




Australian Government

Department of Health
Therapeutic Goods Administration

CANDIDATE INFORMATION

First Assistant Secretary
Medicines Regulation Division
(SES Band 2)
Ref. No. 843

FAS, MEDICINES REGULATION DIVISION

Job Overview	
Position Number	Job Ref No 843
Classification Level	SES Band 2
Job Family	Organisational Leadership
Job Function	Management & Planning
Job Role	Generalist Management
Group	Health Products Regulation Group
Location	Symonston, ACT
Security clearance requirements	Yes
Probation period	6 months (on engagement to the Australian Public Service)
Mandatory qualifications	Yes
Desirable qualifications/experience	Yes
Type of employment:	Fulltime; Ongoing
Contact officer for more information	

Job Requirements	
Overview	<p>The Health Products Regulation Group (HPRG) comprises two regulators - the Therapeutic Goods Administration (TGA) and the Office of Drug Control (ODC). It is part of Australian Government Department of Health.</p> <p>The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure the benefits to consumers outweigh any risks associated with the use of therapeutic goods (including medicines, medical devices and biologicals).</p> <p>The TGA applies a risk management approach designed to ensure that therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy.</p>
Responsibilities of Work Area	<p>The Medicines Regulation Division is one of HPRG's four Divisions and is responsible for the evaluation, market authorisation and regulation of the safety of prescription, over-the-counter and complementary medicines, cells, tissues, blood and blood products to ensure that they meet appropriate standards of quality, safety and efficacy or</p>

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	<p>performance, consistent with their risk.</p> <p>The First Assistant Secretary (FAS) is the head of the Division and has responsibility for overall coordination of regulatory activities including consistent, high quality regulatory work-flows and outcomes, as well as driving the implementation of a range of major reform projects.</p> <p>The FAS, Medicines Regulation Division is one of 6 senior executives who form the Group Executive. The others are:</p> <ul style="list-style-type: none"> • Deputy Secretary, Health Products Regulation • Chief Medical Adviser • Principal Policy and Legal Adviser • FAS, Medical Devices and Product Quality • FAS, Regulatory Practice and Support <p>In September 2016 the Government announced its response to the Expert Panel Review of Medicines and Medical Devices Regulation. The response involved the most significant set of reforms to the medicines regulatory system in Australia in 30 years. In addition, other reforms to cell and tissue regulation, biosimilar and generic medicine regulation, medicines labelling and management of medicines shortages have recently been implemented or are planned. With the legislation and regulations enabling many of the reforms now in place, the task over the next few years is to implement the reforms to best address the needs of patients, health care providers and industry.</p> <p>The appointee will be part of the Group and Department's leadership cohort and will need to develop familiarity with the regulatory functions of the Group and priorities and programs of the broader Department.</p> <p>You will provide advice and assistance to the Deputy Secretary, Secretary and Minister for Health in setting the strategic direction for the TGA and the management of TGA's overall performance within the Department of Health. You will provide high quality input to the development and/or review of regulatory practices, providing strategic and operational cohesion between individual projects and programs to promote a consistent approach. You will be comfortable from a technical and management perspective in leading multidisciplinary teams comprising large numbers of professionally trained (science, medical) staff.</p>
	<p>The Division Head will provide strategic guidance, leadership and</p>

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<p>Job Responsibilities / Duties</p>	<p>direction for the development, delivery and monitoring of the activities of the Medicines Regulation Division and ensure that they are consistent with the strategic directions of the Department and Government policy. This will include implementing strategies that ensure procedural requirements are met and decision making is consistent with relevant legislation.</p> <p>Representing the TGA and the broader Department in senior level discussions with industry, Government and other relevant parties both nationally and internationally.</p> <p>There are four direct Branch Head reports, and a total staffing within the Medicines Authorisation Division Group of about 280. The Branches include:</p> <ul style="list-style-type: none"> • Complementary and OTC Medicines – Responsible for regulating over the counter medicines as well as complementary medicines, which include traditional and herbal medicines, and vitamin and mineral supplements. • Prescription Medicines Authorisation – evaluation of prescription medicines for access to the Australian market. • Scientific Evaluation Branch - Responsible for approving applications to market biologicals and generic medicines in Australia. The Branch also provides scientific advice to support the decisions made across TGA, in particular evaluating the toxicological and pharmaceutical chemistry aspects of therapeutic products and provide expertise in the biological sciences. • Pharmacovigilance and Special Access - Oversight of medicines and vaccines to ensure they maintain an appropriate level of quality, safety and efficacy following entry into the Australian marketplace. The branch also evaluates and authorises certain clinical trials and special access arrangements for all types of therapeutic products.
<p>Job Specific Requirements</p>	<p>The appointee will have:</p> <ul style="list-style-type: none"> • Proven ability to lead professionals in a diverse scientific/regulatory based organisation. • Experience in leading and implementing major organisational change. • The capacity to plan and direct activities to ensure the standards of regulatory schemes and other statutory functions

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	<p>are maintained.</p> <ul style="list-style-type: none"> • A solid knowledge of medicines science and the ability to develop an understanding of regulatory requirements. <p>Security Clearance:</p> <p>The successful applicant must be an Australian Citizen as they will be required to obtain security clearance of at least the Negative Vetting 1 level.</p>
<p>Key Skill Areas Required</p>	<p>The position requires significant understanding of pharmaceutical and medical sciences. Understanding and expertise in regulation and/or public sector administration is a significant advantage.</p> <p>The successful applicant will demonstrate experience in a senior management position within a complex organisation.</p>
<p>Key technical / Systems Knowledge</p>	<p>Tertiary qualifications in science, pharmacy or medicine are required, with postgraduate qualifications highly regarded.</p> <p>Professional experience in a scientific or bio-medical area important Experience in a health, regulatory or a technical environment would be an advantage.</p>

Eligibility

To be employed by the Department of Health applicants must be Australian citizens.

Core Selection Criteria

The criteria below are applied when selecting for Senior Executive Service (SES) positions within the Australia Public Service (APS). The Selection Advisory Panel 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. Relevant capabilities are as follows:

Criterion 1: Shapes Strategic Thinking

- Inspires a Sense of Purpose and Direction
- Strategic Focus
- Ability to Recognise Opportunities, Harness Information

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Shows Judgment, Intelligence and Common Sense

Criterion 2: Achieves Results

Organisational Capability
Professional Expertise
Implements Change
Ability to Clarify Ambiguities
Closure and Delivery

Criterion 3: Exemplifies Personal Drive and Integrity

Professionalism and Probity
Risk-taking and Personal Courage
Action Orientation
Resilience
Self Awareness
Commitment to Personal Development

Criterion 4: Cultivates Productive Working Relationships

Nurtures Internal and External Relationships
Facilitates Co-operation and Partnerships
Values Differences and Diversity
Guide, Mentor and Develop People

Criterion 5: Communicates with Influence

Communicates Clearly
Listens, Understands and Adapts to Different Audiences
Negotiates Persuasively

Criterion 6: Professional Capability

This includes professional skills, knowledge and experience that demonstrate the applicant's professional standing and competency.

The criterion is fundamental to this position and will rank highly in consideration of the relative merits of applicants.

HOW TO APPLY

1. Remuneration

A Senior Executive Band 2 level package which reflects the responsibilities of the positions will be negotiated with the successful candidates, 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).

Applications should consist of:

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

SUBMISSION OF APPLICATIONS

Applications should be lodged electronically (**preferably in one-word document**), **quoting in the subject line**

Ref. No. 843 and emailed to:

admin@██████████.com.au

If you do not have internet access or are experiencing any difficulties lodging your application, please contact the Administration Team through ██████████ or admin@██████████.com.au.

All enquiries should be directed to:

██████████

Ph: ██████████