The Hon Mark Butler MP
Minister for Health and Aged Care

Ref No: MS23-000606

Dr Brendan Murphy
Secretary
Department of Health and Aged Care

Dear Dr Murphy Brendan

I am writing to outline my expectations of how the Department of Health and Aged Care will achieve its regulatory objectives, carry out its regulatory functions, and exercise its powers.

This Statement of Expectations (SOE) will assist with the Australian Government's commitment to effective governance and performance of regulatory functions, guided by the *Public Governance, Performance and Accountability Act 2013* (PGPA Act). It forms part of the Government's commitment to good corporate governance of regulatory bodies and reducing unnecessary burden on business and the community.

This SOE is to be read in conjunction with the SOEs provided by the Assistant Minister for Health and Aged Care, the Hon Ged Kearney MP, to the Gene Technology Regulator and the Executive Director of the Australian Industrial Chemicals Introduction Scheme. Whilst the Government recognises the statutory independence of these entities, the Secretary of the department is the Accountable Authority under the PGPA Act for these regulatory functions.

Separately, within the Health and Aged Care portfolio, I am providing an SOE to the Director of the Professional Services Review. SOEs are also being provided by the Minister for Aged Care and Minister for Sport, the Hon Anika Wells MP to the Chief Executive Officer of Sport Integrity Australia and the Commissioner of the Aged Care Quality and Safety Commission.

Overview
As the responsible Commonwealth Minister this SOE sets out my expectations of the following internal regulatory functions undertaken within the department:

- Regulatory oversight of therapeutic goods:
    - the department is responsible for regulating the manufacture, import, export, and supply of therapeutic goods including medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products, and the scheduling of medicines and poisons
    - this is achieved through administering the *Therapeutics Goods Act 1989*, Therapeutic Goods Regulations 1990, Therapeutic Goods (Medical Devices) Regulations 2002, *Therapeutic Goods (Charges) Act 1989*, and Therapeutic Goods (Charges) Regulations 2018

- Regulatory oversight of controlled drugs:
    - The department regulates and provides advice on the import, export, and manufacture of controlled drugs, as well as the cultivation and production of cannabis for medicinal or scientific purposes to support Australia's obligations under 'The International Drug Control Conventions'. The Office of Drug Control exercises powers conferred through a number of international treaties and domestic legislation and regulations
    - this is achieved through administering the *Therapeutic Goods Act 1989*, Therapeutic Goods Regulations 1990, Customs (Prohibited Imports) Regulations 1956, Customs (Prohibited Exports) Regulations 1957, *Narcotic Drugs Act 1967*, Narcotic Drugs Regulation 2016, *Narcotic Drugs (Licence Charges) Act 2016* and Narcotic Drugs (Licence Charges) Regulation 2016
- Supporting access to high quality hearing services:
    - the department administers the Hearing Services Program which contracts hearing service providers and suppliers of assistive hearing technology to provide eligible people with subsidised hearing services
    - this is achieved through administering the *Hearing Services Administration Act 1997*, Hearing Services Program (Voucher) Instrument 2019, *Australian Hearing Services Act 1991* and Australian Hearing Services (Declared Hearing Services) Determination 2019
- Supporting access to pharmaceutical benefits:
    - the department regulates the location of pharmacies approved to supply pharmaceutical benefits, to ensure an accessible and commercially viable network of pharmacies exists throughout Australia, including in rural and remote areas
    - this is achieved through administering the *National Health Act 1953* and National Health (Australian Community Pharmacy Authority Rules) Determination 2018
- Supporting the integrity of health benefit claims:
    - the department supports the integrity of Australia's publicly subsidised health funding schemes by identifying and treating breaches of legislation, including incorrect claiming, inappropriate practice and fraud by health providers
    - this is achieved through administering the *Human Services (Medicare) Act 1973*, the *National Health Act 1953*, the *Health Insurance Act 1973* and the *Dental Benefits Act 2008*
- Regulatory oversight of private health insurance and private hospitals:
    - The department regulates private health insurers' obligations relating to complying health insurance products and health insurance business (where those obligations do not fall within the prudential regulatory role of the Australian Prudential Regulation Authority). The department also supports patients' access to private healthcare services through the declaration of private hospitals and regulation ensuring benefits are provided by insurers for services delivered through private hospitals
    - this is achieved through administering the *Private Health Insurance Act 2007* and associated subordinate Rules.

The Government recognises and respects the independence of the Secretary as the Accountable Authority of the department's regulatory functions. However, the Government is of the view that regulators should have a risk-based approach to compliance obligations, engagement and enforcement that allows for proportionate responses appropriate to the nature and seriousness of identified risks. This allows regulators to achieve objectives more effectively while recognising that it is not possible to eliminate all risks.

The Government recognises and respects the statutory position of the Chief Executive Medicare and the Chief Executive Medicare's responsibility for decision making and the exercise of powers relating to the Medicare scheme. The powers of the Chief Executive Medicare that are delegated to officers within the department should be exercised with knowledge of the broader regulatory framework and the application of that framework to individual circumstances.

The Government's policy priorities and objectives

Regulatory reform agenda

The regulatory reform agenda is a key component of the Government's plan to boost Australia's productivity and lower the cost of living by ensuring a fit for purpose regulatory environment.

The Government is looking at ways to boost productivity through reducing unnecessary or duplicative regulatory costs. Cooperating with the states and territories and working with international partners identifies opportunities to improve the quality of regulation and lower the cost of living for Australians.

The Government is also improving regulator performance, capability and culture through regulatory stewardship. This supports the Government's commitment to Australian Public Service reform by building trust in government and its institutions and by putting business and community at the centre of policy and services.

I expect the department to contribute to the regulatory reform process by:

- seeking opportunities to reduce duplication and streamline processes in order to improve efficiency and lift productivity, including international harmonisation or alignment with international regulators, where appropriate
- acting in accordance with regulator best practice in its decision-making, policies, processes and communications practices, in order to maximise transparency and minimise compliance costs
- applying the Resource Management Guide 128 Regulator Performance to its regulatory functions to assess its performance and engagement with stakeholders
- incorporating regulator performance reporting into the entity's reporting processes, as required by Resource Management Guide 128 Regulator Performance under the *Public Governance, Performance and Accountability Act 2013*, Public Governance and Performance and Accountability Rule 2014 in order to support greater transparency and accountability of regulator performance
- giving consideration of cost recovery arrangements, where appropriate.

Principles of regulator best practice

In exercising its functions and powers in accordance with these principles, I expect the department to display the following principles of regulator best practice:

1. Continuous improvement and building trust:
    - use qualitative and quantitative analysis as important tools for assessing and reporting on performance, and to support continuous improvement
    - promote a work culture that builds public confidence in the department's work and promotes trust in Government decision-making
2. Risk-based and data-driven:
    - actively understand, engage with and effectively mitigate strategic risks in order to successfully manage its regulatory functions without unnecessarily impeding the operations of regulated entities
    - use data sources that meet relevant data assurance standards for assessing and reporting on the quality of statistical information.

3. Collaboration and engagement:
    - Open, transparent and consistent engagement with stakeholders including industry, government and the broader community is crucial to maintaining competent and innovative regulatory practices. Consequently, I expect the department to:
        - seek opportunities to engage and consult genuinely with stakeholders
        - be receptive to feedback and diverse stakeholder views
        - seek to increase transparency in decision-making processes
        - provide up-to-date, clear and accessible guidance and information to assist regulated entities with compliance, including the sharing of information/intelligence as appropriate and in adherence to any secrecy or privacy obligations.

Innovation and regulatory change

I expect the department to continually monitor the environment in which it operates to ensure regulatory approaches keep pace with changes in technology, industry practices, international regulation, and community expectations.

I also expect the department to regularly review and, where necessary, adjust policies, protocols and operational procedures, to ensure it can respond to the changing social, technological and international regulatory environment and commercial context in which it operates.

Relationship with Minister and portfolio

The department plays an essential role in ensuring that the Government and I are well placed to respond promptly to any policy challenges and opportunities arising from the administration of these regulatory functions. Accordingly, I expect the department to provide accurate and timely policy advice on significant issues relating to these regulatory functions in accordance with the Government's policy priorities and objectives.

As the responsible Minister, I will provide an enabling environment for the department to consistently implement best practice by ensuring you are well informed of the Government's policy direction, as specific initiatives and strategies are being considered.

Statement of Intent

I look forward to the department's reply to this SoE with a Statement of Intent outlining how you will implement the above-mentioned expectations.

Yours sincerely

Mark Butler

20 / 06 /2023