



Language Requirements of IVDD pose trade barrier in Single Market

By Jeanette Marchant—London, UK

The lack of clear labeling requirements within the European Economic Area (EEA) for in vitro diagnostic medical devices is a cause of concern and frustration for in vitro diagnostics (IVD) manufacturers. Since June 7, 2000, when the IVD Directive (98/79/EC) came into effect, few CE-marked IVD devices have appeared on the European market. This is perhaps indicative of the reluctance of manufacturers to second-guess the harmonized standards of the directive while the IVDD has yet to be transposed fully into national legislation in several of the 18 markets of the EEA.

Without clear rules on national language requirements in all of the 15 member countries of the European Union and the three other members of the EEA (Norway, Iceland and Liechtenstein), IVD manufacturers are predictably hesitant to invest in new labeling and packaging. "We don't know what the official requirements are and this is causing delays to the industry," says Kevin Painter, head of quality assurance and regulatory affairs for Bayer Diagnostics' European region. "Labeling is one of the biggest jobs—it's costly and takes a long time."

Although many governments have failed to meet the December 7, 1999 deadline to transpose the IVD directive into their own national legislative framework, manufacturers will not be granted an extended deadline. By December 7, 2003, it will be mandatory for manufacturers to comply with the requirements of the directive, although IVDs already in the distribution chain and which comply with existing national legislation can continue to be supplied to the end user for a further two years (until December 7, 2005).

The indications are that the directive's provisions on labeling mean that information supplied by the manufacturer to the professional user will need to be in more national languages than is currently the case.

"Labels are currently in three to five languages on most products," says John Place, director of the European Diagnostic Manufacturers Association (EDMA). While the major languages of English, French, German, Italian and Spanish are commonly used, the languages of the smaller markets have generally been avoided because of the expense

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involved in translation and printing. (Since 1999, in Portugal it has been a legal requirement to provide labeling in Portuguese.) Now it seems that as many as 12 different languages could be required for participants in the €6 billion (\$5.5 billion) west European IVD market.

The directive allows member states to require that information supplied with an IVD be in the local language when it reaches the end user. The IVD industry does not question the supply of instructions for use (IFU) in the local language for all self-testing devices.

However, it seems that most member states will also require national languages to appear on the labeling of products for professional use, which account for 84% of the west European market, according to EDMA figures.

Denmark and Sweden, the first two member states to transpose the IVDD into national law, require translation of professional-use product labeling and instructions for use into their national languages. Governments are reluctant to be the first to say that their national language is unimportant, notes Place, and even if the professional user is fluent in English, all governments will want their own language. All Danish professional laboratory staff, for example, are taught in English using English text books, so the need for Danish instructions is viewed as unnecessary.

The majority of competent authorities are following the Danish and Swedish lead. In Germany, the largest market for IVD devices with a 25% share of the west European market, the Federal Ministry of

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Health has instructed the Länder (federal provinces) that: "The use of foreign language must really be exceptional and should only be tolerated in particular situations where there is no doubt that the foreign language is correctly understood by the operator and/or user." In France—the third largest European market, with a 17% share—the authorities make no concessions: even information on keyboards and screens of devices must be in French.

Norway, Belgium and the Netherlands will probably be prepared to accept English instructions for use if the manufacturer can prove the competence of the user to understand English. However, the potential liability risk will deter manufacturers from opting for this route, according to Cecilia Brown, director general of the British In Vitro Diagnostics Association (BIVDA).

Furthermore, the definition of "professional use" is not clear-cut, points out Painter. Whereas hospital laboratory users are well versed in using IVD tests, with training frequently provided by the manufacturer, other healthcare professionals who perform testing outside the lab, such as ward nurses and general practitioners, are often unfamiliar with testing and they rarely have received any training. "In some draft transpositions of the directive, authorities are recognizing this other group who are still healthcare professionals but not necessarily experts," says Painter.

The implication for manufacturers is that they may have to make a distinction between routine tests, self-testing and point-of-care testing, which could result in three different types of labeling to address each situation. The Dutch, Belgian and Norwegian draft IVD regulations, for example, indicate that manufacturers will need to assess the likely user of the device in terms of their competence, how frequently they

use the product and whether they will understand the instructions for use. All this will potentially increase the manufacturer's costs.

The costs involved with new labeling, packaging and manuals to comply with local language requirements will hit smaller companies in particular. EDMA estimates the cost to the industry as a whole at around €15 million (\$13.7 million) for each new language that has to be translated. Add to this the compliance costs of meeting the quality standards of the IVDD—estimated by the UK Medical Devices Agency to amount to 2% of turnover for individual companies which have annual revenues of around £500,000 (€800,000/\$731,000)—and small IVD manufacturers will either have to increase prices to offset costs or consider restricting the availability of devices.

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associated with complying with local language requirements. "The language requirements will have a major impact on small companies. They will act as a barrier to trade," says Brown.

The option of splitting packaging into geographical regions, as commonly practiced in the pharmaceutical industry, is not considered a realistic option for IVD manufacturers because the market is not large enough to make this economically feasible. The use of symbols and pictograms, already employed by medical device manufacturers to ease translation problems [see "Symbols Could Reduce Burden of Translating Device Labeling," MDTN Spring 2000], could go some way to reducing the volume of text needed to accommodate all the language requirements. "Symbols will have to be part of the answer," believes Brown. Although the number of symbols for IVDs is limited, an increasing number are being proposed.

The number of printed instructions that must accompany each product is often larger than the IVD itself, increasing the volume of packaging and hence the weight. While not contesting the need to provide labeling in national languages, EDMA is proposing alternative means of delivering instructions for use to professional users other than the traditional "IFU in the kit" concept, which could save costs and reduce logistical complexity. Unlike the consumer who requires the IFU to be supplied with the self-test IVD, professional users could incorporate the information into their standard operating procedures (SOP) from an electronic format, suggests EDMA.

"The IFU doesn't always have to be printed," says Place, suggesting as alternatives CD-ROM or an electronic version made available through the internet. EDMA proposes that manufacturers supply the following information in the national language with the device:

- A reference to the relevant version of the IFU;
- Indication of the various options to obtain the relevant version of the IFU to meet the customer need;
- Warnings and precautions, where appropriate;
- Any specific batch-related information not provided in the IFU, where appropriate;
- Where an IFU is revised, this should be indicated on the outer label or within the device packaging.

It is then the manufacturer's responsibility to ensure that the professional user has the technical means to receive the IFU by the chosen option, ensuring security and safe use. Thus the end user can

receive only essential information in the required language when needed. The added attraction of supplying the IFU electronically is that professional users can incorporate the information into their quality system, thereby eliminating retyping errors.

However, consensus agreement to providing the IFU other than in printed form is needed by the 18 competent authorities, which could be an obstacle to acceptance of EDMA's proposal. In transposing the directive into national legislation, different interpretations have been placed on how the information should be supplied. While some

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countries, such as Denmark, have left it open, others—including Germany, Sweden and the UK—contend that the instructions must be printed and included as a package insert with the product.

The IVDD is out of step with the harmonised labeling standard for IVDs (EN 375/EN591), which was written long after the directive and allows for supply of the IFU by other means, notes Brown. While not an immediate option for companies, she hopes that discussions between industry and competent authorities might pave the way for IFUs to be provided by means other than printed form, thus reducing the costs involved in meeting language requirements. With the expansion of the EU, the potential to include 26 languages on a single CD-ROM has obvious advantages.

In the meantime, it is likely that labeling and instructions for use are going to be required in each member state's local language in printed form. Inevitably, manufacturers will need to assess the economics of complying with national requirements in markets where sales potential is limited: it may be more cost-effective simply to withdraw products from smaller markets.

European IVD Market 1999				
Country	Sales (\$ million)	Sales (€ million)	% change vs 1998 (in local currency)	% Share of Total European Market
Germany	1,341	1,467	+1.3%	25%
Italy	984	1,076	+2.8%	18%
France	913	999	+4.8%	17%
Spain	570	624	+4.0%	10%
UK	484	530	+7.1%	9%
Belgium	174	190	+8.1%	3%
Switzerland*	169	185	+4.8%	3%
Netherlands	153	167	+7.0%	3%
Austria	144	157	+2.8%	3%
Sweden	127	139	+6.6%	2%
Portugal	125	137	+7.2%	2%
Greece	78	85	+1.7%	1%
Norway	67	73	+4.1%	1%
Denmark	66	72	+4.1%	1%
Finland	58	63	+5.1%	1%
Total W Europe	5,451	5,963	+4.4%	100%

* not part of EEA but chooses to transpose Medical Device Directives into national law

Source: EDMA

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