



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

# Uniform Recall Procedure for Therapeutic Goods (URPTG)

Version 2.2, December 2019

**TGA** Health Safety  
Regulation



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## Introduction

This guidance on the Uniform Recall Procedure for Therapeutic Goods (URPTG) provides a consistent approach for undertaking recall and non-recall actions of therapeutic goods supplied, imported into or exported from Australia.

The purpose is to assist the sponsor<sup>1</sup> to conduct recalls and non-recall actions using a standardised systematic procedure.

It enables sponsors to respond efficiently and effectively to issues with a therapeutic good that has or may pose a risk to public health and safety.

This procedure is also applicable when the TGA orders an appropriate responsible entity to conduct a [mandatory recall](#). Civil and criminal penalties apply if you do not comply with a mandatory recall.

## URPTG

- [Overview](#)
- [Recall procedure](#)
- [Recalls and non-recall actions](#)
- [Sponsor's customer letter for recalls](#)
- [Consumer recall notices required for consumer level recalls](#)
- [Roles in recalling therapeutic goods](#)
- [Mandatory recalls](#)

Contact details for:

- [Recall coordinators for therapeutic goods](#)
- [Australian recall coordinator recall notification list](#)

## Templates

To help you with your communications:

- [envelopes for safety-related recalls](#)
- [example consumer recall notice for consumer level recall](#)
- [example sponsor customer's letter](#)
- [example customer acknowledgement form](#)

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<sup>1</sup> Includes the person to whom the goods are on, or cancelled or suspended from the ARTG; or supplying exempt goods; or illegally supplying goods or manufacturing goods



## Version history: URPTG

Version	Description of change	Author	Effective date
V1.0	Publication for consultation	Therapeutic Goods Administration	27 October 2015
V2.0	<p>This version of the URPTG consists of:</p> <ul style="list-style-type: none"> <li>• <a href="#">V2.0 Overview</a></li> <li>• <a href="#">V2.0 Recall procedure</a></li> <li>• <a href="#">V2.0 Recalls and non-recall actions</a></li> <li>• <a href="#">V2.0 Sponsor's customer letter for recalls</a></li> <li>• <a href="#">V2.0 Advertisements: consumer level recalls</a></li> <li>• <a href="#">V2.0 Roles in recalling therapeutic goods</a></li> <li>• <a href="#">V2.0 Mandatory recalls</a></li> </ul>	<p>Recalls and Case Management Section</p> <p>Regulatory Guidance Team</p>	<p>Publication date: 3 October 2017</p> <p>Implementation date: 15 January 2018</p>
V2.1	<p>This version of the URPTG includes clarifying amendments in relation to the new (January 2018) requirements for 'quarantine' actions and introduces a more flexible approach for 'consumer recall notices' required as part of conducting consumer level recalls. (These 'notices' were formerly referred to as 'recall advertisements').</p>	Recalls Section	February 2019
V2.2	<p>This version of the URPTG includes:</p> <ol style="list-style-type: none"> <li>1. additional clarity on the provision of surgeon contact details for implanted therapeutic goods</li> <li>2. amendments related to the online notification of recall and non-recall actions</li> <li>3. removal of the placeholder referring to the National Patient Contact Principles for Patients with Implanted Medical Devices subject to Hazard Alerts</li> <li>4. a second example template for the sponsor's customer letter.</li> </ol> <p>This version also includes a number of other minor editorial amendments.</p>	Recalls Section	December 2019

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# Undertaking recalls and non-recall actions - overview

## Recalls

A product recall is taken to protect the health and safety of consumers from therapeutic goods that are, or may be, affected by an issue with a therapeutic good in relation to its:

- safety
- efficacy (medicines and biologicals)
- performance (medical devices)
- presentation
- quality (for recall purposes, does not include the grade of materials or workmanship).

These issues may be due to non-compliance with specified standards or legislative or manufacturing requirements applicable to the therapeutic good.

## Non-recall actions

Not all issues require recall actions. You can undertake a non-recall action if:

- the therapeutic goods meet all specifications and standards

AND

- there are no deficiencies in safety, quality, efficacy, performance or presentation.

More information is available about [types of non-recall actions](#).

## Undertaking the action

To protect public health and safety, it is important that any recall or non-recall action:

- is undertaken by the sponsor responsible for the therapeutic goods
- follows the [recall procedure](#)
- involves all those who have a [role in the recall](#).

## Identifying issues

Anyone within the supply chain could identify an issue that requires either a recall or non-recall action including:

- The manufacturer (through the implementation of their Quality Management System)
- The Australian sponsor (through adverse event reports or complaints)
- TGA (through our post-market monitoring and compliance activities)
- Other regulators, who notify TGA through international collaborative activities
- Third party audits (e.g. by clients), inspections by other regulators and other avenues.

## Version history: Overview

Version	Description of change	Author	Effective date
V2.0	Publication following a public consultation on a revised edition of the Uniform Recall Procedure for Therapeutic Goods	Recalls and Case Management Section Regulatory Guidance Team	Publication date: 3 October 2017 Implementation date: 15 January 2018

## Recall procedure

We encourage sponsors to follow this procedure to decide, in consultation with us, to take the most appropriate action (recall or non-recall) to mitigate an actual or potential public health risk from a particular good.

However, a TGA delegate of the Secretary of the Australian Government Department of Health (the Secretary) can exercise powers under the [Therapeutic Goods Act 1989](#) (the Act) to [mandate the sponsor to recall](#) therapeutic goods to protect public health.



- ✘ Don't make the mistake of determining the action to take (recall or non-recall) without going through this procedure and obtaining our agreement.

### Which steps to follow

Type of recall	Steps to follow
Immediate recalls	1 and other steps if required
Other recalls	2 to 11
Non-recall actions	2 to 4; 6 to 11 as applicable
Product tampering	1

#### Note

This recall procedure does not apply to blood recalls triggered by Single Donor Notifications (e.g. report of a post-donation illness). The Blood Service also provides a compiled list to the TGA on a monthly basis, broken down into common categories.

### Recall pathways (flowchart)

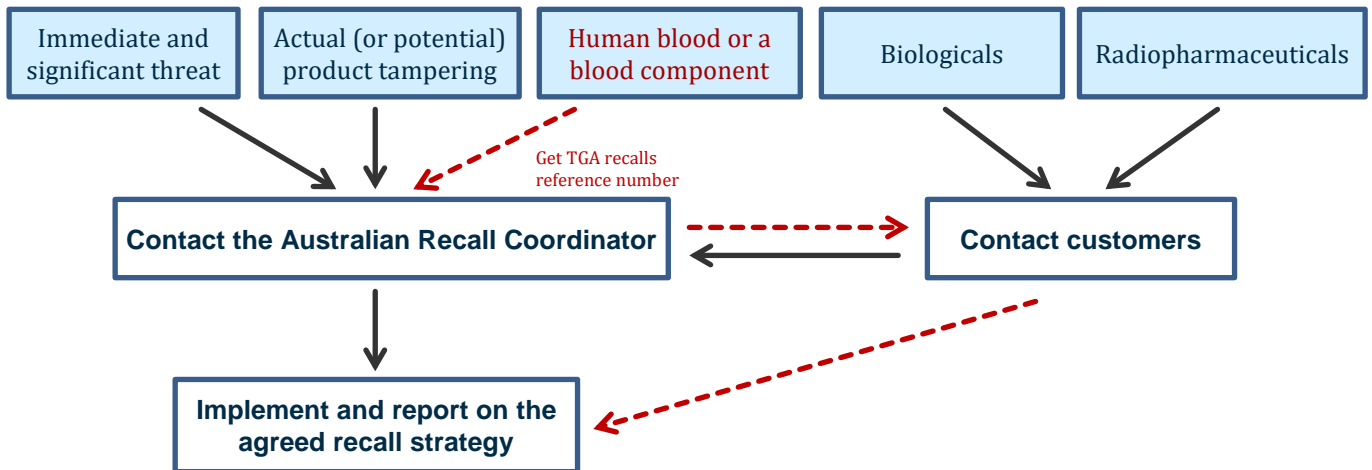
#### Immediate recalls (from Step 1)

Immediate recalls start from Step 1, because it's critical you contact the Australian Recall Coordinator and customers earlier than normal.

The flowchart shows who needs to be contacted (and in what order) for each case. After this initial part of the recall procedure, ensure you follow the remaining steps (Steps 2 to 11).

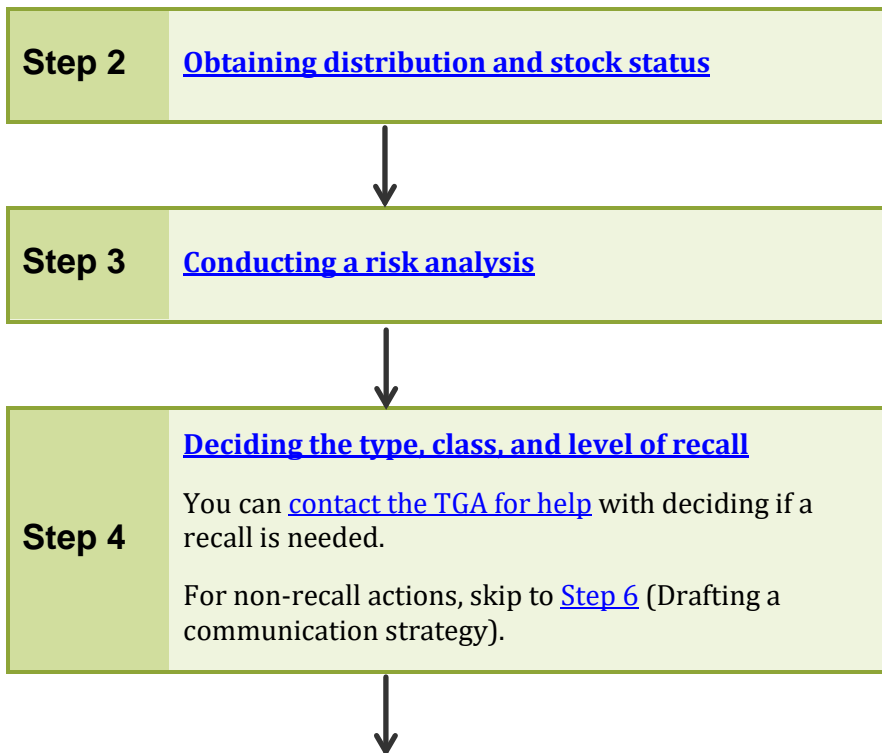
## Step 1

### Immediate recalls

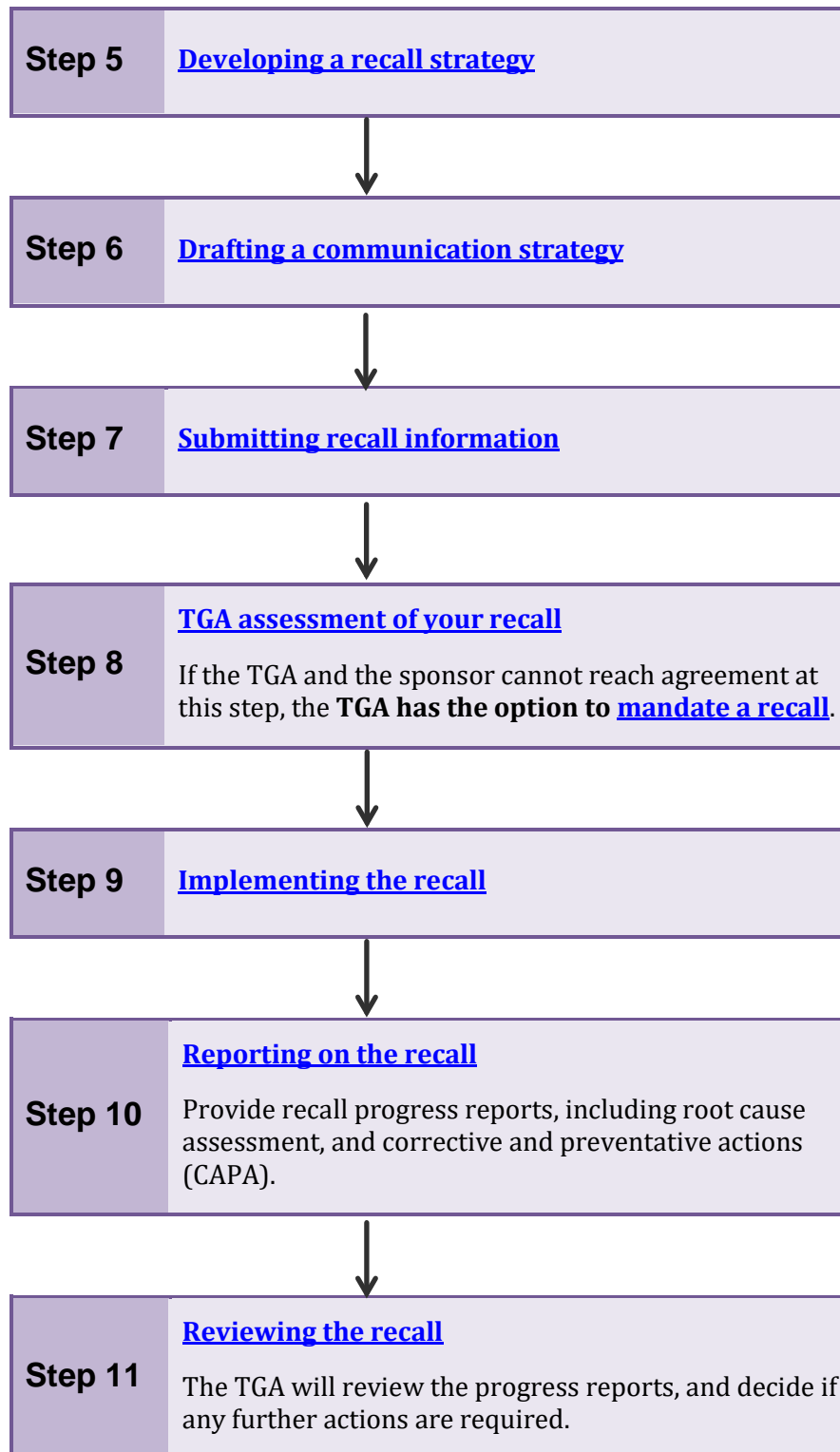


## All other recalls (from Step 2)

### Determining the action to take



## Recalling the goods



## Step 1. Immediate recalls

In circumstances where a sponsor becomes aware of a serious risk associated with a therapeutic good, immediate action may be required to protect the health and safety of consumers, a company, employees or the community as a whole.

Such circumstances may include:

- [Immediate and significant threats and tampering](#)
- [Unsafe or defective radiopharmaceuticals](#)
- [Unsafe or defective biologicals, human blood and blood components](#)

**For all other recalls and non-recall actions** go to [Step 2 Obtaining distribution details and stock](#).

### Immediate and significant threats and tampering

Contact the [Australian Recall Coordinator](#) if either:

- The issue with the goods poses an immediate and significant threat to consumers, a company, employees or the community as a whole.
- There is a crisis involving tampering of therapeutic goods (within 24hrs).

### Tampering of therapeutic goods

Any person who supplies, manufactures or sponsors therapeutic goods must notify TGA of actual or potential tampering (section 42T of the Act):

- Address your notification to the Principal Medical Adviser, c/- the Australian Recall Coordinator
- Email the notification to [recalls@health.gov.au](mailto:recalls@health.gov.au).

[Civil and criminal penalties apply](#) if you do not notify TGA.

Tampering occurs when both:

- The goods are interfered with in a way that affects, or could affect, their quality, safety or efficacy.
- The interference has the potential to cause, or is done for the purpose of causing, injury or harm to any person.

### Crisis management guidelines

The *Crisis Management Guidelines for the management of actual, potential or threatened tampering of medicines, complementary healthcare products and medical devices* include the crisis management structure, your communications and recall strategy.

These guidelines were developed by the Australian Self Medication Industry (ASMI) in consultation with:

- Medicines Australia (MA)
- Complementary Medicines Australia (CMA)
- the Medical Technology Association of Australia (MTAA)

- Consumers Health Forum
- Therapeutic Goods Administration
- State and Territory health departments
- Australian Federal Police
- State and Territory police departments.

We urge you to implement the Crisis Management Guidelines as quickly as possible and ensure that appropriate personnel are trained in their operation.

To obtain a copy of the Crisis Management Guidelines:

- For sponsors who **are members** of the following industry associations – ASMI, MA, CMA, MTAA and the Generic and Biosimilar Medicines Association (GBMA) – refer to the ‘members-only’ page(s) of your association’s website.
- For sponsors who **are not members** of any of the above industry associations, ASMI or the [Australian Recall Coordinator](#) can provide a copy.

Supplementary material is also available: [Product contamination & extortion – a protocol for the therapeutic goods industry](#).

## Radiopharmaceuticals

Contact customers immediately by telephone, email or facsimile to prevent use if:

- the goods do not comply with relevant specifications (some have such short half-lives that they need to be distributed before all quality control test results are available)
- there are doubts as to the quality, safety, efficacy or presentation of the goods.

Seek customers’ acknowledgment that they have quarantined unused goods.

Contact the [Australian Recall Coordinator](#) and follow the remaining steps in this procedure.

Following the TGA’s agreement to the recall action, you must:

- provide the [sponsor’s customer letter](#) to all known recipients of the affected products.
- send your letter to the head of each relevant hospital department of nuclear medicine and pharmacy (for example, ‘Director of Nuclear Medicine’ and ‘Chief Pharmacist’).

## Biologicals, human blood and blood components

There is an issue with [biologicals](#) or human blood and blood components if either:

- The goods do not comply with relevant specifications.
- There are doubts as to the quality, safety, efficacy or presentation of the goods.

## Inform customers

**For biologicals:** contact customers immediately by telephone, email or facsimile to prevent use.

**For blood and blood components:** contact the [Australian Recall Coordinator](#) by telephone to obtain a TGA recalls reference number before contacting customers.



Seek customers' acknowledgment that they have:

- quarantined unused goods
- notified the surgeon (for implanted biologicals)
- notified the clinician for infused blood components based on assessment by the Blood Service.

## Contact us

Complete the [Human blood and tissues recall report form](#) and send it to the TGA.

Contact the [Australian Recall Coordinator](#) and follow the remaining steps in this procedure.

Following the TGA's agreement of the recall action, provide the sponsor's customer letter to all known recipients of the affected products.

## Phone the Australian Recall Coordinator

**1800 020 653** (free call in Australia)

**02 6289 4613** (normal business hours)

**0412 205 568** (after hours – available 24/7 for genuine emergencies, including public holidays)



For more details go to the [contact information](#) on the TGA website.

## Step 2. Obtaining distribution and stock status

As the sponsor<sup>2</sup> undertaking a recall or non-recall action, obtain information to:

- Complete the remaining steps in the recall procedure.
- Assure us that you have effectively mitigated any risks to public health and safety.

### Commercially sensitive or personal information

Identify any commercially sensitive or personal information.

TGA will manage any information that is commercially sensitive or private in nature according to the policy: [Treatment of information provided to TGA](#).



⚠ Do not tell us the names of individual patients for privacy reasons.

### Information to collect

Collect the following:

- [Details of the notifier](#)
- [Describe the issue](#)
- [Therapeutic goods report](#)
- [International regulatory action](#)
- [Sample testing](#)
- [Surgeon details](#)
- [Extra information](#)

⚠ Do not delay if you are missing some of the details.

🔄 Continue through the procedure and when you submit your report to us, tell us what is missing and a timeframe for obtaining the information.

### Details of the notifier

We need to be able to contact you. Provide the name, phone number and email address of the person that the sponsor has made responsible for the recall.

### Describe the issue

Provide all relevant details about the issue and type of therapeutic good including:

- date issue first detected
- photographs that help illustrate the issue (e.g. a broken medical device)

<sup>2</sup> Includes the person to whom the goods are on, or cancelled or suspended from the ARTG; or supplying exempt goods; or illegally supplying goods or manufacturing goods

- how the issue occurred
- history of the incident, with specific dates and times when it occurred or was observed including any reported patient injuries (if applicable).
- failure rate<sup>3</sup>
- potential failure mode<sup>4</sup> due to the issue
- known issues or similar problems that have occurred in the past.

## **Therapeutic goods report**

Give us all the relevant information you have available about the therapeutic goods including:

### ***A description of the therapeutic goods***

- name of the therapeutic good(s)
- [Australian Register of Therapeutic Goods \(ARTG\)](#) number(s) (if the goods are on the ARTG)

For **medicines** also include:

- dosage form
- strength
- pack size.

For **medical devices** also include a unique identifier such as:

- catalogue number
- model reference
- part number
- version number.

**Manufacturing details** including (where applicable):

- lot number
- batch number
- serial number
- expiry date
- manufacturing dates
- donation number or tissue bank number.

### ***Distribution details and stock status of affected goods***

Include (where applicable):

- date released
- quantity of the batch released

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<sup>3</sup> Frequency with which the failure occurs for the affected stock

<sup>4</sup> How the failure will be presented

- dates and quantity distributed to the Australian market
- where the therapeutic good is in the distribution chain
- current undistributed stockholding
- quantity supplied to customers
- whether the goods have been exported from Australia and, if so, to which countries.



⚠ Do not tell us the names of individual patients for privacy reasons.

## International regulatory action

For the issue you are notifying, provide the details of any regulatory action taken by other regulators, such as the European Medicines Agency (EMA), the UK Medicines and Healthcare products Regulatory Agency (MHRA), and the US Food and Drug Administration (FDA) for any therapeutic goods imported or supplied within the Australian market.

## Sample testing

Where applicable, provide results of tests and other investigations on suspect or other samples.

## Surgeon details for implanted therapeutic goods

For implanted therapeutic goods, provide the TGA with the contact details of the relevant surgeons and/or doctors involved.

The TGA collects these contact details so that in the event of an emergency, we can directly contact the relevant parties. This collection is authorised under Australian Privacy Principle 3.6(b), Schedule 1 of the [Privacy Act 1988](#). For general information about privacy, go to [Privacy](#).

Outside of an emergency, affected surgeons and/or doctors will always be contacted by the relevant Australian sponsor.

## Extra information

We may seek additional information after the initial review. Examples include:

- A review of all associated batch manufacturing, packaging, testing, release and distribution records for anomalies that may explain the suspected defect.
- The examination and retesting of retained samples, if appropriate.

Go to [Step 3 Conducting a risk analysis](#).

For immediate recalls go to [Step 9 Implementing the communication and recall strategies](#).

## Step 3. Conducting a risk analysis

As the sponsor, analyse the risks associated with the affected therapeutic good(s). You will need this in Step 4 to help you determine the type of recall or non-recall.

**Immediate recalls:** go to [Step 9](#).

### Medical device risk analysis

We review the [medical device risk analysis report](#) (often known as a health hazard evaluation or HHE report) in Step 8.

### Manufacturer responsibilities

The [manufacturer](#) of medical devices (including in vitro diagnostic (IVD) medical devices) is responsible for implementing an appropriate Quality Management System, and using it to identify any potential risks associated with:

- an adverse event
- a medical device failure
- a complaint.

Risk analysis is part of the risk management process, described in ISO 14971 *Medical devices – application of risk management to medical devices*.

The risk analysis report includes details of:

- the defect or deficiency
- potential failure mode<sup>5</sup>
- failure rate<sup>6</sup>
- how the defect was identified
- any reported patient injuries
- severity and probability of occurrence
- stock affected
- proposed market action by the manufacturer
- potential root causes and corrective actions (if available).

### Sponsors undertaking a recall or non-recall action

As the sponsor, you should receive this risk analysis report when the manufacturer notified you of the device defect.

Make sure you are satisfied with the conclusions and recommendations.

You will be submitting this risk analysis in Step 7.

Go to [Step 4 Deciding the type, class and level of recall](#).

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<sup>5</sup> How the failure will be presented

<sup>6</sup> Frequency with which the failure occurs for the affected stock

***If you do not have the manufacturer's risk analysis***

If you do not have the manufacturer's risk analysis, for example, your recall or non-recall action is in response to information you receive from customers (e.g. consumers or health care professionals):

- Gather as much information as you can to help you determine in Step 4 what action to take.
- Send the report(s) to the manufacturer and request the risk analysis.

Go to [Step 4 Deciding the type, class and level of recall](#).

**Biologicals, human blood and blood components**

The manufacturer of biologicals, human blood and blood components must both:

- investigate adverse events and product complaints
- implement and maintain a written procedure for product recall.

This is specified in the [Code of Good Manufacturing Practice \(GMP\) for human blood and blood components, human tissues and human cellular therapy products](#).

**Sponsor undertaking the recall or non-recall action**

Ensure you are satisfied with the conclusions and recommendations before submitting the risk analysis, and go to [Step 4 Deciding the type, class and level of recall](#).

We will review the manufacturer's investigation report in Step 8.

***Related guidance***

- Appendix 11, Risk management in the [Australian regulatory guidelines for biologicals](#).

**Human blood and blood components**

There are two processes for human blood and blood components:

- Recalls due to process failure and suspected bacterial contamination due to transfusion reaction with a related component.
- Other recalls such as those triggered by Single Donor Notifications (e.g. report of a post donation illness). The Blood Service reports these recalls to TGA by providing a compiled list on a monthly basis, broken down into common categories.

**Medicine risk analysis**

The sponsor (when also the manufacturer) is responsible for analysing the risks with medicines.

If the sponsor is not also the manufacturer, the sponsor may conduct the risk assessment in conjunction with the manufacturer.

In the risk analysis report include details of:

- Both the potential hazards and the likelihood of these hazards
- Whether any illness or injury has already occurred from use of the medicine
- Whether any existing conditions could contribute to a clinical situation that could expose people 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 consequences (immediate or longer term) of occurrence of the hazard
- Alternative treatment options, including the hazard associated with providing no treatment where an alternative is not available
- The potential harm to the user because of the issue
- The likelihood of the issue occurring
- Results of tests and other investigations on suspect or other samples
- The ability of the consumer, caregiver or health professional to discover or identify the issue prior to or during use
- Whether the medicine is outside the manufacturer's specifications
- The availability of another medicine or alternative therapeutic good, or the risk associated with not providing treatment if another medicine or alternative therapeutic good is not available.

Incorporate other relevant analysis or clinical investigation into your risk analysis and ensure you are satisfied with the conclusions and recommendations.

### **Related guidance for this step**

- [Manufacturers and recalling therapeutic goods](#)
- [Sponsors and recalling therapeutic goods](#)

## Step 4. Deciding the type, class and level of recall

Check whether the issue with your therapeutic good(s) requires a recall before you consider a non-recall action.

### Check you need to conduct a recall

Using the information gathered in Steps 2 and 3 go to [Recalls and non-recall actions](#) and follow the guide. This will assist you to decide the:

1. [type of recall](#)
2. [class of recall](#)
3. [level of recall](#)

Check your [role as a sponsor](#) for undertaking a recall.

Ask your TGA Business Services administrator to [update your recall contact details](#).

### Need help

[Contact us](#) if you need help.

Part of our role is to undertake an independent assessment of the risks and ensure that recalls are conducted when appropriate.

### You have a recall?

If after completing this assessment, you think you have a recall:

- ✓ Continue through the recall procedure.
- ✗ Do not delay.

### Don't have a recall?

If, after completing this assessment, you decide the issue with the therapeutic good does not warrant a recall:

- Determine if a [non-recall action](#) may address the issue
- For non-recall actions, go to [Step 6 Drafting a communication strategy](#)



## Step 5. Developing a recall strategy

For recalls:

- Draft a recall strategy, to submit in Step 7 of the recall procedure.

For non-recalls:

- Go to [Step 6 Drafting a communication strategy](#)



⚠ Do not implement your recall strategy until we agree, because the class, level or type of recall may change depending on our independent and objective assessment.

It is important that we agree with your recall strategy. We look at the risks posed by the therapeutic goods and discuss the issues with you to determine the scale of the recall.

You may discuss the recall strategy with us while you develop it, or we may liaise with you when you submit your strategy in Step 7.

### Objectives of a recall

Your recall strategy needs to assure us you are effectively mitigating the risks with the therapeutic goods by:

- Stopping the distribution, sale and use of the affected goods as soon as possible.
- Removing or correcting any goods that are a potential risk to health and safety.
- Preventing further distribution of unsafe goods.
- Informing the relevant authorities of the issue.
- Informing the users of the issue.
- Analysing the root cause and implementing CAPAs<sup>7</sup> to prevent re-occurrence.

### Overview of a recall strategy

Your recall strategy should address:

- consumer, patient and health professional safety
- the nature of the issue with the goods
- the number of complaints (including the number of known injuries or incidents)
- distribution networks
- exported goods
- recovery procedures
- resources for field corrections and availability of alternative goods
- the factors that may affect the duration of the recall.

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<sup>7</sup> Corrective and Preventative Actions

## Preparing a recall strategy

Include the following in your recall strategy:

- The details of the goods involved in the recall
- The issue, including your assessment of the potential hazard or risk posed by the goods
- The proposed type, classification and level for the recall as decided in Step 4
- The number of affected units supplied, relevant dates and their distribution within the supply chain including Pharmaceutical Benefit Scheme (PBS) supply for medicines, if applicable
- Details of any known injuries or incidents associated with the goods
- How you will collect and dispose, destroy or rectify the recalled goods according to any relevant Commonwealth, state and territory requirements
- Strategy for notifying customers of exported goods
- An expected close-out date
- Action taken to identify and correct the cause of the hazard, including the outcome of any root cause analysis or the time period in which such analysis will occur
- Contact details of:
  - the sponsor
  - other entities in the supply chain who supply the goods
  - international recipients of exported goods (if applicable).

## Step 6. Drafting a communication strategy

Your first contact should be with the TGA, except for [biologicals](#) and [radiopharmaceuticals](#).

You do not require a communication strategy if you are recalling human blood and blood components.

Follow this step to prepare your communication strategy for both recalls and non-recall actions.

### Recall communication strategies

#### The purpose of communicating a recall

To prevent injuries by identifying, removing and /or rectifying goods that do not meet specifications.

#### The goal

Enable those in the supply chain to know about and comply with the recall notice.

Cooperation between everyone in the supply chain is essential for the effectiveness of the recall and for notifying everyone involved.



⚠ Do not implement your communication strategy until we agree because it may change depending on our independent and objective review of your proposal.

### Contents of a communication strategy

Include:

- A description of your intended audience within Australia and in other countries, if you have exported the goods.
- Methods for communicating with those in the supply chain.
- A draft copy of the sponsor's proposed customer letter, consumer recall notices, etc.

Match the communication medium to the target audience and target the relevant demographic for the recalled goods.

Include how you will manage customer enquiries including any complaints.

The minimum requirement for formal written communication is a [sponsor's customer letter](#) sent to all known recipients of the affected therapeutic goods.

### Sponsor's customer letter

Go to [Sponsor's customer letter](#) for recalling therapeutic goods for guidance about:

- how to prepare and address the letter
- what to include
- when and how to send the letter
- addressing customer letters
- an example letter.

## When to send the customer letter

Send your customer letter to all intended recipients within **two working days** of agreement with the Australian Recall Coordinator in Step 9.



- ⚠ Do not send this letter until we agree to the content in Step 9.
- ⚠ The letter may change depending on our independent and objective assessment.

## Consumer recall notices

The sponsor arranges and pays for consumer recall notices required for consumer level recalls unless they have complete and accurate distribution lists identifying all end-users.

Go to [Consumer recall notices required for consumer level recalls](#) for guidance on how to prepare your notice including:

- Headings for notices
- Text for notices
- Product information
- Communication strategy
- When and where to publish the notices

## Media release

It may be necessary to issue a media release for some Class I and Class II consumer level recalls.

Develop the text of a proposed media release, which should:

- contain sufficient detail to define the affected goods uniquely
- give a clear explanation of the issue without causing unnecessary alarm
- describe the potential risks due to the issue with the goods
- state the appropriate actions to be taken by the consumer
- provide a phone number (preferably toll-free) for consumers to obtain further information.

Send us the draft media release in [Step 7](#).

We may seek expert advice when we review this in [Step 8](#).

## Step 7. Submitting recall information

For recalls and non-recall actions, undertake one of the following:

### Preferred method:

- Submit an online recall or non-recall notification through the [TGA Business Services portal](#). Sponsors, agents and manufacturers should provide all information previously collected within the relevant tabs of the online form.
  - Upon saving the web form, you will receive a new [TGA reference number](#).
  - The TGA Recalls Section will not be able to see the notification until it has been 'validated' and 'submitted'.
  - Documents such as Draft Customer Letters, Distribution Lists, Consumer Level Communication Strategies and Health Hazard Evaluation reports can be uploaded under the 'Supporting Information' tab.
- Alternatively, we will still accept email notification from you until 30 June 2020, sent to [recalls@health.gov.au](mailto:recalls@health.gov.au) with information you currently have including:
  - distribution details and stock status from [Step 2](#)
  - risk analysis from [Step 3](#)
  - type, class and level of recall from [Step 4](#)
  - recall strategy from [Step 5](#)

- Complete the [Human blood and tissues recall report form](#) for biologicals, human blood and blood components. The Blood Service:
  - requests a TGA recall reference number before completing this form. If using the TGA online form, this number can be obtained during the draft submission phase.
  - submits this form, along with the end user recall notification forms (e.g. hospital notification forms) to the TGA after the end-user has been contacted about quarantining the recalled components.

[Contact us](#) if you need help about what to submit.

### **TGA recall reference number**

We will issue a TGA recall reference number.

Use this reference number in all correspondence about this recall, including follow-up actions.

## Step 8. TGA's assessment of your proposed recall action

We will assess your strategies and work with you to address the issue as quickly as possible.

### Analysing risk

We will conduct an independent and objective assessment to verify the strategies are appropriate to mitigate the risks posed by the affected goods.

### Assessing the recall strategy

We will liaise with you on the recall and will provide advice and assistance in relation to letters, consumer recall notices and recall strategies.

### Option to mandate a recall

We prefer to reach agreement with you on an appropriate recall strategy. However, our role is to protect the public health and safety; if necessary we can [mandate a recall](#).

### Reviewing your strategy

When reviewing your recall strategy, we also consider:

- the proposed timeline
- availability of alternative goods and for critical goods, the effect on future supply.

If necessary, we will seek expert advice (e.g. clinicians or technical experts) to help analyse the risks, especially when the nature or significance of the hazards involved is unclear.

Before you proceed with a recall, it is important we agree to:

- The type, class and level of recall
- Your recall strategy, including close-out dates and strategy for exported goods
- Your communication strategy
- The text of all your associated written communications including:
  - sponsor's customer letter
  - paid and/or unpaid consumer recall notices
  - media releases.

### Timeframes to respond

Our timeframe is to respond and process a recall within 7 clear<sup>8</sup> working days, but we usually achieve this within less time.

We review all notifications upon receipt and triage them on a priority basis.

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<sup>8</sup> The day of notification is counted as day zero.

## Agreement letter

Once we agree to your recall and communication strategy, we will send you an agreement letter, which will:

- Specify the agreed details of the recall
- Provide guidance if you need to notify the recall to the Australian Competition and Consumer Commission (ACCC)
- Contain templates for your reports.

## Notifying others

We will notify some organisations directly and publish the details on our website.

## System for Australian Recall Actions (SARA)

We publish all recalls (except blood component recalls) undertaken in Australia in the publicly searchable database, [System for Australian Recall Actions \(SARA\)](#), on the second working day following agreement to the recall strategy.

## Recall, safety alert and quarantine notices

We develop a TGA Recall Notice for all recalls, safety alerts and quarantine actions, which includes the:

- identity of the goods
- nature of the issue
- assessment of user hazard
- distribution of the goods
- proposed action.

We routinely advise recipients that a notice may contain [commercially sensitive and confidential information](#), and not to distribute it to third parties.

We send the TGA Recall Notice by email to:

- the relevant [recall coordinators for each state and territory](#)
- relevant parties listed in the [Australian Recall Coordinator recall notification list](#).

For recalls with wider health implications, we will notify immediately:

- the Australian Government Chief Medical Officer
- the appropriate state and territory Chief Health Officers.

We also share details of recalls with overseas regulatory agencies when appropriate.



## **Publishing TGA alerts**

We publish [TGA alerts](#) on our website to inform and advise consumers and health professionals. The TGA will liaise with you during the preparation of an alert and will provide you with a copy of the alert before it is published.

In deciding on whether to publish an alert, we consider factors including, but not limited to whether the recall action is a:

- hazard alert
- consumer level recall
- vaccine recall
- any other recall that may have wider implications for public health and safety.

TGA alerts contain information on the recall action, including sufficient detail to define the product uniquely. We give a clear explanation of the issue without causing unnecessary alarm and state the appropriate actions that should be taken by the consumer and health professional.

After publication, we also forward the link to the relevant professional colleges and other consumer and public health organisations, as appropriate.

## Step 9. Implementing the recall

For sponsors undertaking a recall:

- Implement your communication and recall strategies once we have agreed to them.

For non-recall actions:

- Make sure that we agree that a recall is not required.

### Send the sponsor's customer letter

Send your sponsor's customer letter to all known customers within two business days from receiving an 'Agreement Letter' from the TGA Recalls Section.

Then, send us a finalised, signed PDF copy of the customer letter.

### Radiopharmaceutical recalls

Send the sponsor's customer letter as a follow-up to your initial contact in [Step 1](#) to:

- all known recipients
- the head of each relevant hospital department of nuclear medicine and pharmacy (for example, 'Director of Nuclear Medicine' and 'Chief Pharmacist').

### Biologicals

Send the sponsor's customer letter to all recipients as a follow-up to your first contact in [Step 1](#).

### Notify the ACCC

Regardless of the agreed action level, report the recall to the ACCC if you are recalling therapeutic goods that are also 'consumer goods'. These are sometimes referred to as 'consumer therapeutic goods'<sup>9</sup>.

- Go to the [Submit a recall page](#) on the ACCC website
- Complete and submit the ACCC online form (preferred method).

### Recovering affected goods

Once we agree to the recall strategy:

- Arrange for the recovery of the goods
- Establish collection points across the distribution network
- Notify relevant parties, including those in the supply chain and consumers of the method of recovery of the recalled goods
- Arrange for the disposal of the returned goods: you may arrange for the returned goods to be held and kept separate until it can be rectified or safely destroyed.

You may use company representatives (medical detailers and sales representatives) to recover goods subject to recall.

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<sup>9</sup> Therapeutic goods intended for personal, domestic or household use

Make sure you observe relevant state, territory and Commonwealth legislation in relation to unauthorised possession of stock (for example, medicines of addiction and restricted substances).

In the case of a [mandatory recall](#), the TGA may require you to take specified steps for the recovery of the therapeutic goods.

### **Customer follow-up**

It is important that you follow-up with your customers to ensure they have received and followed the instructions in your customer letter.

The level of follow up will depend on the risk and class of the recall.

We recommend making two or three attempts to contact customers, if they do not respond to the customer letter.

### **Undertake root cause analysis**

Undertake a root cause analysis of the issues (usually done by the manufacturer) in parallel with the recall process.

We will review the root cause analysis in the final progress report ([Step 11](#)).

This analysis will assist us to assess the ongoing compliance with regulatory requirements under the life-cycle approach described in the [regulatory compliance framework](#).

## Step 10. Reporting on the recall

Produce progress reports using the templates we provide with your agreement letter.

Your reports should be sufficient for us to analyse the effectiveness of the recall in [Step 11](#).

**U** Don't repeat information from a previous report, unless there is a change.

If we are concerned about an aspect of your recall, we will follow this up with you.

### Your reports

Include in your reports:

- the TGA recall reference number (structured as follows: RC-20XX-RN-XXXXX-X)
- effectiveness of the recall
- whether the investigation changed the scope of the recall
- root cause and CAPA taken to prevent recurrence of the problem.

### Timeframes for reports

Submit the progress reports by [email](#) at:

- 2 weeks (initial report)
- 6 weeks (follow-up report)
- 3 months or at another agreed time (final report).

Provide a single report at 4 weeks for human blood and blood components recalled due to process failure and transfusion transmitted bacterial infection.

The Blood Service provides the TGA with compiled lists monthly and trends quarterly basis for recalls triggered by Single Donor Notifications.

### Initial report (2 weeks)

Submit your initial report at the agreed time, usually two weeks after the start of the recall.

Include:

- Dates when parts of the recall strategy were implemented, e.g. when you sent the sponsor's customer letter.
- Descriptions of any major impediments, such as the recall or corrective actions not progressing according to agreed timelines.
- Implications of the initial investigation findings for the scope of the recall, (e.g. whether you or the manufacturer have identified any additional goods with the same issue.)
- Whether you notified overseas suppliers of exported goods about the recall in Australia.

### **Follow-up report (6 weeks)**

This follow-up report is not needed if the recall is completed within 6 weeks or if we agree it's not needed (e.g. small scale recall.)

Submit your follow-up report at the agreed time, usually six weeks after recall implementation.

Include:

- Percentage of customers you contacted who have responded to your requested recall:
  - confirming the amount of affected goods held (including none)
  - agreeing to the recall or corrective action
- Percentage of customers who returned or destroyed their affected goods
- Identity of customers with goods requiring correction
- Descriptions of any major impediments, such as the recall or corrective actions not progressing according to agreed timelines.

### **Final report (3 months or at another agreed time)**

Submit your final report at the agreed time, usually three months after implementing the recall.

Include:

- Percentage of:
  - returned goods
  - returned goods destroyed or disposed. Include a certificate of destruction for destroyed goods.
  - customers with goods that have been corrected, or supplied with the correction
- Your root cause analysis that led to the recall
- Proposed CAPA to prevent recurrence of the issue that led to the recall.

### **Human blood and blood components report (4 weeks)**

Recalls of blood and blood components have a 4-week close out.

Complete a [final report](#) and include details about the:

- fate of the components including any patient implications due to the transfusion of the affected components
- root cause investigation
- CAPA implemented.

## Step 11. Reviewing the recall

### Components of the review

The TGA examines your progress reports to:

- verify you have:
  - completed all the agreed actions with documented evidence
  - justified any discrepancies or inconsistencies
  - provided evidence of the fate of the final goods
- determine whether the following are satisfactory:
  - implementation of the recall
  - the investigation of the issue or hazard that prompted the recall and the root cause identification
  - CAPAs implemented to prevent or minimise recurrence of the issue in the future
- assess the effectiveness of the recall action
- assess ongoing compliance with regulatory requirements.

If the TGA is concerned about an aspect of the recall process, we will follow this up with you.

### Outcomes of the review

Possible outcomes of our review include:

1. Actions and information provided is satisfactory:
  - TGA issues a close-out report to you stating that the recall actions were satisfactory and no additional actions are required at this stage.
  - The information submitted will be used to inform manufacturer inspections and for trending purposes in product reviews.
2. Nature of the root cause or remedial are not apparent:
  - TGA may request additional information, including full CAPA reports for review.
3. Effectiveness of the recall is not satisfactory:
  - TGA will follow-up with you to determine additional action to ensure the recall is effective.
4. Identification of a systemic or serious issue (at any stage of the recall process):
  - TGA may schedule an immediate inspection of the manufacturer.
  - TGA may, after further investigation, cancel, suspend, or impose requirements on, the relevant ARTG entries.

## Version history: Recall procedure

Version	Description of change	Author	Effective date
V1.0	Publication for consultation	Therapeutic Goods Administration	27 October 2015
V2.0	Original publication incorporating feedback from consultation	Recalls and Case Management Section Regulatory Guidance Team	Publication date: 3 October 2017 Implementation date: 15 January 2018
V2.1	This version of the URPTG includes clarifying amendments in relation to the new (January 2018) requirements for 'quarantine' actions and introduces a more flexible approach for 'consumer recall notices' required as part of conducting consumer level recalls. (These 'notices' were formerly referred to as 'recall advertisements').	Recalls Section	February 2019
V2.2	This version of the URPTG includes: <ol style="list-style-type: none"> <li>1. additional clarity on the provision of surgeon contact details for implanted therapeutic goods</li> <li>2. amendments related to the online notification of recall and non-recall actions.</li> </ol>	Recalls Section	December 2019

## Recalls and non-recall actions

Go to [Step 1](#) in the recall procedure for immediate and significant threats; radiopharmaceuticals; biologicals, human blood and blood components.

This information will help sponsors in [Step 4](#) of the recall procedure to decide whether to undertake:

1. a recall and, if so, the type, class and level of recall

OR

2. a non-recall action, if you decide to not undertake a recall.

It is important that the TGA agrees to the type, class and level of recall action (go to [Step 8](#)).

## Types of recall action

Read through the types of recalls. Use your risk analysis and all the information you have to determine which of the following four types of recall actions applies to your situation:

- [Recall](#)
- [Product defect correction](#)
- [Hazard alert](#) (implanted medical devices and biologicals)
- [Product defect alert](#)

### Recall

A recall is one type of recall action.

A recall is conducted to remove therapeutic goods permanently from the market or from use when there are deficiencies or potential deficiencies in safety, quality, efficacy, performance or presentation.

Recall includes:

- Ü Removal from supply or use of products with inherent design or manufacturing defects
- Ü Requests to check and return products found to be defective sent to:
  - pharmacists
  - hospitals
  - pathology laboratories
  - fractionators
  - operating and research facilities
  - biomedical engineers
  - others.

Recall does not include:

- Ü removal of time-expired products where those products were released prior to their expiry. NB: product released after its expiry is considered a process failure in which case the URPTG should be applied.
- Ü removal of appropriate numbers of products for testing to determine whether there are deficiencies relating to quality, safety, efficacy, performance or presentation.



## Product defect correction

A product defect correction is undertaken to correct a specific or potential deficiency.

In some instances, the product can continue to be used if there is robust mitigation in place until a permanent correction has been implemented.

Product defect correction includes:

- Ü the repair, modification, adjustment or re-labelling of therapeutic goods for reasons relating to deficiencies in the quality, safety, efficacy, performance or presentation
- Ü corrections involving a product's expiry date
- Ü updates or changes to any accessories, operating instructions or software
  - This includes updates to Service Manuals and preventative maintenance procedures where the sponsor does not directly undertake service activities e.g. if hospital biomedical engineering staff perform the servicing.

The corrective action may take place at any agreed location, including:

- the user's premises (field correction)
- any other agreed location.

Product defect correction does not include removal of individual products for:

- Ü repair in the event of an incidental malfunction or failure as a result of normal wear and tear or lack of good maintenance
- Ü appropriate preventative maintenance
- Ü modification due to technical improvements (that does not relate to quality, safety, efficacy, performance or presentation).

## Hazard alert (implanted medical devices and biologicals)

A hazard alert is issued for an implanted therapeutic good with a deficiency or potential deficiency relating to its safety, quality, performance or efficacy because implanted goods (medical devices or biologicals) cannot be recalled.

Hazard alerts consist of:

- precautionary information for health professionals, including advice on:
  - situations to be aware of
  - potential complications
- advice about on-going management of affected patients.

A hazard alert may be issued in conjunction with a recall notice for affected products that have not been implanted.

## Product defect alert

Discontinuation of treatment is sometimes riskier than continued use of the deficient product. This occurs for critical therapeutic goods for which there is no alternative product or for which a recall action will result in interruption of patient treatment or a [medicine shortage](#).

Product defect alerts:

- raise awareness of the concerns about safety, quality, efficacy or performance
- describe actions that clinicians or patients may take to mitigate risks due to product deficiencies.

A product defect alert may later be followed by a recall once unaffected or alternative products become available.

## Classes of recalls

Follow this guide to determine the class of recall.

There are three risk classes to convey the seriousness of the issue and degree of risk involved.

- [Class I – Most serious safety-related](#)
- [Class II – Urgent safety-related](#)
- [Class III – Lowest risk](#)

### Class I – Most serious safety-related

A situation in which there is a reasonable probability that the use of, or exposure to, the deficient therapeutic good(s) will cause serious adverse health consequences or death.

#### Class I examples

##### *Medicines (with serious medical consequences)*

- Wrong medicine (label and contents are different)
- Chemical contamination
- Microbial contamination of sterile injectable or ophthalmic medicine
- Mix-up of some medicines ('rogues') with more than one container involved
- Wrong active ingredient in a multi-component medicine

##### *Medical devices*

- Hot/cold gel pack contains a toxic substance that could be ingested accidentally by a child
- Higher fracture rates for implantable cardiac leads that may result in Implantable Cardioverter Defibrillators (ICDs) not providing effective therapy, resulting in serious injury or death
- Software defects resulting in linear accelerators delivering the wrong radiation dose or delivering doses to the wrong location
- Hardware or software failures in ventilators resulting in shut down during its use
- A false result on an IVD test for a medicine with a narrow therapeutic range that could lead to an overdose, causing permanent injury
- A false negative result on an IVD test for a serious or highly contagious disease

***Biologicals and blood components***

- Retained samples of pulmonary allograft showing positive microbial growth of a pathogenic organism
- Blood components accidentally released after donation testing initial-positive to mandatory testing

**Class II – Urgent safety-related**

A situation in which use of, or exposure to, the deficient therapeutic good(s) may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote.

**Class II examples*****Medicines***

When there are medical consequences:

- Mislabelling (e.g. wrong or missing text or figures)
- Missing or incorrect safety information in leaflets or inserts
- Microbial contamination of non-injectable, non-ophthalmic sterile medicine
- Mix-up of medicines in containers ('rogues')
- Non-compliance with specifications, such as in an assay, stability, fill or weight
- Insecure or incorrect closures for medicines such as cytotoxics, potent goods and medicines requiring child-resistant packaging

***Medical devices***

- Microbial contamination of a personal lubricant
- Higher than expected rate of revision surgeries due to mechanical failures to one of the components in a total hip, knee or shoulder implant
- Infusion pumps giving visual or audible alarms due to software or hardware issues resulting in delay in infusion
- Omission of precautionary information on procedures that could cause complications for the patient, such as omission from the Instructions for Use for a catheter of a precaution for certain procedures that could cause complications in its removal
- An IVD test kit that could identify the wrong strain of micro-organism and lead to inappropriate treatment

***Biologicals and blood components***

- Subsequent testing of the bone donor has shown development of cancer
- The culture sample for microbial testing was mislabelled with that of another donor, resulting in the potential for the biological being released with untraceable results
- Suspected bacterial contamination due to adverse transfusion reaction while infusing the blood component manufactured from the same donation
- Geographical or medication deferral not applied or applied incorrectly for the blood donation

## **Class III – Lowest risk**

A situation in which use of, or exposure to, the deficient therapeutic good(s) is not likely to cause adverse health consequences.

### **Class III examples**

The goods meet acceptable standards of safety and efficacy and the issue does not in itself present an imminent risk.

However, if not rectified, the situation may present a hazard in the future.

#### ***Medicines***

- Faulty packaging, such as wrong or missing batch number or expiry date
- Faulty container closure
- Contamination including:
  - microbial spoilage
  - dirt or detritus
  - particulate matter

#### ***Medical devices***

- The outer packaging of a medical device indicates a different size to the one supplied in the box, but it would be obvious to the clinician that the device was the incorrect size
- An IVD reagent is causing calibration failures towards the end of its shelf life, but there is no effect on patient results

#### ***Disinfectants***

- A disinfectant has been mislabelled with an expiry date that predates the actual expiry date

## **Levels of recalls**

The action level (or depth) describes who will be notified of the recall action.

### **Determining the level**

To determine the level consider the following:

- channels by which the product has been distributed
- extent of the distribution
- potential risks to a user because of the issue
- likelihood of the issue with the goods occurring
- ability of the consumer, health professional or caregiver to identify the issue
- whether the good is outside the manufacturer's specifications
- availability of a replacement or alternative good, or the risk associated with not providing treatment if a replacement or alternative good is not available
- whether a recall (if a medicine) will cause a medicine shortage.

There are four levels for a recall:

- [Wholesale level](#)
- [Hospital level](#)
- [Retail level](#)
- [Consumer level](#)

### **Wholesale level**

Includes:

- medicine and medical device wholesalers, who are third parties holding goods to distribute to retailers or other organisations
- State and Territory purchasing authorities.

### **Hospital level**

Includes:

- wholesale level
- hospitals
- nursing homes, hostels and other healthcare institutions
- clinical investigators and the institutions in which clinical investigations are performed
- hospital pharmacies, blood banks, pathology laboratories, operating facilities, fractionators, human tissue banks, other hospital departments
- ambulance services including the Royal Flying Doctor Service.

### **Retail level**

Includes:

- hospital and wholesale levels
- retail pharmacists
- dentists
- health care professionals
- all other retail outlets such as supermarkets, health food stores and online stores.

### **Consumer level**

Includes:

- retail, hospital and wholesale levels
- patients and other consumers.

## Non-recall actions

Not all issues require recall actions. You can conduct a non-recall action if:

- the therapeutic goods meet all specifications and standards

AND

- there are no deficiencies in safety, quality, efficacy, performance or presentation.



If the product does not meet all specifications and therapeutic indications, then conduct a [recall](#).

Make sure that we agree that a non-recall action is appropriate.

There are four types of non-recall actions:

- [Safety alert](#)
- [Product notification](#)
- [Quarantine](#)
- [Product withdrawal](#)

### Safety alert

Safety alerts are issued to provide information on the safe use of therapeutic goods in certain situations where, although meeting all specifications and therapeutic indications, its use could present an unreasonable risk of harm if certain specified precautions are not followed.

A safety alert is generally used for reiterating specific precautions or instructions regarding use of the goods.

We review the final signed safety alert ([Step 8 of the recall procedure](#)) and will:

- contact you with the outcome of our review
- distribute the safety alert to:
  - [state and territory recall coordinators](#)
  - relevant parties listed in the [Australian Recall Coordinator recall notification list](#).

### Product notification

A product notification provides information about a therapeutic good in a situation that is unlikely to involve significant adverse health consequences.

## Quarantine

Consideration should be given to initiating a quarantine of goods if a defect is identified in released goods which has the potential to raise issues related to safety, efficacy (medicines / biologicals) or performance (medical devices).

A quarantine action suspends further supply and distribution of the goods pending your investigation of an issue or incident. The outcome of the investigation will determine further actions.



A quarantine action cannot be undertaken to a consumer level. This action type can only be applied to wholesale, hospital or retail levels.

Any given recall or non-recall action may occur after your quarantine notice is agreed. Distribution of your quarantine notice needs to be commensurate with the depth of supply of the goods, to either the wholesale, hospital or retail level. We review the final signed quarantine notice ([Step 8 of the recall procedure](#)) and will:

- contact you with the outcome of our review
- distribute the quarantine notice to:
  - [state and territory recall coordinators](#)
  - relevant parties listed in the [Australian Recall Coordinator recall notification list](#); and
- any other body as deemed necessary given the nature of the matters at hand e.g. professional bodies.

When you advise us the outcome of the investigation, we will determine whether the quarantine can be lifted or whether further recall action is required (if recall action is required, return to [Step 2 of the recall procedure](#)).

If the quarantine can be lifted, we will review your second notice advising of this action ([Step 8 of the recall procedure](#)) and will:

- contact you with the outcome of our review
- distribute the second notice to:
  - [state and territory recall coordinators](#)
  - relevant parties listed in the [Australian Recall Coordinator recall notification list](#); and
- any other body who received the original notice.

## Product withdrawal

A product withdrawal is used to withdraw products for reasons that are not related to safety, quality, efficacy, performance or presentation e.g. removing a previous model from the market when a new model has been released.

## Version history: Recalls and non-recall actions

Version	Description of change	Author	Effective date
V2.0	Follows a public consultation on a revised edition of the Uniform Recall Procedure for Therapeutic Goods	Recalls and Case Management Section Regulatory Guidance Team	Publication date: 3 October 2017  Implementation date: 15 January 2018
V2.1	Includes clarifying amendments in relation to the new (January 2018) requirements for 'quarantine' actions.	Recalls Section	February 2019
V2.2	This version of the URPTG removes the placeholder referring to the National Patient Contact Principles for Patients with Implanted Medical Devices subject to Hazard Alerts.	Recalls Section	December 2019



# Sponsor's customer letter for recalls

The sponsor's customer letter is part of the [recall procedure](#) and is a factual statement of the reasons for the recall, together with specific details to identify affected goods easily.

## Preparing the customer letter

When preparing the customer letter:

- Ü Use Australian spelling
- Ü Use company letterhead
- Ü Include:
  - the date
  - the name and title of the signatory
  - the TGA recall reference number
  - a statement that the recall is being conducted following consultation with the TGA

You may use the [Example of a sponsor's customer letter](#) as a template.

### Do not use the sponsor's customer letter to:

- Ū downplay the seriousness of the issue
- Ū promote the company or other goods
- Ū promote or encourage marketing of other goods

### Do not:

- Ū send this letter until we agree to the content: [Step 8](#) of the recall procedure
- Ū imply that the actions described in the letter proposed to be carried out by the recipient are at the recipient's discretion
- Ū use the words 'voluntary' or 'voluntarily' as this may cause confusion regarding the user's requirement to perform the required actions.

## 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

**Emails:** start the subject line with 'Urgent' followed by a description of the recall and tag as 'high importance'. For example:

'Urgent product defect correction' or 'Urgent medicine recall', followed by the name of the deficient goods

**Mailed letters:** Label the letter urgent and [label the envelope](#) with **Urgent in bold red type** in the top left corner.

## For Class III recalls

Choose the appropriate heading from the following:

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

## Addressing the letter

How you address the sponsor's customer letter is very important to make sure the most appropriate people in the supply chain receive it.

TGA may request you to provide the letter to specific groups affected by the goods.

Ask the [Australian Recall Coordinator](#) if you need help with the best way to address the letters.

## Medicines

Address a sponsor's customer letter to: 'Chief Pharmacist'.

### *Clinical investigational medicine*

Send the customer letter to each institution involved in the clinical trial and address to both 'Clinical Investigator' **and** 'Chief Pharmacist' (send a copy of the letter to each).

### *Radiopharmaceuticals*

Send your letter to the head of each relevant hospital department of nuclear medicine and pharmacy, for example, 'Director of Nuclear Medicine' and 'Director of Pharmacy'.

## Medical devices

Address the 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)

***Medical device in a clinical trial***

Send the customer letter to each institution using the medical device and address it to 'Clinical Investigator'.

**Biologicals**

Address the customer letter intended for hospitals to:

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

**Describing the goods**

Describe the therapeutic good in sufficient detail to enable unambiguous identification.

**Medicine description**

When describing a recall for a medicine, include:

- the brand name
- AUST L or AUST R number
- batch and/or lot number
- dosage form
- strength
- pack size
- the supplier internal product code if applicable
- a representative picture or diagram.

Sponsors who wish to provide additional product identifiers in their recall communications are welcome to do so.

**Medical devices description**

When describing a recall for a medical device, include:

- the name of the device
- any other name to identify the goods
- make and model
- production identification/manufacturing details – (batch, lot, serial number)
- additional identifiers – (model number, catalogue number, part number)
- ARTG number
- any distinguishing features
- a representative picture or diagram
- the setting in which the device would be used (for example, general surgery)
- for software, the revision number or number range.

Sponsors who wish to provide additional product identifiers in their recall communications are welcome to do so.

## Biologicals

When describing a recall of a biological, include:

- the name of the biological
- ARTG number
- batch and/or lot number
- manufacturer's name
- any other relevant details to identify the goods.

## Issue (reason for the recall)

Provide a clear description of the issue in simple terms.

This description should be easy for the intended recipient to understand.

Describe clearly:

- Ü the circumstances 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 goods
- Ü the health risk associated with the issue, including details of consequences for the patient and health professional using the affected goods
- Ü how to mitigate the risk temporarily
- Ü how this risk or issue will be mitigated or corrected permanently.

### Do not:

- Ū make any comments or provide any descriptions that downplay the level of risk.
- Ū use any advertorial statements.

## Statements of non-compliance

If the goods breach a safety standard that is in force for the type of goods, explain how the goods fail to comply with that standard.

If the goods (if also a consumer good) breach an interim ban or permanent ban by the ACCC, include a statement to that effect.

## Action

State clearly what to do and the steps to take to deal with the problem:

- Emphasise if it is necessary to isolate and quarantine the goods to prevent further use.
- Include advice in a hazard alert about the ongoing management of patients implanted with the affected medical device or biological.
- Provide a review of previously generated patient results for in vitro diagnostic medical devices.
- Request the recall acknowledgement form be returned immediately or by a particular date.
- Describe the procedure to follow when returning the goods (where applicable).

- Inform customers that for medical devices, there will be on-site collection and/or replacement or modification, if this is the case.
- Include specific instructions for packaging biologicals and radiopharmaceuticals before either returning them to the sponsor or disposing of the materials, whichever is relevant.
- Instruct the customer to inform relevant staff.
- Request contact details of any organisation supplied with the goods, or instruct them to provide these organisations with a copy of the sponsor's customer letter (with a timeframe).
- Include instructions to display prominently the recall letter for their staff and customers for a period of either 1 month (where applicable, such as when stock is in transit) or until such time that, the goods are recalled or corrected permanently.

### **Alternative stock**

Where applicable, include advice on:

- issuing alternative goods
- credit for goods returned.

### **Contact details**

Explain who to contact to:

- receive further information
- receive a refund
- arrange for the repair or replacement of the goods.

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

### **Optional information**

You may also include additional information, such as:

- A picture or drawing of the goods (where possible), especially for consumer level recalls; this assists greatly in identifying the affected goods.
- When further supplies are likely to be available.
- Instructions about returning the goods.
- Guidance on clinical management of patients (if appropriate).
- Advice about whether the goods will be discontinued (if appropriate).

## Labelling the envelope

If you are sending letters by mail for safety-related recalls, use a standard envelope with bold red writing in the top left corner.

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.

For example: [Envelopes for safety-related recalls](#)

## Sending customer letters

Send your customer letter to all intended recipients within **two working days** of agreement by the Australian Recall Coordinator in [Step 8](#).



- ⚠ Do not send this letter until we agree to the content in Step 8.
- ⚠ The letter may change depending on our independent and objective assessment of your proposal.

You may use email, mail, facsimile, document delivery systems or appropriate technologies including portals with workflow management and audit capabilities. Make sure you can:

- ✔ Confirm receipt as it reduces the need to follow up with customers to confirm they have received the notice.
- ✔ Comply with all the requirements of this procedure.

Send us a final, signed copy of the sponsor's customer letter in [Step 9](#) of the recall procedure.

### Confirm receipt of the sponsor's customer letter

Follow up any recipients of the sponsor's customer letter who do not respond within the period specified in the customer letter.

Ensure that all affected customers are aware of the recall.

Check that contact details are up-to-date.

## Customer acknowledgement form

A customer's acknowledgement of the recall letter can be an email, 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 goods
- 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 customers to return the form promptly even if they do not have stock. This can be the acknowledgement of receipt of the recall letter.

Provide a means for customers to return the form free of charge e.g. an email address or free facsimile number(s).

## Example of a sponsor's customer letter

We also provide a [template for the 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], following consultation with the Therapeutic Goods Administration (TGA), is conducting an [type of recall] 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/ /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 the affected goods; 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] 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 staff, credit returns staff, biomedical engineers, relevant clinicians who may decide 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.

**Replacement stock** [if applicable]

The replacement 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.]

(signature)

[Name of the company staff responsible for the recall]

[Position]

## Alternate sponsor's customer letter – tabulated format

The below format is useful when communicating complicated actions as it condenses down the key points and key actions into a tabulated instructional communication. This format is intended to execute complicated recall actions as efficiently as possible.

### URGENT MEDICAL DEVICE RECALL or PRODUCT DEFECT CORRECTION

#### Product Name

ARTG:

Sponsor Ref: (if applicable)

TGA Ref:

Date: XX Month 2018XX

Dear [recipient],

Following consultation with the Therapeutic Goods Administration (TGA), [Company] is undertaking a [action type] of the above product. We are contacting you as our records indicate the potentially affected product [has been/ may have been] supplied to your organisation.

ISSUE	<ul style="list-style-type: none"> <li>Issue identified with product</li> </ul>
HAZARD	<ul style="list-style-type: none"> <li>Hazards that may arise from use of potentially affected goods</li> <li></li> <li></li> </ul>
CORRECTIVE ACTION BEING TAKEN	<ul style="list-style-type: none"> <li>Action undertaken by sponsor/manufacturer to rectify issue</li> <li></li> <li></li> </ul>
INSTRUCTIONS FOR USERS	<ul style="list-style-type: none"> <li>Actions for customers both interim and long term if applicable</li> <li>Include instructions for customer response form</li> <li></li> </ul>
CONTACT INFORMATION	<p>For questions regarding this letter, please contact:</p> <p>Australian Contact Person</p>

This action has been undertaken following consultation with the Therapeutic Goods Administration (TGA).

We apologise for any inconvenience caused to your organisation.

Kind Regards,

## Example customer acknowledgement form

We also provide a [template for the 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 Reference: RC-20...**

**[ARTG 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:

<b>Organisation</b>	
<b>Position</b>	
<b>Name</b>	
<b>Email or fax no.</b>	
<b>Telephone no.</b>	
<b>Date</b>	
<b>Signature</b>	

#### 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.

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

**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:**

<b>Name</b>	
<b>Position</b>	
<b>Organisation</b>	
<b>Address</b>	
<b>Email</b>	
<b>Subject of email</b>	[Heading as noted above] of [Product details and description including batch/lot details]
<b>Fax no.</b>	
<b>Telephone no.</b>	

## Version history: Sponsor's customer letter

Version	Description of change	Author	Effective date
V1.0	Publication for consultation	Therapeutic Goods Administration	27 October 2015
V2.0	Publication incorporating feedback from consultation	Recalls and Case Management Section Regulatory Guidance Team	Publication date: 3 October 2017 Implementation date: 15 January 2018
V2.2	This version of the URPTG includes a second example template for the sponsor's customer letter.	Recalls Section	December 2019

# Consumer recall notices required for consumer level recalls

The sponsor arranges and pays for consumer recall notices which are required for consumer level recalls unless they have complete and accurate distribution lists identifying the end-users. This guide relates to [Step 6](#) of the recall procedure.

You may use the [example notice](#) as a template.

## Heading for the consumer recall notices

Use one of the following headings, as appropriate:

### Class I or Class II recalls

- Urgent medicine recall
- Urgent medical device recall
- Urgent product defect correction
- Urgent product defect alert

## Text for the consumer recall notices

The title of the notices should be the same as the customer letters.

Check and obtain our agreement on the text before publication.

You can tailor notices for specific groups of consumers. For example, it may be appropriate for the notices to be in other language(s) as well as English when the goods were sold to customers from specific non-English speaking backgrounds.

Consider whether to publish notices in social media, taking into account the product under recall and how it is distributed.

## Product information

Include:

- name of the goods
- ARTG number
- pack size
- dosage form or model
- batch, lot or serial number
- expiry date (where this appears on the label of the goods)
- TGA recall reference number
- other details necessary to allow absolute identification of the goods
- reason for the recall
- potential risks due to the issues with the goods

- advice on the continued use or supply, including any alternative goods available
- the method of recovery, disposal or specifics of the proposed product correction
- an estimate of the likely time frame for:
  - the correction to be carried out
  - providing replacement stock if you cannot adequately correct the problem
  - availability of unaffected or alternate stock
- a contact telephone number (preferably toll free).

## Communication strategy

Prepare a communication strategy for your recall action, including draft consumer recall notices, which we will review and agree in consultation with you, or instruct in decisions relating to mandatory recalls.

As a sponsor, you will be able to target your customers more directly if you know who they are and how they are accessing your products. If you are unable to identify who your customers are or where the products you sold are most likely to be located, you will need to distribute your consumer recall notice more widely to ensure a successful recall.

**Note:** As the sponsor, you are responsible for paying for these notices.

## When and where to publish

Having regard to the global multimedia environment including the increasing importance of electronic communications, consideration needs to be given to publishing, broadcasting and distributing the consumer recall notices through a variety of means as appropriate, including but not limited to:

- daily print media newspapers
- television and radio
- online newspapers, magazines, newsletters, trade and professional publications
- sponsor's own website
- sponsor media release
- professional medical colleges and societies
- social media networks, e.g. Twitter, Facebook, etc.
- community forums and focus groups
- [Australian Government Primary Health Networks \(PHNs\)](#)
- peak consumer groups, e.g. Consumers' Health Forum, Australian Consumers' Association
- patients enrolled in sponsor developed Patient Support Programs
- health professionals and their patients enrolled in sponsor initiated Product Familiarisation Programs
- patient support groups / health consumer organisations
- industry forums and focus groups.

To ensure consistency and familiarity in raising awareness of consumer level recall actions, your consumer recall notice should be formatted in the same manner as the [example notice](#), wherever practicable to do so.

You should arrange for publication or broadcast of your notice in all forms of media agreed, within three to four business days after sending the customer letter as agreed with us, or as instructed in decisions relating to mandatory recalls.

Where the agreed communication strategy includes publication of your notice in print media daily newspapers, you should ensure the notice will be published:

- Once, in the daily print media newspapers (of each state and territory where the goods were possibly distributed); and
- Preferably in one of the first ten pages of the newspaper; and
- With a minimum size of double column width and 10 cm depth enclosed in a diagonally hatched border (refer to the [example notice](#)).



## Example consumer notification

We also provide a [template for the notice](#).



The image shows a warning sign template for an urgent medicine recall. It features a large black triangle on the left side. The text is centered and enclosed in a border of black diagonal stripes. The text includes the following information:

**URGENT MEDICINE RECALL**  
**<PRODUCT NAME> ELIXIR**  
**120mg paracetamol per 5mL**  
**100mL bottle**  
**Batch number xxxxx, Expiry date: Oct 2017**  
**AUST R xxxxx**

<Company> Pty Ltd, Following consultation with the Therapeutic Goods Administration, is recalling batch xxxxx of <Product name> (which is an analgesic used to treat aches, pains and feverish conditions) because eucalyptus oil has been found in some bottles of this batch. No other batches of <Product name> Elixir are affected by this recall.

If you have a bottle of <Product name> Elixir from batch xxxxx, do not use it. Return it to the place of purchase for a refund or call our customer service line to arrange the return of affected product and refund.

CUSTOMER SERVICE 1800 xxx xxx

Ingestion of eucalyptus oil (other than in small amounts as in throat lozenges and inhalations etc.) may be harmful. As little as a few millilitres of eucalyptus oil may cause nausea, vomiting, dizziness, muscular weakness, delirium and convulsions. Anyone who is concerned in any way about the use of this product should consult their doctor.

<Company name> Pty Ltd sincerely regrets any inconvenience to their customers.

## Version history: Consumer recall notices required for consumer level recalls

Version	Description of change	Author	Effective date
V2.0	Publication follows a public consultation on a revised edition of the Uniform Recall Procedure for Therapeutic Goods	Recalls and Case Management Section Regulatory Guidance Team	Publication date: 3 October 2017 Implementation date: 15 January 2018
V2.1	Introduces a more flexible approach for 'consumer recall notices' required as part of conducting consumer level recalls. (These 'notices' were formerly referred to as 'recall advertisements').	Recalls Section	February 2019

## Roles in recalling therapeutic goods

Recalling therapeutic goods is a collaborative process with many different participants:

- [sponsors](#)
- [manufacturers](#)
- [wholesalers and distributors](#)
- [exporters](#)
- [health professionals](#)
- [consumers](#)
- [TGA](#)
- [state and territory recall coordinators](#)
- [ACCC](#) (for goods that are also consumer goods).

## Sponsors and recalling goods

If you are considering recalling a therapeutic good, follow the [recall procedure](#).

As a sponsor of a therapeutic good, you have ongoing responsibilities to ensure you are prepared for a recall and able to respond appropriately to complaints and problem reports.

## Responsibility for recalling goods

The sponsor is responsible for conducting a recall, but can authorise third parties.

A TGA delegate for the Secretary of the Department of Health can [mandate a recall](#) to protect the public from an unsafe good in accordance with the Act if the manufacturer or sponsor does not undertake the recall.

Civil and criminal penalties apply if you do not comply with a mandatory recall.

## Your recall procedure

Your written recall procedure should take into account and include:

- Immediate recall (Step 1): it is essential that you follow Step 1 - in most cases, this involves contacting the Australian Recall Coordinator straight away.
- A step for noting our agreement to your recall and communication strategies (Step 8).
- The people in your organisation who will be involved in a recall
- How to access current contact details for:
  - TGA
  - businesses and organisations to contact
  - hospitals and other healthcare facilities to contact
  - bodies representing health professionals
  - general retail outlets that may supply your products

- state and territory recall coordinators
- funding bodies
- The actions to take (listed in chronological order), including those described in this procedure
- How you obtain technical details for the recall and any organisational contact details
- How you obtain distribution records (including to any export customers)
- your procedure for documenting the organisations contacted and their responses
- possible arrangements for:
  - returned goods
  - quarantine facilities
  - disposal or modification of the affected goods
  - replacement of the affected stock
  - reimbursing direct costs incurred by those acting on the instructions in your sponsor's customer letter
- report on progress in [Step 10](#) of the recall procedure.

## Communicating with other interested parties

It is your responsibility to communicate with interested parties not directly involved in the recall (e.g. funding bodies).

## Keeping details up-to-date

Have arrangements in place so that your TGA Business Services administrator keeps your recall coordinator details in the system up-to-date.

If you do not have a nominated recall contact person, ask your TGA Business Services administrator to update your records.

## How your administrator nominates recall contacts

The steps for the 'administrator' to nominate recall contacts:

1. Log in to [TGA Business Services](#).
2. View my organisation.
3. View all contacts.
4. Edit a contact or add new contact.
5. Under 'Organisation contact role' select 'RC - Recalls Contact'.
6. Enter a mobile number so we can contact the individual out of hours.
7. Check that the contact is authorised to speak with TGA:
  - a. 'Contact authorisation' appears directly under 'Organisation contact role'
  - b. for your own entry, 'Account settings' will show 'Additional information' if you are authorised to speak to us.

8. Save by selecting either:
  - a. 'Update details' (when editing a contact)
  - b. 'Create' (when adding a contact).

## Distribution records

Keep sufficient records so you can recall any batch of goods from the distribution chain (a condition of entry on the ARTG).

All distribution records should be easy to follow and readily available to us if we ask.

We rely on you for certain details (such as batch size, distribution chains and quantities distributed) that are important for developing a recall strategy.

## Analysing risk

The sponsor (when also the manufacturer) is responsible for analysing the risks with medicines.

If the sponsor is not also the manufacturer, the sponsor may conduct the risk assessment in conjunction with the manufacturer.

## Communicating with your distributors

Make your [wholesalers and distributors](#) aware of their role in the recall of therapeutic goods. Cooperation from wholesalers and distributors is often essential for an effective recall.

Every wholesaler should have a procedure describing how they will conduct a recall if you request them to do so. Wholesalers of scheduled medicines should follow the [Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8](#).

## Manufacturers and recalling goods

If you are considering recalling a therapeutic good, follow the [recall procedure](#).

## Sponsor-manufacturer agreement

The manufacturer and sponsor should have an agreement to ensure that both parties can meet their responsibilities relating to any potential recall.

**Note:** This is not necessary when the manufacturer is also the sponsor.

## Medicine manufacturers

Medicine manufacturers require systems to:

- recall any batch of goods from sale or supply
- investigate any issue, including the root cause
- implement CAPAs.

## Related information and guidance

Refer to the [PIC/S Guide to GMP for Medicinal Products](#) (the PIC/S Guide) for specific references to therapeutic goods recalls.

## For Australian manufacturers with a TGA licence

It is a condition of the licence that you inform us promptly if you intend to initiate a recall.

## Investigating manufacturing issues

Manufacturers are responsible for investigating issues in the manufacturing process that can sometimes lead to a recall. For example, issues with:

- a batch of raw material
- a component part
- the manufacturing process
- the final goods.

## Keeping records

All manufacturers need to maintain records.

### Manufacturers in Australia

Medical device manufacturers keep records for at least 5 years from the last date of manufacture, or for the lifetime of the device, whichever is longer.

Medicine manufacturers retain complete records pertaining to the medicines. The timeframe for keeping these records depends on the expiry date:

- no expiry date: at least six years after manufacture
- with an expiry date: at least one year after the expiry date.

It must be possible to trace the complete history of a batch using understandable, accessible records of manufacture and distribution, as detailed in the [PIC/S Guide](#).

Biologicals' manufacturers retain complete records pertaining to the biologicals for five years (see section 32JA of the [Therapeutic Goods Act 1989](#)).

## Analysing risk

Manufacturers are responsible for conducting risk analyses and investigating medicines, medical devices, biologicals, human blood and blood components.

### Medical device risk analysis

Manufacturers are responsible for analysing the potential risks associated with an adverse event, goods failure or complaint using an appropriate QMS as described in *ISO 14971 Medical devices – application of risk management to medical devices*.

Medical device manufacturers require, as part of an effective QMS (usually in accordance with *ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purposes*):

- a system to recall any batch of goods by notifying sponsors or distributors
- a system to investigate any issue, including identification of root cause and implementation of CAPAs

### *Related information and guidance*

- Section 6 of the [Australian Regulatory Guidelines for Medical Devices](#)
- [IVD conformity assessment overview](#)

## Biologicals, human blood and blood components

The [Code of GMP for human blood and blood components, human tissues and human cellular therapy products](#) requires manufacturers to investigate adverse events and complaints, and to implement and maintain a written procedure for recalling goods.

## Root cause analysis

The manufacturer usually conducts the root cause analysis in parallel with the recall.

## Corrective and preventative actions (CAPA)

When manufacturers identify a manufacturing issue, they implement CAPAs. Sometimes we will ask for the full CAPA report.

## Wholesalers and distributors and recalling goods

Cooperation from wholesalers and distributors is often essential for an effective recall. As a wholesaler, you should have a procedure for conducting a recall at a sponsor's request.

Wholesalers of medicines in schedules 2, 3, 4, and 8 should follow the [Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 & 8](#).

## Your recall procedure

As a wholesaler, your recall procedure should cover:

- the appointment of a person in charge of expediting the recall
- a description of how the goods can be traced within the stock control system
- quarantine arrangements for recalled goods
- how you will handle goods in transit from the sponsor, or returns for credit from purchasers, (includes returns for credit that occur as a usual part of business where the recall was only to wholesale level)
- record keeping, including customer lists
- communication arrangements with the sponsor
- the mechanism for replacing goods, if applicable.

## Levels other than wholesale

For recall actions going to levels beyond you as the wholesaler, you should contact any organisations that would not be on a mailing list used by the sponsor and that you have supplied with the affected goods. Common examples include:

- offshore pharmacies
- exporters supplied by the wholesaler
- clinical trials organisations
- retailers licensed to sell pharmacy-only medicines
- private hospitals
- paramedic organisations
- organisations that may include the affected goods in a new combination of goods.

## Exporters and recalling goods

If you have exported therapeutic goods that are the subject of a recall in Australia:

- include export customers in the communications strategy that you provide us in [Step 7](#) of the recall procedure
- provide the overseas recipients with a written notice as soon as practicable.

## Exporters of consumer products

Within ten days of beginning a safety-related recall action of consumer products in Australia, you are required to notify:

- any overseas recipients
- the Australian Government Minister for consumer safety (about the overseas supply).

This requirement is in addition to notifying the Minister about the recall within 2 days of taking recall action in Australia and is stated in the [Competition and Consumer Act 2010](#) (section 128 (4)).

## Health professionals and recalling goods

Health professionals (including retail pharmacists) have an ethical and professional obligation to safeguard patients during a recall.

As a health professional, you may delegate these tasks to a competent person, but you should remain vigilant.

## Your response to a recall

If there is a recall of a therapeutic good:

- Stop supplying or prescribing the goods subject to the recall.
- Follow the instructions in the sponsor's customer letter.
- Contact the person named in the sponsor's customer letter if you have any queries about the recall.

## When you are a supplier

As a health professional, you may have supplied the recalled therapeutic good to another organisation such as:

- a nursing home
- another pharmacy
- a doctor's surgery
- a laboratory.

Contact any organisation for which you have acted as a supplier and:

- advise them of the recall

AND

- give them a copy of the sponsor's customer letter.



## Hazard alerts

Give individual patients advice in the context of their personal medical circumstances.

Attempt to contact patients as quickly as possible, particularly if you need to take action before their next routine check-up.

Advise patients about the recall, the reasons for it, and the actions patients should take, according to the recall letter and their individual circumstances (for example, if clinical signs indicate a need for medical follow-up).

## Consumer-level recalls

Because of the associated health risks:

- Contact all consumers who have already received the recalled therapeutic good (if appropriate).
- Advise patients about the recall, the reasons for it, and the actions they should take, according to the recall letter and their individual circumstances (for example, if clinical signs indicate a need for medical follow-up).
- Replace the goods held by the patient (if necessary).

## Your recall procedure

If you develop a written procedure for managing recall actions, we suggest you include:

- A list of the actions to take in a chronological order
- How to quarantine stock and manage stock that is in transit
- How to notify relevant staff (including inward goods personnel and clinicians)
- How to communicate with other organisations that have purchased or borrowed the goods
- How to access patient details for a consumer-level recall (if applicable)
- The process to notify patients
- A plan for managing patients implanted with an affected implantable medical device or biological.

## Consumers and recalling goods

A recall will sometimes directly affect you and you may find out about a therapeutic goods recall from:

- your health professional
- the sponsor's customer letter
- a sponsor's consumer recall notice
- the alert information on our website.

In all cases, contact:

- the sponsor for more information about the recall
- your health professional for advice relevant to your personal situation.

## TGA and recalling goods

We are actively involved throughout the recall process.

Once a therapeutic good is available in Australia, we continue to monitor it through [therapeutic product vigilance](#) activities.

This sometimes leads to identifying an issue that is likely to require recall. In this situation, we contact the sponsor and provide all the relevant information.

In rare cases, a TGA delegate of the Secretary will [mandate](#) the sponsor to recall a therapeutic good.

For [immediate recalls](#), phone the [Australian Recall Coordinator](#).



For all recalls, we send the TGA Recall Notice to all [State and Territory recall coordinators](#).

### Our role in recalls

Our role includes:

- Independently and objectively assessing the risk posed by the affected therapeutic goods:
  - this is a critical step in the recall procedure. It verifies, through independent assessment, the potential or real risks to the public and verifies the effectiveness of the proposed recall action to mitigate the potential or real risks to public health and safety.
- Agreeing to the recall and communication strategy:
  - this is critical for ensuring the messages and strategy are commensurate with the risk posed by the affected goods.
- Sending the agreed recall letter to the sponsor.
- Notifying others:
  - includes state and territory recall coordinators
  - [parties contacted](#) are listed on our website.
- Reviewing the recall at the end of the process:
  - sometimes this results in further investigations, such as an inspection of the manufacturer. This is critical for the effectiveness of the recall.

We maintain an up-to-date [list of state and territory recall coordinators](#).

We contact relevant state and territory recall coordinators at [Step 8](#) of the recall procedure.

### Working with ACCC

We liaise with the [ACCC](#) when necessary for safety-related recalls of therapeutic goods that are also consumer goods.

## Providing information

We are responsible for communicating:

- the recall procedure
- details about specific recalls through the public database (SARA)
- TGA alerts for recalls such as hazard alerts, consumer level recalls and recalls that may have wider implications for public health safety. The alert is sent to appropriate organisations and professional colleges after publication.
- the [contact list for the state and territory Recall Coordinators](#)
- a [list of those other parties we contact](#) as part of this procedure.

## State and territory coordinators and recalling goods

[State and territory recall coordinators](#) play an important role in the recall of therapeutic goods.

### Maintaining the alert system

State and territory recall coordinators maintain an alert system for providing recall information within their jurisdictions.

They keep contact details up-to-date for relevant organisations and individuals, including:

- purchasing authorities
- public and private hospitals
- other professional groups.

State and territory recall coordinators need a written procedure for providing recall alerts to their contact list.



Make sure you can use your alert system as a **rapid** alert system in the case of an emergency.

### Communicating within jurisdictions

State and territory recall coordinators:

- Assist the sponsor to implement the communications and recall strategy agreed by us.
- Follow their own procedure for contacting relevant organisations when a sponsor initiates a recall.



We send the state and territory recall coordinators the TGA Recall Notice for all recall actions.

## ACCC and recalling goods

One of the functions of the ACCC is to protect consumers.

When a therapeutic good is a consumer good, the supplier must inform the ACCC about safety-related recalls.

Recall provisions under the Australian Consumer Law apply to consumer goods and include both sponsor initiated recalls and compulsory recalls ordered by the Australian Government Minister for consumer safety (the Minister).

However, therapeutic goods that do not meet the definition of consumer goods<sup>10</sup> are not subject to the Australian Consumer Law for example:

- ❑ medical devices used in hospitals
- ❑ goods used strictly in the practice of medicine and not supplied directly to consumers for personal, domestic or household use.

TGA coordinates recalls of therapeutic goods that are also consumer goods.

When a therapeutic good is also a consumer good, the person carrying out the recall is required to provide the Minister with written notice of the recall within two days of taking that action (Section 128 of the Australian Consumer Law (ACL), Schedule 2, [Competition and Consumer Act 2010](#)).

- Go to the [Submit a recall](#) page on the ACCC website.
- Complete and submit the ACCC online form (preferred method).

## Compulsory recalls

The Minister may also issue a compulsory recall notice for a consumer good.

Sections 124 and 125 of the Australian Consumer Law, Schedule 2, [Competition and Consumer Act 2010](#) sets out the actions the supplier of a compulsorily recalled good is required to take if the supplier repairs or replaces the goods.

## Recalling consumer goods

Suppliers should be mindful of the Consumer Guarantees specified by the ACL.

The consumer can seek a refund, repair or replacement if the quality is unacceptable or the goods are unsafe.

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<sup>10</sup> Goods intended for personal, domestic or household use

## Version history: Roles in recalling therapeutic goods

Version	Description of change	Author	Effective date
V1.0	Publication for consultation Content taken from the URPTG - Uniform Recall Procedure for Therapeutic Goods 2004	Therapeutic Goods Administration	27 October 2015
V2.0	Publication incorporating feedback from consultation	Recalls and Case Management Section Regulatory Guidance Team	Publication date: 3 October 2017 Implementation date: 15 January 2018
V2.1	Editorial amendments to distinguish between sponsor-initiated and compulsory recalls; and to ensure consistency of terminology for 'consumer recall notices.'	Recalls Section	February 2019

## Mandatory recalls

Sponsors of therapeutic goods are encouraged to decide of their own accord, or after recommendation from the TGA, that the recall of a particular product is necessary in order to mitigate an actual or potential deficiency in relation to its safety, quality, performance or efficacy.

However, if necessary the Delegate of the Secretary of the Australian Department of Health (the Secretary) can exercise powers under the *Therapeutic Goods Act 1989* to mandate the sponsor<sup>11</sup> to recall therapeutic goods to protect public health.

## Legislative basis for mandatory recalls

The circumstances for mandating a recall are set out in the [Therapeutic Goods Act 1989](#).

- Medical devices: go to Chapter 4, Part 4–9, s41KA – 41KD.
- Medicines and other therapeutic goods (OTGs): go to Chapter 3, Part 3–2, Division 2A, s30EA – 30ED.
- Biologicals: go to Chapter 3, Part 3–2A, Division 8, s32HA – 32HE.

### Related information and guidance:

- [ACCC and recalling goods](#) for statutory obligations under the ACL.

A TGA delegate of the Secretary can also impose requirements to recall:

- counterfeit therapeutic goods
- therapeutic goods that have been or could possibly be, subject to actual or potential tampering.

These requirements do not apply to goods that cannot be recalled because they have been administered to, or applied in the treatment of, a person.

## Medical device and IVDs

A TGA delegate of the Secretary can require the recall of medical devices from the supply chain when a kind of medical device:

- on the ARTG:
  - does not comply with the essential principles
  - has not been manufactured under the applicable conformity assessment procedures
  - appears to be unacceptable in relation to its quality, safety, or performance
- exempt from requiring entry on the ARTG or is the subject of an approval or authority to enable lawful supply while not on the ARTG:
  - does not comply with the essential principles
  - the manufacturer has not applied the applicable conformity assessment procedures
  - if exempt under the 'emergency' exemption: is not fit to use for its intended purpose

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<sup>11</sup> Includes the person to whom the goods are on or cancelled or suspended from the ARTG or supplying exempt goods; or illegally supplying goods or manufacturing goods

- is supplied, but is not either on the ARTG or exempt from having to be entered on the ARTG, and is not the subject of an approval or authority to enable lawful supply while not on the ARTG
- has been cancelled or suspended from the ARTG.

The requirement to recall a kind of medical device may only relate to some medical devices of that kind.

The exercise of recall powers under these provisions does not affect powers to suspend or cancel entries of kinds of medical devices, under other Parts of the Act.

### Medical devices that do not meet requirements

There are criminal offences and civil penalty provisions relating to medical devices under Chapter 4, Part 4–11 of the [Therapeutic Goods Act 1989](#) when:

- Persons import, supply or export medical devices that do not meet the essential principles.
- Manufacturers of medical devices supplied in Australia did not apply appropriate conformity assessment procedures.

There may be extenuating circumstances preventing compliance to one or more parts of an Essential Principle for a limited time. If this happens, sponsors may seek [consent to import, supply or export medical devices that do not meet an Essential Principle](#).

There are no similar provisions when the manufacturer has not applied the appropriate conformity assessment procedures to manufacture medical devices.

### Medicines and other therapeutic goods

A TGA delegate of the Secretary can require the recall of medicines or [other therapeutic goods \(OTGs\)](#) from supply when:

- A medicine or OTG, (whether registered, listed or exempt from having to be entered onto the ARTG), or the subject of an approval or authority to be supplied while not on the ARTG either:
  - does not comply with an applicable standard
  - is not manufactured according to the manufacturing principles
- A medicine or OTG is illegally supplied (i.e. it is not registered or listed on the ARTG and it is not exempt from having to be entered onto the ARTG, or the subject of an approval or authority to be supplied while not on the ARTG)
- A medicine or OTG is on the ARTG but either:
  - An unlicensed manufacturer carried out one or more manufacturing steps
  - It appears that the quality, safety, efficacy or presentation of the medicine is unacceptable
  - A medicine or OTG has been cancelled or suspended from the ARTG.

The requirement to recall a medicine or OTG may relate to specified batches.

## Medicines that do not meet requirements

There are criminal offences and civil penalty provisions under Chapter 3, Part 3-1, section 14 and 14A of the [Therapeutic Goods Act 1989](#) for importing, supplying or exporting medicines and OTGs that do not comply with standards unless with the consent of the Secretary.

## Related guidance

[Counterfeit therapeutic goods](#)

## Biologicals mandatory recalls

A TGA delegate of the Secretary can require [biologicals](#) to be recalled from supply when:

- A biological, whether included on the ARTG or exempt from having to be entered onto the ARTG, or the subject of an approval or authority to be supplied while not on the ARTG either:
  - does not comply with applicable standards.
  - has not been manufactured according to the manufacturing principles (not applicable to Class 1 biologicals).
- A biological exempt from having to be entered onto the ARTG under the “emergency” exemption is not fit to be used for its intended purpose.
- A biological is illegally supplied (i.e. supplied and it is not included on the ARTG, is not exempt from having to be entered onto the ARTG, and is not the subject of an approval or authority to be supplied while not on the ARTG).
- A biological (other than a Class 1) supplied while on the ARTG but there is a breach of the condition that:
  - The biological be manufactured by the holder of an Australian licence.
  - If manufactured overseas, the biological has been certified to have been made under acceptable manufacturing procedures.
- It appears that the quality, safety or efficacy of the goods that is a biological is unacceptable or that the presentation of the biological is unacceptable.
- The goods have been suspended or cancelled from the ARTG.

## Biologicals that do not meet requirements

Chapter 3, Part 3-2A, Division 2 of the [Act](#) contains criminal offences and civil penalties relating to the import, export, manufacture, supply and use of biologicals in certain circumstances.

## Related guidance

[Counterfeit therapeutic goods](#)



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## Action by a TGA delegate

Under the mandatory recall provisions, a TGA delegate can require the sponsor or Australian manufacturer to either/or:

- Take specified steps, in a specified manner and within such reasonable period as is specified to recall the goods.
- Inform the public or a specified class of persons, in a specified manner and within such reasonable period in relation to the issues and/or publish specified information.
- Inform the public or a specified class of persons, in the specified manner and within such reasonable period as is specified, of specified information, or of information of a specified kind in relation to the goods and/or the issues.
- Publish, in a specified manner and within such reasonable period as is specified, specified information, or information of a specified kind, relating to the manufacture or distribution of goods.

Notify the TGA delegate, in the specified manner and within such reasonable period as is specified, of specified information, or of information of a specified kind, relating to the persons to whom the goods have been supplied. To achieve this, a TGA delegate can require the sponsor to follow requirements of this procedure or a different set of instructions.

A TGA delegate can also require the same person to inform the public (or a specified class of persons) what is happening, or has happened, and why.

## Publishing of mandatory recalls

The requirements a TGA delegate imposes on a person to recall therapeutic goods from supply must be published in the Australian Government Notices Gazette or on the TGA website.

## Failure to comply with mandatory recalls

If a person fails to comply with a requirement imposed to recall a therapeutic good or take other action under the mandatory recall provisions, then depending on the circumstances he or she may:

- be charged with a criminal offence and, if found guilty of that offence by a Court:
  - imprisoned for up to 12 months (or 5 years, if failure to recall the therapeutic goods results in harm or injury to another person)
  - be subject to fines ranging from 1,000 to 4,000 [penalty units](#).
- Have civil penalty proceedings brought against them in a Court, and, if the Court finds the breaches made out, be ordered to pay various civil penalties.

## Counterfeit therapeutic goods

A TGA delegate may require a person who supplies counterfeit therapeutic goods to recall those goods from supply, or take other actions such as public notification (sections 30EA, 32HA and 42E of the [Therapeutic Goods Act 1989](#)).

Therapeutic goods are counterfeit if the label or presentation of the goods; any document or record relating to the goods or their manufacture; or any advertisement for the goods; contains false information relating to the:

- identity or name of the goods
- formulation, composition or design specification of the goods or of any ingredient or component
- presence or absence of any ingredient or component of the goods
- strength or size of the goods (other than the size of any pack in which the goods are contained)
- strength or size of any ingredient or component of the goods
- sponsor, source, manufacturer or place of manufacture of the goods.

## Actual or potential tampering

Any person who supplies, manufactures or sponsors therapeutic goods, or proposes to do so, must notify TGA within 24 hours of becoming aware of a substantial risk of actual or potential tampering to those therapeutic goods.

It is an offence under section 42T of the [Therapeutic Goods Act 1989](#), punishable by imprisonment of up to 12 months or a fine of up to 1,000 penalty units, or both if

- they<sup>12</sup> receive information or demands and know it relates (either expressly or by implication) to actual or potential tampering with some or all of those therapeutic goods, or any other therapeutic goods

AND

- fail to notify the TGA within 24 hours after receiving information or demand.

## How to notify

Address your notification to the Principal Medical Adviser, c/- the Australian Recall Coordinator.

Email the notification to [recalls@health.gov.au](mailto:recalls@health.gov.au).

## Specifying steps for actual or potential tampering

If satisfied that there has been actual or potential tampering, a TGA delegate can require a person who supplies or has supplied the therapeutic goods, or a particular batch or kind of therapeutic goods, to:

- Take action to recall the goods that have been, or could possibly be, subject to tampering.
- Inform the public or other specified persons of the actual or potential tampering.

TGA may impose these requirements under Section 42V of the [Therapeutic Goods Act 1989](#), whether or not a notification has been made.

## Publishing of tampering requirements

When TGA takes action under section 42V of the [Therapeutic Goods Act 1989](#), the particulars of the requirements imposed must be published in the Australian Government Notices Gazette or on the TGA website.

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<sup>12</sup> They means: Any person who supplies, manufactures or sponsors therapeutic goods, or proposes to do so

## Version history: Mandatory recalls

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
V2.0	Publication following consultation	Recalls and Case Management Section Regulatory Guidance Team	Publication date: 3 October 2017 Implementation date: 15 January 2018

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