

New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods

**Part 4:
Wholesaling of Medicines and Medical Devices**

**Part 5:
Uniform Recall Procedure for Medicines and
Medical Devices**



**MINISTRY OF
HEALTH**

MANATU HAUORA

Titles in this series are:

- Part 1: Manufacture of Pharmaceutical Products
- Part 2: Manufacture of Blood and Blood Products
- Part 3: Compounding and Dispensing
- Part 4: Wholesaling of Medicines and Medical Devices
- Part 5: Uniform Recall Procedure for Medicines and Medical Devices

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FOREWORD

Codes of good manufacturing practice (GMP) describe proven systems and procedures for the production and distribution of quality products. They also describe documentation systems to provide a traceable record of every batch or item produced.

This volume, which combines the Code of Wholesaling of Medicines and Medical Devices with a Uniform Recall Procedure for Medicines and Medical Devices, is the fourth in a series of Codes of GMP published by the Therapeutics Section of the Ministry of Health. The wholesaling part of the Code has been written to assist the wholesale section of the pharmaceutical and medical device industry in New Zealand; the recall procedures in Part V are applicable to all sections of the industry.

A Code of GMP must be regarded as no more than a minimum standard. Systems that go beyond the guidelines are encouraged. Every employee engaged in the wholesaling of medicines and medical devices should be aware of this document.

The Wholesaling Code represents a consensus reached by a working party of industry representatives convened by the Ministry. The high quality of the documents that the working party produced indicates the importance all parties placed on promoting high standards in work practices. It reflects what is expected nationally and internationally in order to protect the quality of therapeutic goods distributed in this country.

The Uniform Recall Procedure describes the actions which should be taken when a medicine or medical device needs to be recalled or modified in the field because the product is faulty or potentially unsafe. The Uniform Recall Procedure was developed following agreement reached with representatives of industry.

A handwritten signature in black ink, appearing to read 'David Smyth', written in a cursive style.

David Smyth
Acting Director-General of Health

ACKNOWLEDGMENTS

The Ministry acknowledges the assistance it has received from the “Code of GMP for Wholesaling and Recall” working party, which included representation from the Researched Medicines Industry Association of New Zealand Inc, the Proprietary Medicines Federation, the Association of Independent Pharmaceutical Wholesalers, the New Zealand Hospital Pharmacists’ Association, the Independent Pharmaceutical Manufacturers Association, the Health Industry Suppliers Association of New Zealand and the Ministry of Health. Members were **Brian Day, Melanie MacDonald, Roger Smart, Murray Campbell, Euan Galloway, Bruce Hemmingson, Jeff Douglas, Ross Paterson, Derek Fitzgerald, Trevor Nisbet and Doug Longmire.**

CONTENTS

Part 4:

WHOLESALE OF MEDICINES AND MEDICAL DEVICES

CHAPTER 1: INTRODUCTION	9
CHAPTER 2: APPLICATION AND INTERPRETATION	10
CHAPTER 3: DOCUMENTATION	11
CHAPTER 4: BUILDINGS AND GROUNDS	12
CHAPTER 5: FACILITIES	13
CHAPTER 6: PERSONNEL	14
CHAPTER 7: STOCK HANDLING AND STOCK CONTROL	15
• Security	
• Inwards Goods from Suppliers	
• Damaged Products or Materials	
• Returned Goods	
• Recall Procedures	
CHAPTER 8: TRANSPORT	17
CHAPTER 9: COMPLAINTS	18

Part 5:

UNIFORM RECALL PROCEDURE FOR MEDICINES AND MEDICAL DEVICES

CHAPTER 1: INTRODUCTION	21
CHAPTER 2: RECALL PROCEDURE	22
CHAPTER 3: INTERACTION WITH THE MINISTRY OF HEALTH	23
CHAPTER 4: RECALL LETTER FORMAT	25
• Suggested Recall Letter Format	
• Suggested Acknowledgment Form Format	

Part 5:

**UNIFORM RECALL PROCEDURE FOR MEDICINES AND
MEDICAL DEVICES**

CHAPTER 1

INTRODUCTION

- 1.1 Those responsible for the manufacture and distribution of medicines and medical devices must be able to recall faulty product from the distribution chain.
- 1.2 A recall is a method by which a product that has been distributed is removed from sale or from use and returned to the source of supply or is otherwise dealt with.
- 1.3 A recall may in some cases involve the correction of a fault or the modification of a product in the field.
- 1.4 Every New Zealand agent (that is: manufacturer, importer, distributor, packer, sponsor or owner of a medicine or medical device) and agents involved in medicine and medical device clinical trials should have a predetermined system of recalling a medicine or a medical device.
- 1.5 A recall of a medical device does not include the removal of an individual medical device for repair in the event of malfunction or failure as a result of normal ageing; nor for appropriate maintenance or lack of good maintenance.
- 1.6 The recall of a medical device does not include the removal of individual medical devices for modification due to technical improvement, other than when these improvements overcome inherent design or manufacturing defects.
- 1.7 The procedures and principles outlined in this part of the Code of Good Manufacturing Practice may also be used when a manufacturer or distributor needs to communicate product safety information to consumers, pharmacists or other health professionals.
- 1.8 Manufacturers should also refer to Chapter 8 of Part 1 of this series *Manufacture of Pharmaceutical Products*.

CHAPTER 2

RECALL PROCEDURE

2.1 Every New Zealand agent should have in place a written recall procedure which describes how a recall will be initiated and carried out. Every wholesaler should have a procedure describing how a recall requested by an agent will be conducted.

2.2 A procedure for the initiation and conduct of a recall should have two parts.

The first part should describe how complaints or problems regarding product quality are handled and how a decision to recall is made. It should include:

- the procedure for the reporting of problems within the company
- the assessment of problems by an appropriately qualified person
- the assessment of problem trends
- forwarding of problem reports to manufacturing/packing sites
- reporting of problems to the Ministry of Health
- how a decision to recall is made.

The second part should describe how a recall will be conducted and should include:

- the appointment of a recall co-ordinator
- the actions to be taken, listed in chronological order
- a description of the records that must be kept of the actions taken
- how technical details required for the recall will be obtained
- how distribution records will be obtained
- contact with the Ministry of Health
- contacts that need to be made with other organisations
- how the recall mailing list will be prepared
- mechanism of transmitting the recall
- preparation for the recall letter (see Chapter 4)
- provision of facilities for quarantine and disposal of returned stock
- preparation of a summary report for the Ministry of Health once the recall is completed.

2.3 A recall procedure for a wholesaler should cover:

- the appointment of a person in charge of expediting recalls
- a description of how stock can be traced within the stock control system
- quarantine arrangements for recalled stock
- records to be kept
- response to the agent.

CHAPTER 3

INTERACTION WITH THE MINISTRY OF HEALTH

- 3.1 All recalls must be carried out with the knowledge and consent of the Ministry of Health.
- 3.2 A recall should proceed as follows:
 - a) Initial contact between the company and the Ministry regarding a potential recall.
 - b) Supply of information to the Ministry: technical, distribution, assessment of risk, impact on users etc.
 - c) Decision on recall action is made following consultation between the company and the Ministry.
 - d) The recall action is planned and the recall letter or communication is written. Agreement on the contents of the recall letter is reached with the Ministry and approval to proceed with the recall is given.
 - e) The recall proceeds.
 - f) The Ministry may require progress reports.
 - g) At the completion of the recall the company provides the Ministry with a summary of the actions taken including: data on and the fate of the stock returned, response rate to the recall notification, any further technical information relating to the recall problem, and the action taken to prevent a recurrence of the problem.

Notes:

- An agent must immediately consult the Ministry of Health when there is reason to consider that a product recall may be required.
- The level of recall will generally reflect the safety risk and distribution. A recall may be to consumer, retail and/or hospital, medical professional or wholesaler level.
- A recall may initially be made by telephone, if necessary, but must be promptly followed by written confirmation.
- Thorough records of the recall should be made and should include information on the distribution of the recall letters, the stock returned, stock disposal etc. These records must be maintained and be available for inspection by Ministry staff.
- In the event of a consumer level recall, companies must have planned how this should be conducted so that it can be expedited promptly.

- If the recall is to consumer level, an appropriate paid advertisement and/or press statement should be submitted to the Ministry of Health for review before it is published.

- To report a possible recall, a product fault, or for further information please contact the Ministry of Health:

Tel 04 496 2176 (Medicines)

Tel 04 496 2364 (Medical devices)

or Tel 04 496 2000 (Ministry of Health general number)

Fax 04 496 2340
– faxed material should be marked "**URGENT**"

CHAPTER 4

RECALL LETTER FORMAT

- 4.1 A recall letter should:
- a) Be on the company letterhead.
 - b) Be dated.
 - c) Have a heading that states that it is a recall or product modification. If some other action is required the heading should contain appropriate wording describing this.
 - d) Give the brand name and any other name to identify the product.
 - e) Describe the strength, presentation and pack size of the medicine or give a description of the medical device.
 - f) Include the batch or lot number of the medicine or medical device. In some cases the medical device serial number or model number (or in the case of software, revision number) if present should be stated.
 - g) State the level to which the recall is being made (hospitals, wholesalers, hospital/retail pharmacies, consumer etc).
 - h) State the reason for the recall.
 - i) Indicate the health risk involved.
 - j) Give a clear indication of the action required and the steps to be taken in order to deal with the problem.
 - k) State the need to immediately isolate and quarantine the particular medicine or medical device involved in the recall to prevent further usage.
 - l) Describe the procedure to be followed in returning the medicine or medical device including compensation for return and replacement of product.
 - m) State that consultation has occurred with the Ministry of Health.
 - n) Be signed by the Recall Co-ordinator (or a senior member of the company management).
 - o) Include an acknowledgment form which is required to be returned as proof that the recall letter has been received and acted on. This form should be referred to in the text of the letter.

SUGGESTED RECALL LETTER FORMAT

Company letterhead

Date

Addressee

Level of recall

'Medicine Recall' (or as appropriate)

Product description (name, strength, pack, size etc)

Batch/Lot No.

Recall reason

Health risk

Action to be taken by recipient, eg

- Stop usage/Quarantine
- Return/hold

Statement that the acknowledgment form must be returned even if no stock is held

Further information regarding replacement stock or alternative products, etc if appropriate

Details of compensation

Statement that the recall action has been taken after consultation with the Ministry of Health (or a statement to this effect)

Signature, name and position of person signing the recall letter.

SUGGESTED

ACKNOWLEDGMENT FORM FORMAT

As much of this form as possible should be preprinted

**Acknowledgment Form/
Inventory of returned medicines**
(or other suitable name)

Statement that the form must be completed and returned
even if no stock is held

Product name and description:

Pack size:

Batch No:

Number of packs returned whole packs
partly used packs
(or as appropriate)

Space for returning organisation to indicate if no stock is held

Date

Returning organisation name and address

Signature, name and position of person making the return