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Professor Anthony Lawler  
Deputy Secretary  
Health Products Regulation Group  
Department of Health and Aged Care

Dear Professor Anthony Lawler

### **Impact Analysis – Second Pass Final Assessment – Proposal to introduce mandatory reporting of medical device adverse events by healthcare facilities**

Thank you for your letter of 6 February 2025 submitting an Impact Analysis (IA) for formal Second Pass Final Assessment. I note the IA has been formally certified at the Deputy Secretary level consistent with the *Australian Government Guide to Policy Impact Analysis* (the Guide).

I appreciate the Department's constructive engagement on the IA. The Office of Impact Analysis' (OIA) assessment is that the quality of the analysis is Good Practice. The IA addresses the seven IA questions and follows an appropriate policy development process commensurate with the significance of the problem and magnitude of the proposed intervention. To be considered Exemplary as per the Guide, the IA would have benefitted from further detailed quantification of the likely costs and benefits and a more detailed evaluation plan.

The IA may now be provided to the decision-maker to inform their decision.

### **Next steps**

Ahead of the final decision being announced we would appreciate a copy of the IA in a form meeting the Government's web accessibility requirements. The OIA will then publish the IA, along with your certification, on the OIA's website at [oia.pmc.gov.au](http://oia.pmc.gov.au). The IA must also be included in any Explanatory Memorandum or Statement giving effect to the proposals in the IA, as stipulated in the User Guide to the Australian Government Guide to Policy Impact Analysis.

If you have any further queries, please do not hesitate to contact me.

Yours sincerely

Joanna Abhayaratna  
Executive Director | Office of Impact Analysis  
13 February 2025