Drug exposure during pregnancy and «Parent-Child reports» from Switzerland – instructions / recommendations of Swissmedic

- In case a drug exposure during pregnancy is suspected with a substance known to be noxious, i.e. a substance which is contraindicated and should be avoided during pregnancy due to potential risk of adverse reactions for the foetus/child, **but**

  - **no** complication during pregnancy occurred, **and**

  - **no** harmful effect of the foetus/child at the time of the report is suspected,

  the Individual Case Safety Report (ICSR) should be reported as «non- serious» (within 60 days)

  ⇨ Only the mother should be recorded as «patient»
  ⇨ Coding options (MedDRA_LLTs) e.g.:
  'Drug exposure during pregnancy'
  'Vaccine exposure during pregnancy'
  'Exposure during pregnancy'
  'Maternal exposure during pregnancy'
  'Maternal exposure during pregnancy, first trimester'
  'Maternal exposure during pregnancy, second trimester'
  'Maternal exposure during pregnancy, third trimester'

- In following situations, pregnancy cases from Switzerland (ICSR) are to be **reported to Swissmedic expedited** (not later than 15 calendar days from receipt):

  - if a **serious** or **medically important** complication/harmful effect during pregnancy concerning the mother is suspected in association with a drug

  - if a **serious** or **medically important** complication/harmful effect during pregnancy concerning the **foetus** (e.g. foetal death, abortion, malformation) is suspected in association with a drug – medically important/serious case – **to be submitted as «Parent-Child report»**

    ⇨ Coding options (MedDRA_LLTs) e.g.:
    'Foetal exposure during pregnancy'
    'Foetal exposure during pregnancy, first trimester'
    'Foetal exposure during pregnancy, second trimester'
    'Foetal exposure during pregnancy, third trimester'

  - when a harmful effect for the **neonate** is suspected to be drug related–medically important/serious case – **to be submitted as «Parent-Child report»**

- **Follow-up reports**:

    - New data/information to a case-report, including the outcome of ongoing pregnancy, concerning **the mother only** should be obtained and submitted as **follow-up report of the existing standard** (no Parent-Child) **case**.

    - For new data/information concerning the **foetus/neonate** in relation to a previous standard (mother) case, a **new «Parent-Child report»** should be created and submitted. This new «Parent-Child report» will be **linked to the pre-existing standard case** concerning the mother.

- New **safety signals** concerning exposure during pregnancy (not in form of ICSR but as concise, critical evaluation of the issue) identified on Swiss or international level:

    - For a new potential risk on Swiss or international level in relation with drug exposure during pregnancy (e.g. signal of possible teratogenic effect, new drug risk, drug use or prescribing problem, increase of abnormal outcomes frequency). This should be considered as a new identified **safety signal** for which an **evaluation report** including available data, risk assessment and planned measures must be submitted.

    - For reporting instructions and timelines, following guidance document has to be considered: MU101_20_001e_WL Guidance document Drug Safety Signals HMP (PDF, 251 kB, 01.03.2021) – see 'Risk Management (Signalmanagement, PSURs, RMPs/RMP summaries)'.