



**Australian Government**  
**Department of Health and Ageing**

# **Quarterly Report of the Therapeutic Goods Administration**

**against the**

## **2006 - 2007 Business Plan**

**For the period**

**1 April – 30 June 2007**



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## Glossary

ADEC	Australian Drug Evaluation Committee
ADR	Adverse Drug Reaction
ADRU	Adverse Drug Reactions Unit
AHMAC	Australian Health Ministers' Advisory Council
AHMC	Australian Health Ministers' Conference
ANAO	Australian National Audit Office
ANZTPA	Australia New Zealand Therapeutic Products Authority
AOS	Agency Online System
ASM	Advertising Services Manager
BBC	Bioengineering and Biomaterials Committee
BGTD	Biologics and Genetic Therapies Directorate
BP	British Pharmacopoeia
CASO	Conformity Assessment Standards Order
CHMP	Committee for Medicinal Products for Human Use (in the European Union)
CMEC	Complementary Medicines Evaluation Committee
CMI	Consumer Medicine Information
CMIRG	Complementary Medicines Implementation Reference Group
CoE	Council of Europe
CPP	Certificate of Pharmaceutical Product
CTN	Clinical Trial Notification scheme
CTX	Clinical Trial Exemption scheme
DEAL	Device Electronic Application Lodgement
DFAT	Department of Foreign Affairs And Trade
DITR	Department of Industry, Tourism and Resources
DoHA	Australian Government Department of Health and Ageing
DSEB	Drug Safety and Evaluation Branch
EC MRA	European Communities Mutual Recognition Agreement
ECCMHS	Expert Committee on Complementary Medicines in the Health System
EDQM	European Directorate for the Quality of Medicines
EEL	Export Electronic Lodgement system
ELF	Electronic Listing Facility
EMA	European Medicines Agency
EP	European Pharmacopoeia
GHTF	Global Harmonization Task Force (for medical devices)
GMP	Good Manufacturing Practice
HCT	Human Cellular and Tissue
IJEACCM	Interim Joint Expert Advisory Committee on Complementary Medicines
ISO	International Organization for Standardization
IT	Information Technology
IVD	In Vitro Diagnostic device
JBC	Jurisdictional Blood Committee
JTPPC	Joint Therapeutic Policy and Planning Committee
KRA	Key Result Area
MAB	Manufacturer Assessment Branch
MDEC	Medical Device Evaluation Committee
MDIRC	Medical Device Incident Review Committee
MDSO	Medical Device Standards Orders
MEC	Medicines Evaluation Committee
MIS	Manufacturer's Information System
MoU	Memorandum of Understanding
NBA	National Blood Authority
NCAR	National Competent Authority Reporting scheme

NCCTG	National Coordinating Committee on Therapeutic Goods
NCE	New Chemical Entity
NCSI	NCS International (subsidiary of National Association of Testing Authorities)
NHMRC	National Health and Medical Research Council
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NRL	National Serology Reference Laboratory
OCM	Office of Complementary Medicines
OICG	OCM/Industry Consultation Group
OTC	Over-the-Counter (as in OTC medicines)
PI	Product Information
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme
QMS	Quality Management System
RASML	Required Advisory Statements for Medicine Labels
SAS	Special Access Scheme
SG	Study Group
SIME	Strategic Information Management Environment (TGA's Online Systems)
SOP	Standard Operating Procedure
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
TERG	Technical Expert Reference Group (for manufacturing)
TGA	Therapeutic Goods Administration
TGAL	TGA Laboratories Branch
TGC	Therapeutic Goods Committee
TICC	TGA-Industry Consultative Committee
TMF	Technical Master File
USA	United States of America
WHO	World Health Organization
WHO INN	WHO International Nonproprietary Names
WHO QSS	WHO Quality Safety Standards

# INTRODUCTION

The Therapeutic Goods Administration (TGA) is responsible for the regulation of therapeutic products in Australia and carries out regulatory activities determined by the *Therapeutic Goods Act 1989*. The TGA also provides advice to Ministers in relation to the operation of the current regulatory system for therapeutic products, as well as possible changes to the system to meet future needs of the Australian population.

The *Therapeutic Goods Administration Business Plan 2006-2007* is an integral part of the framework that will guide the work of the TGA during the 2006-2007 financial year. In developing the Business Plan, the TGA used the balanced scorecard approach to monitor four Key Results Areas (KRAs), which are described below. The Business Plan describes the functions and activities to be undertaken by the TGA during 2006-07 and includes relevant performance information linked to the four KRAs and their related Objectives.

Progress of the TGA during the April to June 2007 quarter against the Business Plan is featured in this report. For further information, the Business Plan is located on the TGA website at the following link: [<http://www.tga.gov.au/about/tgabp0607.htm>].

## Key Result Areas

Key Result Areas	Objectives
<b>1. Our stakeholders</b> Engender confidence in our stakeholders that our dealings will be professional, responsible, timely and transparent.	<b>1.1</b> Effective communication and consultation with our stakeholders to facilitate understanding, information sharing and appropriate outcomes
<b>2. Our service delivery</b> Provide and manage regulatory services which are efficient, effective and responsive to the needs of our stakeholders.	<b>2.1</b> Products are regulated throughout their lifecycle commensurate with the assessed level of risk to the community
	<b>2.2</b> International relationships facilitate cooperation and harmonisation in the implementation of regulatory controls
	<b>2.3</b> Regulatory outcomes and business processes operate in a manner consistent with legislative requirements and procedures, and meet agreed timeframes
<b>3. Our business capability</b> Continuously improve our operations by monitoring outcomes and creating opportunities to achieve better results.	<b>3.1</b> Continuously improve internal operational effectiveness and process efficiencies
	<b>3.2</b> A robust risk management approach to all strategic and key operational risk is maintained
	<b>3.3</b> Provide sound financial performance
<b>4. Our people</b> Attract and retain appropriately qualified and skilled people by providing an environment that supports and values them and recognises their contribution.	<b>4.1</b> There is excellent leadership and management
	<b>4.2</b> Staff have appropriate skills and are effective
	<b>4.3</b> Staff have appropriate professional development opportunities
	<b>4.4</b> Policies, procedures and systems support optimal performance and organisational health

The Business Plan and Quarterly Reports against the Plan are structured by program area, as follows:

- Prescription Medicines
- Over The Counter Medicines
- Complementary Medicines
- Medical Devices
- Blood and Tissues
- Exports
- Laboratories and Compliance
- Supporting the Business

This report addresses both continuing responsibilities and major project initiatives for the financial year including activities undertaken as part of the development of regulatory arrangements for the Australia New Zealand Therapeutic Products Authority (ANZTPA) and the proposed joint regulatory scheme for therapeutic products. In July 2007, the New Zealand Government announced that it was unable to secure the support needed to pass their implementing legislation to establish the ANZTPA through its parliament. Work between Australia and New Zealand on the joint agency project has been postponed.

## **PRESCRIPTION MEDICINES PROGRAM**

### **Key Achievements during the April - June 2007 Quarter**

#### **1. New medicines registered during the reporting period**

Exenatide (Byetta)	Eli Lilly Australia Pty Ltd
Human Papillomavirus Vaccine (Cervarix)	GlaxoSmithKline Australia Pty Ltd
Lapatinib (Tykerb)	GlaxoSmithKline Australia Pty Ltd
Zonisamide (Zonegran)	Eisai Australia Pty Ltd

#### **2. Orphan drugs designated during the reporting period**

C1 esterase inhibitor (Berinert P) for the treatment of hereditary angioedema

Eculizumab (Solaris) for the treatment of paroxysmal nocturnal haemoglobinuria

### Ongoing Functions

<i>Strategy/Activity</i>	<i>KRA's</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
Effectively process applications	2.1,2.2	<p>Applications accepted and evaluated within statutory timeframes, where applicable.</p> <p>Number of applications approved.</p> <p>Number of applications rejected.</p> <p>Number of applications withdrawn.</p>	<p>79 Category 1 submissions finalised within timeframes:</p> <ul style="list-style-type: none"> <li>• 72 Category 1 submissions approved</li> <li>• 0 Category 1 submission rejected</li> <li>• 7 Category 1 submissions withdrawn</li> </ul> <p>244 Category 3 submissions finalised within timeframes.</p> <p>240 Category 3 submissions approved</p> <ul style="list-style-type: none"> <li>• 0 Category 3 submission rejected</li> <li>• 4 Category 3 submissions withdrawn</li> </ul> <p>No Category 2 submissions were received.</p>
Receipt and review of Adverse Drug Reaction (ADR) reports and subsequent analysis	2.1,2.3	<p>Reports reviewed by a professional within 3 working days of receipt and reports entered into Adverse Drug Reactions Unit (ADRU) database within two weeks of receipt.</p>	<p>2626 reports received in the quarter.</p> <p>100% reports reviewed by a professional officer within 3 working days of receipt.</p> <p>37.5% reports entered into ADRU database within 2 weeks of receipt.</p>
Provide secretariat support to the Australian Drug Evaluation Committee (ADEC) and its subcommittees	1.1,2.3	<p>Notification of ADEC resolutions to sponsor companies within 5 working days of meeting and gazettal of positive resolutions within one month of meeting.</p> <p>Edited extracts of ratified ADEC minutes provided to all relevant sponsor companies within one month of ratification.</p>	<p>Two meetings of ADEC as held during the quarter</p> <p>All timeframes met.</p> <p>All timeframes met.</p>

<i>Strategy/Activity</i>	<i>KRA's</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
Maintain international cooperation programs	2.2	<p>Participation in international forums.</p> <p>Number of reports exchanged.</p> <p>Processes in place to enable increased international harmonisation.</p>	<p>None this quarter</p> <p>11 Evaluation reports sent to New Zealand, 2 reports received from USA</p> <p>TGA and the Biologics and Genetic Therapies directorate (BGTD) of Health Canada are undertaking a Parallel Review Project. The two agencies will review one or more submissions in parallel with an aim to enhance cooperation between regulators.</p> <p>Continued adoption of international guidelines.</p>

#### **Major Projects**

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
Develop the joint regulatory scheme for prescription medicines, in association with Medsafe and in consultation with relevant stakeholders	2.1,2.2, 2.3,3.1	Ministerial Council Rules, guidelines, systems and procedures for the whole of life cycle regulation of prescription medicines in place for commencement of the joint scheme.	Revised guideline on transition provisions for product licensing prepared.
Improve access to Product Information (PI) and Consumer Medicine Information (CMI) documents	1.1	Plan in place to improve access to PI and CMI through the web.	Responses from the second consultation paper analysed and meetings with key stakeholders to be organised.
Consult on and implement business process reforms	1.1,3.1	<p>Improved pre-market workflow processes within the Drug Safety Evaluation Branch (DSEB) so that the processes better reflect the modern work processes of relevant stakeholders.</p> <p>Development of a greater capacity for planning by DSEB.</p>	The number of applications that are routinely provided to ADEC has been reduced and an internal review process established for applications that had previously been considered by ADEC. Only applications for NCEs, major extension of indications applications (e.g. where the application is the first in its class); and for which there has been a negative recommendation will be routinely sent to ADEC.

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
		Improved transparency of the DSEB's decision-making.	Working Party considering issues to facilitate transparency of decision making in DSEB.
Review of Australian arrangements for clinical trials and access to unapproved therapeutic goods	2.1	Guidance documents prepared.  Transitional arrangements implemented.  Trans-Tasman regulatory framework developed.	Clinical trial framework to be amended depending upon NHMRC ethics review initiatives.
Implement automated ADR reporting fully	2.3	Implementation of electronic reporting of ADR by companies and health professionals.	Electronic reporting through the website accounted for 26% of the reports submitted in the quarter.  Electronic reporting by health professionals through desktop software is in the final phase of testing.  The project to allow full electronic reporting by companies has not been funded
Develop an electronic lodgement facility for prescription medicines	2.3	Implementation of an electronic lodgement facility for all submissions to DSEB	Development and testing of an electronic application form for new chemical entities and generic applications completed. Documentation prepared.

## **OVER THE COUNTER MEDICINES**

### **Key Achievements during the April – June 2007 Quarter**

- 242 applications were finalised during this quarter. The average number of days to complete new applications/variations referred to MEC, variations and notifications was met. The proposed ANZTPA RASML was released for consultation.

### ***Ongoing Functions***

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
Pre-market evaluation of Over The Counter (OTC) medicines according to the requirements of the legislation in a timely and effective matter	2.1,2.3	Applications completed within target timeframes <sup>1</sup> : <ul style="list-style-type: none"> <li>▪ Applications and variations referred to Medicines Evaluation Committee (MEC)– 71 working days<sup>1</sup></li> <li>▪ Variations – 32-45 working days<sup>1</sup></li> <li>▪ Notifications – 20 working days<sup>1</sup>.</li> </ul>	285 applications were received during the quarter. 242 applications were finalised. The average number of days to complete new applications, notifications and variations was met.
Develop, maintain and support the electronic system for OTC medicines	2.3,3.1	Identify and develop modifications by 30 June 2007 to allow for better reporting and smoother processing of applications.	Current on-going minor problems have been identified and reported for further investigation.
Provide secretariat support to the MEC	1.1,2.3	Edited extract of draft MEC minutes provided to relevant sponsors within 5 weeks of MEC meeting.	One MEC meeting was held during the quarter.

### ***Major Projects***

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
Develop the joint regulatory scheme for OTC medicines, in association with Medsafe and in consultation with relevant stakeholders	2.1,2.2, 2.3,3.1	Ministerial Council Rules, guidelines, systems and procedures for the regulation of OTC medicines in place for commencement of the joint scheme.	In conjunction with Medsafe, ongoing development of draft guidelines, processes and procedures progressed.
Minimise the number of applications on hand at the commencement of the ANZTPA	2.3	As few applications as possible are carried over to the ANZTPA.	On-going program to ensure applications do not become long-standing.
Increased screening of applications	2.3	100% of applications are subject to a pre-screening process.	All applications are now subject to pre-screening.

<sup>1</sup> Average time measured quarterly

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
Respond to medicine problem reports regarding the quality, safety and/or efficacy of OTC medicines	2.1,2.3	Assess risk, prioritise action and initiate remedial action (where appropriate) within 2 working days.  Enter problem report information in Post Market database within 5 working days.	Achieved.
Implement reforms in regulation of products at the therapeutic / cosmetic interface	2.1,2.3	Following implementation of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) legislation, related changes to the TGA's Excluded Goods Order are implemented.	NICNAS legislation was passed through the House of Representatives during the winter sitting and is expected to be passed through the Senate during the spring sitting.
RASML	2.3	Phase 2 of the RASML project ready for implementation at commencement of operation of the ANZTPA.	Project is progressing – the proposed ANZTPA RASML was released for consultation.
Standard terminology for the ANZTPA	2.3	Standard terminology ready for implementation at commencement of operation of the ANZTPA.	Project progressing.

# COMPLEMENTARY MEDICINES

## Key Achievements during the April - June 2007 Quarter

- The OCM, following consultation with stakeholders, provided input to the Draft Medicines and Administrative Rules relating to complementary medicines. In addition, the Interim Joint Expert Advisory Committee on Complementary Medicines (IJEACCM) met once during the quarter to consider the suitability of a prioritised list of ingredients supplied in dietary supplements in New Zealand but currently not permitted in Listed medicines in Australia.
- Expert Advisory Committee on Complementary Medicines in the Health System (ECCMHS)

The Therapeutic Goods Administration (TGA) has responsibility for coordinating the implementation of the Government response to the recommendations of the ECCMHS agreed to by Government. The Complementary Medicines Implementation Reference Group (CMIRG), which includes representatives and experts in complementary medicine research, education, industry and consumer matters, met during the quarter to consider further progress on the implementation of recommendations agreed to by Government, including an update from the National Prescribing Service on progress of recommendation 25.

- OCM / Industry Consultation Group

The OCM held one OCM / Industry Consultation Group (OICG) meeting during the quarter. The OICG comprises TGA staff and technical experts nominated by the Australian Self-Medication Industry, the Complementary Healthcare Council of Australia and Natural Products New Zealand. Outcomes from the consultation resulted in:

- Consideration of NHMRC recommended dietary intakes;
- Continuing development of ingredient names guidelines;
- Ongoing development of Compositional Monographs for complementary medicine ingredients;
- Ongoing development of an Order for Homoeopathic and Anthroposophic medicines;
- Ongoing categorisation of herbal components;
- Ongoing review of Coded Indications for Listed medicines; and
- Ongoing development of a regulatory approach for incidental minor excipients.

### Ongoing Functions

Description	KRAs	Performance Measure	Progress to 30 June 2007
Evaluate new complementary medicine substances and products; and provide secretariat support to the Complementary Medicines Evaluation Committee (CMEC)	1.1,2.1, 2.3	<p>Publish Draft Public Recommendations Record on TGA website within 5 working days following each CMEC meeting.</p> <p>Publish Ratified Minutes of CMEC meetings on TGA website within two weeks of ratification by CMEC.</p>	<p>CMEC met on the 13 April (CMEC 61) and 8 June (CMEC 62). The Public Recommendation records were published on the TGA website within 3 days, and the Ratified Minutes published on the website within 2 weeks of the meetings.</p> <p>The following applications were <i>received</i>:</p> <ul style="list-style-type: none"> <li>6 new substance</li> <li>2 product Registrations</li> <li>11 variations to Registration</li> </ul> <p>The following were <i>completed</i>:</p> <ul style="list-style-type: none"> <li>3 variations to Registration</li> <li>4 ingredient safety reviews</li> </ul>
Process Listed medicine applications submitted via the Electronic Listing Facility.	2.1 2.3	100% of Listed medicine applications processed within 2 working days of receipt by the OCM.	579 applications and 385 notifications and variations were received during the quarter. 99% were processed within target timeframes.
Post-market monitoring and review of manufactured complementary medicines.	2.1 2.3	Increase percentage of randomly selected new Listing applications for post-listing audit to 22%.	Approximately 28% of new Listed medicines were selected for Post Market random review during the quarter.
Receive and respond to medicine problem reports regarding the quality, safety and/or efficacy of manufactured complementary medicines	2.1 2.3	<p>From receipt of problem report undertake to assess risk, prioritise action and initiate remedial activity for potential high risk products within 2 working days.</p> <p>Enter problem report information in Post Market and Review Unit database within 5 working days.</p>	Targets being met.

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
Participate in international forums to facilitate harmonisation and recognition of the Australian regulatory system for complementary medicines	2.2 1.1	Invitation by national regulatory agencies and international bodies to participate in forums for the exchange of regulatory information to facilitate recognition and/or harmonisation of regulatory standards and guidelines.	Attended a workshop convened by the US Office of Dietary Supplements on the safety of black cohosh (Bethesda, Maryland, USA).  Attended a workshop convened by the WHO on the "Quality for safety of homoeopathic medicines" (Milan Italy)

### **Major Projects**

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
Develop the joint regulatory scheme for complementary medicines, in association with Medsafe and in consultation with relevant stakeholders	2.1,2.2, 2.3,3.1	Ministerial Council Rules, guidelines, systems and procedures for the regulation of complementary medicines in place for commencement of the joint scheme.	Advice provided to Joint Agency Establishment Group on regulatory issues for complementary medicines for the draft Medicines Rule and draft Therapeutic Products Orders. Work ongoing.  Development of a draft Therapeutic Products Order for Homoeopathic and Anthroposophic Medicines commenced. Work ongoing.
Coordinate implementation of the recommendations of the ECCMHS agreed by Government	2.3	Report progress of implementation to the Complementary Medicines Implementation Reference Group (CMIRG), as directed by the Committee.  Update stakeholders through reporting of progress on TGA website, following progress ratification by CMIRG.	See 'Key Achievements'
In the context of the joint Australia New Zealand regulatory scheme, progress implementation of the Government response to the recommendations of the ECCMHS that relate to the regulation of complementary medicines: • Review the <i>Guideline for Levels and</i>	2.1,2.3	Reviews finalised to facilitate implementation with joint regulatory scheme.	

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
<p><i>Kinds of Evidence to Support Claims for Non-registered Medicines</i>; – (recommendation 4).</p> <ul style="list-style-type: none"> <li>• Continue the review of the registration process for complementary medicines – (recommendation 39) and the identification of incentives to encourage innovation and research in complementary medicines – (recommendation 40).</li> <li>• Continue the review of the regulation of homoeopathic and herbal medicines – (recommendations 10 and 11).</li> <li>• Review compositional guidelines and establish standards that are legally enforceable – (recommendation 2).</li> </ul>			<p>Ongoing consultation through OCM Industry Consultation Group (OICG) and other stakeholder groups. Outcome to be included in ANZTPA Guidelines.</p> <p>Draft Therapeutic Products Order for Homoeopathic and Anthroposophic Medicines being developed. Consultation with OICG and special interest group continues. Work ongoing.</p> <p>Industry agreement on format and data requirements for Composition Monographs. Draft monographs being prepared for consultation.</p>

## MEDICAL DEVICES

### Key Achievements during the April - June 2007 Quarter

- Undertook formal stakeholder consultation on the *In-vitro* Diagnostic Device (IVD) revision of the draft Australia New Zealand Therapeutic Products Regulatory Scheme (Medical Devices) Rule 2007 for the regulation of commercial IVDs under the Australia New Zealand Therapeutic Products Authority (ANZTPA). The consultation period commenced with a series of industry seminars in Melbourne, Sydney and Auckland to explain the draft Rule. Stakeholder comments reviewed and key issues identified.
- Revised and finalised two draft Authority Standards Orders for release as part of phase 3 ANZTPA stakeholder consultation:
  - MDSO 3 Medical Device Standards for Medical Devices Required to be Sterile; and
  - CASO 1 Conformity Assessment Standard for Quality Management Systems and Quality Assurance Techniques.
- Signing of the Memorandum of Understanding (MoU) between Therapeutics Goods Administration and the Health Products and Food Branch, Health Canada, on Quality Management Systems (QMS) certifications for medical devices.
- Implementation of the regulatory framework for re-manufacturing Single Use Devices - health care facilities scheduled to cease re-manufacturing single use devices by 1 July 2007.

### Ongoing Functions

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
Effectively process applications	2.1,2.3,	<p>Applications processed within target timeframes.</p> <p>Number of applications in process.</p> <p>Number of applications rejected.</p>	<p>2965 applications were processed during the reporting period.</p> <p><i>Device Electronic Application Lodgement (DEAL) Applications:-</i>            Manufacturer's Evidence: 926 processed, average time 8 days, target 15 days.            Applications Without Audit: 2784 processed, average time 12 days, target 20 days.            Level 1 Application Audits: 41 processed, average time of 37 days, target 30 days.            Level 2 Application Audit: 106 processed, average time of 98 days, target 60 days.</p> <p>In process: – 473 applications are in hand.</p> <p><i>Conformity Assessment Applications:-</i>            Schedule 3 -            Part 1: 15 processed, average time 55 days, target 90 days.            Part 1.6: 25 processed, average time 116 days, target 120 days.            Part 2: Nil processed            Part 4: 4 processed, average time 96 days, target 90 days.            Part 5: Nil processed</p> <p>Provision of inaccurate or inadequate information in support of applications resulted in a rate of rejection of approximately 15% during the reporting period.</p> <p>Note: Processing times this quarter continue to reflect the effects of the significantly increasing number of applications from sponsors moving their listed/registered devices to included devices to meet the 2007 October deadline.</p>

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
Effectively manage compassionate use/clinical trials programs	2.1,2.3	Clinical Trial Notification scheme (CTN), Clinical Trial Exemption scheme (CTX) and Special Access Scheme (SAS) applications processed within target timeframes.	<p>Targets achieved.</p> <p>During the reporting period, 31 CTN – applications were acknowledged within the target timeframe of 5 days. 557 SAS Category B applications were finalised within the target timeframe of 5 days. No CTX applications were received.</p>
Effectively investigate and monitor adverse incident reports	2.1,2.2, 2.3	<p>Incident reports investigated within target timeframes.</p> <p>Input to GHTF National Competent Authority Reporting (NCAR) scheme.</p>	<p>Number of reports received –280.  Number of reports investigated –153.  Average processing time – 102 working days.  83% completed within target.</p> <p>Outcomes of investigations:  Recalls - 8  Product improvement - 13  Safety alerts -6  TGA news articles - 2  User education - 3  Refer to surveillance – 2  Problem not confirmed -12  Refer to MAB -3  Compliance testing -1</p> <p>Company warning – 5</p>
<p>Effective operation of Expert Committees, including:</p> <ul style="list-style-type: none"> <li>• Medical Device Evaluation Committee (MDEC) and its subcommittees</li> <li>• National Serology Reference Laboratory (NRL) Management Committee and its Scientific Advisory Committee</li> </ul>	1.1, 2.3	Committees operate in accordance with terms of reference, meeting schedules met, minutes and resolutions published in accordance with targets as appropriate.	<p>All meetings held as scheduled including 1 MDEC meeting, 1 MDIRC and BBC meeting. The Cardiac Expert Working Group met in June 2007.</p> <p>MDEC resolutions and meeting report were available on the TGA website within 2 weeks of the meeting.</p>

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
Maintain international cooperation and standards programs, including: <ul style="list-style-type: none"> <li>• GHTF</li> <li>• International Organization for Standardization (ISO)</li> <li>• Asia-Pacific Economic Cooperation</li> <li>• Other regulatory agencies</li> </ul>	2.2	<p>Agreements with international agencies managed and maintained.</p> <p>International relations maintained.</p> <p>Participate in and provide leadership to international meetings and other forums.</p>	<p>Continued work on variation of the EC MRA with DFAT and DITR.</p> <p>MoU with Health Canada signed. Continued work with the implementation of mechanisms for the assessment of manufacturer's Quality Management Systems under the MoU.</p> <p>Participation in GHTF SG1, SG2 and SG 5 meetings in May 2007. TGA remains chair of SG 2.</p>

### **Major Projects**

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
Develop the joint regulatory scheme for medical devices, including In Vitro Diagnostic devices (IVDs) in association with Medsafe and in consultation with relevant stakeholders	2.1,2.2, 2.3,3.1	Ministerial Council Rules, guidelines, systems and procedures for the regulation of medical devices in place for commencement of the joint scheme.	<p>Undertook consultation which included holding stakeholder seminars in Melbourne, Sydney and Auckland on the draft IVD Rule. Reviewed and categorised stakeholder comments.</p> <p>Reviewed stakeholder comments on:</p> <ul style="list-style-type: none"> <li>• MDSO 1 Clinical Evidence;</li> <li>• MDSO 2 Risk Management; and</li> <li>• CASO 2 Quality Assurance Techniques for Animal Tissues and Derivatives.</li> </ul> <p>Under took stakeholder consultation on:</p> <ul style="list-style-type: none"> <li>• MDSO 3 Medical Devices Required to be Sterile; and</li> <li>• CASO 1 Conformity Assessment Standard for Quality Management Systems and Quality Assurance Techniques.</li> </ul>
Effectively manage the transition to the regulatory requirements for medical devices introduced in 2002	1.1,2.3	Transition progress in accordance with project timeframes.	Strategies to assist industry transition products to the medical devices regulatory system continuing. The Therapeutic Goods Amendment Bill 2007 introduced

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
		Minimal disruption to supply of medical devices.	in Parliament on 20 June 2007, which will amend section 9B of the Act to require sponsors to 'lodge' an application by the 4 October 2007.
Finalise and implement commercial IVD regulatory framework	2.1,2.3	Consultation on draft Regulations undertaken.	Consultations on the draft IVD Rule were undertaken, including holding stakeholder seminars in Melbourne, Sydney and Auckland.
Effectively implement regulation of reuse of single use devices	2.1,2.3	Complete consultation with jurisdictions on non-critical and semi-critical single use devices by December 2006.	Re-manufacture of semi-critical and non-critical devices scheduled to cease by 1 July 2007.

## **BLOOD AND TISSUES**

### **Key Achievements during the April – June 2007 Quarter**

- Provision of drafting instructions for the Biologicals Rule to the Office of Legislative Drafting and Publishing. The Biologicals Rule will provide the regulatory framework for blood, blood products and human cellular and tissue therapies.
- Release of the Consultation Paper on the Regulation of Human Cellular and Tissue Therapies (HCTs) under ANZTPA and the completion of associated stakeholder workshops. Consultation closed on 13 June 2007.

### *Ongoing Functions*

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
Review applications for registration of plasma derivatives and related products	2.1,2.3	Review undertaken in accordance with agreed targets.	Target achieved, with 12 submissions reviewed and 16 secondary evaluations completed.
Evaluate fresh blood and tissue Technical Master File (TMF) submissions	2.1,2.3	Evaluation undertaken in accordance with agreed targets.	No submissions were completed in the reporting period.
Evaluate Plasma Master File for blood products for export from imported plasma	2.1,2.3	Evaluation undertaken in accordance with agreed targets.	Target achieved, with 2 submissions reviewed.
Finalise component medical and therapeutic device applications	2.1,2.3	Assessment/evaluation undertaken in accordance with agreed targets.	One application was finalised in the reporting period in accordance with agreed target.
Maintain commitment to international cooperation programs	2.2	Participate in and provide leadership to international meetings and other forums.  Maintain international commitment to Council of Europe (CoE) and World Health Organization (WHO).	Participation in WHO study group on Cell substrates for the production of biologicals.  Participation in International Plasma Fractionation Association workshop on Screening of Blood Borne Pathogens.  Participation in the European Committee on Blood Transfusion.  Participation in the European Pharmacopoeia Group 6B (Human blood and blood products).

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
Provide advice to the National Blood Authority (NBA) and the Department of Health and Ageing (DoHA) on regulatory matters	1.1	Provide timely advice to NBA and DoHA on regulatory issues – on request and through program of regular meetings.	<p>Participated in meeting with the NBA on development of a National blood supply contingency plan.</p> <p>Participated in NBA haemovigilance working party with special reference to recalls and arrangements under ANZTPA.</p> <p>Discussions held with the DoHA in relation to the importation of blood.</p> <p>Participated in meeting of the AHMAC Intergovernmental Committee an Organ and Tissue Donation.</p> <p>Provided papers and participated in AHMAC Jurisdictional Blood Committee (JBC).</p>

### **Major Projects**

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
Facilitate the development and finalisation of a joint regulatory scheme for blood, tissue and cellular therapies for the ANZTPA, in association with Medsafe and in consultation with relevant stakeholders	2.1,2.2 2.3,3.1	Ministerial Council Rules, guidelines, systems and procedures for the regulation of blood, tissue and cellular therapies in place for commencement of the joint scheme.	<p>Drafting instructions for the ANZTPA Biologicals Rule provided to Office of Legislative Drafting and Publishing.</p> <p>Release of the Consultation Paper on the Regulation of Human Cellular and Tissue Therapies under ANZTPA. Consultation closed on 13 June 2007. Stakeholder workshops also completed.</p> <p>Analysis of submissions commenced. This will inform the development of the Biologicals Rule.</p>
Establish Expert Advisory Committee on biological therapeutic product to operate within ANZTPA framework	2.1,2.3 3.2	Expert Advisory Committee operational by commencement of ANZTPA.	Progress ongoing.

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
Finalise a regulatory framework for human cellular and tissue and biological therapies	2.1,2.3	Regulatory model finalised.  Agreement obtained from AHMAC and Australian Health Ministers' Conference (AHMC).	Regulatory framework endorsed by AHMAC in October and AHMC in November 2006. The issue of whether solid organs and reproductive tissue will be included in Class 1 of the framework is due for further consideration by AHMAC in October 2007.  Mapping exercise of legislation regulations for solid organ and assisted reproductive technologies being undertaken by Regulatory Policy and Governance Division, DoHA continuing.  Release of consultation paper on the regulation of human cellular and tissue therapies for public release.
Negotiate Memorandum of Understanding with the NBA	1.1	Draft agreement by September 2006.	Completed in June 2007

# EXPORTS

## **Key Achievements during the April - June 2007 Quarter**

- 542 new Certificate of Pharmaceutical Product (CPP) applications were received during the quarter and all were processed within target timeframes.
- 106 new export-only listing and variation applications were received during the quarter and all were processed within target timeframes.

### *Ongoing Functions*

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</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 manner	2.1,2.3	100% applications completed within target timeframes.  Provide and manage effective and efficient regulatory services measured against stakeholder satisfaction.	542 Certificate of Pharmaceutical Product applications were received during the Apr - Jun 2007 quarter and all were processed within target timeframes.  106 new export-only listing and variation applications were received during the Apr - Jun 2007 quarter and all were processed within target timeframes.  Stakeholders were provided with timely advice. The Export Unit has not received any negative feedback from any stakeholder indicating satisfaction on part of stakeholders.
Develop, maintain and support the electronic system for Export Medicines	2.3	Identify and develop modifications by 30 June 2007 to allow for better reporting and smoother processing of applications.	The Export Electronic Lodgement System is still going through its improvement phase, particularly its Quarterly Reporting System. Once these improvements are on board, reporting of applications will get smoother.
Issue permits for export of blood and tissues under Customs (Prohibited Exports)	2.1	100% permits issued within target timeframes.	100% permits were issued within target timeframe of 24 hour. The number of permits issued during the quarter was 42.
Provide support to stakeholders in resolving issues relating to the export regulatory environment for medicinal products	1.1	Transparency and timeliness of dealings with clients and stakeholders: feedback from stakeholders.  TGA Service Charter is adhered to in all situations.	The TGA Service Charter is fully adhered to in the export dealings with stakeholders. All applications are completed within the agreed timeframes. Any queries by the stakeholders are dealt with professionally.

### **Major Projects**

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
Develop the joint regulatory scheme for therapeutic products intended for export, in association with Medsafe and in consultation with relevant stakeholders	2.1,2.2, 2.3,3.1	Ministerial Council Rules, guidelines, systems and procedures for the regulation of therapeutic products intended for export and for issuing export certificates and permits in place for commencement of the joint scheme.	A draft of ANZTPA Export Guidelines, Export-only Grouping Order and Export Standards Order was completed and endorsed by the Joint Therapeutic Policy and Planning Committee (JTPPC). These documents are ready for the next step i.e. stakeholder's consultation.
Ongoing testing related to the continued development of EEL eg integration of MIS into Strategic Information Management Environment (SIME) Systems including EEL	2.3	Ensure that agreed specifications are delivered by thorough testing of enhancements.	EEL System was tested in line with other TGA electronic systems, to check whether it is compatible with the latest Notes upgrade. The system was found compatible.

# LABORATORIES AND COMPLIANCE

## Key Achievements during the April – June 2007 Quarter

- TGAL conducted Program 1 of the TGA's International Training Calendar:
  - Practical Training in Vaccine Quality Assurance. The participants were from the National Agency of Drug and Food Control, Indonesia (7-25 May).
- All 6 specialist TERGs conducted meetings during the second quarter of 2007. Some TERGs are finalising draft 'position papers' for consideration by MAB's Audit Governance Committee.
- The Chief Auditor attended the PIC/S Committee of Officials meeting in Geneva.
- A MAB auditor participated in the PIC/S Expert Circle on Hospital Pharmacy meeting in Norway. A draft guide for the preparation of medicinal products is being finalised by this Expert Circle.
- The Assistant Secretary for MAB chaired a teleconference with several other national regulatory authorities including Medsafe, Health Canada, Swissmedic and Health Science Authority (Singapore) to progress the development of a more coordinated and resource efficient approach to GMP regulation in 'off-shore' (or third country) sites.

***Ongoing Functions***

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
Conduct initial on-site GMP licence audits of Australian manufacturers	2.3	100% of on-site audits of Australian manufacturers (that are ready for audit when scheduled) are conducted within 3 months from the date of receipt of a new licence application.	Target met
Conduct routine GMP audits of Australian manufacturers	2.3	100% of routine audits are conducted within 6 months from their due (scheduled) dates.	99% met – 1 device audit was an overdue audit and has now been conducted
Conduct initial on-site GMP audits of overseas manufacturers	2.3	90% of on-site audits of overseas manufacturers (that are ready for audit when scheduled) are conducted within 12 months from the date of receipt of an application for overseas audit.	Target almost met; 85% of new overseas audits were conducted within the 12 month target.
Send GMP audit reports to manufacturers	2.3	90% of audit reports are sent to manufacturers within 20 working days from the date of the on-site audit.	Target almost met: 85% of audit reports were sent within the 20 working days target time
Process GMP clearance of overseas manufacturers	2.3	90% of applications for GMP clearance 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.	Target met; 100% processed when specified documents submitted

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
Facilitate a high level of regulatory compliance through a program of targeted and complaint testing for the Prescription, OTC, Complementary Medicines and Medical Device Regulators and in support of TGA enforcement actions	2.1	<p>Targeted testing as per agreed testing programs.</p> <p>Minimum of 800 products tested.</p> <p>For medicines:</p> <ul style="list-style-type: none"> <li>▪ Testing of urgent samples to commence within 1 week of receipt of sample.</li> <li>▪ Timeframes met for testing as agreed with the Regulators.</li> <li>▪ Evaluation of batch release documentation for vaccines and biotechnology products.</li> </ul> <p>For medical devices:</p> <ul style="list-style-type: none"> <li>▪ Urgent and Priority sample testing to commence within 2 days and 14 days of receipt of sample respectively.</li> </ul>	<p>Targets met. TGAL completed testing of a total of 526 samples (282 products) this quarter.</p> <ul style="list-style-type: none"> <li>▪ Testing of 13 of 15 urgent samples commenced within 1 week of receipt.</li> <li>▪ Targets met for all samples except for urgent unregistered products (targets met for 5 of 6 samples).</li> <li>▪ TGAL evaluated batch release documentation for 143 batches of vaccines or biotechnology products this quarter.</li> </ul> <p>Targets met for all samples.</p>

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
<p>Harmonise regulatory controls through commitment to international cooperation programs including:            WHO, GHTF, ISO, Official Medicines Control Laboratories, European Pharmacopoeia (EP), European Directorate for the Quality of Medicines (EDQM), International Laboratory Form of Counterfeit Medicines, Committee for Medicinal Products for Human Use (CHMP)/EMA, United Nations Children's Fund</p>	2.2	<p>Provide high level scientific input to international meetings and forums.</p> <p>Provide timely high level scientific input and advice.</p> <p>Undertake WHO missions and collaborative studies.</p> <p>Participation in EP/EDQM collaborative studies. Results and reports completed within timeframe.</p>	<p>Targets met:</p> <ul style="list-style-type: none"> <li>• Participated in an international collaborative study for calibration of Influenza A/Solomon H1N1 Reference Antigen against live virus reagents. Reported calibration results to the collaborative study co-ordinator at NIBSC, UK.</li> </ul> <p>Attended meetings for</p> <ul style="list-style-type: none"> <li>• WHO QSS Informal Consultation on Regulatory Evaluation of Therapeutic Biological Medicines, Geneva, Switzerland (19-20 April)</li> <li>• WHO INN Ad-Hoc Meeting on Biologicals, Geneva, Switzerland (23-24 April)</li> <li>• Options for Live Attenuated Influenza Vaccines in the Control of Epidemic and Pandemic Influenza, WHO Headquarters, Geneva (12-13 June).</li> <li>• Informal Consultation on Regulatory Preparedness for Human Pandemic Influenza Vaccines, WHO Headquarters, Geneva, Switzerland (14-15 June).</li> <li>• WHO Consultation on Specifications for Medicines and Quality Control Laboratory Issues, Geneva, Switzerland (27-29 June)</li> <li>• 12th Annual Meeting Of European Network Of Official Medicines Control Laboratories (OMCL), Prague, Czech Republic, 7-11 May 2007 The TGA Laboratories have observer status in this network.</li> <li>• Options for the Control of Influenza VI, Toronto, Canada 17-23 June.</li> <li>• ISO TC/198 Sterilization of Health Care Products Meeting in Dublin, Ireland 25-29 June 2007.</li> </ul>

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
Maintain accreditations: <ul style="list-style-type: none"> <li>• ISO 17025</li> <li>• WHO Collaborating Centre for Drug Quality Assurance</li> <li>• WHO Collaborating Centre for the Quality Assurance of Vaccines and other Biologicals</li> </ul>	2.2,3.1	Accreditations maintained.	Targets met.
Enforce the provisions of the <i>Therapeutic Goods Act 1989</i>	2.1	Reports of alleged breaches are assessed within 10 working days and appropriate response initiated.	All alleged breaches of legislation assessed and receipt of complaints acknowledged in writing. Internal SOP's updated to make this policy for the Unit.
Coordinate the recall of therapeutic goods	2.3	Recalls are coordinated/undertaken in accordance with recall protocol and within agreed target timeframes.	Target not achieved - 32% of recalls initiated in the reporting period were closed out within the target timeframe of 90 working days.  It should be noted that > 80% of the recalls for the quarter have subsequently been finalised to the point of receipt of final report from the sponsor. Non compliance with performance targets is multifaceted, and includes delays in submission of final reports by sponsors, increased post recall review of reports by TGA, increasing numbers of device recalls involving multi-staged actions (eg limit use of product at stage 1 followed by product/software corrections at stage 2 often 3-5 months post recall initiation). Sponsors also report resourcing issues for devices problems associated with meeting the October 2007 deadline.
Coordinate the investigation of problems reported for medicines	2.1,2.3	Problem report investigations finalised within target timeframe	Target met – 64% of problems reported for medicines initiated in the reporting period were completed within the target timeframe of 65 working days.
Effective operation of Committees, including: <ul style="list-style-type: none"> <li>• Therapeutic Goods Committee (TGC) and subcommittees</li> </ul>	1.1,2.1, 2.3	Committees operate in accordance with terms of reference; meeting schedules are met; minutes and resolutions are published in accordance with targets as appropriate	One meeting each of TGC (3 May 2007) and NCCTG (2-3 May 2007) this quarter. Outcomes of TGC published on TGA website.

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
<ul style="list-style-type: none"> <li>• NCCTG</li> <li>• Industry Government Crisis Management Committee</li> <li>• Joint Australia New Zealand committees providing advice on standards for therapeutic products in the joint regulatory scheme</li> </ul>			Progression of matters arising from all committees and work supporting joint standards development for the ANZTPA continued. Following stakeholder consultation and a recommendation from TGC, BP 2007 was adopted as the edition of that publication defined under the <i>Therapeutic Goods Act 1989</i> with effect 1 July 2007.
Process advertising complaints and referrals from complaints panels and jurisdictional referrals	2.1	Complaints referred within one week of receipt.  Recommendations actioned within 1 month.	On target
Deal effectively with therapeutic/cosmetic/food interface issues and recurring problem areas.	2.1,2.3	Documented delegations of responsibilities to appropriate people/organisations.  Regulatory policy developed and articulated.	NICNAS legislation for cosmetics was passed through parliament during the winter sitting and is expected to be passed through the senate during the spring sitting. A cosmetic standard is currently being created. The TGA, NICNAS and the ACCC has formed an interface group to help deal with therapeutic/cosmetic interface matters and will have their first meeting on Friday 17 August 2007.
Improve communications with Advertising stakeholders	1.1	Greater consistency in decision making.  Positive feedback from (Advertising Services Managers) ASMs.  Workshops organised for ASMs.	On target  Meetings/teleconferences arranged on an as needed basis.

### **Major Projects**

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
Revise the Code of GMP for Blood and Tissues	3.1,1.1	Code re-drafted for consultation with relevant stakeholders by October 2006.	3 new Codes of GMP are being developed: one specifically for Blood and Blood Products; one for Human Cells and Tissues, and one for Cellular Therapies.  The Blood and Blood Products Code of GMP has been

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
			drafted by the B&T TERG (including industry reps). It is being fine tuned for wider consultation. The two other new codes are in differential draft stages prior to commencing an external consultation process.
Finalise the implementation of the Australian National Audit Office (ANAO) recommendations to improve therapeutic goods regulation, noting that the ANAO is scheduled to conduct a follow-up audit commencing in February 2006	2.3,3.1, 3.2	100% of all ANAO recommendations are fully implemented.  Independent assessment of TGA's implementation of the recommendations to be conducted by the ANAO.	As reported previously (in the last quarter) MAB has been independently audited to assess its progress in addressing the NAO recommendations. The auditor concluded " <u>overall, the actions taken by the TGA to implement the ANAO recommendations relating to GMP audit program risk assessment, development, delivery and monitoring, have been significant and address the issues and concerns raised by the ANAO.</u> "
Update MAB's Quality Management System (QMS) to comply with ISO 9001:2000 and ISO Guide 62	3.1	MAB's QMS to be compliant with ISO 9001:2000 and ISO Guide 62 as assessed by Health Canada and Australia's NCSI.  MAB's QMS achieves NCS International (NCSI) certification.	As reported previously, MAB's quality management system (and its implementation) was deemed to be of a suitably high quality by Health Canada's Assessors.
Address Code of GMP issues of interpretation and application through the newly established TERGs	1.1	100% of TERGs conduct a minimum of 3 meetings in the fiscal year.  Publish information in relation to any guidance documents/explanatory notes that have been agreed in relation to the Code of GMP.	All 6 TERGs have met on the minimum number of occasions.  TERGs are in varying stages of submitting different 'guidance' documents for consideration by MAB's Audit Governance Committee.
Develop a revised Uniform Recall Procedure for Therapeutic Goods	2.3,3.1	Revised recall protocol for ANZTPA developed and agreed by March 2007.	Development of revised document targeted for end of 2007.
Implement a revised computer system for ANZTPA for recording and processing of recalls and medicine problem reports	2.3,3.1	Revised system implemented by June 2007.	Planning for development and enhancement of the system continues to be made within Australia, in preparation for trialling.
Develop, consult and finalise ANZTPA Standards for therapeutic products	2.1,2.2 2.3	Draft Standards finalised for consultation by March 2007.	Finalisation of outstanding issues associated with Therapeutic Products Orders (Medicines Standards) for

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
			medicine labelling, child-resistant packaging and microbiological standards for medicines; ongoing development of requirements for tablets and capsules; stakeholder consultation commenced on packaging standards for specified therapeutic products. All draft Orders undergoing further development through committee processes, agency review, and Office of Legislative Drafting. Progression in line with timeline for start of joint regulatory scheme.
Develop the joint regulatory scheme for the regulation of advertising of therapeutic products, in association with Medsafe and in consultation with relevant stakeholders	2.1,2.2, 2.3,3.1	Ministerial Council Rules, guidelines, systems and procedures for the regulation of advertising of therapeutic products in place for commencement of the joint scheme.	Continued progress through the Advertising Implementation Steering Group. This included development of a draft Advertising Code Order and Working Group meetings on the Central Support Unit and Cost Recovery.

## SUPPORTING THE BUSINESS

### Key Achievements during the April - June 2007 Quarter

- The exposure draft of the Australian Therapeutic Products Bill to establish the proposed Australian New Zealand Therapeutic Products Authority (ANZTPA) was released for public consultation on 2 April 2007.
- The third and final phase of the ANZTPA *Stakeholder Consultation Programme 2006/07* on the proposed regulatory framework commenced on 4 April 2007, with the release for stakeholder comment of three draft technical Orders relating to medical devices.
- Consultation documents on *In-Vitro* diagnostic devices (IVDs) and Human cellular and tissue therapies (HCTs) were released for stakeholder feedback in late April and over 150 stakeholders attended workshops on IVDs and HCTs in Australia and New Zealand during May 2007.
- Phase 3 also saw the release of the draft Scheduling Policy Framework and the draft Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), in addition to further drafts of key Orders.

### Ongoing Functions

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
Provide prompt and efficient financial processes and systems that facilitate business services with our clients	3.1,3.3	100% of applications are released to workflow systems within 48 hours of payment.  Enhancements to online services that permit sponsors to lodge cancellations and applications for low turnover exemptions via the web, developed by June 2007.	The TGA has maintained 99% of applications released for payment in workflow systems over the quarter.  On – line payment option implemented in April 2007 for most applications (except Premier and ELF application)  Enhancements for online submission of cancellation requests and low turnover applications has been deferred and will be completed as part of the AOS redevelopment project.
Facilitate engagement and transparency of TGA business priorities, budget projections and fees and charges proposals through the TGA-Industry Consultative Committee (TICC)	1.1	Two meetings per year plus industry bilateral meetings.	The TGA-Industry Consultative Committee met in May 2007. The TGA introduced the circulation of agenda papers electronically which was supported by members.  New Fees and Charges which took effect from 1 July 2007 were posted to the TGA website in the last week of June 2007.
Ensure compliance with statutory reporting obligations and government accountability frameworks	3.3	No adverse audit findings.  TGA budgets reported in portfolio budget statements and annual report.	No audit findings have arisen from the ANAO's interim audit of TGA.  TGA budget and cost recovery arrangements are included in the 2007-08 portfolio budget statements.
Ensure TGA operates in line with budget forecasts	3.3	Program cost recovery revenues within 5% of budget.  Program expenditures within 5% of expectations, monthly variation within 5%.	Total cost recovery revenue was 6% higher than budget forecasts at \$79.7m for the financial year. Revenue variations were reported for the Registered Medicine (11%), Listed Medicines (-6%), Devices (18%), GMP (-6%) and the Blood Products (-12%) programs.  Total expenditure was on budget. Expenditure variations were reported in the Registered Medicine (-7%), Listed Medicines (-7%), Devices (6%), GMP

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
			(-14%) and the Blood Products (-9%) programs.
Facilitate communication with external stakeholders via the web and other communication services	1.1	<p>Information support provided to regulatory program areas within agreed timeframes.</p> <p>Information provided to external stakeholders in accordance with TGA service charter.</p>	<p>In April 2007, the TGA updated the guidance documents covering its fees and charges arrangements.</p> <p>Reminder notice for the payment of annual charges was posted in June.</p> <p>The 2007-08 fees and charges schedule posted to the TGA website in the last week of June 2007.</p> <p>Support for Regulatory Programs provided as per TGA Website SOPs. The TGA Website is updated with current information as required.</p> <p>Fortnight TGA_Update email Reports provided to external stakeholders via Listserver email.</p> <p>Other sections of the TGA are working towards specialised Listserver email Lists for communicating with specific stakeholders.</p> <p>TGA News published July 2007. Next issue planned for November 2007.</p> <p>Over 2166 Email and 1074 phone enquiries were responded to and more than 4020 publications (in 4 sets) were provided to external stakeholders.</p>
Provide online business services to external stakeholders	2.3	Target availability of 97% or better over each monthly period on a 24 hour basis (applies to TGA owned or leased equipment).	Target achieved.
Continuously improve efficiency of online services	3.1	Increased user satisfaction and a decrease in central and business help desk support calls.	Improved information published on the web forms has led to overall reduction in calls to online services help desk for assistance.
Provide education for new online lodgement systems	1.1	Adequate training programs conducted to educate stakeholders in the new online lodgement systems.	Course content developed. Options for delivery of training under development.

## Major Projects

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
Establish the regulatory framework for the ANZTPA, including the Australian implementing legislation and the Ministerial Council Rules	2.1, 2.2,2.3	Regulatory framework in place for the commencement of the ANZTPA.	<p>The Exposure draft of the Australian Therapeutic Products Bill was released for stakeholder consultation on 2 April 2007.</p> <p>Further progress was also made this quarter on the finalisation of the Ministerial Council Rules and the preparation of technical Orders.</p> <p>At the end of June 07, the regulatory framework was on-track for the establishment of ANZTPA.</p>
Undertake a program of stakeholder consultation to inform the development of the joint regulatory scheme for the ANZTPA	1.1	Stakeholder consultation undertaken in accordance with the principles of the DoHA Stakeholder Engagement Charter.	Phase 3 of the stakeholder consultation programme commenced in April 2007 with the release of a number of draft Orders. Other key Phase 3 documents released for stakeholder feedback include the IVD components of the Medical Devices rule and a consultation paper on HCTs. In support of these consultation documents, stakeholder workshops on IVDs and HCTs were held in Australia and New Zealand during May 2007.
Finalise cost recovery framework for the joint regulatory scheme	3.1,3.3	<p>Consult on proposed Ministerial Council Rules for fees and charges.</p> <p>Fees and charges schedule available on the website four months prior to commencement of the joint regulatory scheme.</p>	An exposure draft of the Therapeutic Products Charges Act has been finalised. Drafting of the Fees and Charges Administration Rule was also nearing completion.
Establish the business infrastructure for the ANZTPA	3.1	Corporate services (including financial management, human resources management, legal services, records management, parliamentary support and communications) and appropriate IT systems in place for commencement of the ANZTPA.	<p>Services separation from the department is continuing across most corporate service areas.</p> <p>On target</p>
Develop and implement a full human resources service delivery model,	3.1,4.1, 4.2,4.3,	In place for commencement of the ANZTPA.	A replacement human resource management system was implemented in previous quarter.

<i>Description</i>	<i>KRAs</i>	<i>Performance Measure</i>	<i>Progress to 30 June 2007</i>
including a Human Resources Management Information System	4.4		
Develop and implement ANZTPA website	1.1	Website in place for commencement of the ANZTPA.	Development of the ANZTPA website ongoing.