



Australian Government

Department of Health

Therapeutic Goods Administration

TGA Reforms: A blueprint for TGA's future

Progress Report as at 31 December 2014

February 2015

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <<http://www.tga.gov.au>>.

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Background to the TGA reforms

The Therapeutic Goods Administration (TGA) was established as part of the Department of Health to safeguard and enhance the health of the Australian community through effective and timely regulation of therapeutic goods.

To ensure that we continue to fulfil our critical public health role and are able to meet industry, health professional and community expectations, several major reviews were undertaken in recent years, including:

- the review to **improve transparency** of the TGA
- the Working Group on **Promotion of Therapeutic Products**
- public consultations on the **regulatory framework for advertising therapeutic goods**
- the Auditor-General's report on Therapeutic Goods Regulation: **Complementary Medicines**
- the informal working group examining the **regulation of complementary medicines** and reasons for low compliance rates with particular regulations
- public consultations on the **medical devices regulatory framework**, and
- the Australian Government **Health Technology Assessment Review**.

In response to the recommendations made in the reviews [TGA reforms: A blueprint for TGA's future](#), (the Blueprint) was released in December 2011.

On 16 July 2012, [Delivering reforms- Implementation plan for TGA reforms: A blueprint for TGA's future](#) - was released publicly with an announcement that the TGA will report on its progress every six months, following consultation with the Australian Therapeutic Goods Advisory Council.

TGA reform themes

Reforms have been grouped into the following themes:

1. communication and stakeholder engagement
2. complementary medicines
3. medical devices
4. advertising of therapeutic products
5. promotion of therapeutic products involving matters of broader health policy which are the responsibility of the Department of Health (Health). Progress on this work will be reported separately.

The reforms are planned to be delivered in three phases, with the period July 2013–December 2015 representing the final phase of delivery of the reforms.

Progress to 31 December 2014

Forty-eight (48) recommendations were proposed for implementation by the TGA during the four year program.

- Thirty eight recommendations have been implemented by 31 December 2014.
- A further ten (10) recommendations are planned for implementation by 31 December 2015.

Appendix A provides information on TGA's progress against each of the recommendations including progress to 31 December 2014 and activity planned for the next six months (until 30 June 2015).

Appendix B provides a planned schedule for implementation of recommendations in the period from 1 January 2015 to 31 December 2015 (remainder of Phase 3).

Recommendations implemented

The term "implemented" indicates that the recommendation has been materially addressed. In some cases, it does not mean that work in a particular area is complete.

For example, Transparency Review Recommendation 10 has been described as implemented as reporting against a full set of agreed Key Performance Indicators (KPIs) has occurred. Ongoing publication of quantitative and qualitative information on the TGA's organisational effectiveness and operational efficiency will continue. Further work will also be undertaken to ensure the KPIs address the common set of performance measures required as part of the Government's [Regulator Performance Framework](#).

In many cases, further activity will be undertaken to embed the outcomes of these recommendations into the business-as-usual functions of TGA, and planned activity for the six months to 30 June 2015 is shown against each recommendation in Appendix A. This appendix also shows recommendations which have been implemented and those on track.

Progressing implementation: 2014-15

One recommendation has been implemented in the six month period to 31 December 2014 (Transparency Review Rec 10):

- The TGA, in conjunction with key stakeholders, develop and publish agreed Key Performance Indicators to provide quantitative and qualitative information on the TGA's organisational effectiveness and operational efficiency.

It is anticipated that a further recommendation will be implemented in the six months to 30 June 2015 (Transparency Review Rec 16):

- The TGA actively promote the distribution of therapeutic goods safety information, and examine mechanisms for improving the timely communication of alerts and recalls, to health practitioners and to consumers.

We will continue consultation processes, preparing regulation impact statements (where required), seeking policy approval for changes and drafting regulations or legislation (where regulatory or legislative change is required). Planned activity for the January – June 2015 period against each Blueprint recommendation is shown in Appendix A.

Review of medicines and medical devices regulation

On 24 October 2014 the Government announced an [Expert Review of Medicines and Medical Devices Regulation](#) (the Review) would be undertaken. The Review will examine specific aspects of the regulatory framework for medicines and medical devices administered by the Therapeutic Goods Administration with a view to identifying:

- areas of unnecessary, duplicative, or ineffective regulation that could be removed or streamlined without undermining the safety or quality of therapeutic goods available in Australia; and
- opportunities to enhance regulatory framework so that Australia continues to be well positioned to respond effectively to global trends in the development, manufacture, marketing and regulation of therapeutic goods.

The Review will provide recommendations on the regulatory frameworks for prescription and over the counter medicines and medical devices by 31 March 2015. The Review of the regulatory framework for the complementary medicines sector will be undertaken during the second quarter of 2015.

Progress of some reforms proposed in the “Blueprint for TGA’s future” is dependent on the outcome of the Expert Review and the Government’s response to the Review’s findings. This includes areas where the Review intersects with reforms such as limitation of “free text claims” for complementary medicines, reforms to advertising and further changes to the regulation of medical devices.

Other aspects of the TGA’s work programme fall outside the remit of the Review and work will continue in these areas. These include:

- the ongoing programme of publication of guidance documents;
- improvements to TGA internal business processes; and
- TGA process reform that does not involve potential regulatory change (for example, confidence building work with European Notified bodies that assess and certify medical devices for the Australian market).

Material variations to delivery

The announcement of the Expert Review of Medicines and Medical Devices Regulation has required a revision to the delivery schedule for some Blueprint recommendations. As outlined above, the nature of possible reform to complementary medicine regulation, therapeutic goods advertising and further changes to the regulation of medical devices in particular are dependent on the Review’s findings and the Government’s subsequent response. Therefore, five recommendations will not be implemented as forecast during 2014-15:

- The TGA improve access and quality of information on the processes for regulation of advertising of therapeutic goods, including the complaint process and the outcomes of complaints (Transparency Review Rec 9)
- To improve the integrity of the self-assessment process for listing complementary medicines on the Australian Register of Therapeutic Goods, the ANAO recommends that Health seeks to finalise work on the ‘coded indications’ project so as to limit the use of inappropriate claims and indications on the ARTG (Auditor-General’s Report Rec 2)
- Modify Electronic Listing Facility system, to include restriction or elimination of access by sponsors to ‘free text’ (Informal Working Group Rec 2a)
- Review current ‘coded indications’ project based on the document ‘Guidelines for levels and kinds of evidence’ and either restrict or eliminate access by sponsors to ‘free text’ in the Electronic Listing Facility (Informal Working Group Rec 4)
- Publication of device product information on the TGA Website (Medical Device Reforms – Proposal 4)

Expected benefits from the reforms

Communication and stakeholder engagement

Of the 34 projects outlined in the [TGA external communications and education framework: Priorities and projects 2013-15](#), 28 have been completed and work on a further five has commenced, work on additional communication and stakeholder engagement projects is outlined in previous reports and in the text below.

Under the reform program, a number of projects were commenced or progressed in 2014 aimed at improving our business processes and reducing regulatory burden for industry.

Since September 2014, TGA educational information has been shown in 250 GP waiting rooms in all capital cities except Darwin, and these are being viewed each month by more than 850,000 people. The content is shown on the Medical Channel, a company that provides television screens and content in medical waiting rooms. 30 second clips about AUST L and AUST R numbers, how to travel with medicines and warnings about buying medicines and devices over the internet were shown and are also available on our TGA You Tube site.

Working in partnership with NPS MedicineWise, we released two online learning modules, [Safety through reporting: online learning modules for health professionals](#), in December 2014. Health professionals are eligible for continuing professional development points after completing the modules.

In the second half of 2014, fourteen TGA speakers presented at the ARCS Scientific Congress and we also had exhibition space and supplied educational material to the delegates.

In response to the increasing number of enquiries our Public Contact Team is receiving from beauticians and beauty spa owners, we presented on advertising of therapeutic goods and shared exhibition space with the ACCC and NICNAS at the Sydney Spa and Beauty Expo. This event was attended by over 10,000 delegates.

In October we had exhibition space at the GP14 Conference and the Pharmaceutical Society of Australia National Congress.

Towards the end of 2014 TGA speakers presented at various conferences, including the AusBiotech National Conference, MedTech 2014, ASMI Conference, Complementary Medicines Australia National Conference, the Clinical Trial Summit organised by the Medical Oncology Group of Australia (MOGA), as well as the World Cancer Congress. Internationally, speakers presented at the WHO International Conference of Drug Regulatory Authorities (Brazil), the DIA Regulatory Conference (Japan) and the 4th International Workshop on Generic Drugs (China).

We have worked on a number of special projects throughout 2014 to make the TGA website more user-friendly for industry, health professionals and consumers. The [Food-Medicine Interface Guidance Tool](#) was built to help manufacturers and importers decide whether their product is regulated as a therapeutic good, and therefore which regulatory requirements apply. We have also created searchable databases providing information on products cancelled from the Australian Register of Therapeutic Goods (ARTG). We updated our [online payment portal](#) to make it easier to pay applications fees and allow users to pay without an invoice.

Over the second half of 2014 the entire public website, www.tga.gov.au, was migrated into a new content management system, called Drupal. This allows us to implement features such as more user friendly online forms, improved navigation and search. The mobile

website was also upgraded, and with 30% of site traffic now coming from mobile devices we will continue to make sure this version of the website is easy to use and navigate.

The Public Contact Team continued to manage the flow of the TGA's main enquiry lines. From 1 July to 31 December 2014, they managed over 10,000 telephone enquiries and just under 4,000 written enquiries to the TGA's general 1800 number and generic email account. Through analysing the nature of these enquiries, the Public Contact Team has made a significant contribution to identifying the information needs of the TGA's stakeholders.

To get an assessment of the impact of our targeted education activities we used an independent market research company to conduct quantitative market research on awareness and perceptions of the TGA in November and December 2014. We used a similar methodology to the [market research](#) conducted in the first half of 2013. Industry, health professionals and consumers were surveyed about their levels of awareness of the therapeutic goods regulatory system, including the role and perceptions of the TGA.

The research found that the awareness of aspects of the regulatory system among health professionals has doubled since 2013. In 2013 and 2014 we targeted many of our educational activities to health professionals, this included having a TGA presence at certain health professional conferences and strongly promoting our email alerting services to this target audience. The consumer research showed that pharmacists and doctors are the most important sources of information about therapeutic goods for consumers. Results from the regulated industry surveys were largely unchanged; however, awareness of TGA consultation activities and of TGA expert advisory committees has significantly increased since 2013 with around three quarters aware of TGA consultations and over two thirds aware of TGA expert advisory committees. In 2013 and 2014 we ran awareness campaigns with industry about our consultation and committee activities.

In line with the [TGA International Engagement Strategy](#), and as part of the Australian Government's agenda to further increase international regulatory cooperation efforts, we have continued our strong program of international stakeholder engagement.

During this period we have continued to explore opportunities to develop bilateral relationships with a number of our international counterparts. We have finalised a new collaborative arrangement with the Singapore Health Sciences Authority, and signed renewed Statements of Authority and Confidentiality Commitments with the United States Food and Drug Administration.

Complementary medicines

Improvements to complementary medicines regulation seek to improve community confidence in the safety and quality of these medicines and strengthen the integrity and transparency of the regulatory framework for complementary medicines. The driver for the reforms was an Australian National Audit Office Audit "Therapeutic Goods Regulation: Complementary Medicines" in 2011.

Whilst some recommendations involve more effective implementation of the existing regulatory framework, implementation of others would require changes to legislation and/or regulations.

- **Key regulatory guidance materials.** Sponsors have always been required to hold evidence to support indications for their product. To assist, the Evidence Guidelines document provides sponsors with information on regulatory requirements and guidance on the evidence they are required to hold to support indications made for listed complementary medicines. A replacement version of the existing Evidence Guidelines, providing clearer assistance for sponsors, was published in March 2014. An update to the Australian Regulatory Guidelines for Complementary Medicines was

made available in December 2013. Updates continued to be made throughout 2014 to ensure currency of the information.

- **Improving the integrity of the listing system for complementary medicines so as to limit the use of inappropriate claims.** The TGA continues to work with industry on updating a comprehensive list of indications which meets the needs of the complementary medicines industry and improves compliance with the regulatory framework. Additional indications were added in December 2014.
- **Publishing outcomes of listing compliance reviews.** The TGA continues to make information available in a timely manner to the Australian public, on cancellations of listed complementary medicines following post-market review.
- **Enhancing post-market monitoring.** To improve compliance with the regulatory framework, the TGA will use information from compliance reviews to develop risk profiles of sponsors and characteristics of medicines to inform the targeted compliance review program.
- **Investigation processes for advertising breaches.** The TGA has a standard procedure for investigations of advertising breaches in place. Regular reporting on progress with investigations and trends in non-compliance is being developed and implemented.

An area of potential change to the regulatory framework is improvements to the integrity of the listing system for complementary medicines through use of permitted indications and removal of “free text” in the listing. Implementation of this would be dependent on a policy decision by government and require legislative/regulatory change. Potential reform of the regulation of permitted indications will be considered in the broader context of the Government’s deregulatory agenda and the Expert Review of Medicines and Medical Devices Regulation.

Medical devices

This set of regulatory reforms seeks to improve community confidence in the safety and quality of medical devices and strengthen the integrity and transparency of the device regulatory framework to ensure that devices available to the public are of acceptable quality and safety, and perform as intended.

Hip, knee and shoulder joint implants (total and partial) were reclassified on 1 July 2012 from Class IIb (medium-high risk medical devices) to Class III (high risk medical devices), increasing regulatory oversight to better assure the products’ safety, quality and performance. Regulatory change to the Therapeutic Goods (Medical Devices) Regulations 2002 includes a transition period, recently extended to 30 June 2015, for devices already in the ARTG. The transition period was extended to enable the TGA to undertake further consultation with affected stakeholders to consider the range of medical devices affected by reclassification, as well as options around the supply of devices for revision surgeries, without affecting the continuity of supply of devices to patients. Communication with industry is ongoing to provide information on the ongoing transition and to ensure that the goals of the reform are achieved.

Recent changes were made to allow Australian medical device manufacturers to use conformity assessment certification from European notified bodies when making applications to the TGA, as was already the case for overseas manufacturers. Previously Australian medical device manufacturers were required to seek a conformity assessment certificate from the TGA if they want to supply their product in Australia. This new approach provides more flexibility for Australian medical device manufacturers and in many cases should remove regulatory duplication and enable products to be available more quickly. Approval for this change was granted as part of the Government’s Industry

Innovation and Competitiveness Agenda, and the amendments to the Therapeutic Goods (Medical Devices) Regulations 2002 came into effect on 5 November 2014.

For a number of years the TGA has been consulting with stakeholders on reforms to increase premarket scrutiny of high risk medical devices. The Expert Review of Medicines and Medical Devices Regulation will examine options for future change to the medical device regulatory framework. Options for amending the way a kind of medical device is included in the ARTG to improve identification and traceability have been overtaken by development of an international system of Unique Device Identifiers (UDIs). This new global approach is to be rolled out by the US Food and Drug Administration over the next seven years, with corresponding UDI provisions under development in Europe. In providing unique identifiers for medical devices this system will improve device traceability as well as providing for better identification of devices by health care professionals and consumers. As the UDI system is being rolled out internationally, there is scope for Australia to harmonise and gain the advantages and efficiencies of this approach, avoiding the duplication and cost of implementing separate product identification measures.

Advertising of therapeutic products to the general public




The advertising of therapeutic goods to the public and health professionals is currently controlled by a combination of statutory measures administered by the TGA and self-regulation through Codes of Practice administered by the relevant industry associations. Advertising to the general public is permitted for the majority of therapeutic goods available for sale, while advertising of Prescription and certain Pharmacist-Only medicines is prohibited. A number of reviews, along with feedback from public consultations and media coverage over recent years have highlighted stakeholder dissatisfaction with the existing advertising regulatory framework for therapeutic goods. The major concern is that the framework is overly complicated, inconsistent, ineffective and inefficient, lacks transparency, and is difficult and costly to administer. In addition, there has been consistent feedback from consumer groups, supported by some media reports that resolution of advertising complaints is too slow.

TGA developed a set of proposals for reforming the advertising regulatory framework in the Consultation Regulatory Impact Statement (RIS) - [*Regulating the advertising of therapeutic goods to the general public*](#) in 2013.

The consultation RIS proposed a number of options primarily focusing on reforming pre-approvals scheme, improving the efficiency of the complaint handling process and aligning sanctions and penalties for dealing with advertising breaches with other comparable provisions within the legislation.

Further consideration of possible regulatory changes will be considered by Government as part of the response to the recommendations of the Expert Review of Medicines and Medical Devices Regulation.

Appendix A: TGA Reforms – Blueprint Recommendation Status

Key: Implemented  On Track  Material Variation 

Blueprint Recommendations addressed		Achievements 1 Jan 2012 –31 Dec 2014	Planned Activity/Next Steps 1 Jan – 30 Jun 2015
Recommendations relating to communication and stakeholder engagement			
Transparency Review Rec 1 – Establish an Australian Therapeutic Goods Advisory Council, with membership representative of major stakeholder groups, to enable more effective stakeholder input into future directions and program implementation. The Council will have an oversight role in the implementation, ongoing monitoring, and evaluation of the recommendations of this review.	Implemented. The Australian Therapeutic Goods Advisory Council (the Council) held its inaugural meeting in 2012. Meetings were also held in February 2013, August 2013, February 2014 and August 2014. The Council provides an oversight role in the implementation, monitoring and evaluation of the Blueprint recommendations.		The Council will next meet in February 2015.
Transparency Review Rec 2 – Define, adopt and publish consultation principles to guide regulatory transparency and accountability.	Implemented. Development of two consultation documents. TGA Consultation Principles and TGA Consultation principles – A Guide for Staff have been finalised and published. A strategy and schedule for participating in events to raise awareness of the TGA has been developed. Participated in a number of public events and conferences.		These principles are being used to guide regulatory transparency and accountability.
Transparency Review Rec 3 – Develop and implement a comprehensive communication strategy to inform and educate. A dedicated communications team should be established within TGA to implement that strategy.	Implemented. Communication team established and resourced. Development and publication, of the TGA External Communication and Education Framework: Priorities and Projects 2013–15 occurred in 2012, and was rolled out in 2013. Development of an accompanying guide for TGA staff. Published reports on market research conducted in relation to TGA communication activities in 2013.		Continue to work on projects outlined in TGA External Communication and Education Framework: Priorities and Projects 2013–15.

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2014	Planned Activity/Next Steps 1 Jan – 30 Jun 2015
<p>Transparency Review Rec 4 – Work transparently with other key providers of information to enhance the information available to the public consistent with the principles of the quality use of medicines.</p>	<p>Implemented.</p> <p>Partnerships with key information providers (including the NPS, Australian Commission on Safety and Quality in Health Care and Australian Medical Association) have been formalised. Letters sent to 56 organisations inviting them to link to material on the TGA website. Consultations with other major information providers have been conducted in the context of the development of the communication and education strategy. Initial focus has been the identification of priorities and opportunities for collaboration.</p> <p>Worked in partnership with NPS to create and disseminate information on topics such as biosimilar medicines.</p> <p>Stronger relationships developed with Australian universities. This includes publishing on the TGA website a series of education modules for final year University students on the work of the TGA, and TGA presentation of lectures at university partners.</p> <p>Major work commenced on the dissemination of education materials identified above, as part of the ongoing work under the Communications and Education Framework.</p> <p>Participated in numerous public events and conferences. A major function at Parliament House recognising 50 years of independent expert advice on prescription medicines.</p>	<p>We will also continue our conference activities including, high-profile participation as keynote speakers for major industry and healthcare professional conferences.</p>

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2014	Planned Activity/Next Steps 1 Jan – 30 Jun 2015
<p>Transparency Review Rec 5 – Develop a plan to ensure information on the key public access portal, the TGA website, is current, accurate, relevant, timely and up to date, and meets the needs of its audiences.</p>	<p>On track. The Public Contact Team implemented. Identification of the most common public enquiries received, to inform the further development of the TGA website and improvements to handling of enquiries.</p> <p>New TGA website homepage launched in November 2013. General improvements to the accessibility of information on the TGA website. A tender process commenced to upgrade the website.</p> <p>Communication about TGA’s post-market regulatory activities on the website strengthened through the launch of databases of adverse events and recalls. An early warning system to inform consumers of potential safety issues.</p> <p>Mobile device version for viewing the full TGA website on devices and smartphones has been launched.</p> <p>Users can now search the Australian Register of Therapeutic Goods from the TGA website.</p> <p>Six videos have been published on the TGA website on:</p> <ul style="list-style-type: none"> • the role of the TGA (for consumers and for health professionals) • the risk versus benefit approach we take to regulating therapeutic goods • information about higher- and lower- risk medicines (AUST R and AUST L) • travelling with medicines and medical devices; and • a summary of supplying therapeutic goods in Australia <p>First education materials were available via social media.</p> <p>The website Content Management System has been upgraded.</p>	<p>Continue to use information gathered through sources such as the Public Contact Team and other enquiries to TGA to identify needs of TGA’s stakeholders.</p>

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2014	Planned Activity/Next Steps 1 Jan – 30 Jun 2015
<p>Transparency Review Rec 6 – The TGA provide user-friendly information on the risk based framework under which it operates, including detailed explanations of how this operates for different classes of therapeutic goods. As a priority, the differences between registered and listed therapeutic goods, and their processes of evaluation, should be explained.</p>	<p>Implemented. A clear explanation of the TGA’s risk based framework for therapeutic goods has been published on the TGA website. Explanation of benefits vs risk approach to regulating therapeutic goods is a particular focus of the External Communication and Education Framework and addressed in several subprojects. New education materials for consumers and health professionals providing information on higher and lower risk medicines have been developed and tested with target audiences.</p> <p>New education materials for consumers and health professionals have been published that specifically describe how we evaluate products and manage risk.</p>	
<p>Transparency Review Rec 7 – The TGA implement mechanisms to educate and inform the public that listed medicines are not evaluated for effectiveness by the TGA prior to market.</p>	<p>Implemented. The TGA is working in partnership with other information providers to achieve a wider public understanding that listed medicines are not evaluated for effectiveness by the TGA prior to market. The booklet “Listed medicines – The role of Australia’s medicines regulator” has been published on the website, and distributed to consumer and health professional groups.</p> <p>New education materials on role of the TGA, risk based approach to regulation and higher and lower risk medicines have been published that specifically describe how we evaluate products and manage risk.</p>	

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2014	Planned Activity/Next Steps 1 Jan – 30 Jun 2015
<p>Transparency Review Rec 8 – The TGA provide clear information on the role of its statutory advisory committees, and adopt a consistent and transparent approach to the publication of information from those committees.</p>	<p>Implemented. Publication on the TGA website of a statement clarifying the role of advisory committees in the context of the TGA's regulatory decision making process. A standardised template developed for commissioning expert advice from committees.</p> <p>A consistent and transparent approach to the publication of committee meeting information has been implemented. Principles for the publishing of committee meeting information have been developed and implemented with the issuing of a meeting statement for all committee meetings from 2013.</p> <p>More comprehensive meeting information has been published during 2014. The initial focus has been on TGA's post-market advisory committees as 'For Official Use Only' issues constrain full public reporting of advice from pre-market advisory committees.</p>	
<p>Transparency Review Rec 9 – The TGA improve access and quality of information on the processes for regulation of advertising of therapeutic goods, including the complaint process and the outcomes of complaints.</p>	<p>Material variation. Development of specifications for the development of a complaints handling IT system, including a reporting function. A consultation on options for reforms to the advertising framework closed on 12 July 2013. Public submissions in response to the consultation RIS reviewed and possible improvements submitted to government to inform the next steps.</p> <p>Refer to Advertising reforms – rec 2.</p> <p>Development of a workflow system for advertising complaints has progressed to user acceptance testing phase. Documentation for workflow system implementation for advertising complaints has been finalised.</p>	<p>Consideration of possible regulatory changes will be considered through the Expert Review of Medicines and Medical Devices Regulation.</p>

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2014	Planned Activity/Next Steps 1 Jan – 30 Jun 2015
<p>Transparency Review Rec 10 – The TGA, in conjunction with key stakeholders, develop and publish agreed Key Performance Indicators to provide quantitative and qualitative information on the TGA’s organisational effectiveness and operational efficiency.</p>	<p>Implemented. The Australian Therapeutic Goods Advisory Council and TGA-Industry Consultative Committee consulted on the Key Performance Indicators.</p> <p>Key Performance Indicators and reporting measures for providing information on TGA’s organisational effectiveness and operational efficiency have been published on the TGA website.</p> <p>Phased implementation of reporting against Key Performance Indicators began, with reporting against KPIs for the period July-Dec 2013 published in March 2014.</p> <p>Initial public reporting against the full set of Key Performance Indicators occurred in August 2014.</p>	<p>Six-monthly reports on the Key Performance Indicators will continue.</p> <p>Review and revise KPIs to ensure they address the common set of performance measures required as part of the Government’s new Regulator Performance Framework.</p>
<p>Transparency Review Rec 11 – Develop and publish a policy on the disclosure of commercially confidential information, noting significant issues for each therapeutic product type. The policy should take into account the practices followed by comparable international regulators.</p>	<p>Implemented. Following formal consultation from other international regulators, industry and interested parties the document <i>“TGA Approach to disclosure of commercially confidential information”</i> was finalised providing guidance as to how official information of a business or commercial nature, provided to the TGA, is treated.</p> <p>References to 'commercial in confidence' have been changed to 'For Official Use Only' in relevant TGA forms.</p> <p>A link is provided to an explanatory statement on the treatment by the TGA of information (including commercially confidential information).</p>	<p>Finalise the guidance documents on the TGA website to remove references to commercial-in-confidence as guidance documents are reviewed.</p> <p>Provide links from all therapeutic area webpages to the commercial-in-confidence material on the TGA website.</p>

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2014	Planned Activity/Next Steps 1 Jan – 30 Jun 2015
<p>Transparency Review Rec 12 – The TGA explore mechanisms for providing explanations on its various regulatory processes, and the TGA adopt publication principles on the outcomes of application assessments, using as an exemplar the Australian Public Assessment Reports (AusPAR).</p>	<p>Implemented <i>The Australian Regulatory Guidelines for Prescription Medicines</i> and its appendices have been updated and published.</p> <p>Over-the-Counter medicines guidelines updated and published, reflecting reformed pre-market evaluation processes.</p> <p>New format developed for presenting regulatory guidelines on the web which is simpler for applicants to use and for the TGA to update.</p> <p>Developed a new concept for explaining the various regulatory processes for the therapeutic goods industry.</p> <p>Developed a program for updating regulatory guidelines using the new web based format.</p>	<p>Ongoing review, updates and maintenance to regulatory guidance will occur as part of business as usual activity.</p>
<p>Transparency Review Rec 13 – Assess the feasibility of developing an on-line system for the submission and tracking of all applications for assessment, which enables the sponsor to ascertain the progress of an application.</p>	<p>Implemented. The TGA electronic Business System (eBS) allows sponsors to see what stage applications are up to.</p> <p>The supporting documentation for medicine applications is large and complex. The TGA published technical specifications for electronic Common Technical Document (eCTD) submissions. These specifications were then used as part of a pilot and TGA successfully received eleven electronic submissions.</p> <p>TGA consulted and received comments from industry on the draft eCTD specifications.</p>	<p>The TGA will develop and publish final specification and guidance material for eCTD submissions so that industry can develop electronic submission systems.</p> <p>The TGA will assess the readiness of industry and the TGA to submit and receive these dossiers in the eCTD format.</p>

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2014	Planned Activity/Next Steps 1 Jan – 30 Jun 2015
<p>Transparency Review Rec 14 – The TGA work with stakeholders to improve labelling and packaging requirements to educate and assist consumers and health practitioners to make informed decisions about the quality use of therapeutic goods.</p>	<p>On track. Stakeholder consultation on an initial paper on proposed regulatory changes to the labelling and packaging of medicines to address consumer safety risks completed. Paper on evidence base published, along with discussion paper on options for regulatory change.</p> <p>A revised Therapeutic Goods Order (TGO) has been drafted.</p> <p>Public consultation was undertaken on the general requirements for medicines, including proposed options in the Regulatory Impact Statement.</p> <p>Submissions have been reviewed.</p>	<p>Publish submissions on TGA website.</p> <p>Revise TGO based on feedback received from public consultation.</p> <p>Consult with stakeholders on proposed changes, and seek advice from Government on next steps.</p>
<p>Transparency Review Rec 15 – The TGA conduct, and report on, a feasibility study into the development of an early post-marketing risk communication scheme for therapeutic goods, with consideration of international models.</p>	<p>Implemented. An assessment of international models was undertaken. Stakeholder consultation on the feasibility of implementing a new-to-market risk communication scheme which signals to people using therapeutic products that a particular product is new, or newly available for a particular use.</p>	<p>This work is to be further progressed in the context of the ongoing maintenance and accuracy of Approved Product Information (PI) and Consumer Medicines Information (CMI) (see comment on <i>Transparency Review Rec 17</i>).</p>

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2014	Planned Activity/Next Steps 1 Jan – 30 Jun 2015
<p>Transparency Review Rec 16 – The TGA actively promote the distribution of therapeutic goods safety information, and examine mechanisms for improving the timely communication of alerts and recalls, to health practitioners and to consumers.</p>	<p>On track. Development, with Medsafe NZ, of a common approach to capturing, management and publication of recall information. The System of Australian Recall Actions providing access to information about recalls action that have been undertaken in Australia The Recall Portal provides access to information about recall actions occurring in Australia and New Zealand. Both databases hold information on Australian recall actions from 1 July 2012.</p> <p>The Early Warning System (EWS) webpage was launched providing information on potential safety concerns.</p> <p>The TGA has identified a number of areas for improvement to the updated Uniform Recall Procedure for Therapeutic Goods (URPTG) and has prepared consultation documentation.</p>	<p>Consultation is expected to be undertaken with a view to finalising the updated URPTG.</p>
<p>Transparency Review Rec 17 – The TGA explore mechanisms to maintain the currency of Consumer Medicines Information (CMI) and Approved Product Information (PI).</p>	<p>Implemented. Stakeholder consultation on the development of proposals to improve access to, and the currency of, PI and CMI to foster quality use of medicines. Consultation included public consultation and industry consultation workshops.</p> <p>Advice has been provided to Government based on the consultations.</p> <p>The Registered Indications Reference Group met in September to consider issues relating to updating registered indications for prescription medicines as they relate to off-label use. The initial focus has been on three medicines (ramipril, dacarbazine and tamoxifen).</p>	<p>A broader reference group will focus on identifying potential solutions to reduce barriers to updating registered indications for prescription medicines in the longer term.</p>

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2014	Planned Activity/Next Steps 1 Jan – 30 Jun 2015
<p>Transparency Review Rec 18 – The TGA progressively develop and implement a system to publish the outcomes of investigations and compliance actions taken.</p>	<p>Implemented. Information on listed complementary medicines cancellations from the ARTG following compliance reviews, including the grounds for cancellation have been published on the TGA Website since October 2012. TGA published a description of its regulatory compliance framework.</p>	<p>Continue to progressively publish outcomes of compliance actions across a fuller range of product types.</p>
<p>Transparency Review Rec 19 – The TGA more effectively facilitate the recognition and reporting of adverse events by health practitioners and consumers, and promote the adverse event reporting system.</p>	<p>Implemented. Strategy to increase consumer and health professional awareness of, and participation in, the adverse event reporting system is being implemented. The strategy includes activities to:</p> <ul style="list-style-type: none"> • promote adverse event reporting • educate health professionals about how and why to report adverse events • improve access to reporting methods <p>Online education activities for health professionals about adverse event reporting relating to medicines, vaccines and medical devices.</p> <p>Online consumer form developed for consumers to report adverse events.</p>	<p>Develop materials to improve consumer and health professional awareness of adverse event reporting.</p>
<p>Transparency Review Rec 20 – The TGA make its Adverse Events Database available to and searchable by, the public in a manner that supports the quality use of therapeutic goods.</p>	<p>Implemented. The public have access to Australian and New Zealand medicines and medical device adverse events data through the release of publicly-searchable databases – the Database of adverse events (DAEN) on TGA.gov.au and the Joint Adverse Event Notification System on ANZTPA.org.</p>	

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2014	Planned Activity/Next Steps 1 Jan – 30 Jun 2015
<p>Transparency Review Rec 21 – The TGA work with State and Territory governments, stakeholders, and other relevant agencies, to improve the visible management of adverse event reporting in support of consumer safety and consistent with the findings of the Horvath Review into Immunisation.</p>	<p>Implemented.</p> <p>Work with the Office of Health Protection (Department of Health), States and Territories has resulted in a better two way exchange of information about adverse events following immunisation (AEFI), including: intensive monitoring of influenza vaccines; enhanced surveillance of Gardasil to include males; and preparation for enhanced surveillance for the new combined measles-mumps-rubella-varicella vaccine.</p> <p>Two searchable databases provide public access to Australian and NZ medicine adverse event data (including for vaccines) and medical devices adverse event data.</p> <p>An Advisory Committee on the Safety of Vaccines (ACSOV) has been established advising both the TGA, on regulatory aspects of vaccine safety, and the Office of Health Protection, on national program aspects.</p> <p>Strategy to increase consumer and health professional awareness of, and participation in, the adverse event reporting system is being implemented.</p>	<p>The Advisory Committee on the Safety of Vaccines (ACSOV) will continue to advise both the TGA, on regulatory aspects of vaccine safety, and the Office of Health Protection, on national program aspects.</p>

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2014	Planned Activity/Next Steps 1 Jan – 30 Jun 2015
Recommendations relating to complementary medicines		
<p>Auditor-General's Report Rec 1 – To achieve timely completion of key guidance material for complementary medicines:</p> <ul style="list-style-type: none"> a. provide a target date for the completion and publication of each key guidance document. b. provide regular progress reports on the development of key guidance documents on the TGA website, to keep industry, health professionals and consumers informed. 	<p>Implemented. Target dates for the completion of each key guidance document published. Regular progress reports on the development of the key guidance documents published. An update to the Australian Regulatory Guidelines for Complementary Medicines has been finalised and published. Revised Evidence Guidelines were published.</p>	
<p>Auditor-General's Report Rec 2 – To improve the integrity of the self-assessment process for listing complementary medicines on the Australian Register of Therapeutic Goods, the ANAO recommends that Health seeks to finalise work on the 'coded indications' project so as to limit the use of inappropriate claims and indications on the ARTG.</p>	<p>Material variation. Public and industry consultations held on permitted (coded) indications. Development of enhancements to Electronic Listing Facility (ELF) application portal to enable implementation of the proposed changes.</p> <p>The TGA has worked with industry on updating a comprehensive list of indications which meets the needs of the complementary medicines industry and improves compliance with the regulatory framework.</p>	<p>Options for reform of the regulation of complementary medicines will be considered by the Expert Review of Medicines and Medical Devices Regulation.</p>
<p>Auditor-General's Report Rec 3 – TGA makes information available in a timely manner to the Australian public, for each listed complementary medicine, stating whether it has been subject to post- market review by the TGA, when it was reviewed, and the outcome of that review.</p>	<p>Implemented. Publication of a Compliance Review Framework on the TGA website.</p> <p>Regular publication on the TGA website of listed complementary medicines cancelled as a result of compliance reviews.</p>	<p>Information on the cancellations of listed complementary medicines following post-market reviews will be published on the TGA website.</p>

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2014	Planned Activity/Next Steps 1 Jan – 30 Jun 2015
<p>Auditor-General's Report Rec 4 – To improve compliance with the regulatory framework, the ANAO recommends that the TGA:</p> <ul style="list-style-type: none"> a. use its random sampling review of listed medicines to develop risk profiles of sponsors and the most significant characteristics of medicines b. use the profiles to inform its program of post-market reviews. 	<p>Implemented. IT reporting system for post-market reviews developed. Risk profiling begun.</p>	<p>Data collected from listing compliance reviews will be used to develop risk profiles to prioritise future compliance review activity.</p>
<p>Auditor-General's Report Rec 5 a – The ANAO recommends that the TGA adopt a standard operating procedure for completing investigations of advertising breaches, incorporating: appropriate timeframes for completing the investigations of advertising breaches; in non- compliance.</p>	<p>Implemented. A standard operating procedure for investigating advertising breaches is in place.</p>	
<p>Auditor-General's Report Rec 5 b – The ANAO recommends that the TGA adopt a standard operating procedure for completing investigations of advertising breaches, incorporating: provision of regular reports to the TGA executive on progress with investigations and trends in non- compliance.</p>	<p>Implemented. Business requirements reviewed and functional specifications for the development of a new advertising workflow system finalised.</p> <p>A workflow system for advertising complaints, to facilitate regular reporting to the TGA Executive progress with complaint investigations and trends in non-compliance.</p>	<p>Reports will be considered by the TGA's Regulatory Compliance Committee.</p>
<p>Informal Working Group Rec 1a – Provide increased information on product labels regarding regulatory assessment undertaken by TGA of complementary medicines.</p>	<p>Implemented. Options in this area were considered in 2012-13 and it was decided not to progress changes at this time.</p>	<p>Transparency Recommendation 7 ("educate and inform the public that listed medicines are not evaluated for effectiveness by the TGA prior to market") will continue to be pursued.</p>

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2014	Planned Activity/Next Steps 1 Jan – 30 Jun 2015
Informal Working Group Rec 1b - Provide increased information on TGA website regarding regulatory assessment undertaken by TGA of complementary medicines.	Implemented. See comment on Auditor General's Report Rec 3 above.	
Informal Working Group Rec 2a - Modify Electronic Listing Facility system, to include restriction or elimination of access by sponsors to 'free text'.	Material variation to delivery. Proposed legislative amendments associated with the permitted (coded) indications for listed medicines are on hold.	Options for reform of the regulation of complementary medicines will be considered by the Expert Review of Medicines and Medical Devices Regulation.
Informal Working Group Rec 2b – Modify Electronic Listing Facility system, to provide guidance and cautionary notes for sponsors using the Electronic Listing Facility, regarding the consequences of misleading and unsubstantiated claims.	Implemented Guidance and cautionary notes have been included in the Electronic Listing Facility system.	
Informal Working Group Rec 3 – Update 'Guidelines for levels and kinds of evidence' and include 'Guidelines for levels and kinds of evidence' in regulation.	Implemented. The Evidence Guidelines document has been revised following two rounds of consultation. Options to include the Evidence Guidelines in regulation were considered and it was decided not to progress changes at this time.	
Informal Working Group Rec 4 – Review current 'coded indications' project based on the document 'Guidelines for levels and kinds of evidence' and either restrict or eliminate access by sponsors to 'free text' in the Electronic Listing Facility.	Material variation to delivery. See comments on Auditor-General's Report Rec 2 and Informal Working Group Rec 2a above.	

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2014	Planned Activity/Next Steps 1 Jan – 30 Jun 2015
Informal Working Group Rec 5 – Apply, enforce and publicise sanctions and penalties, including for advertising breaches, including recalling products from the market that are removed from the ARTG as a result of regulatory action.	Implemented. Regulatory Compliance Framework published.	
Informal Working Group Rec 6 – Enhance sanctions and penalties for repeated breaches of non- compliance (as well as strengthening sanctions and penalties for advertising).	On track. Refer to Advertising Rec 2	

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2014	Planned Activity/Next Steps 1 Jan – 30 Jun 2015
Recommendations relating to medical devices		
Medical Device Reforms – Proposal 1 Reclassification of joint replacement implants.	Implemented. Joint replacement implants re-classified as of 1 July 2012, with a two year transition period concluding on 30 June 2014. Industry and health care practitioner information sessions held.	Transition period has been extended to 30 June 2015. TGA will continue to work with the Medical Technology Association of Australia, the Australian Orthopaedic Association and other stakeholders to resolve issues to ensure the continued availability of orthopaedic devices that are safe and perform as intended. This includes regular communications with industry about the changes and required next steps as well as liaison with healthcare professionals using these products.

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2014	Planned Activity/Next Steps 1 Jan – 30 Jun 2015
<p>Medical Device Reforms –Proposal 2a – Use of third party assessment bodies for Australian manufacturers.</p> <p>Proposal 2b – Increasing pre-market scrutiny for implantable medical devices.</p> <p>Proposal 2c – Recognition of third party assessment bodies.</p>	<p>Implemented.</p> <p>The Regulatory Impact Statement: <i>Changes to premarket assessment requirements for medical devices</i> was released on 1 August 2013, outlining proposals to enhance premarket scrutiny of the higher risk devices, publication of medical device regulatory decisions, and removing the requirement for TGA conformity assessment for Australian medical device manufacturers.</p> <p>Australian medical device manufacturers are able to used conformity assessment certification from European notified bodies when making applications to the TGA.</p>	
<p>Medical Device Reforms –Proposal 3(i) – Amend the way in which a kind of medical device is included in the ARTG.</p>	<p>Implemented.</p> <p>Stakeholder views have been sought on exploring alternative ways to improve traceability of medical devices. International developments and the emerging e-Health agenda are being considered in developing alternate options to amending the way devices are included on the ARTG.</p>	<p>The advantages and efficiencies through a global approach in providing international Unique Device Identifiers in Europe and the USA will be harnessed.</p>
<p>Medical Device Reforms –Proposal 4 – Publication of device product information on the TGA Website.</p>	<p>Material variation to delivery.</p> <p>The RIS exposure draft addressing Proposal 2 incorporated an intention to seek stakeholder views on publication of an AusPAR style document for medical devices.</p>	<p>Possible regulatory changes will be considered by the Expert Review of Medicines and Medical Devices Regulation.</p>

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2014	Planned Activity/Next Steps 1 Jan – 30 Jun 2015
Recommendations relating to advertising of therapeutic products to the general public		
Advertising Consultation – Rec 1 Publish the report on advertising reform on the website, once finalised.	Implemented. The <i>Advertising Regulatory Framework – Options for Reform</i> report published on the TGA website in May 2012.	
Advertising Consultation – Rec 2 – Reforms to advertising framework.	Implemented. Public consultation paper incorporating proposals for future regulation of advertising - “ <i>Consultation Regulation Impact Statement - Regulating the advertising of therapeutic goods to the general public</i> ” (consultation RIS) closed on 12 July 2013. 1276 public submissions in response to the consultation RIS reviewed and submitted to Government options for improvements to the regulatory arrangements for the advertising of therapeutic goods to the general public.	
Advertising Consultation – Rec 2a – Modify pre-approvals process to include medical devices and pay TV (advertising claims about the efficacy of a product to be assessed by the TGA).	Implemented. See comment on Advertising Rec 2 above.	
Advertising Consultation – Rec 2b –Establish a single entry point for all complaints, with some handled by TGA (complaints about the efficacy of a product to be assessed by the TGA).	On track. The public consultation paper - “Consultation Regulation Impact Statement - Regulating the advertising of therapeutic goods to the general public” (consultation RIS) which closed on 12 July 2013 incorporated consideration of a single entry point.	Possible regulatory changes will be considered by the Expert Review of Medicines and Medical Devices Regulation.
Advertising Consultation – Rec 2c – Develop a more effective approach to sanctions and penalties (including use of the infringement notice provisions).	Implemented. See comment on Advertising Rec 2 above.	

Appendix B: Implementation Schedule

	Phase 3 – July 2013 to December 2015: Mature and sustainable performance			
	July 2014 – June 2015		July 2015 – December 2015	
	Recommendations Implemented		Recommendations Implemented	
Stream 2 – Communication & Stakeholder Engagement <i>Projects that deliver on recommendations for better communications and stakeholder engagement</i>	<ul style="list-style-type: none"> Provide information on TGA's organisational effectiveness Improved communication of recalls 	TR10 TR 16	<ul style="list-style-type: none"> Ongoing improvements to information on TGA website Enhance information on processes for regulation of advertising Improve labelling and packaging 	TR5 TR9 TR14
Stream 3 – Advertising <i>Projects that deliver on recommendations for reform of Advertising</i>			<ul style="list-style-type: none"> Single entry point for advertising complaints 	Adv2b
Stream 4 – Complementary Medicines <i>Projects that deliver on recommendations for reform of Complementary Medicines</i>			<ul style="list-style-type: none"> Finalise 'coded' indications 	A-G2 IWG2(a) IWG4
			<ul style="list-style-type: none"> Consult and provide advice to government on sanctions 	IWG6
Stream 5- Medical Devices <i>Projects that deliver on recommendations for reform of Medical Devices</i>			<ul style="list-style-type: none"> Publish device product information 	MD4

Legend: TR= Transparency Review A-G=Auditor-General Report on Complementary Medicines Adv=Advertising Consultations IWG= Informal Working Group on Complementary Medicines MD=Medical Devices Reform Consultations

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia

Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6232 8605

<http://www.tga.gov.au>

Reference/Publication #