



## Attachment 1: 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, quality and efficacy/performance 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 informing scientific and clinical debate to support the safe and effective use of therapeutic goods.
- **Responsive** to emerging local and global regulatory issues.

### Priorities

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

- continue to regulate therapeutic goods for safety, effectiveness/performance and quality.
- pursue international regulatory convergence and work sharing.
- continue a program of quality improvement in regulatory processes and reform in key areas, according to government priorities.

### 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 that is contemporary with international best practice.
- Redeveloping major industry guidance documents and providing more information—in a simple to access style—about regulatory decisions and processes.

#### Engaging with our Stakeholders

- Developing, enhancing and maintaining relationships with consumers and health professionals and maintaining appropriate relationships with industry.
- Enhancing international regulatory cooperation through better exchange of information, work sharing and capacity building.
- Minimise duplication of effort through stronger collaboration with overseas regulators and assessment bodies.

#### Managing Key Relationships

- Promoting and enhancing collaborative and cooperative relationships with the rest of the Department of Health.
- Proactive monitoring and management of emerging issues and strong communication with the Assistant Minister and Minister.

#### 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.
- Manage major strategic, financial and operational risks.
- Improve business processes and systems to improve client services.
- Contribute to the Government's deregulation and red tape reduction agenda by identifying and progressing opportunities to better regulate according to product risk.

#### Delivering through our People

- Maintaining a capable workforce that adapts flexibly to changes introduced through regulatory reform, deregulation initiatives and other priorities of government.
- Maintaining effective levels of performance and provide for continuous learning to improve our capability.
- 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.

### Indicators of Performance

Measurement of performance will include the monitoring and reporting of:

- Improved community and industry understanding of TGA's regulatory role and decision-making.
- High stakeholder satisfaction and participation with our consultative processes.
- Adherence to timeliness and performance commitments made under the TGA customer service standards.
- Pre- and postmarket business operations are consistent and meet agreed service/timeliness standards.
- Non-compliance and safety issues identified by TGA at an early stage and appropriate, effective responses implemented.
- Indicators of organisational health including attraction, development and retention of staff who can respond appropriately to both current and emerging regulatory needs.
- Financial performance aligns with financial targets.
- Compliance with statutory reporting obligations and government accountability frameworks.
- International co-operation demonstrated to enhance regulatory harmonisation and improve TGA efficiency
- Evidence from internal reviews and Administrative Appeals Tribunal decisions that TGA is regulating consistently with the legislation.

### 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 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 continuing the therapeutic goods reform process.