Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

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Business Plan 2022–23

Contents

Message from the Deputy Secretary

The COVID-19 pandemic dramatically changed the health landscape in Australia, substantially affecting the health sector, consumers, and the way we work. The Therapeutic Goods Administration's (TGA) focus necessarily shifted over time, from evaluating face masks, rapid antigen tests and vaccines to monitoring their performance and safety, while maintaining our commitment to providing the best regulatory outcomes for Australians.

The pandemic, however, did not stop our focus on delivering other regulatory responsibilities. In the coming year, we will embed our learnings from the pandemic to optimise our daily operations. We will also continue major reforms, including TGA's digital and business transformation, to further streamline our business systems and modernise IT infrastructure. Initiatives such as building a new website, digitising the Poisons Standard and improving the Australian Register of Therapeutic Goods will facilitate simpler, faster interactions with the TGA. It will also allow for greater transparency in the regulation of medicines and medical devices.

The last two years have been a time of incredible work pressure for our staff as we have responded to the COVID-19 pandemic. Our people have continued to demonstrate commitment and resilience, and further, the flexibility to adapt to new ways of working. Moving into our purpose-built facilities, including state-of-the-art laboratories, is providing the environment to support our delivery of a world-class regulatory system for therapeutic goods. We are committed to maintaining a culture where all our employees feel respected and included, and we'll continue to focus on our regulatory science capability outlined in the HPRG *Regulatory Science Strategy 2020–2025*.

In 2022-23, we will continue to increase our engagement with patients, consumers, industry and health professionals by strengthening relationships with representative bodies, organisations and individuals. Our risk-based compliance and enforcement activities will be essential in maintaining the quality, safety and efficacy of therapeutic goods and maintaining confidence in these products.

We will continue our leadership role in international collaboration to build a more globally aligned regulatory framework and collaborate on joint evaluations of a large number of products. The *TGA's International Engagement Strategy 2021-2025* describes how we work with our international regulatory counterparts as well as our important work in the Asia Pacific region.

This Business Plan sets out our product regulation, stakeholder engagement, and compliance and innovation agenda for 2022–23. It supplements the broader Department's Portfolio Budget Statements and Corporate Plan.

Adjunct Prof John Skerritt FTSE FIPAA (Vic)

Our purpose

The Therapeutic Goods Administration (TGA), as part of the Australian Government Department of Health and Aged Care, is responsible for evaluating, assessing and monitoring products that are defined as therapeutic goods. We help Australians stay safe by regulating therapeutic goods for safety, efficacy or performance and quality.

We regulate the manufacture, import, export, supply and advertising of prescription medicines, vaccines, sunscreens, complementary medicines (including vitamins, minerals, herbal and traditional medicines), medical devices, blood and blood products, cellular therapies and biologicals.

Consistent with the *Therapeutic Goods Act 1989,* we:

- apply scientific and clinical expertise to assess whether the benefits of a therapeutic good outweigh any risks to health and safety
- assess the suitability of therapeutic goods for supply, import, and export from Australia
- regulate manufacturers of therapeutic goods to ensure they meet acceptable standards of manufacturing quality
- assess the quality and compliance of therapeutic goods on the market, including through laboratory testing where appropriate
- implement a range of regulatory actions that are proportionate to the potential risk arising from non-compliance or emerging safety concerns.

We achieve this by applying risk-based processes for both pre-market assessment and post-market monitoring, as well as promoting regulatory compliance through clear and transparent decision-making, providing education and guidance, and using innovative technologies and ideas to streamline business functions.

Our vision

Our vision is for **better health and wellbeing for all Australians through regulatory excellence.** This links directly with the Department of Health and Aged Care's vision of **better health and wellbeing for all Australians, now and for future generations.**

Our strategic framework

By regulating therapeutic goods in accordance with the *Therapeutic Goods Act 1989* and supporting regulations, we contribute to the Department's strategic priorities:

- better health and ageing outcomes for all Australians
- an affordable, quality health and aged care system
- better sport outcomes.

We are committed to delivering the Department's Health Protection, Emergency Response and Regulation program through the protection of the health and safety of the Australian community, and the preparedness to respond to national health emergencies and risks through the regulation of therapeutic goods (including medicines, medical devices, and blood, cell, and tissue products). This applies to goods exported, imported, supplied, and manufactured in Australia.

Measuring our performance

We undertake our regulatory functions by applying 3 principles of regulator best practice:

- **Continuous improvement and building trust:**

  We will:

  - use qualitative and quantitative analysis to assess and report on performance, and drive evidence-based continuous improvement
  - promote a culture that builds public confidence in our work and trust in our decision-making.

- **Risk based and data driven:**

  We will:

  - actively understand, engage with, and effectively mitigate strategic risks to successfully manage our 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

- **Collaboration and engagement:**

  We will:

  - seek opportunities to inform, engage and consult with our stakeholders and the Australian community
  - 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.

Using these three principles as a platform, we developed our strategic objectives and performance indicators. We consulted with industry representatives to ensure these met their expectations of us. Through internal and external consultation, we arrived at the following strategic objectives:

1 – Improve public health outcomes through regulation

2 – Actively engage with our stakeholders

3 – Promote compliance with regulatory requirements

4 – Innovate and continuously improve

Strategic objective 1 – Improve public health outcomes through regulation

Australia's expertise in regulation is recognised around the world. The safety of the Australian community will be maintained by our high standards of therapeutic goods regulation and helping to shape as well as remaining responsive to world-wide practices. The TGA continues to implement regulatory reforms with a focus on simplifying pathways and processes for consumers, healthcare professionals and industry while delivering efficient, best practice regulatory decisions.

Performance Indicators

1.1 Product approvals and regulatory assessments are delivered in accordance with statutory timeframes and non-statutory targets.

1.2 Provide timely access to innovative therapies and emerging technologies that respond to public health needs.

1.3 Propose and support design of regulatory reforms when evidence of value and real benefit is determined, or when risks can be appropriately managed.

Our focus for 2022-23

a. Continuing prioritised evaluations and post-market safety and performance monitoring of COVID-19 related products, including new medicines and vaccines (and medicines and vaccines for new populations), face masks and tests for detecting COVID-19 (including multiplex tests that also detect Influenza and other respiratory viruses).

b. Implementing reforms to the supply, manufacture, labelling, packaging, and compounding of medicinal cannabis products to help provide quality assurance and consistency in the products supplied.

c. Continued engagement, both domestically and internationally, to build flexible and robust regulatory evaluation processes, ensuring expedited access for Australian patients and healthcare professionals without compromising our regulatory standards.

d. Working with National Regulatory Authorities within the Pacific and South East Asia to strengthen regulatory systems, resulting in faster access to products for communicable diseases and minimising supply of products that are of poor quality or present health risks.

e. Continuing implementation of the Action Plan for Medical Devices. These reforms will improve how devices get on the market; strengthen monitoring and follow-up of devices already in use; and provide more information to patients about the devices they use.

f. Implementing recent reforms to better accommodate new technologies such as medical device software, medical apps and personalised medical devices.

g. Progressing the development and international alignment of the Unique Device Identification system, to improve product safety and surveillance of products in Australian supply chain.

h. Progressing the implementation and international alignment of the Unique Device Identification system by establishing the regulatory framework, refining the technical solution, and commencing early adopter projects, to ensure early notification of patient safety issues and to improve Australia's post-market medical device adverse event system.

i. Progressing process and policy reforms to facilitate repurposing of existing medicines to address unmet medical needs.

j. Reforming clinical trials regulation (particularly of medical devices and cell and tissue products) to address safety concerns.

k. Implement enhancements to medical device adverse event reporting including development of processes for mandatory reporting of adverse events by healthcare facilities.

l. Communicate how TGA implements Real World Evidence (RWE) and Patient Reported outcomes (PROs) in its evaluation of medicines and medical devices and implement regulatory guidance for industry on how to use RWE and PROs in regulatory submissions.

m. Continued education and enforcement of prescription only access to nicotine vaping products to reduce vaping and smoking uptake by children and adolescents, and reviewing the regulatory framework including the effectiveness of compliance and enforcement actions.

n. Investigating possible access controls on paracetamol, in-light of several recent overdose deaths.

o. Continuing the design and implementation of reforms to improve recall actions for all therapeutic goods.

p. Progressing improvements to the scheduling of cosmetic and fragrances in the Poisons Standard.

Strategic objective 2 – Actively engage with our stakeholders

We aim to be open and responsive to feedback about our practices and regulatory decisions. We engage regularly with many stakeholders and offer a range of mechanisms for the public, health practitioners and regulated entities to engage with us, collaborate and provide feedback. This supports reduced regulatory burden, a regulatory system aligned to risk and a globally aligned regulatory framework that is responsive to the latest medical and scientific developments.

Performance Indicators

2.1 Respond in a timely manner and effectively to enquiries and be clear about our regulatory decisions.

2.2 Actively communicate and educate stakeholders.

2.3 Collaborate with domestic and international health system stakeholders to address regulatory issues and understand the impact of changing policies, practices, and services.

Our focus for 2022-23

a. Implementing a new enquiry management model that will improve the timeliness, efficiency and documentation on how the TGA responds to enquiries from sponsors, health professionals and the public.

b. Continuing engagement with industry and increasing engagement with consumer groups to improve regulatory practices and transparency of our regulatory decisions.

c. Continuing our partnerships with international regulators, including through alliances such as Project Orbis, the Pharmaceutical Inspection Cooperation Scheme, the International Coalition of Medicines Regulatory Authorities, the International Medical Devices Regulators' Forum, and the ACCESS Consortium, to strengthen working arrangements, align regulatory practices and collaborate on regulatory policies.

d. Undertaking public awareness and education activities to inform consumers, health professionals and businesses about priority topics.

e. Introducing a priority review pathway for biologicals to enable faster patient access to cell and tissue therapies.

f. Learning about the perspectives and emerging issues relevant to our stakeholders through stakeholder surveys, public consultations, market research, and formal and informal forums.

g. Supporting small and medium sized enterprises (SMEs) and Australian innovators unfamiliar with therapeutic goods regulation to better understand regulatory requirements.

h. Continuing to develop and publish new and updated guidance material that assists regulated entities to understand and meet their regulatory obligations.

i. Continuing education and awareness raising activities to support adverse event reporting by consumers and health professionals.

Strategic objective 3 – Promote compliance with regulatory requirements

We will promote and monitor the quality, safety, and efficacy or performance of therapeutic goods to support community confidence in these products. Data collected from monitoring activities will be used to identify trends in non-compliance and prioritise compliance reviews and education activities. In doing this we will manage risks proportionately.

Performance Indicators

3.1 Data and intelligence are used to identify risks of non-compliance and inform compliance strategy.

3.2 Serious, deliberate, and repeated non-compliance is addressed.

3.3 Product safety, quality, efficacy, and performance issues are identified and assessed proportionally with the risk being managed.

Our focus for 2022-23

a. Implementing the Good Clinical Practice Inspection and Pharmacovigilance Inspection Programs to help medicines clinical trial sites and medicines sponsors respectively to understand their obligations and confirm compliance.

b. Undertaking education and communication activities to enable compliance with regulatory requirements, including in relation to manufacturing, importation and advertising of therapeutic goods.

c. Monitoring and enforcing compliance on the import, export, manufacture, supply and advertising of therapeutic goods.

d. Addressing serious, deliberate and repeated non-compliance through appropriate and proportionate enforcement responses, collaborating with other local and international health and law enforcement agencies as appropriate.

e. Enhancing our data analytics capability and further embedding operational intelligence to enhance the effectiveness and targeting of our education, compliance and enforcement activities, for example, in Listed Medicines compliance reviews.

Strategic objective 4 – Innovate and continuously improve

We will aim to continuously improve our performance and make regulatory decisions in the context of impacts on the whole health system. This will include building staff capability and a culture that identifies and implements improved practices.

Performance Indicators

4.1 Continuously improve services, processes, and systems to ensure they are fit for purpose.

4.2 Promote an impartial, flexible, and innovative workforce.

Our focus for 2022-23

a. Progressing the implementation of new IT and business systems for TGA services, product evaluation and workflow management via the Health Product Portal.

b. Consolidating TGA's data assets to better support TGA's regulatory activities.

c. Modernising the TGA Laboratories through transferring laboratory services to the new purpose-built facility at Fairbairn.

d. Redeveloping the TGA and Office of Drug Control (ODC) websites to provide a more user centric design and modern digital services and information useful for consumers, healthcare professionals and industry.

e. Developing a searchable database for the Poisons Standard which will explain medicines and chemicals scheduling decisions in plain English.

f. Increasing transparency of and streamline sharing of adverse event data through improvements to the Database of Adverse Event Notifications (DAEN-medicines) and implementation of new data exchange methods that enable receipt and sharing of adverse event information with state and territory health departments and health care professionals.

g. Building and maintaining links with universities, international regulators, and industry to improve our regulatory practices and enhancing our responsiveness to emerging technologies.

h. Creating and propagating data products across the TGA which combine key data sources into a single, consolidated view and increase data analytics capabilities.

i. Improving the use and integration of data to better manage and prevent medicine shortages through earlier detection and analysis of shortage signals.

j. Improving post-market monitoring systems for medical devices including early detection and action on emerging safety issues, allowing us to notify consumers earlier.

k. Developing updated complaints and feedback handling processes to be accountable and foster continuous improvement.

Reporting

Reporting on our performance against the TGA Business Plan will primarily include the Department's Portfolio Budget Statements and Annual Report, and the *TGA Performance Report*.

The *TGA Performance Report* will be published following the cessation of the 2022-23 financial year and will combine our previous *Performance Statistics Report* and *Regulator Performance Framework (KPI) Report* into one performance report, consisting of both qualitative and quantitative performance data to more clearly outline how we performed as a regulator against the business plan. The *Half-Yearly Performance Snapshot Report* will no longer be prepared under the revised performance framework.

In addition, we will continue to publish a range of performance information on the TGA website, including:

- laboratory testing results and summary reports, including up-to-date regular vaccine batch release data
- monitoring, compliance, and investigations outcomes, and advertising compliance reports
- post-market reviews
- an annual stakeholder survey
- publications detailing how we are improving access to therapeutic goods for consumers.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Regulatory Engagement and Planning Branch	1 July 2022

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