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.

18/05/2021

Contents

Part One: General Policy Statement

The purpose of this Bill is to amend the Medicines Act 1981 (the principal Act) to clarify the appropriate use of provisional consents to sell and use medicines, and ensure that New Zealanders continue to have timely access to safe and effective medicines.

The Bill meets these objectives by amending section 23 of the principal Act to allow the Minister of Health to give provisional consent for a medicine if the Minister is of the opinion that it is desirable that the medicine be sold, supplied or used. The amendment removes the requirement for the sale, supply or use to be for a limited number of patients. This is consistent with the policy intent that New Zealanders have access to safe and effective medicines where there is public health need.

The amendment would enable the Minister to grant provisional consent for medicines where justified, due to an identified public health need and where limited information means that a full consent process (under section 20) is not feasible.

The amendment does not affect existing requirements related to the safety, quality and efficacy of the medicines and an assessment of the therapeutic benefits and risks, as set out under sections 21 and 22 of the principal Act.

The amendment does not affect the ability for conditions to be imposed on the use of the medicine (under section 23(3)(c)), where these are justified and consistent with the Minister's reasons for granting the provisional consent.

Provision is made in new Schedule 1AA for the validation of the provisional consent of the COVID-19 Pfizer vaccine, together with Necon 0.5/35 Tablets; 0.9% Sodium Chloride Injection, Solution for infusion 0.9 %; Panvax vaccine, Suspension for injection 30 mcg/0.5mL Pandemic Influenza vaccine; Brevinor 28 day, Tablet Australian Stock; and H5N1 Influenza Vaccine, Suspension for injection 30 mcg/0.5mL Seqirus.

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**

2.2.1. If so, was a National Interest Analysis report prepared to inform a Parliamentary examination of the proposed New Zealand action in relation to the treaty?	**NO**

Regulatory impact analysis

2.3. Were any regulatory impact statements provided to inform the policy decisions that led to this Bill?	**NO**
Treasury advised that the proposal is exempt from the requirement to provide a Regulatory Impact Statement on the grounds that it has no or only minor impacts on businesses, individuals, and not-for-profit entities.	

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**
N/A	

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?	**NO**

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**

2.6. For the policy to be given effect by this Bill, are the potential costs or benefits likely to be affected 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 Bill does not affect New Zealand's international obligations.

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?
The content of the Bill does not specifically impact rights and interests of Māori protected by the Treaty of Waitangi, and in the case of customary interests, also protected at common law.

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**
The Ministry of Justice will provide advice to the Attorney-General. This is generally expected to be available on the Ministry of Justice's website upon introduction of a Bill. Such advice, or reports, will be accessible on the Ministry's website at http://www.justice.govt.nz/policy/constitutional-law-and-human-rights/human-rights/bill-of-rights/	

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**

3.4.1. Was the Ministry of Justice consulted about these provisions?	**NO**
N/A	

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**

3.5.1. Was the Privacy Commissioner consulted about these provisions?	**NO**

N/A

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?	**NO**
Work to review the Medicines Act has been ongoing for a number of years and is planned to be replaced by a new Therapeutic Products Bill, with a focus on ensuring timely access to safe medicines. Public consultation of the draft Therapeutics Products Bill (December 2018 to April 2019) reflected broad support from across stakeholders for a range of approval pathways that are proportionate to the risks of the products and their use.	

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 proposals have been developed in consultation with the Department of the Prime Minister and Cabinet, Ministry of Justice, Crown Law and the Parliamentary Counsel Office.	

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?	YES
The Bill has retrospective effect and relates to matters that are subject to legal proceedings. On 18 May 2021, the High Court released a judgment commenting on the reference to a "limited number of patients" in s 23(1) and urging the Crown to consider this matter carefully. The Legislation Guidelines note that legislation with retrospective effect needs to be justified as being in the public interest and should impair the rights of litigants no more than is reasonably necessary to serve that interest. They also note that retrospective legislation may be appropriate if it is essential to public safety. The validations proposed are in the public interest because of the need to access medicines subject to a provisional consent and, in the case of the provisional consent granted for the Pfizer COVID-19 vaccine, are essential to public health because of the potential impact on the rollout of the vaccine.	

Strict liability or reversal of the 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?	**NO**

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**