Australian Dental Industry Association

4 September 2023

Therapeutic Goods Administration
via email: devicereforms@tga.gov.au

Dear Therapeutic Goods Administration Medical Device Reforms team,

Re: Proposed application audit framework for medical devices

On behalf of the Australian Dental Industry Association (ADIA), we appreciate the opportunity to respond to the proposed application audit framework.

As the peak industry body representing suppliers, manufacturers and wholesalers to Australian oral health practitioners, ADIA's vision is for an industry that empowers oral health professionals to advance the health and wellbeing of all Australians.

We welcome the Therapeutic Goods Administration's commitment to a more responsive and risk-based approach to selecting applications for audit and a framework that allows regulatory effort to be streamlined. Through ongoing review and continuous improvement, the goal to reduce regulatory burden and cost, and provide the healthcare system with timely access to safe and effective technologies is aligned with our aim to enable improvements in the health and wellbeing of all people living in Australia.

Our responses to the consultation questions are provided. Please do not hesitate to contact us for further assistance.

Yours faithfully

[redacted]

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ADIA responses to the consultation on

Proposed application audit framework for medical devices

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?

ADIA believe that the identified risk factors that influence audit selection detailed by the TGA in this proposal are consistent with the expectation of Australian sponsors. However, clearer guidance from the TGA on specific details including documentation format, age of reports and other mandatory documentation requirements would assist in improving the quality of applications.

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?

ADIA notes that the current application audit process can take up to a year to be approved/or withdrawn. It is hoped that the proposal to reduce the types of medical devices requiring mandatory application audits will enable existing TGA resources to be used to reduce application audit times and focus on other audit types.

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?

ADIA welcomes the proposal to remove these high-risk medical device categories from the mandatory audits process in conjunction with the requirements outlined in Consultation Proposal 5.

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?

Establishing this pathway for Class III medical devices would be beneficial for Australian sponsors. It would provide additional pathways for registration and facilitate access to market, compared to the current TGA conformity assessment route.

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?

ADIA are not concerned with the proposal to require submission of IFU with Class III applications using EU MDR pathway, as this document would be publicly available. Australian sponsors should also have access or hold the CER on file. However, considerations around the size of the documents needing to be uploaded as a mandatory requirement through the TGA portal need to be taken into account.

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

ADIA notes that there does not seem to be a statutory timeframe for the completion of audit phases, nor for the TGA to assess responses. The queuing time prior to the assessment period is not specified and historically this has often been lengthy.

ADIA recommend that the TGA consider ways of limiting multiple rounds of questions that often arise from requests for additional detail in the technical file and supporting evidence. This commonly occurs as the TGA audit questions are very general and require further clarification. Providing more specific and clear questions would facilitate improvements in timeframes.

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

ADIA welcome the implementation of milestone tracking and predicted completion timeframes as a positive step in the process. The current system is still very unpredictable, particularly due to the additional queuing steps in the application audit process and evaluation steps. The queuing steps have not been quantified or given a maximum timeframe.

It is noted that the TGA has legislative requirements on the timeframe for sponsors to respond to requests from the TGA under S41FD of the Therapeutic Goods Act, but no timeframe for the TGA to complete assessment steps, aside from the mandatory timeframe for completion of applications within 255 working days.

It is hoped that the proposed changes provide the TGA with more predictability in the evaluation process and that with appropriate resourcing a commitment to more accurate timeframes for the audits phase can be made.