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Addressing European Environmental Legislation

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Medical device companies need to meet European requirements designed to protect the environment. The deadlines for some of the requirements have already passed. This article discusses a European Regulation and two Directives, and a means for meeting environmental requirements in an effective manner.

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Increasing array of environmental legislation

European environmental legislation that applies to medical device companies has increased dramatically during the past five years. European Directives and, in some cases, regulations, have been adopted on packaging, electronic waste, hazardous substances, chemicals and other areas that may apply to medical device companies.

The deadlines for complying with certain requirements have already passed. In other cases, national requirements have not been implemented and it is unclear when full implementation will occur. In addition, environmental legislation often excludes some types of products. For these reasons, medical device companies manufacturing or marketing in Europe should be aware of the environmental requirements that apply to their operations and products, and take all necessary actions to ensure compliance. This means that adequate resources need to be dedicated to this activity.

REACH requirements

The Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and restriction of Chemicals (REACH)[1] was adopted on 18 December 2006. The Regulation is binding in its entirety and directly applicable in all Member States. It establishes a framework to control chemicals placed on the European Union (EU) market by specifying requirements for chemical substances, including additives necessary for stability of the substances, impurities resulting from the processes used, and preparations; a preparation is defined as a mixture or solution composed of two or more substances. The Regulation covers the manufacture, placing on the market or use of chemical substances on their own, in preparations or in articles, and to the placing on the market of preparations. It applies to manufacturers, importers and downstream users. A medical device manufacturer who uses substances subject to the REACH Regulation in the course of his/her industrial or professional activities is considered a downstream user.

The Regulation also sets up a new European Chemicals Agency (ECHA), located in Helsinki, Finland, to manage the registration, evaluation, authorisation and restriction processes for chemical substances to ensure consistency across the EU. The Agency was formally inaugurated in June 2008. Its website (http://echa.europa.eu/home_en.asp) contains a significant amount of information on REACH requirements, including links to the legislation, templates that can be used within the context of REACH, guidance documents and "Navigator," which is a tool designed to assist industry in determining its obligations under REACH.

REACH is of primary concern to chemical manufacturers, →

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who need to ensure that the substances they produce that are covered by REACH are properly registered. Medical device companies using these substances in their products, amongst other responsibilities, will need to know whether or not this has been done. In this regard, if manufacturers or importers of chemicals wish to continue manufacturing or importing these chemicals without interruption, they should have preregistered with the ECHA by 1 December 2008. According to the ECHA, it is estimated that more than 180 000 preregistration files will be submitted in total. After this date, chemicals may only be placed on the EU market after submission of a file, which must include full safety data and test results. If this has not been done and if a full registration file is not submitted in 2009, the chemical substance could face removal from the market.

It is critical that medical device company managers understand the basic requirements of the REACH regulation, identify the substances that are subject to the regulation, identify the substances that need to be registered and ensure that suppliers have registered these substances. In addition, any manufacturer, importer, or where relevant, downstream user may appoint a third party representative for all proceedings under Article 11, Article 19, Title III and Article 53 to undertake discussions with other manufacturers, importers, or where relevant, downstream users. It should be noted, however, full responsibility for complying with the obligations under the Regulation remains with the manufacturer, importer or downstream user.

WEEE Directive

Directive 2002/96/EC of 27 January 2003 on waste electrical and electronic equipment (WEEE)[2] was adopted to limit the amount of waste from electrical and electronic equipment, including waste from electromedical devices, destined for landfill after the item has reached the end of its useful life. The WEEE Directive requires that producers and importers of electrical and electronic equipment register with the relevant national authorities and advise those authorities of the weight of products they place on the EU market.

The Directive also requires that producers mark their products with a symbol to discourage end users from disposing of them in general waste. The mark indicates that the equipment has been put on the market after 13 August 2005. Readers should refer to EN 50419:2005, Marking of Electrical and Electronic Equipment in Accordance with Article 11(2) of Directive 2002/96/EC (WEEE), which specifies the symbol that is to be used, which is a crossed out "wheelie bin" with a black horizontal bar beneath it.

Manufacturers must also make available advice on how to dismantle and dispose of the equipment in the least hazardous and most environmentally friendly way. In addition, producers and importers are also financially responsible for the recovery and environmentally sound disposal of their products at end of life, usually by means of national collection schemes.

Each Member State must transpose Directive 2002/96/EC into its own national laws and regulations. For this reason, medical device producers and importers must identify the regulations that apply to them in a particular Member State. For example, the Italian Law Decree (Decreto Legislativo) of July 2005, No. 151, which became effective on 13 August 2005, transposes the WEEE Directive into Italian law. Because the means to ensure full compliance was not initially in place, another Law Decree was issued on 31 July 2007 announcing that full implementation of Law Decree No. 151 would become effective on 31 July 2007. The Law Decree, which is only in the Italian language, is available from www.parlamento.it/leggi/deleghe/07151dl.htm. The Italian Ministry of Environment will be responsible for managing registration. Only manufacturers, importers, distributors and representatives located in Italy can register. For this reason, medical device companies located outside Italy that market products in Italy need to ensure that the relevant party understands and fulfills the obligations of the Law Decree. The need to identify national requirements regarding compliance with the WEEE Directive applies to each Member State where products subject to this Directive are marketed.

Medical device companies should also establish any needed data collection procedures, identify a suitable waste collection scheme and meet the requirements for equipment disassembly instructions.

Hazardous substances

Electrical and Electronic Equipment (EEE) can contain a variety of hazardous materials that will ultimately be released into the environment through disposal in landfills. Directive 2002/95/EC of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment[3] requires the substitution of various heavy metals (lead, mercury, cadmium and hexavalent chromium) and brominated flame retardants (polybrominated biphenyls or polybrominated diphenyl ethers) in new electrical and electronic equipment placed on the market from 1 July 2006. This Directive is also known as the Restriction of Hazardous Substances (RoHS) Directive.

The RoHS Directive has meant that manufacturers of EEE have had to seek alternatives to many types of materials used in EEE, including the traditional lead/tin solder for making electrical connections and those used in flow-soldering machines for printed circuit boards. Manufacturers of EEE have in some cases had to completely re-equip assembly lines and repair workshops to comply. This has also resulted in electronic components

designed for use with lead solder being made obsolete and forced medical device manufacturers to use lead-free components earlier than required by law.

Although medical devices were specifically excluded from the scope of RoHS when it was first published, their inclusion from approximately 2012 is likely in the next revision of the Directive, a draft of which is due to be published soon.

ISO 14001: An effective compliance tool

A discussion of all the current and evolving environmentally related European requirements and standards that could affect the operations of medical device companies is beyond the scope of this article. For example, there is a new collateral standard, EN 60601-1-9:2008, Medical Electrical Equipment, Part 1-9: General Requirements for Basic Safety and Essential Performance, Collateral Standard: Requirements for Environmentally Conscious Design. This describes the steps that manufacturers should take at the design stage to minimise the environmental impact of their devices. In addition, many readers will be familiar with the Packaging and Packaging Waste Directive (94/62/EC), which mandates that producers and importers who place packaged products on the EU market must ensure that the amount of packaging is the minimum necessary and does not contain any specified hazardous substances.

With the increasing environmental legislation, maintaining compliance is becoming more challenging and problematic. Many medical device companies have not yet developed a coherent strategy for identifying and meeting the requirements. Regulatory personnel understand and are comfortable with the regulatory issues related to demonstrating device performance and safety claims, but environmental requirements can be daunting and outside their area of knowledge and expertise.

An ISO 14001[4] environmental management system (EMS) can provide assurances of compliance with environmental legislation. Although ISO 14001 is not currently being used as a regulatory tool, having an ISO 14001-compliant EMS can lead to operating cost reductions by providing better management of resources and reductions in waste. In addition, ISO 14001 is based on principles that are similar to medical device quality system principles and can be successfully incorporated in existing quality systems.

Lastly, purchasers are becoming much more environmentally aware and are assessing companies for their environmental activities. Having a positive environmental image is therefore a distinct competitive advantage. For example, larger purchasers are sometimes now demanding evidence of environmental responsibility, which is especially true in the area of public procurement. Operating under a certified EMS means that evidence of any environmentally related actions are readily available. Prudent companies will also recognise that an increased emphasis on corporate social responsibility is inevitable and ISO 14001 plays a fundamental role in demonstrating this.

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