

Revision of “Guideline on Risk assessment of Medicinal Products on Human Reproduction and Lactation: from Data to Labelling”

Industry Stakeholder Platform - Operation of EU Pharmacovigilance

Guidance update

20 October 2026

Presented by Dinah Duarte | Pharmacovigilance Office

London, 24 July 2008
EMA/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**

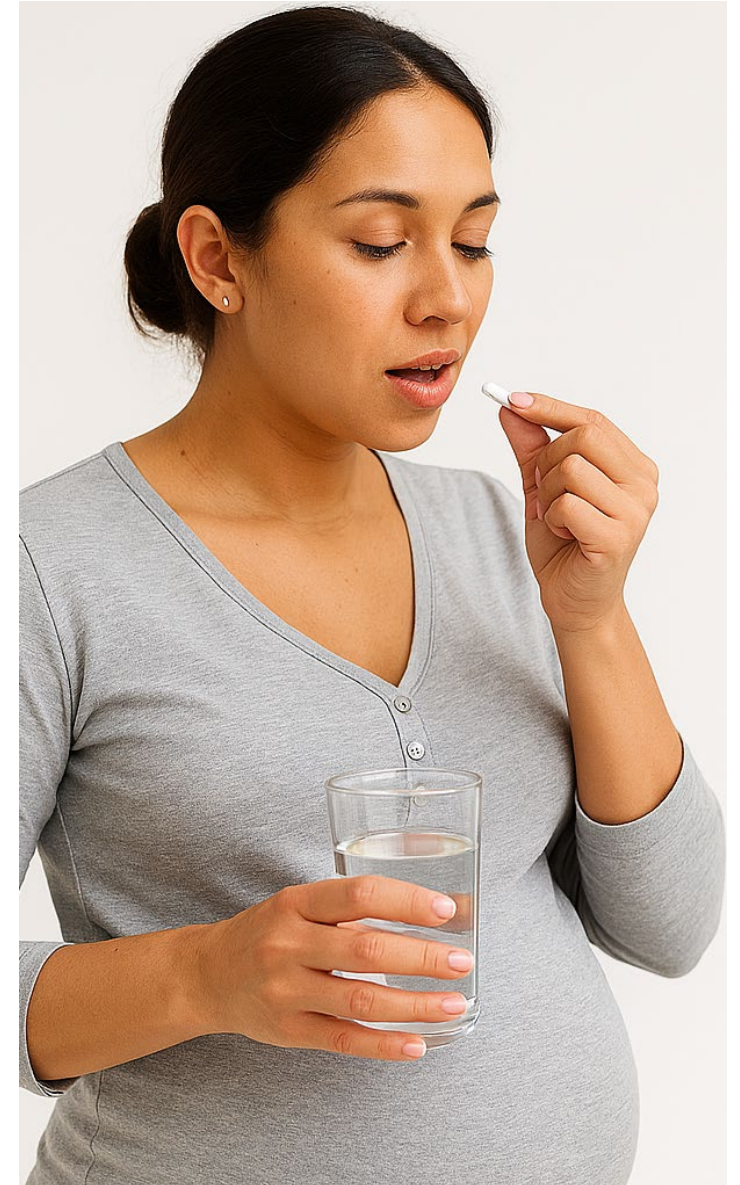
DRAFT AGREED BY MULTIDISCIPLINARY EXPERT GROUP	June 2005
DRAFT AGREED BY THE SAFETY WORKING PARTY/EFFICACY WORKING PARTY/ PHARMACO-VIGILANCE WORKING PARTY	November 2005
DISCUSSION AT THE HERBAL COMMITTEE FOR MEDICINAL PRODUCTS (HMPC) MEETING	March 2006
ADOPTION BY CHMP FOR RELEASE FOR CONSULTATION	March 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

KEYWORDS

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

Background

- **Trigger:** [PRAC work plan 2024](#); [CHMP Workplan 2025](#), [CHMP work plan 2026](#), [PRAC work plan 2026](#)
- **Scope:** guidance on integration of clinical & nonclinical data (Fertility, Pregnancy, Breastfeeding) for the assessment of risk of an adverse maternal, or child effect in humans -> translate assessments into recommendations -> Communicate recommendations as standard texts in labelling (SmPC & PL) -> HCP & Pt to make individual benefit-risk decisions.
- **Multi-stakeholders drafting group on GL revision** e.g. PRAC and CHMP, non-clinical, clinical, pharmacoepidemiology labelling expertise
- **Deliverables:**
 - 1. [Concept paper](#) (CP) on the scope of GL revision
 - **2. updated Guideline**
- **GL areas planned to be updated:** [Concept paper revision GL risk assessment human reproduction lactation for PC](#). Public consultation (May-Sept/24) after adoption by PRAC & CHMP (April/24)



Concept paper (2024) | Key points

1

Pregnancy

Non-clinical assessment

- Align with ICH(R3) on e.g. interpretation of exposure margins, new approach methods

Clinical assessment

- Broader description of adverse pregnancy outcomes, inc. long-term (neurodevelopmental disorders)
- Further methodology considerations

2

Breastfeeding

Estimating levels in breast milk; potential adverse effects in breastfeed infant & current risk assessment

3

Integration of data

Risk assessment & Recommendations & wording for product information

4

Updated standard texts both SmPC & PL

Fertility (new), breastfeeding, pregnancy, **females who can become pregnant (new)**, **PL (new)**

Guideline revision | Title & structure

CHMP - GL ON RISK ASSESSMENT OF MEDICINAL PRODUCTS ON HUMAN REPRODUCTION AND LACTATION: FROM DATA TO LABELLING (2009)

- 5 NON-CLINICAL ASSESSMENT.....
 - 5.1 Deficiencies in available data.....
 - 5.2 No effect detected
 - 5.3 Effects detected
 - 5.4 Class alert.....
- 6 CLINICAL ASSESSMENT.....
 - 6.1 Effects on Male and Female Fertility.....
 - 6.2 Developmental effects:.....
 - 6.2.1 Assessment of malformative effects:
 - 6.2.1.1 No evidence of increased frequency of malformations
 - 6.2.1.2 A suggested or suspected malformative effect is based on:.....
 - 6.2.1.3 A demonstrated malformative effect is defined when:.....
 - 6.2.2 Assessment of fetal and/or neonatal toxicity:.....

- 7 LACTATION.....
- 8 INTEGRATION: FROM DATA TO LABELLING.....
- 8.1 General principles
- 8.1.1 Fertility.....
- 8.1.2 Pregnancy.....
- 8.1.3 Lactation.....
- 8.2 CONTRAINDICATION.....
 - 8.2.1 Principles for contraindication in pregnancy.....
 - 8.2.1.1 Human experience.....
 - 8.2.1.2 Relevant non-clinical studies
 - 8.2.1.3 Need for treatment.....
 - 8.2.2 Lactation.....
- 8.3 Women of childbearing potential / Contraception
- 9 REFERENCES.....
- APPENDIX 1.....
- APPENDIX 2.....
- APPENDIX 3.....

CHMP/PRAC - Guideline on risk assessment of medicinal products in human reproduction and breastfeeding: from data to product information

15 April 2026
EMA/CHMP/PRAC/203927/2005 Rev.1
Committee for Medicinal Products for Human Use (CHMP)
Pharmacovigilance Risk Assessment Committee (PRAC)

Guideline on risk assessment of medicinal products in human reproduction and breastfeeding: from data to product information

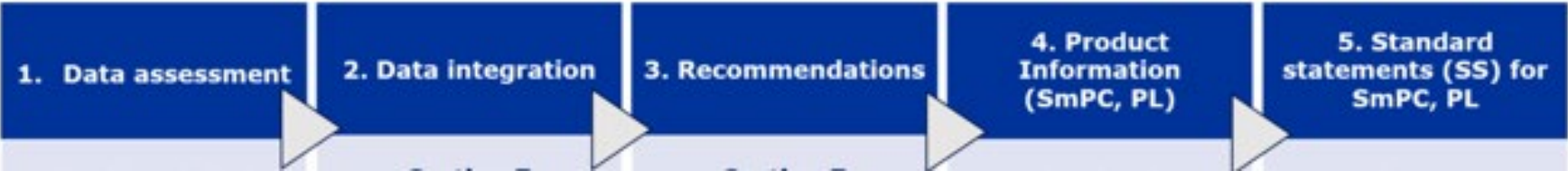
Draft

Draft agreed by Committee for Medicinal Products for Human Use (CHMP); Pharmacovigilance Risk Assessment Committee (PRAC)	13 April 2026
Adopted by CHMP and PRAC for release for consultation	<DD Month YYYY>
Start of public consultation	<DD Month YYYY>
End of consultation (deadline for comments)	<DD Month YYYY>
Agreed by Committee for Medicinal Products for Human Use (CHMP); Pharmacovigilance Risk Assessment Committee (PRAC)	<DD Month YYYY>
Adopted by Committee for Medicinal Products for Human Use (CHMP); Pharmacovigilance Risk Assessment Committee (PRAC)	<DD Month YYYY>

This guideline replaces “Guideline on Risk Assessment of Medicinal Products on Human Reproduction and Lactation: from Data to Labelling (EMA/CHMP/203927/2005)”

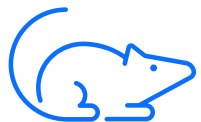
Comments should be provided using this [EUSurvey](#) form (add the link to the form). For any technical issues, please contact the [EUSurvey Support](#).

Keywords	Pregnancy, lactation, breastfeeding, fertility, contraindication, risk minimisation, non-clinical assessment, clinical assessment, risk assessment, SmPC, Package Leaflet.
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Stepwise process of risk assessment: from data to product information

Guideline revision | Examples of new/revised topics



Non-clinical assessment

New / Expanded

- New approach methods (NAMs)
- Weight-of-evidence (WoE) approach
- More guidance: species selection, exposure margins, mechanistic data



Clinical assessment

New / Expanded Pregnancy

- Details on adverse pregnancy outcomes (E.g. neonatal outcomes, NDDs)
- Extended methodology for assessing pregnancy outcomes, incl. key epidemiological considerations

New / Expanded Fertility

- Clearer integration of NC vs clinical findings



Assessment re. breastfeeding

New / Expanded

- Focus on clinical data e.g. mother/infant PK, PD, class effects, level in breast milk & estimated transfer to infant
- “Major” vs “complementary” evidence sources & factors for risk assessment

Progress update since last info day (2024)

Concept paper public consultation

May – Sept 2024

PRAC & CHMP drafting group

CP comments

Nov 2024 – Jan 2025

PRAC & CHMP drafting group

(Re)drafting/updating guideline

Jan 2025 - Apr 2026

PRAC & CHMP drafting group

internal & Committee consultation comments

May – Oct 2026

CHMP & PRAC adoption

Nov - Dec 2026

Public consultation of revised GL

Nov - Dec 2026

Guideline revision | Anticipated impact

- **Update population specific scientific and regulatory guidance** e.g. developments in non-clinical field and post-authorisation data
- **How to communicate potential or identified risks**
- **Address specific information needs** for HCP and patients/individuals planning pregnancy, being pregnant, or planning breastfeeding
- **Facilitate consistent recommendations** to pregnancy and breastfeeding related sections of the SmPC and PL during the life cycle of a medicinal product.

Public consultation will be launched shortly...



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Thank you

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