

Editorial

Medical devices: new regulations, new responsibilities

Statutory regulations within the European Community (EC) are now replacing existing voluntary codes of practice, in order to ensure that essential requirements concerning the safety, performance, and marketing of medical devices are met. This is in line with the Consumer Protection Act of 1987 and will have a major bearing in cardiology practice with the growth of invasive and interventional techniques. The object of the new regulations is to help to protect patients and staff by the safe use of equipment which has been designed, tested, and manufactured to set standards. More will be expected of manufacturers who, in return, will benefit from the harmonisation of different systems across the European Union. Once a device has been approved by a Notified Body, a manufacturer can market the device without any further procedures in any of the 12 EC countries as well as the five of the seven European Free Trade Association countries (Switzerland and Liechtenstein excluded). Such approved devices will carry a CE mark. Once the transitional period, which allows voluntary adherence to existing national regulations, is over and the directives are fully implemented, each medical device purchased in each member state within the European Union must carry the CE marking.¹

The directives

There are three directives:

(a) The Active Implantable Medical Devices Directive (AIMDD) came into effect in January 1993 and, after a two year transitional period, became compulsory in January 1995. All devices within this group including pacemakers and implantable defibrillators will have to show a CE marking from 1995.

(b) The Medical Devices Directive (MDD) covers most other medical equipment including bandages, disposables, implants, and imaging equipment. Within each directive there are four categories depending on the level of risk inherent in the use of a device (Class I, IIa, IIb, III). Most cardiac devices will fall into class III and these include disposable diagnostic equipment, interventional tools, implantable devices including stents, umbrella devices, and heart valves. This directive came into effect in January 1995, with a three and a half year transitional period before it becomes compulsory in June 1998.

(c) The In-Vitro Diagnostic Medical Devices Directive incorporates reagents and equipment used in vitro for specimens obtained from the human body. This is unlikely to come into effect before 1997.

Regulatory Authority Responsibilities

COMPETENT AUTHORITY

The regulatory authority in each member state is known as the competent authority. This body acts on behalf of the government of a member state to ensure that the requirements of the directives are carried out in that particular member state. In the United Kingdom, the

competent authority is the Secretary of State acting through the Medical Devices Agency. Responsibilities include enforcing the regulations using the powers of the Consumer Protection Act, handling all submissions for clinical investigations, ensuring that adverse incidents related to devices are reported, undertaking appropriate measures for unsafe devices and, finally, designating Notified Bodies within the United Kingdom to carry out conformity assessment procedures.

NOTIFIED BODIES

These are certified organisations designated by the Competent Authority. The responsibilities include carrying out conformity assessment procedures to ensure that a device complies with essential requirements before a CE marking is applied for. It will also regularly audit relevant manufacturers.

Manufacturers' responsibilities

- Application to the competent authority in each member state (in which a clinical investigation is being carried out) for authorisation to proceed. There is a 60 day limit on this procedure at the end of which, if the manufacturer has not heard to the contrary, the clinical investigation may proceed.

- Reporting to the competent authority all serious device related incidents, including malfunctions or deterioration in the characteristics and performance of a device that may lead to a patient's death or deterioration in health; or any technical or medical reason resulting in the recall of a device from the market or the issue of a manufacturer's advisory note. The competent authority will then investigate and take appropriate action, including modification or withdrawal of the device from the market.

Doctors' responsibilities

- In the event of a serious device-related adverse incident in the United Kingdom, the user should still report to the National Reporting and Investigation Centre, a voluntary system operated by the Medical Devices Agency. With the introduction of the Medical Devices Directives similar reports should also be sent to the manufacturers, who will then be obliged by law to report to the competent authority.

- The CE marking means that the device satisfies the requirements essential for it to be fit for its intended purpose. This will inevitably lead to tighter control over operators customising existing devices or using them for purposes other than those for which they were originally intended.

- In the event of an operator discovering a new use or a modification of a device, this will not get automatic approval by the manufacturer because it will no longer be able to carry the CE marking; moreover, any incidents will have to be reported by law, putting the manufacturer

in a difficult position. Any modifications will be the responsibility of the operator (and/or the Trust he/she works for). Any such modifications will need to be approved not only by the local research ethics committee but also by the manufacturer. Indeed, it may be necessary for the manufacturer to carry out a further clinical investigation to demonstrate the safety and performance of this modification.

● The vigilance system which legally binds the manufacturers to report serious incidents will implicitly put further responsibility on suppliers to make sure that the devices marketed are properly used by appropriately trained operators. With an ever-increasing number of more technically advanced devices in cardiac work, proper training procedures will have to be introduced, as they have been for minimal invasive surgery. When the Rashkind double umbrella device for closure of patent arterial duct was introduced, the manufacturer set up a few training centres and a structure to disseminate experience to newly recruited units. The level of training should be proportional to the skill required as well as to the risks inherent in a particular device. The implications in children, because of their longer life expectancy, are self-evident.²

Three papers in the October 1994 issue of the *British Heart Journal*, relating to the use of the Rashkind device, touch on a number of these points. Gatzoulis *et al* described their experience in catheter closure of patent arterial ducts in children under the age of two years using Boston modification for the delivery system in three out of 29 children.³ With the modified technique, the delivery system can be introduced through a much smaller sheath which, provided the integrity of the device is not compromised, is desirable in small children. The paper by Redington and Rigby, which described the application of a modification to the umbrella in order to close atrial communications is, undoubtedly, an important contribution, particularly in the management of patients who marginally satisfy the classic criteria for a Fontan operation.⁴ When the CE marking comes into force, however, such modifications made to a device should preferably be done after formal evaluation along the lines recommended by the Medical Devices Directives. It will be essential to demonstrate that modifications are still compatible with the essential requirements in safety and performance. It will therefore be necessary to prove (a) the existing design is inadequate; (b) that the alteration will address and rectify any problems; and (c) that modification of the device does not alter the structure or material properties. If the manufacturer accepts the need for modification and agrees with the new design, an appropriate application will need to be made to the local research ethics committee⁵ and through the manufacturer to the competent authority before authorisation for a further clinical investigation is obtained.

Approval by the local research ethics committee does not automatically guarantee permission by the competent authority for clinical investigation to proceed because there may be design, technical, or material reasons for indicating that a clinical investigation is compromising the safety of the patient or user.

The third paper by Rigby and Redington also describes the use of the double umbrella device in a clinical situation other than what it was designed for initially.⁶ It is always advisable to get the approval of the local research ethics committee, particularly for elective procedures where potentially serious problems may arise, as in this instance, because of the proximity of the site of the implantation—that is, the membranous ventricular septum—important to neighbouring structures (in this case the aortic and tricuspid valves and the atrioventricular node). The authors recognise problems with this approach which are largely related to anatomical considerations.

The law

Modification of a device which may result in harm to patients could well make the operator liable under the Consumer Protection Act. This liability was increased from January 1995 for active implantable devices and will apply to other devices from 1998.

Until the CE marking comes into force, manufacturers can import devices without going through stringent controls in design, manufacturing, and marketing. The major manufacturers are registered with the Manufacturers Registration Scheme (MRS), which is a voluntary arrangement, but some small companies may still take the opportunity of this legal loophole to import and sell devices which may not meet the criteria for CE marking in the future. Currently, the National Health Service is advised to buy from manufacturers that are MRS registered.

Historically, medical professionals have had the instinct, initiative, and drive which have led to the very high level of care and treatment now available to the community. In the current market-led health service, the instinct to be innovative to improve patient care, is complicated by pressure to maintain the recognition of, and in some instances, the very existence of one's institution. We have to tread this minefield very carefully to avoid litigation. The tighter controls are intended to increase safety for patients and staff alike and should be welcomed.

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- 1 Ludgate SM, Potter DC. European directives on medical devices. *BMJ* 1993;307:459–60.
- 2 The Ethical Conduct of Research on Children. 1993 Medical Research Council.
- 3 Gatzoulis MA, Rigby ML, Redington AN. Umbrella occlusion of persistent arterial duct in children under two years. *Br Heart J* 1994;72:364–7.
- 4 Redington AN, Rigby ML. Transcatheter closure of interatrial communications with a modified umbrella device. *Br Heart J* 1994;72:372–7.
- 5 Rights and responsibilities of doctors. 1992 BMA Publishing Group.
- 6 Rigby ML, Redington AN. Primary transcatheter umbrella closure of perimembranous ventricular septal defect. *Br Heart J* 1994;72:368–71.