

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Budget Estimates 2017 - 2018, 29 & 30 May 2017

Ref No: SQ17-000748

OUTCOME: 5 - Regulation, Safety and Protection

Topic: Valium Recall

Type of Question: Written Question on Notice

Senator: Watt, Murray

Question:

On the 26 May (TGA) issued a recall action for 5mg valium because of suspected tampering.

- a) Given the possible consequences of this, why was a media statement not issued until the 30th May?
- b) When was the TGA first notified by Roche that there was a tampering issue? Who was notified in the TGA? How were they notified?
- c) Did the Department undertake any public communications to alert the public to the recall, eg advertisements? Please give timing and placement of these activities. Why did this not happen immediately?

Answer:

- a) Upon notification from Roche on late afternoon Thursday 25 May 2017, the Therapeutic Goods Administration (TGA) immediately worked with Roche to set up a consumer level recall. As Valium is a prescription only medicine the most important people to notify in this process are the pharmacists who dispense the product. By evening Friday 26 May 2017, Roche had commenced notifying all pharmacies nationally, and had also referred the matter to the New South Wales Police by this time. Roche also set up a 1800 number to provide consumers with support and advice.

The TGA published a recall alert on the TGA website on the evening of 26 May 2017 which provided information about this issue to the community and the various email newsletters and magazines that pharmacists receive. Publicly available pharmacy publications ran this story over the weekend, as did Choice magazine.

The TGA media release was then issued after these key communications were in place.

- b) The TGA was first notified by Roche on 25 May 2017. Roche contacted Dr Jane Cook, Acting First Assistant Secretary, Medical Devices and Product Quality Division by telephone.

- c) The TGA did undertake public communications to alert the public to the recall. This was initially done by way of the recall alert statement published on the TGA's website on 26 May 2017. This was coordinated with the release of Roche's recall letters to pharmacies. This was followed up on Tuesday, 30 May 2017 with the TGA media release. The TGA also notified all state and territory recall coordinators of this recall action on Wednesday, 31 May 2017.

When such recall actions are necessary, the Australian sponsor also has an obligation to inform the public via the media. Roche, as the relevant sponsor of the Valium product, published advertisements in the major state and territory newspapers as part of the recall process.