Productivity Commission Study: Identifying and Evaluating Regulation Reforms

Public Submission

By the Department of Innovation, Industry, Science and Research

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EXECUTIVE SUMMARY

The Department of Innovation, Industry, Science and Research (the Department) welcomes the opportunity to provide a submission to this review. The Department supports the Government's systematic approach to regulation reform. Reviewing regulation after specific periods, typically on a five yearly basis, is an effective catalyst in facilitating regulation reform. That said, reviews are resource intensive for both business and government. Despite the desirability of comprehensive regulation reviews, multiple factors commonly combine to impede such an approach.

The Department's submission addresses the limitations of stock management tools and suggests alternative review catalysts. The Department also highlights areas for further reform and past review processes where lessons can be learnt for future reforms. The key issues borne out of the paper are:

Promote minimum effective regulation
The Department strongly supports the concept of minimum effective regulation. While acknowledging the necessity of *ex-post* evaluation and its importance to regulation reform, ultimately it is the comprehensive analysis of the impacts of a regulatory proposal in the first instance which will generate the greatest reduction in the regulatory burden on business. The Department considers that the Business Cost Calculator is still the most effective tool available for policy makers to calculate the potential compliance costs of regulation.

Prioritise regulation reviews according to the needs of industry
When assessing a legislation review program, departments should endeavour to prioritise reviews on a needs-based approach that takes into account complaints from industry on the shortcomings of specific regulation. Prioritising along these lines will facilitate targeted regulation reviews and enhance the overall effectiveness and efficiency of the review process. Focusing on the Government's objective in intervening should not necessarily be the main consideration underpinning a review.

Identify potential areas for further targeted regulation reform
The Department has highlighted potential areas for further targeted reform opportunities. This is supported by the provision of five case studies which draw on previous reviews, policy research and clinical trials. These include the regulation of genetically modified organisms and reviews related to the health, medical services and research sectors.

Build on the lessons from past reviews and cross-jurisdictional reforms
The development of new reforms would benefit from the experience of previous reviews and recently completed reforms. To this end, the Department has provided two further case studies that illustrate the effective facilitation and management of cross-jurisdictional regulation reform. These include the transition to the national trade measurement scheme, and institutional arrangements related to building regulation reform. While differing in their structure, valuable lessons can be learned from both examples for future reform undertakings.

INTRODUCTION

The Australian Government has unique responsibilities in fostering a culture of innovation. Government leadership plays a crucial part in doing this by setting the right conditions for industry action. A best practice regulatory framework that is effective and efficient is critical to the support of productive and internationally competitive Australian industries. It will also encourage world-class science, research and innovation. To this end, the Department of Innovation, Industry, Science and Research (the Department) supports the Australian Government's commitment to minimum effective regulation, to ensure regulations are well-designed, enacted only where absolutely necessary and at minimum cost to business.

The process of regulation reform needs to be constantly reinvigorated. It is through this that government is able to continually focus on the extent of the regulatory burden that business face. Accordingly, the Department welcomes and supports the Productivity Commission's (the Commission) efforts in maintaining the momentum in this area.

The need to reinvigorate the process of regulation reform stems from the fine line between the necessity of regulation and the imposition of red tape burdens. It is common for policy makers to under estimate the red tape burdens that flow from new initiatives. However, it is this poor analysis that results in the imposition of unnecessary regulatory burdens for business. Such burdens divert resources away from more productive uses and can create a disincentive to invest and innovate.

Such burdens are magnified for small business as they have less capacity to identify, keep abreast of, and ultimately manage the changing regulatory environment. There are approximately 1.96 million active small businesses in Australia, representing almost 96 per cent of all businesses.[1] Small businesses are a significant component of the Australian economy, contributing approximately 35 per cent of private industry value added in 2009-10 and providing employment for 4.7 million people (as at June 2010), accounting for around 47 per cent of private sector employment.

The Department's responsibilities in relation to innovation, industry and small business policy and support for the deregulation agenda means it is well placed to contribute to the development of options to identify and evaluate regulation reforms. The Department is a key stakeholder in the Best Practice Regulation Framework and continues to work within government to improve the recognition and analysis of small business compliance costs of regulatory policy proposals. In addition, the Department administers business.gov.au (including the Business Consultation website); participated in a trial of annual regulatory forecasting for the 2009-10 Budget; and took the lead role in the APS 200 Project on Public Sector Innovation resulting in the development of the APS Innovation Action Plan[2].

[1] Australian Bureau of Statistics, 2010, No. 8165.0, Counts of Australian Businesses: June 2007-June 2009

[2] DIISR, 2011, www.innovation.gov.au/INNOVATION/PUBLICSECTORINNOVATION/Pages/default.aspx

Frameworks and approaches to identify areas for regulatory reform

Benchmarking and stock management tools

Regulatory burden can be measured in terms of the volume of regulation (stock), or in terms of its administrative cost impact on business. Obtaining accurate and comprehensive estimates of the administrative and compliance burden of regulation on business is inherently difficult due to the cross-jurisdictional nature of the Australian regulatory environment. Regulatory costs to business will also vary depending on the business size and industry, as well as business owner acumen.

The Commission's Issues Paper seeks input into the desirability of particular approaches to drive future reform to existing regulation. In regards to benchmarking, the first consideration in responding should be 'what is the aim of establishing a benchmarking framework'? If the aim is to address compliance costs and improve regulatory outcomes for business, then efforts would be better focused on fostering a greater understanding of the importance of quantifying compliance costs, and in particular cumulative compliance, when developing policy.

This will require a corresponding change in the culture of departments and agencies responsible for developing regulatory initiatives. Box 1 provides an example of the Government's endeavours to facilitate cultural change, the premise of which can be adopted in the regulation reform context. The need for cultural change is also reflected in the *OECD 2010 Review of Regulatory Reform Australia* which noted that it is not simply a matter of further refining regulatory management tools, but rather, the challenge for Australia is to facilitate cultural change[3]. This will ensure that policy making processes and the actions of regulation making institutions deliver regulation that is efficient, effective, supports well functioning markets and fosters a culture of innovation. To date there is no evidence to suggest that improved regulatory impact analysis, including improved quantification of small business costs, has resulted from reforms to the Commonwealth regulatory management framework.

Alternatively, if the aim of establishing a benchmark is to improve the quality and cost effectiveness of regulation, rather than targeting the number of regulatory statutes and instruments, then a form of quantitative measure of the impact of regulation is required. The Business Cost Calculator (BCC) is one such tool designed to assist policy makers to estimate the cost of regulation on business. The Department would suggest however, that such tools are not being utilised in the policy development process. This view is supported by the fact that the BCC was used to support regulatory analysis on only two occasions in the 12 month period from 2009-2010[4].

The Issues Paper notes the limitations of quantification tools such as the BCC in measuring the impact of a reform. It is the Department's view that the BCC remains the most effective tool available for policy makers to calculate the potential cost of

[3] OECD, 2010 Review of Regulatory Reform Australia – Towards a Seamless National Economy, p.88
[4] Office of Best Practice Regulation, 2010, *Best Practice Regulation Report 2009-2010*, p.15

regulation. The BCC, or similar, enables policy makers to sequentially consider the range of potential impacts imposed on business. The ensuing process of articulating the impacts and the anticipated compliance activities required of business, based on supporting evidence, provides policy makers with a better informed understanding of the regulatory impacts and the range of compliance costs.

Box 1. **Australian Public Service (APS) Innovation Action Plan**

The Government is committed to cultural change and promoting innovation in the regulatory reform agenda. The 2011 *APS Innovation Action Plan* builds on this objective by providing the platform and agenda to build an innovative culture in the APS generally.

The role of the APS is to support the Australian Government in responding to economic, social and environmental challenges, through effective policy development and service delivery. It needs to employ the most up-to-date thinking and approaches to deal with increasingly complex issues including demographic pressures, fiscal constraint, and ever-increasing expectations of the public and the business community. To thrive in the continually changing world environment, the APS needs the leadership and mandate to deliver innovative solutions to address multi-dimensional issues and problems.

The *APS Innovation Action Plan* provides that mandate. It acknowledges that harnessing the innovative potential of the APS and the wider citizenry is critical to success, and so it sets out principles and a structure to achieve this. Complementing other APS reform initiatives, the Action Plan provides a framework for embedding innovation in the APS to achieve better outcomes.

The *APS Innovation Action Plan* provides the platform and agenda to build an innovative culture in the APS by supporting creativity, responsiveness and delivery excellence. Innovation is not new to the APS, with many agencies having implemented innovative initiatives and many individuals having embraced innovation. However, efforts to systematically embed innovation into the operation of the APS are relatively recent.

The *APS Innovation Action Plan* is designed to assist the APS develop an innovative culture. Adopting this approach to deliver innovation in regulatory practices will subsequently facilitate innovation in the broader economy.

A systematic quantification analysis provides regulators with an informed understanding of the administrative or regulatory objectives of a regulatory proposal. In turn, this will facilitate a more effective role in administering the regulation, that is consistent with the intentions of the policy maker, without imposing unnecessary burdens on business.

The one-in one-out rule is not necessarily an effective approach to reducing the overall cost of regulation. The main shortcoming of this approach in its current form

is that it simply looks at the number of instruments repealed or added, which in no way compares to any regulation cost reduction or cost increase for business. The Issues Paper notes that tools such as one-in one-out impose a discipline on agencies to reduce regulation; however, currently there is no consequence for additional regulatory instruments and imposing unnecessary burdens on business.

The Department appreciates that the Commission has been asked to focus on *ex-post* evaluation. However, reviews are not the panacea to alleviating the regulatory burden on business. Focusing on existing regulation, without paying enough attention to the new regulation, may in fact lead to more poorly designed regulation that increases rather than reduces the overall regulatory burden[5]. This is further evidenced in the Issues Paper which notes that there is little comparison of the actual outcomes with the Regulation Impact Statement analysis once the regulation is in operation. In essence, *ex-post* reviews of existing regulation must be integrated with *ex-ante* assessment of newly developed regulations.

Prioritising Reviews

The Issues Paper outlines that the evaluation and review of regulation is resource intensive and that changes to regulation potentially involve costs to businesses. For many businesses, and particularly small businesses, the awareness raising and knowledge seeking process is a major component of administrative burden. Finding out what needs to be done, who to talk to and chasing down details is a time consuming task. Frequently changing regulations make it difficult to keep up with compliance demands, increasing the risk of non-compliance.

To this end, when identifying alternative principles or drivers for regulatory reform, the Department supports a 'needs analysis' approach as an effective catalyst to facilitate targeted regulatory reviews. The adoption of a 'needs analysis' would be particularly useful in scheduling reviews for those regulations that have not been reviewed in any capacity for more than five years. Cognisant that reviews are resource intensive for both industry and government alike, the greatest benefit from such reviews would therefore be gained by prioritising them according to need.

When assessing their legislation review program, Departments should have regard for a needs based approach. Prioritising regulatory reviews according to need would effectively be industry-driven based on complaints and observations from business that the regulation is not achieving its objective; conflicts with other regulations; and/or has clear negative unintended consequences, such as substantive compliance costs.

In addition, the Issues Paper touches on performance monitoring and the concept of perception surveys. Organisations such as the OECD have previously suggested that governments should, through perception surveys, regularly assess the perception of regulation among businesses[6]. Effective ongoing monitoring of the impacts of

[5] OECD, 2010, Cutting Red Tape – Why is Administrative Simplification So Complicated? Looking beyond 2010, p.56.
[6] OECD, 2010, Cutting Red Tape – Why is Administrative Simplification So Complicated? Looking beyond 2010, p.82.

regulatory intervention however can be difficult to achieve without imposing additional burdens on business. Policy makers therefore need to be mindful that such monitoring of regulation is potentially counterproductive, particularly where the objective of the intervention is business facilitation.

For this reason it should be understood that performance data on regulatory intervention is likely to be limited, and that extensive consultation would be required when conducting regulatory reviews. This further emphasises the need for regulatory reviews aimed at reducing burdens on business to be prioritised according to need as outlined above.

Another potentially effective approach to identifying and prioritising areas for regulatory reform is to systemically map regulatory reform processes. This will facilitate:

- easier prioritisation of reform processes;
- minimisation of duplication and omission in relation to reform processes;
- a reduction in reform fatigue whereby submissions to one process can be used by another appropriate process;
- greater planning by potential submitters in relation to their input; and
- increased identification of subsequent or related reform processes.

The Department further suggests that the following factors could be taken into account when identifying areas for regulatory reform:

- submissions to existing review processes;
- policy research (**Attachment A** provides a case study on genetically modified organisms);
- engagement with peak bodies and directly with industry and individuals (**Attachment B** provides a case study on clinical trials); and
- larger reform processes which often identify areas for more detailed regulatory reform (**Attachments C** and **D** provide an example of the Health Technology Assessment Review and the subsequent, more detailed reform processes).

The Health Technology Assessment Review[7] was conducted to streamline regulation. It is an example of prioritising regulatory reform that illustrates undertaking a large reform process can be difficult, particularly with numerous stakeholders and vested interests. The prioritisation for a review in a similar manner to the Health Technology Assessment Review could also result from an examination of regulation on a principles basis (**Attachment E** refers).

Evaluating regulation reforms

Embracing a comprehensive approach to the evaluation of regulation, which extends beyond the scrutiny of the immediate cost savings to business to include the broader

[7] Department of Health, 2010, www.health.gov.au/internet/main/publishing.nsf/Content/hta-review

societal benefits, whilst desirable, is often not practical. Reviews are resource intensive – and from a government perspective, adequate funding is often not available to undertake a comprehensive review and the broader the scope of the review, the greater the cost.

Accordingly, the scope of reviews within government tends to be sized down. The reduced scope of a review however does not necessarily limit its effectiveness. To ensure the efficiency of the review, there should be a targeted focus on the regulatory burdens on business. As a minimum, such reviews should assess whether the regulatory intervention: imposes the minimum necessary cost on business; conflicts or complements other regulatory interventions; and whether there are any unintended consequences, negative or positive. Reviews aimed at reducing burdens on business do not necessarily need to focus on assessing the value or otherwise of the Government's objective in intervening.

Monitoring and evaluating regulation

When evaluating and measuring regulatory reform outcomes, the time taken for reform and the impact of reform (or lack thereof) should be taken into account. Further, the reform should be appropriately measured and reported. For example, a simple method for increasing transparency could be publication of a timeline that provides a schedule for the implementation of elements of reform.

The resources available to implement reform affect the speed of implementation. Temporary resourcing of bodies to progress reform can yield long term gains and may either reduce future resourcing requirements, or, increase the benefits of regulation. In some cases it may be preferable to temporarily resource the implementation of an existing reform rather than resource a further regulatory review.

To effectively review regulation with a view to reducing the regulatory burdens on business, policy officers first need an appreciation of the evaluation process. Such an understanding enables those involved in the development of regulatory interventions to successfully develop effective performance indicators. With knowledge of performance indicators, policy officers are able to contribute positively to developing sound evaluations.

A well constructed and appropriate evaluation program ultimately provides a sound base for the assessment of the policy's performance. Significantly, this will limit the imposition of additional burdens on business when seeking business participation through progress reporting or similar mechanisms. It facilitates the collection of baseline data, providing a frame of reference for the policy. Therefore when policy officers consider how and when a policy is to be evaluated, consideration should be given to incorporating an evaluation strategy into the policy design and or legislation.

That said, the importance of the Government's ongoing consultation with industry should not be neglected. Consultation should not be limited to a defined period during the regulatory impact analysis process; rather it should be part of the continual cycle of policy design, evaluation and renewal.

Lessons from previous reviews

The development of new reforms would benefit from a consideration of previous reviews and recently completed reforms. The Department has direct experience in the oversight of complex cross-jurisdictional regulatory reform. While not explicitly requested in the Commission's Terms of Reference, the Department sees merit in highlighting different, yet equally successful, approaches to cross-jurisdictional regulation reform. Accordingly, the Department has provided two case studies that have successfully achieved regulatory reform. COAG instigation has been the catalyst with both examples.

The first case study summarises the management of the transition to a national trade measurement scheme. The Department has produced a report on the transition that covers all aspects of the project and details some of the lessons learned through the process. The report is not a guide to best practice; rather it provides a valuable insight into the management and oversight of a significant, complex cross-jurisdictional regulatory reform. It is an honest account of the transition process and identifies areas that could have been improved. The insights and key findings of the report could be applied to any project where the functions and responsibilities are being transferred from the states and territories to the Commonwealth.

The second case study depicts a model working arrangement that has consistently facilitated cross-jurisdictional cooperation in building regulation reform. In recent years building regulation has become more complex as societal objectives are integrated into reform initiatives, increasingly instigated at the COAG level. The structure of the Building Ministers' Forum and the Australian Building Codes Board has been integral to facilitating the reform initiatives in the built environment.

Attachment A

Case Study: Regulation of genetically modified organisms (Commonwealth/state duplication)

Regulatory reform of genetically modified organisms (GMOs) is necessary to increase Australia's productivity – to assist agriculture productivity and to foster the development of an Australian bio-based industry sector.

In 2005, the Australian Bureau of Agriculture and Resource Economics cautioned that Australia could lose between $1.5 billion and $5.8 billion in gross national product within the next 10 years if GM crops were not adopted.[8]

A significant use of biotechnology is expected to be outside the traditional areas of food and pharmaceuticals, in the industrial biotechnology sector. The value of bio-based chemicals (other than pharmaceuticals) will increase from 1.8 percent of all chemical production in 2005 to between 12 per cent and 20 per cent by 2015[9]. A recent report by the World Economic Forum (WEF)[10] concluded that converting biomass into fuels, energy, and chemicals has the potential to generate upwards of $230 billion to the global economy by 2020. It is estimated that in Australia, bio-based products could generate in excess of $20 billion annually in platform chemicals by 2020, in addition to income from renewable energy.[11]

Opportunities exist to improve the efficiency of gene technology regulation and enhance the ability of the legislation to support new and emerging biotechnology industries and applications. For example, inconsistencies between the Commonwealth and state and territory governments regarding the growing of certain GM crops on a commercial basis, hampers innovation and creates uncertainty for businesses. This, in turn, creates a disincentive for investment.

A study, commissioned by the Department of Agriculture Fisheries and Forestry in 2007,[12] surveyed supply-chain participants about the effects on existing GM crop regulations finding that the majority (76 per cent) said the most significant barrier to market access for GM crops, in particular GM canola, was lack of consistency between national and state regulatory systems. In a submission to the *Review of the Moratorium on Genetically Modified Canola in Victoria* 2007, Dow AgroSciences Australia stated that 'there is no incentive for technology providers to conduct the 3-5 years (minimum) preliminary work on Australian crop varieties required to commercialise technology already in place elsewhere if Commonwealth approval can be overridden by a state Government. Removing the moratorium on canola, only, does not remove the disincentive for investment in other crops.[13]

[8] Apted 2005
[9] OECD, 2009, *The Bioeconomy to 2030: Designing a Policy Agenda*
[10] World Economic Forum, 2010, *The Future of Industrial Biorefineries*
[11] Biorefinery Scoping Study: Tropical Biomass, 2010
[12] *A National Market Access Framework for GM Canola and Future GM Crops* (2007)
[13] *Review of the Moratorium on Genetically Modified Canola in Victoria* 2007, Submission 82, p.2

The Australian industrial biotechnology sector has noted that the Australian regulatory framework could also be amended to meet the challenges of industrial scale bio-based production. Issues such as scale, containment and organisms with multiple modifications may create problems for regulators in the future. Providing a consistent regulatory framework enables certainty for investments by industry to develop globally competitive bio-based industries. This will drive economic growth nationally, particularly in rural and regional centres.

Attachment B

Case study: Clinical Trials Ethics Review Harmonisation

Industry has been advocating reform of the ethics approval process for clinical trials of unapproved therapeutic goods (drugs, biologicals and medical devices) for many years. Under the Therapeutic Goods Administration (TGA) Clinical Trial Notification (CTN) scheme, all material relating to a proposed trial, including the trial protocol, is submitted directly to a Human Research Ethics Committee (HREC) by the researcher at the request of the sponsor. The TGA does not review any data relating to the clinical trial. The HREC is responsible for assessing the scientific validity of the trial design, the safety and efficacy of the medicine or device, the ethical acceptability of the trial process and for approval of the trial protocol.[14]

For many years the CTN scheme gave Australia a competitive advantage in timely ethics approval and led to a significant expansion of clinical trial activity. However, as the number of trial centres and trials conducted grew, co-ordination of the HREC approvals process became a significant issue. Trials conducted across multiple centres often required duplicative ethics reviews, which could lead to significant costs and delays in trial commencement.

In 2003, the TGA and National Health and Medical Research Council (NHMRC) commissioned a *Review of Access to Unapproved Therapeutic Goods*. The 2005 report by Banscott Health Consulting canvassed a range of options for streamlining ethical review processes. The Government gave its response in 2006. A resulting initiative, endorsed by the Australian Health Ministers Advisory Council (AHMAC), was that NHMRC facilitate the development and implementation of a national system where the review by the HREC would be recognised by all institutions participating in a collaborative research project. AHMAC's direction that state and territory systems should be 'harmonised' recognised that jurisdictional statutory and administrative frameworks impacting research in public health organisations differ.[15]

The resulting NHMRC Harmonisation of Multi-centre Ethical Review (HoMER) project has taken a number of years to implement, with key state jurisdictions now expected to accept HREC reviews conducted in other states through the HoMER system by early 2012. While the project was initiated in 2006, real progress in developing a work program did not occur until the second half of 2008. It became apparent that there were widely divergent practices with regard to ethics and research governance processes, and much time was devoted to developing common approaches and good practice models. The NHMRC implemented a HREC Certification process in 2010, and by 2011, 33 HRECs received national certification.

During this time, industry concerns continued to be raised, in particular through the release of the Pharmaceuticals Industry Strategy Group report, released in December 2008. The report called for the HoMER process to be accelerated.

[14] www.tga.gov.au/pdf/clinical-trials-guidelines.pdf
[15] www.nhmrc.gov.au/health_ethics/homer/index.htm

The Australian Government established a Clinical Trials Action Group (CTAG) in October 2009, which was asked to investigate how to ensure the rapid uptake of the NHMRC HoMER initiative. The CTAG made a number of recommendations to seek AHMAC's endorsement to implement HoMER processes, and collect performance information on trial activity and approval timeliness.

While the AHMAC has yet to finally approve HoMER, and HoMER has yet to be fully implemented by state jurisdictions, the NHMRC point out that at any time, HRECs can accept each others ethical reviews. The national certification process gives 'accepting' HREC's assurance that the 'reviewing' HREC meets the required national standards. However, jurisdictions are still working to develop guidance on legislative differences, monitoring and reporting, training and changes to IT systems before moving to full mutual recognition. The HoMER and CTAG forums are continuing to work with jurisdictions on issues regarding approval timeliness and performance measurement.

The ethics review issue highlights the difficulty in achieving process reforms across jurisdictions with differing legislative requirements and administrative arrangements. The underlying regulations may not necessarily need reform, but the systems and arrangements supporting the administration of those regulations need to be adequately resourced and fit for purpose. There have been calls for the Australian Government to fund initiatives such as training, IT systems and insurance arrangements to facilitate a national system. It was not possible to undertake such initiatives due to budgetary constraints. The CTAG process also highlighted the need for complex reforms to be championed at a high (possibly ministerial) level with progress regularly reviewed.

Privacy regulation impacts on health research

There are a number of areas where privacy regulations impact on the conduct of medical research. For example, the introduction of electronic health records provides opportunities for the re-use of patient information to inform later stage or related trials. Given the increasing costs of drug development there will be greater pressure to find efficiencies to conduct research, particularly in the conduct of clinical trials. However, HREC approval to access research participants' records under the *Privacy Act 1988* is generally given for a defined period, and re-use of patient information without consent, requires HREC approval that the benefit of the research substantially outweighs the privacy benefit.[16] There is a clear need to establish appropriate consent frameworks which will comply with privacy legislation, in order to ensure Australian research is not unduly impeded. There is a strong case for a periodic review of this legislation to ensure that the balance between the need for privacy and the need to investigate new therapies continues to reflect community values.

[16] www.nhmrc.gov.au/publications/synopses/e43syn.htm

Attachment C

Case Study: Reforms to the medical devices regulatory framework

In 2010, following the Health Technology Assessment (HTA) Review, the Therapeutic Goods Administration (TGA) conducted a consultation process regarding proposed reforms to the medical devices regulatory framework.[17] The Department made a submission but the outcomes of this process are not yet publicly available.

While regulation is necessary to ensure the safety of medical devices, there is a risk that the combined outcome of this regulatory reform process may be an increase in regulation. Increased regulation is inconsistent with the HTA Review which was conducted to streamline regulation.

The TGA is currently the sole assessor of medical technologies for market entry in Australia. TGA's current cost-recovery model and fee structure can result in significant costs for medical device companies and substantial delays in assessment. This can affect the ability of medical device businesses to commercialise innovation and their financial viability.

Regulations affecting the medical devices industry require a balance between the protection of patient safety and access to innovative technologies to improve health outcomes. There also needs to be a balance between appropriate regulation and an efficient and sustainable industry. This is an area of particular interest to the Department.

To minimise unnecessary costs for medical devices companies operating in a global market, any reforms to the regulatory framework need to be aligned with overseas frameworks, such as those operating in the European Union (EU) and the USA.

The Department and industry strongly support the use of accredited third party conformity assessment bodies, other than the TGA, for Australian manufacturers. The Department considers that there is an urgent need for reform in this area given its history. Appropriate safety assessment by third parties has the potential to save considerable time and money for Australian medical device and In Vitro Diagnostic (IVD) manufacturers which could provide a choice of conformity assessment pathways as is the case in the EU.[18]

According to industry, the TGA's proposed increases in the requirements for pre-market assessment appear to be beyond the requirements of comparable markets and could impose significant costs to businesses and delays in medical devices reaching

[17] Department of Health and Ageing, 2010, *Reforms in the Medical Devices Regulatory Framework* Discussion paper
www.tga.gov.au/newsroom/consult-devices-reforms-101130.htm

[18] [According to industry information gathered by DIISR to inform its submission to the 2008 TGA consultation, *Use of Third Party Conformity Assessment Bodies for Medical Devices Manufactured in Australia*, assessment in larger markets, such as for a European CE mark is often quicker at around 90 days versus around nine months in Australia; and cheaper at around AUD 5000 for the European market versus around AUD 100,000 in Australia.]

the market.[19] For example, the proposed reclassification of joint replacement implants aligns with the EU regulatory system but has the potential to add significant costs to industry.[20]

Furthermore, some of the proposed changes outlined in the TGA discussion paper appear to add to the regulatory burden of medical devices companies. For example, the proposal to enhance the ability to identify devices that have been approved by the TGA for supply in Australia, through Australian specific labelling requirements, could lead to significant administrative and regulatory costs and delays to industry. Further, it could provide disincentives for the inclusion of Australia in global distribution arrangements. Alternatives could be based on the use of a global Unique Device Identifier (UDI) or the use of e-labelling to avoid duplication of effort for manufacturers.

Additionally, the proposal concerning the increase in TGA requirements to publish medical device information could significantly increase costs for industry. Such requirements may enhance information available to consumers. However, the proposed requirements need to be appropriate for the medical device or IVD, some of which are not sold directly to the consumer (such as TGA approved artificial hips), and protect any associated commercial-in-confidence material.

Any reforms to the medical devices regulatory framework need to take costs and impacts into account and have a reliable evidential basis to justify proportional changes. A Regulatory Impact Statement should include industry input to ensure that it is comprehensive and accurate.

Regulatory reform that encourages the development and commercialisation of medical devices in Australia while maintaining appropriate safety standards could:

- increase associated Australian employment;
- increase competition and innovation in the Australian medical devices market; and
- lower the cost of quality health outcomes in Australia in the long term through greater availability of safe and improved medical devices.

[19] AusBiotech estimates that the proposed changes requiring Conformity Assessment rather than the current Level 2 Application Audit would increase fees per device eight time for Class III and active implantable medical devices (AIMD implants): AusBiotech Ltd submission to the TGA consultation, *Reforms in the Medical Devices Regulatory Framework*, December 2010, p9.

[20] The Medical Technology Association of Australia (MTAA) has indicated that the costs would increase four times for smaller companies (from the current $100,000 to $400,000) and twelve times for larger companies (from $1 million to $12 million) as well as additional annual recurrent costs: MTAA submission to the TGA consultation, *Reforms in the Medical Devices Regulatory Framework*, December 2010, p14.

Attachment D

Proposed changes to Medical Services Advisory Committee processes

Following the Health Technology Assessment (HTA) Review, a subsequent regulation reform process was undertaken. The Department of Health and Ageing prepared a discussion paper in 2010 entitled *Proposal for Changes to the Medical Services Advisory Committee (MSAC) Processes for Applications for Public Funding*[21] as a basis for further consultation with stakeholders on the implementation of changes to address recommendations in the HTA Review. The Department made a submission to this process.

The Department strongly supports reform of MSAC processes in line with the findings of the HTA Review. An example of one such reform is accepting submissions from industry and pre-lodgement meetings with other HTA secretariats to enable seamless management of the assessment of products. However, the Department is concerned that a fundamental aim of the HTA Review, to reduce regulatory costs of HTA in Australia, appears to be inadequately addressed through MSAC's proposed approach to a number of issues.

A critical factor needed to improve the business environment for health technology is to substantially shorten the time taken for MSAC assessment. This assessment process takes between two to three years. This has a considerable impact on innovation and the business viability of medical device firms.

To provide certainty for businesses, time and cost information needs to be accurate, public, prominent and related to all elements of MSAC processes. Furthermore, to be transparent and administratively efficient, application forms should be tested and refined with applicants for user friendliness and to ensure industry understanding of each element and how it is used in MSAC assessment.

The MSAC issues paper refers to the design of research questions and international health technology assessment developments associated with public interim funding but it does not provide detailed criteria for public interim funding.

An example of a major regulatory cost to business is a product that is prevented, or substantially delayed, from market entry due to an ill-adapted or non-existent regulatory pathway for assessment.

Reforms are needed to improve MSAC application processes to enhance business predictability for planning purposes and ease of use of MSAC processes. Ease of use includes reducing the complexity of applications from the applicant's standpoint and increasing business understanding of MSAC assessment processes. Mechanisms are also needed for business to manage their active applications with MSAC.

[21] Department of Health and Ageing, 2010, www.msac.gov.au/internet/msac/publishing.nsf/content/home-1/$File/MSAC%20Discussion%20Paper.pdf

This is particularly important for new and innovative products and drug-device combinations. MSAC processes should accept evidence other than the traditional large clinical studies, literature review or meta-analyses. For product assessment, where traditional forms of evidence are insufficient (often because they are new), innovations should not be excluded from the market entirely due to a narrow view of valid evidence for assessment.

Attachment E

Case study: principles of health regulation

In Australia, the regulation of health and related matters is often treated separately to other areas of regulation. This is generally due to the ethical and moral considerations that have been integrated into the mechanisms for the provision of health services to the whole population. Australia's health outcomes reflect the success of this approach especially when compared with health outcomes in other countries that do not have these concerns built into their policies and regulations. However, this approach can mean that reviews of health regulation can be difficult to initiate, carry out, progress, implement and evaluate. This is borne out by the Department's and others experience during the initiation and subsequent phases of the review of regulation associated with Health Technology Assessment (see **Attachment A**).

It is not clear whether some types of health regulation will be identified for review, and possible reform, using the common methods of identification in the Issues Paper. The interactions between the various stakeholders involved in the provision and receipt of health services means that there could be many opposed to such reviews. Often the stakeholders with the most to lose from a review and reform process are the most powerful in terms of political, economic and strategic influence – making some areas of review unlikely to proceed.

The National Medicines Policy aims to improve positive health outcomes for all Australians through their access to and wise use of medicines. There is an endorsed and well-established framework based on partnerships, whereby governments, health educators, health practitioners, other healthcare providers and suppliers, the medicines industry, healthcare consumers and the media, work together to promote the objectives of the policy.

Some aspects of regulation governing access to medicines are controlled by formal Agreements between specific stakeholder groups and the government. These Agreements, while designed to deliver the specific outcomes for patients and consumers of medicines, may, in some cases, do so at the cost of restricting businesses as well as service delivery innovation. Review of such regulation may lead to measures that provide such services in better and more efficient ways.

Attachment F

Report on the Transition to a National Trade Measurement Scheme

On 1 July 2010, the new national system of trade measurement commenced under the administration and regulatory oversight of the National Measurement Institute (NMI). The NMI is a division of the Department. The establishment of the national system of trade measurement was the culmination of three years of work undertaken by 12 project teams and numerous working groups, from Commonwealth and state and territory governments, to streamline trade measurement regulations. The new national scheme replaced eight state and territory trade measurement systems and removed inconsistencies in the interpretations and the administration of the regulations.

To mark the one year anniversary of the new scheme, the Department released a report[22] on the transition to the national trade measurement scheme. The report provides an insight into the reform process, documents key findings, outlines the residual issues and details some of the lessons learnt through the reform process. The outcomes in the report can be applied to other cross-jurisdictional reforms, particularly where functions and responsibilities are being transferred to the Commonwealth.

An inference throughout the report is that reforms of this magnitude need to be led at the Commonwealth level. Despite the invaluable cooperation of the states and territories, the leadership, direction and focus that the Commonwealth can provide is paramount in establishing the right framework and policy signposts to successfully achieve complex reforms, such as the transition to a national trade measurement scheme. The key findings of the report are summarised below:

Planning – An initial scoping phase is integral to any transition project. The report recommends a 6-12 month scoping phase prior to the transition phase. The extent of planning should be commensurate with the regulatory reform being proposed. An extensive planning process will ensure adequate and efficient resource allocation (both during the transition phase and significantly, in the ensuing years thereafter), identify risks and critical deadlines and facilitate appropriate governance requirements which will aid knowledge transfer strategies.

Governance – A key outcome of the planning phase is to ensure appropriate governance levels at all levels. The importance of establishing clear reporting lines between decision makers and government officials should not be understated. The report identified some residual issues that stemmed from a lack of clarity in the reporting lines and in the decision-making powers of representatives at meetings. Determining formal governance arrangements in the first instance, with consideration of a streamlined governance process, would aid all facets of the project ensuring a greater efficiency and effectiveness overall.

[22] National Measurement Institute, www.measurement.gov.au/Documents/NTMTransitionReport.pdf 2011

Stakeholder management – Stakeholder management is vital to any cross-jurisdictional reform. The transparency and open communication channels established by the NMI through their consultative framework facilitated the transfer and sharing of information between jurisdictions which was essential for the success of the project. Furthermore, the comprehensive communication strategies implemented were effective in reaching a diverse group of stakeholders. A successful consultation/awareness campaign is necessary to minimise any unnecessary burden on business. The wide-ranging, timely campaign, adopted by the NMI was integral in facilitating the seamless transition to a national scheme.

Attachment G

Building Regulatory Reform

Building regulation reform has been an iterative process for a number of decades. The working arrangement of the Building Ministers' Forum (BMF) and the Australian Building Codes Board (ABCB) demonstrate a model of Commonwealth, state and territory cooperation that has proven to be remarkably successful and resilient to external pressures, but sufficiently flexible to adapt to changing societal expectations.

Ultimately, the success of building regulation reform has been underpinned by establishing a reputation for implementing regulatory change through robust assessment processes and strong consultative processes with state-based regulators and a broad range of stakeholders. Evidencing a strong commitment to best practice regulation, the ABCB has prepared numerous Regulation Impact Statements, both at the consultation and decision making stage, and all have complied in full with the COAG best practice regulation requirements[23].

The building regulation landscape has altered markedly since the nine governments first agreed to develop a national set of building requirements. The Building Code of Australia (BCA) has evolved from a 'prescriptive' regulation (or code) to a 'performance-based' code. This evolution has facilitated innovative building design and product solutions for the built environment. The traditional role of health and life safety in building regulation has now expanded to include societal objectives, such as disabled access to buildings and improved energy efficiency requirements.

Most recently, there has been an expansion of the building regulatory framework into other areas of the 'building envelope' through the implementation of the COAG initiated National Construction Code (NCC). The development of the NCC has resulted in a substantial reduction in the total number of state and territory based differences, specifically in relation to plumbing requirements.

Institutional Arrangements

The BMF is an ad hoc forum of Commonwealth, state and territory ministers responsible for building and plumbing regulation. Its primary function is to oversight the operation of the ABCB. This is achieved through an intergovernmental agreement (IGA), which commenced in 1994. It was amended in 2001 and revised in 2006 following independent reviews in 2000 and by the Productivity Commission in 2004.

The ABCB is a joint Commonwealth, state and territory entity operating under the Department portfolio by way of an IGA agreed by the BMF. Established in 1994, the ABCB has provided a stable platform to drive a nationally consistent approach to the regulatory reform agenda in a policy area that is the constitutional domain of state and territory governments. The Board of the ABCB has 15 members comprising: an independent Chair, based on majority support from the jurisdictions; officials from the nine jurisdictions; a representative from the Australian Local Government Association and four industry representatives. ABCB intellectual property is jointly owned by the nine governments through a legally binding deed.

[23] OBPR, 2010, 2009, 2008, *Best Practice Regulation Report 2009-10, 2008-2009, 2007-08*

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