Availability of MD and IVD – obligation to inform in case of interruption or discontinuation of supply (Article 10a of MDR/IVDR)

As of the 10th of January 2025, manufacturers are required to provide information if they anticipate an interruption or discontinuation of supply of certain medical devices (MD) or in vitro diagnostic medical devices (IVD). This information must be communicated at least six months in advance to the competent authority (of the country, in which they are established), to the distributors and health institutions to which they directly supply. Introduced by Regulation (EU) 2024/1860, this mechanism enables competent authorities and health institutions to consider mitigation measures to ensure patient care.

Roles and responsibilities of economic operators

Manufacturer

Manufacturers must provide the information at least six months before the anticipated interruption or discontinuation of supply of certain MD and IVD, unless unexpected circumstances (natural disaster, sudden inability of raw materials). However, it is encouraged to provide the information earlier in time where possible.

- ➔ *An interruption of supply is defined as a temporary inability to supply the device with an expected duration of more than 60 days.*
- ➔ *A discontinuation of supply means that the manufacturer no longer places the device on the European Union market.*

The obligation to inform applies only to MD and IVD for which it is reasonably foreseeable that the interruption or discontinuation could cause **serious harm or a risk of serious harm to patients or public health** in one or more Member States. « Serious harm or a risk of serious harm to patients or public health » means any serious harm to patients or any threat to public health that has occurred, or which is reasonably foreseeable to occur. Prior to any notification, the manufacturer must assess the impact of the interruption or discontinuation of the supply of MD and IVD, taking into account, in particular, the consequences of the unavailability of treatment or diagnosis. Indeed, certain shortages may lead to an imminent risk of death, a serious deterioration of patient health, or a life-threatening condition in the absence of adequate alternatives. For further details, please refer to the MDCG document Q&A - Regulation (EU) 2024/1860 Article 10a MDR and IVDR.
When the manufacturer has determined that the interruption or discontinuation of supply of the device could cause a serious harm or a serious risk of harm to patients or public health, they inform the relevant parties to whom they directly supply:

- The economic operators
- The health institutions
- The healthcare professionals
- The competent authority of the Member State where it or its authorised representative is established.

If the manufacturer does not directly supply to health institutions or healthcare professionals, they must inform the relevant economic operators in the supply chain, who must then inform the health institutions.

Manufacturers are not required to inform if:

- ***They replace the device with a similar one.***
- ***They have a stock to meet the demand during an interruption.***
- ***Health institutions have confirmed that no serious harm would occur from a device discontinuation or supply interruption.***

Authorised Representative

The manufacturer cannot delegate its legal responsibility for this obligation. Nevertheless, it can engage the assistance of its authorised representative, other economic operators or a third party, in the practical implementation of the required operational tasks.

Distributors and importers

The responsibility for onward information sharing in the downstream supply chain lies with the economic operators following the receipt of the information from the manufacturer or another economic operator.

- **Importers:** Upon receipt of this information from the manufacturer, the importers of the device in question must, without undue delay, forward the information, as provided by the manufacturer, to all the distributors to whom they directly supply the device.
- **Distributors:** Upon receipt of the information from the importers, distributors must, without undue delay, forward it, as provided by the manufacturer, to all other distributors to whom they supply the device in question, as well as to the health institutions they supply.

The information must always be forwarded as it was provided by the manufacturer, to preserve the integrity of the initial communication, until it reaches the relevant health institutions, or healthcare professionals.
As a reminder, in accordance with Article 25 of the MDR/IVDR, economic operators must maintain an appropriate level of traceability of devices. They must be able to identify their upstream suppliers and downstream customers.

Application to systems and procedure packs

Article 10a (1) of the MDR/IVDR also applies to manufacturers of individual CE-marked devices within a system or procedure pack. These responsibilities include:

- **Manufacturer's responsibility:** manufacturers of CE-marked devices must inform the relevant parties (including the competent authority and the system or procedure pack producer) of any interruption or discontinuation of their devices.
- **Sharing information:** Upon receiving this information, the system or procedure pack producer must, without undue delay, transmit this information to other economic operators, health institutions and healthcare professionals.

Notification of an interruption or a discontinuation of device under Art.10a in Luxembourg

Any manufacturer established in Luxembourg, or having its authorized representative established in Luxembourg, must notify the Directorate of Health using the Manufacturer Information Form available on the European Commission's website. This form should be sent as soon as possible to meddevices@ms.etat.lu.

All required information in the form must be completed. For a better assessment of the situation, additional information may be provided on a voluntary basis. If the form is updated, the modified sections must be clearly indicated.

For any questions, please contact the medical device market surveillance authority in Luxembourg, the Pharmacy and Medicines Division within the Directorate of Health, by email to meddevices@ms.etat.lu

To learn more

Q&A - Regulation (EU) 2024/1860 Article 10a MDR and IVDR
Manufacturer Information Form