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Health Products and Food Branch Inspectorate
Inspectorat de la Direction générale des produits de santé et des aliments



Recall Medical Devices

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Overview

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- **Responsibilities**
- **Regulatory Requirements**
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 - » Recall Procedure
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Definitions

Recall:

- Recall in respect of a medical device that has been **sold**, means any action taken by the manufacturer, importer or distributor of the device to recall or **correct** the device, or to notify its owners and users of its defectiveness or potential defectiveness after becoming aware that the device
 - » may be hazardous to health,
 - » may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety, or
 - » may not meet the requirements of the Food and Drugs Act or the Medical Devices Regulations.



Definitions

Sell:

- **Sell includes offer for sale, expose for sale, have in possession for sale and distribute whether or not the distribution is made for consideration.**

Correction:

- **Correction means the repair, modification, adjustment, relabelling or inspection (including patient monitoring) of a product without its physical removal.**



Responsibilities

Manufacturers, Importers and Distributors:


- **take steps necessary to minimize risk to consumers**
- **comply with all applicable regulatory requirements concerning recalls such as:**
 - » an effective, documented recall procedure
 - » distribution records that are sufficient to support an effective recall
 - » reporting recalls to Health Canada (manufacturers and importers)



Responsibilities

Health Canada:

- Evaluate the company's recall strategy
- Request a health hazard evaluation as required
- Provide scientific, technical or operational advice
- Evaluate corrective actions taken to prevent recurrence of the problem
- Monitor recall effectiveness
- Facilitate public awareness
- Where recall action is deemed inadequate, take steps to minimize the risk




Regulatory Requirements

Distribution Records:

➤ Section 53, Medical Devices Regulations:


“The distribution record shall contain sufficient information to permit complete and rapid withdrawal of the medical device from the market.”



Regulatory Requirements

Distribution Records (... cont'd):

- **Section 53: sufficient information to**
 - » fully identify the affected device
 - » determine quantity purchased/imported
 - » determine quantity still within company control
 - » determine quantity distributed and to whom
 - » facilitate compliance with recall reporting requirements




Regulatory Requirements

Distribution Records:

➤ Section 54, Medical Devices Regulations:

- “(1) The distribution record maintained by a manufacturer of an implant shall also contain a record of the information received on the implant registration cards forwarded to the manufacturer from a health care facility pursuant to section 67.*
- (2) The manufacturer of an implant shall update the information referred to in subsection (1) in accordance with any information received from the health care facility or the patient.”*



Regulatory Requirements


Distribution Records (... cont'd):

➤ Section 55, Medical Devices Regulations:

“The manufacturer, importer and distributor shall retain the distribution record maintained in respect of a medical device for the longer of

(a) the projected useful life of the device, and


(b) two years after the date the device is shipped.”



Regulatory Requirements

Distribution Records (... cont'd):

- **Section 56, Medical Devices Regulations:**
“Distribution records shall be maintained in a manner that will allow their timely retrieval.”
- **It is recommended that all records be retrievable within a 24-hour time period.**
- **Paper records should be stored in conditions which will maintain their integrity.**



Regulatory Requirements


Recall Procedure:

➤ **Section 58(b), Medical Devices Regulations:**

“The manufacturer, importer and distributor of a medical device shall each establish and implement documented procedures that will enable the manufacturer, importer or distributor to carry out

(a) ...


(b) an effective and timely recall of the device.”



Regulatory Requirements

Recall Procedure (... cont'd):


- **Section 58(b): What should an adequate recall procedure include?**
- **Purpose**
- **Scope**
 - » cover all medical devices handled by the company including imported/distributed devices of other manufacturers
- **References**
 - » Regulations
 - » Manufacturer's agreement(s)
- **Regulatory definition of “recall”**



Regulatory Requirements

Recall Procedure (... cont'd):


- **Responsibilities for key stages such as:**
 - » Recall initiation
 - » Risk evaluation
 - » Recall strategy
 - » Coordination & communication format
 - » Time limits consistent with risk level
 - » Reporting to Health Canada
 - » Effectiveness checks
 - » Criteria for closure



Regulatory Requirements

Recall Reporting:

- **Section 64 - initial report**
- **Section 65 - final report**




Regulatory Requirements

Recall Reporting (... cont'd)

Section 64 - initial recall report:

- Identification of device
- Manufacturer, importer information
- Reason for recall
- Risk evaluation
- Distribution information
- Recall notice
- Proposed recall strategy
- Action to prevent recurrence




Regulatory Requirements

Recall Reporting ... Section 64 (... cont'd)

Risk Evaluation:

- Nature and degree of seriousness of the hazard according to **priorities** (I, II, or III)
- Nature and size of the population at risk
- Whether any disease or injuries or death have already occurred from the use of the device



Regulatory Requirements


Recall Reporting ... Section 64 (... cont'd)

Recall Priorities:

Priority I: a situation in which there is a reasonable probability that the use of, or exposure to, a recalled product will cause serious adverse health consequences or death

Priority II: a situation in which the use of, or exposure to, a recalled product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote

Priority III: a situation in which the use of, or exposure to, a recalled product is not likely to cause any adverse health consequences




Regulatory Requirements

Recall Reporting ... Section 64 (... cont'd)

Recall Strategy: a planned course of actions for conducting a specific recall

- Depth of recall
- Recall communications
- Level of effectiveness checks
- Control of returned stocks if applicable
- Timeliness: initiation date, progress reports to Health Canada and anticipated closure date



Regulatory Requirements

Recall Reporting (... cont'd)

Section 65 - final recall report:

- **Results of the recall**
- **Action taken to prevent recurrence of the problem**



Web Posting

Medical device recalls are posted on the Inspectorate web site of Health Canada as follows:

- **Recall Posting Date**
- **Trade Name**
- **Manufacturer**
- **Recall Start Date**
- **Recall Number**
- **Hazard Classification**
- **Model/Catalog #, Lot/Serial #**
- **Reason for Recall**



Thank You!