Environmental Legislation in the EU – What Medical Device Manufacturers Need to Know

Andrew Vaughan explains the current requirements and looks at how they might change.

The European Commission has since the 1970s been firmly committed to the environment and sustainability, operating at both member state level and internationally. One of the primary objectives of the European Union's current environmental action programme – the European Sixth Environmental Action Programme, which was adopted in July 2002 and which sets out priorities until the year 2010 – is to harmonise environmental policy cross-nationally among the region's member states.

The commission adopted the 2003 Integrated Product Policy to limit products' environmental impacts

In June 2003, the commission adopted its Integrated Product Policy, which covers all products and services and is aimed at limiting the environmental impacts of these in the EU. The IPP strategy calls for the involvement of all parties concerned at all possible levels of action throughout the life-cycle of the product, requiring that manufacturers embrace eco-design, so as to ensure products on the market are more environmentally sustainable. Distributors are encouraged to stock such products and to inform customers of their availability and the benefits of their use. The IPP strategy concentrates on the three decision-making stages of placing a new product on the market that affect the environmental consequences of a product's life cycle. These are:

- the eco-design of products, so that life cycle impacts are minimised;
- the application of the "polluter pays principle" in deciding product price; and
- ensuring consumers are making informed choices based on environmental data.

A number of financial mechanisms are likely to be introduced in the future to help achieve the IPP objectives, such as giving preferential tax rates to products meeting certain environmental criteria.

The policy has led to number of directives and regulations that affect device manufacturers

A number of environmentally related directives and regulations exist as a direct result of this policy, many of which already have, or will in future have, a direct impact on medical device manufacturers and distributors. This article considers the significance of these.

The Packaging and Packaging Waste Directive

The Packaging and Packaging Waste Directive (Directive 94/62/EC[1,2]) resulted from a concern by the EU regarding the amount of packaging ending up in landfill. This was considered to be not only wasteful in terms of the demands on precious space in landfill sites, but represented a waste of resources that could and should be recovered and reused/recycled. The objective of the P&PWD was, therefore, to limit the amount of packaging used to that which is absolutely necessary, encourage the use of environmentally sustainable materials and recover used packaging for reuse or recycling.

The directive is almost 15 years old, and, while many manufacturers and importers, including those involved in medical device manufacture and distribution, understand the "packaging waste" part of the directive well, there is evidence that conformance with the essential requirements of the "packaging" part of the directive is still patchy.

The polluter pays principle is at the heart of the directive on packaging and packaging waste

The polluter pays principle is at the heart of this directive and it achieves its objectives by having two parts: packaging construction and packaging recovery.

Packaging construction

All packaging placed on the EU market must meet the essential requirements of Annex II to the P&PWD. The essential requirements stipulate that packaging used to surround products is the minimum necessary to achieve the desired purpose, will not contain more than very limited amounts of specified hazardous substances, and is made from materials that are recoverable and recyclable. "Composite" materials (ie two or more materials combined, so they cannot be disassembled by hand) are discouraged. There are a number of harmonised standards that can be used by manufacturers to aid compliance with the P&PWD essential requirements (see Table 1). Complying with the standards gives a presumption of conformity with the essential requirements of the directive.

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There are a series of harmonised standards to aid compliance with the P&PWD

Table 1. EU harmonised standards that can be used by manufacturers to aid compliance with the essential requirements of the Packaging and Packaging Waste Directive (Directive 94/62/EC)

Standard No	Title
EN 13427:2004	Packaging – Requirements for the use of European Standards in the field of packaging and packaging waste
EN 13428:2004	Packaging – Requirements specific to manufacturing and composition – Prevention by source reduction
EN 13429:2004	Packaging – Reuse
EN 13430:2004	Packaging – Requirements for packaging recoverable by material recycling
EN 13431:2004	Packaging – Requirements for packaging recoverable in the form of energy recovery, including specification of minimum inferior calorific value
EN 13432:2000	Packaging – Requirements for packaging recoverable through composting and biodegradation – Test scheme and evaluation criteria for the final acceptance of packaging

Packaging recovery

As well as ensuring that packaging is the minimum for a particular product and is recoverable, organisations placing packaging on the market are expected to fund the recovery of that packaging (usually through compliance schemes) after it has fulfilled its purpose. To this end, manufacturers and importers of all products, including medical devices, placing packaging on the EU market (ie surrounding their products) are expected to keep a record of the amount of packaging they place on the market by material type, and by their position in the supply chain. The materials to be recorded are paper (including cardboard), plastic, metal (eg steel and aluminium), wood, glass and "other" (eg textiles). National transpositions may differ in how the requirements are met, and these may include thresholds below which individual organisations may not have to report data.

The Restriction on Hazardous Substances Directive

The RoHS Directive aims to eliminate specified substances from electrical and electronic equipment

The objective of the directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive; Directive 2002/95/EC[3,4]) is to eliminate specified hazardous substances from electrical and electronic equipment, so they are not released into the environment during the product's life, and especially at end of life should the product be disposed of in landfill.

The directive bans six substances: lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyls (PBB), and polybrominated diphenyl ethers (PBDE). The scope of products covered is taken from the Waste Electrical and Electronic Equipment (WEEE) Directive[5] (see below), covering electrical and electronic equipment listed in Annex 1A to the WEEE Directive. WEEE Annex 1B provides a non-exhaustive list of examples. The various products covered by the RoHS Directive are arranged into ten categories, from large household appliances to vending machines. Medical devices (Category 8, except those that are implanted or are "infected") as well as monitoring and control equipment (Category 9) are, at the moment, specifically exempted.

Probably the most significant change resulting from the RoHS Directive is the enforced move away from lead-based solder in electrical and electronic equipment. Because manufacturers of other types of products have already had to seek alternatives, many medical device manufacturers have found that they have been forced to follow suit, as "leaded" components become obsolete.

Manufacturers subject to the RoHS Directive are expected to exercise due diligence in obtaining confirmation that none of the components incorporated into their products contains any of the banned substances in excess of defined thresholds. They must be able to access this documentation in order to demonstrate compliance should it become necessary. RoHS-banned substances may be used in certain specific applications, however, and these are set out in the annex to the directive. The annex is updated from time to time and so care should be taken to ensure that any previous exemptions are still current.

Medical devices will probably become subject to the RoHS Directive from 2014

The RoHS Directive is currently under review[6] and indications are that there will be a substantial number of changes, the most significant of which is likely to be that the scope of the directive will no longer reference the WEEE Directive. In addition, medical devices are most probably destined to become subject to the RoHS Directive from 2014, and *in vitro* diagnostic devices from 2016. Active implantable medical devices will probably remain outside the scope of

RoHS until at least 2020. RoHS may well also become a "CE marking" directive, which will require a conformity assessment process, with the possible involvement of a notified body.

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It is likely that device manufacturers will be able to integrate the RoHS conformity assessment procedures with those for medical devices. However, details are still sketchy and a lot may depend on national transpositions.

It is also proposed that there will be an automatic expiration of any exemptions after four years; it will, therefore, be incumbent on manufacturers to ensure, should they wish exemptions to continue, that applications are submitted and justified well ahead of time.

The list of banned substances may also be moved from the directive's articles to an annex. This would simplify future amendment, so substances could be added (and in theory removed) without the need to amend the directive by going through the full political process.

Exact details of the RoHS revision should become clearer towards the middle of 2009.

WEEE Directive

Medical devices are not exempt from the WEEE Directive

The WEEE Directive is responsible for ensuring that any electrical and electronic equipment (EEE) placed on the market is recovered at the end of life in an environmentally responsible way. Although medical devices are currently exempt from the scope of the RoHS Directive, they are not exempt from the WEEE Directive. Producers are responsible for recording the weight of EEE they place on the market, by official category, and reporting this to the relevant national authorities. Producers are then, in principle, responsible for financing the recovery and environmentally responsible disposal of the EEE they place on the market. However, in the case of "business to business" (B2B) transactions, the financing of end of life EEE can be decided by a contractual arrangement between the parties.

Figure 1. Crossed out wheeled bin in accordance with EN 50419

The WEEE Directive also has two parts. The first requires EEE to be labelled to indicate that it should not be disposed of in domestic waste streams, and the second requires manufacturers to make available disassembly instructions, so that at end of life, recyclable components and materials can be identified and recovered safely. Figure 1 shows the symbol of a crossed out wheeled bin that is to be placed on all EEE marketed in Europe, according to European Standard EN 50419[7]. The bar underneath the pictogram indicates that the product was placed on the market after 13 August 2005 and that the manufacturer is financially responsible for product recovery at the end of its life.

Changes such as a target for the recovery rate of old devices have been proposed

The WEEE Directive is also being reviewed at present and a proposal from the European Commission was published in December 2008[8]. A number of changes are proposed, including the introduction of a target for the recovery rate of medical devices, and transfer of the directive's scope to the RoHS Directive. There may also be requirements to be fulfilled in order to be able to ship used EEE outside the EU and not have it classified as "waste". This is because the EU is becoming very concerned about old devices finding their way to developing nations under the classification of "second use", whereas in fact they are just being sent as waste for dismantling/disposal with inappropriate processes, which can have severe risks to the environment and those undertaking the recovery work.

As there is a significant market for the "second use" of medical devices in developing countries, manufacturers and importers who send devices to second markets outside of the EU should be aware of these potential new restrictions, as it will make sending medical devices to second markets more onerous.

Energy-using Products Directive (EuP)

Directive 2005/32/EC[9], which establishes a framework for the setting of eco-design requirements for energy-using products, is the first eco-design directive, and its intention is to reduce the environmental impact of electrical and electronic products placed on the market. The directive itself – known as the EuP Directive – calls upon a number of "implementing measures" that are sector specific, and these will contain the criteria that have to be met for each type of product. Although a number of market sectors have been selected for analysis to date, at the time of writing only one implementing measure had been published, and that relates to the "stand-by" and "off" modes for devices used in the home[10]. Although the directive is aimed at energy-using products, it is not only the energy consumption aspect of the product that can be targeted by implementing measures, as any environmental aspect of a product can be addressed.

Medical devices are not mentioned in the first wave of implementing measures planned, although some medical device applications have been mooted as candidates for analysis at some

point in the future. At least one medical device sector is proposing a voluntary agreement to reduce the environmental impacts of their products outside of the EuP Directive.

IEC 60601-1-9 requires that manufacturers assess their proposed products' environmental impact

The International Electrotechnical Commission has already taken a step in this direction by the publication of international standard IEC 60601-1-9[11], which is one of the collateral standards in the series for electrical medical equipment. This standard is aimed at conserving raw materials and energy, minimising the generation of waste and protecting human health and the environment. The standard requires that a manufacturer assesses the environmental impact of the proposed medical device across all life cycle phases and minimises those impacts where practicable. The manufacturer must also advise the user on how to use the device in the most environmentally sensitive way.

Batteries Directive

The Batteries Directive (Directive 2006/66[12]) is primarily of concern to battery manufacturers, but does include provisions that impact those who incorporate batteries into their products. The Batteries Directive restricts the materials that can be used for batteries (apart from for certain applications) and requires that batteries should be removed from equipment at end of life, preferably by the user, although it is accepted that in certain circumstances removal by a treatment centre may be more appropriate. There is an exemption from the removal requirement "where, for safety, performance, medical or data integrity reasons, continuity of power supply is necessary and requires a permanent connection between the appliance and the battery".

There is an issue with the removal of batteries that power single-use devices

There is an issue with the removal of batteries that power single-use medical devices where such devices may become infected during use. This is because it is clearly undesirable for health and safety reasons to dismantle an infected device to retrieve the battery, and because the device is designed as "single use", reprocessing to remove contamination may not be a viable option. At the time of writing, this issue was under discussion with the national authorities.

Medical device manufacturers who incorporate batteries into their products may also have to register as "producers" under the Batteries Directive, keep records of batteries they place on the market in their products, and be responsible for financing the recovery of the batteries they supply, but this will become clearer with the publication of guidance.

REACH Regulation

There have been increasing levels of concern in recent years about the number of chemicals in use in the EU. Although the exact number of chemicals used is unknown, it certainly runs to tens of thousands, and the effects of those chemicals on human health and the environment are, with few exceptions, not fully understood. The purpose of the REACH regulation[13] is to develop an increased understanding of the hazards associated with chemicals, and to control their use where necessary. Because REACH is a regulation as opposed to a directive, it is effective in all member states without the need for it to be transposed into national legislation.

The REACH regulation is, by any standards, a substantial piece of legislation, and although it will be of concern primarily to EU manufacturers and importers of chemicals, it can impact anyone in the supply chain, especially if chemicals or substances are supplied on, or used in manufacturing/service processes in a novel way. All in the supply chain need to be aware of the regulation's requirements. The passage of information up and down the supply chain is a key feature of REACH, and downstream users of chemicals will be obliged to follow any instructions provided to them in Safety Data Sheets as these SDSs will detail how to manage risks posed by the chemicals. One important exemption, however, is pharmaceuticals, which are not subject to these REACH requirements.

REACH requires that all chemicals be pre-registered and registered with the ECHA

The regulation requires that all chemicals need to be registered with the European Chemicals Agency[14], based in Finland, and this was to be achieved in two stages. The first stage was pre-registration, which simply involved a notification to the ECHA that a chemical was in use within the EU. Pre-registration meant that the chemical could continue to be used within the EU. Downstream users of chemicals should ensure with their suppliers that chemicals they use or supply on have been pre-registered with the ECHA. The period for pre-registration expired on 1 December 2008 and since this date the second stage has come into effect.

The second stage requires that all chemicals intended for use within the EU undergo a formal assessment to determine their impacts on human health and the environment. Since 1 December 2008, chemicals that have not been pre-registered cannot be used until they have undergone formal assessment. Pre-registered chemicals will also have to undergo assessment eventually, although this will happen progressively over a number of years, depending on the amount of substance being used and the substance's "level of concern", starting with chemicals designated as "Substances of Very High Concern". A list of SVHC chemicals has been published by the ECHA[15], and various regulatory requirements already apply to these chemicals. SVHCs may need to be

authorised for specific uses. It is worth noting here that DEHP, often used as a softener for plastics used in medical devices, is classed as an SVHC, and is also the subject of a labelling requirement under the latest amendment to the Medical Devices Directive (via Directive 2007/47/EC[16]).

DEHP, used as a softener for plastics in medical devices, is classed as a substance of very high concern

All companies in the supply chain, including medical device manufacturers, should have a documented inventory of the chemicals/substances they are holding/supplying, and have a clear understanding of their responsibilities with regard to the regulatory requirements.

The European Commission has adopted a new proposal for a regulation on the Classification, Labelling and Packaging of Substances and Mixtures[17], which will, after a transitional period, replace certain requirements of the current directives related to the classification, packaging and labelling of dangerous substances[18] and preparations[19].

The new proposal incorporates the classification criteria and labelling rules agreed at UN level, known as the Globally Harmonised System of Classification and Labelling of Chemicals (GHS). It will introduce new classification criteria, hazard symbols and labelling phrases, while taking account of elements that are part of the current EU legislation.

Green Public Procurement

The EU has recognised that public procurement can play a very powerful part in the market, and is therefore keen to use the purchasing power of public bodies to influence manufacturers and importers in supplying "green" products. Since many medical devices are purchased by public bodies in the EU, this is likely to be of significant importance over the next few years. The European Commission is preparing a "toolkit" for public purchasers of products, including medical devices, to assist the setting of environmental criteria for purchased products.

The EU is keen use public bodies' purchasing power to influence the supply of green products

Waste

The EU is becoming increasingly concerned about the two billion tonnes of waste produced within its boundaries each year, especially as this amount is continuing to increase. There will, therefore, be an increased emphasis on waste prevention in the future. Producer responsibility is already a key component of waste legislation, and those who place products on the market will find themselves increasingly responsible for what happens to those products at end of life. Producers, including medical device manufacturers, will, therefore, have to be much more aware of what impacts their products have throughout their life, and especially how they should be handled when they are no longer required.

Environmental Management Systems

The amount of environmental legislation in Europe is set to increase, and the legislation already in place can be expected to become increasingly stringent. The main issue for manufacturers is how to manage this increase and ensure compliance is maintained, both for themselves and their products. Environmental Management Systems have a role to play here, as they provide a tool to monitor legislation and keep manufacturers/producers compliant. The best known EMS is the ISO 14001 standard[20], which follows a similar methodology to ISO 9001 (quality management) and ISO 13485 (quality management systems specifically for medical device manufacturers). All these standards can be successfully combined into an Integrated Management System, providing an efficient and effective compliance regime. Although ISO 14001 is not used currently as a regulatory tool, there is an increasing school of thought that it may well become so in the future. Having a certified ISO 14001 EMS, therefore, may well confer certain advantages as time passes. In any event, purchasers are starting to request details of potential suppliers' environmental activities and a certified ISO 14001 EMS usually provides the necessary assurances.

Purchasers are starting to request details of potential suppliers' environmental activities

Conclusion

With the current global concerns over climate change and the tangible effects human beings are having on the environment, there is no doubt that the amount of environmental legislation is set to increase still further, and the EU is in the forefront of this movement. Whilst medical devices are currently exempt from certain requirements, these exemptions will not last forever. Medical device manufacturers must, therefore, both inform themselves of the present legislation and monitor what new regulations are on the horizon, to ensure that not only are they playing their part by minimising the environmental impacts of their products, but they are also staying inside the law.

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