



Australian Government

Department of Health

Therapeutic Goods Administration

TGA Reforms: A blueprint for TGA's future

Progress Report as at 31 December 2013

February 2014

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>>.

Copyright

© Commonwealth of Australia 2014

This work is copyright. You may reproduce the whole or part of this work in unaltered form for your own personal use or, if you are part of an organisation, for internal use within your organisation, but only if you or your organisation do not use the reproduction for any commercial purpose and retain this copyright notice and all disclaimer notices as part of that reproduction. Apart from rights to use as permitted by the *Copyright Act 1968* or allowed by this copyright notice, all other rights are reserved and you are not allowed to reproduce the whole or any part of this work in any way (electronic or otherwise) without first being given specific written permission from the Commonwealth to do so. Requests and inquiries concerning reproduction and rights are to be sent to the TGA Copyright Officer, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606 or emailed to <tga.copyright@tga.gov.au>.

Contents

Background to the TGA reforms	4
TGA reform themes	4
Progress to 31 December 2013	4
Recommendations implemented _____	5
Progressing implementation: 2013-14 _____	6
Expected benefits from the reforms	6
Communication and stakeholder engagement _____	6
Complementary medicines _____	7
Medical devices _____	8
Advertising of therapeutic products to the general public _____	8
Appendix A: TGA Reforms – Blueprint	
Recommendation Status	10
Recommendations relating to communication and stakeholder engagement _____	10
Recommendations relating to complementary medicines _____	20
Recommendations relating to medical devices _____	23
Recommendations relating to advertising of therapeutic products to the general public _____	24
Appendix B: Implementation Schedule	26

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: Phase 1: January 2012–June 2012, Phase 2: July 2012–June 2013 and Phase 3: July 2013–December 2015.

Progress to 31 December 2013

Forty-eight (48) recommendations will be implemented by the TGA during the four year program:

1. Four (4) recommendations were implemented by 30 June 2012 (as planned).
2. A further twenty-four (24) recommendations have been implemented by 30 June 2013.
3. A further twenty (20) recommendations will be implemented by 31 December 2015. Three of the twelve (12) recommendations forecast for delivery in 2013-14 have been implemented in the first half of the financial year. The remaining 9 recommendations are on track for implementation by 30 June 2014. One recommendation forecast for delivery in 2014-15 has also been implemented.

Appendix A provides information on TGA's progress against each of the recommendations including progress to 31 December 2013 and activity planned for the next six months (until 30 June 2014).

Appendix B provides a planned schedule for implementation of recommendations in the period from 1 July 2013 to 31 December 2015 (Phase 3).

Recommendations implemented

As at 31 December 2013, thirty-two recommendations have been implemented.

Three recommendations relating to complementary medicines have been implemented in the first half of 2013-14. Information from compliance reviews is being used to develop risk profiles of sponsors and characteristics of medicines to inform the targeted compliance review program. This addresses Auditor-General's Recommendations 4a and 4b.

In response to Auditor-General's Recommendation 5b, an IT reporting system has been developed to enable provision of regular reports to the TGA executive on progress with investigations and trends in non-compliance.

Transparency review recommendation 4 which relates to working with key information providers has also been implemented. This recommendation was forecast to be implemented in 2014-15.

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 Recommendation 8 has been described as "implemented" because the role of advisory committees in the context of TGA's regulatory decisions has been described publicly, including on the TGA website. Further work will occur in 2013-14 to finalise principles for publishing committee meeting information. A further example is Transparency Recommendation 13. The recommended assessment into the feasibility of developing an on-line system for the submission and tracking of all applications is complete, as is the process to procure a new system for electronic lodgement of supporting industry application data. The commissioning phase for new systems will involve wide-ranging changes to work practices and opportunities for efficiencies in processes for industry. Introducing these changes will require consultation with industry, and revision of TGA work practices over the next two years.

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 2014 is shown against each recommendation in Appendix A. This appendix also shows recommendations which have been implemented and those on track.

Progressing implementation: 2013-14

There are nine remaining recommendations forecast to be implemented by June 30, 2014. Delivery of these recommendations is on track. The TGA will continue tasks such as undertaking consultation processes, preparing regulation impact statements (where required), seeking policy approval for changes and drafting legislation (where legislative change is required). Planned activity for the Jan -June 2014 period against each Blueprint recommendation is shown in Appendix A.

Expected benefits from the reforms

Communication and stakeholder engagement

Over the last six months, the TGA has continued to improve its communication, education and stakeholder engagement activities through the implementation of the [TGA external communications and education framework: Priorities and projects 2013-15](#).

There has been a significant focus on the development of [educational materials](#) targeting specific audiences. In December 2013 we published and disseminated six information modules to educate final year university students on the work of the TGA. These modules have been provided in editable form so that can either be viewed in isolation, delivered by a lecturer as provided or particular slides incorporated into teaching materials by universities.

We have also developed new educational materials for consumers and health professionals on five topics: the role of the TGA; 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 how to become a commercial supplier of a therapeutic good. These were tested with target audiences in December 2013 and following some modifications will be released publicly in February 2014.

In addition to these projects, we have worked in partnership with other medicines and health information providers to create and disseminate information on a number of topics such as: the regulation of sunscreens containing nanoparticles, biosimilar medicines, adverse event reporting and medicine shortages.

We continued to participate in numerous public events and conferences in various capacities, ranging from providing speakers to purchasing exhibition space at conferences. Since July 2013, this has included exhibition spaces at events held by the Australian College of Nursing, the Pharmaceutical Society of Australia, the Australian Society of Anaesthetists and the Australian Students' Medical Association.

The TGA has also provided speakers to events held both domestically and internationally. This includes providing speakers at events organised by the Australian Self Medication Industry, New Zealand Self Medication Industry, Medical Technology Association of Australia, Medical Technology Association of New Zealand, the Public Health Association of Australia and the Complementary Healthcare Council. Presentations given at other events are available on our [website](#).

Over the period we have also regularly engaged with many other stakeholders through formal meetings, including the Global Drug Safety Colloquium held in Brisbane and the Food Regulation Implementation Standing Committee in Perth. These opportunities enhance the ongoing stakeholder engagement that occurs through regular interactions and through our advisory and consultative committees.

Efforts to improve our website are ongoing. A major upgrade to the website occurred in November 2013; a new homepage was launched and the site was made more user friendly for people viewing it on devices and smartphones.

In July 2013 we incorporated the Australian Register of Therapeutic Goods (ARTG) into the website search engine. Users can now get results quickly and easily, and view the ARTG entries alongside all other information about the product/s without having to conduct the search separately through the eBusiness portal (The eBS search functionality is still available.)

From August 2012 to July 2013 the TGA piloted a central unit, the Public Contact Team (PCT) to manage the flow of the TGA's main enquiry lines. This pilot was successful, and the PCT became an operational unit from July 2013. During 2013 we received 32,907 enquiries to the TGA's general 1800 number and generic email account, and through documenting the nature of these enquiries the PCT has made a significant contribution to identifying the needs of the TGA's stakeholders.

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 is an Australian National Audit Office Audit "Therapeutic Goods Regulation: Complementary Medicines" which reported in 2011. Major recommendations of that audit were:

- Timely completion of key guidance materials
- Improving the integrity of the listing system for complementary medicines so as to limit the use of inappropriate claims
- Achieving greater transparency regarding the post-market review of listed products
- Enhancing post-market monitoring so as to more efficiently focus post-market resources towards problem areas
- Developing more efficient processing of advertising complaints

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, is being finalised for publication. In addition, an update to the Australian Regulatory Guidelines for Complementary Medicines was made available in December 2013.
- **Publishing outcomes of listing compliance reviews.** The TGA will continue 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 reports 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. Public and industry consultations have been held to develop potential approaches for discussion with government.

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 from 1 July 2012 to 30 June 2014 for devices already in the ARTG. During this reporting period the assessment of reclassification applications has been a priority, with the TGA receiving applications to reclassify existing medical devices from late 2012. Communication with industry is ongoing to provide information on the ongoing transition and to ensure that the goals of the reform are achieved.

The Regulation Impact Statement: Changes to premarket assessment requirements for medical devices 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. Options to enhance the premarket scrutiny of the highest risk devices are being further developed in consultation with stakeholders. The aim of reforms is to ensure appropriate regulatory scrutiny of devices to protect public health and safety while also reducing unnecessary administrative and regulatory burden and delays to market for industry and delays in access to new technologies for healthcare consumers. It is expected further consultation on these options will be undertaken in the first half of 2014.

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-Only, Controlled Drug and certain Pharmacist -Only medicines is prohibited, and only price information can be provided in print materials.

A number of reviews, along with feedback from public consultations and media coverage over recent years have highlighted the dissatisfaction with the existing advertising regulatory framework for therapeutic goods. The major concern is that the framework is overly complicated, 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.

To address the above concerns, the TGA developed a set of proposals for reforming the advertising regulatory framework based upon the outcomes of the recent advertising reviews. These proposals were further refined in the *Consultation Regulatory Impact Statement (RIS) - Regulating the advertising of therapeutic goods to the general public (31 May 2013)* which closed on 19 July 2013.

The RIS proposed a number of reform option primarily focusing on the pre-approvals scheme, complaint handling procedures and sanctions and penalties for dealing with advertising breaches.

Over the last 6 months, the TGA has reviewed the submissions made in response to the Consultation RIS and submitted to Government options for improvements to the regulatory arrangements for the advertising of therapeutic goods to the general public.

Appendix A: TGA Reforms – Blueprint Recommendation Status

Key: Implemented  On Track  |

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2013	Planned Activity/Next Steps 1 Jan 2014 –30 June 2014
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 and August 2013. The Council provides an oversight role in the implementation, monitoring and evaluation of the Blueprint recommendations.	The Council will meet in February 2014 and continue to meet twice a year.
Transparency Review Rec 2 – Define, adopt and publish consultation principles to guide regulatory transparency and accountability.	Implemented. Development of two consultation documents. <i>TGA Consultation Principles</i> and <i>TGA Consultation principles – A Guide for Staff</i> 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.	Following implementation of this recommendation the new framework has been adopted. New work will commence on better communication material about the food-medicine interface, and the dissemination of new materials will be a priority from Jan to June 2014 (see below).

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2013	Planned Activity/Next Steps 1 Jan 2014 –30 June 2014
<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. 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 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.</p>	<p>From January to June 2014 major work will commence on the dissemination of education materials identified above, as part of the ongoing work under the Communications and Education Framework.</p> <p>We will also continue our business-as-usual speaker and conference activities including, high-profile participation in:</p> <ul style="list-style-type: none"> • Hospital Procurement and Supply Chain Reform conference (February) • ASMI roundtable (March) • International Electromaterials Symposium (February), • AusMed Tech (April), Centre for International Regulatory Sciences (April) • Pharmaceutical Science World Congress in April • National Medicines Symposium in May • ARCS (Regulatory and Clinical Science, June) • Drug Information Association Global conference (June) <p>A number of educational activities are planned with industry including ARCS seminars and webinars.</p>

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2013	Planned Activity/Next Steps 1 Jan 2014 –30 June 2014
<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. A new approach to managing the TGA's enquiry handling has been adopted. The Public Contact Team implemented as business-as-usual activity. 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.</p> <p>Work through stakeholder surveys and market research to evaluate the effectiveness of information on the TGA website in meeting the communication and information needs of key stakeholders.</p> <p>Communication about TGA's post-market regulatory activities on the website strengthened through the launch of:</p> <ul style="list-style-type: none"> databases for searching adverse events for medicines and medical devices databases of therapeutic goods recalls early warning system to inform consumers of potential safety issues. <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>Continue testing new communication and education materials that are audience-centered, based on outcomes of research into the communication and education needs of major stakeholders.</p> <p>The website will become more interactive with new dynamic content on:</p> <ul style="list-style-type: none"> the role of the TGA 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 how to become a commercial supplier of a therapeutic good <p>The Product Information and Consumer Medicine Information results will also be added into the TGA website search engine.</p>

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2013	Planned Activity/Next Steps 1 Jan 2014 –30 June 2014
<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 <i>External Communication and Education Framework</i> 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>Following implementation of this recommendation, further work will be undertaken to develop and implement a media plan to communicate the TGA’s risk based framework more broadly. New education materials for consumers and health professionals will be 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. New education materials for consumers and health professionals on the risk vs benefit approach to regulating therapeutic goods have been developed and tested with target audiences.</p>	<p>New educational materials on role of the TGA, risk based approach to regulation and higher and lower risk medicines reinforce the messages about listed medicines. Dissemination of these materials will be a priority over the next six months.</p>

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2013	Planned Activity/Next Steps 1 Jan 2014 –30 June 2014
<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 will be published during 2014. The initial focus will be on TGA's post-market advisory committees as there are a number of commercial-in-confidence issues with 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>On track. Development of specifications for the development of a complaints handling IT system, including a reporting function. A consultation paper 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.</p>	<p>Finalise documentation for workflow system implementation for advertising complaints.</p>

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2013	Planned Activity/Next Steps 1 Jan 2014 –30 June 2014
<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>On track. The Australian Therapeutic Goods Advisory Council (the Council) and TGA-Industry Consultative Committee have been 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 will begin, with reporting against KPIs for the period July-Dec 2013 to be reviewed by the Australian Therapeutic Goods Advisory Council in Feb, 2014 and the TGA-Industry Consultative Committee in March 2014 and publicly thereafter.</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. Comments from other international regulators, industry and interested parties were sought through formal consultation on the paper “Draft TGA approach to the disclosure of commercially confidential material”.</p>	<p>Monitor developments in approach to release of such information by comparative national therapeutic goods regulators and in the context of the new International Coalition of Medicines Regulatory Authorities, commence collaborative work on identifying and addressing constraints to sharing information, particularly for orphan and generic drugs.</p>

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2013	Planned Activity/Next Steps 1 Jan 2014 –30 June 2014
<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>On track. <i>The Australian Regulatory Guidelines for Prescription Medicines</i> and its appendices have been updated and published.</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>Develop program for updating regulatory guidelines using the new web based format.</p> <p>Over the-Counter medicines guidelines updated and published, reflecting reformed pre-market evaluation processes.</p>	<p>Publish updated guidance materials for complementary medicines and commence work on updated guidance for medical devices. This includes the development of guidance information for clinical requirements for different types of medical devices.</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. Assessment of the capability of TGA systems to provide sponsors with access to an on-line system has been undertaken. Contractor engaged to implement an electronic Common Technical Document (eCTD) Review Tool which will enable validation, review and management of electronic dossiers submitted for evaluation.</p>	<p>Selection and initial commissioning of selected system, including training of TGA evaluators.</p> <p>Commence work to enable sponsors of OTC medicines to track the status of their applications. The OTC work will provide proof of concept of feasibility of on-line submission and tracking for other products. This work also forms part of the harmonization activities as part of development of the joint regulatory framework for ANZTPA.</p>

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2013	Planned Activity/Next Steps 1 Jan 2014 –30 June 2014
<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>Seek further input from consumers, health professionals and industry and complete Regulatory Impact Statement before finalising TGO and accompanying guidance documents.</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 as part of harmonization activities as part of the development of the joint regulatory framework for ANZTPA, and 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>
<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>This work is to be further progressed as part of harmonization activities as part of the development of the joint regulatory framework for ANZTPA. In association with Medsafe, NZ, review and update the Uniform Recall Procedure for Therapeutic Goods (URPTG).</p> <p>Improve and promote the web page that provides advice for sponsors on how to initiate a recall.</p>

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2013	Planned Activity/Next Steps 1 Jan 2014 –30 June 2014
Transparency Review Rec 17 – The TGA explore mechanisms to maintain the currency of Consumer Medicines Information (CMI) and Approved Product Information (PI).	On track. 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 includes public consultation and industry consultation workshops.	Work on this recommendation will be considered in the context of developing a model for a new-to-market risk communication scheme (see comment on Transparency Review Rec 15) as part of the development of the joint regulatory framework for ANZTPA.
Transparency Review Rec 18 – The TGA progressively develop and implement a system to publish the outcomes of investigations and compliance actions taken.	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.	Progressively publish outcomes of compliance actions across a fuller range of product types.
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.	On track. Development of a strategy to increase consumer and health professional awareness of, and participation in, the adverse event reporting system.	Implementation of the strategy to increase consumer and health professional awareness of, and participation in, the adverse event reporting system. Develop improved health professional and consumer reporting forms and web service to allow users of prescribing software to send adverse drug reaction reports directly to the TGA.
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.	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.	

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2013	Planned Activity/Next Steps 1 Jan 2014 –30 June 2014
<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>Activities to encourage health professional and consumer reporting of adverse events have been implemented.</p> <p>Commenced development of a strategy for improving adverse event reporting and provided an overview of the strategy at consultation workshops.</p>	<p>Implement recommendations of the Horvath Implementation Steering Committee on improving AEFI reporting through stakeholder consultation to inform development and delivery of activities to: improve access to reporting methods; raise awareness of adverse event reporting; and provide education about adverse event reporting.</p>

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2013	Planned Activity/Next Steps 1 Jan 2014 –30 June 2014
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.</p>	<p>Evidence Guidelines to be finalised and 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>On track. 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>Policy approval will be sought from Government on options, including legislative and regulatory change options, to limit the use of inappropriate claims.</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. Regular publication on the TGA website of listed complementary medicines cancelled.</p>	<p>Continue publication on the TGA website of cancellations of listed complementary medicines following post-market reviews.</p>

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2013	Planned Activity/Next Steps 1 Jan 2014 –30 June 2014
<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>Continue development of risk profiles of sponsors and characteristics of medicines to better inform the targeted compliance review program.</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>Development of a workflow system for advertising complaints, to facilitate reporting to the TGA Executive progressed to user acceptance testing phase.</p>	<p>Finalise pathways and other documentation for workflow system implementation for advertising complaints, to facilitate regular reporting on 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 instead be pursued</p>

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2013	Planned Activity/Next Steps
		1 Jan 2014 –30 June 2014
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 2 – Modify Electronic Listing Facility system, to: (a) include restriction or elimination of access by sponsors to 'free text'; (b) Provide guidance and cautionary notes for sponsors using the Electronic Listing Facility, regarding the consequences of misleading and unsubstantiated claims.	On track. See comment on Auditor-General's Report Rec 2 above.	Guidance and cautionary notes will be 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.	On track. See comments on Auditor-General's Report Rec 2 above. The Evidence Guidelines document has been revised following two rounds of consultation.	
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.	On track. See comments on Auditor-General's Report Rec 2 and Informal Working Group Rec 2a above.	
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.	

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2013	Planned Activity/Next Steps 1 Jan 2014 –30 June 2014
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 2013	Planned Activity/Next Steps 1 Jan 2014 –30 June 2014
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 continues until 30 June 2014. TGA will continue to work with the Medical Technology Association of Australia's Orthopaedic Working Group 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 other areas of the healthcare sector using these products.
Medical Device Reforms –Proposal 2a – Use of third party assessment bodies for Australian manufacturers. Proposal 2b – Increasing pre-market scrutiny for implantable medical devices. Proposal 2c – Recognition of third party assessment bodies	Implemented. 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.	Modified options to enhance the premarket scrutiny of the highest risk medical devices will be developed, in conjunction with assessment of approaches to better integrate assessment for regulatory and reimbursement purposes. A new Regulatory Impact Statement incorporating these options will be developed and released for comment, prior to seeking final policy approval of reforms.

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2013	Planned Activity/Next Steps
		1 Jan 2014 –30 June 2014
Medical Device Reforms –Proposal 3(i) – Amend the way in which a kind of medical device is included in the ARTG.	Implemented. 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.	The advantages and efficiencies through a global approach in providing international Unique Device Identifiers in Europe and the USA will be harnessed.
Medical Device Reforms –Proposal 4 – Publication of device product information on the TGA Website.	On track. The RIS exposure draft addressing Proposal 2 incorporated an intention to seek stakeholder views on publication of an AusPAR style document for medical devices.	Further consultation will be undertaken with stakeholders on the format of device product information, including a briefer version of AusPAR style documentation.

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2013	Planned Activity/Next Steps 1 Jan 2014 –30 June 2014
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 Advertising Regulatory Framework – Options for Reform report published on the TGA website in May 2012.	

Blueprint Recommendations addressed	Achievements 1 Jan 2012 –31 Dec 2013	Planned Activity/Next Steps 1 Jan 2014 –30 June 2014
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. Public submissions in response to the consultation RIS reviewed and possible improvements submitted to government to inform the next steps.	
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 - <i>“Consultation Regulation Impact Statement - Regulating the advertising of therapeutic goods to the general public”</i> (consultation RIS) which closed on 12 July 2013 incorporated consideration of a single entry point.	Potential reform options to be considered by government.
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

	<i>Phase 3 – July 2013 to December 2015: Mature and sustainable performance</i>					
	July 2013 – June 2014		July 2014 – June 2015		July 2015 – December 2015	
	Recommendations Implemented		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"> Ongoing activity with other key providers of information Post market risk communication Publicise compliance outcomes Promote adverse event reporting 	TR4 TR16 TR17 TR19	<ul style="list-style-type: none"> Enhance information on processes for regulation of advertising. Provide information on TGA's organisational effectiveness 	TR9 TR10	<ul style="list-style-type: none"> Ongoing improvements to information on TGA website Enhanced explanations of regulatory processes. Improve labelling and packaging. Consult and provide advice to government on sanctions 	TR5 TR12 TR14 IWG6
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 Improve guidelines and information Reports on advertising breaches 	A-G2 A-G4(a) A-G4(b) A-G5(b) IWG2(a) IWG2(b) IWG3 IWG4				
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 #