Australian Government

Department of Health

Therapeutic Goods Administration

Therapeutic Goods Administration

Regulator Performance Framework Self-assessment Report

July 2018 to June 2019

Contents

About the Therapeutic Goods Administration

The Therapeutic Goods Administration (TGA) is part of the Department of Health and is responsible for assessing whether therapeutic goods available for supply in Australia are safe and fit for their intended purpose. Approved therapeutic goods can be lawfully manufactured and supplied in Australia and include prescription medicines, over-the-counter medicines, complementary medicines, biologicals, and medical devices.

Products for which therapeutic claims are made are entered on the Australian Register of Therapeutic Goods (ARTG).

Some examples of goods that the TGA regulates the supply of include:

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

We also play a regulatory role in overseeing the manufacturing process and advertising of therapeutic goods in Australia.

More information about how therapeutic goods are regulated can be found on our website at www.tga.gov.au.

Overview for 2018-19

Balancing the demands of regulatory reform, while maintaining our core business of providing high quality regulation of therapeutic goods in Australia, continues to be both a challenge and a priority.

In 2018-19 we continued to progress the implementation of the Government's response to the Review of Medicines and Medical Devices Regulation (MMDR) as announced in the 2016-17 Budget. Implementing the Government's reforms provides a number of opportunities for improving therapeutic goods regulation and reducing regulatory burden for industry.

Key program milestones achieved in the 2018-19 financial year include: the commencement of the new Therapeutic Goods Advertising Code; the TGA commencing as the single body responsible for handling advertising complaints; an integrated system for acceptance, administration and evaluation of all ingredient applications for listed medicines; commencement of a review of the marketing authorisation process for generic prescription medicines; and establishing the medicine shortages information initiative.

Regulator Performance Framework

The Australian Government is committed to reducing the cost of unnecessary or inefficient regulation imposed on business, community organisations and individuals. The Regulator Performance Framework (RPF) establishes a common set of performance measures for the comprehensive assessment of regulator performance and their engagement with stakeholders. The way regulators administer regulations can have a major effect on the burden imposed, and therefore the framework aims to encourage regulators to undertake their functions with the minimum impact necessary to achieve regulatory objectives.

The RPF comprises six outcomes-based Key Performance Indicators (KPIs) and associated measures. The KPIs articulate the Government's overarching expectations of regulator performance, namely that:

1. Regulators do not unnecessarily impede the efficient operation of regulated entities
2. Communication with regulated entities is clear, targeted and effective
3. Actions undertaken by regulators are proportionate to the 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.

Under the RPF, regulators are required to undertake an annual self assessment of regulatory performance against the six KPIs.

The metrics used to assess performance are a mix of qualitative and quantitative measurements that have been agreed through a ministerially approved stakeholder consultation mechanism, and approved by the Minister.

External validation

The results of this self-assessment are required to be validated by the TGA Industry Forum (TIF) as the approved stakeholder consultation mechanism.

The TIF is comprised of industry peak bodies. They provide assessment of our performance during the reporting period and all feedback is considered in detail.

Certification by the Accountable Authority

The self assessment is required to be certified by the Secretary of the Department of Health as the Accountable Authority under the *Public Governance, Performance and Accountability Act 2013* and the *Therapeutic Goods Act 1989*.

Rating scale

Met	Substantially met	Not met
Strong performance against all of the measures under the KPI	Strong performance against most of the measures under the KPI	Poor performance against all of the measures under the KPI

Summary of self-assessment results

Regulator Performance Framework KPIs		Ratings for 2018-19
KPI 1	Regulators do not unnecessarily impede the efficient operation of regulated entities.	**Met**
KPI 2	Communication with regulated entities is clear, targeted and effective	**Met**
KPI 3	Actions undertaken by regulators are proportionate to the regulatory risk being managed.	**Met**
KPI 4	Compliance and monitoring approaches are streamlined and coordinated.	**Met**
KPI 5	Regulators are open and transparent in their dealings with regulated entities.	**Substantially met**
KPI 6	Regulators actively contribute to the continuous improvement of regulatory frameworks.	**Met**

Overall Assessment

Using the above performance ratings, targets have been met for most measures under the six KPIs.

Our performance and activities continue to be reported through various publications available on the Health and TGA websites. We also raised awareness of our regulatory framework with stakeholders through meetings, workshops, webinars, publication of materials on our website, social media promotion and improved response times to email and phone enquires. Our commitment to the TGA Customer Service Standards is an ongoing project. We have not yet reached 100% in terms of timeliness of our responses which has resulted in our self-assessment for KPI 5 being maintained as 'Substantially met'.

We have engaged with stakeholders at all levels, providing information and assistance for the ongoing operation of their relevant regulated entities. We expanded our engagement with Small to Medium Enterprises (SMEs) with SME Assist, allowing more opportunities for sponsor understanding and input to be provided into TGA processes.

The establishment of the TGA Facebook page has expanded the way we communicate, and helped us emphasise our commitment to being open and transparent as a regulator. During the reporting period we also hosted webinars, targeted and public consultation, and provided eLearning and contemporary guidance material through our website to assist our stakeholders to navigate changes to regulations. We also continued to publish the results of consultations on the TGA website.

We have utilised risk-based models in areas such as advertising, recalls and product testing, to minimise impact on regulated entities. We continued to monitor potential non-compliance, and considered emerging trends and compliance history when undertaking intervention.

Our ongoing collaboration with international regulators, as well as various state and territory bodies, has streamlined our compliance and monitoring activities in areas such as breast implants, manufacturing inspections, and medicine shortages.

We supported and educated our stakeholders by working collaboratively with the industry through business improvements and the implementation of new reforms. Our annual stakeholder survey had an increased response rate from medical professionals and the industry, the results of which help us provide better regulatory advice and services in the future.

In 2018-19, the annual bilateral meetings with peak industry bodies to consult on fees and charges were extended to four additional peak bodies. In addition, a consultation paper on proposed fees and charges for 2019–20 was also released publicly to provide opportunity for wider industry and other stakeholders' comments.

Opportunities for improvement

The self assessment process highlighted areas of ongoing focus for continuous improvement in our regulatory performance.

In 2019–20 we will continue to increase our engagement and strengthen our relationships with regulated entities and peak industry 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, work sharing, and work collaboration activities.

We will continue to implement regulatory reforms, as well as maintaining our core activities associated with providing high quality regulation of therapeutic goods in Australia.

2018-19 Performance Reporting

KPI 1 - Regulators do not unnecessarily impede the efficient operation of regulated entities

Measures/metrics	Evidence (performance in 2018–19)	
KPI 1.1 Regulators demonstrate an understanding of the operating environment of the industry or organisation, or the circumstances of individuals and the current and emerging issues that affect the sector.	Ongoing engagement with industry provides opportunities for us to identify and assess issues, respond to emerging risks, and introduce change to stakeholders in a manner that does not impede their functions. In addition, it allows stakeholders to provide input on key areas of policy development throughout the process. In 2018-19 we participated in over 70 formal stakeholder forums that included industry events, regulatory workshops for stakeholders and bilateral meetings with industry groups. Highlights included: • The TGA Consultative Committee and TGA Industry Forum each meeting twice during this period. Attending stakeholders used the opportunity to have input into TGA activities and discuss regulatory activities and priorities. • Attending, presenting and receiving feedback from the bi-monthly Medicines Australia Regulatory Affairs Working Group meetings in addition to regular targeted consultation with the Generic and Biosimilar Medicines Association. • Hosting four meetings of the Regulatory and Technical Consultative Forum for Medical Devices to discuss issues of a regulatory and technical nature with industry. • The TGA held regular stakeholder advisory committee meetings throughout 2019. These included the Advisory Committee on Medical Devices (seven meetings), including a specialist orthopaedic meeting to review data issued by the National Joint Registry; the Advisory Committee on Medicines (six meetings) which provided independent advice to the Minister for Health and the TGA on issues relating to the safety, quality and efficacy of medicines supplied in Australia; and the Advisory Committee on Vaccines which provided independent advice relating to vaccines supplied in Australia and issues relating to safe use in national immunisation programs. • Meeting with the TGA-Industry Working Group on Good Manufacturing Practice (TIWGG) and TIWGG Technical Working Groups. The meetings allowed members to provide feedback on Good Manufacturing Practice (GMP) service delivery in TGA and the adoption of PIC/S Guide PE009-13. • Establishing partnerships with SMEs including universities, industry organisations and state and federal government agencies to deliver workshops and information sessions tailored to those new to therapeutic goods regulation. • The TGA was an active participant in the annual conferences of industry bodies including Complementary Medicines Australia, Medical Technology Association of Australia, Medicines Australia, and AusBiotec Pty Ltd. Attending these annual conferences allows us to develop an understanding of current and future issues and priorities of the industry.	**Self-assessed rating: Met**

KPI 1 - Regulators do not unnecessarily impede the efficient operation of regulated entities

Measures/metrics	Evidence (performance in 2018–19)	
KPI 1.1 (continued)	During 2018-19 the TGA became the single body responsible for handling complaints about the advertising of therapeutic goods to the public. A new Therapeutic Goods Advertising Code was implemented and a formal advertising education program instituted. The Therapeutic Goods Advertising Consultative Committee (TGACC) was formed to support these changes, with three meetings held in the reporting period. The TGACC brings together members from industry, health care professionals and practitioners, health organisations, media and advertisers and a varied group of consumer interests. We also met with individual stakeholders, including Consumer Healthcare Products Australia, Complementary Medicines Australia, Accord Australasia, Medical Technology Association of Australia and Direct Selling Australia, to understand the implications of proposed changes to the advertising requirements on their constituents.	
KPI 1.2 Regulators take actions to minimise the potential for unintended negative impacts of regulatory activities on regulated entities or affected supplier industries and supply chains.	We continued to comply with the best practice regulation requirements. During 2018-19 the TGA sought advice from the Office of Best Practice Regulation (OBPR) on 21 occasions as to whether a Regulatory Impact Statement (RIS) would be required for proposed reforms. The OBPR determined one RIS was required and the TGA is in the process of undertaking the appropriate level of consultation and analysis prior to completing the RIS. Where the OBPR confirmed a RIS was not required, prior to introducing the reforms the TGA engaged with all potentially affected parties to explore opportunities for the best outcome. We published 31 public consultations on the TGA website, giving regulated entities the opportunity to provide input on any potential for unintended negative impacts that were not considered prior to proposed implementation. Significant consultations undertaken included: • Advertising code guidance • Reviewing the latest Pharmaceutical Inspection Co-operation Scheme Guide to GMP products for Medicinal Products (PIC/S Guide PE009-13 and PIC/S Guide PE009-14) • Good Clinical Practice (GCP) Inspections Pilot Program • Whether the TGA should publish that a prescription medicine is under evaluation • TGA-Industry Working Group on Good Manufacturing Practice (TIWGG) and the Medicinal Cannabis Industry Association • Medical device reforms and action plan, including the proposed establishment of a Unique Device Identifier system, and the regulation of software as a medical device.	**Self-assessed rating: Met**

KPI 1 - Regulators do not unnecessarily impede the efficient operation of regulated entities

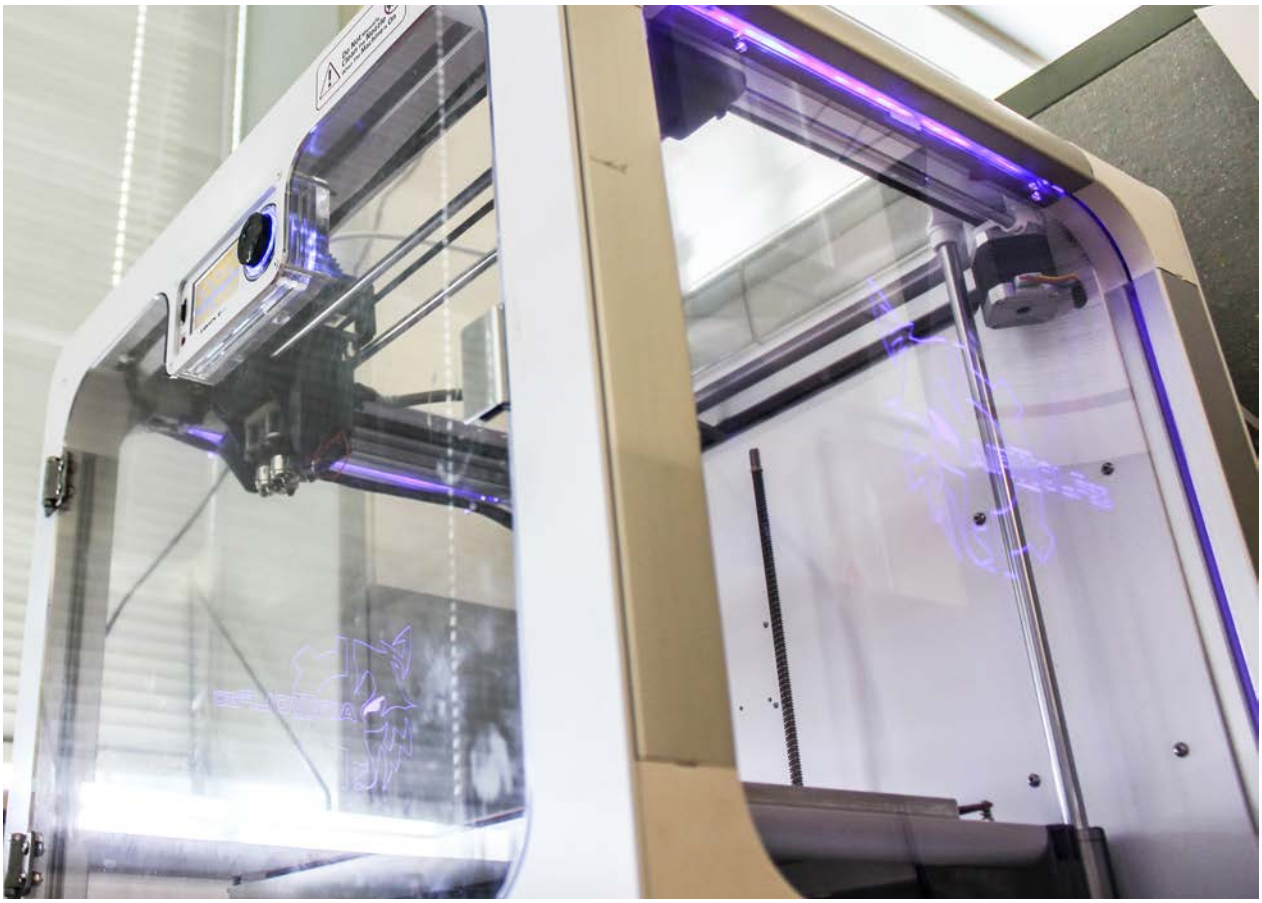
Measures/metrics	Evidence (performance in 2018–19)	
KPI 1.3 Regulators implement continuous improvement strategies to reduce the costs of compliance for those they regulate.	New provisional and expedited approval pathways of medicines and devices introduced in 2017–18 were embedded and reviewed for efficacy and uptake. The TGA approved 19 prescription medicine registrations that were processed via the expedited pathways, and made a further nine provisional determinations and nine priority determinations for prescription medicines. Regarding medical devices, the TGA has made 1 conformity assessment (priority applicant) designation. In April 2019 the TGA established a team to look at emerging medical device technology. The team is conducting regular webinars (both educational and reforms based) to keep industry and consumers informed of regulatory requirements for emerging technologies. Cybersecurity guidance was published to support industry and consumers. Twelve advertising workshops were held for regulated entities about the new Therapeutic Goods Advertising Code. These were attended by approximately 400 industry representatives. Three webinars were held to support stakeholders unable to attend in person. In our capacity as a WHO-designated Essential Regulatory Laboratory, we supplied influenza reagents to vaccine manufacturers worldwide. The TGA has now introduced an online ordering system to streamline the process for industry. We commenced a review of the generic medicine market authorisation process. The review identified opportunities to reduce the costs of compliance for generic medicine sponsors by reducing regulatory barriers for applicants, making regulatory requirements clearer and more transparent, and reducing Australia-specific regulatory requirements. Public consultation on the proposed reforms was held in early 2019. Implementation of the proposed reforms is expected to occur from late 2019 to June 2020. Thirteen public consultations were conducted in relation to medical device regulation, progressing recommendations of the MMDR and seeking views on proposed enhancements. An additional four consultations were conducted by the International Medical Device Regulator Forum, of which TGA is a member. Details of all past and current TGA consultations are available on our website. The Uniform Recall Procedure for Therapeutic Goods was amended to introduce a more flexible and cost effective method for industry to communicate its consumer level recall actions to members of the general public. The TGA commenced the development of an online e-form to facilitate more efficient notification and processing of industry recall notifications.	**Self-assessed rating: Met**

External validators acknowledged our willingness to consult with industry using both formal and informal avenues. Feedback recognised the ongoing revision of regulations and regulatory guidelines required to meet the needs of patient safety and industry. Feedback also acknowledged efforts made to increase the effectiveness of our operations, such as accepting comparable overseas regulator reports as evidence for applications. Overall, stakeholders' comments were mixed, with industry members representing some of the smaller sectors noting that they have not yet realised much benefit from the numerous reform processes we have undertaken. Stakeholders encouraged us to continue to engage early and often, including prior to formal consultations.

Identified opportunities for improvement

The TGA regularly hosts and attends both formal and informal meetings with industry and other stakeholders. These meetings provide insight into the current and emerging issues being experienced by regulated entities as well as providing transparency for industry as to the processes and constraints of the TGA. We will continue to seek feedback to improve the effectiveness of our workshops and activities. We will also use these workshops and informal meetings to seek feedback and stakeholder input ahead of publishing formal consultations.

There is ongoing work involved in reviewing and enhancing our education material for industry and consumers. We are also working to improve the support we provide to SMEs, researchers, start-ups and interested organisations to help them better understand regulatory requirements.



KPI 2 - Communication with regulated entities is clear, targeted and effective

Measures/metrics	Evidence (performance in 2018–19)	
KPI 2.1 Regulators provide guidance and information that is up to date, clear, accessible and concise through media appropriate to the target audience.	The TGA continually reviews, develops and updates regulatory guidance to reflect current best practice, as well as to comply with Australian Government requirements and international standards for web content accessibility. In September 2018 the TGA Facebook page was launched. This created an additional channel to educate and inform stakeholders and consumers about the role of the TGA in providing safe medicines and medical devices to Australians. During this period, we created 351 posts and gained 5,924 followers. Twelve webinars on different topics relating to regulation of therapeutic goods were hosted by the TGA. The average webinar attendance was 148 attendees. The TGA Advertising hub, with related eLearning and video, decision tree, guidance and new fact sheets, went live on 1 July 2018 to support the new complaints handling framework and the changes to the Advertising Code. This included specific materials for consumers on identifying non-compliant advertising and complaints processes. The News section of the TGA website averaged 42 items per month which consisted of announcements and information updates. These were also communicated via other channels, such as social media and email subscription lists, keeping stakeholders informed of published guidance, current issues, media releases, upcoming consultations, and other relevant information. In this reporting period 62 new guidance documents were published, and 50 existing guidance documents were updated. During this period important updated guidelines came into effect outlining regulators responsibilities regarding a number of regulatory changes: updated exemption status for tampons, menstrual cups and disinfectants; the introduction of new legislation requiring patient implant cards and information leaflets to be supplied (including for permanently implantable devices); providing updated information on issues that are of high interest to consumers and stakeholders (e.g. the breast implant and transvaginal (urogynaecological) surgical mesh hubs on the TGA website).	**Self-assessed rating: Met**

KPI 2 - Communication with regulated entities is clear, targeted and effective

Measures/metrics	Evidence (performance in 2018–19)	
KPI 2.2 Regulators consider the impact on regulated entities and engage with industry groups and representatives of the affected stakeholders before changing policies, practices or service standards	We engage in extensive formal consultation prior to changing policies, practice and service standards, and where regulation is being amended, to ensure that industry is informed and consulted prior to implementing change. In addition to the consultations mentioned at KPI 1, we held the following stakeholder meetings throughout the period: • Met with the TGACC on three occasions on the proposed amendments to the 2018 Advertising Code. • Held a pre-consultation meeting with peak industry association representatives and technical experts from a number of manufacturers (prescription, OTC and complementary medicines) prior to drafting the updated Therapeutic Goods (Standard for Tablets, Capsules and Pills) (TGO 101) Order 2019. • Undertook targeted consultation via TIWGG for GMP Clearance process changes throughout the reporting period. This included additional consultation regarding PIC/S Guide PE009-14 and the Good Clinical Practice Inspections Pilot Program. • Held discussions within the Regulatory and Technical Consultative Forum regarding updating the Medical Device Incident Reporting Scheme guidance document for sponsors. • Held discussion with the Regulatory Affairs Working Group regarding multiple areas, including opportunities for further process reforms to the standard medicine pathways, updates for older medicines and the industry's request to have an earlier view during the evaluation process on what regulatory decisions are likely to be. • Held regular discussions with the complementary medicines industry working groups including Complementary and OTC Medicines Regulatory & Technical Consultative Forum (COMTECH), Consumer Healthcare Products Australia (CHP Australia), Accord Australasia, Advisory Committee on Complementary Medicines (ACCM) and Chinese Medicine Board of Australia (CMBA) regarding general interest items that affect industry and MMDR reforms. • We also further built our understanding of commercial sensitivities for the ingredient supply industry. We contacted more than 200 proprietary ingredient suppliers and used the information received to inform our public consultation on making more information about ingredients in medicines available to consumers.	**Self-assessed rating: Met**

KPI 2 - Communication with regulated entities is clear, targeted and effective

Measures/metrics	Evidence (performance in 2018–19)	
KPI 2.3 Regulators' decisions and advice are provided in a timely manner, clearly articulating expectations and the underlying reasons for decisions.	As detailed in the TGA's Annual Performance Statistics Report, during the reporting period 99% of prescription medicine applications and 100% of device applications were completed within legislated timeframes. In addition to publication of recall actions in the System for Australian Recall Actions database, a detailed TGA web statement is published for certain recall actions like Hazard Alerts for implantable medical devices, consumer level recalls and any other recalls that may have wider implications for public health and safety. These web statements include additional advice to consumers and healthcare professionals regarding the recall action undertaken. During the period there were 25 new or updated web statements and these were published within one to three business days following approval of the recall action, unless there were extenuating circumstances. This timeframe allows sponsors the opportunity to commence the required action prior to it being further publicised. We have processed 2443 applications for inclusion of medical devices in the ARTG, and also conducted: • 156 level 1 compulsory audits (30-day target time frame – mean 24, median 15). • 236 level 2 Compulsory audits (60-day target time frame – mean 99, median 85). • 201 non-compulsory audits (mean 99 days, median 56 days). We also have completed 273 of 279 conformity assessment applications in this period. We approved 5,451 applications for prescription medicines, including 38 new chemical and biological entities, 53 extensions of indications and 73 major variations. 11 of the new medicines and extension applications were evaluated as priority applications. The time for approval for each of the pathways was well within legislated or operational timelines. For major applications: • 38 new chemical entities/new biological entities/biosimilars approved in a median 202 working days (for standard pathway; legislated 255 working days) • 53 extensions of indications approved in a median 197 working days (for standard pathway; legislated 255 working days) • 11 medicines and indications approved via the priority evaluations pathway in a median 123 working days (operational target of 150 working days). Five applications for registered complementary medicines were approved, and 18 variations completed. 221 new over-the-counter medicines were approved, with 938 changes to existing medicines.	Self-assessed rating: Met

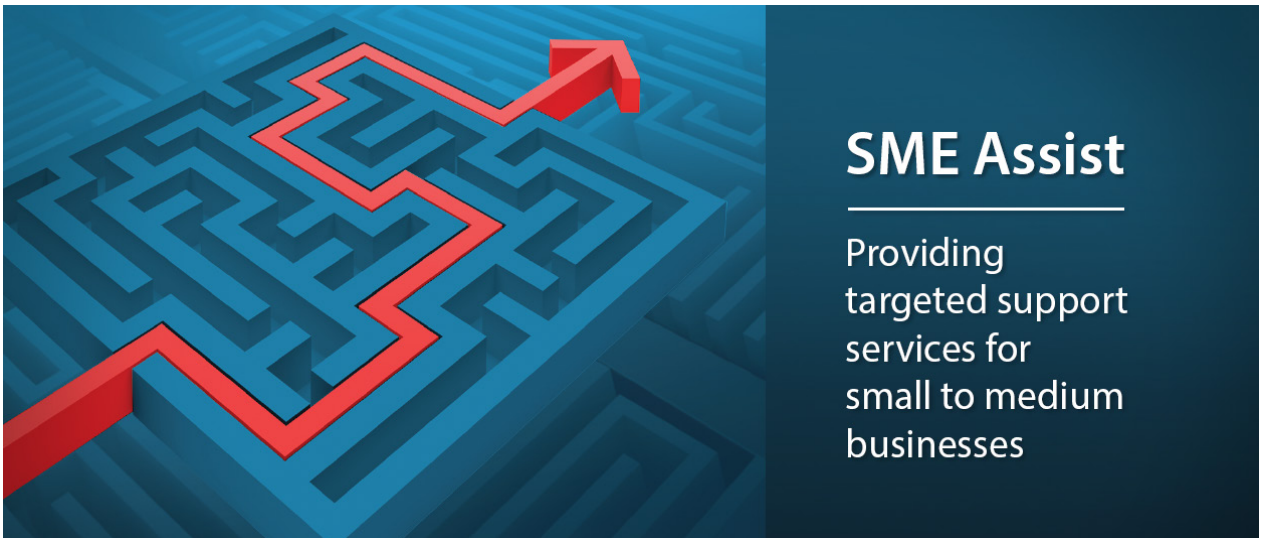
KPI 2 - Communication with regulated entities is clear, targeted and effective

Measures/metrics	Evidence (performance in 2018–19)	
KPI 2.4 Regulators' advice is consistent and supports predictable outcomes.	We are working to ensure that all published guidance material is of a high quality, is user focussed, accessible and adheres to Digital Transformation Agency standards. We held six SME Assist 'Meeting Your Obligations' workshops (an increase of one compared to2017–18) and two targeted information sessions on subjects relevant to specific industry groups. The workshops had a total of 417 participants (an 85% increase from the last reporting period) and feedback was overwhelmingly positive. 14 internal reviews of regulatory decisions were finalised in this period, and 5 (36%) had their decisions revoked or substituted without consideration of additional information. All internal reviews were completed within legislated timeframes. During this period, we were party to five matters before the Administrative Appeals Tribunal. Two matters were dismissed, one was resolved, one upheld and one is ongoing. None of the outcomes were related to issues relating to quality of TGA decisions.	Self-assessed rating: Met

External validators commended our efforts to consult with the industry on relevant and significant issues through formal and informal channels, as well as providing additional channels of communication such as the TGA Facebook page. Stakeholder comments noted that some of our communication could have been more timely, for example consultations for legislation with known sunsetting dates could have been published earlier, and emphasised that guidance material and workshops were the most valuable forms of targeted communication.

Identified opportunities for improvement

We will continue to review and adapt our services to ensure we meet industry's education needs by providing up to date, high quality and relevant content on the TGA website and relevant social media channels. We are also committed to direct communication with stakeholders, and to providing clear and consistent advice in a timely manner. We will continue to engage with industry to educate them on their regulatory responsibilities, and raise our awareness of the issues they are facing.



KPI 3 - Actions undertaken by regulators are proportionate to the regulatory risk being managed

Measures/metrics	Evidence (performance in 2018-19)	
KPI 3.1 Regulators apply a risk-based, proportionate approach to compliance obligations, engagement and regulatory enforcement actions.	We have implemented a new advertising complaints handling framework underpinned by a risk-based model for the categorisation of complaints. This model assists us to concentrate our time and efforts on the advertising matters that represent the greatest risk to public health and safety. During this period, 2,436 cases have been generated from complaints and 1,601 cases were closed. Cases assessed as having a low risk to public health and safety are generally handled using an educative approach and closed quickly. For the 1,480 cases categorised as low, 1,057 Regulatory Obligations letters were sent informing advertisers of alleged non-compliance and providing them guidance to rectify their advertising and assist with future compliance. For the cases categorised as medium risk, we issued a number of warning letters and in some cases guidance letters. Both types of letters require action and response. Infringement notices with a financial penalty were also issued to two advertisers. Court action was taken against one advertiser in a high risk case, resulting in a $10 million penalty against the company, reflecting the very real danger to public health and safety posed by the conduct of the advertiser. We prioritise matters that pose a risk to public health and safety. A case of advertising claiming to treat a serious condition that generally requires diagnosis and ongoing treatment by a medical professional was categorised as critical. The advertiser was directed to immediately cease advertising of a product after eight serious breaches of the *Therapeutic Goods Act 1989* and the Advertising Code were identified. When this did not occur, regulatory action was escalated and a directions notice was issued to the advertiser to permanently cease advertising of the product. The advertiser subsequently complied. 3,271 compliance investigations in relation to the supply, manufacture, import or export of therapeutic goods were finalised, and 1,069,946 units of non-compliant goods were destroyed during this time. Outcomes of compliance activities are further detailed in the 2018-19 Annual Performance Statistics Report. Laboratory test results continue to be published in the Database of TGA Laboratory Testing Results on the TGA website. The database provides the results of testing of 380 products from the November 2018 release, and 467 products from the May 2019 release. In early 2019 the TGA started the periodic publication of more detailed reports related to specific testing projects. These reports provide additional context and detail regarding significant testing projects undertaken by the TGA Laboratories.	**Self-assessed rating: Met**

KPI 3 - Actions undertaken by regulators are proportionate to the regulatory risk being managed

Measures/metrics	Evidence (performance in 2018-19)	
KPI 3.2 Regulators' preferred approach to regulatory risk is regularly reassessed. Strategies, activities and enforcement actions are amended to reflect changing priorities that result from new and evolving regulatory threats, without diminishing regulatory certainty or impact.	We continue to work with other agencies to identify threats to the Australian public and Australian market, including participating in the international Operation Pangea every year which targets the trafficking of illicit pharmaceuticals and medical devices. We have established a Compliance and enforcement hub on the TGA website to provide a central location for information on our compliance approach and our compliance actions and outcomes. The hub contains information about our compliance activities and educational resources, and provides an avenue for reporting suspected non-compliant activity. Our Regulatory Compliance and Risk Committee meets six times a year. It operates as a community of practice for identification and consideration of improvements to compliance frameworks, and facilitates data and information sharing across the compliance streams. The committee also prepares the annual compliance plan. We have established an internal Enforcement Committee to ensure a consistent and appropriate approach to higher level enforcement actions.	**Self-assessed rating: Met**

KPI 3 - Actions undertaken by regulators are proportionate to the regulatory risk being managed

Measures/metrics	Evidence (performance in 2018-19)	
KPI 3.3 Regulators recognise the compliance record of regulated entities, including using earned autonomy where this is appropriate. All available and relevant data on compliance, including evidence of relevant external verification is considered.	We review risks associated with monitoring and compliance and streamline activities to minimise impact on regulated entities. The risk-based model that underpins the new advertising complaints handling framework enables us to focus resources on the advertising matters that represent the greatest risk to public health and safety. The model describes the actions the TGA may take when dealing with non-compliance, noting that the most serious sanctions (such as court action) are reserved for the most egregious cases. The model recognises that where the advertiser has not previously come to our attention and their advertising does not pose a threat to public health or safety or target vulnerable consumers, then an educational approach is the best course of action. We evaluate the level of risk to determine the classification and level to which a recall is undertaken. We consider the significance of the hazard, the channels by which the goods have been distributed, and the level to which distribution has taken place. The levels include consumer level, retail level, hospital level or wholesale level. Recall actions vary depending on the deficiency of the therapeutic good and the risk the deficiency poses to public health and safety. Out of the 666 recalls issued for medicines, medical devices and biologicals undertaken during the reporting period, 91 were Class I (can or have resulted in serious injury or death to patients or users), 477 were Class II (potential to cause illness, injury or result in mistreatment) and 98 were Class III (issues may not pose a significant hazard to health, but action potentially required). We use a risk-based approach to the selection and prioritisation of products for testing within the Laboratories Branch, with an aim to investigating the potential risk of non-compliance, and to monitor continuing compliance if required. Development of the testing plan is governed by a risk management framework based on ISO 31000:2009 - Risk management—Principles and guidelines. We also employ a risk-based approach to the frequency of facility inspections. Manufacturer performance at inspection is categorised as good, satisfactory, marginal and unacceptable with further granularity provided by applying a high, medium or low risk rating. These ratings are applied when setting the date for reinspection. The compliance outcomes from inspections overall have shown an increase in satisfactory compliance with less marginal compliance inspection results.	**Self-assessed rating: Met**

External validators called for due consideration prior to enacting reforms to ensure that impacts to industry are always fully realised, and that the level of regulation is proportionate to the regulated products. This comment was made by industry groups representing manufacturers and sponsors of lower-risk products. Feedback noted that that our risk-based approach continues to be in line with the Australian regulatory framework and international best practice, and that the enforcement actions of the revised Therapeutic Goods Advertising Code is a good example of such.

Identified opportunities for improvement

We will continue to apply a proportionate, risk-based approach to our monitoring and compliance activities. We commit to ongoing collaboration with law enforcement in our states and territories as well as at a national and international level.

KPI 4 - Compliance and monitoring approaches are streamlined and co-ordinated

Measures/metrics	Evidence (performance in 2018–19)	
KPI 4.1 Regulators' information requests are tailored and only made when necessary to secure regulatory objectives, and only then in a way that minimises impact.	We performed a review of regulatory letter templates during the period, amending them to provide clearer articulation of regulatory requirements, decisions, and the reasons behind the decision. We also participate in the Medical Devices Single Audit Program, which allows agencies from Australia, Brazil, USA, Canada and Japan to collaborate and provide oversight without additional onus on industry	Self-assessed rating: Met
KPI 4.2 Regulators' frequency of information collection is minimised and coordinated with similar processes including those of other regulators so that, as far as possible, information is only requested once.	Whenever possible, we complement information from sponsors with information already gathered by other regulators, such as our international counterparts. One joint GMP inspection was conducted during this period, and there were four occasions where the TGA observed an international regulator on inspection to facilitate information sharing. We undertake desktop GMP clearances for overseas manufacturers, with consideration of decisions made by comparable regulators, and share manufacturing inspection schedules with our international counterparts. The TGA is part of an international work-sharing initiative involving Australia, Canada, Singapore and Switzerland (the ACSS Consortium). We work collaboratively through a joint-review of new active substances (chemical or biological entities). This partnership incentivises early registration of new medicines within Australia and benefits the community by improving timely access to the most recent and innovative treatment options. The ACSS partnership maximises the use of up to date international technical expertise, and ensures a consistent, contemporary approach to assessing the benefits and risks associated with the use of new medicines. This brings greater alignment of regulatory approaches, technical requirements and better use of resources, which reduces duplication and improves efficiency.	Self-assessed rating: Met
KPI 4.3 Regulators utilise existing information to limit the reliance on requests from regulated entities and share the information among other regulators, where possible.	Wherever possible we share information with our international counterparts, and with state and territory health departments. We are also members of several forums and working groups dedicated to identifying opportunities for collaboration and increasing international synergy. Reporting of medicine shortages was made mandatory as of 1 January 2019 to better support health professionals and assist patient care, based on the recommendations of a working group formed of sponsors, stakeholders and medical professionals. The TGA continues to be a member of the International Medical Device Regulators Forum National Competent Authorities Report, a program that allows us to provide and receive knowledge with other regulators. For example, we have undertaken regular meetings with international regulators, states and territories, and expert working groups on breast implants and ventilators. We continue to work with the Food Standards Australia New Zealand (FSANZ), Customs, the Australian Government Department of Agriculture, the Australian Federal Police and relevant state and territory agencies as appropriate when it is necessary to decide whether products are regulated as food or as therapeutic goods (food-medicine interface).	Self-assessed rating: Met

KPI 4 - Compliance and monitoring approaches are streamlined and co-ordinated

Measures/metrics	Evidence (performance in 2018–19)	
KPI 4.4 Regulators base monitoring and inspection approaches on risk and, where possible, take into account the circumstance and operational needs of the regulated entity.	Our processes have been developed to ensure as little impact as possible on regulated entities during the monitoring and inspection process. The inspection timeline in based on a risk approach unless it has been identified that there may be issues with a specific facility that requires attention at a time earlier than the normal inspection calendar. Furthermore, in some cases we forgo an inspection due to our desktop assessment program. During the period we conducted total of 264 inspections (189 domestic and 75 international) of regulated entities. 85% of international inspections received a satisfactory compliance on inspection, and 80% of domestic inspections. Further details on the GMP Inspection Program are available in the 2018-19 Annual Performance Statistics Report. We also conducted 69 on-site audits (35 domestic and 34 international) of medical device manufacturers. 100% of international audits received a satisfactory compliance rating, while the rate was 93% for domestic audits. We finalised 3,271 compliance cases in the reporting period, including issuing 2,489 warning letters, 9 infringement notices and 1 criminal prosecution.	**Self-assessed rating: Met**

External validators agreed that we provided a coordinated approach to compliance and monitoring, and unanimously endorsed our self-assessed rating of 'met'. They also noted that our partnerships with overseas regulators, and our involvement with the Australia, Canada, Singapore and Switzerland consortium, reduced duplication and improved our efficiency as a regulator. Feedback included some suggested areas of focus for future streamlining opportunities.

Identified opportunities for improvement

Collaboration and international alignment are ongoing activities centred around continuous development, with additional countries being assessed for inclusion in our list of comparable overseas regulators. We will continue to consult with stakeholders to identify areas for improvement.

KPI 5 - Regulators are open and transparent in their dealings with regulated entities

Measures/metrics	Evidence (performance in 2018-19)	
KPI 5.1 Regulators' risk-based frameworks are publicly available in a format which is clear, understandable and accessible.	We publish specific information detailing how we apply a risk-based framework to compliance activity. We continually review and update the content available on our website to ensure readability and understanding. We have targeted information available on our website for SMEs, start-ups, researchers and those unfamiliar with therapeutic goods regulation. The SME Assist web resources are designed to assist these industry stakeholders in navigating regulatory requirements and meeting their compliance obligations. New resources added over the reporting period include educational decision tools such as 'What do I require to have a listed medicine in the ARTG'. We have also made adopted international ICH/EU guidance more transparent by providing a searchable database, as well as improving the accessibility by reformatting prescription medicines registration guidelines.	Self-assessed rating: Met
KPI 5.2 Regulators are open and responsive to requests from regulated entities regarding the operation of the regulatory framework, and approaches implemented by regulators.	We utilise a number of different media for communicating with regulated entities including email, website information, Facebook and offering a first contact point Regulatory Assistance Section (RAS) that manages our central enquiry lines. We are looking to enhance the enquiry management system used by RAS to improve the stakeholder experience. During the reporting period, RAS managed 24,220 telephone and email enquiries; 27% from industry and regulated entities, 22% from health professionals, 41% from the public and the remainder from other stakeholders. 94% of all enquiries received by RAS during the reporting period met the timeframes outlined in the TGA Customer Service Standards, i.e. to acknowledge emails within 5 working days and respond to voicemail messages within two working days. The failure to meet response timeframes in all cases was due to staffing shortages in the last quarter of 2018, and is why we have rated ourselves as only 'substantially met' against this KPI. 81% of enquiries received over the period October to December 2018 met timeframes. This issue was resolved and over 98% of enquiries received between January to June 2019 met timeframes. SME Assist responded to 150 emails enquiries, in addition to those relating to specific events—a 65% increase from the previous reporting period. There were 79,000 visitors to the SME Assist web pages (up 11% from 2017–18). These pages provide tailored information to those new to therapeutic goods regulation. Formal and informal stakeholder interactions are detailed in KPI 1.1.	Self-assessed rating: Substantially met

KPI 5 - Regulators are open and transparent in their dealings with regulated entities

Measures/metrics	Evidence (performance in 2018-19)	
KPI 5.3 Regulators' performance measurement results are published in a timely manner to ensure accountability to the public.	We publish a number of reports annually detailing our performance and activities. These reports meet the Australian Government reporting requirements and provide transparency of our activities. The following reports are available on the Health and TGA websites: • July to December Half Yearly Performance Snapshot (March) • Database of TGA Laboratory Testing Results (May and November) • Annual Health Portfolio Budget Statements (May) • July to June Annual Performance Statistics Report (October) • Department of Health Annual Report (October) • Annual Stakeholder Survey (December) • Annual Regulator Performance Framework Self-Assessment Report (December)	**Self-assessed rating: Met**

External validators agreed that we have consistently been open and transparent through all forms of communication, and agreed with our self-assessed rating of 'substantially met'. Stakeholder feedback encouraged us to be more proactive in communicating changes in milestone dates, which would assist industry more broadly.

Identified opportunities for improvement

We will continue to publish performance and activity reports, as well as regularly revise and update guidance material, to enable transparency to our stakeholders. We will also review our reporting activities to examine if we can provide more specific detail relevant to industry, such as milestone data.

We will also to continue to uphold our Customer Service Standards, including the timely management of telephone and email enquiries, and ensuring that our responses are clear and easy to understand. We will continue to review our Customer Service Standards and consult with industry to resolve these issues for future interactions.

KPI 6 - Regulators actively contribute to the continuous improvement of regulatory frameworks

Measures/metrics	Evidence (performance in 2018-19)	
KPI 6.1 Regulators establish cooperative and collaborative relationships with stakeholders to promote trust and improve the efficiency and effectiveness of the regulatory framework.	Each July we undertake an annual stakeholder survey to measure our performance. In total, we received 4,069 responses to the 2019 stakeholder survey, which was up from 2,535 in2017–18. Health professionals and those working in the medical industry made up just under half of the responses (1,974). 83.7% of respondents agreed the TGA performs its role with integrity, showing that there is significant trust in our organisation from industry, health professionals and the general public. Full details of the survey will be published on our website. SME Assist has systematically used a variety of methods to engage with target audiences. These have included providing online guidance and interactive decision tools, face-face training events as well as social media channels, the SME Assist subscription list, and exhibition booths at industry conferences. The stakeholder survey indicated that one third of SME survey participants had heard of SME Assist, with 38% of that group having accessed the service. Eighty per cent of these users agreed or strongly agreed that the service was targeted to its audience, and 78% felt that the information was useful. We held a one-day workshop with prescription medicine sponsors in March to better understand their use of the variations guidance documents so as to present a more effective and informative guide. The unanimous response of participants was that the experience was very valuable and they would participate in such a workshop again if available. We held workshops with medical device sponsors and health professionals to discuss the proposed reforms for the reclassification of spinal implant devices, systems and procedures packs, and low risk devices. Participants provided positive feedback regarding the level of engagement offered by the TGA and with respect to the clear pathways established for future work in this space. To support the reviews arising from the consultation ***Prescription strong (Schedule 8) opioid use and misuse in Australia - options for a regulatory response,*** TGA established the Opioids Regulatory Advisory Group (ORAG), comprising prescriber, palliative care, addiction medicine, pain medicine and consumer stakeholders. ORAG met in October 2018 and May 2019 and provided expert advice regarding the proposed amended indication for fentanyl patch products, the wording for inclusion within the boxed warning and class statement for opioids and the list of products in scope for additional smaller pack sizes. ORAG also provided advice on the Consumer Medicines Information (CMI) review. ORAG endorsed the interim findings of the TGA reviews and the various professional bodies undertook to work with TGA on guidelines and communication with their members. The TGA coordinates the Medicinal Cannabis Access Working Group meetings, consisting of representatives from the TGA, the Office of Drug Control and each of the state and territory health departments, to promote collaboration between the Commonwealth Department of Health and state and territory health departments on issues relating to patient access to medicinal cannabis.	**Self-assessed rating: Met**

KPI 6 - Regulators actively contribute to the continuous improvement of regulatory frameworks

Measures/metrics	Evidence (performance in 2018-19)	
KPI 6.1 (continued)	The Therapeutic Goods Advertising Consultative Committee meets quarterly and is the key consultative committee for the regulation of advertising. It consists of members representing consumers, health professionals, industry, media and government bodies. The Committee provides a forum for engagement on issues and policy relating to therapeutic goods advertising and assists with reviewing and shaping TGA reporting activities with respect to advertising compliance. It also provides input on the development of education and compliance priorities.	
KPI 6.2 Regulators engage stakeholders in the development of options to reduce compliance costs. This could include industry self-regulation, changes to the overarching regulatory framework, or other strategies to streamline monitoring and compliance approaches.	By seeking out practical solutions, the TGA has identified and implemented a number of reforms to improve how we do our business, which has resulted in the removal of any unnecessary regulatory burden that had previously been imposed on affected stakeholders. In addition to the 21 reform proposals that were considered by the Office of Best Practice Regulation (see KPI 1.2), approximately 13 reform proposals were considered minor in nature and a decision was made by the TGA to progress these streamlining processes. An example of is the re-classification of some Faecal Microbiota Transplant (FMT) products as Class 1 biologicals, when collected, manufactured and used in hospitals. Each year we conduct meetings with industry bodies as part of our ongoing business improvements, with the aim of reducing compliance costs. The TGA has continued to implement further reforms to streamline and simplify the regulation of low risk products to reduce the regulatory burden for those products that represent a very low safety risk to consumers. A consultation paper on the proposed fees and charges for 2019–20 was released publicly to provide opportunity for wider industry and other stakeholders' comments. Based on stakeholder feedback, the TGA has enhanced the consultation process for the 2019–20 fees and charges. We also brought forward the bilateral meetings to December 2018 to provide more opportunity for discussion of changes to sponsors. Industry bilateral meetings were offered to four additional peak bodies.	Self-assessed rating: Met
KPI 6.3 Regulators regularly share feedback from stakeholders and performance information (including from inspections) with policy departments to improve the operation of the regulatory framework and administrative processes.	We work collaboratively with policy areas across the Department of Health to inform and improve operations in areas related to our regulatory framework. We work closely with other Government Departments, regulators and statutory authorities to ensure effective and consistent regulatory functions. For medical devices, we have worked collaboratively with states and territories within the context of our expert work group for acute care ventilators, breast implants and with the Australian Commission on Safety and Quality in Health Care on the safe introduction of neuraxial devices compliant with latest standards into Australia. We have also worked collaboratively with the ACCC on a number of issues, including button batteries in devices.	Self-assessed rating: Met

Most external validators agreed that we actively contribute to the continued improvement of regulatory frameworks. Feedback noted that the TGA has undertaken significant regulatory reforms, and advocated for continuing international collaboration to keep abreast of regulation challenges associated with advances in medical technology. Stakeholder comments called for well considered singular major reforms when possible rather than a staggered implementation approach, as they contend that this would minimise impact on industry and reduce compliance costs and 'change fatigue'.

Identified opportunities for improvement

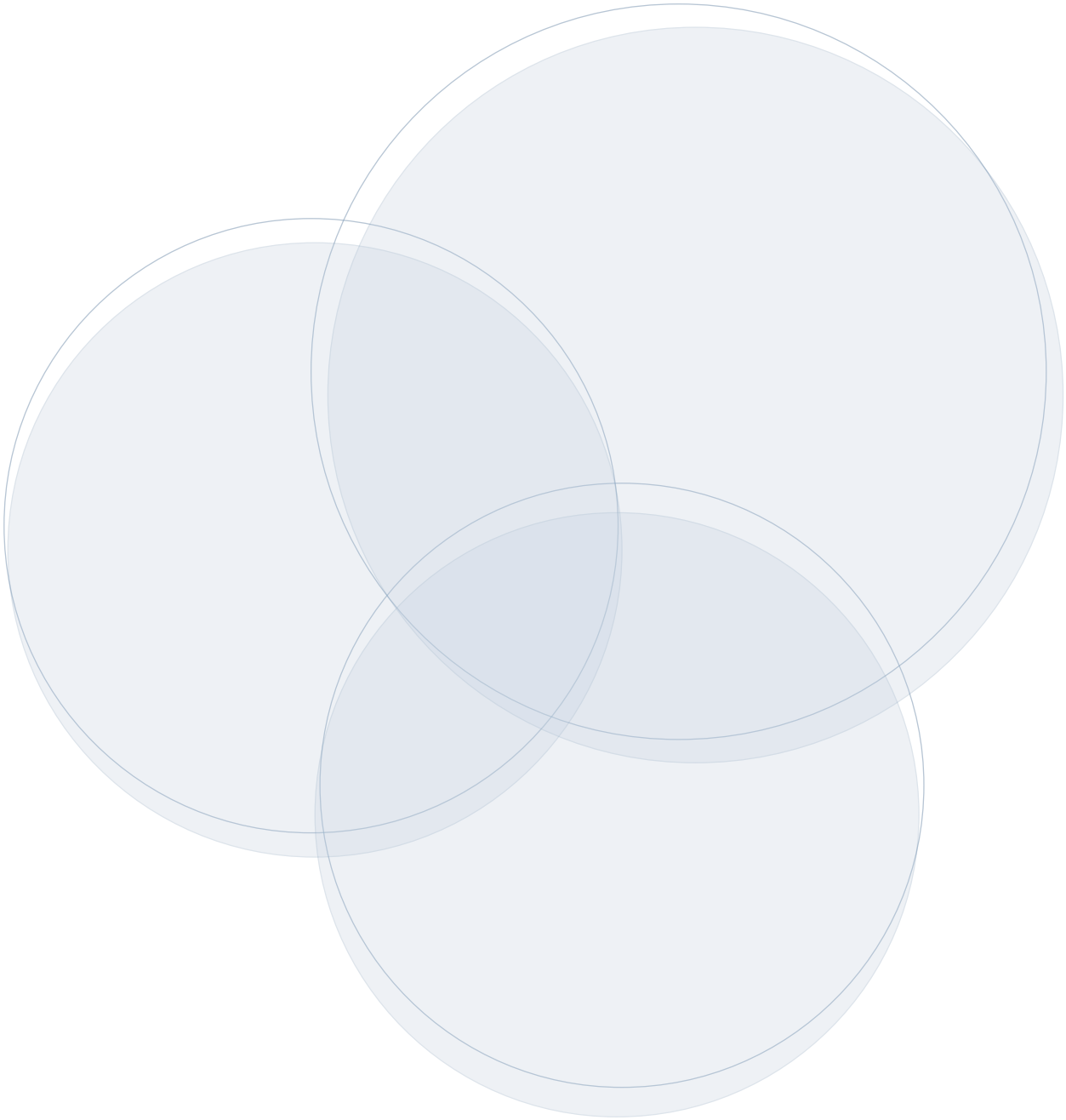
We will continue to provide ongoing support and education to stakeholders, and to work collaboratively with industry to minimise the burden of change, for example with the change to regulations for autologous cell and tissue products.

We will continue to seek and implement feedback from stakeholders, including conducting regular stakeholder surveys.

Glossary

Acronym	Description
AAT	Administrative Appeals Tribunal
ACSS	Australia-Canada-Singapore-Switzerland Consortium
AEFI	Adverse Events Following Immunisation
AEMS	Adverse Event Management System
ANVISA	National Health Surveillance Agency Brazil
ARCBS	Australian Red Cross Blood Service
ARGATG	Australian Regulatory Guidelines for Advertising Therapeutic Goods
ARTG	Australian Register of Therapeutic Goods
AusPARs	Australian Public Assessment Reports
CMI	Consumer Medicine Information
CORs	Comparable Overseas Regulators
eCTD	electronic Common Technical Documents
EDI	Electronic Data Interchange
EMA	European Medicines Agency
EOI	Extension of Indications
GMP	Good Manufacturing Practice
HTML	Hypertext Markup Language
IMDRF	International Medical Device Regulators Forum
IVDs	In Vitro Diagnostic Devices
KPIs	Key Performance Indicators
NCE	New Chemical Entity
NeeS	Non eCTD electronic Submissions
NCCIWG	Nationally Coordinated Codeine Implementation Working Group
MDSAP	Medical Devices Single Audit Program
MMDR	Review of Medicines and Medical Device Regulation
OBPR	Office of Best Practice Regulation
ODC	Office of Drug Control

PDF	Portable Document Format
PI	Product Information
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
PLAC	Prostheses List Advisory Committee
PVIP	Pharmacovigilance Inspection Program
RAWG	Regulatory Affairs Working Group
RCRC	Regulatory Compliance and Risk Committee
RegTech	Regulatory and Technical Consultative Forum
RIS	Regulation Impact Statement
SARA	System for Australian Recall Actions
SAS	Special Access Scheme
SLA	Service Level Agreement
SMEs	Small to Medium Enterprises
TGA	Therapeutic Goods Administration
TGACC	Therapeutic Goods Advertising Consultative Committee
TGO	Therapeutic Goods Order
TIF	TGA Industry Forum
TIWGG	TGA-Industry Working Group on GMP
USFDA	United States Food and Drug Administration



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