

Guide to Vigilance System for Medical Devices



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1 SCOPE

This guide describes the Health Products Regulatory Authority's (HPRA) vigilance system for medical devices as required by the relevant Articles of Directives 93/42/EEC, 90/385/EEC, and 98/79/EC, and additionally outlines how the system operates in Ireland.

2 INTRODUCTION

The Medical Devices Directive (93/42/EEC), the Active Implantable Medical Devices Directive (90/385/EEC) and the *In-vitro* Diagnostics Medical Devices Directive (98/79/EC) include requirements for medical devices manufacturers to report certain types of incidents to the Competent Authority (CA).

The HPRA became the CA on 1 October 2001 for general medical devices and active implantable medical devices, under the Statutory Instruments S.I. No. 252 of 1994, S.I. No. 253 of 1994 respectively, and also S.I. No. 444 of 2001. The HPRA also became the CA on 29 June 2001 for *in-vitro* diagnostic medical devices under S.I. No. 304 of 2001.

The Directives also outline the obligations on CAs to share details of certain incidents reported to them, between each other and with the European Commission. The vigilance system is the name given to the process of notification and evaluation of these incidents.

Under the Irish medical devices legislation, the CA is obliged to institute and co-ordinate a reporting system for incidents associated with the use of medical devices in Ireland. The system is intended to protect the health and safety of patients, users and others by reducing the likelihood of the same type of incident being repeated in the European Economic Area (EEA) and to correct product problems.

This is achieved by:

- a) the evaluation of reported incidents by the CA and Member States, if appropriate
- b) the dissemination of information which could be used to prevent a reoccurrence of the incident, or to alleviate consequences of such incidents, as required
- c) the device being modified or taken off the market, as required.

3 REQUIREMENTS OF THE VIGILANCE SYSTEM

The European Commission has issued guidelines setting out the requirements of the reporting system for medical devices and *in-vitro* diagnostic medical devices, titled the 'European Commission Guidelines on Medical Devices Vigilance System MEDDEV 2.12-1'. This guideline sets out the reporting system requirements and includes:

- a) Definitions
- b) Advice on how to operate the reporting system
- c) Guidelines on what types of incidents should be reported, and timescales for reporting incidents and field safety corrective actions
- d) A recommended format for a manufacturer's incident report from manufacturers to CAs
- e) A recommended format for a manufacturer's field safety corrective action report (FSCA) to CAs
- f) A recommended template for a field safety notice (FSN)
- g) A recommended template for a national CA report
- h) Responsibilities of a CA
- i) Responsibilities of the Notified Bodies
- j) Role of the European Commission
- k) Role of users
- l) Guidelines on what types of incidents are communicated to Member States and to the European Commission in CA reports
- m) A suggested hierarchy for determining a lead CA where necessary.

It is strongly advised that manufacturers obtain a copy of this guideline and use it in the handling of vigilance reports. Manufacturers should also ensure that these guidelines are made known to their authorised representatives in the EEA, persons responsible for placing devices on the market and any other agents authorised to act on their behalf for purposes related to medical device vigilance, so that the manufacturer's responsibilities may be fulfilled. The manufacturer should also consider informing official distributors and other relevant groups as appropriate.

It is pointed out that the guidance outlined in the above European guidance document in relation to CAs is applied by the HPRA.

All data held by the HPRA in relation to vigilance is held in confidence as outlined by Article 15 of the Active Implantable Medical Devices Directive (90/385/EEC), Article 20 of the Medical Devices Directive (93/42/EEC) and Article 19 of the *In-vitro* Diagnostics Medical Devices Directive (98/79/EC).

4 WHO SHOULD REPORT

Manufacturers should report all serious incidents to the appropriate national CA on whose territory the incident occurred. In Ireland, all incidents occurring in Ireland should be reported to the HPRA.

While currently there is no mandatory reporting system for users, reporting of serious incidents by the user is encouraged. The user should also ensure that the manufacturer is informed of the incident and that the user has separately reported it to the HPRA (see also

section 11). Further information is also contained in the HPRA 'Guide to incident reporting for general medical devices and active implantable medical devices' and also in the 'Guide to incident reporting for *in-vitro* diagnostic medical devices'.

5 WHAT SHOULD BE REPORTED

As required by the legislation, the following types of incidents and FSCA should be reported by the manufacturer to the HPRA:

- a) Any malfunction of 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 to deterioration in health*.
- b) Any technical or medical reason due to a *risk of serious injury or death* resulting in the recall of a device from the market by the manufacturer or the issuance of an advisory notice.

Suggestions as to the type of incidents to be reported are provided in section 5 of the European Commission Guidelines on a Medical Devices Vigilance System MEDDEV 2.12-1.

If incidents occur outside the EEA, which lead to corrective action relevant to CE marked devices which are on sale or are in use in the EEA, then manufacturers should notify the relevant Competent Authorities within the EEA, including the Competent Authority where the legal manufacturer is located.

6 TIMESCALE FOR THE INITIAL REPORTING OF AN INCIDENT

A vigilance report should be made as soon as possible to the Vigilance and Compliance Section of the Human Products Safety Monitoring Department of the HPRA. Notification from the manufacturer to the HPRA should occur within:

- a) 2 days for a serious public health threat
- b) 10 days for death or unanticipated serious deterioration in the state of health
- c) 30 days for others

These are the timelines outlined in Section 5.1.7 of the 'European Commission Guidelines on a Medical Devices Vigilance System MEDDEV 2.12-1'.

7 WHO WILL INVESTIGATE AN INCIDENT

The manufacturer has the responsibility for investigating the incident and reporting the outcome to the HPRA, which monitors the initial action. The HPRA is to be informed of

progress with the ongoing investigation by way of an interim report and may be consulted at any point by the manufacturer. In addition the HPRA may contact the manufacturer at any stage during the investigative stage to determine progress or to request information. The HPRA may also take action or request the manufacturer to take further action to supplement the actions already taken.

In certain cases, where the manufacturer is not able to carry out the investigation, the HPRA may investigate the vigilance issue. In this case, the manufacturer will be informed of the outcome.

The manufacturer should prepare a final report using the recommended template in the European Commission Guidelines on a Medical Devices Vigilance System MEDDEV 2.12-1 after the investigation is complete (see below). This should be forwarded to the HPRA where it is reviewed by the relevant HPRA staff and external experts, as appropriate. The manufacturer should ensure that the required post-investigation corrective action(s) is completed. The CA may advise other CA's of the outcome, as required. In certain cases the CA may also monitor experience with similar devices made by different manufacturers.

8 FORMS FOR VIGILANCE REPORTING

The HPRA requires that the manufacturer uses the report format in Annex 10.3: Manufacturer's Incident Report Form and Annex 10.4: Field Safety Corrective Action Form, of the European Commission Guidelines, as appropriate. The Manufacturer's Incident Report Form should be used for both the initial and/or a final report and the 'type of report' box should be ticked as appropriate.

The 'Manufacturer's incident report form' and the 'Field safety corrective action report form' are available on request from the HPRA, may be downloaded from the HPRA website or can be obtained in the European Commission Guidelines on a Medical Devices Vigilance System MEDDEV 2.12-1.

While it is recommended that these forms be used for reporting, other formats may be acceptable provided all the fields required by the European guideline are covered.

8.1 Initial report

The report should be filled in with as much detail as is available at the time of making the report. It must be pointed out that a report should not be unduly delayed because of incomplete information.

- a) An identifiable reporter i.e. manufacturer or a healthcare professional
- b) The name of the medical device or IVD

- c) The manufacturer of the device if the report is made by the healthcare professional or user
- d) Incident date, description and outcome
- e) Distributor of the device on the Irish market and where possible on the EU market
- f) Manufacturer's preliminary comments.

The HPRA and external experts, where necessary, carry out an assessment of the report provided by the manufacturer. They will then liaise with the manufacturer regarding the overall report, preliminary comments and the proposed timescale for follow-up. If the initial report is by means other than by letter post (e.g. fax, telephone or e-mail) it should be followed up as soon as possible by written confirmation.

8.2 Final report

A more detailed report is required by the manufacturer that covers detail on the investigation carried out. The root cause identified, any proposed corrective actions and any other relevant details should be included.

When the final report is received it is again reviewed. If no further action is required the file is closed and the manufacturer is informed. If further action is required the following possibilities may need to be considered:

- a) Additional surveillance or follow-up of devices in use
- b) Corrective action on future production
- c) Corrective action on devices in use
- d) Dissemination of information to users e.g. by way of advisory notice
- e) Recall
- f) Keeping the European Commission and other CAs informed
- g) Further user education

If corrective action is required, the manufacturer must inform the HPRA of the action required. If it is considered necessary by the HPRA to disseminate information to the users the HPRA will consult with the manufacturer, and medical practitioner if appropriate.

If a FSCA (including a recall) is deemed necessary then the manufacturer must issue a FSN in conjunction with the FSCA initiation. Copies of this FSN should be forwarded to the HPRA for review. The HPRA 'Guide to field safety corrective actions for medical devices' and 'Guide to incident reporting for *in-vitro* diagnostic medical devices' should be referred to in the event of a FSCA.

In certain cases it may be considered necessary by the HPRA to provide further education to the users of the device or in some cases manufacturers of similar devices.

9 LIAISON WITH OTHER COMPETENT AUTHORITIES

Medical device vigilance reports may be received from other CAs within the EEA. In this case, the HPRA will ensure assessment and follow through of the report for the Irish market. The manufacturer, where possible, should provide the identity of distributors to the CA where the report was initially lodged. This will provide invaluable assistance in determining where the product is in use on the EEA market.

The HPRA, after receiving a medical device vigilance report via this route, will determine if the medical devices in question is on the Irish market. If the contact details of the distributors for the Irish market are not available from the reporting CA then the manufacturer will be contacted by the HPRA to provide details on the distributor and details of the locations supplied.

If the HPRA is the co-ordinating CA then it will liaise directly with the manufacturer with regard to the vigilance report and outcome on behalf of the other EEA member states.

10 LIAISON WITH THE EUROPEAN COMMISSION

The European Commission, in addition to the CAs, is copied on any information relating to FSCA and any issues where there is serious risk to the safety of patients or other users, but where no corrective action is yet established. These CA reports are treated confidentially and are not forwarded onward to users or other interested parties.

Regarding serious risk to the safety of patients or other users, Article 14b of the General Medical Devices Directive (93/42/EEC), Article 13 of the *In-Vitro* Diagnostic Medical Device (98/79/EC) and Article 14 of the Active Implantable Medical Devices Directive (90/385/EEC) allow for necessary and justified transitional action in relation to a product or group of products, limiting the availability of such products in order to ensure that public health requirements are observed.

In addition the 'safeguard clause' (Article 8 of the Medical Devices Directive (93/42/EEC) and the *In-Vitro* Diagnostics Medical Devices Directive (98/79/EC) and Article 7 of the Active Implantable Medical Devices Directive (90/385/EEC)) may be invoked where it is considered that the medical device in question may compromise the health and safety of the patient, users or, where applicable, other persons. If the safeguard clause is to be used the HPRA will notify the EU Commission and the manufacturer immediately.

11 USER REPORTING SYSTEM

Currently, reporting of incidents by the user is not mandatory in Irish law. However, users are encouraged to report any incidents, particularly those that result in death, to the HPRA. Users

should report incidents to the manufacturer so that the manufacturer can instigate an investigation and, if necessary, implement any corrective action that is required post-investigation.

Users should report incidents to the HPRA using the *Medical Device Incident User Report Form*, which is available on request from the HPRA or may be downloaded from the HPRA website. All information supplied will be treated confidentially. However, the manufacturer will be contacted to determine the cause of the incident and to instigate an investigation. If the medical device in question is available it should not be tampered with but should be placed in a safe place so that examination, if deemed necessary, can be carried out at a later date.

12 WHO TO CONTACT AT THE HPRA

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

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

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