Australian Government

Department of Health

Therapeutic Goods Administration

Therapeutic Goods Administration

Business Plan

2018–19

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Introduction

The Therapeutic Goods Administration (TGA) is part of the Health Products Regulation Group (HPRG) within the Department of Health and is committed to delivering a world class, efficient and timely regulatory system for therapeutic goods.

HPRG comprises three divisions, which are supported by the Regulatory Legal Services Branch, the Principal Legal and Policy Advisor and the Chief Medical Advisor. Medicines Regulation Division and Medical Devices and Product Quality Division apply risk-based approaches to evaluating, assessing and monitoring therapeutic goods. Regulatory Practice and Support Division supports international cooperation and convergence; stewards compliance and enforcement activity; provides regulatory education, guidance and assistance; and facilitates our cost recovery arrangements.

This Business Plan sets out our product regulation, regulatory reform, international engagement and regulatory compliance agenda for 2018–19 and the steps we will take to achieve our vision.

It supplements the *Health Portfolio Budget Statements* and the *Department of Health Corporate Plan* and is supported by the Australian Government's *Regulator Performance Framework* and the TGA *International Strategy 2016–2020*. Details are provided on how we will meet our key deliverables in relation to the regulation of therapeutic goods.

The TGA Business Plan is updated annually and is a central part of our activity planning and performance monitoring framework.

Within this Business Plan we have provided an overview of our key commitments and a list of outcomes we will deliver in 2018–19.

Vision

Our vision is:

Better health and wellbeing for all Australians through regulatory excellence

This links directly with the Department of Health vision:

Better health and wellbeing for all Australians now and for future generations

We protect the health and safety of the community by regulating therapeutic goods. We strive for regulatory excellence through our:

- purpose – who we are and what we do
- principles – how we will conduct ourselves
- priorities – what we will focus on
- people – focussing on our staff development and wellbeing
- stakeholders– through transparency, meaningful engagement and education

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 and reduced inequality**
- **Affordable, accessible, efficient, and high quality health and aged care system**

Our commitment to achieving the department's strategic priorities is articulated through:

- **Regulation that protects the health and safety of the community, while minimising unnecessary compliance burdens.** We protect the health and safety of the Australian community through effective, timely and risk proportionate regulation of therapeutic goods (including medicines, medical devices, blood, cell and tissue products). This applies to goods exported, imported, supplied and manufactured in Australia.

In 2018–19 we will continue to implement regulatory reforms, including those associated with the Government Response to the Expert Panel Review of Medicines and Medical Devices Regulation (the MMDR Review). In addition, we will implement a number of other major and necessary reforms to the regulatory system, as well as maintaining our core activities associated with providing high quality regulation of therapeutic goods in Australia.

Environment

The health landscape is complicated and dynamic. In response to this changing environment, we continue to innovate to improve our business processes, including through better use of the data provided by our stakeholders and improved data analytics.

Scientific advancements such as new cancer treatments and new technologies such as 3D bioprinting continue to bring opportunities for Australians. They also require a regulatory framework that is contemporary, adaptable and supports innovation. Our challenge is to capitalise on advancements in technology while ensuring that regulation is appropriate to manage risk.

We continue to improve the regulatory system through our focus on implementing Government priorities and regulatory reforms. Implementation of the Government response to the MMDR Review began in 2016-17, with changes to our legislation and regulation enabling a significant number of reforms to be put into place in 2017-18. This year we will focus on implementing these reforms as well as other business and regulatory improvements. In doing this, we will ensure that stakeholders and consumers are informed about any changes to regulation and processes.

In 2018-19 we will increase our engagement with patients, consumers and health professionals by strengthening relationships with representative peak bodies. To remain competitive globally and to reduce duplication in the regulatory review of products we will also continue to collaborate with our international regulatory counterparts on information and work sharing activities.

Purpose

"*Our role is to enable access to safe and effective medicines, medical devices, a safer blood supply and cell and tissue therapies that benefit as many people in the community as possible. No product is without risk and uncertainty and the role of the TGA is to assess and balance these factors along with benefits in our decision-making.*"

Adjunct Professor John Skerritt
Deputy Secretary, Health Products Regulation Group

The TGA is responsible for protecting the health and safety of the community by regulating therapeutic goods for safety, efficacy, performance and quality. 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 (in response to non-compliance or emerging safety concerns) that are proportionate to the potential risk arising from the non-compliance or safety risk.

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 and using innovative technologies and ideas to streamline business functions.

Principles

As a Commonwealth regulator we adhere to following principles:

- We are committed to maintaining the trust and confidence of the Australian public
- We are accountable to the government of the day and the Australian public and work cooperatively with the industry that we regulate.
- We communicate meaningfully with stakeholders, providing transparency across our regulatory practice.
- We assess evidence in making decisions and recognise the value of taking a risk-based approach to regulatory, compliance and enforcement activity.
- We perform our functions consistently to ensure predictable outcomes in like decisions.

Priorities

In 2018–19 our key priorities are identified under four main activity streams:

1. **Product regulation** – through our core regulatory activity ('business as usual') and business process improvements.
2. **Regulatory reform** – including activities associated with the continued implementation of recommendations from the Medicines and Medical Devices Regulation Review.
3. **International engagement** – through activities associated with the promotion of international work sharing and regulatory convergence.
4. **Regulatory education and compliance** – through monitoring, targeted compliance and enforcement activities and appropriate action.

Our priorities are derived from:

- our legislative framework
- the Long-Term National Health Plan, as articulated in the *Health Portfolio Budget Statements*
- the *Department of Health Corporate Plan*
- the Government Response to the Medicines and Medical Devices Regulation Review
- the Key Performance Indicators (KPIs) outlined in the *Regulator Performance Framework*
- emerging public health issues and emerging government policies that affect regulation
- proactively responding to innovations in therapeutic goods, which may require updates to regulation
- international work sharing and harmonisation.

Reporting

In order to provide transparency to industry, healthcare professionals and the Australian public we publish a number of reports on the TGA website.

We respond to the performance commitments outlined in the *Health Portfolio Budget Statements 2018–19* in the context of the *Department of Health Annual Report.* In addition, we demonstrate achievement against these priorities through reports and other information on our website.

We report in detail on our performance through the TGA *Annual Performance Statistics Report* which provides data for the July to June period each year. We also publish a *Half Yearly Performance Snapshot* with a subset of data covering July to December.

We provide transparency and are held accountable to our stakeholders by reporting against the six KPIs under the *Regulator Performance Framework*. These outcomes-based KPIs articulate the overarching expectations of regulators' performance:

1. Regulators do not unnecessarily impede the efficient operation of regulated entities.
2. Communication with regulated entities will be clear, targeted and effective.
3. Actions undertaken by regulators are proportionate to the regulatory risk being managed.
4. Compliance and monitoring approaches are streamlined and coordinated.
5. Regulators are open and transparent in their dealings with regulated entities.
6. Regulators actively contribute to the continuous improvement of regulatory frameworks.

We prepare a Self-Assessment Report that provides a qualitative measure of our performance against the Framework. This report involves our external validator (the TGA Industry Forum, comprised of ten peak industry associations) assessing our performance against the KPIs and assisting us with identifying opportunities for improvement of our practices and processes followed by reporting on performance to the Minister annually. We use this feedback to inform our future priorities.

In addition, we publish performance information through the following documents, which are available on our website:

- prescription medicines approvals reporting
- laboratory testing results
- monitoring, compliance and investigations outcomes
- post-market reviews
- annual stakeholder survey
- publications detailing how we are improving access to therapeutic goods for consumers and streamlining regulatory processes by implementing the Government Response to the MMDR Review.

This framework allows us to set out what we plan to do at the beginning of the financial year and then report on what we have achieved by the end of the period.

Funding

The TGA annual budget is currently around $163 million and we operate on a full cost recovery basis. The regulatory costs are recovered through fees and charges levied on sponsors and manufacturers of therapeutic goods. We use an activity based costing model to calculate the relevant costs for each activity we undertake.

Our Cost Recovery Implementation Statement (CRIS) provides information on how we implement cost recovery activities associated with the registration and listing of medicines and inclusion of medical devices, including in vitro diagnostic devices (IVDs), and biologicals on the Australian Register of Therapeutic Goods (ARTG) and their ongoing monitoring and surveillance. The CRIS (available on our website) is prepared and updated at least annually as required under the Australian Government Cost Recovery Guidelines.

The 2016-17 Budget measure, Improving the Regulation of Therapeutic Goods in Australia, permitted $20.4 million to be invested (from TGA reserves) to meet the costs of implementing the regulatory reforms arising from the MMDR Review. As a result of implementing these reforms a number of changes were required to existing fees and charges as well as the introduction of new fees.

Product regulation

We are responsible for assessing whether therapeutic goods available for supply in Australia are safe and fit for their intended purpose. Products for which therapeutic claims are made are assessed by the TGA and, if approved, are entered on the ARTG. These therapeutic goods can be lawfully supplied in Australia and include prescription medicines, over-the-counter medicines, complementary medicines, biologicals, and medical devices. We regulate the supply of:

- medicines prescribed by a doctor, dentist or other approved prescribing health care professional
- medicines available from behind the pharmacy counter
- medicines available in the general pharmacy
- medicines available from retail outlets
- complementary medicines, such as vitamins, herbal and traditional medicines
- medical devices, from simple devices like bandages to complex technologies like heart pacemakers
- in vitro diagnostic medical devices (IVDs) such as blood tests used to test for various diseases or conditions
- vaccines, blood products, and other biologicals.

We conduct pre-market assessment, post-market monitoring and enforcement of standards, licensing of Australian manufacturers and verifying overseas manufacturers' compliance to local and adopted international standards.

We continuously look for opportunities to reduce regulatory burden on stakeholders by strengthening our relationships and understanding their business without compromising the health and safety of Australians.

Outlined in the table on page 9 is the work we will be doing as part of our ongoing regulatory reform and business as usual activities.

Regulatory reform

There are a range of reforms forecast for delivery in 2018–19, including those developed in response to the MMDR Review. All reforms are aimed to support better health outcomes for Australians and to reduce regulatory burden.

Implementation of the Government Response to the MMDR Review will continue throughout 2018–19 and we will consolidate those reforms already implemented. The MMDR Review assessed the regulatory framework for medicines and medical devices in Australia and made a number of recommendations to improve the availability of high quality, safe and efficacious products in a timely way to the community.

Aside from the MMDR reforms we will also be implementing other reforms to ensure a greater emphasis on transparency of regulatory decision-making processes, improve efficiencies in our business processes and adopt a more strategic approach to the use of information technology to support regulatory operations.

Overviews of our 2018-19 MMDR and other major regulatory reform activities are provided in the tables on pages 9 and 12.

MMDR Regulatory reform activities for 2018-19	
Outcome	**Activities**
Prescription medicine reforms	· Continue implementation of priority and provisional approval pathways · Deliver communication materials targeting patients and health professionals on priority and provisionally registered medicines · Take advantage of opportunities for collaboration and international work-sharing, with a particular focus on greater work-sharing in the evaluation of new chemical entities · Effective promotion and use of expedited submission pathways for new chemical and biological entities · Review minor variations categorisation policy and cost-recovery in collaboration with industry · Reformat Product Information (PI) documents to maximise usability for health care professionals
Complementary and over-the-counter medicine reforms	· Introduce the 'label claimer' for assessed listed medicines · Fully implement approved listed medicines pathway · Introduce an enhanced post-market monitoring scheme for complementary medicines · Introduce incentives to encourage research and development of new ingredients for listed complementary medicines · Take advantage of opportunities for collaboration and international work-sharing through greater worksharing of ingredient assessments

MMDR Regulatory reform activities for 2018-19	
Outcome	**Activities**
Medical device reforms	· Finalise the process to enable a system of Australian designated bodies to undertake conformity assessments of medical devices · Propose further regulatory amendments to harmonise medical devices regulation with the European Union regulatory framework · Finalise the process required for the use of comparable overseas regulatory approvals · Clarify classification and pre-market approval requirements for IVD companion diagnostics to align with both the new European IVD regulations and the US Food and Drug Administration (FDA) · Begin accepting applications for priority designation of novel medical devices, with potential for significant patient benefit, leading to faster approvals
Post-market monitoring reforms	· Implement a new Adverse Event Management System to improve and streamline the way sponsors, health professionals, state and territory health departments and consumers submit adverse event reports electronically · Maintain the Pharmacovigilance Inspection Scheme to ensure medicine sponsors are meeting their post-market regulatory requirement · Promote the Black Triangle Scheme for high risk medicines to encourage adverse event reporting by healthcare professionals and consumers · Enhance the post-market monitoring system for medical devices to make it easier for consumers to report adverse events, better documentation of reports and investigations and an improved data analytics capability
Access to unapproved therapeutic products reforms	· Implement an online application system for access to unapproved goods under the Special Access Scheme, including for medicinal cannabis · Implement an online application system for access to unapproved goods under the Authorised Prescriber scheme
Scheduling Policy Framework, advertising of pharmacist only medicine	· Implement a revised approach to allow advertising of pharmacist only medicines to the public unless it is determined that advertising of a particular substance is not appropriate

MMDR Regulatory reform activities for 2018-19	
Outcome	**Activities**
Low risk therapeutic goods reforms	· Implement further reforms to the regulation of low risk therapeutic products, for example hard service disinfectants, sunscreens, class I medical devices, antiperspirants and ear candles
Advertising of therapeutic goods reforms	· Implement the amended Therapeutic Goods Advertising Code on 1 January 2019 · Implement a streamlined advertising complaints handling scheme which includes establishing a single complaints management process along with a new IT system for advertising complaints management · Continue a comprehensive education campaign to underpin advertising reforms
Other	· Improve the Clinical Trial Notification system

Other major regulatory reform activities for 2018-19	
Outcome	**Activities**
Prescription medicines	· Continue implementation of new orphan criteria to ensure better targeting of fee waivers · Review the current prescription medicines submissions process in consultation with stakeholders · Enhance business processes and IT systems to support prescription medicines reforms and future electronic submissions · Scoping and analysis for a new Clinical Trials Notification System · Consultation on the development of priority pathways for the evaluation of generic medicines · Implementation of improved business and regulatory processes, relating to the evaluation of generic medicines · Working with industry stakeholders to improve the quality of dossiers submitted in support of applications for new generic medicines · Implement new labelling requirements for neuromuscular blocking agents to assist in minimising medication errors · Update guidance material to reflect best practice in the presentation of information on medicine labels · Implement further improvements to automated forms and business processes for minor variations to prescription medicines, including recognition of additional types of variations that can be 'notified' to the TGA
Complementary and over-the-counter medicine reforms	· Remove pre-market evaluation of Herbal Component Names
Exports reforms	· Investigate the streamlining of the exports only listing, certificate of pharmaceutical (CPP) and certificate of listed product (CLP) by transitioning to an electronic process (where possible) and engaging with the World Health Organization (WHO) and relevant overseas regulators in reducing regulatory burden · Investigate improvements to monitoring and compliance activities around export only listing, certificate of pharmaceutical and listed product with a view to ensuring the export of quality, safe goods from Australia

Other major regulatory reform activities for 2018-19	
Outcome	**Activities**
Biologicals reforms	· Implement restrictions to advertising for autologous human cells and tissues from 1 July 2018 and bring therapies involving significant processing within the regulatory framework for biologicals by July 2019 · Update the Australian Regulatory Guidelines for Biologicals · Review the regulation of faecal microbial transplant products
Medical device reforms	· Propose regulatory amendments for the emerging technologies of software as a medical device and the medical application of 3D printing (cognisant of international harmonisation) · Begin accepting certificates issued through the Medical Device Single Audit Program as manufacturers evidence for ARTG inclusion · Begin accepting Instructions For Use issued in electronic format (eIFU) for medical devices that are intended for professional use
Post-market monitoring reforms	· Enhance the post-market monitoring system for medical devices including early detection and action in relation to emerging issues · Mandatory reporting of medicines shortages · Implement regulatory options supported by public consultation to address the issue of opioid abuse and misuse. This includes review of opioid indications, pack sizes, Consumer Medicines Information and label warnings in addition to working with external stakeholders to improve healthcare professional and patient education.
Good Clinical Practice Reforms	· Develop and implement a voluntary pilot program of Good Clinical Practice (GCP) inspections

Business as usual activities

Product regulation activities for 2018-19	
Outcome	**Activities**
Pre-market evaluation, assessment and approval of medicines, medical devices, biologicals and other therapeutic goods supplied in Australia	**Evaluation and assessment** · Evaluate and process applications within legislated or target timeframes for market authorisation of prescription, over-the-counter and complementary medicines, biologicals, blood components and medical devices (including IVDs) that are imported into, exported from, manufactured and/or supplied in Australia · Regulate devices and medicines through their lifecycle (pre and post-market) by efficient and accountable regulatory practice · Provide access to unapproved therapeutic goods for use in Australia where no alternative treatment is available through the Special Access Scheme (SAS) and the Authorised Prescriber scheme · Process notifications and applications for SAS, Clinical Trials, Authorised Prescriber, and short term access to alternative medicines within specified timeframes · Issue licenses and permits for medicinal cannabis to support domestic patient and international export requirements · Updating and maintaining the Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons) **Risk management** · Increase monitoring of Risk Management Plans required by sponsors for high risk medicines to ensure they are undertaking the monitoring and risk mitigation activities identified in the plan

Product regulation activities for 2018-19	
Outcome	**Activities**
Ongoing monitoring of the safety, efficacy, performance and quality of medicines, medical devices, biologicals and other therapeutic goods	**Safety** · Investigate safety issues in a timely manner, using a risk-based framework · Monitor safety signals associated with the use of therapeutic goods and undertake safety investigations and actions · Investigate the role of large health datasets such as the Medicare Benefits Schedule and the Pharmaceutical Benefits Scheme in monitoring and safety issue detection · Remove from the market products that pose an unacceptable risk to consumers · Following extensive stakeholder consultation and workshops in 2017/18 for the appropriate use or avoiding the misue of strong opioids, the TGA will: – review available product pack sizes for opioids commonly used to treat acute pain – review the indications for the opioid products used to treat pain – review the indications and regulatory controls around fentanyl – review the label warnings and content of Consumer Medicines Information (CMI) documents for opioids – work with stakeholders to raise health professional and consumer awareness about pain management guidelines, including the use of non-opioid alternatives for the management of chronic pain; and safe disposal of opioid products. · Update the Therapeutic Goods (Permissible Ingredients) Determination on a quarterly basis to reflect evaluation undertaken on the safety and quality of ingredients available for use in listed medicines · Continue to maintain the Poisons Standard, the national regulatory framework for the access of substances, and provide advice to key stakeholders within the department, across industry, government and consumer sectors **Manufacturing quality** · Regulate manufacturers of therapeutic goods through risk-based inspection and desk-top assessment programs to confirm the quality of therapeutic goods supplied in Australia from domestic and international manufacturers meet specified standards and principles · Undertake risk-based testing to monitor medicines, medical

Product regulation activities for 2018-19	
Outcome	**Activities**
	devices and biologicals supplied in Australia for compliance with required standards and essential principles respectively · Ongoing six monthly publication of laboratory compliance testing results on the TGA website **Education and compliance** · Streamline compliance activities using a risk-prioritisation model with increased education activities with stakeholders to address non-compliance · Monitor compliance, including the quality, supply and advertising of therapeutic goods and enforce compliance utilising new sanction and penalty tools where required · Continue education and awareness raising activities to support adverse event reporting by consumers and health professionals · Manage our digital submission and monitoring systems for prescription and over-the-counter medicines · Monitor and review the new designation process and eligibility criteria for orphan drugs
Business activities to support regulatory outcomes and a fully cost recovered framework	**Governance and support functions** · Ensure that fees and charges appropriately reflect the regulatory effort involved and our cost recovery obligations · Implement any agreed recommendations of the Australian National Audit Office's Application of *Cost Recovery Principles Audit* · Continue to support and maintain governance arrangements for our statutory advisory committees, manage specialist expert advisory groups and source specialist advice when necessary to strengthen our regulatory decision making processes · Provide timely, accurate and appropriate information to support parliamentary, media, Freedom of Information, reporting and secretariat services · Continue to self-assess the performance of legislative instruments that are scheduled to sunset to ensure that regulatory instruments are achieving their objectives efficiently and effectively. · Ongoing stakeholder engagement through stakeholder surveys, public consultations, market research, and formal and informal forums.

Product regulation activities for 2018-19	
Outcome	**Activities**
	Regulatory guidance · Continue to produce new and updated guidance that is accessible and user friendly · Implement an enquiry management solution to support and streamline the tracking of general enquiries **Education** · Deliver regulatory education materials, including eLearning, webinars and fact sheets, that improve understanding of regulatory processes and requirements for consumers, health professionals and industry · Support SMEs, researchers and those unfamiliar with therapeutic goods regulation to better understand regulatory requirements · Transition to a new website that is accessible, easy to navigate, accurate, and enables engagement with stakeholders including industry and the general public · Build our education capability and offerings including enhanced engagement with consumer and industry stakeholders on a broad range of issues impacting the regulation of therapeutic goods · Manage the TGA's social media presence through existing Twitter, YouTube and Slideshare, and introduce a new channel through a TGA Facebook site
Monitor and enforce compliance of therapeutic goods	· Reduce low compliance risk through education and guidance undertaken by proactive communication strategies consistent with the regulatory compliance framework · Monitor the market for signals of potential non-compliance across the range of regulatory areas covered by the *Therapeutic Goods Act 1989* and employ a uniform risk-based approach to determining the significance of signals detected and the appropriate regulatory response · Develop individual Compliance Plans to set out the specific activities to be undertaken to mitigate the compliance risks in the regulation of therapeutic goods · Address high risk compliance through correcting behaviour by deterrence and detection and through cooperation with state, territory, federal and international partners

International engagement

As the challenges and priorities of therapeutic goods regulators have much in common, international engagement provides opportunities for discussing common challenges and learning from one another. In addition, closer alignment of international regulatory frameworks to provide opportunities for the increased use of assessments from comparable regulators in reaching regulatory decisions in Australia. Other benefits arise from the sharing of regulatory best practice, and when we are able to assist less advanced regulators to strengthen their capabilities.

An Annual International Operations Plan for 2018-19, published on our website, identifies projects and activities, as well as the benefits to be realised from those activities. This Plan is based on the *International Engagement Strategy 2016-2020*, which sets out three main goals for our international work. These goals are:

- contributing to public health and safety through regulation
- working with others to improve regulatory systems, including our own
- participating in work sharing and convergence activities.

The beneficiaries of our international regulatory collaboration activities are:

- patients – through earlier access to medicines and medical devices
- regional public health – by working towards disease elimination
- industry – through faster market access and lower costs
- regulators in our region – through the sharing of best practice and expertise
- regulators in OECD countries – through reduced workloads and less duplication.

We will continue to actively participate in fora that bring together regulators from across the world and provide the opportunities to collaborate and influence international regulatory policy. Closer to home, we are working with counterpart regulators in the Indo-Pacific region and Pacific Island countries in programs aimed at strengthening regulatory capacity and ensuring access to medicines of assured quality.

Details of our international activities are outlined in the table on page 19.

International engagement activities for 2018-19	
Outcome	**Activities**
Improved public health and safety	· Partnering with the Department of Foreign Affairs and Trade to implement the Indo-Pacific Regulatory Strengthening Program and Pacific Medicines Testing Program – these programs strengthen the capacity of less advanced regulators within participating Indo-Pacific countries to access new and priority therapeutic products to combat malaria and tuberculosis – reduce the incidence and impact of substandard and counterfeit medicines · Engagement with overseas regulators to further international efforts to ensure the safety, quality and effectiveness of therapeutic goods – we participate in regulator forums that include: the International Coalition of Medicines Regulatory Authorities; the Australia, Canada, Singapore and Switzerland Consortium; the International Pharmaceutical Regulators Programme; the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Schemes; the International Medical Devices Regulators Forum; and forums convened by the World Health Organization

International engagement activities for 2018-19	
Outcome	**Activities**
Improved regulatory systems	· Establishing new relationships and working with comparable overseas regulators to increase efficiencies in regulatory systems and processes, for example, to accelerate regulatory alignment, fast track approval processes for certain medicines and medical devices, and explore how risk assessments and determinations by comparable overseas regulators can be used more extensively · Enhancing pharmacovigilance activities and engagement with overseas counterparts to identify sources of supply to alleviate medicine shortages; undertake quality system audits of manufacturing facilities; strengthen intelligence with respect to provisionally approved medicines; and facilitating the exchange of information about medical device adverse events
Advanced work sharing, information sharing and regulatory convergence	· Participating in programs to develop enhanced collaboration frameworks with comparable overseas counterparts and promote the use of aligned regulatory systems and processes to reduce unnecessary duplication of effort across regulators · Supporting the development of standards that ensure the safety and quality of products by working with standard setting bodies, including the International Organization for Standardization and Standards Australia

Regulatory compliance

We are committed to protecting the health of the Australian public through intelligence-led, risk- based compliance and enforcement activity and are dedicated to working with industry and consumers to support voluntary compliance. Over the year we will be seeking to harmonise our compliance functions through better use of data collection and streamline compliance processes. We will also work towards greater transparency through the publication of compliance activity outcomes.

We update our Compliance and Enforcement Plan annually and also develop individual targeted Regulatory Compliance Plans to mitigate the compliance risks of areas that are identified as high risk. In line with ongoing monitoring of areas showing high risk of non-compliance we have developed a Cosmetic Industry Compliance Plan to target unapproved, unregistered and counterfeit therapeutic goods used in the cosmetic industry.

We will also include updates to the sanctions and penalties applicable to breaches of the *Therapeutic Goods Act 1989* and supporting regulations.

This year, as we do every year, we will work to improve our relationships with key stakeholders within the Commonwealth and our state and territory counterparts. These relationships facilitate intelligence-led, risk-based activity and provide us with further opportunities to remove illegal and/or non-compliant therapeutic goods from the Australian market, thereby protecting the Australian public from goods that pose an unacceptable risk to health and safety.

Further compliance and enforcement activities are planned for 2018-19 as detailed in the table on page 22.

Compliance activities for 2018-19	
Outcome	**Activities**
Protect the health of the Australian public through intelligence-led, risk-based compliance and enforcement activities	· Streamline compliance activities by using the case categorisation and prioritisation model and increase education activities with stakeholders to address non-compliance · Educate consumers about counterfeit therapeutic goods through publishing safety alerts
Collaboration across TGA on compliance target areas	· Develop and implement a Strategic Threat Assessment · Review the streamlined submission process to ensure suitability for evaluators and applicants · Design and implement efficient and effective software solutions · Apply, where appropriate, the new sanctions and penalties framework · Continue to develop and maintain our domestic and international relationships · Use four individual Compliance Plans to set out actions to be undertaken in the areas across the cosmetic industry, performance image enhancing drugs, medicinal cannabis and medical devices.

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