Australian Government

Delivering reforms –

Implementation plan for *TGA Reforms: A blueprint for TGA's future*

July 2012

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Implementation plan for TGA Reforms: *A blueprint for TGA's future*

About the Therapeutic Goods Administration (TGA)

- The TGA is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- 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 <www.tga.gov.au>.

Contents

Executive Summary 8

Overview 9

Background to the Blueprint reforms 9

The objectives and scope of the Blueprint reforms 9

Working effectively with consumers, health professionals, industry and government 10

The benefits for consumers, health professionals, industry and government 11

A phased approach 11

Managing implementation 12

Governance 13

Monitoring implementation 13

Funding implementation 13

Attachment A—Implementing the Blueprint reforms 14

Recommendations relating to communication and stakeholder engagement 14

Recommendations relating to complementary medicines 21

Recommendations relating to medical devices 24

Recommendations relating to advertising of therapeutic products 25

Recommendations relating to promotion of therapeutic products 26

Attachment B—The Blueprint Implementation Schedule 28

Executive summary

The Therapeutic Goods Administration is implementing a comprehensive package of reforms drawn together by the Australian Government and announced in December 2011 in the *TGA reforms: A blueprint for TGA's future* (the Blueprint).

The Blueprint reforms aim to improve community understanding of the TGA's regulatory processes and decisions, and enhance public trust and confidence in the safety and quality of therapeutic goods. In particular, the reforms aim to improve understanding of the role that the TGA plays in ensuring that Australians have timely access to the therapeutic goods that they need, and that these goods meet appropriate standards of quality, safety and efficacy.

The reforms also aim to ensure that the regulatory framework for therapeutic goods can be adapted to scientific developments and emerging community expectations about therapeutic goods.

This document provides an overview of the TGA's planned actions in response to the Blueprint reforms and how it will report on its progress in achieving the required outcomes.

Throughout the implementation of the Blueprint reforms, the TGA will consult with the Australian Therapeutic Goods Advisory Council and will take account of feedback from stakeholders.

The TGA is also committed to working collaboratively with its external stakeholders—consumers, health professionals and industry—to ensure the Blueprint reforms are implemented effectively, and that stronger relationships are established for the future.

The Blueprint reforms are grouped into the following key themes:

- communication and stakeholder engagement;
- advertising of therapeutic products;
- complementary medicines;
- medical devices; and
- promotion of therapeutic products.

Reform in each of these areas will be achieved incrementally over four years, in three phases. The priorities are:

- better managing our communication;
- better managing our practice; and
- mature and sustainable performance.

Overview

Background to the Blueprint reforms

On 8 December 2011, the Parliamentary Secretary for Health and Ageing, the Honourable Catherine King MP, released a package of reforms for the TGA outlined in *TGA reforms: A blueprint for TGA's future* (the Blueprint).

The Blueprint incorporates reforms arising from major reviews in 2010 and 2011 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**.

The TGA is responsible for implementing the Blueprint recommendations, with the exception of the recommendations made by the Working Group on Promotion of Therapeutic Products (the Working Group). Those recommendations involve matters of broader health policy and are the responsibility of the Regulatory Policy and Governance Division of the Department of Health and Ageing. In the 2012 Budget, the Australian Government provided $1.4 million over four years to further assist industry to respond to recommendations by the Working Group and support stronger self-regulation, better communication and shared systems for complaints reporting.

In addition to the Blueprint reforms, there is additional significant reform activity already underway within the TGA. There is also an ongoing program of work being jointly delivered by the TGA and Medsafe NZ in the lead up to the creation of the Australia New Zealand Therapeutic Products Authority (ANTZPA).

The objectives and scope of the Blueprint reforms

The objectives of the Blueprint reforms, and this implementation plan, are to:

- enhance the TGA's current processes to ensure that the regulatory framework in which it operates can be readily adapted to new scientific developments and emerging community expectations;
- improve the Australian community's understanding of the TGA's regulatory processes and decisions;
- enhance public trust in the safety and quality of therapeutic goods; and
- ensure the TGA effectively implements plans to inform the community of its role in providing timely access to the therapeutic goods that Australians need, and that these goods meet appropriate standards of quality, safety and efficacy.

Implementing the Blueprint reforms will require the TGA to:

- deliver outcomes that respond to the Government's Blueprint recommendations (see Attachment 1: Correlation of recommendations);
- achieve operational reforms needed to deliver benefits from those recommendations; and
- ensure that concurrent reform activities underway at the TGA in addition to the Blueprint reforms (ANZTPA and other activities) are achieved in a coordinated way.

Working effectively with consumers, health professionals, industry and government

Effective engagement with external stakeholders is a priority in the implementation of the Blueprint reforms. Consistent with the Government's commitment to openness and transparency, the TGA is adopting a strong focus on enhancing its communication and engagement with consumers, health professionals and the therapeutic goods industry throughout the Blueprint implementation projects and other concurrent reforms.

Where possible, the TGA will use its existing communication forums and channels to engage with consumers, health professionals and the therapeutic goods industry, but will investigate and develop other communication channels, including stakeholder engagement methods, to support the effective delivery of wide ranging reform projects as required.

By engaging external stakeholders effectively, the TGA will:

- raise consumer, health professional and the therapeutic goods industry awareness about the program of Blueprint reforms;
- engage external stakeholders with an interest in or affected by individual reforms in reform activities; and
- provide support throughout the implementation.

The benefits for consumers, health professionals, industry and government

The outcome	The benefit
Transparency	Clearly communicates TGA's role as a regulator in the health system, and ensures TGA decisions are evidence-based and better understood.
Empowerment	Improves access to information that assists consumers in their healthcare decision making.
Confidence	Increases consumer and health professionals' confidence in the effective regulation of therapeutic products.
Visibility	Increases awareness of the TGA's proactive role as the therapeutic goods regulator—creating 'active transparency'.
Integrity	Increases compliance with industry requirements, and the active participation of consumers and health professionals in the safety monitoring system.
Consistency	Creates a more consistent approach to regulation across different classes of therapeutic goods.
Efficiency	Assists the TGA to realise better productivity in delivering its functions.
Influence	Increases recognition of the TGA's scientific expertise and its role in informing scientific debate.
Reputation	The TGA's reputation as a trusted and effective regulator is reinforced and enhanced.

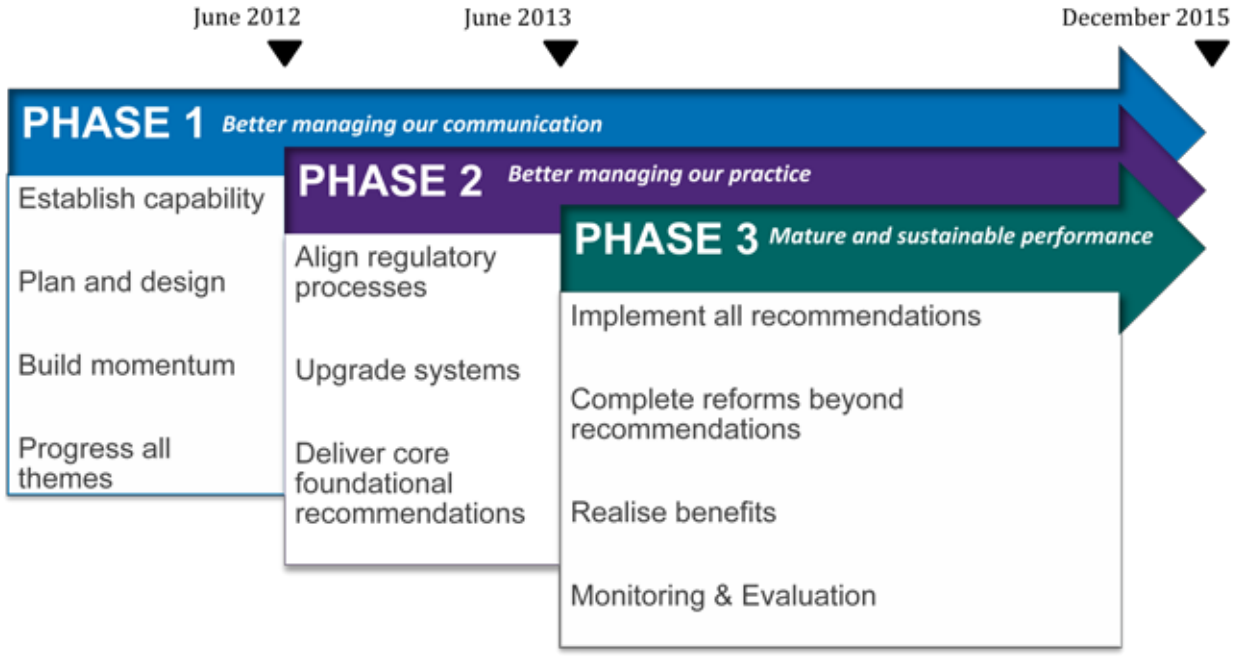
A phased approach

The phasing of the Blueprint reforms over four years will:

- allow the TGA to plan for and deliver early outcomes that will build confidence in the implementation plan and the TGA as it implements the Blueprint reforms;

- allow effective outcomes of the Blueprint reforms to occur in harmony, or as part of, the TGA's daily business activities, and take advantage of opportunities to embed positive change in its business as usual processes as it occurs;
- provide milestones for internal and external stakeholders to use to evaluate progress; and
- provide opportunities to evaluate lessons learned throughout the implementation of the Blueprint reforms, including early achievements or challenges, and make necessary changes to the implementation plan.

The three implementation phases (January–June 2012; July 2012–June 2013 and July 2013–December 2015) are outlined in the figure below.



Attachment A provides more detail about the TGA's plan to implement the Blueprint reforms. Attachment B provides an implementation schedule for the plan.

Managing implementation

Implementing the Blueprint reforms will involve six streams of activity:

1. communication and stakeholder engagement
2. advertising of therapeutic products
3. complementary medicines
4. medical devices
5. governance and management
6. organisational change

Streams 1 to 4 correspond to the themes set out in the Blueprint. Streams 5 and 6 are intended to underpin the delivery of the reforms and provide the TGA with capability to deliver, future reforms. All Blueprint reform work streams will be delivered through discreet and definable implementation projects.

Governance

The Government has announced that it will establish an Australian Therapeutic Goods Advisory Council (the Council) to encourage wider community input into the future direction of the TGA, including the implementation of the Blueprint reforms.

The Council will provide advice to the TGA National Manager, including on whether the TGA's Blueprint reform activities are meeting the needs and expectations of consumers, health professionals and the therapeutic goods industry.

Additional governance will be provided by the Blueprint Steering Committee established by the Department of Health and Ageing, which will monitor progress and ensure the implementation plan is delivering the required benefits.

Internally, the TGA Executive Committee will monitor and evaluate the delivery of the implementation plan and ensure the Blueprint reform recommendations, for which the TGA is responsible, are integrated effectively into the TGA's business operations. Separate steering committees have also been established within the TGA management structure to support the delivery of implementation plan streams and projects.

Monitoring implementation

The Office of Program Management has been established within the TGA to support the management of this implementation plan and monitor its progress. The Office will help ensure resources are used optimally and the Blueprint reform projects deliver their intended benefits in a reasonable timeframe. Progress will be reviewed and findings reported and published annually, with incremental results used to progressively inform improvements or refinements to the implementation plan as required.

Funding implementation

The full cost of regulating therapeutic goods is met through cost recovery from the regulated therapeutic goods industry.

Attachment A—Implementing the Blueprint reforms

Recommendations relating to communication and stakeholder engagement

Recommendation	Comment
Transparency Review - Rec 1 The TGA 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.	**July 2012 to June 2013** The Australian Therapeutic Goods Advisory Council will be established during 2012.
Transparency Review – Rec 2 The TGA define, adopt and publish consultation principles to guide regulatory transparency and accountability.	**July 2012 to June 2013** Consultation principles will be agreed during 2012 following consideration and feedback from the Australian Therapeutic Goods Advisory Council and other key stakeholders. The implementation of the Blueprint reforms will be undertaken in line with with the consultation principles.
Transparency Review - Rec 3 The TGA develop and implement a comprehensive communication strategy to inform and educate. A dedicated communications team should be established within TGA to implement that strategy.	**July 2012 to June 2013** A draft communication strategy has been developed ready for consultation with stakeholders. It will be finalised in 2012. Additional resources have been allocated to the TGA Communications Section to assist in the implementation of the communication strategy.
Transparency Review - Rec 4 The TGA work transparently with other key providers of information to enhance the information available to the public (community and stakeholders), consistent with the principles of the quality use of medicines.	**July 2012 to June 2013** The TGA will work with the National Prescribing Service Ltd and other information providers to establish agreement on the provision of information. **July 2013 to December 2015** A prioritised program of Memoranda Of Understanding and other arrangements appropriate to the circumstances will be implemented.

Recommendation	Comment
Transparency Review - Rec 5 The TGA 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.	**January to June 2012** The TGA has identified the most common enquiries received to inform the development of the TGA website and improvements to handling of public enquiries. In May 2012 the TGA released improvements to its e-Business website that make it easier to find information in the Australian Register of Therapeutic Goods (ARTG), and store and analyse the results of searches of the ARTG. **July 2012 to June 2013** The TGA will continue to make more information available to the public through the TGA website and other channels (for example the National Prescribing Service). An improved TGA website search engine will be released and a pilot project conducted to trial more effective public contact management. **July 2013 to December 2015** The TGA will also develop a longer term approach to content management and a channel management strategy. Market research and consultation with website users on their information needs will inform the TGA's approach.
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.	**July 2012 to June 2013** A clear explanation of the TGA's risk based framework was published on the TGA website in May 2012. More detailed explanations of the risk framework as it applies to different classes of therapeutic goods will be made available, initially focusing on listed complementary medicines. **July 2013 to December 2015** Lessons learned from this work will guide a program of updates to information on classes of therapeutic goods in addition to listed complementary medicines.
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.	**July 2012 to June 2013** The TGA will work in partnership with other information providers to develop ways to achieve wider public understanding that listed medicines are not evaluated for effectiveness by the TGA prior to market.
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.	**July 2012 to June 2013** The TGA will develop a consistent approach to providing an appropriate level of information on the outcomes and work of the different TGA statutory advisory committees. This approach will take account of the role of statutory advisory committees and the interests of consumers, health professionals and the therapeutic goods industry.

Recommendation	Comment
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.	**July 2013 to December 2015** Taking into account the outcomes of advertising reform (see Recommendations relating to Advertising of Recommendations relating to advertising of therapeutic products below), the TGA will improve the information available on advertising regulation including: · revising the TGA website pages relating to advertising; · developing a publicly accessible advertising database that includes information about complaints and their outcome; and · publishing decisions on advertising matters, including any advertising sanctions.
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. This may be achieved in conjunction with the proposed Australian Therapeutic Goods Advisory Council.	**July 2012 to June 2013** The TGA will identify and publish key performance information. Key performance indicators for the TGA will be developed for consideration by the Australian Therapeutic Goods Advisory Council and other stakeholders. **July 2013 to December 2015** Key performance indicators for the TGA will be agreed and reporting against the indicators will commence.
Transparency Review - Rec 11 The TGA 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.	**January to June 2012** The TGA is undertaking a stock take of the circumstances in which the TGA holds commercially confidential information and a comparative analysis of international approaches to the publication of commercially confidential information. **July 2012 to June 2013** Public consultation will be undertaken on an issues paper on the disclosure of commercially confidential information, to inform the development of TGA policy on commercially confidential information (taking into account the TGA's obligations under the FOI Act). Once the policy is finalised, a plan will be developed for implementation throughout TGA's processes. **July 2013 to December 2015** Implementation of the policy will be completed.

Recommendation	Comment
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).	**July 2012 to June 2013** The TGA will review and update the current *Australian Regulatory Guidelines for Prescription Medicines* (ARGPM), using a new format proposed for all TGA regulatory guidelines. The new format will be simpler for applicants, and simpler for the TGA to update. The updated ARGPM will be finalised after taking stakeholder feedback into account. The TGA will consult with stakeholders on publication principles on the outcomes of application assessments as part of business process reforms underway in relation to Over-the-Counter Medicines and Medical Devices. **July 2013 to December 2015** The TGA will release the update to the ARGPM and publish a timetable for the development of revised or new regulatory guidelines. This timetable will align with the implementation of business process reforms underway in relation to Over-the-Counter Medicines and Medical Devices. The TGA will progressively implement the new guidance framework and the publication principles on the outcomes of applications for these classes of therapeutic goods. The TGA will consult with stakeholders on publication principles on the outcomes of application assessments for other therapeutic goods as appropriate.
Transparency Review - Rec 13 The TGA assess and report on 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.	**July 2012 to June 2013** A review of the capability of TGA's systems to provide sponsors with access to an on-line system for submission and tracking for all applications for assessment will be undertaken. The review will include consultation with sponsors to identify their needs. A program of enhancements to the TGA's application processing systems will be developed. This will include an evaluation of an electronic Common Technical Document review tool capable of validating electronic submissions and provide evaluators with the capability to review submissions on screen. **July 2013 to December 2015** The program of enhancements to TGA information technology systems will continue.

Recommendation	Comment
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.	**January to June 2012** A consultation paper on proposed regulatory changes to the labelling and packaging of medicines (excluding medical devices) to address consumer safety risks was released in May 2012. The public has until 24 August 2012 to comment. **July 2012 to June 2013** Outcomes of the consultation process will be published. Based on submissions to this consultation and previously identified deficiencies in the current Therapeutic Goods Order (TGO), a revised TGO will be drafted. The draft TGO will be subject to further public consultation to help determine the industry impact of the proposed changes and inform the Regulatory Impact Statement. The final TGO will be registered as a legislative instrument and any changes will take effect for new medicines. **July 2013 to December 2015** A transition period will provide the therapeutic goods industry with time to comply with revised requirements for existing medicines.
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.	**July 2012 to June 2013** The TGA will conduct an evaluation of a post-market risk communication scheme for products coming onto the market. This evaluation will include public consultation. **July 2013 to December 2015** An evaluation report will be provided to the Government for consideration.

Recommendation	Comment
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.	**January to June 2012** The TGA and Medsafe NZ have commenced work on establishing a trans-Tasman early warning system for advising the public of potential "signals" on the safety of therapeutic goods that are being investigated. Work has also commenced on developing a common approach to publication of alerts and recall information. **July 2012 to June 2013** The TGA will: · review the notifications system and consult consumers and health professionals on potential improvements; · examine the feasibility of developing a system to allow public searching of the regulators' actions; and · publish all hazard alert and recall notices on the TGA website. **July 2013 to December 2015** If found feasible, develop and implement a system to allow public searching of actions.
Transparency Review - Rec 17 The TGA explore mechanisms to maintain the currency of Consumer Medicines Information and Approved Product Information.	**July 2012 to June 2013** The TGA will consider processes and regulatory changes that would help ensure that Consumer Medicines Information (CMI) and approved Product Information (PI) reflect current circumstances. The TGA will also examine options for improving access to and information about CMIs and PIs. Public consultation will inform the development of these proposals. Advice on any proposals requiring regulatory change will be provided to the Government. **July 2013 to December 2015** The TGA will provide feedback on any proposed changes and the process for their implementation.
Transparency Review - Rec 18 The TGA progressively develop and implement a system to publish the outcomes of investigations and compliance actions taken.	**July 2012 to June 2013** The TGA will commence providing information on the outcomes of post-market reviews of complementary medicines (see ***Auditor-General's Report on Therapeutic Goods Regulation: Complementary Medicines*—Rec 3** below). **July 2013 to December 2015** The TGA will progressively broaden this approach to providing information on the outcomes of investigations and compliance actions to other classes of therapeutic goods.

Recommendation	Comment
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.	**January to June 2012** In March 2012 the TGA released an on-line system for the reporting of problems with medical devices. **July 2012 to June 2013** A strategy will be developed to increase consumer and health professional awareness of, and participation in, the adverse event reporting system. This strategy will include how the TGA provides information about the rationale for actions taken by TGA in relation to adverse event reports and how reported events can be followed up.
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.	**July 2012 to June 2013** The public will have access to Australian adverse drug reaction data through the release of a publicly-searchable database. Further work will be undertaken to provide the public with access to Australian and New Zealand adverse drug and medical device incident data.
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.	**January to June 2012** The TGA will continue to work with stakeholders to ensure the timely sharing of information relating to influenza vaccine adverse events. In February 2012 the TGA provided information on the 2012 seasonal influenza vaccines for use in children and encouraged health professionals and consumers to report all adverse events associated with influenza vaccinations to the TGA or through State and Territory arrangements. **July 2012 to June 2013** A more comprehensive strategy for improving the sharing of information on adverse events will be developed in collaboration with relevant information providers. **July 2013 to December 2015** The TGA will progressively implement information sharing arrangements with other information providers.

Recommendations relating to complementary medicines

Recommendation	Comment
The Auditor-General report was tabled in Parliament on 12 September 2011	
Auditor-General's Report on Therapeutic Goods Regulation: Complementary Medicines - Rec 1 To achieve timely completion of key guidance material for complementary medicines, the ANAO recommends that DoHA: **a.** provides a target date for the completion and publication of each key guidance document; and b. provides regular progress reports on the development of key guidance documents on the TGA website, to keep industry, health professionals and consumers informed.	**January to June 2012** In June 2012 the TGA published dates for the completion of key regulatory guidance materials that underpin the regulation of complementary medicines. Regular progress reports on an update to the *Australian Regulatory Guidelines for Complementary Medicines* (ARGCM) to reflect the current legislative framework and processes will be published on the TGA website. **July 2012 to June 2013** An update of ARGCM is scheduled for release in September 2012. Comments will be invited through public consultation to inform a further update that will be published by June 2013. See comment on **Informal Working Group Examining Complementary Medicines Regulation and Reasons for Low Compliance Rates - Rec 3** below**.**
Auditor-General's Report on Therapeutic Goods Regulation: Complementary Medicines - Rec 2 To improve the integrity of the self-assessment process for listing complementary medicines on the Australian Register of Therapeutic Goods (ARTG), the ANAO recommends that DoHA seeks to finalise work on the 'coded indications' project so as to limit the use of inappropriate claims and indications on the ARTG.	**July 2012 to June 2013** By December 2012, the TGA intends to rationalise and expand the number of coded indications available through the assessment of common indications currently found in free text in existing Listed Complementary Medicines. Further steps such as eliminating the free text field, requiring sponsors to use only the available coded indications or to apply for a new coded indication would require legislative amendment. As such the TGA will consult stakeholders on this recommendation.
Auditor-General's Report on Therapeutic Goods Regulation: Complementary Medicines - Rec 3 The ANAO recommends that the 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.	**July 2012 to June 2013** The TGA will provide the public with information on the complementary medicines that have been subject to post-market reviews and the outcomes of reviews.

Recommendation	Comment
Auditor-General's Report on Therapeutic Goods Regulation: Complementary Medicines - Rec 4 To improve compliance with the regulatory framework, the ANAO recommends that the TGA: **a.** use its random sampling review of listed medicines to develop risk profiles of sponsors and the most significant characteristics of medicines; and b. use the profiles to inform its program of post-market reviews.	**July 2012 to June 2013** A risk-based approach to undertaking complementary medicines post-market reviews will be implemented. This will include the development and application of risk profiles to inform the selection of post-market reviews.
Auditor-General's Report on Therapeutic Goods Regulation: Complementary Medicines - Rec 5 The ANAO recommends that the TGA adopt a standard operating procedure for completing investigations of advertising breaches. In developing the procedure TGA should incorporate: **a.** appropriate timeframes for completing the investigations of advertising breaches; and b. the provision of regular reports to the TGA executive on progress with investigations and trends in non-compliance.	**July 2012 to June 2013** A standard operating procedure for investigating advertising breaches will be implemented from July 2012. Timeframes will be developed for completing investigations. Regular reporting of investigations into advertising breaches to the TGA Executive will begin.
Informal Working Group Examining Complementary Medicines Regulation and Reasons for Low Compliance Rates - Rec 1 Provide increased information: **a.** on product labels regarding regulatory assessment undertaken by TGA of complementary medicines; and b. on TGA website regarding regulatory assessment undertaken by TGA of complementary medicines.	**July 2012 to June 2013** The TGA will consult stakeholders on options to amend labelling of complementary medicines to provide consumers with clear information, particularly in relation to explaining the meaning of the listed medicine ('AUST L') category. The TGA website will be improved to educate consumers about the regulatory arrangements that apply to complementary medicines.

Recommendation	Comment
Informal Working Group Examining Complementary Medicines Regulation and Reasons for Low Compliance Rates - Rec 2a 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.	See comment on ***Auditor-General's Report on Therapeutic Goods Regulation: Complementary Medicines*** **—Rec 2** above.
Informal Working Group Examining Complementary Medicines Regulation and Reasons for Low Compliance Rates - Rec 3 Update 'Guidelines for levels and kinds of evidence' and include 'Guidelines for levels and kinds of evidence' in regulation.	**January to June 2012** An 'Evidence Required to Support Indications for Listed Medicines (excluding sunscreens and disinfectants)' document (the Evidence document) was released for stakeholder comment in April 2012. **July 2012 to June 2013** The Evidence document is scheduled for release in July 2012 and will be refined with feedback received through public consultation in 2012. The TGA will seek to include the finalised Evidence document in the regulations.
Informal Working Group Examining Complementary Medicines Regulation and Reasons for Low Compliance Rates - 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.	See comment on ***Auditor-General's Report on Therapeutic Goods Regulation: Complementary Medicines—Rec 2*** and ***Informal Working Group Examining Complementary Medicines Regulation and Reasons for Low Compliance Rates—Rec 2a*** above.
Informal Working Group Examining Complementary Medicines Regulation and Reasons for Low Compliance Rates - 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, where circumstances warrant.	**July 2012 to June 2013** This recommendation will be considered as part of the TGA's response to ***Advertising consultation—Rec 2c.*** (See below).
Informal Working Group Examining Complementary Medicines Regulation and Reasons for Low Compliance Rates - Rec 6 Enhance sanctions and penalties for repeated breaches of non-compliance (as well as strengthening sanctions and penalties for advertising).	**July 2012 to June 2013** This recommendation will be considered as part of the TGA's response to ***Advertising consultation—Rec 2c.*** (See below).

Recommendations relating to medical devices

Recommendation	Comment
Comments are subject to revision following the Government's response to the *Senate Inquiry into the Regulatory Standards for the Approval of Medical Devices* and the *Senate Inquiry into the role of the government and the TGA regarding medical devices, particularly Poly Implant Prosthese (PIP) breast implants*.	
Medical Device Reforms – Proposal 1 Reclassification of joint replacement implants.	**January to June 2012** Regulatory changes to reclassify hip, knee and shoulder joint replacement implants (total and partial) are under consideration. **July 2012 to June 2013** The TGA will provide the therapeutic goods industry with information and assistance to implement the new classifications during a transition period (to commence 1 July 2012, subject to regulatory approval). **July 2013 to December 2015** The transition period is planned to end on 30 June 2014. The TGA will consult the therapeutic goods industry on any outstanding implementation issues and take action to remove any non-conforming entries on the ARTG.
Medical Device Reforms – Proposals 2A Use of third party assessment bodies for Australian manufacturers. **Medical Device Reforms – Proposal 2B** Increasing pre-market scrutiny for implantable medical devices. **Medical Device Reforms – Proposals 2C** Recognition of third party assessment bodies.	**July 2012 to June 2013** The TGA will further develop these proposals in consultation with stakeholders and provide advice to Government.
Medical Device Reforms – Proposal 3(i) Amend the way in which a kind of medical device is included in the ARTG.	**July 2012 to June 2013** The TGA will work with stakeholders to develop a proposal to provide device product names with a planned implementation from 1 July 2013.
Medical Device Reforms – Proposal 3(ii) Enhance the ability to identify devices that have been approved by the TGA for supply in Australia by having the ARTG identifier on the label.	Not agreed by Government.
Medical Device Reforms – Proposal 4 Publication of device product information on the TGA website.	**July 2013 to December 2015** The TGA will work with stakeholders to develop a proposal to provide product information for medical devices with implementation planned from 1 July 2014.

Recommendations relating to advertising of therapeutic products

Recommendation	Comment
Advertising consultation – Rec 1 Publish the report on advertising reform on the website, once finalised.	**January to June 2012** The *Advertising Regulatory Framework – Options for Reform* report was published on the TGA website in May 2012
Advertising consultation – Rec 2 Reforms to advertising framework. **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). **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). **Advertising consultation – Rec 2c.** Develop a more effective approach to sanctions and penalties (including use of the infringement notice provisions).	**July 2012 to June 2013** The TGA will consult further with stakeholders on the recommendations for reform outlined in the '*Options for Reform*' report and provide advice to Government. The TGA will work with Complaints Resolution Panel to develop advertising complaint handling processes to support the implementation of a single entry point for all advertising complaints. **July 2013 to December 2015** The TGA will implement a single entry point for all advertising complaints.

Recommendations relating to promotion of therapeutic products

Recommendation	Comment
Working Group on Promotion of Therapeutic Products - Rec 1 The artificial difference in the Position Paper between 'high risk' and 'low risk' products be set aside, with application of a sector specific industry code to be determined by coverage of the relevant therapeutic sector to a specific product.	Therapeutic goods industry associations are implementing this recommendation.
Working Group on Promotion of Therapeutic Products - Rec 2 Consistency of therapeutic sector industry codes of practice be facilitated by each therapeutic industry association, incorporating in its code the high level principles, operational coverage areas and governance provisions developed by the working group.	Therapeutic goods industry associations are implementing this recommendation.
Working Group on Promotion of Therapeutic Products - Rec 3 Each industry association must determine the steps required to be taken to implement the working group's recommendation 2, and the time by which these steps will be completed. Each industry association will advise the Government of the anticipated completion date for implementation.	Therapeutic goods industry associations are implementing this recommendation.
Working Group on Promotion of Therapeutic Products - Rec 4 Information on therapeutic industry codes be made available to the public via the internet, with access to the complaints processes and links to each of the applicable codes. The industry associations will work with the Government to identify the most appropriate vehicle to make the information available.	The Australian Government has provided funding in the 2012-13 Budget to support industry to implement this recommendation.
Working Group on Promotion of Therapeutic Products - Rec 5 TGA include on its application forms (whether electronic or paper) a requirement for an applicant to nominate the relevant code of practice to which it will subscribe, as a condition of registration/listing on the ARTG.	The Australian Government currently does not support this recommendation as proposed.
Working Group on Promotion of Therapeutic Products - Rec 6 TGA provide on the ARTG public summary for each product, information on the nomination of an industry code, in a searchable format.	The Australian Government currently does not support this recommendation as proposed.
Working Group on Promotion of Therapeutic Products - Rec 7 Industry associations work with TGA to develop a process for notification to an association when an applicant nominates that association's code of practice.	The Australian Government does not support this recommendation as currently proposed.
Working Group on Promotion of Therapeutic Products - Rec 8 Industry associations develop comprehensive training programs on the codes to ensure that non-members (as well as members) are educated on the requirements of the relevant code.	Therapeutic goods industry associations are implementing this recommendation.
Working Group on Promotion of Therapeutic Products - Rec 9 The effectiveness of voluntary registration be evaluated annually and that consideration be given to mandatory nomination of a code if voluntary registration proves ineffective to achieve the Government's objectives.	The Australian Government has provided funding in the 2012-13 Budget to support industry to implement this recommendation.

Recommendation	Comment
Working Group on Promotion of Therapeutic Products - Rec 10 AHPRA and AHMAC be encouraged to advocate changes to health professional codes to more closely reflect the mutuality of obligations between industry and healthcare professionals, to ensure ethical promotion of therapeutic products.	The Government will refer this matter to AHPRA (Australian Health Practitioners' Registration Authority) and National Boards.
Working Group on Promotion of Therapeutic Products - Rec 11 The healthcare professional colleges and associations actively pursue alignment of their professional codes and/or guidelines to be consistent with the principles and areas of operational coverage.	The Government will refer this matter to National Boards and professional colleges.
Working Group on Promotion of Therapeutic Products - Rec 12 Education on relationships with the therapeutic industry be included in the training of healthcare professional students, in addition to education on the healthcare professional codes and guidelines.	The Government will refer this matter to healthcare professional associations and/or education bodies.
Working Group on Promotion of Therapeutic Products - Rec 13 An educative complaints portal be established as a mechanism to assist channelling complaints to the appropriate industry association. The industry associations will work with the Government to identify the most appropriate vehicle for this purpose.	The Australian Government has provided funding in the 2012-13 Budget to support industry to implement this recommendation.
Working Group on Promotion of Therapeutic Products - Rec 14 Each industry association provides on its website, a link to the complaints mechanism for each other therapeutic industry sector.	Therapeutic goods industry associations are implementing this recommendation.
Working Group on Promotion of Therapeutic Products - Rec 15 The industry associations actively engage in the education on and dissemination of the outcomes of the deliberations of the working group, with assistance from the Government as appropriate.	The Australian Government has provided funding in the 2012-13 Budget to support industry to implement this recommendation.
Working Group on Promotion of Therapeutic Products - Rec 16 The establishment of a process to evaluate, on an ongoing basis, the implementation of the recommendations of the working group.	The Australian Government has provided funding in the 2012-13 Budget to support industry to implement this recommendation.
Working Group on Promotion of Therapeutic Products - Rec 17 The Government form a permanent advisory group, similar in composition to the working group, with responsibility for the oversight of implementation of the working group's recommendations, and with a mandate to regularly report to Government on the effectiveness of the implementation against the evaluation criteria set out above.	The Australian Government has provided funding in the 2012-13 Budget to support industry to implement this recommendation.
Working Group on Promotion of Therapeutic Products - Rec 18 The Government review the National Medicines Policy (NMP) and consider replicating its policy coverage through the development of analogous policies for other therapeutic product sectors.	The Australian Government does not support this recommendation as currently proposed.

Attachment B—The Blueprint Implementation Schedule

The table below outlines the phase in which each recommendation for which the TGA is responsible is expected to be completed.

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**	***Phase 1 – January 2012 to June 2012*** ***Better managing our communication*** **Establish capability** **Plan and design** **Build momentum** **Progress all themes**	***Phase 2 – July 2012 to June 2013*** ***Better managing our practice*** **Align regulatory processes** **Consult stakeholders** **Deliver core foundational recommendations**	***Phase 3 – July 2013 to December 2015*** ***Mature and sustainable performance*** **Implement all recommendations** **Upgrade business systems** **Realise benefits** **Monitoring and Evaluation**
	Recommendations Completed	**Recommendations Completed**	**Recommendations Completed**
STREAM 1 – GOVERNANCE & MANAGEMENT *Managing and governing projects to deliver an integrated program of reform*	· Planning · Resourcing · Governance · Program Management · Strategic Alignment	· Governance · Program Management · Annual Reviews	· Governance · Program Management · Annual Reviews
STREAM 2 – COMMUNICATION & STAKEHOLDER ENGAGEMENT *Projects that deliver on recommendations for better communications and stakeholder engagement*		· Australian Therapeutic Goods Advisory Council TR1 TR13 · Consultation principles TR2 TR15 · Communication strategy TR3 TR18 · Application processing review TR7 TR20 · Regulatory Risk Framework TR8 IWG5 · Evaluate post-market risk communication scheme TR11 · Public access to adverse event data · Publicise compliance outcomes	· Improved guidelines TR4 TR14 · Improved communication of adverse events, alerts and recalls TR5 TR16 TR6 TR17 TR9 TR19 · CMI/PI updated TR10 TR21 · Consult and provide advice to government on sanctions TR12 IWG6
STREAM 3 – ADVERTISING *Projects that deliver on recommendations for reform of Advertising*	· 'Options for Reform' Report released Adv1	· Consult and provide advice to government Adv2 Adv2a Adv2c	· Single entry point for advertising complaints Adv2b
STREAM 4 – COMPLEMENTARY MEDICINES *Projects that deliver on recommendations for reform of Complementary Medicines*	· Publication of key guidance documents A-G1(a) A-G1(b)	· Improved guidelines and information A-G2 IWG1(a) · Post market compliance reforms A-G3 IWG1(b) · Procedures for investigating advertising breaches A-G4(a) IWG2(a) A-G4(b) IWG2(b) A-G5(a) IWG3 A-G5(b) IWG4	
STREAM 5 – MEDICAL DEVICES *Projects that deliver on recommendations for reform of Medical Devices*	· Reclassify joint replacement implants MD1	· Consult on improved device information MD2A · Consult and provide advice to government on proposals for increased pre-market scrutiny and third party assessment bodies MD2B MD2C	· Provide product name information MD3(i) · Production product information MD4
STREAM 6 – ORGANISATION CHANGE *Projects and activities that support reform and deliver sustainable outcomes, including engaging TGA staff to understand, support and adopt reform changes*	· Develop TGA staff engagement strategy · Establish organisational change capability	· Implement organisational change and staff engagement strategy · Identify IT system requirements · Assess implications for regulatory framework and legislation	· Embed organisational change · Progressively implement business systems upgrade · Progressively implement amendments to legislation
Key Milestones	**Implementation Plan Published**	**Annual Review 1**	**Annual Review 2** **Annual Review 3**

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Reference/Publication R12/916164