Australian Government

Department of Health

Therapeutic Goods Administration

Regulator Performance Framework

Self-assessment Report

July 2017 to June 2018

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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 supermarkets, the general pharmacy or from behind the pharmacy counter
- vaccines
- complementary medicines, including vitamins, herbal and traditional medicines
- medical devices, from simple devices like bandages to complex technologies like heart pacemakers
- tampons and disinfectants
- products used to test for various diseases or conditions (in vitro diagnostic devices (IVDs)), such as blood tests
- blood, blood components and biologicals (cells and tissues).

We also play a regulatory role in overseeing manufacturing processes in Australia and overseas, and advertising of therapeutic goods.

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

Overview for 2017-18

In 2017-18 we continued to progress the implementation of the Australian Government's response to the Review of Medicines and Medical Devices Regulation (MMDR) as announced in the 2016-17 Budget, and have enacted multiple changes to our legislation to enable this transition.

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. Some highlights from this reporting period include reforming our orphan drug program, creating a new Special Access Scheme (SAS) pathway, implementing new provisional approval and priority review pathways for prescription medicines, and improving our international synergy and cooperation activities with overseas regulators.

Regulator Performance Framework

The Australian Government has developed a framework to measure the performance of regulators. The Regulator Performance Framework (the Framework) comprises six outcomes-based key performance indicators (KPIs) as listed below to articulate the Government's overarching expectations of regulator performance:

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 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.

These KPIs are supported by measures of good regulatory performance to assist regulators in assessing their achievement against the KPIs.

The Framework aims to encourage regulators to undertake their functions with the minimum impact necessary to achieve regulatory objectives and to effect positive ongoing and lasting change within regulators. The Framework will allow regulators to report objectively on the outcomes of their efforts to administer regulation fairly, effectively and efficiently.

The Framework has applied since 1 July 2015, with the first assessment period being the 2015-16 financial year. Our reports are published annually on the TGA website.

Self-assessment against the Framework

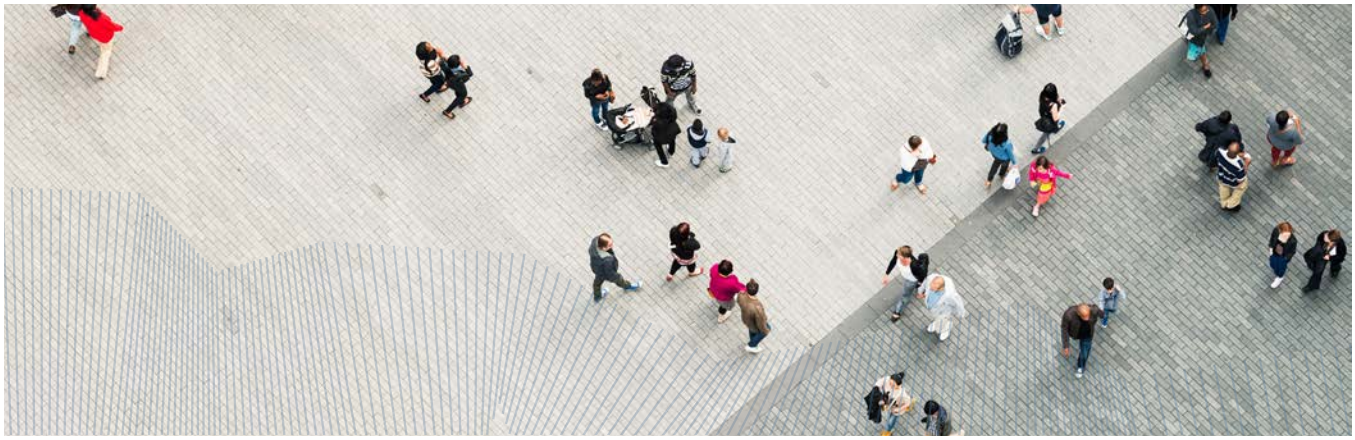
Each year, regulators are required to undertake a process of self-assessment against the KPIs provided in the Framework. The Framework includes a series of measures explaining how regulators may assess themselves against the KPIs. Underneath the measures, we have developed further metrics that detail how we interpret the KPIs and measures. We are required to align some of these against our legislated requirements under the *Therapeutic Goods Act 1989* and Therapeutic Goods Regulations 1990.

At the conclusion of the reporting period we gather evidence in support of the metrics and measures that represent our performance against the KPIs. This evidence was gathered from multiple data sources including published advice on our website, market research, public consultations, and international and domestic stakeholder forums. Using this evidence, we assess ourselves against the KPIs, giving a rating of met, substantially met or not met.

We provide our draft self-assessment report to our external validator, the TGA Industry Forum (TIF), comprised of industry peak bodies, to provide their assessment of our performance during the reporting period. All feedback is considered in detail.

The report is then finalised and published on the TGA website, identifying our self-assessment rating, the feedback provided by our external validator, and opportunities for improvement in our next reporting period.

In this way, we continually improve as a regulator and enhance our responsiveness to our regulated entities. This process benefits both the therapeutic goods industry and the Australian public.



Self-assessment rating at a glance in 2017-18

Using the following performance ratings, we have self-assessed against the KPIs provided in the Regulator Performance Framework.

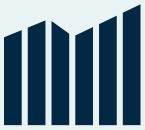
Performance rating key

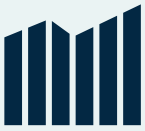
KPI met
Strong performance against *all* of the measures under the KPI.

KPI substantially met
Strong performance against *most* of the measures under the KPI.

KPI not met
Poor performance against *all* of the measures under the KPI.

External validation
Comments received from our external validators (TGA Industry Forum).

Self-assessment rating and summary of overall performance		
KPI	Comments	Our ongoing focus for 2018-19
KPI 1 ***Met*** Regulators do not unnecessarily impede the efficient operation of regulated entities 	We held regular formal stakeholder forums and participated in industry events as well as senior executive meetings with peak bodies such as: • the Australian Self Medication Industry • Medical Technology Association of Australia • CMA and stakeholder meetings with technical working groups. We hosted a workshop for small to medium businesses 'Meeting Your Obligations' at the Good Manufacturing Practice (GMP) Forum, and implemented a number of initiatives through the Business Improvement Program.	We will continue to work with industry to improve the efficiency and transparency of processes through formal stakeholder engagement and other appropriate forums.

Self-assessment rating and summary of overall performance		
KPI	Comments	Our ongoing focus for 2018-19
KPI 2 ***Met*** Communication with regulated entities is clear, targeted and effective 	We communicated through webinars and other forums, delivery of changes to the therapeutic goods advertising framework through extensive targeted and public consultations, and changes to the regulation of autologous human cell and tissue products.	We will continue to work towards processing applications within specified timeframes while providing effective communication through • update of guidance documents to improve clarity of the regulatory requirements • educational activities to improve awareness and understanding of the therapeutic goods advertising requirements • ongoing support to providers during the transition period for changes to the regulation of autologous human cell and tissue products.
KPI 3 ***Met*** Actions undertaken by regulators are proportionate to the regulatory risk being managed 	We took a risk-based approach which was proportionate to the therapeutic products we regulate. We continued to monitor signals of non-compliance and considered compliance history when undertaking intervention. We continued to triage and prioritise advertising complaints based on the risk that the advertising could pose to public health and safety.	We will continue to be transparent in our regulatory compliance activities by publishing outcomes on our website. The new advertising complaints handling model will streamline processing and more closely align actions with regulatory risk.
KPI 4 ***Met*** Compliance and monitoring approaches are streamlined and coordinated 	We have built a Case Categorisation and Prioritisation Model to ensure consistent triaging and risk based responses to alleged breaches of the Therapeutic Goods Act 1989. A new notifications process for very low risk variations to biologicals and to the registered medicines was introduced, allowing the use of a single electronic form to request certain types of changes to a medicine.	We will continue to consult with our stakeholders on improvements relating to reporting medical device adverse events. We will continue to collaborate with our international colleagues and explore opportunities to utilise existing information. We will align our processes with international best practice whenever possible.

Self-assessment rating and summary of overall performance		
KPI	Comments	Our ongoing focus for 2018-19
KPI 5 ***Substantially met*** Regulators are open and transparent in their dealings with regulated entities 	We continued to raise awareness of our regulatory framework through our various interactions with industry and other stakeholders through workshops, publication of educational material, engaging with the TGA Industry Forum, and maintaining our telephone and email enquiry lines. In addition, we published monthly and annual performance reports on our website. We have rated ourselves as 'substantially met' against this KPI because we did not meet the TGA Customer Service Standards in all cases when responding to email and telephone enquiries. This was partly due to the transition to a new enquiry management system, which resulted in some enquiry data being lost during the July-September 2017 period.	To provide transparency to our stakeholders, we will continue to publish performance and activity reporting on our website, as well as revise and update regulatory guidance material. We will continue to develop our enquiry management system to ensure timely management of telephone and email enquiries.
KPI 6 ***Met*** Regulators actively contribute to the continuous improvement of regulatory frameworks 	We maintained high levels of stakeholder engagement through market research, continued business improvements as well as interactions with other Government Departments and comparable regulators. We have implemented a number of reforms, including streamlining the advertising framework. A new electronic notifications process for very low risk variations to prescription medicines was introduced in late 2017. This followed the earlier introduction of a similar process for non-prescription registered medicines. TGA approval for these variations is made automatically, if the application passes electronic validation and payment is received, reducing compliance costs and approval times. We implemented an improved streamlined and coordinated approach to the implementation of the new provisional approval pathway for the registration of prescription medicines, providing earlier access to certain new medicines.	We will continue to provide ongoing support and education to providers during the transition period for changes to regulations, for example, autologous human cell and tissue products. We will continue to improve our engagement with consumers and other stakeholders to ensure confidence in the efficacy, performance and quality of therapeutic goods in Australia. This will include actively responding to feedback provided in our annual stakeholder survey. We will continue to review and update the Case Categorisation and Prioritisation Model to align with best practice compliance and monitoring approaches.

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

The performance rating of **Met** is supported by the work we implemented in a number of initiatives through the Business Improvement Program aimed at understanding industry needs and reducing compliance costs, including electronic lodgement of data packages in support of applications for entry of products on the ARTG.

External validators recognised we have undertaken significant work in our endeavour to strike a balance between ensuring patient safety through regulation of therapeutic goods, while not impeding patient access to new therapeutic products. Validators appreciate the increased levels of engagement, in particular, workshops and the establishment of targeted assistance for small to medium enterprises. It was suggested for future assessments that we include a more systematic evaluation/feedback process following workshops to gauge the effectiveness of interactions.

		Evidence
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.*	Increased our online engagement through webinars and improved digital submission processes. Online and in person consultations. Workshops. Bilateral meetings.
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.*	Significant engagement associated with implementing the Government Response to the Expert Panel Review of Medicines and Medical Devices Regulation (MMDR) outcomes, including hosting a stakeholder day and public consultation. Four meetings were held with the Therapeutic Goods Advertising Code Council and the complaints resolution panel which were subsequently abolished on 30 June 2018, when TGA became the single advertising complaints handling body as one of the MMDR reforms.
KPI 1.3	*Regulators implement continuous improvement strategies to reduce the costs of compliance for those they regulate.*	Improved performance against the Australian Government Digital Transition Policy. Launch of initiatives that provide regulation clarity to stakeholders. Targeted assistance for new small-to-medium enterprises including hosting six SME Assist workshops in capital cities.

Continuous improvement 2018-19

We will continue to work with industry to improve the efficiency and transparency of processes through formal stakeholder engagement and other appropriate forums. We will also review our workshops for effectiveness, and implement a feedback process to support this.

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.

1.1a

Number of TGA participations in industry formal stakeholder forums, including meetings and working groups and feedback received on TGA presentations.

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 function. In 2017-18 we participated in formal stakeholder forums that included industry events, regulatory workshops for stakeholders and bilateral meetings with industry groups.

We conducted six SME Assist 'Meeting Your Obligations' workshops in capital cities for small to medium enterprises (SMEs), attended by 226 people. These workshops were designed to help stakeholders new to therapeutic goods regulation to understand regulatory requirements and followed the launch of our SME Assist service in June 2017. Feedback from workshops was overwhelmingly positive with 90% of attendees indicating they would recommend the workshop to a colleague. SME Assist also held two 'drop-in' days where small and medium businesses had the opportunity to meet one-on-one with TGA specialists to discuss their regulatory obligations specific to their type of therapeutic good, including medicines and medical devices.

In the lead up to the second tranche of legislative changes to implement aspects of the Government's response to the MMDR Review, we conducted a stakeholder day and a brief public consultation. We also conducted five sector specific targeted stakeholder workshops to progress key elements of the reforms to advertising, including proposed changes to the Therapeutic Goods Advertising Code.

In June 2018, we hosted the inaugural 2018 GMP Forum which was attended by 450 delegates and received very positive feedback. As a result of significant stakeholder interest in the event, registrations were closed early due to the venue capacity being reached.

We met formally with the TGA-Industry Working Group on GMP (TIWGG) four times during the reporting period. TIWGG members provided feedback on a range of suggested GMP service delivery matters for the TGA's consideration and were also consulted on the adoption of the new version of the PIC/S Guide.

We participated in several stakeholder meetings with technical working groups, including sunscreens and complementary medicines, to develop and revise technical guidance as a result of the adoption of version 13 of the PIC/S guide to GMP for medicinal products. Presentations were provided to the Parental Drug Association and the Cosmetics and Pharmaceuticals Special Interest Group on the adoption of version 13 of the PIC/S guide to GMP for medicinal products including the transitional arrangements and expectations.

Prior to the commencement of pharmacovigilance inspections, we held a number of Pharmacovigilance Inspection Program information sessions in Sydney, Melbourne and Brisbane in September-October 2017. The sessions provided a detailed overview of the program and gave participants the opportunity to ask questions. The feedback provided by participants was generally positive, commenting that they appreciated the opportunity to learn more about the program and ask questions.

In October 2017 we co-hosted the Medical Devices Sponsor Information Day with cooperation with industry peak bodies, to provide attendees with a better understanding of the regulatory framework for medical devices. The day was targeted at those new to the medical devices industry, and was attended by approximately 180 people. The material presented was co-designed by TGA and industry presenters to provide attendees with a good understanding of the regulatory landscape from both perspectives. Feedback from attendees was very positive, with many appreciating the opportunity to speak directly with TGA regulatory staff.

We hosted a workshop in August 2017 to discuss regulatory considerations for additive manufacturing (3D printing) of medical devices, which was attended by representatives from the medical devices industry, custom-made medical device makers, commercial 3D printing organisations, academics/researchers, medical specialists, consumer advocates, and Government organisations such as the CSIRO. This workshop was designed to inform a public TGA consultation held between November and December that year. The workshop provided all attendees an opportunity to inform this ongoing discussion which will contribute the final regulatory approach for medical devices made in this way.

We met formally with the Nationally Coordinated Codeine Implementation Working Group six times during the reporting period. The purpose of this working group was to assist with the implementation of a communication and engagement strategy for the changes to the availability of low-dose codeine containing medicines. A series of workshops on the up-scheduling of codeine was held in November 2017.

The Scheduling Working Group met twice to discuss the new Scheduling Policy Framework. This group comprised representatives from the states and territories, the medicines and chemical scheduling advisory committees, industry groups and professionals from the medicine, pharmacy and chemicals sectors as well as consumer representatives. The group agreed proposed statements on advertising of pharmacist-only medicines and identified potential medicines that were potentially suitable. In addition, they commenced work on a framework and guidelines for proactively identifying medicinal substances for consideration for rescheduling from S4 (prescription only) to S3 (pharmacist only) or S2 (pharmacy only).

In April 2018 we presented to the Medicines Australia Regulatory Affairs Working Group on reforms and improvement activities. This included changes to the regulation of autologous human cells and tissues, implementation of comparable overseas regulator processes as well as considerations in the regulation of faecal microbiota transplantation material.

We held quarterly meetings with medical device industry peak bodies via the Regulatory and Technical consultative Forum (RegTech) to prioritise and discuss issues of concern, including opportunities to improve current regulatory practices and compliance. This forum benefits industry in a number of ways, including having the opportunity to provide feedback on draft regulatory guidance, in addition to the opportunity to provide industry advice on proposed regulatory reforms. RegTech acted as an important forum for the discussion of major medical device regulatory reforms to medical devices and in vitro diagnostics, including alignment with European regulatory systems, comparable overseas regulators, companion diagnostics and changes to the regulation of implantable devices. They also discussed reforms to TGA fees and charges for medical devices and proposed a range of business process changes and reporting requirements, several of which have now been adopted.

We held two formal meetings with the Australian Red Cross Blood Service (ARCBS) to discuss strategic issues related to the ongoing safety and quality of blood and blood product regulation, nationally and internationally. We also met quarterly via video conference to discuss ongoing and upcoming regulatory matters. The meetings provided opportunities for participants to discuss ongoing evaluations and flag upcoming submissions to assist management of submission workflow and to provide the ARCBS with clarity on the blood regulatory environment. Specific issues discussed include monitoring results on the safety of the blood supply and the regulatory response to possible emerging transfusion-transmitted infections, regulatory implications of blood donor exclusion criteria, regulation to maintain the safety of donated plasma and processing into plasma products, reforms to standards for products, and regulatory and infectious disease safety implications of potential use of platelets after prolonged storage.

1.1b

Information on informal interactions with industry and how they are able to build understanding, for example ad hoc meetings between senior TGA staff and industry on specific issues and educational seminars for TGA staff on industry business activities.

We strive to maintain an open and transparent relationship with industry through frequent and informal engagement. These interactions provide our staff with opportunities to enhance their knowledge of emerging issues, technologies, products and priorities. By maintaining an open dialogue with regulated entities we are better able to tailor our formal consultations and public information to address areas of concern. Further information is available at KPI 2.2a.

In 2017-18, we held many informal interactions with industry including the rollout of the codeine strategy and reviewing blood regulations and standards. We view consultation as key to staying aware of issues, innovation and challenges relevant to industry.

Some further examples include:

- proposed list of comparable overseas regulators (CORs) and details of the COR report-based process for prescription medicines. Stakeholders who previously expressed an interest in these reforms as well as international regulators that could be impacted by the process were targeted for this consultation.
- how to optimise ARTG entries and pay fees on the minimum number of entries, while complying with therapeutic goods regulatory requirements. This work was intended to assist the medical device industry transition to a new application fee for Class I medical devices introduced from 1 July 2018.

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.

1.2a

Evidence of continued compliance with our practice of engagement with industry before a regulation impact statement (RIS) is finalised, to minimise the potential for unintended impacts on regulated entities and product supply.

For any proposed changes to the regulatory framework we ensure that we work with affected stakeholders and the Office of Best Practice Regulation (OBPR). In situations where the OBPR has determined that a RIS is not required we still engage with those likely to be affected. This is to ensure that we minimise the potential for unintended impacts associated with any changes to the way we do our business. It also provides us with an opportunity to explore other options that may provide a better outcome.

We performed a gap analysis in relation to the changes with PIC/S Guide to GMP version 13 that included consultations with industry. Industry agreement was received and we also confirmed with OBPR that a RIS was not required.

In 2017-18 there were no RISs finalised as none were required by OBPR.

KPI 1.3 Regulators implement continuous improvement strategies to reduce the costs of compliance for those they regulate.

1.3a

Progress towards implementation of the Australian Government Digital Transition Policy.

The Government's Digital Transition Policy plays a key role in supporting digital transformation initiatives and driving e-government. Digital record keeping means that the majority of an agency's records will be created, stored and managed digitally and, where possible, incoming paper records will be scanned so that new paper files are not created. To facilitate this, a Special Access Scheme (SAS) online system has been developed to allow for better electronic submission management from industry in future. The online system aims to reduce administrative burden experienced by health practitioners associated with the existing paper based process; reduce TGA processing times; and allow users to effectively and efficiently manage SAS applications and notifications.

In June 2018, the TGA implemented a new Electronic Data Interchange (EDI) Service for the submission of medicine and vaccine adverse event reports. The EDI makes it possible for sponsors to submit these reports directly to the TGA's adverse event database from their IT systems. Use of this service eliminates significant manual processing for industry and data entry for the TGA.

1.3b

Progress of the strategies being implemented under the business improvement program and other specific projects aimed at reducing compliance costs for industry.

We continue to improve our information and communications technologies to better meet the needs of consumer, health professionals and industry.

We implemented a number of initiatives through the Business Services site, aimed at reducing compliance costs for industry. These included:

- GMP Clearance Solution project
- TGA Business Services, a base for electronic commerce, electronic lodgement of data packages in support of applications for entry of products on the ARTG and online client access to legally appropriate information
- an eForm to support applications for minor variations to prescription medicines that is a significant enhancement of a form that has been in use since July 2017
- implementation of a new notifications process for very low risk variations to biologicals and to registered medicines (prescription and non-prescription).

Additionally, we have delivered online business improvements as part of the implementation of the recommendations from the Government's response to the MMDR.

Key reforms introduced during 2017-18 include:

Prescription medicines regulatory reforms:

- a new provisional approval pathway has been established to provide earlier access to certain promising new medicines
- evaluation of prescription medicines through reports from a comparable international regulator, with accompanying faster review times
- a new notifications process for very low risk variations to biologicals and to registered medicines (prescription and non-prescription) was introduced

Medical devices regulatory reforms (derived from legislative changes):

- expedited approval pathway was introduced for 'novel' medical devices, to increase the speed to market emerging technologies for life threatening or seriously debilitating conditions
- Australian conformity assessment bodies, which the TGA has designated to have the necessary competence; and the facilities and processes to undertake conformity assessments of medical devices
- new pathways enabling specific overseas assessments and approvals to be used either in supporting an abridged assessment of an application for a TGA conformity assessment certificate, or supporting applications for inclusion of medical devices in the ARTG

Strengthening the post-market monitoring of medicines:

- Black Triangle Scheme to provide a simple means for practitioners and patients to identify certain types of new prescription medicines, and to encourage the reporting of adverse events associated with use
- Pharmacovigilance Inspection Program implemented to help sponsors of medicines to meet their pharmacovigilance obligations
- phased implementation of Product Information reformatting

Complementary medicines:

- changes to the regulatory framework to allow consumers to make more informed product choices
- indications available for use for listed medicines are now contained in a 'list of permitted indications'
- a third pathway for sponsors to allow access to higher level indications than those on the list of permitted indications

Advertising reforms:

- the revised framework includes a single, centralised complaints handling system to be managed by the TGA from 1 July 2018
- the Therapeutic Goods Advertising Code has also been revised with the new Code to take effect from 1 January 2019. The Code is the key advertising compliance standard that sets out minimum requirements and underpins the regulatory framework for the advertising of therapeutic goods to the public
- the range of investigation and enforcement powers relating to compliance and monitoring have been strengthened and broadened through amendments to the *Therapeutic Goods Act 1989* which standardise monitoring, investigation, infringement notices and injunctions
- an education program for the new advertising framework which includes webinars, training seminars and an e-learning program, with guidance and other education materials now available on the TGA website

Support functions:

The SME Assist service provided targeted support to small to medium enterprises, researchers, start-ups and any interested organisation to help them better understand regulatory requirements.

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

Our performance rating of **Met** is supported through our successful communication through webinar and other forums, delivery of changes to the therapeutic goods advertising framework through extensive targeted and public consultations, and changes to the regulation of autologous human cell and tissue products shaped by industry feedback.

External validators commended our active participation in regulatory reform initiatives and our consultation with industry on relevant and significant developments. Validators also appreciated our proactive communication through various forums, and our strengthened presence in social media.

		Evidence
KPI 2.1	*Regulators provide guidance and information that is up to date, clear, accessible and concise through media appropriate to the target audience.*	Improvements to our website content, and improved compliance with accessibility requirements. Improved guidance material published, with a particular focus on new and changed regulatory requirements.
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.*	Hosted 21 public consultations. Conducted 3 webinars. Considerable consultation including co-design activity where processes are being varied.
KPI 2.3	*Regulators' decisions and advice are provided in a timely manner, clearly articulating expectations and the underlying reasons for decisions.*	Continued processing of applications within target timeframes. Published the first edition of the *Australian Regulatory Guidelines for Advertising Therapeutic Goods*, as well as the *Half Yearly Performance Snapshot* containing performance statistics for July to December 2017.
KPI 2.4	*Regulators' advice is consistent and supports predictable outcomes.*	24 reviews of original decisions were completed, with two (8%) being substituted.

Continuous improvement 2018-19

We will continue to work towards processing applications within specified timeframes while providing effective communication through:

- update of guidance documents to improve clarity of the regulatory requirements
- educational activities to improve awareness and understanding of the therapeutic goods advertising requirements
- ongoing support and education to providers during the transition period on the recent changes to the regulation of autologous human cell and tissue products
- more direct communication with stakeholders, who would be potentially impacted by medicines and chemical scheduling changes

KPI 2.1 Regulators provide guidance and information that is up to date, clear, accessible and concise through media appropriate to the target audience.

2.1a

Percentage of pages on the TGA website that comply with the Australian Government accessibility requirements.

We continually develop, review and update regulatory and technical guidance material to comply with Australian Government requirements and international standards for web content accessibility.

We have continued to refine our standard database model so data can be easily discovered, navigated and disseminated. A number of new datasets are now regularly published, including TGA laboratory testing results, section 19A approvals to import and supply medicines to address medicine shortages, and prescription medicines determination and designation notices. We have also begun to introduce search/sort functionality in some sections of the TGA website, for example Australian public assessment reports and compliance following TGA intervention on advertising complaints.

90% of the information on our website is WCAG2.0 compliant and we are working on business improvements to allow us to reach 100% compliance.

We actively monitor and review material on the website to ensure it meets compliance requirements, and is user-focused.

2.1b

Improvements made to guidance documents, forms, and information on the TGA website.

In 2017-18 we undertook significant work in improving our guidance material with a focus on providing information about new and changed regulatory requirements, such as those resulting from the implementation of the Government's response to the MMDR reforms.

A range of guidance documents for sponsors was published on the TGA website, including:

- comparable overseas regulator report-based processes for medicines
- information on new pathways for the provisional approval of prescription medicines and for assessed listed complementary medicines
- updated and new guidance on pharmacovigilance, biovigilance and recalls
- the first edition of the *Australian Regulatory Guidelines for Advertising Therapeutic Goods*
- new guidance on upcoming changes to regulations of autologous human cell and tissue products
- updated specifications for electronic Common Technical Documents (eCTD) and Non eCTD electronic Submissions
- expectations for demonstrating compliance to PIC/S guide to GMP for medicinal products.

An additional eForm was implemented through TGA Business Services in March 2018 to allow prescription medicines sponsors to apply to extend orphan drug designations and/or provisional determinations, with supporting guidance material published on the TGA website.

2.1c

Number of educational materials and other documents developed or updated for stakeholders (industry, consumer, health professionals). Number of downloads of these from the website and social media, and data on user satisfaction where available.

We publish a range of educational material for consumers, health professionals and industry to assist with informing stakeholders about changes to therapeutic goods regulation and regulatory reform activity.

Sample of the number of views or downloads of new or updated publications for industry for the period July 2017 to June 2018

Name of material	New or updated	Publication medium	Number of views/ downloads
Medicinal cannabis products: Patient information	New	PDF and HTML on TGA and Office of Drug Control (ODC) websites	1,306 page views 170 PDF downloads
Guidance for the use of medicinal cannabis in Australia: Patient information	New	PDF and HTML on TGA and ODC websites	10,563 page views 1,180 PDF downloads
Guidance for the use of medicinal cannabis in Australia - overview	New	PDF and HTML on TGA and ODC websites	11,709 page views 1,397 PDF downloads
Guidance for the use of medicinal cannabis in the treatment of chronic non-cancer pain in Australia	New	PDF and HTML on TGA and ODC websites	10,273 page views 1,077 PDF downloads
Codeine Information Hub	New	TGA website	66,188 page views
Medicines and medical devices regulation review	Update	TGA website	6,636 page views
Which clinical trials scheme should I choose?	New	TGA website	6,798 uses of interactive decision tools 45,013 page views

Consumer and Health Professional content: downloads and views through various TGA media channels for July 2017 to June 2018			
Name of material	New or updated	Publication medium	Number of views/ downloads
Presentations: Codeine up-scheduling workshops, Wagga Wagga, Brisbane, Perth and Melbourne	New	Web page and slides	2974 page views 1178 PDF downloads 1751 Video views
Tips for talking about codeine: Guidance for health professionals with prescribing authority	New	Fact sheet in PDF and HTML	4,378 page views 552 PDF downloads
Tips for talking about codeine: Guidance for pharmacists	New	Fact sheet in PDF and HTML	1,703 page views 265 PDF downloads
Physiotherapist fact sheet: Talking to people about the changes to codeine access	New	Fact sheet in PDF and HTML	2,009 page views 294 PDF downloads
Black Triangle Scheme web page	Updated	HTML	100,281 page views

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.

2.2a

Details of formal consultations completed during the reporting period, including evidence that the TGA has closely considered submissions from stakeholders.

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. We also conduct consultation as part of our broader stakeholder engagement work, and to ensure our business practices remain fit for purpose.

We publish information about all formal consultations on our website. We review all submissions and provide feedback through our website, including the publication of submissions received. At the conclusion of a consultation, we publish a TGA Response and Outcome Summary. Where we are required to produce a RIS any feedback from consultations may form part of the RIS.

A stakeholder forum and public consultation on exposure drafts of bills to amend the *Therapeutic Goods Act 1989* were held in August-September 2017 as part of the legislative response to the MMDR.

The feedback received from stakeholders resulted in a number of changes to the bills prior to being introduced to the Australian Parliament. The bills passed both Houses on 15 February 2018 and received assent on 5 March 2018.

Three advertising-specific public consultations were also conducted in the reporting period. The first consultation in September 2017 sought stakeholder views on a range of proposed changes to improve the Therapeutic Goods Advertising Code and a possible framework for the advertising of pharmacist-only (Schedule 3) medicines to the public.

Following consideration of submissions received in response to these consultations, we commenced work to draft the revised Code by conducting six targeted stakeholder consultation forums in February-March 2018 to seek more detailed advice on the changes proposed.

A further public consultation was held in late March 2018 to seek stakeholder views on the proposed draft Code and an associated guidance document, with a further targeted stakeholder consultation on the requirements for advertising of pharmacist-only medicines.

The final public consultation conducted in the reporting period (in May 2018) sought comments from stakeholders on our proposed advertising complaints handling model (see KPI 2.2b).

Further public consultations included:

- the proposal to remake Therapeutic Goods Order No. 77 - Microbiological Standards for Medicines (TGO 77) without technical comment
- seeking comments on the proposed options to revise TGO 75, standard for haematopoietic progenitor cells derived from cord blood
- seeking comments on the alignment with European medical device regulatory framework, Up-classification of surgical mesh, and Patient Implant Cards
- proposed regulatory changes related to personalised and 3D printed medical devices

2.2b

Evidence of discussions with affected stakeholders before TGA processes are changed.

In addition to formal consultation processes, we continually engage with sponsors and industry groups that may be affected by changes to regulatory or business processes. We held a number of webinars to provide open communication channels for industry. Further details about our conference and event participation are available on our website.

We hosted three successful webinars (update on the therapeutic goods advertising reforms, changes to the regulation of autologous human cells and tissue products, and eCTD Module 1.3 best practices), engaging with almost 600 stakeholders (with an average of 82% participation from industry) allowing them to listen in and engage with us easily from any computer anywhere in the world.

To identify any potential impact of implementing changes to the labelling of Neuromuscular Blocking Agents, we actively engaged in informal discussions with affected medicine sponsors and health professional groups. This included releasing a costing survey for sponsors to estimate costs associated with each regulatory option, as well as informal discussions on the proposed changes to legislation.

As part of implementing the advertising recommendations resulting from the MMDR, we carefully considered the processes for the receipt and handling of complaints about the advertising of therapeutic goods and how the process could be streamlined. The proposed processes were the subject of a public consultation in May 2018. During the consultation period, we also presented information on the proposed process to stakeholders through a targeted stakeholder forum, a public webinar and an industry training seminar.

We held several informal meetings with stakeholders to assist with developing the communications strategy for consumers and health professionals on the priority and provisional pathways. These meetings informed the timing of commencing the communications strategy, the staging of communications activities and the draft key messages which were the subject of broader consultation in May-June 2018.

Numerous discussions occurred with industry stakeholders in relation to changes to GMP Fees and Charges. These included bilateral consultations with therapeutics peak bodies (14 occasions), roadshow events with manufacturers and sponsors (over three days), discussions within the TGA-Industry Working Group on Good Manufacturing Practice and additional meetings on request.

We met with medical device peak bodies at the RegTech forum in November 2017 and in February and May 2018, and covered a range of changes (implemented and planned) to regulatory and business processes with a focus on MMDR regulatory changes.

KPI 2.3 Regulators' decisions and advice are provided in a timely manner, clearly articulating expectations and the underlying reasons for decisions.

2.3a

Information for consumers, health professionals and industry on the basis for the TGA's decision making, including any work to improve the quality of our decision making.

We ran a series of workshops for a wide range of health professionals in Melbourne and Perth (November 2017), and Brisbane and Wagga Wagga (December 2017) on the upscheduling of codeine. These workshops included specialist speakers covering pain management in a rural setting, the complexities of opioid treatment in pain management and alternative options to codeine in the pharmacy. In addition we published a codeine information web-hub that provides accessible information for various health professionals and consumers.

We published six new guidance documents for health professionals in December 2017 on medicinal cannabis treatment in epilepsy, multiple sclerosis, nausea and vomiting, palliative care and chronic non-cancer pain. Two guidance documents aimed for consumers were also published; patient information guidance in December 2017, and an overview factsheet in May 2018.

We published seven new guidance documents in March 2018 to support the implementation of the new provisional approval pathway for prescription medicines. This guidance assists industry in using the new pathway to apply for provisional registration on the basis of preliminary clinical data. It also included a landing page for industry which provides an overview of the purpose of the pathway and eligibility requirements.

In June 2018, we published the first version of the *Australian Regulatory Guidelines for Advertising Therapeutic Goods*. The Guidelines inform advertisers (including sponsors, manufacturers, importers, pharmacists and health professionals) of their responsibilities when advertising therapeutic goods and explains how the advertising legislation is applied.

2.3b

Percentage of pre-market applications and post-market activities processed in target timeframes.

Detailed statistics on the processing of pre-market applications and post-market activities with associated timeframes are provided in the *TGA Annual Performance Statistics Report*, July 2017 to June 2018. We also published a *Half Yearly Performance Snapshot* which contained a subset of data covering July to December 2017. Both reports have been published on our website.

Percentage of pre-market applications processed within their respective timeframes:

- 100% of prescription medicine applications (new chemical entity, fixed dose combinations, extension of indications and generic medicines)
- 100% of medical device conformity assessment applications were processed within the legislated timeframe (255 days) and 98% of the applications were processed within the agreed timeframe (200 days)
- medical device (not IVDs) inclusion applications not selected for audit – non-compulsory audit 73%, Level 1 compulsory audit 67% and Level 2 compulsory audit 58%
- IVD Medical device – Level 1 non-compulsory audit 60%, level 2 non-compulsory audit 43%.

Percentage of OTC medicine applications processed within target time

Application type		Percentage
N1	An application submitted as a clone	96
N2	An application which complies with an OTC medicine monograph	100
N3	New application for a 'generic' medicine other than those 'generic' medicines in levels N1, N2 or N4	97
N4	An application for a 'generic' medicine where the medicine: • requires supporting safety and/or efficacy (clinical/ toxicological) data or a justification for not providing such data; and/or • requires a higher level of assessment due to the umbrella branding segment of the product name; and/or • has not been previously registered as an OTC medicine following down-scheduling	95
N5	An application for a new product that is an extension to a 'generic category' product containing a new chemical entity as an active ingredient	100

2.3c

Publication of information for health professionals, consumers and industry when medicines are registered and/or new information arises on therapeutic goods.

We regularly issued news updates, tweets, public notices and safety information for consumers, health professionals, industry and the community. The Product Information (PI) and Consumer Medicine Information (CMI) documents are also published on our website where applicable and when ARTG entries are included.

Quantity of information by type published on the TGA website for the period July 2017 to June 2018

Type on information	Number
Australian Public Assessment Reports	67
Expert advisory committee meeting statements	28
Scheduling advisory committee interim and final decisions	7
New Chemical Entities (NCE) approvals	35
Extension of Indications (EOI) approvals	62
Web statements: medicines and medical device safety alerts/suspensions	Medicines - 56 Medical devices - 38 Suspensions - 19 Alerts - 19
Recalls (SARA database)[a]	Medicines - 38 Medical devices - 555 Biologicals - 25
Recalls related web statements [b]	22
Medicines Safety Updates	4
Medical Devices Safety Updates	6
Medicine shortage web statements	New - 2 Updated - 5

a The searchable database known as the System for Australian Recall Actions (SARA) provides consumers, healthcare professionals, sponsors, wholesalers, hospitals and retailers with access to information about recalls actions undertaken in Australia.

b In addition to publication of recall actions in the SARA 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.

KPI 2.4 Regulators' advice is consistent and supports predictable outcomes.

2.4a

Percentage of substantive regulatory decisions subject to internal review, for which the original decision is revoked and substituted, without consideration of additional information.

We estimate that we make more than 34,000 regulatory decisions per year. In 2017-18, 24 internal reviews of regulatory decisions were finalised. These included two (8%) where the original decision was revoked and substituted without consideration of additional information.

All internal reviews were completed within the prescribed legislated timeframes.

2.4b

Outcomes of matters referred by sponsors to the Administrative Appeals Tribunal (AAT), including where TGA decisions are upheld, and where the outcome is indicative of an issue about the quality of the decision.

In 2017-18, we were party to 11 matters before the AAT. Of the 11 matters, one applicant seeking review of the original decision withdrew their appeal. Three matters were resolved by way of consent orders. Two matters progressed to hearing and the TGA's original decision was upheld by the AAT in both cases. The remaining five matters before the AAT were ongoing at the time this report was prepared.

None of the outcomes that eventuated indicated any issue relating to the quality of TGA decisions.

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

The performance rating of **Met** is supported by our risk-based approach being proportionate to the therapeutic products we regulate. We continue to monitor activities and prioritise inspections based on risk assessment results and compliance history, and to publish safety alerts and other relevant information on our website.

Most external validators agree that our risk-based approach is in line with the Australian regulatory framework and international best practice where the regulation is proportionate to the regulated products. It was acknowledged that we have made significant improvements in this area during the past year.

		Evidence
KPI 3.1	*Regulators apply a risk-based, proportionate approach to compliance obligations, engagement and regulatory enforcement actions.*	Effective prioritisation of compliance activity through the regulatory framework and Regulatory Compliance and Enforcement Plan. Publication of safety alerts, cancellations from the ARTG and destruction of counterfeit products.
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.*	Monitoring and appropriate prioritisation through the Regulatory Compliance Committee. Amendments made to legislation based on stakeholder feedback, including MMDR reforms.
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.*	Monitoring and compliance activities are informed by risk assessment, risk based prioritisation and compliance performance history including inspections of manufacturing facilities and product testing.

Continuous improvement 2018-19

We will continue to be transparent in our regulatory compliance activities by publishing outcomes on our website. An increased amount of information will be published on complementary medicines compliance actions and advertising complaint handling. The new advertising complaints handling model will streamline processing and more closely align actions with regulatory risk.

KPI 3.1 Regulators apply a risk-based, proportionate approach to compliance obligations, engagement and regulatory enforcement actions.

3.1a

Outcomes of completed investigations of alleged offences.

During 2017-18, a compliance plan was initiated for contraventions of the *Therapeutic Goods Act 1989* regarding unapproved therapeutic goods used in the cosmetics industry. The compliance plan incorporates a multi-faceted approach to perceived non-compliance using education, guidance and where appropriate, enforcement. The compliance plan also adopts a multi-jurisdictional approach to the industry by relevant state, territory and Commonwealth agencies.

39 compliance investigations were completed during this period, and over 850,000 units of goods were seized and destroyed by the TGA and Australian Border Force.

Following investigations by the TGA, convictions on criminal charges for dealing with unapproved therapeutic goods or counterfeit medicines were:

- two persons were sentenced in relation to two criminal charges each of the manufacturing and supplying of therapeutic goods not included on the ARTG. The individuals were convicted and fined $750 each
- one person was sentenced in relation to eight criminal charges of importing therapeutic goods not included on the ARTG. The individual was convicted and fined $2,000
- an Australian Proprietary Company and its director were sentenced in relation to one criminal charge of supplying counterfeit therapeutic goods. The company was convicted and fined $4,400.

Actions under the compliance plan	
Regulatory outcomes of closed cases	No. of cases
Goods destroyed	24
Goods released	5
Goods exported	2
Referred internally	2
Referred externally	3
No offence detected	2
Website compliant	1
Total cases closed	39

Regulatory actions completed	
Action	No. of completed actions
Warning letter	32
Regulatory visit	7
Goods destroyed	24

Some cases have resulted in multiple regulatory actions. For example, a warning letter may be issued through a regulatory visit that resulted in the destruction of goods.

Number of compliance matters that were dealt with by the TGA resulting in Australian Border Force seizing imported goods and subsequently facilitating destruction in 2017-18	
Number of destruction certificates issued	Number of units destroyed[a]
2,414	850,514

a A unit equates to an individual tablet, capsule, vial, ampoule, container or syringe.

3.1b

Publication of evidence of compliance activities to support the continued availability of safe, effective and high quality therapeutic goods for the Australian public.

We use a risk management approach to identify entities at risk of unintentional or deliberate non-compliance, and to collect information related to alleged breaches of the *Therapeutic Goods Act 1989* and the Therapeutic Goods Regulations 1990. Evidence relating to our compliance activities is published on our website through a range of reports, notices and results, providing transparency for our stakeholders. Our *Half Yearly Performance Snapshot* (July to December) and A*nnual Performance Statistics Report* (July to June) include statistics on our regulatory compliance activities.

We publish details of medicines and medical devices (including IVDs) that have been cancelled or suspended from the ARTG, including the provisions under which the cancellation or suspension was undertaken, and the grounds for each cancellation or suspension.

We received 38 recommendations from the Complaints Resolution Panel to order specific advertisers to comply with advertising requirements. Recommendations are generally resolved by taking an educative approach with advertisers. No Regulation 9 orders (to withdraw an advertisement and publish a retraction or correction) were issued in 2017-18. We commenced publishing the outcomes from resolved recommendations in mid-September 2017 with 32 outcomes published. However, the first batch of publications included matters finalised in 2016.

We continue to provide information to the public about the 2,000 plus samples tested each year to increase understanding of how our testing program contributes to the regulation of therapeutic goods. The Database of TGA Laboratory Testing Results provides consumers and health professionals with information about products that we have tested, whether they passed or failed and if required, what regulatory action was taken.

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.

3.2a

Information on the TGA's risk framework published on the TGA website, and regularly kept up-to-date.

The *Therapeutic Goods Act 1989* underpins our work and outlines a risk-based regulatory framework for therapeutic goods. The Government announced in July 2017 that TGA would take on the role of the single body responsible for handling advertising complaints from 1 July 2018 (subject to a review after three years).

The Review also recommended that consideration be given to broadening enforcement powers to benefit consumers through appropriate compliance with advertising regulatory requirements, and to deter inappropriate and misleading advertising of therapeutic goods. Following further consultation, the enhanced sanctions and penalties were included in the *Therapeutic Goods Act 1989* on 5 March 2018.

We consulted with stakeholders on the design of the streamlined complaints management framework in May 2018. The proposal outlined a risk-based framework where the level of regulatory intervention is appropriate and proportionate with the risk associated with the advertising of therapeutic goods, with a particular emphasis on whether reliance on advertising claims by consumers could pose a health and safety risk to the public.

The final framework, including any changes arising from the consultation and issues put forward for implementation are scheduled for publication on the TGA website on early 2018-19.

We use a Regulatory Compliance and Enforcement Plan and Risk Compliance Plan to guide the prioritisation of investigations and risk management activities. These plans ensure consistent decision making in relation to regulatory activities and are published on our website.

We also publish a Scheduling Policy Framework and handbook, which provides information on risk assessment in the scheduling process for medicines, and publish more information on submissions.

3.2b

Information on activities undertaken to ensure that a risk-based approach is taken to prioritise complaints and other signals of possible non-compliance with regulatory requirements.

The TGA takes risk assessment seriously, and prioritises all intervention activity based on risk, with emphasis on managing risk to public health and safety.

We have a Regulatory Compliance and Risk Committee (RCRC) that meets six times per year. The RCRC considers matters of significance to TGA that fall within the definition of compliance risk and management. This committee oversight provides transparency and consistency in regulatory action prioritisation across the TGA.

We participate in Operation Pangea each year, partnering with Canada, Ireland, Israel, Singapore, Switzerland, the United Kingdom and the United States to promote actions aimed at combating and preventing the smuggling and trafficking of illicit and counterfeit pharmaceuticals and medical devices that have been marketed and sold online. Non-compliant behaviour identified in the course of the operation is referred internally for consideration of further regulatory action under the Case Categorisation and Prioritisation Model. During the reporting period, 21 suspected counterfeit products were identified as part of the operation and referred for further assessment.

In accordance with our Regulatory Compliance Framework and regulatory responsibilities, where an advertising complaint is received it is triaged and prioritised based on the risks that the advertising could pose, primarily to public health and safety. In 2017-18 we received 445 complaints about the advertising of therapeutic goods.

Reports related to adverse events or complaints with medical devices are risk assessed and investigated where the risk is unacceptable. New medicine signals from a range of sources including adverse event reporting and the medical literature are risk assesses and prioritised.

The Pharmacovigilance Inspection Program uses a risk-based approach to identify and prioritise sponsors for inspections. A Risk Assessment Survey was completed in early 2018. Sponsors who completed the survey were assigned a risk score. Those who did not complete the survey were assigned the highest risk score. Inspections have been scheduled according to risk, taking into account the risk score and other information such as unusual adverse events reporting patterns.

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.

3.3a

Information on activities undertaken to ensure that a risk-based approach is taken to monitoring and compliance activities.

We review risks associated with monitoring and compliance and streamline activities to minimise impact on regulated entities.

We use a risk-based approach to determine the classification and level to which a recall is undertaken by considering 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.

All recalls are risk assessed and classified into Class I, II and III which assists with prioritising of the recall actions. Class I and II actions are safety related with highest priority given to Class I issues which can or have resulted in serious injury or death. Class II issues are those which could cause illness, injury or result in mistreatment. Class III actions occur when issues may not pose a significant hazard to health, but action may be initiated for other reasons e.g. quality related issues.

Out of the 618 recalls for medicines, medical devices and biologicals undertaken during the reporting period, 112 were Class I, 422 were Class II and 84 were Class III.

As part of our GMP risk-based inspection programme, inspectors employ risk-based inspection frequency matrices to guide the frequency of inspections. Manufacturer performance at inspection is categorised as good (A1), satisfactory (A2), marginal (A3) 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 matrix also takes into account product and process risks. In conjunction with this risk matrix, consistent achievement of a good outcome is also recognised by reduced scope reinspections with inspectors spending less time onsite depending on the risk rating achieved. Before scheduling inspections, we also consider emerging trends, recalls, adverse events, results of laboratory testing, feedback and inspections undertaken by other regulators and manufacturer profiles that have been updated to reflect any significant changes with the manufacturer.

Our laboratory testing program safeguards and enhances the health of the Australian community through the effective monitoring and laboratory testing of therapeutic goods to verify they are of an acceptable quality. We have continued to implement an improved risk management approach when selecting and prioritising products for laboratory testing. A risk assessment tool considers particular product groups against 16 risk sources to identify those with the highest relative risk. The resulting testing plan is independently reviewed annually to ensure it is appropriate, risk-based and addresses priority areas.

Additionally, we use a risk matrix and signal detection to monitor issues with medical devices and medicine to ensure that we are concentrating our efforts on devices and medicines that have or are likely to cause death, serious injury or illness.

KPI 4 Compliance and monitoring approaches are streamlined and coordinated

The performance rating of **Met** is supported by our ongoing participation in international forums and collaboration with other regulators in work-sharing activities. We have established an intelligence team, and are improving our investigations and enforcement capability, while working towards better regulatory tools to provide a robust sanction and penalty regime.

Most external validators agreed that our compliance and monitoring approaches are streamlined and coordinated, and noted considerable improvements since the implementation of the MMDR reforms.

		Evidence
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.*	Improved guidance provided to assist with initial provision of information. Voluntary compliance encouraged by seeking information through informal mechanisms.
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.*	Streamlined and coordinated approach to capturing compliance information. Working towards international convergence. Sharing manufacturing inspection schedules with international regulators and joint GMP inspections.
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.*	Increased use of assessments from CORs. Worked collaboratively with health professionals and industry to share information, including chairing the Medicines Shortages Working Party and Nationally Coordinated Codeine Implementation Working Group (NCCIWG). Driving collaboration and information sharing between Commonwealth, state and territory bodies.
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.*	Monitoring and inspection activities are prioritised by risk assessments, and tailored based on compliance history, industry trends, testing results and impact to sponsors.

Continuous improvement 2018-19

We will continue to consult with our stakeholders on improvements relating to reporting medical device adverse events.

We will continue to collaborate with our international colleagues and explore opportunities to utilise existing information. We will align our processes with international best practice whenever possible and consider opportunities for mutual recognition, particularly with Health Canada under the Regulatory Cooperation Initiative program focusing on joint GMP inspections and desktop assessment processes for GMP clearances.

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.

4.1a

Information on activities undertaken to minimise the need for, or number of, requests for information to sponsors under the relevant legislation.

We have improved the way we liaise with sponsors through our medical device adverse event report investigations and post-market reviews. A standard request template is used which is familiar to sponsors that have received the request for information.

Accessing unapproved medical cannabis products typically requires both Commonwealth and state/territory Health Department approval. On 2 March 2018 the NSW and Commonwealth governments announced streamlined patient access by introducing a single application process for health professionals to remove duplication with separate applications. The combined NSW/Commonwealth application form was published on 21 March 2018. This will be supported by an online system going forward.

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.

4.2a

Progress of business improvements, and other specific projects, so that sponsors will only need to provide some information to the TGA once (refer to KPI 1.3).

Initiatives undertaken where sponsors only have to provide information once is captured in KPI 1.3b.

In addition, submission of Periodic Safety Update Reports is a common condition of registration for prescription medicines. Where possible, the submission frequency and timing of these reports is being aligned with international reporting requirements. This reduces the reporting burden on sponsors and removes the need for sponsors to prepare addendums to European reports to fulfil Australian reporting requirements.

Medical device regulations require annual reports for a subset of devices. This data includes information for the year under review only. Therefore, requests are repeated only when absolutely necessary to ensure up to date information is available to adequately monitor the safety and performance of a device. We will complement the information we gather from sponsors by utilising data already collected by the Australian Orthopaedic Association National Joint Replacement Registry, Australian Institute of Health and Welfare and the Prostheses List Advisory Committee (PLAC).

4.2b

Information on cooperative activities carried out with international regulators to minimise information collection from industry (such as joint GMP inspections).

We undertake desktop GMP clearances for overseas manufacturers in place of inspections, taking into consideration regulatory decisions by other comparable regulators. Using the approved clearances during the reporting period, 92.9% of GMP reviews were based on evidence from overseas regulatory agencies.

We contribute regularly to a system of sharing manufacturer inspection schedules with the United States of America's Food and Drug Administration (USFDA), the European Medicines Agency (EMA), Health Canada and PIC/S participating authorities. This activity aims to identify opportunities for joint inspections with international regulators and therefore minimises burden on industry as well as strengthens relationships between the TGA and other agencies.

We contributed to the review of PIC/S strategies and policies as part of the participation in PIC/S working groups, aiming for mutual recognition of decisions on GMP inspections. We conducted seven joint GMP inspections during 2017-18, five in India and two in Victoria.

We participate in the Medical Devices Single Audit Program (MDSAP), which provides for a single program of audits to satisfy the needs of the participating Regulatory Authorities. TGA, the National Health Surveillance Agency (ANVISA Brazil), Health Canada, Pharmaceuticals and Medical Devices Agency (Japan) and the USFDA pool resources to provide oversight of auditing organisations that conduct audits on behalf of these regulators. Audit reports and certification details are submitted to an IT portal allowing the participating regulatory authorities to have access to this information without the need to request it from sponsors or manufacturers.

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.

4.3a

The use of information from, or in collaboration with, other regulators; for example, development of processes for sharing with international regulators, the number of product evaluation and inspection reports shared.

We collaborated with international agencies through development of templates and policies to encourage and support further industry participation. These included work-sharing initiative arrangements of evaluations of New Chemical Entities and Biosimilars to reduce regulatory burden on industry (so that manufacturers do not have to go through evaluation processes twice), therefore shortening timeframes.

We also shared evaluation reports with other international agencies, and continue to engage in international alignment through harmonised data requirements and templates, leading to shorter assessment times.

The Australia-Canada-Singapore-Switzerland (ACSS) Consortium is a collaborative through which we work with Health Canada, Singapore's Health Sciences Authority, and the Swiss Agency for Therapeutic Products to build synergies and share knowledge in order to enhance the effectiveness and efficiency of their respective regulatory systems.

In 2017-18, ACSS made significant progress on information sharing and regulatory convergence, with a work-sharing trial resulting in the near-simultaneous approval of a new generic medicine in Australia, Canada and Switzerland within statutory timeframes.

Similarly, ACSS collaborated on work-sharing the evaluation of a new medicine for the treatment of prostate cancer. The evaluation was shared between the TGA and Health Canada and resulted in the approval of the drug in Australia and Canada within 80 days.

We participate in other forums that aim to identify areas of synergy across regulators including the International Coalition of Medicines Regulatory Authorities and the International Pharmaceutical Regulators Programme.

We are also a participating authority of the PIC/S. This scheme is a non-binding, informal cooperative arrangement between 52 participating authorities in the field of GMP of medicinal products for human or veterinary use. We participate in PIC/S working groups developing and promoting harmonised GMP standards and quality systems. PIC/S also facilitates cooperation and networking between competent authorities, regional and international organisations, thus increasing mutual confidence.

During 2017, we shared two inspection reports with overseas regulators, and received three reports directly from overseas inspectors.

In addition to work-sharing, we are increasingly making use of assessments from CORs and international assessment bodies, where possible. For example, European medical device assessments support over 90% of medical devices included on the ARTG.

We are a founding member of the International Medical Device Regulators Forum (IMDRF) which seeks to harmonise regulatory requirements internationally and minimise duplication for industry. We have actively participated in a number of IMDRF working groups including those on Adverse Event Terminology, Good Regulatory Review Practices, Standards, and Regulated Product Submissions.

We actively participate within the Australia-Canada-Singapore-Switzerland (ACSS) Consortium New Chemical Entities (NCE) Working Group, which focuses on developing opportunities to reduce regulatory effort through the greater alignment of regulatory approaches and technical requirements. The ACSS NCE working group has successfully completed an innovative work sharing pilot for apulatamide, a new prostate cancer treatment, with the pilot delivering timely and concurrent market authorisation decisions to both of the participating countries, streamlined evaluation processes for industry and the opportunity to leverage international technical knowledge.

4.3b

Collaborative work undertaken with health professionals. For example, interactions on significant medicine shortages, recall actions or safety issues.

Medicine shortages have become an increasing problem in the past few years. In the second half of 2017, we formed a working group to develop a strategy for the improved management and communication of medicine shortages, comprising of sponsor organisations and key organisations representing healthcare professionals, the Pharmacy Guild, the Pharmaceutical Society of Australia, the Australian Medical Association and the Society of Hospital Pharmacists of Australia. These organisations assisted us to deliver a revised strategy for the management and communication of medicine shortages in Australia that will involve mandatory reporting of all medicine shortages to the TGA.

These and other healthcare professional organisations also participated in consultations which helped to inform the development of a mandatory reporting scheme. The timely reporting and communication of shortages will enable the relevant stakeholders, including health professionals, to take appropriate action for patient treatment in the event of a shortage. The implementation of the new mandatory reporting scheme is scheduled to commence on 1 January 2019 with the recent passage of the Therapeutic Goods Amendment (2018 Measures No. 1) Bill 2018 through both houses of the Australian Parliament.

We recently updated the system used to collect and process adverse event reports to medicines. We engaged with health professionals during the development of the new online forms for the new Adverse Event Management System (AEMS). Nominated health professionals interacted and provided feedback on an early prototype of the AEMS online forms in October 2017. The involvement of health professionals during the development of the online forms resulted in a better end product.

One of the recommendations from the review of the MMDR was to implement an online system to manage applications and notifications for the use of unapproved therapeutic goods under the SAS. We worked collaboratively with healthcare professionals in the development of the new online system. This collaboration included moderated user testing sessions with healthcare professionals to inform the design and functionality of the system, as well as a period in which a select number of hospitals were able use the system prior to its public launch. Use of this online system reduces administrative burden on health practitioners and allows users to manage the SAS applications and notifications they submit to us.

We have also undertaken education of health professionals via the inSite program to encourage adverse event reporting of medical devices. The inSite program also provides support and information regarding recall actions.

We participated in the monthly TGA-Jurisdictional Immunisation Coordinators teleconference which included discussions on: implementation of adverse events following immunisation (AEFI) monitoring programmes for vaccines newly added to the National Immunisation Program Schedule, provision of summary information regarding AEFI reporting, newly identified vaccine safety signals or vaccine quality issues and timely reporting to the TGA as required.

Consultations were held with representatives from the health profession, private and public hospital associations, and state and territory health departments on the implementation (and information requirements) of Patient Implant Cards and patient information leaflets for implantable medical devices. The consultations were to inform the sector of the availability and objectives of the consumer information materials.

The collaboration between health care professionals, other jurisdictions and stakeholders and the TGA to minimise the risk to the community from over the counter opioid codeine, was one of the strongest endeavours in this period. The National Codeine Communication Strategy was implemented through the Nationally Coordinated Codeine Implementation Working Group (NCCIWG). Subsequent to an upscheduling of codeine to prescription only status, the NCCIWG provided the vehicle to actively engage with key external stakeholders to build relationships, help resolve divergent views, understand sensitivities and promulgate key messages. NCCIWG was chaired by the TGA's Chief Medical Advisor and included representatives from jurisdictional health departments, industry lobby and consumer groups as well as peak professional health organisations.

NCCIWG ensured a collaborative network with peak professional bodies, consumer advocacy groups and medical communication organisations, and together we delivered key messages and education material to affected stakeholders through print, video, radio and social media. This information and other multi-sector communications (consumer, pharmacist and rural GPs fact sheets) was available on an external Codeine Information Hub which served as a focal point for a successful social media campaign that broadcast the tangible benefits of the changes to consumers.

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.

4.4a

Information on activities undertaken to ensure that a risk-based approach is taken to monitoring and compliance activities (refer to KPI 3.3).

KPI 3.3 provides detailed information of the activities undertaken to ensure we use a risk-based approach to monitoring and compliance activities.

As a consequence of access to Medical Devices Single Audit Program audit reports it is anticipated that operational adjustments will provide for a further refinement of the risk-based approach to the scope, frequency and duration of audits conducted under our medical devices audit program.

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

Our performance rating against KPI 5 is **Substantially Met**. Although the majority of the deliverables under this KPI were met, some responses to our stakeholder survey have indicated dissatisfaction in their dealings with the TGA. We are reviewing our Customer Service Standards and consulting with industry to resolve these issues for future interactions.

We continued to raise awareness of our regulatory framework through our various interactions with industry and other stakeholders through workshops, publication of educational material and maintaining our telephone and email enquiry lines.

There was consensus with our external validators that we are open and transparent with our dealings, particularly through formal consultations, meetings, webinars and electronic notifications. Validators also agreed that the SME Assist platform has been a proactive measure in supporting SMEs and serves as an example to be followed by other Australian Government regulators. However, two validators raised concerns that a change in operating procedures for handling external enquiries has led to reduced clarity in communication with our organisation.

		Evidence
KPI 5.1	*Regulators' risk-based frameworks are publicly available in a format which is clear, understandable and accessible.*	Strong internal governance framework to support our risk and compliance activity. Introduced new pathway for complementary medicines to enter the ARTG, the assessed listed medicines pathway.
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.*	Addressed over 200,000 public and industry enquiries through our information lines. SME Assist provides direct education and support to SMEs and research and start-ups, including responding to more than 230 phone and email enquiries.
KPI 5.3	*Regulators' performance measurement results are published in a timely manner to ensure accountability to the public.*	Publication of performance reports for 2017-18 including: *Annual Performance Statistics Report* *Half Yearly Performance Snapshot* *Regulator Performance Framework Self-Assessment (KPI) Report.*

Continuous improvement 2018-19

To provide transparency to our stakeholders, we will continue to publish performance and activity reporting on our website, as well as revise and update regulatory guidance material.

We will continue to develop our enquiry management system to ensure the timely management of telephone and email enquiries, as well as ensuring that our responses are clear and easy to understand.

KPI 5.1 Regulators' risk-based frameworks are publicly available in a format which is clear, understandable and accessible.

5.1a

Information on the TGA's risk framework published on the TGA website (refer to KPI 3.2).

We publish specific information detailing how we apply a risk-based framework to compliance activity. We also provide updates on regulatory risk to the Department of Health Audit and Risk Committee. We continue to invest in providing education and transparency about the regulatory framework through our website, social media profile, industry workshops and publication of educational material.

5.1b

Information on the TGA's regulatory compliance framework published on the TGA website, with evidence of systems for regular review and updates.

We publish our Regulatory Compliance Framework on the TGA website, which outlines to stakeholders how we manage our compliance function under the legislation and sets out our overall approach to compliance. We also publish the Database of TGA Laboratory Testing Results, which provides consumers and health professionals information regarding compliance programs and associated regulatory action.

Details of court outcomes of criminal investigations following the finalisation of the criminal prosecution and sentencing process are also published on our website. During the reporting period three criminal matters were finalised and details published.

Safety alerts are published when therapeutic goods that we have tested are found to be counterfeit. Over the period we published 49 counterfeit safety alerts.

More information about our regulatory compliance framework is provided in KPIs 3.2 and 3.3.

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.

5.2a

Adherence to quantitative standards of service commitments and agreed performance measures in relation to responding to enquiries received through the TGA's public information lines.

We maintain a number of telephone and email based information lines that receive enquiries from industry stakeholders. Together, these information lines dealt with approximately 200,000 telephone and email enquiries during 2017-18. These numbers demonstrate our high level of interactions with our stakeholders, including industry, healthcare professionals and the public.

The Regulatory Assistance Section manages our central telephone, email, fax and letter enquiry lines. During the reporting period 29,138 enquiries were received by the Section, with 26% being from industry, 34% from health professionals, 36% from the public, and the remainder from other government departments and internal enquiries. Where responses were provided by the Section, 48 enquiries from industry (1.6% of total enquiries) were not responded to within the timeframes outlined in the TGA Customer Service Standards, i.e. to acknowledge letters and emails within five working days and respond to voice mail messages within two working days. During this time, the Section transitioned to a new enquiry management system, resulting in some data being unavailable for the period July to September 2017. This may have impacted our ability to manage all enquiries within the specified timeframes.

The dedicated SME Assist support service, established to help SMEs to better understand and navigate therapeutic goods regulation, responded to more than 230 phone and email enquiries. A key barrier for small to medium enterprises is a lack of understanding about the pathways and requirements for market authorisation and post-market monitoring for therapeutic goods. SME Assist provides web-based tools, support materials and training workshops specifically targeted at SMEs, researchers and start-ups to better understand their regulatory obligations.

In 2017-18, we received four complaints against the TGA Customer Service Standards, all of which were responded to and resolved in accordance with our relevant policies.

5.2b

Information on interactions with industry.

Please refer to KPIs 1.1a and 1.1b, which provide detailed information on the extensive formal and informal interactions with industry stakeholders undertaken during the reporting period.

KPI 5.3 Regulators' performance measurement results are published in a timely manner to ensure accountability to the public.

5.3a

Information on ongoing reporting activities including applicable timeframes.

We report on our performance and activity in compliance with the Governments reporting requirements and the Public Governance and Accountability Act 2013 where applicable to provide transparency to our stakeholders and the Australian public through the following reports. These reports are published on the TGA or Department of Health website.

- *Half Yearly Performance Snapshot* (July to December)
- *Annual Performance Statistics Report* (July to June)
- *Regulator Performance Framework Self-Assessment Report* (annual)
- *Health Portfolio Budget Statements* (annual)
- *Department of Health Annual Report*
- *Prescription Medicines and Biologicals TGA Annual Summaries*
- *Database of TGA Laboratory Testing Results* (May and November)
- *Annual Stakeholder Survey*

Through these reports, stakeholders can assess our performance against Government objectives, our responsiveness to industry and our efficacy against regulatory requirements.

In 2017-18, we commenced publication of TGA decisions to designate a medicine as an orphan drug, or to make a priority or provisional determination, based on assessment against the relevant eligibility criteria. This provides transparency for our stakeholders on these regulatory decisions.

Additionally, we publish information detailing how we are improving access to therapeutic goods for consumers and streamlining regulatory processes for industry by implementing the Government's Response to the MMDR.

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

The performance rating of **Met** is supported by our stakeholder engagement through market research, continued business improvements, and the implementation of reforms as well as interactions with other Government Departments and comparable regulators.

External validators agreed the TGA is committed to continuous improvements; particularly through the implementation of the MMDR reforms and mandatory reporting of medicines shortages.

		Evidence
KPI 6.1	*Regulators establish cooperative and collaborative relationships with stakeholders to promote trust and improve the efficiency and effectiveness of the regulatory framework.*	Increase in responses to stakeholder survey. Created a consumer-specific survey to engage with the general public.
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.*	Undertook significant consultation with industry. Reduction in compliance costs for industry through introduction of electronic and combined forms and assessments.
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.*	Cooperation within the Department of Health to align evidence requirements where possible. Cooperation and collaboration with Commonwealth, state and territory entities to ensure the efficacy of our regulatory functions, notably with Australian Border Force for compliance purposes.

Continuous improvement 2018-19

We will continue to provide ongoing support and education to providers during the transition period for changes to regulations, for example, autologous human cell and tissue products.

We will continue to improve our engagement with consumers and other stakeholders to ensure confidence in the efficacy, performance and quality of therapeutic goods in Australia. This will include actively responding to feedback provided in our annual stakeholder survey.

KPI 6.1 Regulators establish cooperative and collaborative relationships with stakeholders to promote trust and improve the efficiency and effectiveness of the regulatory framework.

6.1a

Market research conducted on an annual basis to measure consumer, health professional and industry trust in—and engagement with—the regulatory framework.

For the first time in 2017–18, we conducted two separate surveys: a consumer-specific survey and a multi-stakeholder survey for health professionals, industry and other stakeholders.

We emailed more than 25,000 stakeholders inviting them to participate in our surveys. They were also published online and shared via social media. In addition, we engaged a market research company to survey a representative sample of Australian consumers, which was stratified by age, gender and location.

The total number of respondents to the 2017-18 surveys was 3,981, a significant increase from 2,535 respondents in 2016-17. Respondents identified as health professionals (216), medical products industry members (1,531), and others (505), including, for example, retailers, government, academics, and media. The total number of consumer respondents was 1,729: 684 through sharing with our own networks and 1,045 from the purchased sample. The multi-stakeholder and consumer-specific surveys were tailored for their respective audiences but included common questions for comparison.

Industry and health professionals continue to maintain a high level of trust, with 86% of industry, and 79% of health professionals agreeing that TGA performs its role ethically and with integrity. Industry also agrees TGA gets the right balance between risk and benefit, with 70% satisfaction, while health professionals are less satisfied, with 59% agreeing TGA gets the risk balance right. Perceptions of balance may relate to the TGA's regulatory decisions in each year. For example, the up-scheduling of codeine in 2018 was contentious for some, which may be reflected in the apparent reduction in the proportion of health professionals who agreed or strongly agreed that the TGA achieves the right regulatory balance. The urogynaecological mesh review, debate about the up-scheduling of codeine and access to medicinal cannabis products may have also contributed to the comparatively low proportion of consumers who agreed or strongly agreed with the regulatory balance item (45%).

Survey responses indicate that stakeholders were generally satisfied with their experiences of communicating with the TGA. Industry respondents were the most satisfied, and consumers were the least satisfied. Many stakeholders had infrequent contact with the TGA, highlighting that a single experience can shape overall communication satisfaction. Of those respondents who contacted the TGA in the last two years, 42% of respondents in the multi-stakeholder survey and 71% of respondents in the consumer survey contacted the TGA about once a year or less. Open-text comments suggest that the timeliness, clarity and completeness of TGA responses to enquires can be a source of dissatisfaction for some.

Stakeholders were also generally satisfied with the TGA website, though some respondents commented that it can be hard to find information. Overall satisfaction with the TGA website was highest among industry respondents and lowest among consumers. Satisfaction levels for health professionals and industry respondents were comparable to the 2016–17 survey findings.

6.1b

Stakeholder engagement and satisfaction with TGA consultative processes.

In our annual program of market research (see KPI 6.1a), we ask questions to gauge stakeholder engagement and satisfaction with our consultative processes. More than half of industry respondents agreed or strongly agreed that the TGA is collaborative, provides opportunities for input into key decisions, and listens to feedback. Health professionals and consumers reported comparatively lower levels of agreement.

Collaboration and feedback

	The TGA provides opportunities to input into key decisions that impact me		The TGA listens to feedback		The TGA is collaborative[a]	
	2017	2018	2017	2018	2017	2018
Industry	57%	62%	49%	52%	57%	57%
Health professionals	46%	39%	50%	38%	51%	42%
Consumers	N/A	26%	N/A	24%	N/A	N/A

a This item was not included in the consumer-specific survey.

Around half of health professional were satisfied or very satisfied with their consultation experience. Almost 70% of industry respondents were also satisfied or very satisfied overall with their experience. Respondents who were dissatisfied expressed a desire for more consultation, longer consultation periods, and more feedback regarding the TGA's response to consultation inputs.

Consultations

	Overall satisfaction with consultations		Overall dissatisfaction with consultations	
	2017	2018	2017	2018
Industry	68%	69%	8%	11%
Health professionals	57%	56%	12%	35%

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.

6.2a

Evidence of continuous compliance with our practice of engagement with industry before a RIS is finalised.

Additional information about our formal consultations is published on our website and detailed information is reported under KPI 2.2a.

6.2b

Progress of business improvements and other projects aimed at reducing compliance costs.

We aim to reduce compliance costs to regulated entities by regularly engaging with our stakeholders and maintaining a cycle of continuous business improvements.

New labelling requirements for Neuromuscular Blocking Agents were introduced in mid-2018. To reduce the compliance costs for medicine sponsors, these new labelling requirements were incorporated into the existing transition period for the Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines. Sponsors have until 1 September 2020 to comply with the new requirements. By incorporating the changes into this document, affected medicine sponsors can combine label changes into a single application to the TGA, thereby reducing compliance costs.

Please refer to KPI 1.3b for further information.

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.

6.3a

Information on cooperation and collaboration with policy areas of our Department.

As part of the Department of Health, we work collaboratively with policy areas in the Department and with portfolio agencies to improve the operation of our regulatory framework:

- Technology Assessment and Access Division regarding the interface between provisional registration of medicines by TGA and possible Pharmaceutical Benefits Scheme reimbursement via the Managed Access Program
- Tobacco Control Branch, Office of Drug Control, National Industrial Chemicals Notification and Assessment Scheme and National Integrity of Sport Unit regarding scheduling proposals
- Performance, Evaluation and Quality Branch regarding the interface between the National Patient Contact Principles for patients with implanted medical devices subject to hazard alerts and the Uniform Recall Procedure for Therapeutic Goods
- Medical Benefits Division for the changes to the availability of low-dose codeine containing medicines
- PLAC to align parallel processing and promote sharing of information where appropriate to streamline assessments. The committee chairs of the PLAC, the Medical Services Advisory Committee, and the TGA's Advisory Committee on Medical Devices met periodically to discuss opportunities to better coordinate activities
- Health Economics and Research Division, Medical Benefits Division and Portfolio Strategies Division to draft the Government response to the Senate Community Affairs References Committee Inquiry into the Number of Women in Australia who have had Transvaginal Mesh Implants and Related Matters.
- We also work with Immunisation Branch in OHP on vaccines including a joint committee ACV.

6.3b

Information on interactions with other Australian government departments, regulators and statutory authorities.

We work closely with related Australian Government departments, regulators and statutory authorities to ensure the effectiveness of our regulatory functions, including interactions with:

- Australian Pesticides and Veterinary Medicines Authority, Food Standards Australia New Zealand and state and territory health departments regarding scheduling proposals
- National Health and Medical Research Council and Department of Health and Human Services Victoria on clinical trials, including the new version of the Australian Clinical Trial Handbook
- HealthPACT on new and innovative medical devices
- Australian Competition and Consumer Commission and state and territory health departments on therapeutic goods recalls and complaints about the advertising of therapeutic goods
- Department of Industry, Innovation and Science regarding interactions with SMEs
- Consumer Health Regulators Group
- state and territory health departments regarding changes to the availability of low-dose codeine containing medicines and other scheduling matters
- OBPR to ensure that regulations that are being considered are appropriate, responsive and comply with the Government's regulation policy framework
- Department of Foreign Affairs and Trade on implementing programs under the Health Security Initiative for the Indo-Pacific region and development of free trade agreements and treaties
- The Department of Environment and Energy regarding the proposed ratification of the 'Minamata Convention on Mercury' to minimise impacts of mercury on human health and environment.

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