



## Safety information a priority for device users, regulators and manufacturers

By Jeanette Marchant—London, UK

The increasing emphasis being placed by regulators on patient and user safety means that medical device manufacturers must ensure that they provide essential product safety information to end users. However, coping with the increasing amount of information required for labeling and instructions for use while at the same time meeting local language and specific information needs is proving a minefield for manufacturers.

While the use of symbols and pictograms helps manufacturers to provide the necessary information on medical devices to customers, it is becoming increasingly difficult to comply with all the regulatory requirements. "The information we have to put on the label is growing," says Dr Berthold Scheffczyk, head of label and leaflet design for medical devices and medicines at B Braun Melsungen.

The German company aims to market its products with one label and leaflet for different countries, including up to 22 languages. "With 22 languages it is almost impossible to put the leaflet in single packages," says Dr Scheffczyk. With the exception of

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catheters, which are long and in large volume packs, multilingual leaflets are placed in the smallest selling unit which contains up to 100 single packages of Class II and III devices.

The leaflet in the single pack is in English and German only, and customers are provided with additional multi-language leaflets by the local representative on request. An electronic form of the information from B Braun's website will also be available when the company has completed compiling its online product leaflets for medical devices.

Local language requirements continue to be a contentious issue for device manufacturers. Floris Boele, corporate regulatory affairs manager of Philips Medical Systems (The Netherlands), says: "Our kind of imaging equipment is mostly used by healthcare professionals who well understand the English language." Although he believes that regulatory authorities should accept that instructions for use are needed only in English if users have been trained in the English language, he expects that local languages will increasingly be favored, thus increasing manufacturers' workload and costs. Translating instruction manuals for medical imaging equipment, which run into hundreds of pages, can cost up to \$30,000 for just one language, according to Boele.

Although most device manufacturers aim to use the same basic text for their instruction manuals and leaflets for the global

market, providing the same information to all end users of devices may not be sufficient to address local needs. John Reabe, who is responsible for Smith & Nephew's orthopedic device labeling worldwide, says that although the company has standard wording for all its products, additional information is required for the Japanese market to explain what instruments to use. "Basic information is needed for medical staff," explains Reabe. Because there are so many hospitals in Japan, orthopedic implant procedures are not performed as frequently in each hospital as in European or U.S. hospitals. Consequently, nurses and other medical staff may need more instructions for use of these devices than their Western counterparts.

To overcome the problem of increasingly large leaflets and manuals, manufacturers are exploring alternative ways of providing product information. "We talk about CD-ROM periodically and it would be nice to do that," says Reabe. Philips Medical Systems is also investigating the feasibility of publishing instruction manuals in a more sophisticated manner. The Medical Device Directive states that instructions for use must be readily accessible by the user, says Boele: "But the directive is not very precise on how this should be delivered."

The Medical Device Directive requires that "each device must be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of potential users." In addition to the information on the label, every smallest selling unit of a medical device other than those in Class I or IIa should be accompanied by Instructions for Use.

Although the work involved in producing an electronic format might not reduce costs initially, Boele anticipates that savings might be achieved in the long run. "I assume it might be less costly in the remainder of the process to the customer. You don't have to

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print it, you don't have to distribute it by DHL: you can put it on the Internet." And because computers are an integral part of imaging systems, providing an electronic format would not present a problem for the end user, says Boele.

For other devices, however, the situation is less straightforward. Since customers must have direct access to such information, says Dr Scheffczyk, alternatives to printed information are currently not feasible. "You can't expect the end user to have a PC in their workplace, or even a connection to the Internet. It is therefore difficult to put a CD-ROM in every pack or to say 'look on the Internet at our website'." So long as there are customers who do

not have the hardware to read CD-ROMs or access the Internet, compliance with the legislation must remain limited to hard-copy documentation.

There is also the issue of product liability, notes Dr Scheffczyk. Although there are fewer product liability problems with medical devices than medicines, if manufacturers have not done everything to inform the end user about potential risks with their devices, the insurer will not pay in the event of a liability case.

Furthermore, the increasing emphasis being placed on safety by regulators in the EU, U.S. and Japan means that warnings are needed on labels as well as leaflets, says Dr Scheffczyk. Although most symbols are well understood within the healthcare community, the triangle containing an exclamation mark is

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ambiguous. According to the ISO norm it means "look at the leaflet" but some people think it is just a general hazard warning.

In order to ensure that users of devices are aware of the potential risks, it might be best if all warnings appeared on the labels, as is the case for medicines. Dr Scheffczyk envisages that in the future the regulations which apply to medicines will also apply to medical devices: "We will have one label for each country, like medicines."

While such a scenario might be extreme, device labeling is a key component of the risk management process. "The whole of labeling is an educational exercise. It's not just merely discharging the responsibilities of the directive," according to Richard Moore, technical affairs director at EUCOMED, the European medical technologies industry association.

#### One language for device terms

If more, not less information is expected to appear on labels, manufacturers will need recourse to more symbols and pictograms to free up space for essential information. Manufacturers are employing available symbols wherever possible, although Boe notes that the US has a tendency to require written warnings rather than relying on pictograms. He would also like to see more symbols included in international standards for safety warnings.

The newly-published Global Medical Device Nomenclature (GMDN) has a potential role in labeling, says Moore, who was part of the policy group which wrote the GMDN. Published as an ISO Technical Specification and as a CEN Technical Report in December 2001, the GMDN provides some 7,000 primary terms and definitions, each with its own unique numeric code. For the first time, medical devices have individual generic descriptions

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which can be used on a global basis. "People have different terms for implants and instruments. So now everyone can talk the same language," says Smith & Nephew's Reabe.

Originally conceived of for the exchange of regulatory data, the GMDN has a range of potential applications. "It's been suggested that the GMDN code could be used in labeling," says Moore. If the numeric code is used on a device it will obviate the need to include a complex device name on the label which has to be translated, although it remains to be seen how it can be implemented, he says.

Currently the GMDN is available only in English as an 800-page printed document and read-only CD-ROM. Translation into Japanese is well under way and German and Spanish versions are also in the pipeline. "I would imagine we would probably have two or three language versions by the end of the year. Certainly in the next two years I would expect it to be translated into quite a few languages," according to Moore.

Existing nomenclature systems used as the basis for the GMDN include the US FDA's Classification Names for Medical Devices (CNMD), the Japanese Federation of Medical Devices Associations' system (JFMDA), the Norsk klassifisering koding & nomenklatur (NKKN) developed in Norway, the US system developed by the Emergency Care Research Institute (ECRI) called the Universal Medical Device Nomenclature System (UMDNS), ISO 9999 for technical aids, and the European Diagnostic

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Manufacturers Association's (EDMA) nomenclature for IVDs. Some 15,000 terms are currently covered by the GMDN, according to Mark Wasmuth of the British Standards Institute (BSI), which is acting as the GMDN maintenance agency secretariat. Because the terms have been compiled from several databases, synonyms are cross-referenced, indicating the preferred term. For example, "suture" may also be referred to as "stitching material".

Use of the GMDN is expected to become compulsory throughout the EU, while other regulatory authorities including the US FDA and the Japanese Ministry of Health and Labor are expected to implement it.

While regulators have generally endorsed the GMDN and users are expected to use it for inventory control, manufacturers are waiting to see whether they have to use it for regulatory reasons and what the commercial benefits might be, says Wasmuth. Potential commercial applications could be trends analysis, stock control and electronic purchasing.

**For further information on the Global Medical Device Nomenclature: [www.gmdn.org](http://www.gmdn.org)**

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