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Pathology Technology Australia

Response to TGA IVD Companion Diagnostics (CDx) version updated 1.3 March 2024

17 June 2024

The members of Pathology Technology Australia (PTA) appreciate the opportunity to comment on the TGA IVD Companion Diagnostic (CDx). Members have provided feedback and responses below are a summary of this feedback.

PTA response

As per our previous review of the previous rendition of this document in December 2023, feedback from members has been consistent in the uniformly positive review of this guidance, with good detail and well written from both the medicine/biological and CDx perspective.

As members had reviewed in detail previously, there has not been a significant increase in additional comments. However, I have provided a summary of these comments below.

CDx testing Identification guide. Figure 1.

On review of Figure 1, members have indicated there appears to be an assumption that applicants will have a detailed understanding of the standard of care or testing in Australia. For overseas manufacturers this may be difficult to determine. There is a footnote to contact TGA if there are questions or concerns. Members have suggested inclusion of examples to clarify this point.

Additionally, it may be worth providing additional information on pre-submission meetings at this point, as it may be more effective for sponsors to prepare for a presubmission meeting, rather than multiple informal contacts with TGA, when better efficiency may be gained with one meeting. Note: Suggest using the updated reference of Regulatory Engagement meetings to align with the recent rebranding, (if the proposal has been accepted) which may avoid confusion in the future with new sponsors.

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Abridged evaluations and overseas evidence.

A minor observation was made that this header should be changed to include CDx IVD to ensure clarity to the reader that it applies to the CDx product only. e.g **Abridged evaluation and overseas evidence for CDx IVDs**.

TGA CDx list

The inclusion of the link to this document, is welcome and members are in agreement to the usefulness of this list.

What do device sponsors need to do?

This section is straightforward and provides good detail on the information that needs to be provided with the CDx application. It was deemed that it may be more appropriate to move the abridged evaluations and overseas section to this area, so new sponsors can be clear that if they have overseas evidence, they may not be required to submit all this information in their initial application. PTA would be in favour of moving these details to this section.

PTA summary

As mentioned, our previous review was quiet in depth, and it is validating to see updates and previous feedback has been incorporated into this draft. PTA are grateful to have the opportunity to provide final feedback on this updated draft and apart from the minor clarification and suggestions detailed in this response, members continue to be supportive of the detail and content in this document.

As always, PTA recognises all the work the TGA have contributed to this updated draft and welcome continual collaboration between TGA and the IVD Industry.

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