EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Why is it so difficult to treat pregnant & breastfeeding women and what can EMA do to help?

Workshop on benefit-risk of medicines used during pregnancy and breastfeeding

Presented by Corinne de Vries on 22 September 2020
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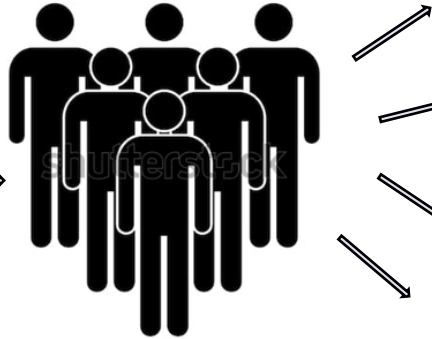
Why is it so difficult to treat pregnant & breastfeeding women?



Reality of medicine use in pregnancy

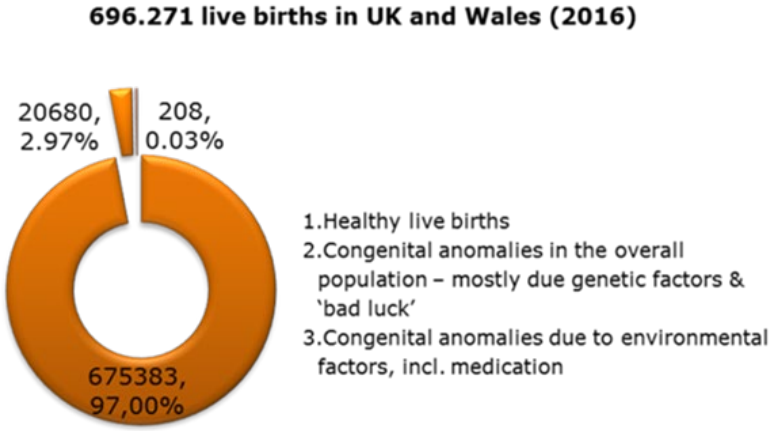
130 million births globally per annum, 5 million in Europe

In high resource countries:

90% of pregnant women take medications in pregnancy

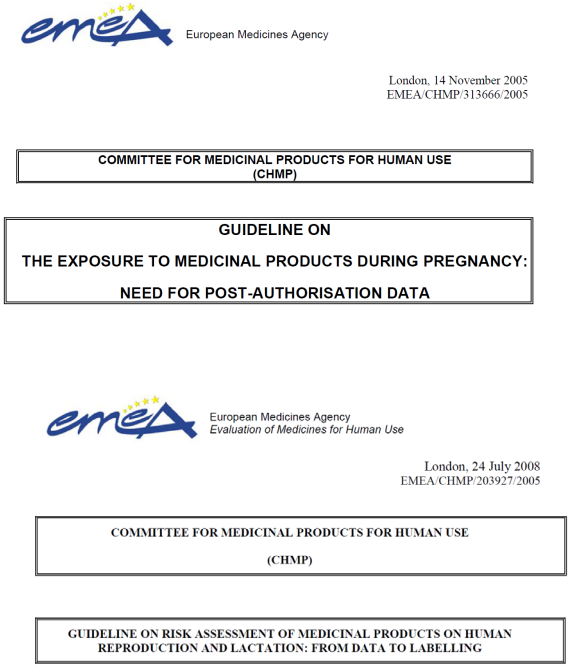
- 25% chronic diseases
- Infections
- Complications of pregnancy
- Unplanned pregnancies

Similar disorders, plus 10% postnatal depression, in breastfeeding



The remit of regulators…

- Expectations from our stakeholders vs the legal basis for our work
- Product-specific benefit-risk, not relative benefit-risk
- Precautionary principle & being risk-proportionate



European Medicines Agency

London, 14 November 2005
EMEA/CHMP/313666/2005

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

GUIDELINE ON

THE EXPOSURE TO MEDICINAL PRODUCTS DURING PREGNANCY:

NEED FOR POST-AUTHORISATION DATA

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

HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 EMA/653036/2019 DRAFT FOR PUBLIC CONSULTATION
2 4 December 2019

3 Guideline on good pharmacovigilance practices (GVP)
4 Product- or Population-Specific Considerations III: Pregnant and
5 breastfeeding women

What can EMA do to help?

Better use of existing methods

- PSURs, EUDRAVigilance analyses, PK studies in breastfeeding
- Translated into good risk minimisation measures

Together with our stakeholders, tackle old problems with new solutions…

- Innovative non-clinical methods
- Epigenetics
- Hybrid study designs
- Human breast milk studies / biobank
- Sustainable infrastructure for evidence generation

Possibilities & data capture at different regulatory stages

Preclinical

- Better use of PK
- Development & regulatory acceptance of novel methods

Clinical trials

- Think differently about BR(AN)
- Obtaining the benefits while protecting women

Post authorisation

- Better use of existing & development of novel methods & infrastructure

Product communication

- Communicating uncertainty of risk
- Content and communication skills

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#PregnancyEMAWorkshop

Thank you for your attention

Further information

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