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Product Recalls: What the New EU Guidance on Vigilance Doesn't Tell You

Practical advice for non-European manufacturers on implementing a recall without running afoul of competent authorities

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New guidance on European postmarketing vigilance procedures was published in April 2007 and came into force on January 1, 2008. MEDDEV 2.12-1 rev 5, which is a revision of the 2001 document, provides more guidance on the implementation of a field safety corrective action than its precursor, and that is to be applauded. But it is largely silent on the practical implementation of a recall and what competent authorities (CAs) will expect from non-European device manufacturers who are selling their products in an EU member state.

The guidance document will almost certainly result in increased numbers of follow-up questions from the CAs in the event of a recall. Is your company prepared to cope with this surge? For example, what are you going to tell the authorities when they ask to see proof that your distributors have issued a field safety notice (FSN)? Will you be able to confirm that affected hospitals and users have been informed? Do you have a signed recall response sheet drafted in the national language of the countries in which the hospitals are located?

In the past, it was not uncommon for distributors to inform users of a recall by phone or by having a salesman drop by rather than faxing or mailing the notification. CAs want to formalize this process. Remember: it is the responsibility of the manufacturer or authorized representative (AR) to take the necessary steps to ensure that the recall is correctly implemented in the field.

It is vital that your company's recall procedure include directives for your distributors. It is also imperative to add clauses to your distribution contract concerning the vigilance system and product traceability. Here are some other essential points that manufacturers exporting medical products to the European Union should take into consideration.

Preparing a voluntary recall

Having concluded that a recall is necessary based on a formal, written risk analysis, the manufacturer should prepare an FSN based on the sample form in the MEDDEV 2.12-1 rev 5 document as well as a user recall response sheet (which is not appended in the guidelines). The AR should then submit the FSN for approval to a CA. Meanwhile, the

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manufacturer should be mining its traceability system for a list of affected distributors with product references, lot numbers, date of shipping and, of course, full distributor contact information. A cover letter prepared by the manufacturer should go out to the distributors explaining that an FSN with the response recall sheet translated into their national language will be sent by fax or mail to affected users. This letter should also remind distributors that they must send a copy of their translated FSN and affected users list to the manufacturer and/or the authorized representative, because this information will be requested by the CA.

Notifying the CAs

With the exception of the aforementioned early-stage FSN approval, CA notifications should be made, if not before, then at the same time as the recall action. Your company's AR is responsible for these notifications. Upon receiving the FSN, the AR must prepare a field safety corrective action report for each affected country. A template for the report is included in MEDDEV 2.12-1 rev 5. The report should include the number of recalled devices per country and an appended English-language FSN. Upon approval by the manufacturer, the AR will send out the notifications. The representative is also responsible for diligently maintaining records showing that the notifications were correctly transmitted.

Answering CA queries

The type and quantity of follow-up questions from the CAs will depend on the countries. Twelve to 24 hours after receiving the notification, some will contact the AR by a return e-mail. This is typical of authorities in Ireland, France, Germany, Belgium, Portugal, Denmark, and the United Kingdom. Don't be surprised if they bombard you with as many as 10 questions, including a nasty one along the lines of: "How can you be sure that no other lot numbers or products are affected by the problem connected with the recall?" The CA may also ask to see copies of the FSN and response sheet in its national language, a list of affected hospitals and users with full contact information, risk analysis documents, signed copies of hospital response sheets, and, when available, a completed recall close report. Some CAs, primarily from Eastern Europe, will contact the national distributor directly.

Close report

A close report that lists the number of units returned compared with the number that were initially shipped and the status of incidents reported during the recall should be sent to the CAs, even if they did not submit any questions. Your notified body may want to see the close report, as well.

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