Medical Devices — 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 MHRA is the government agency responsible for ensuring that medical devices and medicines work, and are acceptably safe.

The MHRA has a specific Centre for Assistive Technology in Blackpool. Tel: 01253 596000
Email: bav@mhra.gsi.gov.uk

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 AT staff in Blackpool or London, 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 a medical device?

Medical devices and equipment are items used for the diagnosis and/or treatment of disease, for monitoring patients, or as assistive technology.
Examples of assistive technology include:
Mobility aids (wheelchairs, walking aids, artificial limbs) ♦ Communication and hearing aids♦ Posture management (from simple cushions to complex support systems) ♦ Pressure management (pressure redistribution/relief cushions and mattresses) ♦ Moving and handling systems (hoists, slings, slider boards, bath lifts) ♦ Hospital and community beds, mattresses and accessories ♦ Therapy equipment ♦ Telecare (personal alarm systems, home care systems etc) ♦ Devices for the alleviation of, or compensation for, a disability or those used during rehabilitation.

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
- poor training
- inappropriate local modifications/adjustments
- inadequate maintenance process
- inadequate/inappropriate repairs/replacement parts
- unsuitable storage/use conditions
- inadequate end of life/scrapping information/policies.

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

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

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 MHRA have been given the opportunity to carry out our own investigation.

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 at the earliest opportunity, following any local incident reporting policies.

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 email or fax it to us:
email: aic@mhra.gsi.gov.uk fax: 020 3118 9814 **Adverse Incident hotline: 020 3080 7080**

website publication