

# Impact Summary: Amendment of fees specified in the Medicines Regulations 1984

## Section 1: General information

**Purpose**

The Ministry of Health is solely responsible for the analysis and advice set out in this Impact Summary, except as otherwise explicitly indicated. This analysis and advice has been produced for the purpose of informing final decisions to proceed with a policy change to be taken by or on behalf of Cabinet

**Key Limitations or Constraints on Analysis**

The analysis in this report is based on medicine application numbers forecast over the last 5 years. This forecast has limitations as it is retrospective rather than looking at upcoming medicine pipelines. Changes in trends, such as new medicine types, constraints on manufacturing or supply chains, cannot be predicted by retrospective trends.

International pipeline information can be less relevant in New Zealand due to the impact of PHARMAC, where funding decisions can influence whether a medicine application is applied for. Obtaining future trends from companies would be piecemeal, and administrative burdensome.

**Responsible Manager: (signature and date)**

Chris James  
**Group Manager**  
**Medsafe**  
Date: 28 July 2021

*To be completed by quality assurers:*

**Quality Assurance Reviewing Agency:**

Ministry of Health

**Quality Assurance Assessment:**

The Ministry of Health QA panel has reviewed the Impact Statement titled “Amendment of fees specified in the Medicines Regulations 1984”, produced by Medsafe and dated June 2021.

The panel considers that the Impact Statement **meets** the quality assurance criteria.

**Reviewer Comments and Recommendations:**

The Impact Statement is clear, complete, considered and concise. The analysis is balanced in its presentation of the information and the major impacts are identified and assessed.

## Section 2: Problem definition and objectives

### 2.1 What is the policy problem or opportunity?

#### *Medsafe Fees Review*

Medsafe is a business unit of the Ministry of Health and is responsible for the regulation of therapeutic products in New Zealand. Medsafe is 90% funded by third-party fees for the evaluation of medicines for consent to market and licensing of activities such as manufacturing therapeutic products, conducting clinical trials and the operation of pharmacies.

Medsafe has an undertaking with Audit New Zealand to a three-year fees review cycle. The last fees review was in 2017. This ensures that changes in the regulatory scheme environment are responded to, such as changes in application volumes, increasing regulatory function costs, and Consumer Price Index (CPI) changes. During the 2017 fees review, industry requested that Medsafe undertake regular reviews rather than ad hoc changes. This is also an opportunity to review whether Medsafe is equitably assigning fees across the system.

Medsafe is obligated to collect fees in accordance with a cost recovery model<sup>1</sup>. The costing model requires updating each review to consider any changes in the cost of carrying out the regulatory functions funded from fees.

The scope of the review included fees for the following:

- applications for approval of new and changed medicines and related products, approval of clinical trials, licences for manufacturing and packing, pharmacy licences, wholesale and sale by retail licences, and hawkker licences, required under the Medicines Act and Regulations
- auditing of non-licensed manufacturers and the issue of regulatory statements and certificates made outside the Act, that are fees for service.

#### *Why is the current situation a problem?*

##### *Changes in application numbers and types*

The Medsafe cost model relies on the number and types of applications received, and forecast revenue is based on an application volume assumptions. The assumptions on application numbers and complexity used in the 2017 fees review are no longer valid as there have been changes in the mix and volume of applications received. Additionally, new medicine types have emerged, such as biosimilars, that require more evaluation time than the current fee structure provides for, and extensions of indications that require significant clinical evaluation. These are currently under-recovering the costs of evaluation.

##### *Memorandum account*

Medsafe operates under a memorandum account and is responsible for its management. Memorandum accounts were established to improve transparency around outputs that are fully cost recovered from third parties through fees, levies or charges,

<sup>1</sup> The Treasury (2017), *Guidelines for Setting Charges in the Public Sector*, Office of the Controller and Auditor-General (2008), *Charging Fees for Public Sector Goods and Services*.

and to provide a genuine commitment from departments to not benefit from over recovery<sup>2</sup>.

Between the years 2006 and 2016, Medsafe was running a positive memorandum account where fees over recovered the work undertaken. By 2017, Medsafe had balanced the memorandum account and a 2017 fees review resulted in a readjustment to maintain a balanced memorandum account by imposing a 15% increase on a small number of fees. This 15% increase equated to the increase in CPI over the previous 10 years where no fee adjustments had been made.

Since the new fee increase was introduced in 2018, the Medsafe memorandum account has gone into deficit and Medsafe is obligated to investigate and remedy this situation. Rises in expenditure and reductions in application volumes are usual drivers of this situation.

**Table 1: Movement in the Medsafe memorandum account**

<b>(\$000)</b>	<b>2015/16</b>	<b>2016/17</b>	<b>2017/18</b>	<b>2018/19</b>	<b>2019/20</b>
Opening balance	2,636	1,288	6	(1,310)	(2,046)
Revenue	7,427	7,646	7,309	8,746	8,400
Expenditure	(8,775)	(8,928)	(8,625)	(9,482)	(8,839)
Annual Surplus/(Deficit)	(1,348)	(1,282)	(1,316)	(736)	(439)
Closing balance	1,288	6	(1,310)	(2,046)	(2,485)

The total forecast expenditure for 2020/21 fees review is \$12.96 million (GST exclusive), of which \$11.39 million is budgeted to come from fees charged to industry, assuming the proposed fee changes are implemented. The additional \$2.1 million 2021/22 expenditure forecast is an increase of 19% over the 2017 budget. The increase is mainly due to increased personnel costs (\$1.1 million), which are a combination of an annual increase in salaries (2%) and budgeting for an increase in staff; an allowance to clear the memorandum account balance over 5 years; and additional operating costs, in particular upgrading obsolete technology.

Both the industry and Medsafe are interested in retaining and improving the temporary electronic file transfer system (EFT) put in place during the COVID-19 pandemic lockdown.

<sup>2</sup> Treasury Circular 2011/10: *Guidance on the Operation of Departmental Memorandum Accounts*

### *Other costs*

Medsafe has contracts with other services such as ESR<sup>3</sup>, the SMARTI database and the Centre for Adverse Reaction Monitoring that require periodic review and renewal. Changes in contract costs occur and need to be recovered.

### *Regulatory framework*

The Medicines Act 1981 allows for the collection and cost recovery of fees, and includes the ability to waive fees in certain circumstances. Fees can only be charged on submission of a medicine's application, or licence application – there is no legislative ability to charge for annual fees.

Fee maximums are specified in regulation 61 and Schedule 5A of the Medicines Regulations 1984. Medsafe has worked within the current maximums for over 10 years and with costs increasing, the maximums are becoming restrictive and preventing Medsafe from adequately cost recovering.

## **2.2 Who is affected and how?**

The proposals for increases in fees for medicine and licence applications will affect all fee payers. Fee payers for Medsafe activities are:

- Pharmaceutical companies for both medicine applications and manufacturing licences
- Clinical trial applicants
- Pharmacy licence holders

Fee payers are increasingly concerned about timeframes for approvals of medicines, as time out of the market can incur significant lost revenue.

Pharmaceutical companies (the most affected by the proposals) have mixed views, depending on the proposal that delivers them the least impact on their costs but delivers the improvements they seek.

Clinical trial applicants have essentially no change to their fees so we are not expecting any changes to behaviour. We expect that there will be resistance from pharmacy licence holders to even small increases.

Medsafe is seeking to limit behaviour change as a result of these fees. It is expected that some fee payers may look to rationalise their portfolios but the proposals are aimed at mitigating this by ensuring the more significant increases are limited to those who impose those costs. A large proportion of the fee payers (licence holders, low risk medicine sponsors) will only be affected by the CPI increase.

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<sup>3</sup> New Zealand's Crown Research Institute specialising in science for communities

## 2.3 What are the objectives sought in relation to the identified problem?

The objectives of the fee review were:

- to align Medsafe cost recovery with best practice guidance issued by the Treasury<sup>4</sup> and Office of the Controller and Auditor-General<sup>5</sup>
- to fulfil the commitment to review fees every 3 years, as undertaken with Audit New Zealand
- to provide for sustainable ongoing management of Medsafe funding, and reduce the current memorandum account deficit
- to set charges in a principled manner that spreads costs fairly, equitably and consistently
- to undertake a transparent process.

The following cost recovery principles were applied:

- Equity – that fees are fairly attributed to the beneficiaries of the service
- Efficiency that decisions on volume and standards of service, and costs to recover are consistent with the efficient allocation of resources.
- Effectiveness – that the desired outcomes are going to be achieved by the activity.
- Justifiability – that 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
- Simplicity and consistency – fee structures are simple and consistent so that fee payers understand the fee they have to pay and helps them plan their business effectively

The cost model used by Medsafe to establish the level of fees was reviewed by PricewaterhouseCoopers to ensure the assumptions remained sound. The report concluded that the cost model was appropriate.

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<sup>4</sup> The Treasury (2017), *Guidelines for Setting Charges in the Public Sector*.

<sup>5</sup> Office of the Controller and Auditor-General (2008), *Charging Fees for Public Sector Goods and Services*.

## Section 3: Options identification

### 3.1 What options have been considered?

#### Option 1

**Status quo:** *this option means that no changes to fees are implemented.*

This option is not feasible due as this will lead to the continuing decline of the Memorandum Account and will lead to Medsafe needing to cut expenditure. One of the main expenses for Medsafe is staff, and we are committed to providing adequate service levels for clients of Medsafe by recruiting and maintaining appropriately skilled people. Reducing staff would impact severely on the service to Medsafe clients, and ultimately adversely affect healthcare professionals and the public by reducing the choice of medicines available.

While the improvement initiatives could continue to be progressed, staff availability to undertake this work would be compromised and the improvements may take an extended time to complete. There would be no replacement of obsolete technology as this requires investment.

This option will not require amendments to the Medicines Regulations 1984.

#### Option 2

**Flat fee increase only:** *this option would apply the full required increase across all fees charged.*

The flat fee increase is calculated as **19%** to achieve the objectives of the fees review.

Option 2 would provide a sustainable basis for Medsafe, covering expenditure, providing for service improvements, and addressing the memorandum account balance.

Against the status quo, there is a positive economic benefit in that the regulator can maintain and improve services that ultimately have a positive impact on the pharmaceutical industry, pharmacies and other fee payers, and on the New Zealand public in being able to access safe and effective medicines.

It meets the principles of efficiency, effectiveness, justifiability and simplicity, but does not meet the principles of transparency and equity. This option spreads the costs evenly over all fee payers, some of whom never make applications in the areas where cost recovery has fallen behind and would therefore not gain full benefits from the 19% increases in fees.

There is no change to other compliance costs for fee-payers as no change would be made to processes. However, by maintaining the EFT, the recent reduction in compliance costs applied during the COVID-19 lockdown (in terms of CD-ROMs, postage and time) will be maintained and future improvements would further reduce compliance costs (eg, accepting e-CTD applications). In addition, staff should have more time to revise guidance to improve compliance requirements and reduce costs further.

This option requires the amendment of regulation 61 of the Regulations, in particular clauses (1), and (3) – (8). Regulation 61 states the maximum fees Medsafe can charge under the Medicines legislation.

### Option 3

**Proposed cost recovery fees and the CPI increase:** *this is a mixture of cost recovery and the CPI increase, with the CPI increase affecting all applications but the cost recovery increases only affecting those set out in the proposals.*

The CPI increase on fees is calculated at 4.2% over a three-year period and is applied to all fees, except clinical trial fees. Cost recovery adjustments are made to a targeted group of fees where cost recovery has not been reviewed for some time. Other adjustments are proposed to ensure a more logical benchmarking approach.

As with the flat fee option, Option 3 addresses the current financial situation of Medsafe, and provides positive economic and access impact for the New Zealand public. It also results in no change to other compliance costs for fee payers, and maintains the recent reduction in compliance costs with the EFT.

Regarding the principles of cost recovery, Option 3 meets all the principles. Only those costs needed to continue Medsafe’s sustainability and improvements are proposed (efficiency and justifiability), the cost model and Medsafe’s approach are reviewed in the PwC report (transparency), and an overcomplication of fees has been avoided by benchmark adjustments that follow a logic pattern (simplicity and consistency).

In particular, it meets the transparency principle in that this option clearly shows where the additional fees have been applied and the cost recovery analysis shows why the fees have been applied. This option also meets the equity principle, where costs have been placed where they lie, in the areas where the most effort applies. This ensures fee-payers are only paying for the Medsafe effort that is required for their applications/licences.

This option requires the amendment of regulation 61 of the Regulations, in particular clauses (1) and (4) – (7) (Table 2).

<b>Table 2: Proposed amendments to Regulation 61</b>			
<b>Regulation 61</b>	<b>Fee Type description</b>	<b>Old fee (maximum)</b>	<b>New fee (maximum)</b>
(1)	Schedule 5A licences	See below	
(4)	Fee for any other application made under section 21 for the consent of the Minister under section 20 of the Act (new medicines other than new novel medicines)	\$43,875	\$79,877
(5)	New related products	\$5,500	\$5,731
(6)	Provisional consent under section 23	\$8,437	\$85,202



(7)	Changed medicine notifications	\$3,200	\$3,334
Schedule 5A	Licence application fees		
	Licence to manufacture medicines	\$13,750	\$14,328
	Licence to pack medicines	\$845	\$880
	Licence to sell medicines by retails	\$845	\$880
	Licence to sell medicines by wholesale	\$1,054	\$1,123
	Licence to hawk medicines	\$845	\$880
	Combined licence to pack and sell by retail	\$300	\$313
	Licence to operate a pharmacy	\$1,030	\$1,097

Clauses (2), (3) and (8)-(10) have no change to the fee

### Analysis of the options

<b>Table 3: Options analysis against cost recovery principles<sup>6</sup></b>			
<b>Principle</b>	<b>Status Quo (Option 1)</b>	<b>Flat fee (Option 2)</b>	<b>Cost recovery + CPI (Option 3)</b>
Equity – fee payers pay on the basis of the effort of their application	-- Cost recovery not being achieved in some areas	-- Fee applied without discretion	++ Fees targeted to where effort lies
Efficiency	- Not consistent with the efficient allocation of resources	- Is not consistent with the efficient allocation of resources	++ Is not consistent with the efficient allocation of resources

<sup>6</sup> The principles are:

- *Equity – that fees are fairly attributed to the beneficiaries of the service*
- *Efficiency - that decisions on volume and standards of service, and costs to recover, are consistent with the efficient allocation of resources.*
- *Effectiveness – that the desired outcomes are going to be achieved by the activity.*
- *Justifiability – that 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*
- *Simplicity and consistency – fee structures are simple and consistent so that fee payers understand the fee they have to pay and helps them plan their business effectively*

Effectiveness	-- Will not achieve the desired outcome	++ Will achieve the desired outcome	++ Will achieve the desired outcome
Justifiability	-- Costs are not being recovered	-- The fee increase is blunt and for some fee payers is unreasonable	++ The fee increases are appropriate and reasonable as they are targeted
Transparency	0	-- While fees are clear, it is more difficult to identify the underlying rationale	++ There is clear rationale for the increases
Simplicity and consistency	- Some inconsistency in fee structure	++ Fee structure is simple as only a flat fee has been applied	+ Alignment and changes result in a more logical fee structure but changes are targeted
<b>Total</b>	--	--	++

- Does not meet the principle

+ Meets the principle

### 3.2 Which of these options is the proposed approach?

The preferred option is Option 3 as it delivers the expected revenue to maintain the running of Medsafe, cover the additional costs of external contracts, provides investment for improved technology that will lead to efficiency gains, and contributes towards moving the memorandum account closer to zero.

This option also places costs where they lie and ensures that fee payers who do not use certain pathways are not subsidising those who do. Consultation has indicated that this is the preferred option by the majority of affected fee payers.

In summary, Option 3 meets the objectives of the fees review and the cost recovery principles.

Option 2 was not considered feasible as it is non-discretionary and unjustifiably places additional costs on types of evaluations/licences where the fee review found there was sufficient cost recovery.

## Section 4: Impact Analysis (Proposed approach)

### 4.1 Summary table of costs and benefits

<b>Affected parties</b> <i>(identify)</i>	<b>Comment:</b> nature of cost or benefit (eg, ongoing, one-off), evidence and assumption (eg, compliance rates), risks	<b>Impact</b> <i>\$m present value where appropriate, for monetised impacts; high, medium or low for non-monetised impacts</i>
<b>Additional costs of proposed approach, compared to taking no action</b>		
Fee payers	Increased fees to pay; potentially some rationalisation of their medicine portfolios	Targeted increase totalling \$2.1m (19%)
Medsafe	No additional costs	No additional monetised costs;
Wider government	No cost	No cost
New Zealand public	Potential reduced types of approved medicines	(Low)
<b>Total Monetised Cost</b>		\$2.1m
<b>Non-monetised costs</b>		<i>(Medium)</i>
<b>Expected benefits of proposed approach, compared to taking no action</b>		
Regulated parties	Improved efficiencies, fairer allocation of costs across the fee payers, increased certainty of costs,	(Medium) – should provide certainty of fees to be paid, and improved timeliness
Regulators	Open and transparent fee regime, ability to be agile with changing regulatory landscapes	Increases in revenue by \$2.1m (19%)
Wider government	An agile regulator who can manage workloads more effectively	(Medium)
New Zealand public	Medicines continue to be robustly evaluated for safety, quality and efficacy	(Low)
<b>Total Monetised Benefit</b>		\$2.1m
<b>Non-monetised benefits</b>		<i>(Medium)</i>

#### **4.2 What other impacts is this approach likely to have?**

This approach may cause some rationalisation of medicine applications to Medsafe, impacting on the number of approved medicines PHARMAC can consider for funding. However, PHARMAC prefers to fund approved medicines over unapproved medicines, which provides an incentive to submit applications for approval.

## Section 5: Stakeholder views

### 5.1 What do stakeholders think about the problem and the proposed solution?

All fee payers who have consented medicines, current licences and approvals for clinical trials on the Medsafe database were consulted on the three options and the specific changes. 31 submissions were received, three from organisations representing a large number of fee payers.

24 (77%) of submitters supported the drivers of the increased fees. 18 (58%) supported the preferred option with 10% not indicating a preference. Much of the lack of support for Option 3 concerned the actual mix of fee changes under Option 3, as some felt the targeted increases were substantial and indicated this could cause a rationalisation of their medicine portfolios. They supported this view by noting that the New Zealand medicine market is small and is impacted by PHARMAC decisions, so taking the risk of applying for a medicine is less attractive if the fees are high (or perceived to be disproportionately high).

In response, Medsafe has modified some of the specific proposals under Option 3 include limiting the types of applications referred under section 24(5)<sup>7</sup> that would incur the increased fees to those that are currently usually already referred<sup>8</sup>, such as indication changes and with some fee reductions. Revision of provisional consent fees were also considered and minor changes made to reflect more accurately the evaluation work required.

Fee payers are highly motivated by the time taken to market, so efficiencies for both Medsafe and the fee payers will be further explored.

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<sup>7</sup> Changed medicine notifications for substantial changes can be referred under s 24(5) of the Medicines Act to be considered as new medicines, where longer timeframes can be applied.

<sup>8</sup> The proposal consulted suggested including some new referral categories.

## Section 6: Implementation and operation

### 6.1 How will the new arrangements be given effect?

The maximum levels of the fees are stated in the Medicines Regulations 1984 and as the proposals are increasing the fees, the Regulations require amendment. Additionally, in order to effect the desired cost recovery proposals for complex changed medicine notifications, the regulations require amendment to allow for new medicine fees (and the regulation 61A waiver) to apply to these types of applications. The regulation-making powers under the Medicines Act 1981 do allow for this amendment, and Medsafe will ensure that this regulation is appropriately applied.

Medsafe produces a fee schedule and this will be amended and published on the Medsafe website. Medsafe will also amend the IT system to update the fees and revise application forms to indicate to industry where higher fees may be expected.

Fee payers have indicated that they would prefer the date of implementation to occur no earlier than 1 January 2022. The impact of waiting until then is that the Medsafe memorandum account will continue to move into deficit over that time. Positives are that fee payers will be able to incorporate the changes into their budget cycles much more easily, ensuring a smooth flow of applications rather than them choosing not to submit.

While fee payers prefer sufficient notice of fee changes, there is a risk that companies may flood Medsafe with applications just prior to the fee changes, This has happened in the past and negatively impacted on the workflow, creating a crunch on timelines (one timeline is statutory) and poor quality applications. This resulted in poor outcomes for applicants with delays to the completion of their applications.

Applicants will have communications reminding them that rushing to take advantage of the current fees is a false economy as, as quoted by an industry member, time out of the market is more expensive than the fees themselves.

## Section 7: Monitoring, evaluation and review

### 7.1 How will the impact of the new arrangements be monitored?

When fee changes take effect, Medsafe will monitor the effectiveness and efficiency of those changes against the objectives.

This will include the movement of the memorandum account and volume trends, and evaluation and licence issuing times. This will occur on an ongoing basis alongside the monthly reporting of key performance indicators and annual reporting to stakeholders that Medsafe undertakes.

### 7.2 When and how will the new arrangements be reviewed?

Medsafe intends to comprehensively review the fees and the cost recovery regime every three years in the absence of new therapeutic products legislation, as new legislation will redesign the fees model. This review will include:

- Impacts on the volumes of applications and licences as a result of the change in fees
- Impacts on the memorandum account trend
- Consumer Price Index adjustments
- Improvements

Industry has indicated that a review should be done more frequently, and while we agree that there may be scope for small adjustments within three years, it is not practical to undertake comprehensive review more frequently. However, the monitoring system set up during this fees review can be utilised to spot trends and adjustments early.