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[redacted] response to the consultation "Proposed application audit framework for medical devices"

Consultation questions	Response
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?	Concerns: • If the devices are IVDR certified and TGA decides to not accept the clinical evidence this can be very problematic and disruptive to supplying devices to Australia. Establishing new clinical evidence is costly from a financial and time perspective. It is unlikely that an overseas manufacturer would perform any additional studies specifically for Australia when the device is supplied to the rest of the world. • The duration to get products to market can vary affecting the currency of the clinical evidence. The 2-year period may not always be achieved, and audit application times may extend up to 18 months. Typically, devices are planned to be released to the EU market first and it can take some time before release to Australia. Proposal: • Issue new guidance documents so manufacturers understand what acceptable clinical evidence is.
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?	No concerns, proposal is welcomed.
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?	No concerns, proposal is welcomed.
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?	No concerns, proposal is welcomed.
5. Are there any concerns with formalising the requirement for the submission of:	Concerns: • Potential for increased application time.

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(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?	• The EU notified body reviews clinical evidence and documents the outcome of its assessment in the performance evaluation report (Annex IX (QMS) Chapter II - Design examination) and this document must be provided with the ARTG application. Nonetheless, clinical, and analytical reports are available however the first concern raised in response to consultation question 1 is also relevant here.
6. Do you have feedback about further measures to improve assessment timeframes?	It is proposed that this requirement should only apply to repeated requests for information (of the same request). It must also be ensured that following the presentation of information from a sponsor, all information is reviewed and requests for information relating to the information presented is requested then and not in a later request for information.
7. What information could the TGA provide that would be useful for sponsors to have greater visibility of application timeframes?	It is proposed the following status updates and an approximate status time frame is provided for each application. For example: 1. Application pre-assessment (due by date x) 2. Request for information (due by date x) 3. Under review (due by date x) It would also be very helpful to know the current place in queue for each application. It is proposed that when a request for information is sent and the sponsor responds, the application is prioritized. Another proposal is to establish a sponsor queue for existing and new sponsors as preference should be given to sponsors with existing entries and a good track record offering an 'express lane' to ARTG inclusion.

Regards,

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