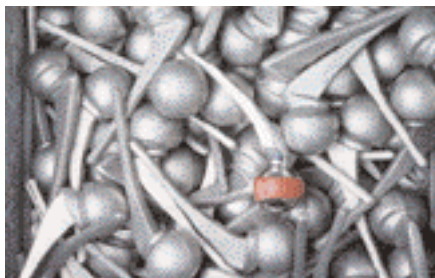


GOVERNMENT AGENCIES

(1) THE STRUCTURE AND FUNCTIONS OF THE MEDICAL DEVICES AGENCY

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Prosthetic hip joints, artificial limbs and wheelchairs are three items in the diverse array of products that are classed as medical devices. In this article, the work of the Medical Devices Agency in controlling their quality and safety is described

What is it that links all of the following commonly used items of medical equipment: artificial eyes, dental material and restoratives, examination gloves, hospital beds, resuscitators, sutures, clips and staples?

Under European Union (EU) legislation that has been transposed into United Kingdom law, they are all classed as “medical devices”, and their quality, safety, and performance is monitored and controlled in the UK by the Medical Devices Agency (MDA). Medical devices in effect cover all products, except medicines, used in health care for the diagnosis, prevention, monitoring, or treatment of illness or handicap. The vast and diverse range of products considered medical devices is listed in Panel 1.

The MDA is tasked with the following: “To take all reasonable steps to protect the public health and safeguard the interest of patients and users by ensuring that medical devices and equipment meet appropriate standards of safety, quality and performance and that they comply with relevant Directives of the European Union.”

The MDA, formerly called the Medical Devices Directorate, became an executive agency of the UK Department of Health in September 1994. Up-to-date information on all aspects of the work of the MDA, its structure, and functions can be found at www.medical-devices.gov.uk.

It has recently been announced by the UK Department of Health that the MDA and the organisation responsible for the regulation of medicinal products, the Medicines Control Agency, will merge to become a single executive agency in April 2003. This will create a single body for both medicines and medical devices, which mirrors the situation in many other European countries and in the United States. One rationale for the creation of the new single entity is that, in the development of new therapeutic products, there is increasing blurring of the distinction

between medical devices and medicinal products. The merged organisation will have a new chairman, and non-executive members will be invited on to the new agency's board. It is to be called the Medicines and healthcare Products Regulatory Agency. Its location has not been announced.

The main functions of the MDA, which are not expected to change within the new organisation, are:

- 1 To investigate adverse incidents associated with medical devices and their use, and help prevent further incidents by communicating findings to those who make and/or use devices
- 1 To provide advice and guidance on performance and safety aspects of medical devices, and their use, to a wide range of customers, stake holders, and beneficiaries of its services (These include device users, their managers and professional bodies, ministers and members of Parliament, the Department of Health and the NHS Executive, and manufacturers.)
- 1 To negotiate EU directives and implement and enforce UK regulations for medical devices
- 1 To contribute to the preparation of non-statutory safety and performance standards for medical devices in support of EU directives and international harmonisation
- 1 To manage an external programme to evaluate medical devices, and provide consultancy advice, which enables device users and purchasers to select equipment suitable for their needs and which contributes to improved equipment design, safety, and performance

- 1 To provide support services for the activities above, including central management, financial and management information, personnel functions and human resource development, and clinical advice

The agency is headed by a chief executive, Dr David Jefferys, appointed by the Secretary of State for Health and accountable through him to Parliament for the day-to-day running of the agency.

The MDA is the oldest organisation of its kind in the world, established as a part of the NHS in 1948. As a result, it has accumulated considerable experience in the standards applicable to medical devices and their evaluation. This gives the MDA a unique international status. However, the agency's function has had to evolve to take account of rapid advances in technology, the development of a world market in device technology and manufacture and the introduction of statutory regulations for the industry.

Until relatively recently, there were no statutory controls on the manufacture of medical devices; such controls as existed were voluntary. As a member of the EU, the UK was one of the first member states to adopt the statutory unified system for Europe. The UK's long experience of controls ensures that the MDA is a leading player among EU regulatory bodies for medical devices. Equally importantly, the MDA has played a key role in developing EU directives for medical devices, whose primary role is to ensure the safety of the patient.

One of the MDA's most important tasks is to ensure that those in health care responsible for buying medical devices have access to an effective quality control and evaluation service. The device evaluation service provides advice on the quality, safety, and performance of medical devices to help purchasers make appropriate choices for their individual needs.

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Panel 1: Examples of products legally considered to be medical devices

Anaesthetic machines and monitors	Diagnostic X-ray equipment	Infusion pumps and controllers	Pressure sore relief devices
Apnoea monitors	Dialysers	Intra-uterine devices	Radiotherapy machines
Artificial limbs	Dressing and wound healing devices	Intravascular catheters and cannulae	Resuscitators
Artificial eyes	Electrosurgery devices	Laboratory equipment covered by IVD directive	Scalpels
Blood transfusion and filtration devices	Endoscopes	Lithotripters	Special support seating
Breast implants	Enteral and parenteral feeding systems	Medical textiles, hosiery and surgical supports	Sphygmomanometers
Cardiac monitors	Equipment for disabled people	Medical lasers	Suction devices
Cardiopulmonary bypass devices	Examination gloves	Operating tables	Surgical instruments and gloves
Clinical thermometers	Fetal monitors	Orthopaedic implants	Sutures, clips and staples
Condoms	Hearing aids and inserts	Ostomy and incontinence appliances	Syringes and needles
Contact lenses and prescribable spectacles	Heart valves	Pacemakers	Ultrasound imagers
CT scanners	Hospital beds	Physiotherapy equipment	Urinary catheters, vaginal speculae and drainage bags
Defibrillators	Hydrocephalus shunt	Prescribable footwear	Ventilators
Dental equipment and dentures	Incontinence pads		Walking aids
	Infant incubators and warmers		Wheelchairs

The primary responsibility of the MDA is to ensure that medical devices achieve their fullest potential to help health care professionals give patients and other users the high standard of care they have a right to expect.

THE ORGANISATION

The MDA is based in offices at the Elephant and Castle in south-east London. Reflecting the diversity of products that are classed as medical devices, there is a wide range of specialities represented among the MDA's 150 staff, who include chemists, engineers, materials scientists, medical and nursing staff, microbiologists, pharmacists, physicists, professionally qualified technologists and toxicologists.

Rapid advances in medical device technology require staff to spend a considerable amount of time keeping up to date. This is facilitated and augmented by the experience and skills of a network of experts in hospitals and universities in the UK and overseas.

The agency's activities are organised into mutually interacting business areas, each with a defined responsibility (Table 2). Each are considered in more detail below.

Clinical (Medical and Nursing) The clinical team is the channel for professional communication with doctors and nurses in the NHS, the Royal Colleges and other professional bodies. It is essential that there is effective and direct two-way communication between the MDA and practising clinical experts who need support, guidance or information on the safe and effective use of medical devices. The team actively contributes to the investigation of adverse incidents, the evaluation of medical devices, the scrutiny of proposals from manufacturers for clinical investigations with medical devices in the UK, and the negotiation and enforcement of EU legislation.

Doctors, nurses, and other users are also given up-to-date information about medical device technology, advising as necessary on

the correct use of the complete range of medical devices, including those used in the community.

There are regulations that govern the carrying out of clinical investigations using medical devices. The MDA has to be notified by the manufacturer 60 days before a device intended for clinical investigation is made available to a medical practitioner. Under the notification procedure, if the MDA does not raise any objections during that time, the clinical investigation can begin. However, objections may be raised if the MDA believes that there might be a risk to the health or safety of patients or users. The MDA aims to ensure that the notification to manufacturers is achieved as quickly as possible, commensurate with the degree of perceived risk of the device. Clinical investigations with non-invasive, non-implantable devices are therefore likely to be approved more quickly than those to be undertaken with active implantable devices.

A meeting is often held between the MDA and the manufacturer before submission of a notification of a clinical investigation. This helps the MDA to understand the device and any related problems and for advice to be given about device safety issues and the data to be received in the notification. The manufacturer must show that all aspects of the essential requirements (defined in EU legislation) have been addressed other than those that are the subject of the investigation.

Notification to the UK competent authority (ie, the MDA) may be made at the same time as a submission to a multi-centre research ethics committee (MREC) or local research ethics committee (LREC). The clinical investigation can begin provided LREC approval is obtained.

Device Technology and Safety Technically qualified experts in Device Technology and Safety (DTS) help improve the safety and reliability of medical devices. Adverse incidents are investigated, and the reasons for failure discovered. Guidance for device

users is intended to prevent further incidents. It also defines best practice for the use and maintenance of devices so that potential hazards can be avoided.

The adverse incident centre receives incident reports (over 7,200 in 2000) and coordinates expert investigation into problems. In many cases, a solution is reached with the co-operation of the manufacturer (eg, by withdrawal of a faulty batch, or in changes to design or instructions for use). In some cases, the MDA alerts users to a problem by issuing a hazard notice or device alert (specific advice for immediate action) or a safety notice (information which users need to avoid a potential hazard).

Some incidents have occurred as a result of devices being used in ways for which they are not designed, others because the device has not been used in accordance with the manufacturer's operating instructions and still more because of inadequate training.

Failure to understand how to set up infusion pumps correctly has been a recurring problem. Some instances were caused by the use of an infusion pump model with which staff were unfamiliar and had not been given appropriate training. Others have been caused by incorrectly setting the infusion rate.

A second example is the incorrect interpretation of the output from an ultrasound foetal monitor in which the heartbeat of the mother was being recorded rather than that of the foetus, which was subsequently still-born. These errors have been attributed to likely failure to train users adequately.

Thirdly, a patient fell to the floor from a stretcher sling because the buckle straps were not securely fastened. The operators threaded the straps through the buckles from the wrong direction. The straps supported the patient's weight for a short time, but as he was lifted clear of the bed, the buckles suddenly released, dropping him on to the floor. The stretcher had been borrowed from another ward and the operators had not read the instructions or been trained in its use.

Panel 2: Medical Devices Agency business areas and functions

CHIEF EXECUTIVE

CLINICAL

- 1 Medical and nursing advice to all functions of the agency, the Department of Health, the NHS and professional bodies
- 1 Assessing clinical investigation applications

DEVICE TECHNOLOGY AND SAFETY

- 1 Adverse incident centre
- 1 Sterile, surgical and *in vitro* diagnostic devices
- 1 Rehabilitation and transfer equipment
- 1 Wheeled mobility
- 1 Devices for diagnostic imaging, therapy, measurement, electrosurgery and disability
- 1 Critical care devices
- 1 Implants and materials

EUROPEAN AND REGULATORY AFFAIRS

- 1 Medical devices directives and regulations, guidance and enforcement
- 1 Notified body designation and monitoring
- 1 Registration of medical devices manufacturers and assessment of notifications for clinical trials
- 1 Global harmonisation task force issues
- 1 Global medical devices nomenclature system
- 1 Mutual recognition agreements

DEVICE EVALUATION SERVICE

- 1 Technical and user evaluations of devices for pathology, diagnostic imaging and life support

CORPORATE FINANCE

- 1 Financial and management information

CORPORATE SERVICES

- 1 Human resources, planning, office services, information systems and library

Device Bulletins are documents that contain guidance and information of a more general management interest. They are written as a result of experience gained from adverse incident investigations, contacts with manufacturers and users, device evaluations, and other sources of information. Recent examples include guidance on blood pressure measurement devices and information on issues surrounding the reuse of single-use devices.

The experience and knowledge gained from incident investigations determines the advice given by the MDA to the Department of Health, the NHS, and the independent health care sector. It also gives the agency an authoritative standing in its dealings with manufacturers and international regulators.

European and Regulatory Affairs European and Regulatory Affairs (ERA) represents the MDA and hence the UK on all regulatory matters affecting medical devices. This has included negotiating with

in the EU to create three medical devices directives which set out safety and performance requirements for medical devices and procedures for checking that products comply with the requirements. Devices that do comply can be labelled with a CE mark. These three directives have been transposed into UK law as medical device Regulations (see "The regulatory control of medical devices" below).

The ERA works with its European partners to try to ensure consistent interpretation and implementation of these directives across the EU.

As the competent authority for medical devices, the agency has five main functions for which ERA is responsible:

1. Enforcing the regulations that implement the EU directives
2. Providing detailed advice to manufacturers and others on the regulations (to assist in this, the ERA publishes a series of Directive Bulletins that provide a comprehensive guide to the directives

and their implementation and keep the medical devices industry and others in touch with developments)

3. Assessing notifications from manufacturers intending to run clinical trials of their devices, to protect the safety of patients and users
4. Designating and monitoring notified bodies (independent certification bodies which manufacturers use to check that their products comply with the directives)
5. Maintaining a register of UK manufacturers of low risk devices and *in vitro* diagnostic devices

The Device Technology and Safety business (see above) is responsible for one further function:

6. Operating the vigilance system for adverse incidents reported by manufacturers

The ERA is also active on the international stage: it participates in the Global Harmonisation Task Force which aims to harmonise device Regulations across various trading blocs (eg, the EU, the United States and Japan). It also is responsible for implementing mutual recognition agreements, in which assessments of quality and safety of a medical device by one competent authority are recognised by another competent authority. Such agreements have been concluded with the US, Canada and Australia.

Device Evaluation Service The MDA manages a major programme to evaluate medical devices and equipment used for pathology, diagnostic imaging, life support and disability. Most of the work is commissioned from specialists in the NHS and universities.

Devices are tested for performance and safety, as well as technical specification, in both clinical and laboratory settings. The aim is not primarily to identify any potential deficiencies of performance, but to provide a clear idea of what the equipment can do, its ease of use, and its suitability for different environments and applications.

Over three million people in Britain depend on disability equipment, including wheelchairs, artificial limbs, walking aids, and equipment for daily living. The agency's Blackpool unit has specialised equipment for testing wheelchairs and artificial limbs to European or international standards. It also uses its laboratory to support adverse incident investigations and the development of standards.

The evaluation programme provides a range of services, including consultancy advice, published reports and comparative surveys. These services enable device users to select equipment suitable for their needs, provide information to purchasers of supplies, and contribute to improved equipment design and performance. About 100 evaluation reports are published each year. The range of recent reports illustrates the diversity of the evaluation programme's work: they have included anaesthetic work-

stations, defibrillators, infusion pumps, magnetic resonance and computed tomography scanners, wheelchairs, and moving and handling equipment.

The reports provide users with an objective appraisal when selecting equipment for purchase. They also offer essential information to anyone involved in the design, production and testing of medical devices.

THE REGULATORY CONTROL OF MEDICAL DEVICES

The quality and safety of medical devices is paramount. Quality and safety cannot be provided by legislation — they have to be built into the design and manufacturing processes for each product — but legislation is required to ensure that standards are applied uniformly and fairly across EU member states. Most legislation for medical devices is of relatively recent origin, although the UK has had medical device regulations for a considerably longer period.

The first directive, fully in force in the UK by December 1994, was the Active Implantable Medical Devices Directive (90/358/EEC). It covers all powered medical devices implanted and left in place in the human body. The most common example is a cardiac pacemaker. In the UK, the active implantable medical devices directive is implemented by the Active Implantable Medical Devices Regulations (SI 1995 No 1671, as amended) which came into force on 1 January 1995.

The Medical Devices Directive (93/42/EEC) covers most medical devices from first aid bandages to hip prostheses, and X-ray equipment to heart valves. Implementation into UK legislation was achieved by the Medical Devices Regulations (SI 1994 No 3017).

The In Vitro Diagnostic Medical Devices Directive (98/79/EC) covers any reagent, reagent product, calibrator, control material, kit, instrument, and apparatus that is used *in vitro* for the examination of specimens, including blood and tissues from human bodies. Pregnancy test kits and kits for the testing of hepatitis B are examples. It came into effect in the UK in June 2000, with a transition period until 7 December 2003.

The CE mark The CE mark is a mechanism to show that a manufacturer believes that its product satisfies the relevant essential requirements in the appropriate directive and that the product is fit for its intended purpose. It also denotes that the product is considered safe for use in its intended purpose and has been tested to demonstrate this.

Notified body Independent assessment of the compliance of a medical device with the relevant essential requirements listed in the legislation is carried out by a notified body, which is, in effect, a certification organisation. Once the notified body is satisfied that the product does comply with the essential

requirements, the manufacturer can apply the CE mark to its product.

THE VIGILANCE SYSTEM AND THE SAFETY OF MEDICAL DEVICE

Adverse incidents most commonly arise due to poor management or inadequate training. Other causes include:

- 1 Defects in the design of the device or in its instructions for use
- 1 Poor quality control during manufacture
- 1 Damage in transit
- 1 Inadequate processing, repair or maintenance
- 1 Degradation of the device due to overlong use or inappropriate storage
- 1 User error

The vigilance system The medical devices directives described above require that manufacturers report any serious or potentially serious adverse incidents to the MDA. The MDA shares that information with other EU member state medical device competent authorities and the European Commission if an adverse incident has required corrective action or poses a threat to patient safety. The sharing of the information is intended to prevent the reoccurrence of the incidence or to alleviate the consequences of such incidents. The notification and evaluation of adverse incidents in the use of devices is called the “vigilance system”.

All manufacturers of medical devices are also legally bound to report to the MDA any instance when they issue a recall of a device prompted by a risk of serious injury or death through the device’s continued use.

An adverse incident may also cause indirect harm to a patient, even though the device does not itself come into contact with the patient. For example, if there is an instrument fault (eg, in an automated analyser, classed as an *in vitro* device), incorrect pathology results (a false negative or a false positive) may be recorded and these might adversely affect the patient by their receiving inappropriate treatment or not receiving treatment required.

All adverse incident reports received are acknowledged by the MDA and the information entered on to the Agency’s database. No further action may be required in most of the incidents reported either because the problem has been resolved locally or by the manufacturer, or the report can be linked to an ongoing investigation.

For those reports that are further investigated, the method of investigation depends on the seriousness of the incident. Where there has been a death or serious deterioration in health, an investigation (called a “section investigation”) is led by one of the MDA’s device specialists. The user and manufacturer may be visited, the site of the incident investigated and the device tested, either by the manufacturer, the MDA, or an independent test house. Such investigations often result in the release of safety advice by the MDA.

For less serious incidents, the investigation (termed “AIC [adverse incident centre] investigations”) is usually carried out by the device manufacturer and its progress is monitored by the MDA. The person who initially reported the incident is copied all correspondence concerning, and the results of, the investigation.

Safety warnings Safety warnings are issued by the MDA to health and social care providers and other users of medical devices. The warnings concern particular problems and risks, and recommend appropriate courses of action to minimise these. There are three levels of warning notices issued by the MDA.

Hazard notices are issued following death or serious injury, or where death or serious injury would have occurred but for fortuitous circumstances or the timely intervention of health care personnel. They are also issued where it is clear that the medical device caused the incident and where immediate action is necessary to prevent recurrence.

Device alerts are distributed where there is the potential for death or serious injury, or there may be implications arising from the long-term use of the medical device. The recipient is expected to take immediate action on the advice issued.

Safety notices are used to recommend or inform where action by the recipient will improve safety, to repeat warnings on long-standing problems or to support or follow up a manufacturer’s modifications to a medical device.

Committee on Safety of Devices A Committee on Safety of Devices has been set up to advise Ministers and complement the work of the MDA. The CSD takes a strategic view of initiatives to make medical devices, and their use, safer and more effective. It also offers advice on the development of device-related policies, advises on the format and targeting of MDA’s communications with the NHS, and acts as part of the quality assurance system.

The CSD was set up in April 2001 and met for the first time on 19 July 2001. It meets three times a year and the minutes are published on the internet (www.medical-devices.gov.uk). A number of ad hoc groups and working parties have been established. The CSD and the MDA are supported in their work by a panel of almost 100 external experts.

The role of liaison officers Each NHS acute trust, most primary care trusts and social services department in England have nominated a liaison officer. The liaison officer helps to encourage the reporting of adverse incidents and play a major role in the dissemination of MDA safety warnings. The responsibility for the dissemination of MDA safety warnings to the private sector and to care homes now falls to the National Care Standards Commission.

An article on the work of the Medicines Control Agency will be published shortly