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EUROPEAN MEDICINES AGENCY

# Update on the EU-Good Pharmacovigilance Practices (EU-GVP)

## 20th EMA Industry Stakeholder Platform – Operation of EU Pharmacovigilance

13 November 2025

Presented by Priya Bahri

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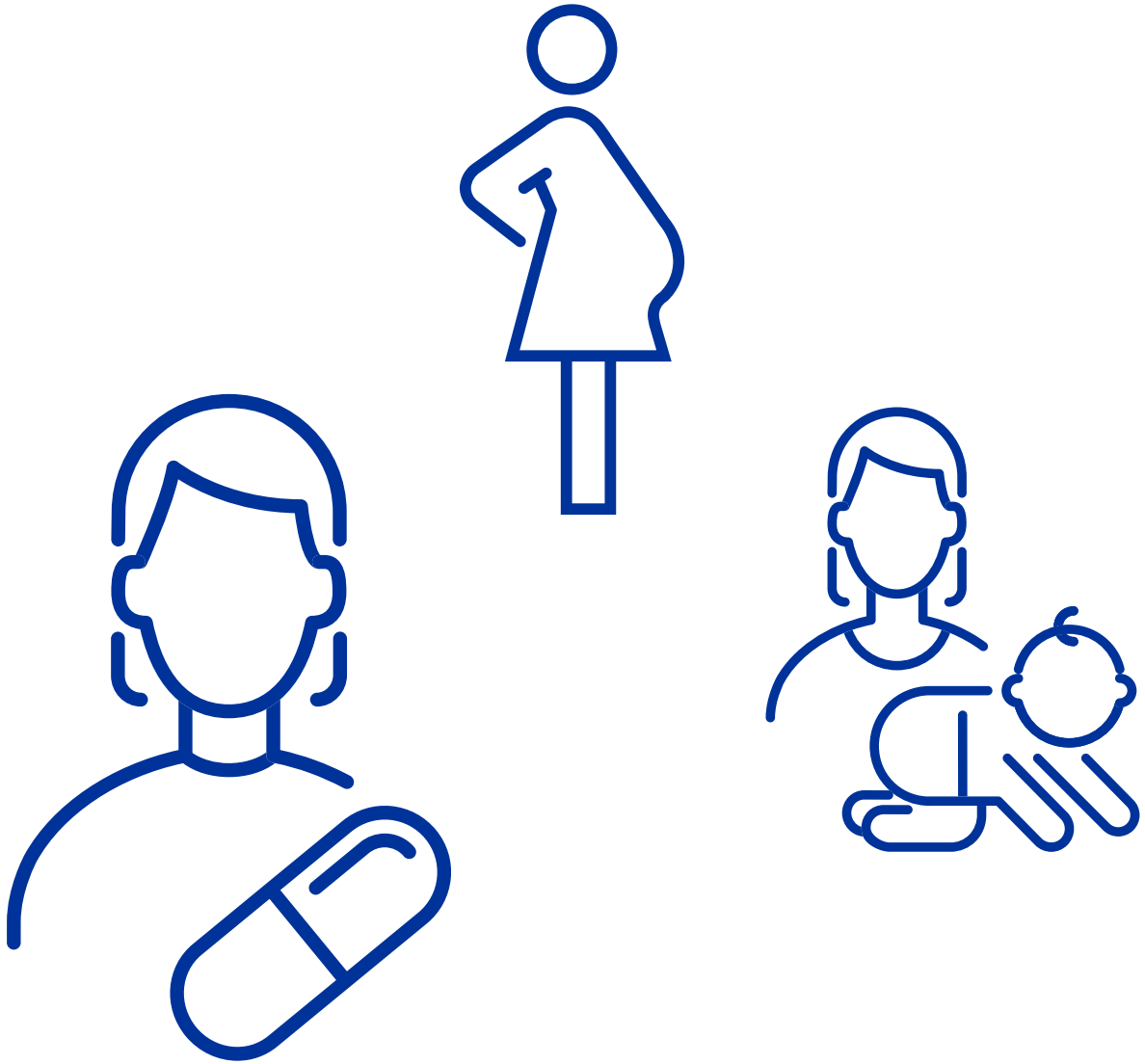
# **2025:** Major achievements in the area of identifying, assessing and minimising embryo-fetal risks



# New GVP Product- or Population-Specific Considerations III: Pregnant and breastfeeding women and their children exposed in utero or via breastmilk

HMA Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH

EMA/690023/2021

## 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

| | |
|---|---|
| Draft finalised by the Agency in collaboration with Member States | 27 November 2019 |
| Draft agreed by the EU Network Pharmacovigilance Oversight Group (EU-POG) | 29 November 2019 |
| Draft adopted by Executive Director | 4 December 2019 |
| Release for public consultation | 6 December 2019 |
| End of consultation | 28 February 2020 |
| Revised draft agreed by the Agency's Pharmacovigilance Risk Assessment Committee (PRAC) and finalised by the Agency in collaboration with Member States | 16 October 2025 |
| Revised draft agreed by the Co-ordination Group for Mutual Recognition and Decentralised Procedures – human (CMDh) | |
| Revised agreed by the Head of Human Medicines Division as final under delegated authority by the Executive Director | |
| Date for coming into effect | |





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# New Addendum I to GVP Module XVI on risk minimisation measures (RMM) for medicinal products with embryo-fetal risks

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SCIENCE MEDICINES HEALTH

22 August 2025
EMA/608947/2021

## Guideline on good pharmacovigilance practices (GVP)

Module XVI Addendum I – Risk minimisation measures for medicinal products with embryo-fetal risks

| | |
|---|---|
| Draft agreed by the Agency's Pharmacovigilance Risk Assessment Committee (PRAC) finalised by the Agency in collaboration with Member States | 9 November 2021 |
| Draft agreed by the EU Network Pharmacovigilance Oversight Group (EU-POG) | 3 January 2022 |
| Draft adopted by Executive Director | 3 March 2022 |
| Release for public consultation | 14 March 2022 |
| End of consultation (deadline for comments) | 31 May 2022 |
| Revised draft agreed by the Agency's Pharmacovigilance Risk Assessment Committee (PRAC) and finalised by the Agency in collaboration with Member States | 8 August 2025 |
| Revised draft agreed by the Co-ordination group for Mutual recognition and Decentralised procedures – human (CMDh) | 10 August 2025 |
| Revised agreed by the Head of Human Medicines Division as final under delegated authority by the Executive Director | 22 August 2025 |
| Date for coming into effect* | 29 August 2025 |

* This revised final guidance is applicable to new applications for marketing authorisation, new risk minimisation measures and new studies evaluating risk minimisation measures for authorised medicinal products but not immediately applicable to existing risk minimisation measures and ongoing activities regarding risk minimisation measures; however, where existing risk minimisation measures are amended, the revised guidance should be taken into account.

Note: This Addendum to GVP Module XVI has been renumbered from Addendum III (the number it carried as the draft version for public consultation) to Addendum I (the number of this final version), following revision 3 of GVP Module XVI finalised in 2024 (in which the previous Addendum I on educational materials was integrated as envisaged at the time of issuing the previous Addendum I).

See websites for contact details

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# Public consultation of draft in 2022

**Summary of comments analysis**:

- Some stakeholders welcomed the guidance overall
- Inconsistencies were pointed out
- Need to reconsider scope, terminology and approach
- Need to reconcile:
  - ❖ Health of the woman and health of the potential child
  - ❖ Evidence and precaution
  - ❖ Informed choice by the patient vs imposing actions and their consequences on patient

Thank you!

# Patient target populations of RMM

- Females (or individuals) who have reproductive potential
- Females (or individuals) who have or suspect to have become pregnant while using the medicinal product
- Males (or individuals) where seminal fluid may carry potentially harmful levels of the active substance contained in the medicinal product or where the semen/germ cell may be harmed by the product
- Children/adolescents with a view to their future reproductive potential
- Individuals who use the medicinal product and intend to donate blood, to deter their blood donation to avoid a pregnant female receiving such blood donation
- Parents of minor patients/carers of patients described above, as applicable

# Reconciliation 1:
## Linking evidence base for the need for RMM to the risk assessment which considers the medical need

European Medicines Agency
*Evaluation of Medicines for Human Use*

London, 24 July 2008
EMEA/CHMP/203927/2005

**COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE**

**(CHMP)**

**GUIDELINE ON RISK ASSESSMENT OF MEDICINAL PRODUCTS ON HUMAN REPRODUCTION AND LACTATION: FROM DATA TO LABELLING**

| | |
|---|---|
| **DRAFT AGREED BY MULTIDISCIPLINARY EXPERT GROUP** | June 2005 |
| **DRAFT AGREED BY THE SAFETY WORKING PARTY/EFFICACY WORKING PARTY/ PHARMACO-VIGILANCE WORKING PARTY** | November 2005 |
| **DISCUSSION AT THE HERBAL COMMITTEE FOR MEDICINAL PRODUCTS (HMPC) MEETING** | March 2006 |
| **ADOPTION BY CHMP FOR RELEASE FOR CONSULTATION** | March 2006 |
| **END OF CONSULTATION (DEADLINE FOR COMMENTS)** | 30 September 2006 |
| **AGREED BY MULTIDISCIPLINARY EXPERT GROUP** | July 2008 |
| **ADOPTION BY CHMP** | 24 July 2008 |
| **DATE FOR COMING INTO EFFECT** | January 2009 |

Under revision

| | |
|---|---|
| **KEYWORDS** | Pregnancy, lactation, contraindication, non-clinical assessment, clinical assessment, risk assessment, labelling, SPC. |

# Reconciliation 2:
## Considering health equity and ethics

"The overall guiding principle is that RMM for embryo-fetal risks should not compromise addressing the medical needs of a patient when there is no suitable alternative treatment available. Patients and healthcare professionals should be adequately informed about the risks and the actions for minimising the risks."

# Reconciliation 3:
## Introducing patient-centredness

- Risk counselling as an explicit risk minimisation action
- Clarifications on the risk minimisation actions to avoid becoming pregnant (i.e. not to engage in activities that could lead to becoming pregnant or to apply contraceptive measures, and to contact the prescribing healthcare professional, before stopping the actions to avoid becoming pregnant; and details on supportive actions RMM actions to be taken by healthcare professionals)
- Clinical context and implementability to be considered for requiring (additional) risk minimisation measures (as per GVP Module XVI) or a pregnancy prevention programme (PPP)

# RMM actions to prevent exposure of an embryo/fetus proactively before a pregnancy occurs

- Risk counselling
- Taking actions to avoid becoming pregnant
- Pregnancy testing
- Supervising treatment by an experienced or specialist physician
- Avoiding blood and semen/sperm donation

# Pregnancy prevention programme (PPP)

- Core elements for PPPs tailored to the typical clinical situation for the medicinal product
- A PPP is constituted at least of:

❑ Contraindication, or a contraindication unless there is no suitable alternative treatment for the patient during pregnancy

❑ Risk counselling

❑ Taking actions to avoid becoming pregnant

❑ Pregnancy testing

❑ Supervising treatment by an experienced or specialist physician, including conducting regular medication reviews

❑ Reminder statement regarding the embryo-fetal risks on the outer packaging

❑ Educational/safety advice material(s) for healthcare professionals

❑ Educational/safety advice material(s) for patients

# RMM actions if exposure of an embryo/fetus may have occurred

RMM actions to be the patient:

- Contacting the prescribing healthcare professional promptly to discuss the embryo-fetal risks and actions for managing the patient's medical condition and minimising the embryo-fetal risks

Appropriate actions to be taken by an experienced or specialist physician, to manage the patient's medical condition and minimising embryo-fetal risks after discussion with the patient may include but may not be limited to:

- Interrupting the use of the medicinal product
- Switching to suitable alternative treatment
- Dose reduction
- Specific prenatal monitoring

# Revision of scope, alignment with 2024 of Module GVP XVI and editing for clarity and sensitivities

**Table of contents**

# **2026:** Revisions of GVP documents following legal and ICH updates


# Revisions for legal amendments – planned release

Official Journal
of the European Union

EN
L series

2025/1466

23.7.2025

**COMMISSION IMPLEMENTING REGULATION (EU) 2025/1466**

**of 22 July 2025**

**amending Implementing Regulation (EU) No 520/2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council**

No need for public consultation:

- Module I on Pharmacovigilance systems: Q2 2026
- Module II on PSMF: Q4 2026
- Module III on inspections: Q1 2026 (mature draft already under review)
- Module VII ADD I on RMM implementation updates in PSURs: Q2 2026
- Module VIII on PASS: Q2 2026
- Module IX on signals: Q2 2026

Need for public consultation:

- Module IV on audits: Q3 2026
- Module VI on ICSRs: Q4 2026

# Revisions for ICH

INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED GUIDELINE

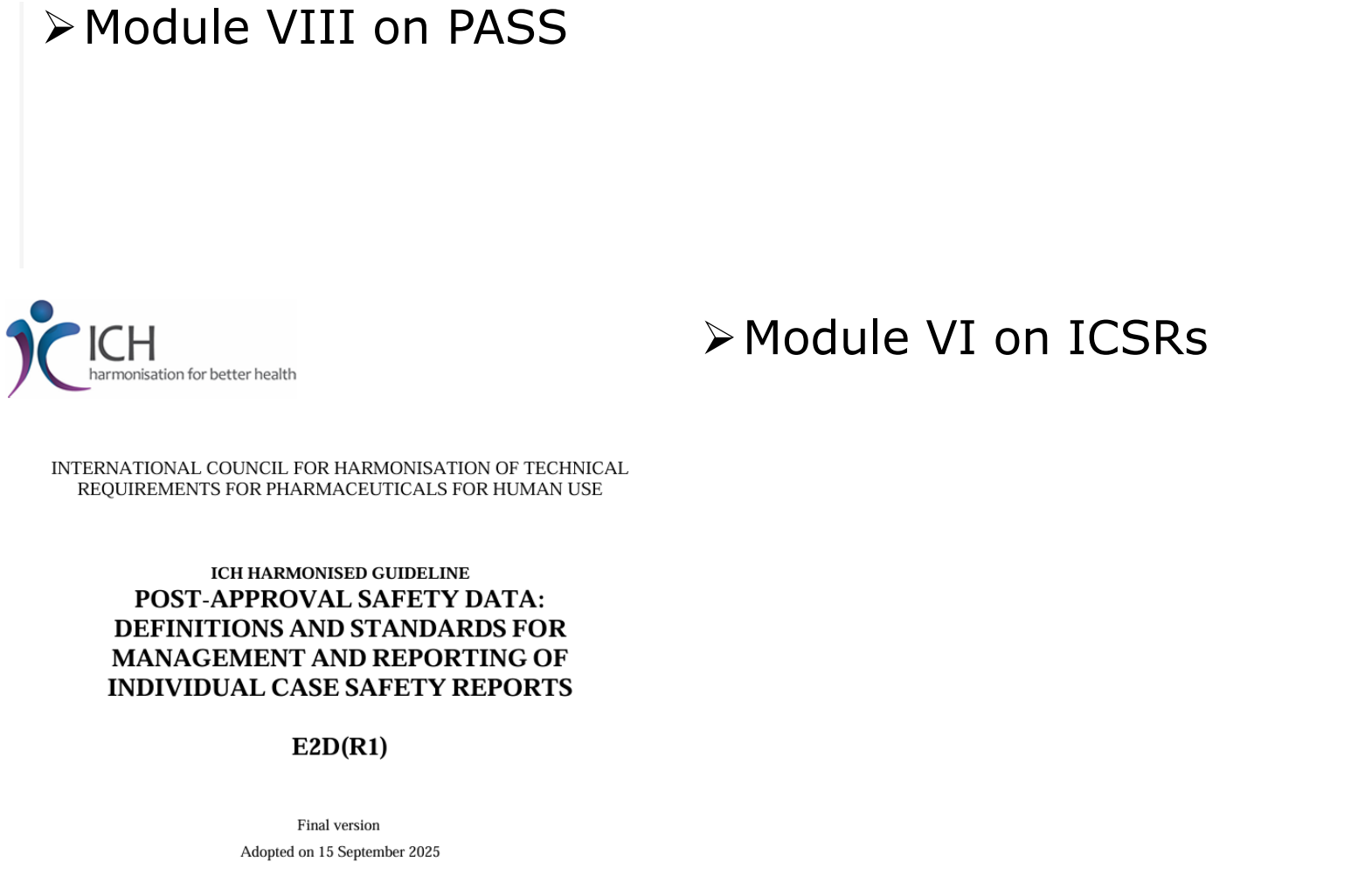
General Principles on Planning, Designing, Analysing, and Reporting of Non-interventional Studies That Utilise Real-World Data for Safety Assessment of Medicines

M14

Final Version

Adopted on 04 September 2025

- Module VIII on PASS



INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED GUIDELINE

POST-APPROVAL SAFETY DATA: DEFINITIONS AND STANDARDS FOR MANAGEMENT AND REPORTING OF INDIVIDUAL CASE SAFETY REPORTS

E2D(R1)

Final version

Adopted on 15 September 2025

- Module VI on ICSRs

# Other revisions – planned release

- Module V on RMP: Q2 2026 for public consultation
- Module XV on safety communication: Q4 2026 (not for public consultation)
- Considerations P.I on vaccines: Q3 2026 for public consultation

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# Thank you

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