TGA ONLINE RECALL SUBMISSION FORM

Example requirements for quality submissions

This document aims to provide guidance for completing the TGA Recall Online Submission Form.
Table 1 provides multiple examples of the required format for sponsor submissions, and TGA recommendations for each field of the

An example of how this will appear in the TGA System for Australian Reca

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TGA Recalls Section
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Table 1. *Suggested Sponsor Submissions and TGA Recalls Team Recommendations for each Required Field of the Online Recall Submission Form.*

Required Field	Suggested Sponsor Submission	TGA Requirements
Proposed Problem Description:	Specific lots could be contaminated with *Staphylococcus aureus*. Sterility testing identified the issue after the product's release. The contamination could lead to patient infection, fever or further medical treatment. To date, no adverse events have been reported. --- There is an error in the Instruction for Use (IFU) and product labelling. The 'Limitations' section of the IFU and warning labels state the Safe Working Load to be 200kg. The correct Safe Working Load is 160kg. There is a risk the device could be used beyond its safe weight capacity, leading to a patient fall. There have been 2 customer complaints, with no injuries or adverse events reported.	• Only include relevant information regarding the product problem. • [IF APPLICABLE] Include a statement regarding the impact this may have on regular use of the product. • [IF APPLICABLE] Provide a concluding statement regarding the number of adverse events reported within Australia and/or worldwide. • This is a short summary which will appear on the public database (SARA). Please keep any complicated scientific terminology to a MINIMUM. • Please remove all trademark symbols (™) and (®). • Please do not include the words 'voluntary' or 'voluntarily'. • Use of Australian spelling is required as per the URPTG. • **It is NOT acceptable to enter *'See attached documents'* instead of the required information.**
Proposed Hazard Description:	The contamination could lead to patient infection, fever, or further medical treatment. The likelihood of serious injury has been assessed as remote. --- There is a risk that the product may be used beyond it's safe weight capacity, which could result in collapse/breakage of the device and a patient fall or injury.	• Provide a short statement regarding the potential short-term or long-term hazards that use of this product may have on the user or the immediate environment. • This information should align with the Health Hazard Evaluation (HHE) or risk assessment documentation.

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Proposed Action Description:	Immediately identify all affected lot numbers and quarantine on site to prevent further use. The sponsor will arrange for the collection of all affected products and provide a full refund. --- A new IFU and warning labels will be provided to customers. The IFU update is expected by the end of July 2023. In the meantime, customers may use the product, but the weight capacity must not exceed 160kg.	• Include actions to be taken immediately by users, including returning/discarding quarantining products. • Include any required workarounds or temporary fixes. If this will not fit in the field, include a brief summary. • [IF APPLICABLE] Include any future actions to be taken by the sponsor, as well as an approximate timeframe for the correction (i.e. '… by Q3 2023'). • This is a short summary which will appear on the public database (SARA). Please keep any complicated terminology to a MINIMUM. • AVOID phrasing in the 2nd person i.e. "You should return product to…"
Product Description:	BestTest Horse Blood Agar Kits. An in vitro diagnostic medical device (IVD) Lot Numbers: AU123, AU124, AU125 Product Code: PC0001 Batch Numbers 33AU, 34AU Expiry Date: 01/01/2025 ARTG 987654321 (BestTest Ltd – Horse Blood Agar IVDs) --- Guerilla Ultra Light Infusion Sets. Size M/L Product Codes: P3V, P4V Multiple Batch Numbers	• The first sentence must be the name of the product(s) affected. • Include all relevant product identifiers (i.e. Batch Numbers, Lot Numbers, Catalogue Numbers, Kit Numbers, UDI, etc.) • Include the ARTG of affected product(s) and if space permits the ARTG description. • If no ARTG, include whether the product is exempt, excluded, or supplied under the Special Access Scheme (SAS), etc. • If the affected device is an IVD, please include the following statement as part of the product description title: 'An in vitro diagnostic medical device (IVD)'. • Please remove all trademark symbols (™) and (®).\ • If more than 15 Lot/Batch/Product numbers, say "Multiple lot numbers"

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	UDI: U20830546185689, U3645298576421 ARTG 9919919 (Guerilla Special Care Pty Ltd – Intravenous administration sets, disposable) --- Elendil, 200mg/mL multipurpose liquid bottle, raspberry flavour Product Code: P52s Lot Number: LOTR91301 Expiry Date: 31/05/2024 Supplied via the Special Access Scheme (SAS)	
Recall Contact:	1800 000 000 – Guerilla Special Care Customer Service --- 0412 000 000 – Mr Bob Marley, Best Buddi Products	• This is the contact number which will appear on the public SARA database. • This should correspond with the number provided in the customer letter • It needs to be an Australian contact • Depending upon the recall, it can be either an individual person or a customer service number
Product Code (or Catalogue/Part Number):	Product Code: PC0001	• Product Identifying number.
Product Identifiers (i.e. Batch, Serial, Lot Numbers):	Lot Numbers: AU123, AU124, AU125. Batch Numbers 33AU, 34AU	• Product Identifying Numbers.

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Manufacture Date:	DD/MM/YYYY	
Expiry Date:	DD/MM/YYYY	
Release Date:	DD/MM/YYYY	• Date affected products released by Manufacturer.
Batch Size:	123456 Units	• Number of goods imported/sold within Australian Market.
Product Distribution Details:	12 hospitals in NSW, QLD and VIC 83 facilities nationally excluding ACT and NT	• Number of affected customers and what states the products were distributed. • If more than five states/territories are impacted, the format is *"…nationally excluding X and Y"* • Please remember to attach an excel customer list in the following format: State, Customer, and Suburb. • If the customer list includes physicians, provide the name of the applicable hospital they operate from. • If the affected product is supplied directly to individual consumers, please list these customers separately. • Please notify the TGA Recalls team if not all end users are identifiable or contactable. • If the Product Distribution Details are not available at the time of submission, please notify the TGA Recalls team.
Current or Previous Overseas Actions:	MHRA-REF: 00001111 (www. MHRA-REF:00001111.com) FDA-REF: 11110000 (www.FDA-REF.com)	• Include a reference number for any overseas actions taken. • [IF APPLICABLE] Include a link to the overseas action.

Australian Government
Department of Health
Therapeutic Goods Administration

Recall Action Notification

Guerilla – Ultra Light Infusion Sets. Size M/L

Important information on the System for Australian Recall Actions

The TGA publishes information about therapeutic goods supplied in the Australian market that have been subject to a recall action in a publicly searchable database.
Recall action means action taken by the responsible entity (being the person who is responsible for taking the recall action) to resolve a problem with therapeutic goods supplied in the Australian market that have, or may potentially have, deficiencies relating to safety, quality, efficacy (performance) or presentation.

- **Recall actions include: the permanent removal of therapeutic goods from supply in the market, the taking of corrective action in relation to therapeutic goods (such as repair, modification, adjustment or relabelling) and, in the case of medical devices that have been implanted into patients, the issuing of a hazard alert containing information for health practitioners on how to manage patients.**
- **More information about Australian recall actions is available at <**http://tga.gov.au/safety/recalls-about.htm**>**
- **If you are taking a medicine, using a medical device or have had a medical device implanted into you, that is the subject to a recall action, and you have any concerns you should seek advice from a health professional. <**http://www.healthdirect.org.au/**>**

About the release of this information

While reasonable care is taken to ensure that the information is an accurate record of recall actions that responsible entities have reported to the TGA or of which the TGA has become aware, the TGA does not guarantee or warrant the accuracy, reliability, completeness or currency of the information or its usefulness in achieving any purpose.
To the fullest extent permitted by law, including but not limited to section 61A of the Therapeutic Goods Act 1989, the TGA will not be liable for any loss, damage, cost or expense incurred in or arising by reason of any person relying on this information.
The information contained in the SARA database is released under s 61(5C) of the Therapeutic Goods Act 1989. Copyright restrictions apply to the System of Australian Recall actions (SARA) <http://tga.gov.au/about/website-copyright.htm>.

Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2023-RN-02809-1
Product Name/Description[iii]	Guerilla Ultra Light Infusion Sets. Size M/L Product Codes: P3V, P4V Multiple Batch Numbers UDI: U20830546185689, U3645298576421 ARTG 9919919 (Guerilla Special Care Pty Ltd – Intravenous administration sets, disposable)
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class II
Recall Action Commencement Date[vi]	01/05/2023
Responsible Entity[vii]	Guerilla Special Care Pty Ltd
Reason / Issue[viii]	Specific lots could be contaminated with Staphylococcus aureus. Sterility testing identified the issue after the product's release. The contamination could lead to patient infection, fever or further medical treatment. To date, no adverse events have been reported.
Recall Action[ix]	Recall

Appendix 1. System for Australian Recall Actions

Recall Action Instructions[x]	Immediately identify all affected lot numbers and quarantine on site to prevent further use. The sponsor will arrange for the collection of all affected products and provide a full refund.
Contact Information[xi]	1800 000 000 – Guerilla Special Care Customer Service

Footnotes

[i] Type of Product: Medicine, Medical Device, or Biological

[ii] TGA Recall Reference: Unique number given by the TGA

[iii] Product Name/Description: Brand name (including active ingredient for medicines) and may include generic reference for the kind of medical devices. Includes all necessary information such as affected: catalogue / model and / or batch / serial numbers.

[iv] Recall Action Level: The level to which the recall action is to be undertaken. This is based on the significance of the risk and the channels through which the goods have been distributed. The recall action levels are / Wholesale / Hospital / Retail / Consumer.

- **Wholesale** - includes wholesalers and state purchasing authorities.
- **Hospital** - includes nursing homes and institutions, hospital pharmacists, ambulance services, blood and tissue banks and laboratories as well as wholesale as appropriate.
- **Retail** - includes retail pharmacists, medical, dental and other health care professionals as well as wholesale and hospital as appropriate.
- **Consumer** - includes patients and consumers, as well as wholesale, hospital and retail levels as appropriate.

[v] Recall Action Classification**: Recall actions of therapeutic goods are classified based on the potential risk the deficiency poses to patients / consumers. They are classified as Class I, Class II or Class III.

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

[vi] Recall Action Commencement Date: The date the recall strategy and communication was agreed by the TGA.

[vii] Responsible Entity: Sponsor / Supplier / Importer responsible for the recall actions.

[viii] Reason / Issue: Reason for the recall action.

[ix] Recall Action: Recall action is an action taken to resolve a problem with a therapeutic good already supplied in the market for which there are issues or deficiencies in relation to safety, quality, efficacy (performance) or presentation. There are four distinct recall actions – recall, product defect correction, hazard alert and product defect alert.

- **Recall** - The permanent removal of an affected therapeutic good from supply or use in the market.
- **Product defect correction** - Repair, modification, adjustment or re-labelling of a therapeutic good. The corrective action may take place at the user's premises or any other agreed location.
- **Hazard alert** - Information issued to healthcare professionals about issues or deficiencies relating to an implanted medical device or biological product and advice about the ongoing management of patients.
- **Product defect alert** - Information issued to raise awareness about issues or deficiencies for a therapeutic good where a recall action will result in interruption of patient treatment or a medicine shortage, including advice to reduce potential risks of using affected goods.

[x]

[xi] Recall Action Instructions: What customers with affected goods should do.

[xii] Contact Information: Who the customer should contact for additional information and clarification regarding the recall action.

[xiii] ** These definitions are applicable to the 2022 Uniform Recall Procedure for Therapeutic Goods (Implemented from June 2022).