From: [redacted]
Sent: Thursday, 10 August 2023 7:53 PM
To: Device Reforms
Cc: [redacted]
Subject: Written response to the application audit framework proposals for medical devices

Dear Device Reforms Department,

Thank you for providing us with the consultation paper on "Proposed application audit framework for medical devices". We truly appreciate the effort you've put into preparing this comprehensive paper and giving us the opportunity to give our feedback.

Please find below feedback regarding the proposals outlined in the paper:

Consultation question 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? The propositions made in the document are adequate and will improve the application audit framework.
An option would be to give the sponsor more opportunity during the preliminary assessment stage to clarify potential discrepancies such as clinical aspect to facilitate a more effective process without essentially going through an audit.
The purpose is to have more communication during this crucial phase (preliminary assessment), so that TGA has more evidence to decide whether or not to go ahead with an audit.

Consultation question 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 related to this proposal. This appears to be an appropriate approach.

Consultation question 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 about this proposal. We encourage to go ahead with this proposal. This appears to be an appropriate reform. We encourage efforts to implement this proposal.

Consultation question 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?
We support the idea of establishing a pathway for class III medical devices based on MDSAP certification and US FDA 510(k) approval. The merits seem to outweigh the risks, facilitating access to inclusion for these US FDA 510(k) approved class III medical devices. Non-mandatory audits can still be set up by the TGA. In addition, increased surveillance can be maintained for at least the first few years of market release.

Consultation question 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? This is a good proposal, IFU and CER are major documents to maintained and updated by the manufacturer, especially for class III medical devices.
(b) IFU and Performance evaluation (clinical and analytical) reports for all Class 4 IVDs supported by EU IVDR certification? N/A – No comments to submit for class 4 IVDs.

Consultation question 6

Do you have feedback about further measures to improve assessment timeframes?
To better leverage existing submissions and product approvals for the same product portfolio. The proposed audit workflow proposed in figure 8 is a significant improvement.

Consultation question 7

What information could the TGA provide that would be useful for sponsors to have greater visibility of application timeframes?
Level 2 audits can take a considerable amount of time, so it's vital to have visibility. For instance, to be able to log on the portal and have more details on the progress and status of the submission. Such as information on: at what stage the submission is, approximate time required, be able to schedule a call with the assessor, what documents are being reviewed …

Once again thank you for giving us the opportunity to contribute to the advancement of this initiative. Would it be possible to have a communication on the next steps related to this consultation ?
If these proposals are approved, what would be the estimated time required to implement them ?

If you need any further details, please feel free to reach out to me.

Best regards,
[redacted]

[redacted]