Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Therapeutic Goods Recall Processes

Discussion Paper

Seeking feedback on improvements to the recalls process

Version 1.0, January 2023

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Contents

Overview

The Therapeutic Goods Administration (TGA) is seeking feedback on proposed changes to the therapeutic goods recall process.

Recalling medicines, medical devices and biologicals, when they are not fit for purpose, is the responsibility of the product's 'sponsor'. Under the *Therapeutic Goods Act 1989* (the Act), this is the person or company legally responsible for the product. However, before starting any recall action, the sponsor should consult with the TGA for agreement on the type of recall and how it will occur. They should also tell us how it is progressing and when it is complete.

Recalls should be done in accordance with the procedures in our guidance document - the *Uniform Recall Procedure for Therapeutic Goods* (URPTG).

In some instances, such as to ensure public safety, the TGA can mandate a recall. This is done in line with the URPTG.

Why are we seeking your feedback?

The URPTG has been in place for many years and while it has been effective, there have been changes to our regulatory landscape over time. There are new types of products being used, increased complexity in supply chains and changes to the ways in which we communicate.

We are investigating a range of potential improvements to the way recalls are managed. Some are complex – changes to legislation or IT systems – which will take more time. In other areas, we have worked with our stakeholders on possible solutions and now need feedback to confirm they will deliver the intended benefits or details on how best to implement them.

Background

What are recalls?

The current URPTG defines a number of 'recall' and 'non-recall' actions which can be used in response to an identified problem with a therapeutic good that is in the marketplace. Sometimes, consumers and patients must stop using the product immediately and it must be destroyed or returned. In other situations, it is safe to continue use but healthcare providers or consumers need to be alerted or advised of the problem.

Depending on the type of problem and the risk it poses, the sponsor and their customers may need to:

- return products
- quarantine products
- destroy products on site
- make changes or repairs to the product
- be aware of the problem but continue using the product. This can happen with critical products where there are no alternatives.

Following the URPTG is voluntary but doing so helps ensure that the right people know about the problem and know what they need to do in response. The TGA has the power to mandate a recall in certain circumstances, but most recalls are performed voluntarily and according to the URPTG.

The Recall Reforms Program

After receiving feedback about the current recalls process from stakeholders including peak industry associations, individual sponsors, state and territory health departments, health professionals and consumer and patient support groups, we established a Recall Reforms Program.

In 2021 and 2022, we held workshops and meetings with many of our stakeholder groups to identify areas for improvement. In response, we have reviewed our operational processes, how we communicate, our guidance documents, legislative powers and IT capability.

We are working on three main areas of reform, in a staged approach:

- Phase 1: we have made many updates to our internal processes and some editorial clarifications to the current URPTG. The updated URPTG was published in June 2022.
- Phase 2: Further revisions to the URPTG are anticipated after we consider the feedback we receive on the proposed changes set out in this Discussion Paper.
- Phase 3: we are reviewing TGA's existing mandatory powers to determine how these can support effective recall processes. If potential gaps are identified, we will seek consideration from the Government to strengthen the Therapeutic Goods Act. We are also investigating improvements to our IT systems.

Critical factors include TGA's ability to obtain information about supply and to release information to those affected by a recall. The importance of supply chain visibility has come to the fore during the COVID pandemic and there are government initiatives for medicines and medical devices which have the potential to support enhanced recall processes.

Similarly, the TGA is undergoing a Transformation Program to improve the way we deliver services to our stakeholders. Proposals for significant infrastructure changes, for example to our IT systems used in the recalls process, would need consideration within the scope of this Program.

Further consultation on these more complex issues will occur as proposals are developed and, if needed, after relevant government approvals are given.

What are the TGA's powers?

Sponsors must ensure the products they supply are safe, fit for purpose and meet relevant quality standards for their entire service or shelf life.

When a problem is identified with products already in the market, the sponsor has obligations under the Act to report this to the TGA. This allows us to confirm that appropriate corrective actions are undertaken to ensure the safety of patients and consumers.

The Secretary of the Department of Health and Aged Care (in practice their delegate within the TGA) has powers under the Act to:

- mandate specific recalls
- release information to ensure the safe use of therapeutic goods
- require information or documents from sponsors
- impose legal conditions to allow ongoing supply.

The Act also includes penalty provisions applying to sponsors who supply unsafe goods or who do not comply with reporting obligations on quality defects, significant safety issues and serious adverse events.

Generally, sponsors use the procedures in the URPTG when conducting a recall. The URPTG is not a legislative requirement but is recognised as best practice to ensure poor quality or unsafe goods are effectively and efficiently removed from the market.

What happens if a recall is not done properly?

Sometimes sponsors don't conduct recalls following the URPTG. This could include:

- conducting the action without notifying the TGA
- not being able to assure us that the products have been withdrawn or fixed properly
- ineffective communication to customers and patients.

If this happens, there is always a concern that unsafe or defective products remain with patients and consumers who may be unaware of the risk.

The TGA acts in the interests of patient safety. Should a sponsor conduct an ineffective recall, we will work with them on further actions to ensure the risks are addressed. We may consider regulatory action in certain circumstances, including where:

- the person or company has repeated breaches and is not willing to comply or
- their actions pose a significant risk to patient safety or public health.

Phase 3 of our Reforms Program will include a review of our existing powers and advice will be provided to the Government on the need for any changes.

What is covered in this discussion paper?

We want to know what you think about the changes proposed in Phase 2 of our reforms. These are grouped into five themes:

1. **Increasing awareness and understanding about recalls**
2. **Improving communication**
3. **Better recall descriptions**
4. **Improving sponsor letters and other recall documents**
5. **Reporting progress with a recall.**

We also welcome any other comments or suggestions you would like to provide.

How to respond

We have posed questions within this discussion paper to help guide your feedback. You can also give us any additional comments and attach a separate response document if you wish.

You do not have to answer all the questions and none are compulsory.

You can

- submit your views by clicking the link below – this will step you through our questions

https://consultations.tga.gov.au/tga/feedback-on-improvements-to-the-recalls-process

OR

- download the full discussion paper and upload your own response document on the final page of the link above.

Themes

1. Increasing awareness and understanding

We need to increase the general awareness and understanding about recalls in Australia. This will improve health outcomes by reducing the risk of consumers or patients being harmed by unsafe products.

The URPTG currently includes a 10-step procedure for sponsors describing how to undertake an effective recall. It covers gathering information and drafting documents through to reviewing the outcomes of the recall, plus:

- information on the roles of different stakeholders
- advice on consumer level recall strategies
- template documents
- information on situations where the TGA will make a sponsor recall their product (mandated recalls).

We also have general information about recalls on the TGA website. There are business and after-hours phone numbers for sponsors or public enquiries.

However, some sponsors have told us they do not have enough guidance and would like more assistance to communicate effectively with their customers.

Other stakeholders, including patient groups, healthcare associations and consumers, have told us they have a limited level of awareness and understanding about recalls. They are concerned that this may lead to delays in people taking action.

Improvements we are making to increase the effectiveness and awareness of recalls for all stakeholders include:

- updating our guidance to include more general advice for sponsors – including sending recall notices, tracking responses, etc
- developing educational sessions about recalls for sponsors – e.g. ‘how to undertake an effective recall’
- workshops or seminars for health professionals on how to effectively respond to a recall
- creating more general awareness and educational material for consumers
- better use of the TGA social media channels, including campaign-based messaging
- upgrading our public information database – the System for Australian Recall Actions (SARA) to make it more searchable, user-friendly and modern

- including more visual content with our recall alerts
- having targeted information for different stakeholder groups for significant recalls
- including Unique Identifiers in recall information (where and when they become available).

Discussion Questions

Q1. Did you know where to find guidance or information on recalls prior to reading this paper?

Q2. Do you have any feedback on our current recall guidance in the URPTG or on our website? What do you like about it? How could it improve?

Q3. What are your preferred recommendations from the above list? Please pick your top three preferences in order of 1st, 2nd and 3rd.

Q4. Do you have any other suggestions or strategies to improve our guidance and increase awareness of recalls?

2. Improving communication

Good communication about a recall is critical to ensure the right people know about it and understand what they should do. We have identified improvements to different aspects of our recall communication:

- Who we contact and consult with, before allowing the sponsor to start a recall
- How information is distributed
- Communicating in complex supply networks
- The timing of recall notifications
- The content of our recall notices.

Who we contact and consult with, before the sponsor starts a recall

Before commencing a recall, the sponsor must get our agreement on the proposed action.

Recalls can involve:

- wholesalers and retailers
- hospitals – public and private
- professional bodies and healthcare associations
- patient advocacy/support groups
- consumers and patients
- other government departments or regulators such as the Australian Competition and Consumer Commission (ACCC)

so, it is important that we contact or consult with the right people to confirm the best way to proceed. This helps us better protect patients or consumers and develop strategies to reduce the risk of a recall interrupting essential healthcare.

Stakeholder engagement before a recall

If there is a risk that an urgent recall might cause significant supply disruptions or changes to the way patients are cared for, we send a notification to the State and Territory (S&T) recall coordinators prior to starting the recall. The S&T recall coordinators work within their government health departments and maintain an alert network which they use to contact relevant organisations within their jurisdiction.

Our urgent notification to the states and territories may:

- provide early advice on the recall, to allow mitigation strategies to be developed
- ask whether supply or ongoing patient care will be significantly affected
- request urgent feedback on what we are proposing to do i.e. remove products from supply, quarantine those not yet in supply, etc.

We are now expanding this process to include other stakeholders who will have an interest in a particular recall. Examples could be contacting Diabetes Australia when there is a serious problem with a glucose meter or The Royal Australian and New Zealand College of Radiologists (RANZCR) when there's a significant recall of X-ray machines.

We are also using our urgent notifications to provide more than just early advice or feedback on a shortage/supply issue. We also:

- ask for comment or input on our recall communication strategy, language and content, especially where special interest groups are affected.
- request assistance to communicate the recall more widely and effectively.

We have started this process with some stakeholders. However, we want to build stronger relationships with all stakeholders and encourage more productive, 'two-way' communication while continuing to ensure that we do not unnecessarily delay the commencement and publication of a recall.

Once a recall has been agreed, we also notify other relevant stakeholders who are on our Recall Notification List. These are groups who should be aware of certain types of recalls. We need to know if there are more stakeholders, such as patient groups and professional healthcare associations, who should be on this list.

Discussion Questions

Q5. Do you see any benefits if we communicate more with different stakeholders, such as patient advocacy groups and professional bodies, before commencing a recall?

Q6. If yes, why do you think this is important? If no, what are your concerns and are there situations when we should not consult before commencing a recall?

Q7. Are there other questions we should be asking in our urgent notification of a potential recall?

Q8. If you represent an organisation with an interest in recalls and don't receive notifications, would you like to be added to one of our lists? If yes, please give us the contact details we can use.

How information is distributed

When a recall starts, the sponsor notifies their customers using the agreed communication strategy. This usually involves sending a letter explaining why the recall has occurred and any required actions. Sometimes customers are contacted directly by phone, text message alert or site visits. Social media or print advertisements are also used for significant actions.

We also send out information on the recall by:

- email notification to key stakeholders (such as the S&T Recall Coordinators and Recall Notification List)
- publication of the summary in the SARA database on the TGA website
- publication of news alerts on significant recalls on the TGA website and email distribution to people who have subscribed to alerts on our website
- social media posts.

Using multiple communication channels will achieve greater awareness of recalls. Sometimes however, people impacted by a recall do not find out quickly or cannot find accurate information.

Reaching some customers can be difficult when they are not traceable, for example with over-the-counter sales of therapeutic goods at supermarkets, pharmacies and other retail outlets.

Particularly for serious safety-related recalls, we want to use the most effective communication channels to reach as many patients and consumers as possible. Options to improve how our information is distributed include:

- Increase our communication channels, including asking relevant partner organisations such as patient advocacy groups to send out information using their established networks
- Better and more targeted use of social media
- Use existing third-party communication networks, such as patient newsletters and private broadcast channels
- Improving our website subscription service to allow automated emails/text message alerts for certain types of recalls
- Asking retailers to display the recall notice in their shopfront
- Better outreach to groups representing vulnerable consumers, such as culturally and linguistically diverse (CALD) consumers, First Nations consumers, older consumers and consumers with a disability.

Discussion Questions

Q9. If you have seen any recall communication material, what did you think? Could you rate it out of 5 on the following aspects? (5 being very good, 1 being very bad) -

- Was it easy to find?

- Easy to read?
- Was the key message clear?
- Did it explain how to get more information?

Q10. What do you think are the best options from the above list to improve our communications? Could you rank them from most beneficial (1st) to the least benefit (2nd)?

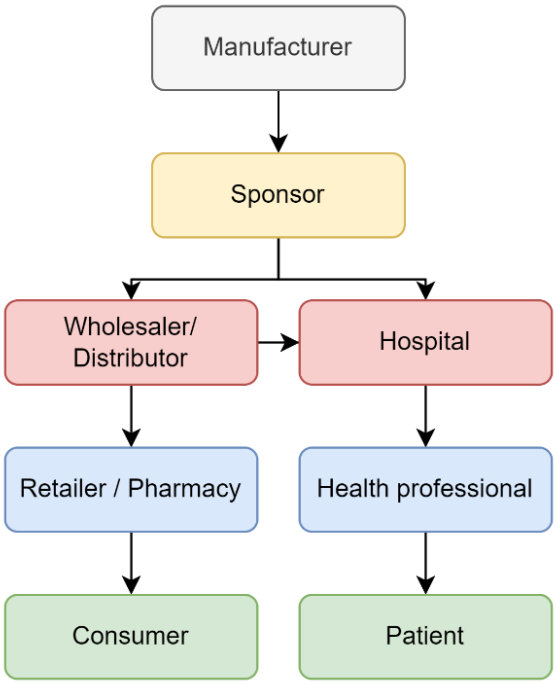
Q11. Please give us any other suggestions you have. What other communication methods could we use to increase the distribution of recall information?

Communicating in complex supply networks

When a sponsor notifies us of a new proposed recall, they give us their customer list. This includes wholesale and retail companies, pharmacies and hospitals who have been supplied with the affected product. We share these customer details with the S&T recall coordinators. The coordinators then assist with identifying, tracing and quarantining the product within the public hospital systems, and notifying other relevant organisations within their jurisdictions who may be affected.

At the same time, the sponsor notifies everyone on their customer list. Customers are advised that if they have supplied or on-sold the products to another organisation, they should pass on the recall information immediately.

Medicines and medical devices aren't always supplied directly from the sponsor to a consumer or patient. The supply network can include:



It can be even more complex when the products are sent between different departments within an organisation, for instance in local health districts and hospital departments. Without good records it can be difficult to know exactly who has the affected products.

We have been evaluating how this complexity affects how recalls are efficiently performed. It is important to know:

- The role or responsibility of each stakeholder
- How different groups communicate or share recall information
- How different stakeholders use data and identifiers to perform tracking and tracing

Discussion Questions

Q12. Do you regularly receive either the TGA's recall notices or the recall letters from sponsors? Do you receive the same information from multiple sources?

Q13. If you are part of a supply chain (wholesale, retail, hospital procurement, etc), to whom do you regularly need to pass recall information?

Q14. Are there any known or foreseeable weaknesses in this communication chain?

Q15. If you are a stakeholder who needs to track the recalled products, how do you do this effectively?

Q16. Are there more efficient ways for recall information to reach the people who need to know?

Q17. How could we improve the visibility and transparency of therapeutic goods supply chains? For example, should government require sponsors to have a regulatory obligation to document their supply chain and goods distributed by any subsequent (downstream) supplier?

Q18. Should we have more guidance for retailers, pharmacists or other healthcare providers on how to advise consumers or patients about recalls?

The timing of recall notifications

Currently, we distribute recall information by notifying key stakeholders and including the recall summary in the public SARA database two working days after agreement between us and the sponsor to commence the recall. This allows time for the sponsor to distribute the recall letter to their customers first.

Some stakeholders have suggested this time delay should be removed.

This timeframe has been in place for many years and has not changed since recall letters were distributed by regular mail and facsimile. Most recall letters are now sent as emails so the delay might not be needed.

Advantages to reducing the time delay include –

- synchronising our recall communications with those from the sponsor
- other stakeholders in the health system receiving recall information faster.

A potential risk of reducing the time delay would be customers finding out about the recall from other channels before they are notified by the sponsor. This may increase confusion or reduce confidence in the process. For instance, if a customer first finds out about a recall from someone other than the sponsor, they might ask specific questions to the wrong person, questions which would have been best directed to the sponsor.

However, our communications are important to notify other key stakeholders in the health system and increase awareness of a recall in case the sponsor is not able to contact all customers effectively. Some stakeholders also consider the TGA's communication as an important verification step to assure them of the validity of the recall action.

We could:

- Publish recall information on the next working day after agreement with the sponsor
- distribute and publicise recall information on the same day as the agreement of the recall
- develop and formalise a risked-based approach, where higher risk recalls are publicised within a shorter timeframe or
- make no change if the current approach is felt to be still fit for purpose.

Discussion Questions

Q19. Do you think the current timeframe for TGA's release of recall information is appropriate?

Q20. Do you think TGA should always wait until we have the sponsor's agreement on the recall before sending any information to other stakeholders?

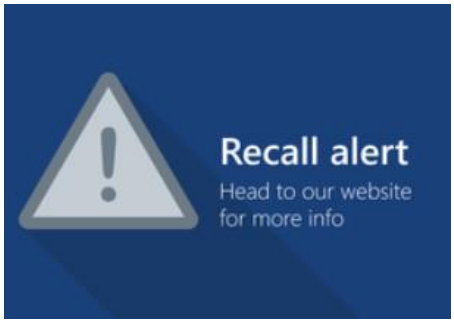
Q21. Which of the above options do you think is best, and why?

Q22. What risks do you see with any of the above options?

The content of our recall notices

When we notify others of a new recall via email, we attach a summary notice about the action. This includes the main details –

- type of product
- the commencement date
- the level and type of recall
- the sponsor's name
- the reason/s for the recall
- instructions for customers.



Feedback concerning the content of our recall notices has highlighted that –

- an approximate timeframe when the issue is expected to be resolved is not always included
- there is not always enough information to determine the risk or the full customer actions
- our emails do not include a copy of the sponsor's customer letter, which provides more detail.

We have a new process to consistently include an approximate timeframe for completion of the recall in the summary information.

When the approximate timeframe is unknown, we say why in the recall summary. In these situations, there are more reporting requirements on the sponsor, including giving additional updates on the status of the investigation and correction.

The notice attached to the email is designed to be a quick and succinct summary of the recall. There are also IT character limits on the summary, as this information needs to be uploaded to the SARA database. This can mean that the full actions required for complicated corrections or workarounds cannot be included in the recall summary.

For complicated product corrections, the summary may simply advise that the full instructions are provided in the sponsor's customer letter.

Example of the condensed customer instructions in our recall notice:

PROPOSED CUSTOMER ACTIONS:	*Sponsor A* is advising customers that an updated software version will be released to rectify the issue. The new software will be available for download from the Sponsor's website by the end of September 2022. In the interim, customers are advised to review the full workaround instructions in the customer letter (supplied to impacted facilities by *Sponsor A*) to mitigate the risk of incorrect patient results.

This means that stakeholders such as the S&T Recall Coordinators do not always receive the full information. To address this, we could:

- provide the sponsor's customer letter with our recall summary notice
- stop providing our recall summary notice (reducing overlap and administrative burden), and instead provide the sponsor's customer letter only with our alert email.

If we include the sponsor's customer letter with our email alert, then all key stakeholders have easy access to the full instructions. However, this may lead to duplicate recall letters, sent using different channels, being received by customers. This may lead to confusion, the need for cross-checking and unnecessary extra work.

Discussion Questions

Q23. If you receive our recall email notifications, what is your feedback on the content of the email and Recall Notice?

Q24. Would providing the sponsor's customer letter with our email notifications be beneficial? Should we continue to provide the recall summary notice, or just provide the sponsor's customer letter and a link to the SARA database summary?

Q25. Do you have any other suggestions to improve our recall communications?

3. Better recall descriptions

The URPTG defines different types of 'recall' and 'non-recall' actions.

We have received feedback that the current terminology and categories are -

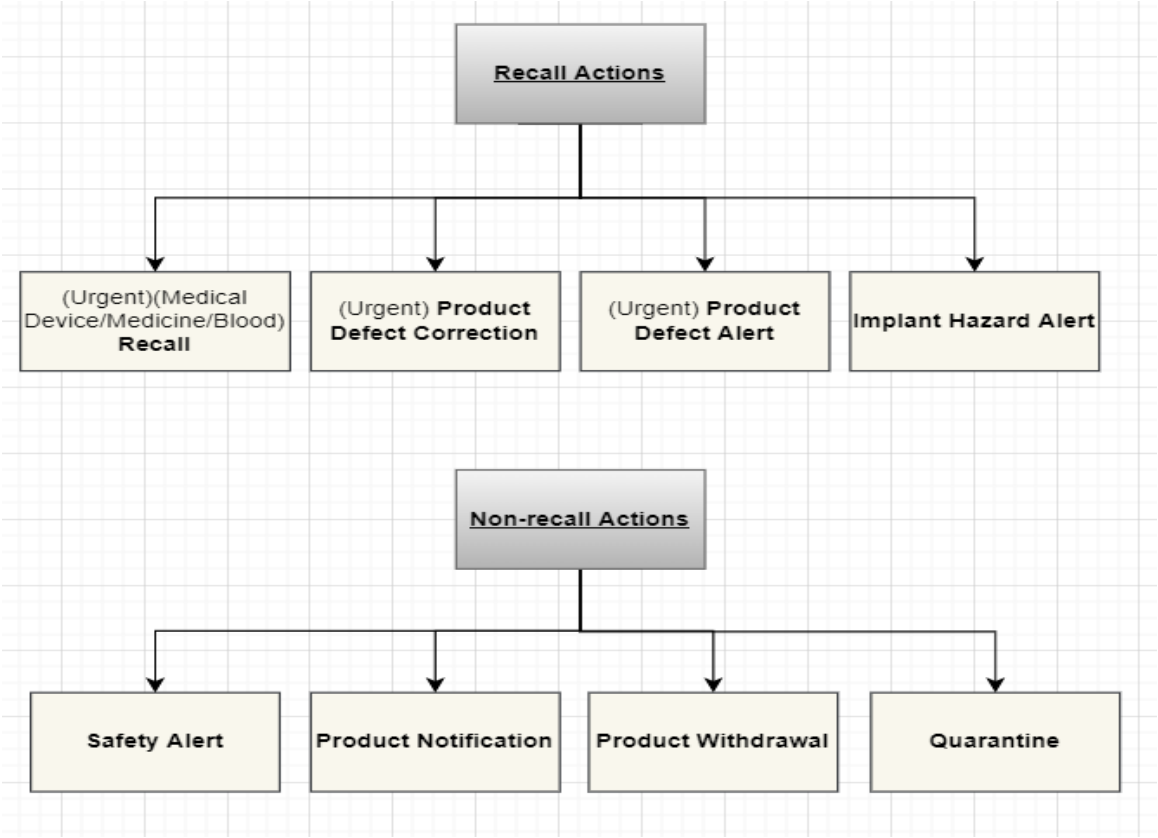
- unclear or confusing – sponsors and customers don't understand the difference between 'Safety Alert', 'Hazard Alert', 'Product Defect Alert' and 'Product Defect Correction'.

- overly-complex, difficult for non-experts – there are too many recall categories. Having 'recall' and 'non-recall' is an unnecessary layer of complexity.

- overlapping terms – while there will always be some recalls with complicated instructions, there is sometimes overlap when an action could be considered a Safety Alert or a Product Notification or a Product Defect Alert.

A simplified terminology structure would reduce unnecessary time spent discussing which is the most suitable category. It could also improve clarity of recall letters for customers.

The URPTG currently includes 4 different types of recall actions and 4 different types of non-recall actions.

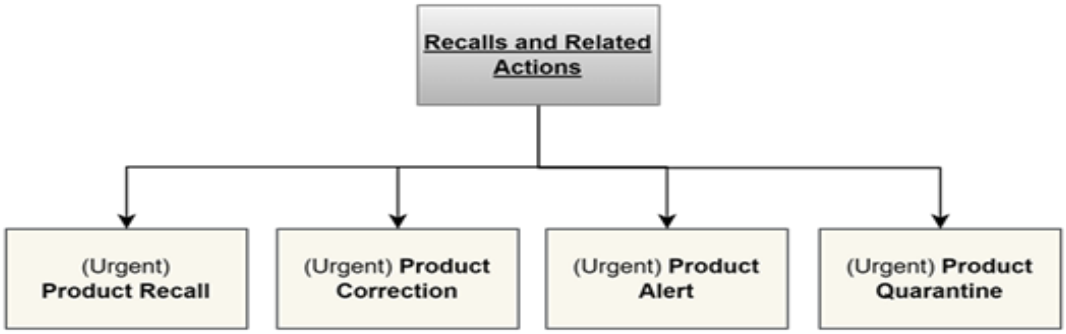


Review of Overseas Terminology

As well as reviewing our current and previous Australian recall terminology, we reviewed the recall categories and terminology used internationally. Recalls can affect more than one country and using the same terms may help reduce any confusion. However, regulators overseas (such as the US Food and Drug Administration and Health Canada) all use different recall terminology, have inter-related terms that are complex like our current approach or use similar terms differently. We have decided that alignment is not possible and no particular approach is appropriate to completely adopt for use in Australia.

Simplified Australian terminology

We have developed a simplified terminology to use in Australia:



The four categories are differentiated by the action required of customers/end users:

- Recall – 'someone needs to **return/destroy** the product'
- Product Correction – 'someone needs to **correct/fix** the product'
- Product Alert – 'someone needs to **know something** about the product'
- Quarantine – 'someone needs to **stop supply and use** of the product, pending further advice.'

Advantages

- The recall and non-recall categories have been removed to make the model simpler.
- The current recall category 'Product Defect Correction' has been renamed 'Product Correction', as the word 'defect' is not appropriate in all instances.
- Four current recall/non recall 'alert' categories (safety alert, hazard alert, product defect alert and product notification) are all covered under the one title 'Product Alert'.
- Quarantine remains the same as the current model, as a unique action. A quarantine may still progress to a recall or a correction.

Questions

Q26. Do you agree with the new recall descriptions?

Q27. If yes, what do you like about them? What are the benefits you see?

Q28. If no, what are your concerns?

Q29. Do you have any other suggestions for new terminology?

4. Improving sponsor letters and other recall documents

The quality of recall documents is very important because safety information must be delivered quickly and clearly. The URPTG includes several templates to help sponsors draft

- customer letters
- acknowledgement forms (completed by customers who receive the sponsor's letter)
- customer/distribution lists.

The information in some recall letters is not delivered as effectively as in others. Sometimes the key message is missed because sponsors use different templates or wording. If customers don't recognise that the letter is about a recall, they might not read it.

We have included our current URPTG templates as an appendix to this paper. From feedback, we have identified the following problems with these three documents.

Customer letter

- The templates in the URPTG are not frequently used by sponsors.
- The initial drafts from the sponsors often contain unnecessary information, promote the company or other goods, do not include the health risk, or are not structured appropriately and require significant changes by the TGA.

- The key recall message is not given prominence, increasing the likelihood of someone missing this important information.
- The level (wholesale, retail, etc.) or class (Class I, Class II, etc.) of the recall is not included in the URPTG templates or the sponsors' drafts but some customers want this information.
- The timeframe for the return or the correction of the product might not be included.
- It's not clear what is meant by 'closeout'. Is this the TGA closing the recall or is this the sponsor's expected timeframe for returning product?

Customer list

- Different formats are used by different sponsors.
- A lot of administrative work is required to compile the data, which delays the recall process.
- Incomplete/incorrect customer details limits product tracking for stakeholders such as the S&T recall coordinators.

Acknowledgment form

- Forms are often not filled out and returned to the sponsor.
- The template is outdated and not appropriate for all recall actions.
- Physically signing the acknowledgement form is seen as accepting liability by some customers.
- If the response rate is too low, this delays the TGA's recall closeout process.

Options to improve recall documents

- Work with sponsors to modernise our templates for customer letters, acknowledgment forms, customer lists and mail envelopes to increase their usage.
- Require sponsors to submit customer list details in a consistent format, including the number of units supplied.
- Require sponsors to use the TGA templates for customer letters, thus standardising recall communications in Australia.
- Include on all recall letters the key details of the action (the action category, the hazard classification (class I, class II, etc.) the action level (hospital, retail, etc.).
- Include greater use of electronic acknowledgement forms (e.g. include a survey link or a QR code and that can be easily operated by the customer's mobile).

Benefits

- Greater consistency in recall communications may create transparency and better understanding.
- Recall letters will stand out and will be more quickly recognised by customers.
- Better customer list submissions will reduce delays and improve tracking of recalled products.
- Improving the ways customers respond to a recall could increase the number of customer responses/returned products. This will reduce the number of faulty goods remaining in use and protect patients from injury.

Questions

Q30. What do you think of our current templates?

- Do you have any feedback on the current content or draft wording?
- Do you have any feedback on the presentation/style of the templates?
- Are the templates easy to read? Will the key message be clear?

Q31. If you have received recall letters before, what information did you find most useful? Was there anything important missing, or you struggled to find?

Q32. Do you agree with the above suggested options? If yes, what do you like about them?

Q33. If no, what are your concerns?

Q34. Do you have any other suggestions for improving our recall documents?

5. Reporting progress with a recall

Under the URPTG, sponsors tell us how a recall is progressing by sending us reports at certain fixed points. We are considering changing these follow-up reports because they –

- often are of limited value
- may create unnecessary regulatory burden
- the fixed set of questions may not be relevant in every case
- are not well understood by sponsors
- are a 'one size fits all' approach that may not be appropriate for all recalls.

Currently, the URPTG requires sponsors to submit reports at -

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

We have included our current reporting requirements in the Appendix to this paper.

These reports require sponsors to address the effectiveness of the recall but different information is provided at each stage. The reports include aspects such as -

- whether the recall is progressing according to agreed timelines
- number of customers who have responded
- amount of stock returned or corrected
- any root cause or Corrective and Preventive Actions (CAPA) taken to prevent reoccurrence of the problem.

Initial report at 2 weeks

The initial report has limited value as it's largely used to confirm that the recall has been initiated and there has been no major impediments or changes to the scope. Sponsors must have already given us the final signed customer letter and we consider this proof of the recall starting.

If the initial report was removed, we would reiterate to sponsors that major problems or changes must be reported to the TGA at *any* stage of the recall, not just at the time of submitting the standard follow up reports.

Flexibility in reporting requirements

It seems appropriate that we take a better risk-based approach to the reporting requirements.

For instance, some low-risk actions may only require one report.

Some exceptional recalls (e.g. high risk, consumer level recalls or actions with wider health implications) may require additional reporting (e.g. 3 or more reports), tailored to each set of circumstances.

For actions with a lengthy correction or close out timeframe, specific updates on the status of the investigations and corrective actions may also be required.

However, for the majority of recalls, the suggested new requirements would be:

- 6 weeks (interim report)
- 3 months or at another agreed time (final report).

Accuracy of information in reports

Sponsors often do not include the right information in the follow-up reports, in particular the final report. To help address this, the URPTG was updated in June 2022 to include greater clarification on the submission of final reports and additional guidance regarding root cause, CAPA (corrective and preventative action) information, customer follow-up attempts and continuing sponsor responsibilities after the issuing of a TGA close out letter.

We are also:

- re-designing or changing the content requirements for recall close out reports
- providing further guidance on reporting requirements including mock examples or educational material for sponsors
- investigating better pathways for sponsors to submit follow up information to the TGA, such as through the eBusiness Portal rather than email
- automating follow-up reminders for overdue reports.
- investigating regulatory penalties for sponsors not willing to comply with reporting requirements.

Questions

Q35. Do you agree with the proposal to remove the initial report (2 weeks) as a requirement under most circumstances?

Q36. Do you agree that a risk-based approach to the reporting requirements would be beneficial? If not, what are your concerns?

Q37. Do you think the questions asked of sponsors in the reports are appropriate?

Q38. Would further guidance on recall reporting requirements and suitable CAPA information be helpful?

Making a submission

To provide feedback, please provide your submission using the file upload function on the Consultation Hub web page. You do not have to address all points. However, when responding, please clearly identify the section you are responding to.

Submissions may include any further data or information that may assist us to make an informed decision. Submissions may also include, for example, suggested improvements or an assessment of how the proposed change will affect you.

All submissions will be considered until the closing date and may be published on the Consultation Hub web page with your consent.

Privacy and your personal information

We collect your personal information in this submission in order to:

- Contact you if we need to seek clarification of issues raised in your submission or to check whether you consent to certain information that you have provided being made publicly available; and
- Help provide context about your submission (e.g. to determine whether you are an individual or a director of a company or representing an interest group).

We may disclose your name, work title, company, and submission on the Internet (i.e. make this information publicly available) with your consent. You may specify whether there is anything in your submission which you would prefer to not be published online (e.g. names, email addresses, proprietary information) by:

- Providing an additional, redacted copy of your submission; or
- Providing details of content not to be published e.g. “Do not publish pages 3-5”, “Please redact contact details”; or
- Identifying any text within your submission to remain confidential by having it clearly marked 'IN CONFIDENCE' and highlighted in grey.

Please do not include personal information about other individuals in the body of your submission. Personal information in this context means information or an opinion about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion. The TGA will not publish personal information about you/others without your/their consent unless authorised or required by law.

Response timeframe

- This paper opened on Monday 30 January 2023.
- Interested parties should respond by close of business Monday 13 March 2023. Please note that late submissions after this date may not be considered.
- Following consideration of submissions, summaries of this discussion will be published to the Consultation Hub web page.

Enquiries

Please contact us if you have any questions relating to this consultation at the following email address: recalls.reforms@health.gov.au

Appendix

Please see the following templates and example documents -

1) Mock example of a current TGA Recall Notice summary
2) URPTG templates for sponsor recall letters, acknowledgement form, and a consumer recall notice
3) The current reporting requirement templates for sponsors (2 week, 6 week, and 3 month reports)

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

Reference/Publication # D22-6083338

Mock example of a current TGA Recall Notice summary

Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

URGENT MEDICAL DEVICE RECALL*

LEVEL: Hospital

CLASS: Class I

REFERENCE: RC-2022-RN-09999-1

DATE AGREED: 01/01/2022

PRODUCT: **The VGV - Very Good Ventilator - Version 6000**

Affected model numbers: A1234 to G12345

ARTG 999999
(Very Good Sponsor Pty Ltd – Portable ventilator, electric)

SPONSOR: Very Good Sponsor Pty Ltd

CONTACT INFORMATION: 1800 123 123 123 – Vincent Golas

REASON: Very Good Sponsor has received reports of unexpected shutdown of the VGV A6000. This issue occurs intermittently if the user attempts to change the ventilation settings via the GUI or touchscreen. In all reported cases, the system has produced an audible alarm, however the touchscreen becomes unresponsive.

An unexpected shutdown of the VGV could in a worst-case scenario result in a lack of ventilation and delayed treatment, respiratory failure, or death.

Further investigations have shown a failure rate of around 1.4% across the product range.

To date, 4 reports have been received globally in relation to this issue, with no permanent injuries or patient deaths reported.

PROPOSED CUSTOMER ACTIONS: Customers are advised to inspect their units immediately to determine if they are from the affected model number range and quarantine any units not in clinical use.

If the unit is currently providing clinical treatment, customers should determine if it is safe to switch the patient to an alternative means of ventilation following their standard healthcare practices. If the patient cannot be transferred to another ventilator then supplementary observation, appropriate for the patient's condition, is also recommended.

Very Good Sponsor Pty Ltd will contact all impacted customers to arrange for the return of any affected units and provide replacements. Replacement models will be available from the manufacturer by March 2023.

The sponsor is expected to dispatch letters to all affected customers within two working days of the agreed date. **Please do not contact the sponsor for further information unless you believe that you have the goods under recall and have not received a recall letter.**

Product Distribution: 999 hospitals and healthcare facilities in NSW, QLD, VIC and WA

Product export status: New Zealand, New Caledonia, and Papua New Guinea

This issue was first identified by the Sponsor

This information has been published in the TGA's searchable database, the System for Australian Recall Actions (SARA) – https://apps.tga.gov.au/Prod/sara/arn-detail.aspx?k=RC-2022-RN-09999-1

*For further details about Recall Actions, please refer to http://tga.gov.au/safety/recalls-about.htm

1) *URPTG templates for sponsor recall letters, acknowledgement form, and a consumer recall notice.*

Example sponsor customer's letter

[Company's letterhead]

[Date]

[Name and title of the recipient]

[Address]

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

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

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

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

[Problem/ Issue]

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

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

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

[Statement of non-compliance, if applicable.]

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

[Other product identification details.]

Action

Inspect your stock [**immediately** (for Class I and II) and quarantine affected stock <batch numbers> on hand to prevent further use].

[For a hazard alert, provide advice about the ongoing management of patients implanted with the affected medical device or biological.]

Complete the attached acknowledgement form [**immediately** (for Class I and II) or by a specific date for Class III] **even if you do not have any affected stock** and return it to [email address; fax number (preferably free fax) or other document delivery system] to reconcile this process.

Return affected stock on hand to the address below with the completed inventory form [or provide details for stock return]. [If applicable]

[Address for return of affected stock]

Ensure relevant staff members are informed of this recall, including [locums, inwards goods staff, credit returns staff, biomedical engineers, relevant clinicians who may decide to monitor for adverse events, as applicable].

If you have supplied or transferred any potentially affected product to another facility or organisation, let that facility know of the recall [**immediately** (for Class I and II)] by providing a copy of this letter.

Place this letter in a prominent position for at least one month.

Replacement stock [if applicable]

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

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

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

Thank you for your assistance in helping us to manage this recall.

[**OR**

[Company name] Pty Ltd sincerely regrets any inconvenience caused to your organisation.]

(signature)

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

[Position]

Alternate sponsor's customer letter – tabulated format

URGENT MEDICINE/MEDICAL DEVICE RECALL or PRODUCT DEFECT CORRECTION

Product Name

Batch/Lot Number(s): Expiry Date(s):

ARTG:

Sponsor Ref: (if applicable)

TGA Ref:

Date: XX Month 20XX

Dear [recipient],

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

ISSUE	• Issue identified with product
HAZARD	• Hazards that may arise from use of potentially affected goods • •
CORRECTIVE ACTION BEING TAKEN	• Action undertaken by sponsor/manufacturer to rectify issue • •
INSTRUCTIONS FOR USERS	• Actions for customers both interim and long term if applicable • Include instructions for customer response form •
CONTACT INFORMATION	For questions regarding this letter, please contact: Australian Contact Person Phone Number and Email

We apologise for any inconvenience caused to your organisation.

Kind Regards,

Example customer acknowledgement form

Customer acknowledgement form

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

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

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

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

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

FROM:

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

Affected Stock [Recall and Product Defect Correction only]

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

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

Product	**Batch/Lot/Date**	**Quantity of stock received**	**Quantity of unused stock subject to recall (currently in quarantine)**

Total affected product		
Other Relevant Details:		

Other organisations

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

☐ No

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

OR

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

Return completed forms by fax or email to:

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

Example consumer recall notice

URGENT MEDICINE RECALL

<PRODUCT NAME> ELIXIR

120mg paracetamol per 5mL

100mL bottle

Batch number xxxxx, Expiry date: Oct 2017

AUST R xxxxx

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

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

CUSTOMER SERVICE 1800 xxx xxx

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

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

2) The current reporting requirements for sponsors (2 week, 6 week, and 3 month reports)

Attachment 2: Reporting Requirements

Reports should be submitted electronically to the Recalls Section via recalls@health.gov.au

Please include the relevant TGA Recall reference number in the email subject line – e.g. RC-XXXX-RN-XXXXX-X

2 WEEK REPORT REQUIREMENTS:

1. Has the recall/corrective action been initiated? Confirm that the agreed action has begun. e.g. the approved letter has been dispatched to all the customers previously provided to the TGA.	**[ ] YES**	**[ ] NO.** Please explain:
2. Has a signed copy of the customer letter been provided to TGA Recalls?	**[ ] YES**	**[ ] NO.** Please ensure a signed copy of the letter is provided.
3. Is the recall/corrective action progressing without major impediments? e.g. The recall/corrective action is progressing as per the agreed timelines	**[ ] YES**	**[ ] NO.** Please explain:

4. Have the initial investigation findings changed the scope of the recall/correction e.g. Additional units or products have not been identified with the same defect	**[ ] NO**	**[ ] YES.** Please advise:
5. For any product exported from Australia, have the overseas supplier(s) been informed of the recall/correction action being undertaken in Australia. <u>Please list countries product has been exported to.</u>	**[ ] YES** **[ ] No exports**	**[ ] NO.** Please explain:

6 WEEK REPORTING REQUIREMENTS:

1. Have ALL the customers that you contacted responded to your requested recall/corrective action? Have customers confirmed their amount of affected product (including none) and that they agree to the recall/corrective action.	**[ ] YES**	**[ ] NO.** Please advise the % of customers that have responded ……....% And; <u>Detail attempts made to contact non-responding customers:</u>

2. (a) Recall - Have ALL customers returned or destroyed their affected units; or **(b) Correction - Have ALL customers with units requiring correction been identified?**	**[ ] YES** **[ ] No goods left to recall or correct.**	**[ ] NO.** Please advise when this is expected to occur:
3. Is the recall/corrective action progressing without major impediments? e.g. The recall/corrective action is progressing as per the agreed timelines	**[ ] YES**	**[ ] NO.** Please detail:

3 MONTH CLOSE OUT REPORTING REQUIREMENTS (or by the previously agreed time):

1. (a) Recall - Has ALL returned stock been destroyed/disposed/returned to the manufacturer?*; or	**[ ] YES**	**[ ] NO.** Please explain & advise when this is expected to occur:

1. (b) Correction - Have ALL units been corrected or have ALL customers been supplied with the correction? ***A Certificate of destruction is to be provided where the goods have been destroyed and consignment documentation is to be provided where the goods have been returned to the manufacturer.**		Please provide a list of non-responding customers:
2. What was the root cause of the defect that led to the recall/corrective action?	Please detail:	
3. What remedial action has the manufacturer proposed to prevent the recurrence of the defect that led to the recall/corrective action?	Please detail:	
4. If the response rate was not 100% at the time of the six week report, have ALL customers that you contacted now responded to your requested recall/corrective action?	**[ ] YES**	**[ ] NO.** Please advise the % of customers that have responded ……....% And; Detail attempts made to contact remaining customers

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Reference/Publication # D22-6083338