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MultiLingual Computing, Inc. • 319 North First Avenue, Suite 2 • Sandpoint, Idaho 83864-1495 USA • 208-263-8178 • Fax 208-263-6310



# Language requirements for EU medical device labels

*Libor Safar, Helen Colquhoun & Cheryl Hill*

It's now two decades since the European Commission established the current regulatory framework for marketing medical devices in Europe. This framework, through the individual directives, has also defined the language and translation requirements for medical device labels.

Although the system is well established, its practical application is not completely clear-cut. In practice, a certain degree of latitude exists for medical device manufacturers, while application in individual European Union (EU) countries may also vary in certain situations. In addition, the system is likely to undergo possible changes, as all three EU medical device directives are currently under review.

Medical devices in the EU are regulated by three main directives: the Medical Device Directive (MDD) from 1993 (MDD 93/42/EEC), the In Vitro Diagnostics Devices Directive (IVDD) from 1998 (IVDD 98/79/EC) and the Active Implantable Medical Devices Directive from 1990 (90/385/EEC). They all have been amended since the original directives were published, but all three provide the same option to EU member states to require medical device labeling to be in the official language of that state.

It is worth highlighting that labeling of medical devices has a much wider meaning than is perhaps the case with medicines. A label would be any written, printed or graphic material that is affixed to a given medical device or any of its containers or wrappers, any materials accompanying the medical device or any materials related to the identification, technical description and/or use of the medical device. So in practice this would include labels, packaging, instructions for use, user interface or display screens, as well as marketing materials, patient literature or technical information.

While the wording in individual directives differs, each essentially stipulates that member states may require specific information related to the use of medical devices to be in their national language(s) or in other community language(s). The MDD directive goes on to specify that this applies regardless of whether the device is for professional or other use.

The majority of member states exercise this option through their local legislation, and require that information on how to use the device be presented in the official language of the state where the device will be marketed. Derogations (exemptions) from the competent authorities – which enact the directives within their territory and which can specify one or more notified bodies to act as third-party assessors of product compliance – are possible, but not guaranteed. Medical device companies must apply to the competent authorities in a given country and present compelling evidence in order to receive a derogation.

## Medical devices vs. medicines

Overall, this makes the regulatory process for medical devices and its translation requirements different from the more centralized and unified approach that exists for medicines. The latter is more recent, with the marketing authorization procedures for medicinal products based primarily on the Directive 2001/83/EC and Regulation (EC) No 726/2004.

These specify a more direct requirement for translations of pharmaceutical labeling and package leaflets – the specific information must be provided in the official languages of a given member state (rather than "may be required"). In addition, the EU established the European Medicines Agency (EMA), which administers the centralized procedure for marketing authorization. This allows direct access to all EU and European Economic Area (EEA) and European Free Trade Association (EFTA) countries via a single application, whereby the product information such as summary of product characteristics, labeling and package leaflets needs to be submitted in all EU languages plus Icelandic and Norwegian.

The agency is also a hub of the European medicines network, which comprises over 40 national competent authorities in the



*Libor Safar is marketing manager at Moravia Worldwide. Helen Colquhoun (center) is senior vice president at CROMSOURCE. She is a physician with more than 20 years' experience in the pharmaceutical, biotech and medical device industries. Cheryl Hill is the regulatory manager for CROMSOURCE. She holds a graduate certificate in advanced regulatory affairs and has worked in the medical device industry since 2000 and in regulatory affairs since 2006.*

| Country | EU Since | Language |
|---|---|---|
| Austria | 1995 | German |
| Belgium | 1952 | Dutch, French, German |
| Bulgaria | 2007 | Bulgarian |
| Cyprus | 2004 | Greek, Turkish |
| Czech Republic | 2004 | Czech |
| Denmark | 1973 | Danish |
| Estonia | 2004 | Estonian |
| Finland | 1995 | Finnish, Swedish |
| France | 1952 | French |
| Germany | 1952 | German |
| Greece | 1981 | Greek |
| Hungary | 2004 | Hungarian |
| Ireland | 1973 | Irish, English |
| Italy | 1952 | Italian |
| Latvia | 2004 | Latvian |
| Lithuania | 2004 | Lithuanian |
| Luxembourg | 1952 | Luxembourgish,* French, German |
| Malta | 2004 | Maltese, English |
| Netherlands | 1952 | Dutch |
| Poland | 2004 | Polish |
| Portugal | 1986 | Portuguese |
| Romania | 2007 | Romanian |
| Slovakia | 2004 | Slovak |
| Slovenia | 2004 | Slovenian |
| Spain | 1986 | Spanish |
| Sweden | 1995 | Swedish |
| United Kingdom | 1973 | English |

*Although Luxembourgish is the national language of Luxembourg, it is not an official language of the EU.

Table 1: Countries and official languages of the EU.

30 EU and EEA-EFTA countries, and plays a role in the other decentralized or mutual recognition procedures, which allow for a marketing authorization in a selected number of countries.

## Roadmap 2012

As things stand, a number of deficiencies exist in the EU medical device regulation, which the European Commission is currently trying to address. The current system is seen as too fragmented and difficult to follow, not reflecting the advances brought by new medical devices and technologies. Last but not least, it is hampered by the national variations as well as incoherent interpretation and implementation in individual countries.

The objective is a fundamental revision of the existing directives, and the current Roadmap 2012 outlines some more or less radical possible approaches, while there are calls for a new centralized EU body to oversee medical devices, not dissimilar to the way the EMA works for medicines.

Although the new direction for the EU medical device regulation is expected to become clearer during 2012 and will take years to implement, it is safe to assume that it will provide for a more centralized and simplified process, which will also affect the language and translation requirements.

## Risks of noncompliance

Medical device labeling materials contain information on the intended use and the safe operation of the device. Prevention of injury is one of the driving factors behind the language requirement for device labels.

Should injury occur due to a misunderstanding of the intended use or the operating instructions, the consequences could be traumatic for the end user, the patient or both. The consequences of improper device use can range from minor injury to more catastrophic ones, and possibly death. Penalties for noncompliance are determined by the individual member states and can range from removal of the device from the market to criminal prosecution of corporate executives.

## Where English is acceptable, and where it's not

At the moment, the EU is composed of 27 member states. There are 23 official languages spoken in the EU (Table 1).

As part of the research, the contract research organization Pleiad (now CROMSOURCE) reviewed the websites of every competent authority in each of the 27 member states in order to determine the language requirements for labeling a professional-use only medical device in their state. In five cases the websites contained the necessary information in English, and no additional confirmation of the authorities was required. In 22 cases, the competent authority was contacted. 17 authorities responded, and five (France, Greece, Romania, Spain and Czech Republic) did not.

The majority of member states, 21, require medical device labeling to be in their official language regardless of whether the device is intended for layman use or professional use. However, six member states will accept labeling provided in English as long as the device is for professional use only.

In addition to Ireland and the United Kingdom, Cyprus, Luxembourg, Malta and Poland will accept English for medical device labeling as long as the device is for professional use only. Devices for layman use must be translated into the official language of the state as indicated in Table 1.

The competent authorities in the countries shown in Table 2 require medical device labels to be translated into their national language regardless of the end user. Although Table 2 attempts to streamline the labeling language requirements, the medical device manufacturer is advised to discuss the language requirements for its specific device with the competent authority. Several authorities have indicated a willingness to limit the national language requirement to the device identification label and to operating and safety information. User interfaces that include standard symbols may not need to be translated. Also, technical information such as maintenance procedures as well as professional literature may not need to be translated.

In addition to the 27 member states, the EU also has areas known as outermost regions. An outermost region is a region that is part of the EU and is associated with a member state but is located outside of the EU. EU laws, including the device directives (MDD, IVDD and AIMDD) and the associated translation requirements, apply to these regions. There are seven outermost regions. Medical devices marketed in these

| Country | Required Language |
|---|---|
| Austria | German |
| Belgium | Dutch and French [a,b] |
| Bulgaria | Bulgarian |
| Czech Republic | Czech [a] |
| Denmark | Danish |
| Estonia | Estonian [c] |
| Finland | Finnish, Swedish [e] |
| France | French [a] |
| Germany | German |
| Greece | Greek [a] |
| Hungary | Hungarian [c] |
| Italy | Italian |
| Latvia | Latvian |
| Lithuania | Lithuanian |
| Netherlands | Dutch |
| Portugal | Portuguese |
| Romania | Romanian [a] |
| Slovakia | Slovak |
| Slovenia | Slovenian [d] |
| Spain | Spanish [a] |
| Sweden | Swedish |

**a** Confirmed by industry sources.
**b** Mixed responses regarding whether or not the labels must be provided in German.
**c** Technical information, professional literature and user interfaces do not need to be translated into the member state official language.
**d** If a medical device is intended solely to be used for performing a registered activity, the instructions for use can be written in the language understandable for the user.
**e** Instructions and other information accompanying medical devices must be in Finnish, Swedish or English. Information intended for users or patients to safely operate a device must be in both Finnish and Swedish.

Table 2: Required language according to country.

regions should have the labeling translated into the appropriate language as noted in Table 3.

As summarized in the tables and text, the majority of member states exercise the option given to them by the directives (MDD, IVDD and AIMDD) and require labeling materials to be submitted in the official language of the member state regardless of the intended user of the device. However, medical device companies may apply to the competent authorities for derogations or exemptions from the translation requirements of the directives. The competent authorities will review the application and may grant the derogation if presented with a compelling reason.

Translating labeling for medical devices designed for lay users is, for the most part, a given and effectively nonnegotiable. However, nuances do exist. For example, according to Annex I, point 13 of the MDD, instructions for use do not need to be included with Class I and Class IIa devices as long as those devices are able to be used safely without instruction. This research has confirmed that in the case of medical devices for professional use only, a certain degree of latitude exists in the EU for medical device manufacturers. In practice, many manufacturers choose to translate labeling for all EU countries in which they market their medical devices for professional use, regardless of whether this is actually a requirement, despite the additional costs. It is another way of minimizing the potential risks associated with using their products and so a sound risk-reduction measure. It is also a strong marketing tool.

While professional users of medical devices tend to be, by definition, well-educated and to possess a good knowledge of English, many will still prefer information to be provided in their native language. Last but not least, the way health care systems work in the EU, there is typically a wide range of buyers or other influencers in the purchasing process. For them, availability of information in their own language may be a factor.

## E-labeling

Electronic labeling or e-labeling is an option for manufacturers of certain medical devices, and one that is set to enjoy a wider adoption supported by a new regulation in the EU. The Commission Regulation (EU) No 207/2012 applies to certain professional devices under MDD or AIMDD and will come into effect on March 1, 2013.

E-labeling promises to reduce the costs of delivering labeling information to professional users in the EU, which may otherwise rise, especially in the case of updates and changes. It should also ensure users always have access to the most up-to-date information. Another benefit of e-labeling is that it will allow for the use of animation or video, which may increase the understanding of the proper use of the device. However, the use of video may increase the cost of translation if the member states require e-labeling to be translated. Before implementing an e-labeling program, device manufacturers must conduct a risk assessment demonstrating that providing materials in electronic format either maintains or improves the safety level.

| Member state | Outermost regions | Official language |
|---|---|---|
| France | French Guiana | French |
| | Guadeloupe | |
| | Martinique | |
| | Réunion | |
| Portugal | Azores | Portuguese |
| | Madeira | |
| Spain | Canary Islands | Spanish |

Table 3: EU member states and their outermost regions.

E-labeling can be provided on portable electronic storage media, such as a CD, or on a website. If provided on portable electronic storage media, a website address should be included to inform the user where updates to the instructions will be posted. This new e-labeling regulation does not set any specific language obligations. These are governed by the laws of individual EU member states, but it does state that manufacturers that provide instructions for use in electronic form need to indicate on their websites in which EU languages those instructions are available. One thing that medical device manufacturers need to bear in mind is that e-labeling processes should be reviewed by a notified body during conformity assessment.

Much in the medical device industry revolves around risk assessment and risk reduction. Translation of medical device labeling is mostly a legal requirement in the EU, but in some situations, it is more of a risk-related or marketing decision. The upcoming changes in the EU medical device regulations are hoped to bring more clarity to the decision-making and more consistency across individual EU member states. They should help put the whole system on a new level that will reflect the recent advances brought by They should help put the whole system on a new level that will reflect the recent advances brought by new medical devices and technologies. **M**