In - Person

EMA Risk Management Information Day

From Guidance to Practice: Operationalising the New EU GVP Requirements for Pregnancy and Breastfeeding Safety

Overview

The DIA–EMA Risk Management Information Day 2026 will provide an overview of key developments in EU pharmacovigilance guidance related to the safe use of medicines during pregnancy and breastfeeding as well as updates in GVP Module V Risk Management Plans and GVP Module VIII Post authorisation safety studies (PASS),

A central focus will be on the Guideline on good pharmacovigilance practices (GVP): Product- or Population-Specific Considerations III: Pregnant and breastfeeding women and their children exposed in utero or via breastmilk, published on the EMA website since February 2026. The programme will introduce the main concepts of the guideline and facilitate discussion on initial implementation experiences from both industry and regulators.

The event will also explore practical aspects of applying the GVP Addendum I to Module XVI on minimizing embryo–fetal risk, published in August 2025, highlighting early learnings related to the new approach to Pregnancy Prevention Programmes (PPP) and other risk-minimisation activities. In addition, participants will receive updates on ongoing EMA initiatives addressing pregnancy-related safety, including work on methodologies and regulatory approaches supporting the translation of evidence from data to product information.

Furthermore, updates to GVP Module V – Risk Management Plans will also be discussed, focusing on upcoming clarifications and expectations relevant to industry and regulators. The programme will also address updates to GVP Module VIII (Post authorisation safety studies (PASS), including new requirements for study protocols, study reports, and feasibility assessments, reflecting recent changes to the PASS guideline introduced through ICH M14 and their European implementation, illustrated with a practical study protocol example.

Key Topics

GVP Considerations PIII – Data collection during pregnancy and breastfeeding - Regulatory insights and Industry aspects of implementation.

- GVP – Addendum I to Module XVI on minimizing embryo-fetal risk medicines: Regulatory insights and Industry aspects of implementation.
- GVP Module V - Risk Management Plan updates
- GVP Module VIII - Post authorisation safety studies (PASS) - updates

Target Audience

- Individuals experienced in risk management and risk minimization development and evaluation at small to medium enterprises (SMEs)
- Patients and Healthcare Professionals (HCP) Communities Representatives
- Qualified Persons Responsible For Pharmacovigilance (QPPVs)
- MAAs/MAHs for innovator products and generic products
- Assessors at National Competent Authorities (NCAs)
- Contract Research Organisations (CROs)
- Risk Communication Experts

DATE & LOCATION

08 Sep 2026

09:00 - 17:00 CET

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam, NL

PROGRAMME COMMITTEE

Georgy Genov
Human Medicines Division
Head of Pharmacovigilance (PhV) Office, European Medicines Agency (EMA), EU

Ulla Wändel Liminga
PRAC Chair, Swedish Medical Products Agency (MPA), SE

Robert Massouh
Head of Risk Management and Benefit-Risk Evaluation, GSK, UK

Viola Macolic Sarinic
PRAC Scientific Lead, Pharmacovigilance Office, EMA, EU

Priya Bahri
Senior Lead, Pharmacovigilance Office, EMA, EU

EUROPEAN MEDICINES AGENCY
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Agenda

08:30 - 09:00 **Onsite Registration**

09:00 - 09:15 **Welcome & Opening Remarks**
Speakers: Georgy Genov - EMA, Head of Pharmacovigilance Office & Ulla Wändel Liminga, PRAC Chair

- Overview of the day and objectives
- Setting the regulatory context

Session 1: GVP P.III: Pregnancy and Breastfeeding – Data Collection, Regulatory Expectations and Early Experience

Chair: Priya Bahri, EMA

09:15 - 09:40 **GVP P.III – Key Concepts and Practical Implications for Pregnancy and Breastfeeding**
Speaker: Viola Macolić Šarinić, EMA

- Scope and objectives of GVP P.III
- Structured data collection during pregnancy and breastfeeding
- Integration into PSURs, RMPs and signal management
- Strengthening the evidence base to support regulatory decision-making

09:40 - 10:05 **PRAC Perspective – Expectations, Early Experience and Good Practices**
Speaker: Ulla Wändel Liminga, PRAC

- Regulatory expectations for implementation of GVP P.III
- Early assessment insights
- Presentation of pregnancy and breastfeeding data in PSURs – reflecting the newly proposed structured approach
- Common gaps observed and examples of good practices

10:05 - 10:20 **Q&A and Discussion**

10:20 - 10:50 **COFFEE BREAK**

Session 2: GVP Module XVI Addendum I: Deep Dive into Embryo–Fetal Risk Minimisation & Early Experience

Chair: Viola Macolić Šarinić, EMA

10:50 - 11:30 **Addendum I – Regulatory Rationale, Implementation Reflections and Learning from Experience**
Speakers: Priya Bahri, EMA and Liana Martirosyan, PRAC co-chair

- Overview of the Addendum I to GVP Module XVI
- Evolution of the EU approach to Pregnancy Prevention Programmes (PPP)
- Reflections on valproate risk minimisation measures – where outcomes have not fully met expectations and how this informs a strengthened future framework
- How the Addendum aims to address identified gaps and improve effectiveness of RMMs

11:30 - 11:50 **Industry Perspective – A Qualitative study to investigate Risk Minimisation Effectiveness Barriers in Women Of ChildBearing Potential (WOCBP)**
Speaker: Mathieu Lamy, Sanofi

- Example of Grounded Theory methodology – GVP Module XVI Addendum II alignment
- Reflections on collaboration with Regulators, Academia, CRO, and National Ethics
- Challenges in achieving Behavioural Change in HCPs and patients
- Industry perspectives on aRMMs effectiveness evaluation

11:50 - 12:05 **Q&A and Discussion**

12:05 - 13:05 **LUNCH BREAK**

Speakers & Panelists

Anna Beckmeyer-Borowko
Associate Director Epidemiologist
Novartis Pharma, CH

Emil Cochino
Scientific Senior Specialist (Risk Management)
European Medicines Agency, EU

Eva Jirsova
PRAC member
Pharmacovigilance Assesor
State Institute For Drug Control, CZ

Mathieu Lamy
Director Pharmacoepidemiologist,
Sanofi, BE

Liana Martirosyan
PRAC Member and PRAC Vice-Chair
Medicines Evaluation Board (MEB), NL

Cosimo Zaccharia
Senior PhV specialist
European Medicines Agency, EU

Session 3: Signal Detection in Pregnancy and Evidence Generation in Breastfeeding

Chairs: Robert Massouh, GSK and Eva Jirsova, PRAC member

13:05 - 13:25 **Signal Detection Algorithms in Pregnancy-Related Safety**

Speaker: Cosimo Zaccaria, EMA

- Signal identification in pregnancy exposure data
- Methodological challenges and limitations
- Application of structured algorithms and interpretation of findings
- Implications for regulatory assessment

13:25 - 13:50 **Breastfeeding Considerations – Evidence Generation and Risk Communication**

Speaker: Eva Jirsova, PRAC member

- Exposure through breastmilk and assessment of clinical relevance
- Challenges in generating robust data
- Translation of emerging evidence into product information
- Communication to healthcare professionals and patients

Session 4: Industry approaches in pre- and post-authorisation data generation

Chair: Robert Massouh, GSK

13:50 - 14:10 **Industry Approaches - A pre-authorisation framework to support earlier and more Robust generation of data in individuals of childbearing potential**

Speaker: Speaker Invited (ViiV)

14:10 - 14:30 **Industry Approaches – Pregnancy Outcomes Intensive Monitoring (PRIM) - a Post-authorisation method for enhanced PV data collection and processing**

Speaker: Anna Beckmeyer-Borowko, Novartis

14:30 - 14:40 **Q&A and Discussion**

Session 5: Panel Discussion: Bridging Expectations and Reality

14:40 - 15:40 **Pregnancy & Breastfeeding Safety: Bridging Regulatory Expectations and Real-World Implementation**

Moderator: Viola Macolić Šarinić, EMA

Panellists:

- EMA representative (tbc)
- Ulla Wändel Liminga, PRAC Chair
- Liana Martirosyan, PRAC Co-Chair
- Eva Jirsova, PRAC member
- Anna Beckmeyer-Borowko, Novartis
- Academia representative (tbc)
- Patient representative (tbc)
- Healthcare Professional (HCP) representative (tbc)

Discussion Topics:

- Aligning regulatory expectations under GVP P.III and Addendum I with operational feasibility
- Evaluating and measuring effectiveness of Pregnancy Prevention Programmes (PPP)
- Learning from past experience (including valproate) to strengthen future frameworks
- Methodological robustness of signal detection in pregnancy
- Evidence gaps in breastfeeding and approaches to reduce uncertainty
- Translating emerging data into meaningful and balanced product information
- Collaborative approaches between regulators, industry, academia and patient/HCP communities

Interactive audience engagement is encouraged.

15:40 : 16:00 **COFFEE BREAK**

Session 6: What's New: PASS and Risk Management Plan Updates

Chair: TBC

16:00 - 16:15 **GVP Module VIII (PASS) – New Requirements and ICH M14 Implementation**

Speaker: EMA representative (tbc)

- Updates to study protocol requirements
- Feasibility assessments and methodological expectations
- Study reports and regulatory review
- European implementation of ICH M14
- Practical considerations illustrated with a study protocol example

16:15 - 16:30 **GVP Module V – Updates to Risk Management Plans: Forward-Looking Regulatory Developments**

Speaker: Emil Cochino, EMA

- Broader updates and clarifications to Module V
- Strengthened expectations for structured risk identification and characterisation
- Integration of evolving methodologies and lifecycle risk management principles
- Implications for industry implementation and regulatory assessment
- Preparing for the future implementation of the updated RMP framework across therapeutic areas

16:30 - 16:40 **Q&A and Discussion**

16:40- 17:00 **WRAP UP and KEY TAKEAWAYS**

Speakers: Liana Martirosyan, PRAC Co-Chair and Georgy Genov, EMA

- Key reflections from the day
- Regulatory and implementation priorities
- Looking ahead