AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

Dr John Skerritt
National Manager
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

12 June 2013

Dear Dr Skerritt,

Thank you for the opportunity to comment on the proposal paper on the *Proposed amendments to the new regulatory framework for In Vitro Diagnostic medical devices (IVDs).*

AusBiotech is a well-connected network of over 3,000 members in the life sciences, including therapeutics, medical technology (devices and diagnostics), food technology and agricultural, environmental and industrial biotechnology sectors; working on behalf of members for more than 25 years to provide representation to promote the global growth of Australian biotechnology.

Specifically, AusBiotech would like to make the following comments:

Issue 1: Timeframe for valid applications for inclusion in the ARTG
AusBiotech considers that ***Proposal 1A: A staged transition to the new IVD framework*** is reasonable and appropriate. Specifically we make the following points:

- Although the four year transition period would appear to be sufficient to ensure that manufacturers obtain conformity assessment certificates for their Class 4 IVD products, in practice this has not been the case.
- AusBiotech understands that there is a backlog of conformity assessments that are currently under review by the TGA and there is some concern from industry that the TGA will not be able to complete the assessments by the June 2014 deadline, potentially leading to disruption to supply of Class 4 IVDs.
- The proposal to change the June 2014 requirement for Class 4 IVDs from a valid inclusion application to a valid TGA conformity assessment application is supported. It is considered that this will provide sufficient time for industry to submit valid applications.
- The revised deadline of June 2015 for a valid inclusion application for Class4 IVDs is also supported on the provision that the TGA ensures sufficient resources are available for the appropriate completion of all conformity assessments that are submitted by the June 2014 deadline, prior to this deadline.
- AusBiotech considers that if the revised deadline is adopted then industry should not be charged annual fees until the June 2015 deadline for Class 2 and 3 IVDs manufactured in Australia and all Class 4 inclusion entries. This will ensure that manufacturers/sponsors who have submitted valid inclusion applications by the original deadline are not penalised by this change in timelines.

AusBiotech do not support Proposal 1B: ***retain existing timeframes for transition to new regulatory framework.***

Issue 2: Regulatory Requirements for Class 4 In-House IVDs

AusBiotech considers that Proposal 2A, ***a modified conformity assessment procedure for the regulation of Class 4 in-house IVDs predicated on commercial IVDs*** is a reasonable compromise between protecting patient safety by ensuring high quality IVDs and practical challenges presented by some relatively low volume tests such as those which use cadaveric samples.

AusBiotech believe these critical IVDs should be subject to the same level of premarket review to ensure that they have appropriate performance and quality, regardless of whether they are manufactured by a commercial manufacturer or in-house by a medical testing laboratory.

However, the points raised in the consultation document regarding in-house IVDs that are predicated on commercial IVDs are valid. Namely:

•It would generally be difficult for a laboratory to supply complete manufacturing information for an in-house IVD based on a commercial IVD, even though such information would have already been reviewed if the commercial IVD is included on the ARTG, and

•where a commercial IVD has already been reviewed before being placed on the ARTG it does not make sense to re-review this complete set of data when a minor change has been made in-house.

If such a provision is adopted generally there would be strong disincentive for commercial manufacturers (including in-house IVD manufacturers) to develop and commit the resources required to validate Class 4 IVDs for supplemental donor screening because laboratories could simply adapt in-house a Class 3 IVD for donor screening. Therefore, further consideration regarding the implementation of this proposal is required to ensure that a loophole is not created that exempts high risk assays from the requisite regulatory review.

AusBiotech believes that Proposal 2B**: *A modified conformity assessment procedure for the regulation of all Class 4 in-house IVDs*** is not appropriate as the proposal would:

- Implement a two-tiered system for ensuring the quality and performance of these critical IVDs depending whether they are manufactured in-house or by a commercial manufacturer.
- AusBiotech have concerns that GMP and/or NATA auditors will not have sufficient resources to ensure that Class 4 in-house IVDs are manufactured and validated appropriately. A design examination and quality management system assessment require over a year for the TGA to perform. It is unclear how such a rigorous assessment can be compressed into a two or even four day GMP/NATA audit. Such reduced assessment of the product would provide less assurance that these critical IVDs are appropriate for patient safety.
- Reduce transparency for all stakeholders because in-house IVDs would not be required to be entered on the ARTG. This is especially pertinent given that it is likely that the reasoning underlying TGA decisions regarding conformity assessments and inclusion applications will be published in the future. Patients and end-user could potentially have no information on why an in-house Class 4 IVD is considered to be safe and effective compared to a published decision for a commercial IVD.
- Be a significant disincentive for commercial manufacturers to develop Class 4 IVDs for the Australian market because of much greater regulatory burden and fees compared to in-house manufacturers.

Issue 3: Performance Evaluations for Design Examinations

The potential benefit of conducting practical laboratory testing with Australian samples and under Australian conditions to confirm the manufacturer's intended purpose and claims appears largely redundant given the requirement for the manufacturer to provide data that is representative of performance in the Australian population.

Essential principle 15(1) states that "*An IVD medical device must be designed and manufactured in a way in which the analytical and clinical characteristics support the intended use, based on appropriate scientific and technical methods.*"

An applicant must already provide data supporting compliance with this essential principle i.e. the applicant must demonstrate that an IVD's analytical and clinical characteristics are appropriate for its intended use in the Australian population. The proposed ad-hoc performance evaluations for Class 4 IVDs encompass a much wider range of IVDs than the HIV and HCV IVDs which were previously subject to performance evaluations. The introduction of such evaluations would:

- Add a level of uncertainty into the timeline and requirements for approval. In some cases product will need to be supplied for the performance evaluation and the conformity assessment would take additional time,potentially up to a year, to be completed
- Add to the TGA's costs which would in turn need to be recovered from industry, potentially in the form of higher fees. Conformity assessment fees for Class 4 IVDs in Australia are already very high in comparison to the size of Australia's IVD market.

It is considered that these factors would be a substantial disincentive for Class 4 IVDs to bring innovative products to Australia. The requirement for performance evaluations also has the potential to delay approval of latest healthcare technology by up to a year while the evaluation is performed.

However, if performance evaluations are considered necessary then explicit guidelines on which products would be subject to a performance evaluation would need to be developed in consultation with industry. Such guidelines would be essential to provide industry with a degree of certainty regarding approval timelines and requirements.

It is noted that the current suggestions of the products that would be subject to performance evaluations e.g. products using a new technology, a new IVD used to detect a serious infectious disease, are skewed against innovative products. The criteria for conducting performance evaluations needs to be carefully considered so that manufacturers of innovative healthcare technology are not deterred from the Australian market so as not to restrict access of the Australian population to such innovation.

Included in the scope of the guidelines should be the option for the manufacturer to conduct their own studies to generate the evidence of the performance of the product with samples representative of the Australian population and/or under Australian conditions. Such studies could potentially be expediently performed by the manufacturer, reducing the time to market, and the burden on the TGA and improving access to the latest innovation, without compromising the integrity of the data used to validate the performance of the product in the Australian population.

Issue 4: Regulation of tests for predisposition or susceptibility to disease
This proposal would provide an appropriate and clear pathway for the regulation of such tests.
The proposal to amend the definition of a medical device to include predisposition and susceptibility tests is considered reasonable.

Yours sincerely

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