IRISH MEDICINES BOARD

GUIDE TO INCIDENT REPORTING FOR GENERAL MEDICAL DEVICES AND ACTIVE IMPLANTABLE MEDICAL DEVICES

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This guide does not purport to be an interpretation of the law and/or regulations and is for guidance purposes only.

CONTENTS

1. SCOPE

This guide has been written to support, and to be used in association with, the information outlined in the Irish Medicines Board's (IMB) *Guide to the Vigilance System for Medical Devices*. This guide focuses on the area of incidents, defining what incidents are and outlines the different roles and responsibilities, which users, distributors and manufacturers have in the handling of such incidents.

The IMB is also the Competent Authority (CA) for *in-vitro* diagnostic medical devices. However, this guide does not cover the area of *in-vitro* diagnostic medical devices. This area is dealt with separately in the *Guide to Incident Reporting for In-vitro Diagnostic Medical Devices*.

2. INTRODUCTION

The Irish Medicines Board, as the Competent Authority for general medical devices and active implantable medical devices, has the responsibility of coordinating and recording details relating to incidents. This process is referred to as the vigilance system and is outlined in the *Guide to the Vigilance System for Medical Devices*.

For the above process to be effective it is important that the user, distributor and manufacturer have a clear understanding of what an incident is and the actions that must be taken on the discovery of an incident.

3. DEFINITION OF AN INCIDENT

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

Incidents in medical devices may arise due to:

- shortcomings in the design or manufacture of the device itself
- inadequate instructions for use
- inadequate servicing and maintenance
- locally initiated modifications or adjustments
- inappropriate user practice
- inappropriate management procedures
- inappropriate environment in which a device is used or stored
- selection of the incorrect device for the purpose

This list does not purport to be definitive and each case should be handled individually.

The aim of incident reporting is to improve the protection of health and safety of patients, users and others by reducing the likelihood of the same type of incident being repeated in different places at different times.

This is achieved by the evaluation of the **reported incidents** and where appropriate, dissemination of information that could be used to prevent such repetitions or to alleviate the consequences of such incidents.

4. THE AIMS AND OBJECTIVES OF INCIDENT REPORTING

The Medical Devices Directive 93/42/EEC outlines that there is a **mandatory obligation** on the manufacturer to report all incidents that occur to the CA of the State in which they occur. In Ireland, this is the IMB. User reporting is **not** mandatory in Irish law but is strongly encouraged by the IMB.

Article 10 of the Medical Devices Directive 93/42/EEC states that manufacturer must report:

a) any malfunction or deterioration in the characteristics and performance of a device, as well as any inaccuracies in the instruction leaflet which might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health.

b) any technical or medical reason in relation to the characteristics or performance of a device for the reasons referred to in subparagraph (a) leading to systematic recall of devices of the same type by the manufacturer.

A device which shows no malfunction or deterioration but nevertheless has a characteristic which could lead to an incident should be reported.

5. WHAT INCIDENTS NEED TO BE REPORTED TO THE IMB

The following describes the type of incidents that should be reported to the IMB as outlined in the European Commission Guidelines on a Medical Devices Vigilance System MEDDEV 2.12-1 rev 6.

Any event which meets all three basic reporting criteria A – C listed below is considered as an incident and must be reported to the relevant national CA. The criteria are that;

A An event has occurred

This also includes situations where testing performed on the device, examination of the information supplied with the device or any scientific information indicates some factor that could lead or has led to an event.

Typical events include, but are not limited to:

(i) A malfunction or deterioration in the characteristics or performance. A malfunction or deterioration should be understood as a failure of a device to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions.
(ii) False positive or false negative test result falling outside the declared performance of the test.
(iii) Unanticipated reaction or unanticipated side effect.
(iv) Interactions with other substances or products.
(v) Degradation / destruction of the device (e.g. fire).
(vi) Inappropriate therapy.
(vii) An inaccuracy in the labelling, instructions for use and/or promotional materials. Inaccuracies include omissions and deficiencies. Omissions do not include the absence of information that should generally be known by the intended users.

B The manufacturer's device is suspected to be a contributory cause of the incident

In assessing the link between the device and the incident the manufacturer should take account of:

(i) The opinion, based on available evidence, of healthcare professionals
(ii) The results of the manufacturer's own preliminary assessment of the incident
(iii) Evidence of previous, similar incidents
(iv) Other evidence held by the manufacturer

This judgement may be difficult when there are multiple devices and drugs involved. In complex situations, it should be assumed that the device may have caused or contributed to the incident and the manufacturers should err on the side of caution.

C The event led, or might have led, to one of the following outcomes

(i) Death of a patient, user or other person
(ii) Serious deterioration in state of health of a patient, user or other person. A serious deterioration in state of health can include:
- life-threatening illness

- permanent impairment of a body function or permanent damage to a body structure
- a condition necessitating medical or surgical intervention to prevent a) or b). Examples include clinically relevant increase in the duration of a surgical procedure or a condition that requires hospitalisation or significant prolongation of existing hospitalisation
- any indirect harm (see definition under 4.11) as a consequence of an incorrect diagnostic or IVD test results when used within manufacturer's instructions for use
- foetal distress, foetal death or any congenital abnormality or birth defects

Note: Not all incidents lead to death or a serious deterioration in health. The non-occurrence of such a result might have been due to other fortunate circumstances or to the intervention of healthcare personnel.

It is sufficient that:

i) An incident associated with a device happened, and
ii) the incident was such that, if it occurred again, it might lead to death or serious deterioration in health.

Users should report all problems, faults and incidents that occur with medical devices to the manufacturer so that a follow-up investigation can be carried out.

In Ireland the first point of contact may be the distributor and in this case users should ask the distributor to advise the manufacturer of the problem, fault or incident.

On receipt of the notification from the user, the manufacturers should assess the reported problem. He must determine if it is a problem that fulfils the criteria of the vigilance system. It is the manufacturer that is obliged to report the incident to the IMB. Where the manufacturer or user is unsure of whether the incident should be reported to the IMB, they should seek advice from the IMB.

6. WHAT INCIDENTS DO NOT NEED TO BE REPORTED

Device-related problems or minor failures and discrepancies that are not reportable under the vigilance system should be recorded locally by either, or both, the manufacturer, distributor and user to assist in trend analysis. Multiple similar events or trends should be communicated to the IMB, as they may be indicators of potential future problems or may point to inadequacy in the quality assurance system.

The following categories of incidents **are not usually reportable** to the IMB:

- Deficiencies of a new device that are found prior to use, i.e. deficiencies before putting into service or placing on the market by the manufacturer.
- Incidents that occur independently of the device but are the result of the patient's medical condition.
- Incidents where there are expected or foreseeable side effects.
- Incidents where there is negligible likelihood of the occurrence of death or serious injury.
- Incidents that occur when a device is in use beyond its service life or shelf life.

Note: Since 1998, manufacturers are obliged by way of Directive 93/42/EEC to provide the service life or shelf life of a medical device. Medical devices placed on the market before that date may not have a specified service life or shelf life. In this case the user should endeavour to determine a shelf life with the manufacturer where possible. It is very important in this case that all services / maintenance records are reviewed and appropriate records are kept in relation to all equipment.

7. THE ROLE OF USERS IN INCIDENT REPORTING

There is no mandatory requirement on users to report but it is strongly encouraged that at the time of reporting to the manufacturer, the user also informs the IMB.

All users of medical devices, including staff and contractors, should be aware of their responsibilities with regard to incident reporting.

They should be aware of any relevant local hospital (HSE, voluntary or private) procedures that they need to follow.

Ideally such procedures should ensure that:

- All staff understand what an incident is and what they should do on discovery of an incident.

- All incidents are promptly acted upon.

- The manufacturer / distributor is promptly informed of the incident.

- When it has been identified that the incident is one that needs to be reported to the IMB, the IMB must be promptly informed in writing using the IMB *Medical Device Incident User Report Form*, which can be downloaded from the IMB website, www.imb.ie.

Note: Initial notification will be accepted by phone but it must be followed up in writing.

- Following the occurrence of an incident, appropriate local action is taken to ensure the safety of patient, user and other person that was involved in the incident.

- All details relating to incidents are recorded accurately; including date, time, the incident and the name, model, serial / lot numbers of the device.

- The devices involved in the incident together with other material evidence (e.g. packaging) are clearly identified and kept in quarantine, where practicable, until all interested parties, including the IMB, have been consulted and the investigation is completed.

- Where the quarantine is not practicable, the state of the device at the time of the incident is recorded for use in any subsequent investigation. Where possible, it is recommended that photographic evidence is taken.

- The manufacturer is given access to the device for examination, interviews with staff / users, access to any other relevant information as deemed appropriate.

- When the hospital / agency or the patient wishes to retain the device as evidence, it is strongly advised that the manufacturer is allowed 'supervised examination' of the device to help them determine the root cause of the fault.

- Following the local examination of the device, which was involved in the incident, it is, in most instances, returned to the manufacturer for further testing or disposal. In some instances the hospital, patient or the IMB may wish to retain the device for their own independent examination. In this instance the responsibility for the safe keeping of the devices lies with the body requesting the examination.

- Regular reviews are taken to ensure that the procedures are effective and are being followed.

- Several proactive preventative steps can be taken by professional users to prevent or reduce the likelihood of an incident occurring, e.g. documentation and training.

- Development of local procedures to ensure there is appropriate medical device equipment management including, purchase, training, documentation, repairs, servicing, and storage.

- Development of appropriate local procedures to ensure that all medical devices are traceable i.e. hospital equipment, devices used in patient homes or patient implanted devices. This will facilitate the prompt location of devices in instances where corrective action or a recall of product or patient for assessments required.

8. THE ROLE OF DISTRIBUTORS IN INCIDENT REPORTING

All distributors of medical devices, including sub-contractors, repair and service companies, should be aware of how to handle incidents that are reported to them. There is no mandatory obligation on the distributor outlined in Directive 93/42/EEC but it is good practice and in the best interest of the distributor to understand the legislation as they are often the first point of contact for Irish healthcare professionals.

All distributors should be familiar with Article 10 of Medical Devices Directive 93/42/EEC, and Article 10 of the Active Implantable Medical Devices Directive 90/385/EEC, which outlines the requirements that the manufacturer must meet to comply with the post-market surveillance aspects of the regulations.

All distributors should have clear agreed procedures with the manufacturers they represent, which define the way in which the distributor should address all the post market surveillance issues that arise on the Irish market, including;

- Supply and commissioning of devices
- Manufacturer / distributor and user device acceptance
- Training in the use of the device
- Service and repair (where applicable)
- Training in the service and repair (where applicable)
- Incident reporting
- Circulation of advisory notices
- Implementation of field safety corrective action

In particular the distributor and the manufacturer should have an agreed practice outlining:

- How the investigation or evaluation of incidents, if appropriate, should be conducted by the distributor on behalf of the manufacturer
- How and what information should be recorded
- How the different parties should be advised of the incident, including the IMB.
- What testing / evaluation needs to be conducted and where
- The circulation of field safety notices

9. THE ROLE OF MANUFACTURERS IN INCIDENT REPORTING

All manufacturers of medical devices should be aware of their responsibility with regard to incident reporting and investigation.

All manufacturers should be familiar with Article 10 of the Medical Devices Directive 93/42/EEC and Article 10 of the Active Implantable Medical Devices Directive 90/385/EEC, which outlines the requirements that the manufacturer must meet to comply with the post-market surveillance aspects of the regulations:

- The mandatory obligation of the manufacturer to report all incidents and reporting of such incidents should be built into the quality system.

- The mandatory obligation of the manufacturer to report the incident as soon as possible after they have been advised of the incident.

The following paragraph describes the **timescale for the initial reporting of an incident** to the IMB as outlined in the MEDDEV 2.12-1 rev 6.

Upon becoming aware that an event has occurred and that one of its devices may have caused or contributed to that event, the medical devices manufacturer must determine whether it is an incident. The following time lines apply:

Serious public health threat
Immediately, (without any delay that could not be justified) but not later than two calendar days after awareness by the manufacturer of this threat.

Death or unanticipated serious deterioration in state of health
Immediately, (without any delay that could not be justified) after the manufacturer established a link between the device and the event but not later than ten elapsed calendar days following the date of awareness of the event.

Others
Immediately, (without any delay that could not be justified) after the manufacturer established a link between the device and the event but not later than thirty elapsed calendar days following the date of awareness of the event.

If after becoming aware of a potentially reportable incident there is still uncertainty about whether the event is reportable, the manufacturer must submit a report within the timeframe required for that type of incident.

- The manufacturer must ensure that all incidents are examined and investigated in a timely and appropriate manner.

- The manufacturer must ensure that he establishes an effective communication system with all parties involved, the user, the distributor and the IMB.

- The manufacturer must ensure that his distributor knows what to do on the receipt of an incident report and understands his role in the investigation process.

- The manufacturer must ensure that he carries out a detailed investigation or if he is not in a position to do so that he informs the IMB that he is unable to pursue the investigation.

- The manufacturer must ensure that he informs users of any associated risks with their products. He must organise and coordinate any identified field safety corrective action in a timely manner. He must organise and coordinate the device recall if it is identified as necessary. He must also ensure that all recalled product is reconciled.

- In carrying out the above, the manufacturer must ensure that his distributor knows his role in the completion of corrective actions and recalls.

The manufacturer must submit the relevant documentation in relation to the incident to the Human Products Safety Monitoring Department of the IMB. The *Manufacturer's Incident Report Form* and the *Field Safety Corrective Action Report Form* may be downloaded from the IMB website, www.imb.ie or obtained from the European Commission Guidelines on a Medical Devices Vigilance System MEDDEV 2.12-1 rev 6. The MEDDEV vigilance forms can be downloaded from the European Commission website, www.ec.europa.eu.

The final vigilance report must outline the manufacturer's investigation findings and his suggested corrective action, for example:

- No action
- Include data in the manufacturer's trend analysis
- Additional surveillance or follow up of devices in use
- Corrective action on future production or the devices in use
- Recall
- Dissemination of information to users

10. THE ROLE OF THE IMB IN INCIDENT REPORTING

As referred to earlier, the IMB as the CA for medical devices in Ireland has the responsibility of coordinating and recording details relating to incidents occurring in Ireland.

The IMB must therefore:

- Record and investigate all incidents that it is aware of.
- Monitor the progress of the manufacturer's investigation ensuring that it is thorough covering all aspects, in a timely manner.
- In particular circumstances carry out the complete investigation, when the manufacturer is not in a position to do so.
- Consult with relevant independent experts when additional expertise or analysis is required.
- Review all documentation and information resulting from the investigation and determine if the proposed action outlined by the manufacturer is the most appropriate.
- Review field safety notices prior to their circulation to users (not a mandatory requirement of the legislation but advisable, if possible).
- When necessary meet with the manufacturer to assist with discussion and analysis.

Following review of the documentation provided by the manufacturer, the IMB may decide:

- To take no action but record the incident for future trend analysis.
- To gather more information.
- To make further recommendations to the manufacturer.
- To advise the European Commission and other CAs. (The drafting of the CA report is done in consultation with the manufacturer.)
- To consult with the relevant Notified Bodies on matters relating to conformity assessment.
- To consult with the European Commission e.g. re-classification.
- To recommend further user education.
- To provide recommendations to users.
- To carry out further action to supplement the manufacturer's action.

11. HOW TO REPORT AN INCIDENT TO THE IMB

All incidents should be reported as soon as possible. Serious cases, where death or serious injury has occurred, should be reported to us by the fastest means available, preferably on-line, fax or e-mail followed up by a confirmatory telephone call. Any telephone reports necessary should be followed up as soon as possible with a written report form.

Users (professional or other) who wish to report an incident occurring in Ireland that has arisen with a device should report using the *Medical Device Incident Report Form*, which is available on request from the IMB or may be downloaded from the IMB website, www.imb.ie.

The *Manufacturer's Incident Report Form* and the *Field Safety Corrective Action report form* are available on request from the IMB or may be downloaded form the IMB website. They can also be obtained in the European Commission Guidelines on a Medical Devices Vigilance System MEDDEV 2.12-1 rev 6. This form should be completed and submitted by the manufacturer when initially notifying the IMB of an incident occurring in Ireland and the initiating an investigation **and** when the investigation has been completed.

Note: The IMB does not have a reporting form that can be completed by the distributor. The distributor must advise the manufacturer of all incidents and once advised the manufacturer must coordinate the investigation including the reporting of the incident to the CA.

12. WHO TO CONTACT AT THE IMB

This guide and associated documents can be found under the medical devices section of the IMB website, www.imb.ie.

Alternatively, they can be obtained from the IMB directly as follows:

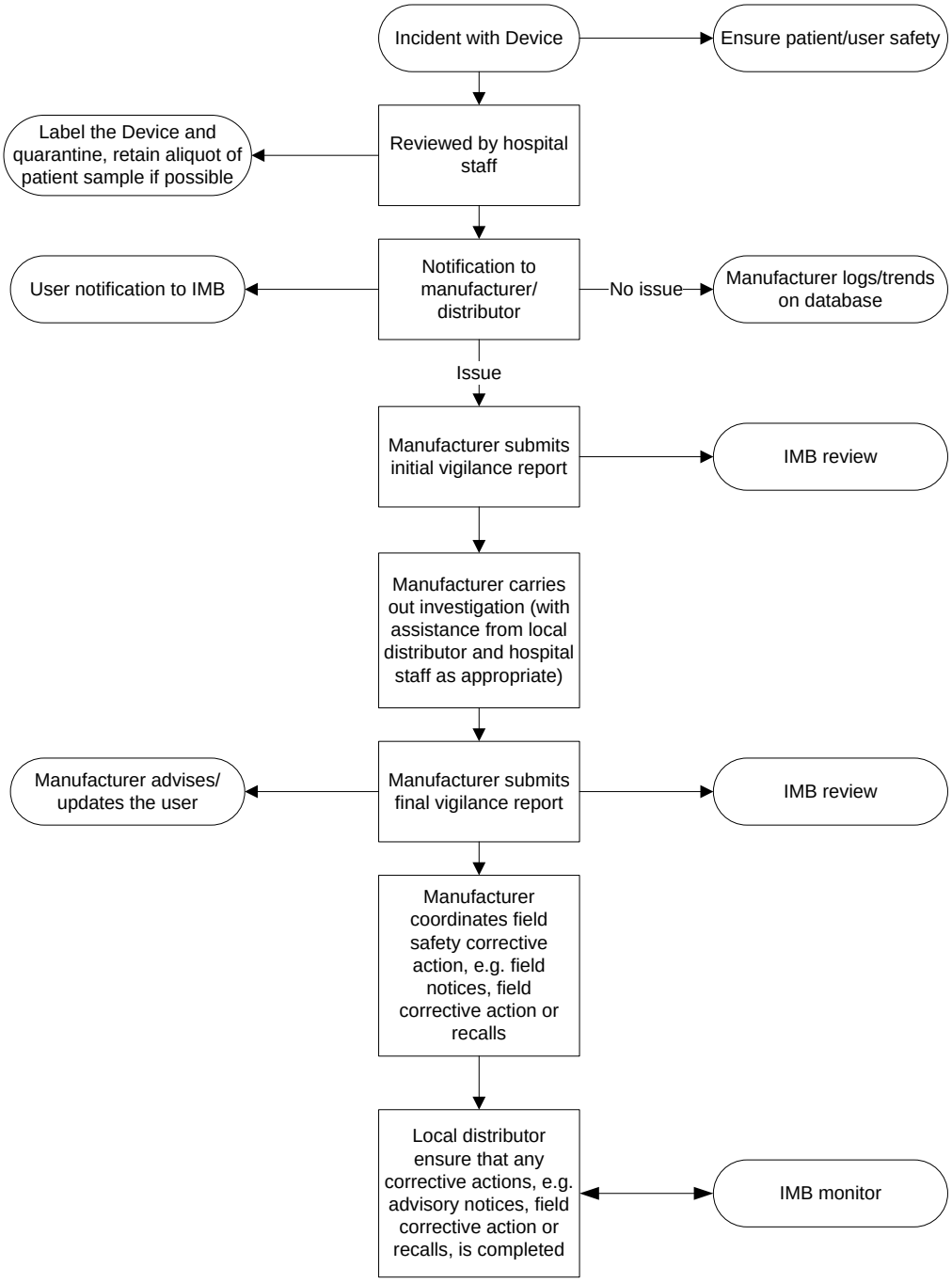
Human Products Safety Monitoring Department
Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
Email: vigilance@imb.ie

The IMB encourages communication with the medical device sector. Should you have specific queries please address them to the Human Products Safety Monitoring Department of the IMB who will endeavour to be of assistance.

Communication can be made by telephone, fax, e-mail or by post to the above address.

APPENDIX 1 INCIDENT FLOW CHART



APPENDIX 2 BIBLIOGRAPHY

1. IMB Guidance Note 6 - Glossary of Terms for Medical Devices

2. IMB *Guide to the Vigilance System for Medical Devices*

3. IMB *Guide to Field Safety Corrective Actions for Medical Devices and In-vitro Diagnostic Medical Devices*

4. MEDDEV 2.12-1 rev 6 European Commission Guidelines on a Medical Devices Vigilance System