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Medical Devices: Latest News Regarding Electronic Instructions for Use

EU Regulatory Committee on Medical Devices approves regulation on e-instructions for use of medical devices

On 26 September 2011, the EU Regulatory Committee on Medical Devices has approved the draft Regulation on electronic instructions for use (IFUs) of medical devices. Electronic IFUs (or e-labels) have the potential to not only improve patient safety and reduce the medical technology industry's environmental impact, but also to ensure that the correct IFUs are available at the right time in the right place, while facilitating their storage. Integrating animation, one of the many features of e-labels, considerably reduces the risk of misinterpretation of the instructions and facilitates translation into the different EU languages. Moreover, storing, controlling and distributing e-instructions is easier than with traditional paper instructions. Additionally, they allow for reduced packaging, fitted around the device itself rather than around a paper manual which can be several times larger than the actual device.

To avoid any differing interpretation once the Regulation comes into effect, the Commission should develop further guidance which puts the responsibility for deciding in which languages the electronic IFUs will be made available in the hands of manufacturers, based on their business strategy.

However, here are the main points of the draft regulation:

The regulation sets out conditions according to which instructions for use (IFU) may be provided in electronic form instead of paper form for professional users only. Although the definition of "instructions for use in electronic form" is IFUs that are either displayed in electronic form by the device, contained in a portable electronic storage media supplied with the device, or available through a Website, the draft regulation requests that IFUs should also be available through a Website.

IFUs have to be provided in paper form on request, and a specific risk assessment by the manufacturer and information on how to gain access to the IFUs are needed. This risk assessment should show that it maintains or improves the level of safety obtained by providing the IFUs in paper form, and should be updated in view of the experience gained in the post-marketing phase.

Except for Class I medical devices, as defined in Annex IX to Directive 93/42/EEC, the fulfillment of the requirements in the regulation should be reviewed by a notified body during its audit based on a specific sampling method.

The other main points of the draft regulation include the following:

• In their catalogs or other appropriate device information support documents, medical device manufacturers shall provide information on software and hardware requirements needed to display the IFUs;

• Manufacturers shall have a system in place to indicate clearly when the IFUs have been revised and inform users of the device if the revision was necessary for safety reasons;

• For devices with a defined expiration date, manufacturers shall keep the IFUs available for users in electronic form for at least two years after the expiration date;

• For devices without a defined expiration date and for implantable devices, manufacturers shall keep the IFUs available for users in electronic form for fifteen years after the last device has been manufactured;

• Manufacturers shall clearly indicate on the packaging for each unit or on the sales packaging how to access the IFUs in electronic form, and inform users that they may request and obtain at no additional cost the IFUs in paper form at anytime;

• The information on how to access the IFUs in electronic form shall contain the following: any information needed to view the IFUs; a unique reference giving direct access and any other information needed by users to identify and access the appropriate IFUs; relevant manufacturer contact details; where, how, and within which timeframe IFUs in paper form can be obtained.

• Information via video or audio files may be offered in addition to the text.

Next steps :

The regulation will now be submitted to the Council and European Parliament who will have 3 months to exercise their right of scrutiny and evaluate whether the European Commission has exceeded its powers with this proposed Regulation. Final publication and entry into force is expected at the beginning of 2012.

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