Bundesverband Medizintechnologie e.V.

Position paper

Serious AI Incident Reporting – Application to AI Medical Devices

Alignment with and integration into existing reporting processes under the EU Medical Device Regulation

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Introduction

BVMed welcomes the European Commission's efforts to further clarify the reporting obligations for serious incidents under the AI Act and appreciates the development of accompanying guidance, including practical examples. This work represents an important step toward ensuring certainty and consistent application across the Union, particularly for high-risk AI systems integrated into medical devices.

At the same time, it is essential to recognize that the EU Medical Device Regulation (MDR) has already established a mature, robust, and strictly enforced regulatory framework for serious incident reporting, which has been implemented and is in application for years.

BVMed considers it crucial that the implementation of the AI Act builds on, and is fully aligned with, the established MDR framework. To avoid parallel structures, redundant reporting pathways, and overlapping or inconsistent authority responsibilities, incident reporting requirements under the AI Act for medical devices should be entirely integrated into existing MDR processes.

BVMed calls on the European Commission to ensure clear alignment between the Medical Device Regulation (MDR) and the Artificial Intelligence Act (AI Act) by taking the following actions:

1) **Recognize existing MDR obligations: The MDR already includes comprehensive and well-established requirements for reporting serious incidents related to patient and public health — requirements that are highly comparable to those under the AI Act.**
2) **Avoid duplicative reporting: Any additional reporting obligations under the AI Act concerning fundamental rights should be integrated into the existing MDR reporting framework — and, in the future, into EUDAMED — to prevent duplication and parallel reporting structures.**
3) **Ensure consistent surveillance across Member States: Member States should designate the same competent authorities responsible for MDR serious incident reporting to also oversee AI Act reporting for medical devices. This approach, as reflected in Germany's draft implementing law[1], would ensure coherence and prevent the creation of redundant administrative structures.**
4) **Maintain consistent reporting timelines: The reporting timelines established under the MDR already meet — and in some cases exceed — those required under the AI Act. These timelines should be maintained to ensure clarity and the continued timely reporting of serious incidents.**

[1] Referentenentwurf für ein Gesetz zur Durchführung der KI-Verordnung; September 12th 2025

1.
Recognize existing MDR obligations

Article 73 of the **AI Act** requires providers of high-risk AI systems placed on the Union market to report serious incidents to the market surveillance authorities of the Member States where the incident occurred. Similar obligations are set out for **medical devices** regulated under the **MDR** in Article 2(65) and 87 and include incidents that directly or indirectly led, might have led, or might lead to the death of a patient, user, or other person, or to a temporary or permanent serious deterioration of their state of health, as well as a serious public health threat.

This is recognized in the AI-Act by limiting reporting obligations for AI medical devices in Article 73(10) to serious incidents related to the protection of fundamental rights pursuant to point (c) of Article 3(49) AI Act, meaning fundamental rights as enshrined in the EU Charter of Fundamental Rights, including, for example, the protection of personal data.

The MDR already includes comprehensive and well-established requirements for reporting serious incidents related to patient and public health — requirements that are highly comparable to those under the AI Act.

2.
Avoid duplicative reporting

If a medical device manufacturer identifies an event as a (potential) serious incident, the manufacturer is obliged to report it under Article 87(1) MDR to the competent authority of the Member State where the incident occurred. In addition, serious incidents under the MDR must be reported to the notified body that issued the certificate for the affected device.

Incident reports are to be submitted via the European database on medical devices (EUDAMED). As EUDAMED has not yet been declared fully functional, reporting currently occurs through national systems (typically via national databases – e.g. in Germany, reports are submitted via the German Medical Device Information and Database System (DMIDS)).

Thus, any additional reporting obligations under the AI Act concerning fundamental rights should be integrated into the existing MDR reporting framework — and, in the future, into EUDAMED — to prevent duplication and parallel reporting structures.

3.
Ensure consistent surveillance across Member States: Example Germany

Serious incidents under Article 87 MDR must be reported in Germany, pursuant to §71(1) of the Medical Device Law Implementing Act (MPDG), to the competent federal authority. Under §85(2) MPDG, this role is fulfilled by the Federal Institute for Drugs and Medical Devices (BfArM).

According to Article 1 §2(2) of the draft of the German AI-Act implementing law, the authority responsible for medical device market-surveillance activities under the MDR will also assume these responsibilities under the AI Act for AI medical devices.

All EU Member States should designate the same competent authorities responsible for MDR serious incident reporting to also oversee AI Act reporting for medical devices. This approach would ensure coherence and prevent the creation of redundant administrative structures.

4.
Maintain consistent reporting timelines

Depending on the severity of the incident, manufacturers of medical devices must report a serious incident within two, ten, or fifteen calendar days (Articles 87(3), (4) and (5) MDR). Under Article 73(2) AI Act, serious incidents must be reported within a maximum of fifteen days. This timeline is already met and ensured by the MDR reporting deadlines.

Reporting timelines under the AI Act and MDR are aligned, ensuring regulatory clarity and continued timely reporting of serious incidents.

BVMed
Bundesverband Medizintechnologie e.V.
German Medical Technology Association
Georgenstraße 25, 10117 Berlin
+49 30 246 255 - 0
www.bvmed.de
info@bvmed.de