Medicines & Healthcare products Regulatory Agency

Guidance

Assistive technology: definition and safe use

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Contents

This publication is available at https://www.gov.uk/government/publications/assistive-technology-definition-and-safe-use/assistive-technology-definition-and-safe-use

1. Introduction

The phrase ‘assistive technology’ is used to describe products or systems that support and assist individuals with disabilities, restricted mobility or other impairments to perform functions that might otherwise be difficult or impossible.

It is important to be clear on terminology, just because a product is used in a healthcare environment or by a healthcare professional, this does not necessarily mean it is a medical device.

An assistive technology product can be classed as a medical device, which requires it to be appropriately conformity marked (https://www.gov.uk/guidance/regulating-medical-devices-from-1-january-2021) and regulated through the UK Medical Devices Regulations 2002 (https://www.legislation.gov.uk/ukdsi/2020/9780348213805/contents) (as amended) (UK MDR 2002) in Great Britain. However, assistive technology products can also be considered an ‘aid for daily living’, and these products will only be considered a medical device if the manufacturer has stated that they have a medical purpose.

In Northern Ireland different rules apply to those in Great Britain - see the section Regulation in Northern Ireland (https://www.gov.uk/government/publications/assistive-technology-definition-and-safe-use/assistive-technology-definition-and-safe-use#NI).

Navigating medical device legislation can be complex, therefore the MHRA will always consider each product on a case-by-case basis when giving advice.

The government has put in place transitional agreements to extend acceptance of CE marked medical devices in Great Britain. For more detail on this see the implementation update (https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices-and-extension-of-standstill-period/implementation-of-the-future-regulations) on work towards a strengthened future medical devices regime.

2. Definitions

2.1 Medical device

‘…means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application, which:

a) is intended by its manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- investigation, replacement or modification of the anatomy or of a physiological process, or
- control of conception, and

b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means.’

This guidance relates to the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (https://www.legislation.gov.uk/uksi/2020/1478/contents/made) sets out the specific requirements for Northern Ireland.

Medical purpose

Medical devices are products that are intended to be used for a medical purpose. The manufacturer will state the medical purpose of their product in their labelling, instructions for use or service manual and promotional material. Medical devices can diagnose, monitor or treat disease and help people with physical impairments become more independent.

Primary intended purpose

Some products may have various purposes. For example, a commode, which is intended to be used by individuals with disabilities or mobility issues, may appear to have a toiletry purpose or a medical purpose. A commode is primarily intended to be used for toiletry purposes rather than a medical purpose, so it would not normally be considered as a medical device. But, a seemingly basic device such as a prescribed walking aid would be considered a medical device, as its primary function is to relieve symptoms of previous injury by taking the weight off an injured limb.

2.2 Assistive technology

Products or systems that support and help individuals with disabilities, restricted mobility or other impairments to perform functions that might otherwise be difficult or impossible. These devices support individuals to improve or maintain their daily quality of life by easing or compensating for an injury or disability.

2.3 Aids for daily living

Products that help people carry out day-to-day activities. Although they may be used by those with disabilities or other impairments, in healthcare environments or by healthcare professionals, many of these products may be used by anyone and will not have a specific medical purpose or direct link to the individuals concerned.

3. Assistive technology: medical device or not?

Equipment intended for alleviation of, or compensation for, a disability may or may not be a medical device. The determining factor will be whether there is a direct link between the corrective function of the equipment and the intended user. Although two products may appear to be similar in function, one may be a medical device whilst the other is not. This will depend entirely on the claims made by the manufacturer for each product.

3.1 Example

A manufacturer sells 2 different kinds of portable wheelchairs: a self-propelled wheelchair intended for use by people with disabilities or difficulty in walking and another that is intended to be used by hospital porters to transport patients around the hospital.

The first is a medical device because there is a clear link between the corrective function (compensation for injury or disability by providing a mode of transportation) and the individual (persons with disabilities or difficulty in walking).

The second wheelchair is not a medical device because although the purpose is also to provide transportation, it is not specifically intended to be used only by those with disabilities or difficulty walking. It is an aid for the porter to transfer anyone around the hospital quickly and safely.

Other examples of medical devices:

- baths with integrated hoists
- communication aids
- epilepsy / enuresis monitor
- external limb prostheses and accessories
- hearing aids
- orthopaedic footwear
- orthoses (lower/upper limb, spinal, abdominal, neck, head)
- patient hoists
- pressure management (pressure redistribution/relief cushions and mattresses)
- posture management (from simple cushions to complex support systems)
- slider boards
- standing aids
- walking / standing frames
- walking sticks / crutches
- wheelchairs (including powered wheelchairs)
- mobility scooters

3.2 Regulation

Under the UK MDR 2002 most assistive technology devices are likely to be classified as Class I (https://www.gov.uk/government/collections/guidance-on-class-1-medical-devices) or custom-made medical devices (https://www.gov.uk/government/publications/custom-made-medical-devices). Assistive technology devices may also be manufactured in-house by healthcare establishments (https://www.gov.uk/government/publications/in-house-manufacture-of-medical-devices) rather than bought from manufacturers.

4. For one or for all

The distinction between intended use by specific individuals and ‘by all’ is a key factor when considering whether a product is a medical device. Unless a manufacturer specifies that a product is intended to be used by individuals for a stated medical purpose, the product could be used by anyone, regardless of whether they have a medical condition. If a product can be used by anyone then it is unlikely to be a medical device.

4.1 Example

Walking sticks for people who have difficulty walking or other mobility issues are generally considered to be medical devices because they have a clear medical purpose and a clear link between the corrective function (to aid mobility) and the individual (person using the walking stick).

However, walking sticks which are intended for recreational use (i.e. hill-walking or mountaineering) would not be considered medical devices because they do not have a clear medical purpose and can be used by anyone, regardless of whether the individual using the stick has mobility issues or not.

4.2 Example

Cushions which are intended to relieve pressure and prevent pressure sores for use by wheelchair users who spend long hours sitting in the chair would likely be considered a medical device because they have a clear medical purpose and a clear link between the corrective function (to relieve pressure and prevent pressure sores) and the individual (wheelchair user).

However, ordinary cushions (including those used in hospital or healthcare environments) would not be considered medical devices because their primary purpose is for comfort and they can be used by anyone.

4.3 Aids for daily living – not medical devices

As described in the definitions section (2.3), there are many products that help people carry out day-to-day activities. Although they may be used by people with disabilities or other impairments, in healthcare environments or by healthcare professionals, many of these products may be used by anyone and will not have a

specific medical purpose or direct link to the individuals concerned. Such products are usually referred to as ‘aids for daily living’ and are not considered medical devices.

For example:

- acoustic signals at traffic lights
- bariatric chairs and stools
- bath with easy access door
- chair riser
- grab rails (at doorways, stairs, beds etc.)
- personal alarm systems (including fall alarms)
- portable ramps, wheelchair vehicle restraints
- rise and recline chairs
- shower chair
- special water taps
- stair lifts
- toilet equipment (toilets seats, shower seats, commodes)

It is important to note that just because a product is used by individuals with disabilities or other impairments and has the CE* or UKCA marking, this does not necessarily mean it is a medical device.

For example, white sticks used by people who are blind or visually impaired are likely to be regulated as Personal Protective Equipment (PPE) as they do not aid walking, but rather they act as protection while the user is moving.

Hip protectors for prevention of injury for those at risk of falling would also be likely to come within the remit of the PPE regulations. Such products are likely to be regulated as PPE rather than through medical device legislation.

If you have a problem with such a product, please contact your local Trading Standards Office (https://www.gov.uk/find-local-trading-standards-office). The Office for Product Safety and Standards (https://www.gov.uk/government/organisations/office-for-product-safety-and-standards) provides information on consumer recalls.

Where uncertain on whether a product is a medical device please consult the MHRA guidance on borderlines with medical devices (https://www.gov.uk/government/publications/borderlines-with-medical-devices).

*CE marked medical devices continue to be accepted on the Great Britain market with the deadline depending on the type of device and legislation it complies with, with the latest deadline being 30 June 2030. For more information see

our guidance on how medical devices are regulated in the UK (https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk).

5. Regulation in Northern Ireland

Under the terms of the Northern Ireland Protocol (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/840230/Revised_Protocol_to_the_Withdrawal_Agreement.pdf), the rules for placing medical devices on the Northern Ireland market differ from those applicable to Great Britain.

5.1 Legislation in Northern Ireland

Unlike Great Britain, the Medical Device Regulations (2017/745) and the in vitro Diagnostic Medical Device Regulations (2017/746) apply in Northern Ireland in line with the EU's implementation timeline.

Medical devices placed on the market in Northern Ireland must fully comply with the requirements of 2017/745 and 2017/746. The MHRA continues to be responsible for the regulation of medical devices in the UK.

Any decisions made by the MHRA regarding whether a product is a medical device may apply in both Great Britain and Northern Ireland. Decisions will be made in line with the appropriate legislation for the region.

For more information please see our guidance on how medical devices are regulated in the UK (https://www.gov.uk/guidance/regulating-medical-devices-from-1-january-2021).

6. Safety issues

6.1 What can go wrong

Problems with an assistive technology device may include:

- issues arising as a result of inadequate repair or maintenance instructions from the manufacturer
- absence of individual risk assessment for users of prescribed assistive technology device including entrapment risks. Incidents have been reported with a range of assistive technology including bed rails (Bed rails: management and safe use (https://www.gov.uk/guidance/bed-rails-management-and-safe-use)) and wheelchair lapbelts
- risk of injury due to use of assistive technology devices (including the prescribed ones) that are not appropriate for specific needs of the user
- poor or lack of training in how to use/repair/maintain the device
- device documentation (e.g. instructions for use, technical/operation manual etc.):
  - not complete
  - confusing
  - not present with the device
- errors in use:
  - not following/adhering to the intended use of the device, including end of service life guidance
  - not following the manufacturer's instructions on charging battery operated devices (inappropriate frequency of charge, use of incompatible charger, overcharging the battery)
  - overloading the device, exceeding maximum allowed weight load
  - not performing visual checks prior use of the device
- inappropriate local modifications/adjustments
- inadequate maintenance process
- inadequate or inappropriate repairs/replacement parts
- problems from storage/use conditions
- inadequate end-of-life/scrapping information from the manufacturer or provider
- incompatibility or the lack of compatibility information with other devices
- problems with the device itself:
  - failure of the device, e.g. cracks, leaks, detachments
  - design
  - production
  - packaging
- medical devices that are not appropriately conformity marked being supplied to the UK
- aids for daily living that are incorrectly marked and marketed as medical devices in the UK

6.2 Examples of good practice using assistive technology devices*

- an appropriate risk assessment should be carried out before the initial prescription of the device and reviewed after significant change in user's condition or needs
- for non-prescribed devices, users and/or carers should consult with provider or relevant healthcare professional to select the right device suitable for individual needs of the user
- users and/or carers (including non-professional carers) should be appropriately trained in the use of the device
- users and carers should ensure they have read and understood the instructions for use and are aware of the warnings and counterindications indicated by the manufacturer of the device
- users and/or carers should always follow the manufacturer's instructions when using, charging, cleaning, or disposing of the device
- prior to using the device, it is recommended to have a visual check of the device to avoid injury in case the device is faulty
- maintenance should be performed to the device as frequently as indicated by the manufacturer or Health Safety Executive (LOLER) (https://www.hse.gov.uk/work-equipment-machinery/loler.htm)
- for powered devices, the battery should be charged as often as indicated by the manufacturer of the device. Failure to follow manufacturer recommendations can result in battery faults which can, rarely, cause fires
- only the battery charger that is supplied with the device should be used, to avoid risk of battery failure and potentially fire
- batteries should never run flat, this can result in battery failure.

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*The list is not exhaustive

7. What to do with a failed device

If you are a personal user:

- do not use the device if you are worried about its safety, for example if it doesn't feel safe to use as described in the instructions

- contact your healthcare professional if you were given the device by them or if not, contact the retailer or manufacturer

If you are a professional user:

- quarantine the device
- contact the manufacturer and ask them to collect and analyse the device

8. What to do next

Report suspected or actual side effects or adverse events involving medical devices through your local incident reporting system and/or your national incident reporting authority as appropriate:

8.1 England

Healthcare professionals and patients/members of the public: report through the MHRA's Yellow Card (https://yellowcard.mhra.gov.uk/) system.

8.2 Northern Ireland

Healthcare professionals: report through the NI Department of Health incident reporting form (https://www.health-ni.gov.uk/articles/reporting-adverse-incident).

Patients/members of the public: report through the MHRA's Yellow Card (https://yellowcard.mhra.gov.uk/) system.

8.3 Scotland

Healthcare professionals: report using the Scottish Department of Health incident reporting form (https://www.nss.nhs.scot/health-facilities/incidents-and-alerts/report-an-incident/).

Patients/members of the public: report through the MHRA's Yellow Card (https://yellowcard.mhra.gov.uk/) system.

8.4 Wales

Healthcare professionals and patients/members of the public: report through the MHRA's Yellow Card (https://yellowcard.mhra.gov.uk/) system.

9. What happens to your report

When you submit a report, you will receive a notification of submission which will contain your unique reference number. Your report will go onto our database after a quality check, sometimes we may need to get in touch with you for more information.

Our specialised database allows us to process and analyse the reports rapidly to make them available to detect new safety issues. Every report therefore could be a potential safety issue or 'signal'.

Potential signals are evaluated and triaged to identify previously unidentified potential hazards, and new information including on recognised effects or safety issues. Your Yellow Card report will be considered in the context of all other reports received

The MHRA may use your Yellow Card report in a range of different ways, including:

- Highlighting the report as a possible safety issue on the MHRA database and keeping a close watch on the safety of the product by monitoring similar reports.
- Noting the patient perspective of the effect, fault, or complication, to better understand the impact on the people who use the product.
- Requesting additional information from you so MHRA expert scientists and specialists can better understand the suspected potential safety issue.
- Conducting a specific analysis of similar Yellow Card reports to identify potential new safety signals.
- Requesting further information from other sources, including from the manufacturer(s).

- Discussing the suspected side effect, adverse medical device incident or problem with other medicines regulatory agencies and experts in the field.

The MHRA will always:

- send your report to the manufacturer for their internal investigation. (For patients – details of your report will only be passed on if you have consented to the sharing of your information at the time of reporting your Yellow Card)
- request the manufacturer to review and if they investigate, to provide details of their findings. This is because the manufacturer has a legal obligation to submit vigilance reports to the MHRA when certain types of incidents that involve their device occur in the UK.

The manufacturer must also take appropriate safety action when required.

For more information on Yellow Card, please see https://yellowcard.mhra.gov.uk/information (https://yellowcard.mhra.gov.uk/information)

10. Why you should report

To:

- first identify a device issue of national significance, or to help to trigger a cascade of corrective actions
- help form a full picture of issues experienced in the UK as the more evidence there is, the more likely it is that action can be undertaken
- improve quality of clinical/care services to users
- prevent serious harm to others
- fulfil your duty of candour (if you are a healthcare professional)

10.1 Examples of actions taken following reported incidents

Example 1

A report of a drive wheel detaching from a powered wheelchair whilst in use resulting in the chair tilting to one side:

- key things were missing from the technical manual and the manufacturer corrected it
- the manufacturer issued a Field Safety Notice (FSN) and MHRA issued a safety message Medical Device Alert (MDA) (a precursor to the National Patient Safety Alert and Device Safety Information) to make sure users were aware of the problem

Example 2

The MHRA identified an emerging trend in handle fractures of a walking stick. As a result, the manufacturer:

- issued an FSN to customers, giving the instruction to remove and destroy affected devices from use
- made changes in the device production and implemented a new testing routine

Example 3

A patient died after falling out of a sling during transfer from a bed due to a clip disconnection:

- the manufacturer issued an FSN to remind users of the importance of doing a risk assessment before using the sling for the first time and carrying out pre-use checks
- the manufacturer updated the instructions for use of the sling
- MHRA issued a Medical Device Alert to make sure users were aware of the problem

Example 4

MHRA identified continued reporting of serious injuries and deaths due to entrapment and falls with bed rails. In many cases, the MHRA's existing guidance had not been followed:

- The guidance on bedrails was revised, in collaboration with a number of partner organisations, and also included reference to other recent incidents that had been received on other devices such as bed grab handles and lateral turning devices.
- The guidance was highlighted to users by issuing a National Patient Safety Alert (https://www.gov.uk/drug-device-alerts/national-patient-safety-alert-medical-beds-trolleys-bed-rails-bed-grab-handles-and-lateral-turning-devices-risk-of-death-from-entrapment-or-falls-natpsa-slash-2023-slash-010-slash-mhra).

Example 5

Joint work with the Health & Safety Executive (HSE) and National Patient Safety Agency (NPSA), now a part of NHS England/Improvement, showed a number of incidents which illustrated poor maintenance and use of hoists and slings. This led to the MHRA issuing a safety message (https://www.england.nhs.uk/2015/10/risk-death-and-serious-harm-falling-hoists/) jointly with the HSE and NPSA, highlighting the need for regular maintenance and proper training in the use of these devices.

11. Other guidance

Regulatory:

Class 1 medical devices (https://www.gov.uk/government/collections/guidance-on-class-1-medical-devices)

Custom-made medical devices (https://www.gov.uk/government/publications/custom-made-medical-devices)

Medical devices: legal requirements for special medical products (https://www.gov.uk/government/publications/medical-devices-legal-requirements-for-specific-medical-devices/medical-devices-legal-requirements-for-specific-medical-devices)

Medical devices: software applications (apps) (https://www.gov.uk/government/publications/medical-devices-software-applications-apps)

MHRA guidance on borderlines with medical devices (https://www.gov.uk/government/publications/borderlines-with-medical-devices).

Devices – general:

Devices in practice: checklists for using medical devices (https://www.gov.uk/government/publications/devices-in-practice-checklists-for-using-medical-devices)

Device-specific:

Bed rails: management and safe use (https://www.gov.uk/government/publications/bed-rails-management-and-safe-use)

Occupied wheelchairs in cars and private transport – reminders of safe use (https://www.gov.uk/government/publications/occupied-wheelchairs-in-cars-and-private-transport-reminders-of-safe-use)

Risk of death and serious harm by falling from hoists (https://www.england.nhs.uk/2015/10/risk-death-and-serious-harm-falling-hoists/)

Medical devices: information for users and patients (https://www.gov.uk/guidance/medical-devices-information-for-users-and-patients)

Managing medical devices: guidance for healthcare and social services organisations on managing medical devices in practice (https://www.gov.uk/government/publications/managing-medical-devices)

11.1 From other organisations

Department for Transport: mobility scooters and powered wheelchairs on the road - some guidance for users (https://www.gov.uk/government/publications/mobility-scooters-and-powered-wheelchairs-on-the-road-some-guidance-for-users)

Posture and Mobility Group: BPG1: Transportation of People Seated in Wheelchairs (revision 1, V2.2) (https://www.pmguk.co.uk/resources/best-practice-guidelines/bpg1-2019-revision) and All Wales Best Practice Guidelines: Seating and Pressure Ulcers (https://www.pmguk.co.uk/resources/best-practice-guidelines/all-wales-bpg)

British Health Care Trades Association (BHTA): Get wise leaflets (https://www.bhta.com/get-wise/) and Lithium battery safety guidance (https://www.bhta.com/lithium-battery-safety-guidance/)

Care Quality Commission (CQC): Issue 13: Protecting people using wheelchairs - Care Quality Commission (cqc.org.uk) (https://www.cqc.org.uk/guidance-providers/learning-safety-incidents/issue-13-protecting-people-using-wheelchairs)

Health and Safety Executive (HSE): guidance on Moving and handling equipment (https://www.hse.gov.uk/healthservices/moving-handling-equipment.htm)

NHS: Wheelchair Positioning Guide (https://www.berkshirehealthcare.nhs.uk/media/109514755/ebw-wheelchair-general-positioning-guide-berkshire-healthcare.pdf)

London Fire Brigade: Fire safety advice for users of healthcare products and equipment (https://www.london-fire.gov.uk/media/irjak0jd/f5324-final-fire-safety-advice-for-users-of-health-care-products-and-equipment-v4-march-2024.pdf)

World Health Organization (WHO) guidance: Assistive product specifications and how to use them (https://iris.who.int/bitstream/handle/10665/339851/9789240020283-

eng.pdf)