Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Budget Estimates 2017 - 2018, 29 & 30 May 2017

Ref No: SQ17-000969

OUTCOME: 5 - Regulation, Safety and Protection

Topic: Prostheses - Heart Stent

Type of Question: Written Question on Notice

Senator: Griff, Stirling

Question:

a) What is the Department's role when a product has been found to have an increased risk compared to comparable products (with regards to withdrawing the product, issuing recalls if relevant, communicating with doctors and patients)?
b) Does it have a role in ensuring the manufacturer adequately communicates with doctors, and patients if applicable?

Answer:

a) Under the *Therapeutic Goods Act 1989* (the Act) Australian suppliers and manufacturers are required to report adverse events and other information that relates to any malfunction or deterioration in the device to the Therapeutic Goods Administration (TGA). The TGA risk assesses this information and probes additional sources of information such as other regulators databases and published literature.

The investigation may lead to several outcomes, including recall, and suspension and/or cancellation of the product entry on the Australian Register of Therapeutic Goods.

The TGA contacts other health and safety organisations and the state and territory health departments in ensuring that those affected by the issue are informed as soon as possible. The TGA can mandate cancellation of products from the Register using powers in the Act. These cancellations are published on the TGA's website.

The TGA also has the power to mandate a recall of product from service. However, the TGA's remit does not include informing patients directly or issuing the recall notice. The Australian supplier is responsible for notifying doctors, patients and those to whom they supplied the product. The TGA publishes information about these recalls on its website and notifies all State and Territory recall coordinators of the recall action. The public and healthcare professionals are also notified of actions taken via a Safety Alert or a Hazard Alert, which are both published on the TGA's website.

b) Yes, the TGA does have a role in ensuring the manufacturer adequately communicates the issue.

The manufacturer is responsible for ensuring that its instructions for use for the products they make are able to be followed by an appropriately qualified user. The TGA reviews instructions for use as part of pre-market assessment and may also do so as part of post market reviews.

Regarding actions such as a recall, the Australian supplier (sponsor) is responsible for contacting its customers to alert them of the situation and the removal of products from the shelf where applicable.

The TGA is responsible for regulating products from manufacturers and sponsors. It does not have any powers to regulate clinical practice. Therefore, the *Therapeutic Goods Act 1989* and associated regulations enables it to ensure that the Australian supplier informs its customers in the case of recalls. These customers may be doctors, health care facilities or patients. In the case of devices inserted in a patient at a hospital the customer is usually the hospital or the doctor. The hospital and/or doctor are advised to contact the patient where appropriate and provide follow-up care.