Australian Government

Department of Health, Disability and Ageing

Secretary

Senator the Hon Katy Gallagher
Minister for Finance
Parliament House
Canberra ACT 2600

Dear Minister

Thank you for the correspondence from yourself and the Treasurer, regarding regulatory reform opportunities within the Department of Health, Disability and Ageing to bolster productivity growth.

The department administers regulatory functions across therapeutic goods, gene technology, health services, private health insurance and private hospitals. Our regulators are at the forefront of maintaining the safety of Australians within a rapidly evolving care economy. The department can play a role in lifting productivity by applying a risk-based and data-driven regulatory approach that is adaptive, proportionate, and supportive of both innovation and growth.

Our regulatory authorities have implemented significant reforms to streamline regulatory processes, enhance transparency and support innovation in recent years (Attachment A). For example the Therapeutic Goods Administration (TGA) has accelerated approvals for medicines and medical devices while safeguarding public health. The Office of the Gene Technology Regulator (OGTR) has also modernised its systems to simplify applications and declarations.

Additionally, the Government completed the first comprehensive review of health technology assessment (HTA) policy and methods in 2024. The aim was to ensure Australians can continue to access effective, safe and affordable health technologies equitably and in a timely way. The department is working with an implementation advisory group to prioritise and sequence review recommendations. Reforms to accelerate regulatory processes for medicines and other therapeutic products should also flow on to the assessment of these products for funding. This will ensure that products reach the Australian market faster and affordably.

Phone: (02) 6289 8400 **Email:** Blair.Comley@health.gov.au
Yaradhang Building, 23 Furzer Street, Woden ACT 2606 - GPO Box 9848 Canberra ACT 2601 - **www.health.gov.au**

To support the Economic Reform Roundtable in August, we have identified additional tangible, near-term actions across our internal regulators that can be implemented quickly to drive impact (Attachment B). These actions are within legislative frameworks or are well advanced through the legislative process, including:

- supporting the TGA to utilise AI for evaluation of medicines already approved by one comparable overseas regulator to reduce evaluation time, by up to 70 days over the next 4 years;
- supporting use of AI in assessments conducted by the Pharmaceutical Benefits Advisory Committee and Medical Services Advisory Committee. This is to ensure faster regulatory approvals lead on to rapid access for Australians to more affordable and effective medicines and treatments.
- delivering the OGTR's streamlined approval pathways for research and commercialisation, secure IT systems and contemporary enforcement and compliance tools; and
- amending private health insurance rules to promote contemporary models of care for privately insured patients through greater use of hospital in the home services.

We have also identified opportunities for longer-term regulatory reforms that could further bolster productivity (Attachment C). These reforms will require legislative change and additional funding to:

- enable TGA's collaboration and data sharing with international regulators and domestic HTA bodies, and data capability uplift to accelerate pre-market assessment and post market monitoring and detection of non-compliance; and
- align regulatory and compliance frameworks across different parts of the health system including National Disability Insurance Scheme (NDIS), aged care, Medicare Benefits Schedule (MBS), Pharmaceutical Benefits Scheme (PBS) and hospitals.

In addition, the department has put forward proposals to Treasury's Economic Reform Taskforce to improve digitalisation and system integration across the health, disability and aged care sectors. These initiatives will help to reduce regulatory burden without compromising the health and safety of Australians.

I note that you have also written to the Aged Care Quality and Safety Commission and Food Standards Australia New Zealand within the Health, Disability and Ageing portfolio. They will respond separately.

In our policy capacity, the department will continue to work with these portfolio agencies to progress opportunities for productivity and regulatory alignment. Areas of collaboration underway include:

- options for mutual regulation of audits through the *Care Economy Regulatory Alignment* project;
- alignment of worker screening between aged care and the NDIS; and
- scoping opportunities to streamline or automate reporting requirements.

Thank you for the opportunity to feed these proposals into the Economic Reform Roundtable. As you would be aware, Minister Butler will host a Health, Disability and Ageing Economic Reform Roundtable on 13 August 2025. This forum will provide a further opportunity to consider reforms that will bolster productivity, resilience and budget sustainability, including ways to improve the regulatory environment.

Yours sincerely

[redacted]

Blair Comley PSM

1 August 2025

Attachment A – Recent regulatory reforms

Internal regulator/regulatory function	Action undertaken
Therapeutic Goods Administration (TGA)	Over the past 2 years the TGA has advanced a comprehensive reform agenda to strengthen public health protections and modernise regulatory frameworks. This has included world-leading reforms to the regulation of vaping products, significant progress under the Action Plan for Medical Devices, and a program to address the impact of AI in healthcare. These changes have simplified application processes, and improved transparency while safeguarding public health and supporting innovation. They ensure Australia's regulatory systems remain globally aligned and ready for future challenges in the rapidly evolving health products sector.
Office of Drug Control (ODC)	Over the past 5 years the ODC has undertaken significant reform, including changes to regulatory activities and to introduce a cost recovery model. The reform reflects the recommendations of the independent review of the regulation of medicinal cannabis. Government invested in a new digital platform to streamline application processes and facilitate better interactions with regulated entities.
Office of the Gene Technology Regulator (OGTR)	In 2021-22, the OGTR completed an IT system modernisation project to streamline and improve processing and application processes. In 2022-23, the OGTR introduced two additional digital forms to simplify accreditation applications and declarations.
The Australian Industrial Chemicals Introduction Scheme (AICIS)	AICIS works to protect the environment by assessing the risks of industrial chemicals and promoting safer use. The rules that support the scheme and contain the technical operational details of AICIS were amended in April 2024 to ensure the scheme remains contemporary and fit-for-purpose. These changes, based on data and the experiences of the regulated industry, consider the risk proportionality of certain requirements of the Rules. These new rules replace disproportionately burdensome mechanisms with simpler and more flexible requirements.

Attachment B – Actions that can be completed in the near-term

Internal regulator/regulatory function	Proposed action or reform
Therapeutic Goods Administration (TGA)	The TGA, and regulators around the globe, face increasing pressure to respond to growing demand for pharmaceuticals evaluation. AI is significantly accelerating drug development by significantly reducing clinical trial duration, potentially bringing new therapies to the market faster. This will reduce the lead time between research and development and submission to the regulator, accelerating the number and rate of new medicine applications. Failing to respond appropriately will unreasonably delay Australians' access to innovative emerging treatments. To respond, the TGA has initiated a program of work to shorten evaluation timelines for prescription medicine submissions. Continued optimisation of business processes, driven through investment in and use of automation and AI, is projected to markedly reduce decision time. **Incorporating AI into the evaluation of medicines already approved by one comparable overseas regulator will markedly reduce evaluation time by up to 70 calendar days over the next 4 years, while still effectively mitigating the risk of introducing new treatments**. This mirrors the approach taken by the UK's regulator, which expedited evaluation of overseas approval by leveraging AI. While funding will be required to achieve this, the necessary reforms could be delivered without the need for any legislative change.
Health technology assessment (HTA)	HTA ensures that major public spending programs, like Medicare and the PBS, fund health services and technologies that are safe, effective and cost effective. These services and treatments keep our population healthy and productive. **Supporting use of AI in assessments conducted by the Pharmaceutical Benefits Advisory Committee and Medical Services Advisory Committee would markedly reduce evaluation time.** This accelerates access for Australians to more affordable and effective medicines and treatments.
Office of Drug Control (ODC)	A review of current legislation relating to the regulation of controlled substances across the Commonwealth and States and Territories is to be undertaken in 2025-26. This will identify duplication and inefficiencies in regulation across all levels of government. It will also identify areas within the national supply chain where controlled substances may be diverted for illicit purposes, risking public health. The implementation of review outcomes will increase

	productivity and business opportunities and reduce red tape for regulated entities. **Incorporating AI would reduce application timeframes and support industry in bringing products to market faster.** ODC can leverage similar work being undertaken across the department to achieve these results. While funding will be required to achieve this, the necessary reforms could be delivered without the need for any legislative change.
Office of the Gene Technology Regulator (OGTR)	The Gene Technology Scheme has been operational for almost 25 years. Reforms to this scheme are needed to improve productivity, sustainability and safety of the gene technology sector. In 2021, all gene technology Ministers agreed to develop a package of reforms. The reforms will modernise the scheme by delivering **streamlined approval pathways for research and commercialisation, secure IT systems and applicant interfaces, contemporary enforcement and compliance tools and cost recovery for specific activities**. The government's commitment to pass the package of legislative reforms to the scheme and provide funding for implementation of the reforms is required. Reform requires amendments to the *Gene Technology Act 2000*. Draft amendments of this Act were consulted on at the end of 2024 and drafting instructions for final amendments to the bill are being prepared. Additionally, government support to approve and fund cost recovery for the scheme in late 2026 with further cost recovery following passage of the amendment is needed.
Private Health Insurance (PHI)	The department can make regulatory changes to PHI rules to facilitate greater use of hospital in the home services for privately insured patients. These services deliver contemporary care to patients and can often be delivered more efficiently that services delivered in the traditional hospital setting, and will therefore improve productivity.
Private hospitals and Private Health Insurance (PHI)	The range of contracted funding arrangements between private hospitals and PHI mean time and money is wasted. Including on: (i) protracted contract negotiations; and (ii) managing patient care differently to maximise available funding, including length of stay. The non-price terms and conditions in contracts are also highly variable, resulting in high operational costs and increased risk of technical disputes over claims. Standard payment terms, reporting and audit arrangements and the adoption of common episodes of care coding and reporting would increase efficiency. It would also deliver nationally consistent

	reporting across the public and private hospital sector. Consultation on these changes could commence late 2025, for implementation from 2026. Implementation arrangements would depend on the approach settled with the sector.
Pharmacies for supply of pharmaceutical benefits scheme (PBS) medications	The approval processes for pharmacies to supply PBS medications is continuously reviewed. The government is proposing to amend the Ministerial Discretion approval process from a **two-phase process, which takes six months, to a single-phase process that will take four months**. This will allow pharmacists to know sooner whether they have been granted approval and allow the community faster access to medicines from those pharmacies that are approved. The amendment Bill was introduced in the Senate on 23 July 2025.

Attachment C– Longer-term opportunities for regulatory reform

Internal regulator/regulatory function	Proposed action or reform
Therapeutic Goods Administration (TGA)	Over the next 5 to 10 years, the TGA anticipates a doubling of new therapeutic goods applications for prescription medicines, medical devices and therapeutic software and AI. An upward trajectory of processing times and reported non-compliance poses a challenge to ensure continued timely access to safe and effective therapeutic goods. The proposal seeks to: • accelerate the TGA's (and other health regulators) shift to cloud based and structured data capabilities, integration of AI, and streamlining of business processes, to accelerate pre-market assessment, enhance post-market monitoring, and optimise the detection and management of non-compliance. • increase the TGA's (and other health regulators) capability for collaboration and data sharing with international regulators and domestic Health Technology Assessment (HTA) bodies, driving earlier adoption of emerging treatments and • embed world class data and digital capabilities into core business operations to drive effective, efficient and sustainable best-practice regulation.
Integrity of health benefit claims	The NDIS, aged care, Medicare Benefits Schedule (MBS), Pharmaceutical Benefits Scheme (PBS), and hospital funding represent a significant share of total Commonwealth program outlays. These programs share workforces, service providers and clients—yet they operate through disparate **compliance and regulatory frameworks that increase cost and complexity. Consolidating payment and payment integrity infrastructure across these programs presents a high-value opportunity to enhance quality, drive system-wide productivity, and improve fiscal management. Strengthening regulatory and compliance functions** would further amplify these benefits, laying the groundwork for coordinated reform and improved payment integrity across the care, disability, and health sectors.