

Consultation Draft

August 2010

Uniform Recall Procedure for Medicines and Medical Devices

FOREWORD

Your comment is invited on a draft update of the *Uniform Recall Procedure for Medicines and Medical Devices (the Recall Code)*. **Feedback should be provided by 27 August 2010** (see below for further details).

Medsafe gratefully acknowledges the assistance of members of a working party in developing this consultation draft. The members of the working party have practical experience in the conduct of recalls and are nominees of the following organisations:

- Pharmacy Guild
- Pharmaceutical Society
- Pharmacy Council
- NZ Hospital Pharmacists' Association
- Medical Council
- Researched Medicines Industry Inc (RMI)
- Self-Medication Industry (SMI)
- Medical Technology Association of New Zealand (MTANZ)
- PHARMAC
- District Health Boards NZ
- ProPharma

The working party will review the analysis of submissions received on this draft and reconvene in early September to inform the development of the final product.

Background to this consultation

Following a small cluster of consumer level recalls of medicines in the first half of 2010, and concern raised by some pharmacists and the Pharmacy Guild about the adequacy of recompense they receive for work undertaken during recalls, the Minister of Health asked the Director-General of Health to review the pharmacy recalls process and provide advice within a month.

The purpose of the review was to assess the current process, procedures^{*} and contracting arrangements for pharmacies in respect of their role in medicine recalls, including whether pharmacies are being provided appropriate recompense under the current recall process.

Key findings of the review in relation to guidance about the recalls process were that the guidance available to parties involved in the recall of medicines needs to be

^{*} See <http://www.medsafe.govt.nz/downloads/GMPPart5.pdf>.

updated and improved, and that the current process for recalls in New Zealand should be made clearer. In particular there is a need to:

- clarify the roles and responsibilities of parties responsible for part of the recalls process, and
- improve communication between the different points of contact in the recall process.

A number of legal issues were also identified during the review, including how the medicines and privacy legislation, and payment rules under the District Health Board Pharmacy Agreement should be interpreted in a recall situation.

Medsafe has therefore been tasked with leading a process to immediately review and update the Recall Code (with input from a working group whose members *inter alia* have practical experience in the conduct of recalls). This process is to deliver an updated Code by 30 September 2010 that will:

- update the Uniform Recall Procedure for Medicines and Medical Devices (Part 5 of the NZ Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods)*
- address the roles and responsibilities of, and communication between all parties involved in the medicines recall process, including professional bodies, and specify the actions required of each party where appropriate,*
- address legal issues identified during the review.*

The issue of costs incurred by health providers participating in a recall is not being addressed in the process to update the Recall Code. Instead, the Ministry of Health will convene a parallel process to address the issues of:

- when recompense for service costs is appropriate*
- who should bear responsibility*
- how to estimate the size of these costs*
- what reasonable recompense for them might be*

and will complete this work by the end of November 2010.

Stewart Jessamine
Group Manager
Medsafe

HOW TO MAKE A SUBMISSION

Please send your submission on the draft 2010 Recall Code to:

Email: info@medsafe.govt.nz

(E-mailed submissions will be acknowledged on receipt).

Hard copies (not required if an e-mailed submission has been received) should be sent to:

Recall Code Update
Medsafe Project team
Medsafe
Ministry of Health
PO Box 5013
Wellington 6145

The closing date for submissions is 27 August 2010.

Please use the submission form on the next page to provide your contact details and indicate your areas of interest.

The final version of the updated Recall Code will be published on the Medsafe website (www.medsafe.govt.nz). Submitters will receive an e-mail to advise when the updated Code is available.

SUBMITTER INFORMATION

Please provide your contact details below. In your submission, please identify the paragraph numbers your points refer to.

Name:	
If this submission is made on behalf of an organisation, please name that organisation here:	
Please provide a brief description of the organisation if applicable:	
Address/email:	
Interest in this topic (for example, consumer, health professional, manufacturer of pharmaceuticals etc.):	

Please note that all correspondence may be requested by any member of the public under the Official Information Act 1982. If there is any part of your correspondence that you consider should be properly withheld under the legislation of the Act, please make this clear in your submission, noting the reasons why you would like the information to be withheld.

If information from your submission is requested under the Act, the Ministry of Health will release your submission to the person who requested it. However, if you are an individual, rather than an organisation, the Ministry will remove your personal details from the submission if you check the following box:

- I **do not** give permission for my personal details to be released to persons under the Official Information Act 1982.

All submissions will be acknowledged, and a summary of submissions will be sent to those who request a copy. The summary will include the names of all those who made a submission. In the case of individuals who withhold permission to release personal details, the name of the organisation will be given if supplied.

CONSULTATION DRAFT
AUGUST 2010

UNIFORM RECALL PROCEDURE
FOR
MEDICINES AND MEDICAL DEVICES

GLOSSARY OF TERMS

Medicine

The term *Medicine* is defined in section 3 of the Medicines Act 1981. It includes prescription and non-prescription medicines, unapproved medicines and human blood products.

Medical Device

The term *Medical Device* is defined in section 2 of the Medicines Act 1981. It includes a diverse range of products such as condoms and gloves, implants, surgical instruments, complex electronic equipment (and its associated software) and in-vitro diagnostic devices.

Sponsor

The term sponsor means the party that is legally responsible for all aspects of the product. This may be a New Zealand resident manufacturer or proprietor, or supplier, or importer or exporter.

1 INTRODUCTION

- 1.1 Those responsible for the import, manufacture and/or distribution of medicines and medical devices (Sponsors) must be able to recall product from the distribution chain when it becomes apparent that product in the distribution chain does not meet acceptable standards of safety, quality, or efficacy (or performance). Distribution can take many forms, including supply of samples (e.g. to doctors) or loan of devices by the NZ sponsor.
- 1.2 This Code provides guidance to sponsors, wholesalers, retailers and health professionals on the effective conduct of recalls of medicines and medical devices, including their roles and responsibilities. Significantly, the Code describes a partnership approach to protecting the public that relies on the application of uniform procedures and effective communication between the parties participating in the recall action.
- 1.3 The recall process involves the following phases of activity:
 - **An initiation phase** when problem identification, risk assessment, the decision to recall and the planning for the recall occurs
 - **An implementation phase** when the recall notice is issued by the sponsor and the requested recall action is undertaken
 - **A review phase** when monitoring and review of the effectiveness of the recall action is undertaken by the sponsor with oversight from Medsafe.
- 1.4 In parallel with the recall process, the sponsor/manufacturer, with oversight by Medsafe, needs to complete an analysis of the reasons for the defect and implement a prevention strategy. A diagram of the recall process is provided in Appendix 1.
- 1.5 The procedures and principles outlined in this document may also be used when a manufacturer or distributor needs to communicate product defect safety information (such as safety alerts and cautions) to consumers, pharmacists or other healthcare professionals.
- 1.6 Every New Zealand sponsor and agent involved in medicine and medical device clinical trials must have a predetermined system of recalling a medicine or a medical device.
- 1.7 Manufacturers should also refer to Chapter 8 of Part 1 of this series of Good Manufacturing Practice documents - *Manufacture of Pharmaceutical Products*.

2 Types of Recalls - Seriousness

2.1 Medsafe uses an internationally agreed classification system for recalls to convey the seriousness of the defect and the level of risk associated with medicines recalls:

- **Class I** recalls are those where defects are potentially life-threatening or could cause a serious risk to health
- **Class II** recalls are those where defects could cause illness or mistreatment but are not Class I
- **Class III** recalls are those where defects may not pose a significant hazard to health, but withdrawal may be initiated for other reasons

2.2 Categories of corrective action include:

- Recall
- Field correction (medical device)
- Hazard alert (medical devices)
- Safety alert (medicines)
- Product Advisory (medical device)
- Dear Healthcare Professional Letter

2.3 A recall is a method by which a medicine or medical device that has been distributed is removed from sale or from use and returned to the source or is otherwise dealt with.

2.4 A recall may in some cases involve:

- the correction of a fault
- the exchange of a device
- the modification of a product in the field, including changes to software, to correct safety issues
- the destruction of a device
- the provision of safety-related advice by a manufacturer regarding the use of a device, (irrespective of whether the device is still being supplied, e.g. implants).

2.5 Recall 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
- 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.

2.6 Modification is a type of recall for a medical device and may include:

- Retrofit in accordance with the manufacturer's modification or design change
- Permanent or temporary changes to the labelling or instructions for use
- Software upgrades, including those carried out by remote access

- Modifications to the clinical management of patients to address a risk of serious injury or death related specifically to the characteristics of the device
- For implantable devices it is often clinically unjustifiable to explant the device. Corrective action taking the form of special patient follow-up, irrespective of whether any affected un-implanted devices remain available for return
- For any diagnostic device (e.g. in vitro diagnostic imaging equipment or devices) the retesting of affected patients, samples or the review of previous results
- Advice on a change in the way the device is used (e.g. IVDS manufacturer advises revised quality control procedure – use of third party controls or more frequent calibration).

2.7 Recall levels include:

- Wholesale – product held by a third party for distribution to retailers or other organisations before being supplied to end users
- Hospitals and Laboratories
- Retail (includes community pharmacies, medical, dental and other healthcare professionals, and general retail outlets)
- Consumer/Public – product supplied to the general public through any or all of the above distribution channels. This level of recall is used where there is a significant risk of harm to the consumer or user.

3 REPORTING A DEFECT

- 3.1 This section explains the role that persons other than the sponsor play in reporting a potential defect in a medicine or medical device. (The obligations of the NZ sponsor are explained in section 4).
- 3.2 During distribution or use of a medicine or medical device an error or incident may occur whereby it is noticed that the finished product does not conform to its specification or for some other reason appears defective (e.g. the finding of an incorrect strength on the label of a bottle of tablets). This should not be confused with an adverse reaction where the product conforms to its specification but an adverse event or reaction is observed.
- 3.3 Healthcare professionals, patients, laboratory staff and others have an important role in reporting defects. While many problems will be isolated, some may be more widespread, perhaps affecting an entire batch of medicine or model of a medical device and requiring a product recall. Examples include incorrect readings on a type of device or the presence of particulates in vials of an injectable product. It is therefore important to report the defect so that the problem can be investigated and further action taken if appropriate.
- 3.4 Reporting of defects by healthcare professionals or laboratory staff should be carried out as follows:
- a) Contact the sponsor company. Telephone numbers can be found in the back of *MIMs New Ethicals*, on product packaging, in telephone books and on the internet;

AND

- b) Report significant defects or concerns to Medsafe through email, fax or by phone (see Appendix 2 for contact details). The following information will be useful if available:
- Product name and strength (if applicable)
 - Supplier
 - Batch/lot number/serial number (if known)
 - Expiry date (if applicable and known)
 - Defect and details of any associated clinical incident
 - The healthcare professional or laboratory staff member's view on why the suspected defect is considered significant.

Note: (a) A reporting form for medical device defects is available at <http://www.medsafe.govt.nz/downloads/device.doc>

(b) Adverse events for medicines are reported to: the Centre for Adverse Reactions Monitoring (CARM) (see Contact details Appendix 2)

(c) If unsure whether the problem could be a product defect or an adverse event, report to Medsafe.

- 3.5 Consumers are encouraged to report any problems to the place of supply, e.g. the pharmacy the medicine was supplied from or the healthcare professional who provided the device. The healthcare professional is then responsible for communicating appropriately. Medsafe can also be contacted for potentially serious problems (see Appendix 2 for contact details).

4 RECALL PROCEDURE – OBLIGATIONS OF SPONSORS

- 4.1 Every New Zealand sponsor must have in place a written recall procedure which describes how a recall will be initiated and carried out.
- 4.2 A procedure for the initiation and conduct of a recall must have two parts. The first part must describe how complaints or problems regarding product quality are handled and how a decision to recall is made. It must include:
- The company's procedure for receiving complaints or problem reports
 - Arrangements to ensure that each problem report is adequately assessed by a person who is appropriately qualified to assess the nature and significance of the problem report
 - Trends analysis of problem reports
 - Consideration of a quarantine for stock on hand
 - Forwarding problem reports to manufacturing/packing sites
 - Reporting of problems to Medsafe
 - How a decision to recall is made, including input from Medsafe.
- 4.3 The second part must describe how a recall will be conducted and 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 and the retention period for the records (which must be a minimum of 5 years)
 - Communication of the recall to those enacting the recall, including initial phone calls, emails, faxes and mail advising of the recall. Dates of contact and a list of contacts advised should be kept. (See also Appendix 8).
 - Arrangements, including the provision of quarantine facilities, for returned stock
 - Arrangements for the disposal or modification of affected stock
 - How technical details required for the recall will be obtained
 - How distribution records will be obtained
 - Contact with Medsafe (and PHARMAC as appropriate)
 - The different levels of recalls
 - Contacts that need to be made with other organisations depending on level of recall
 - How the recall communication list will be prepared
 - Mechanism for transmitting the recall notice (note: email, telephone or fax: communication method must be agreed with Medsafe)
 - Preparation of the recall letter (see section 7)
 - Preparation of a summary report for Medsafe once the recall is completed.

- Pre-planning of the additional arrangements and communication required in the event of a recall, e.g. an extra fax line, particularly in a consumer level recall.
- 4.4 Each sponsor is responsible for providing Medsafe with after-hours contact numbers and keeping these up-to-date.

5 RECALL PROCEDURE – OBLIGATIONS OF WHOLESALERS

5.1 Every wholesaler must have a procedure describing how a recall requested by a sponsor will be conducted.

5.2 A recall procedure for a wholesaler must 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
- How stock in transit from the sponsor or returns for credit from purchasers will be handled (this includes returns for credit that occur as usual part of business where the recall was only to wholesaler level)
- Record keeping (records are to be kept for a minimum of 5 years)
- Response to the sponsor
- Mechanism for stock replacement for pharmacies or other purchasers if applicable
- For recalls going to levels lower than wholesale, the wholesaler must contact any organisations they have supplied to which would not be on a mailing list used by the supplier. Common examples include:
 - an off-shore pharmacy
 - an exporter supplied by the New Zealand wholesaler
 - clinical trials organisations
 - retailers licensed to sell Pharmacy-Only medicines
 - private hospitals
 - Ministry of Defence
 - paramedic organisations.

6 SPONSOR INTERACTION WITH MEDSAFE

- 6.1 All recalls must be carried out with the knowledge and consent of Medsafe.
- 6.2 A sponsor must immediately consult Medsafe when there is reason to consider that a product recall may be required. Refer to Appendix 2 for contact details. Faxed material should be marked "URGENT".
- 6.3 The International classification and level of recall is determined by consultation between the NZ sponsor and Medsafe.
- 6.4 The level of recall will generally reflect the safety risk and distribution pattern.
- 6.5 The risk assessment includes consideration of the following factors:
- The potential harm to the patient as a result of the issue
 - The likelihood of the issue occurring
 - The ability of the patient, healthcare professional or caregiver to discover/identify the issue should it occur
 - Whether the product is outside the manufacturer's specifications
 - The availability of an alternative product.
- 6.6 Following the initial contact with Medsafe a recall shall proceed as follows:
- a) Supply of information to Medsafe: technical, distribution, assessment of risk, impact on users etc. Information that may be required from the NZ sponsor is included in Appendix 3
 - b) Decision on recall action is made following consultation between the company and Medsafe
 - c) The recall action is planned and the recall letter or communication is written, (see Appendices 4-6 for templates). Agreement on the recall plan, contents of the recall letter and (for consumer level), advertisements and possibly media releases is reached with Medsafe and approval to proceed with the recall is given
 - d) The recall proceeds – see Appendix 8 for details on distribution lists and organisations to contact
 - e) Non-responders are followed up: to assess the effectiveness of the recall, and to check that contact details are up-to-date
 - f) Medsafe may require progress reports (generally at two and six weeks after initiation of the recall)
 - g) At the completion of the recall the company provides Medsafe 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.
- 6.7 Medsafe will publish all recalls on the Medsafe website.

7 RECALL LETTER FORMAT

7.1 A recall letter should:

- Be on the company letterhead
- Be dated
- Have a prominent heading that states that it is a recall or product modification and the Class of the recall. In the case of Class I or Class II recalls, “URGENT RECALL” is also to be used. If some other action is required the heading should contain appropriate wording describing this
- Give the brand name and any other name to identify the product
- Describe the strength, presentation and pack size of the medicine or give a description of the medical device
- 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
- State the level to which the recall is being made (hospitals, wholesalers, hospital/community pharmacies, consumer etc.)
- State the reason for the recall
- Indicate the health risk involved
- Give a clear indication of the action required and the steps to be taken in order to deal with the problem
- State the need to immediately isolate and quarantine the particular medicine or medical device involved in the recall to prevent further usage
- Describe the procedure to be followed in returning the medicine or medical device including compensation for return and replacement of product, and facility for free courier
- State that consultation has occurred with Medsafe
- Be signed by the Recall Co-ordinator (or a senior member of the company management)
- 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
- Provide a contact name and telephone number (preferably a freephone number)
- Additional information may be included in the recall letter, where appropriate. Such information may be:
 - an indication of alternative products that may be used
 - an indication of when further supplies will be available
 - special instructions with respect to return of the product
 - information on clinical management (if appropriate)

- Avoid the use of the word “voluntary” within the letter as well as any comments or descriptions that downplay the level of risk.

7.2 An acknowledgment form should:

- State the name, pack size, batch number/s and presentation of the product
- Have a place to record the quantity of full packs being returned, and (if applicable depending on product and level of recall) a place to record the quantity of part-packs being returned
- Have a place to record the name of the organisation and name and designation and signature of the person acknowledging the recall
- Have a place to record the date of completion of the form
- Include a statement that even if no stock is held the form must still be returned to the Recall Co-ordinator as acknowledgment of receipt of notice of the recall
- Provide a means by which the form may be returned free of charge; for instance, a reply-paid envelope may be enclosed, a free fax number may be provided.

7.3 Patient returns (if applicable) should be on a separate acknowledgement form to stock returns, so that stock on hand can be returned immediately

7.4 The recall letter and form should be faxed or sent in a distinctive envelope which has printed on it, in bold red print on the top left hand corner, the wording:

MEDICINE RECALL OR MEDICAL DEVICE RECALL
ACTION IMMEDIATELY ACTION IMMEDIATELY

or words of a similar meaning. If faxed, the fax should bear the wording in large bold letters

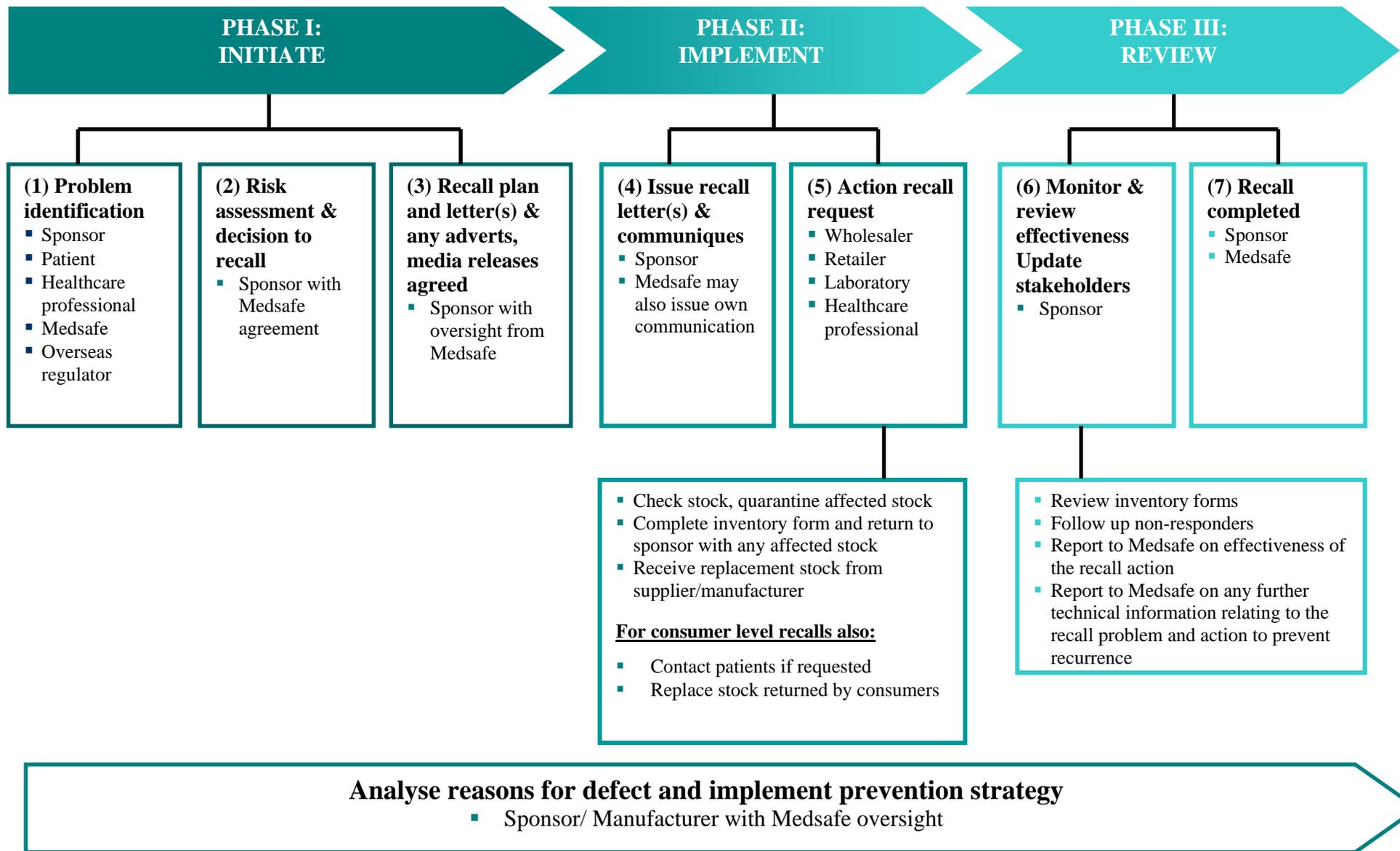
7.5 Appendices 4-6 include templates for the recall letter and acknowledgment form.

8 RECALL PROCEDURE – OBLIGATIONS OF HEALTHCARE PROFESSIONALS IN RECALLS

- 8.1 Healthcare professionals have an ethical and professional obligation to safeguard patients in a recall. The healthcare professional may delegate these tasks to a competent person, but must remain vigilant for clinical repercussions.
- 8.2 In a recall to healthcare professional level, any healthcare professional supplying or using an affected medicine or medical device must ensure patient safety by ensuring that they:
- check, quarantine and return stock as outlined in the recall letter
 - promptly return the acknowledgement form, including for nil returns
 - inform other relevant staff in their organisation
 - prominently display the recall notice for staff for a month
 - discuss the recall notice at their next health and safety meeting
- 8.3 In a recall to patient level, any healthcare professional supplying a medicine or medical device must ensure patient safety by following the instructions in the recall notice, in relation to:
- contact with patients who have been supplied with the product being recalled
 - advice to patients about the recall, the reasons for it, and the actions the patient should take according to the recall letter and the individual patient's circumstances (for example if clinical signs indicate a need for medical follow up)
 - replacement of stock held by the patient where required
- 8.4 Where stock that may have been affected has been exported or supplied to another organisation (e.g. nursing home, another pharmacy, a doctor's surgery, a laboratory) this organisation also needs to be contacted to advise of the recall and to advise the process for the replacement of any product that might be affected.
- 8.5 Information on the application of requirements in privacy law and the medicines legislation to recall situations is provided in Appendix 9.
- 8.6 In cases of queries about the recall, the NZ sponsor should be contacted as per the contact details on the recall letter.
- 8.7 Information on recalls may also be available on the Medsafe website <http://www.medsafe.govt.nz/hot/recalls.asp>

Note: Healthcare professionals can also play an important role in **reporting defects**. Advice on this is provided in section 3.

Appendix 1: DIAGRAM OF THE RECALL PROCESS



Appendix 2: CONTACT DETAILS FOR MEDSAFE

For a potential recall, the preferred initial contact is by telephone.

During office hours (Monday to Friday)

Contact Medsafe by:

Telephone	(04) 819 6800	Ask to report a product defect and specify whether it relates to a medicine or medical device
Fax	(04) 819 6806	Use a bold heading: “ Urgent Recall ” and specify if the problem relates to a medicine or medical device
Email	recalls@moh.govt.nz	

After office hours (emergencies only):

Telephone	[to be advised]
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Note: Adverse Events for medicines are to be reported to the Centre for Adverse Reactions Monitoring (CARM):

Telephone	+64 3 479-7247 (CARM Director)
Fax	+64-3-479-7150
Email	carmnz@stonebow.otago.ac.nz
Website	http://carm.otago.ac.nz/ (allows on-line reporting)

Adverse Events for medical devices are to be reported to Medsafe, and can be reported by anyone, including patients, caregivers, healthcare professionals and suppliers. For further details, go to: <http://www.medsafe.govt.nz/profs/defect/device.asp>.

A reporting form, common to both New Zealand and Australia, should be used to report safety and/or quality issues concerning medical devices to Medsafe. Simply download the form <http://www.medsafe.govt.nz/downloads/device.doc> to your computer and fill it in.

Suppliers of medical devices may prefer to submit reports to Medsafe using the TGA MDIR 03b form. When a supplier uses this form to report a New Zealand event to Medsafe the WAND Device Notification Number should be substituted for the ARTG number.

Completed forms should be sent to Medsafe via email or fax using the recalls contact details above, or by post (PO Box 5013, Wellington).

Appendix 3: INFORMATION THAT MAY BE REQUIRED FOR A PRODUCT DEFECT REPORT

Medsafe may require the following information from NZ agents for problem medicine reports. Only the information shown in bold is required for the **initial** contact with Medsafe, which should be made promptly. The remaining information, when applicable, should be supplied as soon as possible.

- **Name and details of New Zealand sponsor**
- **Name, telephone and fax number of the person reporting the problem**
- **Product name – brand name and INN or generic name**
- **Dose form, strength, pack size**
- **Nature of the problem/issue including number of similar reports received**
- Description of the product or its intended purpose
- History of the incident with specific dates when it occurred/was observed
- Unique identifier for the medical device (i.e. catalogue reference, model reference, part number, etc.)
- Details of the affected sub-set of product (e.g. lot number/s, batch number/s, version number/s, serial number/s, manufacturing date range, expiry date/s, etc.)
- Name and details of manufacturer/packer
- New Zealand regulatory status (i.e. for medicines TT50 file number, for devices WAND device notification identifier)
- Quantity of product in New Zealand
- Dates of first and last distribution to the New Zealand market
- Stock status (i.e. where product is in the distribution chain, current undistributed stockholding, quantity supplied to customers, etc.)
- List of where affected and potentially affected product has been supplied to
- Whether the product has been exported from New Zealand, and if so, to which countries
- An assessment of the health risk posed by the problem/issue
- Action proposed by sponsor
- Proposed recall classification
- Proposed recall level
- Availability of unaffected or alternative product.

The following may also be required if further investigation is needed after the initial review:

- NZ sponsor and/or manufacturer risk assessment, including, if appropriate, a clinical assessment
- A review of all associated batch manufacturing, packaging, testing, release and distribution records for anomalies which may explain the suspected defect
- Examination, and retesting, if appropriate, of retained samples
- Details of any actions to be taken by the NZ sponsor and/or manufacturer to correct the defect in the future.

Appendix 4: SUGGESTED FORMAT FOR RECALL LETTER

Company letterhead

Date

Addressee

Class of recall

'Urgent Medicine or Medical Device Recall'

(as appropriate; the term "urgent" is only used for Class I and II recalls)

- Product description (name, strength, pack, size etc.)
- Batch/Lot No./Serial number. No other batches or strengths are affected by this recall.
- Level of recall (e.g. wholesaler level recall)
- Recall reason
- Health risk
- Action to be taken by recipient, e.g.:
 - Stop usage/Quarantine
 - Return/hold – if returning, specify where, when and how to return, a date for returns may be necessary, to include a copy of the acknowledgement form with returned stock as well as faxing back (if applicable)
- State that the acknowledgment form must be returned even if no stocks is held
- Further information regarding details of replacement stock or alternative products, etc. if appropriate and mechanism of supply
- Details of compensation which may include stock replacement
- Contact details including a telephone number, preferably freephone number
- Advise to please keep this letter in a prominent position for at least one month and make sure all staff members are aware of this recall
- This recall action has been taken after consultation with Medsafe (or a statement to this effect).

For consumer-level recalls, provide patient level information such as:

- An instruction to please contact all patients dispensed <product name> since <date> and advise them to return their <dose form> to <their pharmacy> for replacement.

- If patient returns are to be returned to the supplier, specify to black out/remove patient names from labels to preserve patient confidentiality
- Provision of further information on when patients should contact their doctor for follow up, if necessary, e.g. any patient noticing any ill effect should be referred to a doctor.
- When/how consumer advertising will occur and the advice it will give to consumers (e.g., in newspapers nationwide starting <date> and will advise patients to return to <pharmacies/other specified provider> for replacements
- What notification has been provided to other healthcare professionals
- An instruction to replace the <product/number of <dose form> with the same product from an unaffected batch (or other alternative as described)

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

Appendix 5: SUGGESTED FORMAT FOR ACKNOWLEDGEMENT FORM

As much of this form as possible should be pre-printed

Acknowledgment Form Inventory of affected stock on hand

(Name of product)

If no stock on hand of the product in question a NIL declaration must be faxed to <preferably freefax number> or must be posted in the reply paid envelope **promptly** as acknowledgement of receipt of the recall notice.

- Product name and description:
- Pack size:
- Batch No:
- Number of packs returned:
 - [xxxx] whole packs
 - [xxxx] partly used packs
 - (or as appropriate)

Provide space for returning organisation to indicate if no stock is held

- Date
- Returning organisation name and address (pre-printed if possible)
- Signature, name and position of person making the return
- Fax back this form then enclose a copy of this form with returned stock to:
<distributor's company name and address>

Attention: <name/description e.g. Recalled medicines>

Appendix 6: SUGGESTED FORMAT FOR DEAR HEALTHCARE PROFESSIONAL LETTER

Company letterhead

Date

Addressee

Level of recall

'Urgent Medicine or Medical Device Recall'

(as appropriate; the term "urgent" is only used for Class I and II recalls)

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

Batch/Lot No./Serial numbers affected. No other batches, pack sizes or strengths are affected by this recall

Level of recall (e.g. consumer level recall)

Recall reason

Health risk

Action to be taken by recipient, e.g.

- Please be aware that patients taking <product description> may have been undertreated
- Check any stock you may have, for example samples or supplies from practitioner supply orders

Examples of patient level information:

- Please contact all patients prescribed <product name> since <date> and advise them to return their <dose form> to <their pharmacy> for replacement and to determine if their clinical status needs to be assessed
- Please contact all patients prescribed <product name> since <date> and advise them to return their <dose form> to <their pharmacy> for replacement
- Provide further information on when patients should contact their doctor for follow up, if necessary, e.g. any patient noticing any ill effect should be referred to a doctor
- Consumer advertising will occur in newspapers nationwide starting <date> and will advise patients to return to <pharmacies/other specified provider> for replacements.

This recall action has been taken after consultation with Medsafe

Contact telephone number, preferably freephone number

Please make sure all staff members are aware of this recall and keep this letter in a prominent place for one month.

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

Appendix 7: CONDUCTING A CONSUMER LEVEL RECALL

Consumer level recalls require careful planning and execution in a compressed timeframe. They need to be effective because they occur when defective product is considered to pose a significant risk of death or serious harm. An essential element for their success is good communication between the sponsor and all the other parties participating in the recall. This enables the recall to occur in an orderly and properly sequenced manner in order to avoid confusion.

Advice on planning and implementation of consumer level recalls is provided below.

Part 1 – Sponsor Checklist of Required Actions

1. An **initial teleconference with Medsafe and key stakeholders** has been convened to share and agree the communications plan
2. **Consumer Level Recall advertisement** has been submitted to Medsafe for approval
 - a. Medsafe has approved the Consumer Level Recall advertisement
 - b. Space for the advertisement to appear in all daily newspapers has been booked
 - c. Confirmation of the booking has been supplied to Medsafe
 - d. Medsafe has been supplied with the content of the agreed advertisement so it can be put onto the Medsafe website
 - e. A copy of the Consumer Level Recall advertisement has been put on the company website
3. **Correspondence (recall letters) to known end-users**, wholesalers, retailers, pharmacists, etc, who are affected by this recall has been prepared so that it will arrive prior to the publication of the public advertisement
 - a. Key stakeholders (participating in initial briefing teleconference) have sighted and agreed communications letters
4. A **media release** has been prepared, and this has been approved by Medsafe.
 - a. Staff responding to telephone calls, emails, faxes and external enquiries relating to this issue have a **question and answer document** which provides guidance on how to advise consumers of the correct action to take with respect to the recall, and respond to queries from wholesalers, pharmacists and end-users.
 - b. If the telephone is only being answered during business hours a means of receiving **telephone calls outside business hours** – answering machine, answering service, diversion of calls to mobile, etc. – has been set up
 - c. A **system for documenting telephone calls** has been established to record the names and contact details of callers, the number of calls, the types of inquiries, and action taken.

Part 2 - Format of a Consumer Level Recall Advertisement

A Consumer Level Recall Advertisement must conform to the Ministry of Consumer Affairs guidelines for recall notices as detailed in “Carrying Out a Product Recall: A Guide for Importers and Retailers”. This publication is available from their website at www.consumeraffairs.govt.nz

- The advertisement should appear in the first section of the newspaper, preferably on a right hand page. The advertisement should NOT appear in the public notices or anywhere within the classified advertising
- Medsafe recommends that the recall advertisement should be two columns wide and be no smaller than 36 column centimetres
- The advertisement must have a crosshatch border surrounding it to distinguish the notice from other advertisements. (See Part 5 of this Appendix for an example of a Consumer Level Recall Advertisement)
- It is recommended that the symbol “Danger Triangle” is included immediately before the heading of the advertisement
- The advertisement should clearly state in bold, upper-case letters “URGENT MEDICINE/MEDICAL DEVICE RECALL”, or similar
- Consider whether an illustration of the product being recalled would be helpful
- If no illustration is included in the advertisement then the text should give a clear, plain language description of the product
- The advertisement should use black text on a plain white background
- Critical information should be in bold lettering
- A serif type font should be used with a minimum font size of 10 point.

Part 3 – Content of Consumer Level Recall Advertisement

The recall advertisement (and media release if applicable) should clearly state the following information:

- What the product is, including brand, make and model, strength and dose form
- A description of the sub-set of affected product through the use of:
 - Batch/lot numbers
 - Serial number range
 - Date of manufacture
 - Date of expiry
 - Or any other identifying markings
- A description of the product and its application
- Where and when the product was sold
- A clear description of the potential problem
- What the effect of the problem is
- The urgency of reacting to the recall
- Instructions for the return, repair, replacement or refund of the product
- A statement to the effect that “This recall is being conducted following consultation with Medsafe, Ministry of Health” must appear in the advertisement
- The contact details of the sponsor, along with a free-call telephone number, should appear at the bottom of the advertisement along with the statement, “For more information please contact”
- The word voluntary is not to be used. The recall is not to be downplayed.

Part 4 – Publication of a Consumer Level Recall Advertisement

- A Consumer level Recall Advertisement should appear simultaneously (or as close as possible) in all regional daily newspapers and in appropriate community newspapers
- The additional use of electronic media is strongly encouraged.

The Newspaper Advertising Bureau (NAB) provides a single point of contact for advice on the placement of advertisements in newspapers and can assist in the preparation of the notice and the booking of advertising space in all newspapers. Note that the NAB will require prepayment unless the booking is made through an accredited advertising agency or media buyer. See www.nabs.co.nz for contact details and more information.

The NAB has a document on product recalls, <http://www.nabs.co.nz/file/fileid/7449>. However, the Uniform Recall Procedure for Medicines and Medical Devices takes precedence where there is any discrepancy.

URGENT MEDICAL DEVICE RECALL

Product – Acme Green Widgets
Catalogue No. – 1313
Batch – Manufactured before 6 June 2010



Acme Green Widgets are small battery powered medical devices that are designed to provide relief for head-colds by increasing the size of the nasal pathways to improve breathing.

Acme Green Widgets were sold via Discount Pharmacy stores and Big George's Medical Device Emporium and Laundrette between 15 February 2009 and 13 July 2010.

Due to an error in manufacturing some Acme Green Widgets produced before 6 June 2010 may have had their battery incorrectly fitted. This may lead to the devices overheating and exploding. There have been no reports of any fatal injuries as a result of this occurring.

Action

- **Consumers are recommended to immediately discontinue use of all Acme Green Widgets.**
- **Please place the device in a sturdy metal container and ensure the lid is locked**
- **Contact the Acme Corporation on 0800-111-111 to arrange for your Acme Green Widget to be collected and replaced**

This recall is being conducted following consultation with Medsafe, Ministry of Health.

For further information contact the Acme Corporation
on 0800-111-111

Appendix 8: ORGANISATIONS AND DISTRIBUTION LISTS

It is important that distribution of recall notices has correct coverage. Commercially available databases administered by distribution organisations may not be completely up to date and the owners are likely to allow those listed to opt-out of receiving communications. Health professionals such as general practitioners frequently opt-out to avoid unwanted advertising.

For this reason sponsors should endeavour to use a contacts database that is likely to provide the optimal practicable reach to the target audience.

For community pharmacies go to:

For general practitioners go to:

For hospitals go to:

The following organisations may be able to enhance the effectiveness of recalls by informing their members that a recall has been initiated:

- Pharmacy organisations
 - Pharmaceutical Society of New Zealand
 - Pharmacy Guild of New Zealand
 - Pharmacy marketing groups (e.g. Pharmacybrands, Radius)
 - New Zealand Hospital Pharmacists' Association
- Doctor organisations
 - New Zealand Medical Association
 - New Zealand Royal College of General Practitioners
 - Specialist Colleges
 - Primary Care New Zealand
- Researched Medicines Industry Association Inc.
- Self Medication Industry Association
- Physiotherapy
- Dental organisations
- Laboratories
- DHB contacts
- ACC (for mobility aids and assistive technology)
- National Radiation Laboratory (for irradiating devices)
- National Joint Registry (for orthopaedic implants)

Note for such organisations: In the interest of patient safety and minimising confusion:

- Use the same wording as the sponsor notice as much as possible when relaying to members
- Refer media back to the sponsor company where possible

APPENDIX 9: GUIDANCE ON LEGAL ISSUES

To be developed later and incorporated in the final version of the update.