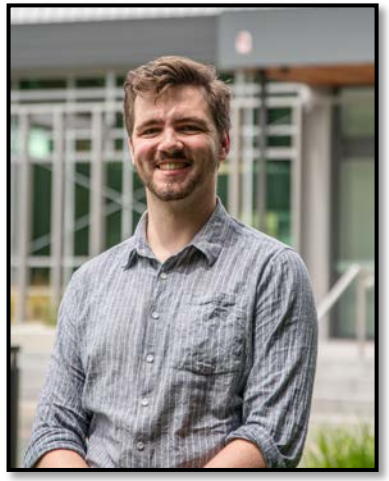
The Procedure for Recalls, Product Alerts, and Product Corrections (PRAC)

What you need to know



Jack Casey
Project Officer/SME
Manufacturing Quality Branch
Department of Health and Aged Care,
Therapeutic Goods Administration

Acknowledgement of Country

In the spirit of reconciliation, the Department of Health and Aged Care acknowledges the Traditional Custodians of country throughout Australia and their connections to land, sea and community.

We pay our respect to their Elders past and present and extend that respect to all Aboriginal and Torres Strait Islander peoples today

Housekeeping

This webinar is being recorded and will be available for access in the upcoming weeks

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- Click on the **Apps** icon
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- Live Poll (use survey tab when prompted)

Using the QR code

Scan the QR code to access Slido from your mobile device

The Procedure for Recalls, Product Alerts, and Product Corrections (PRAC)

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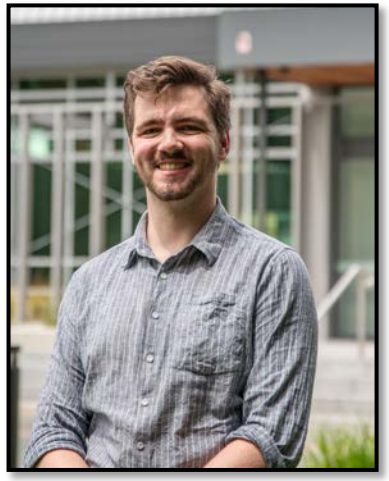

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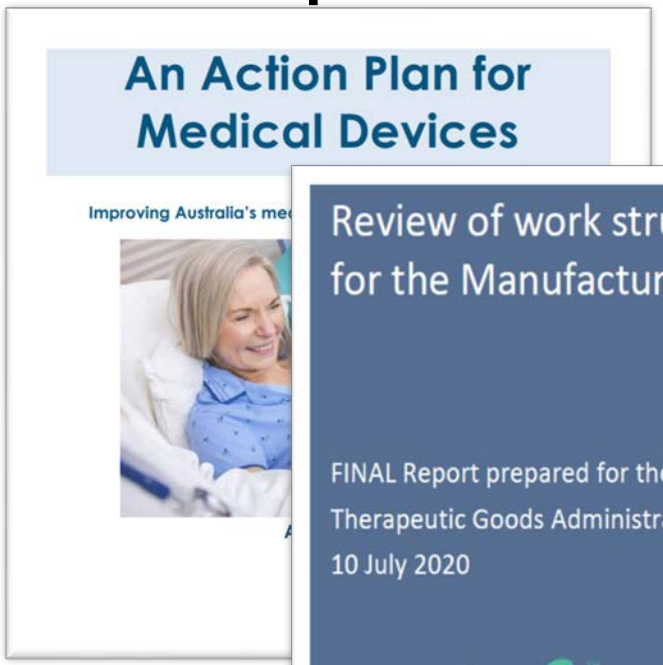
What this webinar will cover

- Why this is happening
- What's changing
- What you'll need to do
- What happens next

Why this is happening

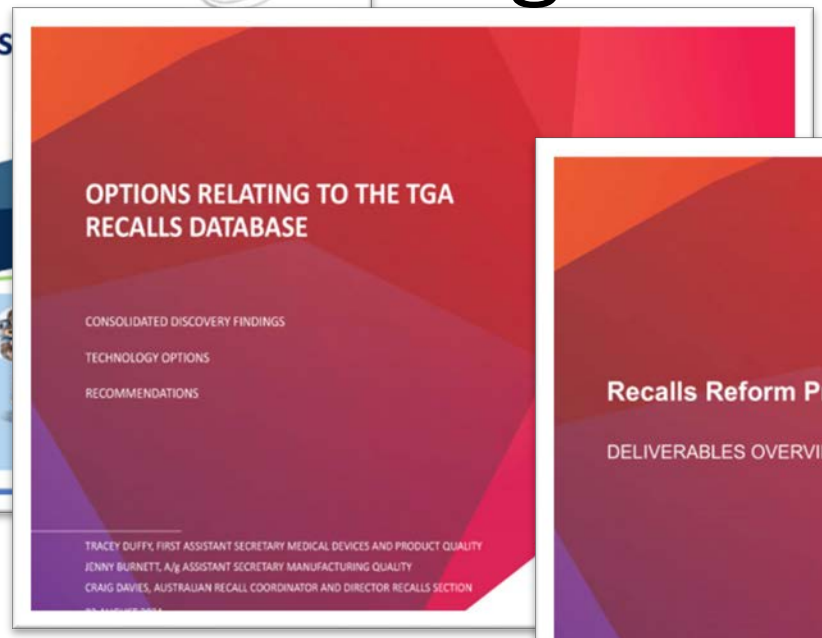
Apr 2019



Jul 2020

Nov 2020

Aug 2021



Nov 2021

Why this is happening

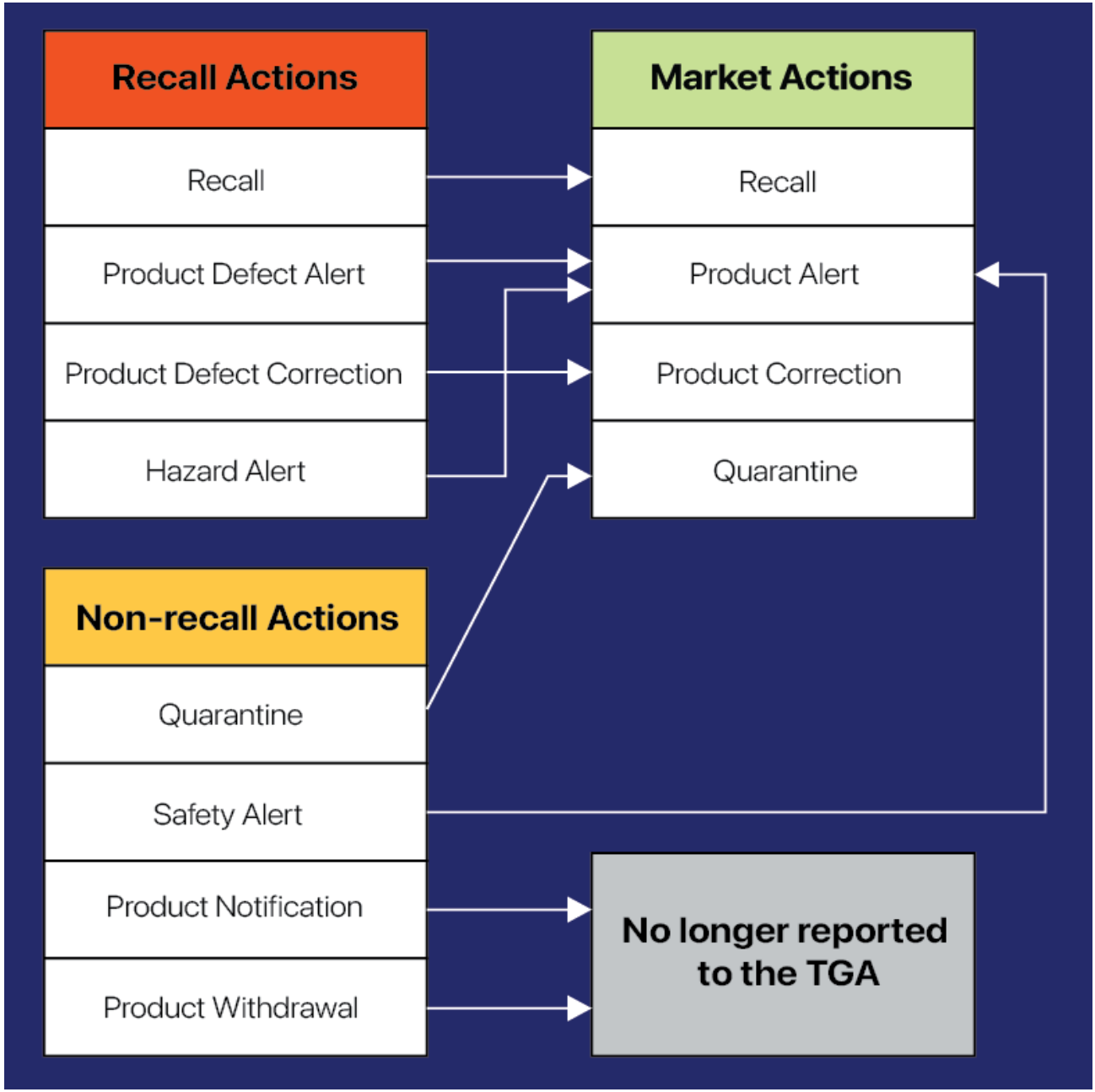
Jan - Mar 2023

Feedback

- **Put key information up front**
- **Change terminology**
- **Clarify processes**
- **Improve templates**

What's changing

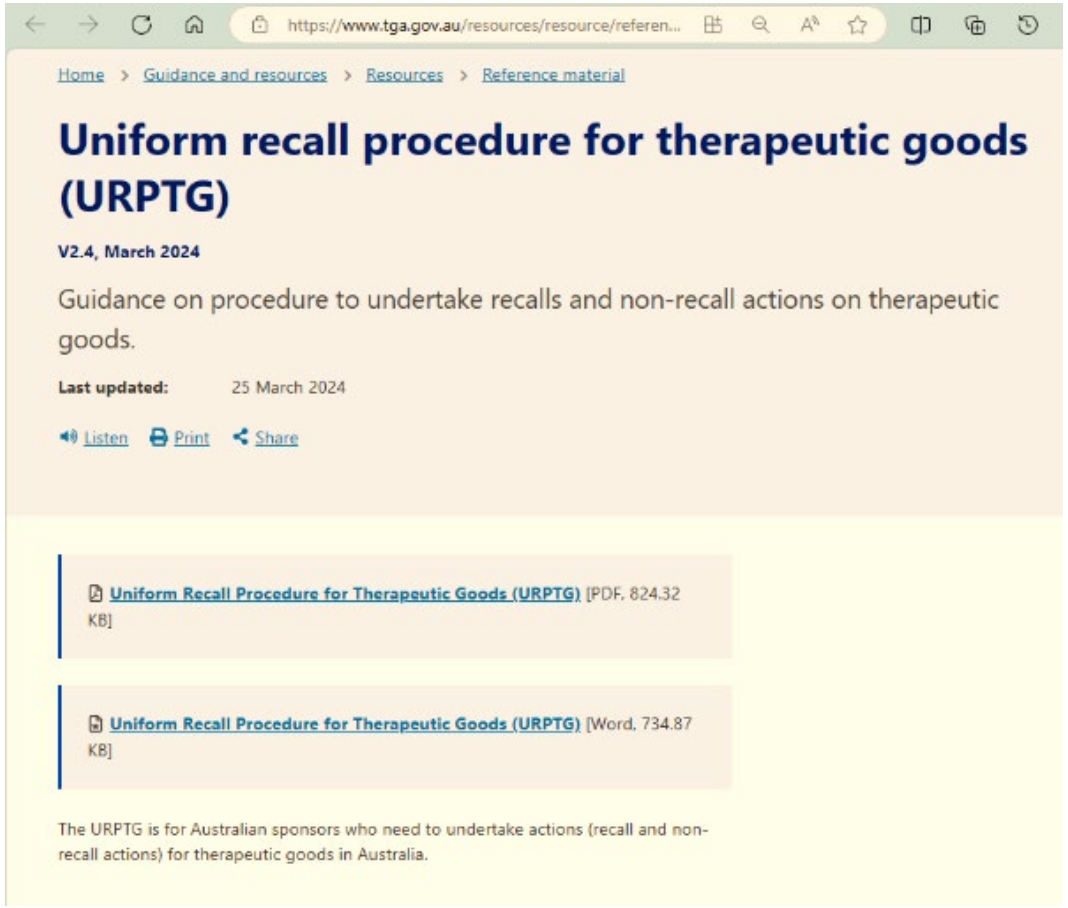
- Written for you
- New terminology
- Clarity
- Takes effect 05 March



What is changing

Yellow tint
URPTG

Blue tint
PRAC


https://www.tga.gov.au/resources/resource/referen...
Home › Guidance and resources › Resources › Reference material
Uniform recall procedure for therapeutic goods (URPTG)
V2.4, March 2024
Guidance on procedure to undertake recalls and non-recall actions on therapeutic goods.
Last updated: 25 March 2024
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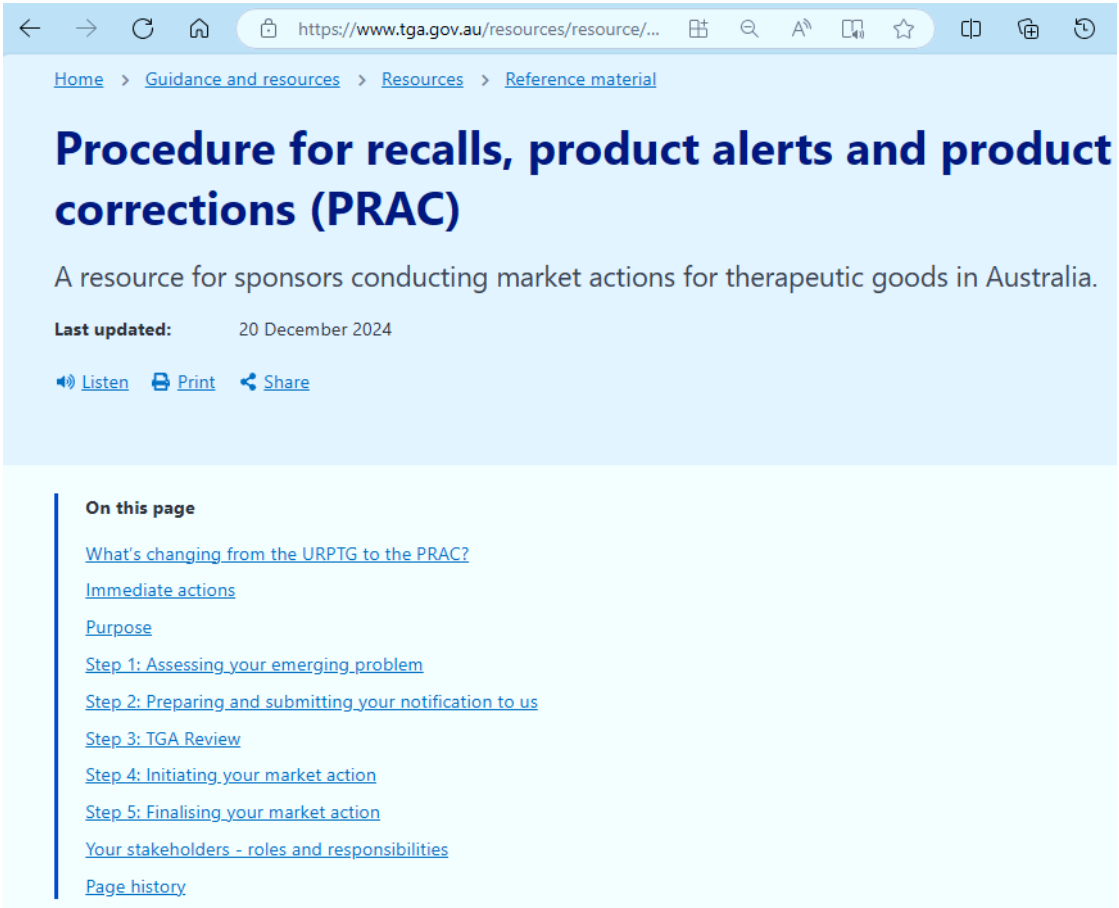
Uniform Recall Procedure for Therapeutic Goods (URPTG) [PDF, 824.32 KB]
Uniform Recall Procedure for Therapeutic Goods (URPTG) [Word, 734.87 KB]
The URPTG is for Australian sponsors who need to undertake actions (recall and non-recall actions) for therapeutic goods in Australia.


https://www.tga.gov.au/resources/resource/...
Home › Guidance and resources › Resources › Reference material
Procedure for recalls, product alerts and product corrections (PRAC)
A resource for sponsors conducting market actions for therapeutic goods in Australia.
Last updated: 20 December 2024
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Immediate actions
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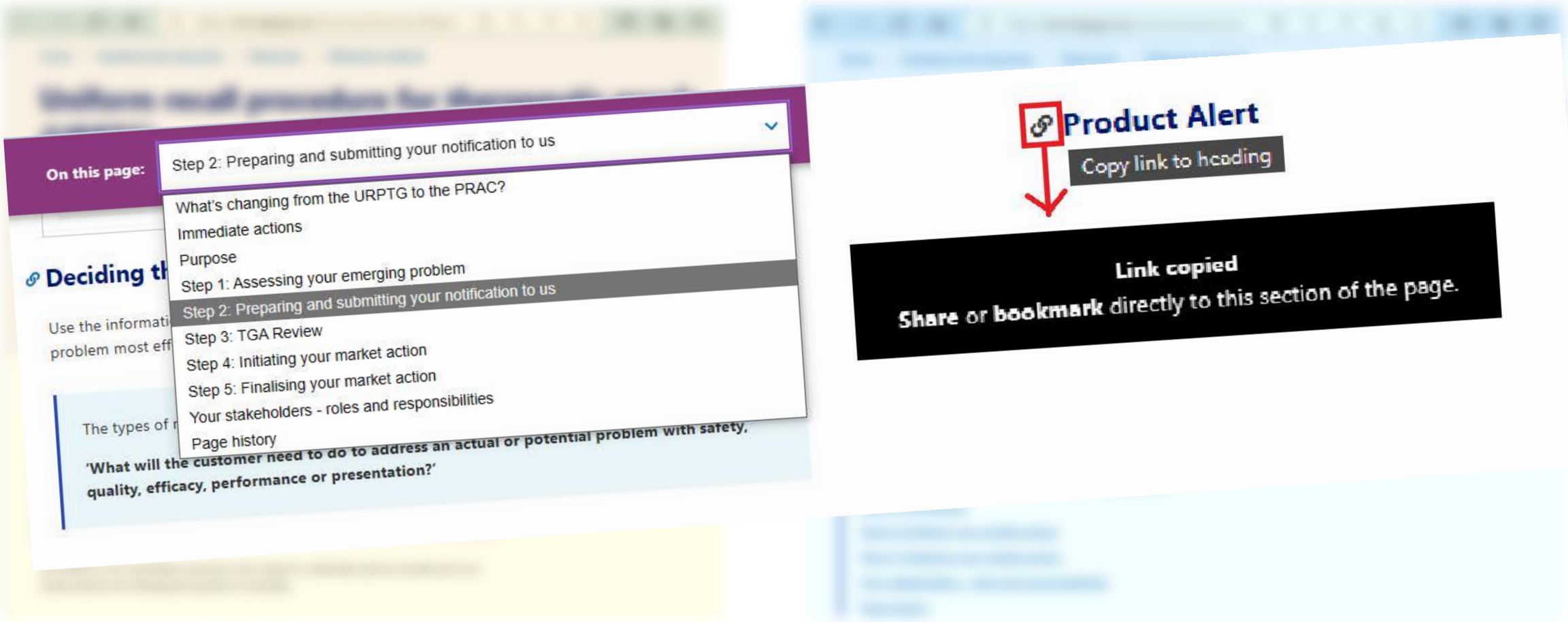
Step 2: Preparing and submitting your notification to us
Step 3: TGA Review
Step 4: Initiating your market action
Step 5: Finalising your market action
Your stakeholders - roles and responsibilities
Page history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Procedure for Recall and Non-Recall Actions

Step 1.

Step 2.

Step 3.

Step 4.

Step 5.

Step 6.

Step 7.

Step 8.

Step 9.

Step 10

Procedure for Recall and Non-Recall Actions

Step 1. Obtaining information and distribution status

Step 2. Conducting a risk analysis

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

Step 4. Developing an action strategy

Step 5. Drafting a communication strategy

Step 6. Submitting the notification

Step 7. TGA's assessment of your proposed action

Step 8. Implementing the action

Step 9. Reporting on the recall action

Step 10. Reviewing the recall

Step 1: Assessing your emerging problem

Step 2: Preparing and submitting your notification to us

Step 3: TGA Review

Step 4: Initiating your market action

Step 5: Finalising your market action

An issue with a therapeutic good is identified by consumers, healthcare providers, health departments, sponsors, manufacturers, labs, retailers, overseas regulators, research facilities, TGA, etc.

The sponsor submits a recall notice and works with the TGA to agree on the appropriate recall and communications strategy.

Key stages

Manage Emerging Issue → Submit Notification → Approve Recall → Implement Recall → Finalise Recall

The sponsor (in conjunction with the manufacture as needed) performs a risk assessment to determine the necessary actions to be taken

TGA reviews and assesses the documentation to ensure completeness, compliance and quality and publishes the recall to state and territory coordinators and the TGA website.

The sponsor notifies the TGA of the corrective action taken within the appropriate timeframe. If the report is satisfactory, TGA issues a close-out report and shares recall information other TGA stakeholders.

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.

Immediate actions

If your problem relates to any of the following

- Imminent and significant risks to patient lives or public health
- Actual or suspected tampering
- Radiopharmaceuticals
- Blood or blood components
- Biological or human tissue

You should do the following

- **Immediately** instruct your customers to quarantine affected goods
- To prevent further use or supply, confirm that your customers have:
  - notified impacted surgeons or clinicians (where applicable)
  - notified other areas who may have received the goods
- **Then** contact us (details below) promptly and be prepared to follow our instructions

Contact us as soon as possible if you're unsure whether to take an immediate action. For instance, if the action could create a shortage or disrupt critical patient care, etc.

343 words

119 words

An issue with a therapeutic good is identified by consumers, healthcare providers, health departments, sponsors, manufacturers, labs, retailers, overseas regulators, research facilities, TGA, etc.

Manage Emerging Issue

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

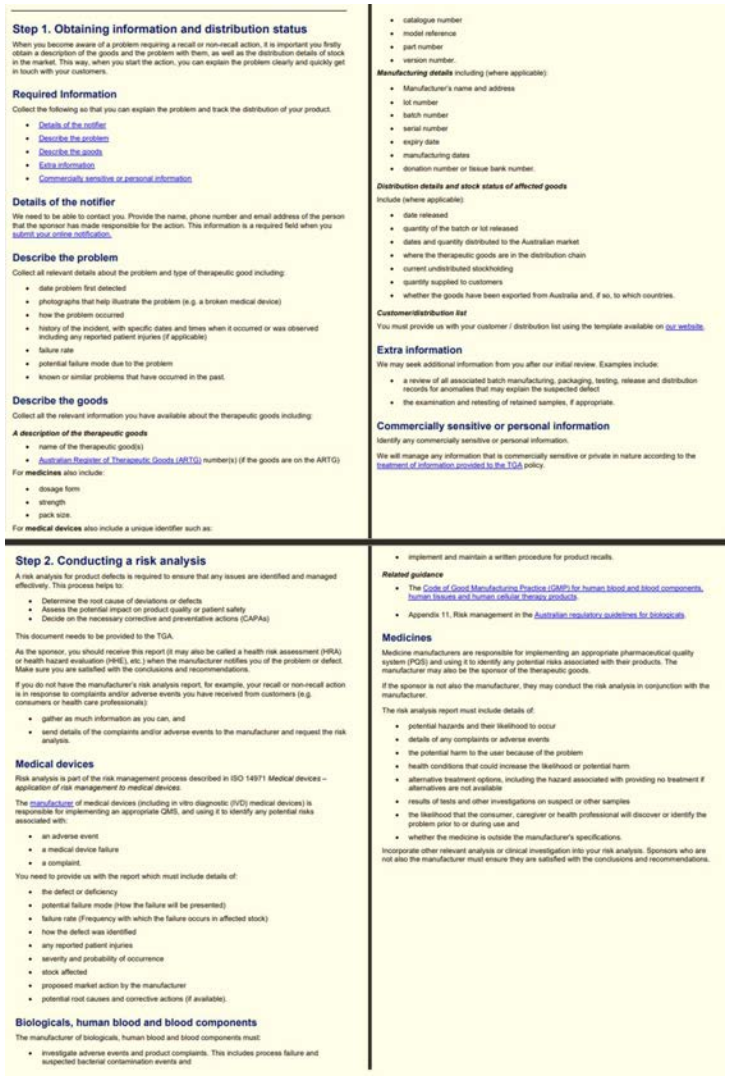
Step 1	**Obtaining distribution and stock status**
Step 2	**Conducting a risk analysis**

- Details of good
- Risk analysis

An issue with a therapeutic good is identified by consumers, healthcare providers, health departments, sponsors, manufacturers, labs, retailers, overseas regulators, research facilities, TGA, etc.

Manage Emerging Issue

- Details of good
- Risk analysis



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 1: Assessing your emerging problem

You should gather as much information about your problem as possible, to ensure that we can assess your notification promptly once submitted. For safety-related problems, do not delay in notifying us even if you are missing some details - we would rather be aware of emerging problems, especially ones with significant safety risks.

Details of affected goods

You should know:

Product identifiers	Quantity and distribution	Problem details
• Product Name • ARTG Number(s) • Batch/Lot/Serial Numbers • Manufacture Date(s) • Expiry Date(s) • CTN Number(s) for goods involved in Clinical Trials	• Date released to the Australian market • Quantity of affected stock in the market • Monthly consumption or reorder rate (if applicable) • Your approximate market share for the kind of product • States and Territories with the affected product • Types of customers the goods have been distributed to (e.g. supermarkets, hospitals, etc.) • Export status (if applicable) • Countries and dates of export	• How the problem occurs/occurred • What happens when the problem occurs • When and how you became aware of the problem • The number of complaints and/or reports of patient deaths, injuries or other harms (if any) • Photographs or pictures that help illustrate the problem

You should also know the following details for specific types of products:

Medicines	Medical devices	Bloods and biologicals
• Dosage form (e.g. tablet, liquid, injectable) • Strength • Pack size • Average/recommended daily dose	• Catalogue Number • Part Number • Model Number • Software Version Number • Unique Device Identifier(s)	• Primary Donation Number • Secondary Identifier Number (if applicable) • Tissue Bank Number • Donation type • Date of Donation

Risk analyses

When a manufacturer notifies you of a problem or defect, you should receive their risk analysis (also called health risk assessments (HRA), health hazard evaluations (HHE), etc.). Ensure that you are aware of the conclusions of your manufacturer's risk assessment when submitting it to us.

If you do not have the manufacturer's risk analysis for any reason (for example, if the problem has arisen from local complaints and/or adverse events), you should:

- gather as much information as you can
- detail the complaints and/or adverse events to the manufacturer and request a risk analysis from them.

What the risk analysis should include

We will follow up if the following is not addressed:

Details of the problem	Hazard severity	Manufacturer's proposed corrective action
• Details of the affected goods • How and when the problem was first identified • How the problem occurs • Estimated frequency of occurrence • Adverse event details (including international reports) • The ability of the consumer, caregiver, or health professional to discover or identify the issue prior to or during use	• A probability/severity assessment or matrix, including definitions and how the conclusion was reached • Medical conditions that may contribute to/worsen the hazard • Alternative treatment options • Hazard of providing no treatment if alternatives are not available	• Root Cause analysis • Tests and investigation results • Preliminary Corrective and Preventive Action (CAPA) if identified • Date CAPA was opened

Commercially sensitive or personal information

You must call attention to commercially sensitive information in your notification.

Do not give us any personal information or private details of any patients/individuals.

We will manage any information that is commercially sensitive or private in line with the TGA's privacy policy.

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Classes of recalls 26
Levels of recalls 29
Non-recall actions 31

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

Determining the class of market action

Class I - Critical safety-related

- The problem presents a reasonable possibility of serious injury or death.
- Class I actions must feature the word 'Critical' in the title of the customer letter.

Class II - Urgent safety-related

- The problem presents a reasonable possibility of temporary or minor injury, and/or the likelihood of serious injury or death is remote.
- Class II actions must feature the word 'Urgent' in the title of the customer letter.

Class III - Lowest risk

The problem is not likely to lead to injury, and/or the chance of a temporary or minor injury is remote. Class III actions usually address non-safety related problems.

How we determine the class

The class of a market action considers the severity of the potential harm, weighed against the likelihood of that harm occurring.

For instance, some harms might be very severe (i.e. a permanent injury) but extremely unlikely, while others might be less severe (i.e. short delay to treatment) but more likely to occur. We consider all scenarios, in particular, the worst-case scenario, when evaluating the potential risk and determining the Class.

Our classification of your action is informed by your submitted risk assessment. You may use the table below to inform your suggested Class, but it should not replace your normal risk assessment approach.

Likelihood of harm occurring

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 harm may ever occur

Severity of harm

Critical	Very severe injury, likely permanent damage, may require major surgery, potential to be life-threatening if medical intervention 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 effects

		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

Show description of image

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 warran 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

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

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

Check whether the problem with your therapeutic good(s) requires a recall action before y
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 re
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

You do not have a recall action

If, after completing this assessment, you think the problem with the therapeutic good does
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

- for non-recall actions, go to Step 5 Drafting a communication strategy

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

Deciding the type of market action

Use the information you have gathered in Step 1 to determine the action which would mitigate the problem most effectively.

> The types of market action can be understood by asking:
>
> **'What will the customer need to do to address an actual or potential problem with safety, quality, efficacy, performance or presentation?'**

Recall

'... **return/dispose** of the product.'

Recalls permanently remove products from the market.

They include:

- Removing products with design, manufacturing, or safety defects
- Requesting customers to check and return any defective products.

Customers may need to:

- Return products to you or to the place of purchase
- Dispose of the product and contact you for a refund, replacement or credit.

Recalls do not include:

- Removing expired products that were released before expiry
- Removal of an appropriate but small number of products from the market to test for deficiencies.

Product Correction

'... **correct/fix** the product.'

Product Corrections address specific or potential deficiencies.

They include:

- Repair, modification, adjustment, or re-labelling of products due to quality, safety, efficacy, performance, or presentation problems
- Updates to accessories, software, operating instructions, patient information leaflets, implant cards, service manuals, and preventative maintenance procedures (even if performed by the customer)
- Corrections to expiry dates, batch numbers, etc.

Some products can remain in use if there is an effective safeguard or workaround until a permanent fix is performed.

The correction can be performed at the customer's premises or any other agreed location.

Product Corrections do not include:

- Repairs due to incidental malfunction from normal wear and tear or poor customer maintenance
- Preventative maintenance
- Modifications for technical improvements unrelated to quality, safety, efficacy, performance, or presentation.

Product Alert

'... **know something** about the product.'

Product alerts raise awareness about deficiencies, potential deficiencies, or other concerns with the use of a product.

They are appropriate when:

- stopping treatment could pose a greater risk than continued use of the affected product i.e. the product provides critical treatment and there are no alternatives.
- the affected product cannot physically be recalled (i.e. implanted therapeutic goods)
- concerns or post-market signals indicate that users are not following established precautions or instructions.

The alert may:

- advise on patient management strategies
- describe precautionary actions for clinicians or users
- detail when alternative products or treatments are expected to be available following investigation
- reiterate existing product safety information for an otherwise safe product
- detail potential/emerging problems with the product.

Product Alerts may later develop into a Recall or Product Correction if alternative products or corrections become available, or if further investigation alters the risk.

Quarantine

'... **avoid use or supply** of the product, pending further advice.'

Quarantines temporarily suspend use and/or distribution of products already in the market, pending further investigation of a problem.

It should be considered if a potential defect could affect safety, quality, efficacy or performance of a product.

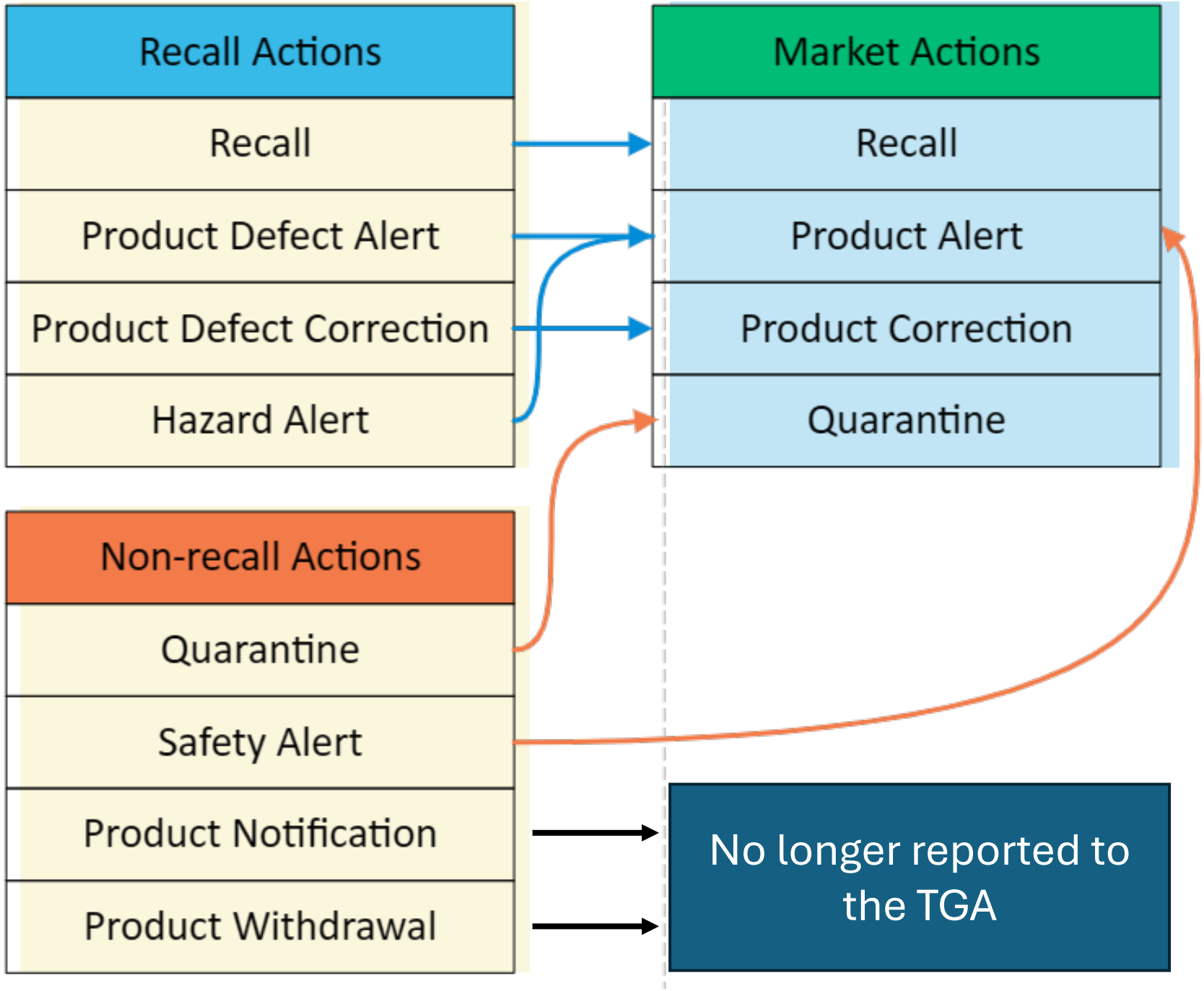
After issuing the quarantine, your investigation should determine:

- how the problem is occurring
- the risk posed by the problem vs the benefit of continued use
- the proposed next steps.

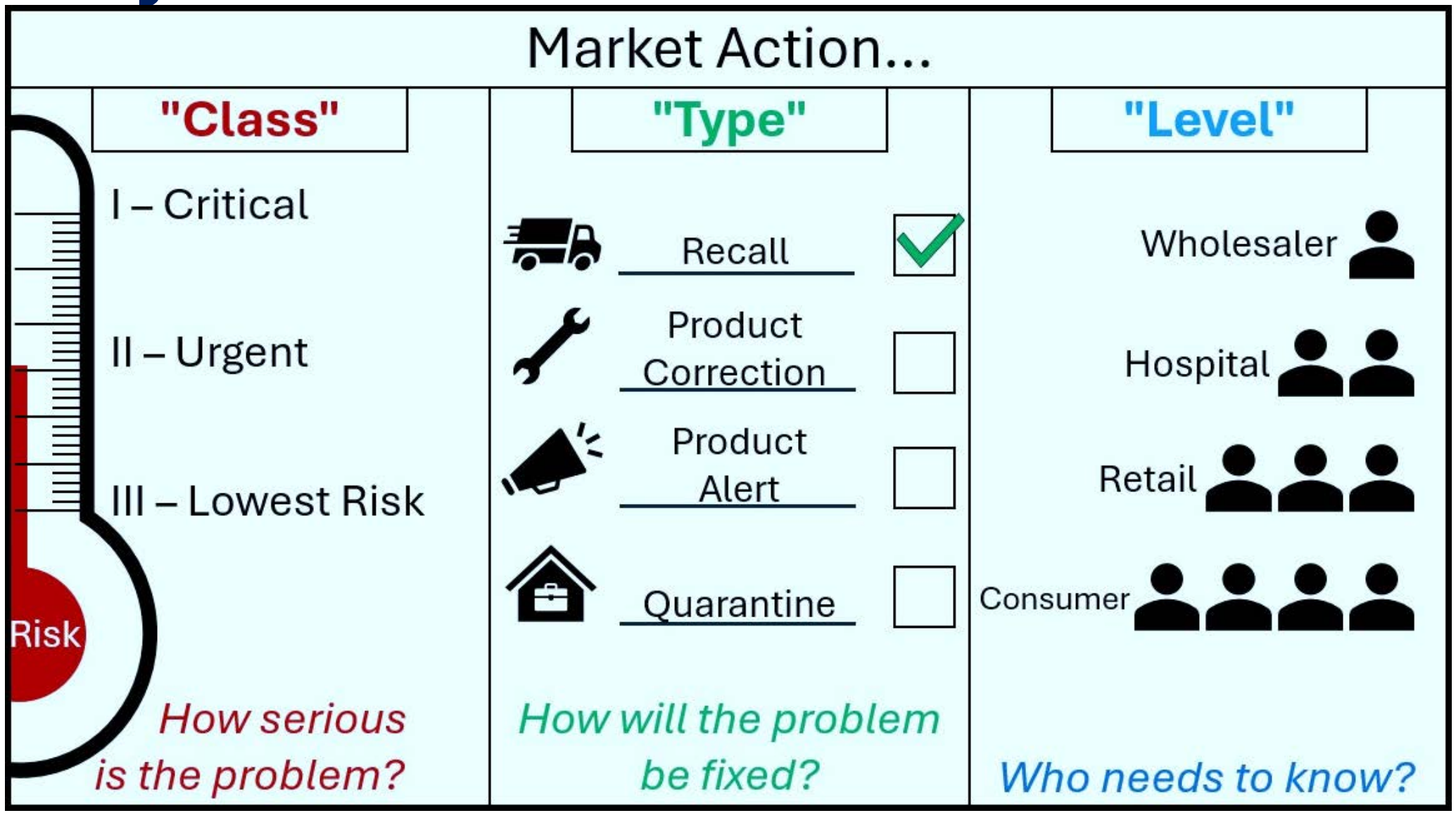
Following your investigation, we will work with you to determine whether the quarantine can be lifted, or if further action (such as a recall or product correction) is required to address the problem.

If we decide your quarantine can be lifted, we must approve your end-of-quarantine communication before you can distribute it to your customers.

New Terminology



Key Definitions



Wholesale	Hospital	Retail	Consumer
• Medicine / medical device wholesalers/ distributors • Third parties holding goods to distribute to retailers or other organisations • State and territory purchasing authorities	Wholesale level, as well as: • Hospitals (including dispensary pharmacies, tissue banks, etc.) • Dental Clinics • Nursing homes and respite facilities • Institutions involved in clinical investigations • Health care professionals, clinics, and private surgery rooms • Ambulance services (including the Royal Flying Doctor Service).	Hospital and Wholesale levels, as well as: • Retail pharmacists • Retail outlets such as supermarkets, health food stores and online stores • Other health professionals not working in the medical, dental, or nursing professions	Retail, Hospital and Wholesale levels, as well as: • patients and other consumers.

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.

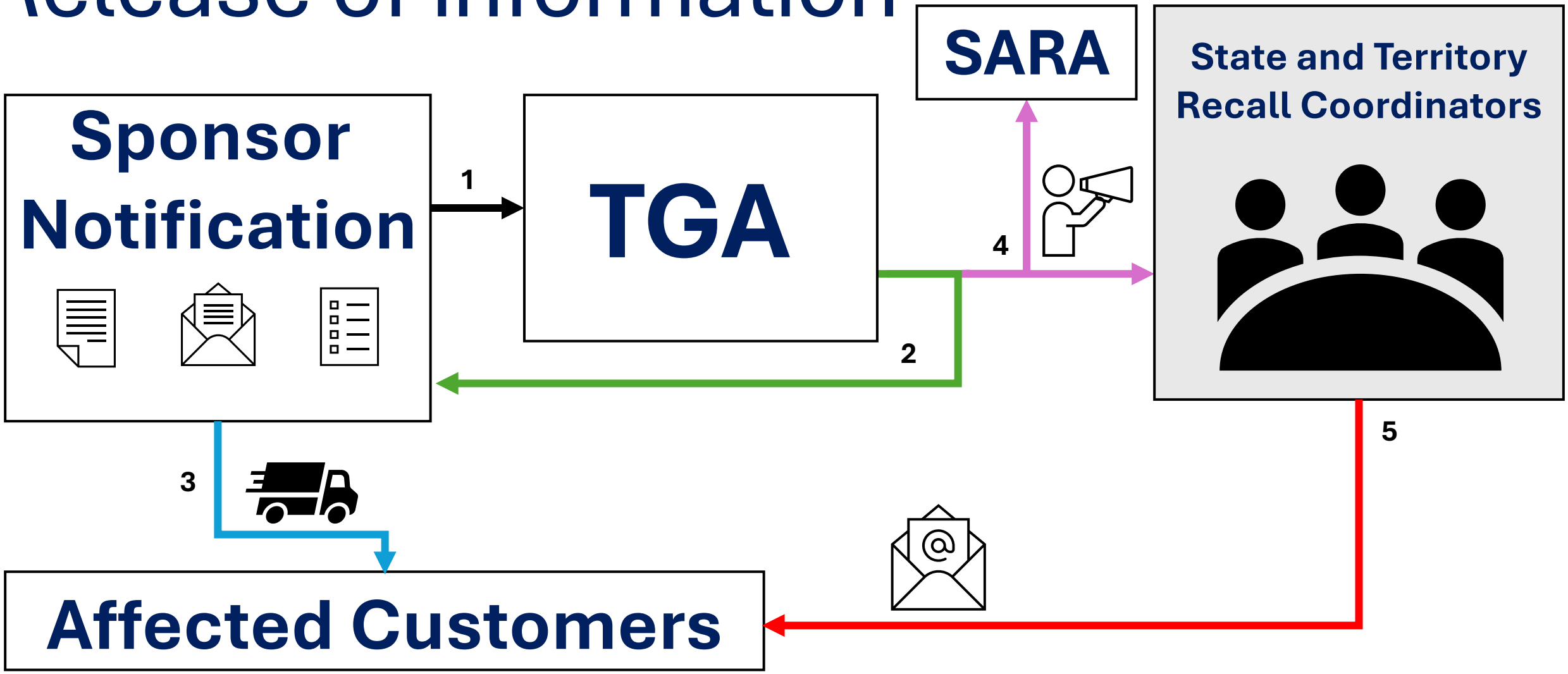
Every wholesaler should have a procedure describing how they will conduct a recall action if you request them to do so. Wholesalers of scheduled medicines should follow the Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8.

State and territory recall coordinators

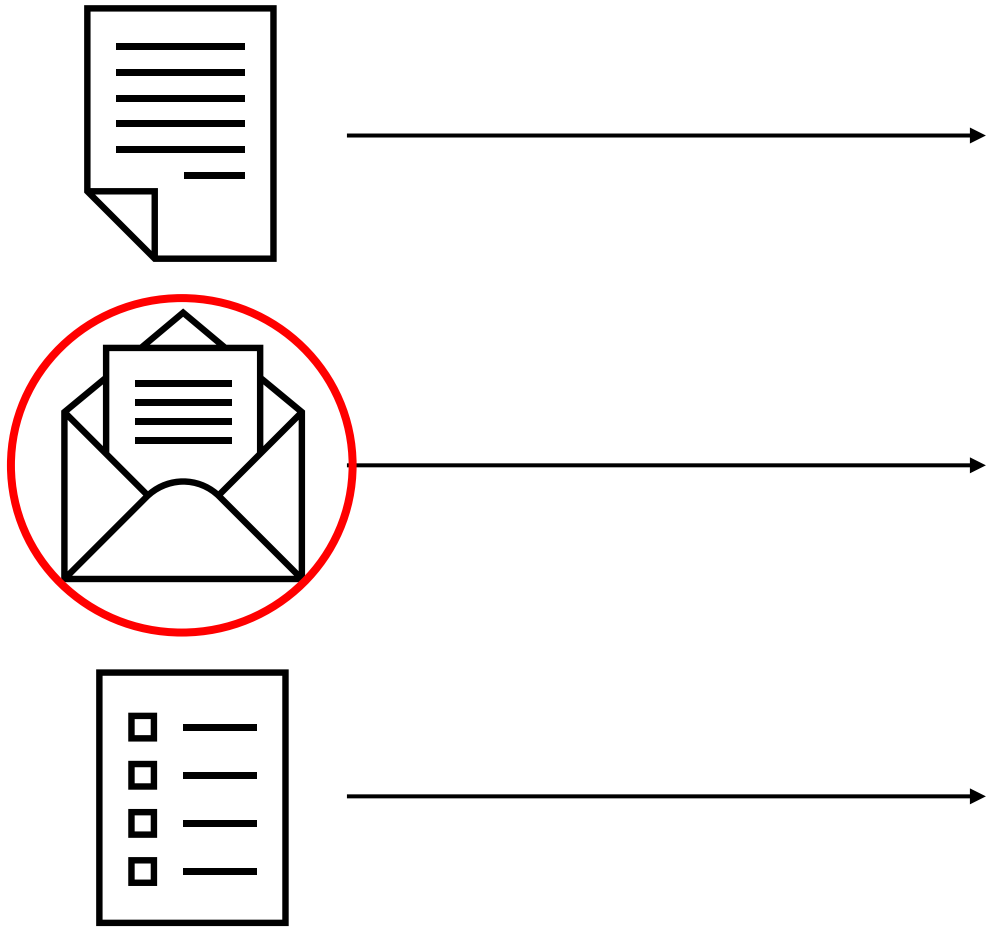
State and territory recall coordinators maintain their own alert systems and procedures for communicating market action information to their jurisdictions. This system includes contact details for relevant organisations and health professionals who may be affected.

If you cannot reach a customer when attempting to follow up with them, you may contact a state or territory recall coordinator to see if they have more up-to-date contact information.

Release of information



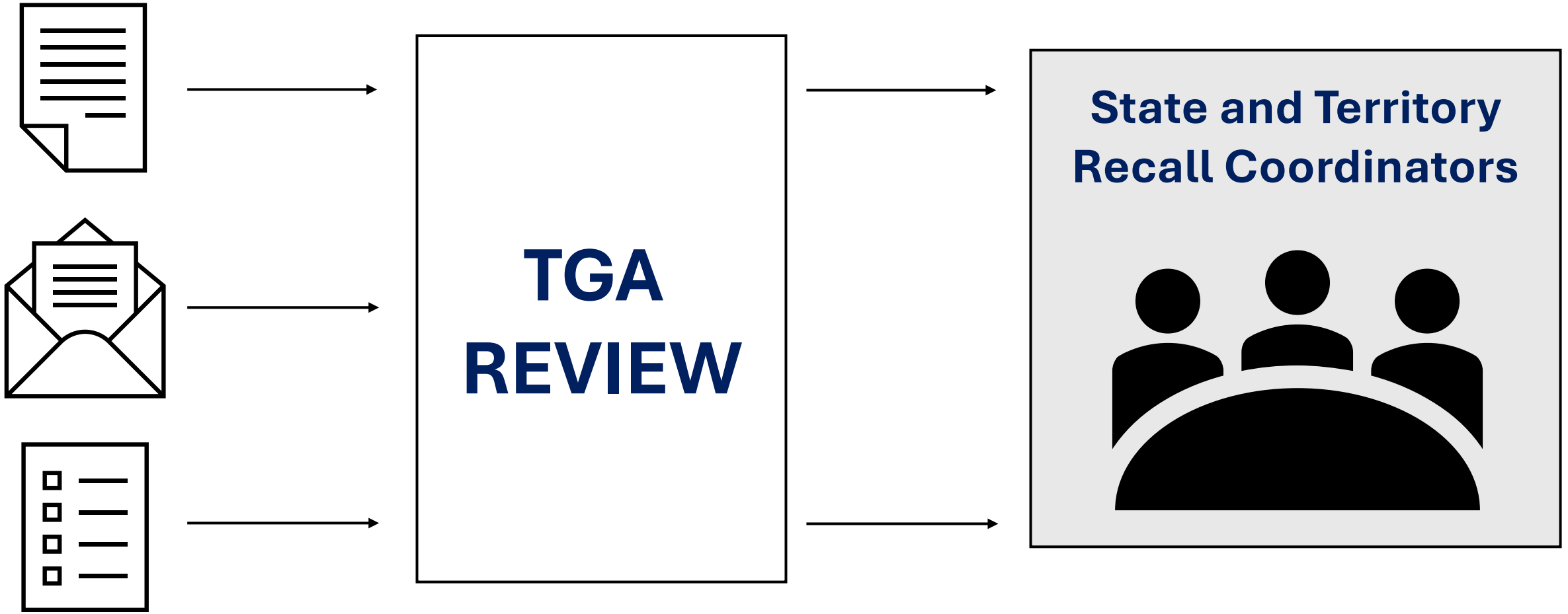
Specific changes



State and Territory Recall Coordinators

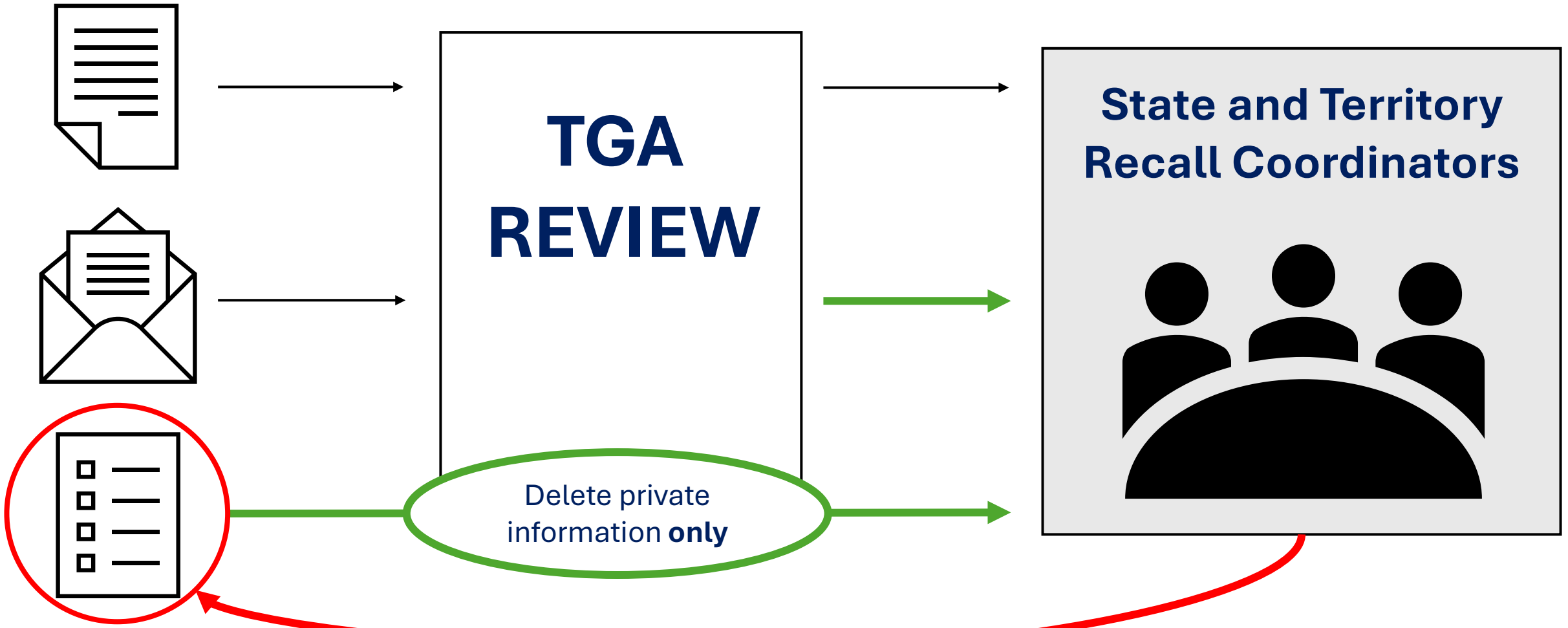
URPTG

Specific changes



PRAC

Specific changes



Direct follow up from States and Territories

Specific changes

Collecting customer responses

Once you have distributed the letter, you should receive confirmation from your customers that they have received, read and understood your customer letter by returning a completed response form.

You must keep records of your customers' responses, so that you can keep us informed of the progress of your action. This is essential to closing out the action (Step 5).

> We prefer that you collect customer responses via post, email, or electronic form.
>
> If you receive acknowledgements via telephone or through a site visit, ensure that you record the name and contact details of the person responding to the action and the date this occurred. We may ask you for these details.

Following up with customers who do not respond

We expect you to attempt **at least 3 times** (not including your original attempt to contact them) to follow up with customers who do not respond to your customer letter. Use multiple contact methods including email, phone, registered post, and site visits as appropriate.

If a customer is responsive but routinely difficult to reach, consider asking them to review the phone number you have on file for them, and/or whether they could establish a group email inbox, so that your correspondence will be visible to their colleagues.

Specific changes

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

Statements on your website/social media

If you have been advised to also announce the action on your website, this statement should reflect the wording of the TGA web statement.

Information published on your own website or social media should be publicly available for the length of time specified in our agreement letter (minimum of 3 months). We may adjust this requirement when we review your closeout report.

Specific changes

Step 5: Finalising your market action

Reporting requirements

You are required to periodically report to us about the progress of your action. Additional reporting requirements may be imposed at our discretion.

- You must use the reporting templates included in the agreement letter. They are also available on our website – see the templates page
- These reports are typically due at 6 weeks (interim) and 12 weeks (closeout) after commencing the action
- Different reporting timeframes may be agreed on a case-by-case basis
- If the action is not completed by the 12th week, you will be asked to provide a valid reason for the delay and additional reports at a frequency determined by us
- For certain actions, such as for blood component recalls, we may require only one report. The due date will be provided in the agreement letter

complete (all goods returned/corrected,

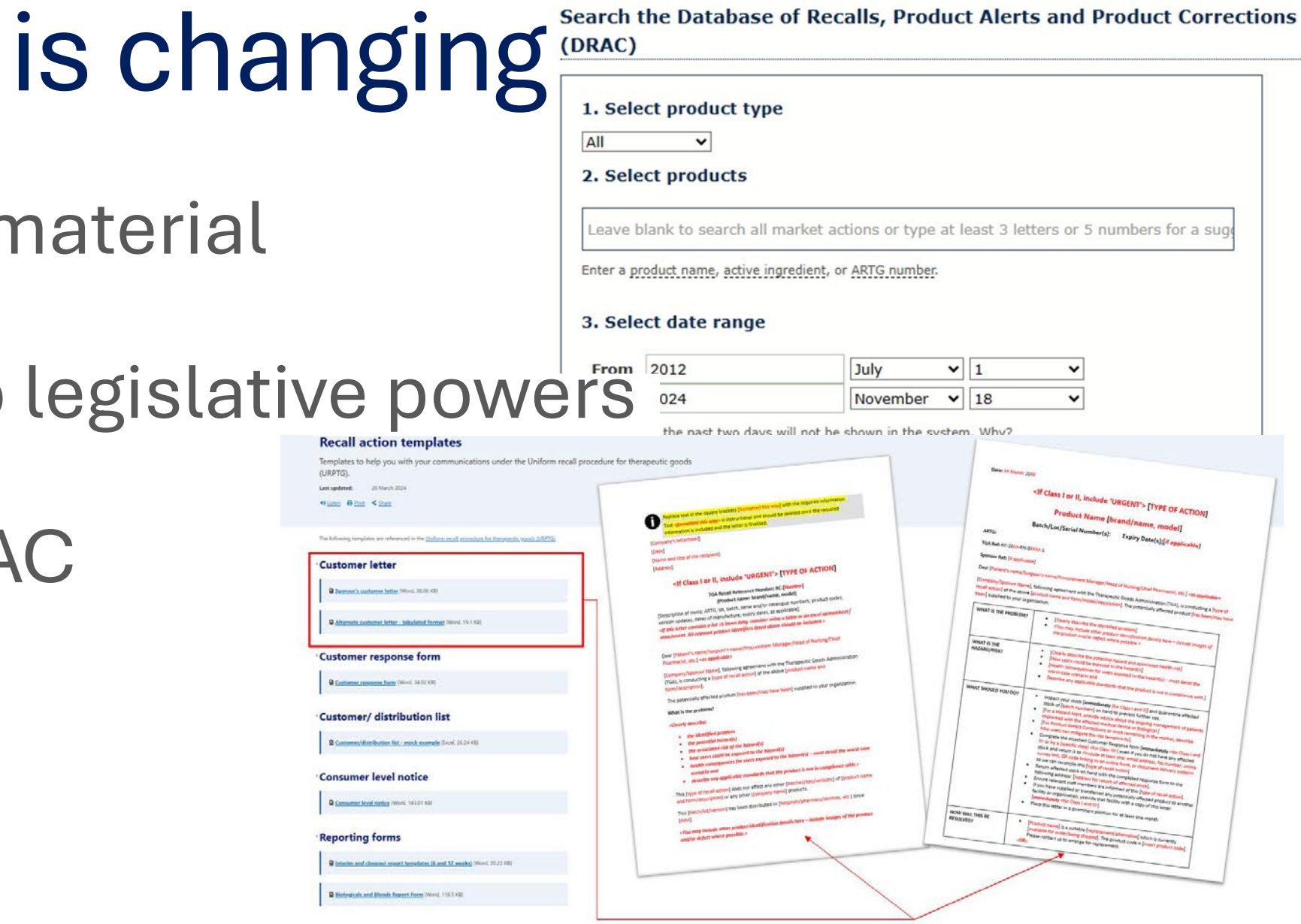
These reports are typically due at 6 weeks (interim) and 12 weeks (closeout) after commencing the action

Different reporting timeframes may be agreed on a case-by-case basis

If the action is not completed by the 12th week, you will be asked to provide a valid reason for the delay and additional reports at a frequency determined by us

What else is changing

- Supporting material
- Approach to legislative powers
- SARA → DRAC



What you need to do

- Read the PRAC
- Ask questions
- QMS Preparation

Recalls Section

recalls@health.gov.au

What happens next

- 5 March 2025
    - New Actions
    - Ongoing Actions
- Legislative Guidance

What happens next

- PRAC updates

Electronic response forms

You may use a QR code / link to an online survey response form to allow customers to respond to you electronically. Your QR code / electronic form must:

- be linked under the header 'response form' in your customer letter
- match the text of the response form template
- be working when you submit your notification so we can review the text of the response form.

Electronic response forms

You may use a QR code / link to an online survey response form to allow customers to respond to you electronically. Your QR code / electronic form should~~must~~:

- be linked under the header 'response form' in your customer letter
- align with~~match~~ the text of ~~the~~our response form template
- be working when you submit your notification so we can review the text of the link or electronic ~~response~~ form.

Ask us questions

How to access and use Slido

Through the Slido application in Webex

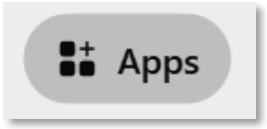
- Click on the **Apps** icon
- Select **Slido**
- Open the **Q&A** tab to ask questions
- Live Poll (use survey tab when prompted)

Using the QR code

Scan the QR code to access Slido from your mobile device

How did we go?

Take a moment to complete our survey



Use the app in Webex

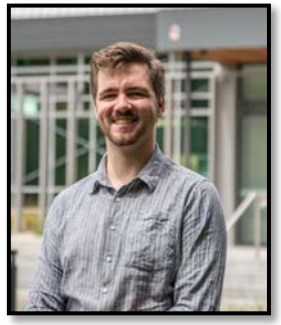
Use the QR code

Questions?

Ask us through Slido

Use the app in Webex

Use the QR code



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Sharon Bennett
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Questions

Can you confirm that the new PRAC is still voluntary like the URPTG?

Will licensees be required to perform a "mock up" of the new PRAC?

Can the responsibility of advising state and territories [...] be transferred to the company conducting the recall?

Can you clarify Due Dates for "Closing Report"?

What is the cut-off of TGA's assessment?

E.g. Notification under review prior [X] March under URPTG and from [Y] March onwards under PRAC

can you differentiate between recall approval and execution from a manufacturer perspective?

Are *monthly consumption / reorder rate / approximate market share* mandatory details to submit?

Step 1: Assessing your emerging problem

Details of affected goods

Quantity and distribution

- Monthly consumption or reorder rate (if applicable)
- Your approximate market share for the kind of product

Questions

Could you create a national database of Recall Contacts? (Pharmacies, Hospitals, etc)

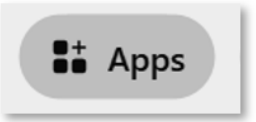
Can you provide risk analysis templates for sponsors to use?

Do all OOS stability results need to be reported to TGA?

Will all reports submitted and reviewed in RAMP be published in SARA/DRAC?

Questions

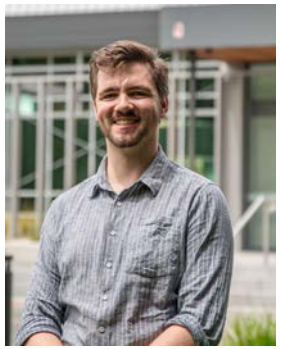
Take a moment to complete our survey



Use the app in Webex

Use the QR code

Questions



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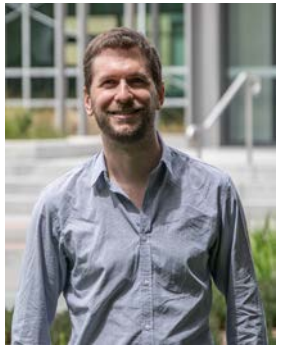

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Contact us

Recalls Section

recalls@health.gov.au

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Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration