Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Budget Estimates 2017 - 2018, 29 & 30 May 2017

Ref No: SQ17-000963

OUTCOME: 5 - Regulation, Safety and Protection

Topic: Prostheses - Heart Stent

Type of Question: Written Question on Notice

Senator: Griff, Stirling

Question:

a) In March, the US FDA advised of increased risks of adverse cardiac events in people with the Absorb GT1 Bioresorbable Vascular Scaffold (BVS) by Abbott Vascular. Can the Department advise how many Australian patients have been implanted with this device?

b) Given a review of two year data shows a higher risk (11 percent vs 7.9 percent) of major adverse cardiac events for this device compared with the XIENCE stent, how many additional heart attacks are expected due to this device being implanted in the last 12 months?

Answer:

According to annual reports submitted by the sponsor, between 1 July 2014 and 30 June 2016, a total of 921 units of the Absorb BVS device were supplied in Australia (consisting of 475 in the first reporting year and 446 in the second reporting year). The device continued to be supplied up until its recall date of 21 April 2017. The Therapeutic Goods Administration (TGA) only has data regarding the number of devices supplied and not the number of patients on whom the devices were implanted. It is likely that this figure will be somewhat less than 921 as a proportion of the devices will not have been used.

The headline increased risk of 11 per cent vs 7.9 per cent refers to “target lesion failures”, which include but are not limited to acute myocardial infarctions. The precise pattern of use in Australia also affects the number of expected events observed for a host of patient factors and risk related to the vessel type in which this device has been used.