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New GVP guidance on minimising embryo-fetal risks of medicines

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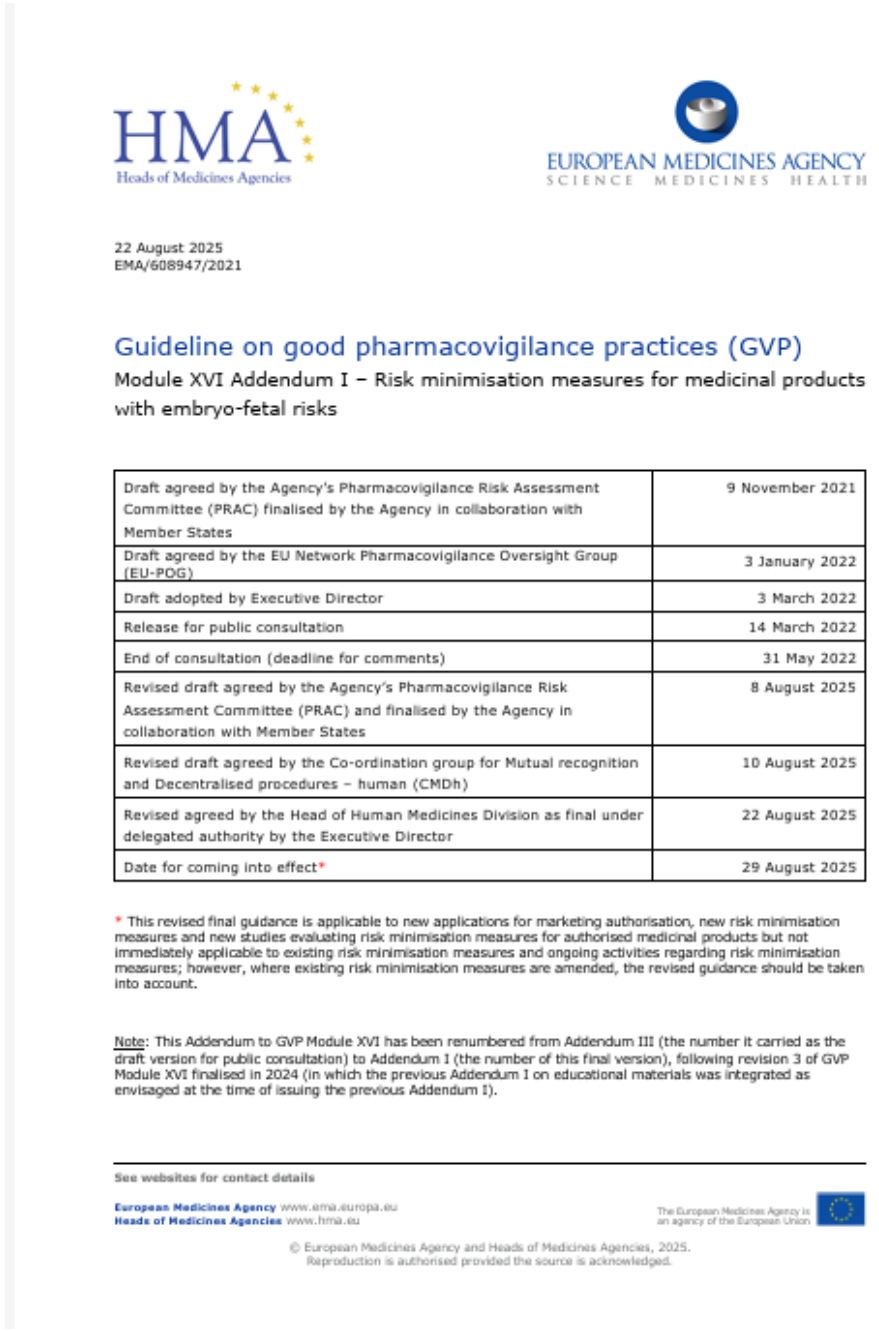
PCWP-HCPWP 24 September 2025



HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
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

European Medicines Agency www.ema.europa.eu
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Public consultation of draft in 2022

Public consultation comments from 33 parties:

- General comments: **90**
- Introduction: **39**
- Criteria: **99**
- Figure: **18**
- Pregnancy prevention programme: **122**
- Other: **1**

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 (access to most beneficial treatment) vs health of the potential child
  - Evidence (and strength of evidence) vs precaution
  - Informed choice by the patient vs imposing actions and their consequences on patient

Thank you!

Reconciliation 1: Linking evidence base for the need for risk minimisation measures (RMM) to risk assessment

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: 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: Patient-centredness and autonomy, and ethics

- Clarifications on the RMM actions to avoid becoming pregnant when needed for using a medicinal product with embryo-fetal risks
- Risk counselling as an explicit RMM action
- Introduction of core elements to define pregnancy prevention programmes (PPP) for tailoring PPPs, where needed, to the clinical situation typical for the given medicinal product

Taking actions to avoid becoming pregnant

RMM actions to be taken by a female patient who has reproductive potential:

- Not engage in activities that could lead to becoming pregnant; or
- Apply contraceptive measures, and
- Contact the prescribing healthcare professional, before stopping the actions to avoid becoming pregnant

RMM actions to be taken by healthcare professionals, to support the patient:

- Assessment of the reproductive potential and risk counselling
- Prescription of effective contraceptive measures as applicable
- Providing the patient with educational/safety advice material(s) (= additional RMM materials)

Risk counselling

- To be conducted by a healthcare professional in a personal dialogue and aiming at ensuring the patient's (carer's) full understanding
- To be integrated in the therapeutic decision-making at the time of first prescription; may also be required during and after use of the medicinal product, taking into account the patient's (changing) reproductive potential, engagement in activities that could lead to becoming pregnant and/or consideration of a pregnancy
- To include:

➢ Embryo-fetal risks of the medicinal product

➢ Need to manage the patient's medical condition, the treatment options and the risks of the medical condition for a potential embryo/fetus

➢ Actions to avoid becoming pregnant, including options of contraceptive measures and other RMM actions

➢ Need to promptly contact the prescribing healthcare professional if questions regarding the treatment, the embryo-fetal risks of the medicinal product or the RMM arise

➢ Need for consultation by an experienced or specialist physician if the patient is considering a pregnancy or if exposure of an embryo/fetus to the concerned medicinal product may have occurred, to discuss the embryo-fetal risks and actions for managing the patient's medical condition and minimising the embryo-fetal risks

Pregnancy prevention programme (PPP)

- 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

Revision of scope, alignment of structure and terminology with revision 3 of Module GVP XVI of 2024 and approaches, and editing for clarity and sensitivities

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Thank you

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