IVD AUSTRALIA

*The industry where innovation saves more Australian lives*

# Submission to the Senate Inquiry into the *THERAPEUTIC GOODS AMENDMENT (2016 MEASURES NO. 1) BILL 2016* on behalf of the Australian IVD Industry

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# EXECUTIVE SUMMARY

IVD Australia is pleased to provide the Senate Inquiry with comments from the IVD industry in regard to the Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016 (the Bill). IVD Australia will offer comment on those measures applicable to in-vitro devices (IVDs).

IVD Australia is the peak body representing Australian sponsors and manufacturers of in vitro diagnostics.

In vitro (literally "in glass") diagnostics (IVDs) comprise the instruments and reagents that are used to perform pathology tests requested by General Practitioners or specialist Physicians. These tests 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 or home pregnancy test kits. Supply of IVD products is regulated for the Government by the Therapeutic Goods Administration.

Australia's leading pathology laboratory supply companies formed IVD Australia in July 2009 and we currently represent Australian manufacturers, multi-national and local distributors of Pathology tests, as well as regulatory consultants working in the IVD sector. Our industry currently supplies products valued at over AUD 1.2 billion per annum and employs over 3,000 staff in multinationals, local distributors, local manufacturers and exporters and regulatory consultant companies; many of which are SMEs.

IVD tests are a key contributor to the Australian health care system, powering medical discoveries and transforming patient care. These tests are performed on samples taken from the body and are used in a broad range of applications. Diagnostic tests provide critical insights at every stage of medical care – prevention, detection, diagnosis, treatment, and successful management of health conditions. Diagnostic tests are often the least expensive component of the health care pathway, yet they influence more than 70 % of health care expenditures. They facilitate evidence-based medicine, improve quality of care, promote wellness, enable early detection of disease, and reduce overall health care costs.

Technological advances and automation have made tests easier to use and more accurate, and have led to more precise and more timely reports. These advances have led to point of care tests that facilitate more rapid decision-making by medical practitioners. Other advances, made possible by discoveries about the human genome, have opened the door to personalised medicine approaches that can tailor medical treatment to individual patient needs, transforming modern medicine.

IVD Australia supports the regulatory proposals contained within the Review of Medicines and Medical Devices Regulation (MMDR), through the reduction in unnecessary red tape and regulation on the IVD industries, whilst maintaining safety and integrity of the regulatory process.

IVD Australia supports the principals of the amendments proposed, however some of the changes outlined in the Bill do require further consultation and subsequent clarification as detailed in this submission.

IVD Australia would be very happy to add to this written submission with verbal evidence to the committee should that be considered helpful.

Dr Wendy-Jane Morrow
CEO, IVD Australia

# NEW PATHWAYS FOR APPROVAL OF MEDICAL DEVICES

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 that 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 – for example, 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 many BAU submissions already face unacceptable delays in approval timeframes.

IVD Australia agrees the proposed 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?
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.

## IVD Australia Recommendations

**Recommendation 1: Definition of 'novel device'**

The Bill does not include a definition of a 'novel device' that would qualify such a device for the expedited approval pathway. This does not require an amendment to the legislation, but IVD Australia would like to ask the Committee to recommend to the Government that 'novel device' be clearly defined in the medical devices regulations.

**Recommendation 2: Resourcing the Priority Pathway**

This does not require an amendment to the legislation but IVD Australia would like to ask the Committee to recommend to the Government that the TGA needs to adequately resource the Priority Review pathway so that BAU applications comprising the majority of regulatory submissions (not less than 90%) are not delayed.

# ENABLING AUSTRALIAN 'NOTIFIED BODIES' TO UNDERTAKE CONFORMITY ASSESSMENT OF MEDICAL DEVICES

IVD Australia strongly supports the establishment of Australian 'notified bodies' to undertake conformity assessment of IVDs. We also understand the requirement for any third party designated body to have a presence in Australia from a regulatory and legal perspective. However, IVD Australia does not see a need for these third party bodies to hold expertise within Australia for all kinds of IVDs. Given the size of both the Australian market and the population this would be unrealistic.

IVD Australia anticipates that the majority of designated authorities would be local affiliates of global organisations that are also designated as EU notified bodies. These organisations would then be able to pull expertise from a global pool in order to undertake the required technical assessments of IVDs.

Just as manufacturers now concurrently apply for Quality Management System certification for ISO13485, CMDCAS ISO13485 and, for example, EU 98/79/EC Annex IV certification, the expectation is manufacturers would apply for Australian Conformity assessment certification also with those notified bodies designated to undertake certification. With the implementation of the Medical Device Single Audit Program (MDSAP) this alignment is even more applicable.

With the introduction of third party designated bodies to undertake Australian Conformity Assessment, IVD Australia sees no need for the TGA to retain the ability to undertake these types of assessments. The additional administrative burden this would entail would be passed on to industry and potentially make the whole program unviable, regardless of the mechanism of charging.

IVD Australia fully supports third party designated Australian conformity assessment bodies being able to assess ALL medical devices, including Class 4 IVDs, subject to competency assessments.

With the introduction of the IVD Medical Device Regulations in Europe there will be much greater harmonisation between the Australian Regulations and the European Regulations. This also opens the way for concurrent assessment by suitably qualified and designated bodies. The concern is that with the implementation of the IVD Medical Device Regulations, notified bodies will not have the capacity to take on additional certification work in the next five years.

IVD Australia fully supports third party designated Australian conformity assessment bodies being able to assess ALL medical devices, including Class 4 IVDs, subject to competency assessments. This is subject to the assumption that most designated bodies will be a branch of a larger global organisation that will be able to access relevant expertise in order to have the capability to undertake these assessments. Given that the majority of high risk devices, particularly IVDs, are already assessed by competent notified bodies in Europe this capability is already established.

While some local manufacturers will rely on 'home market' regulatory approval, IVD Australia has always assumed TGA would retain the overall responsibility for regulatory approval for inclusion on the Australian Register of Therapeutic Goods (ARTG). While the TGA would not undertake conformity assessments, IVD Australia expects that TGA oversight as a Designating Authority would be stringent enough to avoid any of the problems seen in Europe historically.

IVD Australia supports parallel review by bodies designated across multiple jurisdictions such as occurs now for QMS certification. This is the only way to achieve a sustainable designation process from both a cost recovery and timeliness to market perspective.

IVD Australia does not want to see a similar process to today, whereby European certification is needed to support assessment by an Australian designated authority. This avenue would continue to foster the duplication of assessment and the high local workload which is already criticised by industry and leads to long lead times to market for high risk devices.

There should be a set fee for designation for all conformity assessment bodies dependent on scope. This should be transparent and equal for all bodies so that there is no likelihood of disadvantaging any one body. This fee should purely cover the cost of designation of the body.

The costs for the requisite changes within TGA, eg, reorganisation and retraining to become a Designation Authority, should be covered by annual fees, in the same way that other operating and post-market costs are covered. This retains a level of equity for all sponsors and manufacturers.

Costs for auditing of overseas facilities of the designated body should also be included in a annual fees as this now potentially becomes a cost to all industry. However, depending on the implementation of the program, should lower risk devices continue to rely on other overseas certification, the cost of overseas audits may have to be born by those who use the Australian designated bodies.

As stated below, TGA should cease to offer TGA Conformity Assessments and become a Designating Authority only for the purposes of conformity assessment. Only in exceptional circumstances, eg, Class 4 In-house IVDs should it undertake any form of TGA conformity assessment itself.

## IVD Australia Recommendations

**Recommendation 3: TGA not be designated a third party Conformity Assessment Body**

This does not require an amendment to the legislation but IVD Australia would like to ask the Committee to recommend to the Government that the TGA cease to undertake Conformity Assessment certification activities and focus on re-training as a Designation Authority, similar to the MHRA in the United Kingdom. This will potentially reduce the likelihood of costs increasing and making the whole process untenable in the long term. The duplication of administrative oversight and costs if the TGA is both a Designating Authority and Conformity Assessment reviewer is unlikely to be sustainable given Australia already is one, if not the, most expensive regulatory jurisdiction in the world.

Even if cost-neutral, industry is unlikely to select TGA as the Conformity Assessment body if the third party alternative leads to significantly shorter timelines to market and/or review of changes. Particularly if this can be done in conjunction with assessment for other jurisdictions.

# ENABLING HEALTH PRACTITIONERS TO SUPPLY CERTAIN THERAPEUTIC GOODS NOT ON THE REGISTER TO PATIENTS UNDER A NOTIFICATION SCHEME

The Review recommended that criteria be developed for identifying certain therapeutic goods that are not in the Register that may be able to be supplied to patients other than those who are gravely ill by notification to the TGA rather than, as is the case currently, requiring the prior approval of the Secretary (Review recommendation 24).

Most therapeutic goods are required to undergo an evaluation for quality safety and efficacy and be included on the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in Australia. In recognition that there are circumstances where patients need access to therapeutic goods that are not on the ARTG, the TGA manages a Special Access Scheme (SAS).

It is expected that therapeutic goods qualifying for the proposed SAS path (comprised of notification rather than application) will be products with a public history of safe use in comparable overseas countries but, for commercial reasons, have not been included in the ARTG. IVD Australia supports this change because it streamlines the Special Access Scheme (SAS) process for Category B patients.

Replacing the pre-approval pathway with a notification pathway should not be a mechanism that can be used to bypass the requirement for IVDs to be included on the ARTG. Eligibility for this pathway needs to be very well defined and should only be possible to access in 'exceptional circumstances where goods on the ARTG are not clinically suitable for a patient'.

### IVD Australia Recommendations

**Recommendation 4: Definition of eligibility**

The Bill does not include a definition of a device that would qualify such a device for supply without pre-market approval. This does not require an amendment to the legislation, but IVD Australia would like to ask the Committee to recommend to the Government that the requirements be clearly defined in the medical devices regulations.

## STRENGTHENING POST-MARKETING ACTIVITY

The Review recommended that the TGA develop a more comprehensive post-market monitoring scheme for medical devices (recommendation 27).

IVD Australia believes that the equilibrium of pre- and post- market monitoring should be weighted towards post-market. This would ensure no delay for patient access to innovative or improved IVDs while ensuring IVDs are safe and effective. The life of IVDs is significantly shorter than that of medicines, and therefore, long and overly burdensome premarket processes, such as large amount of premarket clinical trials data, would not be appropriate for IVDs.

Whereas the clinical setting requires that IVD quality be high, it is not feasible to demand that all IVDs be assessed in the pre-market phase in the same manner, given both the number of products available for a very broad range of analytes and the resources available to conduct assessments. This has led, internationally, to the use of a risk-based approach to assessment, in which IVDs are classified according to the risk they pose to public and individual health, and taking into account the potential outcomes and impact if the test does not perform properly or is not available. The risk class then determines the level of scrutiny applied for the regulatory assessment, ensuring that resources are focused on those IVDs associated with the greatest potential risk. Post-market surveillance should aim to ensure that IVDs continue to meet the same quality, safety and performance requirements as when they were initially placed on the market.

### IVD Australia Recommendations

**Recommendation 5: Requirements for post-market surveillance of IVDs**

Strengthening of post-market activity should utilise established methods for post-market monitoring of IVDs currently in use internationally.

# AMENDMENTS TO TGA STATUTORY ADVISORY COMMITTEES

IVD Australia supports rationalising the number of advisory committees from nine to five, and in particular the consolidation of the Advisory Committee on the Safety of Medical Devices (ACSMD) functions into the existing Advisory Committee on Medical Devices (ACMD).

IVD Australia recognises the important role of statutory advisory committees in offering independent medical and scientific advice to the Minister and the TGA on the safety, performance and manufacturing of IVDs supplied in Australia.

IVD Australia also believes that these committees and their decisions should be transparent and based on guidelines and principles rather than personal opinions.

# OTHER AMENDMENTS

Other changes contained in the TG Amendment cover administrative aspects such as cancellation of approval in the event of sponsor providing false or misleading information, reinstatement on payment of annual fees and conditions of inclusion in the ARTG.

IVD Australia does not have any objections against these changes introduced by the Bill.

# FINANCIAL IMPACT STATEMENT

The Government allocated $13.5 million in both operating and capital expenses from the Budget in 2016 2017 to improve the regulation of therapeutic goods in Australia. The TGA special account reserves (comprised of revenue from industry fees and charges) will be used to fund this allocation. Industry is concerned that should this allocation be required to be replaced in the future, this will necessitate a substantial increase in said fees and charges, placing an increased financial burden on industry.

## IVD Australia Recommendations

**Recommendation 6: Transparency of TGA Funding**

The Therapeutic Goods Industry should be advised of any requirement to recoup the $13.5 million from industry fees and charges charged to industry by the TGA as a 100% cost recovery regulator.

# CONCLUSORY STATEMENT

The Bill is an essential step in the attainment of sustainable regulation of IVDs in Australia. These reforms, which are strongly supported by stakeholders, have been more than a decade in discussions, two years in review and IVD Australia urges the Senate Inquiry to support these much-needed reforms.