

An “interruption of supply” should be understood as the consequence of a manufacturer confirming that they cannot or are unwilling to operate as previously intended or planned in relation to the supply of a device, which can lead to a temporary disruption of supply.

This leaflet provides guidance for medical device manufacturers on the requirements introduced by Article 10a of the MDR (EU) 2017/745, as amended by Regulation (EU) 2024/1860.

PART A - GENERAL



- **Key Dates**

- Article 10a applies starting **January 10, 2025**.

- **Scope of the Obligation**

- Applies to all models or type of devices, placed on the Union market (excluding custom-made devices) where supply disruptions could cause serious harm to patients or public health.

- **Risk Assessment**

- It is the responsibility of the manufacturer to assess whether the disruption may result in serious harm to patients.

PART B - MANUFACTURERS' OBLIGATIONS



•Who to Inform:

- Directly supplied economic operators (EO), health institutions (HI), and healthcare professionals (HCP) to whom the manufacturer directly supplies the device .
- The competent authority (CA) of the Member State where the manufacturer or authorized representative is established.

•Timeline:

- Notifications must be issued **at least six months** in advance.
- In exceptional circumstances, inform without undue delay. Sudden events like natural disasters or unforeseen economic challenges may justify shorter notification periods.

•Required Content:

- Use the Manufacturer Information Form for notifications.
- Specify reasons in your notification to the CA for the disruption (e.g., regulatory, manufacturing, supply chain, or business-related).

•Identifying Serious Risks

- Manufacturers must assess potential harm, including: Risk of death or serious health deterioration. And Lack of suitable alternatives for diagnosis or treatment.

•Indicators for Risk Assessment:

- Device relevance (e.g., life-saving or essential for vulnerable populations).
- Availability of alternative solutions or devices.
- Market share and existing stock levels.

PART C - OTHER ECONOMIC OPERATORS' OBLIGATIONS



•Economic Operators' Role

- Maintain traceability of devices per MDR/IVDR Article 25.
- Ensure timely communication of received notifications.

•Downstream Information Flow

- Importers and distributors must relay information to their downstream partners, including health institutions and professionals, without undue delay.
- Integrity of the original manufacturer's communication must be preserved.

Contact Information

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