How to report an incident to the HPRA

If a medical device poses a risk to your health and safety, stop using it where possible and report the problem to your healthcare provider, the HPRA and the manufacturer of the device. You should report any unexpected problem or malfunction that may affect your health or cause or contribute to an injury, for example a blood glucose meter giving an incorrect blood glucose reading, leading to incorrect treatment.

You can report incidents to the HPRA by filling in our online user report form on www.hpra.ie. If you would prefer to fill out a printed copy of the form, you can download it from our website or request a copy by phone or e-mail.

More information

This is one in a series of information leaflets that you can get from the HPRA and from our website: www.hpra.ie.

The Health Products Regulatory Authority (HPRA)

Our role is to protect and enhance public and animal health by regulating medicines, medical devices and other health products.

What does the HPRA do?

As the regulatory authority, we monitor the safety of all medical devices available in Ireland. Our aim is to make sure that these products do not compromise the health and safety of the patient or the person using them. We also work to ensure that medical device manufacturers comply with all safety regulations.

(The HPRA cannot provide advice on which medical devices you should buy.)
Buying a medical device online

One in three Irish internet users now buy everyday products online. While only a few people buy medical devices online, the potential risk to users is relatively high. Buying a medical device over the internet may give you privacy and save you money, but the risks associated with the device may be higher.

While genuine devices are available online, some other devices that are advertised may pose a threat to your health. Some medical devices may not work or be tested properly, may not be intended for your condition, may be only for healthcare professionals to use or may even be fake.

Things to consider

If you are planning to buy a medical device over the internet you should consider the following:

• Talk to a health care professional, such as your GP, before buying a medical device.
• Make sure that the device you are planning on buying has a CE mark.
• Devices that are CE marked and sold on the European market must come from a registered business premises in Europe. Look for a European address.
• Be wary of medical devices that make elaborate claims – they may not be true.
• You should only buy prescription devices, such as contact lenses, from trusted websites that know your prescription.
• Don’t buy devices from auction sites.
• Try to buy directly from the manufacturer or an authorised dealer. If there is one, fill in the warranty form so that the manufacturer can contact you if they need to, for example if they need to recall the product.

What is a medical device?

A medical device is a healthcare product or piece of equipment that a person uses for a medical purpose. It is not a medicine or drug. Medical devices can diagnose, monitor or treat disease and help people with physical impairments become more independent.

Examples of medical devices include contact lenses, pregnancy tests, wheelchairs, blood pressure meters, blood glucose meters, test strips and more complex equipment like cardiac defibrillators and HIV testing kits.

A valid medical device bears a CE mark, which indicates that it meets the basic requirements for safety and effectiveness under European law.

This leaflet gives you information about medical devices and highlights some key issues about buying them online.