Wednesday, January 11, 2017

Director
Business Improvement and Support Section
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Director

IVD Australia Response to the Consultation: Accelerated Assessment of Medical Devices - Priority Review Pathway - Implementation

IVD Australia welcomes the opportunity to comment as part of the TGA consultation on the Accelerated Assessment of Medical Devices - Priority Review Pathway - Implementation.

While IVD Australia, in principle, supports a Priority Review pathway for new and novel devices for patients in immediate need there is some concern that this is a lot of effort for a very minimal number of devices which only require this pathway to be put in place due to the lengthy TGA timeframes with which all industry must contend. Industry as a whole would benefit more though addressing the intrinsic issues which surround the TGA assessment processes.

There is concern that a Priority Review program should truly only apply to novel devices which are meeting a critical clinical need. Commercial viability should not be a criteria for determining Priority Review. Time to market is important for all devices as industry seeks to continually improve the performance of devices and the quality of healthcare to consumers. This is particularly so for the IVD industry where assays are frequently being improved and modified.

'Time to market is critical to the success of many new products and has a major impact on the commercial viability of many new innovations'

Additionally, submissions being assessed as 'Business as Usual' (BAU) must not have adversely impacted approval times by those undergoing Priority Review as BAU submissions already often face unacceptably long approval timeframes.

Please find attached further comments.

Yours sincerely

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IVD Australia Comments
Accelerated Assessment of Medical Devices

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CURRENT ENVIRONMENT	
7	While IVD Australia, in principle, supports a Priority Review pathway for new and novel devices for patients in immediate need there is some concern that this is a lot of effort for a very minimal number of devices which only require this pathway to be put in place due to the lengthy TGA timeframes with which all industry must contend. Industry as a whole would benefit more though addressing the intrinsic issues which surround the TGA assessment processes. One of the major issues to consider is whether or not this pathway would be required once the Implementation of Recommendations Fifteen and Sixteen which are part of the consultation paper 'Designation of Australian conformity assessment bodies for medical devices'. Should this program be successful, manufacturers could access Australian conformity assessment certification for all devices in an acceptable timeframe. In addition, there is concern that a Priority Review program should truly only apply to novel devices which are meeting a critical clinical need. Commercial viability should not be a criteria for determining Priority Review. Time to market is important for all devices as industry seeks to continually improve the performance of devices and the quality of healthcare to consumers. This is particularly so for the IVD industry where assays are frequently being improved and modified. Based on the criteria for Priority Review, if the clinical need exists then priority is based on either the urgency of the need for the device, eg, an IVD test for a highly communicable life-threatening disease, or that a medical device will lead to significant improvement in quality of life or life expectancy. *'Time to market is critical to the success of many new products and has a major impact on the commercial viability of many new innovations'* Submissions being assessed as 'Business as Usual (BAU)' must not have adversely impacted approval times by those undergoing Priority Review as BAU submissions already often face unacceptably long approval timeframes.
PRINCIPLES AND CRITERIA	
9	IVD Australia agrees the criteria for restricting acceptance for Priority Review to the truly new or novel devices for patients in immediate need are acceptable. Further considerations should be: 1) If more than one manufacturer/sponsor comes forward to request Priority Review for a new or novel device does the TGA allow both to follow the Priority Review pathway?

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	2) What timeframe is acceptable to consider two new and novel products to be 'launched/available' at the same time so that both should be considered for Priority Review? 3) For IVDs ONLY, priority should not be only based on public health benefit. Early availability in Australia could result in a major public OR personal health benefit. For example, a pre-natal test to definitively rule out genetic predisposition to a condition leading to serious deterioration in quality of life at an early age could be deemed a critical clinical need. The estimated likelihood of making an application for a medical device to have priority review for the IVD industry would be low and/or infrequent in most cases. However, it is foreseeable that areas such as genetic testing and companion diagnostics, for example, may be more likely to access priority review.
PROPOSED IMPLEMENTATION OF PRIORITY REVIEW	
13	Implementation of priority review is acceptable to IVD Australia as outlined in the consultation paper. Areas requiring clarification are: 1) Devices designated for Priority Review which go to the front of the queue should not be placed ahead of submissions that are, say, 90% complete. Submissions at this stage of assessment which have gone through the 'Business as Usual' pathway will most likely have been under assessment for a lengthy period of time as it is. To further penalise these applications is unacceptable and would potentially lead the TGA to go beyond allowable timeframes, where these apply; for example, 255 working days for design examination. Also, as TGA themselves have stated, to pick up a submission after a lengthy break causes longer review times as the assessor must get back up to speed on the submission. 2) It is not clear that placing Priority Review applications at the front of the queue will guarantee ongoing prioritisation as the submission progresses through the assessment phase. Given '*Standard business as usual assessment requirements will be applied with no truncation or omission of assessment processes',* it is not clear how the submission stays in a priority pathway. Does prioritisation also include being placed at the top of the queue in areas which traditionally have bottlenecks, for example, Clinical Evaluation review. 3) If additional conditions are placed on the certification and our ARTG inclusion, by what process are these conditions ultimately removed, where applicable to do so? Does this follow the same process as any inclusion which has special conditions attached? 4) It is not clear why sponsors should *'provide for publication, consumer information about the product, such as description, its use and benefits'* for a healthcare professional only device, eg, the majority of IVDs. This requirement should not be universal and the requirement for this information should be determined as part of the conditions for approval.

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TGA OPERATIONAL IMPACTS	
16	The post-implementation review as outlined by TGA is acceptable to IVD Australia, in particular application and assessment fees which both discourage wholesale application and reflect the level of resources required to implement this pathway such that it does not adversely impact 'Business as usual' applications. IVD Australia assumes that under the Priority Review pathway most assessments would be at the full scheduled fee or above given the nature of the products being accepted under the scheme. The post-implementation review should include the criteria outlined by the TGA but should be comprehensive in reviewing all aspects of the implementation. In particular, the impact on 'Business as Usual' assessments MUST be analysed to ensure that the majority of industry is not adversely impacted for the commercial advantage of a few. The timeframe for review should be 2 years to: a) Allow time for applications under the Priority Review pathway to be received and processed by TGA. b) To ensure the process is reviewed early enough to prevent major backlogs, and/or allow inequalities or other problems to be detected and rectified as quickly as possible.