IVD AUSTRALIA

The industry where innovation saves more Australian lives

Submission to the 2018 Consultation on R&D Tax Incentive Legislative Amendments on behalf of the IVD Industry in Australia

CONTENTS

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 focus of the IVD Australia submission is to highlight aspects that the implementation of the changes may result in unintended consequences.

1. The calculation of the tax offset for companies with a turnover of $20 million or more; and
2. The clinical trial definition excludes the in-vitro diagnostics industry.

IVD Australia Recommendations

IVD Australia Recommendation 1:

That improved certainty needs to be introduced into the tiers to reduce a company's financial exposure when undertaking R&D in Australia.

IVD Australia Recommendation 2:

That the clinical trial definition be expanded to incorporate all therapeutic goods regulated by the Therapeutic Goods Administration, including: in-vitro diagnostics, medical devices and biologicals in line with the Therapeutic Goods Act 1989.

IVD Australia Recommendation 3:

That the Therapeutic Goods Administration is consulted on inclusion of IVD relevant terminology including, but not limited to, clinical performance and companion diagnostic is included in the definition and/or guidance material.

IVD Australia Recommendation 4:

That the definition remove the requirement for clinical trials to be conducted in human subjects, to enable the exemption provisions to be implemented in a way that would allow IVD companies to receive a tax refund for conducting preclinical studies.

IVD Australia Recommendation 1

That improved certainty needs to be introduced into the tiers to reduce a company's financial exposure when undertaking R&D in Australia.

Question 1 & 2

For companies with aggregated annual turnover of $20 million or more, the Consultation Paper states that:

> *… the Government will introduce an R&D premium that ties the rates of the non-refundable R&D tax offset to the incremental intensity of R&D expenditure as a proportion of total expenditure for the year. The marginal R&D premium will be the claimant's company tax rate plus:*
>
> - *4 percentage points for R&D expenditure between 0 per cent to 2 per cent R&D intensity;*
> - *6.5 percentage points for R&D expenditure above 2 per cent to 5 per cent R&D intensity;*
> - *9 percentage points for R&D expenditure above 5 per cent to 10 per cent R&D intensity; and*
> - *12.5 percentage points for R&D expenditure above 10 per cent R&D intensity.*
>
> *The R&D expenditure threshold — the maximum amount of R&D expenditure eligible for concessional R&D tax offsets — will be increased from $100 million to $150 million per annum.*[4]

The complexity of the new arrangements for companies with aggregated annual turnover of $20 million or more will result in increased financial uncertainty and risk incurred in making R&D investment decisions. The only non-variable in the calculation under the previous arrangements (the 43% tax offset rate) has been removed, this will impact decisions to invest significantly in R&D in Australia instead of internationally (USA, Canada, Europe and particularly Asia) and likely continue the trend to conduct trials off-shore. The commencement date of July 2018 may also impact current and scheduled trials commencing in 2018.

Variables:

The tiered approach to calculating the offset based on incremental R&D intensity is overly complicated and compounds the added uncertainty in calculating the tax offset. The greater the number of variables introduced in predicting a company's financial position, the greater the level of financial uncertainty and risk. Calculation of R&D Intensity will be extraordinarily complex and introduces too many new variables:

- **Total Expenditure**: Companies will have to estimate their total expenditure as part of their calculation of R&D intensity instead of turnover, predicting expenditure is more uncertain than predicting turnover and could result in under, or over investment;
- **R&D Expenditure**: Companies will no longer be able to use one calculation to determine their R&D expenditure and will need to produce scenarios, potentially resulting in errors due to a higher or lower percentage points;
- **Cashflow**: R&D investment decisions are made prospectively based on predicted cash flow, including the predicted value of the tax offset, this would now need to include variables of percentage points;
- **R&D Intensity**: the final outcome may differ significantly from the anticipated outcome, resulting in unintended consequences.

Unintended Consequences

Many international IVD Companies have diverse and non-consolidated business structures and as a consequence of the variables the following may occur:

- companies may overinvest in R&D placing them in financial difficulty; or
- companies may underinvest in R&D which would have a detrimental effect on patients, healthcare and the economy; or
- companies will invest in R&D offshore with unfavourable effects on the economy.

Improved certainty needs to be introduced into the arrangements to reduce a company's financial exposure when calculating the tax offset for R&D.

IVD Australia Recommendation 2

That the clinical trial definition be expanded to incorporate all therapeutic goods regulated by the Therapeutic Goods Administration, including: in-vitro diagnostics, medical devices and biologicals in line with the Therapeutic Goods Act 1989.

Question 4

The definition provided for the purposes of the R&D program, as noted in the Explanatory Materials states:

> "*A clinical trial is a planned study of the safety or efficacy in humans of an intervention (including a medicine, treatment or diagnostic procedure) with the aim of achieving at least one of the following:*
>
> - *the discovery, or verification, of clinical, pharmacological or other pharmacodynamic effects;*
> - *the identification of adverse reactions or adverse effects;*
> - *the study of absorption, distribution, metabolism or excretion*."[5]

This definition does not cover a large portion of the therapeutic goods sector that engages in R & D.

The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating therapeutic goods including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products.[6]

A new regulatory framework commenced on 1 July 2010 that ensures all IVDs will undergo a level of regulatory scrutiny that is commensurate with the risks associated with their use. The framework adopts the philosophies and recommendations of the ***Global Harmonization Task Force (GHTF)*** for IVDs, ensuring that requirements are internationally aligned. The legislation incorporates accepted best practice relating to safety, quality and risk management procedures, and provides the flexibility and capacity to regulate new and changing technology and emerging diseases.

Under the new framework IVDs are regulated as a subset of medical devices. The Therapeutic Goods Regulations (Medical Devices) 2002 have been amended to include IVDs. Due to the unique nature of IVDs there are several points of difference between the regulation of IVDs and other medical devices. These include a separate classification system for IVDs and some additional essential principles specific to IVDs.

The Therapeutic Goods R*egulations define a medical device to be an IVD if:*

- it is a reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system, whether used alone or in combination with another diagnostic product for in vitro use; and
- it is intended by the manufacturer to be used in vitro for the examination of specimens derived from the human body, solely or principally for:
    - giving information about a physiological or pathological state or a congenital abnormality; or
    - determining safety and compatibility with a potential recipient; or
    - monitoring therapeutic measures.

The definition of an IVD specifically excludes products intended for general laboratory use that are not manufactured, sold or presented for use as an IVD. Products that are not intended for therapeutic use, including tests for parentage and kinship testing, drug tests used in sport, most tests for alcohol or the detection of illicit drugs (unless a medical intended use is assigned), fall outside the legislation. Products that are intended exclusively for veterinary purposes will also fall outside the scope of the regulations.

The regulatory framework has the following features:

- all IVDs for therapeutic use are included;
- continued inclusion in the Australian Register of Therapeutic Goods (ARTG) as a basis for legal supply;
- all IVDs to comply with a set of essential principles for the quality, safety and performance of the IVD;
- an IVD classification scheme based on different levels of risk for each class of device;
- a choice of procedures (known as conformity assessment procedures), based on the risk classification, to be applied by manufacturers to demonstrate initial and on-going compliance with the essential principles;
- use of compliance with recognised standards as a means to demonstrate that the essential principles and conformity assessment procedures have been met;
- provision for post market activities, including compliance testing, adverse event reporting and recalls;
- mechanisms for access to IVDs not entered on the ARTG in cases of special need.[7]

IVD Australia Recommendation 3

That the TGA is consulted on inclusion of IVD relevant terminology including, but not limited to, clinical performance and companion diagnostic is included in the definition and/or guidance material.

Question 4

As a result of the current definition of a clinical trial, terminology does not include IVD-relevant terminology:

‘Clinical performance’ of an IVD is demonstrated by correlating the use of an IVD with a specific clinical condition, in accordance with the target population and intended user.

‘Companion diagnostics’ are a combination of an in vitro diagnostic device that is used in combination with a specific drug or biological product (therapeutic product).

Brief Example Highlighting the Use of Companion Diagnostics

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.

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.

IVD Australia Recommendation 4

That the definition remove the requirement for clinical trials to be conducted in human subjects, to enable the exemption provisions to be implemented in a way that would allow IVD companies to receive a tax refund for conducting preclinical studies.

Question 4

Limiting the current definition to the trials being conducted in humans may unintentionally limit the scope of the exemption provisions.

IVD companies invest significantly in conducting preclinical stage of IVD development, as IVDs are not generally tested 'in' human subjects, they are only tested on human samples. Consequently, restricting the definition of clinical trials to those conducted only 'in humans' may inappropriately exclude these products from the exemption provisions. Therefore the value of applying the cap exemption provisions for medical devices is limited.

The significant cost of preclinical studies is a unique consideration for medical devices, including IVDs, and it may be possible that in some instances, these costs exceed those of conducting the clinical trials in human subjects. As such, IVD Australia considers that the exemption provisions should be implemented in a way that would allow IVD companies to receive an uncapped tax refund for conducting preclinical studies.

Conclusion

The Importance of IVDs to Australian Healthcare and the Australian Economy

IVD Australia accepts the challenges to the Government of implementing a fair and equitable R&D system with acceptable budgetary impacts that also benefit the economy by encouraging increased R&D within Australia. Whilst overall, we believe the proposal will have stronger compliance and administrative improvements; companies may suffer from unintended and severe consequences as outlined in this response.

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 resulting in more companies with an aggregated annual turnover of $20 million or more.

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.

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.[1,8] Supply of IVDs in Australia is regulated for the Government by the Therapeutic Goods Administration (TGA).

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.

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

Addenda

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 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.

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.[2] 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.

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).[9]

[2] 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.

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 nearly AUD 1 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.

1 Centre for International Economics (CIE), *The economic value of pathology: achieving better health, and a better use of health resources*, 2016, p. 9.

2 Pathology Australia (2016) *Budget Submission.*

3 *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.

4 Consultation on the draft Treasury Laws Amendment (Research and Development Incentive) Bill 2018 and Explanatory Materials, June 2018, p. 5

5 IBID, p. 3

6 Source: https://www.tga.gov.au/tga-basics

7 Source: https://www.tga.gov.au/overview-regulatory-framework-vitro-diagnostic-medical-devices

8 IbisWorld, *Pathology Services in Australia: O8631*, 2009, p. 44.

9 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.