Assistive Technology

Reporting Adverse Incidents

Who we are

The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency of the Department of health.

The aim of MHRA is to enhance and safeguard the public's health by ensuring that medical devices and medicines meet appropriate standards of safety and effectiveness in use.

The Adverse Incident Centre (AIC) is the MHRA's focal point for reporting incidents involving medical devices.

The MHRA has a specific Centre for Assistive Technology in Blackpool (tel: 01253 596000 e-mail bav@mhra.gsi.gov.uk).

What is a medical device?

Medical devices and equipment are items used for the diagnosis and/or treatment of disease, or for monitoring patients or as assistive technology.

Examples of assistive technology include:

- mobility aids (wheelchairs, artificial limbs)
- environmental controls (personal alarm systems, remote control of doors, windows and other common household tasks)
- speech and hearing aids
- pressure management (pressure redistribution/relief)
- moving and handling systems (hoists, slider boards
- aids for daily living (chairs, commodes, bath aids)

Other medical device examples (see www.mhra.gov.uk for more)

- defibrillators, pacemakers and monitors
- scanners and x-ray machines
- surgical implants and surgical instruments
- syringes and needles
- IVD's

What should be reported

Any adverse incident involving a medical device should be reported, especially if the incident has led to, or were it to occur again, could lead to:

- death
- serious injury (eg falls in the elderly or serious injury to a carer or member of staff)
- medical or surgical intervention or hospitalisation

Other minor injury or safety or quality problems should also be reported as these can help demonstrate trends or highlight inadequate design or manufacturing or supply systems.

What we do

Each incident is recorded on our database.

We initially assess all reports of adverse incidents involving medical devices. A risk assessment is carried out based on the information available to determine whether an investigation is undertaken directly by us or by the manufacturer on our behalf.

Every report is acknowledged and all reporters are advised of the nature and outcome of the investigation.

What is an adverse incident?

An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of users or other persons.

Causes of incidents involving medical devices may include:

- shortcomings in the device itself
- inadequate user instructions from the manufacturer or poor training
- inappropriate local modifications or adjustments
- inadequate maintenance process
- inadequate or inappropriate repairs or replacement parts
- unsuitable storage or use conditions
- inadequate end of life/scrapping information or policies
- any other safety issues

What happens to the device?

Devices that have been involved in an incident should be quarantined. They should not be repaired, returned to the manufacturer or discarded until we have been given the opportunity to carry out our own investigation. Further advice on individual cases may be obtained from the MHRA Centre for Assistive Technology on 01253 596000.

If sending an item for investigation, please follow published MHRA advice on decontamination (see www.mhra.gov.uk).

Remember:
it is illegal to send contaminated items through the post.

How to report an incident

Adverse incidents should be reported to MHRA at the earliest opportunity and also copied to any local incident reporting systems.

We prefer you to use the online reporting system via our website: www.mhra.gov.uk

However, if necessary you may also download a form from our website and e-mail or fax it to us: e-mail: aic@mhra.gsi.gov.uk fax: 020 7084 3109.

Adverse Incident hotline: 020 7084 3080