In Confidence

Office of the Associate Minister of Health
Chair, Cabinet Legislation Committee

Medicines (Fees) Amendment Regulations 2026

Proposal

1 This paper seeks authorisation for submission to the Executive Council of the Medicines (Fees) Amendment Regulations 2026.

Policy

2 The Medicines Act 1981 was amended in November 2025 to introduce a new, significantly shorter, verification pathway for medicines to be approved for distribution in New Zealand. If a new medicine has been approved for use by two recognised regulatory authorities overseas, then it can be approved for distribution in New Zealand within 30 working days of being accepted onto the verification pathway.

3 Cabinet agreement on the verification pathway in 2024 included the potential for pre-screening and evaluation fees to be set [SOU-24-MIN-0114]. Setting the fees requires an amendment to the Medicines Regulations 1984.

4 On 13 April 2026, Cabinet agreed to introduce the following fees for the verification pathway into the Medicines Regulations 1984:

4.1 High risk medicine with a new active ingredient: $42,601

4.2 $1,730 for the validation (pre-screening) phase of the verification pathway, to accompany an application to the verification pathway [CBC-26-MIN-0011 refers]

5 In practice, fee waivers will be used to provide for lower fees for some applications:

5.1 High risk medicine other than one with a new active ingredient: $31,951

5.2 Intermediate risk medicine: $21,301.

Timing and 28-day rule

6 The draft Amendment Regulations will comply with the 28-day rule and will come into force on 3 July 2026.

Compliance

7 The regulations comply with:

7.1 the principles of the Treaty of Waitangi;

7.2 advice from the Treaty Provisions Officials Group on any Treaty of Waitangi provisions;

7.3 the rights and freedoms contained in the New Zealand Bill of Rights Act 1990 or the Human Rights Act 1993;

7.4 the principles and guidelines set out in the Privacy Act 2020;

7.5 relevant international standards and obligations;

7.6 the Legislation Guidelines (2021 edition), which are maintained by the Legislation Design and Advisory Committee.

8 The Medicines Act 1981 requires consultation with affected parties before amending the regulations. Medsafe consulted on the fees from 2 to 13 March 2026 with pharmaceutical companies and industry groups and received five submissions. None of the submitters indicated that the fees would be a significant barrier to use of the pathway, and feedback suggested that the reduced timeframes are likely to be the most significant factor to encourage uptake.

Regulations Review Committee

9 There are no grounds for the Regulations Review Committee to draw the draft Amendment Regulations to the attention of the House of Representatives under Standing Orders.

Certification by Parliamentary Counsel

10 The draft Amendment Regulations were certified by the Parliamentary Counsel Office as being in order for submission to Cabinet.

Impact Analysis

11 A Cost Recovery Impact Statement accompanied the policy paper [CBC-26-SUB-0011]. The QA panel considered that the statement met the quality assurance criteria.

Publicity

12 I will make an announcement when the amendments come into effect in July 2026. At the same time, the pathway rules and fees will be published on the Medsafe website, along with Medsafe's guidelines.

Proactive release

13 This paper will be released, with any redactions as appropriate under the Official Information Act 1982, when the verification pathway comes into effect.

Consultation

14 The Department of the Prime Minister and Cabinet, the Ministry of Regulation, Treasury, the Ministry of Foreign Affairs and Trade, the Ministry of Business, Innovation and Employment were consulted on this paper.

Recommendations

I recommend that the Cabinet Legislation Committee:

1 note that in November 2025, the Medicines Act 1981 was amended to introduce the new, streamlined Verification Pathway for New Medicine Applications;

2 note that on 13 April 2026 Cabinet agreed to amend the Medicines Regulations 1984 to provide for:

2.1 a fee of $42,601 for the verification phase, and to accompany an application to the verification pathway; and

2.2 a fee of $1,730 for the validation (pre-screening) phase of the verification pathway, to accompany an application to the verification pathway [CBC-26-MIN-0011 refers]

3 note that the Medicines (Fees) Amendment Regulations 2026 will give effect to the decision referred to in paragraph 2 above;

4 authorise the submission to the Executive Council of the Medicines (Fees) Amendment Regulations 2026;

5 note that the Medicines (Fees) Amendment Regulations 2026 come into force on 3 July 2026.

Authorised for lodgement

Hon David Seymour

Associate Minister of Health