EMA Information Day on Services and Systems in Pharmacovigilance: Preparing for Business Change

7 December 2015
European Medicines Agency, London, United Kingdom

PROGRAMME COMMITTEE

Paolo Alcini, Head of Data Standardisation and Analytics, Business Data & Analytics Department, European Medicines Agency (EMA), EU

Peter Arlett, Head, Pharmacovigilance Department, European Medicines Agency (EMA), EU

Sabine Brosch, Monitoring and Incident Management, Pharmacovigilance, European Medicines Agency (EMA), EU

Anja van Haren, EudraVigilance Coordinator, Medicines Evaluation Board (MEB), NL

Margaret Walters, Director & Deputy EU Qualified Person for Pharmacovigilance, Merck Sharp & Dohme Ltd, UK

FACULTY

Steven Blumenthal, Director, Global Safety, Merck & Co., Inc.

Ana Cochino, Scientific Administrator, EMA

Gaby Danan, Pharmacovigilance Expert, France

Francois Domergue, Scientific Administrator, Data Standardisation and Analytics, EMA

Georgy Genov, Head of Signal Management, EMA

Evdokia Korakianiti, Head of Procedure Management, EMA

David Lewis, Global Head of Pharmacovigilance, Novartis

Subhash Mistry, Manager Systems Management, Pharmacovigilance, GlaxoSmithKline

Miranda Moussa, Manager Medical Devices, Association of the European Self-Medication Industry (AESGP)

Murielle Musset, Literature Surveillance Team Lead (Pharmacovigilance), Sanofi

Tom Paternoster, Scientific Administrator, EMA

Irene Rager, Head of Service E, Procedure Management Department, EMA

Details of the Information Day
Location: European Medicines Agency
30 Churchill Place
Canary Wharf - London E14 5EU - United Kingdom

Capacity: The event is limited to 85 participants

OVERVIEW

New European Union (EU) Pharmacovigilance legislation foresees various information systems to enhance pharmacovigilance, particularly to support the collection, management and analysis of data, information and knowledge. These systems will contribute to the promotion and protection of public health through optimisation of the safe and effective use of medicines. They should also facilitate pharmacovigilance, delivering rationalisation and efficiency gains and to improve the relevant business functions to maximise the benefits for stakeholders.

This information day is primarily aimed at providing marketing-authorisation holders (MAHs) with information on the development of the enhanced systems, helping MAHs prepare for the business change to come and to allow detailed discussions on recently launched services.

The topics to be addressed relate to key system and service developments including – new functionalities for adverse drug reaction reporting (including discussion of the Change Management Plan), medical literature monitoring, the database of medicinal products (Article 57) as well as the Periodic Safety Update Report (PSUR) Repository.

KEY TOPICS

- Adverse reaction reporting and analysis, EudraVigilance system changes to come
- EMA service of medical literature monitoring for reports of suspected adverse drug reactions
- Article 57 database and how data on medicines are used for pharmacovigilance
- PSUR Repository: preparing for mandatory use in 2016

TARGET AUDIENCE

- Qualified Persons Responsible for Pharmacovigilance (QPPVs)
- Individuals involved in pharmacovigilance, safety database and information management
- IT system developers and data managers

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1995 2015 EMA

DIA DEVELOP INNOVATE ADVANCE

08:00 **REGISTRATION**

08:45 **KEY NOTE**

THE PHARMACOVIGILANCE PROGRAMME AND UPDATE ON ENHANCEMENTS TO EU PHARMACOVIGILANCE

Peter Arlett, EMA

The key note will provide an introduction to the pharmacovigilance programme, which encompasses various information systems to enhance pharmacovigilance, with the aim of delivering rationalisation and efficiency gains. It will also look beyond the systems and services and lay out the main enhancements in pharmacovigilance for 2016.

09:15 **SESSION 1**

ADVERSE REACTION REPORTING AND ANALYSIS, EUDRAVIGILANCE SYSTEM CHANGES TO COME

Session co-chairs:
Peter Arlett, EMA, and Anja Van Haren, MEB

Taking into account the requirements set out in pharmacovigilance legislation, this session will focus on the preparation for the use of the new data format ISO/ICH ICSR E2B(R3), for the simplified reporting to EudraVigilance, and for the implementation of the revised EudraVigilance Access Policy, which will lead to increased access to adverse reactions reports and industry responsibilities for signal detection.

Presentation and Discussion of the EudraVigilance Change Management Plan
Francois Domergue, EMA

Revision of the EudraVigilance Access Policy on Suspected Adverse Reactions – Direction of Travel
Sabine Brosch, EMA

10:30 Coffee Break

11:00 **SESSION 1 CONT.**

ADVERSE REACTION REPORTING AND ANALYSIS, EUDRAVIGILANCE SYSTEM CHANGES TO COME

Signal Management at the EMA, Planned Revision of GVP Module IX (Signal Management) and the Scientific Guideline on Signal Detection
Georgy Genov, EMA

Industry Readiness for the New EudraVigilance
David Lewis, Novartis

Discussant: Gaby Danan, France

12:15 Sandwich Lunch

13:00 **SESSION 2**

PSUR REPOSITORY – ACHIEVEMENTS AND NEXT STEPS

Session co-chairs:
Evdokia Korakianiti, EMA, and David Lewis, Novartis

This session will focus on the latest PSUR Repository achievements and next steps towards the simplification of PSUR submissions benefiting pharmaceutical industry and NCAs taking into account that the Repository will be mandatory on 13 June 2016.

PSUR Repository – Status Update and Next Steps
Irene Rager, EMA

Experience with the use of the Repository
Steven Blumenthal, Merck & Co., Inc.

Discussant: David Lewis, Novartis

14:00 **SESSION 3**

EMA SERVICE OF MEDICAL LITERATURE MONITORING FOR REPORTS OF SUSPECTED ADVERSE DRUG REACTIONS

Session co-chairs:
Sabine Brosch, EMA, and Margaret Walters, Merck Sharp & Dohme

This session will focus on the recently launched medical literature monitoring service including the impact of the EMA medical literature service on the NCAs' and pharmaceutical companies' business processes and experience to date.

How the Service Works and Experience to Date
Tom Paternoster, EMA

Industry Experience and Feedback
Murielle Musset, Sanofi

Discussants: Anja van Haren, MEB and Miranda Moussa, AESGP

15:15 Coffee Break

15:45 **SESSION 4**

ARTICLE 57 DATABASE AND HOW DATA IN MEDICINES IS USED FOR PHARMACOVIGILANCE

Session co-chairs:
Sabine Brosch, EMA, and Subhash Mistry, GlaxoSmithKline

This session will focus on the achievements of the Article 57 database in delivering structured and quality assured information on medicinal products authorised in the EU that can support EU terminologies of products, substances, and organisations used to power pharmacovigilance and regulatory systems. Key emphasis will be put on the current and future use of the data in support of pharmacovigilance and how data quality is assured.

Current Status on Article 57 Submissions and Quality Assurance
Ana Cochino, EMA

Article 57 – Use of the Data for Public Health and Better Regulation
Paolo Alcini, EMA

Article 57 Database – an Industry Perspective
Subhash Mistry, GlaxoSmithKline

Discussant: David Lewis, Novartis

17:00 End of the Information Day

REGISTRATION FORM

EMA Information Day on Services and Systems in Pharmacovigilance | ID#15594

7 December 2015 | European Medicines Agency, London, United Kingdom

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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

REGISTRATION FEES*	Fees*
Industry	400.00 EUR ❑
Government/Academia/Charitable/Non-Profit (full time)	200.00 EUR ❑

Registration fee includes: refreshments, sandwich lunch, delegate material as well as electronic access to presentations.

Payment is due 30 days after registration and must be paid in full by commencement of the event.

HOTEL INFORMATION

Recommended Hotel:

Hilton London Docklands Riverside
265 Rotherhithe Street
London, SE16 5HW
United Kingdom
Telephone: +44 20 7231 1001
Email: reservations.docklands@hilton.com

Please contact hotel directly for the best available rate.

The hotel is situated opposite of Canary Wharf, conveniently connected by a shuttle boat. The landing stage is in walking distance to the European Medicines Agency (10 min). The ferry ticket is included in the room rate. Please make sure you receive it when checking in.

Cancellation Policy

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

If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee.

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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 office of any such substitutions as soon as possible.

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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 Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET. Tel. :+41 61 225 51 51 Fax: +41 61 225 51 52
Email: EMEA@DIAglobal.org Mail: DIA EMEA, Küchengasse 16, 4051 Basel, Switzerland Web: www.DIAglobal.org

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Job Title

Company

Address

Postal Code

City

Country

Telephone Number Fax Number

email (Required for confirmation)

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

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❑ **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, Course ID # 15594 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, Middle East and Africa.**

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Date	Signature