Australian Government
Department of Health
Therapeutic Goods Administration

Sponsor's customer letter for recalling therapeutic goods

Note: This information is part of the Consultation: Revised edition of the Uniform Recall Procedure for Therapeutic Goods

Version 1.0, October 2015

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <https://www.tga.gov.au>.

Version history

Version	Description of change	Author	Effective date
V1.0	Publication for consultation Content taken from the URPTG - Uniform Recall Procedure for Therapeutic Goods	Therapeutic Goods Administration	27 October 2015

Contents

Introduction

When undertaking a recall action the sponsor is required to write a customer letter as part of the Uniform Recall Procedure for Therapeutic Goods.

Do not send the customer letter until the TGA has agreed to the content.

Sponsor's customer letter

The sponsor's customer letter is a factual statement of the reasons for the recall action, together with specific details that will allow easy identification of the deficient product.

Do not send this letter until the TGA has agreed to the content. See Step 10 of the Uniform Recall Procedure for Therapeutic Goods.

Use company letterhead and include in your sponsor's customer letter:

- the date
- the name and title of the signatory
- the TGA recall reference number
- a statement that the recall action is being conducted following consultation with the TGA.

Use Australian spelling.

You may use the Example of a sponsor's customer letter as a template.

Do **not** include the phrase 'voluntary recall' in the sponsor's customer letter, or imply that the actions described in the letter are at the discretion of the recipient.

Addressing sponsor's customer letters

How you address the sponsor's customer letter is very important. The letter needs to be received by the most appropriate individuals in the supply chain. The TGA may request the customer letter to be provided to specific groups affected by the product deficiency. Ask the Australian Recall Coordinator for assistance if you would like help in determining the most effective way to address the letters.

Medicines

For **medicines**, address a sponsor's customer letter to:

- 'Chief Pharmacist'.

For a **clinical investigational medicine**, send the sponsor's customer letter to each institution involved in the clinical trial and address to:

- 'Clinical Investigator'

and

- 'Chief Pharmacist' (a copy of the letter to each).

For **radiopharmaceuticals**, send your letter to the head of each relevant department of nuclear medicine and pharmacy:

- 'Director of Nuclear Medicine' (for example).

Medical devices

For **medical devices**, address a sponsor's customer letter intended for hospitals to:

- 'Chief Executive Officer' - marked to the attention of the head of the appropriate department
- 'Chief Biomedical Engineer' (if appropriate)
- 'Director of Nursing Units'
- any other areas within the hospital and or distribution chain
- surgeons (in the case of hazard alerts).

For a **medical device in a clinical trial**, send the sponsor's customer letter to each institution using the medical device and address to:

- 'Clinical Investigator'.

Biologicals

For biologicals, address a sponsor's customer letter intended for hospitals to:

- 'Senior Scientist and/or Pathologist'
- the recipients' surgeons, if details are available.

Headings

For **Class I or II recalls**, choose the appropriate heading from the following:

- Urgent Medicine Recall
- Urgent Medical Device Recall
- Urgent Biologicals Recall
- Urgent Product Defect Correction
- Implant Hazard Alert
- Urgent Product Defect Alert.

For **Class III recalls**, choose the appropriate heading from the following:

- Medicine Recall
- Medical Device Recall
- Biologicals Recall
- Product Defect Correction
- Product Defect Alert.

Description of items

You need to describe the product in sufficient detail to enable absolute identification.

Medicine description

When describing a medicine to be recalled, include:

- the brand name
- AUST L or AUST R number
- batch and/or lot number
- dosage form
- strength
- pack size
- the product code or another appropriate identifying code where applicable
- a representative picture or diagram.

Medical devices

When describing medical devices to be recalled, include:

- name
- any other name to identify the product
- make and model
- identification number (batch, lot, serial number, number range, model number, catalogue number, part number, order number)
- ARTG number
- any distinguishing features
- a representative picture or diagram
- a statement that indicates the setting in which the device would be used (for example, general surgery)
- for software, the revision number or number range.

Biologicals

When describing biologicals to be recalled, include:

- name
- ARTG number
- batch and/or lot number
- manufacturers name
- any relevant details to identify the product.

Issue (reason for the recall action)

Provide a clear description of the issue in simple terms. This description should be easy for the intended recipient to understand.

Do not make any comments or provide any descriptions that downplay the level of risk. Advertorial statements are not allowed in the customer letter.

Describe clearly:

- the circumstances under which the user would be exposed to the maximum potential hazard and associated risk that could result from the reasonably foreseeable use or misuse of the product
- the health risk associated with the issue, including details of consequences for the patient and health professional using an affected product
- how to mitigate the risk temporarily
- how this risk or issue will be mitigated or corrected permanently.

Statements of non-compliance

If the product breaches a safety standard that is in force for the product type, explain how the product fails to comply with that safety standard.

If the product breaches an interim ban or permanent ban on the consumer goods, include a statement to that effect.

Action

State clearly the action required and the steps to be taken in order to deal with the issue:

- if it is necessary to isolate and quarantine the product immediately to prevent further usage, emphasise this
- for a hazard alert, provide advice about the ongoing management of patients implanted with the affected medical device or biological
- request immediate return of the recall acknowledgement form, or ask return by a particular date
- describe the procedure to be followed when returning the product (where applicable)
- for medical devices, state that there will be on-site collection and/or replacement or modification, if this is the case

- for biologicals and radiopharmaceuticals, include specific instructions about packaging before return to the sponsor or disposal of the materials, whichever is relevant
- instruct the customer to inform relevant staff
- request contact details of any other organisation that they have supplied with the product, or instruct them to provide these organisations with a copy of the sponsor's customer letter (with a timeframe)
- state that the letter should be kept in a location prominently displayed to the customer and frequented by staff for one month (where applicable, such as when stock is in transit) or until such time that, the product is recalled or corrected permanently.

Alternative stock

Where applicable, include advice on:

- the issue of replacement product
- product correction to be used
- credit for product returned.

Contact details

Explain who to contact to:

- receive further information
- receive a refund
- have the product repaired or replaced.

Include business and after hours numbers (preferably toll free numbers) as well as email and website addresses.

Optional information

You may also include appropriate additional information in the sponsor's customer letter, such as:

- a picture or drawing of the product (where possible), especially for consumer level recalls; this assists greatly in identifying the affected products
- when further supplies are likely to be available
- special instructions relating to the return of the product
- information on clinical management of patients (if appropriate)
- information if the product will be discontinued (if appropriate).

Customer acknowledgement form

A customer's acknowledgement of the recall action letter can be an email, post or facsimile reply form or an acknowledgement or inventory of affected stock on-hand form.

You may use the Example customer acknowledgement form as a template.

In your acknowledgement form, make it as easy as possible for your customer to complete the form quickly. Do this by including:

- the name, pack size, batch number(s) and presentation of the product
- a place to record nil stock held or the quantity of full packs or units being returned
- a place to record the quantity of part-packs being returned, if this is applicable
- a place to record the name of the organisation, and the name, designation and signature of the person acknowledging the recall
- a place to record the date of completion of the form.

Ask for the form to be returned promptly even if no stock is held; this can be the acknowledgement of receipt of the recall action letter. Provide a means by which the form can be returned free of charge, such as:

- an email address
- free facsimile number(s).

Consumer return form

If you are asking consumers to return product to your customers, provide two forms:

- affected stock on-hand form (customer acknowledgement form)
- consumer return form.

In your consumer return form, provide instructions on removing consumer details from the product, if this is relevant.

Envelopes for sponsor's customer letters

For safety-related recalls, use a standard envelope with bold red writing in the top left corner if you post the letter. The printed bold red type, at least one centimetre high, should say one of the following:

- Urgent Medicine Recall
- Urgent Medical Device Recall
- Urgent Biologicals Recall
- Urgent Product Defect Correction
- Implant Hazard Alert
- Urgent Product Defect Alert.

Underline these words with three red bars of increasing thickness.

Example sponsor's customer letter

[Company's letterhead]

[Date]

[Name and title of the recipient]

[Address]

[Heading (e.g. URGENT MEDICINE/MEDICAL DEVICE RECALL/IMPLANT HAZARD ALERT)]

TGA Recall Reference Number: [Number]
[Product name: brand/name, model]

[Description of items: ARTG, lot, batch, serial and catalogue numbers; product codes; versions; dates of manufacture; and expiry dates, as applicable]

[Company Name], after consultation with the Therapeutic Goods Administration (TGA), is conducting an [type of recall action] of the above [product name and form/description]. We are contacting you as the potentially affected product [has been/may have been] supplied to your organisation.

[Problem/Deficiency/Issue]

[Describe the circumstances under which the user would be exposed to the potential hazard and associated risk that could result from the reasonably foreseeable use or misuse of the product.]

The health risk associated with this issue is [details of consequences for the patient and health professional using an affected product; include the worst-case scenario].

[Describe how to mitigate the risk temporarily and how this risk or issue will be mitigated or corrected permanently.]

[Statement of non-compliance, if applicable.]

This recall does not affect any other [batches/lots/versions] of [product name and form/description] or any other [company name] products [as applicable]. This [batch/lot/version] has been distributed to [hospitals/pharmacy/dentists, etc.] since [date]. [Other product identification details.]

Action

- Inspect your stock [**immediately** (For Class I and II) and quarantine affected stock <batch numbers> on hand to prevent further use].
- [For a hazard alert, provide advice about the ongoing management of patients implanted with the affected medical device or biological.]
- Complete the attached acknowledgement form [**immediately** (For Class I and II) or by a specific date for Class III] **even if you do not have any affected stock** and return it to [email address; fax number (preferably free fax) or other document delivery system]. This acknowledgement form is required from all recipients to reconcile this process.
- Return affected stock on hand to the address below with the completed inventory form [or provide details for stock return]. [If applicable]

  [Address for return of affected stock]

- Ensure relevant staff members are informed of this recall, including [locums, inwards goods, credit returns staff, biomedical engineers, relevant clinicians who may need to monitor for adverse events, as applicable].
- If you have supplied or transferred any potentially affected product to another facility or organisation, let that facility know of the recall [**immediately** (For Class I and II)] by providing a copy of this letter.
- Place this letter in a prominent position for at least one month.

Alternative stock [if applicable]

The alternative stock to [product name and form/description] is [details of alternate product], which is [currently available for order/being shipped]. The product code is [product code]. Please contact [details] to arrange for replacement.

OR No alternative stock is available currently. Alternative stock is expected to be available from [company] on [date] and will be [available for order/shipped to you].

For further information please call [contact number and, if applicable, contact name].

Thank you for your assistance in helping us to manage this recall.
[**OR** [Company name] Pty Ltd sincerely regrets any inconvenience caused to your organisation.]

Yours sincerely,

(Signature)

[Name of the responsible staff for the recall action from the company]

[Position]

Example customer acknowledgement form

Customer acknowledgement form

Please complete this form *even if you do not have any affected stock.*

[Heading (e.g. URGENT MEDICAL DEVICE RECALL/IMPLANT HAZARD ALERT)]

TGA Recall Reference Number: [Number]
[Product Name: brand/name, model]

[Description of items: ARTG, lot, batch, serial and catalogue numbers; product codes; versions; dates of manufacture; and expiry dates, as applicable]

On behalf of this organisation I acknowledge receipt of the [Heading] notice date [insert date of notice] relating to the above product.

FROM:

Organisation	
Position	
Name	
Email or fax no.	
Telephone no.	
Date	
Signature	

Affected Stock [Recall and Product Defect Correction only]

If you have **no affected** stock, tick this box: ☐

If you have affected stock, please complete the stock details table below.

Product	**Batch/Lot/Date**	Quantity of stock received	Quantity of unused stock subject to recall (currently in quarantine)
Total affected product			
Other Relevant Details:			

Other organisations

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

☐ No

☐ Yes I/we will forward all the recall information to the suppliers/distributors/customers

OR

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

Return completed forms by fax or email to:

Name	
Position	
Organisation	
Address	
Email	
Subject of email	[Heading] of [Product details and description including batch/lot details]
Fax no.	
Telephone no.	

Therapeutic Goods Administration

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Reference/Publication #