Australian Government
Department of Health
Therapeutic Goods Administration

Uniform Recall Procedure for Therapeutic Goods

New version published October 2017

- Web based format – easy to navigate
- Step-by-step protocol with supporting information
- New terminologies and changed terminologies
- Roles & responsibilities of different participants
- Risk classification – inclusion of probability aspects
- Greater clarification on the requirements for medical devices (including IVDs)
- Refined information required to assess a recall action

Old Terminology

Recall actions

- Recall
- Recall for Product Correction
- Hazard Alert

Non-recall actions

- Safety Alert
- Product Notification
- Withdrawal
- Recovery

New Terminology

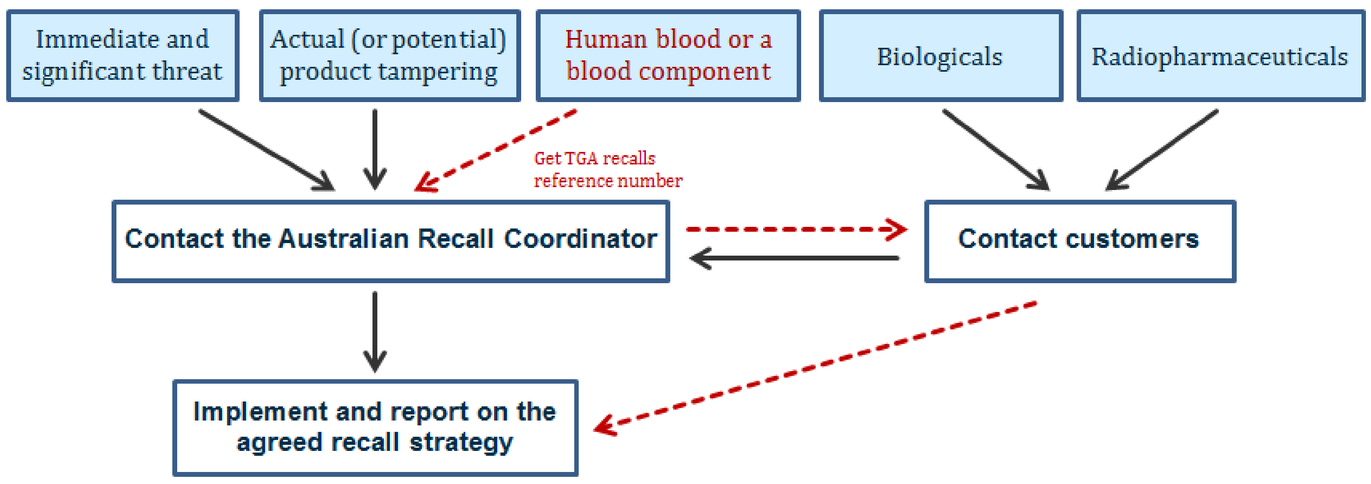
Recall actions

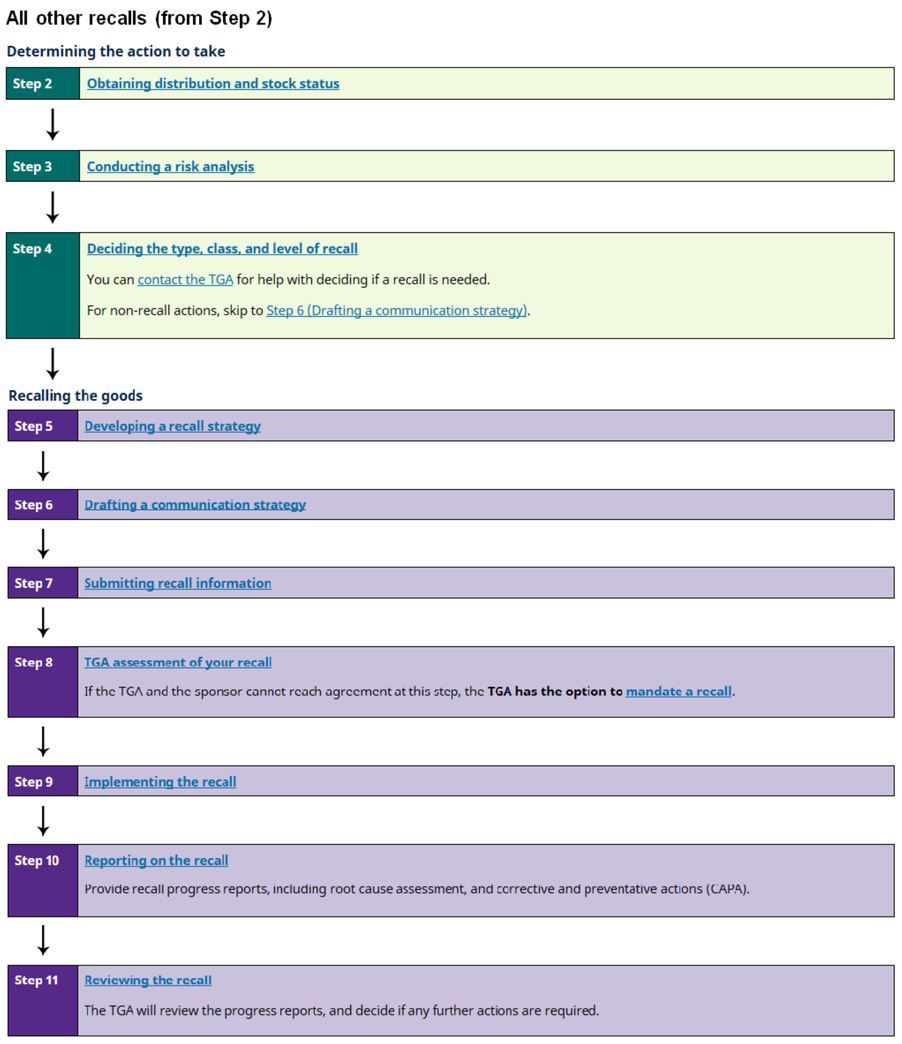
- Recall
- Product Defect Correction
- Hazard Alert
- Product Defect Alert

Non-recall actions

- Safety Alert
- Product Notification
- Quarantine
- Product Withdrawal

New flowcharts





Changes to Recall Classifications

Class I

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

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

A situation in which use of, or exposure to, the deficient product is not likely to cause adverse health consequences.

Need more information?

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

Need more information? www.tga.gov.au email: devices@tga.gov.au

TGA Health Safety Regulation