Australian Government

Department of Health and Ageing

Therapeutic Goods Administration

CANDIDATE INFORMATION

NATIONAL MANAGER

Therapeutic Goods Administration

(SES Band 3)

January 2012

[redacted]

Executive Search

THERAPEUTIC GOODS ADMINISTRATION

1. Background

The Therapeutic Goods Administration, which is a business unit of the Department of Health and Ageing, is responsible for regulating prescription, over-the-counter and complementary medicines, medical devices and manufacturers of therapeutic goods. It also monitors incidents once products are on the market, and assesses the suitability of medicines and medical devices for export from Australia. It does this through the application of the *Therapeutic Goods Act 1989* (the Act). The Act provides a national framework for the regulation of therapeutic goods in Australia and outlines a risk based regulatory framework for therapeutic goods where the level of regulation reflects the assessed risk of the therapeutic good. Products on the market in Australia are required to be manufactured to an appropriate quality, and must be safe to use as intended.

Essentially, the Act requires any product for which therapeutic claims are made to be included in the Australian Register of Therapeutic Goods (ARTG) before it can be supplied in Australia. To include a therapeutic product on the ARTG, a supplier needs to apply to the TGA including the required safety and efficacy information. The TGA will review the application, with input from external experts if necessary, and then make a market authorisation decision as to whether or not to allow the product to be marketed. The TGA then engages in ongoing post-marketing surveillance, inspection and investigation.

Higher risk products must demonstrate that they are effective in treating the conditions for which they are approved; low risk products need only demonstrate that they are of an acceptable quality and that they do not present significant safety risks.

The TGA carries out its regulatory activities consistent with the objectives of the Act and 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.

In administering the Act, the TGA fosters relationships with other governments and government agencies, health professionals, consumers and the therapeutic goods industry.

The TGA has over 500 staff, with a diverse workforce including medical practitioners, scientists, chemists, laboratory technicians, compliance auditors and investigators, accountants, and lawyers, amongst a range of other roles.

The TGA aims to attract and retain skilled staff and supports a culture of high performance, continuous learning, and scientific excellence through a focus on:

- effective leadership and management;
- a shared commitment to protecting the community; and
- being an employer of choice.

2. Mission

To safeguard public health in Australia through administration of a national framework for the regulation of therapeutic products, which is consistent with international best practice and ensures the timely availability of therapeutic products in Australia that are of good quality and safe for their intended purpose.

3. Vision

To be recognised nationally and internationally as a best practice regulator of therapeutic products with the confidence and respect of governments, the community and the regulated industry.

4. Overview of Reforms within the TGA

The TGA commenced major internal reform in 2009-10 aimed at ensuring that it can meet the expectations of the Australian community and deliver most effectively the functions required of it by the Australian Government.

In July 2010, the TGA implemented new structural arrangements to separate its regulatory functions into two groups: the *Market Authorisation Group* (MAG), which manages the pre-market assessment and authorisation of therapeutic products, and the *Monitoring and Compliance Group* (MCG), which monitors post-market performance of therapeutic products. These regulatory activities are supported by the *Regulatory Support Group* (RSG) which is the TGA in-house regulatory support and corporate business unit.

This was the first major organisational restructure within the TGA since 1989 and will continue to facilitate the achievement of the key priorities outlined below. In 2011-12, the TGA will undertake additional reforms, such as implementing the outcomes of the reviews of:

- transparency;

- advertising;
- medical device regulation; and
- complementary medicine regulation.

In addition, the TGA will progress closer business to business regulatory arrangements with the New Zealand regulator, Medsafe.

5. Key Priorities

The TGA's key priorities have been developed in response to emerging expectations of the role of therapeutic goods regulation around the world, mindful of the needs of the Australian health system and community in the 21st century.

The TGA's six key priorities are:

1. *Increase the Australian community's understanding of our regulatory processes and decisions so as to enhance the public trust in the safety and quality of therapeutic goods.*
2. *Take action to ensure that the objectives of the Therapeutic Goods Act continue to be met through an effective regulatory framework.*
3. *Ensure the robustness and consistency of regulatory decision-making and record keeping across the organisation.*
4. *Advance the application of regulatory science to ensure it is capable of meeting the challenges of new product development, emerging safety issues and changing community needs and expectations.*
5. *Enhance our business processes to achieve greater efficiency and predictability for handling applications for market authorisation in order to ensure timely access to therapeutic goods for the community.*
6. *Ensure that the application of our resources matches the level of risk associated with both the type of products regulated and the regulatory risk associated with our pre and post-market oversight of those products.*

Each priority is underpinned by strategies, TGA projects and activities that support the organisation's ongoing regulatory activities.

6. TGA Organisational Structure

The TGA regulatory offices consist of three core groups:

1. The **Market Authorisation Group** is responsible for the evaluation and authorisation of therapeutic goods to ensure they meet appropriate standards of quality, safety and efficacy or performance, consistent with their risk.

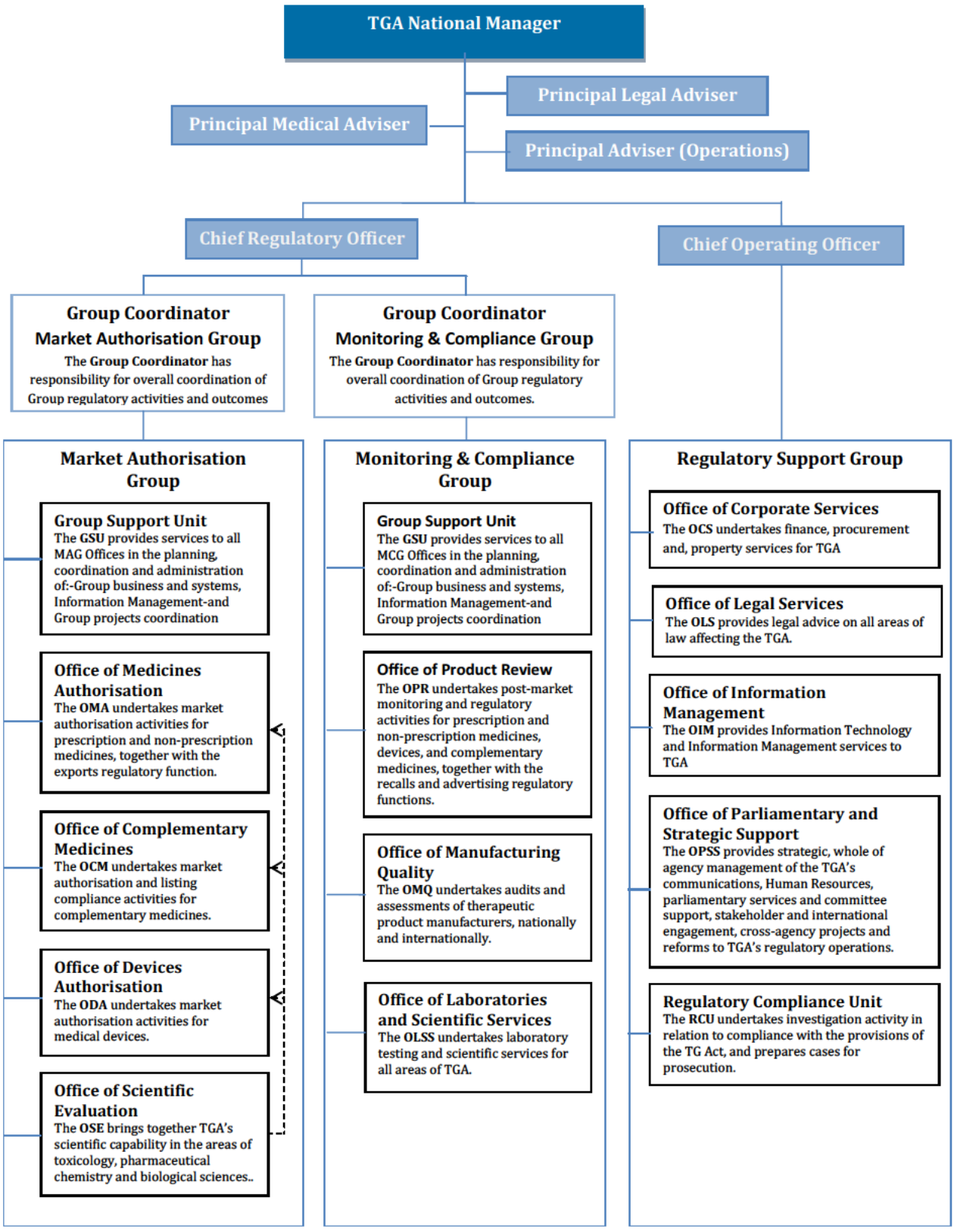
2. The **Monitoring and Compliance Group** is responsible for monitoring of therapeutic goods on the Australian market to ensure that they comply with required standards of quality, safety, efficacy and performance.

3. The **Regulatory Support Group** provides the business systems and support services that enable the TGA to undertake its regulatory responsibilities.

An organisation chart that details the offices within these groups follows.

For further information please visit the TGA website: http://www.tga.gov.au

THERAPEUTIC GOODS ADMINISTRATION



THE POSITION AND THE PERSON

Title: National Manager

Reports to: Secretary, Department of Health and Ageing

Location: Canberra

1. Position Overview

As National Manager of the TGA, you will report to the Secretary of the Department of Health and Ageing and assume overall responsibility for the leadership, strategic direction and governance of this high profile federal government agency with more than 600 people and $100m plus annual cost recovery-funded budget. You will oversee implementation of recently announced *TGA reforms: A blueprint for TGA's future*, and ensure the TGA enhances current policies and processes to continue to adapt with flexibility and agility to new scientific developments and emerging community expectations. You will also play a key role in the creation of an Australia-New Zealand international regulatory agency which involves significant senior national and international engagement.

2. Relevant Experience

To be a strong contender, you will need to be an outstanding leader and manager with well-honed policy advisory and resource management skills and a proven record of achievement as a senior executive, ideally gained in a large, complex and operationally diverse health care, regulatory or other professional organisation. You will have exceptional communication and representational skills, proven capacity to drive change, and a demonstrated ability to engage senior stakeholders and broker decisions through collaboration.

3. Managerial and Personal Attributes

The appointee will be expected to:

- Possess a high level of professional and personal integrity.
- Demonstrate sound judgement and a balanced and professional approach when providing strategic policy advice.
- Have well developed presentation and representational skills and the ability to communicate effectively with both lay and professional audiences.

- Be articulate and persuasive and capable of guiding negotiations to a point of resolution in a facilitative way.
- Be capable of engendering loyalty and respect and generating a high level of commitment from staff within the TGA.
- Have the drive, energy and enthusiasm necessary to make a major contribution within the Heath and Ageing portfolio.

4. Qualifications

Appropriate tertiary qualifications will be well regarded.

SELECTION CRITERIA

The criteria below are applied when selecting for Senior Executive Service (SES) positions within the Australia Public Service (APS). When considering applicants, Selection Advisory Panels will seek evidence of performance against each of the criteria. SES selection panels may use a range of methods to identify work outcomes, capabilities and behaviours that demonstrate performance. It is therefore in the interests of candidates to present their application in a way that demonstrates significant outcomes associated with each of the criteria, as well as the capabilities and behaviours that underpin them. (Please note that it is not necessary to address the capabilities and behaviours individually.)

1 Shape Strategic Thinking

Relevant capabilities and behaviours:

- inspires a sense of purpose and direction
- strategic focus
- ability to recognise opportunities, harness information
- shows judgement, intelligence and common sense

2 Achieve Results

Relevant capabilities and behaviours:

- organisational capability
- professional expertise
- implements change
- ability to clarify ambiguities
- closure and delivery

3 Exemplify Personal Drive and Integrity

Relevant capabilities and behaviours:

- professionalism and probity
- risk-taking and personal courage
- action orientation
- resilience
- self awareness
- commitment to personal development

4 Cultivate Productive Working Relationships

Relevant capabilities and behaviours:

- nurtures internal and external relationships

SELECTION CRITERIA

- facilitates co-operation and partnerships
- values differences and diversity
- guides, mentors and develops people

5 Communicate with Influence

Relevant capabilities and behaviours:

- communicates clearly
- listens, understands and adapts to different audiences
- negotiates persuasively

REMUNERATION, TENURE AND CONDITIONS

1. Remuneration

A senior executive package which reflects the importance of the position will be negotiated with the successful candidate, comprising:

- salary and performance bonus;
- superannuation;
- an executive vehicle cash-out allowance; and
- non-cash benefits (which could include parking, airport lounge membership, laptop and mobile phone).

2. Tenure

The successful candidate will be offered ongoing employment.

3. Eligibility

To be employed by the Department of Health and Ageing applicants **must** be Australian citizens or have permanent residency status pending the granting of Australian citizenship.

This is a position of trust and the successful candidate will be subject to a security clearance.

HOW TO APPLY

Applications should consist of:

1. a brief covering letter;
2. details of relevant skills, knowledge and experience in terms of the selection criteria; and
3. a Curriculum Vitae setting out relevant personal particulars, employment history, qualifications and experience.

The preferred method of submission of applications is by email in **Word format** to:

[redacted]

Please note:

It is our standard practice to acknowledge the receipt of all applications. All applications are acknowledged by return email asap (usually within a few minutes on a weekday).

Applicants who do not have access to email should forward their applications to:

[redacted]
PO Box [redacted]
[redacted]

If further information is required, please call [redacted] on [redacted]

Applications close on 13 February 2012