# General instructions / recommendations for submission of adverse events following immunisation (AEFI)

Suspected **«serious»** and **«non-serious»–«unlabelled»** AEFI are to be reported to Swissmedic according to Swiss legal requirements.

Additionally, reporting of **«non-serious» – «labelled» AEFI** is **strongly recommended** by Swissmedic.

**Each AEFI report forwarded to SMC shall contain:**

**1. In structured data reporting fields**

- Dose number (if series) and dates of vaccinations
- Vaccine batch number (this information can be repeated in free-text)
- Most vaccines are a dose series. If an AEFI occurs for each dose in a series:
  1. Enter the vaccine each time as a suspected drug for each dose with different «StartDate/EndDate»
  2. If the AEFI is the same as with the earlier exposure to the vaccine, check «yes» under the field «Rechallenge» for the second vaccine dose.

**2. Include in the Case Narrative free-text**

- Side of administration: left or right
- Body site of administration (e.g. thigh muscle, deltoid muscle)
- Latency: time from exposure to onset of symptoms and signs
- Vaccination history if relevant or unusual (e.g. delayed schedule, missed childhood immunisations)
- Severity and course/outcome of AEFI
- Results of relevant laboratory, radiological, surgical, pathological, etc. investigations
- Batch Number: request always and if not available, state clearly in case narrative, e.g. «batch number requested but unavailable».

**3.** New identified **safety signals** (not in form of Individual Case Safety Reports (ICSR) but as concise, critical evaluation of the issue) identified on Swiss or international level:

**Not later than 15 calendar days** for a new potential risk identified by the **MAH** on Swiss or international level in relation with immunisation (e.g. new potential risk, vaccine use or prescribing problem, increase of abnormal outcomes frequency). This should be considered as an identified **safety signal** for which an **evaluation report** including available data, risk assessment and planned measures must be submitted.