EMA Risk Management Plan Information Day

Event #18594
25 October 2018
European Medicines Agency, London, United Kingdom

PROGRAMME COMMITTEE

Zaide Frias, Head of Human Medicines Evaluation Division, EMA, EU
Sabine Straus, Medicines Evaluation Board, Pharmacovigilance Risk Assessment Committee (PRAC) Member
Jordi Llinares Garcia, Head of Scientific and Regulatory Management Department, EMA, EU
Peter Arlett, Head of Pharmacovigilance and Epidemiology Department, EMA, EU
Marin Banovac, Scientific Officer, Oncology, Haematology and Diagnostics, Scientific and Regulatory Management Department, EMA, EU

FACULTY

Juan Garcia Burgos, Head of Medical and Health Information, EMA, EU
Núria Semis-Costa, Scientific Officer, Rheumatology, Respiratory, Gastroenterology and Immunology, Scientific and Regulatory Management Department, EMA, EU
Priya Bahri, Principal Scientific Administrator, Surveillance & Epidemiology Service, Pharmacovigilance Department, EMA, EU
Roberto De Lisa, Scientific Officer, Paediatric Medicines Office, EMA, EU
Corinne De Vries, Head of the Science and Innovation Support Office, EMA, EU
Jan Petracek, CEO, PrimeVigilance, CZ
Inge Zomerdijk, Pharmacovigilance Assessor, MEB, NL
David Haerry, European AIDS Treatment Group, BE
James Milligan, Vice President Patient Safety, AstraZeneca, UK
Phillip Eichorn, Senior Director in Worldwide Safety & Regulatory, Pfizer , UK

OVERVIEW

The focus of this Information Day will be on providing an update of ongoing Agency's activities with regard to medicines' risk management. This Risk Management Plan (RMP) Information Day will be an opportunity to provide marketing authorisation holders (MAHs) and marketing authorisation applicants (MAAs) practical advice on RMP drafting in view of the full implementation of the RMP revision 2 template after the transitional period has elapsed, as well as to interactively exchange experiences on the revision 2 RMP format between the regulators and industry.

The increasing number of biosimilars being authorised highlighted a need to better streamline the safety specification for biologicals so that only risks that are important for risk management and relevant for the benefit-risk of the product are included in the RMP. A dedicated session of the Information Day will also serve as a platform to discuss the streamlining of safety specification for biologicals with a special focus on biosimilars.

Updates on the work on the risk management aspects of the new GVP guidance on special populations such as children and elderly will be provided.

Other topics include a trilateral session between the regulators patients and industry on risk communication and patients' access to information on the safety of medicines.

The panel is happy to answer questions from the audience submitted to ema@diaglobal.org by 25 September 2018 latest.

KEY TOPICS

- GVP V rev.2 practical session – regulators and industry perspective on the implementation of the revised RMP template
- Identifying safety concerns for biologicals and biosimilars
- Update on new GVP guidelines in development (Paediatrics, Older people, Pregnancy and breastfeeding)
- Risk communication

TARGET AUDIENCE

- Individuals involved in risk management planning, risk minimisation development and post authorisation safety studies at small to medium enterprises (SMEs), MAAs / MAHs for generic products, MAAs / MAHs for innovator products and Contract Research Organisations (CROs)
- Qualified Persons responsible for Pharmacovigilance (QPPVs)
- Assessors at National Competent Authorities (NCAs)
- Risk communication experts
- Patients and Healthcare professional (HCP) group representatives

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 115 participants

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DIA

08:00 REGISTRATION

08:45 WELCOME NOTE

Zaide Frias, EMA and **Sabine Straus**, MEB

09:00 SESSION 1

GVP V REVISION 2: PRACTICAL APPROACH ON IMPLEMENTATION OF REVISED RMP TEMPLATE

Session chair: **Sabine Straus**, MEB

This session will provide practical advice and insights on the implementation of the revised RMP template from EMA, industry and regulator perspective. Based on questions received from the audience, the panel invites to an interactive discussion on the experience with the implementation of the GVP V Revision 2 template.

GVP V and RMP Template Revision 2 – Implementation progress; updates on the EMA project Quality of the RMP submissions
Nuria Semis Costa, EMA

Lessons from 200 Updated RMPs
Jan Petracek, PrimeVigilance

Revision of GVP Module V: experiences from the regulators
Inge Zomerdijk, MEB

Q&A/Panel Discussion

10:45 COFFEE BREAK

11:15 SESSION 2

SAFETY SPECIFICATIONS FOR BIOSIMILARS

Session chair: **Marin Banovac**, EMA

With the increasing number of biosimilars entering the market, the PRAC highlighted the need to better streamline the safety specifications for biosimilars. This session will update all stakeholders involved in ongoing EMA and PRAC activities with regards to the safety specification for biosimilars.

EMA recommendations on streamlining safety specification for biologicals
Núria Semis-Costa, EMA

Safety Concerns and Biosimilars: Challenges and Uncertainties
Phillip Eichorn, Pfizer

Q&A/Panel Discussion

12:30 SANDWICH LUNCH

13:30 SESSION 3

GVP GUIDELINES ON SPECIAL POPULATIONS

Session chair: **Priya Bahri**, EMA

Pharmacovigilance guidelines (GVP) in special populations, i.e. children, older patients and women concerning pregnancy and breastfeeding, are currently being developed. The RMP Info Day will offer the opportunity to share the current status of the guidelines with a special emphasis on the impact of new guidelines on medicines risk management in these populations. Furthermore, this will be an opportunity to solicit input from stakeholders for further development specifically of the GVP on older people to enhance medicines' safety in the geriatric population.

GVP for Paediatrics
Roberto De Lisa, EMA

GVP for Older People
Priya Bahri, EMA

GVP for Pregnancy
Corinne De Vries, EMA

15:00 COFFEE BREAK

15:30 SESSION 4

RISK COMMUNICATION

Session chairs: **Juan Garcia Burgos**, EMA and **Marin Banovac**, EMA

In recent years, EMA has taken several measures to improve patients' access to information on the safety of medicines and on actions planned to manage the important risks of EU medicines. The session on risk communication will bring together the patients, the regulators and the industry in a trilateral discussion on risk communication and better understanding of the patients' needs and expectations in this respect.

The role of regulators in communicating benefits and risks
Juan Garcia Burgos, EMA

Patient Perspective
David Haerry, European AIDS Treatment Group

Effective risk communication- can we shift the paradigm and why it matters
James Milligan, Astra Zeneca

16:30 END OF INFORMATION DAY

REGISTRATION FORM

ID #18594

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PLEASE REGISTER ONLINE OR SEND YOUR COMPLETED REGISTRATION FORM TO DIA CONTACT CENTRE TEAM,
E-mail: basel@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: Online access to presentations, 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

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*(Direct E-mail Adress required for Presentation Access)

DIA reserves the right to include your name and affiliation on the attendee list.

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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.**

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

Date	Signature

TERMS AND CONDITIONS

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All cancellations must be made in writing and be received at the DIA 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 reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA 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.

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The DIA Contact Centre 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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