Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Uniform Recall Procedure for Therapeutic Goods (URPTG)

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Uniform Recall Procedure for Therapeutic Goods (URPTG) 1

Purpose of this document

This document is for Australian sponsors who need to undertake actions (recall and non-recall actions) for therapeutic goods in Australia.

It outlines the processes to respond efficiently and effectively to problems with therapeutic goods that could pose a risk to public health and safety.

It also explains the roles and responsibilities of all stakeholders who are involved in therapeutic good recalls.

Contact details

Contact the Australian Recall Coordinator

Ph: 1800 020 653 (free call in Australia)

Ph: 02 6289 4613 (normal business hours)

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

Email: recalls@health.gov.au

For more details go to the contact information on the TGA website –

- Recall coordinators for therapeutic goods | Therapeutic Goods Administration (TGA)
- Australian Recall Coordinator notification list | Therapeutic Goods Administration (TGA)

Templates

To help you with your communications:

- example sponsor customer's letter
- example customer response form
- example customer/distribution list
- example consumer recall notice for consumer level recall

Overview of Recall and Non-Recall Actions

Recall and non-recall actions are when an action is taken on therapeutic goods already supplied to the market when a problem has been identified.

If the problem with your product relates to any of the following, refer to **Procedures for taking immediate action** and follow all instructions.

- Immediate or significant health risks
- Product tampering
- Recalls of certain therapeutic goods:
    - Radiopharmaceuticals
    - Blood or blood components
    - Biological or human tissues

Why perform a recall action?

Recall actions are taken to address a problem with therapeutic goods related to:

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

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

There are 4 types of recall action:

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

For a description of the situations these actions best suit, see types of recall actions.

Why perform a non-recall action?

Not all problems require a recall action. Non-recall actions are appropriate if:

- the therapeutic goods meet all required specifications and standards, and
- there are no deficiencies in safety, quality, efficacy, performance, or presentation.

There are 4 types of non-recall action:

- Safety Alert
- Product notification
- Quarantine
- Product withdrawal

For a description of the situations these actions best suit, see types of non-recall actions.

Undertaking an action

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

- is undertaken by the sponsor or the person responsible for supplying the therapeutic goods
- follows this procedure and
- involves all those who have a role in the recall or who are impacted by it.

Sponsors or suppliers must follow the procedure to decide the most appropriate action (immediate, recall or non-recall) in consultation with the TGA to mitigate an actual or potential public health risk from a particular therapeutic good.

Alternatively, delegates of the Secretary of the Australian Government Department of Health and Aged Care can exercise powers under the *Therapeutic Goods Act 1989* (the Act) to impose a requirement to perform a recall of therapeutic goods to protect public health.

Procedures for taking immediate actions

In circumstances where a sponsor becomes aware of a serious problem associated with a therapeutic good, an immediate recall action may be required. Such circumstances include:

- Problems that pose immediate or significant health risks
- Product tampering
- Problems involving certain therapeutic goods:
    - Radiopharmaceuticals
    - Blood/blood component
    - Biological/human tissue

Problems that pose immediate or significant health risks

Contact the Australian Recall Coordinator if the problem with the goods poses an immediate and significant safety risk to the community as a whole.

Such risks include imminent risk of death or serious injury as well as potential disruptions to critical lifesaving medicines, medical devices, or clinical services.

Product tampering

Tampering occurs when:

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

The Act includes criminal penalty provisions applying to sponsors who fail to notify the Secretary of actual or potential tampering. Further information can be found under Actual or potential tampering.

Problems involving certain therapeutic goods

Radiopharmaceuticals, biologicals, bloods and blood components must be used within a specific timeframe. An immediate action for such goods is required when:

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

Firstly, inform your customers of the immediate action

Contact customers immediately by telephone and/or email to prevent use.

Seek customers' response advising that they have:

- quarantined unused goods
- notified the surgeon (for biologicals)
- notified the clinician for infused blood components (for bloods and blood components)

Then, inform the TGA of the immediate action

Contact the Australian Recall Coordinator and follow the remaining steps in this procedure.

For biologicals, bloods and blood components, complete the Human blood and tissues recall report form and send it to the TGA.

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

Procedure for Recall and Non-Recall Actions

Follow Steps 1-10 in order. If you decide on a non-recall action, you may skip Step 4.

Gathering Information

Step 1	**Obtaining distribution and stock status**
Step 2	**Conducting a risk analysis**

Determining your action strategy

Step 3	**Deciding the type, class, and level of your action**
Step 4	**Developing an action strategy** Non-recall actions may skip this step
Step 5	**Drafting a communication strategy**

Submitting your notification

Step 6	**Submitting the notification**
Step 7	**TGA assessment of your proposed action**

Initiating your action

Step 8	**Implementing the action**

Reporting on and finalising your action

Step 9	**Reporting on the action**
Step 10	**Reviewing the action** The TGA will review the progress reports and decide if any further actions are required.

Step 1. Obtaining information and distribution status

When you become aware of a problem requiring a recall or non-recall action, it is important you firstly obtain a description of the goods and the problem with them, as well as the distribution details of stock in the market. This way, when you start the action, you can explain the problem clearly and quickly get in touch with your customers.

Required Information

Collect the following so that you can explain the problem and track the distribution of your product.

- Details of the notifier
- Describe the problem
- Describe the goods
- Extra information
- Commercially sensitive or personal 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 action. This information is a required field when you submit your online notification.

Describe the problem

Collect all relevant details about the problem and type of therapeutic good including:

- date problem first detected
- photographs that help illustrate the problem (e.g. a broken medical device)
- how the problem 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
- potential failure mode due to the problem
- known or similar problems that have occurred in the past.

Describe the goods

Collect 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):

- Manufacturer's name and address
- 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 or lot released
- dates and quantity distributed to the Australian market
- where the therapeutic goods are 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.

Customer/distribution list

You must provide us with your customer / distribution list using the template available on our website.

Extra information

We may seek additional information from you after our 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.

Commercially sensitive or personal information

Identify any commercially sensitive or personal information.

We will manage any information that is commercially sensitive or private in nature according to the treatment of information provided to the TGA policy.

Step 2. Conducting a risk analysis

A risk analysis for product defects is required to ensure that any issues are identified and managed effectively. This process helps to:

- Determine the root cause of deviations or defects
- Assess the potential impact on product quality or patient safety
- Decide on the necessary corrective and preventative actions (CAPAs)

This document needs to be provided to the TGA.

As the sponsor, you should receive this report (it may also be called a health risk assessment (HRA) or health hazard evaluation (HHE), etc.) when the manufacturer notifies you of the problem or defect. Make sure you are satisfied with the conclusions and recommendations.

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

- gather as much information as you can, and
- send details of the complaints and/or adverse events to the manufacturer and request the risk analysis.

Medical devices

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

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

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

You need to provide us with the report which must include details of:

- the defect or deficiency
- potential failure mode (How the failure will be presented)
- failure rate (Frequency with which the failure occurs in affected stock)
- 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).

Biologicals, human blood and blood components

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

- investigate adverse events and product complaints. This includes process failure and suspected bacterial contamination events and

- implement and maintain a written procedure for product recalls.

Related guidance

- The Code of Good Manufacturing Practice (GMP) for human blood and blood components, human tissues and human cellular therapy products.
- Appendix 11, Risk management in the Australian regulatory guidelines for biologicals.

Medicines

Medicine manufacturers are responsible for implementing an appropriate pharmaceutical quality system (PQS) and using it to identify any potential risks associated with their products. The manufacturer may also be the sponsor of the therapeutic goods.

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

The risk analysis report must include details of:

- potential hazards and their likelihood to occur
- details of any complaints or adverse events
- the potential harm to the user because of the problem
- health conditions that could increase the likelihood or potential harm
- alternative treatment options, including the hazard associated with providing no treatment if alternatives are not available
- results of tests and other investigations on suspect or other samples
- the likelihood that the consumer, caregiver or health professional will discover or identify the problem prior to or during use and
- whether the medicine is outside the manufacturer's specifications.

Incorporate other relevant analysis or clinical investigation into your risk analysis. Sponsors who are not also the manufacturer must ensure they are satisfied with the conclusions and recommendations.

Step 3. Deciding the type, class and level of recall

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

Check you need to conduct a recall action

Use the information gathered in Steps 1 and 2 to assist you in deciding the:

1. type of recall
2. class of recall
3. level of recall

Need help?

Contact us if you need help.

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

You have a recall action

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

- continue working through these recall procedures
- do not delay notifying us.

You do not have a recall action

If, after completing this assessment, you think the problem with the therapeutic good does not warrant a recall action:

- determine if a non-recall action may address the problem and
- for non-recall actions, go to Step 5 Drafting a communication strategy

Step 4. Developing an action strategy

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 action.

Do not implement your recall strategy until we have agreed with it.

The class, level or type of recall action may change following our assessment.

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 6.

Objectives of a recall action

Your recall strategy needs to assure us you are effectively mitigating the risks 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 problem
- informing the users of the problem
- analysing the root cause and implementing corrective and preventative actions (CAPAs) to prevent re-occurrence.

Overview of a recall strategy

Your recall strategy should address:

- consumer, patient and health professional safety
- the nature of the problem 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 action.

Preparing a recall strategy

Include the following in your recall strategy:

- the details of the goods involved in the recall action
- the problem, including your assessment of the potential hazard or risk posed by the goods
- the proposed type, classification and level for the recall action as decided in Step 3
- 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 5. Drafting a communication strategy

Your communication strategy is vital to informing all stakeholders of the problem with the goods. Providing clear and concise information will assist all stakeholders understand what actions they need to take.

We must agree to your communication strategy before you implement it because it may change following our review of your submission.

Communication strategy – required documents

- Draft customer letter and
- Customer response form.

For information about how to format your letter, see sponsor's customer letter for recall actions.

When to send the customer letter

Your customer letter should be sent to all impacted customers (not including individual consumers in the case of consumer-level actions) within **2 business days** of agreement with the Australian Recall Coordinator in Step 8.

Communication strategy

The required documents for consumer level and other significant or high-risk recall actions may include:

- Draft consumer recall notice and
- Draft media release.

Consumer recall notices may be prepared for your website, social media, print media (or all) depending on the impacted patient demographic. The consumer recall notices section contains guidance on how to prepare your notice.

Depending on the situation, target audience and their demographic(s), these may be required. If you have not provided them, you may be asked to do so during our review of your proposed action.

Media release

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

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

- contain sufficient detail to define the specific affected goods
- clearly explain the problem and associated risks without causing unnecessary alarm
- state the appropriate actions to be taken by the consumer
- provide a toll-free phone number for consumers.

Send us the draft media release in Step 6. We may seek expert advice when we review this in Step 7.

Step 6. Submitting the notification

For all actions, you must submit your online notification to us through the TGA Business Services portal (TBS). Use the information gathered in the previous steps to fill relevant tabs in the form.

This applies to organisations that already have a TGA client identification number (Client ID), as well as new organisations submitting their first recall action.

Upon saving the web form, you will receive a new TGA reference number (in the format RC-20XX-RN-01234-1, where '20XX' is the year in which the notification was submitted).

Refer to this "RC Number" in all correspondence about the action.

DO:

- Upload your draft customer letter, risk documentation, distribution lists, communication strategy documents and any other supporting documentation in the 'Supporting Information' tab.
- Click on the 'Validate' button and the 'Submit' button to complete your notification to the TGA Recalls Section. We will not receive your notification until you have done this.
- Contact us if you need help about what to submit.

DO NOT:

- Use words such as, "refer to attached documents" in the TBS form.
    - Fields must be populated with meaningful and descriptive information.
    - We will follow up with sponsors who provide insufficient information in these fields.

If you have any queries about the TBS portal, or do not have access yet:

- refer to our guide about getting started with the TGA or
- contact the TBS Helpdesk at ebs@tga.gov.au or 1800 010 624.

- For therapeutic goods supplied in some Australian states and territories, sponsors, agents and manufacturers may be required (by that state or territory) to use a third-party notification service to communicate their recall action.
- This is not a TGA requirement.
- If this applies to you, you **do not** need to submit a duplicate notification to us via the TBS portal. We will receive your notification automatically from the third-party. We will follow up with you if we require more information or clarification.
- If using this third-party service, it remains very important that you **do not** proceed to notify customers until you have received an 'Agreement Letter' from the TGA Recalls Section.

Step 7. TGA's assessment of your proposed action

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

Analysing risk

We will conduct an independent and objective assessment to verify that the proposed action strategy can mitigate the risks posed by the affected goods.

Assessing the action strategy

We will assess your proposed action then liaise with you. We may edit proposed recall strategies, customer letters and consumer recall notices as needed.

Option to mandate a recall action

We prefer to reach agreement with you on an appropriate recall strategy. However, our role is to protect public health and safety so 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 action within 7 business days. (The day of submission counts as day 0).

We review all notifications upon receipt and triage them on a risk-based approach.

Issuing the 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 action
- provide guidance if you need to notify the recall action to the Australian Competition and Consumer Commission (ACCC) and

- contain the templates you will need to provide your follow up reports to us.

Notifying stakeholders prior to our Agreement

When a recall action may cause significant supply disruptions or serious changes to the way patients are cared for, this may require us to send an '**Early Advice Notice**' to the State and territory recall coordinators, relevant health professional guilds or patient stakeholder groups prior to us agreeing to the action with the sponsor.

An Early Advice Notice may:

- provide advice or raise awareness on the upcoming recall action, to allow mitigation strategies to be developed
- ask whether supply or ongoing patient care will be significantly affected by the proposed action, or if it will result in a critical shortage of the therapeutic goods
- request urgent feedback on the proposed action e.g. remove products from supply, quarantine those not yet in supply, adequacy of any proposed workarounds or mitigation strategies, etc.

These notices are released under s.61 of the *Therapeutic Goods Act 1989.* Sponsors will have the opportunity to review the text of the Early Advice Notice, and the notice will include a statement saying that the advice is being sent in consultation with the sponsor.

Recipients of the Early Advice Notice are advised that:

- the information is **not** a communication about an agreed recall action and is therefore subject to change.
- it should remain confidential, should not be widely disseminated and only provided to those persons who can directly assist with providing input or advice in response to the matters raised in the Notice.

The requested response time to the Early Advice Notice will vary and be based on the risk and/or urgency of the matter.

Notifying stakeholders after our Agreement

Following our agreement to the recall, we will notify some organisations directly and publish the details on our website.

System for Australian Recall Actions (SARA)

We publish all recalls (except clinical trial and blood component recalls) undertaken in Australia in the publicly searchable database, System for Australian Recall Actions (SARA), on the 2nd business day following agreement to the recall strategy.

TGA Recall, Safety Alert and Quarantine Notices

We develop a TGA notice for all recall actions, safety alerts and quarantine actions, which includes the:

- identity of the goods
- nature of the problem
- assessment of user hazard
- distribution of the goods (for recall actions) and
- 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.

In most circumstances, the notice is sent to recipients on the 2nd business day following agreement. This will align with the publication of the action on the SARA database.

Earlier notification (i.e. one business day or immediately following agreement) will be considered on a case by case basis for some high-risk circumstances, such as imminent life-threatening scenarios or serious large-scale impacts on clinical services.

We will contact you when a notification earlier than 2 business days is considered necessary and advise when it will occur.

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

Publishing TGA alerts

We publish alerts on our website to inform and advise consumers and health professionals. We 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 if we need 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 or
- any other recall action that may have wider implications for public health and safety.

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

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

Step 8. Implementing the action

For sponsors undertaking a recall action:

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

For non-recall actions:

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

Send the sponsor's customer letter

Send your sponsor's customer letter to all known customers within 2 business days from receiving our 'Agreement Letter'.

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

Notify the ACCC

Regardless of the agreed action level, report the recall action to the ACCC if you are recalling therapeutic goods that are also 'consumer goods'. For more information see Recalls and the ACCC.

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 and
- arrange for the disposal of the returned goods: you may arrange for the returned goods to be held and kept separate until they can be rectified or safely destroyed.

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

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, we 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.

Make 3 or more attempts to contact customers via various mediums (including but not limited to email, mail and/or phone), if they do not respond to the initial customer letter.

Undertake root cause analysis

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

We will review the root cause analysis in the final progress report (Step 10).

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 9. Reporting on the recall action

Use the templates provided in the agreement letter or available on the TGA website to produce follow-up reports.

These reports will be used to determine the effectiveness of the recall in Step 10, so you should ensure that you have addressed all items completely before submitting them.

We will follow up with sponsors if required or when incomplete information has been submitted.

Submitting your reports

Submit your progress reports to us by email - recalls@health.gov.au.

The subject line should include: the TGA Recall Reference Number (ie: RC-20XX-RN-XXXXX-X) as well as the type of report being submitted.

Timeframes for reports

The TGA Agreement Letter will contain the timeframes for your reports. These are typically:

- Interim report (6 weeks)
- Closeout report (3 months or at another agreed time)

The timeframes for these reports will be agreed with sponsors on a case-by-case basis.

We may impose additional reporting requirements, as needed, for high risk or delayed actions.

Human blood and blood component recalls require only one report at 4 weeks. This single report should use the blood closeout report template.

Interim report (6 weeks)

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

Submit your interim report at the agreed time, usually 6 weeks after implementation of the recall action.

Closeout report (3 months or at another agreed time)

Submit your final report at the agreed time, usually 3 months after implementing the recall.

The Closeout report must include a comprehensive short summary of the root cause and CAPA information, regardless of whether this information was provided earlier. The report must also provide information which demonstrates that the recall action has been effective, carried out and completed in line with the Agreement Letter.

The Closeout report may be submitted prior to the agreed time, if all affected therapeutic goods have been returned or corrected and all requirements of the report have been fulfilled.

Step 10. Reviewing the recall

Components of the review

We review your Interim and Closeout reports to:

- verify you have:
- completed all the agreed actions with documented evidence
- justified any discrepancies or inconsistencies
- provided evidence that the agreed action for the affected goods has been implemented
- determine whether the following are satisfactory:
- implementation of the recall action
- the investigation of the problem or hazard that prompted the recall action and the root cause identification
- CAPAs implemented to prevent or minimise recurrence of the problem in the future
- assess the effectiveness of the recall action and

- assess ongoing compliance with regulatory requirements.

If we are 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:

Actions and information provided is satisfactory:

- we will issue a close-out letter to you stating that the recall action has been satisfactory and no additional actions are required at this stage
- the information submitted will be used to inform upcoming manufacturer inspections and for trending purposes in post-market or other product reviews
- we may issue a close out letter for an action where the number of goods returned or corrected is not 100%. In the event a previously non-responding customer contacts you after we have issued a close out letter, you are still responsible for undertaking any corrective actions for the life of the good (i.e. the service life of the device or until a medicine is expired). Please note if the product is a consumer good, you should also fulfil any requirements in the Australian Consumer Law.

Nature of the root cause or remedial actions are not apparent:

- we may request additional information, including full CAPA reports for review.

Effectiveness of the recall is not satisfactory:

- we will follow-up with you to determine additional action to ensure the recall action is effective.

Identification of a systemic or serious problem (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.

Recall and non-recall actions

This information will help sponsors in Step 3 of the recall procedure to decide whether to undertake:

- a **recall action** and, if so, its type, class and level

OR

- a **non-recall action**, if you propose to not undertake a recall action.

It is important that we agree to the type, class and level of recall action before you commence (go to Step 7).

For specific guidance regarding market notifications for Medical Device Cybersecurity, please refer to 'Post-market guidance' within Medical device cyber security guidance for industry.

Types of recall actions

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

Removal from supply or use of products with inherent design or manufacturing defects

Requests to check and return products found to be defective sent to your customers, such as:

- pharmacists
- hospitals
- pathology laboratories
- fractionators
- operating and research facilities
- biomedical engineers
- others.

Recall does not include:

- 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 or
- 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:

- the repair, modification, adjustment or re-labelling of therapeutic goods for reasons relating to deficiencies in the quality, safety, efficacy, performance or presentation
- corrections involving a product's expiry date
- updates or changes to any accessories, operating instructions, patient information leaflets and patient implant cards 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:

- repair in the event of an incidental malfunction or failure as a result of normal wear and tear or lack of good maintenance
- appropriate preventative maintenance
- 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, a medical device supply disruption 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 hazard classification (“class”) of the recall action.

There are three risk classes to convey the seriousness of the problem 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 accidently 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 problems 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) will not cause adverse health consequences, or where the probability of minor adverse consequences is remote. Class III actions are typically concerned with matters other than product safety.

Class III examples

The goods meet acceptable standards of safety and efficacy and the problem 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 ARTG number or sponsor’s name and details.

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.

Estimating the class from the likelihood and severity of the problem

The following guide may be used to estimate the class of the action.

We will review your notification and may change the class to better fit the nature of the hazard.

Likelihood of Hazard Occurrence	
Likely	Has occurred, is occurring frequently, or is expected to occur again within a short period of time
Sometimes	Is expected to occur or reoccur at some time, but not within a short period
Rarely	May occur at some point, or a low number of instances expected for a high use product
Unlikely	Has not occurred, or an extremely limited number of instances. Very unlikely the problem may ever occur

Severity of Hazard	
Critical	Very severe injury, likely permanent damage, may require major surgery, potential to be life-threatening if medical invention is not obtained, or death
Serious	Results in more significant injury, impairment requiring professional medical treatment, or the potential of significant sequelae
Minor	May result in minor temporary injury or impairment not requiring professional medical intervention
Negligible	No risk to health, or extremely mild such as user inconvenience, temporary discomfort with no lasting effect

		Severity			
		Negligible	**Minor**	**Serious**	**Critical**
Likelihood	**Likely**	Class III	Class II	Class I	Class I
	Sometimes	Class III	Class II	Class II	Class I
	Rarely	Class III	Class II	Class II	Class I
	Unlikely	Class III	Class III	Class II	Class II

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 problem

- likelihood of the problem with the goods occurring
- ability of the consumer, health professional or caregiver to identify the problem
- 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 will cause a medicine shortage or medical device supply disruption.

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, respite facilities 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 problems 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 7 of the 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

A quarantine action suspends further supply and distribution of the goods pending your investigation of a problem. The outcome of the investigation will determine what further actions are required.

Quarantine of goods should be considered if a defect is identified in released goods which has the potential to cause problems with the safety, efficacy (medicines / biologicals) or performance (medical devices) of a therapeutic good.

Quarantine actions 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 7 of the 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 1 of the recall procedure).

If the quarantine can be lifted, we will review your second notice advising of this action (Step 7 of the 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.

Sponsor's customer letter for recall actions

The sponsor's customer letter is a factual statement of the reasons for the recall, together with specific details to easily identify the affected goods.

Preparing the customer letter

When preparing the customer letter:

- use Australian spelling
- use company letterhead
- include:
- the date
- the name and title of the signatory

- the TGA recall reference number
- a statement that the recall action is being conducted following consultation with the TGA.

Do not use the sponsor's customer letter to:

- downplay the seriousness of the problem
- promote the company or other goods
- promote or encourage marketing of other goods.

Do not:

- send this letter until we agree to the content: Step 7 of the recall procedure
- imply that the actions described in the letter proposed to be carried out by the recipient are at the recipient's discretion.
- 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.

We 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 letter.

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
- Unique Device Identification (UDI) as applicable
- 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 description

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.

Problem (reason for the recall)

Provide a clear description of the problem in simple terms.

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

Describe clearly:

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

Do not:

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

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 customer response 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) and
- 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 photo or picture of the goods (where possible), especially for consumer level recall actions. This assists in clearly 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)

Sending customer letters

Send your customer letter to all intended recipients within **2 business days** of agreement by the Australian Recall Coordinator in Step 7.

Do not send this letter until we agree to the content in Step 7.

The letter may change depending on our independent and objective assessment of your proposed action.

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 8 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 current and accurate.

Customer response form

A customer's response confirms they have received the sponsor's customer letter which is expected for all recall actions. Their response can be provided by:

- returning the completed customer response form to the sponsor
- an email
- facsimile response form
- online survey link
- QR code provided in the customer letter linking to an online form or
- providing details of the inventory of affected stock on-hand.

In your response form, QR code or link, make it as easy as possible for your customer to quickly complete and return to you. 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 and
- a place to record the date of completion of the form.

Ask customers to return the form promptly even if they do not have any remaining stock.

Provide a means for customers to return the form free of charge e.g. an email address or online form.

If you need to contact customers via telephone and/or physical site visits following distribution of the customer letter and they confirm receipt of the letter, this can be considered a response even if a completed response form is not returned to you.

In these instances, you should retain a clear record of the telephone conversation or site visit. This will assist you with reconciling the recall action and reporting response rates to us. A completed response form remains the preferred option and should be your first priority.

Consumer recall notices required for consumer level recall actions

The sponsor arranges and pays for consumer recall notices which are required for consumer level recall actions unless the sponsor has complete and accurate distribution lists identifying all customers or end-users. This guide relates to Step 5 of the recall procedure.

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 problem/s with the goods
- advice on the continued use or supply, including availability of any alternative goods
- 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 correct the problem
- availability of unaffected or alternate stock and
- 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.

Knowing your customers and how they access your products helps you target them more directly. You must distribute your consumer recall notice more widely if you cannot identify your customers or how they purchase and find information about your products.

Note: As the sponsor, you are responsible for paying for these consumer recall 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.
- targeted SMS alerts (using mailing lists or customer details)
- community forums and focus groups
- Australian Government Primary Health Networks (PHNs)
- peak consumer groups, e.g. Consumers' Health Forum, Australian Consumers' Association (CHOICE)
- 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.

You should arrange for publication or broadcast of your notice in all forms of media agreed, within 3 to 4 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.

If you publish information on your own website or digital forum, it must be publicly available for a minimum of 3 months or for the time specified within the TGA Agreement Letter. This time may be shortened or extended after we review your Closeout report.

We also provide a template for the notice.

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 therapeutic goods that are also “consumer goods” – as defined by the Australian Consumer Law).

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 action but can authorise third parties.

A TGA delegate for the Secretary of the Department of Health and Aged Care 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 include:

- Immediate actions: it is essential that you follow the instructions, this involves contacting the Australian Recall Coordinator straight away
- step for noting our agreement to your recall action and communication strategy (Step 7)
- the people in your organisation who will be involved in a recall action
- 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 action 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 9 of the recall procedure.

Communicating with other interested parties

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

Keeping details current and accurate

Have arrangements in place so that your TGA Business Services administrator keeps your recall coordinator details in the system current and accurate.

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:
    - 'Contact authorisation' appears directly under 'Organisation contact role'
    - for your own entry, 'Account settings' will show 'Additional information' if you are authorised to speak to us
8. save by selecting either:
    - 'Update details' (when editing a contact)
    - '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 recall actions for therapeutic goods. Cooperation from wholesalers and distributors is often essential for an effective recall action.

Every wholesaler should have a procedure describing how they will conduct a recall action 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 therapeutic 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 action.

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

Medicine manufacturers

Medicine manufacturers are required to:

- recall any batch of goods from sale or supply
- document investigations into any problems that occur during the manufacturing process, this documentation should include a root cause analysis
- 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 recall actions.

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 problems

Manufacturers are responsible for investigating problems that occur in the manufacturing process that could lead to a recall action. For example, problems with:

- a batch of raw material
- a component part
- the manufacturing process or
- 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 6 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 and
- a system to investigate any problem, 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 action.

Corrective and preventative actions (CAPAs)

When manufacturers identify a problem, 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 action. As a wholesaler, you should have a procedure for conducting a recall action 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 action
- 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 action was only to wholesale level)
- record keeping, including customer lists
- communication arrangements with the sponsor and
- 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 and
- 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 action in Australia:

- include export customers in the communications strategy that you provide us in Step 6 of the recall procedure and
- provide the overseas recipients with a written notice as soon as practicable.

Exporters of consumer goods

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

- any overseas recipients and
- 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 therapeutic goods

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

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

Your response to a recall action

If there is a recall action for a therapeutic good:

- stop supplying or prescribing the goods subject to the recall
- follow the instructions in the sponsor’s customer letter and
- contact the person named in the sponsor’s customer letter if you have any queries about the recall action.

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 or
- a laboratory.

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

- advise them of the recall action 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 Hazard Alert, the reasons for it, and the actions patients should take, according to the sponsor's customer letter and their individual circumstances (for example, if clinical signs indicate a need for medical follow-up).

Consumer-level recall actions

Because of the associated health risks:

- contact all consumers who have already received the recalled therapeutic good (if appropriate)
- advise patients about the recall action, 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) and
- 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 action (if applicable)
- the process for notifying patients and
- a plan for managing patients with implanted therapeutic goods.

Consumers and recalling goods

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

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

In all cases, contact:

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

TGA and recalling therapeutic goods

We are actively involved throughout the recall process.

Once a therapeutic good is available in Australia, we continue to monitor it through product vigilance activities.

This sometimes leads to identifying a problem 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 actions, contact the Australian Recall Coordinator.

For all recall actions, we send the TGA Recall Notice to all State and Territory recall coordinators.

Our role in recall actions

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 action 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 and
- reviewing the recall action 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 a current list of state and territory recall coordinators.

We contact relevant state and territory recall coordinators at Step 7 of the recall procedure.

We liaise with the ACCC when necessary for safety-related recall actions for therapeutic goods that are also “consumer goods” (See ACCC and recalling goods, below).

Providing information

We are responsible for communicating:

- the recall procedure
- details about specific recall actions through our public database, the System for Australian Recall Actions (SARA) and
- TGA alerts for recall actions 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 after publication.

State and territory recall coordinators and recalling therapeutic goods

State and territory recall coordinators play an important role in recall actions for 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 current for relevant organisations and individuals, including:

- purchasing authorities
- public and private hospitals and
- 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 and
- 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.

Recalls and the ACCC

The Australian Competition and Consumer Commission (ACCC) is Australia's national competition, consumer, fair trading and product safety regulator.

One of their roles as a regulator is to identify and address the risk of serious injury and death from safety hazards posed by "consumer goods". Consumer goods are defined in the Australian Consumer Law (ACL) as goods that are intended to be used, or are of a kind likely to be used, for personal, domestic or household use or consumption.

Some therapeutic goods are also consumer goods.

When should I report a problem to the ACCC?

When there is a safety-related recall action for a therapeutic good which is also a consumer good, the person carrying out the recall action is required to notify the ACCC within 2 days of taking that action.

The ACCC receives this notice on behalf of the Australian Government Minister responsible for the ACL (refer to Section 128 of the ACL, Schedule 2, *Competition and Consumer Act 2010*).

To notify a recall action to the ACCC, go to Submit a recall on the ACCC website, then complete and submit the online form.

Will the TGA or the ACCC be the lead regulator for my recall action?

In general, if the problem with a therapeutic good that is also a consumer good arises from non-compliance with a safety standard or ban under Part 3-3 of the ACL or a safety information standard under Part 3-4 of the ACL, the ACCC will be the lead regulator for the recall action. In all other cases, the TGA remains the lead regulator for the problem, refer to the flowchart on the following page.

Examples

Sponsor A wishes to report a problem with a therapeutic good – the Sponsor's '*Pregnancy Testing Kit A'* is powered by button batteries. All required warnings are provided on the packaging to indicate that the device contains button batteries.

However, the battery compartment is not secure, leading to batteries falling out of the device. The sponsor has received multiple complaints about this problem.

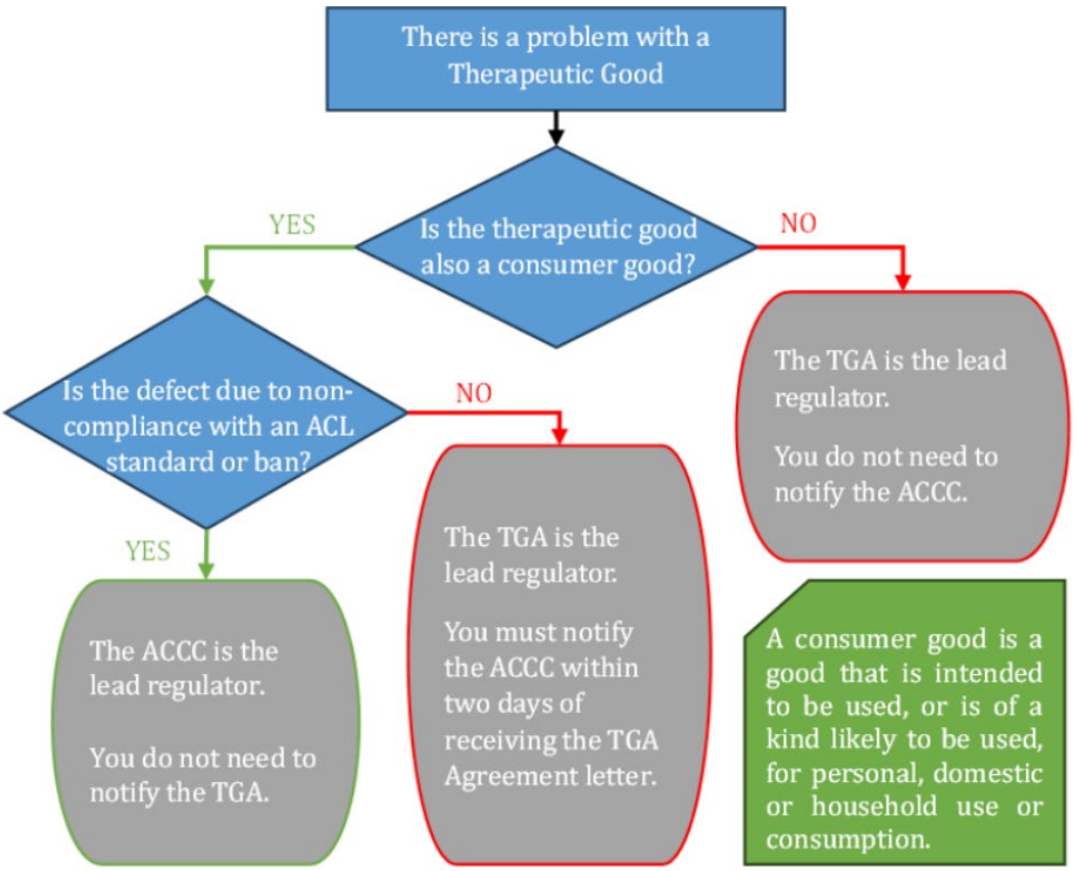
Before submitting the action to the TGA, the sponsor checks the ACCC's Product Bans and Mandatory Standards webpage and finds that their product does not comply with the Mandatory Standard for products containing Button Batteries.

Instead of submitting a notification to the TGA, the sponsor must notify the ACCC that it is recalling the product within 2 days of taking the action.

What if a consumer good defect is not related to an ACCC product ban or mandatory standard?

If the pregnancy testing kit was experiencing another problem but is compliant with the relevant mandatory standards, the TGA would be the lead regulator for this recall action.

However, the sponsor is still required to notify the ACCC of this within 2 days of taking action. This is because the kit is defined as a therapeutic good AND a consumer good. In practice, suppliers should provide this notice to the ACCC when they receive the agreement letter from the TGA.



What if I report the problem to the wrong regulator?

Notifications inadvertently submitted to the TGA which relate to ACCC Product Bans and Mandatory Standards will be referred to the ACCC by the TGA and we will inform you when we do this. Likewise, notifying the ACCC of a problem for which the TGA is the lead regulator will result in the case being referred to the TGA.

Resources

- Conducting a consumer product safety recall
- Consumer rights and guarantees
- Memorandum of Understanding – TGA and ACCC April 2023

Mandatory recalls

Sponsors of therapeutic goods are encouraged to decide of their own accord, or after recommendation from us, 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 and Aged Care (the Secretary) can exercise powers under the *Therapeutic Goods Act 1989* to mandate the sponsor to recall therapeutic goods to protect public health.

These powers apply to the person to whom the goods are entered on, cancelled or suspended from the ARTG and also to persons who are supplying goods not entered on the ARTG e.g. exempt goods or illegally imported, supplied or manufactured goods.

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 Devices 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
- 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.

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.

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 problems 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 problems
- 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 or
- sponsor, source, manufacturer or place of manufacture of the goods.

Actual or potential tampering

Any person who manufactures, supplies, or sponsors therapeutic goods, or proposes to do so, must notify the 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 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 Australian Recall Coordinator via 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.

Version history

Version	Description of change	Author	Effective date
V1.0	Publication for consultation	Therapeutic Goods Administration	27 October 2015
V2.0	Publication and implementation of new version	Recalls and Case Management Section	15 January 2018
V2.1	Amendments in relation to the new requirements for 'quarantine' actions, the introduction of a more flexible approach for 'consumer recall notices' and minor editorial amendments.	Recalls Section	February 2019
V2.2	Amendments around the provision of surgeon contact details, the online notification process and provision of a second example template for the sponsor's customer letter.	Recalls Section	December 2019
V2.3	Amendments around distribution details, submissions, reporting and communication strategy requirements for recall actions. Also provides a sample format for the submission of customer / distribution lists.	Recalls Section	June 2022

Version	Description of change	Author	Effective date
V2.4	This version of the URPTG includes: • additional clarity on the requirements for immediate recalls • removal of the requirement for monthly compiled lists of Single Donor Notifications from the Blood Service • new information on the 'Early Advice' process • clarification on the timing for release of recall information by the TGA • refined recall reporting requirements, including more flexible timeframes and removal of the 2-week report • additional clarity around the definition of Class III recall actions, including a guide for estimating the classification • additional clarity on the requirements for customer acknowledgement forms (now called customer response forms) • removal of the recall action document templates. All templates will now be available on the TGA website • clarification concerning the TGA and ACCC 'lead regulator' roles for recalls of therapeutic goods that are also consumer goods and • removal of outdated guidance, such as information concerning addressing letters, labelling envelopes and submitting notifications via email. This version also includes several other minor editorial amendments.	Recalls Section	March 2024

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Reference/Publication #