

When to report a medical device adverse incident?

Step-by-Step Guide

1 When to Report



Any incident which has occurred during use of the medical device which might lead to or might have led to death of a patient, or user or of other persons or to a serious deterioration in their state of health.

2 Action



Take appropriate local action to ensure the safety of patients, users and others. Report the incident via your local medical device governance structure e.g. medical device committee, vigilance officer, quality & safety committee, etc.

3 Quarantine



The devices involved in the incident together with other material evidence (e.g. packaging, associated consumables) should be clearly identified and kept in quarantine, where practicable. Where quarantine is not practicable, the state of the device at the time of the incident should be recorded, including photographic evidence.

4 Information



Record all details relating to the incident including name, model, serial/lot numbers, manufacturer of the device and the date and time of the incident. Record device user details at time of incident.

5 Notify



All incidents should be reported as soon as possible to the manufacturer and the HPRa. Serious incidents should be reported to the HPRa by the fastest means available, preferably by completing the Medical Device Incident User Report Form on-line at www.hpra.ie or by submitting the form by email to devicesafety@hpra.ie.

6 Assistance



Provide the manufacturer with appropriate assistance to facilitate completion of their investigation; this may include access to the device for examination, interviews with staff / users, access to any other relevant information.

Medical Devices and *In-vitro* Diagnostic Medical Devices

ADVERSE INCIDENT REPORTING

What is the role of the Health Products Regulatory Authority (HPRA) in medical device vigilance?

The HPRA is the competent authority for medical devices in Ireland and maintains a medical devices vigilance system to protect the health and safety of patients, users and others. This is achieved by the evaluation of vigilance reports from manufacturers, users and other stakeholders, providing information to users on the safe use of medical devices and where appropriate, evaluating an action for the market place e.g. device recall or device modification.

What is a medical device?

A product used in healthcare for the diagnosis, prevention, monitoring or treatment of an illness or handicap. This does not include a medicine. There is a wide array of medical devices ranging from sterile dressings and wheelchairs to glucometers, infusion pumps, cardiac pacemakers and implants to name of few. The term medical device also covers *in-vitro* diagnostic test kits, reagents, calibrators and related software. Examples include blood group test kits, HIV kits and blood glucose monitors.

All medical devices placed on the Irish market must bear a CE mark.

What incidents involving medical devices should the user report to the HPRA?

Any incident which has occurred during use of the device which might lead to or might have led to death of a patient, or user or of other persons or to a serious deterioration in their state of health. This could include an inadequacy in the labelling or instructions for use of the device or inappropriate decontamination instructions, which may impact on the safe decontamination of reusable medical devices.

In the majority of cases, IVD and *in-vitro* fertilisation/assisted reproductive technology will, due to their intended use, not directly lead to physical injury or damage to health of people. These devices are more likely to lead to indirect harm which may occur as a consequence of the medical decision, action taken/not taken on the basis of information or result(s) provided by the device (i.e. misdiagnosis, delayed diagnosis/treatment, transfusion of inappropriate materials, etc.). Such events, if they might lead to or have led to the death or serious deterioration in the health of the patient or user or others, should also be reported.

Why report adverse incidents to the HPRA?

Increased levels of reporting from all device users may help in the early detection of adverse trends or safety issues. The evaluation of these reports may result in:

- The dissemination of information, which may be used to prevent recurrence of the incident, or to alleviate the consequences of such incidents and / or
 - The device being updated, modified or taken off the market in cases when it's necessary to do so.
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Who should report adverse incidents to the HPRA?

Any person who prepares and/or uses a medical device during its life cycle. This is not limited to users in a healthcare setting. This also includes patients who use medical devices in the home and their carers and family members.

How does a user report adverse incidents to the HPRA?

Users should complete the Medical Device Incident User Report Form, which is available on the HPRA website www.hpra.ie or the report form can be obtained directly from the HPRA at devicesafety@hpra.ie. Reports are also accepted by telephone, fax or e-mail, particularly if the situation is considered urgent but should be followed up with a report form.

What is my role as user after I submit a vigilance report to the HPRA?

As the user, the HPRA recommend informing the manufacturer of the incident, retaining the device for inspection and being available to provide additional information to the HPRA and the manufacturer as necessary. Your assistance in this regard is very valuable. The manufacturer has a legal obligation to investigate the incident and complete a manufacturer's incident report, which is submitted to the HPRA for review.

What can I do to prevent adverse incidents from happening?

- only purchase devices which are CE marked
 - read the instructions for use thoroughly before use
 - ensure that the device is serviced regularly and maintained appropriately
 - report incidents to the HPRA and the manufacturer
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