



Australian Government

Department of Health
Therapeutic Goods Administration

CANDIDATE INFORMATION

FIRST ASSISTANT SECRETARY

Medicines Regulation Division

**Department of Health,
Therapeutic Goods
Administration**

August 2021

First Assistant Secretary, Medicines Regulation Division, Therapeutic Goods Administration

Position description

Duties

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.

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).

The TGA applies a risk management approach designed to ensure that therapeutic goods supplied in Australia meet acceptable standards of quality, safety, and efficacy.

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 workflows and outcomes, as well as driving the implementation of a range of major reform projects.

The Division Head will provide strategic guidance, leadership and 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.

Representing the TGA and the broader Department in senior level discussions with industry, Government and other relevant parties both nationally and internationally.

The key responsibilities of the role are:

- Maintaining agility to respond to COVID-19 pandemic-related priorities across government, including working with international regulators to ensure rapid evaluation of treatments and vaccines and a high level of post-market safety monitoring.
- Responding to scientific advancements and emerging technologies to support timely access to new therapeutics, including gene technologies and cell and tissue products
- Reform projects that address important public health challenges issues, for example to address medicine shortages, better clinical trial oversight, regulation of new therapies and repurposing of medicines.
- Participate in digital transformation of TGA's business processes and IT systems
- Working closely with countries in the Indo-Pacific to strengthen their regulatory functions, particular access to medicines and vaccines for COVID-19
- Manage our workforce effectively by implementing strategies that attract and retain high quality, appropriately qualified and diverse staff.
- Create an environment where our staff are engaged and supported to undertake their work including by responding to issues raised in staff surveys.

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.

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.

Relevant Experience

The successful applicant will have had demonstrated experience in a senior management position within a complex organisation, you will be experienced in providing strategic leadership and direction and building the capability of your team and the organisation more broadly.

You will need to be forward thinking, self-motivated, resilient, and adept at building relationships in a large complex and fast-paced environment. Your strong leadership credentials and ability to engender trust and respect will be complemented by sound judgement, a strong focus on results and the ability to resolve complex issues in a public sector context, including by winning support, marshalling resources and leveraging relationships.

The position requires training in and significant understanding of pharmaceutical and medical sciences. Understanding and expertise in regulation and/or public sector administration is a significant advantage.

The successful applicant will have had demonstrated experience in a senior management position within a complex organisation.

Leadership and Personal Attributes

The TGA is seeking leaders with:

- An exceptional results orientation based on leading by example with a resilient and positive approach to issues resolution
- Proven ability to lead legal professionals in a diverse scientific/regulatory based organisation, and to collaborate with others in areas outside their own professional legal training
- A solid knowledge of medicines science and clinical use, together with experience in or the ability to develop an understanding of regulatory requirements.
- A focus on nurturing people and relationships to ensure an inclusive and collaborative approach, where people are challenged and supported to be creative, innovative, and contribute to the best of their ability
- Experience in leading and implementing major organisational change.
- The ability to develop an understanding of regulatory requirements for therapeutic goods.
- The ability to confidently manage and lead in a dynamic environment. This includes the ability to create and unite people behind a strategic vision, astute judgement, political nous, engaging with positively and creatively with risk, and the ability to lead and support people through change
- First class communication and interpersonal skills that build relationships based on understanding, respect, and trust, ensuring Health listens to and learns from stakeholders

- The intelligence, persuasiveness, professionalism, authenticity, and credibility necessary to leverage both formal and informal authority
- Excellent self-awareness and a proactive approach to their own personal and professional development, to the development and of their staff and to building the capability of the organisation.

Qualifications

Tertiary qualifications in medicine and/ or postgraduate qualifications in a relevant science discipline or pharmacy are required.

Professional experience in a medical or biomedical scientific area important Experience in a health, regulatory or a technical environment would be an advantage.

Remuneration

These are critical senior appointments and the remuneration packages will therefore be structured to attract and retain outstanding appointees. The packages will include an attractive base salary, an executive vehicle allowance (cash), non-cash benefits (such as parking, airport lounge membership, learning and development and IT equipment) and employer sponsored superannuation.

Location

The position is based in Symonston, ACT (relocating to Fairbairn ACT in early 2022).

Assistance with Relocation

Assistance with removal expenses and / or short term accommodation assistance may be provided if interstate relocation is involved.

Other Conditions

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

These are positions of trust and successful candidates will be subject to a security clearance.

RecruitAbility

RecruitAbility applies to this vacancy. You will be invited to participate in further assessment activity for the vacancy if you choose to apply under the RecruitAbility scheme; declare you have a disability; and meet the minimum requirements for the job. For more information see: www.apsc.gov.au/priorities/disability/recruitability.

The Department

Background

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, vaccines, cells, tissues, blood and blood products to ensure that they meet appropriate standards of quality, safety and efficacy or performance, consistent with their risk. It has a critical role in Australia's health system, emphasised through its role in approvals and safety monitoring of medicines and vaccine for COVID-19 during the current pandemic.

The FAS, Medicines Regulation Division is one of 5 senior executives who form the Group Executive. The others are:

- Deputy Secretary, Health Products Regulation
- Principal Policy and Legal Adviser
- FAS, Medical Devices and Product Quality
- FAS, Regulatory Practice and Support

The Department's Behaviours in Action

To achieve the Department's vision, the Executive fosters a culture where all staff:

- Collaborate to innovate – work with others to make a difference
- Invest in high performance – nurture talent and builds capability in others
- Trust and empower – build trust to exercise responsibility
- Listen and appreciate – listen with intent and value contributions
- Walk the talk – lead by example and embrace change

Further information about the Department can be found at: <https://www.health.gov.au/about-us>

APS Values

Every person in the Department is expected to uphold the Australian Public Service (APS) Values of being:

- Impartial – The APS is apolitical and provides the Government with advice that is frank, honest, timely and based on the best available evidence
- Committed to service – The APS is professional, objective, innovative and efficient, and works collaboratively to achieve the best results for the Australian community and the Government
- Accountable – The APS is open and accountable to the Australian community under the law and within the framework of Ministerial responsibility
- Respectful – The APS respects all people, including their rights and their heritage
- Ethical – The APS demonstrates leadership, is trustworthy, and acts with integrity in all that it does.

Preparing your application and how to apply

Your application should include a CV, covering letter and a response of no more than **one page**, to the following selection criteria.

In preparing your response, it is in the interest of candidates to present their application in a way that demonstrates significant outcomes associated with each of the following 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).

[Insert how to apply and EIG contact information here]

1. Achieves Sustained Results

Relevant capabilities and behaviours:

- organisational capability
- professional expertise

- implements change
- ability to clarify ambiguities
- closure and delivery

2. Cultivates productive working relationships

Relevant capabilities and behaviours:

- nurtures internal and external relationships
- facilitates co-operation and partnerships
- values differences and diversity
- guides, mentors, and develops people

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. Communicates with influence

Relevant capabilities and behaviours:

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

5. Shapes 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

6. Professional Capability

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