HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Incident Reporting for *In-vitro* Diagnostic Medical Devices

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

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1 SCOPE

This guide has been written to support and to be used in association with the information outlined in the Health Products Regulatory Authority's (HPRA) 'Guide to the vigilance system for medical devices'. This guide focuses on the area of incidents for *in-vitro* diagnostic medical devices (IVDs), defining what incidents are and outlining the different roles and responsibilities which users, distributors and manufacturers have in the handling of such incidents.

2 INTRODUCTION

The Health Products Regulatory Authority, as the Competent Authority (CA) for general medical devices, active implantable medical devices and *in-vitro* diagnostic 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'.

This guide pertains to incidents for products that fall within the category of an IVD as defined by the Directive 98/79/EC. Broadly, an IVD is a device intended by a manufacturer for use for the *in-vitro* examination of specimens derived from the human body to provide information regarding a physiological, pathological or therapeutic state. IVDs are classified on the basis of the risk associated with them and the relative dangers to the public and/or a patient treatment/diagnosis by an IVD failing to perform as intended. For further information on IVDs and products that are excluded from the scope of the legislation, reference should be made to the HPRA 'Guide to the *in-vitro* diagnostic medical devices legislation'.

For this 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 patients, users or other persons.

As the majority of IVDs do not come into contact with patients it can be difficult to demonstrate direct harm to patients, unless the device itself causes deterioration in state of health. Harm to patients is more likely to be indirect, as a result of an action taken or not taken on the basis of an incorrect result obtained with an IVD.

In addition, it may be difficult to determine if a serious deterioration in the state of a patient's health was or could be the consequence of an erroneous test result obtained with an IVD, or if

the harm was the consequence of an error by the user or third party. There should be a predisposition to report under such circumstances.

In the case of potential errors by users or third parties, labelling and instructions for use should be carefully reviewed for any possible inadequacy. This is particularly true for devices used for self-testing where a medical decision may be made directly by the user who is the patient. Inadequacies in the information supplied by the manufacturer that led or could have led to harm to users, patients or third parties should be reported.

Incidents for IVDs most likely result as a consequence of a medical decision or action taken or not taken on the basis of information or result(s) provided by the IVD.

Examples of these types of incidents include:
- misdiagnosis
- delayed diagnosis
- delayed treatment
- inappropriate treatment
- transfusion of inappropriate materials

Incidents for IVDs may arise due to:
- shortcomings in the design or manufacture of the IVD itself
- inadequate instructions for use
- inadequate servicing and maintenance
- locally initiated modifications or adjustments
- inappropriate user practice
- inappropriate management procedures
- inappropriate environment in which an IVD is used or stored
- selection of the incorrect IVD 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 *In-vitro* Diagnostic Medical Devices Directive 98/79/EC 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 HPRA. User reporting is **not** mandatory in Irish law but is strongly encouraged by the HPRA.

Article 11 of the *In-vitro* Diagnostic Medical Devices Directive 98/79/EC 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.

An IVD 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 HPRA

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

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 IVD, examination of the information supplied with the IVD 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 an IVD 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 IVD (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 IVD is suspected to be a contributory cause of the incident

In assessing the link between the IVD 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 combination IVDs involved. In complex situations, it should be assumed that the IVD may have caused or contributed to the incident and the manufacturers should err on the side of caution.

For incidents involving combination IVDs the manufacturer of each IVD should submit a separate incident report to the HPRA.

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 as a consequence of an incorrect diagnostic or IVD test results when used within the manufacturer's instructions for use
- foetal distress, foetal death or any congenital abnormality or birth defects

Note: Not all incidents lead to death or 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 an IVD 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 IVDs 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 and 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 HPRA. Where the manufacturer or user is unsure of whether the incident should be reported to the HPRA, they should seek advice from the HPRA.

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 HPRA, 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 HPRA:

- Deficiencies of a new IVD 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 IVD 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 an IVD is in use beyond its service life or shelf life do not need to be reported.

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 HPRA.

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

They should be aware of any relevant local hospital/health board 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 are promptly informed of the incident.
- When it has been identified that the incident is one that needs to be reported to the HPRA, the HPRA must be promptly informed in writing using the HPRA *Medical Devices Incident User Report Form*, which can be downloaded from the 'Publications and Forms' section of www.hpra.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 the 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 IVD involved in the incident together with other material evidence (e.g. patient sample, reagent or packaging) are clearly identified and kept in quarantine, where practicable, until all interested parties, including the HPRA, 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 IVD for examination, interviews with staff/users, access to any other relevant information as deemed appropriate.
- When the hospital/agency or the patient wish to retain the device as evidence, it is strongly advised that the manufacturer is allowed 'supervised examination' of the IVD to help them determine the root cause of the fault.
- Following the local examination of the IVD, 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 HPRA 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, point of care IVDs or devices used in patient homes. This will facilitate the prompt location of IVDs 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 IVDs, 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 98/79/EEC legislation 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 11 of the IVD Directive 98/79/EC, 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 IVD acceptance criteria
- Training in the use of the device
- Service and repair (where applicable)
- Training in the service and repair (where applicable)
- Incident reporting
- Circulation of field safety 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 HPRA.
- 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 11 of the IVD Directive 98/79/EC, 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 HPRA as outlined in the MEDDEV 2.12-1.
Upon becoming aware that an event has occurred and that one of its IVDs may have caused or contributed to that event, the manufacturer must determine whether it is an incident. The following time lines apply in a case of:

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 10 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 30 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 an effective communication system is established with all parties involved, the user, the distributor and the HPRA.
- The manufacturer must ensure that their distributor knows what to do on the receipt of an incident report and understands their role in the investigation process.
- The manufacturer must ensure that a detailed investigation is carried out, or if not in a position to do so, that the HPRA is informed that they are unable to pursue the investigation.
- The manufacturer must ensure that users of any associated risks with their products are informed. The manufacturer must organise and coordinate any identified field safety corrective action in a timely manner, and organise and coordinate the device recall if it is identified as necessary. The manufacturer must also ensure that all recalled product is reconciled.
- In carrying out the above, the manufacturer must ensure that their distributor knows their role in the completion of field safety corrective actions and recalls.

- The manufacturer must submit the relevant documentation in relation to the incident to the Medical Devices Department of the HPRA.

The 'Manufacturer's Incident Report Form and the Field Safety Corrective Action Report Form' may be downloaded from 'Publications and Forms' section of www.hpra.ie, or obtained from the European Commission Guidelines on Medical Devices Vigilance System MEDDEV 2.12/1. The MEDDEV vigilance forms can be down loaded from the European Commission website.

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

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

10 THE ROLE OF THE HPRA IN INCIDENT REPORTING

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

The HPRA 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 HPRA 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, where possible.)
- 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 HPRA

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 and within the required timelines, preferably on-line, fax or email 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 User Report Form', which is available on request from the HPRA or may be downloaded from the 'Publications and Forms' section of www.hpra.ie.

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

Note: The HPRA 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 HPRA

This guide and associated documents can be found under the 'Publications and Forms' section of www.hpra.ie.

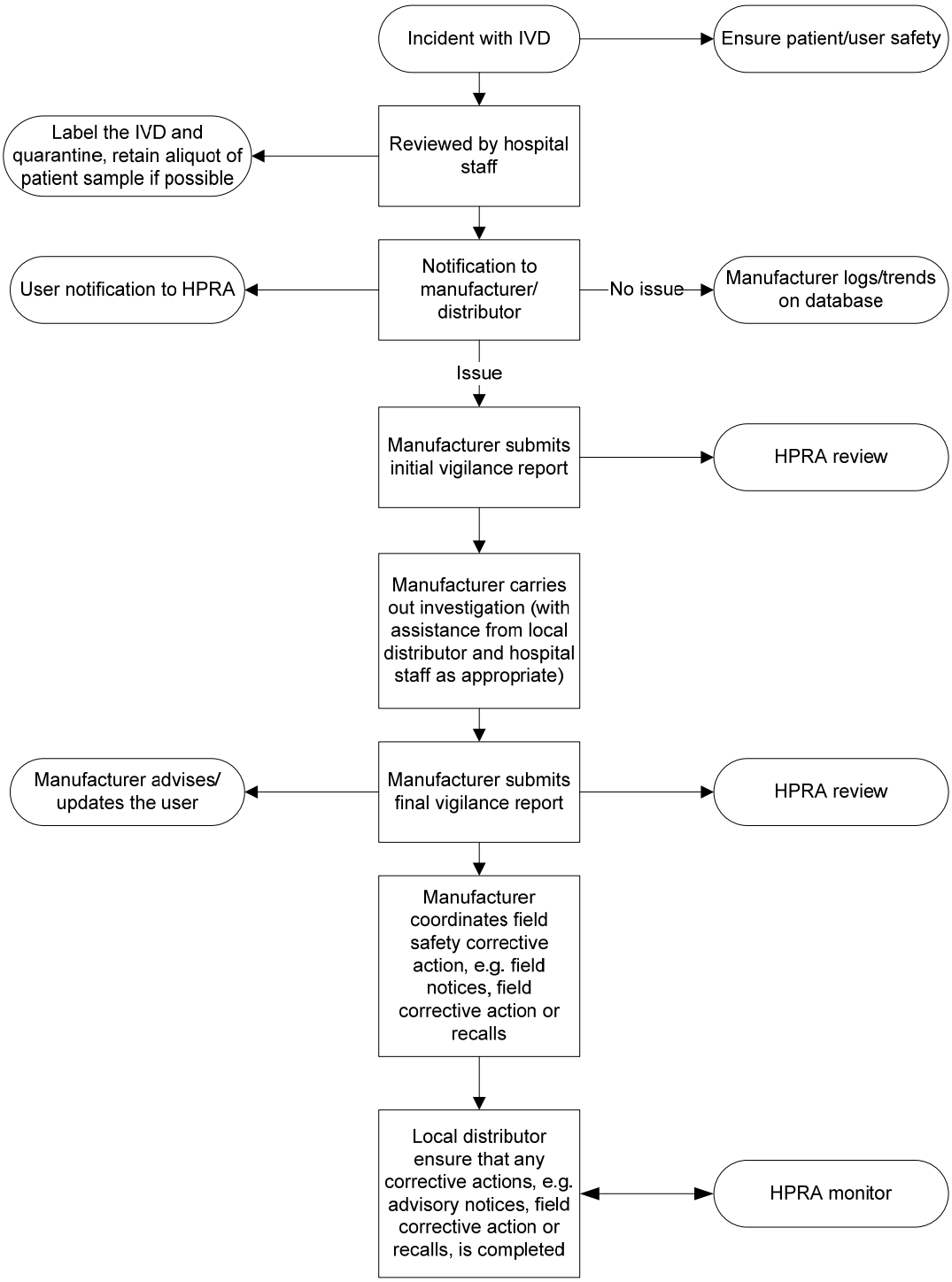
Alternatively, they can be obtained from the HPRA directly as follows:
Medical Devices Department
Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
D02 XP77

Telephone: +353-1-6764971
Fax: +353-1-6344033
Email: devicesafety@hpra.ie

The HPRA encourages communication with the medical device sector. Should you have specific queries please address them to the Medical Devices Department of the HPRA who will endeavour to be of assistance.

Communication can be made by telephone, fax, email or by post to the above address.

APPENDIX 1 INCIDENT FLOW CHART



APPENDIX 2 BIBLIOGRAPHY

1 Guidance Note 6 - Glossary of Terms for Medical Devices

2 HPRA 'Guide to the vigilance system for medical devices'

3 HPRA 'Guide to field safety corrective actions for medical devices and *in-vitro* diagnostic medical devices'

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