



Information Day on Risk Management Planning and Post-Authorisation Studies

7 November 2016

European Medicines Agency, London, United Kingdom

PROGRAMME COMMITTEE

Emil Cochino

Scientific Officer, Anti-infectives and Vaccines, Scientific and Regulatory Management Department

Giampiero Mazzaglia

Scientific Officer, Endocrinology, Metabolism and Cardiovascular, Scientific and Regulatory Management 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

Almath Spooner

Vice Chair of the Pharmacovigilance Risk Assessment Committee (PRAC)
Pharmacovigilance and Risk Management Lead, Health Products Regulatory Authority (HPRA), IE

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 110 participants

NEED FOR THIS INFORMATION DAY

The European Medicines Agency has proposed significant changes to EU pharmacovigilance guideline on risk management plans (GVP Module V). In particular this aims to further clarify the activities on which a risk management plan should focus during the life cycle of a product 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. In parallel, major changes have been proposed to the integrated RMP template.

This Information Day is aimed primarily at providing marketing authorisation holders (MAHs) and marketing authorisation applicants (MAAs) with insights with the major revisions on the guidance on risk management. Practical examples will be used to illustrate the matters highlighted.

The guideline on Post authorisation safety studies (PASS) has setup the procedure for requiring PASS "whenever there are concerns about the risks of an authorised medicinal product". Experience with the request of PASS has led to the recognised need to better understand which elements should be considered for a PASS to be required. The information day will provide insight into the current activities on the topic and it will share the lesson learned from the experience through the EMA committees.

Coupled to these developments and directly contributing to their success, the new EU pharmacovigilance system has brought a greater opportunity for civil society to participate in the assessment and overall monitoring of the benefits and risks of medicines. Central to this progress in engaging patients and the public in medicines safety has been a fresh mandate for the European system to communicate risks effectively, and in a timely and transparent manner.

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". EMA's plans to transition the use of the updated RMP template and the implications for Applicants' submissions will also be presented.
- Developing lean, fit for purpose risk management plan documents in EU and the interplay with other benefit-risk monitoring processes. Highlights will include selected type of products, including upcoming plans for detailed guidance on Advanced Therapy Medicinal Products (ATMP).
- Involvement of healthcare professionals, patients and consumer groups in the design and evaluation of risk management activities in EU. Experience with public engagement in PRAC evaluations and decisions.
- Risk communication as a key instrument for risk management
- EMA updates on post authorisation safety studies (PASS) with a focus on defining key criteria for regulator's requesting a study and PASS classification in the Pharmacovigilance Plan

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

08:30 **REGISTRATION**

08:45 **WELCOME NOTE**

09:00 **SESSION 1**

RISK MANAGEMENT PLANNING IN EU: DESIGNING FIT FOR PURPOSE RISK MANAGEMENT PLANS – REGULATORY UPDATES

Key changes in GVP Module V's approach to risk identification and risk management will be highlighted in this session. EMA will present the expected impact of the changes with the view of improving the quality of RMP documents submitted for regulatory review in EU, while PRAC and industry representatives will describe important points for the assessors and MA applicants included in the updated GVP guidance.

10:30 **COFFEE BREAK**

11:00 **SESSION 2**

RISK MANAGEMENT PLANNING IN THE EU: DESIGNING FIT FOR PURPOSE RISK MANAGEMENT PLANS – PRACTICAL CONSIDERATIONS ON PRODUCT SUBMISSIONS

Impact of changes in GVP Module V on ongoing and future applications will be described in this session. EMA will present the expected impact of the changes with the view of improving the quality of RMP documents submitted for regulatory review in EU. Ongoing work on ATMP pharmacovigilance requirements guidance will be presented.

12:30 **SANDWICH LUNCH**

13:30 **SESSION 3**

RISK MANAGEMENT, RISK COMMUNICATION AND PUBLIC ENGAGEMENT

Key guiding principles of the EU system are openness, inclusivity, flexibility and timeliness. To empower citizens, EMA makes publicly available early ever-more information on the assessment of data, the decision-making process and the overall monitoring of medicine safety. The Agency regularly publishes information on the evaluation of safety signals, PSURs, RMPs and PAS. Publishing this information as soon as it becomes available keeps the public up to date with ongoing safety evaluations, but it also supports the pharmaceutical industry and the EU Regulatory Network in facilitating the implementation of safety decisions across EU.

15:00 **COFFEE BREAK**

15:30 **SESSION 4**

POST AUTHORISATION SAFETY STUDIES (PASS): OPTIMISING THE USE OF CRITERIA FOR REQUEST AND CLASSIFICATION

Speakers in this session will discuss what makes a PASS eligible for to be imposed as a condition of a marketing authorisation or to be requested as additional pharmacovigilance activity in the RMP. In addition lessons learned from the EMA committees experience with previous classification exercises will be presented.

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

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 <input type="checkbox"/>
Government/Academia/Charitable/Non-Profit (full time)	200.00 EUR <input type="checkbox"/>

*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.

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.

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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 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>

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- Industry (Member/Non-member) € 200.00
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