



A Summary of the Requirements for e-Labeling

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Acceptability with In Vitro Diagnostics, why not other Medical Devices?

The discussion and debate surrounding e-labeling has been around for a number of years. In January 2007, IVD Guidance MEDDEV 2.14.3 was published in which e-labeling was acceptable for in-vitro diagnostic medical devices. This pushed the question to the forefront “if e-labeling is acceptable for IVDs, then why not for other medical devices?” Although the January 2007 guidance did not seamlessly apply across the board to all medical devices, many of the concepts did. The fact that this guidance was written and acceptable for IVDs gave industry experts and professionals a positive outlook that the same could be done for other types of medical devices. This door was officially left open by the EU when Directive 2007/47/EC, drafted in September 2007 and fully implemented in March 2010, stated the following in paragraph (10): “In the light of technical progress in information technology and medical devices, a process should be provided to allow information supplied by the manufacturer to be available by other means.” A copy of Directive 2007/47/EC can be downloaded free of charge from the Excel Translations’ website: <http://www.lifesciencetranslations.com/industry-directive-mdd.php>

When will e-Labeling be Officially Adopted?

The proposed date of adoption by the World Trade Organization’s Committee on Technical Barriers to Trade is December 14, 2011 with the proposed date of entry into force being December 14, 2012. A draft regulation was sent to the WTO on June 8, 2011 with a task force meeting that occurred on July 1, 2011 to analyze and discuss the regulation’s latest version. Comments from stakeholders in this regulation are due by August 8th 2011.

Labeling in an Electronic Format is Far from Cut and Dry.

As mentioned above, the technological benefits of e-labeling are recognized by the European Union; however, having labeling available in electronic formats cannot

be achieved without some serious considerations. Throughout the course of our day we may frequently create and distribute electronic copies of documents as if it were second nature. The process of creating electronic copies of labeling is not as simple as merely generating an Adobe PDF document. The draft regulation sent to the WTO for adoption has specific guidelines regarding what types of medical devices can use e-labeling, what types of documents can be available in an electronic format, and what types of steps must be taken to mitigate risk. A copy of this draft regulation is available for download:

http://www.lifesciencestranslations.com/pdf/eec381_en_1_1.pdf

along with the summary of these guidelines presented below in this report.

e-Labeling Criteria and Conditions

Medical devices and medical device manufacturers must meet a number of criteria conditions in order for it to be acceptable to offer their labeling in electronic format. First, the only labeling that can be provided in electric format are the Instructions For Use (IFU). Manufacturers can provide the IFU in electronic form instead of paper form for the following types of devices:

- Active implantable devices and their accessories;
- Implantable devices and their accessories;
- Medical devices and their accessories which contain a built-in system for visually displaying the IFU; and
- Stand alone software

Manufacturers can use electronic format IFU only if the devices and accessories listed above are for use exclusively by professional users and if the use by any other person is not reasonable foreseeable. The users must be professionals in the medical industry (doctor, nurse, technician, etc.) using the device as a part of their work in the context of a professional healthcare activity. This means that medical devices purchased in retail outlets or over-the-counter (OTC) for use at

home cannot have electronic IFUs. Additionally, a paper copy of the IFU must be available within 7 calendar days upon request or be accompanied with the device upon delivery. The manufacturer, if they don't ship a paper copy with the device, needs to send the paper copy when requested and this copy needs to reach the requestor within 7 calendar days. If they choose to ship a paper copy with the device, then the preceding requirement is not necessary.

e-Labeling Requirements

In addition to the conditions and criteria described above, there are requirements which must be followed when making IFUs available electronically. Before the IFU is electronically available, manufacturers must have a documented risk assessment covering a number of elements listed in Article 4 of the requirements document. These elements are clearly listed and contain, but are not limited to, items such as user access to electronic resources needed, safeguards to ensure that the electronic information cannot be tampered with, and safety and back-up mechanisms in case of a hardware or software fault. The risk assessment is to be updated as knowledge is gained from experience of the end users. The result of this risk assessment is to show that providing IFUs in an electronic format will maintain or improve the level of safety rather than providing IFUs in paper format.

There can be no misunderstanding regarding how electronic IFUs are to be accessed and used; therefore there must be a printed IFU for the e-label itself. This must be located in their catalogue or other medical device information support. Evidence of verification and validation of the electronic IFU is required as well. Also, information regarding foreseeable medical emergency situations must be printed on a leaflet or displayed on the device along with instructions on how to start the device for devices with a built-in system which visually displays the IFU. Regarding these devices which have a built-in system, the manufacturer must ensure that displaying the IFU on this system does not affect the safe use of the device.

Regardless of how the e-labeling is provided, either with the device on electronic storage such as a CD or DVD or built-into the device visually displaying the e-IFU, the e-label must also be available through a website. The website itself must comply with the following requirements when containing an e-IFU:

- The website must provide the e-IFU in a commonly used format that can be read with freely available software (i.e. pdf);
- The website will be protected against both hardware and software intrusion;
- Downtime and display errors of the website will be reduced as much as possible;
- The website will mention the EU languages which the manufacturer provides the e-IFU;
- The website will fulfill the requirements of Directive 95/45/EC (Protection of individuals with regard to the processing and free movement of personal data);
- The internet address of the website will be displayed as required within the information the manufacturer provides regarding how to access the e-IFU and will be directly accessible for at least 2 years after the expiration date (for devices with a defined expiration date) and for 15 years after the last device has been manufactured (for devices without a defined expiration date); and
- All previous versions of the e-IFU with their date of their publication will also be available on the website.

Regarding the requirement to be fully compliant with Directive 95/45/EC, this applies to potential personal data exchanged between a manufacturer and a doctor. Additionally there is an e-Privacy directive effective May 2011 which references cookie acceptance rules and Directive 2009/136/EC which requires manufacturers to have a mandatory method to handle the notification of

personal data breaches. Directive 2009/136/EC provides guidance on when notification of a personal data breach to an individual is required.

Some Final Thoughts

There are many items to consider when making your labeling available in electronic format rather than just providing hard copy. If you choose to provide your IFU in electronic format, you must have a procedure in place to send a paper copy of the IFU when requested. As you can see from the brief summary, e-labeling is restricted to only the IFU for certain types of end users in certain types of professional situations. The e-labeling requirement is not self contained, meaning that there are other requirements and directives which must be adhered to in addition to the requirements which apply directly to labeling in an electronic format. The key to achieving this compliance is organization of all the information securely in the multiple formats and multiple locations.

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