PHARMACY GUILD
OF NEW ZEALAND

Consumer level medicine recall guide

Pharmacists have an ethical and professional obligation to safeguard patients in any recall action.

This guide is to help you manage consumer level medicine recalls. We recommend you use this guide in conjunction with the New Zealand Medicine and Medical Devices Recall Code, 2015, available here.

Every pharmacy should have a written procedure describing how a recall action will be conducted (see appendix 1).

Below is the recommended process for a consumer-level recall.

Step 1: Ensure the recall notice is displayed for your staff for one month.

Step 2: Pharmacist to check and quarantine current stock of the medicine:

- If no stock is affected, fax or email a nil return on the acknowledgement form.
- If stock is affected, fax or email information on the acknowledgement form. Remove affected stock from the dispensary and quarantine it until it is returned as indicated on the recall notice.

Step 3: Identify and contact any patients, practitioners, clinics or any other organisation you have supplied this medicine to in the given time frame. This may require looking at both your prescription and restricted medicine records (see appendix 2, record of patient contact).

- Three attempts should be made to contact the patient – by phone, email or text.
- Best practice is for these phone calls to be made by a pharmacist or by a pharmacy technician under the direct supervision of a pharmacist.

Step 4: When a patient returns medicine, supplied by you or another pharmacy, collect the medicine and document patient details. When instructed supply the patient with a new unaffected medicine as per instructions in the product recall notice and record the details.

Step 5: When giving the replacement medicine ensure the patient has not suffered any ill-effects from the recalled medicine. Refer the patient to their medical practitioner, if required.

Step 6: Return/dispose recalled medicine as instructed in the product recall notice to the wholesaler from which the product was purchased or as directed in the product recall notice. All returned stock will be credited on receipt from your wholesaler. You might be able to invoice the manufacturer freight costs.

Note: All documentation from a recall must be kept for seven years

Appendix 1: Medicines and medical devices recall standard operating procedure (SOP)

Purpose: To describe the procedure to follow in the event of a medicine or medical device recall.

Personnel: Pharmacist manager/designated dispensary staff member.

Pharmacy Quality Audit Requirements

- Is there an appropriate SOP for handling and documenting medicine recalls?
- Does the pharmacy follow their SOP for handling medicine recalls and retain the record of recalls?

Procedure

- This pharmacy abides by the Medsafe New Zealand medicines and medical devices recall code, which can be found at http://www.medsafe.govt.nz/safety/RecallCode.pdf
- On receipt of a product recall notice the dispensing pharmacist must check current stock.
- If stock is affected, remove from shelf and quarantine until it is collected, returned to the manufacturer, or disposed of as indicated on the recall notice.
- Even if no stock is affected, a nil return on the acknowledgement form must be returned to the drug company by fax, email or post as indicated on the recall notice.
- A photocopy of the 'returns form' should be held in the dispensary in the Medicine Recall file for reference. The Medicine Recall file is located [enter location].
- Ensure the date and who completed the 'return' is stated.
- Documentation of recalls is kept for seven years.
- Ensure recall notice is displayed to staff. This must be left in a prominent place for one month after the date of the recall.
- Reorder stock to replace recalled product if necessary. Check the recall notice as sometimes the company will send you replacement stock.
- For patient level recalls: members of the public need to be contacted. When this happens, every effort should be made to contact those customers who may have been affected by the recall, eg, by reviewing prescription or compounding records then trying to contact by phone, email or letter.
    - Identify affected patients and locate contact details.
    - Three attempts should be made to contact the patient – by phone, email or text.
    - If none of these methods work you can post them a letter to their last known address.
    - Best practice is for these phone calls to be made by a pharmacist or by a pharmacy technician under the direct supervision of a pharmacist.
- When a patient returns medicine, whether dispensed by you or another pharmacy, collect the recalled medicine, document patient details and replace the medicine as per the recall notice or subsequent communications from Medsafe or the supplier of the medicine.
- Please note depending on what the medicine is and why it was recalled there might be a need to replace the medicine with a different brand or potentially even a different chemical entity in the same class of medicines.

- When giving the replacement medicine ensure the patient has not suffered any ill-effects from the recalled medicine. Make sure they understand any differences between what they were taking and the new medicine you are supplying. Refer the patient to their medical practitioner, if required.
- If a refund or replacement product is to be sent to you for the returned products, check at a later date to make sure that this has occurred.
- Record the details of the patient level recall on the recall template.
  See Appendix 2 Record of patient contact

Appendix 2: Record of patient contact

Recall of [insert medicine brand name]

Date: XX/XX/XXXX

Patient name	Contact attempt 1	Contact attempt 2	Contact attempt 3	Other
Example: John Smith	Phone	X	X	