Australian Government
Department of Health
Therapeutic Goods Administration

New Online Web Form for submitting Recall and Non-Recall actions

- **The Recalls Section has released a new Online Form for submitting Recall/Non-Recall Actions for the TGA's assessment.**
- **This streamlines the process and provides greater service to sponsors, replacing our current practice of sponsors submitting new actions for assessment via email to recalls@health.gov.au**

Accessing and using the Online Form

- To access the Online Submission Form, please log into your TBS Portal, and go to Applications →Recalls →Recall/ Non-Recall Submission.
- Information can then be entered into the tabs provided. An example of a correct submission is provided over the page.
- Documents such as Draft Customer Letters, Distribution Lists and Health Hazard Evaluation reports can be uploaded under the 'Supporting Information' tab.
- Upon saving the web form, you will receive a new TGA reference number (i.e. RC-YYYY-RN-XXXXX-X).
- The TGA will not be able to see the notification until it has been 'validated' and 'submitted' by the sponsor.
- Any further updates for the action can still be sent via email to recalls@health.gov.au, quoting the TGA reference number in the subject line.

Before submitting recall or non-recall information to the TGA, please refer to the Uniform recall procedure for therapeutic goods (URPTG) which outlines a consistent approach for undertaking both recall and non-recall actions of therapeutic goods supplied, imported into or exported from Australia. The URPTG can be downloaded from the TGA website at https://www.tga.gov.au/publication/uniform-recall-procedure-therapeutic-goods-urptg

Need more information?

https://www.tga.gov.au/URPTG

Some tips for good quality recall/non-recall web submissions

- Incomplete or unclear entries may lead to submissions being delayed in processing, combined with the need for our staff to make further enquiries as to the matters at hand.
- Only include relevant information in the product and problem description fields.
- Please remove all trademark symbols (™, ® and ©).
- Please do not include the words 'voluntary' or 'voluntarily' in the submission.
- Please remember to include the ARTG number(s) in the product description field, and if space permits the ARTG description.
- Please remember to attach an excel customer list in the following format: State, Customer, and Suburb.
- If applicable, please include any overseas export distribution from Australia.
- Please see the attached example for the correct structure and formatting of a recall submission.

The TGA Recalls Online Submission Form

Example Submission Requirements for the Recalls Online Submission Form

This document aims to provide guidance for completing the TGA Recalls Online Submission Form.

Table 1 provides a suggested format for sponsor submissions and TGA recommendations for each required field of the online recall submission form.
An example of how this will appear in the TGA System for Australian Recall Actions (SARA) database is provided in Appendix 1.

TGA Recalls Section
recalls@health.gov.au

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

Required Field	Suggested Sponsor Submission	TGA Recommendation
Proposed Problem Description:	BestTest-Company has received reports stating that specific lots of the BestTest Horse Blood Agar have shown increased rates of the outer sterile packaging being compromised on delivery to customers. This packaging defect may not be immediately identifiable by customers. Use of potentially compromised BestTest Horse Blood Agar plates may result in a delay in reporting patient results, or in a worst case, patient misdiagnosis. To date, there have been no reports of adverse events related to this issue.	• 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. • 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
Proposed Hazard Description:	Clinical samples tested using compromised BestTest Horse Blood Agar plates may result in patient misdiagnosis or a potential delay in generating accurate patient results.	• 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.
Proposed Action Description:	Customers are advised to immediately identify all affected lot numbers of BestTest Horse Blood Agar and quarantine on site to prevent further use. BestTest-Company will arrange for the collection of all affected product and provide customers a full refund.	• Provide a statement of actions to be taken for immediate users of the product. • [IF APPLICABLE] Provide a statement regarding future actions to be undertaken by the immediate user of the product. • [IF APPLICABLE] Provide a statement regarding future actions to be taken by the sponsor.
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	• The first sentence should be the identifying name of the product(s) affected. • Include all relevant product identifiers (i.e. Batch Numbers, Lot Numbers, Catalogue Numbers, Kit Numbers etc.) • Include the ARTG of affected product(s) and if space permits the ARTG description.

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

	Expiry 01/01/2020 ARTG 987654321 (BestTest-Company Ltd – Horse Blood Agar IVDs)	• 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 (®).
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.
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 and QLD and 3 pharmacies in TAS.	• Number of affected customers and what states the products were distributed to. • Please remember to attach an excel customer list in the following format: State, Customer, and Suburb. • If the customer list includes physicians, please provide them in a separate list that includes the names of the hospital/s that 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.

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

		• 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.

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Recall Action Notification

BestTest Horse Blood Agar Kits. An *in vitro* diagnostic medical device (IVD).

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.

Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2019-RN-00000-1
Product Name/Description[iii]	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 01/01/2020 ARTG 987654321 (BestTest-Company Ltd – Horse Blood Agar, IVD)
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class II
Recall Action Commencement Date[vi]	01/01/2020
Responsible Entity[vii]	BestTest-Company Ltd
Reason / Issue[viii]	BestTest-Company has received reports stating that specific lots of the BestTest Horse Blood Agar have shown increased rates of the outer sterile packaging being compromised on delivery to customers. This packaging defect may not be immediately identifiable by customers. Use of potentially compromised BestTest Horse Blood Agar plates may result in a delay in reporting patient results, or in a worst case, patient misdiagnosis. To date, there have been no reports of adverse events related to this issue.
Recall Action[ix]	Recall

Appendix 1. System for Australian Recall Actions

Recall Action Instructions[x]	Customers are advised to immediately identify all affected lot numbers of BestTest Horse Blood Agar and quarantine on site to prevent further use. BestTest-Company will arrange for the collection of all affected product and provide customers a full refund.
Contact Information[xi]	1800 000 000 - BestTest-Company Ltd 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 2017 URPTG (Implemented from Jan 15 2018). Recall Action types and Recall Action Classifications prior to 15 Jan 2018 can be found at https://www.tga.gov.au/sites/default/files/recalls- urptg-170412.pdf