15 December 2021

Therapeutic Goods Administration

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Dear colleagues

MIGA submission – Mandatory reporting of medical device adverse events

As a medical defence organisation and healthcare professional indemnity insurer, MIGA welcomes the opportunity to provide feedback to the TGA's discussion paper, *Potential for Mandatory Reporting of Medical Device Adverse Events by Healthcare Facilities in Australia.*

MIGA supports larger healthcare facilities being required to report medical device adverse events, but opposes such obligations being placed on individual doctors, other health professionals or smaller healthcare facilities, particularly general or specialist medical practices.

It acknowledges the imperative of early reporting of adverse events to ensure patient safety and the potential benefits of mandatory reporting by healthcare facilities identified in the discussion paper.

Reporting requirements should be confined to those facilities which

- Are registered / licensed as hospitals or day procedure centres / surgeries under state / territory legislation
- Other facilities accredited through national schemes which are frequent users of medical devices, such as diagnostic imaging and pathology services.

It is these facilities that are best placed to deal with the inevitable complexity and demands of a mandatory reporting regime, and which are most likely to see a range of adverse events.

Consistently with US and Canadian approaches, and the reality that individuals' reporting obligations in other countries are often dealt with by facilities, MIGA sees imposition of such obligations on individuals or smaller healthcare facilities as potentially being unduly burdensome, unhelpful and unnecessary.

MIGA has not encountered reluctance amongst doctors to report medical device adverse events. It suspects there is a lack of broader professional awareness of possible reporting mechanisms. Accordingly it would support further educational initiatives for the healthcare profession to encourage voluntary medical device adverse event reporting by individual doctors, professionals and smaller facilities.

If these approaches were found to be insufficient to ensure early reporting of medical device adverse events, further analysis and consultation could then be undertaken on what additional, targeted reporting obligations would be necessary to ensure appropriate early reporting.

Where possible, mandatory reporting criteria should be being consistent with existing hospital / day procedure centre incident reporting systems to reduce misunderstanding and maximise value of adverse event reporting generally.

Accountability for reporting medical device adverse events by certain facilities should adopt an 'education first' approach, ensuring awareness of reporting requirements, accompanied by other encouragement / incentives where appropriate.

Negative consequences, such as penalties or impacts on funding, for non-compliance with mandatory reporting obligations should only be considered as a last resort where 'positive' compliance efforts have failed.

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If you have any questions or would like to discuss, please contact Timothy Bowen, [redacted]

Yours sincerely

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