Understanding the Italian job

The Italian Ministry of Health has introduced new medical device registration requirements. ***Roger Gray*** *unravels the complexities of the revised procedure.*

Two recent Italian decrees dated 20 February 2007 and 20 March 2007 have introduced new procedures for registering medical devices distributed in Italy into a new databank within the Ministry of Health (MoH) web portal.

The MoH states that the purpose of the new system is to improve the previous registration process and enhance device traceability by assigning a registration number to each device, thereby facilitating MoH market surveillance and vigilance activities.

The new databank will also be used to generate a complete list (called a 'Repertorio') of devices that are sold to the Italian National Health Service (Servizio Sanitario Nazionale, SSN).

Therefore, for companies who wish to sell their products to the Italian NHS, the registration in the 'Repertorio' will require a fee of 100 Euros for each device or group of devices that share the same 'technical file'.

If a company does not wish to sell its products to the Italian NHS, the fee is not required, but the registration process is still mandatory.

Registration without paying the fee will allow sales to Italian private hospitals, thus the fee is not intended by the MoH to be a registration fee under the directives, but a fee for reimbursement under the NHS.

The new registration requirements apply to medical devices, kits and systems covered by Article 12 of the MDD, and active implantable medical devices. They do not cover custom-made devices, in vitro diagnostic medical devices or devices intended for clinical investigations.

The introduction of these requirements is in two phases. From 1 May 2007 the new procedures must be followed for any devices that will be introduced into the Italian market after that date, and registration must be completed before the device(s) can be sold in Italy.

If the products are to be offered for sale to the Italian NHS, the 'Repertorio' fee must be paid. Companies with devices that were registered with the Italian MoH under the previous system before 1 May 2007 have until 31 December 2008 to comply with the new requirements, including payment of the 'Repertorio' fee.

> "The stated purpose is to improve the registration process and enhance device traceability"

Registration process

Companies wishing to register will need to follow the process described in the 'Manuale Utente Profilo Fabbricante DM' (User Manual for the Medical Device Data Bank), which is available in Italian and, more recently, in English, and can be found on the MoH website at: www.ministerosalute.it/pubblicazioni/ppRisultato.jsp?id=632.

There are 70 questions to be answered for each device or family of devices, and certain documents must be provided electronically and attached to the online submission. Although the user manual is now available in English, the questionnaire on the website is only in Italian.

The registration process can be completed by the manufacturer or other individuals that the manufacturer may designate.

Device distributors are thus able to register devices on behalf of non-Italian manufacturers, but whoever is designated to carry out this task should have a thorough understanding of both the registration requirements and the generic regulatory aspects of compliance with the directives, otherwise the

registration process may become even more complex.

Some Italian organisations are offering a service to manufacturers to enter the necessary data into the MoH website.

The procedures for obtaining access to the database and for designating an individual for performing the registration are specified in the MoH web page (this is in English): www.ministerosalute.it/dispositivi/paginainterna.jsp?id=395&menu=registrazione.

This includes a link to the form that has to be completed for notifying the MoH of the identity of the person responsible for inserting data in the registration databank.

User manual for the medical device databank

The information required for registration is specified in Annex 1 of the Italian Decree of 20 February 2007.

All the data fields which relate to the required information are listed and described in the 'User Manual for the Medical Device Databank'.

Pages 45-47 of the manual contain a section entitled 'Documentazione' (Documentation). This lists the information that should be provided, which can be in the form of attached files or links to files. The manual specifies that all the fields in this section must be completed in order to successfully finalise the registration process.

One field, called 'Scheda Tecnica', is neither the English equivalent of Technical File nor of Technical Documentation.

However, the manual specifies the various types of information that the MoH considers to be part of the 'Scheda Tecnica', which is similar to the information that was required under the previous Italian device registration process.

Documentation to be provided

Among the more obvious documents that need to be attached online to the application are:

- Labelling (Etichetta);
- Instructions for use (Istruzioni per l'uso);
- Images of the medical device (Immagine del DM);
- Scientific literature supporting the clinical evidence of performance and safety (Bibligrafia Scientifica).

However, the elements of the 'Scheda Tecnica' may be more difficult to locate and select, because they are not clearly related to the generally understood parts of a 'technical file', including a schematic of the functioning or use ('Schema di funzionamento/utilizzo'), plus any information on maintenance and storage, which does not relate directly to universally recognised terminology, and can therefore lead to various interpretations of what the MoH means.

The process of complying with the new Italian registration requirements is therefore not straightforward, but manufacturers having a clear understanding of relevant regulatory requirements and guidelines related to technical documentation and technical files, will minimise any subsequent requests for further information from the MoH.

Such guidelines include the NB-MED/2.5.1 recommendation, available from www.teamnb.org, and the Global Harmonization Task Force (GHTF) guidance document ***'Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)'***, which be downloaded from the website www.ghtf.org/sg1/sg1-proposed.html ●

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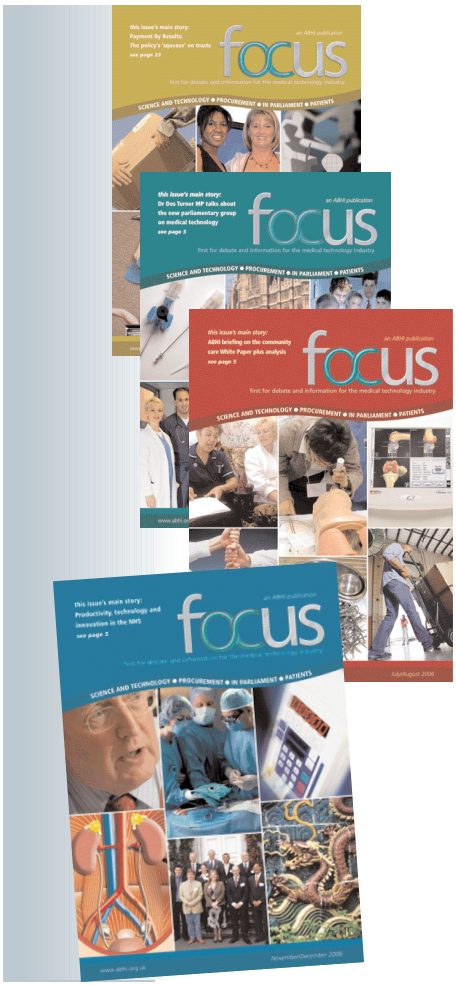

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