EMA Information Day on Risk Management Planning – Implementation of GVP V and RMP Template Rev 2 Guidance

Event #17594
19 December 2017
European Medicines Agency, London, United Kingdom

PROGRAMME COMMITTEE

Enrica Alteri, Head of Human Medicines Research and Development Support Division, EMA, EU

Emil Cochino, Scientific Officer, Anti-infectives and Vaccines, Scientific and Regulatory Management Department, EMA, EU

Zaïde Frias, Head of Human Medicines Evaluation Division, EMA, EU

Jordi Llinares Garcia, Head of Scientific and Regulatory Management Department, EMA, EU

Georgy Genov, Acting head of Pharmacovigilance and Epidemiology Department, EMA, EU

June Raine, Pharmacovigilance Risk Assessment Committee (PRAC) Chair
Director of Vigilance and Risk Management of Medicines, Medicines and Healthcare products Regulatory Agency (MHRA), UK

Sabine Straus, PRAC member
Medicines Evaluation Board (MEB), NL

FACULTY

Nils Lilienthal, Pharmacovigilance assessor (Drug safety), Federal Institute for Drugs and Medical Devices (BfArM)

Željana Margan Koletić, PRAC member
Croatian Agency for Medicinal Products and Medical Devices (HALMED), Croatia

Núria Semis-Costa, Scientific Officer, Rheumatology, Respiratory, Gastroenterology and Immunology, Scientific and Regulatory Management Department, EMA, EU

Valerie Simmons, EU QPPV, Global Patient Safety, Eli Lilly and Company Ltd., UK

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 95 participants

OVERVIEW

The European Medicines Agency has published significant changes to EU pharmacovigilance guideline on risk management plans (GVP Module V and RMP Template Rev 2). These updates aim to further clarify the activities on which a risk management plan should focus to ensure optimal health promotion and protection based on a risk-proportionate planning of activities that directs resources to areas where the need for additional information and risk minimisation is greatest.

This Information Day is aimed primarily at providing marketing authorisation holders (MAHs) and marketing authorisation applicants (MAAs) with practical advice on RMP drafting using the principles of risk assessment and management included in GVP V Rev 2.

Content requirements and procedural advice for RMP submission will be presented with practical examples provided, based on frequent questions from applicants, assessors, and EMA Risk Management Specialists. Highlights will include types of products with different legal basis application (e.g. generics, fixed dose combination products, biosimilars).

Feedback from the Industry will be discussed and EMA and PRAC view on topics raised will be provided.

The Q&A and panel discussion sessions will include the response to questions received in advance or raised during the presentations.

Participants are invited to send questions related to their experience with implementation of Rev 2 by 10 December to emaevents@diaglobal.org**.**

KEY TOPICS

- Updates on risk management planning in the EU, with a focus on the recent revision of "Good Pharmacovigilance Guideline (GPV) Module V - Risk Management Systems".
- RMP content requirements and practical advice on risk identification: new active substances, generics, biosimilars
- Procedural requirements for RMP updates
- Common elements in the RMP and PSUR safety specifications – building the justification for (re)classification of safety concerns

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), with a focus on medical writers building RMPs for new products or transitioning from Rev 1 to Rev 2 of the RMP Template
- Qualified Persons responsible for Pharmacovigilance (QPPVs)
- Assessors at National Competent Authorities (NCAs)
- Patients and Healthcare professional (HCP) group representatives

EUROPEAN MEDICINES AGENCY
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DIA

08:00 **REGISTRATION**

09:00 **WELCOME NOTE**

Jordi Llinares Garcia, EMA, and June Raine, MHRA

09:15 **SESSION 1**

RISK MANAGEMENT PLANNING IN THE EU: DESIGNING FIT FOR PURPOSE RISK MANAGEMENT PLANS – GVP V AND RMP TEMPLATE REV 2 GUIDANCE

Session Chairs: Jordi Llinares Garcia, EMA, and June Raine, MHRA

Key changes in the approach of GVP Module V to risk identification and risk management and their impact in the RMP Template will be highlighted in this session. EMA will present key points raised by stakeholders on the implementation of the updated guidance with practical advice.

Practical advice on the implementations of principles of risk management – GVP V Rev2
Emil Cochino, EMA

Practical advice on RMP content requirements based on RMP Template Rev 2 guidance
Núria Semis-Costa, EMA

Q&A/Panel Discussion

10:30 **COFFEE BREAK**

11:00 **SESSION 2**

CHALLENGES IN IMPLEMENTING THE UPDATED RMP GUIDANCE – STAKEHOLDERS' PERSPECTIVE

Session Chairs: Željana Margan Koletić, HALMED, and Jordi Llinares Garcia, EMA

PRAC and Industry's perspectives on the implementation of the updated guidance will be complemented by additional EMA guidance and advice on procedural aspects of RMP submission.

PRAC perspective on RMP guidance
Sabine Straus, MEB

Procedural aspects of RMP update – EMA advice on procedural topics raised by stakeholders
Emil Cochino, EMA, and Núria Semis-Costa, EMA

RMP guidance implementation – Industry perspective
Valerie Simmons, Eli Lilly

Q&A/Panel Discussion

12:45 **SANDWICH LUNCH**

13:30 **SESSION 3**

THE EU RISK MANAGEMENT SYSTEM: STAKEHOLDERS INTERACTION – AREAS OF FUTURE FOCUS

Session Chairs: Emil Cochino, EMA, and Sabine Straus, MEB

Areas where RM guidance is still being developed will be introduced by EMA; Assessor's view on further guidance will be complemented by an open panel discussion.

Practical advice on content requirements for generic, biosimilar, and fixed dose combination medicinal products; Product life cycle
Núria Semis-Costa, EMA

Expectations and Practical Advice from the view of an Assessor
Nils Lilienthal, BfArM

Q&A/Panel Discussion

15:00 **END OF THE INFORMATION DAY**

Participants are invited to send questions related to their experience with implementation of Rev 2 by 10 December to emaevents@diaglobal.org**.**

REGISTRATION FORM

ID #17594

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19 December 2017 | European Medicines Agency | London, United Kingdom

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: refreshments, sandwich lunch, delegate material and electronic access to presentations.

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

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 #17594 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.**

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

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 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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