



Australian Government

Department of Health

Therapeutic Goods Administration

# Examples of different classes of recall action

**Note:** This information is part of the [Consultation: Revised edition of the Uniform Recall Procedure for Therapeutic Goods](#)

Version 1.0, October 2015

**TGA** Health Safety  
Regulation

# About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <<https://www.tga.gov.au>>.

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## Version history

Version	Description of change	Author	Effective date
V1.0	Publication for consultation  Content taken from the URPTG - Uniform Recall Procedure for Therapeutic Goods	Therapeutic Goods Administration	27 October 2015

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# Introduction

As part of the [Uniform Recall Procedure for Therapeutic Goods](#), the TGA classifies recalls into three risk classes to convey the seriousness of the deficiency and the degree of risk involved. Unlike the classes used for medical devices and biologicals, a Class I recall is the most serious.

- **Class I recall** - a situation in which there is a reasonable probability that the use of, or exposure to, a deficient product will cause serious adverse health consequences or death.
- **Class II recall** - a situation in which use of, or exposure to, a deficient product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- **Class III recall** - a situation in which use of, or exposure to, a deficient product is not likely to cause adverse health consequences.

Class I and Class II recalls are safety-related, whereas Class III recalls are not safety-related.

## Class I examples

**Medicine** examples of Class I recalls:

- wrong product (label and contents are different products) with serious medical consequences
- chemical contamination with serious medical consequences
- microbial contamination of sterile injectable or ophthalmic product
- mix-up of some products ('rogues') with more than one container involved
- wrong active ingredient in a multi-component product with serious medical consequences.

**Medical device** examples of Class I recalls:

- hot/cold gel pack contains a toxic substance that could be ingested accidentally by a young 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 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
- False negative result on an IVD test for a serious or highly contagious disease.

**Biologicals and blood component** examples of Class I recalls:

- retained samples of pulmonary allograft showed positive microbial growth of a pathogenic organism
- blood components accidentally released after donation tested initial-positive to mandatory testing.

## Class II examples

### **Medicine** examples of Class II recalls:

- mislabelling (for example, wrong or missing text or figures)
- missing or incorrect safety information in leaflets or inserts
- microbial contamination of non-injectable, non-ophthalmic sterile product with medical consequences
- mix-up of products in containers ('rogues')
- non-compliance with specification, such as in an assay, stability, fill or weight resulting in medical consequences
- insecure or incorrect closures for medicines such as cytotoxics, potent products and medicines requiring child-resistant packaging resulting in medical consequences.

### **Medical device** examples of Class II recalls:

- 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 issues 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 component** examples of Class II recalls:

- 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 examples

A Class III recall is a non-safety related recall. The product meets acceptable standards of safety and efficacy and the issue does not in itself present an imminent risk. However, if not rectified, the situation may present a hazard in the future.

### **Medicine** examples of Class III recalls:

- faulty packaging, such as wrong or missing batch number or expiry date

- faulty closure not resulting in any medical consequences
- contamination with no medical consequences, including:
  - microbial spoilage
  - dirt or detritus
  - particulate matter.

**Medical device** examples of Class III recalls:

- a disinfectant has been mislabelled with an expiry date that predates the actual expiry date
- the outer packaging of a medical device indicates a different size to that which is actually in the 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.

## **Therapeutic Goods Administration**

PO Box 100 Woden ACT 2606 Australia

Email: [info@tga.gov.au](mailto:info@tga.gov.au) Phone: 1800 020 653 Fax: 02 6232 8605

<https://www.tga.gov.au>

Reference/Publication #