

# **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**



**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

*Published with the permission of the Director-General of Health*

ISBN: 0-478-067-38

## 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', with a stylized flourish at the end.

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 4:**

**WHOLESALE OF MEDICINES AND MEDICAL DEVICES**

# CHAPTER 1

## INTRODUCTION

- 1.1 Wholesale distribution forms part of the supply chain of medicines, medical devices, related products and materials used in their manufacture. Wholesalers are responsible for the effective, safe and efficient handling, storage and distribution of medicines and medical devices, whilst they are moving between their site of manufacture and the retail outlet or end-user.
- 1.2 The Code sets out the appropriate standards for meeting these responsibilities. Compliance with the requirements of the Code will be used as a basis for assessing applications for licensing purposes.
- 1.3 The Code does not deal with statutory requirements unless they are an integral part of good manufacturing practice. However, licensees need to understand and comply with their legal obligations.
- 1.4 The Code does not cover the requirements for a licence to pack medicines. These are covered in the *New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods Part 1: Manufacture of Pharmaceutical Products*.

\*

## CHAPTER 2

### APPLICATION AND INTERPRETATION

- 2.1 The Code applies to importers and wholesale distributors of medicines and medical devices and to manufacturers and packers who have wholesaling functions in their business.
- 2.2 In the Code:
- the word "*goods*" includes medicines, related products and medical devices
  - the word "*hazardous*" means goods which, by virtue of their irritant, corrosive, volatile, explosive or highly toxic nature, pose an extra risk in storage or handling
  - the term "*Controlled Drugs*" means those substances listed in the Schedules to the Misuse of Drugs Act 1975 and amendments.



## CHAPTER 3

### DOCUMENTATION

- 3.1 All procedures intended to safeguard the quality of goods and to prevent mixups should be documented.
- 3.2 Records, registers and returns of Controlled Drugs shall be kept in accordance with the appropriate legislation.
- 3.3 Records of the receipt and sale of all goods shall be kept in accordance with the medicines legislation.
- 3.4 An invoice or packing slip should accompany each delivery of goods.

## CHAPTER 4

### BUILDINGS AND GROUNDS

- 4.1 Warehouse premises should be built for or adapted to the function of wholesaling medicines and medical devices.
- 4.2 The grounds should be established and maintained in an orderly condition that minimises the likelihood of dirt, dust or other contaminants entering the premises.
- 4.3 The premises should provide sufficient space for the orderly receipt, warehousing and despatch of goods.
- 4.4 The premises should be maintained in a clean and sanitary state. They should be kept free from accumulated waste, dirt and debris.
- 4.5 Waste materials should be collected in receptacles or areas set aside for this purpose and disposed of frequently.
- 4.6 A written cleaning programme for the premises should be available. Cleaning equipment should be stored hygienically.
- 4.7 The buildings should be kept free of rodents, vermin, birds, insects, animals and pests.
- 4.8 The building should protect stored goods from contamination, deterioration, excessive heat cold and exposure to direct sunlight.
- 4.9 The receiving and despatch bays, docks, platforms or similar areas should provide protection against dust, dirt and rain.
- 4.10 Warehousing functions should be carried out in a part of the premises separated from any manufacturing or packing operations.
- 4.11 There should be a documented quarantine system for isolation of goods where necessary. This includes isolation of faulty or leaking packs, recalled and expired goods.
- 4.12 The premises should be well lit and ventilated.
- 4.13 The premises should provide sufficient security to prevent access by unauthorised people.
- 4.14 Perimeter security of the building should be adequate to prevent unlawful entry into the premises.
- 4.15 Where appropriate all exits and entrances should be controlled by a monitored alarm system after hours.

## CHAPTER 5

### FACILITIES

- 5.1 Storage conditions should be monitored to ensure that the conditions specified by the manufacturers of the products are met. A record of the monitoring should be maintained.
- 5.2 Controlled temperature storage environments should be monitored using suitable temperature recording devices. A record of the monitoring should be maintained.
- 5.3 Controlled temperature environments should be fitted with a monitored alarm where appropriate to indicate any temperature deviations outside specifications.
- 5.4 Where the temperature has deviated outside the limits of the specifications, a written procedure should be followed to review the use of any goods affected.
- 5.5 Instruments or equipment used for monitoring temperature should be regularly checked to ensure accuracy to a level appropriate for the product.
- 5.6 Controlled Drugs must be securely stored as required by the appropriate legislation.
- 5.7 There should be suitable storage conditions for toxic and hazardous substances.

## CHAPTER 6

### PERSONNEL

- 6.1 All personnel responsible for ensuring that goods are correctly handled, stored and distributed should have the appropriate training and experience that will enable them to carry out these tasks effectively and responsibly.
- 6.2 Personal hygiene should be of a standard which avoids contamination of any product.
- 6.3 Job descriptions which clearly define the duties and responsibilities of each staff member should be maintained.

## CHAPTER 7

### STOCK HANDLING AND STOCK CONTROL

- 7.1 The handling and storage of goods should be in accordance with established procedures designed to prevent contamination or deterioration, damage to packs or confusion of products.
- 7.2 The integrity of seals on all goods should be checked and maintained. Particular attention should be given to sterile products.
- 7.3 Manufacturers' special instructions relating to the storage or handling of products should be followed.
- 7.4 Storage areas should be adequate and organised to permit segregation and identification of the goods stored.
- 7.5 Documented procedures should be followed to ensure a high level of cleanliness in refrigerated rooms and cabinets, with specific attention being paid to the avoidance of mould growth.
- 7.6 There should be a documented procedure which should be followed to ensure stock rotation.
- 7.7 Goods bearing an expiry date should not be sold after expiry. Expired goods should be withdrawn from sale and quarantined for disposal in accordance with agreement between manufacturer and wholesaler. There should be a documented procedure for this.
- 7.8 Spills should be cleaned up quickly under the supervision of a responsible person. A written procedure should be followed for dealing with hazardous items, eg, cytotoxic medicines, flammable goods, oxidising agents, etc.

#### *Security*

- 7.9 Access to goods storage areas should be controlled to prevent unauthorised entry.
- 7.10 Visitors, workmen or other persons who are not members of the staff, must always be accompanied by a staff member when access is required to the medicines storage area.
- 7.11 There should be procedures in place that will minimise the possibility of theft by staff or others.

### ***Inwards Goods from Suppliers***

- 7.12 Importers should have documented systems which ensure that goods are not mishandled or exposed to adverse storage conditions en route.
- 7.13 Incoming goods should be placed in quarantine until the required documentation is available, and checks show that the goods are those expected, are those described in the documents and that they are undamaged.
- 7.14 Importers must ensure that they possess data and certificates according to the requirements of the Medicines legislation. There should be documented procedures to ensure that these requirements are met.
- 7.15 There should be a documented system for recognition and correct handling of Controlled Drugs, cytotoxics, hazardous goods and those goods requiring special storage conditions, or with a short shelf life.
- 7.16 Goods which are not acceptable for any reason should remain in quarantine.

### ***Damaged Products or Materials***

- 7.17 A responsible person should be appointed to examine damaged or suspect goods.
- 7.18 Goods with broken seals, damaged packaging, or suspected contamination should be placed in quarantine until a decision has been made on the appropriate action by a responsible person.

### ***Returned Goods***

- 7.19 Returned goods should not be resold unless there is evidence that they have been stored securely and under suitable conditions since they left the wholesaler. There should be a documented procedure for this.
- 7.20 An appropriately trained, responsible person should be appointed to determine and document the fate of returned goods.
- 7.21 Goods which have been damaged or withheld from sale and which are not immediately destroyed should be placed in quarantine until appropriate action can be taken. There should be a documented procedure for dealing with these goods.

### ***Recall Procedures***

- 7.22 There should be a written procedure for implementing recalls and dealing with recalled goods. See *Part 5: Uniform Recall Procedure for Medicines and Medical Devices*.

## CHAPTER 8

### TRANSPORT

- 8.1 Containers for delivery of goods should be clean and odour-free and provide adequate protection for the goods during transportation.
- 8.2 Goods requiring refrigerated or frozen storage should be transported in insulated containers with appropriate cooling agents. The cooling agent should not cause freezing of goods marked "Refrigerate – Do not freeze".
- 8.3 Maintenance of correct storage temperatures during transportation should be validated and documented, where appropriate.
- 8.4 Medicines requiring low temperature storage should be delivered by the fastest practical means.
- 8.5 Deliveries containing Controlled Drugs should not indicate on the container that Controlled Drugs are included.
- 8.6 Controlled Drugs should be delivered by a secure system which should be documented. It is the responsibility of consignors to ensure that Controlled Drugs are sent to the appropriate person at the correct address.
- 8.7 Prescription medicines should be delivered by a secure system. \*
- 8.8 Cytotoxic substances should be transported in such a way as to be self contained in the event of breakage. The packaging of cytotoxic substances should bear a label stating that cytotoxic substances are enclosed. Safe handling procedures necessary in the event of damage, should also be stated on the package.

## CHAPTER 9

### COMPLAINTS

- 9.1 Complaints regarding goods or their packaging should be recorded and actioned according to a documented system. Complaints that do not concern the wholesaling activity should be referred promptly to the agent or manufacturer, as appropriate.
- 9.2 Complaints regarding wholesaling activities which compromise the quality of goods should be recorded and actioned according to a documented system.



**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



Therapeutics Section 1995