Date: 4th September 2023

Consultation response - Proposed application audit framework for medical devices - Reckitt Benckiser

Dear Therapeutic Goods Administration,

Reckitt Benckiser is a global consumer health company and owner of well-known household brands such Nurofen, Strepsils, Dettol, and retail devices such condoms and personal lubricants under Durex and K-Y. Thank you for the opportunity to provide feedback on the proposed application audit framework for medical devices. Our comments are as follows:

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?

With regards to the currency of the clinical evidence (page 15), we suggest that it is appropriate that the clinical evaluation report is dated within 5 years, rather than 2 years as stated. The Regulatory strategy for ARTG inclusion is predominately reliant on EC certification and as such, it would take longer than 2 years before an application will be lodged in Australia. Our concern is that a 2 year period sets a cut-off for TGA assessors to unnecessarily target applications with a longer than 2 years clinical evidence file and delaying the route to market of new and innovative medical device technologies.

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?

Reckitt is supportive of this risk-based approach as it helps alleviate the resources constraints on the TGA whilst focusing resources where they are most appropriate.

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 as PMAs are already assessed by the FDA and the clinical evidence is deemed to be appropriate to support the safety and efficacy of high-risk devices.

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?

Reckitt is supportive of the single application pathway proposal for class III devices based on MDSAP and US FDA 510(k), but we urge the TGA to weigh up the benefits of diverting resources to set up a new process amidst MDR and UDI transitions, the merits would be insignificant if only a very small proportion of medical devices rely on this pathway to enter the Australian market (we understand that currently >95% of devices on the ARTG rely on the EC certification pathway).

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

Reckitt have no concerns with formalising the requirement to provide the IFU and CER in the application for all Class III devices and are pleased that current practices will be formalised to give greater transparency to Sponsors.

It is important that the submission of the CER is supported by the TGA digital transformation process so it is as easy and as efficient as possible for sponsors. CERs can be extremely large files and often not possible to be sent via email.

Consultation question 6

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

We very much welcome the flowchart on page 24 as it gives really clear steps in the workflow and expected timeframes at each step. We understand the need to limit the number of substantial rounds of review to reduce application queues and improve the quality of applications, however we also would like the TGA to ensure that the supporting documents such as cover letters, application dossiers are reviewed carefully so no new questions are introduced in the second round of substantial RFI which limits the opportunities for sponsors to provide a satisfactory response. This is especially critical for novel/breakthrough technology where both the sponsor and the TGA should be given the opportunity to learn and understand the new technology.

If within the system's capability, it would be beneficial to add the different stages of application in the TBS.

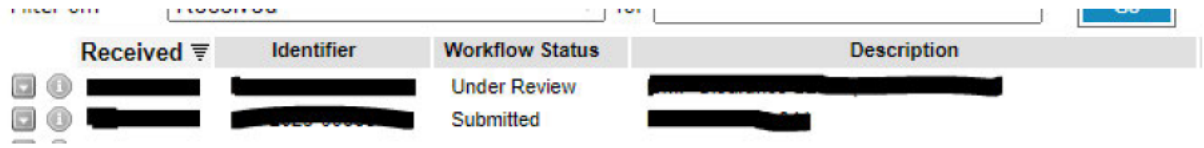
We would also like the TGA to provide guidance on the definition of "substantial review" as currently this is unclear.

Consultation question 7

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

Where an application is subject to an audit, it would be useful to understand the typical TGA timeframe for a response following provision of any additional information requested.

We also recommend adding the different stages of application in the sponsor TBS portal in the workflow status column within the Submission page, an example given in the pictured below:



if the workflow steps such as displayed in figure 8 could be included in TBS, this would allow sponsors to quickly identify at which stage of the review process their application is at, and allow regulatory professionals to provide timely business updates to inform product launch strategies and decisions.

Thank you once again for the opportunity to provide feedback on this consultation to help shape the regulatory landscape of medical devices in Australia.

Reckitt Benckiser