MDSAP Transmittal Number: 2025-05

Transmittal Date: 2025/16/07

Title: Replacement of the Therapeutic Goods Administration (TGA) Uniform Recall Procedure for Therapeutic Goods (URPTG) with the Procedure for recalls, product alerts and product corrections (PRAC)

Purpose: From 5 March 2025, the TGA URPTG has been replaced by the PRAC. The PRAC is a guidance document, there have been no legislative changes. The process for Sponsors performing a market action remains largely the same. However, the introduction of the PRAC includes some key changes, including the following:

1. Updated Terminology and Simplified Categories:

- The PRAC replaces the categories of “recall” and “non-recall” actions with a single, unified term: “market actions”. See Diagram 1 below for a summary of terminology changes.
- The term “product defect correction” replaces the previous “product correction” for actions addressing specific deficiencies.

2. Streamlined Process:

- The recall process has been condensed from 10 steps to 5 steps, reducing administrative complexity. This streamlining is intended to make compliance more straightforward for manufacturers and Sponsors while maintaining public safety.
- The PRAC retains reforms from the final URPTG version (V2.4, March 2024), such as flexible reporting requirements and removal of the mandatory 2-week status update report.

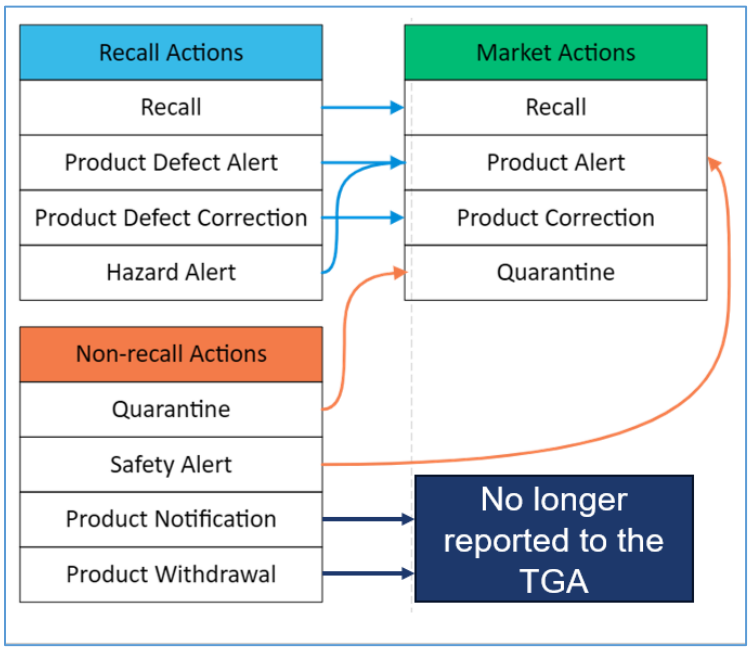
3. Enhanced Transparency and Tools:

- The PRAC introduces greater transparency in the “Early Advice” process, where manufacturers or Sponsors notify the TGA of potential issues. This includes clearer guidance on when to contact the TGA, especially for imminent or significant risks to public health.
- User-friendly templates are now available directly from the TGA website, replacing embedded templates in the URPTG.

4. IT System Enhancements:

- The TGA is upgrading its IT infrastructure, including the TBS Portal and the System for Australian Recall Actions (SARA), which will be renamed the Database for Recalls, Product Alerts and Product Corrections (DRAC) from March 2025.

Diagram 1 – Updated PRAC Terminology



Manufacturers retain responsibility to either report Market Actions directly to the TGA or to the Sponsor. The manufacturer needs to support the Sponsor to investigate, assess the risks and address problems with medical devices. The written agreement between the Sponsor and Manufacturer will define responsibilities.

Sponsors and manufacturers are expected to update internal procedures to align with PRAC requirements. For full details and access to PRAC documentation, please visit the TGA website.

The Audit Approach (MDSAP AU P0002) will be revised to change references from the URPTG to the PRAC, otherwise the content in Chapter 3, Task 12 and Chapter 4, Task 2 will not change. In addition, TGA regulatory training modules will be similarly revised.

If further clarification is required, please contact the TGA at mdsap@health.gov.au

Approver: RAC Chair, Tracey Duffy

Effective Date: 2025/16/07

Distribution: AOs, RAs, website

Action Requested: Update auditing procedures to verify manufacturers are aware of the new TGA PRAC

Issued by: Andrew Bathgate (APM)