Recalls & Advisory Notices
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Purpose: This procedure covers the actions to be taken once Acme or a National Competent Authority receives information concerning an “Incident” involving a Medical Device. An “Incident” being any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, 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. It follows the Guidelines on a Medical Devices Vigilance System (1) and is applicable to “Incidents” occurring within the Member States of the European Economic Area (EEA) and Switzerland.

Responsibility: Overall responsibility is with the Quality and Technical Departments in conjunction with the Managing Director.

Scope: Acme management, Authorised Representatives and persons responsible for placing the product on the market.

1. General Principles

1.1 The procedure outlines the European system for the notification and evaluation of “Incidents” and Field Safety Corrective Actions (FSCA) involving medical devices, known as the Medical Device Vigilance System. **Note: A FSCA is a synonym for recall or withdrawal as defined in the Guidelines.**

1.2 The principal purpose of the Medical Device Vigilance System is to improve the protection of health and safety of patients, users and others by reducing the likelihood of recurrence of the incident elsewhere. This is to be achieved by the evaluation of reported “Incidents” and, where appropriate, dissemination of information, which could be used to prevent such repetitions, or to alleviate the consequences of such incidents.

1.3 Once a potential “Incident” occurs, the reporting route is generally to Acme directly by the customer as a “complaint” or it can be via the Competent Authority (in the UK the MHRA), who the customer may contact in the first instance. This route is outside Acme’s control.

1.4 An initial assessment of the “complaint” can be raised from the “Handling of Complaints” Procedure, SOP 19 and recorded on a “Customer Complaint Sheet”, MLD 11.02.

1.5 **Note:** In the Guidelines, reporting under the Medical Device Vigilance System is not usually required when:

- Deficiency of a device found by the user prior to its use
- Event caused by patient conditions
- Service life or shelf-life exceeded
- Protection against a fault functioned correctly
- Expected and foreseeable side-effects
- Negligible likelihood of occurrence of death or serious deterioration in state of health

1.6 An initial investigation will commence on receipt of the product involved in the complaint. The “Handling of Complaints” Procedure indicates that a more detailed analysis may be required depending on the analysis of results. This will initiate an “Assessment for Recall/Advisory Notices” investigation and subsequent report (available template, MLD 11.03).

1.7 Upon the findings documented by the Technical Department’s analysis, a review will be held and chaired by the Managing Director, and attended by the relevant managers from the departments involved. The review will be minuted and documented.

1.8 The review must consider whether or not an “Incident” has occurred. Any event that meets all three basic reporting criteria (a) – (c) listed below is considered as an “Incident” and must be reported to the relevant National Competent Authority. The criteria are that:

a. An event has occurred.
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b. Acme’s device is suspected to be a contributory cause of the “Incident” (e.g. a malfunction or deterioration in the characteristics or performance).

c. The event led, or might have led, to one of the following outcomes:
   - death of a patient, user or other person
   - serious deterioration in state of health of a patient, user or other person

Refer directly to the Guidelines; examples of “Incidents” are given in Annex 1.

1.9 Where necessary, a “HOLD” label (MLD 2.05) will be allocated to any affected lots of products and/or components and these will be quarantined until the final outcome is established.

2. Incident Reporting

2.1 Once an “Incident” has been confirmed 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 2 calendar days after awareness by Acme of this threat.
   - **Death or unanticipated serious deterioration in state of health**: IMMEDIATELY (without any delay that could not be justified) after Acme has 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 Acme has 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, Acme must submit a report within the timeframe required for that type of incident.

All report times refer to when the National Competent Authority must first be notified.

2.2 In general, the report should be made to the National Competent Authority in the country of occurrence of the “Incident” unless specified differently in the Guidelines.

2.3 Acme must submit an “Initial Incident Report” to the National Competent Authority for recording and evaluation. The “Complaint Report Sheet”, “Assessment for Recall/Advisory Notices” report, the management review minutes and any other relevant documents or pictures can act as the source of the initial report. Each initial report must lead to a final report unless the initial and the final report are combined into one report. A report form template for a “Manufacturer’s Incident Report” is given in Annex 3 of the Guidelines and a Word format is available at:

Note: not every “Incident” report will lead to a corrective action.

2.4 Acme will provide a follow-up-report to the National Competent Authority if the investigation time reaches the time line given to the National Competent Authority within the initial report.

2.5 There will be a final report that is a written statement of the outcome of the investigation and of any action. Examples of actions may include:
   - no action;
   - additional surveillance of devices in use;
   - preventive action on future production;
   - FSCA (i.e. recall or withdrawal).

Note: The Notified Body will be kept informed of any issues affecting certification.
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3. **Recalls**

3.1 The Medical Device Directive (2) requires Acme to report to the National Competent Authority any technical or medical reason leading to a systematic recall of devices of the same type by Acme. Those reasons are any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use that might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health.

3.2 Once a recall action has been established (3)*, this will be notified by Acme to the customers via a Field Safety Notice (Annex 5), a template for which is available as MLD 11.07, “Urgent Field Safety Notice”.

* Recommended in the Guidelines.

3.3 Acme should issue a notification to the Competent Authorities of all countries affected at the same time and also to the National Competent Authority responsible for the company. A report form template for the notification “Field Service Corrective Action” is given in Annex 4 of the Guidelines and a Word format is available at: http://ec.europa.eu/enterprise/medical_devices/meddev/report_form_field_safety_corrective_action.doc

A copy of the “Urgent Field Safety Notice” will accompany the notification.

3.4 Any defective products either returned by the customer and/or in Acme quarantine will be disposed of or re-worked as appropriate.

3.5 Figure 1 represents the flow of actions followed under the vigilance system.

3.6 Note: The National Competent Authority should place Acme’s final report on file and make any other observations necessary. The files investigation may then be endorsed as “complete”.

In the case of the UK (MHRA) there is further guidance on the EU vigilance system (4). The expected interaction with the MHRA with respect to a FSCA directly from this guidance (Appendix E) is given in Figure 2.

**References**

1. Guidelines on Medical Device Vigilance System; MEDDEV 2.12-1 rev 5; April 2007
4. MHRA Directives Bulletin no.3 – Guidance on the operation of the EU vigilance system in the UK, September 2008
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Figure 1

Complaints Flow Chart
Illustrating the Reporting of Recalls (Guidelines on Medical Device Vigilance System; MEDDEV 2.12-1 rev 5; April 2007)

Initial Customer Complaint (can be via e.g. MHRA)

Initial Investigation (Report on MLD 11.02)

Potential justifiable cause?

Yes

No

Issue customer letter, (MLD 11.01 template) indicating findings

Return goods in accordance with SOPs 6 & 22

Incident?

Yes

No

Conduct Corrective Action in accordance with SOP 19

Issue customer letter, (MLD 11.01 template) indicating faults & corrective actions

Recall or Withdrawal

Further detailed assessment (Report on MLD 11.03)

Confirmed?

Yes

No

Issue Manufacturer’s Incident Report (Annex 3) – Final

Issue Field Safety Corrective Action (FSCA) with UFSN to Competent Authority (Annex 4)

Keep Notified Body informed of any issues affecting certification

Issue Manufacturer’s Incident Report (Annex 3) – Initial/Follow-up

FSCA required?

Yes

No

Issue Manufacturer’s Incident Report (Annex 3) – Final
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Figure 2: FSCA flow chart: manufacturer interaction with the MHRA

- Determine whether hospital/retail level FSCA etc
- Advise notified body where applicable
- Optional
  MHRA provides comments on draft FSCA letter
- Discuss proposed FSCA with the MHRA
- Copy of FSCA letter to other affected CAs
- Advise customers of FSCA by fastest appropriate means (e.g. tel, fax, visit etc.) depending on urgency
- Ensure customers receive written copy of FSN
- Progress FSCA – reconciliation against distributed product etc.
- Initial FSCA report form and copy of final FSN to the MHRA
- Agree milestones with the MHRA for interim and final reports
- Interim reports to the MHRA as necessary
- Final report to the MHRA

MHRA reviews need for separate notice
### 8.5 Improvement

#### 8.5.1 Continual improvement *(General)*

The organization shall *continually improve the* identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

*The organization shall establish documented procedures for the issue and implementation of advisory notices.*

*These procedures shall be capable of being implemented at any time.*

*Records of all customer complaint investigations shall be maintained (4.2.4).*

*If investigation determines that the activities outside the organization contributed to the customer complaint, relevant information shall be exchanged between the organizations involved (see 4.1).*

*If any customer complaint is not followed by corrective and/or preventive action, the reason shall be authorized (see 5.5.1) and recorded (see 4.2.4).*

*If national or regional regulations require notification of adverse events that meet specified reporting criteria, the organization shall establish documented procedures to such notification to regulatory authorities.*
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<th>Author: J Bloggs</th>
<th>Date: 4/12/07</th>
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<td>Details</td>
<td>The original procedure was based on Guidelines on a Medical Vigilance System from 1998, substantial changes have occurred since that time, e.g. incorporating GHTF guidance. The current guidelines (MEDDEV 2.12-1 rev 5) date from April 2007. These contain extra and updated templates for reporting of “Incidents”. Based on this, the procedure has been totally rewritten. Reference original procedure “Recall and Advisory Notices”, issue 4.</td>
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<td>Details</td>
<td>Where appropriate, reference to the Medical Device Standard BS EN ISO 13485 is indicated in blue and BS EN ISO 9001 in red. Text of clauses (sub-clauses) referenced added. Reference to MHRA Directives bulletin added (4) and the Figure 2, the expected interactions in the UK with the MHRA.</td>
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