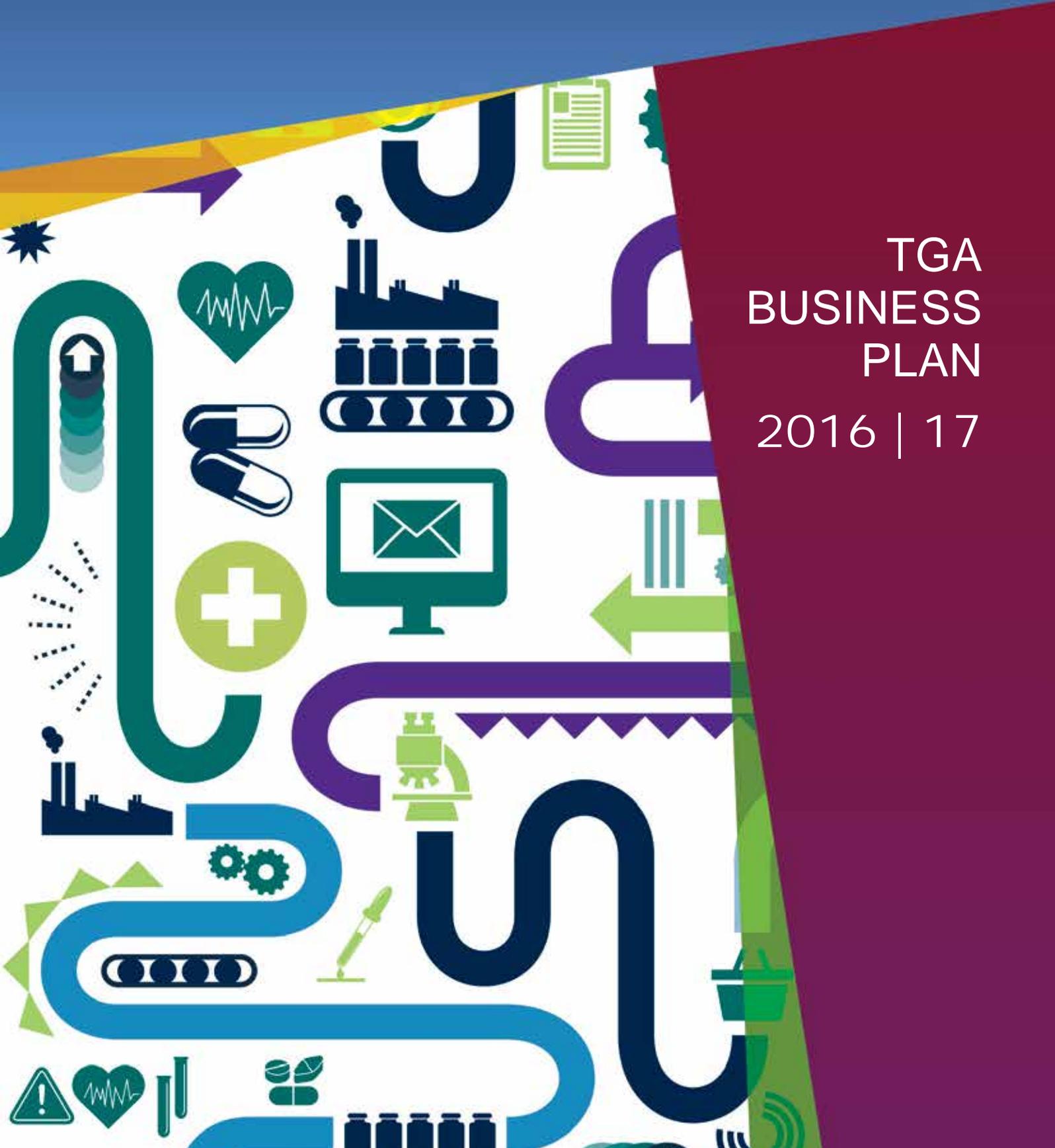




Australian Government  
Department of Health  
Therapeutic Goods Administration



TGA  
BUSINESS  
PLAN  
2016 | 17

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# Strategic considerations

## Overview

The Therapeutic Goods Administration (TGA) safeguards and enhances the health of the Australian community through the effective and timely administration of the *Therapeutic Goods Act 1989*.

As part of the Department of Health, our activities contribute towards the Department's delivery of its vision to provide better health and wellbeing for all Australians, now and for future generations.

We contribute to the Department's strategic priorities, namely:

- ***Better health and ageing outcomes and reduced inequality***, by enabling timely access to new medicines, medical devices, blood, cell and tissue therapies through the establishment and maintenance of a national system of controls. These controls relate to the safety, effectiveness/ performance, quality and timely availability of therapeutic goods that are used in Australia, whether produced in Australia or elsewhere, or are exported from Australia.
- ***Affordable, accessible, efficient, and high quality health and aged care system***, through a national framework that applies a risk-based management approach to regulation that protects the health and safety of the community while minimising unnecessary compliance burdens. This allows for the States and Territories to adopt a uniform approach to control the availability and accessibility, and ensure the safe handling of poisons (including medicines, agricultural and industrial chemicals) in Australia.

We continue to work in a dynamic environment. One of our key priorities in 2016-17 is implementing the Government's response to the Expert Panel Review of Medicines and Medical Devices Regulation (the Review).

We will continue to work on reducing unnecessary, duplicative or ineffective regulation while maintaining our commitment to the provision of high quality regulation of therapeutic goods in Australia.

## Strategic priorities for 2016-17

As outlined in the Health Portfolio Budget Statements, our priorities for 2016-2017 are:

1. Regulating therapeutic goods for safety, effectiveness/performance and quality
2. Participating in international regulatory convergence and work sharing activities
3. Promoting best practice regulation.



## 1. Regulating therapeutic goods for safety, effectiveness/performance and quality

### *Strategies underpinning this priority*

- Support the Australian community in having timely access to therapeutic goods and advances
- Use a risk management approach to carry out assessment and monitoring to ensure therapeutic goods available in Australia are of an acceptable standard
- Maintain an effective regulatory framework that is contemporary and in line with international best practice
- Implement policies, management and processes that use the highest quality scientific methods, governance and management skills, and integrate seamlessly across the Department
- Maintain adequate expertise on our statutory advisory committees and source specialist advice to ensure there are mechanisms to strengthen our regulatory decision making processes
- Provide up-to-date and relevant information to stakeholders about regulatory decisions and processes.

## 2. Participating in international regulatory convergence and work sharing activities

### *Strategies underpinning this priority*

- Streamline effort and reduce international duplication in pre- and post-market evaluation of therapeutic goods and their manufacture through:
  - enhanced international collaboration through harmonisation of standards
  - participation in international regulatory convergence and work sharing initiatives.

## 3. Promoting best practice regulation

### *Strategies underpinning this priority*

- Enhance partnerships with consumers, healthcare professionals and other regulatory agencies
- Maintain appropriate relationships with industry
- Promote an effective regulatory framework that is contemporary and in line with Australian and international best practice
- Maintain a robust risk management approach to all strategic and key operational risks
- Update and maintain clear and transparent guidance to help industry and other stakeholders to navigate regulatory process
- Contribute to the Government's regulatory reform agenda.



## How we undertake our role

We undertake our role by:

- applying scientific and clinical expertise to ensure that the benefits of a product outweigh any risk
- assessing the suitability of therapeutic goods for supply in and export from Australia
- regulating manufacturers of therapeutic goods to enable them to meet acceptable standards of manufacturing quality
- assessing the quality and compliance of therapeutic goods on the market, including through laboratory testing where appropriate
- implementing a range of regulatory actions (in response to non-compliance or unexpected safety concerns) that are proportionate to the potential risk arising from the non-compliance or safety risk
- working collaboratively with consumers, health professionals, industry, technical and scientific specialists and our international regulatory counterparts.

We achieve this by:

- applying risk-based processes for both pre-market assessment and post-market monitoring and compliance strategies
- promoting regulatory compliance through clear and transparent regulatory guidance
- articulating underlying reasons for regulatory decisions and providing them in a timely manner
- using innovative technologies and ideas to streamline business functions and promote effective and timely communication
- reporting on our performance to industry and other stakeholders.

## Guiding principles

The *Regulator Performance Framework* comprises six outcomes-based key performance indicators (KPIs) to articulate the Government's overarching expectation of regulator performance, namely that:

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

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.

Further information on the KPIs and measures for our regulation are available on our website.

## Deliverables and measures of success

Our deliverables and measures of their success are derived from:

- the Health Portfolio Budget Statements 2016-17
- the Department's Corporate Plan 2016-17
- the KPIs in the *Regulator Performance Framework*.

We will continue to publish performance information, including:

- annual self-assessment against the *Regulator Performance Framework*
- data in the Department of Health's Annual Report
- annual Performance Statistics Reports for July to June with a smaller subset of data (Half Yearly Performance Report Snapshot) covering the half yearly period July to December.

## Managing priorities

Implementing the Government's response to the Review will be a significant program of work that needs to be carried out in a staggered approach so that we maintain continuity of our routine regulatory business. As part of the Department of Health, we will implement and resource reform activities alongside the following priorities during 2016-17:

### 1. Refine our regulatory practices

- assessing our performance against the *Regulator Performance Framework* to fulfil our functions with the minimum impact necessary to achieve regulatory objectives
- adopting Australian and international best regulatory practice
- developing regulatory guidance to be more accessible and provide greater transparency about regulatory requirements
- refining the way we communicate regulatory decisions to enable a better understanding of the issues and enhance future compliance methods, governance and management skills, and integrating these across our organisation
- managing major strategic, financial and operational risks in line with the Department's Risk Management Policy.

### 2. Engage with our stakeholders and manage key relationships

- monitoring and management of emerging issues and timely proactive communication with the responsible Ministers
- actively promoting and enhancing collaborative and cooperative relationships with other parts of the Department
- enhancing relationships with consumers and healthcare professionals
- maintaining appropriate relationships with industry
- enhancing international regulatory cooperation and minimising duplication of effort through stronger collaboration with overseas regulators and assessment bodies.

### 3. Enhance our business capability

- implementing cohesive policies, management and processes that use the highest quality scientific and clinical methods, governance and management skills, and integrating these across our organisation
- improving business processes and systems to increase internal efficiencies and to provide effective regulatory services.

### 4. Deliver through our people

- continuing to implement the Department's Capability Program to strengthen leadership and culture; improving strategic capability; effective governance and delivery frameworks; relative risk management; and active stakeholder engagement
- maintaining a capable workforce that adapts flexibly to change through regulatory reform, business improvement initiatives and other priorities of Government
- providing for continuous learning to develop our staff
- implementing human resource management policies, procedures and systems that continue to promote the Australian Public Service (APS) Code of Conduct and the Australian Public Service Commission Integrated Leadership System
- responding to the 2016 APS Employee Census results through the implementation of a range of initiatives that focus on major survey outcomes.



## Regulatory reform

### Medicines and Medical Devices Regulation Review

The Australian Government response to the Review of Medicines and Medical Devices Regulation (the Review) was released by Minister Ley on 15 September 2016. The Review was undertaken by an Expert Panel and included extensive stakeholder consultation with consumers, industry and health professionals. The Expert Panel delivered two reports that assessed the regulatory framework for medicines and medical devices in Australia.

The Review reports recognised our excellent reputation in ensuring the timely availability of high quality, safe and efficacious therapeutic goods, whilst identifying opportunities to enhance both the regulatory framework and processes.

The Government's response to the Review identifies ways to improve access to therapeutic goods for consumers and remove unnecessary red-tape for industry, while maintaining the safety of therapeutic goods in Australia. The response indicates the Government's support for 56 of the 58 recommendations for reform made by the Expert Panel. Recommendations 29 and 30, relating to our decision-making and governance arrangements, were rejected by the Government.

These regulatory reform activities relate to all of our strategic priorities for 2016-17, particularly the second priority of 'Participating in international regulatory convergence and work sharing activities', and the third priority of 'Promoting best practice regulation'.

The reforms will be progressively rolled out over 18 to 24 months with new regulatory pathways for some medicines in place within 12 months. Further consultations with consumers, health professionals and industry will focus on how to implement the recommendations.

The main areas of reform over the next two years are as follows:

### Prescription medicine regulatory reforms

The reforms to the regulation of prescription medicines will result in new medicines coming to market sooner in Australia, while maintaining a framework for safety, quality and efficacy. This will be achieved by making greater use of assessments from comparable overseas regulators and introducing priority review and provisional approval pathways for new medicines in certain circumstances. To increase flexibility for industry and decrease approval times, several new pathways for registering medicines will be implemented:

- work sharing arrangements with comparable overseas regulators;
- increased use of assessments done by comparable overseas regulators; and
- implementation of priority review and provisional approvals in appropriate circumstances.

Reforms to the regulation of medicines will also include adopting a more risk-based approach to the regulation of variations to existing medicines.

A detailed assessment of the effort required for the different pathways for new applications and variations will be carried out, and fees for the new pathways will be proposed.



## Medical device regulatory reforms

The reforms to the regulation of medical devices will provide earlier access to new medical devices for Australian consumers and health professionals, and potentially reduce the costs for industry through:

- increasing flexibility in pre-market assessment processes, including establishing a process for expediting approval in certain circumstances
- enabling the establishment of commercial bodies in Australia designated to undertake medical device assessments
- increasing the use of assessments from comparable overseas regulators.

## Complementary medicine regulatory reforms

The reforms to the regulation of complementary medicines will:

- support consumer health decisions by increasing the information available on the efficacy of complementary medicines
- improve transparency for both industry and consumers by establishing a catalogue of approved ingredients and a list of permitted indications for use in complementary medicines.

The reforms will also increase certainty of processes and increase flexibility for industry by:

- making greater use of assessments for ingredients by comparable overseas regulators
- implementing an additional and new approval pathway for new complementary medicines
- introducing statutory timeframes for the approval of new ingredients
- adopting a risk-based approach to the variations of complementary medicines.

## Simplifying regulatory arrangements for advertising of medicines and medical devices

The reforms will simplify the regulation of advertising therapeutic products to the public by:

- ceasing pre-approval of advertisements in favour of a more self-regulatory regime
- implementing a more transparent and efficient complaints management process
- increasing consistency in the regulation of advertising across different types of therapeutic goods
- implementing a formal education program for industry to encourage compliance
- broadening and strengthening our investigation and enforcement powers.

## Streamlined regulation of patient-specific access to therapeutic products

The reforms will see modifications to the Special Access Scheme (SAS), including the development and implementation of transparent criteria for the automatic approval of access to certain unapproved therapeutic products for use in patients who have a non-life threatening condition. These products would need to be inherently lower in risk or have well-established patterns of use.

In addition, these reforms will also:

- establish an integrated, online system to manage SAS notifications
- reduce the regulatory requirements for Authorised Prescribers of unapproved therapeutic products.

The reforms will apply a risk-based approach to accessing products that are not on the Australian Register of Therapeutic Goods (ARTG), thereby reducing regulatory burden. Patients will be more efficiently protected from potential harm through better monitoring of the use patterns of these products.

### **Improved post-market surveillance**

More extensive post-market and pharmacovigilance activities will be carried out to ensure medicines and medical devices are appropriately monitored for safety, quality and efficacy. These will seek to further support and enhance the current post-market monitoring framework in Australia, and include: system improvements and enhancements to enable greater collection of adverse events information; improvements to the capability to undertake signal detection; improved monitoring of Risk Management Plans; and ensuring sponsors meet their regulatory obligations.

### **Regulatory support and guidance**

Enhanced support for small and medium sized enterprises to help them navigate regulatory processes for medicines and medical devices will be established, along with improved regulatory guidance information.

### **TGA advisory committees**

Statutory committees are defined as those established through an Act of Parliament or by Regulations. Our statutory committees are comprised mainly of external expert members who are appointed by the Minister for Health to provide critical specialist advice to the TGA's delegated decision makers. In addition, experts in consumer and patient issues on committees also provide valuable advice from the viewpoint of users of medicines, devices or other

products that we regulate. Under the *Therapeutic Goods Regulations 1990*, these individuals provide advice to delegates of the Secretary of Health to assist them in carrying out decisions.

#### *Statutory committees*

Efficiencies will be achieved through reducing the number of statutory advisory committees that provide independent expert advice to us. The existing eleven advisory committees will be replaced by seven committees to provide advice on specific clinical and scientific matters to aid regulatory decision making, in particular on applications for the market approval of new products and safety issues relating to particular products or product groups. The following statutory committees will be established or maintained:

- Advisory Committee for Medicines
- Advisory Committee on Complementary Medicines
- Advisory Committee for Devices
- Advisory Committee for Vaccines
- Advisory Committee for Biologicals
- Advisory Committee on Chemicals Scheduling
- Advisory Committee on Medicines Scheduling

### **Further reviews**

The reforms will support further reviews to potentially streamline the regulatory framework for low-risk products and increase consumer access to these products.

The reviews to be undertaken fall into two main categories:

- review of appropriate regulatory frameworks for low-risk products
- review of the Scheduling Policy Framework for medicines.

## Our deliverables

### Regulating therapeutic goods for safety, effectiveness/ performance and quality

In addition to commencing implementation of reform activities in 2016-17, we will continue to provide a world class, efficient and timely regulatory system for therapeutic goods, which involves and engages stakeholders to ensure the safe use of medicines, medical devices, cell and tissue products, blood and blood products.

#### Core activities

Our three divisions, the Medicines Regulation Division, the Medical Devices and Product Quality Division and the Regulatory Practice and Support Division, apply risk-based approaches to regulating therapeutic goods. We continuously look for opportunities to reduce regulatory burden on industry and health professionals without compromising the health and safety of Australians.

Core activities include ongoing monitoring of the quality, safety and effectiveness of biologicals, medicines and medical devices supplied in Australia through:

- evaluating applications within legislated or target timeframes for market authorisation of prescription, over-the-counter and complementary medicines, biologicals, blood components and tissue products and medical devices (including *in vitro* diagnostic medical devices) that are imported into, exported from, manufactured and/or supplied in Australia
- regulating manufacturers of therapeutic goods through an audit and inspection program to ensure the quality of therapeutic goods supplied in Australia from domestic and international manufacturers meet specified standards
- providing access to unapproved therapeutic goods, including medicinal cannabis for use in Australia where no alternative treatment is available through the Special Access Scheme, Authorised Prescriber Scheme and through Clinical Trials
- monitoring compliance, including the quality, supply and advertising of therapeutic goods and enforcing compliance where required
- monitoring safety signals associated with the use of therapeutic goods and undertaking safety investigations and actions
- ensuring products that pose an unacceptable risk to consumers are removed from the market
- ongoing lot release assessments of vaccines, including the seasonal influenza vaccine
- providing operational regulatory policy advice and support services that ensure efficient, best practice regulatory operations
- improving business processes and supporting project and change management across the divisions
- providing support to a wide range of business functions which enable the operation of a fully cost-recovered framework.

Projects for 2016-17	
Activity	Deliverables
<p><b>Regulate and monitor medicines, biologicals, and medical devices (including <i>in vitro</i> diagnostic medical devices)</b></p> <p><i>* These core activities align with our regulatory reform program of work.</i></p>	<p><b>Prescription Medicine Evaluation</b></p> <ul style="list-style-type: none"> <li>• Develop and implement more efficient processes for the evaluation of generic medicines*</li> <li>• Develop frameworks to support the use of overseas reports and work-sharing arrangements in evaluating applications for prescription medicines*</li> <li>• Consider potential antimicrobial resistance strategies during assessment of antimicrobials</li> <li>• Continue education and awareness raising activities to support adverse event reporting by consumers and health professionals</li> <li>• Develop criteria to identify comparable overseas regulators for the approval of medicines*</li> <li>• Implement a revised risk-based process for evaluating variations to registered medicines, specifically the introduction of a notification process for low risk changes</li> <li>• Complete the implementation of our digital submission and monitoring systems for prescription and over the counter (OTC) medicines</li> <li>• Develop a new designation process and criteria for orphan medicines</li> <li>• Update guidance on pharmacovigilance requirements of medicine sponsors for products on the ARTG and identify mechanisms for ensuring compliance*</li> <li>• Develop two expedited pathways (priority review and provisional approval) for the registration of novel prescription medicines that address unmet clinical needs for Australian consumers.*</li> </ul> <p><b>Medicines and Chemicals Access</b></p> <ul style="list-style-type: none"> <li>• Continue to oversee the Poisons Standard, the national regulatory framework for the scheduling of medicines and poisons, and provide advice to key stakeholders within the Department, across industry, government and consumer sectors.</li> </ul> <p><b>Complementary Medicines</b></p> <ul style="list-style-type: none"> <li>• Implement processes and systems to support streamlined applications to register complementary medicine products and evaluate new substances for listed medicines</li> </ul>

Projects for 2016-17	
Activity	Deliverables
	<ul style="list-style-type: none"> <li>· Develop streamlined post-market monitoring processes for complaints and improve the timeliness of listed medicine compliance reviews</li> <li>· Continue education and awareness raising activities to support adverse event reporting by consumers and health professionals.</li> </ul> <p><b>Biologicals</b></p> <ul style="list-style-type: none"> <li>· Finalise implementation of the Biologicals transition strategy</li> <li>· Provide guidance on requirements for biologicals including sponsors post-market obligations</li> <li>· Determine whether changes to the regulatory framework for autologous cells are required.</li> </ul> <p><b>Medical Devices</b></p> <ul style="list-style-type: none"> <li>· Develop criteria to identify comparable overseas regulators for the approval of medical devices*</li> <li>· Finalise and publish <i>Clinical Evidence Guidelines</i> for medical devices</li> <li>· Continue to implement the <i>In Vitro</i> Diagnostic Framework, with a transition period ending on 30 June 2017</li> <li>· Further refine medical device conformity assessments as part of the Business Improvement Program.</li> </ul> <p><b>Unapproved Products and Medicine Shortages</b></p> <ul style="list-style-type: none"> <li>· Complete the implementation of our medicine shortage management and communication strategy</li> <li>· Continue to improve timely access to Clinical Trials through further improvements to the Clinical Trial notification scheme</li> <li>· Implement changes to enable the use of medicinal cannabis in Australia.</li> </ul> <p><b>Advisory Committees</b></p> <ul style="list-style-type: none"> <li>· Continue to support and maintain governance arrangements for our statutory advisory committees and manage specialist expert advisory groups in providing flexible expert advice to support our regulatory functions*</li> </ul>

Projects for 2016-17	
Activity	Deliverables
<p><b>Regulate manufacturing quality, together with recalls and regulatory functions</b></p> <p><i>* This core activity aligns with our regulatory reform program of work.</i></p>	<ul style="list-style-type: none"> <li>Continue to implement a framework to manage compliance risk that provides incentives for consistent high level compliance and disincentives for non-compliant behaviours.*</li> </ul>
<p><b>Monitor and enforce compliance of therapeutic goods</b></p> <p><i>* This core activity aligns with our regulatory reform program of work.</i></p>	<ul style="list-style-type: none"> <li>Monitor compliance with public and customer notification of recall actions and ensure that appropriate corrective and preventative actions have been implemented by Australian sponsors</li> <li>Continue to cooperate with the Department of Immigration and Border Protection and other government departments and agencies to develop targeted approaches to prevent the import and/or export of illegal therapeutic goods</li> <li>Finalise implementation of a new risk-based laboratory testing program to monitor compliance of medicines and medical devices supplied in Australia with required standards</li> <li>Implement the Expert Panel Review reforms to simplify regulatory arrangements for advertising of medicines and medical devices.*</li> </ul>



Projects for 2016-17	
Activity	Deliverables
<p><b>Provide support services that enable us to more effectively undertake our regulatory responsibilities and effectively participate in international work sharing initiatives</b></p> <p><i>* This core activity aligns with our regulatory reform program of work.</i></p>	<p><b>Stakeholder Access to Information</b></p> <ul style="list-style-type: none"> <li>Undertake consultation and implement a specific range of support activities that are targeted towards small to medium enterprises to help them better understand the regulatory framework*</li> <li>Provide timely, accurate and appropriate information for parliamentary, Freedom of Information, reporting and secretariat activities</li> <li>Continue to develop simpler and targeted education materials and social media content targeted to areas of demand</li> <li>Continue to improve search and content structure on our website.</li> </ul> <p><b>Internal Efficiencies</b></p> <ul style="list-style-type: none"> <li>Improve provision of services to projects through assessment of regulatory business initiatives, governance of approved projects and post-project evaluation</li> <li>Transition from the current financial management and information management solutions to a single, streamlined financial and regulatory process management system (SAP) consistent with the broader Department</li> <li>Complete the remaining scope of work on the information technology (IT) based Business Improvements Project to ensure that technology is able to be leveraged for the Medicines and Medical Devices Regulation review system requirements. This scope of work also includes the implementation of an enquiry management solution to support and streamline the tracking of general enquiries</li> <li>Further develop IT architecture and supporting protocols for sharing confidential information with trusted international regulators that incorporate appropriate security measures to protect information from unauthorised use or accidental modification, loss or release.</li> </ul>

## Participating in international regulatory convergence and work sharing activities

We participate in international collaborative activities with many international agencies and overseas regulators. These activities can help to reduce our effort in pre- and post-market evaluation of therapeutic goods, while enabling more informed and consistent regulatory decisions about the safety, effectiveness/performance and quality of therapeutic goods available in Australia.

### Core activities

During 2016-17 we will continue to actively engage with our international regulatory counterparts, as well as with regional and international organisations, to support the implementation of consistent science-based standards that underpin the safety and quality of therapeutic goods throughout the supply chain.

This includes continued participation in international regulatory convergence and work sharing activities to:

- identify opportunities for Australia to respond effectively to global trends in the development, manufacture, marketing and regulation of therapeutic goods
- develop internationally consistent regulatory requirements, where appropriate
- increase collaboration in the evaluation of therapeutic goods between Australia and comparable overseas regulators
- contribute to the development of mutual reliance frameworks that reduce red tape for therapeutic goods manufacturers and sponsors.



Projects for 2016-17	
Activity	Deliverables
<p><b>Enhance cooperation and work sharing with international regulators in the pre-market assessment and post-market monitoring of medicines and medical devices</b></p> <p><i>* This core activity aligns with our regulatory reform program of work.</i></p>	<ul style="list-style-type: none"> <li>• Increase exchange of, and the use of the evaluation reports of trusted international regulators to support Australian regulatory decision making*</li> <li>• Make effective use of external expertise and regulatory science initiatives led by other regulators</li> <li>• Continue development of a program of confidence building for Notified Body evaluation of medical devices with the European Union</li> <li>• Continue the Trans-Tasman cooperation between regulatory schemes through: <ul style="list-style-type: none"> <li>– enhanced information sharing in regulatory compliance and pharmacovigilance, laboratory tests, investigations into quality defects or manufacturing errors and recall actions undertaken</li> <li>– continued sharing of a common approach to OTC medicine pre-market business processes</li> <li>– further mutual recognition of TGA and Medsafe Good Manufacturing Practice (GMP) inspections of manufacturers</li> </ul> </li> <li>• Continue to strengthen the post-market monitoring collaboration for therapeutic products</li> <li>• Improve understanding of international regulators' processes to increase opportunities for collaboration, for example: <ul style="list-style-type: none"> <li>– continuing collaboration through the Australia – Canada – Singapore – Switzerland consortium, particularly on the generic medicines work sharing trial</li> <li>– greater use of safety evaluations for new complementary medicine ingredients performed by overseas regulators, including with Canada, Singapore and Switzerland</li> <li>– continuing to progress work sharing opportunities, including with Health Canada through the Regulatory Cooperation Initiative.</li> </ul> </li> </ul>
<p><b>Influence the international regulatory harmonisation agenda through participation in key multilateral fora</b></p>	<ul style="list-style-type: none"> <li>• Continue to contribute to influencing the development and harmonisation of international regulatory standards through strategic engagement in international bilateral and multilateral activities:</li> </ul>

<b>Projects for 2016-17</b>	
<b>Activity</b>	<b>Deliverables</b>
	<ul style="list-style-type: none"> <li>– influence the international regulatory and standards harmonisation agenda through active engagement with international initiatives as well as with standard-setting bodies including: the International Council for Harmonisation, the World Health Organization, the Pharmaceutical Inspection Co-operation Scheme, the International Standards Organisation, the International Coalition of Medicines Regulatory Authorities (ICMRA), the Australia, Canada, Singapore and Switzerland Consortium, the International Medical Devices Regulators Forum (IMDRF), the Medical Device Single Audit Program (MDSAP) and the International Generic Drugs Regulators Programme</li> <li>• Identify new opportunities for augmenting our international engagement</li> <li>• Continue to lead the ICMRA pharmacovigilance project to enhance cooperation between medicines regulators</li> <li>• Contribute to regional capacity building through participation in forums such as the Regional Alliance Steering Committee for National Regulatory Authorities for Vaccines.</li> </ul>
<p><b>Enhance post-market monitoring</b></p> <p><i>* This core activity aligns with our regulatory reform program of work.</i></p>	<ul style="list-style-type: none"> <li>• Upgrade the database for collecting and analysing adverse events to allow more effective international sharing of information and improved signal detection*</li> <li>• Incorporate better and expanded classification of adverse events, via work on the IMDRF working groups, to improve international sharing of information.</li> </ul>
<p><b>Engage in activities to reduce duplication and improve efficiencies in inspection of manufacturing sites</b></p>	<ul style="list-style-type: none"> <li>• Develop protocols and criteria for exchange of manufacturing inspection information with trusted international regulators</li> <li>• Progress opportunities for work sharing with Health Canada on GMP inspections and desktop assessments and identify opportunities for work sharing with other trusted international regulators.</li> </ul>
<p><b>Contribute to the reduction in the number of new cases, and improved treatment of, malaria in the Asia-Pacific</b></p>	<ul style="list-style-type: none"> <li>• Co-chair the Asia Pacific Leaders Malaria Alliance regulators working group to support the timely market authorisation of new medicines and diagnostics for malaria therapy in the Asia-Pacific region.</li> </ul>



## Promoting best practice regulation

We will continue to identify opportunities and implement actions to reduce regulatory burden on industry, consistent with the Government's regulatory reform agenda, while continuing to meet the objectives of safeguarding and enhancing the health of the Australian community.

### Core activities

In 2016-17 we will design and commence implementation of the Government's agreed regulatory reforms.

Implementation will also continue on other reform activities that will optimise a range of regulatory processes and improve the way we communicate with the public and health care professionals about the decision making process and the benefits and risks of therapeutic goods.

Projects for 2016-17	
Activity	Deliverables
<p><b>Improve the integrity of the self-assessment/pre-market business process for complementary medicines new substances</b></p>	<ul style="list-style-type: none"> <li>Continue to work on "permitted indications" to potentially limit the use of inappropriate claims and indications for listed medicines on the ARTG</li> <li>Finalise an online catalogue of ingredients permitted for use in listed medicines and the conditions associated with their use</li> <li>Develop an application portal which enables applicants to lodge applications for new ingredients for listed medicines electronically, and guidance documents supporting the new application process.</li> </ul>
<p><b>Provide advice to government on reform options for orphan drugs that provide more equitable access to people with rare diseases, while managing implications for TGA revenue</b></p>	<ul style="list-style-type: none"> <li>Develop a final proposal based on feedback from consultations and discussions with key stakeholder groups, followed by a sponsor guidance document.</li> </ul>

<b>Projects for 2016-17</b>	
<b>Activity</b>	<b>Deliverables</b>
<p><b>Provide more user-friendly information on the risk-based framework under which TGA operates, including additional explanations of regulatory processes</b></p>	<ul style="list-style-type: none"> <li>• Implement a communication and education plan to communicate our risk-based framework more broadly</li> <li>• Provide clear regulatory guidance that assists industry and other key stakeholders, including consumers, to understand and adhere with regulatory requirements</li> <li>• Develop detailed explanations of how the framework operates for different classes of therapeutic goods</li> <li>• Continue improvements in webpage design and format.</li> </ul>
<p><b>Assess approaches for the regulation of autologous stem cells</b></p>	<ul style="list-style-type: none"> <li>• Seek Ministerial approval for options for reforming regulations and processes based upon public consultation.</li> </ul>
<p><b>Reform processes surrounding access to unapproved therapeutic products through the Special Access Scheme</b></p> <p><i>* This core activity aligns with our regulatory reform program of work.</i></p>	<ul style="list-style-type: none"> <li>• Commence implementation of preferred options, including systems for electronic applications and/or notifications.*</li> </ul>
<p><b>Streamline the application process for medical devices</b></p>	<ul style="list-style-type: none"> <li>• Participate in an IMDRF pilot of the Regulated Product Submission for medical devices</li> <li>• Trial and evaluate the effectiveness and potential to adopt the IMDRF Medical Devices Single Audit Program.</li> </ul>
<p><b>Work with other key providers to enhance the information available to the public</b></p>	<ul style="list-style-type: none"> <li>• Continue to participate in conferences and events including plenary presentations, as well as other educational activities with key stakeholders and partner organisations</li> <li>• Continue to disseminate communication and educational materials and test new materials that are audience-centred, based on outcomes of research into the needs of major stakeholders.</li> </ul>
<p><b>Publish the results of post-market compliance testing on our website</b></p>	<ul style="list-style-type: none"> <li>• Commence implementation of a strategy to increase understanding of the TGA and our procedures for the ongoing monitoring of products, including through publication of laboratory compliance testing on our website.</li> </ul>

## Version history

<b>Version</b>	<b>Description of change</b>	<b>Author</b>	<b>Effective date</b>
V1.0	Original publication	Reporting & Collaboration Services/ Regulatory Engagement and Planning Branch	29/11/2016

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