IVD AUSTRALIA

The industry where innovation saves more Australian lives

Submission to the 2017–2018 Budget on behalf of the IVD Industry in Australia

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Executive Summary

Pathology is an essential medical service which enables accurate diagnosis of disease. It directly affects health outcomes by providing the clinician with the information required to treat and manage patients appropriately. It enables identification of those at risk of disease, guides treatment and monitoring of progress, and helps to ensure that the best possible health outcomes are achieved. By providing the certainty needed for the earliest possible treatment, and by helping to avoid unnecessary treatments and hospital admissions, pathology also directly reduces the costs of healthcare. The benefits of pathology to both patients and the wider community are very clear. Quality of life is maximised, people are more productive, and the economy and community are strengthened.[1] Pathology is essential in the management of the majority of diseases, especially chronic diseases such as diabetes, cardiovascular disease, cancer, arthritis, hepatitis and HIV.[2]

IVD Australia supports the current MBS Review into "how services can be aligned with contemporary clinical evidence and practice and improve health outcomes for patients".

It has been acknowledged that over the past 20 years growth in pathology outlays have been contained due to the investment by providers in efficiencies within the private pathology sector. IVD Australia member companies have played a significant role as suppliers and enablers in achieving this result through the provision of highly automated pathology instruments coupled with world best practice in after sales support.

IVD sponsors and manufacturers in Australia are already under significant cost pressures. It is widely acknowledged that, whilst Australia has world's best practice in its private and public pathology services, prices received by IVD suppliers are among the developed world's lowest. The increased costs expected from the introduction of the new TGA regulations for IVDs will add significantly to the cost of IVD suppliers over the next few years. Together, these margin pressures may mean that suppliers will withdraw tests from the market or not seek to introduce new tests with low reimbursement or low volume.

Pathology has been subject to marked fee restraint. The schedule fee for an average pathology item of service is 4 % lower in 2008 than it was in 1988 – during this time CPI and AWE have increased by over 180 %.[3] Unless there is a financially viable IVD industry in Australia the world class pathology service currently provided to Australian healthcare consumers cannot be maintained.

The key issues remain:

- The underlying problems with reimbursement remain. These are the lack of:
  - Statistics that reflect the true use of pathology tests in Australia;
  - A straightforward methodology to price new tests;
  - Improved processes that reflect the dynamic nature of the industry.

- The benefits of pathology driven diagnosis in keeping patients out of hospital are not recognised by the MBS system:
  - There is no mechanism to move funds from areas where savings could be made to those areas such as pathology where the savings can be generated;
  - Lack of global and Australian data that provides legitimate detail on the impact that pathology has on healthcare expenditure
  - Reimbursement of pathology items on the MBS has fallen over the past 20 years as the rebates have not been increased but costs of in pathology have escalated at least in line with the Consumer Price Index (CPI).

These key issues have a direct impact on Australian patient access to diagnostic tests.

IVD Australia Recommendations

IVD Australia Recommendation 1:

That the Government abolish coning of pathology tests and, recognising that spending on pathology makes health spending more efficient, implement a reimbursement system that appropriately reflects the value of tests.

IVD Australia Recommendation 2:

That the Government fund research that considers a number of pathology tests and the direct or indirect impact that these have on clinical outcome and quality of life; and develop a standardised protocol that provides details on requirements for legitimate studies, timelines, costs, and expected outcomes.

IVD Australia Recommendation 3:

That the Government not cut the Bulk-Billing Incentive BI until other appropriate measures being in place.

IVD Australia Recommendation 4:

That the Government take the opportunity to obtain the benefits offered by the increasing number of pharmacogenomic tests that are now, and will be, available.

IVD Australia Recommendation 5:

That the Government develop an appropriate reimbursement schedule for Point of Care Testing; and a simplified accreditation standard that reflects Point of Care Testing requirements and users outside the traditional laboratory setting.

IVD Australia Recommendation 1

That the Government abolish coning of pathology tests and, recognising that spending on pathology makes health spending more efficient, implement a reimbursement system that appropriately reflects the value of tests.

Coning of Pathology Tests

The coning system is used to 'share' any overpricing and/or efficiency gains achieved over time. Its purpose is to minimise the cost to Government (and taxpayers) of pathology by: (indirectly) disincentivising 'over-ordering' by GPs and specialists; and recognising that the unit costs of providing more than three tests on a sample are, on average, likely to be lower. Coning is not reflective of value and is highly distortionary. It is a partial proxy for volume discounting. Economies of scale are more achievable for larger corporations and this encourages consolidation and results in closures of smaller businesses.

MBS Data is Flawed

MBS data only captures items paid for by the Commonwealth and *not* those items which have been coned out. MBS data does not include those tests for which no Commonwealth reimbursement is paid. IVD Australia believes that MBS funded services account for not more than 65 % of all pathology undertaken in Australia. The remaining 35 % of tests are either coned out, undertaken in public laboratories such as those funded through the States in public hospitals or are undertaken in health practitioner's premises and in patient's homes. These would include tests such as blood glucose using point of care (PoCT) IVD products.

The Cost of Coning to Industry

While coning is largely pragmatic, it disconnects costs (inputs) and funding and does not provide a transparent system for incentivising pathology providers to minimise costs or innovate to improve quality services:

- it voids the opportunity to gather accurate data on pathology activity and costs as far as the MBS is concerned; and
- **it sanctions a cost model for practices that *necessitates an element of cross subsidisation* because it acts as a uncontrollable business cost to practices.**

The cost of coning to pathology providers cannot be precisely determined, but Pathology Australia estimates $200 million in test costs is absorbed by pathology practices each year.[4]

The Cost of Coning to Government

The cost of coning to the government is incomplete data from the MBS. A recent study (2013) investigated the completeness of recording of pathology tests in Australian Medical Benefits Schedule (MBS) claims data.[5] With some exceptions, MBS claims data records only the three most expensive pathology items in an episode of care, and this practice ('episode coning') means that pathology tests can be under-recorded.

> *It is important to consider under-reporting of pathology tests as a result of episode coning when interpreting MBS claims data. Episode coning creates uncertainty about whether a person has received any given pathology test. The extent of this uncertainty can be*

estimated by determining the proportion of episodes in which the test may have been performed but was not recorded due to episode coning.[6]

One of the most widely used pathology tests in Australia is the full blood examination (FBE). In 2014– 15 there were 11.4 million FBEs recorded by the MBS, for an MBS scheduled fee of $14.45. The actual number is estimated by industry to be closer to 28 million – including those FBEs not funded by the MBS due to being coned out or performed on public patients in public hospitals.[7]

Reimbursement that Appropriately Reflects Value

The pathology Sector in Australia is one of the most critical in terms of provision of health delivery in Australia. It directly but quietly influences the lives of most Australians - over 70 % of the population visit a general practitioner (GP) each year and nearly 50 % of the population have at least 1 pathology test performed each year.[8]

The current model of healthcare reimbursement in Australia is however predicated on a series of funding silos that provide the mechanism for distribution of Government money. These silos are built on traditional divisions:

- Pharmaceuticals – through the Pharmaceutical Benefits Scheme (PBS);
- Medical Devices – through the MBS Prosthesis List;
- Diagnostic Imaging – through the MBS;
- Medical Services – through the MBS;
- Private pathology Services – through the MBS pathology Table; and
- Public pathology Services - indirectly through block grants to the States

There is zero to minimal connection between the various silos and decisions that affect expenditure in one area are not considered in relationship to the other areas. Changes to the MBS pathology items are in general not considered in relationship to the effects they may have on other funding areas, and the general thrust is to reduce spending or spending growth in each of the areas. However this “silo” approach dramatically constrains the health system to a model based on the assessment of “illness”. Patients are initially assessed by GPs who are paid via the MBS but increasingly require a patient contribution. They often then have pathology tests and diagnostic imaging (DI) performed by private providers which, in the case of pathology, are usually paid for by the MBS (predominately bulk-billed). They are prescribed pharmaceuticals which are paid for by the PBS but which generally require a co-contribution from the patient. They are often admitted to hospitals based on their pathology results but **the benefits of pathology driven diagnosis in keeping patients out of hospital are not recognised by the MBS system.**

In all this activity, there is no mechanism to move funds from areas where savings could be made to those areas such as pathology where the savings can be generated. This issue was recognised in the Review of Health Technology Assessment in Australia[9] that recommended the assessment of co-technologies and dependent technologies, such as a pharmaceutical and the pathology test necessary for its safe and /or effective use), be coordinated through a single entry point so as to provide consolidated, comprehensive advice to the Government.

In-vitro diagnostic technology is developing rapidly and, if an application for funding through MSAC takes 3 or 4 years, there is every likelihood that the test may have been superseded by an improved or superior test. This could certainly be the case in the genomic and personalised medicine area where new tests are being released almost every day. Whilst use of these tests may add to the overall cost of pathology, the benefits that they offer, not only in economic terms through savings on unnecessary pharmaceuticals, but also in reduced side effects and better patient compliance, greatly exceed the cost involved in performing them.

IVD Australia Recommendation 2

That the Government fund research that considers a number of pathology tests and the direct or indirect impact that these have on clinical outcome and quality of life; and develop a standardised protocol that provides details on requirements for legitimate studies, timelines, costs, and expected outcomes.

Genome-era diagnostics will increasingly produce tangible financial benefits as healthcare becomes more targeted, personalised and efficient.

> *Economic analysis on the impact of pathology tests for colorectal cancer has found that:*
> - *expanding testing from KRAS to RAS provides net cost savings to the Australian Government by decreasing anti-EGFR antibody treatment costs through ruling out treatment for those that won't respond well,[67] and*
> - *an expanding testing to include all RAS mutations and limiting subsidy of cetuximab to those patients demonstrated to have no RAS mutations both reduces harms and improves health outcomes, and the cost of RAS mutation testing is negligible compared to the cost of therapy for patients with metastatic colorectal cancer.[68 10]*

Examples of Savings Not Realised

- The use of a pharmacogenomic test to stratify patients on cholesterol reduction medication could save up to $400 million in unnecessary prescriptions;
- Helicobacter pylori stool antigen testing which enables detection of ulcer causing bacteria (an Australian discovery) at a cost of $12-15 as opposed to a gastric biopsy at $400-500;
- Lab based tests for mesothelioma at a cost of $20 which replace a PET scan at a cost of $1,000;
- Home-based blood glucose testing which offers the opportunity to reduce the secondary morbidity of diabetes for up to 1 million Australian NIDDM patients.

Healthcare systems throughout the world including Australia are facing several similar and fundamental challenges which impact on all aspects of care including pathology. The overriding concern is an unsustainable growth in health expenditure due to various factors but including:

- People living longer and reaching ages where the demand on healthcare is higher
- Increased chronic health conditions such as diabetes, cancer, mental illness or heart disease accounting for 70 % of total healthcare expenditure.
- Inadequate technology assessment leading to costs of technology outweighing benefits.

Accompanying these factors is the demand from patients and their carers for more personalised healthcare. Collectively all of this is forcing the need for change in how healthcare is delivered.

Health Economics and Evidence

The IVD Industry rapidly and consistently produces diagnostic tests with greater sensitivity, accuracy and reliability. With the aligned potential savings, the benefits of these technological advances should be recognised and embraced. Out of the accompanying research, we have seen the rapid growth and sophistication of many 'new' life-saving, cost reducing diagnostic tools. Next Generation Sequencing and Companion Diagnostics are but two of many exciting developments.

The difficulties faced in reimbursement are compounded for companion diagnostic applications. Although, the development of companion diagnostics is surging across the developed world, regulation and reimbursement, in Australia, of both the pharmaceutical and diagnostic raise issues:

- There is a clear lack of global and Australian data that provides legitimate detail on the impact that pathology has on healthcare expenditure. There is therefore, a need for formalised studies that consider a number of pathology tests and the direct or indirect impact that these assays have on clinical outcome and/or quality of life.
- New tests go through a review process for reimbursement that requires both clinical and economic evidence of effectiveness. The Government needs to collaborate pathology profession and the IVD industry to ensure assessment moves beyond the traditional, analytical quality and diagnostic accuracy, to studies of outcomes with evidence. The extent of this existing economic evidence database is relatively small and there is a need to expand it through more well designed studies, another challenge to be taken up by both the industry and the profession.

In addition to generating more economic evidence, new initiatives are required in determining alternative value models for pathology including how value-adding services can potentially influence test utilization and improve the cost-effectiveness of pathology services. Identification of such value-adding services can then lead to reimbursement models which reflect to a greater deal the value rather than the cost of a test.[11]

IVD Australia Recommendation 3

That the Government not cut the Bulk-Billing Incentive until other appropriate measures being in place. For example: collection centre rent control; and removal of coning.

Further Reduction in Revenue will NOT Continue to Drive Efficiency

Over the past 20 years, growth in pathology outlays have been contained through massive consolidation of providers along with investment in innovative solutions that have delivered efficiencies within the pathology sector. IVD Australia member companies have played a significant role as suppliers and enablers in achieving this result through the provision of highly automated pathology solutions coupled with world best practice in after sales support.

> *The proposals in this report* [Grattan Report] *would reduce revenue for pathology businesses and encourage companies to drive efficiencies through consolidation or further automation.*[12]

Australia is the most consolidated pathology market in the world. There is limited further consolidation to occur without compromising service and/or quality. Today there is strong duopoly in the private sector and public pathology has rationalised to single buying groups in all states and territories outside of Victoria. The reduction in pathology providers directly impacts on IVD companies. IVD sponsors and manufacturers in Australia are already under significant cost pressures. It is widely acknowledged that, whilst Australia has world's best practice in its private and public pathology services, prices received by IVD suppliers are among the developed world's lowest. The increased costs expected from the introduction of the new TGA regulations for IVDs will add significantly to the cost pressures of IVD suppliers from the 2017 financial year. Together, these margin pressures – worsened by continuous cuts to pathology – may mean that suppliers will withdraw tests from the market or not seek to introduce new tests with low reimbursement or low volume.

The introduction of the Bulk-Billing Incentive in 2009 was designed to partially offset a reduction in pathology collection fees of $763 million.

> *From 1 November 2009 the Australian Government introduced bulk billing incentives for diagnostic imaging and pathology tests performed out of hospital, in the form of increased rebates for bulk billed services. These changes were funded by a reduction in pathology collection fees funded by Medicare. Diagnostic imaging was expected to benefit by $601 million for the increased bulk billing. pathology was estimated to gain $348 million in bulk billing incentives but was also the source of an estimated $763 million in savings to Government through reduced collection fees.*[13]

Over the past 20 years, growth in pathology outlays have been contained through massive consolidation of providers along with investment in innovative solutions that have delivered efficiencies within the pathology sector. IVD Australia member companies have played a significant role as suppliers and enablers in achieving this result through the provision of highly automated pathology solutions coupled with world best practice in after sales support.

> *The pathology industry in Australia is characterised by a high degree of concentration and regulated prices. Two companies listed on the Australian Stock Exchange dominate Medicare-billed pathology testing: Sonic Health Care (SHL), with 42.5 per cent of the market, and Primary Health Care (PRY), with 35.6 per cent.*[14]

Consolidation of providers in both public and private pathology have led to significant barriers to entry for both new pathology providers and IVD companies. This issue has already been seen in Queensland with the ACCC needing to intervene in the recent takeover of SDS pathology of the Healthscope operation in that state. Like the pathology providers, we have seen a significant reduction in the number of IVD companies through consolidation or ceasing to maintain a viable business offering.

> *The pathology sector has delivered an efficiency dividend of >40 % over the past 15 years to the Australian public.*
>
> *Repeated fee cuts (seven in the past 15 years) and the increase in bulk billing rates for pathology (now over 98 % for outpatients) has resulted in an efficiency dividend paid back to the Australian population of more than 40 % since 2000. Market consolidation and centralisation of testing has been the result of a series of fee cuts - the cumulative effect of which is that now the indexation of pathology test fees since July 1985 is -18.1 % and since June 2000 is -12.3 %.*[15]

Turning pathology tests into a commodity, by constantly driving prices down, will continue to ensure that only large corporations can survive as smaller companies are driven to liquidation or merger. With a reduction of over 300 providers since 1995, the question is…

How much more efficiency can be gained without compromising service and quality?

Recommendation 4

That the Government take the opportunity to obtain the benefits offered by the increasing number of pharmacogenomic tests that are now, and will be, available.

Impact of the Rapidly Growing Range of Pharmacogenomic Tests

Technological advances and automation have made tests easier to use and more accurate, and have led to more precise and more timely reports. A key advance, made possible by discoveries about the human genome, has opened the door to personalised medicine approaches that can tailor medical treatment to individual patient needs, transforming modern medicine. The impact of the rapidly growing range of pharmacogenomic tests, often referred to as personalised medicine are the result of advances in next generation sequencing.

For example: It has been estimated that between 10 and 60 % of patients do not respond to statins. Improvements in prescribing based on assessment of response could possibly result in significant savings to the community. the use of a PGx test to stratify patients on cholesterol reduction medication could save up to $400 million in unnecessary prescriptions alone.

The ACHR Study (2008) identified a number of areas where the use of genomics is expected to have a substantial impact on diagnosis and treatment, including: Colorectal cancer; Inflammatory bowel disease; Thromboembolism and stroke; HIV and AIDS; Depression; Cardiovascular Disease; Breast and other Cancers.

Prenatal and new-born testing is used to detect genetic disorders and identify infants who need early treatment. In Australia babies are screened for various disorders shortly after birth including phenylketonuria (PKU) and congenital hypothyroidism (CH), two disorders which if left untreated, lead to intellectual disability. The costs of the latter are considerable as shown by Geelhoed et al and summarised in the box below.

On the basis of 25,000 births per year in WA the cost of the testing program is far less than the costs that would result if the expected number of cases of PKU and CH were not treated, thus emphatically showing the economic value of testing.

Costs of program on basis of 25,000 births per year	$569,672
Costs averted from expected cases of PKU and CH per year	$3,449,448
Net annual cost savings	$2,879,776

Many other examples of screening exist, particularly in public health but also screening patients upon admission to hospitals for the presence of antimicrobial resistant microorganisms and the testing of all blood donors for HIV, Viral Hepatitis and certain other diseases, thus minimising the risk of transmitting such diseases to recipients of donor blood.[16]

Recommendation 5

That the Government develop an appropriate reimbursement schedule for Point of Care Testing; and a simplified accreditation standard that reflects Point of Care Testing requirements and users outside the traditional laboratory setting.

Point of Care Testing is Underutilised in Australia

The development of centralised laboratories utilising modern IVDs has however brought greatly improved medical and scientific training, economies of scale and reliable quality assurance.

However, with the development of enabling technologies by the IVD Industry, it is now feasible for many tests that could formerly only be carried out in sophisticated laboratory settings, to be performed in situations such as a hospital ward or clinic near to the patient or whilst the patient waits in a GP practice, in a health clinic or in a pharmacy.

People want greater control over their own healthcare including where and when they are tested, what they are tested for and who does the test. Clinicians require more and faster results. The government aims for more choice, devolution of control to primary care and a greater emphasis on the prediction and prevention of chronic disease. The implication of these drivers for the pathology sector, both providers and suppliers, is that Point of Care Testing (PoCT) is likely to grow in the number of tests performed, the range of analytes and available locations for testing in the coming years.

PoCT is performed throughout rural and remote Australia. However, in many aspects we are behind the rest of the world. Connectivity and data capture is uncommon and few states have PoC managers available to coordinate training and support.

Because of the lack of reimbursement for the testing done, clinicians and healthcare professionals can be more Policy Focused on price being paid for the test rather than the accuracy and quality of the result. Quality Control and correct training on the PoCT method can also be difficult to manage.

PoCT is now recognised as a fully functional complimentary service to those tests provided in routine pathology laboratories for appropriately selected markers and patient groups. The world market for PoCT is estimated to be worth over USD 13.8 billion in 2008 and is growing at over 10 % per annum; over double of that of the IVD sector as a whole[17]. The number of tests available in a PoCT format is expanding rapidly and a large number of jurisdictions have confirmed the benefits of PoCT in containing health costs and improving patient outcomes.[18]

These benefits derive from a number of factors including fewer repeat visits to GPs, fewer specimens sent to labs and lower utilisation of expensive pharmaceuticals. However as indicated previously these benefits generally go unrecognised due to the “silo” approach of Australian healthcare.

Australia is in fact well behind the rest of world in the adoption of PoCT. Tests such as INR for coagulation are routinely used in Europe in a point of care setting and although available in Australia but is not reimbursed via an item number on the MBS. This represents a major disservice to Australian Health consumer.

Tests that have been proven applicable in a PoCT environment include tests for both chronic care as well as acute care[19]. Those for chronic care would cover diabetes, lipid disorders, kidney function, coagulation, heart

failure, and liver function. PoCT available in an acute care setting also covers cardiac, renal, and other critical care functions such as blood gases and electrolytes.

Major Benefits to be Derived from the Use of PoCT

There are major benefits to be derived from the use of PoCT in both chronic care and acute environments.

Firstly, they provide timely and relevant results in the near patient setting, facilitating immediate patient test results/information to aid the treating physician to reach a quicker clinical decision.

Secondly, PoCT instrumentation and devices are available in many technology formats. They range from single use disposable devices (e.g. pregnancy tests) to compact instrumentation that may be handheld (e.g. glucose meters) or have minimal/small desktop foot-prints (e.g. blood gas analysers). PoCT instrumentation typically has the capacity to work off both mains and/or battery power to enable portability to the patient.

Thirdly, PoCT are typically designed on technology platforms that do not require laboratory trained operators at all stages of testing. These enable effective and safe use not only by healthcare professionals such as practice nurses and nurse educators but are also available in test formats suitable for routine use by the patient. PoCT handheld instrumentation is designed to be intuitive to use and consumer use is supported by professional training programs, website resources, call centre support, and other educational/support programs. Training on bench top PoCT analysers can be done in less than a day for many instruments and web based training programs are becoming more common.

Finally, the analytical quality of these instruments has improved greatly over the last 10 years, to the point where they are often at least equivalent to that of lab based instruments. Many instruments such as blood gas devices, INR meters and glucose meters incorporate on-board quality assurance and the software is designed to detect abnormal pre-analytical and analytical conditions, and alert the operator, in some cases by preventing a test from being performed. Internal controls in instruments can alert operators to compromised test results. Appropriate external quality control programs can be performed by HCP operators and the test results along with the QC returned to a central laboratory electronically for review and assessment.

The Australian Government does not fully consider the way in which increased PoCT can contribute to the health of the community, and the sustainability of pathology. Although, the Department of Health has funded developments in this area through its *Quality Use of pathology Program* and there are several examples of successful projects in this area. However, there is a need to extend these further in order to gain the benefits that PoCT can bring. IVD Australia would recommend that the Department of Health investigate the possibility of a program similar to the NDSS for INR testing for coagulation to enable patients to self-test and monitor in a home or GP environment.

Conclusion

Why take action? The Importance of IVDs to Australian Healthcare

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

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

There are more than 1,600 different diagnostic tests currently included on the ARTG today and, in 2013-2014 alone, in excess of 126 million pathology services were delivered in Australia.[a,20] Supply of IVDs in Australia is regulated for the Government by the Therapeutic Goods Administration (TGA).

From the genetic tests that inform personalised cancer treatment to the blood analysis that identifies the right antibiotic to fight an infection, diagnostic tests provide critical insights at every stage of medical care – pre-disposition, prevention, detection, diagnosis, treatment and successful management of health conditions.

Diagnostic tests using IVDs, are performed in laboratories, hospitals, doctors' offices, clinics, on the field, and in the home. They facilitate evidence-based medicine, improve quality of care, promote wellness, enable early detection of disease, and reduce overall health care costs.

Companion diagnostics are an emerging area of IVD use receiving a lot of attention. Companion diagnostics are IVDs that provide information about genomic and proteomic characteristics to help inform use of a specific drug or therapy.

Worldwide the IVD Sector is one of the most concentrated in the whole of the Health Sector. The ten largest IVD manufacturers represent over 75 % of the total market and this concentration is increasing.

Thus, most IVD companies across the world are represented in Australia in one way or another – directly, via a subsidiary, via a distributor or via OEM sales to a third party. This has meant that there is substantial competition within the Australian market, perhaps in excess of any other developed market. This has resulted in effective price competition and in many cases the lowest cost IVDs in the world. For example, the product cost of a panel of specific IgE tests for allergy is around $18.50 in Australia but is typically around $38.50 in Europe.

Whilst Australia can be justifiably proud of its achievements in the area of Health, at present the Australian health system with its focus on hospitals and acute disease is ill-equipped to deal with the emerging challenges

[a] In 2013-2014, Medicare was expected to record in excess of 126 million pathology services (up from 100 million in 2008-2009).

in health; chronic disease, increasing costs and increasing demands from a better informed population. It remains focused on numbers of doctors, hospital beds, and acute hospital funding as the measures of success in the Health sector. But hospital beds are expensive to create and expensive to maintain. Keeping people out of the acute medical system has to be one of the key goals that Australia aspires to over the next 20 years, and the use of pathology services and IVDs are essential in achieving that goal.

RATIONALE: FOR APPROPRIATE FUNDING OF IN-VITRO DIAGNOSTIC PATHOLOGY TESTS

The Changing Demands for Pathology

There is little likelihood that there will be an overall decrease in the volume of pathology testing in Australia no matter what measures are introduced. Across the developed world it is expected that pathology volumes will continue to rise by 5-8 % per annum for a considerable period into the future. This is due to a number of factors:

- Overall growth in population means more tests ordered by the treating HCPs;
- Ageing populations mean more tests ordered by treating HCPs;
- Increased awareness by consumers demanding more tests;
- Focus on chronic disease means more tests ordered by treating HCPs; and
- Increasing GP, specialist and HCP numbers means more tests ordered.

Pathology is a referred service; hence demand comes from requestors and it is counter intuitive to attempt to curb it by penalising the providers rather than by educating the requestors to order the appropriate tests.

There has been an attempt to ensure that healthcare professionals are encouraged to request the correct test or panel of tests at the correct time. The department has proposed to establish episodic panels that are clinically appropriate as well as to develop electronic decision support tools and promote the use of e-health initiatives to assist requestors to “order the right test”. A recent publication from the British In Vitro Diagnostics Associations (BIVDA), the sister association to IVD Australia in the UK, has shown that properly implementing the requesting and performance of just 10 pathology assays could save the NHS more than £I billion per annum.

IVD Australia is supportive of all these initiatives. However care needs to be taken that in the development of these proposals that they do not produce effects other than those intended. For example, episodic panels may make good clinical sense, but if they mean that the patient sample then has to be run on 3 different instruments using differing technologies that may not provide any efficiency for the laboratory and may indeed cost more.

The Rise and Rise of Chronic Disease

One of the major issues for the Government is the conflict generated on the one hand by the focus in restraining the growth in overall health expenditures whilst on the other hand attempting to shift the emphasis from the treatment of acute disease and conditions to a more long term emphasis on prevention and management of chronic diseases, such as diabetes, heart failure, obesity, cancer and mental health. These chronic conditions are the ones that will drive the overall cost of health in Australia, and any review dealing with health economics must acknowledge their importance, and its outcomes and recommendations must reflect the challenge in dealing with them.

The Government is to be commended for directing appropriate focus on these areas, but IVD Australia is concerned that, given this emphasis, the sector will be disadvantaged by changes that seek to unnecessarily restrain costs.

Much of increase in pathology requests by GPs is related to chronic disease. Studies by Sydney University (BEACH data)[21] indicate that there are 20 patient issues that together account for less than 20 % of all problems managed by GPs but which account for more than 70 % of the growth in pathology ordering. These issues are those identified by the Government as part of its Chronic and Preventable Diseases initiative – principally diabetes, hypertension, and obesity. In the period from 2002 – 2008 the Government implemented a number of programs directed specifically at preventative health and chronic disease[22].

These included:

- COAG – reducing the risk of Type 2 Diabetes;
- National Hepatitis C Testing Policy;
- Australian Primary Care Collaboratives Program;
- Divisions of General Practice Program;
- Medicare Safety Net;
- Healthy for Life;
- Childhood Obesity Strategy; and
- Aged Care GP Panels Initiative;

Thus much of the growth in pathology has been due to GPs doing what the Government of the day has implemented.

In fact, it has been strongly argued that pathology testing is significantly under-utilised rather than overused. The Lewin Group[23] has given a number of examples where increased availability and usage of pathology tests would save the community significant sums through earlier detection or stratification of patients into those who would respond to treatment modalities (such as pharmaceuticals, surgical procedures or even diet) and those that are unlikely to respond. Such non-responders cost the taxpayer vast sums in avoidable pharmaceuticals, unnecessary side effects and in the morbidity associated with chronic diseases such as diabetes. The Report concludes that "*Innovation, demonstrated clinical benefit, and appropriate use of laboratory screening and diagnostic tests are essential for achieving the goals of health system reform. Clinical laboratory testing is integral to evidence-based improvements in health care quality, patient outcomes, efficiency, and accountability*."

Wellness not Illness

The Government, through its programs that are focused on preventable and chronic disease, is moving in the right direction to contain the rising costs of healthcare in Australia. Much more needs to be done however in this regard, and the Government needs to ensure that it is not giving conflicting messages.

The announcement of increased training places for doctors in both General practice and specialties is a good example. More "doctors" means more illness will be diagnosed, and more pathology tests requested, and then more hospital beds, nurses and buildings will be required to treat this illness on a long term basis. Thus the direct result of this increase in acute care will be more, not less pathology. IVD Australia is not suggesting that there is not a need for more GPs but the focus ought to be on the long term prevention of illness and on keeping patients out of acute care, rather than on treating them once they have developed a long term condition such as diabetes, coronary disease, or obesity.

The Government must also take the opportunity to obtain the benefits offered by the increasing number of pharmacogenomic (PGx) tests that are now available. Whilst use of these tests will again add to the overall cost of pathology, the benefits that they offer, not only in economic terms through savings on unnecessary pharmaceuticals, but also in reduced side effects and better patient compliance, greatly exceed the cost involved in performing them. For example, the use of a PGx test to stratify patients on cholesterol reduction medication could save up to $400 million in unnecessary prescriptions alone.

A focus on wellness rather than illness would also mean that the progress of patients into acute or chronic care could be prevented or at least delayed. Similarly screening to determine those patients who are predisposed to chronic disease will enable a program of prevention to be instituted. For example, screening for pre-diabetes through the use of glucose tolerance and HbA1c testing will enable those patients who may be predisposed to Type 2 diabetes (NIDDM) to be identified, and a wellness program instituted such that the onset of the disease itself is prevented or at least delayed significantly saving substantial resources for the Australian community. However the Government can then not complain when these programs results in more testing for diabetes and related conditions as part of health care professionals' implementation of them.

Improvements in IVD Technology have NOT been Recognised

Over the past 20 years there has been a rapid development in IVD technology. Analytical methodologies have greatly improved the throughput of analysers and dramatically reduced the level of detection for many analytes.

- New technologies have enabled the development of multi-analyte and multiplexed assays from a single tiny sample.
- New point-of-care technologies have bought the benefit of improved diabetic and coagulation control to millions of patients.
- Advances in computer control and mechano-optics have improved the reliability of analysers and lowered the cost per test whilst greatly increasing the throughput.
- Tests that previously required the intervention of a skilled technician or pathologist over a number of hours can now be done in minutes on a point-of-care instrument.

Improvement in both throughput and cost has led to a dramatic rise in the availability of genomic and companion diagnostics.[b] Over the next several years the number of these tests is expected to rise exponentially. Pharmaceutical companies are more routinely now looking to introduce a companion diagnostics alongside their latest gene therapy in order to improve its effectiveness or reduce unwanted side effects in specifically targeted patients In the past, IVD tests were generally developed over several years, and pathologists and the health system could adopt new tests at a measured rate.

Due to these advancements in IVD and genomic technology, new tests are being introduced every day, and old ones superseded. IVD Australia believes that pressure from patients and healthcare practitioners will lead to increased demands for these newer and better tests. Funding of these within the Australian context will of course require applications to be made through MSAC.

An example: Improving Cancer Survival through Targeted Therapies

[b] The cost of gene sequencing has fallen dramatically over the 8 years since the completion of the Human Genome project. It is now possible to sequence the genome of an individual for less than $10,000 within a week, and this cost and the time required are expected to fall considerably over the next few years.

…patients living with cancer, medical professionals caring for patients living with cancer, and the medicines industry have expressed concerns about the increasing challenges in gaining timely, affordable and equitable patient access to new cancer medicines under current regulatory and reimbursement arrangements in Australia (e.g. Kefford 2012; Tillett 2013; Prostate Cancer Foundation of Australia 2013).[24]

The development of companion diagnostics is exploding across the developed world. The regulation and reimbursement of both the pharmaceutical and diagnostic however raise issues:

- In many cases the number of patients are small and developing acceptable clinical evidence and scientific validity for these assays is difficult; and
- The medicine requires PBAC approval for reimbursement while the IVD requires MSAC approval. The MSAC process despite its recent overhaul is still lengthy and cumbersome.

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

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

- the reforms undertaken in MSAC are not altering the speed of the process overall. In fact, we believe that the reforms have simply moved the delays in the system from the middle of the process where the assessment of the evidence was undertaken, to the front of the process where there will be lengthy delays in the Protocol Advisory Subcommittee (PASC). Hence the overall speed of assessment and recommendation of an IVD will not change dramatically.
- reports that applications to the Pharmaceutical Advisory Committee (PAC) that involve a co-dependent technology such as an IVD are being delayed unless the IVD application is submitted at the same time as the PAC submission.

Even with the new process, 'the complexity and lack of responsiveness of the current system have already resulted in Australia falling behind in the adoption of medical technologies that have been well established in other countries.'[25]

Addenda

Financial Savings Available under Alternative Funding

While the examples quoted in this submission that demonstrate how pathology tests generate economic benefits remain important demonstrations of their value, they are dependent upon linking the use of tests to patient outcomes, which is not always easy to do. The difficulties include tests often being part of a complex intervention, the outcomes of which cannot always be ascribed solely to the use of the test.

The development of pathology services in Australia over the last few decades has been very much about increasing the volume of services and providing good access to testing. Technological developments have facilitated this volume-driven model and enabled testing to be delivered at ever reduced cost. However, with a fee for service model of funding for testing, there have been concerns that there is an excessive drive to deliver large volumes of testing and this in turn has led to accusations about inappropriate testing. More attention has been paid to over- rather than under-testing, although evidence exists that the latter is as prevalent as the former and is of particular concern to patients, but funders of services are obviously more concerned about over-testing.

These issues together with one of declining reimbursement for testing have led to consideration of other ways of how value might be ascribed to a pathology test. A whole range of quality management tools and activities are deployed by laboratories to ensure the quality of the testing but the majority of these are focussed on analytical quality and ensuring that the analytical result is matched to the correct patient specimen. However, there are a range of quality based activities that are based on processes taking place after production of the analytical results and these include consultation, interpretation - sometimes by decision support, and auditing to ensure appropriate testing including correct application and interpretation of results. There is no obligation or explicit fee within reimbursement for such activities so they are performed to varying degrees by different laboratories.

It could be argued that these extra activities have great potential to influence the degree of effectiveness of pathology testing but there is a need to more systematically determine their impact and possibly their value to the overall process of testing. With a better understanding of these additional services and the extent to which they contribute to both quality and value, it might then be possible to determine alternative reimbursement mechanisms which reflect value rather than cost.[26]

Errors in the Grattan Report

In late February 2016, the Grattan Institute released an opinion piece titled ‘Blood money: paying for pathology services’ (the Report). The Report made a series of claims supporting the government’s decision to cut the level of recurrent pathology funding; on the basis that too much government funding was being ‘captured’ by providers without delivering commensurate, or maximum, value to Australians. Throughout much of the Report, data used to corroborate claims is inaccurate and false. It also shows a lack of understanding of the current funding model; the reason for the introduction of the bulk-billing incentive; and the funding cuts already applied to pathology.

The Grattan Report used very rudimentary calculations to deduce that there are sizeable financial gains to be achieved under alternative funding models. This may or may not be the case, however there is certainly insufficient appropriate analysis provided to demonstrate that this is the case. For instance, the $175 million annual savings from narrowing provider margins was been calculated based on:

- assuming it only applies to the two large listed companies that have 78 % of the market;
- reducing total MBS revenue for these companies by 5 %; and
- excluding 11 % of MBS revenue which is assumed to flow to non-private providers.

This is overly simplistic on multiple levels:

- it assumes that implementing a 5 % fee reduction for large companies will not impact on practice behaviour. In all likelihood, such a move would prompt the introduction of co-payments with certain patient groups, more aggressive marketing, cost cutting, innovation, and reallocation of resources within the firm into areas with a better return-on-investment. It cannot be assumed that this would be welfare creating, and would certainly act as a disincentive to practices to achieve a particular scale. It may also act as a disincentive to invest in labour and capital that would enable efficient economies of scale to be achieved
- it ignores the fact that there are private practices other than the two publicly listed companies (so therefore more than 11 % should be deducted from the potential MBS savings pool), and
- it assumes that 5 % is an efficient proxy for economies of scale, over and above the normal commercial return of the business. As mentioned previously, only some of the business is subject to scale economies, and these would be at variable points of the curve of diminishing returns. For volume discounting to be justified, it would first be important to demonstrate that the returns achieved are in access of what would be required to incentivise appropriate commercial innovation and behaviour.

Highlighting a few Pathology Facts

- Bulk-Billing rates in pathology are higher than any other area in health and less than 2 % of patients reported that out-of-pocket costs caused them to defer a test.
- Over the past 20 years, growth in pathology outlays have been contained through massive consolidation of providers along with investment in innovative solutions that have delivered efficiencies within the pathology sector. IVD Australia member companies have played a significant role as suppliers and enablers in achieving this result through the provision of highly automated pathology instruments coupled with world best practice in after sales support.
- Repeated fee cuts (seven in the past 15 years) and the increase in bulk billing rates for pathology (now over 98 % for outpatients) has resulted in an efficiency dividend paid back to the Australian population of more than 40 % since 2000. Market consolidation and centralisation of testing has been the result of a series of fee cuts - the cumulative effect of which is that now the indexation of pathology test fees since July 1985 is -18.1 % and since June 2000 is -12.3 %.
- There has historically been an average increase in the volume of testing of around 8 % per annum without a matching rise in funding which has resulted in a 25-year ‘efficiency’ dividend.
- Economies of scale are subject to diminishing returns. Scale economies are also subject to the purchase of new capital equipment that need to be taken into consideration, which can also accelerate the redundancy of existing equipment that may not be fully depreciated.
- Where GPs order four or more tests, costs are generally absorbed by the pathology practice. pathology Australia estimates $200 million in test costs is absorbed by pathology practices each year.
- Pathology companies are not required to charge the published [MBS] fee, and can charge more or less as they wish, but the BBI is only paid if the patient is bulk-billed with no additional fee charged. There is a high level of scheduled fee observance (99.2 % for out-of-hospital tests) and bulk billing (87.8 %), which indicate that the market is reasonably competitive.
- Pathology has always been unique in terms of the success that the Government has had in containing costs, compared to other aspects of the MBS.
- Comparing tests costs show that for USA, New Zealand and Canada, the Australian cost is comparable.

The IVD Industry

In vitro, literally 'in glass', diagnostics (also called diagnostic tests, pathology tests, and IVDs) comprise the instruments, reagents and consumables that are used to perform pathology tests requested by General Practitioners, specialist Physicians, or other healthcare professionals, tests undertaken in the home such as blood glucose or home pregnancy tests, or those tests undertaken as part of a government screening program, such as the Bowel Cancer Program.

Diagnostic tests using IVD tests, are performed in laboratories, hospitals, doctors' offices, clinics, in the field, and in the home. They facilitate evidence-based medicine, improve quality of care, promote wellness, enable early detection of disease and reduce overall health care costs.

It is estimated that the results obtained from pathology tests are responsible for 70 % of all medical diagnoses and almost 100 % of all cancer diagnosis and make a significant contribution to the management of disease.

There are more than 2,280 different diagnostic tests currently included on the Australian Register of Therapeutic Goods (ARTG) today and, in 2013-2014 alone, in excess of 126 million pathology services were delivered in Australia by private laboratories alone. Supply of pathology tests in Australia is regulated for the Government by the Therapeutic Goods Administration (TGA).

Worldwide the IVD Sector is one of the most concentrated in the whole of the Health Sector. The ten largest IVD manufacturers represent over 75 % of the total market and this concentration is increasing.

Thus, most IVD companies across the world are represented in Australia in one way or another – directly, via a subsidiary, via a distributor or via OEM sales to a third party. This has meant that there is substantial competition within the Australian market, perhaps in excess of any other developed market. This has resulted in effective price competition and in many cases the lowest cost pathology tests in the world.

IVD companies supply the equipment, reagents and technical services to support the pathology providers across Australia.

These companies develop innovative solutions and reagents to meet the changing demands and often drive the disruption that has ensured pathology continues to deliver value to the healthcare system in Australia.

Early diagnosis of disease leads to improved healthcare outcomes and IVD companies are continuously improving the timeliness and accuracy of results in a rapidly evolving health landscape.

IVD companies are driving responsive, customer-centric solutions improving health outcomes through the focus on personalised medicine: stimulating the tailoring of existing drug therapies to individual patients and identifying patient populations that would likely benefit from drug treatment.

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

From the genetic tests that inform personalised cancer treatments to the blood analysis that identifies the right antibiotic to fight an infection, diagnostic tests – and the IVDs they rely on – provide critical insights at every stage of medical care: pre-disposition; prevention; detection; diagnosis; treatment; and successful management of health conditions.

IVD Australia

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

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

IVD Australia is a founding member of Pathology Awareness Australia, a group that represents interests across the entire field of pathology in Australia. This body is conducting the Know pathology, Know Healthcare Campaign on behalf of public pathology laboratories, private pathology companies, pathology professionals and manufacturers and suppliers to industry.

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