Departmental Disclosure Statement

Medicines Amendment Bill

The departmental disclosure statement for a government Bill seeks to bring together in one place a range of information to support and enhance the Parliamentary and public scrutiny of that Bill.

It identifies:

- the general policy intent of the Bill and other background policy material;
- some of the key quality assurance products and processes used to develop and test the content of the Bill;
- the presence of certain significant powers or features in the Bill that might be of particular Parliamentary or public interest and warrant an explanation.

This disclosure statement was prepared by the Ministry of Health.

The Ministry of Health certifies that, to the best of its knowledge and understanding, the information provided is complete and accurate at the date of finalisation below.

20 March 2025

Contents

Part One: General Policy Statement

The purpose of this Bill is to increase patients' access to medicines. It does this by reducing some of the barriers currently in the Medicines Act 1981.

Verification pathway

The Bill implements one of the agreements in the National–ACT and National–New Zealand First coalition agreements to introduce legislation to provide a streamlined medicines approval process to speed up the public's access to approved medicines. It does this by introducing a verification pathway whereby medicines can be approved for distribution in New Zealand if they have been approved by 2 recognised overseas jurisdictions. This will mean that medicines can be available as approved medicines for New Zealanders more quickly and efficiently.

The detailed requirements of this pathway will be set out in secondary legislation (the **rules**). This is because the technical nature of the requirements means that they may need to be refined in a timely way, for example to reflect changes in international best practice or requirements. The Bill provides for the Minister of Health to be responsible for the rules.

Prescription and administration of medicines

The Bill enables more flexible approaches to prescription and administration of medicines so that patients can get access to the medicines they need more efficiently, supported by the latest science and best practice. In doing so, the Bill makes the best use of our health workforce.

Medicines Classification Committee

The Bill also updates the settings for the Medicines Classification Committee, which has an important role in providing access to medicines. The Bill modernises the membership requirements for the Committee and removes outdated provisions from the Act. This will help ensure those requirements can be responsive to change and is similar to how other committees operate under the Act.

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Part Two: Background Material and Policy Information

Published reviews or evaluations

2.1. Are there any publicly available inquiry, review or evaluation reports that have informed, or are relevant to, the policy to be given effect by this Bill?	**NO**

Relevant international treaties

2.2. Does this Bill seek to give effect to New Zealand action in relation to an international treaty?	**NO**

Regulatory impact analysis

2.3. Were any regulatory impact statements provided to inform the policy decisions that led to this Bill?	**YES**
Regulatory Impact Statement: Proposed verification pathway for medicines approvals Agency: Ministry of Health Date: 30 July 2024 Can be accessed: https://www.health.govt.nz/information-releases	

2.3.1. If so, did the RIA Team in the Treasury provide an independent opinion on the quality of any of these regulatory impact statements?	**NO**
The RIS did not meet the threshold for RIA Team assessment.	

2.3.2. Are there aspects of the policy to be given effect by this Bill that were not addressed by, or that now vary materially from, the policy options analysed in these regulatory impact statements?	**YES**
There are two policy proposals that are amendments to the Medicines Act being implemented by this Bill that were not included in the RIS above, and were not considered to meet the threshold for a RIS themselves. Those two policy proposals are: • The enabling of wider prescribing of unapproved medicines. This includes both enabling nurse practitioners to prescribe unapproved medicines in the way medical practitioners currently can, as well as a narrower policy to enable all authorised prescribers to prescribe unapproved medicines where these are a funded alternative to an approved medicine that is in short supply. • The removal of the detailed criteria for the Medicines Classification Committee so that these can instead be set in the Committee's terms.	

Extent of impact analysis available

2.4. Has further impact analysis become available for any aspects of the policy to be given effect by this Bill?	**NO**

2.5. For the policy to be given effect by this Bill, is there analysis available on:	
(a) the size of the potential costs and benefits?	**NO**
(b) the potential for any group of persons to suffer a substantial unavoidable loss of income or wealth?	**NO**
No group of persons will suffer loss of income or wealth as a result of this Bill	

2.6. For the policy to be given effect by this Bill, are the potential costs or benefits likely to be impacted by:	
(a) the level of effective compliance or non-compliance with applicable obligations or standards?	**NO**
(b) the nature and level of regulator effort put into encouraging or securing compliance?	**NO**

Part Three: Testing of Legislative Content

Consistency with New Zealand's international obligations

3.1. What steps have been taken to determine whether the policy to be given effect by this Bill is consistent with New Zealand's international obligations?
The Ministry of Health consulted with the Ministry of Foreign Affairs and Trade. The Bill is consistent with any relevant international trade agreements.

Consistency with the government's Treaty of Waitangi obligations

3.2. What steps have been taken to determine whether the policy to be given effect by this Bill is consistent with the principles of the Treaty of Waitangi?
Population implications of the policy, including for Māori, were considered during policy development. Population groups that have a greater need for medicines are more affected by any hurdles to access. These groups include older people, Māori and Pacific people (due to higher rates of poor health), disabled people, and people with chronic or rare health conditions.

Consistency with the New Zealand Bill of Rights Act 1990

3.3. Has advice been provided to the Attorney-General on whether any provisions of this Bill appear to limit any of the rights and freedoms affirmed in the New Zealand Bill of Rights Act 1990?	**YES**

Offences, penalties and court jurisdictions

3.4. Does this Bill create, amend, or remove:	
(a) offences or penalties (including infringement offences or penalties and civil pecuniary penalty regimes)?	**NO**
(b) the jurisdiction of a court or tribunal (including rights to judicial review or rights of appeal)?	**NO**

Privacy issues

3.5. Does this Bill create, amend or remove any provisions relating to the collection, storage, access to, correction of, use or disclosure of personal information?	**NO**

External consultation

3.6. Has there been any external consultation on the policy to be given effect by this Bill, or on a draft of this Bill?	**YES**
Medsafe, a business unit of the Ministry of Health, met with industry representatives to help inform policy development for the verification pathway. There was wide support for faster reliance pathways generally. Medsafe will also work with industry on the rules setting out the detailed processes. The Ministry also consulted with relevant stakeholders, including Medsafe and Pharmac, during the development of the policy proposals on the amendments to prescribing of unapproved medicines. Stakeholders were generally supportive of the proposal, but highlighted some risks.	

Other testing of proposals

3.7. Have the policy details to be given effect by this Bill been otherwise tested or assessed in any way to ensure the Bill's provisions are workable and complete?	**YES**
The Ministry has tested the relevant provisions of the Bill with Medsafe and Pharmac, as the organisations that will be implementing the provision of the Bill.	

Part Four: Significant Legislative Features

Compulsory acquisition of private property

4.1. Does this Bill contain any provisions that could result in the compulsory acquisition of private property?	**NO**

Charges in the nature of a tax

4.2. Does this Bill create or amend a power to impose a fee, levy or charge in the nature of a tax?	**NO**

Retrospective effect

4.3. Does this Bill affect rights, freedoms, or impose obligations, retrospectively?	**NO**

Strict liability or reversal of the usual burden of proof for offences

4.4. Does this Bill:	
(a) create or amend a strict or absolute liability offence?	**NO**
(b) reverse or modify the usual burden of proof for an offence or a civil pecuniary penalty proceeding?	**NO**

Civil or criminal immunity

4.5. Does this Bill create or amend a civil or criminal immunity for any person?	**NO**

Significant decision-making powers

4.6. Does this Bill create or amend a decision-making power to make a determination about a person's rights, obligations, or interests protected or recognised by law, and that could have a significant impact on those rights, obligations, or interests?	**NO**

Powers to make delegated legislation

4.7. Does this Bill create or amend a power to make delegated legislation that could amend an Act, define the meaning of a term in an Act, or grant an exemption from an Act or delegated legislation?	**NO**

4.8. Does this Bill create or amend any other powers to make delegated legislation?	**YES**
The Bill creates a power for the Minister of Health to make secondary legislation (rules) setting out the detailed processes for the verification pathway. This is appropriate for the technical nature of the detailed processes, while ensuring certainty for industry. The rules will set out the requirements for applications for the Minister's consent via the verification pathway, and related timeframes including for a decision by the Minister.	

Any other unusual provisions or features

4.9. Does this Bill contain any provisions (other than those noted above) that are unusual or call for special comment?	**NO**