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Device Directive Revisions - It is time to revise your labels and IFUs

In our previous edition, we published a comprehensive glossary of revisions to Medical Device Directive 93/42/EEC and Active Implantable Medical Device Directive 90/385/EEC. In this issue, we focus on changes which may affect your currents labels and Instructions for Use (IFU). Knowing the delay for translation and printing, it is time to prepare your mandatory revisions which will become law on 21 March 2010.

Before this date, manufacturers are not obliged to comply with the new requirements introduced by Directive 2007/47/EC. But they may do so on a voluntary basis and may even have an interest to anticipate compliance with the new legislation for avoiding for example too much inventory of non compliant finished products. In the absence of transitional provisions, medical devices placed on the market or put into service after 21 March 2010 must be in conformity with the (new) requirements of the revised directives. It means that if your devices are still on inventory at the manufacturing site, they could not be shipped anymore into the European Union. All devices which have already reached your European distributors, so already "placed on the market", can be sold to hospitals/users after March 2010.
So in case of over-inventory of "future" non compliant devices, the advice is to agree with your European distributors for shipping them the maximum units in February 2010.

The two main subjects for change in the label/IFU concern the information to be given for single-use devices and products containing Phthalates.

IFU and Single-Use devices

Such as written in the previous issue of *Consultants Corner* newsletter, if the device bears an indication that it is for single use, information about the known characteristics and technical factors that could pose a risk if the device were to be re-used must be added to the instructions for use by the manufacturer. For Class I and Class IIa devices, which do not require instructions for use, the information must be made available to the user upon request.

We suggest you to add in your IFU one or more of the main reasons why your medical device is for single use or single patient use such as:

- materials used in the manufacture of the device may not withstand repeated reprocessing *and/or*
- design of the device may not facilitate cleaning and sterilization *and/or*
- device may not perform as intended by the manufacturer if it is reused

and then to describe the risks associated to the given reason(s): such as: This may lead to:

- potential risks of cross infection/contamination associated with using inadequately cleaned and sterilized devices *and/or*
- failure of the device to perform as intended *and/or*
- material degradation *and/or*
- biocompatibility issues *and/or*
- endotoxic reactions caused by the residues from reprocessing

We suggest you also adding a section in your risk analysis where the solution to mitigate these risks is the single use symbol on the product label and information in the IFU.

Phthalates

The Directive's Essential Requirements (Annex 1) section 7.5. request that medical devices containing certain phthalates and intended to administer and/or remove medicines, body fluids or other substances to or from the body or devices intended for transport and storage of such body fluids or substances shall be labelled appropriately.

The European Commission has mandated CEN to produce a standard (prEN 15986) that specifies the technical requirements and a suitable specific label. While awaiting the development of this standard, we give you some recommendations concerning the IFU and the Phthalate symbols to be used on the label.

IFU:
When the above described devices may be used with children, pregnant or nursing mothers, the IFU shall give information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.
Even if the medical devices are excluded from the last EC regulation N°1272/2008 on classification, labeling and packaging of substances and mixtures, it is interesting to consult it for obtaining some information which can be used in your IFU. For example, the Phthalate BBP (benzyl butyl phthalate) is classified as:
- Toxic for reproduction, Category 2 "R61" . The associated phrase to "R61" is: "May cause harm to the unborn child"
- and Toxic for reproduction category.3 "R62" meaning "Possible risk of impaired fertility"

A translation of these chemical risk & safety phrases can found in 23 European languages at:
http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_363/l_36320061220en02410343.pdf
or http://schoolscout24.de/cgi-bin/rsp/rspoutput.cgi

SYMBOL:
A symbol for should be placed on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging.

Eucomed, the European association of medical devices manufacturers have put last month a recommendation that the symbols set out below be used. However, the final standard might be different to what is advised in this document. Until the relevant EN standard is published and harmonized the symbol would require explanation in the instructions for use.

The symbol and qualifier proposed consists of the generic "contains PHT" symbol accompanied by the name of the phthalate classified as CMR 1 or 2, as a qualifier. The position of the name of this phthalate shall be located adjacent to the generic symbol. These examples are illustrative only and do not represent the only ways in which the requirements of the future standard can be met.

Symbol for "CONTAINS or PRESENCE of PHTHALATES": Bis(2-ethylhexyl)phthalate (DEHP)

The presence of this symbol indicates that the material used for the manufacture of this specific medical device contains “DEHP”

Symbol for "CONTAINS or PRESENCE of PHTHALATES”: Dibutyl phthalate (DBP)

or


The presence of this symbol indicates that the material used for the manufacture of this specific type of medical device contains “DBP”.

Symbol for "CONTAINS or PRESENCE of PHTHALATES”: benzyl butyl phthalate (BBP)

or


The presence of this symbol indicates that the material used for the manufacture of this specific type of medical device contains “BBP”

Symbol for “CONTAINS or PRESENCE of PHTHALATES”: Bis(2-ethylhexyl)phthalate (DEHP), Dibutyl phthalate (DBP) and benzyl butyl phthalate (BBP)

The presence of this symbol indicates that the material used for the manufacture of this specific type of medical device, contains several phthalates mentioned with the symbol (DEHP, and/or DBP and/or BBP)

The final standard might be different to what is advised in this document and therefore, MediMark Europe cannot guarantee the accuracy, adequacy or completeness of any information contained in this document, and cannot be held responsible for any errors or omissions, or for the results obtained from the use thereof.

We remind you also that date of issue or the latest revision shall appear in the instructions for use. !

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