

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Supplementary Budget Estimates 2014 - 15, 25 February 2015

Ref No: SQ15-000155

OUTCOME: 7 - Health Infrastructure, Regulation, Safety and Quality

Topic: Joint Prosthesis on the Australian Market

Type of Question: Written Question on Notice

Senator: Xenophon, Nick

Question:

I note the TGA can cancel the Australian Register of Therapeutic Goods (ARTG) entry of hip prosthesis – does the TGA have the power to withdraw joint prostheses from the market for certain recipients – in this case the patient groups I have mentioned?

Answer:

The Therapeutic Goods Administration (TGA) can request the sponsor/manufacture to contraindicate the use of a particular implant for a particular group of patients or conditions. For example, ‘not to be used in people over 65’. This is reflected in the Instructions for Use associated with the prostheses. If the sponsor/manufacture refuses to accept the conditions, the TGA would need to consider whether the product must be cancelled from the Australian Register of Therapeutic Goods. If the sponsor complies, it is then up to surgeons to abide by the contraindications.