

Legislative Statement for the Medicines Amendment Bill

Second 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 has approval from two recognised overseas jurisdictions.

The pathway will provide a shorter, more efficient process for companies 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. This is appropriate for the technical nature of the detailed processes, while ensuring certainty for industry.

Change made by Health Committee – list of recognised regulatory authorities

The Health Committee made one change to the verification pathway. Clause 7 of the original Bill included a list of “recognised regulatory authorities” whose medicines approvals can be relied on by Medsafe for the purpose of giving marketing consent under the verification pathway.

The Health Committee amended the Bill by removing the list and instead inserting criteria for determining the suitability of recognised regulatory authorities. The five criteria are designed to ensure that the regulators are ones that use international guidelines and standards and can therefore work effectively with Medsafe to produce consistent results.

The recognised regulatory authorities will be notified in the New Zealand Gazette following a decision by the Minister.

This change will ensure the list can be kept up-to-date without needing an amendment bill.

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:

- a. enable nurse practitioners and pharmacist prescribers to prescribe unapproved medicines where these are appropriate for a patient's care, in the same way that medical practitioners currently can. The Health Committee added pharmacist prescribers to this proposal because of their substantial relevant training.
- b. Enable all authorised prescribers to prescribe alternative funded unapproved medicines in the case of a supply shortage of an approved medicine. Currently authorised prescriber groups are: midwives, dentists, optometrist prescribers, nurse prescribers and dietician prescribers (as well as medical practitioners, nurse practitioners and pharmacist prescribers)

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

Medicines Classification Committee

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

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) currently 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 (rounded down to the nearest whole number), and that members can hold office for a term of three years, with possibility for reappointment.