

Labeling and language requirements for Medical Devices

Labeling and language requirements under the IVD Directive

The IVD industry has been learning to adjust to the requirements of the European Union's (EU) IVD Directive (98/79/EC).¹ One of those adjustments is in the area of labeling and language. As with the two previous directives for active implantable devices and general medical devices, the IVD Directive requires manufacturers to adhere to a set of regulations regarding labeling and language use. These new regulations are often ambiguous, and many IVD manufacturers are experiencing difficulties navigating through them.

The labeling and language requirements are spelled out in the essential requirements (Annex I) of the directive. These requirements are also supported by a number of other standards, such as EN 375/376 (information supplied with IVD reagents), EN 591/592 (instructions for use in IVD instruments), EN 1041 (information provided with medical devices), and EN 980 part 1 (graphic symbols for labeling medical devices).²

In essence, according to the directive, the labeling and language on each IVD device should provide the information needed to use the device safely and properly, and should take into account the training and knowledge of the potential users. This article further examines the labeling and language requirements that IVD companies have to meet in order to comply with the IVD Directive.

Labeling Issues

Many of the labeling elements that are required under the IVD Directive are similar to those required by FDA. According to the directive, the information required on labels includes:

- Device name and description.
- Name and address of manufacturer.
- Name and address of authorized representative.
- Lot or serial number.
- "Use before" date.
- Statement indicating in vitro use (where appropriate).
- Statement indicating for self-testing use (where appropriate).
- Storage, handling, and operating warnings.
- Any residual risks.
- Intended purpose.³

At the same time, while EN 1041 only specifies that "text must be readable" given a certain distance and lighting intensity, the directive does not specify any minimum font size nor address the use of color.⁴ In addition, the manner in which products are packaged is left to the manufacturer's discretion.

In those cases in which instructions for use must be included with the packaging of a device, the following information must also be provided:

- All label information, except lot number and "use before" date.
- Reagent composition.
- Storage after opening.
- Special equipment.
- Specimen information.
- Use procedure.
- Measurement details.
- Calculation principles.
- Measurements needed for changes in analytical performance.
- Pretreatment.
- Packaging damage.
- Reuse instructions (if applicable).

- Date of issue and revision.⁵

However, there are some substantial differences between the labeling requirements in the United States and those in Europe. First, the directive strongly encourages that wherever possible, the information on labels should be presented as harmonized symbols (see Figure 1). In contrast to FDA requirements, these symbols do not need to be accompanied by text explanations in Europe. Second, most EU member states' transpositions of the directive require labels to be translated into their national languages.



Figure 1. Harmonized symbols that may be used on IVD labels and instructions for use. (click to enlarge)

These additional requirements pose significant challenges to IVD manufacturers' labeling, packaging, and distribution systems. It is not often possible to include all of the product information in English on a small label. Doing so in multiple languages is even more challenging.

Using Symbols

When devising a global labeling strategy, particular emphasis should be placed on the following: evaluating the use of symbols to maximize label real estate; developing a consistent look and feel for labeling to maximize brand manifestation; planning for future languages to be added; and grouping languages together in a way that fits the company's distribution model.

The problem is that these considerations often conflict with one another, and there is no single correct approach. However, few would disagree that the use of symbols on labeling would solve many of these issues. The Global Harmonization Task Force has recommended:

The use of internationally recognized (i.e., standardized) symbols should be encouraged provided that device safety is not compromised by a lack of understanding on the part of the patient or user. Where the meaning of the symbol is not obvious to the device user (who, with some products, could be a member of the public), it should be described in words associated with the symbol.⁶

The major obstacle to the worldwide implementation of symbols is the reluctance of FDA to accept their use. FDA is concerned about the possible inability of the end-user to understand the symbols, which might result in an unsafe use of the product. The agency is also concerned about the constraints of current U.S. labeling regulations regarding words versus symbols. In fact, FDA may have a point. There is often nothing intuitive about the symbols used. Since few laypeople are familiar with their meanings, symbols do require some explanation.

Labeling Solutions

In their effort to meet all of the labeling requirements under the IVD Directive, IVD manufacturers have implemented one of the following approaches.

One size fits all. Fitting all of the languages and symbols onto one label is the least expensive alternative. It also facilitates packaging and label control. However, this alternative is often not feasible because of limited label real estate.

Regional labeling. Some IVD companies are considering using separate U.S. and non-U.S. labels. The U.S. labels would contain no symbols, and the non-U.S. labels for the rest of the world would contain symbols. While this approach may be easy to implement, it presents logistical problems for production planning and inventory control. For example, how many of each set of labels should be manufactured? How should back orders in one set be balanced against overproduction in another set?

On-demand labeling. This alternative calls for inventory to remain unlabeled until an order is received. Inventory is then labeled according to the requirements of each order, affording an IVD manufacturer greater flexibility. However, because inventory is handled more frequently, this approach can be time-consuming and expensive, and has the potential for causing inventory discrepancies.

Combined approach. Some IVD manufacturers have experimented with preprinting labels with high-demand languages while leaving space for another label for other languages that can be applied separately at the time of the order. This overlabeling offers better production planning and inventory control but does not eliminate the time and cost factors.

Whichever approach IVD manufacturers decide to adopt, it is important to consider the pros and cons of the solution as part of a risk analysis. Particularly important is the effect a failure in labeling could have on patients, users, and the environment. Overall, IVD manufacturers should not get hung up on finding the ideal approach to labeling. Instead, manufacturers should focus on getting the job done in a way that works with the company's specific products.

Language Issues

As stated above, the IVD Directive requires labels to be translated into the local languages of the EU member states. Because most U.S. firms tend to deal primarily with the domestic market, they have not had much opportunity to address these multilingual issues. As a result, many IVD companies do not understand fully the complexities of this language requirement.

The 25 current EU members use a total of 20 different languages. While the majority of these countries require translation into their national languages, the requirements often differ from country to country, depending on whether a self-test or professional-use device is involved (see Table I).

Even though each IVD manufacturer's language strategy will be different, some of the steps that are taken are universally similar, including the following: analyzing a company's sales in Europe on a country-by-country basis (often the five or six languages already being used cover 85% of a company's market); analyzing the language requirements of the remaining 15% of a company's market versus revenues generated from that market; and determining if there are suitable exemptions in each of the national transpositions.

Dealing with Translation

Translation is at the heart of meeting the language requirements of the IVD Directive. Given what is at stake, developing a sound translation strategy is important, and choosing a proper translation partner must be researched thoroughly.

However, many IVD manufacturers and their staffs do not have sufficient experience and know-how regarding how to handle translation issues. Managers who are put in charge of dealing with translation typically do not have linguistic backgrounds and do not speak any foreign languages. These managers are handed the translating task on top of their regular responsibilities, leaving them to struggle to develop a strategy to multilingual documentation. As a result, managers have little opportunity to learn the correct approach to translation and end up reinventing the wheel as they go along.

Some IVD companies also seek ways to save short-term dollars by selecting the seemingly least-expensive approach to translation, such as awarding contracts to the lowest-bid vendor or using their distributors. By following these approaches, companies are not taking into account qualifications and are ignoring conflicting demands on internal resources. Industry consultants suggest that manufacturers should not ask their distributors to handle the translation efforts. Since these distributors may have a vested interest in a particular product, they will likely translate a text how they would like it to read, rather than how it should be read.

In addition, few IVD companies have instituted cross-departmental task forces to deal with translation and multilingual labeling. At those companies that have set up CE marking teams, translation issues are ignored until the last possible moment, and these teams generally find it difficult to work together.

One problem is that the roles of the teams are unclear. For example, in-country reviewers are usually not dedicated to proofreading translations. Other questions emerge about which functions should take precedence.