



Symbols Could Reduce Burden of Translating Device Labeling

By Jeanette Marchant—London, UK

For many medical device manufacturers, providing information in local languages for the safe and proper use of their medical devices can be a major labeling headache.

Not only is it a costly exercise, but companies attempting to meet the language requirements of several markets on one label face problems of space and legibility of text. The use of commonly understood symbols to convey information in lieu of text would seem to offer a practical solution, but the reality is not quite so straightforward.

In Europe, the Medical Device Directives may have streamlined the regulatory procedure for achieving marketing clearance, but the regulations have introduced an additional burden for companies in the form of language requirements on labeling. "Before the Medical Device Directives, labeling used to be fairly simple because it was unregulated in most countries," says David Purnell, former director of regulatory affairs and quality management (currently a business manager) at Becton Dickinson (UK). As member states transposed the European directives into national law, the language requirements crept in. Whereas countries such as Greece had previously accepted English labels on devices, they now expect information to be translated into Greek.

Instructions for use of devices sold to non-professionals must be in the local language, but some countries can be flexible in their language requirements for professional use. Depending on the nature of the product, Scandinavian countries and the Netherlands may permit a derogation of the need for the local language, according to Ian Cutler, director of European regulatory affairs at Smith & Nephew. "But my experience is that the number of cases where that happens is few, and it probably only applies to 'medium-risk' products."

And omitting the local language from product information leaves a company vulnerable in court should the device be implicated in patient injury cases. Although it might be argued that surgeons and other medical professionals ought to know how to use certain products, Cutler advises companies to err on the side of caution. But addressing the need to provide several languages on the labeling poses problems of space, particularly on small products,

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says Mike Neale, European regulatory and industry affairs manager for 3M Health Care. In the European Union alone there are 11 official languages, and the expansion of the EU to include central and eastern European countries will push the total to over 20 within the next five years.

Companies can either attempt to satisfy every market with one label; produce individual packs for each market—and this would

depend on volume and market potential for specific products; or divide up their markets to cover a group of languages, such as southern Europe. Dividing up markets, however, increases the number of line items held in stock and the complexity of the labeling process, says Purnell.

One company with a high value/low volume product, according to Cutler, would label its finished products with a generic product code and batch number before sending them to an intermediary holding warehouse. On receipt of orders for a specific market, the appropriate number of labels would be printed in the language required. Not only was this cost-effective but the product was perceived favorably by the customer as being tailored for that market.

However, this is not economically viable for low value/high volume products. An alternative option would be to over-label devices with the appropriate language, either at the manufacturing facility or distribution point. "That requires good manufacturing practice controls, making sure the right label is on the right product, knowing where to put the label, and it will need to be put on neatly," says Cutler.

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In order to simplify medical device labeling information, manufacturers could consider wider use of pictograms and symbols. "By using pictograms where the nature of the product is fairly simple and lends itself to pictograms, you can thereby avoid any foreign language. Certainly it helps to use symbols where they are relevant and exist in some recognized standard," says Cutler.

Becton Dickinson is one company that has chosen to use pictograms. Accurate drawings, such as a needle fitted onto a tube, can obviate the problem of translating, says Purnell. The company's needles carry no translations except on the outer package, where the brand and description can be in as many as 23 languages.

To date, the company has not encountered any regulatory problems with drawings and pictograms for professional-use products. This route is considered by Neale to be more appropriate for low-risk Class I and possibly Class IIa devices. "For Class IIb and III devices it becomes increasingly difficult to use symbology and pictograms alone."

The Medical Device Directive encourages the use of symbols from harmonized standards, which do not require explanatory text. Endorsement by the European Commission of the 11 symbols standardized by the European Standards Committee, CEN, for medical devices (EN 980) has been impeded by the lack of agreement on the symbol for sterility, although most companies are operating as though they have been harmonized. "My advice is to use the symbols and force the case," says Cutler, who is unaware of

any company which uses symbols encountering problems with national authorities.

Manufacturers also have at their disposal a range of symbols from other standards that can be used for medical devices, says Mike Barwick, chairman of the BSI committee on symbols and labeling and chairman of the CEN committee on nomenclature. A basic set of 1500 symbols is contained in the international standard ISO 7000, although many of these relate to non-medical fields such as agricultural equipment.

ISO 780 (1997) covers pictorial markings for handling of goods which contain some useful symbols for packaging. ISO standards do not cover electrical goods that are dealt with by the International Electrotechnical Commission (IEC). There are hundreds of symbols for electromedical equipment, particularly imaging systems, but the IEC standards can be a valuable source for other devices, says Barwick. For example, symbols for "internal diameter" and "external diameter," which were originally proposed for EN 980 but were not required by the MDD, are two IEC symbols that could be useful for catheter manufacturers.

In the international marketplace, there are some regional variations in symbols. In Japan, for example, the set of ISO 780 symbols have subtle differences, such as a broken wine glass for "Fragile" instead of the intact wine glass used in Europe. There are also variations around the world for the types of umbrella and number of raindrops used in the symbol for "Keep Dry," but the image is nevertheless recognized, says Barwick. According to 3M's Neale, who works closely with the company's US office, he has never come across an instance where a symbol has not been understood on both sides of the Atlantic.

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The prospect of a universally accepted set of symbols for medical devices is not ruled out by Barwick: "I would hope it would start to happen in the next year or two." Voting on a Final Draft International Standard (ISO/FDIS 15223) "Medical devices—symbols to be used with medical devices labels, labeling and information to be supplied" is due to be completed on June 3, 2000. "I can't see anything stopping it becoming a standard," says Barwick.

ISO/FDIS 15223 contains 24 symbols in total, including all the EN 980 symbols and proposed symbols for in vitro diagnostics (IVDs) which will eventually be incorporated into EN 980. In its introduction to the draft, the ISO notes the lack of harmonization with regard to the language to be used when presenting information for the safe and proper use of medical devices. "This international standard proposes solutions to these problems through the use of internationally recognized symbols, with precisely defined meanings that transcend language."

Initially, it is recommended that the proposed symbols should "appear together," with the relevant meaning in a language understandable to the end user, enabling wording to accompany the packaging rather than on the pack itself. The need for language could be relaxed for a specific market, says the ISO draft, when a manufacturer can demonstrate that the symbol and its meaning have appeared for a continuous period as required by the relevant regulatory authority, or if 75% of typical end-users recognize the symbol and understand its meaning without prompting.

The need to use explanatory text in conjunction with symbols is a

gray area. While EU law enables companies to use symbols on the label and provide explanatory text on information accompanying the device, such as a leaflet in the pack, other regulatory bodies, such as the Food and Drug Administration, require the text to be with the symbol. Barwick advises companies to check with local authorities whether explanatory text has to be on the label or not, and even whether they actually need any text. Countries that are going down the EU directive road may be more inclined to accept information on a leaflet rather than on the label, he notes.

Medical device manufacturers are able to propose additional symbols to national standards bodies for consideration by ISO/IEC or CEN/CENELEC. While use of symbols needs to be more widespread, they should be kept under control, otherwise there could be a surfeit of symbols, cautions Neale. Companies are also advised to be wary about using proposed symbols.

Cutler would encourage manufacturers to consider using the symbols in ISO/FDIS 15223, although with a caveat. "Take a sensible anticipated decision as to what the symbols are going to be, bearing in mind that if there were some symbols which were still contentious you may have to change all your labeling if the final symbol is different." As Barwick says: "Many are proposed, and many rejected."

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