SWISS MEDTECH

Memo

Vigilance Reporting in Switzerland

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Context:

In 2024, Swissmedic received over 6'300 reports on serious incidents (MD & IVD). It follows up on most serious incidents reported by manufacturers and healthcare professionals, both of whom are required to report serious incidents occurring in Switzerland and Liechtenstein per the Swiss MedDO.

All manufacturers should follow the instructions according to Swissmedic's homepage on reporting incidents for economic operators:
https://www.swissmedic.ch/swissmedic/en/home/medical-devices/reporting-incidents---fscas/hersteller---inverkehrbringer.html

Swissmedic accepts justifications for non-reportable incidents based on MDCG 2023-3 Rev. 2, "Questions and Answers on Vigilance Terms and Concepts" under Regulations (EU) 2017/745 and 2017/746.

Key Industry Challenges:

EU industry claims that Swissmedic's requests are more stringent compared to other EU competent authorities, resulting in more complex and demanding communication.

1. Short response timelines (often 5 working days) for manufacturers to address Swissmedic's inquiries.
2. Challenges to final non-reportable classifications without clear justification.
3. Repeated follow-up questions despite previous justifications provided by manufacturers.

Meetings with MedTech Europe and Swissmedic:

A number of meetings were organized by Swiss Medtech and held in 2023, 2024 and 2025 involving participants from MedTech Europe, Swiss Medtech and Swissmedic. All participants expressed their appreciation that the dialogue was made possible to improve communication, enhance patient safety and identify continuous improvement opportunities in vigilance reporting.

Meeting Goals:

1. Increase efficiency and reduce administrative workload for both industry and Swissmedic regarding vigilance reporting.
2. Ensure patients receive safe and effective medical devices.
3. Find the right balance between demanding product safety details and minimizing administrative burden.

Proposed Solutions:

1. **Short Timelines**
    - Swissmedic may request a 5-day (or even shorter) timelines in urgent cases, such as patient safety risks or when information should be readily available from prior investigations.
    - Manufacturers can request extensions when needed. Swissmedic is open to solutions that reduce workloads on both sides and may consider longer timelines if respected consistently.
2. **Final Non-Reportable Cases**
    - For user reports deemed non-reportable by manufacturers, Swissmedic expects that initial assessment of reportability based on the information provided by the user and information held by the manufacturer is complete, reducing the need for extended timelines.
    - The 15-day timeframe aligns with the manufacturer's awareness date, whether informed by the user or Swissmedic.
    - If a manufacturer has not received the complaint directly from the user and was made aware of the complaint for the first time from the user report provided by Swissmedic, the manufacturer should inform Swissmedic of this situation and perform reportability assessment within the 15-day timeline from the receipt of the user report.
3. **Reducing Follow-Up Questions**
    - While Swissmedic aims to minimize duplicate questions, it may revisit queries related to similar devices if new insights arise (e.g. trending data) over time.
    - **For Non-Reportable Cases:** Manufacturers must provide a clear rationale why the incident was considered non-reportable. MDCG 2023-3 and Swissmedic Guidance document "Incident economic operators" (MU680_20_009) should be consulted as a guidance.
    - Provide concise, understandable information, especially for complex devices, and attach relevant supporting information if needed (e.g. IFU). If necessary, provide a reference within the respective supporting document (e.g. chapter X of report Y) to ensure the scientific officer finds the respective information easily.
    - **For Reportable Cases:** If a device is unavailable for investigation (e.g., lost), document all efforts to retrieve it (e.g., customer follow-ups).

Comments:

- All communication between the manufacturers and Swissmedic is via the responsible **scientific officer**.
- For incidents that are classed as serious and that have occurred in Switzerland or Liechtenstein, a **Manufacturer Incident Report** (MIR) must be completed in English or one of the Swiss national languages. In the new MIR form 7.3.1, specify “Switzerland” in the free text area. By pressing the "submit XML by E-Mail" button at the end of the form, the generated XML file and the PDF file is sent to materiovigilance@swissmedic.ch
- Swissmedic has developed its own **FSCA report form**, based on drafts from the Eudamed vigilance team, to align with the Eudamed vigilance module’s development. To report an FSCA to Swissmedic, the form has to be completed in English or one of the Swiss national languages and send electronically and in machine-readable format to materiovigilance@swissmedic.ch
- Swissmedic recently released a newly expanded version of the guidance document “MU680_20_815e_WL Guidance document CH Guide Manufacturer Incident Report (MIR) (PDF, 360 kB, 20.11.2025)”, which addresses many points in chapter 5.3 regarding expected content to reduce follow-up questions.

If unsolved issues persist, please escalate them to the Head of Regulation & Innovation at Swiss Medtech (armand.linge@swiss-medtech.ch), who will consolidate feedback from all members before addressing it with Swissmedic.