

# OUTCOME 01

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## POPULATION HEALTH

(Therapeutic Goods Administration group of regulators)  
The incidence of preventable mortality, illness  
and injury in Australians is minimised



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# 01

## POPULATION HEALTH

(THERAPEUTIC GOODS ADMINISTRATION GROUP OF REGULATORS)

### Part 1: Outcome Performance Report

The Therapeutic Goods Administration group of regulators includes the Therapeutic Goods Administration (TGA), the Office of the Gene Technology Regulator (OGTR) and the Office of Chemical Safety (OCS) – incorporating the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). This group is responsible for the regulation of therapeutic products, chemicals and gene technology in Australia.

#### Major Achievements

- Released major components of the joint regulatory scheme for therapeutic products between Australia and New Zealand (the draft Medicines Rules and Medical Device Rules) for consultation.
- Progressed towards establishing the Australia New Zealand Therapeutic Products Authority.
- Progressed international cooperation on the regulation of therapeutic goods through the establishment of a formal agreement with Switzerland, and finalised arrangements with Canada.
- Established a new regulatory framework for the supply of cosmetics (joint reform initiative between the National Industrial Chemicals Notification and Assessment Scheme and the Therapeutic Goods Administration).

### Key Strategic Directions for 2005-06

#### Establishment of the Trans Tasman Therapeutic Products Regulatory Scheme

In December 2005, the Therapeutic Products Interim Ministerial Council announced the deferral of the start up date for the joint Trans Tasman Therapeutic Products Regulatory Scheme. The deferral was to allow an extensive consultation program to enable industry, in particular, to review and comment on the legislation and Rules for the new regulatory scheme.

Since then, the TGA and Medsafe (the New Zealand Medicines and Medical Devices Safety Authority) have made steady progress towards the establishment of the Australia New Zealand Therapeutic Products Authority (ANZTPA) and the joint regulatory scheme. The first set of documents detailing the proposed joint regulatory scheme to be operated by the new Authority was released for public consultation on 23 May 2006.

Following the release of the consultation documents, information/consultation sessions were held by Medsafe and the TGA in New Zealand and Australia during June 2006. The meetings provided an opportunity for industry and other interested stakeholders to hear about the proposed regulatory scheme, ask questions and provide preliminary feedback. Submissions from industry, consumers and other interested stakeholders are being sought on the consultation documents, which to date include the draft Rules for medicines and medical devices.

Before the commencement of the joint regulatory scheme, stakeholder consultations need to be completed and legislation introduced and passed by the parliaments of both countries. Further details on the Stakeholder Consultation Programme 2006-07 are available from the ANZTPA web site.<sup>1</sup>

### Agreements with International Agencies in Relation to the Regulation of Therapeutic Products, Chemicals, and Gene Technology

#### *Memorandum of Understanding between the TGA and the Federal Department of Home Affairs acting in the name of the Federal Council of the Swiss Confederation*

The TGA and the Swiss Federal Department of Home Affairs signed a Memorandum of Understanding (MoU) on therapeutic goods in Canberra on 29 March 2006.

Swissmedic (the Swiss Regulatory authority for therapeutic products) and the TGA have developed a strong relationship over the years, particularly in the manufacture of medicines through Good Manufacturing Practice (GMP) inspections and the regulation of medical devices through the Global Harmonisation Task Force and the global device vigilance exchange programs.

The MoU formalised cooperative arrangements for the exchange of information relating to the regulation of all therapeutic products, particularly in the areas of medicines' GMP inspections and post market monitoring of therapeutic products. It also serves to facilitate and encourage the development of collaborative activities and the sharing of information relating to the regulation of medicines and medical devices.

#### *Australia-Canada Memorandum of Understanding on Quality Management Systems Certification for Medical Device Manufacturers*

Memorandum of Understanding negotiations in 2005-06 between the Canadian Health Products and Food Branch (HPFB) and the Australian TGA on the reciprocal recognition of quality management system (QMS) certifications for medical device manufacturers entered the confidence building phase. A rigorous confidence building framework was developed that includes, but is not limited to, a review of documentation and audits of each other's processes, procedures and systems for conducting audits of manufacturers' quality management systems. The confidence building exercise will also include observed on-site audits of medical device manufacturers.

Due to operational considerations, both parties agreed to revise the timelines for the MoU. The confidence building phase of the project (with the exception of the observed audits), is scheduled to be completed by the end of the first quarter of 2007, after which the TGA and the HPFB expect to be able to sign the MoU and receive applications from manufacturers to participate in observed audits.

Under the MoU, QMS certifications issued by the TGA will be recognised by the HPFB and considered as part of an application for a device licence that would allow supply in Canada. Likewise, QMS certifications issued by a participating Canadian registrar will be recognised by the TGA and considered as part of an application for a Conformity Assessment Certificate issued by the TGA.

Once operational, this arrangement will avoid any duplication of QMS audits currently required for manufacturers who export their medical devices to the two jurisdictions.

<sup>1</sup> Accessible at: <[www.anztpa.org/consult/programme0607.htm](http://www.anztpa.org/consult/programme0607.htm)>.

## Therapeutic Products

### *Review of Access to Unapproved Therapeutic Goods*

The TGA and the National Health and Medical Research Council jointly commissioned a report of the Review of Access to Unapproved Therapeutic Goods, which was completed and accepted by the Clinical Trials Review Steering Committee set up to oversee the project. This review was intended to examine the environment for clinical trial research in Australia and New Zealand and to make recommendations to improve existing systems and to advise on a new system for the Trans-Tasman environment.

The report underwent a period of public consultation until 8 July 2005. The TGA encouraged initial submissions from all stakeholders, including the community, through newspaper advertising and the TGA web site.<sup>2</sup> A Government response to the review is being finalised. The Government response to the review will guide any required changes to TGA functions prior to the establishment of ANZTPA and be reflected in the joint regulatory scheme.

## Medical Devices

### *In Vitro Diagnostics Regulatory Framework*

*In vitro diagnostics* (IVDs) are defined as any instrument, equipment or apparatus, reagent (alone or in combination) or control/calibrator, that is intended to be used *in vitro* for the examination of a specimen derived from the human body.

The TGA and industry reached agreement on the proposed IVD regulatory framework and the associated cost recovery arrangements in November 2005.

The IVD regulatory framework will be implemented by the TGA in two stages, commencing with the regulatory framework for commercial IVDs, proposed for 2007. This will be followed by the regulatory framework for in-house IVDs at a date to be determined. Higher risk Class 4 commercial IVDs will have two years to meet the new requirements, while the lower risk Class 1-3 commercial IVDs will have four years to meet the new requirements.

The TGA held a round of industry seminars in early May 2006, in major capital cities, to educate stakeholders about the new requirements. The TGA is working with industry to develop guidance documents on the new regulatory system.

The new regulatory system will bring Australia into line with international best practice for the regulation of IVDs.

## Cellular and Tissue Therapies

### *Proposed Regulatory Framework for Human Tissues and Cellular Therapies*

Currently, some human cell and tissue products are subject to regulation as medicines or medical devices and others are exempted, for example whole organs and products manufactured for individual patients under the supervision of the treating medical practitioner. These arrangements will be brought together within a single office for biologicals under ANZTPA. This office will focus in particular on the transmission of infectious diseases associated with the use of human cells and tissues as therapeutic products. This approach for the regulation of products derived from humans and other biological sources is similar to developments for regulation of biological products in other countries.

During 2005-06, the TGA continued consultations with stakeholder groups on specific issues requiring development to underpin the regulatory framework for human tissues and cellular therapies. Jurisdictional input to the framework and its proposed options for funding arrangements has been a significant milestone in drawing together critical elements of the proposal.

It is proposed that the regulations will be implemented in 2007 and will keep Australia consistent with international best practice.

## Gene Technology Regulation

During 2005-06, the Gene Technology Ministerial Council (GTMC) appointed an independent panel to conduct a review of the *Gene Technology Act 2000* in accordance with Section 194 of the Act. The Department's Acute Care Division provided the independent panel with secretariat support. The panel's report was tabled in the Australian Parliament on 27 April 2006 and Australian, State and Territory government ministers commenced the preparation of a response by all jurisdictions.

Following extensive consultation on proposed technical amendments to the Gene Technology Regulations 2001 with a wide range of interest groups and the public, the Gene Technology

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<sup>2</sup> Accessible at: <[www.tga.gov.au](http://www.tga.gov.au)>.

Amendment Regulations 2005 are being finalised by the Office of the Gene Technology Regulator (OGTR) in conjunction with the Office of Legislative Drafting for consideration by the GTMC.

The OGTR is liaising with the Plant Biosafety Office of the Canadian Food Inspection Agency to establish an officer exchange arrangement to work on areas of mutual regulatory interest.

The risk assessment and risk management plans for all licence applications to deal with genetically modified organisms processed by the OGTR in 2005-06 were prepared in accordance with the Regulator's revised *Risk Analysis Framework*.

legislation. The joint collaboration resulted in the establishment of a new regulatory framework for the supply of cosmetics, which was endorsed by the Australian Government in November 2005.

In 2005-06, NICNAS also established framework controls for chemicals that present low regulatory concern. This resulted in the introduction of special permit categories, which include chemicals produced for export only purposes.

### Chemicals Regulation

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) worked closely with the TGA and industry in 2005-06 to address complex boundary issues between areas of regulation in regards to the supply of cosmetics. This involved clearly defining what is regulated as therapeutic goods and what is regulated under cosmetics

## Part 2: Performance Information

### Performance Information for Departmental Outputs

**Output Group 1. Policy Advice**, including:

- working with relevant policy areas of the Department to provide advice in relation to appropriate national policies and controls for medicines, medical devices, chemicals, gene technology, blood and tissues; and
- advice in relation to collaboration with international stakeholders.

<b>Target:</b>	<i>Quality:</i> Ministers' satisfaction with the quality, relevance and timeliness of our advice for Australian Government decision-making.	
<b>Result:</b>	Target met.	Ministers were satisfied with the quality, relevance and timeliness of advice provided for Australian Government decision making.

**Output Group 3. Agency-specific Service Delivery, including:**

- regulatory activity in relation to therapeutic products, through:
  - pre-market assessment of therapeutic products at a level appropriate to assessed risk;
  - assessment of manufacturers of therapeutic products to ensure compliance with Good Manufacturing Practice requirements; and
  - post-market surveillance and other activities based on risk management and targeted testing of therapeutic products;

<b>Target:</b>	<i>Quality:</i> Evaluations and appeals of decisions on applications for entry of products onto the Australian Register of Therapeutic Goods are made within legislated timeframes, where applicable.	
<b>Result:</b>	Target met.	The statutory timeframes were met for all prescription medicines evaluations in 2005-06. The numbers of submissions relating to prescription medicines are shown in Table 1 at the end of this chapter.
<b>Target:</b>	<i>Quality:</i> Licensing audits and ongoing surveillance audits of Australian and overseas manufacturers are performed within target timeframes.	
<b>Result:</b>	Target met.	All audits and applications were performed within target timeframes.
<b>Target:</b>	<i>Quality:</i> Breaches of the <i>Therapeutic Goods Act 1989</i> are investigated and appropriate action taken.	
<b>Result:</b>	Target met.	During the period 1 July 2005 to 30 June 2006, 464 new referrals breaches were received from stakeholders including members of the public, industry, local and international law enforcement and regulatory agencies with 425 investigations completed. The TGA Surveillance Unit issued 126 formal warnings to persons/companies and charged 12 persons/companies with 116 criminal offences.
<b>Target:</b>	<i>Quality:</i> Consultation with stakeholders on regulatory change in relation to therapeutic products.	
<b>Result:</b>	Target met.	The TGA group of regulators has received feedback from a number of sources that has indicated a generally positive response to inputs to national policy, planning and strategy development and implementation. Examples include consultations with stakeholders on the proposed IVD regulations; the new framework for Human Cellular and Tissue Therapies; workflow practices within the Drug Safety and Evaluation Branch of the TGA; and the review of Australian arrangements for clinical trials and access to unapproved therapeutic goods.
<b>Target:</b>	<i>Quantity:</i> 6,500–8,000 applications for registration, listing, inclusion or variation of products on the Australian Register of Therapeutic Goods processed to completion.	
<b>Result:</b>	Target met.	7,333 applications for registration, listing or inclusion on the Australian Register of Therapeutic Goods were approved in 2005-06.
<b>Target:</b>	<i>Quantity:</i> A minimum of 800 therapeutic products tested as part of post-marketing surveillance.	
<b>Result:</b>	Target met.	TGA Laboratories tested 898 products consisting of 1,780 samples in 2005-06. In addition, TGA Laboratories completed protocol release evaluations for 551 batches of biological medicines.

- regulatory activity in relation to genetically modified organisms (GMOs), through licensing and monitoring of dealings with GMOs;

<b>Target:</b>	<i>Quality:</i> Evaluations and appeals of decisions on applications to deal with GMOs are made within legislated timeframes, where applicable.	
<b>Result:</b>	Target met.	The OGTR received 38 licence applications for dealings involving intentional release of GMOs into the environment and dealings not involving intentional release of GMOs into the environment. The OGTR issued 22 licences to deal with GMOs. All evaluations were completed within statutory timeframes. There were no appeals against Gene Technology Regulator decisions.
<b>Target:</b>	<i>Quality:</i> Non-compliances of the <i>Gene Technology Act 2000</i> are investigated and appropriate action taken.	
<b>Result:</b>	Target met.	All breaches of the <i>Gene Technology Act 2000</i> that were detected through OGTR monitoring activities or self-reported were investigated. In all instances risks to human health and safety and the environment were assessed as negligible and commensurate action was taken, including increased monitoring of certain field trial sites and increased education of licence holders.
<b>Target:</b>	<i>Quality:</i> Consultation with stakeholders on regulatory change in relation to GMOs.	
<b>Result:</b>	Target met.	The OGTR consulted extensively with stakeholders in developing proposed technical amendments to the Gene Technology Regulations 2001 and the revision of the Regulator's <i>Guidelines for the Certification of Physical Containment 1 &amp; 2 Large Scale and Physical Containment 3 Laboratory Facilities</i> .
<b>Target:</b>	<i>Quantity:</i> A minimum of 20% of field trials inspected for compliance with conditions in licences to undertake dealings with GMOs.	
<b>Result:</b>	Target met.	More than 20% of field trials were inspected for compliance with conditions in licences to undertake dealings with GMOs.

- regulatory activity in relation to industrial chemicals, pesticides and veterinary medicines, through:
  - pre-introduction assessment of new industrial chemicals and review of priority existing industrial chemicals (including environmental risk);
  - provision of advice on the public health impact of pesticides and veterinary medicines, which takes into account national and internationally recognised standards; and
  - establishment and maintenance of human health standards;

<b>Target:</b>	<i>Quality:</i> Evaluations and appeals of decisions on applications in relation to: <ul style="list-style-type: none"> <li>• industrial chemicals; and</li> <li>• human health aspects of pesticides and veterinary medicines</li> </ul> are made within legislated timeframes, where applicable.	
<b>Result:</b>	Target met.	<p>The timeframe target of 95% was exceeded for 202 New Chemicals assessment certificates and 120 New Chemical permits. NICNAS declared for assessment 27 Existing Chemicals and completed 11 Priority Existing Chemical and other assessments, and completed 6 hazardous assessments for international agencies exceeding the target of 13 assessments to be completed a year. There were 2 applications involving 3 appellants made to the Administrative Appeals Tribunal. These decisions remain pending.</p> <p>The Director of NICNAS granted confidential listings on the Australian Inventory of Chemical Substances (AICS) for 25 chemicals from a total of 33 applications received, and there are 7 pending applications with 1 listed on the public AICS.</p> <p>The Office of Chemical Safety met 97.5% of timeframes (target 95%) for all 9 major and 55 minor pesticide and veterinary medicine health risk assessments and 53 occupational health and safety assessments, plus 3 permits and 1 extension of use. All of these registration assessment reports were accepted by the Australian Pesticides and Veterinary Medicines Authority. For 2005-06, a total of 10 pesticide reviews were completed. Of these, 6 were completed within the agreed timeframes, partially achieving the target of 95%. 3 of the 10 completed reviews required post-assessment amendments to the health standards.</p> <p>The National Drugs and Poisons Scheduling Committee made 101 scheduling decisions during the year (21 agricultural and veterinary chemicals, 70 medicines and 10 chemicals). Of these, 7 were subject to post meeting comment and all but 1 were confirmed/amended (ie accepted). The Office established or amended, following review, 122 public health standards for pesticides. There were 3 amendments of the <i>Standard for the Uniform Scheduling of Drugs and Poisons</i>, 20th edition; 1 consolidated <i>Standard for the Uniform Scheduling of Drugs and Poisons</i>, 21st edition; and 3 issues of the <i>Handbook of First Aid Instructions, Safety Directions and Warning Statements for Agricultural and Veterinary Chemicals</i>.</p>
<b>Target:</b>	<i>Quality:</i> Breaches of the <i>Industrial Chemicals (Notification and Assessment) Act 1989</i> are investigated and appropriate action taken.	
<b>Result:</b>	Target met.	<p>NICNAS finalised 17 breaches relating to the introduction of new chemicals and audited 15,194 entities concerning registration requirements under the <i>Industrial Chemicals (Notification and Assessment) Act 1989</i>.</p> <p>This compliance effort resulted in remedial action by companies in order to become compliant and 1,233 new registrations.</p>

<b>Target:</b>	<i>Quality:</i> Consultation with stakeholders on regulatory change in relation to industrial chemicals, pesticides and veterinary medicines.	
<b>Result:</b>	Target met.	NICNAS completed public consultations on the discussion paper on a new model for the NICNAS Existing Chemicals Assessment Program.

- provision of licensing, permits and/or monitoring system for prohibited and scheduled substances under the United Nations Drug Treaty.

<b>Target:</b>	<i>Quantity:</i> 95% of permits and licences issued and reporting completed within agreed targets.	
<b>Result:</b>	Target met.	Compliance activities for licit use of controlled substances saw 5,467 permits and 721 licences issued, all within target timeframes (97%). A total of 1.9 million domestic movements of controlled substances for licit purposes were tracked as part of the national anti-drug diversion program. Australia's compliance efforts for the calendar year 2005 were reported to the United Nations International Narcotics Control Board on 30 June 2006 as required.

**Table 1: Prescription Medicines Submissions**

		2004-05	2005-06
<b>Category 1</b>	An application to register a new prescription medicine or a change to a medicine not meeting the requirements for Category 2 or Category 3 applications.	335	366
<b>Category 2</b>	An application to register a prescription medicine where two independent evaluation reports from acceptable countries are available.	0	0
<b>Category 3</b>	An application involving changes to the quality data of medicines already included on the Australian Register of Therapeutic Goods and not involving clinical, non-clinical or bioequivalence data.	989	954

## Outcome 1: Financial Resources Summary

	(A) Budget Estimate* 2005-06 \$'000	(B) Actual 2005-06 \$'000	Variation (Column B minus Column A) \$'000
<b>Administered Expenses</b>			
<b>Program 1.1: Chronic Disease - Early Detection and Prevention</b>			
Appropriation Bill 1/3/5	20,079	20,585	506
	<b>20,079</b>	<b>20,585</b>	<b>506</b>
<b>Program 1.2: Communicable Disease Control</b>			
Appropriation Bill 1/3/5	19,324	17,606	(1,718)
Appropriation Bill 2/4/6	2,266	1,913	(353)
	<b>21,590</b>	<b>19,519</b>	<b>(2,071)</b>
<b>Program 1.3: Drug Strategy</b>			
Appropriation Bill 1/3/5	63,919	57,266	(6,653)
Appropriation Bill 2/4/6	55,294	54,084	(1,210)
	<b>119,213</b>	<b>111,350</b>	<b>(7,863)</b>
<b>Program 1.4: Food and Regulatory Policy</b>			
Appropriation Bill 1/3/5	220	254	34
	<b>220</b>	<b>254</b>	<b>34</b>
<b>Program 1.5: Health Emergency</b>			
Appropriation Bill 1/3/5	-	-	-
Appropriation Bill 2/4/6	-	-	-
	-	-	-
<b>Program 1.6: Immunisation</b>			
<i>National Health Act 1953 - Essential Vaccines</i>	181,493	207,482	25,989
Total Special Appropriations	181,493	207,482	25,989
Appropriation Bill 1/3/5	16,055	9,905	(6,150)
Appropriation Bill 2/4/6	259	304	45
	<b>197,807</b>	<b>217,691</b>	<b>19,884</b>
<b>Program 1.7: Public Health</b>			
Appropriation Bill 1/3/5	21,262	19,057	(2,205)
Appropriation Bill 2/4/6	163,874	163,535	(339)
	<b>185,136</b>	<b>182,592</b>	<b>(2,544)</b>
<b>Total Administered Expenses</b>	<b>544,045</b>	<b>551,991</b>	<b>7,946</b>
<b>Departmental Appropriations</b>			
Output Group 1 - Policy Advice	17,904	17,682	(222)
Output Group 2 - Program Management	26,855	35,699	8,844
<b>Total price of departmental outputs</b>			
<i>(Total revenue from Government and other sources)</i>	<b>44,759</b>	<b>53,381</b>	<b>8,622</b>
Total revenue from Government (appropriations) contributing to price of departmental outputs	42,753	49,518	6,765
Total revenue from other sources	2,006	3,863	1,857
<b>Total price of departmental outputs</b>	<b>44,759</b>	<b>53,381</b>	<b>8,622</b>
<i>(Total revenue from Government and other sources)</i>	<b>44,759</b>	<b>53,381</b>	<b>8,622</b>

	(A) Budget Estimate* 2005-06 \$'000	(B) Actual 2005-06 \$'000	Variation (Column B minus Column A) \$'000
<b>Therapeutic Goods Administration group of regulators</b>			
<b>Therapeutic Goods Administration (TGA)</b>			
Output Group 3 - Agency-specific Service Delivery	73,972	73,224	(748)
<b>Office of the Gene Technology Regulator</b>			
Output Group 3 - Agency-specific Service Delivery	7,843	8,171	328
<b>National Industrial Chemicals Notification and Assessment Scheme</b>			
Output Group 1 - Policy Advice	-	-	-
Output Group 3 - Agency-specific Service Delivery	6,495	8,324	1,829
<b>Total price of TGA group of regulators outputs</b>	<b>88,310</b>	<b>89,719</b>	<b>1,409</b>
Total revenue from Government (appropriations) contributing to price of departmental outputs	9,329	9,329	-
Total revenue from other sources	78,981	80,390	1,409
<b>Total price of TGA group of regulators outputs</b> <i>(Total revenue from Government and other sources)</i>	<b>88,310</b>	<b>89,719</b>	<b>1,409</b>
<b>Total estimated resourcing for Outcome 1</b>			
<i>(Total price of outputs and administered expenses)</i>	<b>677,114</b>	<b>695,091</b>	<b>17,977</b>
<b>Average Staffing Level (Number)</b>			
Department	<b>1,147</b>	<b>886</b>	<b>(261)</b>

The 2006-07 budget has not been provided. The Department of Health and Ageing moved to a new outcome structure for 2006-07 and is no longer appropriated under the 2005-06 outcome structure. Accurate allocation of 2006-07 funding against the 2005-06 outcome structure is not available and inclusion of notional allocations could be misleading to the reader.

\* Budgeted appropriations taken from the 2006-07 Health and Ageing Portfolio Budget Statements and re-aligned to the 2005-06 outcome structure.

