

European Requirements for Product Returns

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Considerable uncertainty exists regarding European requirements for withdrawing a product from the market because of product performance problems that are not related to serious health risks or death. This article discusses the requirements for product returns or other related actions that are outside the scope of the recall notification requirements defined in the medical device Directives.

Lack of specific requirements

The Annexes of the medical device Directives require that manufacturers institute and keep up-to-date a systematic procedure to review experience gained from devices in the post-production phase. They must implement appropriate means to apply any necessary corrective actions, taking account of the nature and risks in relation to the product. In addition, manufacturers must notify the Competent Authorities (CAs) of the following incidents:

- (i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use that might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health
- (ii) any technical or medical reason connected with the characteristics or performance of a device leading, for the reasons referred to in subparagraph (i), to systematic recall of devices of the same type by the manufacturer.

Thus, if a systematic recall is being conducted because of device problems that might lead to or might have led to a death or serious deterioration in the health of a patient or user, it must be notified to the relevant CAs.

The Directives do not specify the procedures to follow, regarding product field corrections, returns, exchanges or other actions resulting from problems associated with minor health risks. For example, a manufacturer decides to request the return of certain product lots because exposure to low temperatures causes unexpected fractures. The defect

is detected prior to use, therefore, the risks to patients is extremely low. This type of product return is not covered by the medical device Directives; however, some CAs require notification of this corrective action. Examples of some of these are discussed later. It should be noted that the term “product-field correction” as used in this article means the modification, repair, adjustment, relabelling, destruction, or inspection of a product at the site of installation or use.

Caution with terminology

As indicated above, the Directives require “systematic recalls” to be notified to the CAs. It should be mentioned that the Active Implantable Medical Device Directive (90/385/EEC) uses the term “withdrawal,” but this term is generally interpreted in the same way as the term “recall.” Therefore, the Directives associate systematic recall with product problems that have led to, or could lead to, deaths or serious deterioration in state of health. In addition, the European MEDDEV Medical Device Vigilance Guidelines,¹ which was issued in 2001, states in section 5.8 that the term “recall” is defined in EN 46001. This definition, which is included in Appendix 2 of the guideline, describes “recall” as circumstances when “... there is a risk of death or serious deterioration to the state of health, the return of a medical device to the supplier, its modification by the supplier at the site of installation, its exchange or its destruction in accordance with →



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the instructions contained in an advisory notice.”

The problem is that EN 46001, which was a European harmonised standard for medical device quality system, has been withdrawn and replaced by the current European harmonised standard, EN ISO 13485:2003, which does not include the term “recall.” This omission was intentional as explained in technical information report (TIR), ISO TIR14969:2004, Medical Devices, Quality Management Systems, Guidance on the Application of ISO 13485:2003.

Clause 8.3.3 of this document explains that actions taken when nonconforming product is detected after delivery or use has started, is sometimes referred to as “product recall.” It further states that because the term “recall” has different definitions in different national or regional jurisdictions, its use in ISO 13485 has been avoided when describing activities of this type.

Therefore, companies need to be careful when using the term “recall” in Europe, particularly when communicating with European CAs. It may be wise to use this term only when referring to product field corrections, returns or other actions resulting from device problems that have led to, or could lead to, a death or serious injury. For example, an authorised representative recently advised a manufacturer to use the term “advisory notice” or “product withdrawal notice” instead of “recall notice” for the withdrawal of a device caused by a device defect that was not related to a risk of death or serious deterioration in the state of health.

Advisory notices defined

Section 5.8, Systematic Recalls, of the MEDDEV Vigilance Guidelines, states that the manufacturer should issue advisory notices when implementing recalls. It also states that the term “advisory notice” is defined in EN 46001. However, EN ISO 13485:2003, which replaces EN 46001, contains a modified definition of “advisory notice,” which is a notice issued by the organisation subsequent to delivery of the medical device, to provide supplementary information and/or to advise what action should be taken in the use of a medical device; the modification of a medical device; the return of the medical device to the organisation that supplied it; or the destruction of a medical device. It states in a note: Issue of an advisory notice may be required to comply with national or regional regulations.

Terms other than “advisory notice” are sometimes used to describe notices of recalls, for example, “recall notices.” Whether associated with a reportable event or not, companies conducting field corrections or requesting that products be returned or exchanged, should issue an advisory notice to the distributor and/or user. The remaining MEDDEV Vigilance Guidelines advice on systematic recalls is based on the premise that the advisory notice is being sent to implement a recall that represents a reportable event. However, companies performing field corrections or product withdrawals that are not associated with a

reportable event may find the guidance useful.

For example, the guidelines state that manufacturers should consider sending copies of advisory notices to CAs together with a report using the same structure as the Final Report used for vigilance reports. In addition, it points out that notification to CAs should be made before or at the same time that recall action is being initiated. Therefore, if a Member State requires notification of product field corrections, returns, withdrawals or other actions not associated with deaths or serious deterioration in the state of health, but does not provide details on how this should be done, the MEDDEV Vigilance Guidelines can be useful in managing this type of notification.

National requirements

It is not always easy to understand whether or not CAs require the reporting of corrective actions undertaken on delivered devices, that is, devices that are no longer under the control of the manufacturer.

France. For example, the French CA has stated that under Article L5212-2 of the French Health Code, a manufacturer or the designated authorised representative must notify the French CA of all device recalls attributable to medical or technical reasons. However, in this case, recall means any product field corrective actions, returns, withdrawals or actions because of medical or technical reasons, whether or not they are considered vigilance events.

Germany. Medical device recalls implemented in Germany must be notified to the German CA. A recall is considered to be a corrective measure leading to the return, exchange, conversion or improvement, isolation or destruction of medical devices. Information on vigilance requirements and a link to the form that should be used for submitting recall reports can be found on the German CA website www.bfarm.de/en/med_dev/vigilance/index.php

United Kingdom. The Medicines and Healthcare products Regulatory Agency has published a guidance document on the recall of medical devices.² This is a 31-page document that discusses recommended actions to take when undertaking a recall of products marketed in the UK. It also includes a model Recall Report Form, which has been adapted from the Final Report form found in the MEDDEV Vigilance Guidelines. However, Section 5 of the UK guidance states that if the manufacturer or authorised representative is reporting an adverse incident that has given rise to the need for a recall, the incident and recall notification may be combined within the proforma “Initial Incident Report” that is included in the MEDDEV Vigilance Guidelines.

It is important to note that in Section 2, the UK guidance refers to the guidance on recalls provided in the MEDDEV Vigilance Guidelines and states that the procedure described may also be applied to recalls that are outside the scope of the notification requirements identified in the medical device Directives. They list this type of recall as actions taken for minor health reasons, which do not pose a risk of death or serious injury to patients or →

other users and particular health monitoring measures.

Need for appropriate procedures

Companies should develop procedures and/or instructions that clearly describe the steps that should be taken when conducting a recall related to the occurrence or possible occurrence of deaths or serious deterioration in the state of health. It is equally important that these, or other appropriate, procedures address the possible existence of national requirements for the notification of product field corrections, withdrawals, returns or other similar actions, where these requirements are broader than the requirements defined in the medical device Directives. In addition, company procedures should describe the process of conducting product field corrections, withdrawals, returns, exchanges or other actions related to device problems associated with minor health risks.

A discussion of United States (US) requirements concerning the product recalls, removal and correction, as defined under US regulations, is beyond the scope of this article. However, it is important to point out that these requirements differ in significant ways from European requirements. Some companies have developed procedures that attempt to cover US and European requirements in the same set of procedures. A satisfactory result is rarely achieved and hardly ever worth the effort. Thus, prudent companies will consider the development of procedures for meeting US requirements that are separate from those needing to meet European requirements.

References

1. Guidelines on a Medical Devices Vigilance System (MEDDEV 2.12-1 rev 4), April 2001. This document can be downloaded from the European Commission website at http://europa.eu.int/comm/enterprise/medical_devices/meddev/index.htm
2. Guidance on the Recall of Medical Devices (2000). This document can be downloaded from the MHRA website at <http://www.mhra.gov.uk> [mdt](#)

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