RACGP
Royal Australian College *of* General Practitioners

Healthy Profession.
Healthy Australia.

16 December 2021

Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

[redacted]

Dear TGA Secretariat,

Re: Potential for Mandatory Reporting of Medical Device Adverse Events by Healthcare Facilities in Australia

The Royal Australian College of General Practitioners (RACGP) welcomes the opportunity to provide comments on the discussion paper for the Potential for Mandatory Reporting of Medical Device Adverse Events by Healthcare Facilities in Australia.

The RACGP supports adverse event reporting. This enables monitoring of product use, performance, and emerging safety and performance issues, which in turn, should enable the Therapeutic Goods Administration (TGA) to take appropriate regulatory action to address any issues. However, the RACGP understands the level of reporting by GPs is generally low, likely due to uncertainty around a GPs duty to report adverse events and the administrative processes required for reporting.

Existing barriers need to be addressed before reporting is made mandatory. We recommend improvements to a more structured voluntary reporting regime are put in place until issues, as outlined below, are addressed and we know the validity and value of the reporting process. Our feedback on processes and barriers are outlined below.

1. ***Platform for reporting***

- Reporting needs to be centralised and independent
- Reports should be able to be efficiently generated in minimum time and duplication of data entry should be minimised
- All healthcare professionals involved in the care of the patient should be notified of any reporting that occurs - the Senate Inquiry into Transvaginal Mesh made 13 recommendations and identified that patients expected their GP to be aware of the foreign device having been inserted and that GPs are aware of potential complications of such procedures.
- At the Senate Inquiry into Transvaginal Mesh there was also a strong consensus across all stakeholder groups for the need for the TGA to establish and maintain an Australian Unique Device Identification Database (AusUDID), which should be linked to the Australian Register of Therapeutic Goods (ARTG), as well as other databases
- Information sharing between different sectors of the health system should be secure, consistent, streamlined and traceable

2. ***Responsibilities for reporting***

- There needs to be clear responsibilities for reporting.
- Practice nurses and other members of the general practice healthcare team should be able to report on behalf of the GP
- In parallel to streamlined reporting mechanisms, Australia should work towards automated adverse event reporting through collection and analysis of de-identified but linked datasets which monitors for signals of particular harms following implantation or first use of the medicine or device. Proactively seeking possible problems, which was done via text messaging for the COVID-19 vaccination, might be a way to get early signals on device harms. This requires attention be given to privacy, data security and carefully constructed limits on what the data within an automated system can be used for.
- Adverse events should also be reported by those running clinical trials and all clinical trials should be registered to reveal publication bias. Promoters of products and procedures to MSAC and PBAC should be held to this standard for all evidence presented to support the product or procedure.

3. ***Barriers to reporting***

- Not knowing who should be reporting.
- Time and resourcing constraints - GPs need to determine the medical device that is causing harm and needs to be reported, know where to report, and complete a report.
- There are no incentives around reporting, and no feedback provided back to the GP on what actions, if any, were taken on submission of the report.
- When to report, especially when there is a suspected but unconfirmed harm from a medical device.
- Real-time access to content of what has been reported and by who, as well as where in the process the assessment has reached. This will also enable people to see if a report has already been lodged and will avoid duplication.
- Common or known harms with devices or medicines are rarely reported because the end user assumes everyone knows about the harm and there is little value in adding another report.

Education and resources are needed to support all medical practitioners, including GPs, in knowing when to report, especially for new medical devices. Consumer education, such as an information leaflet and definition of types of medical device-related incidents or events (provided at an appropriate health literacy level), should also be considered to raise awareness of risks.

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Thank you again for the opportunity to provide feedback on the discussion paper. For any enquiries regarding this letter, please contact Stephan Groombridge, eHealth and Quality Care Manager [redacted]

Yours sincerely

Dr Karen Price
President

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