UROLOGICAL SOCIETY
OF AUSTRALIA
AND NEW ZEALAND

20 December 2021

Ms Tracey Duffy
Medical Devices and Product Quality Division

[redacted]

Dear Tracey

Re: **Potential for Mandatory Reporting to the TGA of Medical Device Adverse Events by Healthcare Facilities**

Thank you for providing USANZ the opportunity to submit a response on mandatory reporting for adverse events related to medical devices. In principle USANZ supports this initiative, however a lot of questions in the survey can only be answered by healthcare facilities. In consultation with our Speciality Advisory Group leaders, we provide the following comments.

- Significant events or significant near misses that have or could have caused harm should be included.
- To capture all minor adverse events will overload the system and will probably then be ignored.
- It needs to be very "user friendly" and “time efficient”.
- *Not all device-related adverse events in patients are due to the device itself.* It may in fact be due to the patient’s constitution, surgeon technical expertise, degree of complexity of the case (e.g., first-time, re-do or multiple re-dos), and how patients are followed-up in the short and long term.
- Mandatory reporting of an adverse event by either sponsor, surgeon or healthcare facility, all the above *confounding factors* may be ‘lost in translation’.
- *Not all device-related adverse events are admitted to a healthcare facility*. Many may be managed outside this setting or not presented at all to doctors or allied health. Therefore, the true extent of the problem is still not known accurately although the more serious problems probably will be as they are more likely to present to a healthcare (HC) facility.
- A HC facility would only be able to do identify an adverse event if the doctor in-charge flags it. It is still ultimately up to the doctor to identify it to be reported. It should not be up to allied health, to make this decision.
- All cases which involve device-related adverse events *should ideally be discussed at a multi-discipline team (MDT) level.* There should be a consensus at an MDT level which flags the event to be reported by the HC facility. For example, the minutes of the MDT can be sent to hospital administration (such as a division of medicine or surgery) which can then be forwarded to the TGA.

By stating that adverse events should be reported by a HC facility to the TGA may not do justice to the device itself or the treating clinician. All the finer details and actual mechanisms by which to achieve this need to be clearly discussed and rationalised.

The above points would form a more appropriate framework by which to achieve this. Confounding factors such as those listed above should be included as accompanying information to each reported case as to be fair to both the product and surgeon involved, as some surgeons may have higher complication rates due to the complexity of cases which they are referred.

[redacted]

This should be a true reflection of the issues at hand. When constructed properly and with care, it will lead to quicker streamlining of the solutions for the problems identified.

Yours sincerely,

A/Prof Prem Rashid
President
Urological Society of Australia and New Zealand