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Hon Andrew Little

Minister of Health
Minister Responsible for the GCSB
Minister Responsible for the NZSIS
Minister for Treaty of Waitangi Negotiations
Minister Responsible for Pike River Re-entry
Lead Coordination Minister for the Government's Response to the Royal Commission's Report into the Terrorist Attack on the Christchurch Mosques

Legislative statement for the Medicines Amendment Bill - First Reading

Presented to the House of Representatives under Standing Order 272

1. The Medicines Amendment Bill (the Bill) amends the Medicines Act 1981 to clarify the use of provisional consents to sell and use medicines in New Zealand and ensure that New Zealanders continue to have timely access to safe and effective medicines through this channel.

2. The Medicines Act (the Act) aims to ensure that medicines and products used in New Zealand meet acceptable standards of safety, quality and efficacy and that the benefits of their use outweigh the risks. It requires all medicines (including vaccines) imported, supplied, sold and administered in New Zealand to be approved, under either section 20 (full consent) or section 23 (provisional consent).

3. The Act is outdated. It is out of step with international regulatory practice, consumer expectations, and has not kept pace with significant technological changes in medicines, advanced therapies and medical devices (e.g. nanotechnologies, gene therapies, insulin pumps). Work is underway to replace the Act with the Therapeutic Products Bill, designed to provide modern, comprehensive regulation of medicine and medical devices, consistent with best practice.

4. This Bill amends the 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. This will help to enable early access to medicines (including vaccines) that meet a significant clinical and/or public health need.

5. 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 should have access to safe and effective medicines where there is public health need, and where the benefits of use are found to outweigh the risks.

6. Provisional consent provided by section 23 is a robust process, which includes an assessment by Medsafe. The consent process typically provides a greater degree of assurance (based on a more detailed assessment of data) than emergency authorisation provisions that are available and applied in other jurisdictions.

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7. 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 Act.

8. 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.

9. Provision is made in new Schedule 1AA for the validation of the provisional consent of:

- Comirnaty (COVID-19 mRNA vaccine) (*Gazette* 2021-go338)
- Necon 0.5/35 (*Gazette* 2020-go2377)
- 0.9% Sodium Chloride Injection (*Gazette* 2020-go3009)
- Panvax vaccine (*Gazette* 2018-go6374)
- Brevinor 28 day (*Gazette* 2020-go1987)
- H5N1 Influenza Vaccine (*Gazette* 2018-go576)