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From: [redacted]
Sent: Friday, 1 September 2023 7:15 PM
To: Device Reforms
Cc: [redacted]
Subject: [redacted] - Proposed application audit framework for medical devices v2.0 feedback

To Who it May Concern,

Consultation questions:

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?**
   A turn-around-time would be appreciated. (Even based on severity would be appreciated, i.e. Clinical review will take to 3 months etc., review of IFU will take one month)
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. This action is understandable, provided a timeline is mentioned for the manufacturers to have some expectation.
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. In addition to US FDA PMA, we would also like to suggest to include PMA from MDSAP countries and/or reference countries, such as EU/Canada/Japan/UK.
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?**
   Merits: Faster Access to Market. This would also allow time for the officers in charge to evaluate other devices that do not fall under this category.
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?**
   No. This action is understandable since the considered class is of the highest risk.
6. **Do you have feedback about further measures to improve assessment timeframes?**
   Turn-over-time would surely be appreciated.

   We've received an audit request for a **Class IIb** Medical Device. (Approved in EU/US)
   This application has been submitted for 1 year 3 months and the feedback we received so far are there are no specific timeline/ turn-around-time for such audit.

   In the duration of 1 year 3 months, we're given around 1 months to prepare and reply to each of TGA's additional request, to which we, as the sponsor and our manufacturer try our best and so far, has successfully met the deadline.
   However, we've received feedback that mentioned about 6-8 month's time to revert with the next response in consideration there is a queue for clinical evaluation.
   In addition to the 1 year 3 months, it would be around 1 year 9 months to maybe 2 years for an input request or the best-case scenario, an approval.

By introducing a turn-over time, for example, by end of the 12 months from submission, we can know if we need to re-submit/ or get an approval, would be more acceptable in our opinion.
A random audit that expanded to 1 year 3 months (and still unknown when will be approved, or worst-case scenario, rejected), unfortunately felt unfair to us, as we do not have any idea what is pending on top of not knowing when we can expect the next action.

In Singapore's case, they have the immediate route approval with specific conditions to be met (2 PMA from reference country/ 1 PMA from reference country (But need to be sold for 3 years in that country)).
They will have the application reviewed concurrently, but this enables the devices to be included in their system first and allow users to access said devices.
These kinds of routes could be considered for devices that are urgently required, and PMA by at least a reference country should also reflect the quality and safety of the device.

7. **What information could the TGA provide that would be useful for sponsors to have greater visibility of application timeframes?**
   The contact details of the officer/ department that is reviewing would be nice. Or the status of the application would also help.

Thank you.

Best Regards
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