Australian Government

Department of Health and Aged Care

Deputy Secretary

Joanna Abhayaratna
Assistant Secretary
Office of Impact Analysis
Department of the Prime Minister and Cabinet
1 National Circuit
BARTON ACT 2600

Email: Helpdesk-OIA@pmc.gov.au

Dear Ms Abhayaratna

Impact Analysis – Introduction of mandatory reporting of medical device adverse events by healthcare facilities – Second Pass Final Assessment

I write in relation to the attached Impact Analysis (IA), prepared for the introduction of mandatory reporting of adverse events involving medical devices by healthcare facilities.

I acknowledge and thank you for your letter of 18 November 2024, and I am satisfied the IA addresses the concerns raised in your correspondence:

- the Regulatory Burden Estimate (RBE) has been revised and assumptions further justified, with the RBE formula updated and the costings table adjusted accordingly
- stronger reasoning has been applied in Question Two to address the need for government intervention and current barriers to voluntary reporting
- a summary of stakeholder views has been elaborated and how it has shaped the proposed options, and
- the multi-criteria analysis has been further expanded and includes detailed explanations and justifications for the weightings of the proposed options.

The IA includes a description of its status at each major decision point in the proposal's development. This has included an early assessment on 15 November 2022 and a First Pass IA, provided to the Government for consideration of the mandatory reporting scheme based on the options provided. It is anticipated that the final certified IA will support the Government's decision to introduce mandatory reporting of medical device adverse event by healthcare facilities.

Accordingly, I am satisfied the IA is consistent with the seven principles for Australian Government policy makers as specified in the *Australian Government Guide to Policy Impact Analysis*. I submit the IA to the Office of Impact Analysis for formal final assessment.

A further detailed description of the matters is in Attachment A.

Yours sincerely

Professor Anthony Lawler
Deputy Secretary
Health Products Regulation Group
6 February 2025

Phone: (02) 5132 6437 **Email:** anthony.lawler@health.gov.au
Gulgana Building, 27 Scherger Drive, Fairbairn ACT 2609 - PO Box 100 Woden ACT 2606 - **www.tga.gov.au**

Attachment A

Responses to OIA First Pass Assessment letter - Attachment A - Further advice – Proposal to introduce mandatory reporting of medical device adverse events by healthcare facilities:

General comments:
The executive summary should provide a summary of the response to all seven IA questions, including reporting the estimated regulatory burden under each option.

- All seven IA questions including the estimated regulatory burden for each option have now been summarised in the executive summary.

Question One: What is the policy problem you are trying to solve?
It would strengthen this section to discuss the impact of data gaps on certainty of the estimated costs and benefits in the IA. In particular, how does the lack of knowledge of level of underreporting affect understanding of the problem and impacts of the problem?

- Signals of issues relating to medical devices are not being received in a timely manner to enable to the TGA to take swift action to remediate the issue and mitigate the risk of patient harm
- The TGA is aware that a volume of medical device-related adverse events are unreported due to reporting by healthcare providers and facilities currently being voluntary in nature
- Underreporting of medical device related adverse events was identified in the Report from the *2017-2018 Senate Inquiry into transvaginal mesh implants and related matters* as an area of significant concern as the number of reported adverse events was substantially less than true number of complications experienced
- Healthcare facilities are a rich data source of health information in the Australian community, however only 4% of medical device adverse events reported to the TGA are provided from these settings. Adverse events are often not reported by consumers, health practitioners or healthcare facilities due to lack of awareness, perceived complexity of reporting process, or concerns about reputational impact
- Whilst reporting to the TGA is mandatory for sponsors of medical devices, and currently accounts for 92.3% of all reports, reporting from healthcare settings would enable signals to be detected earlier including during treatment. This is because often, medical device adverse events can take several years to present, with healthcare facilities often providing treatment before the TGA is made aware of an issue. This was confirmed during the *2017-2018 Senate Inquiry into transvaginal mesh implants and related matters* which found many patients had presented to healthcare facilities and undergone treatment without this having been formally reported.
- Question One of the IA has been revised and updated to include additional details and information on the limitations of the current data landscape for post-market adverse event monitoring in the absence of reporting from healthcare facilities.

- The TGA is an independent regulator, and whilst data from international regulators feeds into TGA's post market activities, the TGA uses this as one of many signals. There is an expectation that the Australian regulator undertake its own signal detection. For example, Australia was the first jurisdiction to undertake regulatory action related to urogynaecological mesh.

Question Two: What is the objective of Government action?
Provide further justification of the need for government intervention. What are some reasons that government intervention is necessary? What evidence is there to justify government intervention as the best way to address the problem? It is not clear on the current barrier to voluntary reporting and how these barriers cannot be overcome without government intervention. If there are alternatives to government intervention (for example, market incentives, sponsors/manufacturers collecting this information), these should be outlined along with any upsides or downsides to these alternatives.

- Government intervention is required to enact the legislative requirement for mandatory reporting of medical device adverse events by healthcare facilities.
- As reporting by healthcare facilities has existed only on a voluntary basis, adverse event data captured within hospital systems is infrequently reported to the TGA, with sponsor awareness of the event reliant upon identification by medical practitioners and patients.
- From 2015 to 2019, the TGA trialled the IRIS InSite voluntary reporting program, targeted at healthcare professionals, with the aim of increasing awareness of and improving reporting of medical device adverse events. Unfortunately, this program did not lead to a sustained increase in reporting levels. In considering the introduction of the mandatory reporting scheme, the TGA reviewed international approaches, particularly in jurisdictions including the United States of America and Canada, where mandatory reporting has resulted in more comprehensive data collection and increased reporting. As previous educational efforts and voluntary measures did not achieve the desired outcomes, and considering successful international models, regulatory intervention was deemed necessary to ensure consistent and reliable reporting practices.
- The government's primary objective in implementing mandatory reporting is to enhance patient safety, through earlier detection of medical device adverse events, and consequential risks arising from their use, in the Australian community. Through earlier intervention, this measure will assist with improving public health outcomes and reducing unnecessary healthcare interventions.
- On 21 March 2023 the *Therapeutic Goods Amendment (2022 Measures No. 1) Bill 2022* was passed, making it mandatory for Australian public and private hospitals and any other health facilities (prescribed by regulations) to report medical devices related adverse events to the TGA.
- Mandatory reporting by healthcare facilities seeks to address the issue of significant under-reporting. Underreporting occurs due to the current voluntary system of reporting for healthcare facilities, which has contributed to the delay in detection of long-term safety issues.

Phone: (02) 5132 6437 **Email:** anthony.lawler@health.gov.au
Gulgana Building, 27 Scherger Drive, Fairbairn ACT 2609 - PO Box 100 Woden ACT 2606 - **www.tga.gov.au**

- A formalised mandatory reporting system for sponsors and manufacturers was introduced by the TGA with the *Therapeutic Goods (Medical Devices) Regulations 2002.*
- The Senate Inquiry identified limited awareness amongst consumers and healthcare practitioners about adverse event reporting. Despite efforts to enhance voluntary reporting in other settings including education initiatives, a pilot program with voluntary participation from jurisdictions, and introduction of streamlined reporting tools, limited evidence of sustained improvements to medical device adverse event reporting remains an issue.
- Government intervention is required to enable rapid information sharing between health care facilities and the TGA to address safety concerns with medical devices.
- The IA has been revised to provide additional details and further clarify the barriers posed by the voluntary reporting system, the limitations of reliance on overseas data, and the rationale for transitioning to a mandatory reporting framework.
- The collection and centralised storage of national data are critical to the early identification of trends and empower informed decision making to undertake public health actions - the results of which aim to deliver beneficial and equitable health outcomes.

Describe barriers and constraints to government action, and actions to address.

- *For example, what if patients choose not to share this sensitive information with the TGA?*
- *This should include an analysis of the government capacity to successfully intervene, including any limitations in funding, skills and resources. If the number of reports made to the TGA increases drastically, will it have the resources to process these reports?*

- The primary barriers to government action are the current lack of awareness among healthcare professionals about reporting mechanisms and the difficulty in navigating complex reporting systems.
- The TGA has undertaken extensive consultation with all Australian jurisdictions, and private, and day hospitals on the upcoming mandate of reporting by healthcare facilities (outlined further within the Impact Assessment) which will be ongoing throughout implementation.
- No sensitive patient information will be handled by the TGA as the mandatory reporting scheme only requires deidentified data. This is an approach aligned with jurisdictional privacy laws and safeguards sensitive information, while enabling effective regulatory oversight.
- The implementation of mandatory reporting by healthcare facilities is expected to result in a significant increase in the number of reports received by the TGA, which will have downstream impacts on workload and resource demands. This will be managed through IT changes for data ingestion and streamlined reporting processes.

  As the scheme matures, it is expected much of the data transfer and analysis will be facilitated through automated gateways, significantly reducing manual efforts and minimising operational burden. These advancements will allow

the TGA to handle higher report volumes efficiently while maintaining high-quality data analysis and decision-making processes.
- The IA included details of the anticipated operational expenses for the TGA, accounting for the increased reporting volumes and implementation of modernised reporting systems.

Outline the problem/benefit with relying on overseas reporting on defective medical devices in lieu of domestic reporting (including the share of approved medical devices are unique to Australia).

- Countries like the USA and Canada have mandated that healthcare facilities report any adverse events that were potentially caused by medical devices. These mandates have led to an increase in reporting of adverse events and have enhanced the quality of reports submitted to regulators, particularly for specific medical devices that individual healthcare professionals might not have access to at the time of incident notification. They also provide healthcare facilities with greater flexibility in allocating resources to report adverse events and are less burdensome than requiring individual healthcare practitioners to report these events.
- Overseas reporting data, however, cannot directly inform the regulatory action within Australia and can only be used as supplementary source to enhance the TGA's signal detection capabilities. Australia is a small proportion of the global market, with global actions and signals assisting to provide early warnings of potential issues.
- Overseas reporting can be useful in detecting broader trends such as increased performance issues or adverse events associated with a particular category of devices.
- However, the TGA is limited in its regulatory jurisdiction and does not have the authority to act on events occurring outside of Australia.
- Regulatory actions in Australia must be based on domestic data and comply with the *Therapeutic Goods Act 1989*. Overseas reports may not align with Australian conditions due to differences in healthcare systems, patient populations, and regulatory frameworks. In addition, the international reports may relate to models of devices that are not supplied in Australia.

Question Three: Options
It would be helpful to discuss any discarded options.

- Discarded options are discussed in Questions Three, Four and Six of the IA.
- Additionally, a multi-criteria analysis (MCA) further elaborates on the rationale for the preferred option (i.e. Option 3A).

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Question Four: Impacts

Describe how this IA has used a multi-criteria analysis (MCA) as the key decision-rule to determine net benefit (i.e. what weightings have been used and how have they been applied?). The Department of Veteran's Affairs Veterans' Compensation and Rehabilitation Legislation Reform IA on the OIA's website is an example of a good practice multi-criteria analysis. Currently, the costs and benefits are laid out as a descriptive list, rather than in MCA format.

- An MCA methodology has been utilised to adequately analyse, assess, and recommend the most suitable policy option. For the purposes of this IA, each policy option, sub-option, and constituent measures, were assessed and ranked relative to each other on the following criteria: 1) Achievement of success; 2) Benefits and costs and 3) Regulatory burden.
- Consultations with key state and territory stakeholders informed the weightings allocated to each criterion listed in the MCA. A 40% weighting was allocated to the achievement of success criterion as a high value was placed on ensuring the policy option selected is facilitating achievement of the fundamental goals of the mandatory reporting framework: improved patient safety, timely identification of risks, and compliance with legislative requirements.
- The regulatory burden criterion was also weighted highly at 40%. Minimising regulatory burden is critical for practical implementation of and compliance with the scheme. Excessive burden could detract healthcare providers from time spent on the provision of clinical care and hinder operational efficiency leading to challenges in implementation and ongoing management of the scheme. A high weighting aligns with feedback from stakeholders who prioritised the need to balance reporting requirements with existing workloads and resources, particularly for smaller facilities such as day hospitals.
- A 20% weighting was applied to the overall benefit and cost across affected populations as it is deemed an important consideration but considered secondary to achieving success criteria. A lower weighting is considered appropriate because stakeholders recognised that initial costs might be high, but the longer-term benefits, such as improved healthcare outcomes, justify the investment.

It would strengthen this section to describe any distributional impacts. Information on this is available in the OIA's guidance note on distributional impacts. In particular, it would be helpful to discuss how the options may impact people with disability, women, people who are culturally and linguistically diverse, First Nations people, people and businesses in regional and remote areas compared to the rest of the population.

- Additional information has been included within the Impact Assessment discussing distributional impacts. The TGA is committed to strengthening Australia's post-market monitoring and compliance of medical devices to support the right of the Australian public to equitable and safe health care.
- Current data on medical device adverse events makes it difficult to determine whether mandatory reporting scheme will impact demographics, socioeconomic status, or organisational factors.

The scheme aims to improve safety for all patients, with no direct gender-specific impacts identified. Over time, data analysis may reveal any disproportionate impacts.

- The mandatory reporting scheme focuses on institutional compliance, with reporting being the responsibility of the chief executive officer, however described. No disproportionate workforce impacts are identified.

It would be helpful to clearly state which impacts have not been quantified and why they have not been quantified. What constraints are there on quantifying the impacts that have been described?

- Demographic, socioeconomic and organisational impacts have not been quantified due to unavailable data.
- The mandatory reporting scheme focuses on institutional compliance and improving patient safety, with no direct gender-specific impacts identified. However, data trend analysis over time may reveal device specific disproportionate impacts.

Regulatory Burden Estimate (RBE)

Please include a line in the IA alongside the RBE table stating "the preferred option will have a $X cost to public hospitals, as per figure 12. These costs have been excluded from the RBE calculation in alignment with the IA Framework which states only costs to individuals, businesses and community orgs are included in the RBE." in both the RBE in the IA and in the Second Pass certification letter.

- The IA has been updated to include the following line: "The preferred option will have a $1.66 million cost to public hospitals, as per figure 12. These costs have been excluded from the RBE calculation in alignment with the IA Framework which states only costs to individuals, businesses and community organisations are included in the RBE". This has also been added to the RBE in the IA.

Please show how the administration costs were calculated, as calculations by the OIA have resulted in different values using the inputs in Appendix B. In particular, the administration cost for the options with batch reporting was very different, and the OIA found this to be higher than on occurrence reporting in each instance.

- The RBE formula in Appendix B has been updated and the administrative and substantive cost calculation updated as a result. A summary table of the average annual regulatory costs for each option over the ten-year default period has been included in the IA describing how costs were calculated. Please refer to Appendix B of the IA.

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Please show how the administration costs were calculated, as calculations by the OIA have resulted in different values using the inputs in Appendix B. In particular, the administration cost for the options with batch reporting was very different, and the OIA found this to be higher than on occurrence reporting in each instance.

- The administrative costs for option 4A (batch reporting) have been updated to $1.86 million (from $1.77 million) and is now lower than the administrative costs for option 4B (on occurrence) which has been updated to $1.91 million (from $1.77 million). Please refer to Appendix B of the IA.

Please show how the compliance costs were calculated, as again the OIA found different values using the inputs in Appendix B.

- The substantive compliance costs for option 4A and 4B have been updated to $3.70 million (from $3.72 million). Please refer to Appendix B of the IA.

Justify all assumptions made in the calculation of the RBE. In particular, why are only 10,000 reports expected to be made per year by healthcare facilities when the data suggests a 10x increase in reports (i.e., what bodies are making the other 90,000 extra reports?)

- The RBE calculation and assumptions is based on the most comparable overseas data from Health Canada.
- Once the mandatory reporting scheme is implemented, healthcare facilities will be required to report medical device adverse events, alongside sponsors who are already mandated to do so. We expect to observe a similar trend to the Canadian data with a 10-fold reporting increase from both sponsors and healthcare facilities, which is based upon an assumption that only 10% of true figure of incidents are being currently reported (i.e. 10,000 reports).
- The assumed increase of approximately 90,000 additional reports are predicted to be submitted by medical device manufacturers and/or sponsors, which again is based upon comparable data from Canada.
- Details of the assumptions and calculations can be found in Appendix B of the IA.

Question Five: Consultation

Provide further description of areas of stakeholder agreement and disagreement, and an overview of the views of each stakeholder group. Did any particular group hold certain views, and were these different between different stakeholder groups?

- A high level of support has been received from stakeholders consulted by the TGA regarding the implementation of mandatory reporting of medical device adverse events by healthcare facilities. Stakeholder groups included healthcare organisations, CRAFT groups, healthcare practitioners, health funds, key state and territory health departments, Australian Commission on Safety and Quality in Health Care (the Commission), Australian Medical Association, Royal Australasian College of Medical Administrators, the private and day hospitals and peak bodies.

- Broad support was also received in earlier consultation activities including the 2021 public consultation of a discussion paper on the *Potential for Mandatory Reporting of Medical Device Adverse Events by Healthcare Facilities in Australia*, 6 roundtables held over 2023, and the 2024 establishment of an Interjurisdictional Steering Committee and Technical Working Group.
- Through consultation, concerns were raised about smaller facilities and their capacity to meet the mandatory reporting requirements, the potential burden and cost, data duplication and quality of data, and the requirement for additional information and education.
- The Interjurisdictional Steering Committee has been instrumental in developing a proposed approach to implementation which includes report centralisation by jurisdiction and the use of existing IT systems wherever possible. The Committee provided a valuable mechanism for jurisdictional education and dissemination of information.
- A detailed summary of the consultation feedback has been integrated into the IA.

Explain how the preferred option was shaped by stakeholder views, or why their views were not adopted.

- The preferred option, Option 3A, was informed by consultation with stakeholders in the Interjurisdictional Steering Committee and Technical Working Group. The feasibility for introducing this option in individual healthcare facilities was discussed over 11 meetings, with a view of balancing government objectives and regulatory burden.
- While there are varying preferences for either batch reporting or reporting on occasion, a batched format does not equate to less reporting as timeframes to report connected to the time an event occurred will apply.
- Some facilities raised the need to ensure appropriate implementation timeframes to enable IT systems to collect and transmit data, and for staff to be training in reporting requirements. A phased approach will provide for these concerns, whilst still ensuring the most serious adverse events are reported to the TGA first.

It would strengthen this section to include any limitations of the consultation process.

- The TGA undertook broad consultation on this measure along with further consultations with industry through forums including the Regulatory and Technical Consultative Forum for medical devices. While stakeholder concerns raised were previously identified, no substantial limitations of the consultation process have been identified.

It would be helpful to explain what the goals of consultation were regarding the scoping and design of the options and the understanding of the impacts of the options.

- The goals of the consultations were multifaceted. Consultation aimed to gain a clear understanding of what data is currently captured in the incident management systems of public and private healthcare facilities to identify

opportunities to build upon existing reporting practices and systems while determining areas requiring development to enable progressive roll out of the scheme. The consultation sought to identify legislative challenges related to privacy or data sharing and ensure that these considerations are factored into the design of the options and reporting requirements. The consultation's focus included education and building awareness to support successful implementation of the scheme. Lastly, consultation was critical to ensure alignment of the reporting framework with the Advisory and the National Safety and Quality Health Service (NSQHS) Standards, as this will ensure health facilities are prepared for accreditation by the Commission under the new reporting requirements.

- The development of options in the IA was deeply informed by stakeholder consultation through roundtables in 2023, jurisdictional steering committee and technical working group meetings in 2024.
- Each consultation provided insights to inform the development of options that balanced patient safety with practical implementation considerations for healthcare facilities and jurisdictions and its impact.
- The impacts of each policy option are detailed in Questions Three, Four and Six of the IA. These consultations will also feed into the development of the final Regulations to support implementation of the scheme as evidenced through the proposed approach to phased implementation.

Conclusion

Explain the decision-making process, including interim and final decision points and the status of the IA at each major decision point to inform decision-makers.

- Following the *2017-2018 Senate Inquiry into transvaginal mesh implants and related matters*, the TGA highlighted the need for rapid information sharing between jurisdictions, healthcare facilities and regulators about medical device safety and efficacy.
- In 2021, a public consultation with key Australian stakeholders, including representatives from each state and territory departments of health, the Commission, a range of healthcare organisations and some Organisation for Economic Co-operation and Development (OECD) health regulators.
- An early assessment IA was completed on 15 November 2022.
- In November 2024, the First Pass IA was provided to the Government for consideration of the mandatory reporting scheme, based on the options provided.
- It is anticipated the Second Pass IA will be submitted in early February 2025.

Discuss the reason why a small increase in regulatory burden ($50,000 difference between Option 3A and Option 3B) has been considered more important than a potentially large gain in timely data. How is this affected by potential changes to the regularity of batch reporting, noting that this has not yet been decided?

- The cost to implement Option 3A is $1.62 million and Option 3B is $1.67 million.

- As noted above, while there are varying preferences for either batch reporting or reporting on occasion, a batched format does not equate to less reporting as timeframes to report connected to the time an event occurred will apply. Option 3B introduces regulatory burden that is unlikely to lead to more timely intervention by the TGA. This is because the most serious adverse events will continue to be reported to the TGA through shorter timeframes.
- While $50,000 difference between Option 3A and Option 3B may appear to be a small increase, the proposed on-occurrence report submission frequency will impose a more significant regulatory burden on the reporting population, and disproportionately affect medical facilities with either limited resources, or much higher patient demand.

Implementation

Include the likelihood and consequences of implementation risks.

The likelihood and consequences of implementation risks have been considered in the IA. To address these, the IA includes practical mitigation strategies aimed at effectively managing and reducing their impact.

Evaluation

Identify expected timing for the evaluation, the evaluation processes (i.e. will there be public reporting and consultation) and if the evaluation will be used to determine updates/continuation of the mandate.

- The preferred option will be evaluated in line with the *Commonwealth Evaluation Policy.*
- Evaluation will monitor the extent to which legislative and regulatory requirements are met by healthcare facilities (i.e. public private and day hospitals).
- It will assess the responsiveness of the TGA to the receipt of additional reports and safety signals generated under the scheme, which will include timely acknowledgement, undertaking of safety actions, and outcome tracking.
- Evaluation will consider the effectiveness of feedback loops to healthcare facilities and industry, as this will support continuous improvement in reporting and safety practices for sponsors and manufacturers as well as healthcare facilities.
- Further details on the evaluation framework have been incorporated into the IA.

It would be helpful to consider any ethical or cultural considerations in the evaluation process.

- Option 3A will be evaluated in line with the *Commonwealth Evaluation Policy,* which include ethical and cultural considerations.

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