TGA reforms: A blueprint for TGA’s future
Program implementation guide for TGA staff

Version 2.0, February 2013
About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Ageing, 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 <www.tga.gov.au>.
# Version history

<table>
<thead>
<tr>
<th>Version</th>
<th>Description of change</th>
<th>Author</th>
<th>Effective date</th>
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<tbody>
<tr>
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</tr>
</tbody>
</table>
## Contents

1. **Introduction**  
   1.1 Background ................................................................. 7  
   1.2 Purpose ........................................................................ 7  
   1.3 Reference ....................................................................... 8  
   1.4 Objectives ..................................................................... 9  
   1.5 Program scope ............................................................. 9  
   1.6 Scope exclusions ........................................................... 9  
   1.7 Success factors ............................................................. 10  

2. **Delivery strategy**  
   2.1 Phased approach .......................................................... 10  
   2.2 Project management approach ....................................... 11  
   2.3 Integrated with ANZTPA ............................................... 14  
   2.4 Consistent regulatory framework .................................... 14  
   2.5 Progressive engagement ............................................... 15  
   2.6 Program management capability .................................... 15  
   2.7 Organisational change management ............................... 16  

3. **Governance**  
   3.1 Principles ....................................................................... 17  
   3.2 Governance approach .................................................. 17  
   3.3 Australian Therapeutic Goods Advisory Council .............. 18  
   3.4 Blueprint Steering Committee ......................................... 18  
   3.5 TGA Executive ............................................................... 19  
   3.6 Reform steering committees .......................................... 19  
   3.7 Roles and responsibilities .............................................. 21  

4. **Program methodology**  
   4.1 Processes and controls ................................................... 23
4.2 Progress reporting ________________________________ 23
4.3 Meetings ________________________________ 24
4.4 Project methodology ________________________________ 24
  4.4.1 Project managers ________________________________ 24
  4.4.2 Responsibility assignment matrix ________________________________ 24
  4.4.3 Resources ________________________________ 24
  4.4.4 Implications for TGA business planning ________________________________ 25

5. Stakeholder engagement 25
  5.1 Effective stakeholder engagement ________________________________ 25
  5.2 Internal stakeholder engagement strategy ________________________________ 26
  5.3 External stakeholder engagement strategy ________________________________ 26
  5.4 Communications plan ________________________________ 27

6. Program monitoring and evaluation 27
  6.1 Measuring the Blueprint objectives ________________________________ 27
  6.2 Measuring the benefits ________________________________ 28
  6.3 Monitoring strategy ________________________________ 29

7. Schedule management 30
  7.1 Schedule control ________________________________ 30
  7.2 Milestones ________________________________ 30

8. Change control 31
  8.1 Definition ________________________________ 31
  8.2 Change process ________________________________ 31
  8.3 Roles and responsibilities ________________________________ 33
  8.4 Change documentation ________________________________ 33
    8.4.1 Change register. ________________________________ 33
    8.4.2 Exception reports ________________________________ 33

9. Risks and issues 34
  9.1 Process ________________________________ 34
  9.2 Constraints ________________________________ 34
9.3 Dependencies ____________________________ 35
9.4 Risk management ____________________________ 35

Attachment A – Project clusters 36
1. Introduction

1.1 Background

On 8 December 2011 the Parliamentary Secretary for Health and Ageing, the Hon Catherine King MP, released a package of reforms for the TGA. These reforms are outlined in “TGA reforms: A blueprint for TGA’s future” (the Blueprint).

The TGA has responsibility for implementation of 48 Blueprint recommendations. The remaining 18 recommendations made by the Working Group on Promotion of Therapeutic Products involve matters of broader health policy and are the responsibility of the Regulatory Policy and Governance Division, Department of Health and Ageing (DoHA).

Of particular relevance to the Blueprint implementation is the ongoing program of work being jointly delivered by the TGA and Medsafe in the lead up to the creation of the Australia New Zealand Therapeutic Products Agency (ANZTPA). Having analysed the scope and nature of the Blueprint and ANZTPA reforms, the TGA has decided to establish one program of work to deliver the TGA’s contribution to both.

The Blueprint reforms will be delivered in three stages from January 2012 to December 2015.

1.2 Purpose

The Program Implementation Guide is an internal TGA guidance document designed to assist project managers, business owners and members of governance committees.

The primary purpose of this Implementation Guide is to provide a single integrated view of the activities and control measures necessary to achieve the objectives of the program. This will be achieved in a way that:

a. clearly identifies critical milestones and dates that must be achieved, in accordance with Phase 1: the High Level Concept Plan;

b. provides a coherent and logical approach to the assembly of the critical milestones in the plan; and

c. establish processes that enable the delivery of a program of projects without conflict of activities, resources or unnecessary duplication of work.

The secondary purpose of the Implementation Guide is to provide a baseline for the measurement and tracking of project progress, and the control of changes to the project.

In developing project summaries to guide the implementation of a complex range of review recommendations, the TGA is seeking to establish projects:

a. to guide the integrated implementation of all recommendations that require the input of a number of offices within TGA;

b. to seek efficiencies through separating project activities from operations;

c. to ensure appropriate engagement of all external stakeholders in a timely and effective manner;
d. to ensure effective linkages to other related initiatives, including those under ANZTPA;

e. as the basis for regular tracking of the progress in implementation;

f. as a risk management tool; and

g. to inform the evaluation of the reform outcomes.

Once the project summaries are completed, the TGA will need to develop more detailed project management plans.

All work carried out to deliver the Blueprint reforms will be carried out within the control process and framework of this plan.

### 1.3 Reference

This Plan should be read in conjunction with the following references:


b. TGA reforms - Blueprint implementation program high level concept plan;

c. TGA reforms - Blueprint implementation project summaries;

d. TGA reforms: A blueprint for TGA’s future – the Australian Government’s response to recommendations from several recent reviews into the TGA;

e. the Review to improve transparency of the TGA (2011);

f. the Working Group on Promotion of Therapeutic Products (2010);

g. the Advertising Regulatory Framework – Options for Reform (2012);

h. the Auditor-General’s report on Therapeutic Goods Regulation: Complementary Medicines (2011);

i. an informal working group examining the regulation of complementary medicines and reasons for low compliance rates (2011);

j. public consultations on the medical devices regulatory framework (2010);

k. the Health Technology Assessment Review (2010);

l. the Agreement between the Government of Australia and the Government of New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products (2003);

m. the Statement of Intent signed by the Australian and New Zealand Prime Ministers (June 2011);

n. the ANZTPA Stakeholder Communications Strategy (2012);

o. the 2012 - 2013 Business Plan Therapeutic Goods Administration (TGA); and

p. the TGA organisational chart.
1.4 Objectives

The objectives of the Blueprint reforms are as follows:

a. **Objective 1.** Enhance public trust in the safety and quality of therapeutic goods.

b. **Objective 2.** Improve the Australian community’s understanding of the TGA’s regulatory processes and decisions.

c. **Objective 3.** 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 they meet appropriate standards of quality, safety and efficacy.

d. **Objective 4.** Enhance the TGA’s current processes to ensure that the regulatory framework within which it operates remains able to adapt with flexibility to new scientific developments and emerging community expectations.

In addition, to these objectives, the ANZTPA projects will be implemented to meet the objectives of the ANZTPA Program. The creation of a joint regulatory scheme across both countries will provide health benefits for consumers, reduced regulatory costs for industry and greater efficiency for governments.

1.5 Program scope

The Blueprint requires fundamental reform of the TGA’s operations and the TGA intends to implement the Government’s responses to each recommendation in the context of broad organisational reform.

In relation to the recommendations contained in the reviews, the Government has agreed to 48 recommendations that relate to the TGA’s operations. The following reforms are the core components of the Blueprint and are included in the scope of activities:

a. work required to deliver the Government’s responses to 48 recommendations as listed in the attachment to the Blueprint document;

b. organisational reforms needed to deliver benefits from recommendations; and

c. deliver the recommendations in ways that meet the requirements of the ANZTPA Business To Business (B2B) and Single Entry Point projects.

1.6 Scope exclusions

The following activities and recommendations are out of scope:

a. ‘Business as Usual (BAU)’ operational improvement activity;

b. Activity Based Costing;

c. The 18 recommendations relating to the Promotion of Therapeutic Products; and

d. Medical Device Reforms – Proposal 3(ii) to which the Government does not agree.
1.7 Success factors

The Blueprint implementation will be successful if it delivers a solution that:

a. delivers the benefits defined in Section 6.2;

b. is delivered within budget;

c. is completed in a timely way;

d. is delivered with maximum support and commitment from TGA staff;

e. contributes effectively to the establishment of ANZTPA;

f. is delivered with minimum possible disruption and cost to industry;

g. ensure business as usual operations continue effectively and efficiently; and

h. effectively manages risks as set out in Chapter 9.

2. Delivery strategy

2.1 Phased approach

The Blueprint reforms comprise a large body of work which will be delivered over four years across several phases. Adopting a phased approach to the implementation of the Blueprint will:

a. assist in sequencing program activities and resources to support the parallel implementation of reforms and the conduct of daily operations;

b. assist in aligning program activities with ANZTPA implementation timeframes;

c. allow the TGA to identify and deliver early outcomes in a methodical way to build confidence and reputation;

d. allow time and a staged approach for the TGA to develop its capabilities and embed change into business;

e. allow greater ability to respond to a changing environment by being able to redirect the focus of the Program in each Phase if required;

f. divide the reform activities into more manageable packages of work providing greater control;

g. provide milestones for managers and stakeholders to evaluate progress in delivering the desired outcomes; and

h. provide opportunities to reflect on achievements and success.

The three phases of the Implementation are outlined in Table 1.
Table 1 - Phases for the Implementation of the Blueprint

<table>
<thead>
<tr>
<th>Phase Number</th>
<th>Phase Name</th>
<th>Phase Description</th>
<th>Phase Timings</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Better managing our communication</td>
<td>Establish capability Plan and design Build momentum Progress all themes</td>
<td>January 2011 - 30 June 2012</td>
</tr>
<tr>
<td>2</td>
<td>Better managing our practice</td>
<td>Align regulatory processes Upgrade systems Deliver core foundational recommendations</td>
<td>July 2012 – 30 June 2013</td>
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</tbody>
</table>

2.2 Project management approach

The Blueprint Implementation Program encompasses six streams of activity. Four correspond to the Correlation of recommendations at Appendix 1 of the Blueprint. Two additional streams assist delivery of the reforms. These core enabling measures will also embed organisational change that will provide organisational capabilities to deliver continuing reform into the future. These provide a basis for ongoing tracking and reporting of progress on the program. The Blueprint program may be summarised as follows:

a. Blueprint Reform Measures
   i. Stream 2: Communications and Engagement
   ii. Stream 3: Advertising
   iii. Stream 4: Complementary Medicines
   iv. Stream 5: Medical Devices

b. Core Enabling Measures
   i. Stream 1: Governance and Management
   ii. Stream 6: Organisational Change

The above streams of work, together with broader reform activities in the TGA, have been clustered into discrete and definable projects. Adopting a project management approach for delivering the reforms reduces delivery risk by providing added clarity, coordination and control. Having clearly defined project activity assists in separating project work from operations. The separation of project and BAU activities ensures dedicated activity to delivering project outcomes, as well as allowing allocated project resources (part time and full time) to be tracked separately for better account management and progress reporting.
Project size and composition varies according to the range of capabilities required. Project teams have been assembled combining the necessary project management and business expertise to deliver the project outcomes. Each project is allocated points of responsibility - the Senior Responsible Officer and a project manager.

To determine the optimum mix of projects for delivering the Blueprint reforms as well as the other reforms underway within the TGA, a number of variables were examined including:

a. the aim of the recommendation;
b. the capabilities required for delivery; and

c. existing reform projects and activities.

The projects that will deliver the program of TGA reforms, including the responses to Blueprint recommendations are shown in Table 2. Attachment A is a diagram mapping each project to a Group within the TGA.
### Table 2 - Allocation of project responsibility within the Blueprint Implementation Program

<table>
<thead>
<tr>
<th>Project</th>
<th>Recommendations</th>
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</thead>
<tbody>
<tr>
<td>MAG1: Medical Devices Reform</td>
<td>MD1, MD2A, MD2B, MD2C, MD3(i), MD4</td>
</tr>
<tr>
<td>MAG3: Over the Counter Medicines BPR (ANZTPA B5)</td>
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<td>MAG4: Prescription Medicines – Minor Variations</td>
<td></td>
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<tr>
<td>MAG5: eLodgement of Variations</td>
<td></td>
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<tr>
<td>MAG6: Regulatory Framework and Guidelines</td>
<td>TR6, TR8, TR11, TR12</td>
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<tr>
<td>MAG7: Labelling and Packaging</td>
<td>TR14</td>
</tr>
<tr>
<td>MAG8: Harmonisation</td>
<td></td>
</tr>
<tr>
<td>MAG9: On-line Applications</td>
<td>TR13</td>
</tr>
<tr>
<td>MCG1: Adverse Events (ANZTPA B1)</td>
<td>TR19, TR20, TR21</td>
</tr>
<tr>
<td>MCG2: Early Warning (ANZTPA B2)</td>
<td>TR16 (part)</td>
</tr>
<tr>
<td>MCG3: Recalls (ANZTPA B3)</td>
<td>TR16 (part)</td>
</tr>
<tr>
<td>MCG4: GMP Auditing (ANZTPA B4)</td>
<td></td>
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<tr>
<td>MCG5: Enhancing Post Market Compliance</td>
<td>TR15, TR17, TR18, IWG5 (part)</td>
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<tr>
<td>MCG6: Advertising</td>
<td>Adv1, Adv2, Adv2a, Adv2b, Adv2c, TR9, IWG5 (part), IWG6</td>
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<td>RSG1: Program Establishment</td>
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<td>RSG2: Strategic Engagement and Information Accessibility</td>
<td>TR1, TR2, TR3, TR4, TR 5, TR7, TR10</td>
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<td>RSG 3: Pilot Public Contact Team - Stage 2</td>
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<td>RSG4: TGA Change Management</td>
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<tr>
<td>Project</td>
<td>Recommendations</td>
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<tr>
<td>RSG5: Improve Internal Business Processes</td>
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<tr>
<td>RSG6: Business Systems Upgrade</td>
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Given the breadth and scope of work needed to implement the Blueprint reforms, the TGA is managing the delivery of all reform related projects as a program level activity. Delivering the Blueprint reforms as a program enables the TGA to establish greater control and standardisation of reform activity. This, in turn, ensures better integration between projects and allows greater visibility of achievements, deadlines and deliverables.

Managing the reform activities in projects draws resources away from operational priorities and the TGA Executive needs visibility of both (if the optimum level of effort is to be divided between projects and business as usual operations). Increasing the number of projects, the organisation has to manage and resource, has introduced additional processes and systems in to the TGA which require increased organisational capability and maturity. To assist in meeting additional demands the Office of Program Management (OPM) has been established to provide the TGA with support and capability (see 2.7 for more detail). The OPM supports the implementation by introducing standardised processes and tools, and coordinating the overall program of work, including supporting the daily activities of project managers on behalf of the SRO. At the same time, the OPM is developing and embedding project management skills and behaviours in the TGA.

### 2.3 Integrated with ANZTPA

The ANZTPA program has bilateral commitment from Australian and New Zealand governments and will eventually see the creation of one agency responsible for regulating therapeutic products in both countries.

In an effort to avoid duplication of work and the inefficient use of resources, the TGA has decided to integrate the Blueprint reform activities with those being undertaken as a first phase of establishing ANZTPA. Establishing the one program of work will also assist in monitoring and controlling such a broad reform agenda spanning the TGA, as well as achieving economies of repetition through standardising project management processes and tools.

The integration of the ANZTPA projects and the Blueprint reforms into a single program will need to be explicitly addressed in the Stakeholder Engagement Strategy developed as part of project RSG2: Strategic Engagement and Information Accessibility. The Stakeholder Engagement Strategy will need to take into account the Stakeholder Communications Strategy agreed by the ANZTPA Ministerial Council in January 2012.

### 2.4 Consistent regulatory framework

The Blueprint reforms are being implemented in line with business process reforms already underway within the TGA. The aim is to standardise regulatory processes to deliver greater clarity and consistency of therapeutic goods regulation.
Wherever possible a common approach is adopted in relation to the regulation of the different types of therapeutic goods (e.g. across prescription medicines, over-the-counter medicines, complementary medicines, medical devices and biologicals). Developing a more consistent regulatory approach may increase the complexity involved in implementing specific Blueprint reforms however it will also deliver long term efficiency and effectiveness benefits.

A more consistent regulatory approach will be further developed under projects MAG6: Regulatory Framework and Guidelines and MCG5: Enhancing Post Market Compliance.

2.5 Progressive engagement

Stakeholder engagement is fundamental to the successful implementation of the Blueprint reforms and is discussed in more detail in Section 5. A key theme of the delivery strategy is for the TGA to engage with stakeholders progressively to maintain their involvement and support.

To improve the transparency of the TGA operations, engagement with consumers, health professionals, industry and Medsafe will be early, iterative, and be incorporated as part of delivering the recommendations. A strategy of progressive engagement improves the quality of outcomes by ensuring regular stakeholder input and feedback throughout the development of each project, thereby increasing the likelihood of delivering quality products.

2.6 Program management capability

As part of Project RSG1: Program Establishment a centralised OPM was established to support the Blueprint implementation activities. The OPM will be developed in two stages:

1. Initially the OPM was established to focus on the following:
   i. develop and own the TGA’s program management framework, methodology and processes;
   ii. provide on-going support to TGA project delivery for all TGA reform projects including the Blueprint and ANZTPA;
   iii. develop a pool of project managers across the TGA to manage day to day project outputs;
   iv. provide professional development to project managers including Cert IV and Diploma qualifications in project management; and
   v. support the TGA Office Heads and staff on their roles and responsibilities under a program management framework.

2. Over time the OPM will evolve into a strategic support role responsible for facilitating portfolio management activities, including:
   i. monitoring and evaluating projects; and
   ii. making recommendations to support decisions about which projects to pursue, continue or cancel.
Embedding a project management methodology supported by skilled staff will eventually evolve into a state where project management becomes a recognised competency and project managers are professionally developed within the TGA.

2.7 Organisational change management

The Blueprint implementation is a catalyst for larger reform within the TGA which will require fundamental change within the organisation. The key organisational change areas the Program will influence are:

a. Adding value to the public health system
b. Increased focus on:
   i. Responsiveness
   ii. Communication
   iii. Consistency
c. Continued focus on:
   i. Efficiency
   ii. Effectiveness

Consequently broader organisational change activities have been integrated into the Blueprint Implementation, i.e. the desire to improve efficiency and effectiveness has led to an approach of standardising project delivery of the Blueprint reforms. The consequent establishment of a program management methodology will support ongoing project delivery in the TGA beyond the Blueprint implementation.

A fundamental aspect of the internal stakeholder engagement strategy will be to communicate with TGA staff about these organisational changes in order to ensure their understanding and support.

Key to gaining TGA staff support for organisational change initiatives will be encouraging their involvement in designing the change, contributing their ideas and receiving feedback is crucial to the success of the Program.

The TGA will need practical support to ensure the organisation has the capability to embrace and embed organisational change. Resources will be needed to develop or redevelop business systems and staff should have access to appropriate professional development training, particularly when the organisational change leads to a change in role.

Project RSG4: TGA Change Management will contain elements of capability development of staff including coaching and mentoring. Project RSG6: Program Cornerstone will develop an IT investment plan to guide the upgrade or replacement of the TGA’s business systems in order to support the Blueprint reforms into the future.
3. Governance

3.1 Principles

The breadth and impact of the Blueprint reforms requires a governance structure able to guide initiatives that cut across existing organisational boundaries.

The governance structure that is being introduced to guide the delivery of the Blueprint implementation outcomes is based on governance principles that will improve the TGA's capability to deliver future TGA projects.

The following principles have been used to develop the Blueprint implementation governance structure:

a. a customised governance solution designed to meet the requirements of delivering reforms across the TGA's operational structure, including the ANZTPA implementation;
b. direct roles for TGA Executives to lead and drive the reforms;
c. the Senior Responsible Officer, supported by the Office of Program Management, will be responsible for the delivery of the projects;
d. Group Coordinators and Office Heads (Business Owners) will be accountable for agreeing business requirements, making policy recommendations, providing business resources and integrating the reforms into their business;
e. there will be clear lines of accountability for the ownership and delivery of every project;
f. Project Managers will report to the Senior Responsible Officer via the Office of Program Management;
g. Project Managers will be out-posted to project teams that will work within business areas that are responsible for integrating project outcomes into operations; and
h. Project Teams combine business and project resources.

3.2 Governance approach

Projects contributing to the implementation of the ANZTPA are overseen by the following governance entities:

a. ANZTPA Implementation Ministerial Council;
b. Secretaries Group, informed by a Trans-Tasman Senior Officials Group; and
c. ANZTPA Business to Business (B2B) Steering Committee.

All TGA projects that contribute to Blueprint and ANZTPA implementation are overseen by the following governance entities:

a. Blueprint Steering Committee; and
b. Reform Steering Committees.
In addition, project committees and working groups are used where appropriate. The creation of these groups is based on the recommendation of the project manager and the OPM, with approval given by the business owner and the SRO.

All steering committees, project committees and working groups are managed formally and require Terms of Reference (TOR). The OPM will develop and maintain TORs for the Blueprint Steering Committee and Reform Steering Committees, as well as support project managers in developing TORs for project committees and working groups.

### 3.3 Australian Therapeutic Goods Advisory Council

The Government agreed consistent with Transparency Review Recommendation 1 for the TGA to establish an Australian Therapeutic Goods Advisory Council (ATGAC) with representation from across the stakeholder base. The ATGAC encourages wider input into the work of the TGA, including the implementation of the Blueprint recommendations.

The Council consists of 15 members appointed for three years based on their background, knowledge and expertise. Australia’s Chief Medical Officer, Professor Chris Baggoley, chairs the Council.

The Council provides strategic advice to the TGA from the perspective of all stakeholder groups, including consumers, healthcare professionals and the therapeutic goods industry on:

- matters relating to organisational planning, management initiatives, performance measures and quality improvement, including services standards and benchmarking;
- increasing public awareness of the safe use of therapeutic goods;
- stakeholder engagement; and
- emerging issues in public health and safety, regulatory policy and processes.

The core focus of the Council is to provide advice to the TGA National Manager, including advice as to whether the TGA’s reform activities meet the needs and expectations of consumers, health professionals and industry.

### 3.4 Blueprint Steering Committee

As part of the announcement of the package of reforms to the TGA, the Government advised that DoHA had been asked to establish a high level steering committee to oversight all aspects of the implementation of the Blueprint reforms: the Blueprint Steering Committee.

The Committee oversees and directs the delivery of the Blueprint, the ANZTPA B2B projects, and such other projects that may be required of the TGA from time to time.

The core focus of the Blueprint Steering Committee is to monitor and evaluate whether the Blueprint implementation is delivering the required benefits, particularly in the area of regulatory policy.

The TGA Blueprint Steering Committee is chaired by Deputy Secretary Butt, DoHA. In addition to the Chair and the National Manager of the TGA (Sponsor), its membership includes two senior members of DoHA.
3.5 TGA Executive

The TGA Executive has overall responsibility for the management of the TGA’s regulatory functions and activities.

The TGA Executive is responsible for implementing the Government’s response to the Recommendations. The core focus of the TGA Executive is to monitor and evaluate the delivery of the Blueprint and to ensure the reforms are integrated into the business.

Internal Committees within the TGA operate to facilitate the exchange of information, and to provide assistance in decision making. The following committees within the TGA also play a role in implementing the Blueprint:

- Regulatory Practice Committee (RPC)
- Information Management and Information Technology Committee (IMITC).

The RPC is responsible for considering the effectiveness of the operation of the therapeutics products regulatory scheme managed within the TGA. It has a particular role in assisting with emerging issues and ensuring that the TGA operates consistently across the various parts of its structure.

The role of the RPC includes making recommendations in regard to:

- proposals for new or varied regulatory arrangements which require changed practices or guidelines;
- proposals requiring changes to the TG Act or regulations; and
- assisting in identifying opportunities for system improvement that lead to better or more efficient management and decision making around regulation, improvements in consistency across the TGA, or in providing responses to new or emerging issues.

The IMITC is responsible for supporting the needs of the business and stakeholders through the delivery and maintenance of high level, secure and reliable IT tools, and through ensuring that the TGA has a strategic approach to managing information.

It particularly assists with planning, resource allocation, budget management, and oversighting project management of information related initiatives. It has a responsibility to consider proposals for significant change to IT or IM systems and is responsible for ensuring the impacts across the entire TGA business are considered before recommending action to the delegate.

3.6 Reform steering committees

There are three Reform Steering Committees guiding the delivery of projects related to the different streams of reform activity:

- the Communication and Stakeholder Engagement Steering Committee (CSESC);
- the Medicines and Advertising Steering Committee (MASC); and
- the Medical Devices Steering Committee (MDSC).

The allocation of projects to Steering Committees is outlined at Table 3.
These committees are chaired by the Senior Responsible Officer or another member of the TGA Executive. Membership of each committee includes the Group Coordinators. Office Heads attend Steering Committees in relation to projects for which they are the business owner and where they have a particular interest in the design or delivery of projects. All members of the TGA Executive have a standing invitation to attend all Reform Steering Committee meetings.

The outcomes of the Steering Committees are reported to the Blueprint Steering Committee, the Departmental committee established to monitor and evaluate whether the Blueprint implementation is adequately assisting the TGA to deliver the benefits of its reform program, particularly in the area of regulatory policy.

The role of the Steering Committees is to:

- Oversee projects contributing to the delivery of the relevant stream of reforms; and
- Ensure that the broad organisational implications of projects are identified and linkages across the TGA are made as appropriate to provide for effective and sustainable implementation.

Table 3 - Allocation of projects to Reform Steering Committees

<table>
<thead>
<tr>
<th>Reform Steering Committee</th>
<th>Projects</th>
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<tbody>
<tr>
<td>Communication and Stakeholder Engagement</td>
<td>MAG6: Regulatory Framework and Guidelines</td>
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<td>MAG9: On-line Applications</td>
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<td>MCG1: Adverse Events (ANZTPA B1)</td>
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<td></td>
<td>MCG2: Early Warning (ANZTPA B2)</td>
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<tr>
<td></td>
<td>MCG3: Recalls (ANZTPA B3)</td>
</tr>
<tr>
<td></td>
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</tr>
<tr>
<td></td>
<td>MCG5: Enhancing Post Market Compliance</td>
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<tr>
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<td>RSG1: Program Establishment</td>
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<td>RSG2: Strategic Engagement and Information Accessibility</td>
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<td>RSG 3: Pilot Public Contact Team - Stage 2</td>
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<td></td>
<td>RSG4: TGA Change Management</td>
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<td>RSG 5: Improve Internal Business Processes</td>
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<td>RSG 6: Program Cornerstone</td>
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<tr>
<td>Medicines and Advertising</td>
<td>MAG2: Complementary Medicines Reform</td>
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<td>MAG3: Over the Counter Medicines BPR (ANZTPA B5)</td>
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<td></td>
<td>MAG4: Prescription Medicines - Variations to the Register</td>
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<td>MAG5: eLodgement of Variation</td>
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<td>MAG7: Labelling and Packaging</td>
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<td>MAG8: Harmonisation</td>
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<td></td>
<td>MAG6: Advertising</td>
</tr>
<tr>
<td>Medical Devices</td>
<td>MAG1: Medical Devices Reform</td>
</tr>
</tbody>
</table>
3.7 Roles and responsibilities

The following table describes the roles and responsibilities within the Program structure.

**Table 4 – Roles and Responsibilities**

<table>
<thead>
<tr>
<th>Role</th>
<th>Responsibilities</th>
</tr>
</thead>
</table>
| National Manager               | Responsible to the Secretary of DoHA, Parliamentary Secretary and Minister for Health and Ageing for the success of the Blueprint Implementation Program and is accountable for:  
• providing leadership on culture and values;  
• keeping project aligned with organisation's strategy and portfolio direction;  
• reporting to the Parliamentary Secretary;  
• reporting to Advisory Council;  
• participating on the Blueprint Steering Committee; and  
• chairing the TGA Executive.  
Reports:  
• monthly to Secretary DoHA;  
• monthly to the Blueprint Steering Committee; and  
• as required to the Parliamentary Secretary. |
| Senior Responsible Officer     | Responsible to the National Manager through the TGA Executive for the success of the Blueprint Implementation Program and is accountable for:  
• keeping program aligned with organisation's strategy and direction;  
• ensuring appropriate level of approval for changes to scope;  
• sign-offs approving move to next phase;  
• signing-off key milestones;  
• governing project risk;  
• focusing on realisation of benefits; and  
• chairing Reform Steering Committees.  
Oversees the projects in their program and assists Project Managers to deliver project outcomes, particularly with:  
• planning;  
• resource allocation;  
• budget;  
• priority setting; and  
• high-level problem solving.  
Also responsible for ensuring policy issues are resolved by the appropriate decision-maker.  
Reports:  
• as considered necessary to the National Manager;  
• monthly to the TGA Executive Committee; and  
• monthly to the Blueprint Steering Committee. |
<table>
<thead>
<tr>
<th>Role</th>
<th>Responsibilities</th>
</tr>
</thead>
</table>
| Office of Program Management| Responsible to the SRO for supporting the Blueprint Implementation, particularly for:  
• providing support and advice to project managers;  
• providing project managers to manage projects;  
• developing and maintaining project document templates and project processes, as well as providing training and education on their use;  
• coordinating project communication between projects, Reform Steering Committees, and Blueprint Steering Committee;  
• providing increased project management skills development and transfer;  
• providing continuity between projects;  
• maintaining project documentation standards;  
• providing secretarial support for the Blueprint Steering Committee and the Reform Steering Committees;  
• conducting quarterly program risks review; and  
• collecting and distributing lessons learnt between projects.  
Reports weekly to the SRO. |
| Project Managers            | Responsible to the SRO for the success of the project and is accountable for:  
• leading the project team;  
• developing the project plan with the project team;  
• managing the project team’s performance of project activities;  
• securing sign-off for project deliverables;  
• managing project risk;  
• project communication, including status reports, escalation of issues that cannot be resolved in the team, risk management updates; and  
• providing feedback and lessons learned.  
Reports:  
• fortnightly on exceptions to the Head of the Office of Program Management;  
• monthly status report to the Reform Steering Committee and Blueprint Steering Committee; and  
• change requests and exception reports as required. |
| Business Owner(s)           | Agrees business requirements and receives project deliverables.  
Responsible to the Reform Steering Committees for:  
• ensuring projects are resourced and supported to deliver required outputs and outcomes;  
• consulting with stakeholders in areas of subject matter expertise;  
• providing business and subject matter expertise for developing requirements and making policy recommendations; and  
• accepting project deliverables and integrating them into business as usual. |
4. Program methodology

4.1 Processes and controls

Program information management is focussed on defining the framework and procedures for the effective flow and storage of program information in a way that will best support effective decision making and delivery of program outcomes.

Communications within the Program must comply with departmental requirements, as specified in the Department of Health and Ageing Chief Executive Instructions and Departmental policy. Project management documentation is consistent with the Department’s project management templates.

Unless otherwise specified in departmental guidelines, information management within the Program comprises:

- a. formal written communication, including regular status reports, acceptance forms, communications to external stakeholders, briefs;
- b. formal meetings, for which minutes will be taken, kept on file and circulated to participants and other relevant stakeholders;
- c. informal communication used for day to day discussion and liaison with project team members. This includes emails, and other informal written mediums. Any decisions of significance that may impact on cost, time or scope, if not covered under the above controls, must be documented and recorded; and
- d. all records will be maintained in the TGA document management system – TRIM.

4.2 Progress reporting

The following formalised reporting is utilised:

- a. each project will provide a monthly status report to the Blueprint Steering Committee via the Reform Steering Committee, focusing on whether the recommendations are being delivered and if they are being integrated into the TGA’s business correctly; and
- b. fortnightly status reports, prepared by the Project Manager on an exceptions basis and as required at the inception and closure stages, to inform the fortnightly project management status meeting of any emerging issues. These meetings will focus on the delivery of work against the schedule, resolution of issues and management of emerging risks.

Additional formal reporting may be warranted from time to time as directed by the Senior Responsible Officer.

Annual reviews will be undertaken to report progress on implementation of the Blueprint. The OPM will coordinate the development of an annual review report with input from all project managers for signature by the Senior Responsible Officer.
4.3 Meetings

Regular meetings and reporting will be incorporated into the management of the Program. The following formalised meetings are used to track the progress of activities:

a. bimonthly Blueprint Steering Committee meetings;
b. monthly Reform Steering Committee meetings, ensuring effective communication and leadership across all aspects of the project;
c. monthly project team meetings, providing an opportunity for communicating progress to the TGA more broadly. Participation of all project team members would be expected; and
d. fortnightly project management meetings, chaired by the Project Manager, with participation by selected project staff depending on the phase of the project.

4.4 Project methodology

4.4.1 Project managers

Project managers will be located within the Office determined by the Reform Steering Committee as the Office most impacted by the change and who take ownership of the project outputs to manage as part of daily operations. Project managers will be dispersed throughout the TGA managing projects. Project managers will be responsible for the development of Project Management Plans and for regularly reporting to the OPM.

4.4.2 Responsibility assignment matrix

The Blueprint implementation is a complex reform with cross-functional impact across the TGA. There are numerous stakeholders with varying degrees of responsibility for the activities needed to deliver projects. Consequently, a Responsibility Assignment Matrix, to support the delivery of projects, has been developed for each project contains five roles:

a. **Responsible** – those who do the work to achieve the task.
b. **Accountable** – those who sign off (approve) work responsible does.
c. **Support** – these are resources allocated to responsible and assist in completing the task.
d. **Consulted** – those whose opinions are sought.
e. **Informed** – those who are kept up-to-date on progress.

4.4.3 Resources

Each project will need to identify, as part of developing project management plans, the resources that are required to deliver the project outputs. These costs are expected to include all the capabilities involved in the project including labour (employee or contractor), supplier (consumables, consultancies, travel, advertising, etc.) and capital costs (IT hardware, software development).
Each project is anticipated to require a range of capabilities to achieve its outcomes including:

- Business Owner (usually one or more Group Coordinator/Office Head)
- Project manager
- Business subject matter expertise - regulatory policy, business process, stakeholder engagement
- Business analysis
- Communication
- Legal advice
- IT application development
- Financial skills (e.g. procurement)

### 4.4.4 Implications for TGA business planning

The information provided in the Project Management Plans will provide an important input to each TGA Office to assist them prepare an annual Office business plan. The Office business plans, in addition to specifying the operational performance priorities and expected outputs, will also identify the contribution each Office will need to make to the delivery of TGA Reforms Projects.

This combined business planning information will assist in the allocation of the available budget across all TGA Offices and the Office of Program Management. As part of the annual business planning process, each Office will seek funding from the TGA Executive for both operational and project activities. In addition, there is a level of reporting at the project level to the Office of Program Management to support program level monitoring and resource management.

The Reform Steering Committees is responsible for ensuring that each Office is contributing to project delivery as outlined in each Project Management Plan. If there are resource conflicts between operational and project requirements, they will be escalated to and resolved by the appropriate governance body, the relevant Office Head, the relevant Reform Steering Committee, or the TGA Executive.

## 5. Stakeholder engagement

### 5.1 Effective stakeholder engagement

Consistent with Recommendation 2 of the Transparency Review, the TGA is developing and implementing consultation principles to guide regulatory transparency and accountability. All Blueprint implementation projects will consider stakeholder consultation and involvement as part of developing detailed project management plans. Effective stakeholder engagement is a critical issue for the Program due to the breadth of stakeholder needs, expectations and influence. It is the basis for identification of internal and external stakeholders and definition of strategies to ensure effective management of their needs, expectations and influence on the project.
5.2 Internal stakeholder engagement strategy

Internal stakeholders are the staff and executives of the TGA, who will normally be engaged formally and informally in a manner consistent with daily business in the TGA. The Blueprint implementation communications plan will include dedicated activities for engaging internal stakeholders, and where possible leverage existing communication forums and channels.

A dedicated intranet site keeps the TGA staff apprised of progress of the Blueprint implementation and how they can provide input. Management of the internal stakeholder engagement will be via project RSG4: TGA Change Management.

5.3 External stakeholder engagement strategy

Key consultation with external stakeholders is primarily through the ATGAC. Consumers, health professionals and industry stakeholders more broadly will be considered at the project level including when any working groups are formed.

Stakeholders will also be able to provide direct feedback and comment to the TGA through attendance and participation in biannual public fora. Comments on TGA discussion papers will be able to be sent to the TGA and the TGA will provide feedback on the views received and what action has been taken to address them.

Where possible the TGA will leverage existing communication forums and channels, in an effort to minimise creating new ones. The TGA website will provide stakeholders with reports on the progress of reforms.

The TGA will provide regular reporting and updates to all stakeholders on the progress of the Blueprint implementation through the ATGAC and the TGA website.

The Blueprint implementation will develop an iterative approach for developing outputs and deliverables with a view to:

a. providing consultation and engagement with consumers, health professionals and industry by raising awareness of the program of reforms;

b. engaging relevant stakeholders in specific reform consultations; and

c. providing support throughout the implementation.

Communication and awareness raising campaigns, such as the "listed" goods campaign recommended in Recommendation 7 of the Transparency Review, will be delivered under the Communications Plan to be developed and managed by project RSG2: Strategic Engagement and Information Accessibility (see 5.4).

Key messages for the engagement strategy are:

a. consistent with the Government’s commitment to openness and transparency, the TGA will adopt a strong focus on improving its communication and engagement with the community;

b. the Australian Government will introduce a comprehensive package of reforms for Australia’s Therapeutic Goods Administration to ensure the regulation of medicines and medical devices is more effective and transparent;

c. the Government is committed to implementing the recommendations and has asked the TGA to progressively implement them over the next four years;
d. the reforms will enhance the regulatory framework, ensuring that it remains adaptable to community and industry expectations;

e. they will also improve the Australian community’s understanding of the TGA’s regulatory processes and decisions and enhance public trust in the safety and quality of therapeutic goods;

f. over the next 12 to 18 months the TGA will give priority to actively engaging with the community and providing improved information and education materials;

g. the TGA will establish an Australian Therapeutic Goods Advisory Council. Representation on this Council will come from across the stakeholder base; including consumers, industry and health providers.

5.4 Communications plan

Project RSG2: Strategic Engagement and Information Accessibility is developing a Communications Plan that defines strategies and approaches for communicating with stakeholders of the Program. This project will be the prime conduit for the Blueprint communications. It will assist other projects and the OPM with their communication planning and will coordinate their communication needs. The Communications Plan will need to take into account the Stakeholder Communications Strategy agreed by the ANZTPA Implementation Ministerial Council in January 2012.

All stakeholder groups will be consulted in the development of stakeholder communication strategies. In the instance of multiple stakeholders in any one stakeholder group, it may be necessary to identify a lead stakeholder representative, such as a peak association, to seek detailed input.

The strategic engagement project will maintain an active log of interactions with selected stakeholders where identified in the Communications Plan. Project Managers of all projects will provide reports to assist in updating the log. The format and frequency of these reports is to be determined by the project.

6. Program monitoring and evaluation

6.1 Measuring the Blueprint objectives

Evaluating whether the objectives of the Blueprint are achieved will be based on analysis of whether the benefits are delivered. Table 5 maps each objective to the benefits which will be used to evaluate if the objective was achieved.
Table 5 - Mapping of the Blueprint Objectives to Reform Benefits

<table>
<thead>
<tr>
<th>Objective</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Objective 1.</strong> Enhance public trust in the safety and quality of therapeutic goods.</td>
<td>Transparency</td>
</tr>
<tr>
<td><strong>Objective 2.</strong> Improve the Australian community’s understanding of the TGA’s regulatory processes and decisions.</td>
<td>Transparency, Visibility, Empowerment</td>
</tr>
<tr>
<td><strong>Objective 3.</strong> 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 they meet appropriate standards of quality, safety and efficacy.</td>
<td>Transparency, Visibility, Effectiveness, Efficiency</td>
</tr>
<tr>
<td><strong>Objective 4.</strong> Enhance the TGA’s current processes to ensure the regulatory framework within which it operates remains able to adapt with flexibility to new scientific developments and emerging community expectations.</td>
<td>Efficiency, Influence, Responsiveness, Consistency</td>
</tr>
</tbody>
</table>

### 6.2 Measuring the benefits

Determining whether the benefits of the Blueprint implementation are being delivered will be of interest to all stakeholders, but particularly the TGA Executive and the Blueprint Steering Committee. Ultimately, it is in measuring the benefits that will determine if the Blueprint implementation has been a success and whether it has met its objectives.
Table 6 lists possible benefits and descriptions, from the TGA Strategic Statement 2012 – 2015, for evaluating whether benefits have been realised.

**Table 6 - Benefits and Beneficiaries**

<table>
<thead>
<tr>
<th>Benefit</th>
<th>Description</th>
<th>Beneficiary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transparency</td>
<td>The TGA's risk management approach to regulation and decision making processes are clearly communicated and decisions are supported with evidence</td>
<td>Consumers Health professionals Industry TGA</td>
</tr>
<tr>
<td>Empowerment</td>
<td>The TGA assists stakeholders to access relevant, meaningful and reliable information.</td>
<td>Consumers Health professionals Industry</td>
</tr>
<tr>
<td>Visibility</td>
<td>Through helping consumers and the community to better understand the role of the TGA</td>
<td>Consumers Health professionals Industry TGA</td>
</tr>
<tr>
<td>Consistency</td>
<td>An equitable and reliable approach to risk management and decision-making.</td>
<td>Industry TGA</td>
</tr>
<tr>
<td>Efficiency</td>
<td>Quality and productivity of all TGA functions is continually improved.</td>
<td>Industry TGA</td>
</tr>
<tr>
<td>Influence</td>
<td>A strong role in informing scientific and clinical debate to support the safe and effective use of therapeutic products.</td>
<td>TGA</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>Action taken by the TGA in relation to regulatory decisions is appropriate and timely</td>
<td>Consumers Health professionals Industry</td>
</tr>
<tr>
<td>Responsiveness</td>
<td>The TGA reacts to emerging local and global regulatory issues affecting the Government and the community.</td>
<td>Consumers Health professionals Industry TGA</td>
</tr>
</tbody>
</table>

Project RSG2: *Strategic Engagement* and Information Accessibility will develop Key Performance Indicators (KPIs) for the TGA. This work will include collaboration with the OPM and project managers to develop KPIs for the benefits in Table 5.

### 6.3 Monitoring strategy

Monitoring the Program is vital to ensure limited resources are not wasted and to ensure products satisfy business requirements as well as deliver intended benefits. The progress of the Blueprint implementation will be monitored mainly by tracking and reporting against the following:

a. Schedule;
b. Budget; and
c. Resource allocation.

Milestones will be used to assist in the close monitoring of progress.

Formal reviews of how the Program is delivering benefits will be conducted annually and toward the end of each phase. If the scheduling of an annual review and an end of phase review coincide, the end of phase review takes precedence and can substitute the annual review. End of phase reviews will inform decisions on whether to continue the next phase as planned, change direction or discontinue the Program.

Careful consideration will be given to monitoring the scope of the work in an effort to avoid wastage and delays. Each project will have a clearly defined scope which will be agreed at the commencement of the project. Project deliverables will be built to meet the requirements of the project scope unless a change in scope is requested and approved as per the change control process detailed in section 8.2. The Blueprint Steering Committee and the Reform Steering Committees will monitor project scope using Exception Reports.

7. Schedule management

7.1 Schedule control

The Blueprint Program Schedule will be base-lined following approval by the Blueprint Steering Committee and maintained by the OPM. This will become the basis for tracking performance in subsequent reports to the Committee.

Project Managers must ensure project schedules are consistent at all times with the Program Schedule. This will require close communication and interaction between project managers and the OPM.

Project schedules shall be managed and reported using professional scheduling tools (MS Project or equivalent).

7.2 Milestones

Milestones will be reported at three levels:

a. Key Milestones are those program milestones that will be reported to the ATGAC and represent the critical events that contribute to completion or direction of the Program;

b. Program Milestones are those necessary for providing visibility of overall progress in the Blueprint Implementation Program schedule and are critical events in the delivery of projects; and

c. Project Milestones are those necessary for providing visibility of overall progress in a project schedule and are critical events in the delivery of project outputs.
8. Change control

8.1 Definition

Change control applies when there is a need to consider a request to expand, adjust or reduce the scope of a project. The potential impact of the proposed change request will determine the level of authority required to approve or reject the request.

Assessing the potential impact of a change request requires the exercise of judgement informed by discussion between the project manager, business owner and the Office of Program Management.

The following three types of change provide guidance:

a. Type 1: changes that must be escalated to the Blueprint Steering Committee:
   i. change in the completion date of a product impacting a scheduled announcement to be made by the Secretary DoHA or at ministerial level;
   ii. major change to a key milestone as defined in section 7.2(a);
   iii. introduce a risk with a rating of High;
   iv. impact the overall delivery of the program; or
b. Type 2: changes that must be escalated to the relevant Reform Steering Committee:
   i. change in the completion date of the Project;
   ii. result in a change in cost of up to 15% of the Project budget;
   iii. result in a change to a program milestone as defined in section 7.2(b);
   iv. introduce a risk with a rating of Significant or higher;
   v. impact other projects overseen by the Reform Steering Committee; or

b. Type 3: changes that may be approved by the Business Owner:
   i. no change on the completion date of the Project;
   ii. no change in cost of the Project budget;
   iii. change to a project milestone as defined in section 7.2(c);
   iv. introduce a risk with a rating of Low or Medium;
   v. impact no other project.

8.2 Change process

The Project Manager shall facilitate the actions of the Change Request (CR) lifecycle as detailed in Figure 1.
Figure 1 – Change Request Lifecycle
8.3 Roles and responsibilities

The roles and responsibilities for the Change Request (CR) are defined in Table 7.

**Table 7 – Change Request Roles and Responsibilities**

<table>
<thead>
<tr>
<th>Role</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>Identify need for change and notify the project manager.</td>
</tr>
<tr>
<td>Project Manager</td>
<td>Register the change. Assess impact of the change request with the business owner and OPM Approval of Type 3 Changes. Submit Exception Report.</td>
</tr>
<tr>
<td>Specialist advice (as required)</td>
<td>Partake in the evaluation.</td>
</tr>
<tr>
<td>Business Owner</td>
<td>Approval of Type 1 Changes</td>
</tr>
<tr>
<td>Reform Steering Committee</td>
<td>Approval of Type 2 Changes. Escalation to Type 1 if required.</td>
</tr>
<tr>
<td>Blueprint Steering Committee</td>
<td>Approval of Type 1 Changes</td>
</tr>
</tbody>
</table>

8.4 Change documentation

8.4.1 Change register

All potential changes will be logged on a Project Change Request Register to be managed by the project manager. The Project Change Request Register must define the following information:

a. Serial identifier;
b. Summary description;
c. Detailed description, including cross reference to relevant project;
d. Originator of the proposed change;
e. Date of proposed change;
f. Status of proposed change (Rejected, Pending, Approved, Closed);
g. Summary of impact (scope, schedule, cost, benefit); and
h. Date of approval or rejection.

8.4.2 Exception reports

Project Managers are to escalate all Type 2 and Type 1 changes using an Exception Report. When submitting Exception Reports they will be accompanied by all supporting
documentation produced as a result of identification, evaluation or decision making related to the change.

Exception Reports are to include baseline information from the beginning of the project so committee members can track the overall change.

9. Risks and issues

9.1 Process

The Program uses a formal risk management process to document and manage risks throughout the life of the Program.

The Program maintains a Program Risk Register where risks and issues are logged on at least a fortnightly basis and incorporated into monthly status reporting and other reporting as required by this guide. The Program Risk Management Register will be managed by the OPM on behalf of the Senior Responsible Officer.

All project risks rated significant or higher shall be managed by the Project Manager and reported through the monthly status reports to the OPM, with escalation to the relevant Reform Steering Committee or the Blueprint Steering Committee as appropriate.

Risks and issues will be monitored and evaluated in accordance with the following descriptions:

a. “Risks” represent possible events that may impact on project outcomes were they to occur; and
b. “Issues” are risks that have eventuated or unanticipated events that may, if not resolved, impact on project outcomes.

Inability to resolve an issue leads to the creation of a corresponding risk, i.e. “the risk that issue x cannot be resolved”.

Each project within the Program will maintain its own Project Risk Register and is to be managed by the project manager on behalf of the SRO.

9.2 Constraints

This Implementation Guide has been developed in consideration of a number of unique constraints. These may be summarised as follows:

a. **Resourcing** – Reform costs are to be met from the TGA’s fees and charges.
b. **Timeframe** – The TGA expects to implement all agreed Blueprint recommendations by December 2015.
c. **Capability** – The TGA has a small but professional workforce with a medical science focus. The Blueprint reforms require change across the TGA to deliver operational outcomes and meet expectations for reform.
d. **Regulation** – All reforms will need to be implemented consistent with the therapeutic goods regulatory framework. Therefore, there will be a need to
assess all proposed changes to ensure that they are consistent with existing legislation or to seek policy approval to introduce legislative changes.

9.3 Dependencies

The ongoing activity implementing the ANZTPA and its associated joint regulatory scheme are a key dependency to delivering the reforms of the Blueprint. Although the planned timeframes for establishing the ANZTPA are similar to those of the Blueprint, the establishment of a joint agency is a complex undertaking with inherent risks and coordinating these two reform programs requires substantial and careful coordination.

Not all of the work being done to implement the Blueprint reforms is the responsibility of the TGA. For example, there are 18 recommendations relating to the promotion of therapeutic goods that require action by industry. The approach to implementing these reforms will need to be considered in the delivery of this plan.

9.4 Risk management

The Risk Management process that shall be applied by the Program is based on industry better practice, in accordance with ISO 31000:2009 Risk Management – Principles and Guidelines. This process is built on a defined risk context and the iterative application of risk management steps, supported by an ongoing communication and review process, as illustrated in the following Figure 2.
Attachment A – Project clusters

The TGA Reforms Blueprint Implementation Program - Proposed Project Clusters is a diagram mapping each project to a Group within the TGA, including market authorisation, monitoring and compliance and regulatory support. Each project shows the relevant Blueprint recommendations, the business owner (group) and links to current TGA projects.