Improvements to the Therapeutic Goods Recall Processes Discussion Paper

The Therapeutic Goods Administration (TGA) is the Australian Government authority responsible for evaluating, assessing and monitoring products that are defined as therapeutic goods. They regulate medicines, medical devices and biologicals to help Australians stay healthy and safe.

The TGA sought feedback on proposed changes to the therapeutic goods recall process.

Recalling medicines, medical devices and biologicals, when they are not fit for purpose, is the responsibility of the product's Sponsor. Under the Therapeutic Goods Act 1989 (the Act), the Sponsor is the person or company legally responsible for the product. However, before starting any recall action, the Sponsor should consult with the TGA for agreement on the type of recall and how it will occur. They should also tell the TGA how it is progressing and when it is complete.

In particular, the TGA asked for feedback across five themes with respect to the recall procedures detailed in the guidance document - the Uniform Recall Procedure for Therapeutic Goods (URPTG):

1. Increasing awareness and understanding about recalls

2. Improving communication

3. Better recall descriptions

4. Improving sponsor letters and other recall documents

5. Reporting progress with a recall

Cancer Council, the Clinical Oncology Society of Australia and the Medical Oncology Group of Australia, in a joint submission, provided support for the proposed changes, emphasising that the TGA needed to ensure that its improvements would provide sufficient, timely and audience appropriate information to health consumers, patients and health practitioners. This information is important to ensure that people with cancer and health practitioners can take appropriate action in response to recalls so that cancer treatment and recovery would experience minimal disruption.

Information about the progress of the consultation, can be found on the consultation's webpage.