Balance Medical Response to: Proposed application audit framework for medical devices

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? **Ensuring clear requirements are published to enable sponsors to gather information prior to submission rather than wait for a request for further information to provide the information.**

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? **If applications for devices are supported by credible overseas regulatory approvals such as CE and FDA then there should be no concern with limiting mandatory audits to only the highest risk devices. Even within Class 3 devices there is a very broad spectrum of devices included and there should be further clarification and consideration of the risks that each contains. This would then identify Class 3 devices of low risk (for example those with an established history and less invasive) that may/should NOT require a mandatory audit, versus those that are more invasive and with a higher risk profile.**

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? Therapeutic Goods Administration Proposed application audit framework for medical devices V2.0 July 2023 Page 26 of 28. **As per my response to Question 2 above, as long as they are supported by credible overseas approvals such as US FDA PMA this should not present an issue.**

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? **The merits of this proposal include more timely assessments/decisions.**

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**

6. Do you have feedback about further measures to improve assessment timeframes? **Limit mandatory assessment to only those devices/IVDs of the highest risk.**

7. What information could the TGA provide that would be useful for sponsors to have greater visibility of application timeframe**? It would be beneficial to be able to have visibility of what part of the assessment process the application is in and expected time frames versus what we see at the moment which is "under review". Also, a contact person that you can reach out to during the process where appropriate or necessary as the general medical device helpdesk can only provide general information versus specifics on an application.**