

## Legislative Statement for the Medicines Amendment Bill

### First reading

#### Presented to the House in accordance with Standing Order 272 J.17

#### Overview

The purpose of the Bill is to improve patients' access to medicines. The Bill does this by:

- 1.1 introducing a verification pathway for medicines approval in New Zealand; and
- 1.2 updating prescribing settings to enable wider prescribing of unapproved medicines in appropriate circumstances.

The Bill also makes minor amendments to the settings for the Medicines Classification Committee.

#### Key legislative amendments

##### *Verification pathway for approval of new medicines*

The Bill amends the Medicines Act 1981 to introduce a new verification pathway as an alternative, expedited option for pharmaceutical companies seeking consent to market medicines in New Zealand.

The verification pathway will enable medicines to be approved with minimal Medsafe assessment if the product meets eligibility criteria, including approval from two recognised overseas jurisdictions.

The pathway will provide a shorter, more efficient process for industry to seek approval for their medicines in New Zealand, while ensuring the New Zealand public can continue to have confidence in the medicines they are taking.

##### *Secondary legislation*

The Bill provides for the detailed processes for the verification pathway to be set in secondary legislation (rules) to be made by the Minister of Health, or a delegated authority. This is appropriate for the technical nature of the detailed processes, while ensuring certainty for industry.

##### *Prescribing of unapproved medicines*

Under the Medicines Act, only medical practitioners have the authority to procure unapproved medicines. The Bill enables wider prescribing of unapproved medicines in certain circumstances to improve timeliness of access to medicines and continuity of care for patients.

The Bill amends the Medicines Act to enable:

- a. nurse practitioners to prescribe unapproved medicines where these are appropriate for a patient's care, in the same way that medical practitioners currently can, and
- b. all authorised prescribers to prescribe alternative funded unapproved medicines in the case of a supply shortage of an approved medicine.

All prescribers will continue to be limited to prescribing medicines that are within the prescriber's scope of practice or their profession's specified list of medicines as published in the New Zealand Gazette.

#### *Medicines Classification Committee*

The Medicines Classification Committee has an important role in the access of medicines by classifying medicines (as prescription, pharmacist-only, pharmacy or general sale/unclassified).

Section 9 of the Medicines Act sets out requirements for the Medicines Classification Committee. The Bill updates these requirements in line with other modern membership provisions. For instance, Section 9(3) requires membership from organisations which no longer exist. The Bill repeals this requirement and amends section 9 to provide that membership be made up of suitably qualified people, with a minimum of seven members.

The amended section 9 also provides for the quorum to be half the number of members plus one, and that members can hold office for a term of three years, with possibility for reappointment.