Preparing for More Active Market Surveillance

Maria Donawa

Competent Authorities are developing increasingly active market surveillance programmes. As a result, they are initiating or broadening the scope of inspection visits. This article discusses the manner in which some of these visits are being conducted and actions that should be taken to prepare for them.

Importance of market surveillance

Most medical device manufacturers invest an enormous amount of effort and resources in ensuring that the medical devices they design and produce are safe, perform as intended, and meet the regulatory requirements that apply to them. When this occurs, patients and users are afforded a high level of protection and access to increasingly beneficial medical technology. However, when manufacturers do not operate responsibly, patients and users and responsible manufacturers need to be protected against the consequences of this behaviour, which can result in unsafe and/or ineffective medical devices. A critical element of regulatory protection measures is the manner in which regulations are enforced. Thus, the actions being taken by European Member States to develop effective market surveillance programmes are extremely important in the overall effectiveness of the European medical device regulatory system.

Market Surveillance Operation Group

The Market Surveillance Operation Group (MSOG) is a Working Group created to co-ordinate national market surveillance activities. It is chaired by Portugal, the European Commission hosts its meetings, and its members are the European national Competent Authorities. MSOG work output is presented to the Medical Devices Experts Group (MDEG). MSOG has been meeting since October 2001 and is working on several surveillance guidance documents, including guidance notes for manufacturers of Class I medical devices, guidance notes for manufacturers of custom-made medical devices, and guidance defining the roles and responsibilities of distributors/importers and Authorised Representatives. When these guidance documents are issued, they will be available on the European Commission website (europa.eu.int/comm/enterprise/medical_devices/index.htm). When these documents become available, readers should refer to the ones that are relevant to their operations to prepare for possible Competent Authority inspection visits.

The Dutch experience

Section 7.3, Market Surveillance, of the Report on the Functioning of the Medical Device Directive[1] (MDD) provides an example of a Member State enforcement activity. To evaluate compliance with the Dutch Decree on medical devices, the Dutch national authority developed a method of evaluating the technical files of Class I medical devices. The method was evaluated in a study. The Dutch Inspectorate of Health Care selected 40 manufacturers whose technical files were to be reviewed by the Laboratory for Medicines and Medical Devices. An evaluation form was used as an aid in this review so that the technical file would be evaluated for compliance with requirements that were deemed essential and the requirements for the content of the file as specified in the Decree.

Readers will surely agree that the results of the evaluation →

Dr Maria E. Donawa

physician, pathologist and pharmacist with 25 years' regulatory experience, worked with the US FDA before becoming President of Donawa Consulting, an international consultancy firm, which provides clinical research, quality management system, regulatory affairs, and European Authorised Representative services to medical technology companies.

were unsatisfactory, although a valid conclusion can only be reached if the details of the method are known. The Report of the Functioning of the Medical Devices Directive states that of the 40 manufacturers whose technical files were reviewed, five withdrew their product registrations. Two of those five "encountered problems with the supply of products" and three appeared not to be manufacturers in accordance with the definition in the Dutch decree.

Thirty-four of the remaining 35 manufacturers submitted a technical file within the specified timeframe. One manufacturer needed one year to complete and send the file. None of the technical files submitted were complete in the view of the Dutch authorities. On average, each file contained five "shortcomings," presumably missing information. The Dutch authorities requested additional information from 20 manufacturers to allow the review to be completed. Because five manufacturers provided the additional information after the closing date of the study, only 29 of 34 technical files were fully evaluated during the study period. Each of these contained at least one deficiency related to one of the essential requirements. There were 109 deficiencies, an average of 3.76 per file, and a range of between one and eight deficiencies per file. Each file contained deficiencies in the labelling and instructions for use.

Competent Authority inspections versus audits

In addition to requesting technical documentation, Competent Authorities sometimes conduct inspection visits. These inspection visits should not be confused with quality system audits. They are not. Instead, these visits are aimed at determining whether or not medical devices have been legally affixed with the CE mark. For this reason, some of the information that may be requested during these visits may be the type that is provided during a quality system audit, but some is not. For example, during an inspection visit, in addition to carefully reviewing product technical documentation, a Competent Authority requested the following procedures and information:

- Standard operating procedure (SOP) for verifying that a Declaration of Conformity has been issued before product release
- SOP for product traceability
- SOP for product storage and transport
- SOP for vigilance and complaints
- Whether or not training of the user is required for use of the device; if yes, the type of training needed and method of conducting the training
- Distribution and sales network structure for products sold in Europe
- Information supplied by the manufacturer in the national language, including product and package labels and instructions for use
- Whether the company operates under a certified quality system
- Whether product servicing is supplied; if so, the manner in which it is organised.

Other Competent Authorities may request other types of information. However, as stated above, it is important to note that these types of inspection visits are not the same as quality system audits. On the contrary, the purpose of these visits is to evaluate whether or not the actions taken, including selected actions performed under the operation of a quality system, where such a system exists, are in compliance with the requirements of the European Directives for medical devices as transposed by national law and regulation. For example, some companies assume that the Competent Authority will find their technical documentation to be satisfactory because a Notified Body has examined the technical documentation. However, the Competent Authority may be evaluating the work of the Notified Body and may or may not agree with conclusions drawn by that Notified Body. For example, during inspection visits, Competent Authorities have questioned the adequacy of device classification rationales and risk analysis information included in technical documentation even though the same technical documentation had been examined by a Notified Body.

Absence of Notified Body involvement

Manufacturers of Class I medical devices should realise that they will be the subject of increasing review and evaluation by Competent Authorities because of the absence of Notified Body involvement in their operations. For this reason, these manufacturers should be especially attentive regarding their ability to demonstrate compliance with the MDD (93/42/EEC).

As mentioned above, MSOG is in the process of developing guidance notes for Class I manufacturers to assist them in complying with national laws and regulations transposing the MDD. This guidance will also be useful in helping those companies prepare for Competent Authority inspection visits. In the meantime, manufacturers of Class I devices can avoid deficiencies in the event of Competent Authority inspection visits by ensuring that the technical files for each of the products or product families that they produce are complete, organised for easy review, and subject to version-control. Manufacturers should be aware of, and conform with, harmonised standards and their current versions, which apply to their operations or products. The same applies to European guidance documents. The basis for concluding that a product meets the definition of a medical device should be documented. It is critical that the rationale for classifying the product as a Class I device is clearly explained and able to withstand the scrutiny of Competent Authority evaluation.

Compliance with all essential requirements must be adequately documented. Many manufacturers use a matrix that lists each essential requirement and the manner in which compliance with the requirement can be demonstrated. Risk management activities and documentation should be based on the harmonised standard EN ISO 14971, Medical devices, Application of risk management to medical devices. The technical documentation should contain sufficient clinical evaluation documentation to →

support the intended purpose and claims of the device. The technical file should contain device labels and instructions for use, which not only comply with the essential requirements, but also with any national language requirements where the devices are marketed. Declarations of Conformity must be drawn up before products are released. An exhaustive list of the documentation that Class I manufacturers should maintain is beyond the scope of this article, however, as mentioned above, MSOG is developing a guidance document, which will assist Class I manufacturers with compliance.

The same points apply to manufacturers of custom-made devices or in vitro diagnostic devices when the conformity assessment procedure does not involve the intervention of a Notified Body. It is expected that Competent Authorities will pay particular attention to the compliance of these manufacturers with device regulatory requirements. Prudent manufacturers of these types of devices will take appropriate actions to ensure full compliance with the Directives and be able to easily demonstrate this compliance.

Managing inspection visits

Regardless of the class of devices that they produce, manufacturers need to be prepared for Competent Authority inspection visits. This preparation should also apply to importers, distributors and Authorised Representatives, where applicable. For example, a checklist of the documentation that is most likely to be requested can be developed and used to ensure it is readily available and up-to-date. The specific list of documents, procedures and checks included on the checklist will depend on the manufacturer and the devices concerned, but it may include

- the rationale that a product meets the definition of a medical device
- the classification rationale specifying the classification rules applied
- technical documentation as required in the Directives; can refer to guidance such as the Notified Body recommendation on technical documentation[2]
- risk analysis and risk management documentation in conformity with EN ISO 14971
- clinical evaluation documentation
- labels, instructions for use or other materials accompanying the device, including accurate translations of these materials, which have been approved for use by the manufacturer
- Declarations of Conformity
- where applicable, device registration documentation in accordance with Article 14 of the MDD
- postmarket surveillance procedures and records
- other documentation, as needed.

References

1. The Report on the Functioning of the Medical Devices Directive (93/42/EEC of 14 June 1993), Medical Devices Experts Group, 5 June 2002, downloadable from <http://europa.eu.int/comm/enterprise/medical_devices/index.htm> then click on "Report of the Medical Devices Experts Group on the Functioning of the Medical Device Directives."
2. Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC and 93/42/EEC, Recommendation, NB-MED/2.5.1/ Rec5. mdt

Maria E. Donawa
Donawa Consulting,
Piazza Albania 10, I-00153 Rome, Italy,
tel. +39 06 578 2665, fax +39 06 574 3786
e-mail: medonawa@donawa.com www.donawa.com