About Australian recall actions

Last updated:
30 June 2022

A recall action is a set of market actions that are undertaken via the Uniform Recall Procedure for Therapeutic Goods (URPTG) to resolve a problem with a therapeutic good already supplied in the Australian market for which there are issues, deficiencies or defects in relation to the safety, quality, efficacy, performance or presentation of the therapeutic good.

There are four distinct recall actions available to sponsors - recall, product defect correction, hazard alert and product defect alert.

- **Recall** - 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.
- **Product defect correction** - undertaken to correct a specific or potential deficiency and includes repair, modification, adjustment or re-labelling of a therapeutic good. Corrections involving a product's expiry date or updates or changes to any accessories, operating instructions or software. The corrective action may take place at the user's premises or any other agreed location. In some instances, the product can continue to be used if there is robust mitigation in place until a permanent correction has been implemented.
- **Hazard alert** - 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 or medicines) cannot be recalled. The hazard alert will typically contain precautionary information issued to healthcare professionals about issues or deficiencies relating to an implanted therapeutic good and advice about the ongoing management of affected patients. There may or may not be advice to consumers in the event the hazard alert is published on the TGA Website. A hazard alert may also be issued in conjunction with a recall notice for affected products that have not yet been implanted.
- **Product defect alert** - allows the informed, continued use of defective but critical therapeutic goods, raises awareness of the issue and describes the precautionary

actions that clinicians or patients may take to mitigate any associated risk. A product defect alert may later be followed by a recall once unaffected or alternative products become available. It is often the case that a product defect alert is utilised where there is no alternative product available at the time and/or for which a recall action will result in a significant interruption of patient treatment or a medicine shortage (https://www.tga.gov.au/node/4023), either of which would likely present greater adverse clinical sequelae than the defect itself.

Recall actions vary on a case-by-case basis depending on the deficiency, issue or defect associated with the therapeutic good and the risk this poses to public health and safety.

A recall action can occur because of straightforward problems, such as labelling or packaging errors, or for more serious and complex problems, such as an unexpected increase in side effects or microbial contamination.

To assist in the identification of the nature of a recall action, they are classified into one of the following classes based on the potential risk the deficiency, issue or defect poses to patients/consumers:

- **Class I - Most serious safety-related -** recall action occurs when there is a reasonable probability that the use of, or exposure to, the deficient therapeutic good(s) will cause serious, permanent or long term adverse health consequences or death.
- **Class II - Urgent safety-related -** recall action occurs when the 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 - Lowest risk -** recall action occurs when the use of, or exposure to, the deficient therapeutic good(s) is not likely to cause adverse health consequences and they are therefore not safety related.

Making a decision to undertake a recall action with sponsors

Australian sponsors may voluntarily notify the TGA, or be contacted in connection with the possibility of initiating a recall action for a therapeutic good as a result of reports referred to the TGA from a variety of external sources, including:

- consumers;
- manufacturers;
- wholesalers;
- retail and hospital pharmacists;
- blood and tissue banks;
- pathology departments;
- overseas regulators;
- research facilities - e.g clinical trials; and/or
- health care professionals.

The TGA may also request agreement for a recall action as a result of:

- analysis and testing of samples of therapeutic goods;
- advice from an expert advisory committee; and/or
- information received from international regulatory authorities.

Conducting an agreed recall action

Once agreed, the TGA coordinates the recall action, advising the product's sponsor or supplier (i.e responsible entity) of the correct procedures to undertake, and for monitoring of the recall action as it is carried out where this is determined to be necessary.

Most recall actions are voluntarily initiated by the person or organisation responsible for the goods, once they become aware of a problem. The sponsor has responsibility for the recovery and disposal of the goods or completion of the agreed corrective action.

If necessary, the TGA does have legislative powers to mandate the recall of therapeutic goods under the *Therapeutic Goods Act 1989 (https://www.legislation.gov.au/Series/C2004A03952)*.

The level to which a recall action has to be undertaken is based on the significance of the risk and the channels through which the goods have been distributed. The recall levels in cascading order are:

- **Wholesale** - includes wholesalers and state/territory purchasing authorities.
- **Hospital** - includes public and private hospitals, nursing homes and other healthcare institutions, hospital pharmacists, ambulance services, blood and tissue banks and

pathology laboratories as well as wholesale as appropriate.

- **Retail** - includes retail pharmacists, medical, dental and other health care professionals, supermarkets, health food stores and online stores as well as wholesale and hospital as appropriate.
- **Consumer** - includes patients and consumers, as well as wholesale, hospital and retail levels as appropriate.

Therefore, in a Retail level recall action, letters are also to be sent by the sponsor to affected wholesalers and hospitals by default.

The TGA will endeavour to recall therapeutic goods to the depth of supply and as such, only affected parties need to be notified of an action as detailed in the customer or distribution list.

Notification of recall actions to stakeholders

Once a recall action has been initiated, the TGA notifies a number of key stakeholders including the state and territory health department recall coordinators. The TGA may also notify other stakeholder groups depending on the type of product being recalled. The contact details (https://www.tga.gov.au/resources/resource/guidance/uniform-recall-procedure-therapeutic-goods-urptg) for the various state and territory health department recall coordinators (https://www.tga.gov.au/how-we-regulate/monitoring-safety-and-shortages/manage-recall/recall-procedures/recall-coordinators-therapeutic-goods) and other stakeholder groups (https://www.tga.gov.au/how-we-regulate/monitoring-safety-and-shortages/manage-recall/recall-procedures/australian-recall-coordinator-notification-list)who may be notified of recalls by the TGA are published on the TGA website.

The TGA has a standard operating procedure to alert the Chief Medical Officer (CMO), state and territory Chief Health Officers (CHOs) and professional organisations (as appropriate) of certain recall actions.

Topics:

Biologicals (https://www.tga.gov.au/products/biologicals-blood-and-tissues-and-advanced-therapies/biologicals)

Medical devices (https://www.tga.gov.au/products/medical-devices)

Medicines (https://www.tga.gov.au/products/medicines)

Safety (https://www.tga.gov.au/safety/safety)

In Vitro Diagnostic medical devices (IVDs) (https://www.tga.gov.au/vitro-diagnostic-medical-devices-ivds)