Office of the Minister of Health

Chair, Cabinet Social Wellbeing Committee

Amendments to fees specified in the Medicines Regulations 1984

Proposal

1 This paper outlines:

- the outcome of the 2020 Medsafe Fees Review and proposes changes to the fees stated in the Medicines Regulations 1984 (the Regulations) to allow for implementation of the fee review proposals; and
- requests approval to draft the amendments to the Regulations.

Relation to government priorities

2 This is an operational adjustment that requires Cabinet approval.

Executive Summary

3 Medsafe has undertaken a scheduled fee review on all fees applied under the medicines legislation. Proposals were developed and consulted with fee payers and the preferred option was a mix of an across the board Consumer Price Index change along with specific adjustments to address longstanding cost recovery inequities. This would significantly increase fees for some types of medicine applications and notifications.

4 In order to implement these fee changes, the Medicines Regulations 1984 that state the maximum fees, require amendment. An amendment is also required to allow some significant changes to medicines to be charged at a cost recovery rate.

5 Once the regulations are amended, implementation of the fee change will occur in October 2021 following final Cabinet decisions with updated guidance, application forms, invoicing and online fee schedule.

Background

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 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.

7 The Medicines Regulations 1984 set out the maximum fees for different types of applications and licences that Medsafe receives under regulation 61. Regulation 61A provides for a fee waiver (in full or in part) of any fee payable under regulation 61. The time required to consider any application, or the degree of complexity should be taken into account when applying for a fee

waiver. Currently, Medsafe fees are at their maximum and any changes to the fees would require an amendment to regulation 61.

8 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.

9 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, *Charging Fees for Public Sector Goods and Services* (Office of the Controller and Auditor-General (2008)).

10 A memorandum account is used to monitor revenue and expenditure associated with fees and identifies the under- or over-recovery for services.

11 Fee payers 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. Therefore, the revenue is tightly associated with the volume of applications each year. Fluctuations in that volume can significantly affect the revenue of Medsafe.

Medsafe Fees Review

12 Medsafe has an undertaking with Audit New Zealand to a three-year fees review cycle. Stakeholders support regular fee reviews to mitigate against the intermittent and significant fee increases that occurred in the past.

13 The last fees review was in 2017, which resulted in a 15% flat fee increase across a small range of applicable fees. No review of the cost recovery approach was done at this time. Despite this, the Medsafe memorandum account has continued to decline and is now in deficit (see Table 1). The 15% increase in 2017 did not reverse the downward trend, and Medsafe has an obligation to manage the memorandum account (Treasury Circular 2011/10: *Guidance on the Operation of Departmental Memorandum Accounts)*.

14

Table 1: Movement in the Medsafe memorandum account

($000)	2015/16	2016/17	2017/18	2018/19	2019/20
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)

15 Medsafe reviewed the trends of application volumes and types (which have changed over the past three years), looked at future investments to improve service (such as improved electronic application infrastructure and increased staff), the assumptions applied to the cost model, and whether cost recovery is being achieved. Cost recovery aspects were reviewed according to the best practice guidance issued by the Treasury and Office of the Controller and Auditor-General.

16 The cost model was reviewed by PricewaterhouseCoopers who concluded that the cost model was sound, and the assumptions were accurate. This allowed the cost model to be updated with the information on trends of application numbers and the forecast expenditure, including any improvements to service as well as the cost recovery outcomes.

Analysis

Fees Review outcomes

17 Analysis of the current fees indicated that many fees have not changed for some years, with no review for increased complexity or increased costs since 2008.

18 New types of medicines, such as biosimilars, have appeared and require a level of assessment that does not align easily with the existing fee categories. There are also some fees that do not reflect the cost of evaluation, such as for new and extended indications that require specialist clinical evaluation, certain complex changes to approved medicines, and the provisional consent pathway.

19 It was determined that changes to the fee levels were required to ensure cost recovery and to ensure the benchmarking of fees is appropriate and logical. Overall, a 19% increase in the Medsafe revenue would enable sustainability, positive movement of the memorandum account and improvements to efficiency to be made.

20 The options arising from the fees review in order to achieve this outcome were:

- Retain the status quo with no fee increases (option 1)
- Apply a 19% increase across all fees (option 2)
- Apply a smaller 4.6% fee increase across all fees and an increase on targeted fees that had fallen out of step with cost recovery mechanisms (option 3).

21 The specific fees under option 3 were outlined in the resulting consultation document. These included more logical benchmarking of some fees, increases in provisional consent fees, increases in changed medicines that are significant changes, and clarifications of some of the current fee charging processes.

Consultation

22 Consultation with all fee payers was undertaken in May 2021. Fee payers include pharmaceutical companies, domestic medicine manufacturers, pharmacy owners, and clinical trial organisations.

23 Common themes of feedback included:

- an acceptance of the need to maintain and sustain Medsafe
- a preference for the mix of a flat fee and targeted cost recovery fees (option 3)
- that evaluation involving additional effort should be paid for but some of the specific proposals need discretion
- that any fee increase should translate to increased efficiencies in timeframes

24 Medsafe is currently undertaking revisions of the specific proposals in light of the feedback from fee payers. Pharmaceutical company fee payers acknowledge that the fees proposed are still lower than that paid to other overseas medicine regulators but argue that the New Zealand market is smaller.

25 They also indicated that some of the significant increases proposed may cause fee payers to rationalise their medicine portfolios, reducing the volume of applications to Medsafe, and subsequently resulting in less revenue and fewer medicines available to the New Zealand population. For these reasons, many fee payers considered that the Crown should pay a larger percentage of Medsafe's costs to ensure a more sustainable future.

Implementation of the proposals

26 While the proposals are quite specific in their fee level, the consequential amendments to the Regulations are mainly technical. Regulation 61 and Schedule 5A of the Medicines Regulations specifies only the maximum fees in certain broad groupings.

27 Regulations 61(1) and 61(5) and Schedule 5A simply require the maximum fee to be amended to implement the proposed changes - this is the calculated Consumer Price Index movement of 4.2% since the last fees review. For regulations 61(4) and 61(6), the change is more substantial with regulation 61(4) rising from $43,875 to $79,877, and regulation 61(6) from $8,800 to $85,202 in order to accommodate cost recovery. These are maximums and fee waivers can (and are intended to) be applied according to the amount of evaluation effort that is required.

Amendment to the Medicines Regulations 1984 for targeted complex changes

28 It is proposed to amend the Medicines Regulations 1984 to enable targeted complex changes to medicines to be charged as new medicines and not at the maximum set by for changed medicines.

29 The Act includes a mechanism where complex changed medicine notifications can be referred under section 24(5) of the Act (and therefore normally captured under regulation 61(7)), to be assessed as new medicines. This allows for a longer time period to be applied for the evaluation (as the current statutory time frame for section 24 changes is 45 calendar days for the initial evaluation and 90 days for the entire evaluation).

30 Proposals from the fees review suggest that medicines referred through section 24(5) to become new medicines should also be subject to the same fees as a new medicine, but with the regulation 61A fee waiver applied. This means that the maximum fee as applied to a full new medicine would be reduced according to the level of evaluation work required for the change.

31 Currently, the regulations do not allow for this –all notices deposited under section 24 have the fee set in regulation 61(7) - $3,200. This fee does not cover the costs of evaluating large amounts of supporting data for applications such as new or extended indications (uses) of medicines.

32 The $3,200 fee for these types of evaluations represents approximately 6% of the current new medicine fee for a high-risk medicine, whereas the actual effort can be at least 50% of a new medicine fee. For example, the recently approved extension of the age range for the Comirnaty COVID-19 vaccine had a fee of $3,200 despite clinical trial data needing to be evaluated, as the change notification was deposited under section 24.

33 Medsafe requires the ability to cost recover on some of these complex changes, and this is supported by stakeholders. It is proposed to amend the Medicines Regulations 1984 to enable the cost recovery fee to be charged.

Implementation of the fee increases

34 Full implementation of the fee changes will predominantly involve changes to the published Medsafe fees schedule, Medsafe guidance documents, associated IT changes for invoicing purposes, and updated application forms.

35 The proposed implementation date is following final Cabinet decisions, although some fee payers have requested that the implementation date is no earlier than January 2022 as they have not budgeted for any increases. Medsafe can implement a split fee, whereby the applicant can pay for a portion of the fee when applying and pay the remainder by a set date the following year. This way of paying was set up during the last fees review on request from fee payers.

Financial Implications

36 The proposals will allow Medsafe to operate sustainably and to meet its cost recovery requirements. The proposals will result in a forecast 19% increase in the Medsafe revenue over the 2017 budget and would reverse the trend of the memorandum account. It is expected that the memorandum account would be balanced within 3-5 years.

Legislative Implications

37 The amendments will be made to the Medicines Regulations 1984 to amend the maximum fees specified in those regulations and to clarify that change applications referred through section 24(5) of the Act are considered new medicines and can be charged as such, if required.

Impact Analysis

Regulatory Impact Statement

38 A Regulatory Impact Summary is attached to this Cabinet paper.

Population Implications

39 This paper has no population impacts as the fees review and associated proposals cover all medicine applications and licences submitted to Medsafe.

Human Rights

40 The proposals in this paper do not raise any issues in relation to the New Zealand Bill of Rights Act 1990 or the Human Rights Act 1993.

Consultation

41 This paper was prepared in consultation with The Treasury, Audit NZ, the Department of Prime Minister and Cabinet, and PHARMAC.

42 PHARMAC has raised concerns that the increase in fees may influence decisions by pharmaceutical companies to apply for medicines in New Zealand. They are also concerned about the increased costs for provisional consents for medicines with supply issues, as this may lead to an increase in the supply of unapproved medicines.

43 Medsafe has considered these during the fees review and has proposed fees that are flexible and reasonable. Pharmaceutical industry decisions on whether to apply for medicine consents usually take into account a range of factors, including the likelihood of PHARMAC funding, and are not solely on Medsafe fees.

Communications

44 The Medsafe fee review outcomes will be communicated to the fee-paying stakeholders by way of the Medsafe website and direct communication with the stakeholders.

Proactive Release

45 Following Cabinet consideration, I propose to release this document in full in accordance with the normal process.

Recommendations

The Minister of Health recommends that the Committee:

1 **Note** that Medsafe has undertaken a fees review in order to meet an undertaking with Audit New Zealand and as part of its obligations to manage its memorandum account;

2 **Note** that the fees review identified a need for increases in fees; some only a Consumer Price Index increase while others a more substantial increase to address cost recovery requirements;

3 **Agree** to the amendment of the maximum fees set in regulation 61 and Schedule 5A of the Medicines Regulations 1984 to allow for the fee review proposals to be implemented;

Regulation 61	Fee Type description	Old fee (maximum)	New fee (maximum)
(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

4 **Agree** that a new regulation is drafted allowing significant changed medicine notifications to be charged as new medicines, with the Regulation 61A waiver also applying;

5 **Invite** the Minister of Health to issue drafting instructions to the Parliamentary Counsel Office to implement these changes through amendments to the Medicines Regulations 1984.

Authorised for lodgement

Hon Andrew Little

Minister of Health

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[1]. 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 hawker 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,

[1] 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[2].

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

($000)	2015/16	2016/17	2017/18	2018/19	2019/20
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.

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

Other costs

Medsafe has contracts with other services such as ESR[3], 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.

3 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[4] and Office of the Controller and Auditor-General[5]
- 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.

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

5 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).

Table 2: Proposed amendments to Regulation 61

Regulation 61	Fee Type description	Old fee (maximum)	New fee (maximum)
(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

Table 3: Options analysis against cost recovery principles[6]

Principle	Status Quo (Option 1)	Flat fee (Option 2)	Cost recovery + CPI (Option 3)
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

[6] 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
Total	**--**	**--**	**++**

- 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

Affected parties *(identify)*	**Comment**: nature of cost or benefit (eg, ongoing, one-off), evidence and assumption (eg, compliance rates), risks	**Impact** *$m present value where appropriate, for monetised impacts; high, medium or low for non-monetised impacts*
Additional costs of proposed approach, compared to taking no action		
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)
Total Monetised Cost		$2.1m
Non-monetised costs		*(Medium)*
Expected benefits of proposed approach, compared to taking no action		
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)
Total Monetised Benefit		$2.1m
Non-monetised benefits		*(Medium)*

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)[7] that would incur the increased fees to those that are currently usually already referred[8], 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.

[7] 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.

[8] 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.

Appendix 1

Proposed amendments to Regulation 61