



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

Industry Stakeholder Platform – Pharmacovigilance guidance update

15 November 2024

Presented by Dinah Duarte | Pharmacovigilance Office

An agency of the European Union



Aim of Guideline: guidance on the integration processes of clinical & non-clinical data for the assessment of the risk of an adverse maternal, foetal or child effect in humans:

- translate the assessments of data into recommendations
- communicate the recommendations on potential/identified risk > Summary of Product Characteristics (SmPC), Package Leaflet (PL)
- examples of standardized text > use pregnancy (P) and breastfeeding (B) -> Health care professionals & Patients to make benefit-risk decisions
- decision scheme on contra-indication during pregnancy



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.

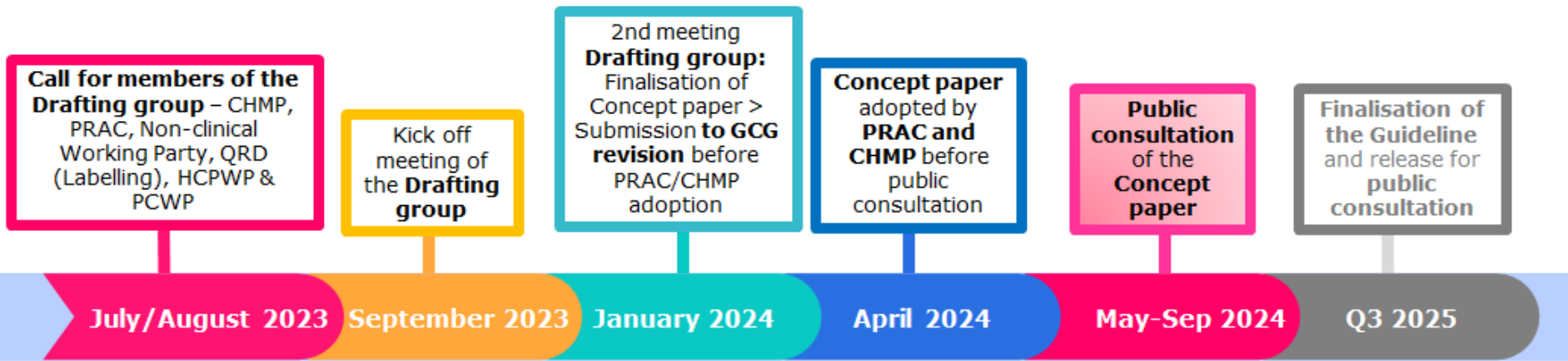


- Lack clinical data on medicines safety during P&B -> area of significant public health need
- Patients/prescribers: more information on medicines safety during P&B -> GL without standard text for PL
- EMA RSS 2025: better communication benefits, risks, uncertainties of medicines use in P&B
- Developments since 2008 impacts on data interpretation relevant for P&B: NC/ReproTox; post-MA data on exposed pregnancies; Breastfeeding info (PBPK modelling, human transfer studies)
- Alignment with other GLs: GVP Product- and Population- Specific Considerations Chapter P.III: Pregnant and breastfeeding women; GVP Module XVI Addendum I on RMM in non-pregnant individuals for medicinal products with teratogenic or adverse effect on (neuro-)development after in-utero exposure

Update '*CHMP Guideline on risk assessment of medicinal products on human reproduction and lactation: from data to labelling (EMA/CHMP/203927/2005)*'

included in PRAC and CHMP work plans for 2023/2024

Multi-stakeholders drafting group – Concept paper on the revision of the Guideline



Drafting group: update Concept paper

Drafting group: update (re-drafting) Guideline

HCPWP – Healthcare professionals working party
PCWP - Patient and consumers working party
GCG – Guideline Consistency Group



- **Key adverse pregnancy outcomes:** teratogenic effects in addition to congenital malformations; Expanded exposure windows beyond 1st trim
- **Non-clinical developments:** more guidance on interpretation of A:H exposure margins; assessment of exposure via breast milk; use new approach methods (NAMs) as alternatives to animals testing.
- **Causality assessment:** further description of key elements that may aid causality assessments of signals of reproductive adverse effects
- **Breastfeeding:** update on current knowledge on risk assessment and recommendations on risk for adverse effects of medicines for infants exposed via breast milk
- **Standard texts:** improve terminology of standard statements (SS) in section 4.6 “Fertility, pregnancy and lactation” of SmPC & SS for the PL; evaluate need to develop SS to SmPC/PL on “male and female fertility”.

- **Objective:** outlines GL areas which are planned to be updated
- Adopted by **PRAC and CHMP** in April/24
- **Public consultation:** 2.5.2024 – 13.9.2024



1 21 March 2024
2 EMA/CHMP/170670/2024
3 Committee for Medicinal Products for Human Use (CHMP); Pharmacovigilance Risk Assessment Committee
4 (PRAC)

5 [Concept paper on revision of the Guideline on Risk Assessment of Medicinal Products on Human Reproduction and Lactation: from Data to Labelling](#)

Agreed by Committee for Medicinal Products for Human Use (CHMP); Pharmacovigilance Risk Assessment Committee (PRAC)	April 2024
Adopted by CHMP for release for consultation	25 April 2024
Start of public consultation	2 May 2024
End of consultation (deadline for comments)	13 September 2024

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10 The concept paper proposes to revise the Guideline on Risk Assessment of Medicinal Products on
11 Human Reproduction and Lactation: from Data to Labelling (EMA/CHMP/203927/2005)

12
13 Comments should be provided using this EUSurvey [form](#). For any technical issues, please contact the [EUSurvey Support](#).

Keywords	<i>Pregnancy, breastfeeding, lactation, fertility, reproductive toxicity, teratogenicity, contraindication, clinical assessment, non-clinical assessment, risk assessment, labelling, Summary of Product Characteristics (SmPC).</i>
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CP public consultation: [Concept paper revision GL risk assessment human reproduction lactation for PC \(europa.eu\)](https://europeancommission.europa.eu/public-consultations/2024/05/05/08/2024-05-08-170670)

Risk assessment of medicinal products on human reproduction and lactation: from data to labelling - Scientific guideline

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Human Scientific guidelines

Page contents

Current effective version

Document history - First version (current)

Related content

Topics

This document describes how to assess the risk of an adverse reproductive/developmental effect in human based on reproductive toxicity studies in animals and human clinical data. It addresses information to be included in the summary of product characteristics on how to use the medicinal product taking into account the nature of the risk.

Keywords: Pregnancy, lactation, contraindication, non-clinical assessment, clinical assessment, risk assessment, labelling, summary of product characteristics (SmPC)

Current effective version



Guideline on risk assessment of medicinal products on human Reproduction and lactation: from data to labelling

Adopted

Legal effective date: 01/01/2009

Reference Number: EMEA/CHMP/203927/2005

English (EN) (162.87 KB - PDF)

First published: 24/07/2008 Last updated: 24/07/2008

View



Concept paper on revision of the Guideline on Risk Assessment of Medicinal Products on Human Reproduction and Lactation: from Data to Labelling

Consultation dates: 02/05/2024 to 31/08/2024

Draft: consultation open

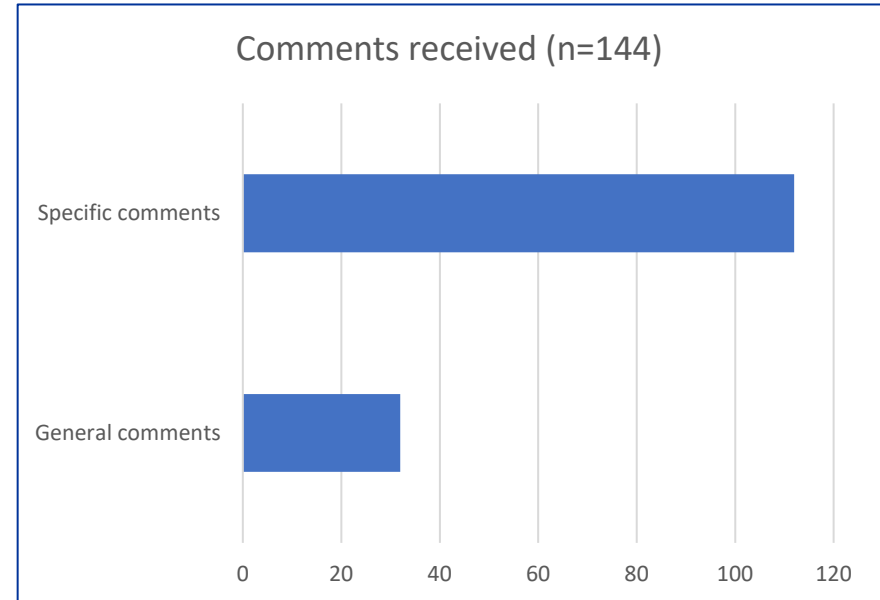
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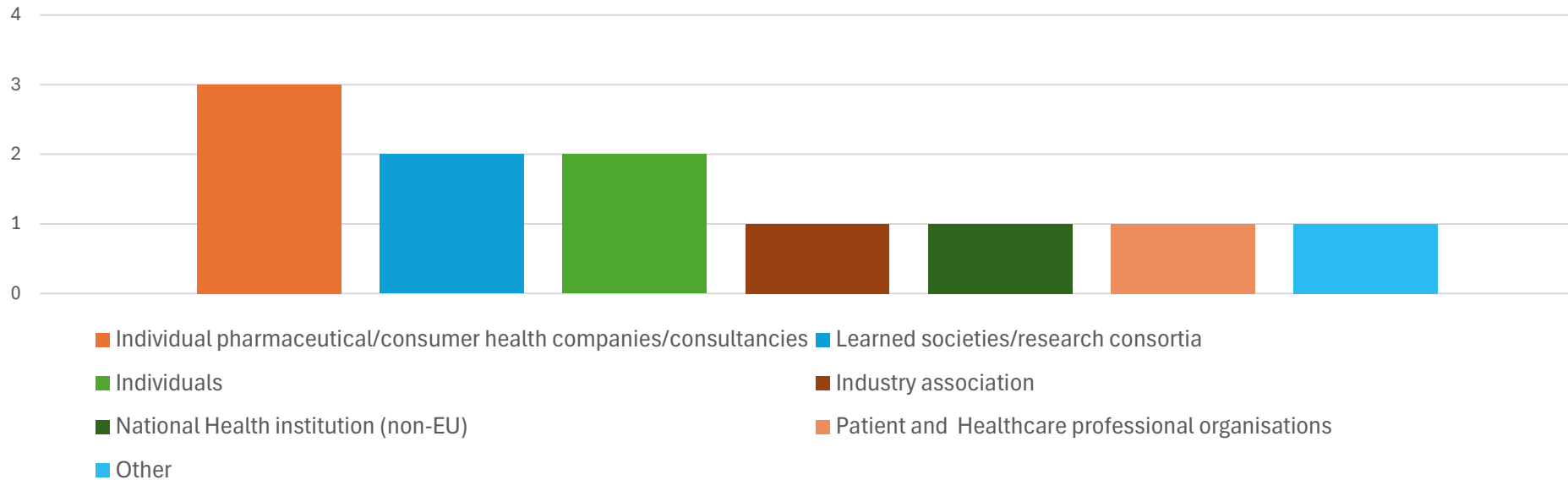
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Type of comments



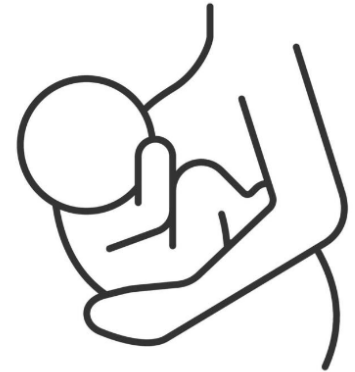
Type of stakeholder

Commenting parties (n=11)





- **How to communicate potential or identified risks**, specifically through the SmPC and PL.
- Contribute to address **specific information needs** for healthcare professionals and patients planning pregnancy, being pregnant, or planning breastfeeding
- Promote **evidence based informed decisions**
- Support management of **diseases during pregnancy and breastfeeding**
- Support **harmonised EU position**; facilitate consistent recommendations to pregnancy and breastfeeding related sections of the SmPC and PI during the life cycle of a medicinal product.





Thank you for your attention

Further information

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