2 January 2024

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

Dear Therapeutic Goods Administration Medical Device Reforms team,

RE: Response to the consultation on the 'Proposed application audit framework for medical devices'

Dentsply Sirona appreciate the opportunity to respond to the consultation on the proposed application audit framework for medical devices. We welcome the TGA working towards a more streamlined, responsive and risk-based approach to application audits. Dentsply Sirona wish to highlight that to ensure Australia continues to attract innovative new products, the framework should ensure predictability in submission processing timelines, including defining response time for the TGA (which is currently lacking).

The detailed responses to each of the consultation questions is detailed below. The consultation question is presented in bold, with the response following.

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 identified risk factors that influence audit selection detailed by the TGA in this proposal are consistent with the expectation of Dentsply Sirona as an Australian sponsor. It will be important that the TGA do review and publish the updated risk factors every two years and provide clear communication on any additional ad-hoc reviews and updates as these occur.

As a Sponsor, Dentsply Sirona would also appreciate clearer published guidance from the TGA covering specific details on documentation requirements to support application audits- including documentation format, acceptable age of reports and any other mandatory requirements that support the efficient review process.

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?

Dentsply Sirona have no concerns with limiting mandatory audits to high-risk devices only. As the current application audit process can take up to a year to be approved/or withdrawn, Dentsply Sirona are hopeful that the proposal will enable existing TGA

resources to be used to reduce application audit times and therefore have a positive outcome.

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?

The proposal that Class III applications using US FDA PMA certification be removed from the mandatory audit process is welcomed by Dentsply Sirona.

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?

Dentsply Sirona see this is a positive proposal. Establishing a pathway using the MDSAP and US FDA 510K approval would be of benefit to Australian sponsors as this provides additional pathways for registration and potentially quicker access to market than the current TGA conformity assessment route. It is likely to involve the submission of additional documentation i.e. specific sections of the technical file like CER, IFU, labelling, risk management plan.

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?

Dentsply Sirona have no concerns with the proposal to require submission of IFU with Class III applications using the EU MDR pathway as this documentation would be publicly available. It is expected that Australian sponsors should have access or hold the CER on file. It is critical that the TGA give due consideration to the size of the documents able to be uploaded through the portal.

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

Dentsply Sirona note that there is no statutory timeframe for the TGA to complete the 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. The TGA has legislative requirements on the timeframe for sponsors to respond to requests from the TGA under S41FD of the Therapeutic Goods Act. The proposal has no timeframe for the TGA to complete assessment steps, aside from the mandatory timeframe for completion of applications within 255 working days. Assessment timeframes would be further improved with defined (legislated) timeframes for the TGA. This would also ensure the predictability with evaluation timeframes that has been requested by Sponsors.

Furthermore, Dentsply Sirona has noted that TGA audit questions can be very general and require further clarification. Dentsply Sirona recommend that the TGA consider 1) ways of limiting multiple rounds of questions that may arise (e.g. from requests for additional detail in the technical file and/or supporting evidence) and 2) providing more specific and clear questions.

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

Dentsply Sirona see the implementation of milestone tracking and predicted completion timeframes as a positive step in the process. The current system is very unpredictable, particularly due to the additional queuing steps in the application audit process, as well as inside the evaluation steps. Dentsply Sirona note that the queuing steps in the proposed framework have not been quantified or given a maximum timeframe. This should be established (as outlined above in response to Question 6). Providing an online tracking system that is easily accessible by the Sponsor and shows the progress of the application would provide appropriate visibility.

Should you have any further questions or need additional detail to clarify any of the responses outlined above, please do not hesitate to contact me for further assistance.

Yours sincerely

Dr Joanne Challinor-Rogers
Director of Quality Assurance and Regulatory Affairs