

# WHY THE MHRA NEEDS YOUR HELP

*Dr Susanne Ludgate, medical director at the Medicines and Healthcare products Regulatory Agency, explains why the agency has launched a strategy to encourage patients to report problems with medical devices direct to it and how pharmacists can help*

This week sees the launch of a new strategy from the devices sector of Medicines and Healthcare products Regulatory Agency, and the agency is calling on pharmacists to help. The strategy aims to encourage patients to report problems with medical devices and equipment direct to the MHRA, and pharmacists can assist by having on view a pamphlet, produced by the agency, setting out information for the general public about whom to contact in the event of needing advice about a device, and how to report adverse events (see *P7*, 29 November, p733). Reporting adverse events is of great importance if user issues are to be identified and satisfactorily corrected.

Over the past few years there has been a huge increase in the number of medical devices being used by patients at home. At the same time, however, the MHRA has been aware that little support for this increasing activity has been provided. This is why the MHRA will be making its pamphlet available in all pharmacies across England.

The agency hopes that pharmacists will help by ensuring that people obtaining medical devices are aware of the pamphlet.

Pharmacists may feel more encouraged to help if they know more about the work of the MHRA devices sector and how it promotes and protects public health.

The MHRA was created on 1 April 2003 through the merger of the Medicines Control Agency and the Medical Devices Agency. Although most clinical professionals are aware of the "medicines" side of the MHRA's work, the "devices" side of this new agency, and the functions it carries out to promote and protect public health, are less well known.

Not everyone is sure of what is included in the definition of a "medical device". The term covers any products, other than medicines, that are used in the health care environment for the diagnosis, treatment, prevention or monitoring of illness or disease. It encompasses a huge variety of products, ranging from the high-technology implantables such as pacemakers, heart valves and joint replacements, to an increasing number of home-use devices such as thermometers, wheelchairs, dressings and over-the-counter test kits.

The MHRA (devices sector) is an executive agency of the Department of Health entrusted with safeguarding public health by working with clinicians, regulators and manufacturers to ensure that all medical devices used in the health service meet appropriate standards of safety, quality and performance and comply with the provisions of the European Medical Devices Directives. It is also the primary source of United Kingdom information and guidance on the safe use of medical devices.

The agency fulfils its roles in a number of ways, eg, operating an adverse incident centre, acting as a European Competent Authority for devices, and providing a medical device evaluation service.

**Adverse incident centre** The agency's adverse incident centre currently receives almost 9,000 device-related adverse incidents every year. Each incident is investigated on a priority scale determined after discussion with the reporter and any relevant clinical or technical staff involved. Investigations may result in a number of actions being taken. Where necessary, warnings and advice are issued by means of "Device Alerts", in order to alert users to real or potential problems. After an investigation, the agency may also work with manufacturers to prevent recurrence of a problem through modifications or recall of a device.

As a result of adverse incidents reported, last year some 56 device alerts were issued to the health service and, in 1,033 cases, manufacturers undertook to improve designs or manufacturing systems.

Although the MHRA receives a number of device-related adverse incident reports directly from the manufacturer, these relate mainly to problems arising from shortcomings in the device or its operating instructions. Increasingly, we know that adverse incidents also occur as a result of user practices, conditions of use, poor maintenance or difficulties with cleaning, decontamination or sterilisation. If improvements are to be made in design, function, materials, ergonomics and instructions for use, therefore, it is vital that the agency continues to receive reports from users who have experience of the device.

**European competent authority** The MHRA acts as the competent authority (regulatory authority) for the negotiation, implementation and enforcement of the European Devices Regulations, a body of legislation that has, over the past few years, replaced the previously existing voluntary system for the control of medical devices within the United Kingdom. Under the provisions of these regulations, no device may be freely sold on the EU market without a CE-mark, which denotes compliance with a number of relevant essential requirements covering device safety and performance.

These regulations also allow strict controls to be applied to devices that present the greatest risk to the health and safety of the patient or user, including surgical implants, such as knees or hip prostheses, or those that come into direct contact with the heart or the central nervous system.

In order to be allowed to affix the CE-mark, manufacturers must go through a

conformity assessment procedure to confirm that the device complies with the relevant requirements. With the exception of low-risk devices, eg, tongue depressors, these assessment procedures must be checked by a certification organisation known as a notified body, of which there are more than 60 throughout Europe.

To demonstrate compliance, particularly with higher-risk devices, eg, breast implants, clinical data may often be required. These data may be obtained from previous clinical experience with the device, or from a compilation of scientific literature relating to the device or a similar device.

If this is not available, the required data will need to be generated from a specifically designed clinical investigation. Such clinical investigations must be notified by the manufacturer to the competent authority, which then has 60 days in which to assess the safety of the device based on the submitted information and inform the applicant of any grounds for objection based on safety issues.

In making an assessment, the competent authority assessors will look carefully at the risk analysis, taking into account the risk from such factors as the design and materials used and the biological safety and human tissue compatibility of the device in question. If objections are raised, the clinical investigation may not proceed, even if it has local research ethics committee approval, although the manufacturer may reapply once the concerns raised have been satisfactorily addressed.

As a competent authority, the devices sector's functions include establishing systems for the designation of notified bodies, handling clinical investigations and managing a statutory vigilance system through which manufacturers are now required by law to report all serious device-related incidents to a competent authority within a given time.

**Device evaluation service** The agency's third major role involves managing an important programme of evaluation of certain medical devices, intended to inform potential purchasers. The work is commissioned from independent research specialists in the NHS or universities. Devices are tested for performance and safety in both clinical and laboratory settings, with the aim of providing a clear idea of the equipment's scope, ease of use and suitability for different environments.

Over 100 evaluation reports are published annually and made available free of charge to the health service. These reports cover a wide range of services, from diagnostic imaging and ultrasound equipment to "active" power-connected equipment, including diathermy and defibrillators, and *in vitro* diagnostic and disability equipment.