachmann, CMDh Chair, European and International Affairs, Federal Institute for Drugs and Medical Devices (BfArM), Germany

Article 20: Recent industry experience with procedures
Ian Hawkins, Head of Hematology Strategy, Celgene Europe Ltd., UK

14:30 **COFFEE BREAK**

15:00 **PANEL DISCUSSION ON IMPACT ON DRUG DEVELOPMENT AND APPROVAL**
Panel Chair:
Isabelle Clamou, Director, EFPIA, Belgium

Panel will discuss impact of the new pharmacovigilance legislation on drug development, approval review and post-approval plans.

The programme committee, speakers and Elisabeth George, Associate Director – Appraisals, National Institute for Health and Care Excellence (NICE), UK, will join the panel.

Special feature
Delegates may submit questions before the conference to Michael.Hediger@diaeurope.org.
These questions will be addressed during the panel discussion on Day 2.

TRAVEL INFORMATION

From the airport:

Heathrow: Take the Central Piccadilly Line to Gloucester Road station.

Standsted: Take the Standsted Express to Liverpool Street. From there, take the Circle or District line to Gloucester Road station.

Luton: Take the 757 bus to Victoria Station. From there, take the Circle or District tube line to Gloucester Road station.

London City: Take the DLR to the Bank station. From there, take the Circle or District tube line to Gloucester Road station.

Gatwick: Take the Gatwick Express to Victoria station. From there, take the Circle or District tube line to Gloucester Road station.

HOTEL INFORMATION

The DIA has blocked a limited number of rooms at the following hotel:

NH Harrington Hall Hotel
5-25 Harrington Gardens
South Kensington, London SW7 4JW, UK
Tel.: +44 207 396 96 96 - Fax: +44 207 398 46 61
Email: bookings@nh-hotels.com

at the rate of:
GBP 180.00 per room/night inclusive of breakfast and VAT.

To make your reservation, please contact the hotel directly at: bookings@nh-hotels.com or by phone: +44 870 735 0358.

Please quote the booking reference:
Group name: DIA
Group code: 19429982

IMPORTANT: Please complete your reservation by 3 May 2013. 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. Cancellations made at least 7 days prior to arrival will not incur any cancellation charges. In case of no show or late cancellation the costs will be charged to the credit card of the guest.

REGISTRATION FORM

Impact of the New Pharmacovigilance Legislation on Regulatory Affairs
4-5 June 2013 I Hotel NH Harrington Hall, London, UK

DIA www.diahome.org
ID #13117

Early-bird rates available for members: Register by 23 April 2013

Join DIA now to qualify for the Early-bird member fee! The Early-bird registration form and accompanying payment must be received by the date above. Early-bird fee applies to industry members only. *(www.diahome.org/membership)*

€ 1'165.00 ❑

FEES (after 23 April 2013)

	Member*	Non-Member*
Industry	€ 1'365.00 ❑	€1'480.00 ❑
Academia/Charitable/Government/Non-profit (Full-time)	€ 683.00 ❑	€ 798.00 ❑
Join DIA now to qualify for the member rate	€ 115.00 ❑	

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 Europe for more information.

Registration fee includes: refreshments, lunches and meeting material.

Payment is 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 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 #13117 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 Europe.**

By signing below, I confirm that I agree with DIA Europe's Terms and Conditions of booking. These are available from the office or on http://www.diahome.org/EUTerms

Date	Signature

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe office five working days prior to the event start date. Cancellations are subject to an administrative fee:

- Full Meeting Cancellation: Industry (Member/Non-member) € 200.00.
- Academia/Charitable/Government /Non-profit (Full-Time) (Member/Non-member) € 100.00.
- Tutorial cancellation € 50.00.

If you do not cancel five working days prior to the event start date 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 or postponed, 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 the DIA Europe 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 Europe in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

The DIA Europe Customer Services 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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