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Advena Ltd are active members of the European Association of Authorised Representatives (EAAR) who have representatives on most of the major European policy making committees, including those for device vigilance, clinical trials, emerging technologies, IVD devices and there are contacts with the Global Harmonization Policy Committee for Europe. Appropriate information from these meetings will be reported in these reports.



Client's Regulatory Update – May 2008

1 ENVIRONMENTAL ISSUES

This is a big subject so this is just a VERY BRIEF review. I stress Advena Ltd are not environmental consultants but there are areas that do, or will, effect medical device manufacturers so you should be aware.

1.1 General

You are all reminded about the ISO 14001 Environmental Management Standard that the EU, and Member States, are encouraging manufacturers to adopt as a matter of principle.

The EU have adopted 5 fundamental principle for environmental legislation

- Polluter pays
- Materials or products may be removed from use if there is evidence of harm BEFORE a full investigation.
- Pollution principles and actions are handled by the member state where the pollution, or potential pollution, is.
- Continuous improvement to reduce levels of pollution and waste.
- Producers are responsible for the product at all stages of the lifecycle, i.e. design to disposal.

1.2 Electronic designs

Those of you designing electronic products should become aware of the standard IEC 60601-1-9; Environmentally Conscious Design of Medical Electrical Equipment. (published in 2007). It is known that the large manufacturers of electronic equipment are design against these requirements. Note; this is not "harmonised" yet re the Medical Device Directives but may well become so.

1.3 Packaging and Packaging Waste Directive

This has been implemented to;

- Reduce the amount of waste to landfill.
- Place limits on heavy metal use.
- Minimizes hazardous substances.
- Require packaging to be designed so it can be recovered/recycled.
- Require European companies/importers distributing products in the EU to join a “compliance” scheme that administers the collection and disposal of packaging waste.

1.4 Waste Electrical and Electronic Equipment Directive. (WEEE)

The objective is to recover end of use electrical equipment and remove potentially harmful components before disposal.

- Wheely bin symbol needed on label.
- European companies/importers distributing products in the EU must join a “compliance” scheme that administers the collection and disposal of waste electronic equipment.
- Information has to be available to users on how to remove harmful items at end of use.

1.5 RoHS

Implemented for the reduction of lead, cadmium, mercury, hexavalent chromium and two types of brominated flame retardants, in products.

- It has been confirmed that Medical Devices are exempt at the moment
- It should be noted that China has a similar regulation now in force.

1.6 Energy using products directive.

This is only a framework directive that will not effect you. It allows the EU to publish regulations for specific product groups. This may effect some parts of medical devices later, i.e. motors, screens/monitors, etc.

1.7 Batteries directive

The EU Batteries Directive will become law in September this year. It will require, amongst other things, certain labeling, require devices to have easily removable batteries, and require suppliers to provide removal instructions. Infected medical devices, and those that require permanent battery connection to assure safety and life support, will be exempt.

1.8 REACH

Covered in last month’s report. Was taken into law in June 2007. Medical devices are not exempt. Responsibility is the manufacturer, or importer if the devices are made outside the EU, and sold within.

1.9 Phthalates

The modifications to the Medical Device Directive requires that if products contain phthalates then it must be noted on the label. The requirement will be fully in force by September 2011.

2 EUROPEAN DIRECTIVES

There has been a notification issued by the EU in Brussels about their desire is to merge all the Medical Device Directives into one law and set up a European Device Agency who will be in charge of registration and inspections etc. The Commission released a public enquiry this month on the 'Recast of the Medical Device Directives' and "complete reform of European regulatory system". Public comments can be made until the end of July. After listening to some of the reactions I would not get too excited about this happening in the next 10 years.

The Cosmetic Directive is to be completely reviewed. (No timing available)

3 TECHNICAL FILES AND THE AUTHORISED REPRESENTATIVE

The Irish Notified body, NSAI, is making observations during audits that Authorised Representatives should hold the full Technical Files on all products being represented by them.

This was discussed by the European Association of Authorised Representatives and it was agreed that members, and the companies they represent, should oppose this move as the Directives state only that technical documentation "must be made available".

4 GERMANY

At a recent trade association meeting we had some interesting revelations about the way some "Landers" in Germany are handling device issues.

To provide some background, Germany comprises of 16 states (*Länder, Bundesländer*), each of which have their own regulations and controls when it comes to medical devices, especially concerning registrations and medical device complaint reporting. Each Lander then has different authority groups working on medical devices, some groups only working in specialist areas i.e. implants. The net result is that Germany has 80 Competent Authorities! Many of these are now starting schemes for inspecting medical device facilities (distributors and manufacturers) in their areas and are drawing random product sample to test (that are used within their jurisdictions) and will ask for the risk management studies on devices sold. Worse still is that some of the Landers are now insisting that the Authorised Representatives are responsible for faulty devices in their markets.

Needless to say, this regulatory nightmare has caused great concerns for consultants and authorised representatives based in Germany.... Conclusion, stick with us, we undertake registrations in the UK and work under the simple UK laws!

5 ITALIAN REGISTRATION

This subject will be fully reviewed by our associate, Maria Donawa, in next month's Medical Device Technology Magazine that I assume most of you receive.

Some companies have managed to get the “smart card” needed but few non Italians have managed a registration.

A complaint has been made to Commission over Italy’s requirements. Italy has stated that by the end of this year, requirements on the web form will appear in both Italian and English. However, any subsequent discussions will need to be in Italian.

Our only recommendation is that you should to leave it up to your Italian distributor at the moment.

6 US and FDA

No specific news to report for client's post-market surveillance procedures.

See: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/cdrhnew.cfm>

7 LABELING AND INSTRUCTIONS FOR USE

There has been some discussion as to whether Competent Authorities, and Notified Bodies, will allow medical device manufacturers to supply the instructions for use on a web site. This has been allowed for sometime for IVDs but sometimes frowned upon for devices.

After a client enquiry we have been told, by a UK Notified Body;

.....I think our position is.... the MHRA are not against this in principle as long as there are adequate safeguards. Hence we need to take this on a case by case basis, regarding internet security, access to manufacturer's name and address and EU rep if applicable and warnings and cautions (risk level of device etc). Also the intended user needs to be considered and their level of expertise. That all being said it is likely that other member states such as Germany would require a hard copy and not accept the web.....

8 UK MHRA REPORT (From the MHRA web site, remember if you are contracted with us to be your Authorised Representative the MHRA is your “Competent Authority”)

No specific news to report for client's post-market surveillance procedures.

See <http://www.mhra.gov.uk/index.htm>

10 CERTIFICATES OF FREE SALE

Whereas these are available in some EU member states for clients of Authorised Representative in that member state (e.g. Italy, Belgium, Switzerland and Ireland) in all the other countries they will only be issued to manufacturing companies who actually have registered offices in that country. Therefore, all we are able to do in the UK, is to have CE certificates notarized. This seems to work for some middle eastern countries who want to buy CE marked devices.

11 CANADA

No specific news to report for client's post-market surveillance procedures.
Web site is; http://www.hc-sc.gc.ca/index_e.html

12 CONFERENCES AND SOURCES OF OTHER INFORMATION

Clients are reminded about the 2008 RAPS conference in Boston in September. (<http://www.raps.org/personifyebusiness/tabid/360/Default.aspx>) . There is a session on the Sunday by our trade association, the European Association of Authorised Representatives, on Authorised Representative and other EU regulatory issues.

There is an excellent handbook available on Medical Device Regulatory Affairs (jointed edited by yours truly) that cover a vast array of subjects in detail and provides regular updates.

This is the "Medical Device Manual" from Euromed Communications, see <http://www.euromed.uk.com/?p=productsMore&iProduct=31>

New, later this year, this manual will provide a supplement on Chinese regulations, this could be of interest to some clients.

13 STANDARDS UP-DATE.

I have a draft test report standard for test methods for compression hosiery, this could be of interest to some clients. It is likely to become a European Standard in the future.

EN 455 is under review, all parts (Medical Gloves)

BS EN Publications	
BS EN 60976:2007	Medical electrical equipment. Medical electron accelerators. Functional performance characteristics. Supersedes BS EN 60976:2001.
British Standards proposed for withdrawal	
BS EN 50103:1996	Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for the active (including active implantable) medical device industry.
British Standards reviewed and confirmed	
BS EN 143:2000	Respiratory protective devices. Particle filters. Requirements, testing, marking.
BS EN 144:-	Respiratory protective devices. Gas cylinder valves.
New work started	
BS EN ISO 10451 (Revision)	Dental implant systems. Contents of technical file. Will supersede BS EN ISO 10451:2002
BS EN 61676:2002/Amendment 1	Medical electrical equipment. Doismetric instruments used for non-invasive measurement of x-ray tube voltage in diagnostic radiology.
Standards out for public comment	
08/30168475 DC	Medical electrical equipment. Part 2-1. Particular requirements for

BS EN 60601-2-1	basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV.
08/30168815 DC BS EN ISO 4049	Dentistry. Polymer-based restorative materials.
08/30168843 DC BS EN ISO 9168	Dentistry. Hose connectors for air driven dental handpieces.
08/30170297 DC	Medical electrical equipment. Requirements for the safety of radiotherapy treatment planning systems.
08/30176484 DC BS EN 455-2	Medical gloves for single use. Part 2. Requirements and testing for physical properties.
08/30179586 DC BS ISO 7199	Cardiovascular implants and artificial organs. Blood-gas exchangers (oxygenators).
BS ISO 15223-2	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 2: Symbol development, selection and validation
IEC Publications	
IEC 60601:-	Medical electrical equipment.
IEC 60601-2-31:2008-05-22(Edition 2)	Particular requirements for basic safety and essential performance of cardiac pacemakers with internal power source.

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