Regulation Impact Statement

for

A New Regulatory Framework for

In vitro Diagnostic Devices (IVDs)

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Regulation Impact Statement

Development and implementation of a new regulatory framework for *in vitro* diagnostic devices (IVDs), including those manufactured commercially and those manufactured within the laboratory in which they are used (in-house IVDs).

1. Background

The Australian Health Ministers' Advisory Council (AHMAC) endorsed the development of a new regulatory framework for IVDs[1] aligned with international best practice in July 2001.

IVDs differ from most general medical devices in that most do not come into direct contact with the patient. Therefore, they cannot cause direct harm to the patient if they fail to perform as intended. However, if the results that are produced from testing are incorrect and are not recognised to be so, indirect harm can occur to patients through incorrect diagnosis or inappropriate treatment. There are also risks that can be attributed directly to the manufacturer, including product instability, reagent or instrument failure, defects in product design or inadequate labelling.

The level of risk associated with an IVD will vary depending on whether it is to be used for monitoring, diagnosis or screening. There is a significantly higher level of risk to public health and safety associated with IVDs used for mass screening of blood and tissue donations for infectious agents such as Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV). The risk to public health associated with IVDs used for diagnosis is generally low (infectious disease are one exception), though the risk to an individual may be high depending on the nature of the condition. Where an IVD is used to monitor treatment, the risk to public health will be very low, with the risk to the individual generally being low to medium.

The Therapeutic Goods Administration (TGA) was specifically asked by AHMAC to address the level of regulatory oversight of in-house IVDs[2], after reports of a State reference laboratory using an unapproved test for Hepatitis C diagnosis. The current regulation of IVDs does not include a provision for in-house IVDs, though they fall within the definition of an IVD. The AHMAC also requested that the TGA incorporate appropriate regulatory controls for genetic tests into the new framework.

In response to the AHMAC recommendations, the TGA set up the *In Vitro* Diagnostics Working Group (the Working Group) under the auspices of the National Coordinating Committee on Therapeutic Goods (NCCTG) to develop a proposed framework for new legislation. The NCCTG is the Commonwealth, State and Territory government sub-committee of AHMAC with responsibility for therapeutic goods.

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[1] An in vitro diagnostic device (IVD) can be defined as any therapeutic device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination (with other diagnostic goods for *in vitro* use), intended by the manufacturer to be used *in vitro* for the examination of specimens (including blood and tissue donations) derived from the human body, solely or principally for the purpose of giving information about a physiological or pathological state or a congenital abnormality or to determine safety and compatibility with potential recipient.

[2] An in house IVD is an assay which is developed de novo, or modified from a published source, or modified or adapted from any other source, within the confines or scope of a laboratory: and validated for use in that laboratory only, and is not supplied for use outside that laboratory.

i. Current regulatory requirements

Framework

When it was introduced in 1991, Australia's regulatory framework for therapeutic goods was the first comprehensive national system in Australia and replaced a mixture of Federal and State responsibilities. The legislative basis for regulation is the *Therapeutic Goods Act 1989* (the Act) which provides for a national and uniform system of control over therapeutic goods in Australia. The basic philosophy of the legislation, which is administered by the TGA, is to ensure the quality, safety, performance and timely availability of therapeutic goods.

The system, which at the time was seen as being at the cutting edge of international regulatory practice, contains four key principles:

- a register, the Australian Register of Therapeutic Goods (ARTG), in which all therapeutic goods imported into, supplied within, or exported from Australia must be included;
- classification of all therapeutic goods into high risk (registrable), medium risk (listable) and low risk (exempt) products. This categorisation of goods determines the degree of pre-market assessment by the TGA prior to inclusion of a product in the ARTG;
- compliance with product standards, as well as labelling and advertising requirements; and
- compliance with manufacturing standards.

'Registrable' goods are subject to detailed pre-market evaluation for quality, safety and performance, whereas 'listable' goods are allowed to be supplied following a brief assessment of quality and safety, based on labelling and product information, and the level of compliance with relevant mandatory standards.

New South Wales, Victoria and Tasmania have adopted the Act by reference or by corresponding legislation. The other States/Territories only regulate the supply of therapeutic goods, through the distribution chain. All States/Territories have responsibility for coordination and oversight of recalls of therapeutic goods.

The Australian Competition and Consumer Commission utilises the *Trade Practices Act [TPA]1974* to enhance the welfare of Australians through the promotion of competition and fair trading and provide for consumer protection. All products and services, including therapeutic goods, are subject to the provisions of the TPA and suppliers of products and services outside the operation of the *Therapeutic Goods Act 1989* are still required to abide by the provisions of the TPA. In particular, Part VA of the TPA provides for the liability of manufacturers and importers for defective goods and entitles a person to seek compensation for injury or damage to property resulting from defective goods.

Regulation of IVDs

For the purposes of entry on to the ARTG the current system classifies IVDs into three categories: registrable, listable and exempt according to an arbitrary list contained in the regulations. Unless specifically excluded or exempt, therapeutic goods may not be supplied to the Australian market unless included as a registered or listed good in the ARTG.

Only two types of IVDs are currently classified as high risk ("registrable") - HIV and HCV *in vitro* diagnostic devices. As such they must demonstrate compliance with Good Manufacturing Practice (GMP) requirements and provide detailed information on manufacturing processes, clinical performance and labelling.

Listable IVDs include those for home use, IVDs included on the Pharmaceutical Benefits Scheme and IVDs that include materials of human origin. Listable IVDs undergo an administrative review for compliance with labelling, advertising and GMP requirements.

The majority of IVDs currently supplied in Australia are exempt from TGA pre-market scrutiny. Exempt products are subject to compliance with standards, labelling and advertising provisions. However, there are virtually no prescribed standards. There is no additional State/Territory legislation related to pre-market requirements.

Consumer protection for IVDs that fall outside of the TGA's regulatory purview is provided through the *Trade Practices Act 1974*.

In October 2002 a new regulatory framework for medical devices was implemented. The framework is based on the international regulatory model developed by the Global Harmonisation Task Force (GHTF). In recognition of the unique properties of IVDs, compared to other groups of medical devices, IVDs were specifically excluded from the new framework with the intention that a new regulatory framework would be developed for IVDs that would align with the requirements for medical devices as a whole.

In-house IVDs

At present the TGA does not regulate in-house IVDs, even though they fall within the definition of an IVD.

Pathology Laboratory Accreditation

The TGA does not have the regulatory authority to regulate laboratory practice or the use of IVDs within a laboratory, and so the proposed new regulatory framework does not address laboratory practice in any way. However, the proposed new framework for regulating IVDs will complement the pathology laboratory accreditation system described below.

In 1986 the Australian Government introduced a compulsory pathology laboratory accreditation system in relation to reimbursement of benefits under Medicare. To be eligible to receive payments under Medicare, laboratories must comply with an industry laboratory accreditation system. This is to ensure laboratories provide an acceptable standard of pathology services. Assessments are conducted by the National Association of Testing Authorities, Australia (NATA) in conjunction with the Royal College of Pathologists of Australasia (RCPA), against national standards established by the National Pathology Accreditation Advisory Council (NPAAC). A small number of pathology services, for example those providing genetic tests that do not attract Medicare benefits, are not accredited.

NPAAC has adopted the international standard for laboratory accreditation ISO/IEC 17025 as the core standard. Validation of in-house tests is covered by Clause 5.4 of ISO/IEC 17025. NPAAC is currently in the process of developing a standard for the validation of in-house IVDs entitled "Requirements for the Validation of In- House In Vitro Diagnostic Devices (IVDs)".

ii. Administration of current policy

The TGA is responsible for the regulation of therapeutic goods in Australia. The TGA is the division of the Department of Health and Ageing with overall responsibility for administering the provisions of the Act.

iii. The IVD industry in Australia

A survey[3] conducted for the purposes of this regulatory proposal estimated the Australian market for IVDs to be worth about $350m a year. The Medical Industry Association of Australia (MIAA), the peak industry body representing IVD sponsors in Australia, puts the estimate of market worth at $500m. The European Device Manufacturers' Association estimates that the Australian market accounts for 1.35% of global sales of IVDs.

[3] *Investigation of the IVD market in Australia, 2003 Piazza Consulting* (the Survey). Survey conducted for the purpose of preparing this Regulation Impact Statement.

From information gathered from the Survey, the number of businesses engaged in supplying IVDs and associated equipment to pathology laboratories in Australia is estimated to be about 160. The market is highly concentrated with the four main suppliers accounting for approximately 70% of sales in Australia. The majority of suppliers would be classified as small business.

The Survey identified over 43,000 different types of IVDs available for sale in the Australian market. The four largest suppliers accounted for just over 18,000 of these IVDs.

Imports account for more than 95% of the local IVD market, with imports coming predominantly from the United States and the European Union. The majority of IVD types (about 75%) are imported proprietary products.

Local manufacture

Local manufacture of IVDs appears to account for less than 5% of IVDs supplied to the Australian market. The Survey identified 17 companies engaged in local manufacture with the majority of these firms also importing third party or proprietary products, which they distribute in the local market.

Australia is a very small market and not large enough for local manufacturers to recoup all the development costs associated with marketing a product so export is essential. All companies engaged in local manufacturing have some level of exports with 3 indicating more than 75% of their sales come from exports. Two firms involved in local manufacturing indicated a turnover of between $25m and $50m, while 5 indicated a turnover of between $10m and $20m

In-house manufacture

The Survey found that there are 640 laboratories involved in pathology testing in Australia. Of these, 48% of laboratories developed in-house IVDs. Of the 73,088 IVDs used by laboratories, 63,365 were commercial assays. This figure differs from the number of commercial assays found by the Survey to be available in Australia because many laboratories are using the same IVD, and so there is double counting. Most in-house IVDs are developed because there is no commercial alternative or the in-house IVD delivers a superior result.

iv. International situation

The European Union (EU), Canada and the United States of America (USA) have frameworks in place for the regulation of all commercially available IVDs. While there are some similarities between the EU and Canadian systems, the US system is quite different.

The Global Harmonisation Task Force (GHTF) is the international forum of medical device regulators and industry representatives whose goal is to develop harmonised principles relating to the regulation of medical devices. The GHTF's membership is comprised of representatives from industry and regulators from the founding member regulatory jurisdictions, Australia, Canada, Japan, the USA and Europe. An IVD specific sub-group of GHTF, on which Australia has representation, has agreed that many of the harmonised principles of regulation adopted for the medical device framework should apply to IVDs. The GHTF member jurisdictions are encouraged to move towards adoption of the GHTF recommendations as they are developed.

The European framework is the only one to specifically refer to in-house IVDs, in that the IVD Directive states that IVDs manufactured within a laboratory are exempt. However, the United Kingdom has recently clarified that IVDs manufactured in-house and then transferred to another laboratory are not covered by the exemption. The Canadian model contains no provisions with respect to in-house IVDs.

In 1997, the USA Food and Drug Administration (FDA) published a regulation classifying the building blocks of in-house IVDs as analyte specific reagents (ASR), and making ASRs subject to incremental regulation like all other laboratory tests. Laboratories must establish the performance

characteristics for each ASR they intend to use and must be accredited to carry out the appropriate level of test complexity.

v. Authority for review

The Australian Health Ministers' Advisory Council endorsed the development of a new IVD regulatory framework aligned with international best practice in July 2001.

2. The issue

i. What is the problem being addressed?

The TGA is proposing the introduction of a new framework for the regulation of IVDs in Australia to address several deficiencies within the existing legislative framework. The most critical deficiency is the inadequacy of the list-based risk-classification process when applied to IVD technologies and the consequent sub-optimal pre-market assessment of many newer technologies. Other deficiencies include the lack of regulatory oversight for a large number of exempt IVDs and inadequate regulation of increasing numbers of home-use IVDs. All of these deficiencies result in increased risks for consumers. Finally, the fact that Australia's unique regulatory framework is out of step with international best practice often results in an increased regulatory burden for industry. These deficiencies are discussed in further detail below.

Prescriptive Framework

The principle of risk classification is applied in regulatory frameworks as a way of mitigating risks inherent in the product being regulated by establishing tighter controls for those products identified as carrying a higher risk burden. In Australia IVDs are classified on a product type-by-type basis, rigidly prescribed in lists of registrable, listable or exempt IVDs, contained within the Schedules of the *Therapeutic Goods Regulations 1990* (the Regulations).

The framework of the legislation is such that IVDs are exempt, except for those described below as registrable or listable. At the time of developing the legislation, it was considered that the TGA should hold information on these specified IVDs, and they were scheduled as being listable.

There are only two types of IVDs categorised as 'registrable'. These are IVDs used for the detection of HIV and Hepatitis C Virus (HCV). The decision to make these IVDs registrable rather than listable was taken in 1995, as a result of concerns about quality of results in testing of blood donations or plasma for manufacture of blood products.

'Listable' goods are allowed to be supplied following a brief assessment of quality and safety, based on labelling and product information, and the level of compliance with relevant mandatory standards. Listable IVDs include IVDs for home use, IVDs included on the Pharmaceutical Benefits Scheme, and IVDs that contain material of human origin. All other IVDs are exempt from ARTG entry, meaning a large number of IVDs are not subject to any regulatory review prior to supply in Australia.

The existing classification system that underpins the regulatory framework is very prescriptive, based on lists of registrable and listable IVDs, exemptions and exclusions. Consequently, a regulatory amendment is required to add new categories of products to the listable or registrable classes, or to move a product category from one class to another. This is an intensive and time-consuming process and one that cannot be undertaken lightly. The Regulations cannot readily accommodate the risks associated with new technologies and the TGA's ability to respond quickly in minimising the risks to public health is impeded. Many new IVDs are treated as 'exempt' regardless of their risk until such time as the legislation can be amended to reclassify them as 'listable' or 'registrable'. This is becoming more problematic as the pace of technological advancement accelerates.

Lack of TGA Regulatory Oversight

There are a large number of IVDs exempt from TGA regulatory oversight, which means the TGA has limited knowledge of many IVDs, how they are being used or their risk profile. The Survey found that over 50% of commercial IVDs currently available in Australia are not subject to any form of pre-market oversight by the TGA.

IVDs that are currently exempt include tests for Hepatitis B, syphilis and blood typing reagents, unless they contain material of human origin. These IVDs are all used to screen the blood supply. To be consistent, all IVDs used to screen the blood supply should be registrable. However, this would necessitate a change to the regulations whenever the policy on blood/organ screening is revised.

The TGA currently has no regulatory oversight of assays developed in-house in commercial or public sector laboratories. It can be argued that in-house assays fall within the definition of an IVD and should be subjected to a similar level of regulatory scrutiny as commercial IVDs, as the risks are the same.

The current very broad grouping provisions applying to listed IVDs, which provide for one entry on the ARTG for IVDs manufactured by a single company, also contribute to the TGA's limited knowledge of IVDs supplied in the market place.

The Survey showed that:

- Local manufacturers of IVDs had no more than one product each currently registered in Australia, whilst an average of 25% of locally manufactured products are listed. An average of 64% (ranging from 0 to 650 for individual manufacturers) of locally manufactured IVDs are currently not subject to pre-market assessment by the TGA.
- In relation to the total number of IVDs imported from a third party company, on average 1% are registered and 32% are listed. The range of exempt IVDs for individual suppliers ranges from 0 to 3000.
- Only 64% of Australian manufacturers who responded reported that they were able to provide performance and safety data for the IVDs manufactured. Only 51% of distributors reported that they were able to provide performance and safety data for more than 75% of IVDs imported. (It may be that although distributors do not hold data, they can obtain it from the manufacturer. However, several were unable to say whether they would be able to obtain that data on request.)

Inappropriate Level of Protection for Consumers

The prescriptive classification system for IVDs means IVDs with similar risks to individual health and public health could be subject to disparate levels of pre-market regulatory scrutiny. For instance, a new test for West Nile Virus or SARS would be listable if it contained material of human origin, otherwise it is exempt. This is potentially detrimental to maintaining public confidence in the safety and performance of IVDs used in Australia in the long term.

The current level of protection afforded consumers is not commensurate with the level of risk. This is particularly so for a number of IVDs used to detect highly transmissible pathogens such as Hepatitis B or rubella. A worst case scenario from inadequate regulatory oversight of IVDs used to detect highly transmissible pathogens would involve the failure of such an IVD during blood screening with the disease subsequently being unknowingly passed on to a number of patients. The information obtained from the Survey suggests that performance and safety data either do not exist or are not available for many of the IVDs now on the Australian market.

There is also a trend developing with increasing numbers of home-use IVDs designed to detect markers for a variety of serious/high risk conditions, such as hepatitis, tuberculosis, cardiac markers and tumour markers. This may have undesirable impacts on consumers who perform these tests in the absence of appropriate clinical feedback and counselling, for example where consumers do their own tests to detect cancer markers or genetic tests. Given these tests are performed by inexperienced layman it is essential that these tests have been subject to pre-market regulatory scrutiny that confirms

that these tests will perform as intended. There is a critical need to ensure the provision of adequate and effective labelling, promotional material, instructions for use and presentation to address the danger of incorrect use and/or interpretation by an inexperienced consumer.

AHMAC has recently agreed that the following IVDs be prohibited from home-use:

a) all those used to test blood and tissues for pathogens or diagnose notifiable infectious diseases, in accordance with recommendations from the National Public Health Partnership;
b) all genetic tests, in accordance with recommendations from the Human Genetics Society of Australasia; and
c) tests for serious disorders, such as cancer and myocardial infarction, because appropriate pre- and post-test counselling are not in place.

The TGA proposes to address this recommendation in the new legislation.

Lack of International Harmonisation

The current framework for regulating the supply of commercial[4] IVDs in Australia is now significantly out of step with those of the United States (US), the European Union (EU) and Canada. The lack of harmonisation also imposes a cost on suppliers of IVDs because of the need to meet different requirements for different markets.

ii. Why is government action needed?

Government action is needed because the risks to consumer health and safety are unlikely to be addressed in any other way given the fragmented nature of the commercial IVD industry and the lack of a broadly representative industry body capable of developing adequate standards and ensuring industry-wide compliance.

3. Objectives

What are the objectives of government action?

The objective of government action is to reduce the risks to public health and safety by putting in place a new set of regulatory requirements for all IVDs supplied in the Australian market that:

- ensures the quality, safety and performance of all IVDs;
- aligns with the regulatory system for medical devices;
- is harmonised with international best practice; and
- minimises the imposts on business.

The framework for new legislation developed by the Working Group proposes that all IVDs are subject to compliance with Essential Principles for quality, safety and performance. There is a risk-based classification scheme, with classification determined by rules. The class into which the IVD falls determines the level of regulatory scrutiny, with manufacturers taking more responsibility for ensuring and certifying compliance of lower risk IVDs.

The framework is based on the GHTF model for medical devices, adopted by Australia in October 2002. By international consensus, IVDs are regulated as a sub-set of medical devices. Now that Australia has adopted the new framework for medical devices, it is important for regulatory consistency that the same framework is put in place for IVDs.

The GHTF is currently developing recommendations for the regulation of IVDs, also using the medical device model as a base. The TGA is therefore actively working with the GHTF to develop a

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[4] Commercial IVDs – those IVDs produced by a manufacturer for sale to an end-user.

regulatory system that is aligned with that expected to be developed by the GHTF and adopted by other regulatory jurisdictions in due course. In the interim, the framework proposed for Australia is closely aligned with those of Europe and Canada.

The regulatory framework adopted by the TGA will be incorporated into the legislation for a Trans-Tasman Joint Agency, and will apply in both Australia and New Zealand.

4. Options

The broad options available options are to either maintain the current system, or adopt an internationally harmonised system, with consideration of the extent of regulation of in-house IVDs.

The proposal to regulate in-house IVDs has been under discussion since 2001, when the Intergovernmental Committee on AIDS and Hepatitis Related Diseases (IGCAHRD) noted the use by a State reference laboratory of an in-house Hepatitis C virus (HCV) test not subject to TGA regulation. The IGCAHRD recommended that the inequity in the regulation of commercial and in-house HCV tests should be corrected. The proposal has been supported by AHMAC and AHMC in the context of development of the new regulatory framework for IVDs.

In addressing this issue, the Working Party noted the unique "manufacturing" environment of a laboratory setting, and the range of factors that may drive development of an in-house test, e.g., lack of a commercial alternative, cost-effectiveness, etc. and recognised there are several options that could contribute to an appropriate level of regulation for in-house tests.

Nevertheless, the Working Party agreed that there was a need to ensure that in-house tests used to screen the blood supply were subject to rigorous assessment and supported the proposal that these tests be regulated by the TGA in the same way as commercial tests of the same kind.

The pathology community has indicated they would support the regulation by TGA of in-house IVDs used in donor screening. The IVD Working Party has further agreed that in-house tests for diseases or pathogens of major public health significance should be regulated by the TGA.

The options available therefore consider the ramifications of replacing the current framework with a harmonised system, and from there, the extent to which it is reasonable and practical to regulate in-house tests within the system.

Option 1 Retain the current regulatory framework

Option 2 Internationally harmonised regulatory framework for commercial IVDs

The key features of Option 2 are as follows:

a) Alignment of the regulatory requirements for commercial IVDs with the new medical devices regulatory framework;
b) all IVDs to meet essential principles for quality, safety and performance, based on the intended purpose of the IVD;
c) change from a list-based to a rules-based risk classification system which takes into account the IVD's intended purpose, the degree of risk to public health, and/or the degree of risk to an individual. There will be four risk classes with Class I being the lowest risk and Class IV being the highest risk;
d) introduction of a choice of established procedures (conformity assessment procedures), based on risk classification, that can be employed by manufacturers to demonstrate compliance with the Australian regulatory requirements;

e) levels of pre-market assessment of IVD performance, including review of specificity, sensitivity, quality and safety, commensurate with risk classification;
f) low risk IVDs will be notified to the TGA enabling sponsors to market these products without undue delay;
g) retention of the ARTG as the central point of control of supply of medical devices in Australia;
h) applications for entry on the ARTG will be streamlined using the Device Electronic Application Lodgement system (DEAL);
i) extension of quality systems requirements to all IVDs;
j) appropriate regulatory controls will be maintained over the manufacturing process and manufacturing premises will be subject to audit by the TGA;
k) replacement of unique, mandatory Australian standards with voluntary international standards as a means to demonstrate compliance with the essential principles;
l) comprehensive manufacturer post market surveillance requirements for IVD safety, quality and performance, with mandatory reporting requirements for adverse incidents;
m) certain higher risk IVDs to be prohibited from home-use;
n) a regulatory framework for IVDs consistent with international best practice and GHTF principles;
o) retention of existing mechanisms of access to unapproved IVDs; and
p) establishment of a subcommittee for IVDs under the auspices of the Medical Devices Evaluation Committee.

The framework proposed for this option requires the manufacturer to put in place a quality system for the manufacture of the goods, to ensure compliance with essential principles for quality, safety and performance, to carry out performance testing and to generate and hold full documentation on manufacturing and performance. The manufacturer must have information on performance limits of the IVD and evidence to demonstrate that the product performs as intended. The level of interaction with the TGA will depend upon the risk classification assigned to the IVD. For instance, Class I (lowest risk) IVDs will be subject only to the manufacturer's declaration that the product meets the requirements, prior to entry onto the ARTG. Manufacturers of Class IV (highest risk) IVDs will need to hold evidence of compliance with the appropriate quality systems standard, through TGA audit, or by certification from appropriate overseas regulatory bodies and submit to the TGA all evidence relating to quality, safety and performance of the IVD. This evidence will be assessed by the TGA and entry onto the ARTG will only occur once that evidence is found to be satisfactory. Manufacturers of Class II and III IVDs will be subject to a level of pre-market scrutiny prior to ARTG entry, but at a lower level than for Class IV IVDs.

Option 3 Internationally harmonised regulatory framework for all IVDs (including in-house IVDs)

As for Option 2 above but incorporating in-house IVDs on the same basis as commercial IVDs.

a) In-house IVDs would be classified according to the established classification rules;
b) Laboratories developing in-house assays would be required to follow the same conformity assessment procedures as manufacturers of commercial IVDs;
c) Individual laboratories manufacturing Class II through IV in-house IVDs would have to undergo conformity assessment by the TGA and wait for TGA approval of tests prior to use; and
d) Should an assay that has not been approved for use by the TGA be required on an urgent basis, special access schemes would be available.

Option 4 Internationally harmonised regulatory framework for commercial IVDs and high risk in-house IVDs only (with most in-house IVDs subject to a validation standard)

As for Option 2 with the internationally harmonised regulatory framework for IVDs extended to the highest risk Class IV and some high risk Class III in-house IVDs. The TGA would regulate high risk

in-house IVDs in the same way as commercial IVDs, but the majority of in-house IVDs would be subject to a validation standard, as accepted by the TGA. The NPAAC standard on validation goes some way to addressing the requirements and is the preferred instrument for regulation. However, the TGA would wish to work with NPAAC to strengthen the standard, or to develop follow-on standards to ensure that there is full and detailed information on the expected level of validation for in-house tests. NPAAC has agreed that further work will be undertaken as necessary.

This option builds on the current laboratory accreditation process, but strengthens the mechanism for validation of high-risk in-house IVDs.

a) All in-house IVDs would be classified using the classification rules developed for commercial IVDs;
b) High risk in-house IVDs to be subject TGA conformity assessment to include:
   all Class IV tests (ie those used for universal screening of blood and tissues and tests that have a diagnostic role for these specific pathogens); also
   any Class III in-house IVDs used to screen the blood supply for pathogens. This includes tests used for non-universal screening or screening selected populations, eg cytomegalovirus (CMV), dengue fever, malaria and West Nile Virus;
c) A TGA-endorsed standard will be the basis for validation of performance characteristics of lower risk Class I to III in-house IVDs, and
d) Laboratories developing the lower risk Class I to III in-house IVDs will be notified to the TGA. Laboratories, rather than the IVDs, will be included on the register.

This option addresses the concerns of the pathology services sector by utilising and strengthening the current system of laboratory accreditation as the basis for assessing validation of most in-house IVDs.

5. Impact analysis

The parties who are primarily affected by the various options for regulating IVDs are as follows:
- Consumers accessing pathology services;
- Businesses importing, distributing and/or manufacturing in vitro diagnostic devices (suppliers);
- Pathology services sector comprising private laboratories, and public laboratories primarily located within the public hospital system; and
- Federal and State governments.

Cost/Benefit Analysis

The costs and benefits discussed below cannot, in many cases, be quantified. This is because the costs will vary with the individual manufacturer. Factors involved include the size and complexity of manufacture, maturity of the manufacturing system in terms of quality system requirements and the level of regulatory compliance already in place for overseas markets. Some manufacturers will have numerous products, which although subject to the same quality system, will require performance data generated for each product. For these it is likely that the quality system will also be complex and require significant documentation and maintenance. Small manufacturers may have only one or two products, requiring a simple quality system. Some IVDs will be complex and/or novel, requiring more effort in development and generation of performance data. The cost of regulatory activities and compliance will therefore vary in range.

The elements of cost for a manufacturer are developmental costs and regulatory costs.

Developmental costs include the cost of generating performance data, and the cost of implementing a quality system. For the larger manufacturers, and particularly for those supplying to large international markets, these costs will have already been met. The Survey found that 80% of the manufacturers who responded indicated that they could provide evidence of compliance with formal

quality systems requirements for at least 75% of the IVDs manufactured. However, only 64% reported that they would be able to provide performance and safety data for more than 75% of their IVDs.

Regulatory costs can be ascribed to
- the cost of generating and holding documentation;
- the TGA's fees and charges, for audit, application, assessment of data and annual charges; and
- the need to employ regulatory personnel.

The TGA is a 100% cost recovery organisation and the cost of regulation will be recovered from those who are regulated, by way of fees and charges for the regulatory activities.

The TGA has let a consultancy to determine the expected cost of the regulation activity. Early results estimate the cost over 5 years (the proposed transition period) to be $11.1m, based on regulation of an estimated 40,000 IVDs. If the worth of the market is put at $500m, this represents an overall cost to industry of 0.45%. The costing model is based on the experience of the TGA in developing a fees and charges model for the medical device legislation. Since IVDs are a subset of medical devices and the frameworks are to be aligned, the work effort in regulating medical devices is known and can be transferred to IVDs. However, some adjustment will be required to prevent over recovery because of the high volume of IVDs on the market.

Option 1 Retain the current regulatory framework

Retaining the current framework would have no new impacts on stakeholders. However this option does not address the problems identified with the current framework (see Section 2). By retaining the current framework Australia would not gain the benefits of an internationally harmonised framework and potential risks to public health and safety remain.

If the current system is maintained, the issue of adequate validation and control of in-house tests, as raised by AHMAC, will need to be addressed through processes outside the TGA, as the TGA does not regulate laboratory practice.

Option 2 Internationally harmonised regulatory framework for commercial IVDs

Benefits
Option 2 will provide significant benefits to consumers, laboratories and governments in terms of assurances about the safety, quality and performance of all commercial IVDs.

Government
The option provides for a system whereby the government is aware of what products are on the market and puts in place a system that regulates all IVDs in a manner proportional to the risk associated with the product.

Government will have greater assurances that it is effectively managing risks to public health and safety associated with commercial IVDs. The same level of assurance will not be provided for IVDs developed in-house.

Consumers
The risks to consumers associated with home-use IVDs will be addressed. Some higher risk IVDs for home-use will not be approved for supply and will need to be withdrawn from the market, while for lower risk home-use IVDs manufacturers will need to demonstrate the safety and performance of these tests, in the hands of consumers, before they can be supplied.

Industry
Harmonisation with GHTF principles, with a rules-based risk classification system, will provide a transparent, consistent regulatory framework that is responsive to changes in technology. Industry will also, in the longer term, benefit from decreased regulatory duplication that will facilitate trade, particularly for Australian exporters.

The Survey found that most (13/14) of the commercial suppliers who answered the relevant question agreed that the current arrangements for regulation would be improved by alignment with overseas standards. Only 3 agreed that the sector is currently well regulated. Most respondents recognised that increased cost would be the major impact.

Pathology sector
Increased assurance of the quality of tests supplied to the market. It was acknowledged during the consultation process that there are problems with some IVDs currently supplied, although it was considered that these are detected through the quality control systems in place within laboratories. Although market forces may operate in eventually excluding these IVDs from the sector, the concern is that these products reached the market in the first instance.

Costs
Government
Any costs to government will occur through the increased cost of commercial IVDs, should suppliers decide to offset costs by increasing prices. The extent to which this may occur will depend upon market forces.

Pathology is a competitive business in which 90% of tests are bulk billed (92% of all laboratories who responded to the Survey obtained Medicare reimbursement for tests they perform). By agreement with the federal government, Medicare expenditure on pathology is limited to an annual increase of 5%.

If IVD suppliers were to increase the costs of their tests following the implementation of the new regulatory framework, it is likely that the pathology laboratories would seek increased government assistance through Medicare reimbursement to offset the rising costs. As a result, the cost of the Medicare Benefits Scheme would increase.

It is recognised that the TGA may need to recruit additional staff who are highly skilled with relevant technical expertise. However, the TGA is a 100% cost recovery organisation and costs will be covered by the fees and charges imposed on industry.

Consumers
As most IVD tests are reimbursed under Medicare cost increases will not impact directly on the majority of consumers.

Industry
There will be an increase in the overall regulatory requirements for many suppliers of IVDs. Smaller distributors are likely to have the most difficulty meeting the new regulatory requirements, particularly those currently operating without a quality system, and some may exit the market.

The major cost for manufacturers will be in the implementation of a quality system. Feedback from Australian manufacturers who have been required to implement a system for the purposes of the medical device legislation puts this cost at between $15,000 - $60,000, depending on the size and complexity of manufacture. However, market pressures in today's commercial world are such that a quality system is expected of manufacturers and most customers will require evidence of compliance with a quality system standard. It is expected that larger manufacturers will already have a system in place.

Costs for sponsors will lie in the need for increased resources for regulatory liaison. The extent of resources required will depend again on the size and complexity of the business. Small companies may be able to absorb the additional work required.

Overseas experience (Canada and EU)[5] suggests that increased levels of regulation may impact on diversity and slow the introduction of new IVD technology. Industry has also expressed concerns that there may be some delays in the availability of some new IVD technologies which could impact on the standard of testing and clinical outcomes.

While suppliers have concerns about the additional regulatory costs, many recognise the longer term benefits of harmonisation with GHTF principles. Harmonisation with GHTF principles may, in the longer term, minimise the negative impacts on consumers of products being withdrawn from the market because imported goods may already have much of the evidence to demonstrate compliance with Australia's requirements while with harmonisation Australian manufacturers will have far easier access to European markets.

It is unlikely that the majority of suppliers will pass on the full impact of additional compliance costs given the considerable purchasing leverage of most laboratories. Based on the Canadian experience[6], the majority of suppliers are likely to absorb any additional cost, at least in the short-term, which will impact on margins.

Australia is a small market (representing less than 1.4% of global sales[7]) and some manufacturers will no longer be able to justify registering some low volume products. However, low volume/low value provisions for reduced fees will continue to apply and should minimise the impact of increased regulatory costs.

Pathology sector
Providers of pathology services are making less profit from many standard tests than they did in the past due to the rise in the volume of tests and the addition of new high-technology tests. Any rise in cost of IVDs as a result of increased regulation will impact on the financial resources of the pathology sector. However, as discussed above, it is unlikely that suppliers will pass on the full impact of additional costs.

In summary
Option 2 addresses all the problems with the current regulatory framework for commercial IVDs by moving to an internationally harmonised regulatory framework with a rules-based risk classification system. However, suppliers are likely to remain concerned that in-house IVDs remain exempt from a similar level of regulatory scrutiny and governments are not able to able to ensure the quality, safety and performance of in-house IVDs, particularly the higher risk in-house IVDs.

The cost of regulation is estimated to be 0.45% of the market worth, plus associated costs of development for some manufacturers. The cost can be offset by the benefits of ensuring that IVDs supplied commercially meet an acceptable standard of quality, safety and performance.

Option 3 Internationally harmonised regulatory framework for all IVDs (including in-house IVDs)

[5] Phone interviews with a French and Canadian manufacturer and survey undertaken by Applied Research Consultants for Health Canada in 2002 to assess the impact of increased regulatory costs through cost recovery.

[6] Survey undertaken by Applied Research Consultants for Health Canada in 2002.

[7] European Diagnostics Manufacturers Association – 2001.

For commercial IVDs option 3 delivers the same benefits and costs as detailed in Option 2 above. Below is a consideration of the additional impacts of extending Option 2 to in-house IVDs.

Benefits

Government and Consumers
This option ensures that all IVDs, regardless of whether they are commercially supplied, or manufactured by a laboratory in-house, will meet the same requirements for quality, safety and performance.

Industry
Industry supports this option because they believe that it will address inequities in the level of regulation between commercial and in-house IVDs. Industry may benefit from decreased activity in in-house manufacture.

Pathology sector
The Survey indicates that majority of the pathology sector (44 of 50 respondents to the relevant question) sees no benefits in this option. However, 16 agreed that the proposal could improve quality assurance and standards. Nine agreed that it could produce increased consumer confidence and provide an improvement in validation, and 5 saw the benefits to include a greater uniformity in laboratory performance and the regulation of non-accredited laboratories.

Costs

Government
The cost would be as for Option 2 in relation to commercial tests. There could be additional costs for the regulation of in-house tests, with the TGA's costs recovered from the pathology sector, as discussed below.

At this stage no other country regulates the development of in-house IVDs to the extent proposed under this option. Australia may be seen as being out of step with the rest of the world in imposing onerous regulatory requirements on in-house IVDs. Government may be subject to criticism if there is any decline in the quality of pathology services in Australia, particularly a restriction in the variety of IVDs available, as a result of increased compliance costs.

Pathology sector
The pathology sector have expressed strong concerns about the adoption of this option indicating that there will be a large increase in compliance costs which may stifle development and use of tests that are used in uncommon cases and restrict patient access to new technology. Some laboratories involved in blood screening suggest that TGA regulation has stifled innovation (however, the extent of regulatory oversight for blood screening is higher than that proposed for IVDs under Option 4).

Some laboratories have indicated that increased compliance costs are likely to lead to a reduction in the level of service unless governments provide supplementary funding. Additional compliance costs are likely to lead to a reduction in innovation and skills development in laboratories. The impact of additional compliance costs on laboratory budgets may mean they have fewer resources to purchase commercial IVDs.

The cost to laboratories of this option would be high. The cost of regulation of a further 10,000 in-house tests is estimated at $2.8m. There would also be the costs of implementation of a quality system, at approximately the same cost as for a commercial manufacturer ($15,000 - $60,000) and the costs of additional staff to implement and maintain the regulatory requirements.

In summary
Option 3 would certainly address concerns about the quality, safety and performance of in-house IVDs. For high risk in-house IVDs such as those used to test for pathogens in the blood supply and those used to test for highly infectious notifiable diseases this level of regulatory scrutiny is justified on the basis of public health and safety. However, for the lower risk in-house IVDs the benefits do not outweigh the costs related to adopting this option.

Given the constraints on health funding, the benefits to consumers and the community afforded by the current arrangements for in-house IVDs far outweigh any negative impacts for suppliers of commercial IVDs as a consequence of laboratories not having with the same compliance costs.

Additional costs are not commensurate with the level of risk. It has been difficult to find an example of a major adverse incident involving an in-house IVD. Laboratories work closely with a clinician in contributing to the overall diagnosis of the patient. In many cases the result of the IVD test is only one aspect of the clinical diagnosis. The highly specialised nature of some in-house IVDs (especially genetics) means that a full and formal validation process would be impractical. For example, for a newborn screening service the commonest disorder dealt with has a birth prevalence of 1:2,500, with most disorders having a prevalence of 1:100,000. The pathology sector has a strong existing commitment to the implementation of quality systems. There is a very high probability that a poorly performing test will be identified.

Option 4 Internationally harmonised regulatory framework for commercial IVDs and high risk in-house IVDs only (with most in-house IVDs subject to a validation standard)

For commercial IVDs Option 4 delivers the same benefits and costs as detailed in option 2 above. Below is a consideration of the additional impacts of extending Option 2 to high risk Class III and IV in-house IVDs, while most other in-house IVDs are regulated by assessing their compliance with a TGA-approved validation standard.

Benefits
All in-house IVDs will be subject to some regulatory scrutiny providing greater assurances about the safety, quality and performance of in-house IVDs.

Government
The Option provides government with adequate assurances about the quality and safety of in-house IVDs in a very cost-effective way and is commensurate with the level of identified risk.

The TGA will have access to the information about the manufacture of in-house IVDs in Australia.

The TGA will be able to ensure that consumer health and safety issues are being adequately protected and will be better positioned to keep abreast of new developments in the IVD market.

Consumers
The regulation of the highest risk Class III and IV in-house IVDs by the TGA, to the same level as commercial IVDs, in recognition of the potential risks to public health and safety from a major incident, will provide additional assurances for consumers.

Industry
The option will go a small way to addressing the concerns of industry about inequities in regulation. There may be some small benefit for industry if laboratories choose to opt out of in-house manufacture of high risk IVDs and purchase commercial products instead.

Pathology Sector
This option is a cost-effective way of addressing the weaknesses in the current framework, namely the total lack of regulatory scrutiny of all in-house IVDs, yet should not have any negative impacts on innovation and skills development in the laboratory.

Costs

Government
This option will not incur the significant costs of Option 3 in relation to the pathology sector and therefore the costs to government will approximate those of Option 2.

Pathology sector
There will be some additional costs for the small number of laboratories that don't currently meet the requirements of Option 4, for development of a quality system and compliance with the regulatory requirements. However, the number of laboratories affected is expected to be very small.

There will be a minimal cost for all laboratories in maintaining the ARTG entry for each laboratory, estimated at a maximum of one day's work initially, with one to two hours work in maintenance each year.

The small number of laboratories currently developing high risk IVDs may cease to do so given the increased compliance costs and the availability of commercial alternatives. However, this cost is outweighed by the public health benefit to consumers who will be assured that all high risk IVDs have been subjected to an appropriate level of regulatory scrutiny by the TGA prior to being supplied in Australia.

In summary
Option 4 is the recommended option.

Option 4 will ensure that all commercial IVDs are regulated in line with international best practice, while also introducing regulatory control over the manufacture of in-house IVDs. It will provide consumers with greater assurances of the quality, safety and performance of in-house IVDs while the overall impact of regulation on laboratories for the majority of lower risk in-house IVDs is limited.

Option 4 is a very cost effective approach to addressing the weaknesses in the current regulatory arrangements and as such should not impose any additional costs on consumers or the community. It also moves towards the development of a level playing field for suppliers and the pathology service providers as they will all be subject to an appropriate level of regulatory requirements. The cost to government of administering the new regulatory framework as it applies to the pathology services sector will be low [5, 6, 7].

Trade impact assessment

The trade impact of the various options is as follows:

- Harmonisation with the GHTF principles (Options 2, 3 or 4) is likely to deliver benefits to global suppliers in the longer term.
- Implementation of Option 3 would impose significant additional costs on the pathology services sector and may slow the offshore expansion plans of some of the larger companies. On the other hand, Option 4 will enhance the sector's reputation for quality and support its expansion in overseas markets, with minimum additional costs for pathology laboratories.
- To the extent that local manufacturers are unable to increase prices to recoup the additional regulatory costs which will apply as a consequence of the implementation of Options 2, 3 or 4, there is likely to be a small negative impact on export performance in the short-term.
- The proposal for regulation of in-house IVDs (Options 3 and 4) will have no impact on trade. IVDs manufactured by a laboratory and supplied outside that laboratory, or exported, fall outside

the definition of an in-house IVD, as they are manufactured for commercial supply. They are therefore subject to regulation as commercial IVDs. This approach is consistent with that of the European Union.

Small business assessment

The majority of suppliers are small companies, with 43% of survey respondents indicating that they employed 10 or less people and had a turnover between $1m and $5m. Many of these businesses are distributors and most local manufacturers are small businesses. The impact of the various options on small business is as follows:

- The most significant impact of Options 2, 3 or 4 on small businesses is likely to be increased compliance costs. This impact is likely to be relatively more significant than it is for larger businesses. The Canadian experience suggests smaller businesses are more likely to increase prices to recoup fees and additional compliance costs than larger businesses.
- The majority of local manufacturers are reasonably well placed to comply with the new requirements as proposed in Option 4 but a number of smaller businesses may experience difficulties.
- Some manufacturers will incur the costs of putting quality systems in place.
- To the extent that smaller local manufacturers are unable to increase prices to recoup regulatory costs because of market forces there is likely to be a negative impact on exports and research and development.
- The Canadian experience suggests that small distributors will be hardest hit and a number are likely to exit the market.
- Many pathology laboratories that manufacture in-house IVDs have indicated that they would not be able to meet the regulatory requirements of Option 3. This would lead to increased costs, as well as a detriment to innovation, as these laboratories move to replace all in-house IVDs with commercial products. This would be of particular concern for laboratories involved in genetic testing where the majority of the IVDs are manufactured in-house.
- Even the smaller pathology laboratories should be able to meet the less onerous requirements of option 4 for the manufacture of in-house IVDs.

6. Consultation

i. Consultation process

The key elements of the consultation process are as follows:

- The establishment of an expert advisory group under the auspices of the National Coordinating Committee on Therapeutic Goods (NCCTG), an AHMAC subcommittee. The NCCTG In Vitro Diagnostic Devices Working Group met 7 times;
- A discussion paper, *"A New Regulatory Framework for In Vitro Diagnostic Devices"* developed by the IVD working group was circulated to over 1200 stakeholders seeking their comment on a number of specific options;
- The TGA conducted presentation and consultation sessions for stakeholders in all States;
- Articles on the regulatory proposals have been published in the Australian Therapeutic Device Bulletin, the TGA News and on the TGA's website, which are distributed to industry and other stakeholders;
- The consultancy firm contracted to prepare a report on the regulatory proposals conducted separate consultations with key stakeholders;
- The consultant undertook a survey to assess the impact of the proposed new regulatory framework on businesses manufacturing and/or distributing IVDs in the Australian market and on public and private sector pathology laboratories;
- Papers have been presented to a number of ministerial advisory and Commonwealth/State liaison committees such as the National Coordinating Committee on Therapeutic goods (NCCTG), the

Australian Health Ministers' Advisory Committee (AHMAC) and the Australian Health Ministers' Conference (AHMC).

i. Views of key stakeholders

Stakeholders generally agreed that:

- the preferred option needs to be consistent with the stated objective of harmonisation with international best practice;
- there is a need to minimise the regulatory requirements by focussing on identified areas of highest risk;
- there is a high level of concern about the cost impact of the regulatory proposals and the strong possibility that small or low volume products will be withdrawn from the Australian market;
- there is the need for a realistic transition period; and
- an expert advisory committee, which includes laboratory professionals, should be established to provide ongoing advice on the management of the new regulatory framework.

Importers/distributors of IVDs expressed the following additional views:

- all in-house IVDs should be included on the ARTG;
- the TGA should not impose unique labelling requirements given the required information is readily available; and
- there is a need for a logical grouping system for ARTG entry to reduce the regulatory burden.

Local manufacturers of IVDs expressed the need for:

- self declaration of Class I products on the ARTG; and
- recognition by the TGA of GMP inspections conducted as part of an overseas (EC, Canada, EU) conformity assessment process, provided the company in question can demonstrate an acceptable compliance record.

The **pathology services sector** (including relevant professional and representative organisations), raised concerns that:

- Option 3 would have a negative impact on the quality of pathology services in Australia given the pressure on health budgets;
- there was a lack of evidence that Option 3 will improve the quality of diagnostic testing in Australian pathology laboratories;
- existing laboratory accreditation systems should be strengthened rather than implementing a new regulatory framework for in-house IVDs;
- the NPAAC draft document "Requirement for the Validation of In-house In Vitro Diagnostic Devices" should address the current lack of a standard for reviewing the validation of in-house tests;
- the preferred option should seek to minimise any additional costs (financial and personnel) on the laboratory sector, particularly public laboratories providing specialised services; and
- innovation and research in Australian laboratories not be compromised by the regulatory framework.

Consumer organisations have expressed strong support for increased regulation of IVDs. Consumer groups have expressed particular concern over home use IVDs for serious conditions that might have high levels of false reports are not safe for home-use or their intended purpose. They are also concerned about the adequacy of information provided to consumers for many home-use IVDs.

State governments are strongly supportive of Option 4, they have expressed similar concerns to the pathology services sector about Option 3.

7. Conclusions and recommended option

Option 4 is the preferred option. It has a number of benefits over other options:

- The introduction of a rules-based risk classification system will ensure the regulatory framework is flexible enough to adapt to changing circumstances without the need for regulatory amendment. This addresses one of the main shortcomings of the current prescriptive regulatory framework;
- Option 4 provides comprehensive regulatory oversight of all IVDs in the market,
- Option 4 ensures an appropriate level or regulation for high risk in-house IVDs, while lower risk in-house IVDs are regulated in a way that is consistent with the level of risk. This will meet the expectations of consumers and provide certainty for all stakeholders;
- It ensures that the requirements for commercial IVDs are aligned with international best practice, thereby minimising regulatory duplication and facilitating both exports and imports;
- Option 4 is the most cost-effective way of addressing the weaknesses in the current arrangements for in-house IVDs; and
- Option 4 provides for increased transparency with regulatory oversight being extended to all IVDs.

Option 1 is not preferred because it does not provide adequate assurances to consumers of the safety, quality and performance of all IVDs available in the Australian market and is not aligned with international best practice. The current framework is too prescriptive and inflexible to ensure adequate regulation of IVDs in the 21st century.

Option 2, while effectively addressing the weaknesses with the currently regulatory arrangements with respect to commercial IVDs, does not address the weaknesses in the current regulatory arrangements for in-house IVDs, particularly to total lack of regulatory scrutiny for high risk in-house IVDs such as those used to screen the blood supply and those used to test for highly infectious notifiable diseases.

Option 3, while providing consumers with adequate assurances on the safety, quality and performance of commercial IVDs, is not the most cost-effective way to address the weaknesses in the current arrangements for in-house IVDs.

8. Implementation and review

Implementation of preferred option

It is proposed that the new requirements will be introduced on 1 July 2005 as part of the Trans Tasman joint legislative framework.

Transition period

It is proposed that currently exempt IVDs be given 2 years to meet the new requirements. If they do not meet these requirements at the end of this period then they will not be approved for sale in the Australian market. All new applications for entry on the ARTG will need to meet the new Requirements. IVDs already on the ARTG on the date of implementation will have five years to transfer to the new regulatory framework.

Review of legislation

The legislation will be reviewed in accordance with National Competition Policy (NCP) principles. The new legislation will be closely monitored by the TGA in cooperation with industry and consumers through a stakeholder/government consultative group.

Regular review of the effectiveness of the new regulatory framework will be undertaken through the TGA's consultative mechanisms and regular reporting to the industry through the annual report.