In Confidence

Office of the Associate Minister of Health

Cabinet Business Committee

Fees for the new Verification Pathway for New Medicine Applications

Proposal

1 This paper seeks authorisation to amend the Medicines Regulations 1984 to introduce fees for processing applications through the new, streamlined Verification Pathway for New Medicine Applications.

Relation to government priorities

2 The verification pathway fulfils a commitment in the National-ACT and National-NZ First Coalition Agreements.

Background

3 In November 2025, the Medicines Act 1981 was amended to introduce a new verification pathway for medicines to be approved for distribution in New Zealand. This change means that 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. This is significantly shorter than the current pathways which involve full or partial evaluation by Medsafe.

4 Secondary legislation is needed before the verification pathway can begin operating. Mandatory operational rules are being developed and consulted on. These will be authorised by myself as Associate Minister of Health.

5 The verification pathway policies agreed to by Cabinet in September 2024 included the potential for applicant fees to be set for pre-screening and evaluation [SOU-24-MIN-0114]. Setting fees requires an amendment to the Medicines Regulations 1984.

Medsafe's fees

6 Medsafe is a business unit of the Ministry of Health and is responsible for the regulation of therapeutic products in New Zealand. Medsafe is over 90 percent cost recovered via third-party fees for consents and licensing activities.

7 Fees charged to assess new and changed medicine applications fund both premarket (approval) work, and for post market work such as monitoring medicine safety (including adverse events), quality complaints and recalls.

8 Medsafe's fees are determined using a standard cost model. The aim is to provide for sustainable ongoing management of Medsafe funding. Fees are set in a way that spreads costs fairly, equitably and consistently, in accordance with the Treasury's guidelines for setting charges in the public sector.

9 Under the Medicines Act, fees may be set in the Medicines Regulations 1984 by Order in Council following consultation with persons or bodies representative of those affected. Regulation 61 sets the maximum fees payable. Regulation 61A permits the Director-General of Health to set waivers or refunds for any fee. Then the waivers and actual fees payable are set out in Medsafe's guidelines.

Proposed fees for Verification Pathway

10 The fees for new medicine applications via the verification pathway are proposed to be:

a. High risk medicine with a new active ingredient: $42,601
b. High risk medicine other than above: $31,951 (includes waiver)
c. Intermediate risk medicine: $21,301 (includes waiver)

11 These fees are designed so that they fund the work required for the verification process as well as contribute to the costs of post-market activities. We expect that many medicines approved by the verification pathway will be new to New Zealand, so the safety monitoring will be significant in some cases. However, overall the fees will cost less than the existing application pathway options (the highest fee is $106,503), which reflects the reduction in pre-approval work. The attached Cost Recovery Impact Statement provides more detail on how the fees were determined.

12 In addition, a flat fee of $1,730 is proposed for the initial validation phase (pre-screening) of the application process. The validation phase is 10 working days when Medsafe assesses whether the application meets the criteria for acceptance onto the verification pathway. This provides an opportunity for the submitter to ensure that their application is complete.

13 Over time, verification pathway fees are likely to increase in line with other new medicine application fee increases as part of the fee review process.

Results of consultation with affected parties

14 The Medicines Act 1981 requires consultation with affected parties before amending the regulations. In response to consultation, five submissions were received from pharmaceutical industry bodies and companies.

15 Submitters did not object to fees in principle. Four submitters thought the proposed fees were too high, based on the pre-approval assessment being less intensive than the existing pathways. The Ministry's response is that the fees also need to cover the post-approval regulatory workload, which makes up a significant part of all the pathways, including the verification pathway once it begins operating.

16 Submitters did not indicate that the fees would be a significant barrier to application volumes. From feedback received, the driver to use the pathway will be the reduced cost compared to the standard pathway, combined with the short timeframes.

Cost-of-living Implications

17 There are no significant cost-of-living implications.

Financial Implications

18 The proposal is expected to be fiscally neutral in line with Medsafe's existing cost recovery model.

Legislative Implications

19 This proposal will require amendments to the Medicines Regulations 1984. The Parliamentary Counsel Office has been consulted.

Impact Analysis

20 A Ministry of Health QA panel has reviewed the Stage 2 Cost Recovery Impact Statement titled 'Medsafe Verification Pathway for New Medicine Applications – Fees', produced by the Ministry of Health and dated March 2026. The panel considers that the Impact Statement Meets the quality assurance criteria.

21 The Impact Statement is clear, concise, consulted, complete and convincing. The analysis is balanced in its presentation of the information. Impacts are identified and appropriately assessed

Climate Implications of Policy Assessment

22 The Climate Implications of Policy Assessment (CIPA) team has been consulted and confirms that the CIPA requirements do not apply to this policy proposal, as the threshold for significance is not met.

Population Implications

23 There are no significant population implications.

Human Rights

24 This proposal is not inconsistent with the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993.

Use of external resources

25 No external resources were used in preparation of the advice in this paper.

Consultation

26 The Treasury Ministry for Regulation, and Pharmac were consulted on this paper. The Department of the Prime Minister and Cabinet were informed. No concerns were raised.

Communications

27 I will announce the verification pathway becoming operational in June 2026. At the same time, the pathway rules and fees will be notified in the New Zealand Gazette and published on the Medsafe website, along with Medsafe's guidelines.

Proactive Release

28 This paper will be released, with any redactions as appropriate under the Official Information Act 1982, when the verification pathway is announced.

Recommendations

29 The Associate Minister of Health recommends that the 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 agree to introduce into the Medicines Regulations 1984:

2.1 a fee of $42,601 for the verification phase, 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;

3 agree that the Regulation 61A waiver and refund provisions in the Medicines Regulations 1984 apply to fees for the verification pathway;

4 Invite the Associate Minister of Health to issue drafting instructions to the Parliamentary Counsel Office to amend the Medicines Regulations 1984 to enable the proposed fees to be implemented.

Authorised for lodgement

Hon David Seymour

Associate Minister of Health