Recall of Therapeutic Goods: Overview and Reforms

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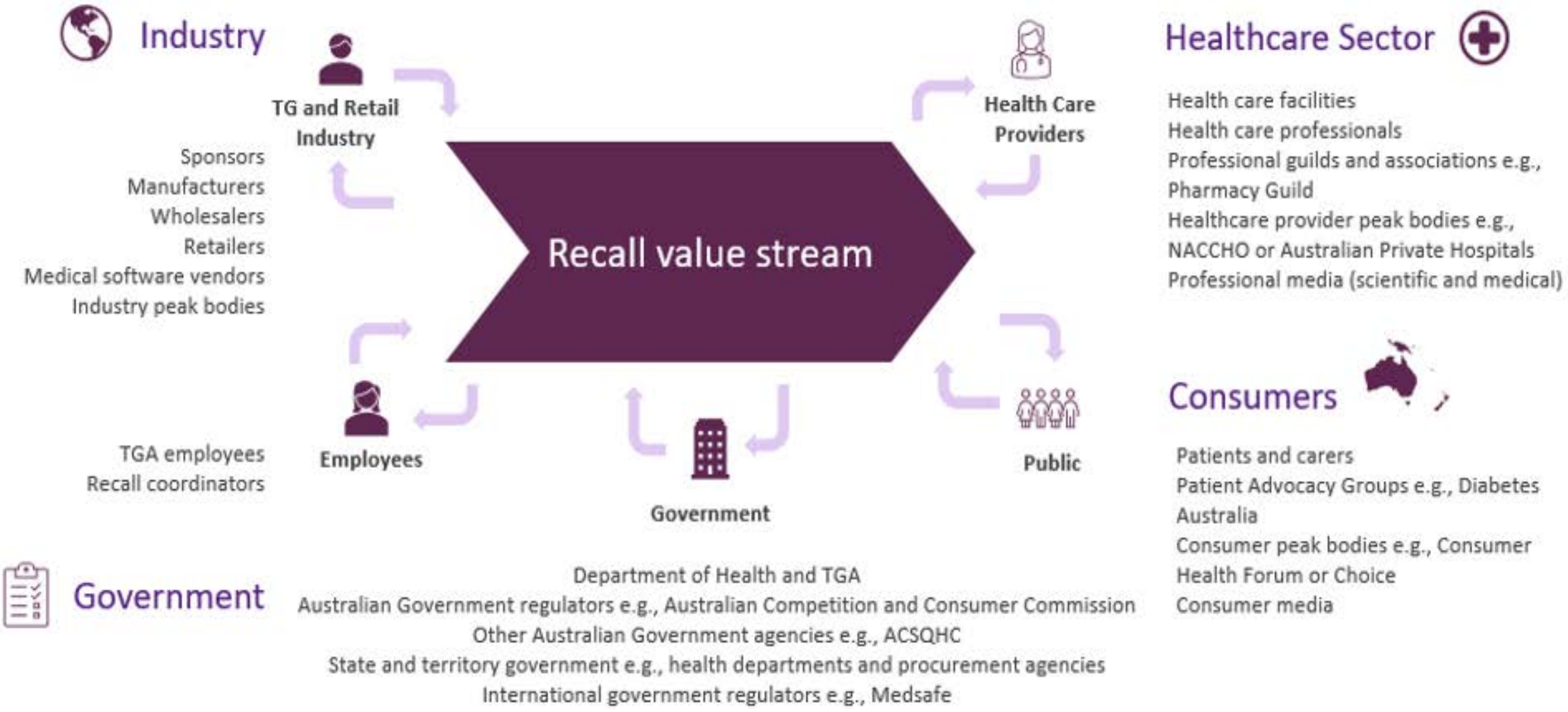
Overview of session

- Roles of different stakeholders
- Recall types and main aspects
- Reforms

All recall stakeholders



What does the TGA do?

- Provide a consistent approach via the Uniform Recall Procedure for Therapeutic Goods – ‘URPTG’*
- Assess proposed recall notifications
- Communicate and monitor progress of the recall
- Review the recall outcomes
- Monitor signals and regulatory compliance
- Publishes recalls in the SARA database
- Also publishes safety advisories for Hazard Alerts & consumer level recalls (and others on a case by case basis)
- ‘Early Advice’ notifications

*URPTG: Version 2.3, June 2022 - https://www.tga.gov.au/publication/uniform-recall-procedure-therapeutic-goods-urptg

What sponsors/ suppliers do

- Respond to product defects / safety issues promptly
- Notify the TGA before commencing recall action
  - Email vs eBS portal
- Contact customers and monitor responses
- Perform any replacements or corrections
- Report outcomes to the TGA
- Implements measures so the issue does not re-occur

Manufacturer responsibilities

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

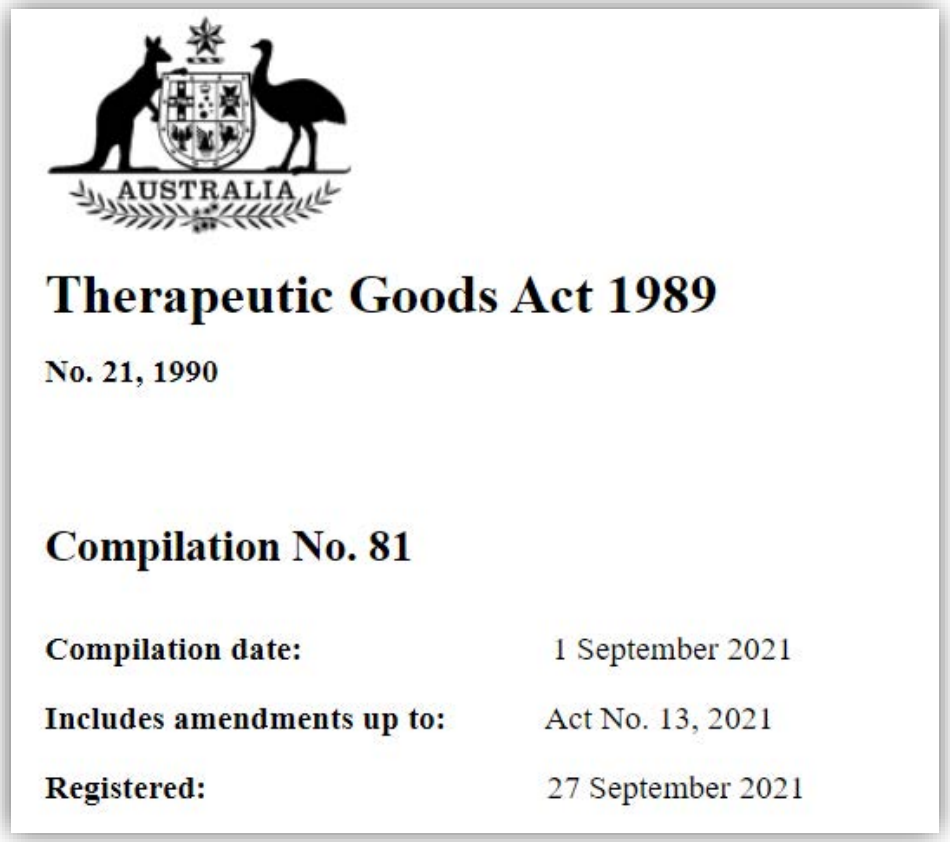
Manage Emerging Issue → Submit Notification → Approve Recall → Implement Recall → Finalise Recall

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.

Key Documents



AUSTRALIA

Therapeutic Goods Act 1989

No. 21, 1990

Compilation No. 81

Compilation date: 1 September 2021

Includes amendments up to: Act No. 13, 2021

Registered: 27 September 2021

Uniform Recall Procedure for Therapeutic Goods

*URPTG: Version 2.3, June 2022 - https://www.tga.gov.au/publication/uniform-recall-procedure-therapeutic-goods-urptg

Public notification & recall of therapeutic goods

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.

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 issue)

Current Action Categories – Recall types

- Four types of **recall actions** are 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: medicine and medical device wholesalers;

Hospital level:

Includes: wholesale level, nursing homes, hostels and other healthcare institutions;

Retail level:

Includes: hospital and wholesale levels, retail pharmacies, supermarkets, convenience stores, petrol stations; and

Consumer level:

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

- *The aim is 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

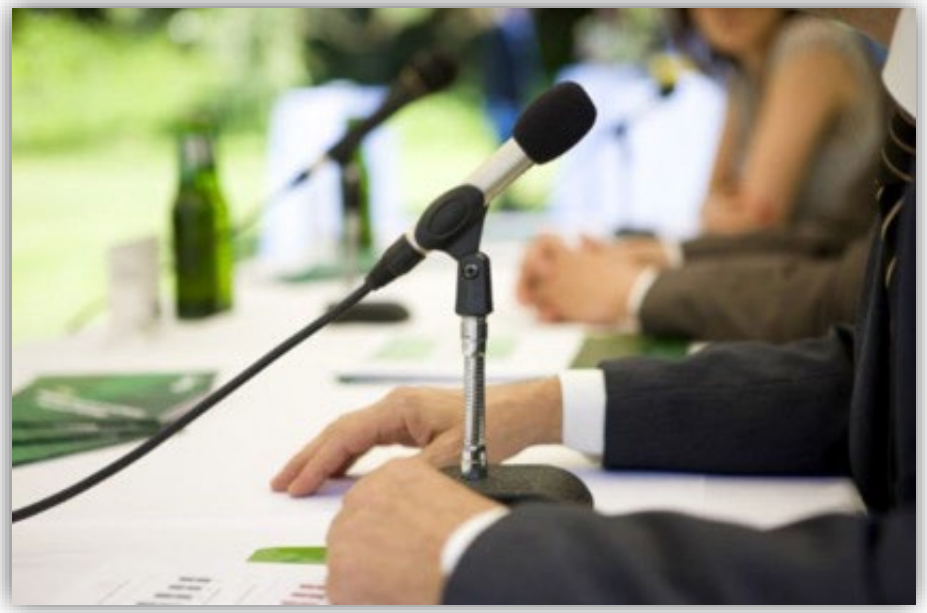
Reforms

- Themes Identified
- Why
- What has been accomplished
- Next steps

Recall Reforms Program

Themes identified

- Information flow inefficiencies
- Difficulty at times identifying the precise product being recalled
- Duplication of effort
- Unclear roles and responsibilities
- Complexity of communication pathways across supply chains
- Difficulty reaching impacted customers
- Processes too manual



Recall Reforms… why?

1. **Address** the issues identified
2. Ensure clear and effective communication of safety related recall information for all stakeholders – and tailored appropriately
3. Faster responses to recall actions to further reduce the risk of consumer / patient harm

What have we done so far?

- Targeted workshops to understand concerns
  - Consumers and healthcare practitioners
  - State and territory governments
  - Industry
- Streamlined internal processes
  - All notifications to come
- New communication approach
  - targeted, early communication with specific patient/consumers/HCP on proposed recall actions
- Enhanced recalls analytics and data model
  - Internal workflow monitoring
  - reporting
- Minor updates to the URPTG
- Public consultation on proposed improvements

What did we hear in the workshops…

- Not enough information
- There is enough information, but it is too technical. Needs more plain language.
- Communication not always effective → Key message not reaching all end users
- Recall terminology overly-complex. Too many categories. Required actions not always clear
  - Simplify the process
  - Improve engagement with stakeholder groups
  - Increase communication channels to reach end users

The Discussion Paper – proposed solutions

Our five main themes were –

- Increasing awareness and understanding about recalls
- Improving communication
- Better recall descriptions
- Improving sponsor letters and other recall documents
- Reporting progress with a recall

70+ responses

A mix of industry, S&T governments, healthcare associations, and patient/consumer groups

Preliminary findings

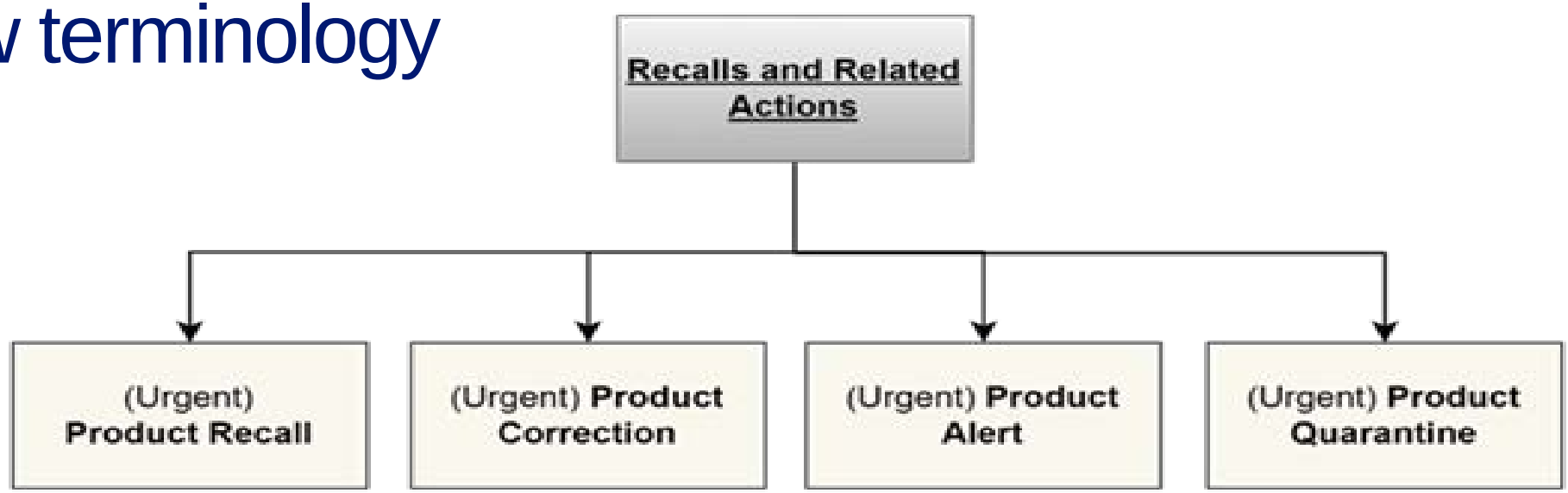
New recall terminology

- Very positive response
- 80% in support of change
- A few concerns about removing the ‘non recall’ pathway
- Confusion around ‘quarantine’ and ‘alert’ categories

Timing for TGA recall notices

- Feedback was fairly mixed - ~40% agree, 30% disagree and 30% ‘unsure’.

New terminology



Recall – ‘someone needs to **return/destroy** the product’

Product Correction – ‘someone needs to **correct/fix** the product’

Product Alert – ‘someone needs to **know something** about the product’

Quarantine – ‘someone needs to **stop supply and use** of the product, pending further advice.’

What are we doing next?

- **Reviewing and analysing all the responses to the Discussion Paper**
- Further engagement with some stakeholder groups
- Reviewing our legislative powers regarding mandating specific actions and complex supply chains
- Recalls education material
- Further updates to the URPTG

Website references

TGA website	www.tga.gov.au
The Uniform Recall Procedure for Therapeutic Goods – ‘URPTG	https://www.tga.gov.au/publication/uniform-recall-procedure-therapeutic-goods-urptg
TGA’s Guidance for requesting reconsideration of an initial decision (Guidance)	https://www.tga.gov.au/resources/resource/guidance/guidance-requesting-reconsideration-initial-decision

Therapeutic Goods Administration (TGA)

Exhibition booth **No.1**

Want to chat with me further? Come visit us.

Questions?

www.tga.gov.au

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration