

Position Description

Position Title	Advisor (Science)			
Team	Medicines Assessment, Product Regulation Branch, Medsafe			
Business Unit	Protection, Regulation and Assurance			
Location	Wellington			
Work Role Group	Technical Specialist	Job Band	16	
Delegated Authority	HR	Nil	Finance	Nil

The Ministry of Health is the Government's principal advisor on health and disability policy. Our job is to protect the health of New Zealanders and, through leadership of the health and disability system, and help New Zealanders to live longer, healthier and more independent lives. We work with health and disability providers and manage a programme of work that supports the Government's priorities.

Business Unit description

The Protection, Regulation and Assurance business unit ensures the quality and safety of health and disability services, protects and promotes the health of New Zealanders and provides assurance and enforcement for both regulatory and contract compliance.

The business unit works closely with the Service Commissioning business unit and district health boards to ensure service quality is a high standard.

Group / team description

Medsafe, a business unit within the Ministry of Health, is the New Zealand Medicines and Medical Devices Safety Authority. Medsafe is responsible for the regulation of therapeutic products in New Zealand.

Medsafe is made up of several Branches and Teams. This position is within one of two Medicines Assessment teams in the Product Regulation Branch. The position reports to the Team Leader and is responsible for work within either Team and may be rotated to other teams within the Product Regulation Branch.

These teams are semi-autonomous within Medsafe, consisting of scientists and pharmacists responsible for the assessment of the safety, quality and efficacy of medicine applications submitted for Ministerial consent to distribute.

Position purpose

The role of the Advisor (Science), Medicines Assessment is to provide technical advice in relation to the regulation of Medicines, with particular emphasis on quality, safety and efficacy issues.

Key accountabilities and performance expectations include but are not limited to:

Key accountabilities	Performance expectations
Specialist advice about the safety, quality and efficacy of new and changed medicines	<ul style="list-style-type: none">• Provide advice on the assessment of new and changed medicines against New Zealand and International Guidelines• Draw on information, research and analysis from all relevant sources for the preparation of advice• Give advice that is consistently evidence based• Write complex advice clearly, succinctly and appropriately for the audience (includes the public, health professionals and ministerial advisory committees)• Apply principle and practice of risk assessment and measurement

Key accountabilities	Performance expectations
Business Unit and Team	<ul style="list-style-type: none"> • Develop and maintain effective working links with other advisors within Medsafe • Provide input, feedback and peer review to the work of other advisors in a consistent and timely manner • Develop strong working relationships with other business unit staff and managers • Participate as a team player and encourage collaboration • Ensure policies and processes are undertaken in accordance with Medsafe's Quality System • Respond to Official Information Act requests in accordance with legislation
Relationship Management	<ul style="list-style-type: none"> • Initiate, develop and maintain effective working relationships with key stakeholders
Specific projects	<ul style="list-style-type: none"> • Participate in Product Regulation related projects
Health and Safety	<p>Take responsibility for meeting the Ministry's obligations in workplace health and safety (H&S) by:</p> <ul style="list-style-type: none"> • observing the Ministry's H&S procedures • participating in health and safety initiatives and training where appropriate • providing suggestions for improvement of health and safety • reporting all accidents/incidents, near misses, and symptoms of discomfort • identifying and reporting workplace hazards

Key relationships

All Ministry employees have a responsibility for managing relationships in some or all of the key sectors we work with. In this role, the key relationships to be developed are as follows:

Reports to:	Medicines Assessment Team Leader
Responsible for:	No staff
Internal Ministry relationships:	Managers and Advisors of Medsafe Ministry of Health management and staff
Public sector:	Ministries and Government agencies with regulatory responsibilities PHARMAC
Health and disability sector:	Health Professionals and their associations Technical Advisory Committees established under the Medicines Act Pharmaceutical Industry
Communities and the public:	Consumers International regulatory agencies, eg, the Australian Therapeutic Goods Administration

Core Ministry behaviours

Client focused	Identifies the client, builds and maintains strong relationships; listens and learns about who they are. Is responsive and open to feedback; is dedicated to exceeding expectations and requirements of both internal and external clients. Anticipates client needs; makes decisions and takes action collaboratively gaining and maintaining trust and respect.
Responsiveness to Māori	Understands the role of the Ministry and health and disability sector in achieving equity and improving Māori health outcomes. Demonstrates how to implement this in terms of system change, policy development and processes, and in service design and delivery. Demonstrates an understanding of Te Tiriti o Waitangi and whānau, hapū, iwi needs, engagement and context.
Values diversity	Recognises that all perspectives and experiences make us better at what we do and encourages this value. Supports the Ministry in reducing barriers and drawing on the capabilities and insights of others. Supports an inclusive work environment.
Actively collaborates	Works effectively and cooperatively with others. Establishes and maintains good working relationships by relating well with all people inside and outside of the Ministry; builds networks and partnerships that contribute to common goals. Uses active listening, diplomacy and tact to build agreements. Supports seeking mutually beneficial solutions where feasible.
Instils trust and confidence	Gains the confidence and trust of others through honesty, integrity and authenticity. Treats others with dignity and respect. Maintains composure under pressure; is open and transparent about goals and motivation; and seeks to bring out the best in others.
Cultivates innovation	Creates new and better ways to succeed by improving performance, adapting to change and making use of technologies. Seeks win-win solutions by challenging the current ways of working, examining processes and systems to achieve high-quality outcomes. Takes appropriate risks and learns from previous experiences.
Drives results	Is proactive and works to improve outcomes while considering short-term and long-term priorities. Changes direction when appropriate. Aligns support for positive outcomes; explored new opportunities and ensures appropriate measurement processes are used and communicated. Acts in a way that supports others to achieve results.
Makes informed decisions	Prioritises work. Makes decisions using judgement, wisdom, experience and analytics to weigh the options and facts. Seeks out all relevant information and best available evidence, challenges assumptions. Uses proven methods to manage uncertainty; moves forward even with incomplete information and tight deadlines. Sees the impact and implications of decisions; shows courage to change direction when necessary.

Role specific / technical capabilities

Technical capabilities specific for this role:

Technical and functional expertise	Has the functional and technical knowledge and skills to do the job at a high level of accomplishment. Maintains and demonstrates a superior knowledge of risk assessment, risk management and technical expertise with respect to the regulation of new and changed medicines.
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Key Selection Criteria

Your application documentation should address the key selection criteria developed for this role. To be considered for the role you need to demonstrate:

Essential experience, skills and qualities

- A tertiary qualification in a relevant field, including pharmacology, biomedical science, biochemistry or other science with an emphasis on medicines
- Technical knowledge of and familiarity with the manufacture, testing and quality control of medicines
- An excellent team player with the ability to engage with others
- Excellent written and oral communication skills
- The ability to manage relationships at all levels
- The ability to analyse complex technical information to provide advice to a wide range of audiences
- The ability to pull together clear ideas and conclusions from large amounts of technical data
- The ability to manage your own workload
- Computer savvy.

Desirable experience, skills and qualities

- A sound understanding of the assessment of bioequivalence
- Experience working in a biological laboratory setting
- Experience, or interest, in working in a regulatory environment
- Understanding of the machinery of government.