



MEDICAL DEVICE TRANSLATION NEWS

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Medical Device Users Receptive to e-labeling

By Jeanette Marchant—London, UK

The additional language requirements for medical devices in the enlarged European Union are driving the search for acceptable alternatives to paper leaflets as a means to provide information for the safe and correct use of devices to professional end users.

Instructions for Use (IFU), which are mandatory for all medical devices except Class I and IIa devices, are now required to be provided in 19 languages in the recently expanded EU. (Although the number of official languages has increased to 20, Malta accepts IFU in English.) This will almost double the size and volume of the paper IFU and entail revision of some packaging designs to accommodate the additional language requirements. Not only does this translate into increased transport and storage costs, but adds to the environmental problem of paper waste.

Electronic labeling could provide the ideal solution by enabling manufacturers of medical devices to provide instructions to professional end users on an electronic support. This could be a CD-ROM or a PDF document that could be downloaded from the internet or a built-in screen that displays the IFU in the operator's language while the device, such as a pacemaker, operates.

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In its current form, the Medical Devices Directive (MDD) does not provide a clear regulatory pathway to e-labeling, since it refers to a "leaflet" and requires medical devices to be accompanied by the IFU. However, revisions to the MDD currently under review would open the door to e-labeling. The European Commission has proposed that the IFU could be provided in a form other than paper and, according to John Brennan, principal administrator at the Directorate General Enterprise, the Commission does not understand member states' reluctance to permit e-labeling.

Although many member states support the concept of e-labeling, Germany, Belgium, Greece, Sweden and the Netherlands are among those which have not embraced the idea. There is reluctance among Competent Authorities about use of the internet, in particular, since it raises issues of accessibility and also implies a shift in responsibility from the manufacturer to the user who would have to actively obtain the IFU.

The results of surveys conducted by industry and regulators to gauge the views of professional users indicate that CD-ROMs could be the way forward in gaining acceptance of e-labeling. A European pilot study by Medtronic in 2004 found that a surprisingly large number of doctors are receptive to CD-ROM manuals. Of the 637 implanting physicians in 11 EU countries who participated in the survey, 35% said they preferred CD manuals for implants (namely, pacemakers and defibrillators) to paper manuals and 28% regarded them as equivalent and did not mind which was provided. Just 4% of doctors surveyed would not accept CDs and required paper manuals. There were no significant differences between countries.

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The conclusions from Medtronic's survey are more positive in some aspects than the results of an opinion survey carried out by the German Federal Institute for Drugs and Medical Devices (BfArM) in March 2004. Although the 14 German medical societies, hospital federations and professional associations who participated in the survey considered that there were advantages with electronic labeling, the BfArM concludes that the majority of professional users will require a paper version of the IFU for every type of medical device in addition to an electronic manual, which is regarded as a supplement to, rather than a replacement of the conventional version.

CD-ROMs are much more accepted by German professional users as an electronic media than the internet or device-integrated screens, according to the BfArM survey. The main advantage of e-labeling is perceived to be the supply of up-to-date information. New electronic technology tools, such as computer animation or live-case-video, are also regarded as enhancing doctors' understanding of the IFU. Other advantages of electronic media cited by professional users included the key word search tools and easy storage, filing and processing.

Management of electronic data could pose problems, such as failure to find the latest CD, while concerns were also raised about technical reliability and data integrity. Access to electronic IFU will be limited by the availability of the necessary computer equipment in the healthcare facility or

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location within the hospital where the medical device is being used – hence the need for a paper version.

Half the German respondents in the BfArM survey thought that e-labeling could be used for any type of medical device, whereas the other half considered that it was most appropriate for active devices and not for single-use devices. There is strong endorsement of e-labeling for in vitro diagnostic devices: “As the responses of the organizations representing users of in vitro diagnostic medical devices are extremely positive, in vitro diagnostic medical devices for use by professional laboratories may probably be considered separately,” concludes the BfArM.

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There is more flexibility in the potential for e-labeling in the IVD sector. The language of the IVD Directive is less restrictive than the MDD in that IFU are required to accompany the device or be included in the packaging, without specifying that this must be a paper form. Furthermore, the European Diagnostic Manufacturers Association has concluded that software intended to guide the user via the monitor cannot be regarded as a label or instruction for use in the meaning of the IVDD. The industry has, therefore, concluded that text displayed on screens could be provided in any language.

Surveys such as that carried out by Medtronic are contributing to a better understanding of customer requirements and the risk benefits of providing electronic manuals. Information derived from medical professionals lend more weight to industry’s arguments that e-labeling should be used only with medical devices intended to be used or handled by professional users in healthcare facilities and that information provided electronically must be easily read using software formats commonly available on a standard PC.

As a precursor to building the case for e-labeling, physicians’ needs and requirements must be assessed. Other companies, including implant manufacturers and the suture industry, are considering following Medtronic’s lead in soliciting the views of their European customers. If surveys can demonstrate the advantages of e-labeling to professional users, without compromising patient safety, such information will help to overcome regulators’ concerns about e-labeling in Europe.

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US Experience

Experience with e-labeling in the US is also fueling the European industry’s drive to prepare the ground for alternatives to paper manuals. Authorized under the provisions of the Medical Device User Fee and Modernization Act (MDUFMA) which was signed into US law in October 2002, e-labeling is permitted for prescription devices intended for use in a healthcare facility. Paper copies of the labeling must be provided on request. Electronic labeling is not restricted to a particular technology so that the internet can be used as well as CD-ROMs.

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Electronic labeling must be provided to the Food and Drug Administration during the review of the product submission. One of the key benefits is that any labeling changes which are required by the FDA can be made immediately, reducing delays in getting the device to market, according to Dr. Tom van der Schatte Olivier, director of regulatory affairs of Cordis’ European business. During Eucomed’s Technical Forum in September 2004, he reviewed the company’s experience with e-labeling for its drug-eluting Cypher stent, which was launched in the US in April 2003.

Cordis initially provided electronic labeling for Cypher through a dedicated website (Cyphersusa.com) although a new site was launched in the fall of 2004 to accommodate more than one product. It is important to differentiate between promotional/educational material and the IFU, he noted. While there are many benefits associated with e-labeling, the process requires dedicated resources, including in-house staff who have validation expertise, including software validation. Access to the Web site must be controlled and differences in products and regulatory status in different countries/regions must be addressed. Restricted internet access is a potential problem, although this may not be the case in ten years’ time.

Electronic labeling does not obviate the need for paper copies completely. Cordis has received 1175 requests a year for printed material since Cypher was released. Nevertheless, based on the success of its experience with the Cypher website, with just two complaints regarding e-labeling out of more than 750,000 Cypher stents sold in the US, the company is committed to e-labeling and is working on enhancements for 2005. “A strong business case and risk assessment are essential,” according to van der Schatte Olivier.

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