

**Senate Community Affairs Committee**

**ANSWERS TO ESTIMATES QUESTIONS ON NOTICE**

**HEALTH PORTFOLIO**

**Budget Estimates 2017 - 2018, 29 & 30 May 2017**

**Ref No:** SQ17-000967

**OUTCOME:** 5 - Regulation, Safety and Protection

**Topic:** Prostheses - Heart Stent

**Type of Question:** Written Question on Notice

**Senator:** Griff, Stirling

**Question:**

Why did the TGA wait for the manufacturer to voluntarily withdraw the product when the FDA became concerned 6 weeks prior?

**Answer:**

It is not correct that the Therapeutic Goods Administration (TGA) waited for the manufacturer to voluntarily withdraw the product.

- The TGA considered the Abbott Absorb Bioresorbable Vascular Scaffold at the 24 February 2017 Advisory Committee on Medical Devices (ACMD) meeting; where the higher than expected adverse event rates at three years were discussed.
- While the ACMD advice was being ratified, independently, the FDA on 18 March 2017 posted a safety alert on its website for the Abbott Absorb Bioresorbable Vascular Scaffold.
- Following ratification of the ACMD advice, the Australian Sponsor, Abbott Vascular Division of Abbott Australasia, on 22 March 2017 was presented with the ACMD advice showing concerns about the elevated adverse event rates.
- The TGA published an alert on its website on 27 March 2017 warning about the increased rate of major adverse cardiac events observed in patients receiving the Absorb BVS, when compared to patients treated with the approved metallic XIENCE drug-eluting stent also manufactured by Abbott.
- On 5 April 2017 the TGA informed the Sponsor that it intended to cancel the product from the Australian Register of Therapeutic Goods (ARTG).
- On 11 April 2017 the Sponsor requested the TGA certification for the Absorb BVS to be revoked and on 18 April 2017 the Absorb BVS was cancelled from the ARTG, preventing its further supply in the general population of Australia.
- On 21 April 2017 Abbott undertook a hospital level Class I recall for all unused stock of this device.
- On 1 June 2017 the FDA published the Australian recall on the FDA website.
- The FDA has not taken any further action on this product following the 18 March warning.