Australian Government

Department of Health and Ageing

Therapeutic Goods Administration

TGA external communication and education framework

Priorities and projects

2013 - 2015

TGA Health Safety Regulation

Introduction

The Therapeutic Goods Administration (TGA) is part of the Department of Health and Ageing (DoHA), and is responsible for safeguarding and enhancing the health of the Australian community through the effective and timely administration of the *Therapeutic Goods Act 1989*.

All Australians will have used a therapeutic good regulated by the TGA at some stage of their lives.

The External Communication and Education Framework: Priorities and projects 2013-2015 (the framework) aims to describe TGA's approach to providing:

- better information that is easily understood by **consumers**
- therapeutic goods information that can be received and shared by **health professionals**
- information that will provide greater certainty on regulatory arrangements for the **therapeutic goods industry**.

The Australian Government's response to reviews of the TGA, *TGA Reforms: a blueprint for TGA's future* (the Blueprint), outlines plans on how TGA will work to improve the Australian community's understanding of the TGA's regulatory processes and decisions. The development and phased implementation of this framework over the next few years is one part of this program.

The intention of this framework and other TGA reforms is to ensure that TGA services are further developed to better reflect the needs of users, be they consumers, health professionals or industry.

It will be sufficiently flexible to allow the TGA to better address high-profile topics as they arise.

The framework does not incorporate media and issues management activities. The TGA will continue to work through specialist media managers on issues management.

There are a number of specific communication and education projects proposed for the next two years that focus on particular areas of the TGA's functions. These projects will be rolled out in a phased manner and targeted to suit the differing needs of consumers, health professionals and industry.

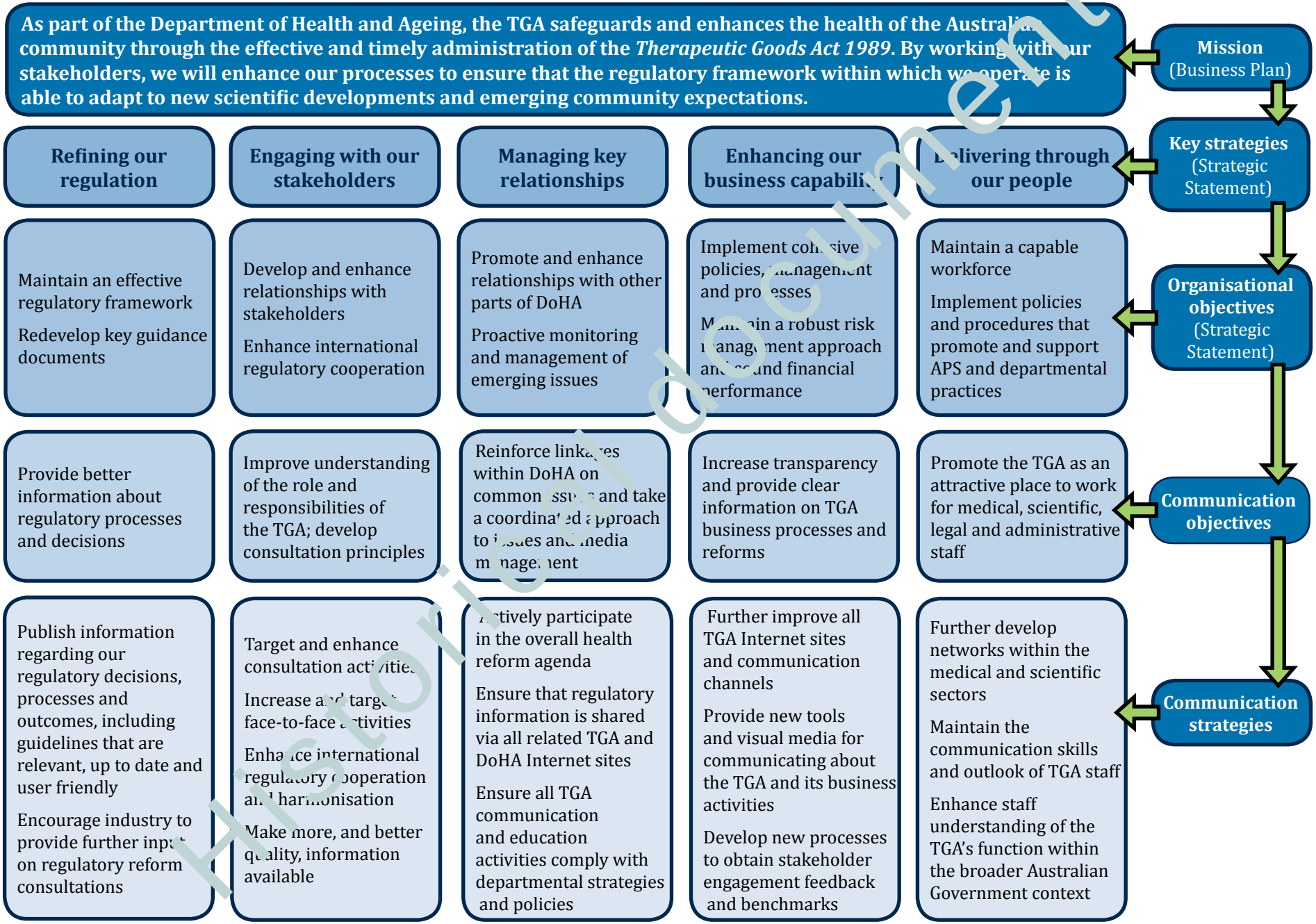
Purpose

The purpose of developing and implementing this framework is to:

- improve understanding of the role and responsibilities of the TGA
- improve transparency in line with TGA reforms
- enhance engagement with external stakeholders on specific issues
- further develop collaboration on communication issues with other government and stakeholder bodies
- develop better mechanisms for two-way communications with consumers, health professionals and industry.

The TGA will achieve this by taking a phased approach over the next two years to deliver communication and education activities that provide information about the TGA's role and responsibilities and the benefits versus risks approach it takes to regulating therapeutic goods.

Overview - how the framework aligns with the *TGA Business Plan* and *TGA Strategic Statement*



Overarching communication and education priorities

The TGA has two overarching communication and education priorities:

- explaining the role and responsibilities of the Australian Government in regulating therapeutic goods
- describing the benefits versus risks approach the TGA takes to regulating therapeutic goods.

Communicating and educating on the role and responsibilities of the TGA

The TGA will provide information about:

- what the TGA is and how it works with other parts of DoHA, the national healthcare system, and international therapeutic goods regulators
- what the TGA does—its roles and responsibilities as the therapeutic goods regulator—including:
  - what therapeutic goods TGA evaluates
  - how therapeutic goods are evaluated (including the differences between registered, listed and included therapeutic goods, and their processes of evaluation)
  - what is involved in the TGA's approval of therapeutic goods—including providing an appropriate level of information on manufacturing inspections, as well as the information on the work of the different TGA statutory advisory committees
  - how therapeutic goods are monitored for safety and for compliance with the regulatory system, and how compliance is enforced
  - the regulatory actions TGA is empowered to take under the Act
  - how its work contributes to the quality use of therapeutic goods, for example, the role it plays in providing Consumer Medicines Information and Product Information
- what the TGA is not able to do, such as:
  - research, develop or manufacture new therapeutic goods
  - provide clinical advice on medication and prescription management for individual patients
  - undertake laboratory testing for every batch of a therapeutic good authorised for supply
  - manage the supply of therapeutic goods (noting that during product shortages the TGA may assist sponsors to provide alternative versions of the therapeutic good)
  - compare different therapeutic goods for cost-effectiveness
  - subsidise provision of therapeutic goods
  - protect the intellectual property of therapeutic goods
  - test low risk complementary medicines and medical devices for efficacy
  - regulate the conduct of medical practitioners or healthcare practitioners more broadly.
- how the TGA is funded, and how it remains impartial and avoids conflicts of interest
- how and when to contact the TGA.

Communicating the benefits versus risks approach to regulating therapeutic goods

The TGA will provide information to help stakeholders understand the benefits versus risks approach it takes in the regulation of therapeutic goods, including:

- risks associated with therapeutic goods that are subject to safety alerts, recalls or cancellations, or other regulatory action
- the role of scientific evidence in demonstrating the safety and quality of therapeutic goods
- the application of different regulatory requirements for approval depending on the nature and level of risk for different therapeutic goods
- what is required of individuals and companies to ensure compliance with the therapeutic goods regulations
- the TGA's compliance framework.

Specific communication and education projects

The TGA is placing increased emphasis on:

- listening to, educating, and communicating with consumers
- developing clearer two-way communications with healthcare professionals and the regulated therapeutic goods industry
- further coordination of communication and education activities with other government organisations and stakeholder bodies.

This will be achieved by creating communications and educational material to meet the needs of different stakeholder groups. The TGA will also use events as opportunities for two-way communication. TGA will also improve existing channels (such as www.tga.gov.au) for stakeholders to provide feedback, as well as investigating and developing new ones.

The TGA will also improve the way consultations are conducted; by developing consultation principles to guide processes for TGA external consultations, regulatory reviews and other external activities. In addition, a calendar of stakeholder consultations will be published on the TGA website.

Some specific stakeholder projects are outlined on the following pages.

Consumers

The TGA will provide clear, consistent and relevant information aimed at building consumer awareness and understanding of the regulation of therapeutic goods and how this can help people to make informed decisions about medicines and medical devices.

This will be achieved through a variety of methods including:

- developing new, targeted publications in online, print and multimedia formats
- improving TGA websites, the management of phone enquiries and the information written by the TGA for consumers
- increasing the number of ways to access TGA information, for example, by developing material for sharing via a broad spectrum of media, including social media
- implementing new processes for obtaining and responding to feedback from consumers, for example feedback forms on TGA websites and undertaking market research
- working with the NPS and other information providers to provide information to consumers that is consistent with the principles of the quality use of medicines.

Communication and education projects include:

- **adverse reactions**—develop a publicly available database where consumers can search information on adverse reactions to medicines and medical devices
- **recalls**—deliver a therapeutic goods recalls portal that enables consumers to find information about recalls, and publish all safety alerts and recall notices on the TGA website
- **safety issues**—deliver a common early warning system to inform consumers of potential safety issues
- **risks**—inform consumers that there are risks associated with all medicines and medical devices, and that they should treat complementary medicines and low risk devices with care
- **travelling with therapeutic goods**—consumer friendly information to assist people when travelling

- **purchasing therapeutic goods from overseas, or via the Internet**—expand the existing education program on associated risks for consumers
- **complaints about therapeutic goods**—what the procedures are, the types of issues the TGA manages, and the issues that are outside its regulatory scope to help consumers know where to go to lodge a complaint
- **registered (AUST R) and listed (AUST L) therapeutic goods**—the differences between them and the processes of evaluation so consumers have a better understanding of the products they use

- **complementary medicines**— explain that most are not required under legislation to be evaluated by the TGA for efficacy before being made available in Australia, so consumers have a better understanding of the products they use
- **post-market reviews of complementary medicines**—provide information on outcomes of TGA reviews so consumers can see the results
- **advertising**—monitoring and investigating advertising issues, the complaints process and how outcomes of complaints are communicated
- **enforcement**—TGA powers and procedures, as well as outcomes of enforcement activities, to help consumers better understand the role and work of the TGA
- **nanoparticles in therapeutic goods**—in particular, how the TGA regulates the quality, safety and efficacy of sunscreens
- **medical devices**—the reform process to their regulation and the benefits and risks associated with different classes of medical devices. Increase understanding amongst consumers that a small proportion of medical devices will and do fail in use
- **food and medicines**—how consumers can distinguish the two, and understand the different regulatory roles undertaken by the TGA, Food Standards Australia New Zealand (FSANZ), and the State and Territory Governments
- **generic medicines**—information to help consumers understand what a generic medicine is and the process the TGA uses to evaluate generic medicines for registration
- **human cell and tissue therapy products**—information to help consumers understand what human cell and tissue therapy products are and the process the TGA uses to evaluate them
- **therapeutic goods cancellations**—once the system has been reviewed, provide an option for notifying consumers about therapeutic goods that have been cancelled and removed from the ARTG, and which can no longer be lawfully supplied in Australia

Consultation

Consultation activities targeting consumers will be undertaken, including on the following reforms:

- proposed regulatory changes to the labelling and packaging of medicines
- guidelines for levels and kinds of evidence for complementary medicines
- options for maintaining the currency of Consumer Medicines Information (CMI) and approved Product Information (PI)
- increasing pre-market scrutiny for implantable medical devices
- the recommendations for advertising reform including a more effective approach to sanctions and penalties.

Health Professionals

The TGA will provide information to health professionals that can be easily received and shared. These communication and education projects will allow health professionals to give advice and make decisions about the safe use of therapeutic goods.

This will be achieved through a variety of methods including:

- developing stronger relationships with universities, colleges and other health professional education providers
- making extensive use of pharmacy, medical and mainstream media to publicise new regulations, warnings or safety alerts, and publish all hazard alert and recall notices on the TGA website
- providing a system for notifying health professionals when certain new products are given marketing authorisation or taken off the market
- increasing health professional awareness of, and participation in, the adverse event reporting system and continuing to work with stakeholders to improve sharing of information on vaccine adverse events
- providing targeted information at selected healthcare conferences.

Communication and education projects include:

- **the role of the TGA**—information for health professionals on what and how we regulate and what we do not regulate, such as areas of professional practice
- **safety information**—improve the system for health professionals to be notified about safety information, including recalls and safety alerts (in particular vaccines and implantable devices)
- **adverse events**—develop a publicly available adverse events database that includes advanced searching options for health professionals, with information on adverse reactions to medicines and medical devices
- **therapeutic goods cancellations**—once the system has been reviewed, provide an option for notifying health professionals about therapeutic goods that have been cancelled and removed from the ARTG, and thus can no longer be lawfully supplied in Australia
- **the Special Access Scheme**—how the scheme operates and how health professionals can access unapproved therapeutic goods
- **statutory advisory committees**— clarify the role of committees and how health professionals can express interest in becoming a member of a TGA advisory committee
- **medical devices**—updates about the reform process on the regulation of medical devices to increase understanding of the meaning and importance of clinical evidence
- **TGA assessment processes**—information on how the products health professionals prescribe or dispense are regulated by the TGA. This includes information on the risk management approach to carrying out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard, and manufactured in accordance with the principles of good manufacturing practice
- **human cell and tissue therapy products**—how they are regulated under recently introduced changes for biological products, including information for health professionals on the classification and approval processes

- **Australia New Zealand Therapeutic Products Agency (ANZTPA)**—outline changes to the regulatory frameworks for therapeutic products

Consultation

Consultation activities targeting health professionals will be undertaken on the following reforms:

- consideration of processes that would help maintain the currency of Consumer Medicines Information (CMI) and approved Product Information (PI)
- proposed options for regulatory changes to the labelling and packaging of medicines
- harmonisation of current Australian ingredient naming with international non-proprietary names
- proposed changes to regulation of extemporaneous compounded medicines
- guidelines for levels and kinds of evidence for complementary medicines
- proposals to increase premarket scrutiny for implantable medical devices
- recommendations for advertising reform for therapeutic products
- the ANZTPA common regulatory framework.

Industry

The TGA will provide clearer information for the therapeutic goods industry to make it easier for them to meet regulatory requirements.

This will be achieved through:

- improving how the TGA presents information on its regulatory processes for different therapeutic goods on the TGA website
- better management of phone enquiries for industry
- further improving the written information available to industry
- providing more opportunities for industry to provide feedback about TGA information

Communication and education projects include:

- **regulatory guidance**—ensuring that major regulatory guidance information is up to date, easy to find and user friendly so industry can better meet regulatory requirements
- **creating a timetable**—providing a timetable for the conduct of consultations so industry can plan how to respond or change to meet potential new processes. This includes a timetable for the release of revised or new regulatory guidelines for comment.
- **international harmonisation**—providing more information on TGA collaborative activities with other major therapeutic products regulators
- **advisory committees**—publishing statements following committee meetings that summarise the matters considered so industry can respond to the feedback in future applications
- **advertising:**
  - the restrictions placed on advertising therapeutic goods
  - what to do if these restrictions are not being upheld, including the TGA's role in terms of monitoring and investigating advertising issues
  - the complaints process and how outcomes of complaints are communicated
- publishing outcomes of **legal proceedings**, **investigation activities** and **compliance** by industry with the *Therapeutic Goods Act 1989*
- **prescription medicines**—implementation of changes to how the TGA allows sponsors to make minor variations to prescription medicines on the ARTG
- **generic medicines**—provide clarity for industry on TGA's processes for evaluation

and registration, and common deficiencies in data sets/applications

- **medical devices**—the reform process being undertaken on regulation of medical devices
- **business process reviews**—information for industry on existing reviews for over-the-counter medicine regulation, postmarket processes and manufacturing quality
- **Australian ingredient naming**—to allow industry to have consistency with other international work on harmonisation of current names with international non-proprietary names

- **human cell and tissue therapy products**—provide clarity for industry on how they are regulated under recently introduced changes for biologicals, including classification and approval processes
- **other therapeutic goods**—provide clarity for industry on the requirements for and regulation of goods including sunscreens, sterilants and disinfectants
- **food and medicines**—how they are distinguished in law, and where the division lies between the roles of the TGA, FSANZ and State and Territory Governments to enable sponsors to appropriately describe and regulate their products as therapeutic goods or foods
- **safety**—working with industry to ensure that the systems for managing safety concerns are easy to use and transparent
- **complaints procedures**—clarify for industry the types of issues that the TGA will manage, and the issues that are outside its regulatory scope
- **ANZTPA**—provide updates on the progress of the project and outline changes to the regulatory and governance frameworks
- **TGA performance information**—provide quantitative and qualitative information that is useful for industry on the TGA's organisational effectiveness and operational efficiency.

Consultation

Consultation activities targeted to industry will be undertaken on the following reforms:

- business process reforms underway in relation to Over-the-Counter Medicines and Medical Devices Review
- options for regulatory changes to the labelling and packaging of medicines
- guidelines for levels and kinds of evidence for complementary medicines
- processes and regulatory changes that would help maintain the currency of Consumer Medicines Information (CMI) and approved Product Information (PI)
- the disclosure of commercially confidential information
- potential medical devices reform options, including use of third party assessment bodies for Australian manufacturers; provision of device product names; recognition of third party assessment bodies and options for increasing premarket scrutiny for implantable medical devices
- advertising reform including more effective approaches to sanctions and penalties
- the ANZTPA common regulatory framework.

Media and issues management

TGA media liaison is managed by the Department of Health and Ageing (DoHA)'s experienced team of media experts in the Media Unit. As with all health regulators, 'hot issues' emerge, often without prior warning, and to ensure the community is accurately informed the media liaison activities must be prompt, efficient and authoritative.

The DoHA Media Unit coordinates appropriate responses and develops communications strategies to manage these issues. This may include media releases, website statements and media liaison. The media services provider works closely with TGA staff in specialist areas, the Principal Medical Adviser and the National Manager in developing responses to issues.

Liaison with other information providers

To avoid duplication, the TGA will partner with other information providers within the health arena to communicate targeted information about the regulation of therapeutic goods. These organisations have existing resources and networks that extend beyond those currently available to the TGA.

For example, the TGA will work with the National Prescribing Service (NPS), the Australian Commission for Safety and Quality in Health Care and other information providers to establish agreement on the provision of information to the public consistent with the principles of the quality use of medicines.

The TGA participates in the Regulators' forum, which is comprised of Australian Government regulators. The forum collaborates on harmonised training and exchange of best practice approaches to regulation of food, agriculture and health.

In addition, the TGA will continue to work closely with the following government agencies:

- The Australian Pesticides and Veterinary Medicines Authority in relation to medicines and poisons scheduling
- Food Standards Australia New Zealand, particularly on which products should be regulated as a food or a medicine
- The National Industrial Chemicals Notification and Assessment Scheme, particularly on the regulation of sunscreens
- The Australian Competition and Consumer Commission in relation to fair trading and consumer issues relating to promotion and use of therapeutic goods and health services, and cases of counterfeit or unsafe medicines
- Central government agencies and the Attorney General's Department on the formation of the ANZTPA
- The Ombudsman's office in relation to provision of information and determination of complaints
- The National Health and Medical Research Council in relation to research, clinical trials and new medical practices.

The TGA will also enhance collaborations, and develop potential areas for increased collaboration, with the following organisations:

- NPS
- the Australian Commission for Safety and Quality in Health Care
- collaborators on issues involving blood and blood products, including the National Blood Authority, the Jurisdictional Blood Committee and the Blood Regulators Network
- State and Territory health departments
- medical colleges and pharmaceutical professional bodies.

Measuring the success of the framework

The TGA is placing increased emphasis on two-way communication, and therefore collecting and analysing feedback from stakeholders will play a critical role in ensuring that communications activities are achieving their desired outcome.

The Australian Therapeutic Goods Advisory Council, which has been established under the Blueprint, will provide further advice on communication priorities and strategies and on whether or not the needs and expectations of consumers, health professionals and the therapeutic goods industry are being met.

There will be a number of other measures used—both qualitative and quantitative—to ensure that communication and education activities are successful. Depending on the subject, these may include:

- market research—including surveys, polls and formal feedback
- statistics—such as number of visitors to the TGA Internet site, number of subscribers to TGA information services and number of participants in TGA consultations
- media analysis—using media monitoring services to monitor and analyse media coverage of issues relating to TGA.
- incidental feedback—provided through phone lines, face to face meetings or correspondence.

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
www.tga.gov.au