

Best Recall Practices Guideline — Part 1 — Medical Devices

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In this first part of a short series of articles about the recall of products in the life sciences sector from the EU and Swiss markets, we look at the [Medical Devices Regulation](#) (MDR) and [In Vitro Diagnostic Medical Devices Regulation](#) (IVDR) (together, the Regulations). These Regulations, soon applicable in the EU, introduce detailed obligations for manufacturers and other economic operators related to recalls of medical devices.

With the MDR applying from May 26, 2021, and the IVDR beginning as of May 26, 2022, manufacturers and other economic operators (i.e., authorized representatives, importers, distributors) should review the new requirements for recalls and withdrawals of nonconforming medical devices. The new rules should be reflected in companies' internal procedures, and relevant personnel should be trained on the updated procedures.

As set out in the Regulations, a recall aims to return a device that was already made available to the end user, whereas a withdrawal aims to prevent a device in the supply chain from being further made available on the EU market. Both recalls and withdrawals can be mandatory or voluntary.

Key note #1 — internal recall procedures: A successful recall requires robust and well-implemented internal procedures. Such procedures must detail the steps to be taken and which functions are responsible in case of nonconformities. The procedures must be practical and comply with applicable laws, and they should therefore be regularly reviewed and updated, in particular when new legislation is forthcoming. Training on recall procedures should generally be part of the company's internal training schedule.

What triggers a recall or withdrawal?

As a general threshold matter, if a medical device is to be placed on the EU market, it must always comply with the applicable general safety and performance requirements. If at any point after the device is placed on the market the manufacturer has reason to believe or it is established that the device no longer fulfills the requirements under the Regulations, the device is deemed nonconforming and the manufacturer is required to immediately address the issue.

The new Regulations do not introduce any explicit threshold that would trigger the obligation of the manufacturer to recall or withdraw a nonconforming medical device from the market. Instead, depending on the type, level of severity, and nature of the nonconformity, the manufacturer is required to act, either by taking the "necessary corrective actions" to bring the device back into conformity or by withdrawing or recalling

the device. In other words, the manufacturer should carefully assess the risk resulting from the nonconformity and then take reasonable steps to address it.

Generally, the Regulations favor the least restrictive measure, thus allowing the manufacturer to consider whether a corrective action would be sufficient to remediate the nonconformity. If a certain corrective action cannot resolve the nonconformity satisfactorily, the manufacturer would need to consider taking a more drastic measure, such as withdrawing or recalling the device from the EU market.

It is critically important that manufacturers document the actions they have taken to address a suspected or confirmed nonconformity and the related risk assessment. It is also advisable that the manufacturer ensure that any corrective or preventive action performed is assessed for its effectiveness within a defined period of time so as to be able to determine (and document) that the measures taken were indeed effective.

Manufacturers should also ensure that they can appropriately communicate with relevant economic operators, as well as the EU member states' national competent authorities (NCAs). Informing the supply chain swiftly and efficiently is often key to successfully addressing a nonconformity.

In addition, where a government authority believes that a device would present an unacceptable risk to the health or safety of patients or users, that authority may require that the manufacturer bring the device into conformity, which could well include a mandatory withdrawal or recall of the product. In such situations, the NCA would communicate the issue to the European Commission, the other EU member states, and where relevant, the manufacturer's notified body.

Key comment #2 — communicating with authorities: Communications with market surveillance authorities often play a key role for any nonconformity. It is critical that notification requirements to applicable government authorities are assessed immediately and, if deemed necessary, that the authorities are provided sufficient information (at a minimum what is required by applicable laws) early on to understand that the company is taking appropriate correct steps to remediate the situation. Incomplete or incorrect reporting can lead to a lack of trust from the authorities and quickly escalate the situation, oftentimes leading to additional oversight from the authorities.

What can trigger a mandatory recall or withdrawal?

Mandatory withdrawals or recalls can occur in the event that the manufacturer does not cooperate with the relevant authority, does not take adequate action to remedy the nonconformity on a voluntary basis, or, in the case of unacceptable health or safety risks, does not act within the timeline the respective authority requires. In such cases, the NCA

may take all appropriate measures to prohibit or restrict the device, including withdrawing or recalling it.

Under the Regulations, measures taken by an NCA to address an unacceptable risk to health and safety can in certain circumstances require the NCAs of the other EU member states to take the same measures.

Manufacturers should also keep in mind that their notified body may restrict, suspend, or withdraw CE certificates in the case of nonconformities.

What are the economic operators' roles in a withdrawal or a recall?

The Regulations introduce the concept of economic operators, and they assign different (albeit overlapping) responsibilities to each key actor in the supply chain of a medical device.

The **manufacturer** is generally responsible for taking all necessary measures to ensure that the devices it places on the market comply with the Regulations. If a nonconformity is suspected, the manufacturer must

- properly examine the level and nature of the nonconformity
- decide which measures are adequate and sufficient to resolve the nonconformity
- take all necessary measures to bring the device back to conformity, including withdrawing or recalling the device
- share the information about the nonconformity with the distributors and, where applicable, the authorized representative and importers
- where the level of risk is high, inform the NCAs, the notified body, and users

If the manufacturer is not established in the EU, its **authorized representative** must

- cooperate and provide the NCAs with all the information and documentation necessary to demonstrate the conformity of a device
- cooperate with the NCAs on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks a device poses

Note that the manufacturer is prohibited from delegating its obligation to implement corrective actions to the authorized representative in the case of a nonconforming device.

In turn, **importers** and **distributors** must

- immediately inform the manufacturer and its authorized representative of any potential or actual nonconformity of a device they have placed on the market
- cooperate with the manufacturer and its authorized representative
- cooperate with the NCAs to eliminate or mitigate the risks a nonconforming device poses

- keep a register containing information about withdrawals or recalls in order to assist any investigation
- where the level of risk is high, inform the NCAs and users

Key note #3 — supply chain notifications: Notifications to and from the supply chain in case of nonconformities should be part of the company's internal procedures (see key note #1). Companies should ensure that required notifications are addressed in the contracts with the supply chain. Where notification requirements are set out by law, companies should take additional steps to ensure that the internal procedures are updated accordingly.

Are withdrawals and recalls reportable?

Under the Regulations, reporting a withdrawal or a recall to the relevant NCAs is mandatory under certain circumstances. Where the manufacturer, importer, or distributor believes that a device presents a “serious risk,” it must inform the relevant NCAs and (where applicable) the relevant notified body. The Regulations do not define what would constitute a serious risk, but as a threshold matter it would include anything that led to, or might have led to, serious deterioration in the health or even the death of a patient or user or anything that might lead to a serious public health threat.

Where the manufacturer conducts a withdrawal or recall as part of a field safety corrective action (FSCA), this information must be included in the information communicated to the NCAs in accordance with the Regulations.

Are withdrawals and recalls published?

Currently there is no consolidated EU website for the publication of withdrawals or recalls of medical devices. However, if the withdrawal or recall is made as part of an FSCA, the manufacturer must publish a field safety notice (FSN) informing patients or users about the corrective actions taken. The FSN will be published through Eudamed (once fully functional), making it accessible to the public.

Penalties for noncompliance

The Regulations do not introduce specific penalties for noncompliance, and they leave the EU member states the freedom to introduce “effective, proportionate, and dissuasive” penalties at the national level. As a consequence, enforcement actions are implemented at the national level and may include administrative investigations, fines, and injunctions. In cases of fraud or serious negligence, economic operators may also face criminal fines and criminal liability. Civil liability may be imposed based on the EU member states’ national rules.

The EU member states were required to implement measures that impose penalties for infringements of the MDR by February 25, 2021, and they will be obliged to do so under the IVDR by February 25, 2022.