# 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

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

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

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

**Heidi Janssen**
Human Medicines Division, Head of Office of Therapies for Endocrine and Cardiovascular Diseases (H-TA-ECV), EMA, EU

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

**Maria Giovanna Satta**
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** – Pharmacovigilance Risk Assessment Committee (PRAC) Vice Chair, 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:

**Hedvig Marie Egeland Nordeng –** PRAC Member, Independent Scientific Expert (nominated by EC), University of Oslo, Norway
**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

**Hedvig Marie Egeland Nordeng –** PRAC Member, Independent Scientific Expert (nominated by EC), University of Oslo, Norway
**Eva Jirsová –** PRAC Member – State Institute for Drug Control, Czech Republic

**17:20** WRAP UP

**17:30** END OF THE INFORMATION DAY