Signal Management Information Day

Event # 17597
27 October 2017
European Medicines Agency, London, United Kingdom

PROGRAMME COMMITTEE

Sabine Straus
Head of Pharmacovigilance
Medicines Evaluation Board (MEB)
The Netherlands
PRAC member

Sabine Brosch
Surveillance and Epidemiology Service
European Medicines Agency (EMA),
European Union (EU)

Georgy Genov
Head of Signal and Incident Management and Acting Head of Pharmacovigilance and Epidemiology Department
EMA, EU

Rodrigo Postigo
Signal and Incident Management Service
EMA, EU

OVERVIEW

This Information Day will provide an update of the key elements related to the signal detection and management activities in the EU essential to the overall surveillance and risk management process of a medicinal product. We will explore the final guidance provided upon finalisation the Good Vigilance Practice Module IX on Signal Management where the different aspects of the EU pharmacovigilance legislation on the topic will be covered. We will also drill down to the EudraVigilance access by Marketing Authorisation Holders and the tools and training provided by the EMA to support the stakeholders. The approaches and perspectives from the different stakeholders involved in the signal management process will be also explored and discussed.

KEY TOPICS

- Good Pharmacovigilance Practice Module IX on Signal Management
- Communication of signals to the Regulatory Authorities
- Marketing Authorisation Holders access to EudraVigilance
- Tools to support Signal Detection and Validation in EudraVigilance
- Stakeholders' involvement in Signal Detection and Management
- Training opportunities

TARGET AUDIENCE

- Qualified Persons Responsible for Pharmacovigilance (QPPVs)
- Professions involved in Signal Detection and Management
- Individuals involved in Clinical Development, Information Management, Safety Databases
- PV Information Technology Professionals

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 146 participants

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DIA

FACULTY

Gianmario Candore
Data Scientist
EMA, EU

Irina Caplanusi
Signal Management Lead, Pharmacovigilance Department
EMA, EU

Julie Durand
Signal Management Lead, Pharmacovigilance Department
EMA, EU

Nick Halsey
Scientific Administrator, Data Collection and Management
EMA, EU

Martin Huber
Pharmacovigilance Division, PRAC member BfArM, Germany

Nils Lilienthal
Pharmacovigilance assessor (Drug safety) BfArM, Germany

David Lewis
Global Head of Pharmacovigilance, Senior Visiting Fellow, Univ. of Hertfordshire
Novartis Pharma AG, Switzerland

Valerie Simmons
EU QPPV, Global Patient Safety
Eli Lilly, UK

Romana Slovakova
Scientific Administrator
EMA, EU

Kiernan Trevett
Senior Pharmacovigilance Inspector
Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

Alison Turney
Surveillance Business Process Advisor, Global Patient Safety
Eli Lilly, USA

Margaret Walters
Director & Deputy EU QPPV
MSD, United Kingdom

Cosimo Zaccaria
Signal Management Lead, Pharmacovigilance Department
EMA, EU

08:00 **REGISTRATION**

08:45 **WELCOME NOTE**

Georgy Genov, EMA

09:00 **SESSION 1**

THE NEW EUDRAVIGILANCE SYSTEM AND IMPLICATIONS FOR SIGNAL MANAGEMENT IN THE EU NETWORK

Session Chairs: Georgy Genov, EMA, and Rodrigo Postigo, EMA

This session will provide an overview of the impact in the EU Signal Management procedure following the go-live of the new EudraVigilance system and the full implementation of the EudraVigilance access policy (Revision 3) in November 2017. The different aspects for implementation of the updated Good Pharmacovigilance Practice Module IX and the submission of validated signals to regulatory authorities will be developed. The role of the PRAC and the expectations following the monitoring of the EudraVigilance data by Marketing Authorisation Holders (MAHs) will be also discussed.

Go-live of the new EudraVigilance system: What will happen in November 2017
Sabine Brosch, EMA

GVP IX Module on Signal Management: Highlights of Revision 1 and practical implementation
Julie Durand, EMA

PRAC expectations on the Signal Management procedure following the go-live of the new EudraVigilance system
Sabine Straus, MEB, PRAC member

Q&A/Panel Discussion
Discussants: Margaret Walters, MSD, Nils Lilienthal, BfArM, Valerie Simmons, Eli Lilly, and Irina Caplanusi, EMA

10:30 **COFFEE BREAK**

11:00 **SESSION 2**

EUDRAVIGILANCE ACCESS BY MAHs – TOOLS FOR SIGNAL DETECTION AND VALIDATION

Session Chairs: Sabine Straus, MEB, and Sabine Brosch, EMA

This session will provide an overview of the EudraVigilance access and data provided to MAHs via the EudraVigilance Data Analysis System (EVDAS) together with the tools and statistical method to support signal detection and validation. The provision of level 2b access through EudraVigilance WEB trader (EVWEB) which includes the case narratives will also be demonstrated.

The MAH Pharmacovigilance queries dashboard: Principles of the EVDAS access for MAHs and EVDAS reports
Gianmario Candore, EMA, and Rodrigo Postigo, EMA

Level 2b access: How to retrieve the case narratives (live demonstration) in EVWEB
Nick Halsey, EMA

The electronic Reaction Monitoring Report (eRMR): Tool for signal detection in EudraVigilance
Cosimo Zaccaria, EMA

Q&A/Panel Discussion
Discussants: Margaret Walters, MSD, Nils Lilienthal, BfArM, Valerie Simmons, Eli Lilly, and Romana Slovakova, EMA

12:30 **SANDWICH LUNCH**

13:30 **SESSION 3**

SIGNAL DETECTION AND MANAGEMENT BY MARKETING AUTHORISATION HOLDERS

Session Chairs: Georgy Genov, EMA, and Sabine Straus, MEB

This session will cover the MAHs perspectives and approaches taken in order to comply with their pharmacovigilance obligations, following the release of the EudraVigilance data. The key changes and modifications of the internal process to incorporate EudraVigilance monitoring will be highlighted. Furthermore, the steps within the signal management process in relation to the key aspects considered during a pharmacovigilance inspection will be explored.

Pharmaceutical industry perspective on the EU Signal Management process: Key changes in the process
David Lewis, Novartis

Signal Management by MAHs: Steps to incorporate the EudraVigilance data into safety surveillance
Alison Turney, Eli Lilly

EU Signal Management process and Pharmacovigilance Inspections: Good practices in the MAHs signal management process
Kiernan Trevett, MHRA

Q&A/Panel Discussion
Discussants: Margaret Walters, MSD, Valerie Simmons, Eli Lilly, and Nils Lilienthal, BfArM

15:00 **COFFEE BREAK**

15:30 **SESSION 4**

EUDRAVIGILANCE DATA FOR SAFETY MONITORING OF MEDICINAL PRODUCTS

Session Chairs: Georgy Genov, EMA, and Sabine Straus, MEB

This session will provide with the perspective and experience of a National Competent Authority with the monitoring of the EudraVigilance data and the role of Lead Member State for the signal management procedure in the EU. The session will also explore the opportunities the EudraVigilance provides together with the optimal use of the data for an effective functioning of the EU regulatory network. The future challenges approaches and research in light of the SMART - Work Stream Methods – Roadmap will be also presented.

Use of EudraVigilance data by National Competent Authorities: The role of the Lead Member States in the EU Signal Management process
Martin Huber, BfArM

Opportunities with the release of EudraVigilance data: Optimal use of the data for signal management and training support
Rodrigo Postigo, EMA

SMART - Work Stream Methods: Roadmap and new perspectives in signal detection
Gianmario Candore, EMA

Q&A/Panel Discussion
Discussants: Margaret Walters, MSD, Nils Lilienthal, BfArM, Valerie Simmons, Eli Lilly, and Cosimo Zaccaria, EMA

17:00 **END OF INFORMATION DAY**

REGISTRATION FORM

ID #17597

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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	500.00 EUR ❑
Government/Academia/Charitable/Non-Profit (full time)	250.00 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.

HOTEL INFORMATION

Participants are kindly requested to make their own hotel reservation.

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

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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 #17597 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 EMEA.**

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

Date	Signature

TERMS AND CONDITIONS

Cancellation Policy

All cancellations must be made in writing and be received at the DIA EMEA office four weeks prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Government/Academia/Charitable/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. DIA EMEA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA EMEA 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 EMEA office of any such substitutions as soon as possible.

Photography and Video 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 EMEA 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 Europe, Middle East & Africa, Küchengasse 16, 4051 Basel, Switzerland Web: www.DIAglobal.org