EMA Risk Management Information Day

15 June 2021
13:30 - 17:30 CEST | Virtual Event

PROGRAMME COMMITTEE

Sabine Straus
Chair of Pharmacovigilance Risk Assessment Committee (PRAC)
Medicines Evaluation Board (MEB), NL

Alexis Nolte
Head of Human Medicines Division, European Medicines Agency (EMA), EU

Evdokia Korakianiti
Human Medicines Division, Head of Quality and Safety of Medicines Department (H-QS), European Medicines Agency (EMA), EU

Georgy Genov
Human Medicines Division, Head of the Pharmacovigilance Office (H-QS-PHV), European Medicines Agency (EMA), EU

Maria Giovanna Satta
Human Medicines Division, Scientific Officer, Risk Management Specialist, Office of Therapies for Neurological and Psychiatric Disorders (H-NEU), European Medicines Agency (EMA), EU

FACULTY

Raymond Anderson
PRAC Member representing Healthcare Professionals (nominated by the EC), Pharmaceutical Group of the European Union (PGEU), BE

Priya Bahri
Human Medicines Division, Principal Scientific Officer, Pharmacovigilance Office, European Medicines Agency (EMA), EU

Hedvig Marie Egeland Nordeng
PRAC Member, Independent scientific expert (nominated by the EC), University of Oslo, NO

Thomas Goedecke
Human Medicines Division, Principal Scientific Officer, Pharmacovigilance Office, European Medicines Agency (EMA), EU

Liana Gross-Martirosyan
Alternate PRAC Member, Medicines Evaluation Board (MEB), NL

Adrien Inoubli
PRAC Member, Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM), FR

David Lewis
EU QPPV, Head QPPV Office, Novartis Pharma GmbH, DE
Senior Visiting Fellow, Department of Clinical & Pharmaceutical Sciences, University of Hertfordshire, UK
Representative of the IMI ConcePTION Consortium

Viola Macolic Sarinic
Human Medicines Division, PRAC Scientific Lead, Pharmacovigilance Office, European Medicines Agency (EMA), EU

Daniel Morales
PRAC Member, Independent scientific expert (nominated by the EC)
University of Dundee, UK / University of Southern Denmark, DK

Núria Semis-Costa
Human Medicines Division, Scientific Officer, Risk Management Specialist, Office of Therapies for Immune and Inflammatory Diseases, Office of Advanced Therapies, EMA, EU

Ulla Wändel Liminga
PRAC Member, Läkemedelsverket, SE

| OVERVIEW

The focus of this Information Day will be an update of the Agency's ongoing activities on medicines' risk management with the opportunity for an interactive platform to exchange experiences between Regulators and Industry.

A dedicated session will focus on the extensive revision of GVP module XVI, with special attention on criteria for selection, development, and implementation of various risk minimisation measures (RMMs) supporting the optimal use of a medicinal product in clinical practice, at any time during its lifecycle.

Principles and methods to evaluate the effectiveness of these measures, as detailed in the newly introduced Addendum II of GVP module XVI, will also be presented, with practical examples of research strategies, challenges, and limitations.

An overview on the development of GVP module product - or population-specific considerations III: pregnant and breastfeeding women – will be provided, together with the key activities of the IMI ConcePTION consortium: ecosystem for evidence on the safety of medicines in pregnancy & breastfeeding.

Due to the current situation related to COVID-19 and possible revised deadlines for public consultations, the specific topics of this information day may be adjusted.

| KEY TOPICS and PREPARATORY-READING

- GVP module XVI – Risk minimisation measures: selection of tools and effectiveness indicators (Rev 3)
- GVP module product - or population-specific considerations III: pregnant and breastfeeding women

| TARGET AUDIENCE

- Individuals experienced in risk management, risk minimisation development and evaluation at small to medium enterprises (SMEs), MAAs/MAHs for generic products, MAAs/MAHs for innovator products and contract research organisations (CROs)
- Assessors at National Competent Authorities (NCAs)
- Risk communication experts
- Patients and healthcare professional (HCP) group representatives
- Qualified persons responsible for Pharmacovigilance (QPPVs)

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DIA

AGENDA | TUESDAY, 15 JUNE 2021 | 13:30 – 17:30 CEST

13:30 LOG IN & WELCOME NOTE BY THE SESSION CHAIRS

Sabine Straus - Chair of Pharmacovigilance Risk Assessment Committee (PRAC), Medicines Evaluation Board (MEB), NL
Maria Giovanna Satta - Scientific Officer, Risk Management Specialist, Office of Therapies for Neurological and Psychiatric Disorders (H-NEU), EMA

13:40 SESSION 1
GVP MODULE XVI – RISK MINIMISATION MEASURES: SELECTION OF TOOLS AND EFFECTIVENESS INDICATORS (REV 3)

SELECTION OF TOOLS FOR RISK MINIMISATION
Núria Semis-Costa, Scientific Officer, Risk Management Specialist, Office of Therapies for Immune and Inflammatory Diseases, Office of Advanced Therapies, EMA, EU

A CLOSER EYE ON PREGNANCY PREVENTION PROGRAMMES (PPP)
Liana Gross-Martirosyan, Alternate PRAC Member, Medicines Evaluation Board (MEB), NL

TOOLS FOR RISK MINIMISATION: FROM THEORY TO PRACTISE
Raymond Anderson, PRAC Member representing Healthcare Professionals (nominated by the European Commission), Pharmaceutical Group of the European Union (PGEU), BE

14:40 BREAK

14:50 SESSION 1 - continued
GVP MODULE XVI – RISK MINIMISATION MEASURES: SELECTION OF TOOLS AND EFFECTIVENESS INDICATORS (REV 3)

METHODS FOR EFFECTIVENESS EVALUATION OF RISK MINIMISATION MEASURES (RMMs)
Thomas Goedecke, Principal Scientific Officer, Pharmacovigilance Office, EMA, EU

MONITORING THE EFFECTIVENESS OF RMMs: FROM THEORY TO PRACTISE
Daniel Morales, PRAC Member, Independent scientific expert (nominated by the European Commission), University of Dundee, UK / University of Southern Denmark, DK

15:30 Q&A AND PANEL DISCUSSION INCLUDING:
Priya Bahri, Principal Scientific Officer, Pharmacovigilance Office, EMA, EU
Viola Macolic Sarinic, PRAC Scientific Lead, Pharmacovigilance Office, EMA, EU

16:00 BREAK

16:10 SESSION 2
GVP MODULE PRODUCT - OR POPULATION-SPECIFIC CONSIDERATIONS III: PREGNANT AND BREASTFEEDING WOMEN

GVP MODULE PRODUCT - OR POPULATION-SPECIFIC CONSIDERATIONS III: PREGNANT AND BREASTFEEDING WOMEN
Hedvig Marie Egeland Nordeng, PRAC Member, Independent scientific expert (nominated by The European Commission), University of Oslo, NO

THE IMI CONCEPTION CONSORTIUM: ECOSYSTEM FOR EVIDENCE ON THE SAFETY OF MEDICINES IN PREGNANCY & BREASTFEEDING
David Lewis, EU QPPV, Head QPPV Office, Novartis Pharma GmbH, DE
Senior Visiting Fellow, Department of Clinical & Pharmaceutical Sciences, University of Hertfordshire, UK
Representative of the IMI ConcePTION Consortium

16:50 Q&A AND PANEL DISCUSSION INCLUDING:
Adrien Inoubli – PRAC Member, ANSM, FR
Ulla Wändel Liminga – PRAC Member, Läkemedelsverket, SE

17:20 WRAP UP

17:30 END OF THE INFORMATION DAY