EMA Risk Management Information Day

09 December 2022
13:30 - 17:30 CEST | Virtual Event

PROGRAMME COMMITTEE

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

Martin Huber
Pharmacovigilance Risk Assessment Committee (PRAC) Vice-Chair
Federal Institute for Drugs and Medical Devices (BfArM), DE

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Human Medicines Division, Head of Therapeutic Areas Department (H-TA), European Medicines Agency (EMA), EU

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Viola Macolic Sarinic
Human Medicines Division, PRAC Scientific Lead, Pharmacovigilance Office (H-QS-PHV), EMA, EU

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Human Medicines Division, Safety Product Lead, Office of Therapies for Neurological and Psychiatric Disorders (H-TA-NEU), EMA, EU

FACULTY

Priya Bahri
Human Medicines Division, Lead Pharmacovigilance and Risk Management Guidance and Policy (H-QS-PHV), EMA, EU

Corinne De Vries
Human Medicines Division, Scientific Evidence Generation, Head of Translational Sciences Office (H-EG-TRA), EMA, EU

Hedvig Marie Egeland Nordeng
PRAC Member, Independent Scientific Expert (nominated by EC), University of Oslo, NO

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

Eva Jirsová
PRAC Member - State Institute for Drug Control, CZ

David Lewis
EU QPPV, Head QPPV Office Novartis Pharma GmbH, DE; Honorary Senior Lecturer (Clinical), Depart of Clinical & Pharmaceutical Sciences, University of Hertfordshire; UK; Representative of the IMI ConcePTION Consortium, UK

Paul Ryan
General Practitioner and Pharmacist; Irish College of General Practitioners (ICGP) Therapeutics Lead and GP; HSE GP Antimicrobial Resistance & Infection Control (AMRIC) Lead, IRL

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, specifically looking at the safety of medicines and COVID-19 vaccines in women of child-bearing potential (WCBP), during pregnancy and breastfeeding, with special attention on challenges and lessons learned in different settings, such as when developing guidance documents, planning strategies for optimising data collection, measuring the effectiveness of risk minimisation measures (RMMs).

| KEY TOPICS and PREPARATORY READING

- GVP module XVI – Addendum III – Pregnancy Prevention Programme (PPP) and other pregnancy-specific risk minimisation measures (RMMs)

- GVP module product – or population-specific considerations III: pregnant and breastfeeding women

Due to the current situation related to COVID-19, the specific topics of this information day may be adjusted.

| 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
- 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
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AGENDA | FRIDAY, 09 DECEMBER 2022 | 13:30 – 17:30 CEST

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

Martin Huber – Vice Chair of Pharmacovigilance Risk Assessment Committee (PRAC) , Federal Institute for Drugs and Medical Devices (BfArM), DE
Maria Giovanna Satta – Safety Product Lead, Office of Therapies for Neurological and Psychiatric Disorders, EMA

SAFETY OF MEDICINES AND COVID-19 VACCINES IN WOMEN OF CHILD – BEARING POTENTIAL, DURING PREGNANCY AND BREASTFEEDING

13:40 SESSION 1

GVP MODULE PRODUCT – OR POPULATION-SPECIFIC CONSIDERATIONS III: PREGNANT AND BREASTFEEDING WOMEN – WHERE WE ARE
Viola Macolic Sarinic – PRAC Scientific Lead, Pharmacovigilance Office, EMA, EU

COVID-19 PANDEMIC – CHALLENGES AND LESSONS LEARNED
Ulla Wändel Liminga – PRAC Member, Läkemedelsverket, SE

EMA PREGNANCY STRATEGY
Corinne De Vries – Head of Translational Sciences Office, EMA, EU

IMI CONCEPTION CONSORTIUM: OPTIMISING DATA COLLECTION IN PREGNANT AND BREASTFEEDING WOMEN
David Lewis – EU QPPV, Head QPPV Office, Novartis Pharma GmbH, DE
Honorary Senior Lecturer (Clinical), Department of Clinical & Pharmaceutical Sciences, University of Hertfordshire, UK; Representative of the IMI ConcePTION Consortium

15:00 BREAK

15:10 Q&A AND PANEL DISCUSSION INCLUDING:

Eva Jirsová – PRAC Member – State Institute for Drug Control, Czech Republic

15:40 SESSION 2

GVP MODULE XVI – ADDENDUM III: PREGNANCY PREVENTION PROGRAMME – WHERE WE ARE
Priya Bahri – Principal Scientific Officer, Pharmacovigilance Office, EMA, EU

TREATING PREGNANT AND BREASTFEEDING WOMEN: THE REALITY OF CLINICAL PRACTICE AS A GP AND PHARMACIST
Paul Ryan – General Practitioner and Pharmacist; Irish College of General Practitioners (ICGP), Therapeutics Lead and GP; HSE GP Antimicrobial Resistance & Infection Control (AMRIC) Lead

MEASURING THE EFFECTIVENESS OF THE PREGNANCY PREVENTION PROGRAMME FOR VALPROATE – CHALLENGES AND LESSONS LEARNED
Liana Gross-Martirosyan – Alternate PRAC Member, Medicines Evaluation Board (MEB)

16:40 BREAK

16:50 Q&A AND PANEL DISCUSSION INCLUDING

Eva Jirsová – PRAC Member – State Institute for Drug Control, Czech Republic

17:20 WRAP UP

17:30 END OF THE INFORMATION DAY