Stage 2 Cost Recovery Impact Statement

Medsafe Verification Pathway for New Medicine Applications - Fees

Agency Disclosure Statement

This Cost Recovery Impact Statement has been prepared by the Ministry of Health.
It provides an analysis of the proposal to introduce application fees in relation to the new Verification Pathway for New Medicine Applications that was introduced by the Medicines Amendment Act 2025.

An area of uncertainty is the estimate of revenue to Medsafe. It is difficult to predict how many applications will be made to the new pathway, and how many of these are ones that would have been made through an existing pathway if the new pathway had not been introduced. The industry body that represents those pharmaceutical companies most likely to utilise the pathway, Medicines New Zealand, has not been able to provide a consolidated estimate from their members.

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Context

Medsafe is a business unit of the Ministry of Health and is responsible for the regulation of therapeutic products in New Zealand. Its functions include the approval (or consenting) of new and changed medicines for distributing in New Zealand, as well as monitoring the ongoing safety of medicines and undertaking enforcement activities to protect the public.

Medsafe is over 90 percent funded by third-party fees, and charges fees for the evaluation of medicines for consent to distribute, licensing of activities such as manufacturing medicines, and conducting clinical trials

Currently there are two types of pathways in operation for applying for approval for a new medicine:

- The standard pathway. This is a full evaluation of data submitted for approval of a medicine. For novel medicines containing a new active ingredient, these consist of thousands of pages. The average time taken for Medsafe to assess these medicines via the standard pathway in 2024/2025 was 216 working days.
- The abbreviated pathway, also called a ‘reliance pathway’ because it relies on an assessment report by another recognised regulatory authority overseas. The average

time taken for Medsafe to assess these medicines by the abbreviated pathway in 2024/2025 was 116 working days (when the applicant responds to requests for further information within set timeframes).

Regulatory framework for Medsafe fees

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 for different types of applications that Medsafe receives. Regulation 61A permits the Director-General of Health to set waivers or refunds for any fee (in full or in part), taking into account:

a) the time reasonably required to consider any application made or notice given under the Act

b) the degree of complexity involved in considering any such application or notice

c) the interests of public health in New Zealand.

Medsafe uses fee waivers to prescribe standard application fees. For example, the current regulations specify a maximum fee of $122,625 for an application for consent of a new medicine that contains an active ingredient that has not previously been approved in New Zealand. When the waivers are applied, the actual fees for this application category submitted via the standard pathway is $106,503. Other new medicine application fees are scaled to this fee, for example and application for an intermediate risk (generic prescription medicine) is half as much; $53,251. These waivers are described in Medsafe's guidelines, with fees published on the Medsafe website.

New pathway introduced for new medicine applications

In November 2025, the Medicines Amendment Act 2025 introduced the verification pathway, a new, fast-track pathway for new medicine applications. The new pathway enables an application for consent to distribute a medicine in New Zealand to be assessed within 30 days of acceptance by Medsafe if the medicine has been approved by two overseas recognised regulatory authorities.[1] The verification pathway fulfils a commitment in the National-ACT and National-NZ First Coalition Agreements.

The Ministry of Health is developing secondary legislation for the operational requirements of the verification pathway, including rules that applications must meet, and setting the fees for applications. The verification pathway is expected to begin operating around June 2026.

The pathway rules were consulted on over February and March. These are for the approval of the Associate Minister of Health and will be published in a gazette notice. Setting the fees for applications to the verification pathway involves amending the Medicines Regulations 1984.

The fees for the verification pathway were consulted on in March 2026.

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1 See the Ministry of Health website for earlier policy documents: Cabinet and briefing material: Introducing a verification pathway for medicines approvals | Ministry of Health NZ

The Regulatory Impact Statement is available on the Ministry for Regulation website: Regulatory Impact Statement Template

Cost Recovery Principles and Objectives

Charging a fee to recover the cost of processing applications for medicine approval is a well-established tool used by comparable regulatory authorities around the world. The fees charged for these activities fund both pre-market (approval) work, and for post market work such as monitoring medicine safety (including adverse events), quality complaints, and recalls. These activities are crucial to safeguarding the safety and quality of New Zealand's supplies of medicines.

The objectives of this proposal are to:

- set charges in a way that promotes New Zealander's timely access to medicines (ie effectiveness).
- generate revenue sufficient to provide for sustainable ongoing management of Medsafe funding in relation to the verification pathway.
- set charges in a principled manner that spreads costs fairly, equitably and consistently

Medsafe is obligated to collect fees by way of a cost recovery model in accordance with the *Guidelines for Setting Charges in the Public Sector* (The Treasury (2017)) and the principles outlined in *Setting and administering fees and levies for cost recovery: Good practice guide* (Office of the Controller and Auditor-General (2021)). The principles are:

- Equity – fees are fairly attributed to the beneficiaries of the service
- Efficiency - decisions on volume and standards of service, and costs to recover are consistent with the efficient allocation of resources.
- Justifiability – costs recovered are appropriate and are not unreasonable
- Transparency – costs are able to be identified and that those impacted by the service have the available information to comment on how the charges are calculated.

Policy Rationale: Why a user charge? And what type is most appropriate?

Medsafe fees are determined using a standard cost model, based on estimating annual expenditure and allowing for annual growth over a three-year period, using an activity-based costing allocation, and estimating application volumes. Individual fees are then derived, and the fees are then scaled within outputs based on the estimated Medsafe effort involved.

The cost model used by Medsafe to establish the level of fees was most recently reviewed by PricewaterhouseCoopers. The report concluded that the cost model was appropriate and met Treasury guidelines.

A memorandum of account is used to monitor revenue and expenditure associated with fees. It ensures that Medsafe is able to operate consistently during peaks and trough periods of revenue. Medsafe has an obligation to manage the memorandum of account to be in balance. (Treasury Circular 2011/10: *Guidance on the Operation of Departmental Memorandum Accounts*).

Proposal: 'One-time' application fee

As with other fees under the Medicines Act, the proposal is that fee payers to the Verification Pathway will pay a 'one-time' fee for most medicine application services. The Medicines Act 1981 does not allow for levies or annual fees and medicine approvals are indefinite. As medicines change over time (for example a pharmaceutical company may use a new manufacturing site), revenue is also generated from fees for assessment of changed medicine notifications.

This CRIS assesses this one option because there are no realistic alternative options, given the legislative constraints on the type of fee possible, and the obligation to balance Medsafe's memorandum of account. The Medicines Act 1981 and Medicines Regulations 1984 do not enable regular licensing or renewal fees. Cross-subsidisation between different application pathways would not align with Treasury and Auditor-General guidelines, as it would not be fair for a group of companies to pay a disproportionately high amount for Medsafe's post-market work.

There are three proposed fee levels designed to be proportionate to the risk profile of the medicine (explained below). The risk of the price being set too low or too high can be addressed in future reviews and adjusted through waivers.

In addition to the application fee, a flat fee of $1,730 is proposed for the validation (screening) phase at the start of the application process. This process is so that Medsafe can ensure that an application is complete at the time of submission, so that it has the highest chance of receiving approval. This fee may be charged more than once if the application has to be re-submitted to the validation phase, although in most cases it will only need to be charged once. The fee may be waived if requested, in situations where an application is resubmitted to another pathway.

The level of the proposed fee and its cost components

The proposed fees for the verification pathway are shown in Table 1 below:

Table 1: Proposed fees for the verification pathway	
Validation fee	$1,730
Higher risk new medicine application (NMA) new active ingredient	$42,601
High risk NMA other	$31,951
Intermediate risk NMA	$21,301
Fees are inclusive of GST	

Several factors have been considered for setting verification pathway application fees, as explained below.

The verification pathway requires a decision within a 30-working day timeframe. Medsafe intends on targeting 20 working days for initial assessment. This will require assessors to pause all other work to prioritise verification NMAs and this is reflected in the cost. While this will have a very positive impact on verification applications, the flow on impact to other assessment work may reduce efficiency, which can result in lower output from medicine assessors as they switch between highly technical assessment work. Medsafe is committed to maintain target timeframes for all assessment work, regardless of application category.

Medsafe's essential post-market workload such as pharmacovigilance reporting and monitoring, market compliance, medicine testing, border monitoring, and investigations, is needed and relates to all medicines regardless of the pathway in which they are approved. This is discussed further in the section below 'Determining the pre-market and post-market fee components'.

New medicine application fees make up a considerable proportion of the revenue generated to regulate a medicine (ie post-market monitoring and other activities) throughout its lifecycle (which can be decades).

Verification fees are proportionate to the fees for other application types (standard, abbreviated), in their respective categories. Any future reviews of Medsafe fees will maintain this proportionality, unless there is good reason not to. Therefore the verification fees are likely to increase in line with other new medicine application fee increases in the near future.

To enable wider use of the pathway, a number of minor variations are able to be included in a verification application without additional fee.

The validation screening fee reflects the short screening timeframe of 10 days. Medsafe's expectation is that applications submitted will be complete and able to be accepted at first round of screening.

Relativity to other fees

Medsafe's new medicine application (NMA) fee schedule is designed so that all fees are proportionate to the highest NMA fee, which is that of the *High risk medicine new active ingredient*. within each pathway, intermediate risk NMA are set at (approximately) 50% of the high risk NMA - new active ingredient, and high risk NMA - other at 75%. A summary of NMA fees is shown in Table 2 below:

Table 2: Relativity of proposed verification pathway fee to other new medicine application (NMA) pathway fees			
Risk profile of medicine	**Full pathway**	**Abbreviated pathway**	**Verification pathway**
High risk NMA – new active ingredient	$106,503	$53,252	$42,601
Proportion of max	*100%*	*50%*	*40%*
High risk NMA - other	$79,877	$39,939	$31,951
Proportionate of max	*75%*	*38%*	*30%*
Intermediate risk NMA	$53,252	$26,626	$21,301
Proportionate of max	*50%*	*25%*	*20%*

Determining the pre-market and post-market fee components

As noted above, the proposed fees cover both pre-market work (eg application processing) and post-market work (eg monitoring).

In relation to a higher risk medicine containing a new active ingredient (a novel cancer therapy for instance), the post-market work required is the same regardless of the way it was approved. The proportion of the fee contributing to post-market activities should therefore be the same. In the case of higher risk medicines containing a new active ingredient, $30,000 has been allocated, as shown in Table 3 below.

The pre-market assessment cost for the verification pathway ($12,601) is based on the relative FTE effort required to complete the work compared to the standard and abbreviated pathway.

Table 3: Comparison of pre-market and post-market new medicine application (NMA) fee components

	Pre-market component	Post-market component	TOTAL
Standard pathway, high risk NMA – new active ingredient	$76,503	$30,000	$106,503
Abbreviated pathway, high risk NMA – new active ingredient	$23,252	$30,000	$53,252
Verification pathway, high risk NMA – new active ingredient	$12,601	$30,000	$42,601

Impact analysis

The main impact of the fee will be to ensure appropriate recovery of costs incurred by Medsafe in implementing the verification pathway.

Impact on Medsafe's revenue

The total revenue generated by the proposed fees is dependent on the volume of applications each year. Fluctuations in that volume can affect the revenue of Medsafe, although not all Medsafe revenue streams will be impacted. For example, fees from Changed Medicine Notification make up approximately 50 percent of Medsafe revenue and will not be impacted.

With regard to the verification pathway, the estimate of revenue to Medsafe is uncertain. It is difficult to predict how many applications will be made to the new pathway, and how many of these are ones that would have been made through an existing pathway if the new pathway had not been introduced.

While pharmaceutical companies have expressed intent to apply to the pathway, we do not have precise estimates. The industry body that represents those pharmaceutical companies most likely to utilise the pathway, Medicines New Zealand, has not been able to provide a consolidated estimate from their members.

It is expected that the impact of this fee structure on Medsafe revenue will be manageable. Table 4 below projects the impacts on Medsafe's revenue under two potential scenarios. In both scenarios, a potential drop in revenue is managed within Medsafe's budget. Medsafe operates a memorandum account which allows for long-term management of budget throughout peaks and throughs of revenue.

Table 4: Potential impacts of verification pathway fees on Medsafe's revenue		
	Scenario 1	**Scenario 2**
Proportion diverted from other, more expensive pathways	20% $-0.55m	40% -$1.4m
Additional verification applications, not otherwise received	15 new applications $0.5m	0 new applications
TOTAL	$-0.19m	-$0.9m
Drop in total Medsafe revenue	-0.4%	-8%
Note: Based on average annual Medsafe TOTAL revenue of $13 million over the last 3 years, (Figures are inclusive of GST).		

Consultation

The Ministry of Health has consulted on the recommended option with pharmaceutical industry bodies and companies likely to wish to use the Verification Pathway. Consultation was conducted via email to Medsafe's mailing list, and ran from 2 to 13 March 2026. Five submissions were received, all from industry bodies and companies.

Four of the submitters thought the proposed fee prices are too high because the pre-approval work is less intensive than the standard or abbreviated pathway. They proposed alternative fees that would be between 33 percent to 20 percent of the highest standard fee (compared with the 40 percent proposed by Medsafe).

The Ministry's response is that much of the costs are driven by the post-market regulatory workload. This work is undertaken for all medicines, regardless of how they are approved. The feedback did not provide any data that had not been considered when setting the proposed fees.

None of the respondents indicated that the fees would be a significant barrier to application volumes. Medicines New Zealand noted that for many companies, the reduced cost compared to the standard pathway, and the short timeframes, will be a driver for use of the pathway – specifically those that submit to New Zealand in their third or fourth 'wave' (i.e. companies will submit to Europe and the USA in the first wave, larger markets such as Canada in second wave, then followed by smaller markets including New Zealand).

Conclusions and recommendations

The recommended option meets the objectives of the proposal. It promotes access to medicines via the Verification Pathway. This option also meets the other objectives of financial sustainability and fairness. It is consistent with Medsafe's model for fees for other

new medicine applications. From feedback received it does not appear that fees will be a primary driver for companies' decisions about when to apply for approval in New Zealand.

Implementation plan

Implementation will be the responsibility of Medsafe. Medsafe has consulted on rules and guidelines setting out the process for applications entering the pathway. Stakeholders are being kept informed through Medsafe's established channels of communication.

Monitoring and evaluation

The operation of the verification pathway will be monitored by Medsafe, with review planned within 12 – 18 months of implementation. Timelines will be reported in its routine annual performance reporting.

The fee price can be adjusted (through waivers) as a result of the review of the verification pathway, or it can be adjusted through future wider fees reviews, as discussed below.

Review

In addition to the review of the verification pathway noted above, Medsafe has an undertaking with Audit New Zealand to a a fees review cycle that results in fee changes every 4-5 years. If a review is an opportunity to adjust the fee structure or quantum if needed. Stakeholders support regular fee reviews because it makes fee increases more predictable and transparent and ensures that Medsafe is sufficiently resources to meet performance target timelines.

The last fees review resulted in updated fees being implemented 2022. The updated fees resulted in a review of the fees model, new fee categories, and a broad increase in fees. The cost model was reviewed by PricewaterhouseCoopers in 2021. They concluded that the cost model was sound, the assumptions were accurate and it was consistent with Treasury guidelines.