Submission to

Senate References Committee on Community Affairs

regarding the Regulatory Standards for the Approval of Medical Devices

July 2011

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Recommendations

IVD Australia recommends that

Recommendation 1

as part of the formation of the Australian and New Zealand Therapeutic Products Agency (ANZTPA), the Agency is created as a separate independent authority with block funding from both Governments.

Recommendation 2

that the TGA Recall procedures be changed to ensure that draft recall letters be processed promptly, but that the TGA not distribute Recall Notifications to State Authorities until the sponsor has had an opportunity to contact affected customers

Who is IVD Australia?

IVD Australia is pleased to provide our submission to the Senate Community Affairs References Committee as part of its deliberations on the *Regulatory Standards for the Approval of Medical Devices*.

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

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

These tests influence over 70% of the medical decisions taken in respect of a patient's health and often comprise over 75% of a patient's health record.

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 $800,000,000 representing in excess of 90% of all IVDs sold in Australia. IVD Australia member companies employ over 2000 people across Australia.

IVD Australia looks forward to the ongoing discussions foreshadowed in the referral. We assure the Committee of our willingness to participate as necessary to achieve a satisfactory outcome regarding the standards covering the regulation of medical devices in Australia.

Introduction

The Terms of Reference into the *Regulatory Standards for the Approval of Medical Devices are*;

Terms of Reference

The regulatory standards for the approval of medical devices in Australia, with particular attention to devices with high revision rates, and in undertaking the inquiry the committee consider:

(a) the role of the Therapeutic Goods Administration in regulating the quality of devices available in Australia;

(b) the cost effectiveness of subsidised devices;

(c) the effectiveness and accuracy of the billing code and prostheses list;

(d) the processes in place to ensure that approved products continue to meet Australian standards;

(e) the safety standards and approval processes for devices that are remanufactured for multiple use;

(f) the processes in place to notify the relevant authorities and the general public of high revision rates or possible faulty devices;

(g) the effectiveness of the current regimes in place to ensure prostheses with high revision rates are identified and the action taken once these devices are identified;

(h) the effectiveness of the implemented recommendations of the Health Technology Assessment; and

(i) any other related matter.

Almost all of the IVDs used in Australia are imported and conversely, a large percentage of the IVDs manufactured in Australia are exported. However the Australian market for IVDs (as well as medical devices in general) represents less than 2% of the world market for these products. Whilst the potential risks posed by IVDs are significantly less than those from high risk medical devices, it is still critically important that regulation impacting IVDs in Australia is consistent with overseas practice and not financially burdensome or resource intensive for sponsors and manufacturers.

Under the new Australian Regulations[1], *in vitro* diagnostics are regulated as a subset of Medical Devices. Thus the Therapeutic Goods (Medical Device) Regulations 2002 apply to IVDs and hence they are captured under this Reference to the Community Affairs References Committee.

Regulation of IVDs in Australia in fact has recently been substantially upgraded with the implementation of the long awaited IVD Framework in July 2010. This framework is based upon the Global Harmonisation Taskforce (GHTF) model and Australia is the first major jurisdiction to implement regulations based on this model. It is anticipated that the EU will move to implementation of regulatory approval based on this model in 2016-17 and other jurisdictions such as China and Japan will also move to adopt it over the longer term.

The GHTF model is a risk based framework where higher risk products such as IVDs that are used to screen the blood supply, those testing for transmissible agents and those sold directly to consumers are subject to a greater degree of regulatory scrutiny. These products are generally required to have a review of their analytical performance and clinical evidence undertaken by the TGA before they are entered onto the Australian Register of Therapeutic Goods (ARTG). In the case of the highest risk products (Class 4), the TGA requires that physical testing of the assay performance be undertaken by an approved independent laboratory. Products of lower risk, for example those testing for hormones or for electrolytes, are subjected to a lower level of oversight, with most requiring only a review of the Manufacturer's Quality System.

As discussed above, the IVD Regulatory Framework was finally introduced on July 1st 2010 after 8 years of delay. The introduction was the subject of detailed negotiation both with the pathology community, and with the sponsors of IVDs, initially through the Medical Technology Association of Australia (MTAA) and then IVD Australia. Whilst the IVD sector was not in complete agreement with all of the changes, particularly those that imposed greatly increased regulatory costs on the sector, it has undertaken to work with the TGA within this new regulatory environment.

Additionally, the Government has recently announced its intent to proceed with the implementation of the Australia New Zealand Therapeutic Products Agency (ANZTPA). This was initially proposed in 2003 but discussions were suspended in 2007. The negotiations involved in the creation of ANZTPA were one of the reasons for the long delay in the implementation of the IVD regulations. Whilst IVD Australia supports the creation of ANZTPA, we are again concerned that adequate resources are provided and that it not result in additional regulatory burden for Australian sponsors and manufacturers.

IVD Australia recognises that the Terms of Reference are primarily concerned with prosthetic devices that may be subject to high revision rates and several relate to remanufactured devices and those on the Prosthesis Benefits List. However a number of the Terms of Reference relate to medical devices in general, and IVD Australia wishes to ensure that its views are heard in relation to IVD regulation.

[1] *Therapeutic Goods (Medical Devices) Regulations 2002* - CommLaw Doc # F2011C00396

Issues

Issue A - the Role of the TGA

As indicated previously, the introduction of the IVD regulations in 2010 has meant that all IVDs now require pre-market assessment under Australian legislation and are required to be entered onto the ARTG prior to their supply in Australia.

IVD Australia has worked closely with the TGA to ensure that this regulatory framework takes into account the requirements of manufacturers and sponsors. We believe that the TGA is the most appropriate authority to regulate therapeutic goods. This structure, requiring an essentially independent regulatory authority is common around the world. It provides a level of confidence in the regulator that is not present if these functions are subsumed within a Government department.

Indeed, IVD Australia believes that the TGA should in fact be a totally independent Government Body in the same way as the National Blood Authority. This would establish it as formally independent and not seen as an arm of Government.

One of the major issues with the current structure is that the TGA is fully cost recovered. This means that the funding for the organisation comes solely from its "customers". This has lead to the perception that the TGA is too close to the industry it regulates and thus makes decisions that favour the position of the industry sectors over that of the health consumer[2].

IVD Australia can confirm that this in fact is not the case. Our negotiations on the IVD framework were lengthy and difficult as we sought to establish a fair and reasonable outcome for industry over the sometimes demanding position proposed by the TGA.

However in order to overcome this perception of industry bias, IVD Australia recommends that the TGA be set up as an independent Authority but with block grant funding to support its community service obligations such as those covering post market surveillance. Indeed the recent announcement of the re-establishment of the Australian New Zealand Therapeutic Products Agency (ANZTPA)[3] is a perfect opportunity to restructure the TGA so that it is no longer a Division of the Department of Health and Ageing but rather a separate Authority reporting to both the Australian and New Zealand Ministers for Health, and funded through both block grants as well as fees and charges on sponsors.

Recent comment in the US has indicated concern that the FDA is proposing to increase its level of cost recovery to 40%. US consumers believe that the FDA is beholden to the therapeutic goods sector at this level of recovery but the current level of 27% is far less than that of the Australian situation of 100% recovery.

In addition, despite industry paying 100% of TGA costs and the ensuing high cost of registration to the industry, the level of "service" provided by the TGA to industry is significantly inadequate. The length of time for approvals, decisions and even billing is not "world-class", delaying the introduction of advances in testing, and make planning and budgeting very difficult for industry.

[2] *Final Report of the Review to improve the Transparency of the Therapeutic Goods Administration, 2011*, p52
[3] http://www.tga.gov.au/about/international-anztpa.htm

Issue B - the cost effectiveness of subsidised devices

Given that most IVDs are reimbursed through the Medical Benefits schedule directly to laboratories and are not in general subsidised through the Prosthesis List or the Pharmaceutical Benefits Scheme, IVD Australia does not offer any comment on this reference

Issue C - the effectiveness and accuracy of the billing code and prostheses list

Given that this reference is specific to prosthetic medical devices, IVD Australia has no comment to make.

Issue D - the processes in place to ensure that approved products continue to meet Australian standards

IVD Australia strongly believes that the processes in place to approve IVD medical devices ensure that only products that meet the highest standards of performance and quality are permitted entry into the Australian market.

IVD Australia does have several concerns however with products that are not subjected to the same level of scrutiny as are commercially supplied IVDs.

Firstly, under the IVD Framework, allowance has been made for the inclusion of laboratory developed, otherwise known as "in-house", tests onto the ARTG under the sponsorship of a laboratory network. Australian laboratories continue to develop tests themselves for a variety of reasons; cost, non availability of a commercial equivalent, or the newness of an assay.

For the highest risk products (Class 4) such as tests to screen the blood supply, the in-house assays are required to undertake the same level of regulatory scrutiny as a commercially supplied assay. For all other risk class assays, the laboratory network is only required to provide the TGA with a list of assays developed and used within the network. No regulatory scrutiny will be applied to this list, nor is the TGA required to list the products.

The regulatory scrutiny that is applied to lower risk assays comes during the triennial inspection of the laboratory by the National Association of Testing Authorities (NATA), when in-house assays are required to be assessed against the National Pathology Accreditation Advisory Council (NPAAC) Guidelines[4] for the development and use of in-house IVDs. IVD Australia is concerned that this may result in inadequate scrutiny of higher risk assays such as Class 3 infectious disease assays, given the time pressure that NATA assessors are already subject to in undertaking laboratory audits, and that the focus will be on laboratory performance rather than assay performance.

[4] *Requirements for the Development and Use of In-house in vitro Diagnostic Devices (IVDs) 2007 Ed*, Department of Health and Ageing, NPAAC

IVD Australia submits that it not good practice for in-house assays to be assessed for use in the Australian market by two different assessment bodies (TGA and NATA) that may have differing interpretation of the performance and stability of assays.

Secondly, IVD Australia is concerned at the growing tendency of healthcare consumers to order products over the internet, which can then be imported and used without any regulatory assessment of the safety or efficacy. This is not generally an issue for professional use assays; however there is a concerning trend for consumers to order products such as home pregnancy tests, strips for diabetes test meters, genetic testing and other "home-use" assays from the web, assuming that these are reputable and reliable. Indeed there have been a number of cases of counterfeit blood glucose test strips sold around the world[5].

It is difficult to determine how to restrict this practice; however in its submission to the TGA transparency review IVD Australia recommended that the TGA move proactively to inform consumers of the risks of such on-line purchasing.

Issue E - the safety standards and approval processes for devices that are remanufactured for multiple use

Given that this Reference relates to medical devices that are re-manufactured and that IVDs are single use devices that are not amenable to remanufacturing, IVD Australia does not have a comment to make.

Issue F - the processes in place to notify the relevant authorities and the general public of high revision rates or possible faulty devices

In Australia, the great bulk of IVDs are supplied to NATA registered laboratories. These IVDs are used by laboratory scientists and pathologists to produce test results that are further scrutinized before they are released to the requesting Healthcare professional. In addition as a condition of registration, laboratories participate in a variety of external quality assurance (EQA) programs, run by the Royal College of Pathologists QAP Division. This focus on Quality has meant that Australian Pathology Laboratories are amongst the best in the world. Often it is Australian laboratories that discover "issues" with IVDs that are then reported back to overseas principals.

Recall provisions are in place for all IVDs and adherence to them is a condition of ARTG entries. These allow for notification to the laboratories and / or the public of faulty devices. In general these procedures work well and allow for recall procedures to be initiated should an issue with an IVD be discovered. However given the large number of pathology tests performed in Australia[6] there are very few instances each year of faulty IVDs being recalled.

[5] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm062706.htm

[6] Medicare statistics indicate that over 130 million pathology tests are performed annually in Australia

The major concern that IVD Australia has with the TGA processes regarding recalls are that they are often slow. The TGA often takes considerable time to approve a recall letter principally due to their insistence on obtaining all distribution information before commencing review of the Recall notice. Once the Recall letter is approved by the TGA it is sent to State Health Authorities who then forward them to laboratories. Often this all happens late on a Friday afternoon and the sponsor then has to send their Recall Notice out during the following week.

The result is that a number of laboratories receive notification of a Recall from the TGA before the receive it from the sponsor or laboratories that were not supplied with a recalled product or the lot / batch of the product that is the subject of the recall often receive an Recall Notification. This often results in confusion and often causes laboratories to cease using product that is not affected by a particular recall.

IVD Australia recommends that the TGA Recall procedures be changed to ensure that draft recall letters be processed promptly, but that the TGA not distribute Recall Notifications to State Authorities until the sponsor has had an opportunity to contact affected customers.

Issue G - the effectiveness of the current regimes in place to ensure prostheses with high revision rates are identified and the action taken once these devices are identified

As this Reference relates specifically to prosthetic devices, IVD Australia makes no comment.

Issue H - the effectiveness of the implemented recommendations of the Health Technology Assessment Review

IVD Australia participated in the Review of Health Technology Assessment (HTA) undertaken jointly by the Department of Health and Ageing and the Department of Finance in 2009. IVD Australia was broadly supportive of the 16 recommendations that came out of the review and the Government's undertaking to implement 13 of them. However IVD Australia believes that the referral to the Committee is premature. These Recommendations are currently in the process of being implemented, and we believe that it is too early to comment yet as to the effectiveness or otherwise of the implemented Recommendations.

IVD Australia continues to have concerns regarding the HTA / Medical Services Advisory Committee processes.

Firstly, we are concerned that the reforms undertaken in MSAC are not altering the speed of the process overall. In fact, we believe that the reforms have simply moved the delays in the system from the middle of the process where the assessment of the evidence was undertaken, to the front of the process where there will be lengthy delays in the Protocol Advisory Subcommittee (PASC). Hence the overall speed of assessment and recommendation of an IVD will not change dramatically.

Secondly we are concerned about reports that applications to the Pharmaceutical Advisory Committee (PAC) that involve a co-dependent technology such as an IVD are being delayed unless the IVD application is submitted at the same time as the PAC submission.