

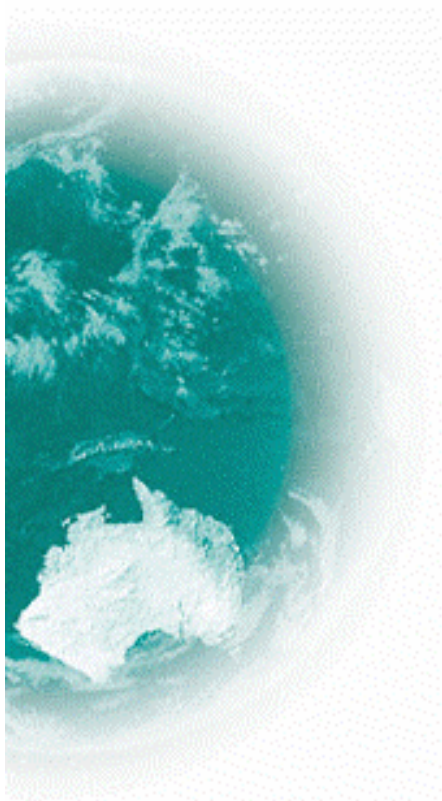


Australian Government
Department of Health and Ageing

Quarterly Report of the Therapeutic Goods Administration Group of Regulators

against the

2005 - 2006 Business Plan



For the period

1 January to 31 March 2006

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GLOSSARY

ACCC	Australian Competition and Consumer Commission
ADEC	Australian Drug Evaluation Committee
ADI	Acceptable Daily Intakes for agricultural and veterinary chemicals
ADR	Adverse drug reaction
ADRU	Adverse Drug Reactions Unit
AGCS	Advisory Group on Chemical Safety
AHMAC	Australian Health Ministers' Advisory Council
AHMC	Australian Health Ministers' Conference
ANAO	Australian National Audit Office
ANZTPA	Australia New Zealand Therapeutic Products Authority
APEC	Asia-Pacific Economic Cooperation
APVMA	Australian Pesticides and Veterinary Medicines Agency
ARCBS	Australian Red Cross Blood Service
ARfD	Acute Reference Doses for agricultural and veterinary chemicals
ARTG	Australian Register of Therapeutic Goods
CFIA	Canadian Food Inspection Agency
CMEC	Complementary Medicines Evaluation Committee
CMI	Consumer Medicine Information
CoE	Council of Europe
CPP	Certificate of Pharmaceutical Product
CTD	Common Technical Document
CTN	Clinical Trial Notification
CTX	Clinical Trial Exemption
DEAL	Device Electronic Application Lodgement
DFAT	Australian Government Department of Foreign Affairs and Trade
DITR	Australian Government Department of Industry, Tourism and Resources
DSEB	Drug Safety and Evaluation Branch
EAC	Expert Advisory Committee
EC	European Commission
EDQM	European Directorate for the Quality Medicines
EEL	Export Electronic Lodgement
EFTA	European Free Trade Association
EU	European Union
EWG	Education Working Group (subcommittee of SILG/MDIAA)
FAISD	First-aid instructions and safety directions
FTA	Free Trade Agreement
GHS	Globalised Harmonised System for the classification and labelling of chemicals
GHTF	Global Harmonization Task Force
GMO	Genetically modified organism
GMP	Good Manufacturing Practice
Hb	Haemoglobin
HR	Human Resources
IJEACCM	Interim Joint Expert Advisory Committee on Complementary Medicines
INCB	International Narcotics Control Board
IPCS	International Programme on Chemical Safety
IRIS	Incident Report Investigation Scheme
ISO	International Organization for Standardization
IT	Information Technology
IVD	<i>In vitro</i> Diagnostic (medical device)
JAEG	Joint Agency Establishment Group
JAMC	Joint Agency Management Committee
JIEACS	Joint Interim Expert Advisory Committee on Standards
MAB	Manufacturer Assessment Branch
MDEC	Medical Devices Evaluation Committee
MDIAA	Medical Device Industry Action Agenda
MDO	Managing Directors Order
MEC	Medicines Evaluation Committee (for OTC medicines)
Medsafe	New Zealand Medicines and Medical Devices Safety Authority

MIAA	Medical Industry Association of Australia
MIANZ	Medical Industry Association of New Zealand Inc
MIS	Manufacturers Information System
MOH	Ministry of Health
MoI	Memorandum of Intention
MoU	Memorandum of Understanding
MRA	Mutual Recognition Agreement
NBA	National Blood Authority
NCCTG	National Coordinating Committee on Therapeutic Goods
NDPSC	National Drugs and Poisons Schedule Committee
NDS	National Drug Strategy
NHMRC	National Health and Medical Research Council
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NRL	National Serology Reference Laboratory
NSAIDs	Non-steroidal anti-inflammatory drugs
OCM	Office of Complementary Medicines
OCS	Office of Chemical Safety
OGTR	Office of the Gene Technology Regulator
OICG	OCM / Industry Consultation Group
OICG	OCM / Industry Consultation Group
OPAL	OTC Medicines Electronic Lodgement System
OTC	Over-the-counter (as in OTC medicine)
PBO	Plant Biosafety Office (Canada)
PEC	Priority Existing Chemical
PI	Product Information
PIL	Permitted Ingredient List
PMF	Plasma Master File
PSUR	Periodic Safety Update Report
QMS	Quality Management System
RAF	Risk Analysis Framework
RASML	Required Advisory Statements for Medicine Labels
RWG	Regulation Working Group (subcommittee of SILG/MDIAA)
SAS	Special Access Scheme
SILG	Strategic Industry Leaders Group (subcommittee of MDIAA)
SIME	TGA's Online Systems (Strategic Information Management Environment)
SOP	Standard Operating Procedure
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
TGA	Therapeutic Goods Administration
TGAL	TGA Laboratories Branch
TGC	Therapeutic Goods Committee
TGO	Therapeutic Goods Order
TICC	TGA-Industry Consultative Committee
TMF	Technical Master File
TOR	Terms of Reference
TPIMC	Therapeutic Products Interim Ministerial Council
TSE	Transmissible Spongiform Encephalopathy
TTMRA	Trans Tasman Mutual Recognition Arrangement
UN	United Nations
URPTG	Uniform Recall Procedure for Therapeutic Goods
USA	United States of America
USFDA	US Food and Drug Administration
WHO	World Health Organization

INTRODUCTION

The Therapeutic Goods Administration (TGA) Group of Regulators includes the 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).

Progress of the TGA Group of Regulators during the October to December 2005 quarter against the *Therapeutic Goods Administration Group of Regulators Business Plan 2005-2006* is featured in this report. For further information, both the Business Plan and the October - December 2005 Quarterly Report are located on the TGA website at the following link: [<http://www.tga.gov.au/about/tgagorbp0506.htm>].

This report is structured as follows:

A. Regulating Therapeutic Products

- A1. Prescription Medicines
- A2. OTC Medicines
- A3. Complementary Medicines
- A4. Medical Devices
- A5. Manufacturer Assessment Program
- A6. Exports Program
- A7. Blood and Tissues
- A8. Recalls Program

B. Regulating Gene Technology

C. Regulating Chemicals

D. Supporting the Business

This report addresses both continuing responsibilities and major project initiatives for the financial year including the development of the regulatory arrangements to apply from 1 July 2006, following the commencement of the Australia New Zealand Therapeutic Products Authority (ANZTPA) and the joint regulatory scheme for therapeutic products the ANZTPA will administer.

A. REGULATING THERAPEUTIC PRODUCTS

A1. Prescription Medicines Program

Key Achievements during the January – March 2006 Quarter

1. Guidelines adopted

EMEA/CHMP/167235/2004	Note for Guidance on Immunotoxicity Studies for Human Pharmaceuticals
CPMP/SWP/799/95	Guideline on the Non-Clinical Documentation for Mixed Marketing Authorisation Applications
EMEA/CHMP/EWP/5872/03 corr	Guideline on Data Monitoring Committees
CHMP/ICH/2/04	Note for Guidance on Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs
EMEA/CHMP/021/97 Rev 1	Guideline on Clinical Investigation of Medicinal Products for the Treatment of Hormone Replacement Therapy of Oestrogen Deficiency Symptoms in Postmenopausal Women
CPMP/EWP/2339/02	Guideline on the Evaluation of the Pharmacokinetics of Medicinal Products in Patients with Impaired Hepatic Function
EMEA/CPMP/EWP/2158/99	Guideline on the Choice of the Non-Inferiority Margin
CHMP/ICH/423/02	Note for guidance on the Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT interval prolongation) by Human Pharmaceuticals
EMEA/CHMP/EWP/5872/03	Guideline on Data Monitoring Committees
EMEA/CPMP/EWP/519/98 rev 1	Note for Guidance on Clinical Investigation of Steroid Contraceptives in Women
CHMP/QWP/297/97 Rev 1 corr	Guideline on summary of requirements for Active Substances in the quality part of the dossier

2. New medicines registered

Alendronate sodium and colecalciferol (Fosamax Plus Once Weekly)	Merck Sharp & Dohme (Australia) Pty Ltd
Benzoyl peroxide and clindamycin phosphate (Duac once daily)	Stiefel Laboratories Pty Ltd

Bortezomib (Velcade)	Janssen-Cilag Pty Ltd
Erlotinib (Tarceva)	Roche Products Pty Ltd
Factor VIII (Octanate)	Octapharma Australia Pty Ltd
Fulvestrant (Faslodex)	AstraZeneca Pty Ltd
Human rotavirus [live attenuated] vaccine (Rotarix)	GlaxoSmithKline Australia Pty Ltd
Measles, mumps, rubella, varicella vaccine (ProQuad)	Merck Sharp & Dohme (Australia) Pty Ltd
Posaconazole (Noxafil)	Schering-Plough Pty Ltd
Yttrium[90Y] chloride (Ytracis)	Schering P/L

3. Orphan drugs designated

Dasatinib	Philadelphia-positive acute lymphoblastic leukaemia (Ph+ ALL)
Galsulfase rch (Naglazyme)	for long-term enzyme replacement therapy in the treatment of patients with mucopolysaccharidosis type VI (MPS VI)
Recombinant Human Iduronate-2-Sulfatase (Idursulfase)	for long-term treatment of patients with Hunter syndrome

4. Consultation documents

- ***Improving access to prescription medicine information***

An Initial Discussion Paper was prepared to provide a basis for scoping further discussions with stakeholders. The Initial Discussion Paper:

- provided background information about the means by which the TGA currently regulates Consumer Medicine Information (CMI) and Product Information (PI) documents;
- provided summary information about some of the ways in which consumers and professionals currently access up-to-date CMI and PI documents;
- identified some of the concerns raised with the TGA regarding access to up-to-date CMI and PI documents; and
- requested information on current mechanisms of information dissemination.

The consultation period of the discussion paper closed on 27 June 2005 and a new consultation paper is being prepared for release in the first half of 2006.

- ***Review of Australian arrangements for clinical trials and access to unapproved therapeutic goods***

This independent review, jointly commissioned by the TGA and the National Health and Medical Research Council (NHMRC), examined current regulatory provisions for clinical trials and access to unapproved therapeutic goods in Australia and

internationally. The consultation period for comment closed on 8 July 2005. A government response has been drafted in collaboration with NHMRC.

- ***Best practice guideline on prescription medicine labelling***

This guideline complements the mandatory standards for medicine labelling set out in TGO 69. The best practice guideline on prescription medicine labelling was developed by a working party of stakeholders, coordinated through the TGA, to guide pharmaceutical sponsors and TGA assessors in the design and review of the acceptability of prescription medicine labelling. It was adopted in November 2005. The guideline enhances the ability of health care professionals and consumers to select the correct medicines, use it safely, and therefore aid in reducing medication errors. The guideline will be reviewed by DSEB and stakeholders early in 2007.

- ***Workflow practices within the Drug Safety and Evaluation Branch of the TGA***

A Discussion Paper was prepared to provide a basis for discussions with stakeholders about possible means by which to streamline processes for evaluation of applications for prescription medicines and increase transparency of decision-making. It draws on the work undertaken by a Working Party formed in late 2002 to review Australia's Prescription Medicines Regulation Workflow Practices. The Discussion Paper was open for comment till 20 January 2006 and a final report is being prepared.

It is anticipated that the TGA will wish to implement any improvements that can be made to their current business processes as a result of this review ahead of the commencement of the trans-Tasman regulatory scheme.

Because the feedback from this consultation will also flow through into the development of business practices for the new agency, the consultation will be conducted jointly by the Drug Safety and Evaluation Branch (DSEB) and the Joint Agency Establishment Group (JAEG) and feedback is being sought from both New Zealand and Australian stakeholders.

5. International Conferences attended during the reporting period

The TGA Laboratories Immunobiology Section Head contributed to the WHO, USFDA and Health Canada Regulatory Preparedness Workshop for Pandemic Influenza in Ottawa (6-13 Mar).

6. Presentations

The TGA Laboratories Immunobiology Section Head gave two presentations in Ottawa, Canada on:

- Whole Virus Vaccines (Mar 9)
- TGA approach to pandemic flu (Mar 8)

7. Collaborative assays

Heparin Sodium Biological Reference Preparation Replacement Study (BSP070)

This study is carried out under the aegis of the Biological Standardisation Programme of the European Directorate for the Quality Medicines (EDQM). The aim is to establish a replacement batch for Heparin BRP batch 2 and to verify the suitability of the candidate

reference preparation to serve as a working reference in tests for potency of unfractionated heparin.

1st WHO International Standard for Alpha-1 Antitrypsin Collaborative Study (NIBSC)

The aim of this study is to establish a WHO International Standard for Alpha-1 Antitrypsin (AAT, or alpha-1-proteinase inhibitor) that will be used to standardise the potency of therapeutic concentrates. The study will also help in fulfilling existing European guidelines for determination of alpha-1-proteinase inhibitor and in developing a pharmacopoeial method.

8. WHO Activities

- The TGA Laboratories Immunobiology Section Head attended a WHO meeting on interpandemic and pandemic vaccines in Geneva (11-19 Feb).
- The World Health Organization has asked Dr P Nandapalan of the Viral Safety Unit to contribute to a study on cell substrates. The aim is to review the latest knowledge and to recommend and coordinate studies on theoretical risks from residual cellular DNA from cell substrates used for vaccine production.

Ongoing functions

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Receive and accept, evaluate and finalise submissions to approve new chemical entities, new generic medicines and product variations	Submissions finalised within 255 working days of acceptance for all category 1 applications and 45 days for category 3 applications	100% within target timeframe	100% finalised within target time frames (category 1 applications and category 3 application).
Receive, accept and finalise CTX applications.	For major CTX variations 50 working days and for minor variations 30 working days	100% within target timeframe	100% finalised within target time frames (4 CTX applications)
Receive notifications for CTN trials	Acknowledge within 10 working days of receipt	100% within target timeframe	100% finalised within target timeframes (1943 CTNs received, mean time 1 days)
Receive applications for Orphan Drug Designations	Finalise within 6 weeks of receipt	50% finalised within target	50% finalised within target (10 received, mean time 37 days)
Receipt and review of PSURs	Professional review of PSURs within 3 months of receipt	50% reviews within target	A system of recording the dates each report is received and reviewed has been instituted. In future it is proposed to record any instances where reports are not reviewed within target timeframe
Provide secretariat support to the Australian Drug Evaluation Committee (ADEC) and its subcommittees	Notification of ADEC resolutions to sponsor companies within 5 working days of meeting and gazettal of positive resolutions within one month of meeting Edited extracts of ratified ADEC minutes provided to all relevant sponsor companies within one month of ratification	100% actions finalised within target timeframes	100% actions finalised within target timeframes

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Undertake program of targeted and complaint testing	Targeted testing as per schedule Complaint sample testing to commence within 1 week of receipt of sample	75% completed as per schedule 100% actions finalised within target timeframes	Targets met. A total 361 samples of prescription medicines were tested during this quarter in accordance with the sampling plan and Service Level Agreement. Four (1.1%) were of unsatisfactory quality. TGAL also tested a total of 61 unregistered samples this quarter. Ten samples of problem or complaint prescription medicines were received during this quarter. All of these were finalised within target timeframes as agreed with the regulator.
Receipt and review of ADR reports and subsequent analysis	Reports reviewed by a professional within 3 working days of receipt and reports entered into ADRU database within two weeks of receipt	100% of actions completed within target	Review by professional officer: 99.3% within target timeframe Entry into ADRU database: 90.6% within target timeframe (Data collected over the period mid-October to end March 2006 only)

Other timeframes

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Industry TGA target timeframes for mean evaluations to move to percentile targets with move to Premier and introduction of new business processes and co-operation industry.	<p>Mean Target Times</p> <p>New chemical entities 150 wd</p> <p>Extensions of indications 160 wd</p> <p>New generic 100 wd</p> <p>PI Review 90 wd</p> <p>Other Cat 1 130 wd</p>	<p>Target timeframes achieved for 60% application in 2005-06, 75% 2006 – 07 and 90% 2007-08</p>	<p>New chemical entities: 7% (mean time 211 days, n = 28)</p> <p>Extensions of indications: 22% (mean time 183 days, n = 27)</p> <p>Major variation: 13% (mean time 191 days, n = 30)</p> <p>New generic: 0% (mean time 196 days, n = 27)</p> <p>PI Review: 49% (mean time 104 days, n = 76)</p> <p>Other Cat 1(minor variation): 49% (mean time 159 days, n = 5))</p> <p>The basis for calculating the number of TGA working days has changed since these targets were agreed: 10 days for a sponsor response before the ADEC meeting is now counted as TGA time, as is the time for sponsors to provide an updated version of the product information after the ADEC meeting. The latter change has added an average of 14 days to the evaluation time for a new chemical entity and 5 days to the evaluation of a submission for an extension of indications.</p>

Major projects

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Develop and implement the joint regulatory scheme for prescription medicines, in association with Medsafe and in consultation with relevant stakeholders	Develop guidelines, processes and procedures for the regulation of prescription medicines under the joint scheme Identify and progress implementation of any changes to IT systems for prescription medicines to meet the needs of the joint scheme	Joint regulatory scheme for prescription medicines in place for commencement of operation of joint agency	Draft regulatory guidelines for prescription medicines under the joint scheme, policies and guidelines for converting an interim product licence for a class II medicine into a joint agency product licence and draft guidelines for Module 1 of the CTD are being developed. Specifications for the electronic lodgement of prescription medicine submissions (application form and provisional record) being developed.
Consultation and implementation of business process reforms	Consultation completed by July 2005 Implementation plan developed by end August 2005 Implement reforms in 2005-06	Targets achieved	Consultation paper prepared released November 2005. Consultation period open till 20 January 2006 Final report being prepared May 2006
Improved access to PI/CMI documents	Consultation completed by July 2005 Implementation plan developed by end August 2005 Implement reforms in 2005-06	Targets achieved	An initial discussion paper on improving access to prescription medicines information was prepared and released for consultation. The initial consultation period closed on 27 June 2005 and a second consultation paper is being prepared for release first half 2006.
Improved Prescription Medicine Labelling	Introduce revised guideline by end of July 2005	Targets achieved	Guideline finalised November 2005
Clinical Trial and Special Access Review	Final consultation phase completed by end July 2005 Implement TGA actions in 2005/06 and 2006/07 in trans Tasman context	Target achieved	On target. Consultation complete and Government response has been drafted in collaboration with NHMRC.

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
ADRU to implement automated ADR reporting fully	Allow electronic reporting of ADR by companies and health professionals	Full electronic facilities available by end 2005-06	<p>Electronic reporting from prescribers through desktop software has moved to Production but requires some work from the IT section and the two software providers before it is advertised as fully functional.</p> <p>A project to provide electronic reporting from sponsors has progressed to the provision of a Statement of Requirements. Comment is has been sought from industry to agree on a priority of the project with stakeholders of the TGA Business Plan and the IT Work Plan.</p>

A2. OTC Medicines Program

Key Achievements during the January – March 2006 Quarter

- A total of 262 applications were finalised during the March quarter. Applications in all categories were completed within the agreed target times other than ‘variations’ where the ‘TGA time’ was 33 working days (target is 32 working days).
- The *Regulation of cosmetic chemicals final report and recommendations* was released in November 2005. This report contains specific recommendations to enable five categories of low risk products to be more appropriately regulated as cosmetics rather than medicines. Interim arrangements have been agreed with the National Industrial Chemical Notification and Assessment Scheme (NICNAS) under which sponsors can apply on a product by product basis to NICNAS for permission to supply as cosmetics. Full implementation will be effected by changes to NICNAS legislation. Copies of the report are available at www.nicnas.gov.au.
- Following initial discussions with industry associations in December 2005, a discussion paper on the regulation of new excipients in topical non-prescription medicines was released. The period for comment has now closed and submissions are under consideration with a formal response expected to be completed during the June quarter.
- Consideration of policy options for the regulation of products containing nanomaterials is continuing. The OTC Section has completed a review of the scientific literature to date particularly in relation to the use of nanomaterial in sunscreen products. Following endorsement of the review’s conclusions by the Medicines Evaluation Committee, the review was published on the TGA web site and the current situation is that whilst no immediate risks are apparent, the TGA will keep a watching brief on any emerging issues and risks in this area.
- A survey of the labelling of OTC products containing non steroidal anti inflammatory drugs (NSAIDs) was undertaken to assess compliance with labelling requirements. The level of compliance with statutory requirements was high, however a number of sponsors agreed to amend their labels at the next print run.
- Further development of a draft Joint Agency label advisory statements document has been undertaken, in consultation with Medsafe. A consultation document is expected to be released in April 2006 (this document will be the equivalent to the current RASML).
- Further development of a draft Joint Agency standard terminology for medicines document has been achieved, in consultation with Medsafe. A consultation document is expected to be released during the June quarter.

Ongoing functions

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Pre-market evaluation of OTC medicines according to the requirements of the legislation in a timely and effective matter	Ensure applications meet agreed timeframes: New applications and variations referred to MEC – 71 working days ¹ Variations – 32-45 working days ¹ Notifications – 20 working days ¹	Applications completed within target timeframes ¹	387 applications were received during the quarter. 262 applications were finalised. Applications in all categories were finalised within agreed the target times other than ‘variations’ where the ‘TGA time’ was 33 working days
Develop, maintain and support the electronic system for OTC medicines	Implement OPAL/MIS integration	OPAL OTC system fully implemented by end of the 1 st quarter 2005-06	The OPAL system is implemented and operational. The ‘clone’ functionality has been restored, is undergoing testing and is expected to return to full operation during the June quarter. The reporting function is under testing and is expected to be fully operational during the June quarter.
Undertake program of targeted and complaint testing	Targeted testing as per schedule Complaint sample testing to commence within 1 week of receipt of sample	75% completed as per schedule 100% actions finalised within target timeframes	Achieved. A total of 52 samples were tested; 10 of these (19.2%) did not meet required standards. TGAL tested a total of 61 samples of unregistered medicines this quarter. Eight problem or complaint samples were tested. All were completed within target timeframes as agreed with the regulators.
Provide secretariat support to the Medicines Evaluation Committee (MEC)	Edited extract of draft MEC minutes provided to relevant sponsors within 5 weeks of MEC meeting	Target achieved	One MEC meeting was held during the quarter. Target met.

¹ Average time measured quarterly

Major projects

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Clear backlogs before commencement of the joint agency	<p>Clear long standing applications by end of 1st quarter 2005-06</p> <p>Clear backlog of data on new excipients by end of 1st quarter 2005-06</p> <p>Process outstanding clone applications by end of 1st quarter 2005-06</p>	Targets achieved	Targets achieved
Screening of applications	<p>Increased technical screening of applications and notifying sponsors of problems</p> <p>Effective communication with Industry regarding common problems</p>	Decreased turnaround time for applications	Targets achieved
Develop and implement the joint regulatory scheme for OTC medicines, in association with Medsafe and in consultation with relevant stakeholders	<p>Develop guidelines, processes and procedures for the regulation of OTC medicines under the joint scheme</p> <p>Identify and progress implementation of any changes to IT systems for OTC medicines to meet the needs of the joint scheme</p> <p>Priority areas:</p> <p>Quality Guidelines to be released for consultation by 1st quarter 2005-06</p> <p>Safety and efficacy guidelines to be released for consultation by end 2nd quarter 2005-06</p> <p>Umbrella branding guidelines to be released for consultation by end 2nd quarter 2005-06</p> <p>Consultation with Industry on data protection and market exclusivity by end 1st quarter 2005-06</p> <p>Implementation of trans Tasman advertising arrangements</p> <p>Transition plan over 2005-06 to be</p>	Joint regulatory scheme for OTC medicines in place for commencement of operation of joint agency	<p>In conjunction with Medsafe, ongoing development of draft guidelines , processes and procedures is underway.</p> <p>Quality, safety, efficacy and umbrella branding guidelines previously agreed with Medsafe. Drafting of 'Product specific guidelines' completed prior to discussion with Medsafe. Finalisation of all guidelines deferred pending release of draft legislation.</p> <p>Draft transition plan completed. Finalisation deferred pending release of</p>

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
	implemented and new arrangements in place by 1 st July 2006		draft legislation.
Review of Regulation of Products at the Cosmetic/Therapeutic interface (TGA, NICNAS, ACCC, MEDSAFE)	Full implementation of agreed recommendations by June 2006	Target achieved	Final report and recommendations published. Interim arrangements agreed with NICNAS. Full implementation to be effected via changes to NICNAS legislation.
Required Advisory Statement for Medicine Labels (RASML)	Finalise Phase 2 of the RASML project. Review advisory statements currently in Australia and New Zealand guidelines and other documents, with a view to incorporating these into RASML	Phase 2 of the RASML project ready for implementation at commencement of operation of joint agency	Draft RASML incorporating all Australian label advisory statements has been completed. A consultation draft is expected to be released during April 2006.

A3. Complementary Medicines Program

Key Achievements during the January-March 2006 Quarter

Major Projects

The Office of Complementary Medicines (OCM) has finalised input into the Draft Medicine Rule relating to complementary medicines following completion of reviews relating to complementary medicine definitions, the regulation of herbal substances and the regulation of homoeopathic medicines.

Ongoing Consultations

The OCM held one OCM / Industry Consultation Group (OICG) meeting during the quarter resulting in:

- Finalisation of input into the proposed Managing Directors Order (MDO) for Medicine Labels in relation to herbal and homoeopathic medicines; and
- Continuing development of the underlying principles that will form the basis for the MDO for Homoeopathic medicines.

Ongoing functions

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Evaluate new complementary medicine substances and products; and Provide secretariat support to the Complementary Medicines Evaluation Committee (CMEC)	Publish Draft Public Recommendations Record on TGA website within 5 working days following CMEC meeting Publish Ratified Minutes from CMEC meetings on TGA website within two weeks of subsequent CMEC meeting	Targets achieved	One CMEC meeting was held during the quarter with both targets met.
Processing of Listed medicine applications submitted via the Electronic Listing Facility.	Listed medicine applications processed within 2 working days of receipt by the OCM	100% finalised within target timeframe	513 applications were received during the quarter. 95% were processed within target timeframes following receipt of the patent certification.
Post-market monitoring and review of manufactured complementary medicines.	Increase percentage of randomly selected new Listing applications for post listing audit	Increase from 15% to 20%	Approximately 20% of new Listed medicines were subject to a Post market random review.
Receive and respond to medicine problem reports regarding the quality, safety and/or efficacy of manufactured complementary medicines	From receipt of problem report undertake to assess risk, prioritise action and initiate remedial activity for potential high risk products within 2 working days Enter problem report information in Post Market and Review Unit database within 5 working days	100% actions finalised within target timeframes	Targets being met.
Undertake program of targeted and complaint testing	Targeted testing as per schedule Complaint sample testing to commence within 1 week of receipt of sample	75% completed as per schedule 100% of actions finalised within target timeframes	Targets met. A total of 61 samples of complementary medicines were tested in this quarter in accordance with the Service Level Agreement. Of these, 19 (31%) were of unsatisfactory quality.

Major projects

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Develop and implement the joint regulatory scheme for complementary medicines, in association with Medsafe and in consultation with relevant stakeholders	Develop guidelines, processes and procedures for the regulation of complementary medicines under the joint scheme Identify and progress implementation of any changes to IT systems for complementary medicines to meet the needs of the joint scheme	Joint regulatory scheme for complementary medicines in place for commencement of operation of joint agency	Please refer to 'Key Achievements' for progress.
In the context of the joint agency, to implement the Government response to the recommendations of the Expert Committee on Complementary Medicines in the Health System that relate to the regulation of complementary medicines.	Finalise review of the regulation of herbal substances – (recommendation 11) Finalise review of the regulation of homoeopathic and related medicines – (recommendation 10) Finalise review of the <i>Guideline for Levels and Kinds of Evidence to Support Claims for Non-registered Medicines</i> ; – (recommendation 4) Develop Guidelines for 'Summary of Evidence' for Class I complementary medicines to be submitted to the joint agency by sponsors – (recommendation 5) Convene stakeholders to review the registration process for complementary medicines – (recommendation 39) Convene stakeholders to identify incentives to encourage innovation and research in complementary medicines –	Review completed by August 2005 Review completed by August 2005 Review completed by June 2006 Guidelines completed by June 2006 Review commenced by August 2005 Review commenced by August 2005	Review completed following consultation in Australia and New Zealand – tasks prioritised; on-going consultation with OICG Review completed following consultation in Australia and New Zealand – tasks prioritised; on-going consultation with OICG and industry expert groups. Due to commence 2006 Due to commence on completion of development of the <i>Guidelines</i> . Review commenced in February 2006 due to reprioritisation of the Expert Committee recommendations. Review commenced in February 2006 due to reprioritisation of the Expert Committee recommendations.

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
	(recommendation 40)		
Oversight the development of a work plan for the New Zealand Permitted Ingredient List (PIL) project	Provide input into the development of a priority list of 80 medicine substances for evaluation under the PIL project and provide advice on the evaluation these substances for use as ingredients in Class I medicines	Priority list finalised and evaluations completed by June 2006	Priority list of PIL substances has been finalised. Evaluated 6 substances during the quarter making a total of 57 substances evaluated so far.

A4. Medical Devices Program

Key Achievements during the January-31 March 2006 Quarter

- Implementation of post-market monitoring program for included medical devices and supporting manufacturing evidence.
- Issuing of drafting instructions for the new regulatory framework for *In-vitro* Diagnostics (IVDs).
- Finalising drafting instructions for the Australia New Zealand Products Authority (ANZTPA) Medical Devices Rule.
- Commencement of 2006 series of stakeholder seminars on medical devices regulatory requirements and Device Electronic Application Lodgement (DEAL) training for the medical devices regulatory system.
- Hosting of a meeting of the Global Harmonization Task Force (GHTF) Study Groups 5 (SG5 has been charged with promoting convergence of regulatory requirements for evidence of the clinical safety and performance of medical devices) in Sydney on 16-18 January 2006.
- Hosting of a meeting of the GHTF Study Group 1 (SG1 has been charged with developing recommendations on pre-market aspects of regulation of medical devices with a view to promoting convergence) in Sydney on 28-31 March 2006.
- Assumed the Chair of GHTF Study Group 2 (SG 2 has been charged with the task of reviewing current adverse event reporting, post-market surveillance and other forms of vigilance for medical devices and performing an analysis of different requirements amongst countries with developed device regulatory systems with a view to harmonising data collection and reporting systems).
- Completed negotiations of, and the signing of, the Swissmedic Memorandum of Understanding (MoU) on 29 March 2006.
- Continued collaboration with industry associations, sponsors and manufacturers on planning and implementing strategies for the five-year transition of medical devices to meet the 2002 legislative framework.

Ongoing functions

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Receive and accept, assess and finalise, applications for conformity assessment	<p>Submissions accepted or terminated within 30 days of receipt</p> <p>Part 1, 4 and 5 submissions finalised within 90 days of acceptance (including 60 days for audit)</p> <p>Assessment of Design Dossier, in accordance with Part 1.6, finalised within 120 days. An additional 60 days will be allowed if the submission is to be considered by MDEC.</p>	100% of submissions finalised within the target timeframe	<p>The average time for applications under Part 1 (including Part 1.6) was 95 days, with a minimum of 14 days and a maximum of 179 days.</p> <p>The average time for applications under Part 1 (excluding Part 1.6) was 95 days. 2 applications were completed in 122 days due to difficulties by the manufacturers to close out non-conformities in one case and rectify technical documentation in the other.</p> <p>All new applications under Part 1.6 were completed within target. Minimum time was 41 days; maximum was 56 days.</p>
Receive and accept, evaluate and finalise submissions for registrations of “other therapeutic goods”	Submission finalised within 90 days of receipt	100% of submissions finalised within the target timeframe	<p>1 application completed in the quarter in 118 days.</p> <p>(Application involved human origin – delayed while awaiting clearance of a related application.)</p>
Receive, evaluate and finalise applications to vary existing registrations	Application finalised within 90 days of receipt	100% of applications finalised within the target timeframe	<p>6 applications were finalised in an average of 72 days. 3 were over target at 99 (pending another variation), 109 (administrative delays) and 132 days (new information provided requiring National Serology Reference Laboratory (NRL) assessment).</p>

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Receive and accept, assess and finalise applications requiring Level 2 application audit	Submissions finalised within 60 days of receipt	100% of submissions finalised within the target timeframe	62 applications requiring mandatory Level 2 audit were completed in the quarter, with an average completion time for approval of 35 days (minimum 10, maximum 114 days). 2 Level 2 non-mandatory application audit was completed, with a time of 35 days.
Receive and accept, assess and finalise applications requiring Level 1 application audit	Submissions finalised within 30 days of receipt	100% of submissions finalised within the target timeframe	76% of applications completed within the target timeframe. 38 of applications were completed. Average completion time for approval of 18 days (minimum 4, maximum 62 days).
Receive and finalise applications for entry of Class IIa and IIb medical devices, not requiring application audit, onto the ARTG through DEAL	Submissions finalised within 20 days of receipt	100% of submissions finalised within the target timeframe	47% of applications were completed within the target timeframes. Average completion time for approval of 21 days (minimum 2, maximum 117 days). (Processing times for device applications have increased in the quarter because of a greater than 200% increase in the numbers of manufacturer evidence notifications received.)
Receive and finalise applications for entry of Class I, Is and Im medical devices, not requiring application audit, onto the ARTG through DEAL	Submissions finalised within 20 days of receipt	100% of submissions finalised within the target timeframe	47% of applications were completed in the target timeframes. Average completion time for approval of 21 days (minimum 2, maximum 117 days). (Processing times for device applications have increased in the quarter because of a greater than 200% increase in the numbers of manufacturer evidence notifications received.)

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Receive and finalise applications for entry through DEAL of medical devices under the EU/EFTA MRA	Submissions finalised within 5 days of receipt	100% of submissions finalised within the target timeframe	DEAL does not currently allow separate identification of these application types.
Receive and accept submission of Manufacturers Evidence through DEAL	Give notice of acceptance with 15 days of receipt	100% of submissions finalised within the target timeframe	86% completed within the target timeframes. Average acceptance time of 15 days (minimum 1, maximum 54 days).
Receive notifications for CTN trials	Acknowledge within 5 working days of receipt	100% of acknowledgements within the target timeframe	Target achieved – 21 CTNs. All acknowledgements completed within 2 days.
Receive, accept and finalise CTX applications	For major CTX variations 50 working days and for minor variations 30 working days	100% of submissions finalised within the target timeframe	No CTX applications were received in the quarter.
Receive and finalise SAS category B applications	Applications finalised within 5 days of receipt	100% of submissions finalised within the target timeframe	Target achieved – 634 SAS Category B applications received. All applications finalised within 2 days.
Provide secretariat support to: 4. the Medical Device Evaluation committee (MDEC) and its subcommittees; and 4. the National Serology Reference Laboratory Management Committee and its Scientific Advisory Committee	Notification of MDEC resolutions to sponsor companies within 5 working days of meetings and resolutions placed on Website within one month of meeting Summary of MDEC meeting placed on Website within 1 month of meeting	100% actions finalised within target timeframes	Target achieved. Recommendations to sponsors within 5 working days following the meeting. Resolutions and meeting report were available on the TGA website within 2 weeks of the meeting. Meetings held as scheduled. NRL meetings held as scheduled, draft minutes were sent to members within 2 months of meetings.

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Undertake program of targeted and complaint testing	Targeted testing completed as per schedule. Urgent and Priority complaint sample testing to commence within 2 days and 14 days of receipt of sample respectively	100% of actions finalised within target timeframes	Targets achieved. A total of 40 samples were tested during this quarter, 7 of these samples (17.5%) were of unsatisfactory quality. Targets achieved. 19 problem or complaint samples were tested during this quarter. All were finalised within agreed timeframes.
Receipt and review of IRIS reports and subsequent analysis	Initial assessment by a Professional within 3 days and by TGA Panel within 14 days of receipt Average time for completion of investigation of reports less than 90 days	100% of actions completed within targets	Target achieved. IRIS received 183 and completed 160 medical device problem and adverse event reports. 314 investigations were still in progress at the end of the reporting period. Target achieved. Average time for completion of the 160 investigations was 74 days. 26 of the 160 investigations (16%) were completed in more than 90 days.
Maintain commitment to international cooperation programs, including: <ul style="list-style-type: none"> • Global Harmonisation Task Force (GHTF); • International Organization for Standardization (ISO); • Asia-Pacific Economic Cooperation (APEC); and • Other National Regulatory Agencies 	Provide timely high level professional input to GHTF Steering Group and Study Group activities Participate in and provide leadership to international meetings and other fora	Targets achieved	TGA hosted a meeting GHTF SG1 in Sydney on 28-31 March 2006. TGA chaired a meeting of GHTF SG2 in Miyazaki, Japan in March 2006. TGA hosted and chaired a meeting of GHTF SG5 in Sydney on 16-18 January 2006. On 19 January 2006, MIAA members were briefed on the work of GHTF SG5.

Major projects

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Finalise and implement the proposed new regulatory framework for IVDs	Finalise fees and charges and reach agreement with stakeholders Finalise frameworks for commercial and in-house IVDs Implement framework	Completed by June 2005 Completed by 31 July 2005 Implemented 1 January 2006	Drafting instructions issued 2 March 2006.
Finalise Guidelines for Medical Devices	Finalise documents	Completed by December 2005	Ongoing. Timeframes revised in line with development of draft Ministerial Rules. Refined the index for the guidance documents. Three new draft guidance documents placed on TGA Website.
Plan and implement strategy for meeting end of transition period for new medical device legislation	Develop and finalise project plan for transition with industry	Project plan finalised by December 2005	Target achieved. Education and training program organised and delivered late March/ early April 2006.
Continue implementation of new regulatory requirements for re-use of single use medical devices	Completed by end transition period - 1 December 2005 Update guidance documents and Website information Participate in education fora	Targets achieved	Transition period for semi and non critical devices extended at request of jurisdictions and agreed by NCCTG. Nominations finalised for NCCTG Expert Working Group to clarify scope of products covered under this regulatory framework to assist the jurisdictions with the transition.
Hospital, household/commercial disinfectants legislative amendments	Complete amendment to TGO 54, Act and Regulations Undertake stakeholder consultations Reach agreement with industry on implementation date	Amendment completed December 2005	Ongoing. A review of stakeholder comments has led to agreement by NCCTG that TGA and NICNAS explore options for regulation of hospital, household and commercial grade disinfectants under the NICNAS scheme.

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Participate in Strategic Industry Leaders Group (SILG) under Medical Devices Industry Action Agenda (MDIAA)	Development of recommendations for industry and government to address issues	Provide advice on regulatory issues	Target achieved. Participated in all SILG and Regulation Working Group (RWG) and Education Working Group (EWG) meetings. The final meeting of MDIAA SILG was held on 15 March 2006. Key actions agreed.
Provision of secretariat services to the SILG Regulation Working Group of MDIAA	Provide high level professional and secretariat support to regulatory subcommittee	Provision of timely services to the committee 100% action finalised within the target timeframes	Target achieved. High level secretariat support provided to all RWG meetings and other MDIAA stakeholder fora. Minutes and Outcomes notes completed within timeframes.
Enhancement of the medical devices Sectoral Annex of the EU/EFTA MRA	Agreement by Australian/EC Joint Committee Develop, agree and implement confidence building program	Agreement by July 2005 Implemented October 2005	TGA/European Commission have reached agreement on the text of the medical devices Sectoral Annex. Amendments to the Treaty are being undertaken by DITR. Discussions with DITR, DFAT and EU regarding implementation are ongoing.
Develop and implement the MoU with Canada on quality system certification for the manufacture of medical devices	Agree confidence building exercises, administrative processes and industry education program	Agreement by August 2005	Target revised to September 2006. Regular teleconferences regarding technical details and administrative provisions.
Develop an MoI with Malaysia	Agree to provisions within MoI	Agreement by May 2006	Awaiting comments from Malaysia on draft MoI.
Develop and implement the MoU with SwissMedic	Finalise wording of MoU Sign and implement the MoU at time agreed by both parties	Finalised July 2005 Implemented not later than December 2005	MoU was signed on 29 March 2006. Two days of meetings between TGA and Swissmedic were held to discuss priority areas for cooperation for the implementation program for the MoU.

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Chair and provide secretariat for GHTF Study Group 5 on Clinical Evidence.	Effectively manage activities of Study Group 5	Deliver Phase 1 Terms of reference by June 2006	<p>TGA hosted and chaired a meeting of GHTF SG5 in Sydney on 16-18 January 2006. At a meeting in Sydney on 19 January 2006, MIAA members were briefed on the work of GHTF SG5.</p> <p>A full range of-Secretariat services were provided.</p> <p>The next meeting of SG5 is scheduled for 25-26 April 2006 to be held in Irvine, California, USA.</p>

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Develop and implement the joint regulatory scheme for medical devices, in association with Medsafe and in consultation with relevant stakeholders	<p>Develop guidelines, processes and procedures for the regulation of medical devices under the joint scheme</p> <p>Identify and progress implementation of any changes to IT systems for medical devices to meet the needs of the joint scheme</p> <p>Priority areas:</p> <p>Review processes and implement changes required to ensure efficient operation within the Joint Agency structure January – June 2006</p> <p>Develop and implement an ISO Guide 62 compliant management system for the issuing of QMS certification July 2006</p> <p>Fundamental processes mapped July 2005</p> <p>Develop training program for New Zealand stakeholders</p> <p>Provide assistance to MIAA and MIANZ to implement advertising requirements for medical devices under the joint scheme</p>	Joint regulatory scheme for medical devices in place for commencement of operation joint agency	<p>Continuing in line with new Joint Agency implementation timeframe.</p> <p>Ongoing.</p> <p>Continuing in line with new Joint Agency implementation timeframe.</p> <p>This item is no longer reported on by the Office of Devices, Blood and Tissues – please refer to Manufacturers Assessment Branch Report.</p> <p>Finalised.</p> <p>Training of New Zealand industry was undertaken in November and December 2005. Further training is scheduled for the 4th Quarter 2005-06.</p> <p>Draft Ministerial Rules near completion for consultation in May 2006.</p>

A5. Manufacturer Assessment Program

Key Achievements during the January-31 March 2006 Quarter

- 100% of routine GMP audits have been conducted within the target timeframe. There are no overdue audits
- 100% of overseas GMP pre-clearances (with full evidence) have been processed within the target timeframe.
- Establishment of MAB Executive Committee (including representation from Medsafe)
- Establishment of MAB Audit Governance Committee (including representation from Medsafe)
- Commenced revision of the Code of GMP for Blood and Tissues
- Further work on development of a draft Strategic plan for managing international GMP equivalence agreements (ANAO recommendation no.2)

Ongoing functions

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Licensing of Australian manufacturers	Initial on-site audits conducted within 3 months from the date of receipt of a new licence application, if the manufacturers are ready for audits	100% of on-site audits of manufacturers ready for audit when scheduled, are conducted within the target timeframe	Target achieved.
	Audit reports are sent to Australian manufacturers within 20 working days from the date of the on-site audit	90% of audit reports are sent within the target time-frame	MAB is unable to accurately report on this performance target; MIS is not fully operational, therefore accurate data is not currently available.
	Responses to audit reports are evaluated and the manufacturer advised of the outcome within 20 working days from the date of receipt of the response	90% of responses are finalised within the target timeframe	MAB is unable to accurately report on this performance target; MIS is not fully operational, therefore accurate data is not currently available.
	New licences issued within 5 working days from audit close-out and payment of fees	90% of new licences issued within the target timeframe	Target achieved
	Routine audits are conducted within 6 months from their due dates	100% of routine audits are conducted within the target timeframe	Target achieved
	Amended licences are issued with 10 working days from date of receipt of request	90% of amended licences issued within the target timeframe	Target achieved

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Certification of overseas manufacturers	<p>Initial on-site audits conducted within 12 months from the date of receipt of an application for overseas audit, if the manufacturers are ready for audits.</p> <p>Audit reports are sent to overseas manufacturers within 20 working days, from the date of the on-site audit</p> <p>Responses to audit reports are evaluated and the manufacturer advised of the outcome within 20 working days from the date of receipt of the response.</p> <p>Routine audits are conducted within 6 months from their due dates.</p>	<p>90% of on-site audits of overseas manufacturers ready for audit when scheduled, are conducted within the target timeframe</p> <p>90% of audit reports are sent within the target time-frame</p> <p>90% of responses are finalised within the target timeframe.</p> <p>100% of routine audits are conducted within the target timeframe.</p>	<p>Target achieved</p> <p>MAB is unable to accurately report on this performance target; MIS is not fully operational, therefore accurate data is not currently available.</p> <p>MAB is unable to accurately report on this performance target; MIS is not fully operational, therefore accurate data is not currently available.</p> <p>Target achieved</p>
GMP clearance of overseas manufacturers	<p>Applications are processed and a GMP clearance letter sent to the sponsor within 20 working days from the date of receipt of the application, provided all the necessary information has been submitted by the sponsor</p> <p>In the case where the sponsor requests the TGA to liaise with the overseas regulator to obtain GMP evidence, the clearance may take up to 12 weeks to process</p>	<p>90% of applications for GMP clearance are finalised within the target timeframe</p>	<p>Target achieved</p>

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
	<p>When GMP evidence for overseas manufacturers is due to expire, 90 day letters are sent to sponsors requesting updated GMP evidence 3 months before expiry dates</p> <p>Once the clearance expires, a Section 31 letter is sent within 1 month of expiry date, allowing the sponsor 30 working days to submit a new GMP clearance application</p> <p>If the sponsor does not respond, a referral will be sent to the relevant TGA product regulators, for their information/appropriate action, within 45 working days of the expiry dates</p>	90% of correspondence sent within the target timeframe	<p>Not achieved: the 90 day letters have not been sent out due to ongoing problems with the MIS.</p> <p>Target achieved</p> <p>Target achieved</p>
Provide audit services to Australian Pesticides and Veterinary Medicines Authority (APVMA)	<p>Timetable of audits and close-out meet APVMA requirements</p> <p>Review and amend MoU with APVMA by July 2005</p> <p>Hold half-yearly liaison meetings with APVMA</p>	Targets achieved	<p>Target achieved</p> <p>Review has commenced; MoU to be revised by July 2006.</p> <p>Target achieved.</p>

Major projects

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Manufacturers Information System (MIS)	MIS fully operational	System fully operational by 31 December 2005	Target not achieved; some ongoing problems with MIS that are being addressed.
Quality Management System is updated to comply with ISO 9001:2000 and ISO Guide 62, and is externally certified	MIS's QMS is updated and an initial audit conducted by a Certification Body	QMS updated and initial audit conducted before 31 December 2005	Target not achieved; QMS is being significantly revised. External audit yet to occur though has been requested.
Agreements with overseas Regulators from which the TGA accepts GMP certification are maintained and current	A Strategic Plan to monitor the regulatory equivalence of countries with which the TGA has GMP agreements, and supporting SOP to commence	Strategic Plan and supporting SOP to commence before July 2005	Draft plan almost complete; for internal review by the TGA Executive by June 2006.
Develop and implement GMP strategies for the joint regulatory scheme	Finalise process mapping by May 2006 Agree protocol for the GMP quality systems by July 2006	GMP strategies in place for commencement of operation joint agency	Target achieved.

A6. Exports Program

Key Achievements during the January-31 March 2006 Quarter

During the January to March 2006 Quarter, 559 new Certificate of Pharmaceutical Product (CPP) applications were received and processed within target timeframes.

Also during this time 87 new export-only listing and variation applications were received and all were processed within target timeframes.

Ongoing functions

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Process applications for listing of export only medicines and requests for export certificates for medicines according to the requirements of the legislation in a timely and effective matter	Ensure applications meet agreed timeframes: Export Only Listing – New application – 30 days Grouping/Variation – 30 days Export Certificates – 15 days	100% completed within target timeframes	559 Certificate of Pharmaceutical Product applications were received during the Jan - Mar 2006 quarter and all were processed within target timeframes. 87 new export-only listing and variation applications were received during the quarter and all were processed within target timeframes.
Develop, maintain and support the electronic system for Export Medicines	Implement EEL/MIS integration	EEL system fully implemented by end of the 1 st quarter 2005-06	EEL implemented. Some improvements to the system have been suggested which are currently being worked on.
Issue permits for export of blood and tissues under Customs (Prohibited Exports) Regulations	Permits issued within 24 hours of receipt of request by the Export Medicines Unit	95% actions finalised within target timeframes	100% of permits issued within target timeframes.

Major projects

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Develop and implement the joint regulatory scheme for therapeutic products intended for export, in association with Medsafe and in consultation with relevant stakeholders	Develop guidelines, processes and procedures for the regulation of export only therapeutic products under the joint scheme Develop guidelines, processes and procedures for issuing of export certificates and permits under the joint scheme Identify and progress implementation of any changes to IT systems for export products to meet the needs of the joint scheme	Joint regulatory scheme for export only therapeutic products and mechanisms for issuing export certificates and permits in place for commencement of operation of joint agency	Work is in progress and on track for the development of the required processes and guidelines before the commencement of the joint agency.

A7. Blood and Tissues Program

Key Achievements during the January-31 March 2006 Quarter

- The implementation of new policy that has minimised the gaps between current practices of the blood service to that of the Council of Europe (CoE) Guide requirements.
- The refinement of a model for the regulation of cell and tissue therapies. Discussions are ongoing with jurisdictions to determine the final model and cost recovery options.
- Performance targets were met for review and evaluation of Category 1 and 3 applications of plasma derivatives and related products, evaluation of Plasma Master Files (PMFs) describing foreign plasma and annual updates and fresh blood and tissue Technical Master File (TMF) submissions including variations and annual updates.

Ongoing functions

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Review applications for registration of plasma derivatives and related products to best practice standards of quality and safety	Complete Category 1 applications within 255 working days 45 days for Category 3 applications	100% of submissions finalised within the target timeframe	All review processes are within required timeframes.
Evaluate PMFs describing foreign plasma and annual updates	100% of submissions finalised within the Category 1 and 3 timeframes	Target achieved	All review processes are within required timeframes.
Evaluate fresh blood and tissue TMF submissions including variations and annual updates	100% finalised within timeframes agreed with industry	Target achieved	All review processes are within required timeframes.
Finalisation of component medical and therapeutic device application	Conformity assessment targets for medical devices as specified by the Medical Devices Program Evaluation targets of therapeutic devices as specified by Medical Devices Program	100% of submissions finalised within the target timeframe	1 component evaluation finalised. Target exceeded due to inadequate data and complexity of issues.
Assessment of Conformity Applications for Class 3 medical devices	Assessments of conformity applications for Class 3 devices finalised within target timeframes as specified by Medical Devices Program	100% of submissions finalised within the target timeframe	Not applicable in this reporting period.
Provide advice to the National Blood Authority, Australian Red Cross Blood Service (ARCBS) and other stakeholders on regulatory matters	Provide advice on request and through program of regular meetings	Target achieved	Target achieved. Advice provided to all specified stakeholders including the DoHA on the FTA Review of Plasma Fractionation Arrangements.
Maintain commitment to international cooperation programs, including: <ul style="list-style-type: none"> • Council of Europe (CoE); and • World Health Organization (WHO) 	Participate in and provide leadership to international meetings and other fora	Target achieved	Target achieved. Meetings of the Council of Europe and the WHO International Congress of Drug Regulatory Agencies attended and presentations provided.

Major projects

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Finalise and implement a regulatory framework for human cellular and tissue and biological therapies for Australia; and Facilitate the development of a joint regulatory system for blood, tissue and cellular therapies to operate under the joint agency	Finalise regulatory model including cost recovery model and obtain agreement of AHMAC, AHMC by December 2005 Establish expert committees with implementation of legislation	Implement new framework by July 2006	Broad frameworks finalised and agreed with NZ MOH and Medsafe. Frameworks now under review by TGA and government stakeholders. Terms of Reference (TOR) for Interim Expert Advisory Committee (EAC) on Biologicals established. Target timeframes revised to coincide with commencement of ANZTPA.
Establish procedures for assessment and evaluation of products that support the National Blood Authority's risk management strategies for maintenance supply of plasma and recombinant products in Australia	Agreement with NBA on procedures to be established by December 2005	Target achieved	The TOR of the proposed EAC on Biologicals reflect risk management processes as exemplified by NBA strategies.
Develop and implement appropriate measures and criteria addressing emerging infectious disease risks and pathogens through a prospective and proactive transparent policy	Initiate and participate in the development of policy and protocols for the risk management of emerging pathogens	Target achieved	Criteria incorporated into the TOR of the proposed Interim EAC on Biologicals.
Establish Risk Management regulatory tool for assessing and minimising the risk of transmission of TSEs in Australia	Program implemented and contribution made by Unit Head and others in the Unit to assist industry with compliance. Program reviewed quarterly. June 2006	Target achieved	Target achieved. Tool established and used in assessing risk profile of product review of externally sourced overseas plasma products.
Progress guidelines that promote the further improvement in donor Hb levels	Include the updated Council of Europe (CoE) Guide in relation to the maintenance of appropriate haemoglobin levels in healthy blood donors in TGA guidelines Update requirements in the blood service	Targets achieved	Australian Red Cross Blood Service (ARCBS) requirements updated. Issue reviewed by CoE meeting.

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
	annual TMF update by April 2006		
Assess new test for malaria antibodies in donors assessed to be at risk of transmitting malaria in transfused blood components	If assessment of test is satisfactory approve implementation of new algorithm for management of donor and blood component selection by September 2005	Target achieved	Test established and in use by ARCBS within approved algorithm.
Evaluate, approve or modify strategies presented by the blood service to meet variances to the CoE Guide requirements identified in the annual gap analysis of current practices and the annually updated CoE Guide	Incorporation in the annual update of the TMF by April 2006	Target achieved	Strategies approved and implemented.
Initiate discussion on possible progression beyond the CoE Guide	Establish criteria that meet some specific issues for Australia to comply with the CoE Guide Establishment of criteria by July 2006	Targets achieved	Issue included into the TOR of the proposed Interim EAC on Biologicals.
Define PMF requirements in relation to acceptance of donor epidemiology and donation screening requirements for the Manufacturing Principles	Consultation with experts and expert committees and development of documents or guidelines completed by July 2006	Target achieved	Issue included into the TOR of the proposed Interim EAC on Biologicals.
Develop a guide for industry for the submission of PMFs and updates	Industry consultation and review of document Guide to be included in the guidelines for prescription medicines as an appendix and available on the joint agency website July 2006	Targets achieved	Consultation initiated with peer international industry body, with meetings to discuss guide scheduled for June 2006.
Complete a Quality System for the Blood and Tissues Unit	Draft SOP's for circulation within the Unit by June 2006	Targets achieved	Standard Operating Procedure (SOP) development ongoing, several SOPs reviewed and implemented. All SOPs issued will require alignment to

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
			trans Tasman process.

A8. Recalls Program

Key Achievements during the January-31 March 2006 Quarter

- Implementation of a new computer database for recalls and medicine problem reports to record and report on the coordination of therapeutic good recalls and investigations into problems with medicines.
- Pilot program initiated to evaluate monthly reporting of non process related blood recalls submitted to the TGA.
- Performance targets met for the recalls of medicines, medical devices and blood for the quarter.
- Consideration by Joint Interim Expert Advisory Committee on Standards (JIEACS) of stakeholder responses to the consultation paper on the default pharmacopoeial standard(s) for the Australia New Zealand Therapeutic Products Authority (ANZTPA). The JIEACS recommendation was provided to the Joint Agency Establishment Group (JAEG) for incorporation into the draft Medicines Rule.
- Consideration by the Therapeutic Goods Committee (TGC), and the JIEACS, of subcommittee reports and draft Managing Director's Order on child-resistant packaging requirements. Release for stakeholder consultation was recommended; the consultation period in Australia and New Zealand to commence in early April 2006.
- An updated version of the draft labelling requirements for medicines for application by the ANZTPA and a Report on Stakeholder Consultation have been prepared; these documents are planned for release in the 4th Quarter 2005-06.
- Stakeholder consultation undertaken on adoption of British Pharmacopoeia 2005 as the edition defined under the *Therapeutic Goods Act 1989*. The TGC has considered responses out-of-session.
- Development work on general requirements for tablets and capsules, and microbiological standards for medicines, to apply under ANZTPA.

Ongoing functions

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Co-ordinate the conduct of medicine recalls	Medicine recalls are finalised within 90 working days	50% of medicine recalls are finalised by sponsors within target timeframes	Target achieved. 51% of medicine recalled in the previous quarter were finalised within target timeframes.
Co-ordinate the conduct of medical device recalls	Medical devices recalls are finalised within 90 working days	50% of medical devices recalls are finalised by sponsors within target timeframes	Target achieved. 52% of medical devices recalled in the previous quarter were finalised within target timeframes.
Co-ordinate the conduct of process related blood recalls	Process related blood recalls are finalised within 90 working days	50% of process related blood recalls are finalised by ARCBS within target timeframes	Target achieved. 80% of process related blood recalls in the previous quarter were finalised within target timeframes.
Co-ordinate the conduct of donor initiated blood recalls	Donor initiated blood recalls are finalised within 65 working days	50% of donor initiated blood recalls are finalised within target timeframes	Target achieved. 89% of donor initiated blood recalls in the previous quarter were finalised within target timeframes.
Co-ordinate the investigation of problems reported for medicines	Problem report investigations are finalised within 65 working days	100% of problem report investigations are finalised within target timeframes	60% of problem report investigations in the previous quarter were finalised within target timeframes.

Other timeframes

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Provide secretariat support to the: <ul style="list-style-type: none"> • Therapeutic Goods Committee (TGC) • National Coordinating Committee on Therapeutic Goods (NCCTG) • Industry Government Crisis Management Committee • Joint Australia New Zealand committees providing advice on standards for therapeutic products in the joint regulatory scheme 	Meetings held as scheduled Advice of outcomes provided to Ministers, regulators and stakeholders within agreed timeframes Summary of TGC meeting placed on TGA website within 1 month of meeting	Targets achieved	Target achieved and meetings held as scheduled. Timely provision of advice to Ministers, regulators and stakeholders achieved. Completion of consideration by JIEACS of stakeholder responses to the consultation paper on the default pharmacopoeial standard(s) for the ANZTPA. Finalisation by the TGC and the JIEACS of a draft Managing Director's Order on child-resistant packaging requirements for application by the ANZTPA, for release for stakeholder consultation early April 2006. Finalisation of an updated version of the draft labelling requirements for medicines for application by the ANZTPA and a Report on Stakeholder Consultation also for release 4 th Quarter 2005-06. Stakeholder consultation undertaken on adoption of British Pharmacopoeia 2005 as the edition of that document defined under the <i>Therapeutic Goods Act 1989</i> .

Major projects

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Develop a uniform recall strategy for therapeutic products in the joint regulatory scheme	Agreed protocol for the recall of therapeutic goods in both Australia & New Zealand	Protocol agreed January 2006	The timeline revised with changes to date of implementation of ANZTPA. Accordingly, discussions are ongoing within the context of the draft Ministerial Rules and the recently implemented computer systems recalls.
	Implement recommendations of the Review of the URPTG in the trans Tasman context; and Implement recommendations relating to recalls of the Australian National Audit Office Report on TGA Regulation of Non-prescription Medicines	Publication of a draft Australia New Zealand Uniform Recall Procedure for Therapeutic Products by March 2006 incorporating, as appropriate, URPTG Review and ANAO recommendations	As above
	Develop new computer system for monitoring recalls and their progress in consultation with stakeholders.	Computer system progressed with <ul style="list-style-type: none"> • process mapping of administrative procedures for recalls in Australia undertaken and finalised by mid-2005; and • acceptance testing of a new system by December 2005 	Completed
	The revised recall processes be documented and appropriate stakeholder training undertaken	Develop TGA Web site information and information package for stakeholders – April 2006	Completed
	Enhancement of quality system for the operation of the Recalls Section	Annual internal audit program introduced May 2006	The timeline has been revised with changes to date of implementation of ANZTPA and the need to include this activity within the trans-Tasman context.

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Implement monthly reporting of Donor Initiated Blood Recalls	<p>Agree on ARCBS risk assessment documentation</p> <p>Incorporation into Recalls database and implementation of mutually agreed format by 31 July 2005</p>	Targets achieved	<p>Target achieved. The types of events that the Australian Red Cross Blood Service (ARCBS) is to report to the TGA have been agreed.</p> <p>Trial data for incorporation into the Recalls database is scheduled for 4th Quarter 2005-06.</p>

B. REGULATING GENE TECHNOLOGY

Key Achievements during the January-31 March 2006 Quarter

The Gene Technology Regulator provided additional advice to the independent panel reviewing the *Gene Technology Act 2000*.

The OGTR provided technical support to the Australian delegation to the Third Meeting of the Parties (MOP3) to the Catagena Protocol on Biosafety, Curitiba, Brazil.

In addition, the OGTR advanced liaison with industry bodies regarding their quality assurance and testing regimes on the national strategy for the unintended presence of unapproved GMOs.

Ongoing functions

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Licensing of dealings with genetically modified organisms (GMOs)	Assessments of new applications are progressed within statutory timeframes	100% completed within target timeframes	100% of assessments for new applications have been completed within target timeframes.
Monitoring of dealings with GMOs	A sample of field trials inspected for compliance with conditions in licences to undertake dealings with GMOs	Minimum of 20% of field trials inspected	5% of field trials were inspected in the reporting period. 5% is one quarter of the annual 20% minimum target.
Prepare and table quarterly reports on the operations of the Regulator during that quarter (a period of 3 months beginning 1 January, April, July and October of any one year)	As soon as practicable after the end of each quarter prepare and give to the Minister a report on the operations of the Regulator during the quarter	Target achieved	The October to December 2005 quarterly report was completed and ready for printing in the reporting period.

Major projects

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Make a submission to the independent review of the <i>Gene Technology Act 2000</i>	Submission prepared by September 2005	Target achieved	In August 2005 the Gene Technology Regulator made a submission to the independent review of the <i>Gene Technology Act 2000</i> . In January 2006 the Regulator met with the independent review panel and provided technical support.
Implement the revised <i>Risk Analysis Framework</i> (RAF) in the conduct of evaluations by the Gene Technology Regulator	100% of assessments of new licence applications are assessed against the RAF	Target achieved	100% of assessments of new licence applications are assessed against the RAF.

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Establish a co-operative arrangement with the Plant Biosafety Office of the Canadian Food Inspection Agency	Officer exchange program to commence by September 2005	Target achieved	It is anticipated that the officer exchange program will now commence in the first half of 2006. The delay is due to the resolution of the number of legal issues encountered by the Canadian Food Inspection Agency (CFIA) Plant Biosafety Office (PBO).
Advise the Gene Technology Ministerial Council on amendments to the <i>Gene Technology Regulations 2001</i>	Advice provided by Gene Technology Regulator by September 2005	Target achieved	In August 2005 the Gene Technology Regulator received approval from the Gene Technology Standing Committee to consult on draft amended Regulations. The comment period closed during the quarter and analysis of submissions commenced. The Gene Technology Ministerial Council did not meet in the reporting period.
Revise Guidelines for Certification of PC Facilities Level 3 and 4 and Large Scale laboratory facilities	Develop a timetable for implementing the revised guidelines	Timetable developed by June 2006	Comments on the revised guidelines for PC3 Laboratory facilities have been received and consolidated. Analysis of the comments is in progress.

C. REGULATING CHEMICALS

Key Achievements during the January – March 2006 Quarter

- OCS Budget for FY 06-07 established with the Australian Pesticides and Veterinary Medicines Authority.
- Represented the Department of Health and Ageing at the International Conference on Chemicals Management, Dubai, United Arab Emirates.
- Building greater international cooperation in the control of illicit drug precursor chemicals: meeting with US Drug Enforcement Agency and Australian Customs Service to discuss precursor traffic in the South Pacific.
- Inaugural meeting of the Advisory Group on Chemical Safety (AGCS).
- Represented Australia at the 6th International Programme on Chemical Safety (IPCS) Programme Advisory Committee meeting, Bangkok, Thailand.
- Successful audit of over 14,000 importers by NICNAS.
- Successfully established interim arrangements for new NICNAS Cosmetics Regulations.

Ongoing functions

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Human health risk assessment of industrial chemicals	Complete assessments of new chemicals Complete review assessments equivalent to 3 PECs & 10 others	Complete 95% of assessments on time Meet 100% of all secondary notification timeframes Peer review 100% of assessments	Target met On target On target
Human health risk assessment of agricultural and veterinary chemicals	Complete 62 public health assessments of new chemicals, 72 occupational health assessments of new chemicals and reviews of six existing chemicals	95% of reports accepted without request for further advice Complete 95% of assessments on time Reduce mean flow-through time of assessments by 5%	Completed 8 public health assessments and 10 occupational health assessments. All reports accepted without request for further advice and completed on time. 100% of assessments were on time. 100% of assessments were accepted without request for further advice. One review was completed and accepted without request for further advice. All reviews were completed within time frames.
Scheduling of drugs and poisons in the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).	Conduct three meetings of the National Drugs and Poisons Scheduling Committee Publish the SUSDP	95% of legislated timeframes for scheduling processes met	NDPSC meeting 46 was held on 21-23 Feb 2006. Amendment 20/3 was considered, together with the ongoing arrangement for consolidation of SUSDP 20 and Amendments 1 and 2 into SUSDP 21.
Develop and maintain Pesticides and Veterinary Medicines health standards	Publish: • ADI List • ArfD List • FAISD Handbook	All publications accurate, complete and timely	All publications are updated and formal approval will be sought for publication.
Provide technical advice & representation in relation to the TTMRA	Prepare interim report on five year work plan	Report provided within agreed timeframe	On target

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Support the National Drug Strategy (NDS) by monitoring the use of controlled substances	Give effect to Australia's obligations under the UN Drug Treaties Issue permits and licences for NDS treaties and monitoring	Meet timeframes for reporting to UN INCB and States and Territories Meet 95% of timeframes for issue of Import/Export licenses/ permits	Quarterly import export statistics for Q4 2005 submitted to UN INCB within agreed timeframe. Monthly State/Territory consumption reports submitted within agreed timeframe. Targets met for issue of import / export licences and permits.

Major projects

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Complete and implement the findings of the review of the existing chemicals program	Implementation complete by June 2006	All agreed recommendations implemented	On target
Complete a situational analysis of GHS for public health scheduling	Analysis of the SUSDP provided to the NDPSC/ NCCTG by June 2006	95% of recommendations accepted	A meeting of the GHS working group was held in Canberra on 20 February. The outcome of the meeting was tabled at the Feb '06 NDPSC.
Complete implementation of Low Regulatory Concern Chemicals legislation	Implementation complete by June 2006	Implementation satisfies time and scope requirements of legislation	On target

D. SUPPORTING THE BUSINESS

Key Achievements during the January - March 2006 Quarter

- The Therapeutic Products Interim Ministerial Council (TPIMC) endorsed a stakeholder consultation program for the ANZTPA joint regulatory scheme and this program was published on the ANZTPA website in March 2006.
- The TPIMC also announced the appointment of an Interim Joint Expert Advisory Committee on Complementary Medicines (IJEACCM) to advise the TPIMC on the quality and safety of substances appropriate for inclusion in a list of ingredients for use in complementary medicines, under the joint regulatory scheme.

Ongoing Functions

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Provide prompt and efficient financial processes and systems that facilitate business services with our clients	<p>Introduce electronic billing and on-line payment services</p> <p>Process client application payments within 48 hours of receipt</p> <p>Process vendor payments by their due date</p> <p>Update information and forms available to clients on the TGA's Website</p>	<p>by October 2005</p> <p>100%</p> <p>95% by due date</p> <p>Documents reviewed every six months</p>	<p>Electronic invoices were introduced in October. Some 40% of sponsors have registered for electronic for invoicing. Online payment solutions are being implemented, but will be delayed until July 2006.</p> <p>The release of applications through SIME workflow systems are consistently released within 48 hours of receipt of payment. A system failure was detected in early January (and has since been corrected) that caused a number of online applications to be delayed.</p> <p>84% of the 3,824 vendor payments were released on time There were only a small number of payments (less than 1%) that were released more than 90 days after the due date</p>
Facilitate timely Industry consultation on the TGA business plan and budget, and fees and charges proposals	<p>Convene TGA-Industry Consultative Committee (TICC) in November and May</p> <p>Provide six months advance notice of changes to fees and charges</p>	<p>Target achieved</p> <p>Cost recovery impact statements prepared</p>	<p>TGA and industry agreed to cost recovery arrangements for in-vitro diagnostic devices. A cost recovery impact statement has been completed.</p> <p>Consultation on 2006-07 fees and charges with industry associations took place in March. A cost recovery impact statement is not required.</p>

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Ensure compliance with statutory reporting obligations and government accountability frameworks	No adverse audit findings TGA Group budgets and results reported in published budget statements and annual report TGA Group operates in line with budget forecasts	Target achieved Target achieved Revenue within 5%; Expenditure within 2.5%	Budget variances were within target except for: <ul style="list-style-type: none"> • Gene Technology expenses remain 8% under budget due to recruitment lags and deferred expenses associated with the review of the Gene Technology Act • Industrial chemicals revenue remains 21% higher than budgeted as a result of higher company registrations. Expenses were 7% under budget largely as result of recruitment lags earlier in the year • Chemical safety revenue was 15% lower than budget due to timing differences in budget phasing of APVMA revenues. Expenses were 5% under budget largely due to savings in employee expenses
Manage IT infrastructure	Maintain IT services to the TGA Group Monitor and facilitate performance of the IT service provider to ensure satisfactory service delivery whilst minimising costs	Targets achieved	Targets achieved
Provide online business services to external stakeholders	Target availability of 97% or better over each monthly period on a 24 hour basis (applies to TGA owned or leased equipment)	Target achieved	Targets achieved
Effective communications with external stakeholders	Ensure that information provision to stakeholders is in accordance with the relevant service charter	Target achieved	TGA Customer Service Charter review based on stakeholder consultation completed.
Enforce the provisions of the <i>Therapeutic Goods Act 1989</i> , the <i>Gene Technology Act 2000</i> and the <i>Industrial Chemicals (Notification</i>	A high level of compliance with the <i>Therapeutic Goods Act 1989</i> , the <i>Gene Technology Act 2000</i> and the <i>Industrial Chemicals (Notification and Assessment) Act</i>	Breaches of the legislation are investigated and appropriate action taken	Breaches of the legislation have been investigated and appropriate action has been taken to achieve compliance with

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
<i>and Assessment) Act 1989</i>	1989		<p>relevant legislation.</p> <p>During the quarter Jan-Mar 06 the TGA Surveillance unit received 97 new referrals of which 96 have been actioned. Two persons/companies were charged with a total of 18 offences in relation to counterfeit medicines. There have been no convictions during this quarter.</p> <p>During this quarter NICNAS carried out 17 compliance audits and inspections. Follow up of the 2004/05 audit program and a new audit of 14,038 unregistered importers of industrial chemicals resulted in 1,176 new registrations and 1,773 companies being exempt from registration. 747 submitted invalid information and are under investigation. Eight companies from a total of 168 are under investigation for non-compliance with the upgrade of their registration tier.</p>

Major Projects

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Prepare enabling legislation for joint agency and joint regulatory scheme	Bill submitted to Spring session of Australian Parliament	Target achieved	On target - an exposure draft of the Bill will be developed for mid-2006.
Finalise Ministerial Council Rules and Australia-only Regulations	Agreed as appropriate with stakeholders	In place for commencement of joint agency	On target.
Resolve all outstanding issues concerning joint agency and joint regulatory scheme with New	Resolution consistent with needs of both countries	Finalised within a timeframe which permits progress on critical path for implementation	Issues resolved.

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
Zealand			
Establish protocols for joint agency to work with Australian Department of Health and Ageing and New Zealand Ministry of Health	Streamlined structures and protocols in place	In place for commencement of joint agency	Work ongoing.
Establish the business infrastructure for the joint agency	<p>Establish financial management, human resource management & industrial relations, legal, records management, parliamentary support, communications and other corporate services for the joint agency</p> <p>Develop and implement appropriate IT systems (including Financial Management and Human Resources Management Information Systems and required modifications to the SIME system) for the joint agency</p>	In place for commencement of joint agency	<ul style="list-style-type: none"> • TGA successfully implemented changes to the annual charges process in October, resulting in all companies being invoiced for product registrations at the same time. • Online payment functionality has been delayed and will be implemented by March 2006 • The implementation of the HR MIS to replace SAP services provided by the Department has been delayed due to configuration delays by the vendor. A revised commencement date has yet to be agreed. <p>The focus of the past quarter in achieving the objectives of the Records Management Strategy include:</p> <ul style="list-style-type: none"> • defining recordkeeping requirements; • establishing appropriate service delivery mechanisms; • preparing for an electronic document solution; and • continuing work in relation to raising awareness levels of records management responsibilities through the ongoing Education and

<i>Description</i>	<i>Target</i>	<i>Performance Measure</i>	<i>Progress to 31 March 2006</i>
			Awareness Sessions.
Joint agency Fees and Charges	Undertake industry and stakeholder consultations in conjunction with release of the exposure draft of legislation Fees and Charges schedule available on the Website six months prior to commencement of the scheme	From July 2005 Target achieved	A consultation paper on a fees and charges model for the joint regulatory scheme is nearing completion. Details of the consultative process will be available following consideration by the Interim Therapeutic Products Ministerial Council.
Develop and implement human resources arrangements for the joint agency	Agreements with staff and employers in place by 1 st quarter 2006	Target achieved	Australian arrangements are on track. The introduction of the new Workchoices legislation may have some impact. This will be closely monitored. New Zealand agreements are the responsibility of the New Zealand Ministry of Health.
Develop and implement joint agency website	Joint agency website in place for commencement of joint agency	Target achieved	The TGA website review consultation underway and finalised on 28 April 2006. Review of consultation to be completed by early June.
Provision of Secretary and support services to the Therapeutic Products Interim Ministerial Council and secretariat services to the Joint Agency Management Committee	Consistent high quality advice and secretariat services	Timely decisions and joint agency implementation by the target date	Secretariat support provided to the satisfaction of the TPIMC and JAMC.