Procedure: Product Recall

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# Purpose

This procedure describes the actions required to promptly and effectively recall therapeutic goods in accordance with:

* The current Uniform Recall Procedure for Therapeutic Goods (issued by the Australian Government)
* Section 65R of the Commonwealth Trade Practices Act
* The current New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods (Part 5: Uniform Recall Procedure for Medicines and Medical Devices).

# Scope

The scope of this procedure includes any products manufactured or marketed by [Company] in Australia or New Zealand and known to be or suspected to be non-conforming.

# Responsibilities

Amend company roles to reflect structure.

|  |  |
| --- | --- |
| Role | Responsibility |
| Quality Manager, Production Manager, Managing Director | * Directs product recall, providing expert input as required. * Provides resources for all actions to be completed. |
| Recall Coordinator | Manages all product recalls according to this procedure. |
| Australian/New Zealand government recall coordinator | * Decides the level of recall required * Approves the company’s actions. |

# Definitions

A **recall** is an action taken to resolve a problem with therapeutic goods for which there are **established deficiencies** in quality, efficacy or safety.

**Recall** means the permanent removal of the therapeutic goods from supply or use due to deficiencies in the quality, safety or efficacy of the goods. This includes:

* requests to pharmacists, doctors, nurses or others to check and return goods found to be defective
* removal from supply or use of goods with inherent design or manufacturing defects.

Recall does **not** include:

* removal of time-expired goods
* removal of appropriate goods to determine whether there are deficiencies relating to the quality, safety or efficacy.

A **recall file** means a file maintained by the recall coordinator to retain hardcopies of all records relating to the recall.

A **customer response log** means an electronic log maintained by the recall coordinator summarising the customer response relating to the recall.

# Procedure

Figure 1 provides a general overview of the recall procedure.



Figure 1: Overview of recall procedure

## Deciding if a product recall is necessary

A decision to recall a product may result from:

* stability testing results
* quality assurance audit
* customer complaint
* tampering of product
* advice received from Government drug evaluation bodies
* regulatory agency contact.

Information from these sources is examined by the quality manager to determine their accuracy and the possible extent, nature and seriousness of the issue. A team is assembled if the initial investigation finds that:

* product does not meet specifications
* product is contaminated, adulterated or altered
* product label or directions for use bear incorrect or inadequate information
* product does not meet claims for stability, sterility, pyrogenicity, safety or potency
* other negative information relating to safety or efficacy
* product packaging has been compromised
* government regulations are not satisfied.

The team will comprise:

* Quality Manager
* Production Manager
* Distribution / Warehouse Manager
* Managing Director
* Recall Coordinator.

The team reviews the information relating to the recall and by performing a formal risk assessment, determines:

* if the product should be recalled
* the extent of the recall
* the proposed method of notifying customers.

## Initiating a recall

If the decision to recall is granted, the following information is collected:

* nature of the problem and type of hazard i.e. risk to the user
* product name and description including dose form, ARTG number, pack size, strength or type
* batch number, item code, lot number and expiry date of affected product
* date manufactured
* quantity of batch, date and amount.

If the affected product is marketed internationally, then the recall coordinator notifies, in writing, the quality head of the company.

The recall log is updated to include:

* a description of the product being recalled
* the type of recall (recall, recall for product correction or hazard alert)
* the date affiliate companies were notified (if applicable).

A recall file is created to store all records relating to the recall.

## Product traceability

The warehouse / distribution expert must query the company sales database to determine which customers have received the affected product and account for all product quantities for later reconciliation. Ideally there will be database queries set up beforehand for the purpose of recall.

If the product has been sent in bulk to third party distribution centres to be further processed into smaller orders, the company must obtain this information so that the affected final customers are known. Ideally, the company and each third party distribution centre will have tested the ability to drill down to specific customers for any bulk lot received.

Effected product still in the company’s warehouses and in transit must also be identified.

If the Recall Coordinator is unable to obtain specific customers to which the affected product has been sent, then all potential customers must be involved in the recall process.

The warehouse / distribution expert may be required to trace finished goods batches affected by a suspect raw material lot number.

## Informing the regulatory authorities of a recall

The recall coordinator informs the Australian and/or New Zealand government recall coordinator of the recall via email. The recall coordinator includes a description of the recall, a draft recall letter (see Section 5.6) and a distribution list.

In some cases, the recall coordinator may contact the Australian and/or New Zealand government recall coordinator by phone while further information relating to the recall is obtained, however this is always followed up in writing.

The Australian and/or New Zealand government recall coordinator determines the classification, level, strategy and completion date for the recall. A response is received via fax or email.

|  |  |
| --- | --- |
| Recall | Description |
| Recall Classification | Class I – the products are potentially life-threatening or could cause serious risk to health  Class II – the products could cause illness or mistreatment, but are not Class I  Class III – the products may not pose a significant risk to hazard to health, but withdrawal may be initiated for other reasons. |
| Recall Level | Wholesale level – including medicine and device wholesalers, state purchasing authorities  Hospital level – including nursing homes, hostels and other institutions, hospitals, pharmacists, personnel in other hospital departments and warehouse level  Retail level – including retail pharmacists, medical, dental and other health care practitioners and wholesale and hospital level  Consumer level – including consumers, patients, wholesale, hospital and retail level. |

If the recall is classified as a retail or consumer level recall, then a media advertisement may also be necessary.

The recall log is updated to include the date that the Australian and/or New Zealand government recall coordinator was informed, interim and final report due dates, the Australian and/or New Zealand government recall coordinator reference and the date that the recall letter was approved.

All correspondence is filed in the recall file.

## Informing the ACCC of a recall

If the recall is safety-related (i.e. there is a risk of injury or harm to patients) it is a legal requirement to inform the ACCC (Australian Competition and Consumer Commission). The Australian and/or New Zealand government recall coordinator will inform the recall coordinator should the ACCC need to be informed.

The recall coordinator informs the ACCC of the recall in writing, and includes:

* a description of the goods subject to recall
* the nature of the defect, or dangerous characteristic of the goods
* whether the goods have been exported (to New Zealand).

The letter is filed in the recall file.

## Preparing a media advertisement

If the recall is at the consumer or retail level, and the consumers or retail outlets cannot be identified, then a media advertisement may be required. The Australian and/or New Zealand government recall coordinator will inform the recall coordinator of such a requirement.

The text for the media advertisement must be approved by the Australian and/or New Zealand government recall coordinator and includes (as applicable):

* a heading (for Class I or II recalls, ‘Urgent Medicines Recall’, or for Class III recalls, ‘Medicines Recall’)
* name of product
* ARTG number (AUST L or AUST R) where this appears on the label of the product
* batch or lot number (s)
* expiry date (s)
* other details to enable absolute identification of the product (e.g. catalogue number, part number, order number, etc.)
* reason(s) for the recall
* a statement on the continued use or supply of the product
* if the hazard is serious, indications of clinical symptoms and advice to consult a medical practitioner, if desired
* an indication of the timeframe for correction of provision of replacement stock
* contact telephone (toll free).

In the case of a Class I or II consumer level recall, a press release may also be required. The text of the media release will be developed by the corporate communications manager (or delegate) in consultation with the Australian and/or New Zealand government recall coordinator.

The media advertisement is filed in the recall file (hardcopy) and recall file (electronic).

## Preparing a recall letter

A recall letter is prepared by the recall coordinator using the company letterhead. A standard envelope is used, measuring 220 by 110 millimetres, with a thin red border along the top edge. The recall letter includes (as applicable):

* a heading (for Class I or II recalls, ‘Urgent Medicines Recall’, or for Class III recalls, ‘Medicines Recall’)
* batch or lot number
* expiry date
* other details to enable absolute identification of the product (e.g. catalogue number, part number, order number, etc.)
* the level at which the recall is being made (wholesale, hospital, retail, consumer)
* reason(s) for the recall
* necessity to identify and quarantine the product from further sale or supply
* the method of recovery (recall only)
* the method of correction (including proposed completion dates) (product correction only)
* the hazard (hazard alert only)
* a statement that consultation with the regulatory authorities has occurred
* a response form (see 5.6.1 Response form) to be returned by the customer as proof that the recall letter has been received and acted upon
* reference to the response form
* a statement that the response form must still be completed even if no affected stock is held
* a statement that a copy of the response form should be sent with any returned product (recall only)
* request to retain the recall letter in a prominent position for one month in case stock is in transit
* contact telephone and facsimile number.

Where the recalled stock has been distributed to a limited number of hospitals and the recall letter is not to be sent to all hospitals, then the following statement is also included:

‘If any of the recalled stock could have been transferred from your hospital to another, please immediately let the hospital know of the recall. It would be appreciated if you would then telephone [insert contact details] (long distance calls reverse charges) so that we can make contact with the hospital supplied from your hospital.’

### Response form

The response form includes (as applicable):

* batch or lot number of affected product
* a place to record the name of the organisation acknowledging the recall
* a place to record the name and signature of the person acknowledging the recall
* a place to record the date that the recall was acknowledged
* a place to record the quantity if stock to be returned (recall only)
* a means to return the response form to the recall coordinator (toll free fax, email).

## Distributing a recall letter

The recall letter and response form is sent in a recall envelope marked as ‘Urgent – Medicine’ or ‘Urgent – Hazard’ (as applicable).

Ideally, this should be two days or less after response from the Australian and/or New Zealand government recall coordinator.

The recall coordinator updates the recall log to include the date that the recall letters were sent.

The recall coordinator sends a copy of the final recall letter to the Australian and/or New Zealand government recall coordinator (if requested).

The recall coordinator sends a copy of the final recall letter to the New Zealand warehouse for their information.

A copy of the letter, the response form and distribution list are filed in the recall file.

## Receiving response forms

When the customer response form is received, the recall coordinator updates the customer response log to indicate the date that the response form was returned and the quantities of affected stock (recall only).

Each response form is filed in the recall file.

## Receiving returned product (recall only)

All returned product is transferred to the quarantine area to identify which stock is being returned as recalled product. This is to prevent warehouse personnel inadvertently returning recalled stock for use.

The recall coordinator reconciles the quantity of stock indicated on the customer response forms with the quantity returned, and updates the customer response log. Any discrepancies are noted and followed up as necessary.

When all product has been returned and reconciled, the recall log is updated, product labelled with reject status labels and transferred to the reject area.

## Destroying returned product

Returned product may be destroyed at an approved incineration facility according to the following procedure:

* The recall coordinator reconciles the amount of returned product from the reject location with the returned product transferred to incineration area.
* The recall coordinator arranges a suitable time with the incineration facility to perform and witness the incineration.
* The recall coordinator prepares a certificate of destruction detailing the date of destruction and the amount of product destroyed. The certificate of destruction is filed in the recall file.

When all returned product is destroyed the recall log is updated.

## Reviewing the root cause of a recall

An investigation to determine the root cause of the recall is carried out using Procedure QP809: Corrective and Preventative Action.

## Reporting a recall

The Australian and/or New Zealand government recall coordinator defines the intervals for interim and final reporting of the recall. At the defined intervals, a report is prepared by the recall coordinator and includes (as applicable):

* confirmation that the recall has been initiated and progressing (and without major impediments)
* proposed completion date for the recall
* the date that recall letters were distributed
* whether the initial investigation findings have changed the scope of the recall
* whether overseas suppliers have been informed of the recall
* confirmation (where practicable) that customers have received the recall letter (including customer list where applicable)
* the result of the recall (quantity returned, corrected, outstanding, follow-up activities, etc.)
* the method of destruction of returned goods
* the actions undertaken to prevent recurrence of the problem (corrective actions).

The recall log is updated to include the dates that each interim report and the final report were sent.

A copy of each interim report and the final report is filed in the recall file.

The recall team meets as and when required to discuss the progress of the recall.

## Closing a recall

The recall is closed when the final report is issued to the Australian and/or New Zealand government recall coordinator.

When the Australian and/or New Zealand government recall coordinator approves the final report, the recall log is updated.

## Recall log

The recall coordinator maintains a recall log. The recall log includes (as applicable):

* product to be recalled
* dates for the notification of the recall to affiliates (as applicable), notification to the Australian and/or New Zealand government recall coordinator, recall letter distribution, interim and final report dates, disposition of returned product
* Australian and/or New Zealand government recall coordinator or affiliate references.
* Customer response log

For each recall, a customer response log is prepared. The customer response log details, for each customer affected by the recall:

* whether the response form has been returned
* the quantities of affected stock
* the quantities of returned stock (recall only).

When the recall is closed, a copy of the customer response log is printed and filed in the recall file.

## Recall file

For each recall, a recall file (hardcopy, electronic or both) is prepared. The file contains records relating to the recall including:

* recall letter
* media advertisements
* ACCC letter
* customer distribution list
* customer response forms
* correspondence relating to the recall
* interim and final reports
* certificate of destruction.

Appendices

Amend as required or delete.

Definitions

Amend as required or delete.

| Term | Definition |
| --- | --- |
|  | Insert terms/abbreviations and definitions for those used within the procedure. Do not include any terms or abbreviations not used within the procedure. |
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| Doc. No. | Document Title |
| QP809 | Corrective and Preventative Action |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

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