IVD AUSTRALIA

Office of Device Authorisation,
Therapeutic Goods Administration
PO Box 100,
Woden, ACT, 2606

**Re: Discussion Paper on "Reforms in the Medical Devices Regulatory Framework"**

Please find attached IVD Australia's Response to the Discussion Paper: ***Reforms in the Medical Devices Regulatory Framework.***

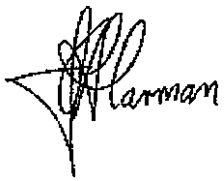
IVD Australia understands the desire of the Health Technology Assessment Review to ensure that the TGA continues to ensure that medical devices supplied to the Australian market are manufactured under appropriate quality procedures and are safe and effective to use.

However in attempting to develop proposals that meet the requirements of Recommendation 8 of the HTA Assessment Review IVD Australia is concerned that the TGA has created a number of issues that will impact on the cost imposed on sponsors and that are in conflict with already agreed conditions on the inclusion of IVDs on the ARTG. Despite these concerns IVD Australia looks forward to working with the TGA and the Office of Device Authorisations to develop a consistent and even handed result.

We would also urge the TGA to consider more centrally located venues for these type of consultation presentations in future. It is appreciated that the consultation discussions were arranged at short notice but the Melbourne presentation for example was held in a facility that meant that almost every attendee apart from the TGA staff had to drive over 50km each way. IVD Australia would be happy to offer its advice on suitable locations should further consultation be required on this or other proposals for reform.

Please contact the undersigned if there are further questions regarding this Response.

Yours sincerely,



Dr Peter Harman,
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17th December 2010

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IVD AUSTRALIA

Submission in response to the

# *Reforms in the Medical Devices Regulatory Framework*

Discussion Paper

December 2010

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# EXECUTIVE SUMMARY AND RECOMMENDATIONS

IVD Australia makes the following comments and recommendations regarding the Proposals put forward by the TGA in its Discussion Paper "Reforms in the Medical Devices Regulatory Framework".

We look forward to further discussion on the Proposals as is mooted in the Discussion Paper on Page 6.

**Proposal 1 - Reclassification of joint replacement implants**

IVD Australia has no comment to offer on this Proposal.

**Proposal 2A - Use of third party assessment bodies for Australian manufacturers**

IVD Australia is supportive of this Proposal.

**Proposal 2B(i) - Devices requiring a TGA Conformity Assessment Certificate to be issued**

IVD Australia has no specific comments on this proposal.

**Proposal 2B(ii) - Applications to be selected for auditing**

IVD Australia has no specific comments on this proposal.

**Proposal 2C(i) - Confidence building for EU Notified Bodies designated under the MRA**

IVD Australia is supportive of this proposal in principle but does not support the option that the TGA proposed for giving greater weight to EC certificates issued by Notified Bodies that have undergone confidence building. IVD Australia also;

- Recommends that any changes to the MRA with Europe in respect to IVD medical devices not be made until the introduction of the revised European IVD Framework

**Proposal 2C(ii) - Recognising Australian third part assessment bodies**

IVD Australia is supportive in principle of this proposal but would seek additional detail on exactly how it is proposed to determine appropriate third party assessment bodies and whether they will be required to have a physical presence in Australia

**Proposal 3(i) - Amend the way in which a kind of device is included on the ARTG**

IVD Australia understands that the TGA believes that there is a need for this proposal but has a number of recommendations regarding its implementation. Specifically, IVD Australia;

- Recommends inclusion of IVD medical devices be at the "family" level for Class 1 and 2 IVDs;

- Recommends that notification of changes to product details as proposed be available via the eBS and that such notifications not incur a charge. Notification of changes to product details should only be required on an annual basis for IVD medical devices;

- Recommends that the process of Variation of Inclusion only be used for substantial change to an Inclusion; and

- Recommends that the transition period for this proposal be set at 3 years (concluding on June 30th 2014) for IVD medical devices;

**Proposal 3(ii) - Enhance the ability to identify devices that have been approved by the TGA for supply in Australia**

IVD Australia is strongly opposed to any changes to sponsor labelling beyond those currently required under Regulation 10.2 and Essential Principle 13.2. IVD Australia however;

- Recommends that the ARTG be modified to enable publically accessible searching by MANUFACTURER in order to enable the easy identification by consumers and healthcare professionals of sponsors' details;

- Recommends that the TGA undertake a Cost Impact Assessment of the effect of any changes before implementation; and

- Recommends that Proposal 3(ii) not be proceeded with if Proposal 3(i) is adopted (with the changes recommended above).

**Proposal 4 - Publication of device product information on the TGA website**

IVD Australia cannot support this proposal at its present level of development. We believe that much more detail is required on exactly what material is to be incorporated onto the ARTG, how it is to be initially entered and how and by whom it is to be updated. Specifically, IVD Australia would like to undertake further consultation regarding the proposal before it can agree to additional IVD information being included on the ARTG;

At this time however IVD Australia;

- Recommends that only successful applications for ARTG inclusion of IVD medical devices that have undergone an mandatory application audit should have any information regarding the product incorporated on the ARTG; and

- Recommends that rejected applications for inclusion of IVD medical devices not be reported on the ARTG.

# IVD AUSTRALIA RESPONSE TO THE DISCUSSION PAPER ON "REFORMS IN THE MEDICAL DEVICES REGULATORY FRAMEWORK"

IVD Australia is pleased to participate in the Consultation process for the TGA's Paper regarding the proposed Reforms in the Medical Devices Regulatory Framework.

IVD Australia is the Association representing Australian sponsors and manufacturers of *in vitro* diagnostics (in Australia).

*In vitro*, literally "*in glass*" diagnostics (IVD's) comprises the instruments and reagents that are used to perform pathology tests requested by General Practioners or specialist Physicians. These are generally performed in accredited Public and Private pathology laboratories across Australia, but IVD's also include over-the-counter tests such as blood glucose meters for diabetes testing and home pregnancy test kits. Supply of these products is regulated for the Government by the Therapeutic Goods Administration.

These tests influence over 80% of the medical decisions taken in respect of a patient's health and often comprise over 75% of a patient's health record. However in terms of cost they generally represent less than 10% of a patient's overall healthcare cost.

IVD Australia was formed in July 2009 and currently represents 60 multinational companies, local distributors and Australian manufacturers of IVDs. Our members supply products valued at over $780,000,000 representing in excess of 90% of all IVDs sold in Australia. They employ over 2000 people across Australia.

Almost all of the IVDs used in Australia are imported and conversely, a large percentage of the IVDs manufactured in Australia are exported. Hence any proposed changes in regulation by the TGA must take account of these market realities.

IVD Australia has been strongly supportive of the Office of Device Authorisation and its predecessor, the Office of Devices, Blood and Tissues, in their efforts to build a harmonised framework for the regulation of Medical Devices and IVDs. This is an important step towards enabling the global IVD industry to begin to operate in a harmonised regulatory environment, a crucial step towards reducing global regulatory burden, and a means of enabling patients to gain faster access to the latest healthcare technology.

The proposed Reforms raise a number of important points for discussion, and we welcome those that lead to this harmonised framework.

It is prudent when discussing important reforms such as these that we fully consider the context in which they will be applied. The Australian market for IVDs (as well as medical devices in general) represents less than 2% of the world market for these products. IVD Australia would be concerned at any reforms that introduce "Australian specific" changes that would then potentially become barriers to entry of IVD products into Australia.

The recent introduction of the IVD Regulations means that IVDs are in fact more "up-to-date" with their regulatory framework than other medical devices. IVD Australia expects that the TGA will abide by agreements reached during the negotiations on the IVD Regulations that may be affected by changes implemented as part of these proposed reforms.

Prior to commenting on each Proposal specifically, we would like to offer the following general comments on the Discussion Paper and subsequent Consultation Meetings;

A) Medical Devices Predominately Affected - IVD Australia considers that these proposals were developed principally with Medical Devices in mind and that a number are specifically not applicable to IVD medical devices. Where we believe that IVDs are unaffected by the changes IVD Australia has made little or no comment on the Proposal .

B) Consultation Process - IVD Australia commends the TGA for this early stage consultation that has given us the opportunity to comment on possible directions before TGA decides on items and develops detail accordingly. IVD Australia also appreciates and supports the TGA's intention to continue to work with stakeholders in formulating the final direction of these reforms.

   Whilst IVD Australia understands that the "Caretaker" provisions around the 2010 Federal election resulted in considerable delay in the reform process coming out of the HTA Review, we are concerned that this has resulted in an unnecessarily abbreviated consultation process. The Discussion Paper was released on 25th October and distributed on 2nd November with less than 2 weeks' notice of the Consultation Meetings and less than 4 weeks available for comments to be made following the Consultation meetings. This has necessarily meant a rushed response and has not, for example, provided sufficient time for a cost impact analysis to be made by sponsors of these proposals.

   Clearly the importance of these proposals to IVD sponsors was evident from the number of questions regarding IVDs at the Consultation Meetings, but it was clear that a number were disappointed at the level of detail presented. In order to address sponsors' concerns regarding lack of detail, we would suggest in future the TGA highlights the intentions behind the lack of detail so that it makes it easy for people to understand why more detail hasn't been provided. In a number of cases it was acknowledged by the TGA that further work would be required to develop the detail. However without clarification regarding the TGA's intentions it is difficult for IVD sponsors and manufacturers to understand the full ramifications of the Proposals and to respond appropriately.

C) Justification for Changes - IVD Australia would suggest that in some cases there is not substantive justification for the changes proposed. The TGA should be undertaking regulatory modification only where there is justifiable reason for change and where there will be significant benefit to health sector consumers and/or sponsors or manufacturers. IVD Australia is concerned that a number of the Reform proposals are justified using outdated data (i.e. Notified Body inconsistency derives from 2002 reports) and concerns about the TGA's review of products from a sector of the community that does not have detailed knowledge of the process.

Some of the changes that are proposed will have significant impacts on sponsors in terms of financial cost or in terms of overhead costs such as staff time and delays to including product on the ARTG. IVD Australia seeks a Cost Recovery Impact Statement on these Proposals to ensure that unnecessary costs are not imposed on the Medical Device sector.

D) IVDs are not medicines - while IVDs can be generally regulated in a similar manner as medical devices, they are inherently different to both medical devices and medicines. IVDs require separate consideration, and this has been taken into account in previous negotiations with TGA on the regulation of IVDs. For example, the number of configurations of IVDs and the unique packaging and shipping/storage conditions required have a significant impact on how labelling must be managed..

   Adoption of processes relevant to medicines should only be considered where there is a true benefit to medical device users. IVD Australia has consistently said that IVDs possess characteristics that mean they demand separate consideration. These differences have been recognised by the Regulations generally permitting IVDs be grouped as a "kind of medical device", even at the Class 4 level for immunohaematology IVDs. They often are supplied in a substantial number of variants and are generally packaged in a different way to other medical devices or medicines.

IVD Australia is surprised that there are several misleading statements in the Proposal document. For example on Page 9 in the 4th paragraph it indicates that "a suitable technical file must be maintained by the manufacturer for Class I medical devices and Class 1 IVDs". A Technical File is compiled if and only if it is required and does not need to be "maintained". What is required to be maintained is the Technical Documentation that supports compliance with the Essential Principles.

IVD Australia again however thanks the TGA for the opportunity to participate in the Reform process. We look forward to the ongoing discussions foreshadowed in the Discussion document and at the Consultation Meetings. We assure the TGA of our willingness to participate as necessary to achieve a workable set of reforms.

# REFORM PROPOSALS

## Proposal 1 - Reclassification of Joint Replacement Implants

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| 1. | **Reclassification of joint replacement implants**<br><br>A new classification rule is added to schedule 2 of the medical device Regulations to reclassify all hip, knee and shoulder joint replacement implants from Class IIb to Class III medical devices. |

Given that this proposal refers specifically to the reclassification of joint replacement implants IVD Australia has no specific comment to make.

## Proposal 2 - Third Party Assessment Bodies and Supporting Reforms:

IVD Australia is concerned that the TGA has determined that these three proposals regarding third party conformity assessment are to be considered and adopted as a single package of reforms. It is not clear why the TGA believes that this is necessary and no cogent reason is advanced as to why this should be done. Given that several of the proposals are intended to apply only to specific classes of implantable medical devices and not to IVD medical devices, it makes no sense from the IVD perspective to have them all linked together and considered only as a "package" of reforms.

IVD Australia is broadly supportive of those proposals as presented which impact on IVD medical devices. We acknowledge the lack of detail regarding a number of them. We have a keen interest in future developing consultation on these matters and note that that our support is conditional on favourable outcomes during these ensuing consultations.

## Proposal 2A - Use of third party assessment bodies for Australian manufacturers

**2A. Use of third party assessment bodies for Australian manufacturers**

That Subregulation 4.1(1) is removed from the medical device Regulations, so as to no longer require Australian medical device manufacturers to hold TGA conformity assessment certification.

Members of IVD Australia welcome this proposed change in the conformity assessment process for Australian manufacturers. This has been supported for a considerable time by industry and by IVD Australia as a means of leveling the playing field for Australian IVD manufacturers. A number of members of IVD Australia contributed to the development of the earlier MTAA position on third party conformity assessment and we are pleased that the proposals from that consultation have been taken into consideration.

IVD Australia is of the opinion that this proposal has the potential to save considerable time and money for Australian IVD manufacturers. It provides Australian manufacturers with a choice of conformity assessment pathways that is commensurate with those available to overseas manufacturers.

However it is imperative that Proposal 2C also be carefully examined to ensure that the full benefits of third party conformity assessment are realised, and indeed do meet the needs of IVD manufacturers.

## Proposal 2B - Increasing pre-market scrutiny for implantable medical devices

**2B. Increasing pre-market scrutiny for implantable medical devices**

**(i) Devices requiring a TGA Conformity Assessment Certificate to be issued**

Subregulation 4.1(2) of the medical device Regulations be amended to require a TGA conformity assessment certificate to also be issued for all Class III and AIMD implantable medical devices.

**(ii) Applications to be selected for auditing**

Regulation 5.3 of the medical device Regulations be amended to require applications for all Class IIb implantable devices to also be selected for an application audit prior to inclusion in the ARTG.

## Proposal 2B(i) - Devices requiring a TGA Conformity Assessment Certificate to be issued

Given that this proposal refers specifically to implantable Class III and AIMD Medical devices only IVD Australia has no specific comments to make.

## Proposal 2B(ii) - Applications to be selected for auditing

Given that this proposal refers to implantable Class IIb medical devices only IVD Australia has no specific comments to make.

In respect of both these Proposals (2B(i & ii)) however, IVD Australia would remind the TGA that specific agreement was reached in the negotiations for the IVD framework that clearly set out the requirements for application audits and conformity assessment, particularly for IVDs at the Class 3 and Class 4 levels. IVD Australia would be strongly opposed to any proposals from the TGA that would mean increased regulation of IVDs within the current framework, or changes to the classification of IVDs.

## Proposal 2C - Recognition of third party assessment bodies

**2C. Recognition of third party assessment bodies**

**(i) Confidence building for EU Notified Bodies designated under the MRA**

That the TGA commence discussions with the EC over a program of confidence building with the designated Notified Bodies under the MRA, which might include sharing of product assessments and observed audits of medical device manufacturers.

**(ii) Recognising Australian third party assessment bodies**

That further consultation be undertaken to investigate the development of a system whereby Australian based assessment bodies can be designated to issue conformity assessment certificates to Australian manufacturers.

## Proposal 2C (i) - Confidence building for EU Notified Bodies designated under the MRA

IVD Australia recognises the need for confidence building between the TGA and overseas notified bodies to enhance the ability of sponsors to use overseas certification. We understand that if the use of third party assessment bodies is to expand, the TGA does need to increase its level of confidence in certificates issued by third party assessment bodies.

IVD Australia does not support the notion that, after the confidence building is undertaken, the TGA would universally give greater weight to EC Certificates issued by Notified Bodies that have undergone confidence building. We are concerned, as set out in the Options for this Proposal, this will mean that European manufacturers will be required to have their EC Certificates issued by a Notified Body specifically designated under the Mutual Recognition Agreement (MRA) in order for them to be accepted in Australia, regardless of the Class or type of product they manufacture.

IVD Australia is opposed to the option put forward that ALL applications supported by non-MRA Notified Body certificates undergo a mandatory application audit. This would clearly result in increased costs to sponsors as it would mean that many Class 2 and Class 3 products under the IVD regulations would require a mandatory application audit. The issue of acceptable Manufacturers Evidence (ME) was a major negotiation point in the development of the IVD Regulations, and IVD Australia is strongly opposed to further changes at this time.

IVD Australia is also concerned that the Proposal will potentially exclude without discretion high quality Notified Bodies that chose not to sign up for the MRA initially. Australia is a very small market and it may not be seen to be worthwhile to pursue Australia-specific capabilities. The Proposal as put forward would exclude such Notified Bodies.

As the TGA is aware very few IVDs under the IVD Directive are required to have assessment performed by Notified Bodies and hence many manufacturers choose ISO Certification Bodies that are not Notified Bodies.

IVD Australia also reminds the TGA that the current MRA is not an MRA for *in vitro* diagnostics and at present has no applicability, and would need significant amendment to include IVDs. The EU Commission is currently commencing review of the IVD Directive but it is anticipated that this may take until 2015 at least before this is completed. IVD Australia recommends that any changes to the MRA in respect of IVDs needs to wait until this is completed.

## Proposal 2C (ii) - Recognising Australian third party assessment bodies

IVD Australia is supportive in principle of the proposal to designate Australian assessment bodies as competent to issue Australian conformity assessment certificates. Such a system would need to be developed similar to the EU Notified Body system.

This would potentially enable local manufacturers to employ a single entity to certify to a number of requirements (CMDCAS, CE Certification, TGA CAC etc).

However IVD Australia question the necessity for these Australian third party assessment bodies to be based in Australia.

There are a number of issues that need to be addressed;

a) As the TGA is aware, the Australian market for medical devices and IVDs is only 2% of the world market and it is difficult to see how overseas based assessment organisations could justify having an office and assessors competent in all areas based here unless there was a substantial ongoing body of work.

b) Would there be an adequate uptake of third party bodies prepared to be located in Australia to assess to Australian Regulations? Given that IVDs are less than 20% of the total MD market and there are a limited number of Australian IVD Manufacturers, it is unlikely that there will be assessment bodies who are prepared to place appropriately qualified and specifically IVD trained auditors in Australia. Our recommendation is that third party assessment bodies for IVDs should be permitted to be located outside of Australia.

c) Who would be responsible for the designation of the Australian Conformity Assessment Bodies? If it is to be the TGA we recommend a separate Office should be established in order to guarantee independence from the current Office of Device Authorisation.

## Proposal 3 - Amending the way in which a medical device is included in the ARTG and enhancing identification of approved devices

**3. Amending the way in which a medical device is included in the ARTG and enhancing identification of approved devices**

**(i) amend the way in which a kind of device is included on the ARTG; and**

**(ii) enhance the ability to identify devices that have been approved by the TGA for supply in Australia.**

## Proposal 3 (i) - Amending the way a kind of device is included in the ARTG

IVD Australia recognises in principle the benefits of this amendment but believes it is not clear that it will substantially increase the level of information pertaining to IVD medical devices.

We have also substantial concerns with the way in which the amendment may operate and the costs to sponsors in maintaining the currency of information on the ARTG.

IVD Australia's concerns lie in the following areas;

a) Model Numbers - IVD sponsors are now required to include products on the ARTG as a "kind of medical device" using the GMDN code and term. In lower risk classes sponsors could often have over 20 - 50 different products under one inclusion with some sponsors of Class 1 IVDs (specimen receptacles for example) having potentially over 1000 products. The concept of adding each one of these products via unique identifiers as is proposed on page 22 is opposed by IVD Australia as this would substantially increase the workload for many sponsors on preparing an application for inclusion.

   IVD Australia recommends that IVDs should be included at present with a listing of the type of product incorporating a description sufficient for identification. This is already available on the Australian Declaration of Conformity which could be attached to the eBS Application. However at the Class 1 and 2 level, given that IVDs are not assessed in detail and are included only at a "product family" level then it is recommended that the description be only at this level.

b) Notification through eBS - any amendment should be able to be done through the eBS system at no charge to the sponsor. For most class 1 or 2 IVD inclusions, there is no requirement for the TGA to undertake any assessment of the product and hence there should be no charge to the sponsor.

   IVD Australia would recommend that variation to the ARTG entry to include new products could be done once a year in the same way as it is proposed that laboratory sponsors provide a list of their Class 1, 2 and 3 in-house IVDs.

c) Variation - IVD Australia believes that the variation process should only be required for a SUBSTANTIAL variation to a product included in an ARTG inclusion and should be kept separate to the notification of a new product in a "kind of medical device".

d) Assessment of Higher Risk Variations - IVD Australia notes that the TGA has proposed that variations to Class IIb medical devices and above would be subject to assessment. IVD Australia reminds the TGA that only certain types of Class 2 and 3 IVDs are subject to mandatory Application Audits (TF Reviews) under the IVD Regulations. We are strongly opposed to a general requirement that addition of any new Class 3 IVD to an inclusion would require an assessment of product on the basis of these Proposals.

   If the original inclusion was not required to undergo an Application Audit on initial lodgment then any subsequent variation due to changes in model must not require an Application Audit.

e) Transition Period - as we are currently only 5 months into the 4 year Transition period under the IVD Regulations IVD Australia does not support any further changes at this time. IVD Sponsors and manufacturers already have had substantial change given the implementation of the IVD regulations on July 1st 2010. We would recommend that if the TGA is proposing to make modifications in the way in which an IVD Medical device is included on the ARTG that this be delayed until the end of the Transition Period on 30th June 2014.

   Despite the best efforts of the TGA and IVD Australia, it is possible that a number of IVDs will be not be transitioned until the end of the 2014 transition period. Changes now to the new legislation processes will cause additional confusion and further delay applications by some sponsors, resulting in pressure on the application process at the end of the transition period.

## Proposal 3 (ii) - Enhancing the identification of approved devices

IVD Australia is wholly opposed to additional changes to the requirements on sponsor labeling of product that would modify what is currently required under Regulation 10.2 and Essential Principle 13.2. Despite the TGA's statement to the contrary, IVD Australia believes the requirement that sponsor label their product with the AUST I number will have a dramatic cost implication for sponsors. Should the TGA wish to proceed with this proposal in any form, IVD Australia would insist on a Regulatory Cost Impact statement being generated.

IVD Australia submits that if Proposal 3(i) is adopted (with appropriate changes) then this would obviate the need for Proposal 3(ii). The additional information required would provide assurance that the product is approved for supply in Australia without the need for additional changes to labeling.

Whilst it is appreciated that medicines regulation requires that the AUST R or AUST L number is included on the label, the situation of IVDs is completely different. Most IVDs are in general not assessed to the same level as medicines. The issue with confidence in an IVD used by an end user being on the ARTG is not the same as that applying to medicines and hence the need to label each IVD with the AUST I number is far less.

IVDs are included on the ARTG as a "kind of device" which attracts a single ARTG number. However there may be hundreds, if not thousands, of configurations of that device included under the ARTG number and thus a large number of different print runs would be required to create new packaging or labels. This is a totally different situation to medicines where there is usually only one version of the product registered or listed at any one time.

At present, where an over-label is used to comply with the requirements of Regulation 10.2 and Essential Principle 13.2, sponsors only require one label with their name and address details in order to comply. If this proposal were to proceed, sponsors of more than one inclusion would be required to have different over-labels for each inclusion. In the case of some sponsors many hundreds of such different labels would be needed. Verification processes would then need to be put in place to ensure that the correct labels was applied to the correct product in each case. Each of these factors adds to the cost of the product, which must then either be absorbed or passed on to the end-user.

Even if the AUST I details are included on the invoice as the final choice in order to comply with Regulation 10.2 and EP 13.2 sponsors will be required to implement significant changes in computer systems. This will come at a cost that far outweighs the additional benefit to the Australian community of having AUST I numbers on the product.

IVD Australia questions the merit of this proposal and what is to be achieved through its introduction. If it is to facilitate a recall then the ARTG number is already known to the sponsor. The addition of an AUST I number on a product will not make a substantive change to this process. If it is the ability for end-users to be aware or to determine that the product is on the ARTG IVD Australia would submit that this is achievable in a far simpler manner.

IVD Australia's strong recommendation would be that changes be made to the ARTG search function to enable search by MANUFACTURER. Information identifying the manufacturer is available on all IVDs and if end users could search the ARTG public database then they could identify the sponsor via this mechanism.

# Proposal 4 - Publication of device product information on the TGA website

| 4. | Publication of device product information on the TGA Website |
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IVD Australia cannot support this proposal at its present level of development.

We are concerned that the TGA is proposing a similar level of information for IVDs as that required for medicines. Each and every medicine undergoes a rigorous assessment process before it is entered onto the ARTG to ensure that it is safe and efficacious. Product Information (PI) and Consumer Medicine Information (CMI) are required to be included in the TGA database for prescription medicines (i.e. high risk medicines). In all cases the PI and CMI have been thoroughly reviewed by the TGA prior to their publication via the TGA database.

IVDs are included in the ARTG as a "kind of medical device" and not every (indeed few) IVDs and their associated documentation will be assessed in detail. There may be a large number of variants of IVDs included under a single ARTG AUST I number. Hence it is not possible for information to be made available on every IVD nor to have every piece of information regarding that product available.

Once again IVD Australia would seek clarification on exactly what the Proposal is trying to achieve.

Information on IVDs is currently made available to healthcare professionals in Australia through a variety of mechanisms such as IFU's, Manufacturer's websites and the like. This material is provided to the laboratory usually with every product and often at the lot level. It is difficult to see how this could be improved upon by creating a separate website where the same information was duplicated.

Similarly, for those IVDs sold directly to consumers, the TGA already assesses the information and sponsors are responsible for ensuring that it is made available to the consumer with the product.

As IVDs are included under a GMDN code the ARTG inclusion can only incorporate information specific to and assessed in relation to the inclusion. The ARTG inclusion cannot contain information regarding specific products that may fall under that inclusion but that have not been assessed.

In the case of IVDs the TGA only assesses a restricted number of IVDs via a Technical File Review and hence the information on clinical evidence, assay performance and the like is only provided to the TGA on this restricted list of products.

If the TGA is seeking to have sponsors provide information on other products, either those that fall within a Application Inclusion that have not been assessed or those from an inclusion that does not require an application audit, then that will mean the TGA is deemed to have reviewed the material provided. If this is then made available on the ARTG website it will give the mistaken impression that the TGA has specifically evaluated the product. If this occurs, it is likely to lead to confusion on the part of the public, who would be unable to access information relating to each product, and could thus cause more problems than benefits.

IVD Australia is further opposed to sponsors being required to provide information at any additional cost to the industry. We believe that the cost to the IVD sector of the recently introduced regulations will be significant enough without the additional imposition of costs, both financial and otherwise, associated with providing material for publication on the TGA website and it keeping it up to date.

Once sponsors have provided information to the TGA then it must be the responsibility of the TGA to manage that information. IVD Instructions for use change on a regular basis and if sponsors are required to notify the TGA of every change and to provide updated IFU's there will be a substantial burden imposed on sponsors and also the TGA.

In respect of rejected applications IVD Australia is not convinced of the overall benefit to the community of publishing rejected applications. Once again most IVDS are not sold directly to the consumer so it questionable whether information on rejections would be of much benefit. In the case of medicines there is merit in making information available on rejected applications as these products have had a detailed review and there is public interest in the reasons for rejection.

Additionally IVD Australia believes that many products are rejected for inclusion on the ARTG due to administrative issues. These administrative issues are often corrected and then a successful application for inclusion is made. To publish details of such rejected applications serves no purpose and would require substantially more work on behalf of the TGA. Additionally it would become considerably harder to determine exactly those applications that were rejected for good and sufficient reason such as safety and efficacy.