



TGA STRATEGIC STATEMENT 2012-2015

The TGA safeguards and enhances the health of the Australian community through the effective and timely administration of the *Therapeutic Goods Act 1989*.

Working with our stakeholders we fulfil this mandate and meet the challenges of protecting public health in Australia through a robust regulatory framework that provides for reliability in regulatory decision making and effectiveness in monitoring ongoing safety of products on the market.

Strategic Direction

To maintain the community's trust in the safety and quality of therapeutic goods, the TGA aims to consistently deliver scientific, clinical and regulatory excellence. We strive to be:

- **Transparent** by clearly communicating our risk management approach to regulation and decision making processes and by supporting decisions with evidence.
- **Visible** through helping consumers and the community to better understand the role of the TGA.
- **Empowering** through assisting stakeholders in accessing relevant, meaningful and reliable information.
- **Consistent** through an equitable and reliable approach to risk management and decision making.
- **Effective** by taking appropriate and timely action in relation to regulatory decisions.
- **Efficient** by continually improving quality and productivity in the delivery of all our functions.
- **Influential** through having a strong role in informing scientific and clinical debate to support the safe and effective use of therapeutic products.
- **Responsive** to emerging local and global regulatory issues affecting the Government and the community.

Priorities

TGA's priorities have been developed in the context of Health and Ageing Portfolio Budget Statements and the Department's corporate plan and related strategies. The TGA's priorities are to:

- Regulate therapeutic goods for safety, effectiveness and quality.
- Implement the TGA Reform Blueprint.
- Establish the Australia New Zealand Therapeutic Products Agency (ANZTPA).

Key Strategies

In implementing and balancing our efforts across our priorities the TGA will focus on the following key strategies:

Refining our Regulation

- Maintaining an effective regulatory framework which aligns with international best practice.
- Redeveloping key guidance documents and providing better information about regulatory decisions and processes.

Engaging with our Stakeholders

- Developing and enhancing relationships with consumers, healthcare professionals, industry and other regulatory agencies.
- Enhancing international regulatory cooperation through better exchange of information, work sharing and capacity building.

Managing Key Relationships

- Promoting and enhancing collaborative and cooperative relationships with other parts of the Department.
- Proactive monitoring and management of emerging issues and enhanced relationships with the Secretary and with the Parliamentary Secretary and Minister (where appropriate).

Enhancing our Business Capability

- Implementing cohesive policies, management and processes that:
 - utilise the highest quality scientific and clinical methods, governance and management skills, and
 - integrate across our organisational groups.
- Maintaining a robust risk management approach to all strategic and key operational risks.
- Maintaining sound financial performance.
- Investing in emerging technology to improve our capability.

Delivering through our People

- Maintaining a capable workforce.
- Implementing human resource management policies, procedures and systems that promote the *APS Code of Conduct*, support the reform agenda of the Australian Public Service and the Department's People Strategy 2010-2015 that provides for effective performance and continuous learning.

Indicators of Performance

Measurement of performance will include the monitoring of:

- Meeting milestone delivery targets and target dates for "Blueprint for TGA's future", including ANZTPA joint agency projects.
- Evidence from Section 60 reviews, Administrative Appeals Tribunal decisions, audits and legal advice that risks are managed well in decision making.
- Compliance with statutory reporting obligations and government accountability frameworks.
- High stakeholder satisfaction and participation with our consultative processes.
- International co-operation demonstrated to enhance regulatory harmonisation and improve capacity of TGA staff.
- Non-compliance and safety issues identified by TGA at an early stage and appropriate, effective responses implemented.
- Improved community and industry understanding of TGA's regulatory role through close management of media issues and public awareness.
- Business operations are consistent and meet agreed service/timeliness standards.
- Financial performance aligns with financial targets.
- Indicators of organisational health including low staff absenteeism, attraction and retention of staff in critical areas, evidence that performance management enhances individual development and contribution to TGA outcomes.
- Adherence to timeliness and performance commitments made under the TGA customer service standards.

Risk Mitigation

The TGA will focus on:

- Reliability and consistency in regulatory decision making and effective monitoring of the safety of products on the market.
- Meeting our key stakeholder expectations to foster community confidence.
- Maintaining alignment with relevant legislation of our processes, regulatory practices and guidance documents.
- Retaining and recruiting capable staff.
- Improving our systems and processes to build and maintain corporate memory.
- Effectively preparing for the implementation of ANZTPA.