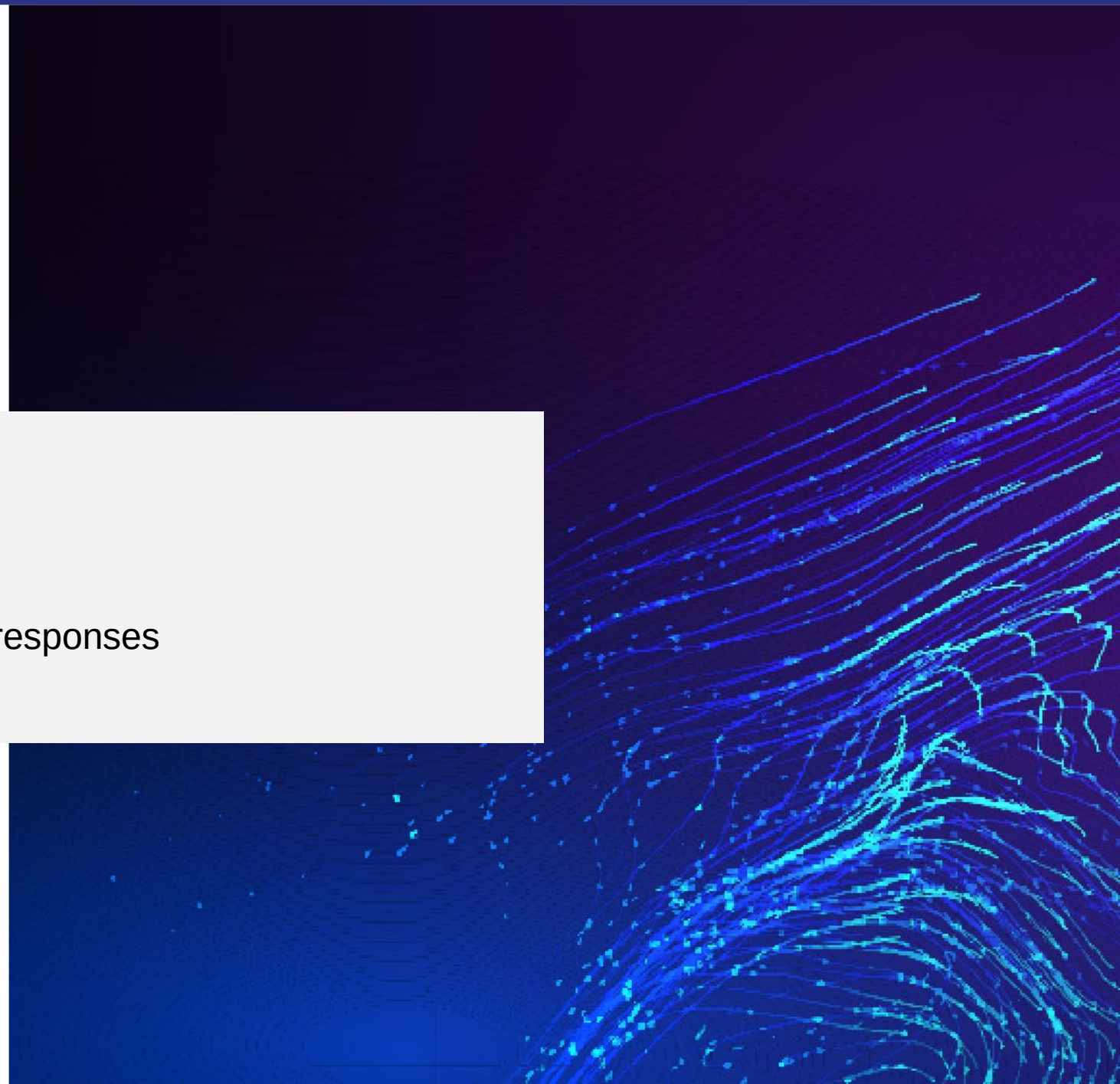
Recalls 101

Sharon Bennett / Brigida Botticelli
Manufacturing Quality Branch
Department of Heath and Aged Care, TGA

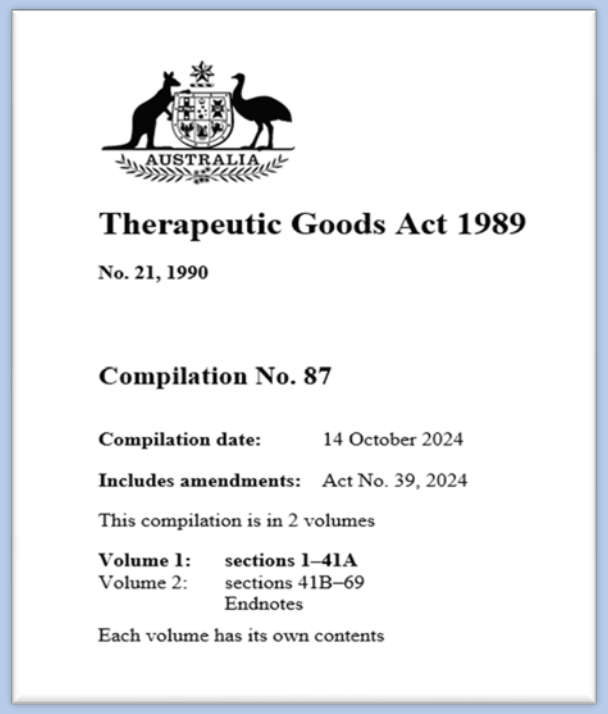
GMP FORUM 2024

Agenda

- Roles of different stakeholders
- Recall action types and main aspects
- Outcomes / reporting obligations and responses



Public notification & recall of therapeutic goods



AUSTRALIA

Therapeutic Goods Act 1989

No. 21, 1990

Compilation No. 87

Compilation date: 14 October 2024

Includes amendments: Act No. 39, 2024

This compilation is in 2 volumes

Volume 1: **sections 1–41A**
Volume 2: sections 41B–69
Endnotes

Each volume has its own contents

Uniform Recall Procedure for Therapeutic Goods

*URPTG: Version 2.4, March 2024 - https://www.tga.gov.au/resources/resource/guidance/uniform-recall-procedure-therapeutic-goods-urptg

If sponsors do not comply with the URPTG, the Therapeutic Goods Act 1989 includes legal powers and processes that allow the TGA to mandate therapeutic goods recalls

Medical devices: Chapter 4, Part 4–9, s41KA – 41KD.

Medicines and other therapeutic goods (OTGs): Chapter 3, Part 3–2, Division 2A, s30EA – 30ED.

Biologicals: Chapter 3, Part 3–2A, Division 8, s32HA – 32HE.

All recall stakeholders

Healthcare Sector

Health care facilities
Health care professionals
Professional guilds and associations e.g., Pharmacy Guild
Healthcare provider peak bodies e.g., NACCHO or Australian Private Hospitals
Professional media (scientific and medical)

Consumers

Patients and carers
Patient Advocacy Groups e.g., Diabetes Australia
Consumer peak bodies e.g., Consumer Health Forum or Choice
Consumer media

Government

Department of Health and TGA
Australian Government regulators e.g., Australian Competition and Consumer Commission
Other Australian Government agencies e.g., ACSQHC
State and territory government e.g., health departments and procurement agencies
International government regulators e.g., Medsafe

What does the TGA do?

- Follows a consistent approach via the Uniform Recall Procedure for Therapeutic Goods (URPTG)
- Assess and agree sponsors' proposed recall notifications
- Communicate and monitor progress of the recall action
- Review the recall outcomes
- Monitor signals and regulatory compliance
- 'Early Advice' notifications

What sponsors need to do

- Promptly respond to product defects / safety problems
- Notify the TGA before commencing recall action
- Contact customers and monitor responses
- Perform any replacements or corrective actions
- Report outcomes to the TGA
- Implement measures so the problem/s does not re-occur

What wholesalers, retailers, hospitals and health professionals do

Upon being contacted by the sponsor/ supplier, they:

- Perform any required actions e.g. quarantine goods, return goods
- Trace products, determine if they were supplied further
- Contact their patients/ customers (depending upon recall level)
- Respond to the sponsor confirming actions

Manufacturer responsibilities

- Have established recall procedures in place
- Have an established relationship with the Australian sponsor
- Identify problems requiring recall notification
- Undertake the risk assessment (usually known as “Health Hazard Evaluation or Assessment” - HHE / HHA)
- Identify the root cause and implement CAPA (Corrective And Preventative Actions)
- Have an effective QMS in place

The End-To-End Recall Process

An issue with a therapeutic good is identified by consumers, healthcare providers, health departments, sponsors, manufacturers, labs, retailers, overseas regulators, research facilities, TGA, etc.

The sponsor submits a recall notice and works with the TGA to agree on the appropriate recall and communications strategy.

During recall strategy implementation, impacted customers are notified by the sponsor and/or health departments.

Customers notify impacted consumers, or they are informed through the media.

Key stages

Manage Emerging Issue → Submit Notification → Approve Recall → Implement Recall → Finalise Recall

The sponsor (in conjunction with the manufacture as needed) performs a risk assessment to determine the necessary actions to be taken

TGA reviews and assesses the documentation to ensure completeness, compliance and quality and publishes the recall to state and territory coordinators and the TGA website.

The sponsor notifies the TGA of the corrective action taken within the appropriate timeframe. If the report is satisfactory, TGA issues a close-out report and shares recall information other TGA stakeholders.

Main recall aspects and decision-making

- **Action** category (the ‘type’ of recall or non-recall)
- **Level** (the ‘depth’ of the recall)
- **Class** (the risk posed by the problem)

Current Action Categories – Recall types

Four types of recall actions defined by the URPTG –

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

- Is the product defective…..?

Four types of non-recall actions defined –

- Safety Alert
- Product Notification
- Quarantine
- Product Withdrawal

Levels (or depth) of Recalls

Wholesale level:

Includes wholesalers, distributors, S&T purchasing authorities

Hospital level:

Includes wholesale level AND hospitals, nursing homes, hostels, pathology labs, other healthcare institutions

Retail level:

Includes hospital and wholesale levels AND retail pharmacies, supermarkets, dental clinics and private healthcare professionals

Consumer level:

Includes retail, hospital and wholesale levels AND patients & other consumers.

- *The aim is generally to recall defective goods to the depth of supply*

Recall Classification

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

What are the barriers we face to the timely approval of recall actions?

When sponsors…

- Do not provide the right information upfront
- Delay responding to requests for information
- Are reluctant to do the action in a specified way
- Do not wish to perform an action at all, or are wilfully defiant
- Do not notify us until after an action has already occurred

Sponsor reporting requirements and recall outcomes

- Sponsor reporting obligations
- Distribution details
- Response rates
- What makes a successful recall action?

Reporting Obligations

The URPTG requires sponsors to submit reports at:

- 6 weeks (progress report) and
- 3 months or at another agreed time (final report).

These reports require sponsors to address:

- Effectiveness of the recall
- If the recall is progressing according to agreed timelines
- Number of customers who have responded
- Amount of stock returned or corrected
- Identification of the root cause
- Corrective and Preventive Actions (CAPAs) taken to prevent reoccurrence of the problem.

Distribution details

- Sponsor must provide their customer list
- This list is used to identify, trace and notify all the relevant organisations/ users who have received affected goods
- We require clear, concise and accurate distribution details from sponsors
- Provided in a formatted way: State, Customer Name, Suburb
- Proofread and checked for accuracy – location / geographical errors, personal information, duplicate entries

Response rates

- Sponsors must follow-up with their customers
- The level of follow up will depend on the risk and class of the recall action
- Sponsors should make three or more attempts to contact customers
- Sponsor should use various mediums to contact non-responding customers
- The TGA may issue a close out letter for an action where the number of goods returned or corrected is not 100%
- Sponsors remain responsible for undertaking any corrective actions for the life of the good, while it remains in the market

What makes a successful recall action?

- ✓ Clear and efficient communication to customers or patients
- ✓ Completing all the agreed actions with documented evidence
- ✓ Timely follow up to non-responders
- ✓ Justification for any discrepancies or inconsistencies
- ✓ Evidence of the fate of the final goods

Questions?

Scan this QR code with your device to submit a question

GMP FORUM 2024

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration