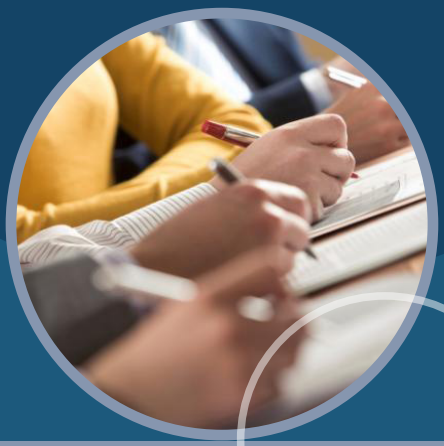

Information Day on New Services and Systems in Pharmacovigilance: Preparing for Business Change

28 April 2015
European Medicines Agency, London, United Kingdom

PROGRAMME COMMITTEE

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

Paolo Alcini
Head, Data Collection and Management, Business Data and Support Department, European Medicines Agency (EMA), EU

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

Gaby Danan
Pharmacovigilance Expert, France

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

ADJACENT EVENT

29 April 2015

Individual Case Safety Report (ICSR) Information Day

European Medicines Agency

NEED FOR THIS PHARMACOVIGILANCE INFORMATION DAY

The new EU Pharmacovigilance legislation has been operational since July 2012 and foresees various information systems to enhance pharmacovigilance. This refers particularly to the support of the collection, management and analysis of data, information and knowledge. These systems will contribute to public health through optimisation of the safe and effective use of medicines. They should also facilitate pharmacovigilance, delivering rationalisation and efficiency gains.

This Information Day is primarily aimed at providing marketing authorisation holders (MAHs) with information to help prepare for the business change to come thus focusing on the most critical questions: what needs to be done and by when.

The topics to be addressed relate to key system and service developments focusing on EudraVigilance - adverse drug reaction reporting and signal management, medical literature monitoring, on the database of medicinal products (Article 57) and pharmacovigilance fees as well as the Periodic Safety Update Report (PSUR) Repository. This further includes an update on new or revised technical guidelines (non-GVP).

KEY TOPICS

- Adverse reaction reporting and signal management and system changes to come
- Article 57 database and how data in medicines could be used for pharmacovigilance
- Pharmacovigilance fees
- EMA service of medical literature monitoring for reports of suspected adverse drug reactions
- PSUR Repository

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

08:30 **REGISTRATION**

08:45 **WELCOME NOTE**

THE PHARMACOVIGILANCE PROGRAMME

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 address the governance for the programme shared between national Competent Authorities in the EEA and the European Medicines Agency.

Peter Richard Arlett, EMA

09:15 **SESSION 1**

EUDRAVIGILANCE: ADVERSE REACTION REPORTING AND SIGNAL MANAGEMENT

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 the implementation of the revised EudraVigilance Access Policy, which will lead to increased access to adverse reactions reports and responsibilities for signal detection.

Session co-chairs: Sabine Brosch, EMA, and Anja van Haren, MEB

New EudraVigilance functionalities and the use of international standards – what MAHs need to do and when?
Nick Halsey, EMA

Revision of the EudraVigilance Access Policy on suspected adverse reactions - Key comments from public consultation and next steps
Sabine Brosch, EMA

How will MAHs be able to access ICSR data?
Francois Domergue, EMA and Gianmario Candore, EMA

The new R3 ICSR form in support of case review for signal management
Marin Banovac, EMA

Discussant: Veronique Demontrond, Sanofi, member of EV-EWG

10:45 **COFFEE BREAK**

11:15 **SESSION 1 CONTINUED**

EUDRAVIGILANCE: ADVERSE REACTION REPORTING AND SIGNAL MANAGEMENT

Signal management at the EMA
Rodrigo Postigo, EMA

Adverse reaction data interchange from EMA to WHO UMC
Magnus Wallberg, WHO–UMC

Discussant: Wendy Huisman, Teva, member of EV-EWG

12:15 **SANDWICH LUNCH**

13:00 **SESSION 2**

DATABASE ON MEDICINAL PRODUCTS (ARTICLE 57) AND PHARMACOVIGILANCE FEES

This session will focus on the achievements of the Article 57 database with the aim to deliver 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 in the EU. Key emphasis will be put on the current and future use of the data in support of pharmacovigilance and how data quality is assured.

Furthermore, the session will allow pharmaceutical companies to get familiar with the recently adopted pharmacovigilance fees regulation and related guidance as well as the advice notes that have been sent out to allow companies to preview the list of 'Chargeable Units' subject to a Pharmacovigilance Fee prior to billing in July 2015.

Session co-chairs: Paolo Alcini, EMA, and Anja van Haren, MEB

Current status on Article 57 submissions: How are and how will the data be used for better pharmacovigilance?
Ilaria del Seppia, EMA

Article 57 – validation and quality control of Article 57 submissions
Ana Cochino, EMA

Pharmacovigilance fees implementation
Claudia Galeazzo, EMA

Discussants:
Subhash Mistry, GSK, member of EV-EWG
Wendy Huisman, Teva, member of EV-EWG
Veronique Demontrond, Sanofi, member of EV-EWG

14:30 **COFFEE BREAK**

15:00 **SESSION 3**

MONITORING OF SELECTED MEDICAL LITERATURE (MLM) FOR SUSPECTED ADVERSE REACTIONS BY THE AGENCY

This session will focus on the implementation of the legal requirement for EMA to monitor selected medical literature for reports of suspected adverse drug reactions containing certain active substances and to enter individual case safety reports into the EU adverse reaction database (EudraVigilance). This session will focus on the impact of the EMA medical literature service, which will be operational from Q2 2015 on the NCAs' and pharmaceutical companies' business processes.

Session co-chairs: Sabine Brosch, EMA, and Anja van Haren, MEB

Change Management: monitoring of medical literature and the entry of relevant information into the EudraVigilance database by the European Medicines Agency
Sabine Brosch, EMA

How to access ICSRs originating from the MLM service
Pedro Oliveira, EMA

Medical literature monitoring pilot with marketing authorisation holders and national Competent Authorities in the EEA – what you need to know
Tom Paternoster-Howe, EMA

Discussant: Wendy Huisman, Teva, member of EV-EWG
Gilles Touraille, EMA

16:30 **SESSION 4**

PSUR REPOSITORY – ACHIEVEMENTS AND NEXT STEPS

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 once the use of the Repository is mandatory, it will include all PSURs, including those that follow the PSUR Single Assessment (PSUSA) and those PSURs which are not part of a Single Assessment.

Session chair: Evdokia Korakianiti, EMA

PSUR Repository – status update and next steps
Irene Rager, EMA

Discussants: Wendy Huisman, Teva, member of EV-EWG
Veronique Demontrond, Sanofi, member of EV-EWG

17:00 **END OF THE INFORMATION DAY**

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.

HOTEL INFORMATION

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

DIA has blocked a limited number of rooms at the rate of GBP 149.00 single/GBP 161.00 double room per night (Friday to Monday) and GBP 179.00 single/GBP 191.00 double room per night (Tuesday to Thursday) including breakfast and VAT. To make your booking please use the reservation link available on the DIA event website.

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.

REGISTRATION FORM

Information Day on New Services and Systems in Pharmacovigilance: Preparing for Business Change
28 April 2015 European Medicines Agency, London, United Kingdom

ID #15222

SEND YOUR COMPLETED REGISTRATION FORM TO DIA EUROPE, MIDDLE EAST & AFRICA CONTACT CENTRE TEAM,
E-mail: diaeurope@diaeurope.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 and delegate material

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

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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

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❑ **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, Event ID #15522 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

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- Industry (Member/Non-member) € 200.00
- Government/Academia/Charitable/Non-Profit (full time) € 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. 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.

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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.
Email diaeurope@diaeurope.org **Tel.** +41 61 225 51 51 **Fax** +41 61 225 51 52
Web www.diaeurope.org **Mail** DIA Europe, Middle East & Africa Contact Centre Team, Küchengasse 16, 4051 Basel, Switzerland

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