Feedback to survey regarding:

TGA - Proposed Application Audit Framework for Medical Devices

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I have read through the documentation regarding the proposed changes to the Audit Framework for Medical Devices within the TGA and its likely impact on sponsors, etc of medical devices.

As a sponsor of a Class 1 Medical Device that endured over 2 years of the TGA's post-market review process (essentially a Level 2 Audit), only to result in all TGA demands being dismissed as unnecessary; I believe I have some intimate and unique insight into the parallels to the pre-listing/approval audit process.

*There are a number of reasons a product may be selected for a **pre-market audit** or **post-market review** including, but not limited to, the following:*

- *Detection of a trend or signal amongst post-market data held by TGA or other regulators. This data can include, but is not limited to, adverse event reports, annual reporting, clinical publications, and device tracking registers.*
- *Information received from, or action taken by, other medical device regulators.*
- *Identification of a safety or performance issue for a similar device currently included in the ARTG.*
- *Unresolved or repeated recalls.*
- *Literature review of available clinical evidence.*

Both these forms of compliance checks share similar triggers, detail, structure (random or targeted) and processes; just instigated at different times in the listing approval/process; one before and one after market release. Regardless of the timing of these processes they are each used for compliance auditing. Although time consuming and resource heavy, an audit process (especially for higher-risk devices) prior to listing/ approval would seem a necessary and logical step.

However, in my case the none of these "reasons" were cited or used for the trigger for the review and false a series of statements were made concerning the nature, purpose, and rationale for the instigation of the review that were false and/or damning indictments of a failed system. Amongst these included that…

- "The review was not a "random" review".
- "The review was not a "targeted" review i.e. resulting from the criteria set out in the policy".
- "As the TGA had a right to conduct a review at any time, my role as a sponsor was just to comply and not question the reasons or detail".

The reality was that the trigger was the untested and unevidenced comments of a single journalist being fed highly speculative information from an internet troll concerning the LifeVac. The TGA then retrospectively attempted to produce reasons that fitted the criteria when questioned about the validity of the trigger.

If the TGA is to change the audit framework for Medical Devices and intends it to be more transparent and give sponsors clarity as to the value and rationale for audits (pre or post market), it needs to undergo some cultural improvements in its attitude to sponsors and commitment to honesty and procedural fairness. There are several flaws in the audit processes and even those suggested in this proposal that need to be addressed to make this process a value-add rather than simply a bureaucratic quota. These include:

a) There is no internal appeals process to question final determinations made by the TGA. The only appeal process is to the Federal Health Minister. Contrary to the statements made by the TGA in regard to fairness and adoption of the APS Code of Conduct, complaints and appeals to the TGA, Health Minister or even FOI requests about the conduct of individuals or their decisions go back to the defendant for investigation and a decision regarding the necessity for further investigation or action.
b) Despite many requests to meet with the TGA officers conducting the audit (that could have quickly and effectively resolved any issues raised), these requests were refused. A face-to-face meeting (that resolved all issues) was only requested by the TGA after directed by the Federal Health Minister as a result of a formal appeal request. This includes the inability to communicate directly with "clinical experts" and the ACMD on clinical matters of which the TGA compliance and regulation officers had little or no expertise. Nearly two years of correspondence and TGA time that could have been alleviated by the elimination of what we used to refer to as "Chinese Whispers".
c) The approach by TGA officers during this audit were purely adversarial. If the TGA wishes to work with sponsors, they need to develop relationships of trust and co-operation rather than relying on threats and mistrust to force process.
d) The TGA clearly does not have the expertise available on all subject matter on which to base their decisions, either at "clinical expert" level or "ACMD". On multiple occasions clinical errors and evidence issues (at both levels) needed to be challenged and corrected due to a lack of expertise on the subject or misreading of the evidence by individuals tasked with making determinations. This of course could only be done through non-clinical third parties managing the process, resulting in more delay and confusion. One early example was the recommendation by the initial "clinical expert" that the LifeVac presented an unacceptable risk to patients as it generated 300 psi of negative pressure in the airway. In fact, the device only produced up to 300mmHg. Needless to say, no clinician in the world would measure or refer to airway pressures in psi nor would they make such a fundamental misreading of the literature on which to base a decision. Similar difficulties were encounters when dealing with the ACMD who the review was referred to after multiple poor clinical understanding. However, at ACMD level it was clear that not only was there a lack of specific knowledge but that unevidenced speculations were a greater part of the recommendations that facts, science, or clinical acumen.
e) There is an inference in the proposed audit framework, that was also in evidence in my case i.e. that the determinations are always correct, accurate and evidence based. Given this assumption the proposed audit process merely deals with the sponsor compliance mechanisms. There is no doubt that if as a sponsor I had simply complied with the demands of the audit reports, this would have not been in the best interests of the public and would have resulted in the loss of life. This was recognised at the eventual face-to-face meeting with the TGA and the determination at that meeting to overturn these requirements has been proven to be correct, given the multiple lives our device has saved since, without any harm.
f) There is already a lack of transparency around the audit processes, and this includes the role and influence external sources have on the decision-making of the TGA and its committees. Input that may be motivated by self-interest or political imperatives, however accepted without scrutiny and undisclosed by the TGA in its deliberations and decision-making.
g) The value of pre or post market audit it supposed to be about the safety and efficacy of medical devices sold to the public. This must represent not just "compliance" but a value-add for sponsors and manufacturers. Despite an audit system, expert committees, appeals to the

minister and two years of effort the granting of an ARTG listing means absolutely nothing regarding the restriction of non-compliance medical device sales in Australia. In our case despite making constant reports since October 2022 of counterfeit LifeVac devices being openly advertised and sold in Australia without ARTG numbers, , the TGA has refused to act to enforce the legislation. The question is, if compliance with the legislation and the decisions of the TGA, initial and ongoing fees, meeting the essential requirements, evidence and risk assessments are so imperative for safety and legality, why is this meaningless for those outside the system?

To address the questions asked specifically (see below)

Consultation questions (consolidated)

1. Is there any additional information that the TGA could publish about the new application audit framework that would help with improving the quality of applications to support more timely inclusion of devices? Keep the TGA Compliance actions and outcomes databases online list up-to-date.

2. Are there any concerns with limiting mandatory audits to high-risk devices only, noting that the TGA may select any device for a non-mandatory audit if required? There are risks associated with this practice obviously, however audits should be based on sound risk management principles.

3. Are there any concerns with not subjecting high risk medical devices (including IVDs) supported by US FDA PMA certification to mandatory audits, noting that the TGA could select any such device for a non-mandatory audit if required? Harmonisation without the necessity to re-invent the wheel would be a much more cost and resource effective regime for the TGA and sponsors.

4. What are the merits or risks of establishing a pathway for Class III medical devices based on MDSAP certification and US FDA 510(k) approval?

5. Are there any concerns with formalising the requirement for the submission of:

(a) IFU and CER for all Class III devices supported by EU MDR certification?

(b) IFU and Performance evaluation (clinical and analytical) reports for all Class 4

IVDs supported by EU IVDR certification?

6. Do you have feedback about further measures to improve assessment timeframes?

7. What information could the TGA provide that would be useful for sponsors to have greater visibility of application timeframes?