MEDSAFE

NEW ZEALAND MEDICINES
AND MEDICAL DEVICES
SAFETY AUTHORITY

A BUSINESS UNIT OF THE
MINISTRY OF HEALTH

NEW ZEALAND MEDICINES AND MEDICAL DEVICES RECALL CODE

Contents

1 INTRODUCTION

This recall code (the Code) provides principles and general guidance to sponsors, wholesalers, retailers and healthcare professionals on the effective conduct of recall actions relating to medicines and medical devices, including their roles and responsibilities. The procedures and guidance outlined in this document may also be used when a sponsor needs to communicate product safety information outside of a recall setting.

Wherever possible the Code reflects best international practices. These may be different for medicines and medical devices. For medical devices the code reflects guidance provided by the Global Harmonization Task Force (GHTF) guidance.

Those responsible for the importation, manufacture or distribution of medicines and medical devices (sponsors) must be able to take prompt corrective action when it becomes apparent that product in the distribution chain does not meet acceptable standards of safety, quality, efficacy or performance.

Significantly, the Code describes a partnership approach to protecting the public that relies on the application of uniform procedures to effect the recall action and to enable effective communication between the parties participating in the recall action process. The appendices provide practical detail designed to facilitate and speed up the process of a recall action.

Where the term “should” is used throughout the Code, it is expressing the intent that the advice be followed in all cases, unless, in any particular circumstance it is agreed that it would be inappropriate to do so.

Recall action is the term used to describe an action taken to resolve a problem with a medicine or a medical device currently in use or available for use because of deficiencies in its quality, safety, efficacy or performance. There are three types of recall action covered by this Code:

(a) permanent removal of product(s) from the market or from use;

(b) correction of a problem (which may sometimes involve temporary removal of the product from the market or from use), where physical removal of the product is not possible or practical but additional information is provided to ensure safe use of the product. This may include rectifying a problem in the field and is more commonly used in relation to medical devices.

(c) a hazard alert issued for a potential issue relating to a medical device that has been implanted in a patient.

The recall action process involves the following phases of activity:

- **An initiation phase** when problem identification, risk assessment, the decision on whether to recall, contact with the funding body when appropriate, and the planning for the recall action occurs.

- **An implementation phase** when the recall action 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 by Medsafe.

In parallel with the recall action process, the sponsor/manufacturer should complete an analysis of the reasons for the defect and design and implement a correction plan to prevent or mitigate against recurrence of the event; and submit this document to Medsafe.

2 COMMON RECALL PROCESS TERMINOLOGY

2.1 Definitions: Recall Actions

Recall action is a market action taken to resolve a problem with therapeutic products in use, or available for use, for which there are issues/deficiencies in respect of their safety, quality, efficacy or performance. This action may be a recall, a recall for product correction, or a hazard alert.

2.1.1 Recall

Recall means the removal of affected therapeutic products from supply or use for reasons relating to established deficiencies in the safety, quality, efficacy or performance of the products.

Recall includes the sending of instructions to locations within the distribution chain (such as wholesalers, pharmacies, hospitals, laboratories, operating and research facilities, biomedical engineers or others) requiring the removal of specified products from use and providing information of their return or disposal.

Recall does not include removal of time-expired products or the removal of a sample of product(s) (for testing) to determine whether there are deficiencies relating to safety, efficacy, quality or performance.

2.1.2 Recall for product correction

Recall for Product Correction advises of the sponsor/manufacturer's intention to repair, modify, adjust, re-label or provide updated instructions for use. This action would be for reasons relating to deficiencies in the safety, quality, efficacy or performance of the affected products.

The corrective action may take place at the user's premises (field correction) or the sponsor's premises or any other agreed location and may involve a period of quarantine.

Recall for Product Correction includes corrections involving a product's expiry date or removal of individual products for modification due to technical improvements; changes to any accessories, or software; correcting deficiencies relating to the safety, efficacy, quality or performance of the products; and changes to the instructions for use or labelling of a medical device.

Recall for Product Correction does not include removal of individual products for repair in the event of malfunction or failure as a result of normal wear and tear or for appropriate maintenance or due to lack of good maintenance; or removal of individual products for modification due to technical improvements other than when these improvements overcome an inherent design or manufacturing defect.

This type of corrective action is more commonly used in relation to medical devices.

2.1.3 Hazard Alert

Hazard Alert means the issuing of precautionary information to healthcare professionals about an implanted medical device. This may be related to a safety, efficacy, quality or performance related condition pertaining to that product. The information supplied may describe situations to be aware of, or advise of potential complications that may have arisen since the device/product was implanted, or provide advice regarding clinical management. A hazard alert may also be issued in conjunction with a notice recalling all un-implanted devices/products.

NOTE: Sponsors should contact Medsafe to discuss whether a planned action is a recall action or a non-recall action before any action is commenced.

2.2 Definitions: Non- Recall Actions

Non-recall actions are actions that can be taken by sponsors to mitigate potential safety risks associated with their products, in situations where a recall is not appropriate.

2.2.1 Safety Alert

A **Safety Alert** includes advice regarding a specific situation with respect to a medical device which, whilst performing to meet all specifications and therapeutic indications, might present an unreasonable risk of substantial harm if certain specified precautions in regard to its use are not observed.

Safety Alerts are intended only to re-iterate information already provided, on the safe use of medical devices. As patient safety is a factor sponsors are encouraged to distribute Safety Alerts in a timely fashion.

Sponsors should use Section 6 of this Code to assist in the dissemination of Safety Alert information.

2.2.2 Product Alert

A **Product Alert** may be issued in response to a situation where some form of market action is required, but a product recall may put the patient at greater risk; ie, no alternative product is available and the risk to the patient of no product is greater than the risk to the patient of using the affected product.

A Product Alert is issued to indicate a safety, efficacy, performance or quality concern and describe actions that should be taken to mitigate the risk, eg, preferentially use specified batches or lot numbers, inspect before use etc. Clinicians or patients may continue to use the affected product if they take the appropriate actions outlined in the Alert.

NOTE: A Product Alert may later be superseded by a Recall.

3 RECALL ACTION CLASSIFICATION

Recall actions of therapeutic products are classified according to the European classification system based on the risk impact to the patients/consumers.

They are: Class I, Class II, and Class III.

Class	**Definitions and Examples**
Class I	A recall action should be classified as a **Class I recall action** if the defect identified in the product is potentially life-threatening or could cause a serious risk to health. Examples: ▪ Wrong product (label is different to contents) ▪ Correct product but wrong strength, with serious medical consequences ▪ Microbial contamination of sterile injectable or ophthalmic product ▪ Chemical contamination with potentially serious medical consequences ▪ Mix up of some products (rogues) with more than one container involved ▪ Wrong active ingredient in a multi-component product with serious medical consequences ▪ Increased failure rates of a medical device ▪ Software defects resulting in incorrect operation of a medical device ▪ Hardware failures resulting in potential patient risk.
Class II	A recall action should be classified as a **Class II recall action** if the defect identified in the product could cause illness or **incorrect** treatment but the risk is not considered serious enough to be Class I. Examples: ▪ Mislabelling (eg, wrong or missing text or figures) ▪ Missing or incorrect information – leaflets or inserts ▪ Chemical/physical contamination (significant impurities, cross-contamination, particulates) ▪ Mix-up of products in containers (‘rogues’) where the mix-up could cause illness or incorrect treatment that would not have serious medical consequences ▪ Non-compliance with specification (eg, assay, stability, fill/weight) ▪ Insecure closure, without serious medical consequences (eg, cytotoxics, child-resistant containers, potent products) ▪ Higher than expected rate of revision surgeries due to mechanical

	failures to one of the components of an implanted device ▪ Software anomalies.
Class III	A recall action can be classified as **Class III recall action** when the identified defect in the product may not pose a hazard to health but where a recall action has been initiated for other reasons, and the risks are not considered to be Class I or II. Examples: ▪ Faulty packaging eg, wrong or missing batch number or expiry date ▪ Faulty closure (not including child-resistant closures).

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4 LEVELS OF RECALL ACTION

The principal factors to be considered when determining the level (or depth) of a recall action are the significance of the risk, and the channels by which the products have been distributed.

NOTE: The organisations targeted in each level will vary according to the distribution channels used for the product being recalled and the reason for the recall action. In certain circumstances, when a product has only been supplied to a limited number of customers/users who are known, a recall may be limited to those customers/users only.

4.1 Wholesale Level

Wholesale level includes:

- Medicine and medical device wholesalers and suppliers.

4.2 Hospital/Laboratory Level

Hospital/Laboratory level may include, as appropriate:

- Hospitals including private hospitals and residential care facilities
- Nursing homes and other health care facilities
- Clinical Trial Sites
- Hospital pharmacies, blood banks, pathology laboratories
- Personnel in other hospital departments
- May also include: wholesale and healthcare professional levels.

4.3 Retail Level

Retail level may include, as appropriate:

- Community pharmacies
- Medical, dental and other health care practitioners
- Other general retail outlets, eg, supermarkets and health food stores (depending on the product)
- May also include: wholesale level and hospital/laboratory levels.

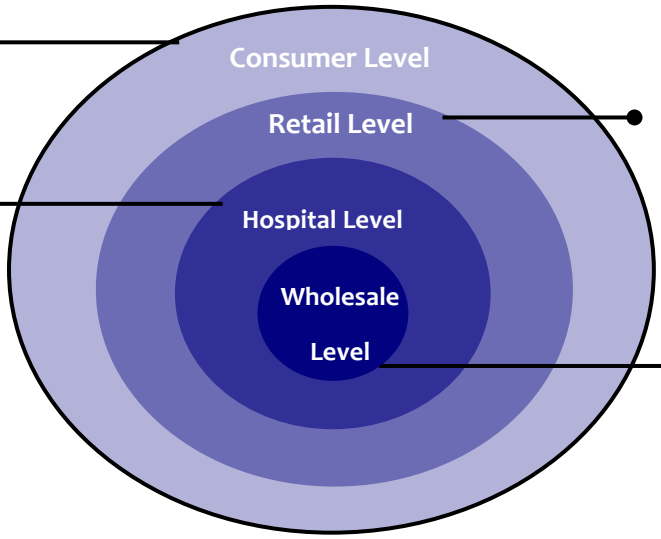
4.4 Consumer Level

Consumer level Includes:

- Patients and other consumers
- May also include: wholesale, hospital/laboratory, and retail levels.

The following diagram shows the levels of recall actions.

Consumer Level is used where there is a significant risk of harm to the consumer or user. It includes Wholesale, Hospital and Retail levels.



Retail Level includes Wholesale and Hospital levels.

Hospital Level includes Wholesale level**.**

Wholesale Level includes medicine and medical device wholesalers

5 RECALL ACTION PROCESS

The recall action process describes actions that may be taken to protect the public when a defective or potentially harmful product has been identified in the market.

The Recall Action Process involves the following phases of activities

Phase 1. **Initiation** - Notification and problem identification, hazard/risk assessment, recall action assessment and agreement (strategy, classification and level, and communication plan).

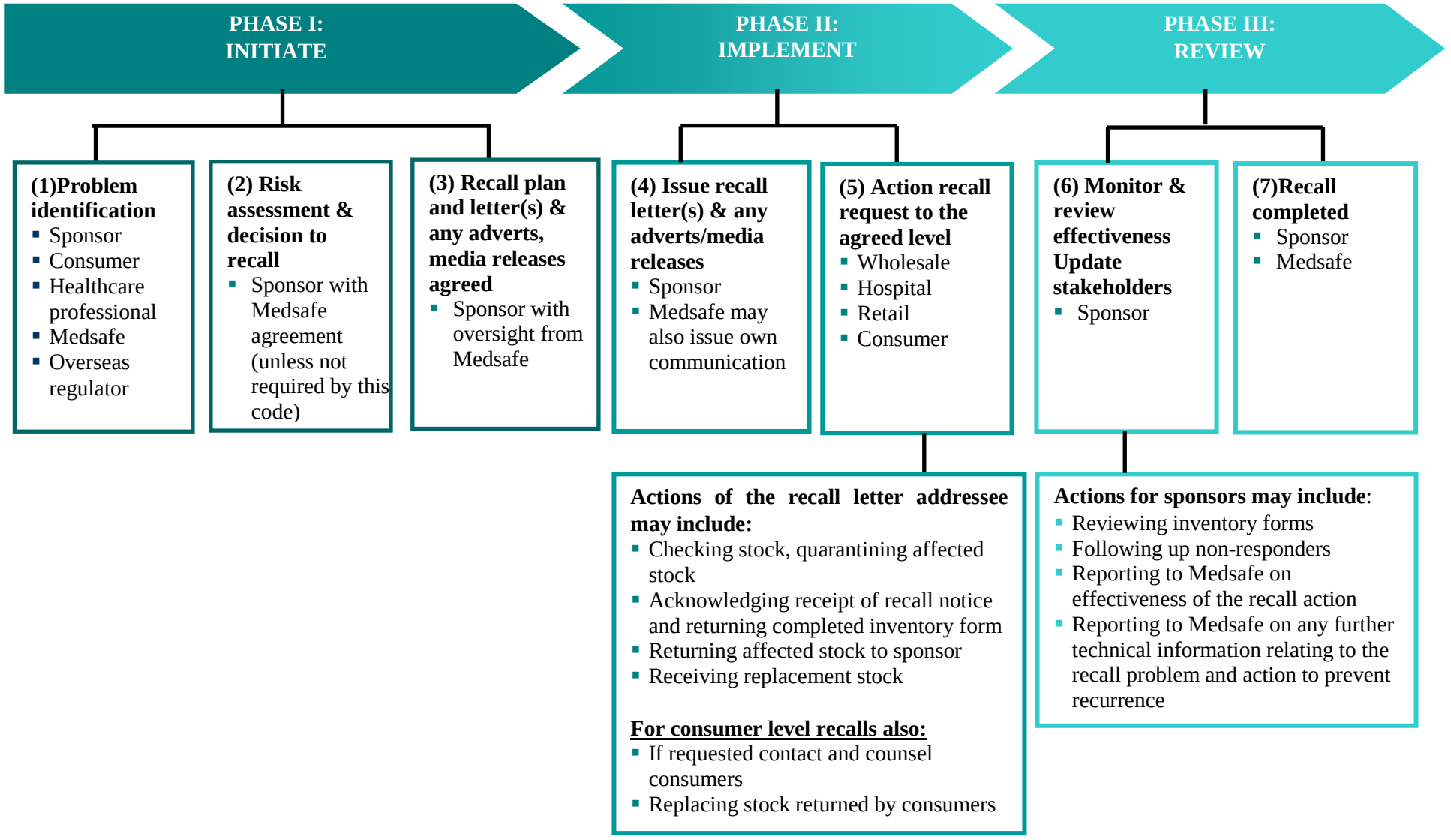
Phase 2. **Implementation** - Sponsor is responsible for notifying the recall action to the agreed level. Medsafe monitors the recall action process to ensure that it is carried out in an effective and timely manner by reviewing progress reports submitted by the sponsor.

Phase 3. **Review / Close Out** - The review / close out documents the effectiveness of the recall action. This phase includes the identification of the root cause of the issue and whether the remedial /corrective actions implemented by the manufacturer are likely to reduce the likelihood of the same issue recurring.

Sponsors and manufacturers of therapeutic products in New Zealand have responsibilities in relation to market recall actions for therapeutic products. These processes and the associated responsibilities are detailed in the following sections

The following diagram shows an overview of the recall action process.

OVERVIEW OF THE RECALL PROCESS



6 RESPONSIBILITIES OF SPONSORS

SPONSOR: The term 'sponsor' refers to the person or organisation that is legally responsible for the product in New Zealand. This may be a New Zealand manufacturer or proprietor, or supplier, or importer or exporter.

Sponsors are responsible for identifying potential issues with their products, assessing the risks of any identified hazards and mitigating those risks. In addition, sponsors and manufacturers are responsible for maintaining records and establishing procedures which will assist in facilitating a recall action should such action become necessary. Sponsors should have access to staff with the required knowledge and expertise of the products and products and regulatory process to effect a recall action.

6.1 Recall Preparation and Planning

Every sponsor should have in place a written recall procedure that describes how a recall action will be initiated and carried out, and should ensure that relevant staff members are appropriately trained in the procedure. Detailed requirements are to be listed in the procedure and must include requirements which correspond to the agreed recall action strategy and reporting requirements.

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

Part 1 – Describe how complaints or problems regarding product quality are handled and when and how a decision to notify Medsafe is made.

The recall procedure should include:

- The company's procedure for receiving complaints or reports of problems
- Arrangements to ensure that each problem report is adequately assessed by a person who is appropriately qualified
- Trends analysis of reported problems
- A procedure to quarantine stock on hand
- A process for forwarding details of reported problems to manufacturing/packing sites
- A process for identifying when to report problems to Medsafe
- A description of how a decision to recall is made, including input from Medsafe.

Prior to notification of an issue or potential recall action to Medsafe, where possible, the sponsor should gather all the relevant information as set out in Section 6.2 such as problem reports (or complaints), details of the product in question, its distribution, potential health impact to patients and the proposed action/response.

Part 2 – Describe how a recall action will be conducted

The second part should include information about:

- The appointment of a co-ordinator for the recall action
- How to access current contact details for Medsafe, funding bodies and the businesses/organisations that may need to be contacted in a recall action situation
- The actions to be taken (listed in chronological order) including contact with Medsafe, PHARMAC and any other relevant funding body
- How technical details required for the recall action will be obtained
- How distribution records (including distribution to any export customers) will be obtained
- The determination of the appropriate level for the recall action
- Preparation of the recall action plan and recall letter(s) (See Appendix 2A-3B for template letters and acknowledgement forms)
- NOTE: The contents of the recall action plan, the recall letter and other communication should be agreed with Medsafe before distribution.
- Planning for communications about the recall action with consumers, wholesalers, distributors, health care professionals, etc, including the method of communication and details of the message
- Determination of the mechanism for transmitting the recall action notice (eg, fax, telephone or email). The communication method should be agreed with Medsafe.
- Contacts for advising the recall action and contacts that may need to be made with other organisations depending on level of recall action and the affected product. Examples include funding organisations, and bodies representing health professionals or general retail outlets
- Arrangements, including the provision of quarantine facilities, for returned product
- Conduct of the recall action, including replacement of affected stock and arrangements for reimbursement of any direct costs incurred by those enacting the instructions in the recall action letter
- Arrangements for the disposal or modification of affected product
- Preparation and submission to Medsafe of progress reports on the recall action
- Preparation of a summary report for Medsafe once the recall action is completed
- A description of the records that should be kept of the actions taken and the retention period for the records (which should be a minimum of six years).

6.2 Initiation Phase

Medicines

The sponsor should immediately consult Medsafe when evaluation of a reported issue concerning a medicine indicates that a recall action may be necessary. Refer to Appendix 1 for contact details. Faxed material should be marked "**URGENT**".

All medicine recall actions should be carried out with the knowledge and agreement of Medsafe.

For medicines, the classification and level of recall action is determined following discussion between the sponsor and Medsafe and will involve an assessment of the health hazard presented by the product. The criteria that will be used by Medsafe for this assessment are described in Section 9. Consultation with external experts may also be appropriate.

The level of recall action will generally reflect the safety risk and distribution pattern of the product.

The risk assessment includes consideration of the following factors:

- The potential harm to the consumer as a result of the issue
- The likelihood of the issue occurring
- The ability of the consumer, healthcare professional or caregiver to discover/identify the issue should it occur
- Whether the product complies with the approved specifications
- The availability of an alternative product, or the risk associated with not providing treatment if an alternative product is not available.

Medical Devices

New Zealand sponsors should discuss the issue with Medsafe prior to initiating any recall or non-recall action.

Where a product distributed in New Zealand is manufactured overseas and a recall action occurs overseas, Medsafe should be informed as soon as possible and advised of the proposed actions for New Zealand. The sponsor should provide Medsafe with copies of proposed notices for New Zealand and ensure that they are appropriate for the New Zealand market.

For all medical devices, whether manufactured in New Zealand or overseas, Medsafe reserves the right to require a different recall action from that proposed by the sponsor.

The level of recall action will generally reflect the safety risk and distribution pattern of the product.

The risk assessment includes consideration of the following factors:

- The potential harm posed by the issue
- The likelihood of the issue occurring
- The ability of the consumer, healthcare professional or caregiver to discover/identify the issue should it occur
- Whether the product complies with the manufacturer's specifications
- The availability of an alternative product, or the risk associated with not providing treatment if an alternative product is not available.

For Both Medicines and Medical Devices

Following the initial contact with Medsafe the process is as follows:

a) Supply of information to Medsafe: technical, distribution, assessment of risk, impact on users etc. Information that may be required from the sponsor is outlined below.
b) Final decision on the type and level of the recall action is made following discussion between the sponsor and Medsafe.
c) The recall procedure is followed and the recall action letter or communication is written (see Appendix 2A-3B for template). This may be in parallel with (a) above.
d) For consumer level recalls see the additional requirements are described later in this section.

Information Requirements

The information required to assure Medsafe that any safety risks will be effectively mitigated is provided below.

Medsafe should be supplied with as much information as possible during the initial contact. If some information is not immediately available, this should not delay prompt notification. Any absence of information should be identified by the sponsor at the initial contact.

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 thereafter.

- Name and details of sponsor
- Name, telephone, email address and fax number of the person reporting the problem
- Product name – brand name and INN or generic name
- Dose form, strength, pack size for a medicine or unique identifier for a medical device (ie, catalogue reference, model reference, part number, etc.)

- Nature of the problem/issue including number of similar reports received
- Description of the product and its intended purpose
- History of the incident with specific dates when it occurred/was observed and frequency
- Details of the affected sub-set of product (eg, 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 (ie, 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 (ie, where product is in the distribution chain, current undistributed stockholding, quantity supplied to customers, etc.)
- A description of the extent of distribution of the affected product
- Whether the product has been exported from New Zealand, and if so, to which countries
- An assessment of the health hazard 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:

- 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 sponsor and/or manufacturer to correct the root cause of the problem.

Hazard/ Risk Assessment

Where a sponsor becomes aware of a possible safety hazard or a potential issue (fault or deficiency) with a therapeutic product that has the potential to cause harm or injury to a person, the sponsor should immediately undertake the following actions:

- Gather and assess the reliability of all available information about the potential issue.
- Identify how the problem occurred.
- Assess all possible ways of addressing the safety-related hazard and decide on a suitable remedy, such as carrying out repair work or a modification (if a medical device) or recalling the product for processing and destruction and discuss with Medsafe.

NOTE**:** A manufacturer may have already conducted a hazard / risk analysis on the possible safety issue. The sponsor should forward the available hazard or risk analysis to Medsafe.

Conducting a Consumer Level Recall Action

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

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

Part 1: Sponsor Checklist of Required Actions

1. **Prepare correspondence (recall action letters) to known end-users**, wholesalers, retailers, hospitals, pharmacists, etc., who are affected by this recall action.

2. **Prepare a consumer level advertisement** and provide to Medsafe for review

    a) Obtain Medsafe agreement to the Consumer Level Recall action advertisement (refer to Appendix 4), or Medsafe agreement that it is not required because contact with all consumer end-users can be assured by another means.

    b) Consider which media can most effectively reach the demographic being targeted. Two different media (eg, print and radio) could be considered.

    c) Book space for the advertisement to appear in all daily newspapers.

    d) Provide the publication schedule for the advertisements to Medsafe when available.

    e) Supply Medsafe with the content of the agreed advertisement so it can be put onto the Medsafe website, and where it exists, the sponsor's website.

3. **Prepare a media release** (where appropriate), which will be reviewed by Medsafe.

4. Handling Communications

a) Ensure staff responding to telephone calls, emails, faxes and external enquiries relating to this issue have a **question and answer document** that provides guidance on how to advise consumers of the correct action to take with respect to the recall action, and respond to queries from wholesalers, pharmacists and end-users.

b) Ensure that 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. – is set up.

c) Ensure a **system for documenting telephone calls** is prepared to record the names and contact details of callers, the number of calls, the types of inquiries, and action taken.

5. An **initial teleconference with Medsafe** (and if required, key stakeholders) has been convened to share and agree the communications plan.

Part 2: Format of a Consumer Level Recall action Advertisement

A Consumer Level Recall action Advertisement should conform to the Ministry of Consumer Affairs guidelines for recall notices as detailed in "Recalling Unsafe Products". 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 action advertisement should be two columns wide and be no smaller than 36 column centimetres
- The advertisement should have a crosshatch border surrounding it to distinguish the notice from other advertisements. (See Appendix 4 for an example of a Consumer Level Recall action Advertisement)
- The symbol "Danger Triangle" should be 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
- Use a font size that is easily readable in the format printed.

Part 3: Content of Consumer Level Recall action Advertisement

The recall action 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 action
- Instructions for the return, repair, replacement or refund of the product
- A statement to the effect that “This recall action is being conducted following consultation with Medsafe, Ministry of Health” should 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 contact < details >”
- The word voluntary is not to be used. The recall action is not to be downplayed (See Appendix 4).

6.3 Implementation Phase

Conducting a recall action includes informing the respective persons/organisations (health care professionals, patients, hospitals, retailers, wholesalers or distributors), monitoring the effectiveness of the recall action and implementing the communication strategy.

A recall action should be implemented in accordance with the procedures set out in this Recall Code.

A recall action should not be initiated until the recall process and correspondence have been discussed and agreed with Medsafe.

Distribution of recall action letter and other communication

- **The final recall action letters and other communication that has been prepared in consultation with Medsafe is distributed to the various stakeholders. (See Appendix 5 for details of distribution lists and other organisations to contact)**

The distribution of recall action notices should have optimal coverage. Sponsors should therefore endeavour to use a contacts database that is likely to provide the optimal practicable reach to the target audience.

Sponsors choosing to use a commercially available database administered by another organisation should ensure that it is up to date and that it includes all members of the target audience, including those who have opted out of receiving routine or advertising material. Some healthcare professionals opt-out of receiving materials/ information to avoid unwanted advertising, but some distribution organisations are able to include such addressees when the communication is an important safety notice such as advice about a recall action.

For medical device recall action notices, contact information for hospitals and District Health Boards is available for download from a link on the navigation panel on the left hand side of the home screen following sign-on to the WAND database on the Medsafe website (http://www.medsafe.govt.nz/regulatory/wand.asp).

Publicising Recall actions

Paid Advertisements

If a recall action is to be conducted at the consumer level and not all consumers can be identified, advertisements paid for by the sponsor are to be inserted as soon as possible in national and regional daily papers. The text of such advertisements should be agreed by Medsafe. The choice of daily newspapers should be made in consultation with Medsafe. Consideration should also be given to the need to inform consumers who are not native speakers of English.

Sponsor Media release

In the case of Class I or II consumer level recalls, it is recommended that the sponsor prepare a media release.

The media release should contain sufficient detail to uniquely define the product, give a clear explanation of the problem (without causing unnecessary alarm) and state the appropriate response by the consumer. A contact telephone number should be provided which provides consumers with 24-hour access to further information (preferably by a free phone or toll free number).

Publication of a Consumer Level Recall action Advertisement

- A Consumer Level Recall action Advertisement should appear simultaneously (or as close as possible) in all regional daily newspapers
- The additional use of other media eg, electronic 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.

Retrieval of the affected product

The sponsor is required to make arrangements for the retrieval of the affected products from the market (where required). These arrangements should include:

- Establishing collection points across the distribution network.
- Notifying the relevant parties, including other entities in the supply chain and consumers of the method of retrieval of the recalled product.
- Arrangements for disposing of the returned product. This may involve arranging for the returned product to be held and kept separate until it can be safely destroyed.

Company representatives (medical detailers and sales representatives) may recover stock that is subject to a recall action, providing the applicable legislative requirements are observed in relation to unauthorised possession of certain stock, eg, medicines of addiction and restricted substances.

6.4 Review Phase

a) Non-responders are followed up by the sponsor to ensure that all affected parties are aware of the recall action, and to check that contact details are up-to-date.
b) Medsafe should be provided with progress reports, generally at two and six weeks after initiation of the recall action, and at other times as requested.
c) At the completion of the recall action the sponsor provides Medsafe with a summary of the actions taken including: data on and the fate of the stock returned, response rate to the recall action notification, any further technical information relating to the recall action problem, and the action taken to prevent a recurrence of the problem.

Progress Reports

The sponsor should provide Medsafe with progress reports on the implementation of the recall action, the response rates, the investigation into the issue and any corrective and preventive actions planned or implemented.

The timing of these reports should be agreed with Medsafe but would normally be at two and six week intervals after initiation of the recall action activity.

Initial Report

To be submitted to Medsafe two weeks after the implementation of the recall action (or as agreed). This report should include

- A copy of the signed recall action letter (if this has not already been provided) and the date recipients were notified.
- Information on the progress of the recall action, response rate and actions initiated or proposed regarding non-responders.
- An initial investigation report.
- Information on what contact has been made with the recipient(s) of any affected product that has been exported from New Zealand.

Follow-up Report

To be submitted to Medsafe six weeks after the implementation of the recall action (or as agreed). This report should include:

- An update on the response rate, actions taken in regards to non-responders and return of stock.
- Confimation that all customers with units requiring correction have been identified.
- Any updated information on the investigation into the root cause and the CAPA's.
- Any other information that may be relevant.

Final Report

A final (close-out) report is required on completion of the recall action.

The timeframe for submission of this report should be agreed at the time the recall action is initiated, but may need to be reviewed. A default timeframe of three months is proposed by Medsafe. The minimum information required for this report is outlined below. The sponsor is not required to repeat information in the close-out report that has already been provided to Medsafe, unless there is a change to that information.

- In the case of a a product recall, information on the status of all recalled product. A certificate of destruction is to be provided where the affected products have been destroyed.

- In the case of a recall for product correction, confirmation that the product correction has been applied to all units with customers (or that all customers have been supplied with the correction)
- An investigation report into the root cause of the issue that led to the recall action and the remedial action(s) proposed and the timing for implementation.

7 RESPONSIBILITIES OF WHOLESALERS

Every wholesaler should have a written procedure describing how a recall action requested by a sponsor will be conducted.

7.1 Recall action Procedure

A recall action procedure for a wholesaler should cover:

- The appointment of a person in charge of expediting recall actions
- A description of how product can be traced within the stock control system
- Quarantine arrangements for recalled products
- How product 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 action was only to wholesaler level)
- Record keeping (records are to be kept for a minimum of - seven years)
- Response to the sponsor
- Mechanism for product replacement for pharmacies or other purchasers if applicable.

For recall actions going to levels beyond wholesale, the wholesaler should contact any organisations it has supplied the affected product to which would not be likely to be on a mailing list used by the sponsor, or notify the sponsor of such organisations. 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
- Organisations that may include the affected product as a component in a new combination product (eg, compounding manufacturers).

8 RESPONSIBILITIES OF HEALTHCARE PROFESSIONALS

Healthcare professionals have an ethical and professional obligation to safeguard consumers in any recall action. The healthcare professional may delegate these tasks to a competent person, but should remain vigilant for clinical repercussions.

Healthcare professionals should be aware of their responsibilities under the Code of Health and Disability Services Consumers' Rights in relation to open disclosure when they are providing advice to consumers who have been treated with a medicine or medical device that is subject of a recall action (see Appendix 6 for guidance on this and other legal issues).

Where product that may have been affected has been exported or supplied to another organisation (eg, nursing home, another pharmacy, a doctor's surgery, a laboratory) this organisation also needs to be contacted to advise of the recall action and to advise the process for the replacement of any product that might be affected.

Information on the application of requirements in privacy law and the medicines legislation to recall action situations is provided in Appendix 6.

In cases of queries about the recall action, the sponsor should be contacted as per the contact details on the recall action letter.

Where the healthcare professional is developing written procedures for managing recall actions consideration should be given to:

- The actions to be taken, listed in chronological order
- How stock is quarantined and stock in transit is managed
- Communication to relevant staff (including inwards goods and clinicians)
- Communication to other organisations the medicine or medical device has been sold or loaned to
- How to access consumer details for a consumer level recall action (if applicable)
- Communication to consumers.

In some instances, physicians with patients under their care who have implanted devices are asked to contact the patients as soon as possible to advise them of the issue. A reasonable attempt should be made to locate and contact the patients to advise them of the safety issue. Should there be any privacy concerns about contacting a patient, please refer to Appendix 6 Guidance on Legal Issues.

NOTE: Healthcare professionals can also play an important role in **reporting defects.** Advice on this is provided in section 10.

8.1 Healthcare Professional Level

In a recall action to healthcare professional level, any healthcare professional supplying, prescribing or using an affected medicine or supplying or having implanted a medical device should safeguard consumer safety by following the instructions in the recall action notice and by ensuring that they:

- Promptly check and quarantine affected product as outlined in the recall action letter
- Promptly return the acknowledgement and inventory of stock on hand form, including nil returns
- Return affected product if applicable
- Carry out any other actions specified in the recall letter
- Inform other relevant staff in their organisation
- Prominently display the recall action notice for staff for a month

8.2 Consumer Level

In a recall action to consumer level, any healthcare professional dispensing or directly supplying the medicine or medical device should ensure consumer safety by following the instructions in the recall action notice, in relation to:

- Contacting consumers who have been supplied with the product being recalled. Initial attempts to contact consumers should occur as quickly as possible because of the health risk associated with the product. If telephone, text or email contact cannot be made in a manner that protects the patient's privacy, the consumer should be advised by mail of the recall and asked to contact the healthcare professional
- Advising consumers about the recall action, the reasons for it, and the actions the consumer should take according to the recall action letter and the individual consumer's circumstances (for example if clinical signs indicate a need for medical follow up)
- Replacing or upgrading product held by the consumer where required

8.3 Responsibilities of DHBs and Private Hospitals (Medical Devices)

District Health Boards and private hospitals should have a designated person, e,g Clinical Product Co-ordinator, to manage actions arising from the issue of a recall action notice for medical devices. This person should:

- Ensure appropriate procedures are in place to manage recall action actions

- Ensure recall action notices are promptly supplied to relevant staff throughout their District Health Board, and are acted on
- Ensure other relevant staff are informed of the recall action where applicable, including, for example, those who may need to know for their clinical management of potentially affected consumers, and those in inwards goods, or biomedical engineering departments
- Encourage medicine adverse incident reporting to Centre for Adverse Reaction Monitoring (CARM)
- Encourage medical device adverse event reporting to the sponsor and Medsafe.

9 RESPONSIBILITIES OF MEDSAFE

Medsafe is responsible for administering the Medicines Act 1981 and the Medicines Regulations 1984.

Medsafe regulates products used for a therapeutic purpose including medicines, related products, medical devices and controlled drugs used as medicines. The objective of the legislation is to manage the risk of avoidable harm associated with the use of these products.

When assessing the health hazard presented by a product that is being considered for recall action, Medsafe will take the following factors into account (as well as any other factors that are relevant to the particular situation):

- Whether any illness or injury has already occurred from use of the product
- Whether any existing conditions could contribute to a clinical situation that could expose humans to a health hazard
- The hazard to individual groups within the exposed population (such as children, the elderly, consumers having surgery or those who are immunocompromised)
- The degree of seriousness of the health hazard to which the population will be exposed
- The likelihood of occurrence of the risk
- The consequence (immediate or longer term) of occurrence of the hazard
- Alternative treatment options, including the risk associated with providing no treatment if an alternative is not available.

The risk classification and level of recall will be agreed by Medsafe and the sponsor/manufacturer on the basis of this information.

Medsafe will publish all recall actions on the Medsafe website. Where additional information for consumers and others is provided, this will be linked from the recall entry in the Medicines Online Recalls Database (MORD).

Medsafe will react promptly when advised of a recall action.

Medsafe will deal with the sponsor in a professional and transparent way to address the issue.

When considering any recall action Medsafe gives priority to the safety of consumers, healthcare professionals and caregivers potentially affected.

Medsafe will examine the progress reports forwarded by the sponsor.

These reports allow Medsafe to assess the effectiveness of the recall action and review the investigation of the reason / root cause for the recall action and remedial action taken to prevent or minimise the recurrence of the problem in the future. Medsafe reviews these reports to determine if the implementation actions, corrective and preventive actions (CAPA) or remedial actions are satisfactory. This includes verifying that:

- All agreed actions were completed and documentary evidence provided
- Any discrepancies or inconsistencies are justified
- Evidence of the fate of the final product provided as agreed in the recall action strategy has been supplied.

If any of the actions as listed above are missing or not justified, Medsafe will follow up with the sponsor.

Where Medsafe is satisfied with the implementation of the recall actions, Medsafe will notify the sponsor that no additional information is required and the investigation will be recommended for closure.

Recall action records held by the sponsor may be reviewed by Medsafe.

Medsafe will review the Recall Code on a regular basis and update where necessary.

10 REPORTING A PROBLEM OR SUSPECTED DEFECT

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 sponsor are explained in section 6).

10.1 Problem Identification

During distribution or use of a medicine or medical device it may become evident that a product quality issue exists or for some other reason the product appears defective (eg, a design flaw in a medical device causing its premature failure). This should not be confused with an adverse reaction where the product conforms to its specification but an adverse event or reaction is observed.

Healthcare professionals, consumers, 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.

10.2 Notification

Reporting of defects by healthcare professionals or laboratory staff should be carried out in accordance with any internal procedures which should include the following:

a) Contact the sponsor company. Telephone numbers can be found in medicine data sheets, in the back of *MIMS New Ethicals* (for medicines), 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 1 for contact details).

The following information will be useful if available:

- Product name, (and strength and dose form in the case of medicines)
- Sponsor
- Batch/lot number/serial number (if known)
- Expiry date (if applicable and known)
- Defect and details of any associated clinical incident
- Name, email address telephone and facsimile numbers of the person reporting the problem
- A photo (if available)

c) If unsure whether the problem could be a product defect or an adverse event or incident relating to the way the product (usually a medical device) was used, report to the product sponsor (if known), otherwise report to Medsafe.

Consumers are encouraged to report any problems to the place of supply, eg, the pharmacy the medicine was supplied from or the healthcare professional who provided the device. The healthcare professional is then responsible for communicating appropriately with the New Zealand sponsor/manufacturer. Medsafe can also be contacted for potentially serious problems (see Appendix 1 for contact details).

Appendix 1: Contact Details for Medsafe

For a potential recall action, the preferred initial contact is by telephone or e-mail.

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 Sponsors use a bold heading: "**Urgent Recall action**" and specify if the problem relates to a medicine or medical device Healthcare professionals use a bold heading "Urgent" and specify if the problem relates to a medicine or medical device
Email	recalls@moh.govt.nz

Adverse events for both medicines and medical devices can be reported by anyone, including consumers, caregivers, healthcare professionals and sponsors.

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)

Note: Adverse Events for medical devices are to be reported to Medsafe . 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.

Sponsors of medical devices may prefer to submit reports to Medsafe using the TGA MDIR 03b form. When a sponsor 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 2A: Recall Action Letter Format – Medicine/ Medical Device

< Sponsors letterhead >

Date

Addressee

(URGENT) <MEDICINE / MEDICAL DEVICE > RECALL

Class of Recall _____

Level of Recall _____

Description of items under recall (Brand, model) <Product Name>

Affected product (Catalogue Number, Order Code Lot number, Batch Number, versions, serial number range, date of manufacture, expiry date)

Issue

Detail about the nature of the issue leading to the recall and how the affected <device / medicine *can be identified.*

Other pertinent information eg, alternative product, date introduced to market, effect on other batches/lots/versions.

Comment on health risk.

Action

- Instruction to **immediately** check / inspect stock, stop using and quarantine affected stock <*batch numbers*> on hand to prevent further use.
- Instruction to advise other relevant staff members of this recall, Instructions if product has been supplied or transferred to another site or organisation.
- Instruction to complete the attached Acknowledgement form even if no affected stock is held and return it. Fax numbers should be NZ numbers and preferably free fax. An option to scan and email the acknowledgement form could also be included
- An instruction regarding the return/replacement of affected stock.
- An instruction to retain this letter in a prominent position for one month in case stock is in transit

Additional information can also be included that expands on information provided earlier in the letter, eg, diagrams showing how to identify affected product, information on when an upgrade may be available, alternative product that may be available for use.

For consumer level recalls, information regarding contacting patients, managing patient returns, follow-up information for patients, whether other healthcare professionals have been notified, and replacement arrangements for returned stock, should also be included.

Company contact information.

A statement that this recall action is being taken by [*Sponsor/ Company Name*], after consultation with Medsafe, New Zealand Ministry of Health.

A statement acknowledging assistance with the recall or apologising for inconvenience caused by the recall.

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

Appendix 2B: Hazard Alert Letter Format – Medical Device

< Sponsors Letter Head>

Date

Appropriate Recall Contact (s) (which may include implanting surgeons or treating clinicians and hospitals)

< Address>

URGENT MEDICAL DEVICE HAZARD ALERT

Class of Recall _____

Level of Recall _____

Description of items under recall (Brand, model) <Product Name>

Affected product (Catalogue Number, , Order Code Lot number, Batch Number, versions, serial number range, date of manufacture, expiry date)

Issue

Detail about the nature of the issue leading to the recall and how the affected devices can be identified.

Details of the consequences for the patient/healthcare professional using an affected product.

Action

- Instruction to ensure all relevant staff members are informed of this hazard alert including *locums, inwards goods, credit returns staff, biomedical engineers, relevant clinicians who may need to monitor for adverse events, as applicable*
- Instructions if product has been supplied or transferred to another organisation
- Instruction regarding contact with patients implanted with the affected device
- Instruction to **confirm** receipt of this hazard alert to complete the attached acknowledgement form and return it to [*fax numbers, preferably free fax*] or scan and email to [*email address*].

Company contact information:

A statement that this recall action is being taken by [*Sponsor/ Company Name*], after consultation with Medsafe, Ministry of Health.

A statement acknowledging assistance with the recall action or apologising for inconvenience

caused by the recall action.

Signature, name and position of person signing the hazard alert letter.

Appendix 3A: Acknowledgement Form Format – Recall Action

Acknowledgement Form

Urgent <Medicine / Medical Device> Recall

Description of items under recall (Brand, model) <Product Name>

Affected product (Catalogue Number, , Order Code Lot number, Batch Number, versions, serial number range, date of manufacture, expiry date)

I acknowledge receipt of the Urgent <Medicine / Medical Device > Recall notice date [*insert date of notice*] relating to the above product.

Affected Stock

If you have **no affected** stock tick this box [ ]

If you have affected stock please complete the table below

Stock details		
Product	**Batch/Lot/Date**	**Quantity**
TOTAL AFFECTED PRODUCT		
Other Relevant Details:		

Has your organisation supplied potentially affected product to any other organisation?

[ ] No

[ ] Yes (please supply names and contact information of the organisations)

OR

[ ] Yes – I / we will forward all the recall action information to the suppliers / distributors / customers

Information on company contact details including contact name, free fax, and/or email information (who the response is to be sent to and how it should be sent).

FROM:

Name		**Date**	
Position		**Telephone No.**	
Email		**Facsimile No.**	
Organisation			
Signature			

Appendix 3B: Customer Acknowledgement Form Format – Hazard Alert

Acknowledgement Form

Hazard Alert

Description of items under recall (Brand, model) <Product Name>

Affected product (Catalogue Number, , Order Code Lot number, Batch Number, versions, serial number range, date of manufacture, expiry date)

I acknowledge receipt of this Alert and confirm that I will / have contacted the affected patients.

FROM:

Name		**Date**	
Position		**Telephone No.**	
Email		**Facsimile No.**	
Organisation			
Signature			

Completed forms are to be returned by fax or email or post to

Name		**Date**	
Position		**Telephone No.**	
Organisation			
Address			
Email		**Facsimile No.**	
Subject: Recall of <Product Details and Description including batch/ lot details> <Insert Details>			

Note: Additional Requirements: <Insert Additional Information>

Appendix 4: Sample Advertisement Consumer Level Recall

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 more information contact the Acme Corporation on 0800-111-111

Appendix 5: Organisations and Distribution Lists

The following pharmacy organisations may be able to enhance the effectiveness of hospital, retail and consumer level medicine recall actions by informing their members that a recall action has been initiated:

- Pharmaceutical Society of New Zealand

  Tel: 04 802 0030
  Fax: 04 382 9297
  Email: p.society@psnz.org.nz

- Pharmacy Guild of New Zealand

  Tel: 04 802 8200
  Fax: 04 384 8085
  Email: enquiries@pgnz.org.nz

- New Zealand Hospital Pharmacists' Association
  Tel: 04 802 0030
  Fax: 04 381 4786

  Email: nzhpa@psnz.org.nz

Sponsors should also consider whether other professional bodies whose members have a particular interest in, or involvement with, the type of product being recalled, may be of assistance in enhancing the effectiveness of a recall action. Medsafe can provide guidance on contact details for such organisations.

Appendix 6: Guidance on Legal Issues

This appendix has been included to provide responses to commonly asked questions about legal issues.

1. Recall Powers

Are there mandatory powers of recall in the medicines legislation?
Yes, but in practice almost all recalls occur as voluntary actions undertaken by sponsors, with oversight from the regulator (Medsafe). This is also common practice internationally. The provisions in the Medicines legislation relating to the mandatory recall of medicines and medical devices are:

- Regulation 50(1)(a) of the Medicines Regulations 1984 that provides that if a notice is in force under section 35 or 37 of the Act, the Director-General may issue an order directing the withdrawal from sale of a medicine or medical device or portion of a medicine or medical device if the Director-General believes on reasonable grounds that withdrawal is necessary to protect the public; and
- Regulation 50(1)(b) of the Medicines Regulations 1984 that provides that the Director-General may issue an order directing the withdrawal from sale of a medicine or medical device or portion of a medicine or medical device that does not conform to the specifications claimed for that medicine or medical device.

6. Pharmacy Issues

Is it lawful to provide a replacement supply of a medicine that is being recalled to consumer level without a new prescription?
Yes, in almost all circumstances the replacement supply can be provided under the cover of the original prescription.
A new prescription is **not required** to authorise the:

- Replacement of recalled product with unaffected stock of the same medicine. In this context, "*same medicine*" means a medicine of the same brand name, dose form and strength as the recalled product
- Replacement of recalled product with another brand of the medicine that has the same active ingredient, dose form and strength as the recalled medicine. Brand substitution should only occur if this is requested in the recall letter in order to deal with a situation where unaffected stock of the recalled product is not available.

NOTE: If brand substitution is requested in the recall letter but the original prescription has been marked "no substitution", the pharmacist will need to get authorisation from the prescriber for the brand switch (because regulation 42(4) of the Medicines Regulations 1984 would apply).

The pharmacist does, however, need to be able to access details of the original prescription in order to be satisfied that replacement supply is appropriate and that what is being supplied is in keeping with the original prescription. This will be straightforward when the consumer returns to the pharmacy where their medicine was dispensed to seek their

replacement medicine. When this does not happen, the pharmacist will need to use the information on the dispensing label of the container being returned by the consumer to make contact with the dispensing pharmacy and confirm the details of the original prescription before providing the replacement medicine. If it is not possible to confirm those details (for example because the unknown customer does not have the container from the original dispensing pharmacy and cannot remember where it was dispensed) a new prescription will be required.

A new prescription is **required** to authorise the:

- Dispensing of a *different* medicine to a consumer who has returned their recalled medicine. This would occur in situations where unaffected stock of the recalled medicine, or of a generic version of that medicine, is not available.
  The requirement would be stated in the recall action letter. The advice for consumers prepared and published by the sponsor would advise consumers of the need to obtain a new prescription before returning the recalled medicine.
- Replacement of recalled product (with unaffected stock of the same medicine or a generic version of the same medicine) where the consumer is not known to the pharmacist and the details of the original prescription cannot be confirmed from records held in that pharmacy, the pharmacy where the recalled medicine was dispensed, or by the original prescriber.

What should a consumer be told about how to obtain replacement medicine when contacted by their pharmacist or prescriber?
The consumer should be asked to bring any unused medicine with them in the container in which it was dispensed and, if possible, return to the pharmacy where the medicine was dispensed in order to receive replacement stock.

What amount of medicine should be dispensed to a consumer when giving a replacement supply?
An amount equivalent to that still left in the container in which the medicine was dispensed should be supplied unless that is impractical (for example in the case of eye drops, metered dose inhalers, tubes of cream etc). In such cases a replacement original pack should be provided. A record of details from the original dispensing label should be kept in the pharmacy for audit purposes.

Should a new container and label be used for the replacement medicine?
Yes. The new label should contain the new date of dispensing, quantity supplied, unique identifier for this supply and state that this is a replacement dispensing.

7. Privacy Issues

Can a health professional request contact or other details for a consumer who needs to be contacted in a recall action situation from another health professional?
Yes. There are a number of justifications for this in the Health Act 1956 and the Health Information Privacy Code 1994.
Under section 22F of the Health Act, a person who is providing health or disability services to an individual may request the disclosure of health information from any person holding

that information (a consumer's contact details or details about medication they are on are considered health information under the Health Information Privacy Code).
Another reason for justifying disclosure of health information in a recall action situation is rule 11(2)(a) of the Health Information Privacy Code on the basis that giving details to another health professional involved in providing health services to a consumer is a directly related purpose (ie, a purpose closely connected with the purpose for which the information was collected). Clearly, providing ongoing medical care to a consumer is a closely related purpose and under rule 11(2)(a) disclosure is permitted in this case even where obtaining individual authorisation is not practicable.
Finally, rule 11(2)(d) would allow for disclosure of details when the recall of a medicine could cause a serious and imminent threat to the health of a person, such as in a Class I recall.
Under section 22F, a valid request may only be refused where the holder believes the individual does not want the information disclosed, where the refusal is authorised by the Health Information Code, or where the person holding the information has a lawful excuse (such as a statutory obligation of confidentiality or one of the grounds in sections 27-29 of the Privacy Act) to refuse the request. There is nothing in the Health Information Privacy Code to prevent a health professional from disclosing such details, nor is there a statutory obligation to refuse so the only valid reason for refusal would be if the health professional involved believed the consumer did not want their details disclosed in which case they should contact the consumer themselves to notify them of a recall action.

What is open disclosure and how does it apply to the recall procedure?
Open Disclosure refers to open communication when things go wrong in health care.
The elements include:

- Providing an expression of regret;
- Giving a factual explanation of what happened;
- Explaining the consequences of the event; and
- Describing the steps being taken to manage the event and prevent a recurrence.

Health and disability service provider organisations have a legal duty to take steps to ensure that open disclosure is practised by staff and supported by management. Its relevance in this case is obviously that a consumer receiving health care should be fully informed in a timely manner about a quality issue with a medicine or medical device that may adversely affect the consumer and has therefore led to a product recall action. This could either be by a pharmacist or doctor during a consumer-level recall action or by a doctor during a consultation where the doctor is aware that a trade-level recall action has taken place and the recall action may be relevant to the reason for the consultation.
There are a number of rights under the Code of Health and Disability Services Consumers' Rights that are relevant to open disclosure. Right 6(1)(e) provides that health and disability service providers have a duty of open disclosure according to legal, professional, ethical and other relevant standards. This duty is not transferable to third parties who are <u>not</u> health and disability service providers. Open disclosure standards are included in the revised Health and Disability Services Standards that must be followed by all health and disability services providers certified under the Health and Disability Services (Safety) Act 2001.