Question on notice no. 8

Portfolio question number: SQ19-000342

2019-20 Budget estimates

Community Affairs Committee, Health Portfolio

Senator Stirling Griff: asked the Department of Health on 5 April 2019—

Senator GRIFF: I've got five items and they can come back to us on notice. But I would just like to hear your view-again, these can be on notice, obviously-on will the TGA be making it mandatory for all long-term implanted devices to be reclassified as class 3 devices? That is a discussions we have had in the past with Professor Skerritt. Will the TGA require all class 3 devices to have two years published independent peer reviewed data to confirm the safety and effectiveness? Will manufacturers and importers of class 3 devices be required to maintain a register of individual patients who are implanted so that, if there are any recall issues, the patient and the hospital can be notified, which isn't currently the case? Does the TGA intend to revise the event reporting system to make reporting of adverse events and device failure mandatory for manufacturers and importers and device use facilities? And the last one: is it TGA's intention to make technical material provided to it by the application process publicly available and searchable so clinicians in particular and researchers can evaluate claims made by manufacturers and importers? If we could have those on notice, that would be fantastic.

Answer —

Please see the attached answer.

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Budget Estimates 2019 - 2020, 05 April 2019

Ref No: SQ19-000342

OUTCOME: 4 - Individual Health Benefits

Topic: Class 3 devices

Type of Question: Hansard Page 69, 10 April 2019

Senator: Stirling Griff

Question:

Senator GRIFF: Will the TGA be making it mandatory for all long-term implanted devices to be reclassified as class 3 devices? Will the TGA require all class 3 devices to have two years published independent peer reviewed data to confirm the safety and effectiveness? Will manufacturers and importers of class 3 devices be required to maintain a register of individual patients who are implanted so that, if there are any recall issues, the patient and the hospital can be notified, which isn't currently the case? Does the TGA intend to revise the event reporting system to make reporting of adverse events and device failure mandatory for manufacturers and importers and device use facilities? And the last one: is it TGA's intention to make technical material provided to it by the application process publicly available and searchable so clinicians in particular and researchers can evaluate claims made by manufacturers and importers?

Answer:

The majority of these devices are currently classified as Class III or Active Implantable Medical Devices and are regulated as the highest risk devices (e.g. joint replacements, surgical meshes, breast implants and pacemakers).

An Action Plan for Medical Devices, released on 4 April 2019, sets out the Therapeutic Goods Administration's (TGA) proposed consultation on whether to reclassify some other categories of devices where safety concerns have been identified, including spinal implants, to be regulated as high-risk. This consultation process has commenced. However it should be emphasised that decisions on device classification are made by Executive Council through regulatory change at the request of the Minister for Health, not TGA.

The current consultation does not propose to make it mandatory for all implantable devices to be reclassified to high-risk. For example, implantable devices such as some dental implants, wrist or ankle joint replacement implants, or ancillary devices, including screws and plates would retain their existing classifications.

The TGA accepts and reviews a wide variety of data in relation to applications for Class III medical devices as outlined in the *Clinical Evidence Guidelines: Medical Devices* (issued February 2017).

These Guidelines were published following consultation and sets out that the duration and kind of data supplied is determined on a case-by-case basis by suitably qualified clinicians and assessors depending on the device in question.

An Action Plan for Medical Devices, released on 4 April 2019, sets out the TGA proposal to consult on whether there should be greater levels of scrutiny of clinical evidence for certain groups of devices.

Although not mandatory, some medical device sponsors already maintain registers of patients who have Class III implantable medical devices (e.g. pacemakers) to assist with software upgrades and have already consulted on recall or safety notifications.

TGA has already consulted on the potential introduction of a Unique Device Identification (UDI) system. Specifically it will allow including device specific information into patients' records that should facilitate better traceability and patients' awareness of any issues related to their device. No decision has been made by Government as to whether or when to implement a UDI system.

The Department of Health has recently published (on behalf of the Council of Australian Governments) a consultation paper, *Maximising the Potential of Clinical Quality Registries* which proposes a systematic approach to registries for all medical interventions, including medical devices with a view to developing a National Policy and Funding Strategy.

During 2019-20, the TGA and Safer Care Victoria are co-leading an Australian Health Ministers Advisory Council project to identify enhanced information sharing between jurisdictions to improve TGA's knowledge of adverse events occurring in state and territory health facilities and for recall information to flow quicker to health facilities.

Whilst it is already mandatory for manufacturers and sponsors to report certain adverse events to the TGA, the number of adverse event reports is low. The TGA has already commenced exploring options to increase the volume and quality of reports it receives and enhance TGA's capability to detect signals of harm at earlier time-points.

An Action Plan for Medical Devices, released on 4 April 2019, sets out the proposal for the TGA to consult on a number of further options to strengthen the monitoring and follow up of devices already in use by patients. This includes consulting on whether it should be mandatory for healthcare facilities to report adverse events, whether to remove some existing exemptions to require more timely and improved reporting of adverse events by sponsors and manufacturers and whether the TGA should increase the frequency of inspections for certain devices and/or introduce onsite auditing of their reporting of adverse events.

Currently technical material is submitted to the TGA on a commercial-in-confidence basis and cannot be disclosed (unless consent is provided by the sponsor) as it contains material that is considered to be a trade secret.

An Action Plan for Medical Devices, released on 4 April 2019, sets out a proposal for the TGA to consult on a number of options to increase transparency of decisions, including to publish more information on how regulatory decisions are made for individual high-risk devices. This could include publishing clinical evidence, searchable incident reports, manufacturers' inspection reports and regulatory actions on individual devices.