

# Regulator Performance Framework

# Self-assessment Report

July 2016 to June 2017













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# 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 assessed by the TGA and entered on the Australian Register of Therapeutic Goods (ARTG). At 30 June 2017 there were 87,258 therapeutic goods on the ARTG.

The TGA regulates the supply of:

The TGA is responsible

for ensuring that

therapeutic goods

available for supply in

Australia are safe and

fit for their intended

purpose

- medicines prescribed by a doctor or dentist
- medicines available in the pharmacy
- · medicines available from other retail outlets
- complementary medicines, such as vitamins, herbal and traditional medicines
- medical devices, from simple devices like bandages to complex technologies like heart pacemakers
- products used to test for various diseases or conditions (in vitro diagnostic devices (IVDs)), such as blood tests
- vaccines, blood products, and other biologics
- other products that make therapeutic claims.

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

More information about how therapeutic goods are regulated in Australia can be found on our website (www.tga.gov.au).

### Overview for 2016-17

In 2016-17 we continued to deliver 'world-class' regulation of therapeutic goods, contributing to better health outcomes for Australians<sup>1</sup>. We began implementing the response to the Review of Medicines and Medical Devices Regulation (MMDR), announced in the 2016-17 Budget. The first legislative changes to implement the reforms were enacted in June 2017. A major challenge was commencing the implementation of regulatory reform, while maintaining core activities associated with providing high quality regulation of therapeutic goods in Australia. This challenge is expected to continue in 2017-18 as implementation of regulatory reform continues.

CEO, Medicines Australia, https://medicinesaustralia.com.au/media-release/independent-review-of-tga-provides-sensible-solutions-to-accelerate-access-to-new-medicines/



### 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) 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 allows 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. Further information on the Government's Framework is available at: https://www.cuttingredtape.gov.au/resources/rpf



### 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 also includes a series of measures that assist in 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 this year's reporting period we gathered 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 the evidence collected, we assessed ourselves against the KPIs, giving ourselves a rating of met, substantially met or not met.

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

We then finalised and published this report, identifying both our self-assessment rating, the feedback provided by our external validator and opportunities for improvement in the 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 2016-17

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.



or online publications and other means.

**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 2017-18			
KPI 1  Met  Regulators do not unnecessarily impede the efficient operation of regulated entities	This rating is based on extensive formal and informal consultation and participation in industry events. We implemented business improvements based on the feedback we received through consultation with industry, resulting in less impost on industry in meeting regulatory requirements. We implemented a number of initiatives associated with business improvement and in response to MMDR recommendations that have been co-designed and influenced through engagement with key stakeholders.	We will continue to focus on providing extensive informal and formal consultation opportunities for regulated entities to ensure that we do not unnecessarily impede their efficient operation. We will ensure that our consultation is appropriately targeted and that industry comments on changes to regulatory practice are appropriately considered.			
KPI 2 Substantially met Communication with regulated entities is clear, targeted and effective	While the majority of our deliverables under this KPI were met we did not meet all our timeframes for application audits on medical devices. The timeframes are not mandated through legislation but are self-imposed. The legislated timeframes for medical device conformity assessments were met in all cases.	We will continue to strive to process applications (including auditing of medical devices) within target timeframes while providing consistency in decision making.  We will continue to deliver regulatory information in a clear, targeted and effective manner through consultations			

Self-assessment rating and summary of overall performance					
KPI	Comments	Our ongoing focus for 2017-18			
KPI 3  Met  Actions undertaken by regulators are proportionate to the regulatory risk being managed	This rating is based on our risk based approach to the regulation of therapeutic products. We have continued to develop risk based frameworks aimed at enhancing voluntary compliance by regulated entities. Our approach to risk is proportionate to the risk regulated. We monitor signals of non-compliance and base our intervention on compliance history.	We will continue to provide transparency with respect to our regulatory compliance activities by publishing the outcomes of the activity undertaken.  Internal system improvements will reduce our reliance on requests for information where we already hold information relevant to an application.			
KPI 4 Substantially met Compliance and monitoring approaches are streamlined and coordinated	This rating is based on our maturing compliance and enforcement framework. We have established an intelligence team, and are improving our investigations and enforcement capability. To support this, new compliance and enforcement powers are proposed in Bill 2 which was introduced into Parliament on 14 September 2017.	We will embed the strategic policies developed over 2016-17 that relate to our monitoring and compliance activities.  We will prioritise our activities in accordance with our Regulatory Compliance and Enforcement Plan and continue to collaborate with Commonwealth, state and territory regulators as well as our international counterparts.			
KPI 5  Met  Regulators are open and transparent in their dealings with regulated entities	This rating is based on our provision of clear and accurate regulatory guidance and education about our regulatory activity. We report extensively about the activity we undertake.  Guidance and education activity included the launch of SME Assist, a program that supports small to medium enterprises and researchers to better understand our regulatory environment and their obligations.	We will continue to revise published regulatory guidance, including through SME Assist, to ensure it is clear, practical and useful to industry.  We will provide more targeted guidance around over-the-counter and complementary medicines.			
KPI 6  Met  Regulators actively contribute to the continuous improvement of regulatory frameworks	This rating is based on our stakeholder engagement and self-evaluation through market research, continued improvements through MMDR and other reforms as well as interactions with other regulators.	Cooperation across the department as well as with other agencies will continue as will consultation through Regulatory Impact Statements.  We will look for opportunities to improve our engagement with consumers and other stakeholders, including our international counterparts, in order to ensure confidence in the efficacy, safety and quality of therapeutic goods in Australia.			

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



We met KPI 1 by undertaking extensive formal and informal consultation and participating in industry events. We implemented business improvements based on feedback we received through consultation with industry, resulting in less impost on industry in meeting regulatory requirements.



Most external validators concluded that our consultation activity demonstrated a good understanding of the operating environment of industry and allowed industry to provide formal feedback on matters of importance.

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.

Over 100 formal stakeholder events and numerous informal events.

Increased our online engagement through webinars.

MMDR 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 through finalising two Regulation Impact Statements (up-scheduling of codeine and medicine labelling).

**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.



#### Continuous improvement 2017-18

We will continue to deliver extensive formal and informal consultation, improving our consultations by ensuring they are targeted to issues identified by industry as significant.

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 2016-17 we participated in over 100 formal stakeholder forums that included attendance and participation at industry events, regulatory workshops for stakeholders and bilateral meetings with industry groups.

We increased our online engagement through webinar meetings, providing a more accessible platform to engage with industry stakeholders irrespective of location. Six webinars were presented in response to topics requested by industry and on key consultations, with attendance ranging between 25 and 125. This improved our understanding of industry views. Feedback on these forums from industry participants and healthcare professionals has been consistently positive.

We are implementing a series of reforms to address MMDR recommendations and have undertaken consultation to inform tangible improvements in our regulatory practices, balancing industry needs with our responsibility to ensure the safety and efficacy of therapeutic goods. An example included a webinar to discuss the proposal to reformat Product Information (PI) documentation with feedback from over 70 industry participants influencing changes to the proposed new format of PIs. Industry lauded the success of these events and, based on this positive feedback, we are planning to increase our webinar engagement in future.

In late 2016, we held an information session and workshop with industry representatives on the proposed eligibility criteria and designation process for the Priority Review and Provisional Approval pathways and the Priority Review registration process. This was also an opportunity to discuss related reforms such as the Orphan Drugs program, the proposed Black Triangle Scheme, and changes to notifications for variations of prescription medicines. We held a further workshop in early 2017 focusing on the Provisional Approval pathway that involved industry, health professional and consumer representatives. These workshops assisted in developing the policy and business processes for the Priority Review and

Provisional Approval pathways. Industry advice has informed many components of the projects, including development of guidance documents, changes to legislation, and the development of new fees.

We engaged in public and targeted consultation with industry on the development of the expedited pathways for prescriptions medicines and an e-Form for minor variations to prescription medicines. Three information sessions regarding the e-form for minor variations to prescription medicines were held to assist industry with navigating the new form and providing feedback on improvements to the e-form which we subsequently implemented.

We delivered 10 presentations and workshops to explain proposed complementary medicines reforms and inform stakeholders about timelines for reform projects well in advance of implementation.

We actively engaged with industry on the decision to up-schedule codeine from February 2018. In 2016-17 we coordinated six meetings of the National Coordinated Codeine Implementation Working Group, comprised of representatives from state and territory health departments and peak professional bodies representing consumers, pharmacists and health professionals. The Working Group agreed to a communication and engagement strategy and developed stakeholder education material for dissemination. We also held a forum in May 2017 to provide industry product sponsors with information on the up-scheduling changes and the implications for their current stocks.

We facilitated quarterly meetings with medical device peak bodies via the Regulatory and Technical Consultative Forum (Reg Tech) to prioritise and discuss issues of concern and propose solutions, including opportunities to improve current regulatory practices and compliance. Industry consultation and advice aided preparations for an information day for medical device sponsors. We held six workshops for sponsors of medical devices to provide education on their roles and post-market responsibilities. Industry feedback was positive and will inform future educational materials.

The TGA-Industry Working Group on Good Manufacturing Practice met three times in 2016-17. Members provided feedback on a range of Good Manufacturing Practice (GMP) issues including development of the Licensing and Certification Guidance document and GMP Clearance Guidelines which provide clarity on our regulatory processes.

Annual bilateral meetings were held in February 2017 with nine peak industry bodies to present our financial performance and discuss fees and changes proposals for 2017-18.

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. Further information is available at KPI 2.2a. 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.

In 2016-17, our informal interactions included:

- hosting meetings with industry to discuss changes to the scheduling of poisons and medicines and remaking of the Poisons Standard legislative instrument
- participation in a Complementary Medicines Regulatory Obligations Seminar, where four presentations were delivered to sponsors, manufacturers and regulatory affairs consultants on regulatory requirements and upcoming reforms to the regulatory framework for complementary medicines
- allowing sponsors extra time to update ARTG records in response to a compliance project for complementary medicines with biomarker indications, thereby reducing likely losses incurred by sponsors
- meetings to discuss licensing and certification of manufacturers and GMP clearance applications submitted by Australian sponsors
- a workshop with the Association of Regulatory Clinical Scientists (ARCS) on Risk Management Plans and pharmacovigilance in June 2017
- participation in an industry forum in May 2017 about the codeine re-scheduling decision.

We provided support to sponsors on potential safety and performance issues with respect to medical devices, including:

- facilitating regular industry presentations on device regulation which gave staff the opportunity to improve their knowledge of emerging technologies, innovative products and industry priorities
- ongoing updates to laboratory stakeholders on the transition period and regulatory requirements for inhouse IVDs
- user testing of new web-based interfaces for Conformity Assessment applications
- provision of assistance to sponsors on the regulatory framework for medical devices via the medical device information line
- meetings with the Australian Red Cross Blood Service to discuss changed inspection frequencies, licensing of mobile sites and implementation of eSignatures on GMP licences.

In August 2016 we hosted an exhibition space at the ARCS Scientific Congress, attended by over 900 delegates from the therapeutics industry and clinical research organisations. This platform provided an informal opportunity for face-to-face engagement with industry representatives and clinical scientists who made ad hoc enquiries relevant to the regulation of therapeutic goods, and to gather input on the regulatory issues that impact on businesses.

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.

In 2016-17 we prepared two RISs, one on the up-scheduling of codeine and the other on medicine labelling. Both of these were found to be compliant by the Office of Best Practice Regulation. We engaged with industry stakeholders prior to finalising the RISs to ensure minimal impact on regulated entities and product supply. The RIS for the re-scheduling of codeine was supported by independent economic modelling conducted by KPMG.

Over the last 10 years stakeholders have alerted us to concerns about labelling and packaging of medicines, including the contribution of naming, labelling and packaging practices to the safety and quality use of medicines. A number of consultation processes have focussed on these concerns, most recently the Transparency Review, the Labelling and Packaging of Medicines Review and the Round Table on Safer Naming, Labelling and Packaging of Medicines.

On 9 August 2016, we announced new requirements for the presentation of information on medicine labels. The new requirements aim to make Australian medicine labels clearer and more consistent and consequently help to avoid medication errors. The new medicine labelling standards require greater prominence and consistent location of information on active ingredients, and specify new allergens to be declared on medicine labels. A four year transition period was provided to allow industry to adopt the label changes with minimal compliance costs.

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 recordkeeping 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.

We are well advanced with the transition to digital processes. During 2016-17 an estimated 90% of submissions for medicines, devices and biologicals were provided in electronic format. This figure increased from 75% in June 2016 and is expected to increase again in the next year. This created efficiencies related to unnecessary duplication, storage costs, easy access to information, and improvement in the delivery of services and response times.

The following initiatives assisted our transition to digital processes:

- internal education to reduce the creation of physical files to meet Digital Continuity 2020 targets
- completion of four digitisation projects
- development of the Prescriptions Medicines minor variation e-form
- completion of the Information and Records Management Strategy.

These initiatives have facilitated end to end digital work processes which provided more mature and efficient services, enabling better productivity and responsiveness to industry.

1.3b Progress of the strategies being implemented under the business improvement program and other specific projects aimed at reducing compliance costs for industry.

During 2016-17 we implemented a number of initiatives through the Business Services site, aimed at reducing compliance costs for industry. These included:

- development of a new online Conformity Assessment application form for medical devices for implementation in 2017-18
- implementation of a new Conformity Assessment Certificate Repository which will facilitate the automatic generation of certificates at the conclusion of a Conformity Assessment application
- development of a new Adverse Event Management System (AEMS) to support both medicines and medical device adverse events, which will be launched in the next reporting period
- launch of a Prescription Medicine Minor Variation e-Form to permit electronic lodgment of forms and supporting evidence for minor variations in prescription medicines.

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



Our self-assessment rating of substantially met is based on medical device timeframes for application audits not being met, although these timeframes are not mandated in legislation. The legislated timeframes for medical device Conformity Assessment were met in all cases.



The level of our consultation with industry was described as "first rate". We were also referred to as a model regulator.

**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.

31 public consultations held with more than 1,600 submissions received and considered.

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.

Launch of the MedSearch app, and continued efforts to ensure availability of therapeutic goods information.

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

22 reviews of original decisions were conducted, with two (9%) being substituted.



### Continuous improvement 2017-18

We will continue to strive to process applications (including audits of medical devices) within target timeframes while providing consistency in decision making.

We will continue to deliver regulatory information in a clear, targeted and effective manner through consultations or online publications and other means.

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. Web Content Accessibility Guidelines (WCAG) requirements include the need for the content to be findable, scannable, readable and accessible. A systematic approach to maintaining content is also applied. We have continued to refine our website search platform and our standard database model through which data can be easily discovered, navigated and disseminated.

90% of TGA information on our website is WCAG2.0 compliant. The remaining content includes a large number of third party documents, for example consultation submissions, Product Information (PI) and Consumer Medicine Information (CMI) documents.

We actively monitor and review material on the website to ensure it meets WCAG2.0 compliance requirements, and is user-focused.

2.1b Improvements made to guidance documents, forms, and information on the TGA website

We have undertaken significant work in improving our guidance material with a focus on providing information about new and changed regulatory requirements, such as those resulting from MMDR reforms.

Two new labelling orders were determined in August 2016 after extensive consultation. We published guidance to help sponsors and manufacturers of medicines meet the new labelling requirements, and information for consumers and health professionals. The new requirements specify more substances that must be declared on a label if they are present in a medicine. We explained the timeframe of the new labelling requirements and listed the allergens that will be declared on labels that meet the new requirements.

Following the decision to down-schedule medicinal cannabis, we published an overview of the regulation of medicinal cannabis which explains the roles of different regulators. We also published specific information about access, manufacture

and conforming with the new therapeutic goods order TGO 93 (Quality Standard for Medicinal Cannabis Products).

As part of MMDR reforms, guidance was developed on the new process to notify us of minor changes to registered medicines that did not affect safety, efficacy or quality. Existing guidance on making minor variations to prescription medicines was also updated. We published new guidance on Priority Review designation and eligibility criteria as part of the implementation of the new Priority Review pathway.

For sponsors of listed medicines, we explained how non-compliance can be avoided. The web page on compliance and education for listed medicines provides advance notice of timeframes, expectations and impacts of compliance reviews. This enables sponsors to prepare for reviews and reduces the likelihood of lost business due to non-compliance.

We provided guidance on:

- products containing folate or folic acid for sponsors
- compounded medicines and dose administration aids for medicine manufacturers
- clinical evidence for medical device manufacturers
- how to vary an ARTG entry for a biological and a medical device.

Over the period we amended or published over 51 new guidance documents.

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2.1c Number of educational materials and other documents developed or updated for stakeholders (industry, consumers, health professionals). Number of downloads of these from the website and social media, and data on user satisfaction where available.

We published 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. Ensuring stakeholders are aware of MMDR reforms and how they impact on industry is critical to successful implementation.

Key materials included:

- a codeine 'Information Hub' centralising information on the codeine scheduling decision
- a webpage with information specific to complementary medicines regulatory reforms
- a draft list of permitted indications and other materials to support implementation of the permitted indications reform, allowing sponsors and industry to comment and suggest additions prior to the list being finalised

- an access to medicinal cannabis flow chart explaining access pathways for unapproved medicinal cannabis products
- a landing page for the new Priority Review pathway for the registration of prescription medicines and guidance documents to assist sponsors with making an application for Priority Review designation.

The information in the following tables focuses on materials either developed or updated during 2016-17. Additional materials are made available to stakeholders via our website and social media channels.

Industry content: downloads and views through various TGA media channels for the period July 2016 to June 2017

Name of material	New or updated	Format	Publication medium	Number of views/ downloads
Medicines and medical devices regulation review	New	Landing page & related content	TGA website	12,810 views
Medicinal cannabis products: overview of regulation	New	Web page	TGA website	6,000 views
SME Assist	New	Landing page & related content	TGA website	3,015 views
Medicinal cannabis - what's happening?	New	Presentation	Slideshare	2,594 views
Current manufacturing inspection trends	New	Presentation	Slideshare	1,470 views
Compliance and education for listed medicines	New	Web page	TGA website	1,435 views
Making an ACE declaration	New	Video	YouTube	473 views

Consumer & Health professional content: downloads and views through various TGA media channels for the period July 2016 to June 2017

Name of material	New or updated	Format	Publication medium	Number of views/ downloads
Access to medicinal cannabis products	New	Web page	TGA website	25,965 views
Australia's medicine labels are becoming clearer	New	Web page	TGA website	8,687 views
<u>MedSearch</u>	New	Landing page & related content	TGA website	3,155 views
Consumer fact sheet: Codeine- containing medicines: Harms and changes to patient access	New	Web page	TGA website	2,429 views
Special Access Scheme: frequently asked questions	New	Web page	TGA website	1,748 views
Oral probiotics indicated for vaginal conditions	Updated	Web page	TGA website	1,435 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 conduct consultations as part of our broader stakeholder engagement work.

For some change processes, such as amendments to our legislation or regulations, a consultation process is required in advance of a decision. The consultation may be part of a RIS or it may be used to inform a RIS that is developed after the feedback from the process has demonstrated a need for change. Where an issue is significant, in order to obtain valuable feedback, we may conduct a consultation absent of any formal requirement to do so. We also use the consultation process to review our existing business practices to ensure they

are operating efficiently, minimise the administrative burden for industry and ensure timely approval of therapeutic goods for use in Australia.

We publish information about all formal consultations on our website including information about the scope of the consultation and timeframe, as well as background to the consultation and how to provide a submission. We review all submissions and provide feedback through our website. The submissions we receive are also published on our website.

At the conclusion of a consultation, we publish a TGA Response and Outcome Summary. The Outcome Summary provides information about our consideration of the feedback of our stakeholders, and how we aim to address their concerns or comments.

During the reporting period we engaged in 31 formal public consultations, 13 of which were undertaken to inform the implementation of MMDR recommendations. Industry feedback has informed our position in relation to upcoming changes to the *Therapeutic Goods Act 1989* and the Therapeutic Goods Regulations 1990.

A key area of the stakeholder survey focuses on collaboration, consultation and feedback. Consistent with the previous reporting period, these measures show more opportunities for improvement compared with other focus areas of the survey. While outcomes for these areas were not as strong overall, the results were generally more positive than negative, with evidence of year on year improvement. The strongest outcomes were in relation to the ability to proivde feedback (68% in 2016-17 compared with 62% in 2015-16), as well as a strong rise in relation to the range of feedback channels (53% compared with 46%) and opportunities to provide input into key decisions (68% compared with 62%).

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, encourage submissions, and invite questions about consultations in an informal setting. Further details about our conference and event participation are available on our website.

Three targeted consultation forums were held to 'co-design' complementary medicines reforms. The forums included large, medium and small sponsors, industry peak bodies, manufacturers and consumers. Discussions assisted in shaping

the content of our public consultation paper and ensured transparency in the development of reforms.

Affected stakeholders, including medicine sponsors, healthcare practitioners and other government bodies were consulted in the review of safe use of flexible intravenous fluid bags. This input informed the decision that new labelling requirements were not an appropriate regulatory measure. Instead, educational material was prepared to inform practitioners of risks and to highlight existing label advisory statements.

The NSW Poisons Information Centre (as representative of all six Australian centres) and potentially affected sponsors were consulted as part of the review and re-making of the ministerial standard *Child-resistant packaging requirements for medicines*.

We presented ARCS webinars on:

- Expert review of medicines and medical devices regulation (December 2016) outlining proposals for implementation of several recommendations from the Review of MMDR relevant to prescription medicines
- including expedited pathways for registration, enhanced post-market monitoring, variations to registered medicines, work sharing with comparable overseas regulators, and the use of overseas assessment reports
- Update on PI reformatting have your say (May 2017) including information on our project to reformat PI documents.

We actively engage with medical device peak industry bodies formally and informally. We hold quarterly meetings of RegTech. A key focus of RegTech in 2016-17 was the transition to the new IVD framework for commercial and in-house IVDs. Guidance material was developed in response to stakeholder consultation and we collaborated with RegTech members to prepare material for a biennial Medical Devices Sponsor Information Day to help industry understand and engage with medical device regulation.

We involved industry representatives in user testing activities for the new online application form for Conformity Assessment; outlined common errors with medical device applications (and clinical evidence) with key industry bodies so they could share this information with their members; and discussed with peak industry groups a project to enhance post market monitoring and analytics for medical devices.



### **Priority Review pathway**

As part of the Government's Response to the Review of Medicines and Medical Devices Regulation, we developed and implemented a Priority Review pathway on 1 July 2017. The Priority review pathway benefits our different stakeholders by:

- providing consumers and healthcare professionals with faster access to new medicines
- providing sponsors with a predictable and transparent pathway to formalise the expedited registration process.

In October 2016, we consulted publicly on the proposed eligibility criteria and designation process for both Priority Review and Provisional Approval. We received 33 submissions, which showed broad stakeholder support for the proposed approach, with suggested modifications to the eligibility criteria; timeframe for lapsing the designation; and publication of designation decisions.

Stakeholder feedback informed the policy position and changes to the Therapeutic Goods Regulations 1990. The eligibility criteria were revised to ensure alignment with similar approaches taken by overseas regulators while meeting the Government's objectives for the expedited pathways.

We received direct feedback from an industry workshop in November 2016 and also eight submissions in response to targeted industry consultation on the Priority Review designation and registration processes conducted in late 2016.

We worked collaboratively with industry to develop our flexible Priority Review business process, with a target timeframe of 150 working days. Industry feedback informed the supporting guidance material which reflects the details of the pathway. The guidance is an evolving document that can be updated to address or clarify new issues as they arise.

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.

In response to the MMDR review, the *Therapeutic Goods Act* 1989 has been amended to provide review and appeal rights for persons who apply to have a new ingredient permitted for use in listed complementary medicines. The legislative amendments increase transparency of our administrative processes, improve procedural fairness and remove barriers to business.

The published guidance documentation on the Priority Review pathway and the Orphan Drug program includes details of how TGA delegates will make decisions regarding eligibility for these designations and how they will be published on our website. This provides transparency of these new processes for sponsors to consider before making an application.

Information on post-market regulatory decisions detailing the basis for the decision are published on our website, including details of medical devices (including IVDs) that have been cancelled or suspended from the ARTG, the provisions under which the cancellation or suspension was undertaken, and the grounds for each.

2.3b Percentage of pre-market applications and post-market activities processed in target timeframes.

Detailed statistics on processing of pre-market applications and post-market activities and associated timeframes are provided in the *TGA Annual Performance Statistics Report 2016-17* which is available on our website.

The percentage of pre-market applications processed within their respective timeframes were:

- 100% of prescription medicine applications (new chemical entity, fixed dose combinations, extension of indications and generic medicines)
- 100% of new over-the-counter medicine applications
- 100% of medical device conformity assessment applications
- 100% of medical device (including IVD) inclusion applications not selected for audit
- medical devices (not-IVD) 59% of non-compulsory audits, 80% of Level 1 compulsory audits and 24% of Level 2 compulsory audits

• IVD medical devices - 80% of non-compulsory audits and 77% of compulsory audits (mTFR).

In relation to post-market activities, 95% of medical device incident reports were processed within target timeframes.

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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 issue news updates, tweets and public notices for consumers, health professionals, industry and the community. When published on our website, ARTG entries include, where applicable, the approved PI and CMI documents. We also launched MedSearch™, an app designed for use by the general community and health professionals which provides easy mobile access to PI and CMI documents for medicines.

Quantity of information by type published on the TGA website for the period July 2016 to June 2017

Type of information	Number
Australian public assessment reports (AusPARs)	51
Expert advisory committee meeting statements	21
Scheduling advisory committee interim and final decisions	12
New Chemical Entities (NCE) approvals	34
Extension of Indications (EOI) approvals	51
Web statements: recalls/medicines safety alerts/suspensions	Medicines - 78 Medical devices – 47
Medicines Safety Updates	5
Medical Devices Safety Updates	6
Early warnings - potential safety issues	2
Medicine shortage web statements	6

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 recall actions undertaken in Australia. In 2016-17, SARA published 632 recall actions which included 32 medicine, 598 medical device and 2 biological recall actions.



### MedSearch App

A graduate group in the Department of Health developed the MedSearch app – taking the product information search capability available on the TGA website and recreating it for iOS and Android mobiles. The app allows health professionals and consumers to quickly search for and retrieve product information, including scientific information about medicines and using medicines safely and effectively. The MedSearch app also includes extra features, such as the ability to add results to a favourites list for easy access.

The availability of the MedSearch app means that medical professionals and consumers can access up to date PI and CMI anytime and from anywhere. This app significantly enhances the availability of information to assist with using medicines safely, effectively and in line with their intended purpose.







#### 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 2016-17 only twenty-two formal regulatory decision reviews were conducted including two (9%) for which the original decision was revoked and substituted without consideration of additional information. Both of these were in relation to Special Access Scheme (SAS) Category B applications.

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 2016-17, we were party to ten matters before the Administrative Appeals Tribunal. Of the ten matters, three applicants seeking review of the original decision withdrew their appeal. One matter was resolved by way of consent orders. One matter progressed to hearing and the TGA's original decision was upheld by the tribunal. In relation to a further matter that went to hearing, the AAT had not handed down its decision by the end of the reporting period. The remaining four matters were before the AAT at the time of preparing this report. 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 self-assessment rating of met is based on our risk based approach to the regulation of therapeutic products. We have continued to develop risk based frameworks aimed at enhancing voluntary compliance by regulated entities. Our approach to risk is proportionate to the risk regulated. We monitor signals of non-compliance and base intervention on compliance history.



Most external validators agreed with our self-assessment, noting that our regulatory framework is risk based and addresses risk similarly to other jurisdictions.

Evidence

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

64% increase in investigations undertaken.

Publication of laboratory results.

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.

Effective prioritisation of compliance activity through the regulatory framework and Regulatory Compliance and Enforcement Plan.

Monitoring and appropriate prioritisation through the Regulatory Compliance Committee.

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 2017-18

We will continue to provide transparency with respect to our regulatory compliance activity by publishing activity outcomes.

Internal systems improvements aim to reduce our reliance on requests for information where we already hold information relevant to an application.

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 the reporting period 5,407 products were investigated, comprising prescription medicines (82%), complementary medicines (11%), Over the Counter medicines (1%), biologicals (0.5%) and medical devices (3%). Of the 2,978 completed investigations, 2,054 warnings were issued. 1,774 of these warnings were for prohibited importation of therapeutic goods and all of these goods were destroyed. 94% of compliance investigations involved the importation of therapeutic goods and 5% involved supply.

There was a significant increase in the number of products investigated (64%). Although we use intelligence from a range of sources, the increase was largely attributable to continued referrals from Australian Border Force in relation to the importation of unapproved prescription medicines.

In 2016-17 forty one safety alerts were published on our website as a result of compliance action.

Our strong compliance and enforcement program ensures that products intended for supply outside of the therapeutic goods regulatory framework are removed from the market. This assists industry in maintaining product integrity and meeting community expectations in relation to the safety and quality of therapeutic goods.

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 compliance to identify entities at risk of unintentional or deliberate non-compliance and to collect intelligence in relation to alleged breaches of the *Therapeutic Goods Act 1989* and the Therapeutic Goods Regulations 1990. Publication of evidence relating to our compliance activities on our website through a range of reports, notices and results provide transparency for industry and other stakeholders. Our *Half Yearly Performance Snapshot July to December 2016* and *Annual Performance Statistics Report July 2016 to June 2017* include detailed 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 44 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. While no Regulation 9 orders (to withdraw an advertisement and publish a retraction or correction) were issued in 2016-17, we are working towards publishing the outcomes of recommendations resolved through an educative approach in the next reporting period.



### Publication of Laboratory Results

The TGA laboratories test therapeutic goods to monitor compliance with regulatory requirements and to investigate adverse events, problems and complaints. The testing program is an important part of our post-market monitoring scheme and whole-of-life-cycle approach to regulation.

We use a risk-based process to determine which products are selected for testing and what tests are performed and we allow capacity to respond quickly to emerging issues in the marketplace.

In response to the Contestability Review of TGA Laboratories and the MMDR Review, in 2016-17 we undertook to publish laboratory testing results to:

- increase transparency and understanding of how our testing program contributes to regulation of therapeutic goods
- increase consumer confidence in therapeutic goods supplied in Australia
- encourage industry knowledge of, and compliance with, legislative requirements
- promote our post-market monitoring activities
- align with other regulators who publish testing results.

The Database of TGA Laboratory Testing Results was launched on 5 June 2017 providing information to the public about the 2000-plus samples we test each year. Consumers and health professionals can now clearly see which products have been tested, whether they passed or failed, and any regulatory action taken.

To complement the database and provide context for the published test results, the TGA website was updated with new content about testing of therapeutic goods. A new series of Tweets was also launched on Twitter with the hashtag #TGAlabs and includes interesting information and hyperlinks to relevant pages on the website.

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. 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, which provides information on risk assessment in the scheduling process for medicines.

We publish information in relation to risk profiles and our compliance activity to encourage voluntary compliance with the regulatory framework. This ensures that sponsors and others are aware of the risk based considerations that inform decision making throughout the life cycle of a product.

A risk based approach is being implemented as part of the Government's response to the Expert Panel Review of Medicines and Medical Devices Regulation. Reforms to the regulatory framework consider where reducing the level of pre-market assessment can occur while maintaining consumer protection. Where necessary, decreased pre-market activity will be balanced by increased post-market activity. Examples of adopting a risk based approach include allowing low risk variations to medicines to be made by notification where changes do not impact on safety, quality or efficacy, and allowing access to products of acceptable risk which are not listed on the ARTG via notifications.

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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.

Where we receive a complaint regarding advertising it is triaged and prioritised based on the risks that the advertising could pose, primarily to public health and safety, in accordance with our Regulatory Compliance Framework and regulatory responsibilities. Over the period we received 432 complaints about the advertising of therapeutic goods.

Further information is available at KPI 3.3.

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 undertake a range of regulatory activities across the organisation and apply a risk based approach as we regulate all stages of the product life cycle. We review risks associated with monitoring and compliance and streamline activities to minimise impact on regulated entities.

We employ risk-based matrices to guide the frequency of inspections of manufacturing facilities. Manufacturer performance at inspection is categorised as good, satisfactory, marginal and unacceptable with further granularity provided by applying a high, medium or low risk rating for the type of products being manufactured when setting the date for reinspection. Manufacturers with a strong history of compliance performance and lower risk are inspected less frequently. Those with poor compliance performance are rated higher risk and are inspected more frequently.

Before scheduling inspections, we 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 significant changes.

In consultation with industry, we have acknowledged the benefit of recognising manufacturers who consistently achieve a good outcome by implementing a modified reinspection regime. In conjunction with this new 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.

We also use a risk based approach to determine the classification and level (consumer, retail, hospital or wholesale) 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.

All recalls are risk assessed and classified into Class I, II or III which aids in prioritising recall actions. Class I and Class II actions are safety related. The highest priority is given to Class I issues which can, or have, resulted in serious injury or death to

patients or users. Class II issues are those which could cause illness, injury or result in mistreatment. Class III issues may not pose a significant hazard to health, but action may be initiated for other reasons e.g. quality related issues.

Of the 632 recalls for medicines, medical devices and biologicals undertaken during the reporting period, 119 were Class I, 462 were Class II and 51 were Class III.

All post-market safety-related activities are undertaken using a risk based approach. In accordance with our pharmacovigilance guidelines, mechanisms are used to monitor the safety of therapeutic goods, including:

- evaluation of Risk Management Plans, which describe how sponsors will monitor and mitigate known and potential safety concerns
- for medicines, regular review of adverse events reported to the Adverse Drug Reaction System
- communications with international regulatory agencies and Australian state and territory health authorities
- reviews of literature.

When a potential safety signal is identified for a therapeutic good it is prioritised for further investigation and follow-up action depending on the level of risk. Other areas of the TGA are notified and may undertake proactive compliance reviews of therapeutic goods or inspections of manufacturing facilities.

In 2016-17 we completed a voluntary pharmacovigilance Inspection Pilot Program. This involved inspection of participating sponsors' pharmacovigilance systems including records of adverse events and reports made to us. Following the success of the pilot, implementation of a full program is underway.

We use a risk management approach to select and prioritise products for testing by our laboratories. A risk assessment tool considers particular product groups against 16 risk sources to identify those with the highest relative risk. The proposed testing plan is independently reviewed annually to ensure it is appropriate, risk based and addresses priority areas.

# KPI 4 Compliance and monitoring approaches are streamlined and coordinated



The self-assessment rating of substantially met is based on our maturing compliance and enforcement framework. 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.



Our external validators provided mixed views on our self-assessment rating, noting that enhanced compliance and enforcement powers need to be coupled with improved compliance and monitoring systems.

**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.

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Sharing manufacturing inpsection 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.

Chairing and coordinating the Medicine Shortages Working Party.

Driving collaboration 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.

Enhancing post market monitoring to support a wider range of product approval pathways, making products available earlier.



### Continuous improvement 2017-18

We will embed the strategic imperatives identified in 2016-17, and prioritise our compliance and monitoring activities accordingly. We will continue to collaborate with Commonwealth, state and territory regulators as well as our international counterparts.

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 continually identify ways to improve our processes to minimise the number of formal requests for information made to regulated entities. We have improved the way we communicate with sponsors of new registered complementary medicines and new ingredients for use in listed medicines. We encourage sponsors of complementary medicines and new listed medicine ingredients to attend pre-submission meetings before submitting applications. This has allowed us to provide tailored advice and clarify the regulatory requirements.

When conducting compliance reviews, we encourage voluntary compliance by seeking information through informal mechanisms. Previously we issued formal notices to commence compliance activity. We now work to gather information we hold prior to contacting sponsors. This saves time for both sponsors and the TGA.

Our Investigation Unit undertakes informal liaison with sponsors when preparing responses to safety-related issues and requests information under the *Therapeutic Goods Act 1989* only when necessary. This liaison typically reaches satisfactory outcomes and formal requests for information are rare.

We have developed a new *Clinical Evidence Guideline for Medical Devices* which provides robust regulatory guidance that clearly communicates pre and post market requirements. This guidance was developed by working with the medical devices industry to pre-empt queries and address areas of confusion and to provide greater clarity and consistency for our own evaluators.

We are continuing to reform our business practices and data storage to make information more accessible and minimise the impact on sponsors from information requests in cases where we may already hold the required information. 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 Refer to KPI 1.3 –

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

Initiatives to collect information from sponsors, including the new TGA Business Services site, are captured under various business improvement programs as outlined in KPI 1.3b.

4.2b Information on cooperative activities carried out with international regulators to minimise information collection from industry (such as joint GMP inspections).

We are heavily engaged in the international regulatory community. Our strong relationships allow us to capitalise on the learnings of other therapeutic goods regulators and to lead regulatory improvement.

We regularly contribute to a system of sharing manufacturer inspection schedules with the United States Food and Drug Administration (US FDA), the European Medicines Agency (EMA), Health Canada and Pharmaceutical Inspection Cooperation Scheme (PIC/S) participating authorities. This activity identifies opportunities for joint inspections with international regulators and minimises burden on industry. We continue to focus on collaboration with other regulators to develop internationally recognised policies and share information that will reduce industry burden through harmonisation of regulatory requirements.

Nine joint GMP inspections were conducted in 2016-17 with agencies including the World Health Organization, the United Kingdom's Medicines and Healthcare Products Regulatory Agency, Health Canada and the US FDA. 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 also continued to collaborate with Health Canada under the Regulatory Cooperation Initiative program focusing on joint inspections and desktop assessment processes.

We have an active role in developing the international model for a Medical Devices Single Audit Program (MDSAP) through the International Medical Device Regulators Forum (IMDRF). The program allows MDSAP recognised auditing organisations to conduct a single audit of a medical device manufacturer that will satisfy the relevant requirements of the multiple regulatory authorities participating in the program.

As part of the TGA's program of pharmacovigilance activities, we regularly engage with other international regulators. Discussions are held with the International Post-Marketing Surveillance Teleconference, which is held bimonthly with the US FDA, Health Canada, New Zealand's MedSafe, the Health Sciences Authority Singapore and Swiss Medic and is co-chaired by the TGA. We also participate in teleconferences with New Zealand's MedSafe to discuss current safety issues and share information. As part of the International Coalition of Medicines Regulatory Agencies we are involved in exchanging experiences and knowledge about the use of health data sets and social media in safety monitoring. In some circumstances these information-sharing activities can help to minimise the need to collect certain information from industry.

We are on the Permanent Forum on International Pharmaceutical Crime management committee. This international enforcement forum protects public health through the exchange of information on crimes and trends and ideas to foster mutual cooperation.

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 maintain active working relationships with overseas regulators through participation in forums and consortia and we continue to expand our international network. Through the MMDR reforms, we are exploring opportunities to increase efficiency and reduce duplication by reducing assessment times for therapeutic goods and streamlining assessment processes between countries.

In 2016-17 we focused on maximising efficiencies in the assessment of therapeutic goods by continuing the generic medicine work sharing trial with other regulators in the Australia, Singapore, Switzerland, Canada (ACSS) consortium. We designed and shared assessment documentation for Complementary Health Products with ACSS and initiated work sharing opportunities for assessing new chemical entities with Health Canada.

We also worked towards streamlining formal information sharing between medicines regulators. The International Generic Drug Regulators Program (IGDRP) has undertaken a number of activities to promote collaboration and convergence amongst international regulators. We actively participate in working groups to align regulatory requirements internationally and minimise duplication for industry, such as:

- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Reproductive Toxicity Working Group
- International Pharmaceutical Regulators Forum Cell Therapy Working Group
- ACSS Generic Medicines Working Group.

We undertake desktop GMP clearances for overseas manufacturers in place of inspections, taking into consideration regulatory decisions by comparable regulators. Of the approved clearances during the reporting period, 92% were based on evidence from overseas regulatory agencies.

Formal processes for the use of international reports in the assessment of complementary medicines and ingredients for use in complementary medicines were designed in 2016-17 and will be implemented in the coming year. In the long term, this work will benefit industry by providing additional flexibility in the data that can be provided in support of applications.

We have continued to develop our work sharing arrangements with other international regulators for new chemical entities, generic medicines, pharmacovigilance and adverse events reporting under ICMRA. We also completed a pilot work sharing project with Health Canada in Periodic Safety Update Report evaluation.

Our involvement in IMDRF working groups on: Improving the quality of international medical device standards for regulatory use; Adverse Event Terminology; Good Regulatory Review Practices; Software as a Medical Device; Review of the National Competent Authority Report Exchange Program; and Regulated Product Submissions will enable consistent global standards, minimising the burden on Australian industry.

4.3b Collaborative work undertaken with health professionals. For example, interactions on significant medicine shortages, recall actions or safety issues.

The TGA chairs the Medicine Shortages Working Party with state and territory health departments, health professional bodies and industry associations to facilitate better communication relating to medicine shortages and dissemination of timely information. We also participate in quarterly meetings with the US FDA, Health Canada, the UK MHRA and the EMA to exchange information on current medicine shortages and processes to minimise their effects and ensure awareness of global shortages that may affect Australian health professionals.

We contact industry regarding medicine shortages to obtain current and accurate information about product inventory. This information is required to assist in answering enquiries from health professionals. We continue to work with industry to provide information on medicine shortages through the Medicine Shortages Information Initiative on our website. We have approved the supply of alternative medicines to health professionals where there is a significant medicine shortage.

Further interaction with the Medicines Shortages Working Party is anticipated following departmental resolution of strategic issues.

We collaborated with ACT Health and NSW Health in undertaking the medical device incident reporting and investigation scheme (IRIS inSite). The IRIS inSite program works closely with health facilities to improve awareness amongst health professionals about medical device adverse event reporting. The program has had a positive impact on the frequency, rate and quality of reports received and consequently our ability to safeguard therapeutic goods in Australia.

The TGA's Chief Medical Adviser works closely with the Commonwealth's Chief Medical Officer, the Clinical Director of the Australian Commission on Safety and Quality in Health Care and the Chief Health Officers of the states and territories to ensure a consistent approach to problems which may develop with medicines and devices.

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

KPI 3.3 provides detail of the activities undertaken to ensure we use a risk based approach to monitoring and compliance activities. We continue to work towards greater cohesion across compliance and monitoring functions, and the maturation of our intelligence function.

Further activities have been undertaken as part of the MMDR reforms which included enhancing post-market monitoring for medicines and medical devices. The program will deliver a range of new and enhanced post-market monitoring capabilities to enable us to proactively minimise, detect and address medicine and medical device safety issues. The capabilities span data analytics, international work and information sharing, adverse event reporting, and compliance. It will provide us with better information about emerging safety issues.

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



The self-assessment rating of met is based on our continued provision of clear and accurate regulatory guidance and education about our regulatory activity. We report extensively about the activity we undertake.



Our external validators mostly agreed that we provide clear and accurate regulatory guidance and education, citing the clinical evidence guideline and the SME portal as positive examples.

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.

Review of the Scheduling Policy Framework in consultation with the Commonwealth, states and territories.

**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.

Addressing approximately 180,000 public and industry enquiries through our information lines.

Launch of SME Assist.

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

Publication of performance reports for 2016-17 including:

Annual Performance Statistics Report Half Yearly Performance Snapshot Regulator Performance Framework Self-Assessment (KPI) Report.

### Continuous improvement 2017-18

We will continue to provide transparency through our annual reporting. We will provide regulatory assistance and improve our capacity to respond to enquiries. As we strengthen our regulatory guidance we anticipate greater compliance with regulatory requirements.

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

5.1a Refer to KPI 3.2 –
Information on the
TGA's risk framework
published on the TGA
website.

We support an open and transparent regulatory framework and continuous improvement as a regulator by providing ample opportunity for industry to provide feedback on our processes. We publish extensively on our website, making guidance and support available to assist with voluntary compliance as well as reporting our performance against regulatory performance timeframes and internally set targets.

We publish specific information detailing how we apply a risk based framework to compliance activity. Internally, we govern risk through our Regulatory Practice Committee and Regulatory Compliance Committee. We also provide regular 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, hotlines and the publication of educational material.

The Scheduling Policy Framework (SPF) governed by the Australian Health Ministers' Advisory Council provides guidance on the factors to be considered in a risk/benefit analysis for decision-makers within the Department of Health in the scheduling processes. The SPF is published on our website and is being reviewed as part of MMDR reforms.

Our therapeutic product vigilance activities are increasing as part of MMDR reforms. In February 2017 we introduced *Therapeutic Product Vigilance Guidelines*, which are available on the TGA website. The guidelines clearly outline our processes relating to product vigilance and the interaction of risk throughout the product lifecycle to support health product vigilance and benefit-risk management.

During 2016-17 we developed an *Orphan Drug Framework* which laid the foundations for an improved Orphan Drug Program. The objectives of the program are to provide incentives to sponsors to bring medicines for a small population to market and make medicines available to patients who would not otherwise be able to access them.

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. We also publish the following types of compliance information:

- Compliance undertakings
- Court actions
- Cancellations
- Suspensions
- Complaints about advertisements
- · Regulatory decisions and notices.

We employ a combination of monitoring strategies postmarket to support our compliance program, which enables us to apply flexible and proportionate responses to noncompliance, as well as proactively encouraging compliance and managing emerging issues. This is achieved through our continued communication strategies, ongoing publication of safety updates and workshops with industry on effective risk minimisation activities to improve the quality of risk management plans submitted with their applications for high risk medicines or vaccines.

Our regulatory compliance environment has been subject to extensive consideration through the review of Medicines and Medical Devices Regulation resulting in improvements to our regulatory framework. We have consulted extensively with stakeholders on proposed legislative reforms. With the passage of amendments to the *Therapeutic Goods Act 1989* and the Therapeutic Goods Regulations 1990 our compliance system will be given greater rigour, providing more certainty to our regulated industry.

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 have dealt with approximately 180,000 enquiries during 2016-17. Although approximate, these numbers demonstrate our high level of responsiveness to industry and the Australian public.

Our Regulatory Assistance Section manages telephone, email, fax and letter enquiry lines. During the reporting period 28,658 enquiries were received by the Section, of which 27% were from industry. Where responses were provided by the Section, 10 from industry 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. This was due to emails being quarantined as possible spam resulting in a delay in the response.

SME Assist, a new service to help small and medium enterprises (SMEs) better understand and navigate therapeutic goods regulation in Australia, was launched on 9 June 2017. A key barrier for small to medium enterprises entering the industry is a lack of understanding as to what the pathways and requirements are 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 and research and development groups developing new medicines and devices to help them understand their regulatory obligations.



# Small to Medium Enterprise (SME) Assist

In the first three weeks of operation SME Assist received 95 registrations from small and medium businesses across the medicines and medical devices sector, as well as 1,291 visits to the new SME Assist entry-point (www.tga.gov.au/sme-assist).

The top three issues of interest have been medical devices (69), complementary medicines (55) and Over the Counter medicines (35). During the month of June, the SME Assist front page received 1,291 page views with 1,006 of these being from unique users.

The new SME Assist service has been well-received by the sector – in particular the introduction of "decision-trees" which help small and medium business to identify and understand whether their product is considered a therapeutic good, and steps to achieve market authorisation. There was an engagement rate of 56.5% and 50.1% with the "Is my good a therapeutic good?" and "What classification is my medical device?" decision trees respectively. This percentage represents the number of people who landed on the page and clicked through the decision tree.

In the first three weeks of the tools becoming available, they have been used in over 200 cases to help companies understand whether therapeutic goods legislation and regulations apply to them, and point them in the right direction for further information and advice.

As part of the launch, education and training sessions were announced, the first of which is to help small and medium business to understand their regulatory obligations.

This initiative addressed issues raised as part of the MMDR review, and will directly contribute to reducing regulatory burden through helping small and medium business understand the requirements and obligations they need to meet for health products used in Australia.

Our Manufacturing Quality areas managed in excess of 10,000 enquiries in relation to GMP and requests for support or assistance from stakeholders in meeting their regulatory obligations.

We also manage a TGA Business Services (TBS) Helpdesk and a Product Billing Helpdesk. Between these two helpdesks we answered more than 50,000 enquiries.

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 Australian Government reporting requirements, the *Public Governance and Accountability Act 2013* and the interests and needs of our stakeholders through the following documents:

- 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 (annual)
- Prescription Medicines Annual Summaries (annual).

These reports are published on our website, or the Department of Health website. Where possible, we include an interactive component to our reporting through infographics to ensure our data is easily comprehensible.

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

We manage a number of advisory committees with external participants, including the:

- Advisory Committee on Biologicals
- Advisory Committee on Complementary Medicines
- Advisory Committee on Medical Devices
- · Advisory Committee on Medicines
- Advisory Committee on Vaccines
- Advisory Committee on Medicines Scheduling
- · Advisory Committee on Chemicals Scheduling.

General details of the matters considered by the Committees at each meeting are made available after the meeting through statements published on our website.

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



Our self-assessment rating of met is based on improvements in our stakeholder survey results, implementation of better consultation practices, finalisation of two regulatory impact statements and continued collaboration with key stakeholders, including Australian Border Force for compliance purposes.



Our external validators view the TGA as committed to continuous improvement, particularly through the implementation of the MMDR recommendations and subsequent regulatory improvements. We continue to work closely with sponsors to continue to improve the regulatory framework.

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.

Stakeholder survey results indicate improved satisfaction with TGA performance.

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.

Finalisation of two Regulatory Impact Statements, following significant consultation with industry.

Reduction in compliance costs for industry through introduction of electronic forms/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 2017-18

Cooperation across the department as well as with other agencies will continue, as will consultation through Regulatory Impact Statements.

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.

We annually survey our stakeholders to ascertain their views about our performance as a regulator of therapeutic goods and publish the full survey results on our website. We use the information collected from our market survey to help our stakeholders make more informed decisions about therapeutic goods and comply with our regulatory requirements.

For 2016-17 we invited 21,214 participants to complete our survey to gauge:

- level of awareness of therapeutic goods regulation, the TGA and specific regulatory activities
- · support and perceptions of us
- preferred sources of information about the regulatory system
- previous contact with us and use of existing information services.

We collected information from 2,535 respondents. Survey participants identified as health professionals (220) and medical products industry members (1,344), which includes product sponsors (766) and product manufacturers (398). Other groups included consumers and community members (13) or 'others' (570) such as retailers, academics, media and government. 388 respondents did not make a selection. Generally we report on the three major stakeholder groups of health professionals, industry and consumers, however with only 13 respondents identifying as consumers in the 2017 survey, we are unable to report those findings.

This survey is particularly informative in the context of our self-assessment against the Framework as it provides direct insight into the views of regulated entities. Key findings in relation to trust in the regulator, based on cooperative and collaborative relationships, for two of the major stakeholder groups are provided in the following tables.

Trust in the TGA to perform ethically and with integrity increased among all stakeholder groups by an average of 3%. Only 6% of health professionals and 4% of industry respondents disagreed that the TGA can be trusted to perform ethically and with

integrity, and 95% of both groups either agreed or were neutral in their responses when asked whether they believe the TGA provides safeguards for the health of Australians.

	Health professionals 2017	Health professionals 2016	Industry 2017	Industry 2016
Trust to perform role ethically and with integrity	84%	83%	90%	87%
Provide safeguards for the health of Australians	67%	74%	73%	77%

Across all surveyed groups, satisfaction with the experience of communicating with the TGA was observed at 69%, with 12% highlighting some level of dissatisfaction. This was an improvement on 2016 satisfaction and dissatisfaction levels of 63% and 15% respectively.

In 2017-18, we will be placing greater emphasis on communicating what the MMDR reforms mean for industry as well as health professionals and consumers. With respect to key decisions, such as those relating to strong opiates and medicinal cannabis we will be proactively engaging with affected groups, through meetings, seminars and educational materials. Our 2017-18 stakeholder survey will look to target feedback from consumer groups to ensure that we continue to improve our consultation and education approach to regulatory reform and decision making.

	Health professionals 2017	Health professionals 2016	Industry 2017	Industry 2016
Satisfaction with communicating with the TGA	70%	57%	70%	64%
Dissatisfaction with communicating with the TGA	10%	18%	11%	15%

More than half of industry respondents found TGA consultations very useful.

	Health professionals 2017	Health professionals 2016	Industry 2017	Industry 2016
TGA consultations very useful	42%	40%	54%	49%
TGA consultations slightly useful	20%	22%	14%	17%

## 6.1b Stakeholder engagement and satisfaction with TGA consultative processes.

Our annual program of market research described under KPI 6.1b found that more than half of respondents either agreed or strongly agreed that the TGA undertakes effective collaboration, consultation and feedback processes, while 24% were neutral.

	2017	2016
Percentage of stakeholders who agree or strongly agree that the TGA collaborates, consults and provides opportunities for feedback effectively	54%	48%
Percentage of stakeholders who disagree or strongly disagree that the TGA collaborates, consults and provides opportunities for feedback effectively	14%	19%

In response to the results from the 2015-16 annual survey, we expanded the membership of the TGA Industry Consultative Committee to include health professional and consumer bodies. The first meeting of the newly established TGA Consultative Committee was held in March 2017 where a range of issues were discussed, including progress of MMDR reforms.

The Government's response to the review of MMDR initiated a significant program of work, including stakeholder consultation to inform implementation of the recommendations. Thirteen MMDR-related public consultations were undertaken in 2016-17 in addition to targeted consultations. These included:

- receiving broad support to proposed implementation of reform projects in response to external consultation on assessment pathways for complementary medicines.
   A public consultation paper was released in February 2017 and 60 submissions were received.
- conducting two workshops, one with industry and the other with industry, health professionals and consumers as part of the development of the Priority Review and Provisional Approval pathways. These workshops were well-attended and we received informal positive feedback from participants on the format and opportunity to provide feedback.
- receiving 30 responses to the public consultation paper on the Provisional Approval pathway and 33 responses to the public consultation paper on the expedited pathways for prescription medicines, demonstrating interest and engagement from stakeholders.

- 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.

Please refer to KPI 1.2a for information on the two RISs finalised during 2016-17. We also engage with regulated entities prior to minor or machinery changes that may not require a RIS, such as updates to guidelines, and improvements to forms and systems used to conduct business. These consultative processes are consistent with our commitment to minimise the potential for unintended financial or resource impacts on industry. Refer to KPI 2.2a and our website for information about our formal consultations.

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. Please refer to KPI 1.3b for further information.



# Reform of Medicines and Medical Devices Regulation

The Government's response to the Review of Medicines and Medical Devices Regulation was released in September 2016, initiating a significant program of work, including stakeholder consultation, legislative changes and business improvement projects. The Review identified ways we can streamline our existing regulatory framework to improve consumers' access to new therapeutic goods, while still ensuring their safety and effectiveness.

Seven areas of work were agreed:

- 1. Increasing flexibility for registration and post-market processes for medicines
- 2. Increasing flexibility for approval and enhanced post-market monitoring of medical devices
- 3. Increasing flexibility for pre-market approval and increased evidence of efficacy of complementary medicines for consumers
- 4. Simplified and more effective regulation of advertising of therapeutic products
- 5. Streamlined regulation of patient-specific access to therapeutic products
- 6 Further reviews
- 7. Rationalisation of TGA statutory advisory committees.

Overarching principals for regulatory reform include maintaining Australia's capacity to undertake assessments of therapeutic goods for safety, quality and efficacy, and for approving the inclusion of therapeutic goods in the ARTG; introducing greater flexibility in approval pathways for both medicines and medical devices; and aligning the level of regulation with product risk.

The first tranche of legislative changes to implement the reforms, the Therapeutic Goods Amendment (2016 Measures No. 1) Act 2017, was enacted in June 2017. Supporting regulations – the Therapeutic Goods Legislation Amendment (2017 Measures No. 1) Regulations 2017 were also endorsed by the Governor-General in June 2017.

The number of TGA statutory advisory committees was reduced from 11 to 7 from 1 January 2017. The Review has reduced red tape for companies importing or manufacturing new medicines, medical devices or complementary medicines, while maintaining the confidence of Australian consumers in the safety, quality, and performance of therapeutic products available to them.

The implementation of regulatory reform that commenced in 2016-17 will continue in 2017-18 in a staged approach to allow for continuity of our routine regulatory business.

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 to promote and protect the health and wellbeing of Australians. We have worked with:

- Medical Benefits Division to streamline the regulation and reimbursement of medical devices; support the activities of the Prostheses List Advisory Committee; and utilise datasets for effective post-market monitoring
- Tobacco Control Branch, Office of Drug Control, National Industrial Chemicals Notification and Assessment Scheme and National Integrity of Sport Unit regarding scheduling proposals
- Pharmaceutical Benefits Division to discuss reforms to regulation of Orphan Drugs, Provisional and Priority pathways and address alignment with reimbursement policies
- Immunisation Branch to support the approval of vaccinations in response to increased rates of meningitis in children
- Jurisdictional Blood Committee to keep them appraised on the progress of relevant medicines approvals.

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:

- Office of Best Practice Regulation in accordance with the requirements provided in the Australian Government Guide to Regulation
- 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
- HealthPACT on new and innovative medical devices

- Australian Commission on Safety and Quality in Health Care and state and territory health departments on postmarket monitoring and vigilance activities for medical devices
- Department of Industry, Innovation and Science on designating medical device conformity assessment bodies under the EU-Australia Mutual Recognition Agreement as assisting with developing the SME Assist program
- other regulators such as the Australian Competition and Consumer Commission and the Australian Health Practitioner Regulation Agency to share information on compliance interests and priorities in relation to investigation and enforcement activities
- Australian Border Force to prevent therapeutic goods or counterfeit goods entering the country
- Department of Environment to understand ingredients which are included in an appendix to the Convention on International Trade in Endangered Species of Wild Fauna and Flora.

We conducted a pilot study with the Department of Foreign Affairs and Trade in March/April 2017 to determine the need for laboratory testing of medicines in four Pacific Island countries. The conclusions of this study were that these countries do not have the capacity to undertake the full range of regulatory activities required to assure the quality, safety and efficacy of priority medicines such as antibiotics and those used to treat non-communicable diseases. The Australian Government is exploring options to provide Pacific Island countries with access to the Australian medicines quality assurance laboratory testing program.

### Opportunities for Continuous Improvement

Our self-assessment along with industry feedback provided through the external validation process have assisted us in identifying opportunities for performance improvement in 2017-18. These include:

- delivering extensive formal and informal consultation, improving our consultation by ensuring we target issues identified by industry as significant
- processing applications within target timeframes while providing consistency in decision making
- delivering regulatory information that is clear, targeted and effective through consultation, online publications and other means
- prioritising our compliance and monitoring activity according to identified strategic objectives and collaborating with Commonwealth, state and territory regulators as well as our international counterparts
- providing transparency through regulatory assistance, responses to enquiries and annual reporting
- continuing cooperation across the department as well as with other agencies.

Many of our resources over 2017-18 will be directed at achieving the further implementation of the MMDR reforms, including:

- provisional approval pathway for promising new medicines that do not yet have a full dossier of clinical data
- certain 'low risk' minor variations to prescription medicines to occur via notification
- new pathway where the TGA has assessed efficacy of listed complementary medicines
- online system to manage SAS applications
- removal of pre-approvals for advertising and a single complaints handling function
- broadening of compliance and enforcement powers
- expedited approval pathway for 'novel' medical devices.

Further information about our planned activity is described in the *TGA Business Plan 2017-18* and is available on the TGA website.

