Vigilance Reporting

Vicky Medley - Head of QMS, Medical Devices

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Why?
About us

What we do

The Medicines and Healthcare products Regulatory Agency regulates medicines and medical devices in the UK.

Recognised globally as an authority in its field, the agency plays a leading role in protecting and improving public health and supports innovation through scientific research and development.
Protecting and promoting your health
The concept of the logo

The logo was designed in the image of the public (men and women of all ages) rejoicing. It means that people take each other’s hands and aim for happiness as one. A picture of a happy heart is hidden between two joyful persons.

The catchphrase

Together with the creation of the logo, the below catchphrase was formulated, in order to serve as “the pillar for promoting the MHLW staff to be unified in their resolve to realize the ideal of health, labour, and welfare administration supported by the public.”

For people, for life, for the future

※ The above catchphrase succinctly expresses the idea that MHLW undertakes a role of protecting people and their lives not only in the present but for the future. Moreover, in order to achieve the purpose of the catchphrase, the action guidelines below are set forth for the Ministry employees to abide by:

…undertakes a role of **protecting** people and their lives not only in the present but for the future.
Adverse Incident Reporting

• Requirement of Medical Device Regulations globally

• Vigilance – European Terminology

• Manufacturers report “death” or “serious deterioration in health” incidents to Competent Authorities

• Competent Authorities record and evaluate centrally and take appropriate action
Requirements
Medical Devices Directive Requirements

• Medical Devices Directive
  • (Article 10 and Annexes II, IV, V, VI, VII)

• Active Implantable Medical Devices Directive
  • (Article 8 and Annexes II, IV, V)

• In-Vitro Diagnostics Devices Directive
  • (Article 11 and Annexes III, IV, VI)
Medical Devices Directive Requirements

MDD / AI MD / IVDD

• ...include an obligation for the manufacturer to notify the Competent Authorities of the following incidents immediately on learning of them...
• (i) Any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which 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.

• (ii) Any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to in subparagraph (i) to systematic recall of devices of the same type by the manufacturer.

• .....Field Safety Notices, Recalls ⇒ Field Safety Corrective Action

Incidents

FSCAs / Recalls
Requirements in ISO 13485

- Clause 7.2.3:
  → Communication with customers regarding advisory notices

- Clause 8.5.1
  → Documented procedures for issue of advisory notices
  → Records required for complaints investigations
  → If CAPA not required, document rationale
  → Compliance with national or regional regulations: reporting to Competent Authorities
Medical Device Vigilance System

System by which manufacturer notifies Competent Authorities of any malfunction or deterioration in the characteristics or performance of a device, or inadequacy of IFU or labelling which might lead to patient harm, or any issues resulting in systematic recall of devices.
Market Surveillance

QMS

PMS

Vigilance

Reactive PMS

Proactive PMS

Post Market Clinical Follow-up

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Vigilance Guidelines MEDDEV 2.12-1

• Reporting of INCIDENTS occurring within the EEA on

a) Devices which carry the CE-mark

b) Devices that do not carry the CE-mark but fall under the directives scope (e.g. custom made devices)

c) Devices that do not carry the CE mark because they were placed on the market before … the medical devices directives

d) Devices that do not carry the CE-mark but where such INCIDENTs lead to CORRECTIVE ACTION(s) relevant to the devices mentioned in a), b) and c)
What’s an Incident?

• An event has occurred

• The Manufacturer’s device is suspected to be a contributory cause of the Incident

• The event led, or might have led, to:
  • Death of a patient, user or other person
  • Serious deterioration in state of health of a patient, user or other person
Might have led to .....?

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:
• An INCIDENT associated with a device happened and
• The INCIDENT was such that, if it occurred again, it might lead to death or serious deterioration in health
Serious?

• 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)
  
  • Any indirect harm 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
Serious Public Health Threat?

• Any event type which results in imminent risk of death, serious deterioration in state of health, or serious illness that requires prompt remedial action. This would include:

• Events that are of significant and unexpected nature such that they become alarming as a potential public health hazard e.g. human immunodeficiency virus (HIV) or Creutzfeldt-Jacob Disease (CJD). These concerns may be identified by either the National Competent Authority or the MANUFACTURER

• The possibility of multiple deaths occurring at short intervals
Reportable Incident

An event occurred

Manufacturer’s device is associated with event

Event led or could lead to death or serious injury of a patient, user or other person

Reportable Incident

- MedDev 2.12.1 and GHTF/SG2/N54R8
Conditions where reporting is not usually required

Deficiency of a device found by the user prior to its use

- MedDev 2.12.1 and GHTF/SG2/N54R8
Conditions where reporting is not usually required

Adverse event caused by patient conditions

- Example from MedDev: A patient died after dialysis treatment. The patient had end-stage-renal disease and died of renal failure, the MANUFACTURER’s investigations revealed the device to be functioning as claimed and the INCIDENT was not attributed to the device.

- MedDev 2.12.1 and GHTF/SG2/N54R8
Conditions where reporting is not usually required

Service life or shelf-life of the medical device exceeded

- MedDev 2.12.1 and GHTF/SG2/N54R8
Conditions where reporting is not usually required

Protection against a fault functioned correctly

- MedDev 2.12.1 and GHTF/SG2/N54R8
Conditions where reporting is not usually required

Expected and foreseeable side effect meeting all of the following criteria:

• clearly identified in the manufacturer’s labelling;
• clinically well known as being foreseeable;
• documented in the risk assessment prior to the occurrence of the incident and
• clinically acceptable in terms of the individual patient benefit

- MedDev 2.12.1 and GHTF/SG2/N54R8
Conditions where reporting is not usually required

Negligible likelihood of death or serious injury

- Example from the MedDev: MANUFACTURER of a pacemaker released on the market identified a software bug and quantified the probability of occurrence of a serious deterioration in state of health with a particular setting to be negligible. No patients experienced adverse health effects.

- MedDev 2.12.1 and GHTF/SG2/N54R8
Reporting is not usually required when

1. Deficiency of a device found by the user prior to its use
2. Adverse event caused by patient conditions
3. Service life or shelf-life of the medical device exceeded
4. Protection against a fault functioned correctly
5. Expected and foreseeable side effects
6. Negligible likelihood of occurrence of death or serious injury

• + Abnormal Use

Not reportable

MedDev 2.12.1 and GHTF/SG2/N54R8
Use errors: when to report

- Death or serious deterioration in state of health
- Serious public health threat
- Significant trend
- Field Safety Corrective Action

Report to National Competent Authority

- MedDev 2.12.1
Must Report - Trends

If a significant increase or trend of events or incidents that are usually excluded from individual reporting

The manufacturer should have suitable systems in place for proactive scrutiny of trends in complaints and incidents occurring with their devices

Report to National Competent Authority

- MedDev 2.12.1
Must Report - Field Safety Corrective Actions

- Field Safety Corrective Actions
- Includes FSCA based on incidents occurring outside the EU
- Field Safety Notices

Report to National Competent Authority and Competent Authorities of all countries affected

- MedDev 2.12.1
Reports

Initial Report  Investigation  Interim Report  Final Report

- MedDev 2.12.1
When to report?

- Directives state “immediately” i.e. without any delay that cannot be justified
- Max defined (calendar days)

<table>
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<tr>
<th>Type of incident</th>
<th>Maximum</th>
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<tbody>
<tr>
<td>Serious Public Health Threat</td>
<td>2 days</td>
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<tr>
<td>Death or Unanticipated Serious Deterioration in the State of Health</td>
<td>10 days</td>
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<tr>
<td>Others</td>
<td>30 days</td>
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**Where to report?**

**Incident** – The Competent Authority in the country the incident occurred.

**FSCA** - CAs of all countries affected + CA in country of manufacturer or EC Representative.

Vigilance contacts for Member States listed on the European Commission website:

Required Reporting to BSI

eVigilance Portal
Web Address

https://medtech.bsi
group.com
Notified Body Assessment

Every QMS Audit
Every design / type examination renewal & as part of most change
Technical File Audits
Unannounced Audits

Assess Impact of Vigilance Issues on the Certification

NB Assessment of Complaints & Vigilance
Competent Authorities

- Informs manufacturer of user reports
- Risk assessment of incident reports and FSCA (including adequacy of manufacturer actions)
- Incident investigation (sometimes)
- Monitoring manufacturer’s follow up actions
- Liaison with Notified Bodies, Users, other Competent Authorities etc
- Dissemination of information to the public (if necessary)
Analysis of Complaints and Adverse Events

Increasing requirement, plus allows review of:

- Rare events
- Unexpected events
- Increase in events
- Severity of events
- Different patient populations affected
- Trends with users

- What impact on risk assessment?
- Requirements for corrective action? (warnings, design changes, recall)
Device Use Experience & Knowledge

- Updates to:
  - Risk Management
  - Clinical Evaluation
  - Instructions for Use

Improve the protection of health and safety of patients, users and others by reducing the likelihood of reoccurrence
Questions?
Thank you

<table>
<thead>
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<td>Links:</td>
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...making excellence a habit™
Additional Information
- For Reference Only
Field Safety Corrective Action (FSCA)

An action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. Such actions should be notified via a field safety notice.

Field Safety Notice (FSN)

A communication to customers and/or users sent out by a manufacturer or its representative in relation to a Field Safety Corrective Action.
EUDAMED

European Databank on Medical Devices. Central repository for:

• data relating to registration of manufacturers and medical devices placed on the Community market,
• data relating to certificates issued, modified, supplemented, suspended, withdrawn or refused,
• data obtained in accordance with the vigilance procedure,
• data concerning clinical investigations.
Device specific guidance documents

MHRA Guidance: www.mhra.gov.uk

- VG01 Joint Replacement Implants
- VG02 Artificial Heart Valves
- VG03 Breast Implants
- VG04 Coronary Stents
- VG05 IVD Blood Glucose Meters
- VG06 Inferior Vena Cava Filters
- VG07 Intraocular Lenses
- VG08 Neurostimulators