

The information Gap on *Safe use of Medicines in Pregnancy & Breastfeeding*

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Reducing the Safety Information GAP



Moving into 21st Century

- **Thalidomide tragedy** resulted in pregnant women's exclusion from clinical trials & research
- Need for a regulatory strategy to protect pregnant & lactating women
 - **EMA Regulatory Science Strategy 2025**
- Address unacceptable societal neglect
- Learn through Pharmacovigilance reporting

The Reality: Impact of Birth Defects



- Estimate: out of 5 million women delivering babies each year, there are about 140.000 birth defects in the EU 27
- Birth defects are estimated to cause 11 % of neonatal death

The Reality: Medicines Use in Pregnancy



- 7 out of 10 pregnant women use Rx medicines
- Pregnant women with asthma, depression, diabetes, epilepsy, HIV/Aids, hypertension etc. need to take medicines during pregnancy
- However, robust evidence how a medicine works in pregnant women and its appropriate dosage is lacking
- Instead often there is “Off label use” and no learning

IMI ConcePTION Survey

- A total of 1910 women from 74 countries completed the questionnaire.
- Approximately 85% of the women reported need for information about medications during pregnancy/lactation.
- Medical doctor (33.1%) and Internet (33.0%) were the most used information sources.

IMI ConcePTION Survey

- Almost half of the women reported their medical doctor as their **preferred information source**
- Over half of the women had experienced discrepancies between different medication information sources
- 405 reported having had difficulties understanding information given, most common reason information was not precise enough.

IMI ConcePTION Survey

- 665 HCP completed the survey
- More than 60% of HCP reported being asked information use on a daily /weekly basis
- Pharmacists, specialists physicians and GPs were most frequently asked
- 60% of HCP were native English speakers

IMI ConcePTION Survey

- Frequently used sources: online database, website, medical specialists, desk references or textbooks

Moving into 21st Century

- *NIH PRGLAC: “Protect women through research instead of from research”*
 - US Secretary of Health and Human Services tasked NIH to identify gaps in knowledge and research on safe and effective therapies for pregnant and lactating women

EIWH Call for Action

Address knowledge gap:

- Improving Post-marketing data collection
- Learning health system – collect Real World Data
- Common rules for pregnancy exposure registries, etc.
- Invest in, support and reward more research in this neglected field

The way forward

EMA Regulatory Science Strategy
2025

Harnessing new digital tools

Set up a regularly updated information
system/knowledge bank