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SCIENCE MEDICINES HEALTH

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

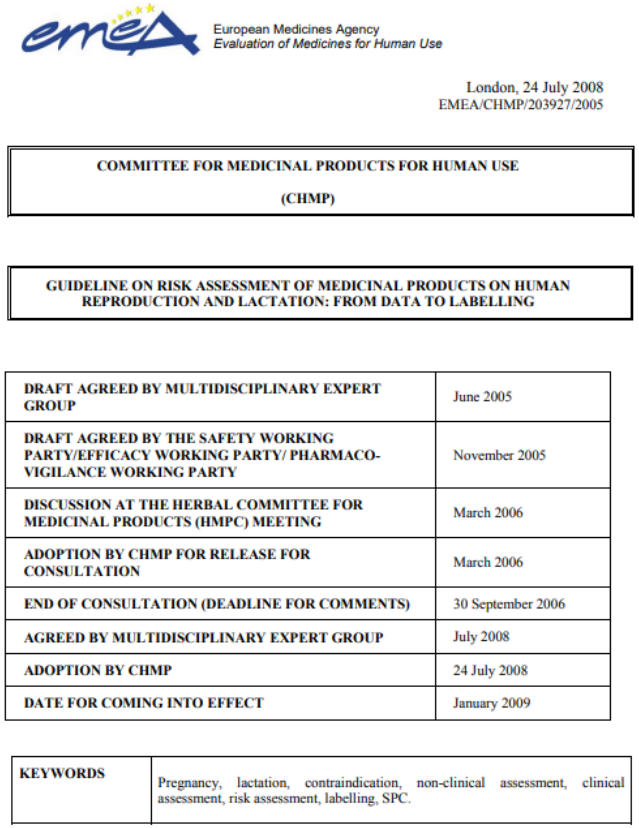
PCWP-HCPWP meeting, 2 June 2024

Dinah Duarte

Background

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 standardised text -> use pregnancy (P) and breastfeeding (B) -> Health care professionals & Patients to make benefit–risk decisions
- decision scheme on contra-indication during pregnancy



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

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

1 Concept paper on Guideline Labelling Pregnancy & Lactation

Problem statement

- 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 -> guideline 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: non-clinical/ReproTox; post-MA data on exposed pregnancies; Breastfeeding info (PBPK* modelling, human transfer studies)
- Alignment with other guidelines: GVP Product- and Population- Specific Considerations Chapter P.III: Pregnant and breastfeeding women; GVP Module XVI Addendum III: Pregnancy prevention programme (PPP) and other pregnancy-specific risk minimisation measures (PRiM)

Update *'CHMP Guideline on risk assessment of medicinal products on human reproduction and lactation: from data to labelling (EMEA/CHMP/203927/2005)'* **included in PRAC and CHMP work plans for 2023/2024**

** PBPK - Physiologically based pharmacokinetic modelling*

Past activities

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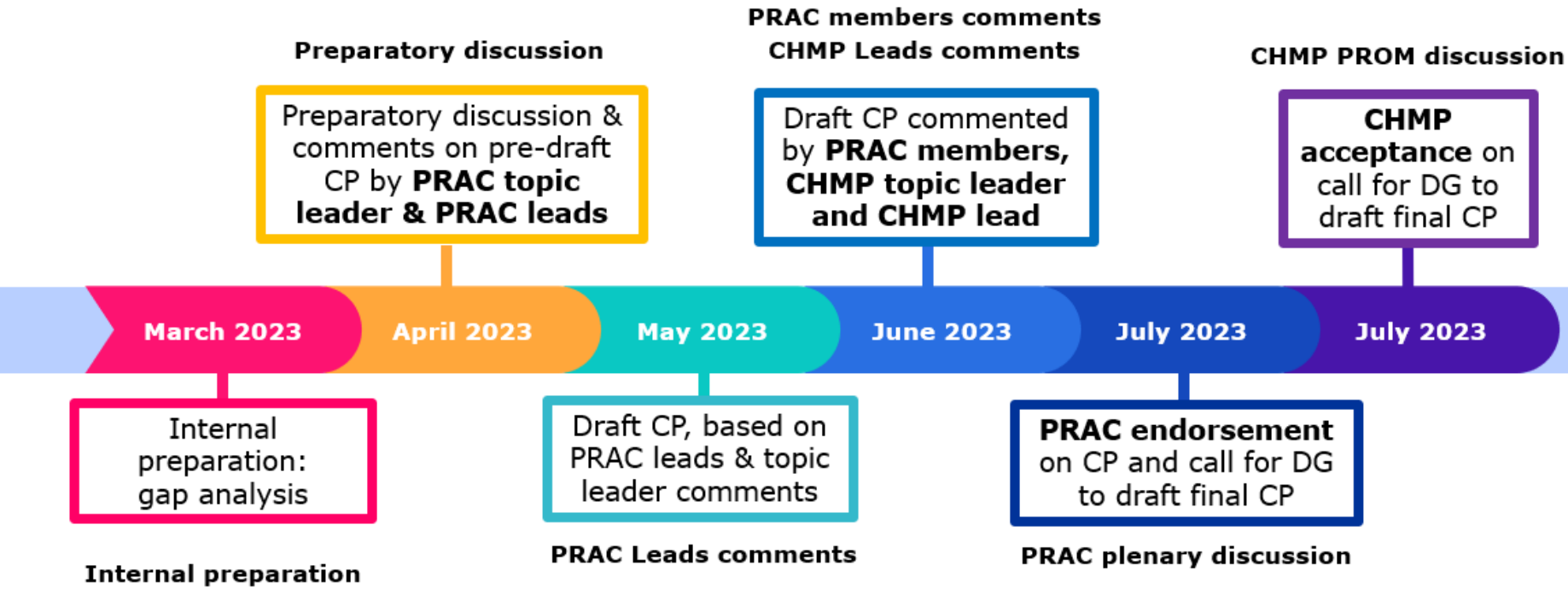
Consultation of PRAC and CHMP leads on drafting of **Concept paper (CP)** on revision of Guideline



DG – Drafting group

Following activities and next steps

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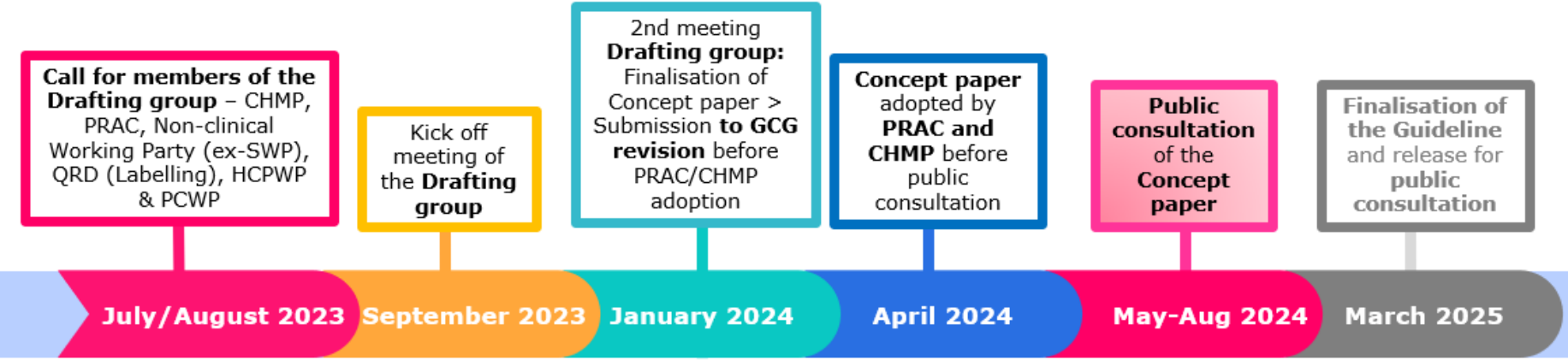
Drafting group – **Concept paper** on the revision of the Guideline



Drafting group: update **Concept paper**

Drafting group: update (re-drafting) **Guideline**

GCG – Guideline Consistency Group

Concept paper – drafting group meetings

- **Objective:** outlines the areas in guideline which are planned for update -> Concept paper
- **Multi-stakeholder drafting group** on Guideline revision: members from **CHMP, PRAC**, NcWP, 3RsWP, QRD, SmPC Advisory Group, EMA Labelling office, EMA pregnancy community, **HCPWP representatives Piera Polidori and Karel Allegaert**
- Representatives from **PCWP** invited and will contribute at later stage Guideline revision

Concept paper – examples of areas in need of revision

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- **Key adverse pregnancy outcomes:** teratogenic effects in addition to congenital malformations; Expanded exposure windows beyond the first trimester of pregnancy and during the entire pregnancy
- **Non-clinical developments:** more guidance on interpretation of Animal:Human exposure margins; assessment of exposure via breast milk; use new approach methods (NAMs) as alternatives to animals testing
- **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".

Concept paper public consultation

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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
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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
Reference Number: EMA/CHMP/170670/2024

English (EN) (399.77 KB - PDF)
First published: 02/05/2024 View

CP public consultation: Concept paper revision GL risk assessment human reproduction lactation for PC (europa.eu)

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

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)	31 August 2024

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

Comments should be provided using this EUSurvey form. For any technical issues, please contact the EUSurvey Support.

Keywords	*Pregnancy, breastfeeding, lactation, fertility, reproductive toxicity, teratogenicity, contraindication, clinical assessment, non-clinical assessment, risk assessment, labelling, Summary of Product Characteristics (SmPC).*

EUSurvey form to provide comments

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Anticipated GL impact

- **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 Pl during the life cycle of a medicinal product.

PCWP and HCPWP are invited to provide comments until 31 August 2024:

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

Thank you for your attention

Further information

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