APPENDIX B.10

DEPARTMENT OF HEALTH

Summary

Health reported 59 measures[1] during the year, with a total net regulatory saving of $96.8 million per year.

In 2015, the Health Portfolio continued to contribute strongly to the Government's regulatory reform agenda.

Health reported a range of decisions taken throughout 2015 that reduced regulatory burden on businesses, community organisations and individuals by introducing electronic processing, simplifying existing processes and guidelines, streamlining and consolidating programmes and removing ineffective regulation. A number of key decisions were taken which increased the compliance burden. These were mainly focussed at issues of patient safety or at strengthening the evidence-base of services delivered. Health's Forward Work Programme for 2016 and 2017 has been developed which identifies a number of deregulation opportunities for forward years.

Health continues to play an important role in building best practice regulatory capabilities through delivering a range of staff engagement and support activities, information and awareness raising sessions, extensive online support material and hosting events such as the 2015 International Best Practice Regulation Seminar. Health maintained a strong focus on stakeholder engagement in the regulatory reform processes. The on-going processes to seek stakeholder ideas and feedback on regulatory reforms include submissions made directly to Health's website as well as to the Cutting Red Tape website. An extensive range of stakeholder consultations was undertaken to inform the Expert Review of Medicines and Medical Regulation. The review has delivered two reports; each report identifying a range of potential opportunities for reform[2].

Health has been at the forefront of implementing major regulatory reform initiatives such as the Regulator Performance Framework (RPF) and the adoption of international standards and risk assessment's criteria. All Health portfolio regulators have successfully developed their RPF evidence metrics in consultation with their stakeholders. The metrics are available publicly on Health's website, and will be used to assess regulators' performance.

[1] Measures counted here only include decisions with a regulatory impact. Measures with a zero regulatory impact have been excluded.

[2] These reports are available at http://www.health.gov.au/internet/main/publishing.nsf/Content/Expert-Review-of-Medicines-and-Medical-Devices-Regulation

Regulatory measures reported since the 2015 Spring Repeal Day[3]

With an impact of greater than $2 million

Health	Review of the Low Value Turnover (LVT) Exemption Scheme (now known as the Annual Charge Exemption (ACE) scheme) • On 1 July 2015, amendments were made to the regulations for the LVT exemption scheme in order to better align it with the Government's Cost Recovery Policy, and to reduce the administrative complexity of the scheme. The resulting ACE scheme allows sponsors to enter their products on the Australian Register of Therapeutic Goods without an annual charge until goods commence turnover. • The Department of Health assessed that 3,679 sponsors will experience a reduction in regulatory burden under the ACE scheme, from no longer having to apply for an exemption from a TGA annual charge on the basis that their entry is a low value turnover entry. Sponsors will also benefit from self-declaration of turnover (no third party accountant certification), the use of online self-service and the removal of annual charge invoices, which are not issued for exempt entries. • The Department of Health has estimated that this will lead to an annual saving of $3.1 million in compliance costs.

[3] These measure descriptions relate to new decisions taken and reported between the Spring 2015 Repeal Day and 31 December 2015. Descriptions of regulatory increases or regulatory decreases generally capture those measures with a regulatory change in excess of $2 million per annum.

2015 regulatory measures, previously reported in conjunction with the Autumn and Spring Repeal Days

These measures below are reproductions of the 2015 Autumn and Spring Repeal Day overview descriptions and have not been amended.[4] *Where necessary, supplementary information is shown as blue text.*

Health	Food Standards Australia New Zealand Amendment Bill (Autumn)
	• As part of the 2015 Autumn Repeal Day, the Minister for Health introduced the Food Standards Australia New Zealand Amendment Bill 2015. • The purpose of the Bill is to reduce the regulatory burden and provide greater clarification for businesses and Food Standards Australia New Zealand (FSANZ) by removing ambiguity and improving consistency in the way the Act outlines procedures FSANZ must undertake in the consideration of food regulatory measures. • The minor amendments are machinery in nature and will not substantially alter the existing arrangements for businesses, non-government organisations or individuals.
Health/Human Services	Amending the *Health and Other Services (Compensation) Act 1995* (Autumn)
	• As part of the 2015 Autumn Repeal Day, sections 18(2) and 23A of the *Health and Other Services (Compensation) Act 1995* (HOSC) will be amended to remove the requirement for compensation recipients to submit a statutory declaration about benefits provided under Commonwealth Government programmes for Medicare, nursing home, residential care and, from 1 July 2015, home care services. • Compensation recipients will save time by being able to declare that the information provided is true and correct using the existing forms required to complete this process, which will be updated to reflect the removal of the statutory declaration requirement. • Section 23(6) of the HOSC Act will also be amended to remove the requirement for a Notice of Judgment or Settlement form to be signed by both the compensation recipient and the compensation payer and instead only the compensation payer is required to sign. • The Department of Health and the Department of Human Services have estimated that this will lead to an annual saving of $41.4 million in compliance costs. **Further Update:** • **The $41.4 million compliance cost saving has been shared equally between the two portfolios.** • **NB: This measure was part of the Omnibus Repeal Day (Autumn 2015) Bill.**

[4] To align this table with the 2015 calendar year, any measures accounted for in the previous annual report have been excluded.

Health	Reducing the burden of the industrial chemicals regulatory framework (Spring)
	• As part of 2015 to 16 Budget the Government announced that the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) will move to a more proportionate risk-based framework to regulate industrial chemicals, including chemicals imported into Australia. • The reforms will allow for greater use of international assessment material by industry and NICNAS, leading to faster entry to market for safer chemicals that have a lower anticipated risk to human health and/or the environment. Allowing for greater use of international assessment material where criteria for the adoption of international standards and risk assessments can be met will also save industry time and effort. Removal of the current legislative requirement for industry to annually report on chemicals introduced under exemptions and permits will also result in substantial regulatory savings. Implementation of the reforms has commenced and will be fully implemented by September 2018. • The Department of Health has estimated that this will lead to an annual saving of $22.7 million in compliance costs.
Health	Removing the Pharmaceutical Benefits Scheme (PBS) subsidy for non-essential over-the-counter medicines (Sixth Community Pharmacy Agreement) (Spring)
	• On 27 May 2015 the Minister for Health announced that as part of the Sixth Community Pharmacy Agreement the Government would delist certain non-essential over-the-counter (OTC) brands of drugs from the Pharmaceutical Benefits Scheme (PBS), from 1 January 2016. • Nearly 12 million scripts a year will no longer be required. Doctors and pharmacists registered under the PBS will no longer be required to prescribe and dispense the delisted OTCs, saving them time and effort. The increase in hours saved will allow for more efficient and effective interactions with patients. Meanwhile, patients will save time and effort by accessing more OTC medicines without a prescription. • The OBPR has agreed that this will lead to an annual saving of $34.9 million in compliance costs.

Health / Human Services	Easier and faster reconciliation of Pharmaceutical Benefits Scheme claims (Spring)
	• In April 2015 the Department of Human Services improved the process for Pharmaceutical Benefits Scheme (PBS) approved suppliers to submit claims to the Department. • Over 5,600 PBS approved suppliers were previously required to submit hardcopy prescriptions to the Department of Human Services as part of a claim process. Ceasing the requirement for approved suppliers to bundle and submit paper prescriptions to the Department now saves time, postage costs and enables easier and faster reconciliation of claims. • The Department of Human Services and Department of Health have estimated this will lead to an annual saving of $18.8 million in compliance costs.
Health	Repeal of Section 3GC of the *Health Insurance Act 1973* (Spring)
	• On 4 September 2015 the Government agreed to repeal Section 3GC of the *Health Insurance Act 1973*, to abolish the Medical Training Review Panel (MTRP), and transfer its functions to the National Medical Training Advisory Network (NMTAN). • The NMTAN was transferred to the Department of Health in August 2014. The NMTAN advises on medical workforce planning, and produces medical training plans to inform government, employers and educators about medical training in Australia. The NMTAN also produces the annual report on medical education and training, including undergraduate, postgraduate and vocational training projections. • There is no regulatory saving or burden associated with this proposal. • **NB: This measure was part of the Omnibus Repeal Day (Spring 2015) Bill.**

Health	Repeal of Section 19AD of the Health Insurance Act 1973 (Spring)
	• The Department of Health is repealing Section 19AD of the *Health Insurance Act 1973* to remove the requirement for a five-yearly review of the operation of the Medicare provider number legislation – Sections 19AA, 3GA and 3GC of the Act. • Removing the requirement to participate in reviews of the Medicare Provider Number legislation will save a small number of rural health workforce agencies time and administration costs to undertake a review process, which does not provide any new information or result in operational improvements to the legislation. The three previous reviews conducted under Section 19AD have not identified anomalies or unintended consequences relating to the introduction of the Medicare provider number legislation and have indicated a general satisfaction by stakeholders with the operation and intent of the legislation. • The Department of Health estimated an annual saving of $3,000 in compliance costs. • **NB: This measure was part of the Omnibus Repeal Day (Spring 2015) Bill.**

Health	Aged Care Act 1997 amendments relating to removal of adviser and administrator panels[5] (Spring)
	• As part of the Spring 2015 Repeal Day, the requirement to use administrator/adviser panels to assist approved aged care providers under sanction (an estimated 15-20 a year), will be abolished. • These panels provide a list of consultants approved by the Department of Social Services, to assist sanctioned providers to return to, and maintain compliance with their responsibilities under the *Aged Care Act 1997*. • Legislating the requirement to use consultants from departmentally approved administrator/adviser panels limits flexibility and competition and does not take into account the fact that, in most cases, approved aged care providers have the knowledge and expertise to determine which consultants would be suitable to meet their obligations. Under this change, approved providers will not be required to have their selected consultant approved by the Department via an administrator/adviser panel, reducing time and administration costs. Approved providers would be required to have the consultant appointed and on site within a specified timeframe, to mitigate risks to care recipients. • The Department of Health estimates this will lead to annual savings of $5 million in compliance costs. • **NB: An early assessment of these changes, relating to non-compliance, was incorrectly categorised under the Regulatory Burden Measurement (RBM) framework. Recognising that there is no regulatory saving or burden accrued under the RBM, the initial $5 million figure has been reproduced here for transparency reasons; noting it was not included within portfolio, or whole-of-government, tallies of regulatory savings during the year.**

International standards and risk assessments

As part of the Industry Innovation and Competitiveness Agenda, announced in October 2014, the Government adopted the principle that if a system, service or product has been approved under a trusted international standard or risk assessment, then our regulators should not impose any additional requirements for approval in Australia, unless it can be demonstrated that there is a good reason for doing so.

In early 2015, Health conducted a review of use of international standards and risk assessments across the portfolio which showed already high levels of engagement of portfolio regulators with international standards. This fed into the process of development of Health specific criteria, as well as a plan to operationalise it, to be used by the portfolio regulators for assessing further opportunities for adopting international standards and risk assessments. These criteria, published on Health's website, provide a framework and a

[5] This measure was implemented by the Department of Social Services but reported as part of the Health schedule to the Omnibus Repeal Day (Spring 2015) Bill due to reallocation of responsibilities under the September 2015 Machinery of Government changes.

transparent process for assessing potential adoption of new international standards and assessments on a case-by-case basis. The criteria and the associated operationalising plan is available at:

http://www.health.gov.au/internet/main/publishing.nsf/Content/RPF-and-International+Standards

Some of the examples of adopting international standards or risk assessments by the Health portfolio agencies are summarised below.

Therapeutic Goods Administration (TGA) reforms

Premarket assessment requirements for Australian manufactured medical devices: New regulations have been introduced to allow Australian manufacturers to obtain market approval for most medical devices using conformity assessment certification from European notified bodies. This initiative removed the requirement for Australian manufacturers to have TGA conformity assessment for the majority of medical devices and In-vitro devices, by allowing Australian manufacturers to choose to either have conformity assessment conducted by the TGA or an alternative conformity assessment body, such as a European notified body.

The Medical Device Single Audit Program: The TGA is actively involved in the Medical Device Single Audit Program (MDSAP) pilot, together with Brazil's Agência Nacional de Vigilância Sanitária (ANVISA), Health Canada, the US Food and Drug Administration and the Japanese Ministry for Health and Labour Workforce. MDSAP is designed to ensure that a single audit of a medical device manufacturer will provide evidence of compliance with medical device market authorisation requirements applicable to all of the participating regulators. Participation in MDSAP will promote greater alignment of regulatory approaches and technical requirements globally based on international standards and best practices. MDSAP has developed guidance documents on assessment methods and audit reports. TGA has started to incorporate outputs from audits performed by third party Auditing Organisations into its business processes to reduce duplication of audits and cost to sponsors.

Increasing harmonisation of international regulatory activities: As part of TGA's ongoing commitment to international regulatory harmonisation activities, the TGA is increasingly utilising information from other regulators to inform decisions about manufacturer compliance with Good Manufacturing Practice (GMP). Over January-June 2014, 1481 desktop clearances for manufacturers were undertaken in place of inspections, taking into consideration regulatory decisions by other comparable regulators. This figure has increased to 2144 for the period January-June 2015. Approximately 95-98% of overseas manufacturer clearances are issued via desktop assessments that take into account overseas regulator decisions.

Alignment with International naming systems: The TGA is currently working on the complex and important task of standardising Australian medicine ingredient names to align with international naming systems, such as the World Health Organization's International Non-proprietary Name (INN) system and other international naming references (e.g. pharmacopoeias). This project aims to improve consistency and achieve greater alignment of TGA with current international naming standards, as far as possible.

Medicines and Medical Devices Review (MMDR): The Report of stage two of the MMDR, released on 20 November 2015, examines, and makes high level recommendations on, the regulatory frameworks for complementary medicines and for the advertising of therapeutic goods. A number of recommendations propose enhancements to the regulatory framework to better align protection with risk, the development of criteria to support the adoption of overseas approvals of new complementary medicines, and the pursuit of opportunities to reduce duplication of regulatory effort.

National Industrial Chemicals Notification and Assessment Scheme (NICNAS) reforms

As part of its Industry, Innovation and Competitiveness Agenda, the Government stated that: "NICNAS will better utilise and increase its acceptance of international risk assessment materials from trusted overseas regulators. This will be part of broader reform to introduce a graduated, risk-based approach to the regulation of industrial chemicals, that will streamline (and, in the case of low-risk chemicals, remove) the need for pre-market assessments of chemicals already authorised for use in comparable countries".

Categorisation of chemicals into classes: International standards and regulatory approaches have informed the development of criteria for categorisation of new industrial chemicals into one of three risk-based classes, with only "Assessed" chemicals (formerly referred to as Class 3–medium to high risk) chemicals being assessed pre-market by NICNAS. NICNAS has identified a streamlined pathway for a chemical categorised as an "Assessed" chemical to be granted the same regulatory treatment as a "Reported" chemical (i.e. introduced into Australia following pre-market advice to NICNAS but without further assessment) , where that chemical has already been assessed by a trusted regulator (defined according to the Health portfolio criteria for determining the appropriateness of adopting international standards and risk assessment materials), and where the risk assessment scope, assumptions and outcomes are relevant in the Australian context.

Use of international regulatory information or action to ensure health and environmental protection: NICNAS will utilise international data and regulatory alerts or actions taken by comparable overseas regulatory authorities to initiate its assessments, where applicable. This process will enable the regulatory scheme to meet the objective of the reforms to ensure Australia's robust health and safety standards are maintained.

Use of international risk assessment materials by NICNAS:

- risk assessment methodologies developed by reputable multilateral bodies, such as the OECD, are adopted by NICNAS, while more stringent applicability criteria are applied to methodologies that have not undergone international validation;
- hazard data generated in any OECD member country in accordance with OECD Test Guidelines and Principles of Good Laboratory Practice are accepted by NICNAS. This approach is in compliance with the OECD Council Decision on Mutual Acceptance of Data (MAD), to which Australia adheres as a member of the OECD. NICNAS will also continue to accept data generated in accordance with guidelines comparable to OECD guidelines, such as the US EPA Test Guidelines for Pesticides and Toxic Substances;
- international resources such as lists of structural alerts as flags of hazard for various endpoints and international databases for use, hazard, exposure and risk assessment information; and
- international computational toxicology tools (e.g. OECD Toolbox, Toxicity Prediction by Komputer Assisted Technology - TOPKAT, Optimised Approach based on Structural Indices Set - OASIS) to predict the toxicity of chemicals and minimise the requirement for animal testing wherever possible.

NICNAS is considering use of IUCLID (an OECD data submission template that is widely accepted internationally, particularly amongst OECD member countries) for electronic submission of chemical data through the ICT system under development for the NICNAS reforms.

Better alignment with international approaches: In developing the reforms, NICNAS will continue to explore opportunities for greater alignment with international approaches such as the treatment of confidential business information and the ability for international companies with business interests in Australia to appoint local agents to make assessment applications on their behalf while still maintaining safeguards.

Further information

If you have a question about the information provided here, please email Mr Glenn Paterson, Acting Assistant Secretary, Best Practice Regulation Branch from the Department of Health at Glenn.Paterson@health.gov.au.