**Response to:** ***The Trans-Tasman Early Warning System***

**Proposed by:** ***Australian Therapeutic Goods Administration & New Zealand Medsafe***

The Medical Technology Association of New Zealand (MTANZ) appreciates the opportunity to respond to the proposed "Trans-Tasman early warning system" and how the process will work in Australia and New Zealand. The purpose of this project between TGA and Medsafe is:

- *To establish a trans-Tasman early warning system for advising the public about potential safety concerns associated with medicines and medical devices*

MTANZ supports the intention of such a system to alert the public to potential safety concerns relating to medical devices and the creation of parallel communication systems for Australia and New Zealand that use the same process.

It is important that the public has confidence and trust in the safety of medical devices placed on the market and that they perform as intended by the manufacturer. Equally, it is important that the information placed on the respective regulators' public website is robust and presented in such a way that it does not result in ill-informed panic by the public.

Under the two different possible types of communication, monitoring communications and alert communications, the proposed engagement with the sponsor / manufacturer is limited. In both instances, the communication will only be to correct any factual inaccuracies. It should be a team effort to resolve any issues and the more constructive engagement with the sponsor / manufacturer, the better the presentation of the required information.

The document does not address the funding of the early warning system which will require considerable resource to ensure maintenance and accuracy. It will be assumed that in Australia the industry will be funding their system because the TGA is fully funded by industry. In New Zealand, it cannot be taken for granted that the industry will fully fund the system. This conversation has not been had yet and needs a principled basis review before any decision is made for funding the system.

The provision of an early warning system to alert the public and relevant stakeholders to the potential safety of a medicine or medical device is a "public good" and therefore, is a responsibility of central government to fund. The therapeutic product safety vigilance process is a required monitoring activity of the regulator and should be independent from the financial dependence on industry to avoid perceived conflict of interests. The regulator should ensure transparency and accountability for decisions relating to the information chosen to be posted on a public website.

The medical technology industry is keen to support a robust process for post-market vigilance and surveillance because the industry has a major responsibility to ensure the safety of their products placed on the market.

This response has been prepared by:

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