Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

COST RECOVERY IMPACT STATEMENT

REGULATION OF IN-VITRO DIAGNOSTIC DEVICES

The TGA will be implementing a new regulatory system for *In-vitro* diagnostic devices (IVDs) on 1 July 2006. Australian Health Ministers' Advisory Council (AHMAC) approved the development of a regulatory model in May 2001. A Regulatory Impact Statement for the regulation of in-vitro diagnostic regulation was approved by the Office of Regulatory Review in January 2004 and the framework was endorsed by AHMAC in March 2004.

As the TGA recovers the full cost of its regulatory activities there will be regulatory costs for sponsors and manufacturers of IVDs with the implementation of this new system. While the TGA currently regulates some IVDs (see below) the introduction of a comprehensive model for the regulation for all IVDs gives rise to a significant change to existing cost recovery arrangements undertaken by the TGA. Accordingly, a Cost Recovery Impact Statement is required to be prepared in accordance with Australian Government Cost Recovery Guidelines (updated in July 2005).

BACKGROUND

The Australian community has an expectation that therapeutic products in the marketplace are safe and of high quality, to level equal to that of countries with comparable standards. The Therapeutic Goods Administration (TGA) is one of the world's front line regulators undertaking rigorous scientific and risk assessments of therapeutic products to ensure safety, quality and efficacy, without undue impact on the timely supply of essential products to consumers and patients.

The IVD industry in Australia

A survey[1] 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 the majority of 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.

From information gathered from a survey commissioned by the TGA, 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.

[1] *Investigation of the IVD market in Australia, 2003 Piazza Consulting* (the Survey). Survey conducted for the purpose of preparing the Regulation Impact Statement for in-vitro diagnostic devices.

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 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.

The current regulatory requirements for IVDs

Therapeutic products are regulated in Australia under the provisions of the *Therapeutic Goods Act 1989* (the Act). Therapeutic products regulation is achieved through a risk management approach to pre-market evaluation and approval of therapeutic products intended for supply, licensing of manufacturers and post-market monitoring and surveillance. The principal activities of the regulatory scheme include:

- Scientific evaluation of medicines, medical devices and blood and tissue products for supply in Australia;
- Licensing and audit of manufacturing standards;
- Monitoring compliance with standards, including testing of products, auditing product data, analysing reportable incidents, investigating complaints, and recalling non-compliant products from the market;
- Surveillance, investigation and enforcement of the provisions of the Act;
- Industry support activities, including the development of guidelines and promoting international harmonisation; and
- Services to Government to support the objects of the Act.

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

- 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.

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 classified as high risk "registrable" – Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV). Sponsors of registrable devices must demonstrate compliance with Good Manufacturing Practice (GMP) requirements and provide detailed information on manufacturing processes, clinical performance and labelling. Registrable IVDs are subject to rigorous performance evaluation by the National Serology Reference Laboratory (NRL):
- IVDs for home use, IVDs included on the Pharmaceutical Benefits Scheme and IVDs that include materials of human origin are all "listable". Listable IVDs undergo an administrative review for compliance with labelling, advertising and GMP requirements but no assessment of performance.
- 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*.

Problems with the current system

Deficiencies with the existing IVD regulatory framework include:

- inadequate pre-market assessment of new technologies (eg can't ensure the protection of the Australian public through high quality IVDs to detect emerging threats such as Bird Flu, SARS and West Nile Virus);
- the level of protection afforded consumers is not commensurate with the level of risk, particularly for a number of IVDs used for mass screening of blood and tissue donations for infectious agents such as Hepatitis B;
- lack of regulatory oversight for a large number of exempt IVDs;
- a unique regulatory framework that is out of step with international best practice, (including Europe and the USA):
  - often results in an increased regulatory burden for industry; and
  - raises the possibility of dumping of inferior quality IVDs in Australia;
  - involves significant numbers of recalls, up to 35% of all medical device recalls, relate to IVDs, mainly due to performance or quality control issues. In addition for IVDs there are often problems with the manufacturer's timeframes for implementing corrective action.

THE NEW IVD REGULATORY SYSTEM

In May 2001 the Australian Health Ministers' Advisory Council (AHMAC) endorsed the development of a new IVD regulatory framework, aligned with international best practice, agreeing that the project would:

- ensure a much safer, collaborative and rigorous approach to the regulation of IVDs, thereby increasing public confidence in the IVDs available;
- bring together a number of initiatives that reach across State/Territory and Commonwealth boundaries including:
  - the HIV and Hepatitis C (HCV) strategies as they relate to the accurate detection and diagnosis of HCV and HIV infection,

    - the review of the Australian Blood Banking and Plasma Product Sector,
    - the need to address the burgeoning array of IVDs intended for home-use,
    - the need for increased public confidence in the quality of IVDs available in Australia; and
- consider the issues surrounding the use of in-house IVD test kits which are currently unregulated.

The new system is aligned with international best practice as defined in the GHTF proposed framework:

- **all** IVDs undergo pre-market assessment in line with their risk classification;
- in line with the level of regulatory control in Europe and the USA;
- ensures no importation of inferior quality IVDs (no dumping);
- no additional regulatory burden for Australian manufacturers who already export to Europe and the USA;
- strong requirements for post market monitoring including detection of batch variations by the NRL and mandatory reporting timeframes for serious adverse events.

It is proposed that there be a 2 year transition period for all Class 4 IVDs used in blood and tissue screening, except immunohaematology products, and a 4 year transition period for all other IVDs.

The proposed system was endorsed by the Australian Health Minister's Conference on 31 July 2003 and by AHMAC on 4 March 2004. Since AHMAC's endorsement the TGA has finalised the details of the regulatory requirements in consultation with the IVD Working Group and negotiated the cost model for commercial IVDs with industry. The agreed framework is aligned with the proposed framework under development by the Global Harmonisation Task Force.

PROPOSED COST RECOVERY ARRANGEMENTS

The TGA recovers the full cost of its regulatory activities within the scope of the Act through fees and charges for services provided to product introducers (sponsors) and manufacturers. Fees and charges are prescribed in regulations made under the Therapeutic *Goods Act 1989, Therapeutic Goods (Medical Devices) Act 2002* and the *Therapeutic Goods (Charges) Act 1990*.

In 2003 the TGA engaged consultants to work with TGA officers to develop a fees & charges model for the new regulatory system for IVDs. The IVD fees and charges model was developed in close consultation with industry in line with the Australian Government's cost recovery policy. The regulatory model was designed to reflect the risks of IVD's to individual and public health and build on the infrastructure and processes already developed by the TGA for the regulation of medical devices. IVDs will be regulated as a subset of medical devices and the IVD fees and charges model has been based on the medical devices fees and charges model.

The Medical Industry Association of Australia (MIAA) indicated their support for the final version of the IVD cost model on 9 November 2005.

Policy Review

The first step in the development (or modification) of cost recovery arrangements is to undertake a policy review that considers the following questions:

- which of the agency's objectives are relevant to the activities or products being considered for cost recovery?
- should cost recovery be introduced?
- what mechanisms, including consultation, should be used for ongoing monitoring of the efficiency and effectiveness of cost recovery arrangements?
- how long (not more than five years) before the cost recovery arrangements should be reviewed again?

Which of the agency's objectives are relevant to the activities or products being considered for cost recovery?

The regulation of IVD's involves various pre-market regulation activities (regulations with which firms or products must comply before a product can be offered for sale) and post-market activities (regulations with which firms or products must comply after a product is available for sale) that involve monitoring compliance with regulations, investigation and enforcement.

Pre-market approvals involve different regulatory processes based on the risk of the IVD to individuals and to public health. Class 1 represents the lowest risk group which permits administrative assessment and self-certification of conformity prior to market approval. Class 2 and 3 involve increasing risk levels and have additional requirements with products subject to application audits, conformity assessment and technical file reviews. Class 4 is the highest risk group and has additional requirements relating to design dossier examinations.

Following approval, companies will be required to maintain certification of conformity (surveillance audits), comply with problem reporting requirements and, for Class 4 IVDs, participate in ongoing quality assurance programs through the National Serology Laboratory.

As with all regulatory arrangements, the TGA will provide information and support to the regulated industry and consumers and will be responsible for the maintenance of the regulatory framework (including regulatory development and advice concerning the operation of the scheme). The cost of activities associated with the development of the coding nomenclature and standards through international for a and the provision of advice regarding the operation of the regulatory scheme to the Parliament are driven by the requirement to regulate IVD's and are considered integral to regulation and appropriate for inclusion in cost recovery arrangements.

Should cost recovery be introduced?

Pre-market approval of an IVD will permit the sponsor to supply products in Australia. The benefits of market approval are limited to the applicant – none of the assessment work will benefit other sponsors. As costs can be identified for the activities undertaken, fees are considered to be an appropriate cost recovery mechanism.

Post market, scheme support and regulatory administration costs are driven by the regulated industry. The beneficiaries of the industry are the companies that sponsor and promote IVD's. Other than in cases of investigation for breaches of the Act, costs cannot be

specifically tied to individual companies. Accordingly, a levy on the regulated industry would be an appropriate form of cost recovery.

Cost recovery is considered an efficient form of financing regulation. It is expected that industry will be able to either absorb the overall cost of regulation (around 0.5% of turnover) or reflect the costs in pricing decisions for the consumer.

What mechanisms, including consultation, should be used for ongoing monitoring of the efficiency and effectiveness of cost recovery arrangements?

The primary mechanism used to monitor TGA activities, performance and costs is the TGA-Industry Consultative Committee (TICC). The TICC meets twice each year to examine the budget and progress on the business plan, with industry associations consulted separately on regulatory matters and cost impacts relating to specific sectors. Industry associations are also consulted in the process of regulatory development and reform, which are taken into account in regulatory impact statements, and in developing cost recovery arrangements..

To constrain budget growth and promote efficiency, the TICC agreed to the establishment of an indexation model to adjust fees and charges each year. Should the TGA seek to increase fees above this level, specific proposals would be brought to TICC for discussion to justify required increases. Material changes to specific cost recovery arrangements or significant changes to the level of cost recovery will be assessed and documented in accordance with the cost recovery policy and guidelines.

How long before the cost recovery arrangements should be reviewed again?

A further assessment of the efficiency and effectiveness of cost recovery arrangements will be undertaken in the context of the development of a joint regulatory scheme for therapeutic products between Australia and New Zealand. Although a firm timeline has yet to be set, it is expected that this process will be conducted over the next twelve months, with a further costing review to be completed within two years of the commencement of the scheme.

Design and Implementation

Charges can be collected in a variety of ways and based on different measures of costs. The design of the cost recovery arrangement should aim to:

- Identify who should pay regulatory charges;
- link charges as closely as possible to the costs of activities performed;
- have clear legal authority;
- be cost-effective to calculate, collect and enforce;
- compliance costs of paying the charges are not excessive; and
- there is a balance between fee certainty and flexibility (monitoring charge levels).

As noted previously, the regulation of IVDs mirrors the arrangements for the regulation of other medical devices. Accordingly, the design of the cost recovery model is similarly based on these arrangements. The cost recovery model is detailed in the Cost Recovery Impact Statement for Therapeutic Products that was completed in 2004-05.

Who should pay cost recovery charges?

Individuals or groups that give rise to the need for regulation should pay cost recovery charges. As charging individual consumers of IVD's is impractical, the charges are proposed to be recovered from the Sponsors of IVD products. Nonetheless, the cost of regulation is expected to be incorporated into the pricing decisions made in relation to IVD products.

How are cost recovery charges to be structured?

Cost recovery charges can be introduced using:

- a fee that charges Sponsors directly for the costs of providing the activity; or
- a levy on a group of Sponsors (legally a form of taxation). Levies need to be established using a tax Act.

Fees are proposed in the cost recovery arrangement for IVDs where the activities are undertaken for a single Sponsor. These include application for inclusion on the Australian Register of Therapeutic Goods (ARTG), application audits; conformity assessment and surveillance audits of quality systems, testing controls and design dossiers (as applicable). The costs are driven by the applicant and the benefits that arise from these activities (the right to continue to manufacture and/or market an IVD) are limited to the applicant.

Some costs will be recovered on an as-incurred basis. This includes travel costs associated with overseas conformity assessments and surveillance audits. Although the effort required to complete these activities are the same as domestic manufacturers, the TGA incurs highly variable costs associated with travel overseas. Overseas travel costs are advised to the Sponsor in writing prior to the performance of a conformity assessment or audit setting out the relevant charges. Reimbursement of costs is simple to administer, is transparent (no hidden costs), and ensures that fees for domestic and overseas services are treated equitably.

The cost recovery arrangements include an annual levy to be applied to all Sponsors of an IVD inclusion on the ARTG in relation to post approval monitoring, product problem reporting and analysis, random testing of devices and auditing of technical files, and the costs of maintaining the regulatory framework and supporting industry compliance with the scheme. These costs are driven by the regulation of the market and may not relate to activities performed for one or other Sponsor. The costs are proposed to be allocated evenly across all IVD product inclusions in the ARTG (with lower risk IVD’s being heavily grouped per inclusion).

IVD regulation is being phased in over four years during which time Sponsors may arrange to apply for inclusion on the ARTG. To avoid the transition disincentive that would otherwise apply, no Sponsor will be charged an annual levy until the final year of transition (2009/10). Application fees have been set to cover costs associated with initial listing, with monitoring and surveillance programs coming on stream in latter years when most products have been registered.

How are fees and charges linked to the costs of activities?

For regulatory products or services, cost recovery charges ideally should reflect as closely as possible the costs of undertaking individual activities.

The TGA uses an activity based costing methodology for the assignment and allocation of all direct, indirect and overhead costs to activities undertaken. The methodology allows costs to be allocated to activities based on their consumption at each stage of the process through to the final product or service. Activity based costing facilitates product costing and pricing, cost analysis and management, resource planning and industry reporting.

The TGA's ABC model is maintained using a proprietary product. A two-stage process is used to firstly attribute costs for corporate activities to each business unit, then a second step is used to assign these costs to activities and services (cost objects). The allocation of corporate costs (including amortisation and depreciation costs related to capital assets) use a range of drivers to allocate costs, including the number of transactions processed, staff numbers, workstations, or floor-space. However, the allocation of costs to regulatory activities and services relies on periodic surveys of staff time (time recording).

In developing the cost of services performed for IVD regulation, the TGA developed a cost model based on the regulatory effort used for other medical devices. The 5-year forecasts in the model were developed in consultation with the industry working group to refine proposals for fee levels.

For each service, the cost model tallies the staff time usually incurred to perform tasks associated with each service, which is then costed for the direct salary, plus on-cost and overhead allocations (based on the ABC model) to provide a cost per activity. The total cost is then derived by multiplying the total number of regulatory activities performed by the cost of each activity. Other overhead costs associated with monitoring compliance, surveillance, recall management, testing and regulatory management were allocated proportionately to the total staff effort developed from the cost model.

A summary of the forecasts of the model is presented in the following table:

	2006-07	2007-08	2008-09	2010-11	2011-12
Total Revenue	1,385,488	2,549,478	1,272,169	2,508,805	1,589,247
Direct Costs	838,316	1,733,523	959,363	1,327,587	1,018,896
Overheads	520,484	363,912	372,598	443,807	455,944
Net Contribution	**26,688**	**452,043**	**- 59,792**	**737,410**	**114,407**

The residual net contribution in the cost model reflects a conservative approach to the introduction of cost recovery for IVDs and recognises the uncertainty in the estimates of the number and classification of IVDs on the market and the route of conformity assessment to be undertaken.

The TGA has committed to review cost recovery for IVDs on a regular basis through the TGA-Industry Consultative Committee and to consult further with industry on charge levels after two years to take account of the actual number of applications received and products entered on the ARTG.

What are the proposed fees and charges?

As noted previously, IVD's will be regulated as a sub-set of medical devices. Many of the activities and business processes are common to medical devices, and so the fees that are applicable have been set to be consistent with other medical devices. In some cases, the resource model estimated costs above, or below, the fees applicable to other medical devices. This may reflect slight differences in assumptions for staff effort as well as the different methods for allocating overheads (actual ABC effort drivers used for other medical devices is more likely to be accurate).

The estimated costs and proposed fees and charges applicable to IVDs are summarised in the following table.

	Fee ($)	Basis of Charge
Application Fees		
In-vitro diagnostic devices - all classes	800	Per kind of device
Variation to amend a product licence that contains incomplete or incorrect information	310	Per licence
Conformity assessment– all procedures and changes	300	Per application
Technical File Reviews		
Class 3 IVDs	4,890	Per audit
Annual Licence Charges		
All classes (note 1)	550	Per kind of device
Conformity Assessment Procedures		
Full quality management system	20,500	Per assessment
Examination of product design	40,600	Per assessment
Type examination	27,400	Per assessment
Production quality assurance	18,100	Per assessment
Abridged assessments –immunoheamotology reagents	12,000	Per assessment
Surveillance audits of manufacturer's quality management system	5,990	Per audit
Supplementary assessment time, including assessor preparation/travel time associated with assessments conducted outside of Australia and New Zealand	300	Per hour
Reasonable travel, accommodation and allowance costs	At cost	

1. Annual charges will not be introduced until 2009/10
2. Reassessment of conformity assessment of manufacturers management and quality system and examinations of product design attract the full initial fee
3. Changes to conformity assessments will be charged at 60% of the initial fee.
4. All charges are expressed in 2006-07 prices having regard to average price and wage movements. Charges may be subject to minor adjustment to align with other medical device fees in 2006-07.

Will cost recovery compliance be cost effective?

The administrative rules for cost recovery for IVDs will be the same as other medical devices.

Sponsors will be required to submit fees at the time of application, although fees for conformity assessments will be notified following validation of the path of conformity and the scheduling of quality system audits.

- Applications will be lodged via the TGA's online electronic lodgment system which permits an invoice to be created at the time of processing. Companies may pay fees by cheque or credit card (online payment systems are being developed).
- Fees for conformity assessment are payable prior to commencement of the assessment.

Annual charges relating to the maintenance of an inclusion on the ARTG are invoiced each year in September. Companies may pay the amount in full or by quarterly installment by cheque or credit card (up to $10k), with online payment options being developed.

The cost recovery arrangements are considered to be cost effective – they are simple, well understood by Sponsors, require payment at the time a service is to be performed, and have low administrative and debt recovery costs.

How will fees and charges be monitored?

The cost recovery arrangements should be balanced to provide predictability to the regulated industry for budget and product planning purposes, yet remain responsive to changes in either cost-model forecasts (over/under-estimation), or structural changes in the regulated industry itself.

Through stakeholder engagement, the TGA has undertaken to closely monitor and report on the take-up of IVD inclusions and related regulatory activities to the affected industries. This will be achieved through the TGA-Industry Consultative Committee (TICC), which includes membership of all three major industry associations (the Medical Industry Association of Australia, Ausbiotech and the Dental Industry Association of Australia). The TICC meets twice each year and undertakes separate industry meetings each year ahead of finalising the TGA's business plan, budget and fees and charges proposals.

The TGA has agreed that annual charges for inclusions will not be introduced until 2009/10, as to do otherwise may create a disincentive for early transition to the scheme. This approach will be reviewed annually, with the final annual charge to be reviewed during 2008/09 when the likely number and classification of IVD's will be better understood.

Stakeholder Consultation

The key elements of the consultation process on the regulatory framework included:

- The establishment of an expert advisory group under the auspices of the National Coordinating Committee on Therapeutic Goods (NCCTG), that included representatives from State and Territory governments, relevant areas of the Commonwealth Department of Health and Ageing and also the following key stakeholder organisations:
  - the Medical Industry Association of Australia (MIAA)
  - the Royal College of Pathologists of Australasia (RCPA)
  - the Australian Association of Pathology Practices (AAPP)
  - the Public Health Laboratory Network (PHLN)

- the National Pathology Accreditation Advisory Committee (NPAAC)
- the Human Genetics Society of Australasia (HGSA), and
- the National Serology Reference Laboratory (NRL), Australia.

- 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 presentations and consultation sessions for stakeholders in all States, and presented papers 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); and
- 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.

In relation to the Cost Recovery Model TGA consultation included:

- A consultancy to undertake 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;
- Stakeholder consultation on the Model in Sydney led to the establishment of a TGA/industry working group to assist the TGA to refine the model. Working Group membership included representatives from MIAA and members from the IVD industry who represented both large and smaller IVD suppliers.

Issues raised by stakeholders during the development of the model included:

- The need for financial support for smaller/start up companies to assist them to meet the new regulatory requirements. It was agreed that it is not the TGA's role to provide or identify potential funding opportunities for industry and that MIAA might like to assist industry with this.
- The impact of the new regulatory requirements on cash flow particularly for suppliers of previously exempt IVDs and the smaller companies, This issue was addressed by extending the transition period for the majority of IVDs from 3 to 4 years to give companies an extended time to meet the regulatory requirements.
- Incentives for managing the transition period. It was agreed to waive annual charges for the first three years following implementation to ensure there is no financial disincentive for those who want to transition to the new regulatory system in the first few years after implementation.
- That there are a large number of IVDs that may only be required occasionally but that access to these IVDS is essential for public health and safety. It was agreed that the TGA's low value/low volume provisions would apply to all IVDs to ensure ongoing supply of crucial IVDs.
- The TGA also worked closely with the industry to develop an appropriate grouping system for all classes of IVDs and to ensure that the application fees and annual charges would result in an equitable sharing of the cost for regulation across all classes of IVDs.

The Medical Industry Association of Australia (MIAA) indicated their support for the final version of the IVD cost model in November 2005, particularly supporting the incentives for the transition period which they indicated would ensure the transition period was manageable for most sponsors, including the smaller companies. MIAA have also commended the TGA on their collaborative approach in the development of the IVD regulatory model and their proposal to work with industry to conduct fee reviews as the transition period progresses.