IVD AUSTRALIA

The industry where innovation saves more Australian lives

Budget Submission: to the Federal Government 2015–2016 for the IVD Industry in Australia

PO Box 298, Parramatta CBD BC, NSW 2124
Phone: 1300 IVD AUS (483 287) Fax: 02 8004 8103 E-Mail: info@ivd.org.au

Introduction to the IVD Industry in Australia

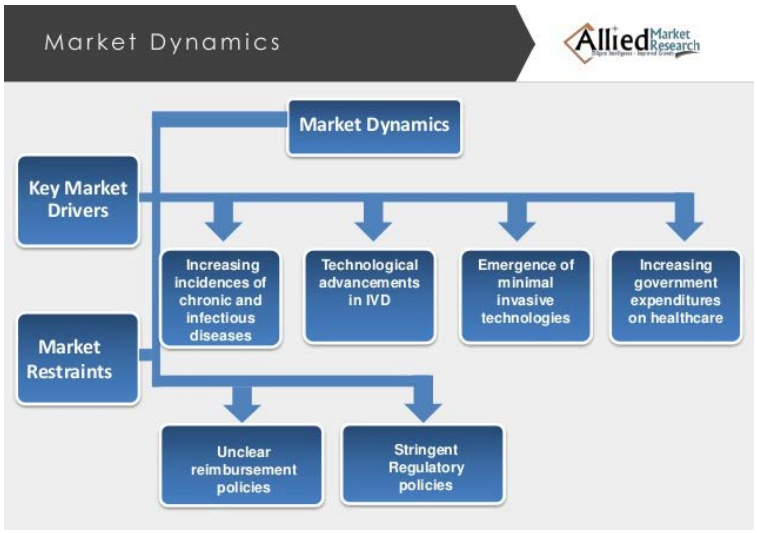
The IVD Industry supplies *in-vitro* diagnostic tests to the pathology sector.

In vitro, literally 'in glass', diagnostics (*in-vitro* diagnostic tests, 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.

The *in-vitro* diagnostics industry – both in Australia and internationally – is vibrant, innovative, and rapidly evolving to keep up with demand for better and faster testing. The IVD industry is the R&D of pathology and drives both efficiency and diagnostic tests that are relevant and impactful on healthcare outcomes in Australia.

The IVD global market revenue was estimated at approximately $USD 53 billion in 2013 and with a compound annual growth rate (CAGR) of 5.34%, by 2020 this will be in the vicinity of $USD 75 billion. Australia is estimated to be comprise about 2% of the world market, putting Australian market revenue at close to $AUD2 billion.[1]

Global market drivers and restraints are shown to the right[2]:



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.[3]

These pathology tests include the innovative areas of genetics and are typically performed in accredited Public and Private pathology laboratories across Australia, but IVDs also include the fast growing and game-changing point of care (POC) devices that can be used in general practice, healthcare clinics, as well as enabling the future of health in the home (HITH). In addition we provide over-the-counter tests such as blood glucose meters for diabetes testing.

---

1 Allied Market Research, *Report Image Global In Vitro Diagnostics (IVD) Market (Technique, Product, Usability, Application, End User, and Geography) - Size, Share, Global Trends, Company Profiles, Demand, Insights, Analysis, Research, Report, Opportunities, Segmentation and Forecast, 2013 – 2020*, reported at http://www.alliedmarketresearch.com/ivd-in-vitro-diagnostics-market

2 Ibid.

3 Australian Association of Pathology Practices Inc, *Pathology in Australia*, 2008 http://pathologyaustralia.com.au/wp-content/uploads/2013/03/Pathology-in-Australia.pdf

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.[4] 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

[4] In 2013-2014, Medicare was expected to record in excess of 126 million pathology services (up from 100 million in 2008-2009). IbisWorld, *Pathology Services in Australia: O8631*, 2009, p44

challenges 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.

Executive Summary

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%.[5]

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;
  - A mechanism to correct longstanding, historical anomalies in reimbursement-setting;
  - 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

[5] *An Analysis of Pathology Test Use in Australia*, A paper by the Australian Association of Pathology Practices Inc, utilising data from the BEACH program, Family Medicine Research Centre, University of Sydney, 2008.

- Reimbursement of Pathology items on the MBS has fallen over the past 20 years as the rebates have not been increased but costs of staff and other costs in Pathology have escalated at least in line with the Consumer Price Index (CPI).

These key issues have a direct impact on medical diagnostic innovation and patient access to new diagnostic tests.

IVD Australia Recommendations

IVD Australia Recommendation 1:

NHMRC be requested to introduce a Research focus on formalised studies that consider 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 2:

The Government look at an expansion of the MBS data collection system to allow it to capture all the data from public laboratories on test usage particularly data on ordering frequency for tests.

IVD Australia Recommendation 3:

The Government considers a complete new reimbursement structure that is evidence based versus the current "episode coning" to manage fee for service that drives demand and not necessarily value.

IVD Australia Recommendation 4:

Pathology providers be required to report completion of tests even though they are not requesting reimbursement, in order to create a complete understanding of pathology requests.

Return on Investment

Better understanding of the contribution of pathology to disease prevention and a more appropriate reimbursement structure could not only result in a better dollar return on investment for the government; but also have outcomes of reducing healthcare costs and saving Australian lives.

REDUCING HEALTHCARE COSTS

Pathology enables the prevention or early diagnosis of many serious and chronic (long term) diseases such as cancer, stroke, heart disease, and diabetes. Early detection increases the patients' likelihood of access to cost-effective treatments. This saves patients, their families, communities, and governments the associated impact of debilitating disease on quality of life and the associated personal cost and financial burden this places on society.

Pathology also allows treatments tailored to the needs of the individual. For example, 1 in 5 breast cancers involve a mutation in a gene called HER-2. Pathology laboratories test biopsy samples for the HER-2

mutation. A drug called Herceptin can be effective against these types of breast cancers, but not other types. Pathology testing can identify cases in which Herceptin will be effective, saving valuable time and money.

The savings to the Government will be seen through lower need for hospitalisations and chronic disease care costs.

SAVING LIVES

Pathology saves the lives of countless Australians each year. Here are just some of the ways in which pathology does this:

- Improved prevention: an unexpectedly high cholesterol result that causes someone to improve their diet and exercise, thereby avoiding a future heart attack;
- Early detection: the discovery of pre-cancerous changes in a routine pap smear, allowing minimally invasive treatment and improving the likely outcome;
- Improved treatment: ensuring that a critically ill patient with a bacterial infection is prescribed antibiotics that will effectively kill the bacteria;
- Trauma situations: ensuring that blood transfused in emergency situations matches the blood type of the patient;
- Through unique biomarkers, provide clinicians the ability to triage the high number of patients presenting to ED with chest pain, querying AMI (acute myocardial infarction).

Without effective pathology services, patients risk delayed diagnosis, invasive treatments late in the illness, medical complications, poorer treatment outcomes or even death.[6]

Desired Outcome: Saving Money in the Health Sector through Appropriate Funding of In-vitro Diagnostic Pathology Tests

Expenditure on Health in Australia

Expenditure on health in Australia was estimated to be $147.4 billion in 2012-13, 9.67% of gross domestic product (GDP) or $6,430 per Australian.[7]

Spending on public hospital services in 2012-13 was estimated at $43.9 billion or 31.6% of total recurrent health expenditure. Expenditure on medical services (including both unreferred and referred medical services) was $25.3 billion, or 18.2% of recurrent expenditure, and medications (including both benefit-paid pharmaceuticals and all other medications), was $19.3 billion (13.9%), were other major contributors to total recurrent health spending.[8]

'Use of pathology tests and diagnostic imaging' is an indicator of governments' objective to ensure that primary healthcare services are appropriate

6 http://knowpathology.com.au/what-is-pathology/
7 http://www.aihw.gov.au/expenditure-faq/
8 http://www.aihw.gov.au/expenditure-faq/

'Use of pathology tests' is defined by two measures:

- MBS items rebated through DHS Medicare for pathology tests requested by vocationally registered GPs and OMPs, per person;
- DHS Medicare benefits paid per person for pathology tests.[9]

This indicator needs to be interpreted with care as appropriate levels of use of pathology tests cannot be determined. A high or increasing level of use can reflect overreliance on tools to support the diagnostic process. A low or decreasing level of use can contribute to misdiagnosis of disease and to relatively poor treatment decisions.

Reporting differences across jurisdictions and over time contributes to consideration of these issues. Pathology tests are important tools used by GPs in the diagnosis of many diseases, and in monitoring response to treatment. Pathology services performed at the request of vocationally registered GPs and OMPs and rebated through DHS Medicare is used as a proxy in reporting against this indicator.

Nationally, the number of rebated MBS items for pathology tests requested by GPs was 3.4 per person in 2012-13.

Australian Government expenditure under DHS Medicare for pathology tests requested by vocationally registered GPs and OMPs (other medical personnel) amounted to $1.5 billion, or around $62 per person, in 2012-13.[10]

Counting the Savings Offered by Pathology

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.[11]

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

[9] SCRGSP (Steering Committee for the Review of Government Service Provision) 2014, *Report on Government Services 2014*, Productivity Commission, Canberra, 11.60-11.63

[10] Productivity Commission, *Annual Report on Government Services 2014*, Chapter 11, p. 11.61-11.62

[11] Australia Bureau of Statistics, *Health Services: Patient Experiences in Australia in 2009,* 2010

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. Hence independent reviews of both Pathology and Diagnostic Imaging Funding have been separately undertaken, as the Government attempts to contain expenditure growth in both these sectors.

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[12] 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.

There is a clear lack of global and Australian data that provides legitimate detail on the impact that Pathology has on healthcare expenditure.

Requirement 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.

There is therefore, a clear need to develop a standardised protocol that provides details on requirements for legitimate studies, timelines, costs, and expected outcomes.

IVD Australia Recommendation 1:
NHMRC be requested to: introduce a Research focus on formalised studies that consider 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.

Accounting for all Pathology Tests

IVD Australia believes that MBS funded services account for only around 65% of all pathology undertaken in Australia. The remaining 35% of tests are either 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. In addition, whilst Pathology items account for over 35% of all Medicare funded services, they only accounted for less than 15% of Medicare outlays in 2007 and this percentage is continuing to fall over time.

[12] Department of Health and Ageing, *Review of Health Technology Assessment in Australia*, 2009, p12

There is a strong need to capture, by some means, the tests that are undertaken in Public Hospitals so that these activities could be aggregated with the private (MBS) statistics to provide a complete account of all pathology testing in Australia. The data available at present is flawed for several reasons:

- It only captures MBS reimbursements to private Pathology; and
- It only historically captures items paid for and not those requested where some items have been coned out;

MBS data does not include those tests for which no Commonwealth reimbursement is paid.

Expansion of the database to capture all tests requested in both private and public labs would allow for the creation of a complete database that would clearly indicate the trends that may be occurring in the genetic testing and in the newer testing areas.

IVD Australia Recommendation 2:
The Government look at an expansion of the MBS data collection system to allow it to capture data from Public laboratories on test usage particularly data on ordering frequency for tests.

Reimbursement Inequities

Though some progress has been made in recent years by MSAC to seek stakeholder views during the process of setting reimbursement for new tests,[13] the underlying problems with reimbursement remain. These are the lack of:

1. Statistics that reflect the true use of pathology tests in Australia;
2. A straightforward methodology to price new tests;
3. A mechanism to correct longstanding, historical anomalies in reimbursement-setting;
4. Improved processes that reflect the dynamic nature of the industry.

These key issues have a direct impact on medical diagnostic innovation and patient access to new diagnostic tests.

MBS payments do not recognise the value new tests provide. The current approach to approving reimbursement for new tests does not support the return on investment that would support the generation of the evidence needed to fully evaluate clinical performance prior to marketing, and, by focusing on matching new tests to existing tests (and their payment rates), it provides little reward for creating additional value. Inconsistencies in test reimbursement force IVD companies to cross-subsidise tests for which reimbursement is too low, and they distort laboratory incentives for efficiency, threatening patient access.

The "Episode Cone" acts to distort the utilization of testing, and there are more effective means at the disposal of the Government to restrict the ordering of unnecessary assays.

[13] The Protocol Advisory Sub-committee (PASC) is a standing sub-committee of MSAC with membership to include decision analysis, health economics, epidemiology, public health, consumer, and clinical expertise. Its focus is on the task of determining Decision Analytic Protocols – that is, defining the decision option(s) or question(s) for public funding of a proposed new medical technologies and procedures prior to final lodgement of an application for its consideration by MSAC. The PASC is established by the MSAC Executive.

The current coning systems works against the interests of the pathology sector in that it effectively penalises the sector greater than 10% of its income, and is unfair in that it applies only to GPs and other requesters and not to Specialist Physicians. If the Government has a concern about inappropriate or unnecessary ordering of assays by requesters, then it should be instigating education and other measures aimed at those whose behaviour is at fault, not attempting to fix the issue by penalising those asked to provide the assays.

IVD Australia Recommendation 3:
The Government considers a complete new reimbursement structure that is evidence based versus the current "episode coning" to manage fee for service that drives demand and not necessarily value.

The Impact of the MBS Coning in Reimbursement

A recent study (2013) investigated the completeness of recording of pathology tests in Australian Medical Benefits Schedule (MBS) claims data, using the example of the prostate-specific antigen (PSA) test. 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.

The report found that: "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."[14]

IVD Australia Recommendation 4:
Pathology providers should be required to report completion of tests even though they are not requesting reimbursement, in order to create a complete understanding of pathology requests.

Cost Containment in Pathology

Medicare outlays on pathology have grown from a level of $1.9 billion in 2005-06 to an estimated $2.05 billion in 2009-10 and are projected to reach $2.42 billion in 2014-15[15]. However growth in services is considerably higher, increasing from 83 million in 2005-06 to 105 million in 2009-10 and are forecasted to grow further to 135 million in 2014-15.

In real terms however reimbursement of Pathology items on the MBS has fallen over the past 20 years as the rebates have not been increased but costs of staff and other costs in Pathology have escalated at least in line with the Consumer Price Index (CPI)[16]. This containment of reimbursement has driven consolidation within the private laboratory sector and has meant that the government and the community have benefited significantly from the resulting efficiencies. There has been a consolidation also in the public sector as the State Governments seek to reduce the overall costs of their health sectors. Indeed over the last 20 years, the total number of "payers" for IVD companies has fallen from more than 200 to less than 25 in 2010.

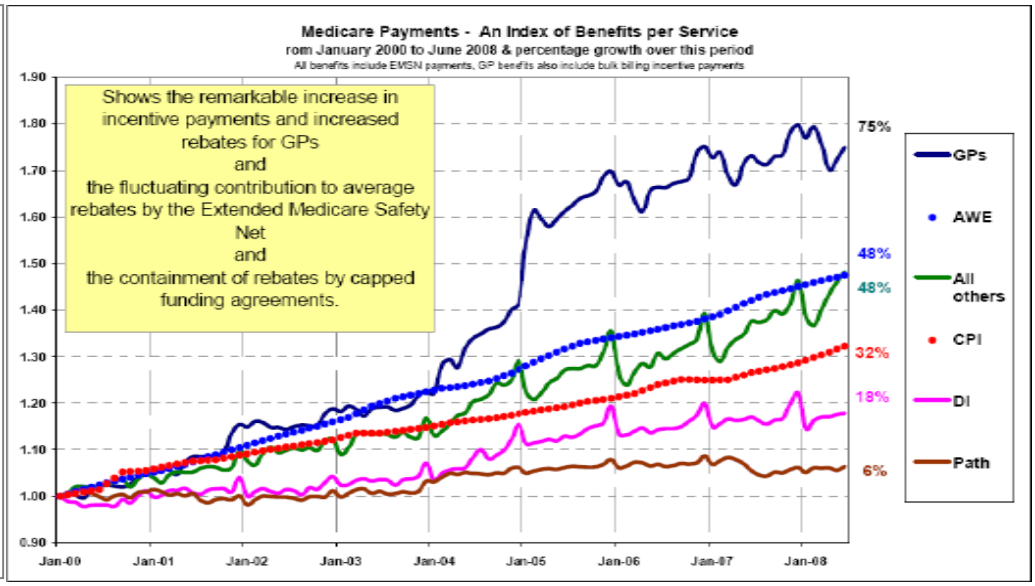
[14] Australian Health Review, 2013 Nov; 37(5), pp. 649-53
[15] IbisWorld, *Pathology Services in Australia: O8631*, 2009, p44
[16] Ibid, p35

This has meant there has been significant price pressure imposed on IVD companies as both the private pathology companies and the state government-run public pathology laboratories attempt to contain their costs and/or improve their profit margins.

One of the major issues throughout this Review is the question of Reimbursement for Service as compared to the cost of providing the service. In many case the cost of providing the service is not reflected in the reimbursement level provided; either because the cost of many fully automated tests such as electrolytes or total IgE has fallen considerably since the PST was introduced in 1980 or, on the other hand, because the reimbursement levels for most tests have not increased over a number of years.

There are a number of stakeholders in the sector including the Public Hospital networks (NCOPP), the Private pathology providers (through Pathology Australia[17]), the suppliers (represented by IVD Australia) and the professional bodies such as Royal College of Pathologists of Australasia (RCPA), Australasian Association of Clinical Biochemists (AACB), Australian Institute of Medical Scientists (AIMS), etc. However there is really ultimately only one customer; the Federal Government buying pathology services on behalf of Australian patients.

At present given the Government support for the Public Hospital network through its payments to the States and the very high rate of bulk-billing through Medicare for pathology test, the Government effectively funds all of pathology testing in Australia. Through the Memorandum of Understanding (MOU) entered into in 1996 by the Government, the College of Pathologists (RCPA) and the Australian Association of Private Pathology (now Pathology Australia), pathology testing has been subject to ongoing and significant fee restraint. The schedule fee for an average pathology item has barely changed since 1988 whilst CPI and Average Weekly Earnings (AWE) have risen considerably since that time. As shown below, the Medicare payments for Pathology only increased by 6% from January 2000 to March 2009, whilst CPI increased by 32% and AWE by 48%. The average payment to GPs increased by 75% over the same period.



Source: AAPP, 2008, **Response to the Strategic Review of Future Funding Arrangements for** DI and **Pathology**

[17] Pathology Australia was previously known as Australian Association of Pathology Practices Inc.

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)[18] 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[19].

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[20] 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

[18] Britt, H. Miller GC et al., 2008, AIHW, *General Practice Activity in Australia 2007-2008*
[19] AAPP, 2008, *An Analysis of Pathology Test Use in Australia*, p20. Note that AAPP is now Pathology Australia
[20] The Lewin Group, *The Value of Laboratory Screening and Diagnostic Tests for Prevention and Health Care Improvement,* 2009

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 HCP's 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[21] 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.[22] 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.

[21] For example: enzyme immunoassay, homogeneous assay technology, chemiluminescence, and fluorescence detection.

[22] 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.

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 Patient Outcomes through Point of Care Testing

Point of Care Testing (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 US$13.8 billion in 2008 and is growing at over 10% per annum; over double of that of the IVD sector as a whole[23]. 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.[24]

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[25]. 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.

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

[23] Price Waterhouse Coopers, 2009, *Diagnostics 2009 - Moving towards personalised Medicine*, p4
[24] The Lewin Group, *The Value of Laboratory Screening and Diagnostic Tests for Prevention and Health Care Improvement,* 2009
[25] Shephard, M, Australian Prescriber, 2010, Vol. 33 / 1, *Point-of-care testing comes of age in Australia*, p6

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.

An example: Improving Cancer Survival through Targeted Therapies

> *…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).*[26]

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:

---

[26] Deloitte Access Economics, *Access to cancer medicines in Australia,* Medicines Australia Oncology Industry Taskforce, July 2013. Accessed via http://medicinesaustralia.com.au/files/2013/07/Access-to-oncology-medicines-1707-FINALV3.pdf, p. i

- 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.'[27]

About IVD Australia

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

IVD Australia was formed in July 2009 and currently represents Australian manufacturers, multi-national and local distributors of IVDs, as well as regulatory consultants working in the IVD sector. Our members currently supply products valued at over $800,000,000 per annum and they employ over 2500 staff in multinationals, local distributors, local manufacturers and exporters and regulatory consultant companies; the majority of which are SME's.

[27] Ibid, p. xi