Response

BD greatly appreciates the opportunity to provide comments to the consultation "***Proposed application audit framework for medical devices***". Please see below our responses to the consultation questions.

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?

BD Response:

Below are our comments on proposals for publication of the risk factors.

- **Frequency of publication of risk factors:**
  In relation to publication of factors that may influence audit selection due to risk factors arising from regulatory intelligence and post market related activities, we recommend that this information be published to sponsors in a more dynamic/ timely manner instead of designated timelines (currently described as being every two years in the consultation). This timely update would enable the sponsors to be better prepared in terms of resources for addressing potential audit related queries and also enable more accurate prediction of timelines of approvals.

- **Risks relevant to the regulation and approval of the device:**
  TGA indicates that devices that are classified differently in Australia compared to other countries may be selected for a non-mandatory audit. We do not believe that this is a significant factor that should determine the need for a non-mandatory audit – especially for lower and medium risk class devices. Regardless of the difference in classification across various jurisdictions, as long the evidence of conformity supports the risk classification of the device in Australia, the application should not be subjected to any additional scrutiny.

- **Risks apparent from the quality of the clinical evidence:**
  Please refer to response to Question 5.

- **General Comments:**

  - Within the consultation TGA lists a number of 'additional documents' that may be requested by exception based on identified risks and the reason the application was selected for an audit for medical devices – such as sterility validation, biocompatibility and viral inactivation reports. Currently, the type of documentation request for a Level 2 audit for medical device applications is limited to the provision of the device IFU, labels, Clinical Evaluation Report (including Magnetic Resonance Safety assessment report), and Risk Assessment documentation. We request that any changes to the current audit framework should not result in the request for additional documentation such as those listed in the consultation paper, as this is not in alignment with TGA's overall intention to simplify the current process while

recognizing the assessments already undertaken as part of other comparator overseas regulator approvals.

- We strongly recommend that TGA provide a robust rationale for selection of certain types of devices and risk factors as sponsors should have visibility to the information that TGA uses to determine the risk factors.

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?

BD Response:

We have no concerns with limiting mandatory audits to high risk devices only.
In relation to the IVD medical devices that are being proposed to be removed from Regulation 5.3, we support TGA's proposal given that there is demonstrated data from the 12 years of mandatory audits on these types of IVDs and a well-established pathology base already in Australia, and hence we do not see there will be a negative impact by not auditing them further.

Within the category of IVD medical devices, we recommend removal of "*an IVD where the TGA is not satisfied that appropriate conformity assessment evidence is held to demonstrate that product assessment has taken place*" from the scope of Regulation 5.3. A device that does not have satisfactory evidence of conformity would not pass TGA's pre-liminary assessment and hence the application would not progress to the next stage. As such there is no value in including these devices within the scope of Regulation 5.3 for mandatory audits.

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?

BD Response:

We have no concerns in relation to not subjecting high risk medical devices supported by US FDA PMA certification to mandatory audits given the very high level of regulatory assessment undertaken by FDA for Pre-Market Approvals. As such we welcome this proposal. TGA however needs to clarify if this proposal will also include "specified medical devices" – i.e. those that contain medicines or materials of animal, microbial, recombinant or human origin.
Although already stated in the consultation, we wish to re-emphasise that applications supported by US FDA Supplements should also be treated in the same manner, provided the sponsor provides the evidence of the original PMA. Else this change in the regulation to exclude PMA supported applications from mandatory audits may not have a significant impact.

We also wish to take this opportunity to make the following recommendations:

- Explore the option of removing mandatory audits for medical devices applications supported by Japan's Ministry of Health, Labour and Welfare (MHLW)/PMDA Pre Market Shonin Approval Certificates in recognition of the extensive level of regulatory review and assessment undertaken by PMDA

- Explore the option of removing mandatory 'Technical File Review' audits for IVD applications supported by US FDA 510 (k) in recognition of the extensive assessment undertaken by FDA. TGA may instead limit the level of assessments a Level 1 audit

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?

BD Response:

BD welcomes TGA's intentions to enable pathways to utilise MDSAP certification and US FDA 510 (k) approval to support a Class III device application. Currently, a number of medical devices, including those that have a difference in risk classification between Europe and Australia are being subjected to TGA Conformity Assessment prior to being included on the ARTG for commercial supply. The extensive regulatory assessment fees and timelines involved with TGA Conformity Assessment applications may limit some sponsors from entering the Australian market for these types of devices. As such, if TGA proceeds with the proposal to enable the use of MDSAP Certification and US FDA 510 (k) to support a Class III ARTG inclusion application, this will enable timely access of these medical devices to Australian patients and consumers.

Additionally, we wish to emphasize that any additional assessments that TGA may undertake to fulfill the requirements of the Design Examination Procedures (under Clause 1.6 of Schedule 3, Part 1 of the Regulations 2002) for product assessment requirements should be limited to only those aspects and assessments that are not within the scope of FDA's 510 (k) assessment.

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? (b) IFU and Performance evaluation (clinical and analytical) reports for all Class 4 IVDs supported by EU IVDR certification?

BD Response:

In principle, BD does not see the provision of the Clinical Evaluation Reports and Instructions for Use (IFU) for all Class III medical device applications supported by MDR, and the provision of the IFU, clinical and analytical performance evaluation reports for Class 4 IVDs supported by EU IVDR certification to be onerous. However, this proposal raises concerns as discussed below:

- Given the extensive scrutiny that Notified Bodies are subjected to in order to be designated by an EU Member State, it would seem to be a deviation from global regulatory reliance for TGA to continue to select MDR/IVDR supported applications for a non-mandatory audit based on the quality of clinical evidence, given that this has already been reviewed and deemed to be acceptable by the Notified Bodies.
- Mandatory requests for the Clinical Evaluation Report would require completion of the pre-liminary assessment within the stipulated 20 days to determine whether the application would be selected for a non-mandatory audit, or not. Given the current backlogs in the TGA's clinical assessment sections, this could result in more applications being selected for the non-mandatory audit, than not, if the preliminary assessment is unable to be completed within the 20 days. The proposal raises similar concerns with the routine submission of clinical and analytical performance evaluation reports for Class 4 IVDs.

Question 6:

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

BD Response:

In order for TGA to pursue this proposal, the following will need to be actioned:

- Given that there may be a variance in the interpretation of "substantial round of questions" amongst the industry and the TGA assessors, TGA should establish a framework and lay out some guidance and definitions on this matter, to avoid, for instance a request for additional documentation (eg: for clarification purposes) as being considered a substantial round.
- Technical documentation submitted to TGA are those that have already been reviewed and accepted by other comparable overseas regulators such as the European Notified Bodies, FDA. The initial request for any technical documentation (either in the form of a Level 2 audit for medical devices or a Technical File Review for IVDs) that would be considered to be within the scope of the audit should be in the form of an S41FH request and should not considered to be 'Round 1" of "substantial review round" of questions (including any documentation that may need to be attached to the device application as per TGA proposal 5).
- There needs to be an opportunity to seek clarification from the reviewer without this being considered a substantial round via email or phone. Any minor clarifications sought by TGA should not be considered part of a "substantial round".
- TGA needs to provide more than the standard 20 working days to respond to a substantial round of questions.

Question 7:

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

BD Response:

Given that commercial launch plans are dependent on TGA approval timelines, sponsors may benefit from the following:

- Notification on whether the application has been selected nor a non-mandatory audit or not, at the end of the 20 days from date of submission.
- If the application is selected for a non-mandatory audit, sponsors need to be updated on when they may expect to receive Round 1 questions. Ideally this would be a regulated time frame.
- Once responses to Round 1 questions have been submitted, sponsors need to be informed as to when the responses will be reviewed by the assessors.
- Through the TGA Digital Transformation Project we envision to be able to self-serve and track details on the various states of the application online.