Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Budget Estimates 2017 - 2018, 29 & 30 May 2017

Ref No: SQ17-000965

OUTCOME: 5 - Regulation, Safety and Protection

Topic: Prostheses - Heart Stent

Type of Question: Written Question on Notice

Senator: Griff, Stirling

Question:

Did the *Absorb GT1 Bioresorbable Vascular Scaffold* device have two years of published peer reviewed results prior to being approved by the PLAC?

Answer:

The Prostheses List Advisory Committee (PLAC) has considered applications to list two of these types of devices:

- *Absorb Bioresorbable Vascular Scaffold; and*
- *Absorb GT1 Bioresorbable Vascular Scaffold*

These devices have two components – a bioresorbable vascular scaffold (stent) and a delivery system. The difference between the two devices is the delivery system. The bioresorbable vascular scaffold is the same.

The PLAC first considered the Absorb Bioresorbable Vascular Scaffold in 2011 and recommended on a number of occasions not to list the device until results from the pivotal Absorb III clinical trial were available.

In May 2016, the Cardiac Prostheses Clinical Advisory Group (a sub-committee of the PLAC) advised the PLAC that there was sufficient clinical evidence from the Absorb III clinical trial (including two years of follow-up data) to support listing the Absorb Bioresorbable Vascular Scaffold on the Prostheses List. The PLAC recommended to the Minister that the device should be listed on the Prostheses List on the basis of this advice.

On 9 December 2016 the PLAC considered the application to list the Absorb GT1 Bioresorbable Vascular Scaffold and advice from the Cardiac Prostheses Clinical Advisory Group that there was no change to the implanted stent for which two years of data was available – it was the same as that already listed as the Absorb Bioresorbable Vascular Scaffold - and there were minor changes only to the delivery catheter. The PLAC noted that the device had not been registered on the Australian Register of Therapeutic Goods (ARTG). The PLAC recommended that the device should be listed on the Prostheses List only after it was registered on the ARTG.