# Medsafe Fees Review

**CONSULTATION DOCUMENT**

**2021**

Glossary

**API** – active ingredient/drug substance

**CEP** – Certificate of Suitability is a document that certifies that the quality of a given drug substance manufactured by a specific site and process can be suitably controlled by the Ph. Eur. monograph for the drug substance with additional tests if necessary

**CMN** – Changed medicine notification.

**CRPN** – Changed related product notification

**DMF** – Drug Master File. Information on the manufacturing of API, commonly supplied separately to the application and directly from the manufacturer to Medsafe

**Electronic file transfer system (EFT)** – a secure online method for medicine sponsors to submit their medicine applications to Medsafe

**NBE** – New biological entity

**NCE** – New chemical entity

**NMA** – New medicine application

**S 24(5)s** – these are changed medicine notifications that are referred under section 24(5) of the Medicines Act to be new medicine applications. There are two types of S 24(5) referrals – under subsection (a) and subsection (b). Subsection (a) is for CMNs that are complex or substantial and cannot be evaluated within the CMN 45 day timeframe. Subsection (b) referrals are for CMNs where the statutory timeframe of a decision within 90 days cannot be met.

# Introduction

**Background**

This consultation document provides proposals on changes to Medsafe fees by way of improved and targeted cost recovery of evaluation and licensing effort and other efficiency changes and asks for stakeholder feedback on these proposals.

Medsafe is responsible for administering the Medicines Act 1981 (the Act) and Medicines Regulations 1984 (the Regulations). Its functions are mainly funded through third party fees set under the Act, with additional Crown funding for enforcement and medical devices activities.

Reviews are conducted to ensure an appropriate balance between cost recovery and Crown funding and ensure those that derive benefit or create risks within the medicines regulatory system pay for those services. There is also a balance between how these fees affect individuals and business and on maintaining/encouraging participation in the regulatory system and wider government policies. Medsafe is committed to a three-year fee review cycle. The last review was in 2017.

Medsafe has a responsibility to be transparent about costs, and how the fees are used to ensure efficiency and effectiveness. This consultation document explains the rationale behind the fees review, the options to achieve the desired outcome of the fees review and indicates how changes in fees will be applied. Any changes to the fees will require amendment of the Regulations.

**Current fees under the Medicines Act 1981 and Medicines Regulations 1984**

The Act under sections 21, 24, 30, 50 and 105, allows fees to be charged for evaluating applications for licences, the approval of new and changed medicines and related products, and for approving clinical trials. A small number of other activities also attract fees. Fees payable for approvals of medicines are contained in regulation 61 of the Regulations, with licence fees are set out in Schedule 5A.

*Regulation 61A Waiver*

The fees specified in the Regulations are maximums. Regulation 61A provides that the Director-General of Health may waive or refund, in whole or in part, a fee otherwise payable under the Regulations. In exercising this power, the Director-General is obliged to have regard to the degree of complexity and time required to consider an application, and the interests of public health in New Zealand.

A ‘standard’ waiver is applied in a number of instances to reduce the fee for approval of a new or changed medicine or related product. Before a waiver is applied, three aspects are considered – time taken, complexity, and the interests of the public of New Zealand. For example, a partial waiver is available for applications made under the abbreviated process for new prescription medicines already approved by a recognised overseas regulator.

The actual fee payable for an application of a particular type, after the application of any standard waiver, is set out in the Schedule of Fees published on the Medsafe website.

**Why a fees review?**

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]](#footnote-1). The costing model requires updating each review to consider any changes in the cost of carrying out the regulatory functions funded from fees.

***Drivers of the fees review***

*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, and to provide a genuine commitment from departments to not benefit from over recovery[[2]](#footnote-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 been running a deficit in recent years and Medsafe is obligated to investigate and remedy this situation. Rises in expenditure and reductions in application volumes are usual drivers of this situation.

*Other costs*

Medsafe has contracts with other services such as ESR[[3]](#footnote-3), the SMARTI database and the Centre for Adverse Reaction Monitoring (CARM) that require periodic review and renewal. Changes in contract costs occur and need to be recovered. Both the industry and Medsafe are interested in retaining and improving the temporary electronic file transfer system put in place during the COVID-19 pandemic lockdown.

**Question 1: Do you agree with the drivers of a fees review?**

**Question 2: Are there any other drivers that should be included?**

**Question 3: How important are these drivers?**

**Objectives of the fees review**

The objectives of the fee review are:

* to align Medsafe cost recovery with best practice guidance issued by the Treasury[[4]](#footnote-4) and Office of the Controller and Auditor-General[[5]](#footnote-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 scope of the review includes 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.

**How to provide feedback**

You can provide feedback by either:

* using our online tool at **https://consult.health.govt.nz/medsafe/31effa6c/**. This is our preferred way to receive feedback.

Note: you can complete your submission over a number of sessions and save it as you go. If you select ‘Save and come back later’, you will be sent an email with a unique link that will let you return to edit and submit your response. This link can be shared with your colleagues if you require their contribution to, or review of, the submission. Once you have completed your submission, you will be sent a pdf copy for your records

or

sending an electronic submission to [medsafeapplications@health.govt.nz](mailto:medsafeapplications@health.govt.nz).

Please include the following information:

* + the title of this discussion document in the Subject box
  + your name and title, your organisation’s name (if you are submitting on behalf of an organisation) and whether your submission represents the whole organisation or a section of it
  + your contact details (such as phone number, address and/or email)
  + whether you want part or all of your submission withheld under the Official Information Act 1982 (see below).

The closing date for submissions is **21 May 2021 at 5pm**.

**Official Information Act 1982 (OIA)**

Submissions are official information and may be the subject of requests for information under the Official Information Act 1982 (OIA). The OIA specifies that information is to be made available to requesters unless there is a good reason for withholding it. **Submitters may indicate grounds for withholding specific information contained in their submissions, such as where they consider information is commercially sensitive or they wish personal information be withheld.** We will consider these requests in accordance with the provisions of the OIA.

We appreciate you taking the time to make a submission

**What will happen after consultation?**

Once the submissions close, Medsafe will review all submissions and produce a summary of submissions with responses from Medsafe to any concerns or suggestions. The submissions will inform any revisions to the proposal.

If changes to the Medicines Regulations 1984 are required, the final proposal will go to Cabinet for approval. Any change to Medsafe processes will be updated post-Cabinet approval but before the implementation date.

**How the Fees Review was undertaken**

Medsafe reviewed the fees currently being charged under the Medicines Regulations 1984. Components considered included:

* application volumes and types
* forecast revenue and forecast expenditure
* assumptions applied in the cost model
* whether cost recovery is being achieved
* future investment to improve service

**Cost model**

Medsafe uses a standard cost model when undertaking a fees review.

The cost model is based on:

* estimating the annual expenditure requirement for Medsafe in 2021/22 and allowing for annual growth over a three-year period
* allocating these costs to outputs (either Crown or industry funded) using an activity-based costing allocation
* estimating the volume of applications, based on an average from the previous five years
* deriving individual fees for each chargeable output by dividing the estimated cost by estimated volumes.

Fees are then scaled within outputs based on the estimated Medsafe effort involved. For example, an intermediate-risk new medicine application (NMA) is costed at 50% of a NCE NMA, and a lower-risk NMA is costed at 10% of a NCE NMA. The effort involved for an abridged application process has been estimated at 50% of the relevant full process for the NCE NMA, other high risk NMA and the intermediate-risk NMA.

The cost model uses the methodology used in the 2008 and 2017 review. The cost model used in 2008 was independently reviewed at the time by Deloitte. For the 2020 fees review, the cost model was reviewed by PriceWaterhouseCoopers (PwC) (Appendix A). At each fee review the cost model is updated in response to changes in the application volumes in the previous 5 years and forecast changes over the next 3 - 5 years.

**Basis of costings and estimated operating budget**

In delivering the services that are to be cost recovered from industry under the Medicines Act, Medsafe incurs direct and indirect costs. Direct costs include personnel and operating costs. Indirect costs include Ministry of Health corporate overhead costs, occupancy costs and depreciation.

**Medsafe cost estimates**

Direct and indirect costs are allocated to Medsafe’s outputs each year and form part of the cost of producing the outputs. The steps undertaken by Medsafe in calculating the costs of the services provided to industry are as follows:

• estimate the time spent by each staff member on each of Medsafe’s outputs on a full-time equivalent (FTE) basis, and allocate personnel costs to each output

• allocate direct operating costs to relevant outputs

• allocate indirect costs to outputs based on the FTE percentage of each output.

Within each output, volumes of each type of fee have been estimated based on five-year trends (with some exceptions see Appendix B for volumes used). Specific fee levels have been derived by dividing the total cost of each output by the estimated volume of applications. 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.

# Forecast expenditure

The following tables show the forecast expenditures, by expense type and output type, that have been used in the fees calculations.

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| **Table 1: Forecast expenditure, by expense type, for Medsafe** | |
| **Expense type** | **2021/22 forecast expenditure**  **($million)** |
| Personnel costs | 5.69 |
| Operating costs | 3.97 |
| Corporate overheads | 2.80 |
| Memorandum account deficit recovery | 0.50 |
| **Total** | **12.96** |
|  |  |
| Total industry-funded activities | 11.39 |
| Total Crown-funded activities | 1.57 |
| **Total** | **12.96** |

|  |  |
| --- | --- |
| **Table 2: Forecast expenditure, by industry output, for Medsafe** | |
| **Output** | **2021/22 forecast cost**  **($million)** |
| New medicine applications – medicine containing a new drug substance | 2.89 |
| New medicine applications – prescription medicine not containing a new drug substance | 1.41 |
| New medicine applications – non-prescription medicine | 0.62 |
| Changed medicine notifications | 5.12 |
| Clinical trial applications | 0.70 |
| Manufacturing assessment (manufacturer and packer licensing) | 0.65 |
| **Total industry-funded activities** | **11.39** |

**Memorandum Account Movement**

Table 3 shows the movement in the Medsafe memorandum account for the last five complete financial years. The memorandum account is externally audited annually and published in the Ministry of Health’s Annual Report.

The memorandum account has recorded annual deficits over this five-year period, moving from a $2.6 million surplus position to $2.5 million deficit position. This is largely due to lower new medicine application volumes than budgeted, however the size of the annual deficit has reduced in the two most recent years.

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| --- | --- | --- | --- | --- | --- |
| **Table 3: 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 |

**Cost Recovery**

Analysis of the cost recovery aspects of the fees were undertaken in line with The Treasury (2017), *Guidelines for Setting Charges in the Public Sector* and the Office of the Controller and Auditor-General (2008), *Charging Fees for Public Sector Goods and Services*.

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

With these principles in mind, the approach undertaken was to ensure that Medsafe would be recovering the actual cost of evaluating the medicine applications and ensure equitable and proportionate payment of fees for all stakeholders. All fees were examined against the effort (risk level and time) required.

It should be noted that this is a review of the existing cost recovery calculations and does not introduce new cost recovery mechanisms.

Cost recovery is reflected in the cost model (see Appendix A).

**Other cost considerations**

**CPI Increase**

Changes to the Consumer Price Index (CPI) was last applied in 2017/18 and was a significant increase of 15% to cover CPI changes over the previous 10 years, where the fees remain unchanged while the memorandum account surplus was cleared. Accordingly, any CPI change between 2018 and 2020 will be lower.

CPI has been calculated using the information on the Reserve Bank inflation calculator for general CPI and is a 4.2% change over the previous 3 years (2017 Q3 to 2020 Q2). This 4.2% has been used as the proxy as to the CPI increases for the 3 year period that this review covers.

**Increased staff**

Medsafe has identified several areas where additional staff would be justified. Additional evaluators would help with improving evaluation timelines. These are intended to be permanent staff changes.

**Contract renewals**

Medsafe has contracts with ESR to provide testing services, with CARM for pharmacovigilance, and for maintenance of our SMARTI database. These contracts are regularly reviewed and adjusted, in the case of ESR on a Ministry-wide basis, and costs are allocated. These contracts benefit sponsor companies by providing efficient, robust and supporting services to the regulation of medicines, and relevant capability (including sustainability).

**Replacement of obsolete technology**

Before the COVID-19 pandemic lockdown, Medsafe primarily worked with electronic files submitted on CD-ROM and in hard copy. This way of doing things was becoming difficult for both Medsafe and industry as:

* CD-ROM technology is essentially now obsolete, and ongoing support of equipment is becoming more difficult.
* Applicants have additional costs to maintain this technology for NZ as this is not the norm for submissions to other regulators
* Storage of the CD-ROMs requires physical space, which is finite and expensive, and are not fully consistent with the requirements of the Public Records Act 2005 (current storage conditions are likely to lead to degradation of the files)
* Sponsors regularly have to transfer information from one format to another and ensure links within the electronic documents work. This is inefficient and has cost to firms of maintaining obsolete technology not used elsewhere.
* Providing hardcopies of documents was originally to ensure authenticity and security of the documents and provide a physical paper trail. Current technology can provide adequate assurance of this.

During the COVID-19 pandemic lockdown level 4 from March 2020, both sponsors and Medsafe had to work from home without access, in many cases, to printers and CD-ROM devices. Medsafe had initiated a pilot on a secure electronic file transfer (EFT) system prior to the lockdown and worked to stand up this system fully in the days before the lockdown. Medsafe also adjusted processes (internal and external) to enable business as usual to continue with minimal disruption to industry. Feedback from industry and Medsafe staff indicates that this approach provided significant efficiency benefits and both parties want to retain the EFT as a permanent feature.

To make the EFT permanent, some improvements need to be made to the infrastructure to ensure ongoing reliability.

* The receiving space for electronic application files needs to be robust to cope with a number of large files, ideally cloud-based
* Final storage of these electronic files needs to be cloud-based
* Transfer of information on the CD-ROMs to electronic files to be stored cloud-based
* A long-term plan to scan physical files to electronic files to be stored cloud-based.
* Improved cyber-security
* Improved business continuity plans

Therefore, resourcing for these improvements have been included in the fees review.

**Question 4: Do you think the forecast numbers of applications is accurate? If not, what factors do you think would change the forecasts?**

**Question 5: Is there other evidence/information that would inform analysis of the review?**

**Question 6: Do you think the cost recovery principles are accurate and complete?**

**Results of the fees analysis**

The fees review has concluded that there is a need for increased revenue from fees to ensure Medsafe is effective and sustainable. Increased revenue will reverse the deficit position of the memorandum account balance and ensure Medsafe does not need to cut expenditure as this will reduce service levels.

**Volumes**

The volume of applications is the basis of Medsafe revenue. It is difficult to predict trends in volumes so the ability to absorb the fluctuations of applications received is important for the sustainability of Medsafe.

**Cost model**

PwC undertook a review of the cost model and concluded that the model used by Medsafe was logical, robust and consistent with the Treasury and the OAG frameworks. Suggested improvements have been made to the model prior to the finalisation of this consultation document. The PwC report *Fee Setting Model – Methodology and Assumption Testing* 18 December 2020 is appended to this consultation document (Appendix A).

**CPI adjustment**

A CPI adjustment to all the fees should be applied to ensure fees keep pace with rising basic costs. CPI has been calculated using the information on the Reserve Bank inflation calculator for general CPI and is a 4.2% change over the previous 3 years (2017 Q3 to 2020 Q2). This 4.2% has been used as the proxy as to the CPI increases for the 3-year period that this review covers.

**Cost recovery**

There are some evaluation and activity costs that require cost recovery adjustments and realignments. Analysis of the current fees (<https://www.medsafe.govt.nz/regulatory/fees.asp> ) indicates that many fees have not changed for some years, with no review for increased complexity or increased costs since 2008. 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 some fees that do not reflect the cost of evaluation, such as the clinical s24(5)(a) referrals for new and extended indications that require specialist clinical evaluation, and the provisional consent pathway.

The review found that there was no need to change the cost recovery component of all fees, as many were based on satisfactory assumptions.

Proposals to change specific fees regarding cost recovery are described in the next section and make up Option 3 – see page 25).

**Memorandum account balance**

To address the existing $2.5 million deficit in the memorandum account, Medsafe proposing to over recover revenue by $0.5 million per annum, over a five-year period.

**Improvements/Investment**

In order to ensure Medsafe remains an effective and efficient regulator, some investment is required in improved technology, increased FTE and contractual relationships with parties such as the Centre for Adverse Reactions (CARM) and ESR.

**Expected impacts of the proposed fee changes**

The resulting forecast expenditure was then placed against the forecast revenue. The cost recovery changes, and the calculated CPI increase covers the forecast expenditure.

Overall, Medsafe expects the proposed fee changes to:

* ensure fees are more effective and equitable
* realign the fees to reflect the proportion of effort by Medsafe
* ensure a steady upward movement towards zero for the memorandum account
* enable improvements in technology to assist stakeholders
* ensure staff continue to be skilled, engaged and efficient
* contribute to improved performance metrics

**Cost recovery proposals**

These proposals (Option 3 – see page 25) will apply in addition to the CPI adjustment, and only affect some fees as described below. While cost recovery was analysed for all fees with a cost recovery component, not all fees are proposed to be affected.

**NCE base fee**

The current maximum for a New Chemical Entity in the Medicines Regulations 1984 is $122,625 (GST inclusive), whereas Medsafe only charges $102,210. This fee was reviewed in terms of cost recovery and it was determined that no change (except for CPI) was justified.

The NCE fee is the benchmark fee, from which evaluation effort is compared. This means that there should be a logical pattern to the fees that makes them more transparent and is also a basis for any fee waivers. Previously, there has been some inconsistencies with benchmarking, i.e. the intermediate risk fee has been benchmarked to the other high risk fee rather than the NCE fee. This has been clarified and adjusted to be more logical and consistent.

**Increased fee for “other high risk” full and abbreviated NMAs, and biosimilars**

**Other high risk NMA**

“Other high risk” NMAs cover medicines that are considered high risk but do not contain a new active ingredient.

In the 2017 fees review, the other high risk NMA fee was not changed. This meant that a misalignment was created in the structure of the fees, where the other high risk NMA fee is the same as the intermediate risk NMA fee (and this flows through to their respective abbreviated applications). In terms of risk and evaluation effort, the other high risk NMA require more effort than intermediate risk medicine NMA, but less than a NCE NMA, as the active ingredient is known but otherwise has the same other components as an NCE. The other high risk evaluation can include significant evaluation effort in terms of clinical information, but has less in terms of the safety and characterisation of the active ingredient and equates more to 75% of the NCE work, rather than the current fee set at 50% of the effort.

**Biosimilars**

In the current schedule of fees, the fee for these types of NMAs is the same as for an intermediate risk NMA, i.e. for a non-biological generic medicine. When comparing a basic example of an intermediate risk NMA, an injectable generic with no bioequivalence component, with a biosimilar it becomes clear that the amount of work required for the assessment of each is significantly different and that the effort for a biosimilar NMA would be significantly under-recovered. Evaluations of these applications include a substantial amount of work regarding the drug substance (being a biological medicine and not covered by a DMF or CEP) as well as a clinical component. This is comparable to an other high risk NMA, which is proposed to be 75% of a NCE fee.

**Proposal**

There is an opportunity to improve transparency in fees setting. It is proposed that the fee for other high risk NMAs is increased to 75% of a NCE application as this better reflects the work effort (ie the effort is between an intermediate risk and a NCE/NBE NMA). It also enables a logical alignment of the other fees in a clear, almost modular structure.

Biosimilars are closer in work effort to a high risk NMA than their current position as an Intermediate risk and so therefore are proposed to be considered as an other high risk NMA.

This proposal will require an amendment of Regulation 61 of the Medicines Regulations 1984 to raise the NMA fee.

**New combination products and new dosage forms**

**New combination products**

New combination products usually are a novel combination of known active ingredients, so much of the characterisation of the product has been done previously. However, the unique combination requires clinical evaluation and finished product manufacturing scrutiny. It was determined that the evaluation effort was lower than an other high risk, but higher than an intermediate risk, mainly due to the clinical component.

**New dose form**

New dose forms are additional to a parent product, where can require clinical evaluation but this is usually less comprehensive. Focus is usually on finished product manufacturing rather than active ingredients and commonly requires additional evaluation of a delivery device such as an inhaler, nasal spray or modified release form. Bioequivalence can be relevant. Therefore, the effort is equivalent to that for an intermediate risk product.

To simplify the fees for new dose forms, it is proposed to merge Grades 1 and 2 into the same category.

Abbreviated applications can be accepted for new dose forms as long as the usual requirements are met that the parent product is identical to that approved in New Zealand.

**Proposal**

It is therefore proposed that combination applications are set at 66% of an NCE.

It is proposed that Grades 1 and 2 should merge and new dose forms are set at 50% of an NCE.

It is also proposed that abbreviated combination and new dose forms are set at 50% of their respective fees.

**Provisional consent**

The original intent for providing provisional consent under section 23 of the Act is to allow for the provision of a medicine that is usually lacking clinical data. This means that patients may be able to get a form of “early access” to a medicine and this provisional consent usually comes with conditions on the length of the provisional approval and any other relevant marketing restrictions. There is an expectation that additional data will be provided within the next 2-4 years and full section 20 approval will then be sought.

The current fee for provisional consent applications, regardless of risk category, is $8,437. It is Medsafe policy that all section 23 applications are considered either a NCE or other high risk application as appropriate. While it is expected the full cost of the evaluation work would be recovered by the full NMA fee charged when converting from a section 23 to a section 20 consent, this may be several years in the future, or the company may choose to withdraw the product (e.g. if it does not receive funding) before converting. In order to properly cost recover, it would be more appropriate to charge a higher initial fee and charge the remainder of the full fee when it is converted. Further to this, the current $8,437 fee does not cost recover the evaluation effort as most S23 applications will have substantial dossiers, only with reduced clinical data.

**Stock shortage provisional consents**

There are also some situations where section 23 consent is sought requiring assessment of very limited data to address a stock shortage. In these cases, a high upfront fee with the expectation of conversion to a full approval would be inappropriate, due to the lack of data to be evaluated and the rare occurrence (as data shows) that a product obtained to address a short-term stock shortage will result in a move to full approval. On the other hand, Medsafe does take on a higher risk when giving these products with limited data a provisional approval and the risk to Medsafe increases with less data provided.

**Renewals of s23 provisional consents**

Once provisional consent is granted, applications must be submitted to renew the consent every 2 years. While these applications currently require limited assessment (mostly administrative and some module 1 updates), this work is done by Team Leaders and does take some time. The current $500 fee does not cover this time nor the cost to publish the renewed consent in the NZ Gazette.

**Proposal**

The proposal is to align the section 23 fee to the NCE or other high risk fee as appropriate, but acknowledge that the dossier is likely to have missing data. For example, the fee calculation for an NCE with limited clinical data will start at the NCE price, but the fee will be waived down due to the outstanding data to 80% of the full application fee. The subsequent s20 conversion fee will be the remainder of the NCE fee (20%).

For stock shortages section 23 applications, the fee calculation will start at the other high risk fee and the waiver be applied according to the situation with the stock shortage (for example to 20% of the other high risk fee if it is very similar to another product on the NZ market and data can be shared). While this situation will not have upfront clarity, it is likely the whole stock shortage situation is unclear and would require close communication with Medsafe on other issues.

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| **Table 4: New Medicine Application Provisional Consent Fees** | | |
| Application for provisional consent to distribute a new medicine – clinical need | 8,437 | **63,902 (or 85,202 if NCE)** |
| Application for provisional consent to distribute a new medicine – stock shortage | 8,437 | **15,975 (or 21,301 if NCE)** |
| **Provisional conversion to s20 – clinical need** | **-** | **15,975 (or 21,301 if NCE)** |
| **Provisional conversion to s20 – stock shortage** | **-** | **63,902 (or 85,202 if NCE)** |
| Application for renewal of provisional consent | 500 | **27,957 (or 37,276 if NCE)** |

**Section 24(5) referrals**

**Rationale**

The Medicines Act has a unique feature where the regulator can refer complex CMNs to be regarded as NMAs. This is done through section 24(5) of the Act when the CMN is sufficiently complex or number of changes means that.

There are two pathways for CMNs to be referred as s24(5)s:

* s24(5)(a): where it is reasonably clear either on receipt of the application or early in the evaluation process that the complexity of the CMN means that CMN timeframes would be unreasonable for both Medsafe and the sponsor. Examples include new indications, new API manufacturing processes, new biological medicine manufacturing changes, or a substantial number of changes to one product at one time.
* S24(5)(b): where referral is necessary because the evaluation cannot be completed within the statutory 90 days. This is usually caused by long response times to questions or complex responses.

Currently s24(5) referrals are primarily treated as CMNs, with a maximum fee of equivalent to the relevant new medicine risk category, but with NMA timeframes. However, under the Medicines Act, CMNs that have been referred under s24(5) are legally new medicines. Many of these changes retain the regular CMN fee – maximum $3,200 per change.

For these complex changes, evaluation involves specialist skills to evaluate the clinical information, the Drug Master File or complex manufacturing changes. The evaluation effort is significantly higher than the fee for these types of applications, which is reflected in the timeframe, but not the fee. There are degrees of complexity even within these categories.

Industry has asked for more certainty with regard to s24(5) referrals. Currently, only some CMN categories are automatically referred (these are noted on the application form). Analysis has shown that complex API manufacturing changes are regularly referred during the early stages of evaluation and should probably be automatically referred to improve certainty.

There is also no current provision for an abbreviated pathway for s24(5) referred products. As NMAs have this pathway option, it is reasonable to extend this to those applications that will be automatically referred or where the sponsor considers a referral is likely.

**Proposal**

To clearly identify that Indications Grade 1 – Grade 3 and API manufacturing process Grade 1 and 2 will be automatically referred through s24(5)(a).

Increase the fees for the automatically referred applications to be NMA fees and scale appropriately to the level of effort.

|  |  |
| --- | --- |
| New indication | 66% of risk category |
| Extended indication | 50% of risk category |
| Active ingredient manufacturing process Grades 1 and 2 | 30% of risk category |

There is **no change** to the fees for other S24(5)(a) referrals nor for S24(5)(b) referrals.

**Clinical trials changes**

Clinical trials has recorded an increasing level of applications in recent years. With efficiencies in dealing with the increased volume, the fees model results in a proposal for no change in the Clinical Trial fee, including that no CPI is applied.

However, two changes are proposed. These are:

* to formalise a new standard fee for an Investigator Led clinical trials. This is currently charged for but is not set out in the Fees Schedule. This will not require any change to the Regulations.
* a new fee for Clinical Trial Amendments (new site new investigator). Medsafe undertakes some administrative activities when a new trial is submitted to the Health Research Council's Standing Committee on Therapeutic Trials (SCOTT) for approval, so it is appropriate for an administrative fee to be charged. It is proposed that this fee is the standard Medsafe administrative fee ($423).

**Benchmarking of Intermediate risk non-prescription medicine**

Benchmarking is also applied to intermediate risk non-prescription medicine NMAs. These are products that have a general sale classification but are usually used in a clinical setting, such as intravenous electrolyte solutions. Generally, the substances involved are low risk but the administration or delivery is of intermediate risk.

The proposal is to have this fee adjusted to be 25% of NCE effort (or 50% of an intermediate risk product).

This change has very little impact on fee payers as there have been no new applications for the last 4 years, and prior to that an average of one application a year.

**Summary of changes**

This table provides an overview of the proposals, taking the existing NCE application fee as 100%. The percentages below are the maximums.

|  |  |  |
| --- | --- | --- |
| **Table 5: Overview of the proposals** | | |
|  | Percentage from NCE base point | Comments |
| **NCE** | 100% | No change other than CPI increase |
| **Other high risk, which now includes biosimilars** | 75% | Adjusted so it is benchmarked appropriately |
| **New fixed dose combination of approved APIs (e.g. innovator + 2 new API, or other company novel combination)** | 66% | Adjusted so it is benchmarked appropriately |
| **New dose forms – high risk and intermediate risk – Grades 1 and 2** | 50% | Adjusted so it is benchmarked appropriately |
| **New dose forms – intermediate risk non-prescription – Grades 1 and 2** | 25% | Adjusted so it is benchmarked appropriately |
| **New dose forms –low risk – Grades 1 and 2** | 10% | No change, other than CPI increase |
| **Intermediate risk - prescription** | 50% | Adjusted so it is benchmarked appropriately. |
| **Intermediate risk non-prescription** | 25% | Adjusted so it is benchmarked appropriately |
| **New Low risk** | 10% | No change, other than CPI increase |
| **New Related products** |  | No change, other than CPI increase |
| **Abbreviated high risk NCE** | 50% | No change, other than CPI increase |
| **Abbreviated other high risk** | 37.5% (ie 50% of 75%) | Consequential change from the benchmarking of the other high risk fee |
| **Abbreviated Intermediate risk - prescription** | 25% | Consequential change from the benchmarking of the Intermediate risk – prescription fee |
| **New provisional consent – clinical need** | 80% of high risk category (all S23s are other high risk or NCE) | Cost recovery change |
| **Provisional conversion to S20 – clinical need** | The remaining 20% of the NCE or other high risk fee, as appropriate | Cost recovery change |
| **New provisional consent – stock shortage** | 20% of high risk category (all S23s are other high risk or NCE) | Cost recovery change |
| **Provisional conversion to S20 – stock shortage** | The remaining 80% of the NCE or other high risk fee, as appropriate | Cost recovery change |
| **Renewal of provisional consent** | 35% of NCE or other high risk | Cost recovery change |
| **CMN** | Maximum equivalent to risk category of the medicine | No change, other than CPI increase |
| **CRPN** | Maximum equivalent to risk category of the medicine | No change, other than CPI increase |
| **Section 24(5)(a) – automatic referrals** | Variable: 66%/50%/35% of risk category | Cost recovery change |
| **Minimum fee (Admin fee)** | 50% of standard CMN fee | No change, other than CPI increase |
| **SACNs** | 50% of standard CMN fee | No change except charge individually, other than CPI increase |
| **Reinstatement NMA** | 25% of risk category | No change, other than CPI increase |

**Clinical trials**

Currently, the fee in Regulation 61 for clinical trials is $9,843 for an application for a clinical trial. The actual charged fee is $7,500.

|  |  |  |  |
| --- | --- | --- | --- |
| **Table 6: Overview of clinical trial changes** | | | |
|  | Current fee | Proposed fee | Comments |
| **Application for consent to conduct a clinical trial** | $7,500 | $7,500 | No change |
| **Additional clinical trial for the same medicine, submitted at the same time** | $3,750 | $3,750 | No change |
| **Investigator-led Clinical Trial** | $1,000 | $1000 | No change, but fee being charged previously not listed in schedule. |
| **Clinical Trial Amendments (new site new investigator)** |  | $415 | Administration fee being introduced. |

**Licensing fees and other application fees**

Licensing fees and other application fees, such as:

* Licensing fees, including manufacturing licences, pharmacy licences, wholesale licences
* Other applications, such as Certificates of Pharmaceutical Product, Dietary Supplement Regulatory Statements for Foreign Governments, Medical Device Regulatory Statements for Foreign Governments

were assessed for cost recovery and CPI increases. No cost recovery changes were identified but the CPI increase will apply.

**Question 7: Do you agree with these proposals? If not, why not?**

**Other proposed changes**

**Self-Assessable Change Notifications (SACNs)**

Currently SACNs submitted with a CMN are not charged any fees, whereas they incur a cost of $415 per change when submitted separately. It is proposed that this be removed and all SACNs be charged the same administrative fee, regardless of how they are submitted as they still require administrative action. This change can be affected through a change in CMN forms and guidelines, rather than requiring changes to the Regulations.

**Additional fees for NMAs that include multiple names, strengths and dosage forms**

While the Medsafe guidelines and schedule of fees indicate a single fee is charged for NMAs regardless of how many names, strengths and dosage forms are proposed, in practice, additional fees are typically applied to additional dosage forms.

It is proposed to formalise additive fees for NMAs for products with multiple names, strengths and/or dosage forms as these are regularly charged for and reflect the effort required. This also improves the transparency of the fees charged. This will be effected through an clarification of the Fees Schedule (see Appendix C for a comparative fees schedule).

**Question 8: do you agree with these other proposals? If not, why not?**

**Options on how to apply the outcomes of the fees review**

Given the outcome of the fees review, three options have been identified. Each option has been assessed against each of the criteria

**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.

While the improvement initiatives would 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.

**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%**.

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

**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 select group fees where cost recovery has not been reviewed for some time.

As with the flat fee option, Option 3 addresses the current financial situation of Medsafe, and provides a positive economic and access impact for the New Zealand public. It also results in no change to 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 effected (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 fee has 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.

**Analysis of the options**

|  |  |  |  |
| --- | --- | --- | --- |
| **Table 7: Options analysis against cost recovery principles** | | | |
| 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 | - | - | + |
| Efficiency | - | + | + |
| Effectiveness | - | + | + |
| Justifiability | - | - | + |
| Transparency | - | - | + |
| Simplicity and consistency | + | + | + |

* Does not meet the principle

+ Meets the principle

|  |  |  |  |
| --- | --- | --- | --- |
| **Table 8: Options analysis of impacts (direct and indirect) to fee payers and Medsafe** | | | |
| **Type of fee payer** | **Status Quo (Option 1)** | **Flat fee (Option 2)** | **Cost recovery + CPI (Option 3)** |
| High risk medicines | *Direct impacts:*  No change in financial impacts.  *Indirect impacts:*  Potential reduction in service levels and increased inefficiencies, leading to increased timelines | *Direct impacts:*  Moderate financial impact  *Indirect impacts:*  Improved efficiencies and better service levels.  Costs spread over all fee payers | *Direct impacts:*  High financial impact in certain areas, but moderate to low in others.  *Indirect impacts:*  More certainty of referrals. Will gain better service levels |
| Intermediate risk medicines | *Direct impacts:*  Low financial impact  *Indirect impacts:*  Potential reduction in service levels and increased inefficiencies, leading to increased timelines | *Direct impacts:*  High financial impact, not equitable.  *Indirect impacts:*  Improved efficiencies and better service levels. | *Direct impacts:*  Moderate to low financial impact. Equitable.  *Indirect impacts:*  Improved efficiencies and better service levels |
| Low risk medicines | *Direct impacts:*  Low financial impact  *Indirect impacts:*  Potential reduction in service levels and increased inefficiencies, leading to increased timelines. Inequities remain | *Direct impacts:*  High financial impact, not equitable.  *Indirect impacts:*  Improved efficiencies and better service levels | *Direct impacts:*  Low financial impact. Equitable.  *Indirect impacts:*  Improved efficiencies and better service levels |
| Clinical trials | No impact | No impact | No impact |
| Licences and other application fees | *Direct impacts:*  Low financial impact  *Indirect impacts:*  Potential reduction in service levels and increased inefficiencies, leading to increased timelines | *Direct impacts:*  High financial impact. Not equitable.  *Indirect impacts:*  Improved efficiencies and better service levels | *Direct impacts:*  Low financial impact. Equitable.  *Indirect impacts:*  Improved efficiencies and better service levels |

**Question 9: Do you agree with the status quo? If not, how would you describe the status quo?**

**Question 10: Would you support retaining the status quo?**

**Question 11: Do you agree with the flat fee only increase? If not, why not?**

**Question 12: Do you agree with the mix of targeted cost recovery and CPI increase? If not, why not?**

**Question 13: Are these all the potential options?**

**Question 14: Do you agree with the impacts stated?**

**Next Steps**

Changes as a result of the consultation will be applied to the proposals, options and the implementation, and a summary of submissions will be published. It is likely that the final proposals in the fees review will require amendment to the Medicines Regulations 1984 to change the limits specified in Regulation 61 and Schedule 5A. These maximums would apply to the following fees:

* Reg 61(4): all NMAs except NCEs
* Reg 61(6): provisional consents

Any change to the Regulations will require Cabinet agreement, and to Medsafe process, policies, guidelines, application forms and the Fees Schedule.

Medsafe will also ensure that any changes arising from the CMN Form A consultation is reflected in the Fees Schedule.

**Implementation**

Any change to the Regulations will be clearly signalled to industry. Medsafe acknowledges that any change in fees can be disruptive to those the change affects, particularly when the budget cycles are not aligned. Many companies set their budgets for a January - December period and Medsafe introducing new fees at other times can mean that some applications, licences or inspections might have to be deferred.

At the last fee review in 2018, at the suggestion from industry, Medsafe implemented a split fee payment where some of the fee is paid at the time of application and the remainder is paid early in the New Year when budgets have been set. It is proposed that this is implemented again if budget cycles do not align, as companies used this successfully, although uptake was minimal. It is expected that any changes in fees will be indicated to industry early enough for their budget setting rounds.

For changes to fee structure, a new schedule of fees, guidance and application forms will be published.

**Question 15: Should Medsafe offer the split fee payment again?**

**Monitoring, evaluation and review**

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[[6]](#footnote-6).

Medsafe intends to review the fees and the cost recovery regime every three years. 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
* CPI adjustments
* Improvements

**Appendices**

**Appendix A: Pricewaterhouse Coopers Report**

**Appendix B: Application volumes used in the Fees Review**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Application by volumes, by fee type** | | | | | | | |
|  | 2015 | 2016 | 2017 | 2018 | 2019 | **5-year average** | Trend |
| **New medicine applications** | | | | | | | |
| New higher-risk medicine containing one or more new active substances | 8 | 6 | 8 | 7 | 7 | **7** |  |
| Any other new higher-risk medicine | 18 | 7 | 11 | 9 | 11 | **11** |  |
| Abridged new higher-risk medicine containing one or more new active substances | 16 | 18 | 12 | 13 | 13 | **14** |  |
| Abridged any other new higher-risk medicine | 16 | 8 | 7 | 14 | 14 | **12** |  |
| New intermediate-risk medicine – prescription medicine | 31 | 22 | 20 | 20 | 13 | **21** | (d) |
| New intermediate-risk medicine – non-prescription medicine | 1 | 1 | - | - | - | **1** | (d) |
| Abridged new intermediate-risk medicine – prescription medicine | 40 | 52 | 44 | 46 | 31 | **42** | (d) |
| New lower-risk medicine | 42 | 26 | 57 | 67 | 59 | **50** | (i) |
| Provisional consent | 0 | 5 | 8 | 2 | 11 | **5** | (i) |
| Renewal of Provisional consent | 9 | 15 | 10 | 10 | 11 | **11** |  |
| **Changed medicine notifications** | | | | | | | |
| CMN notifications | 1366 | 1379 | 1233 | 1389 | 1334 | **1340** |  |
| s24(5) referral | 68 | 87 | 82 | 142 | 138 | **103** | (i) |
| Self-assessable CMN notifications | 1124 | 996 | 1170 | 1182 | 1469 | **1188** | (i) |
| **Related Products** | | | | | | | |
| New related products | 0 | 0 | 1 | 1 | 1 | **1** |  |
| Changed related products | 4 | 8 | 5 | 6 | 4 | **5** |  |
| **Clinical trial applications** | | | | | | | |
| Application for consent to conduct a clinical trial | 149 | 105 | 126 | 125 | 131 | **127** |  |
| Additional clinical trial for the same medicine, submitted at the same time | 7 | 2 | 2 | 3 | 3 | **3** |  |

Key: (i) – increase; (d) decrease; (v) – variable

**Appendix C – Fees Schedule Comparison**

Highlighted text indicates the cost recovery changes.

|  |  |  |
| --- | --- | --- |
| **Type of application** | **Old fee ($)** | **New fee ($)** |
| New higher-risk medicine containing one or more new active substances | 102,210 | 106,503 |
| Any other new higher-risk medicine (including biosimilars) | 43,875 | 79,877 |
| New intermediate-risk medicine – prescription medicine | 43,875 | 53,252 |
| New intermediate-risk medicine – non-prescription medicine | 10,220 | 26,626 |
| New lower-risk medicine | 10,220 | 10,649 |
| Additional dose form – higher-risk medicine – Grade 1 or 2 | 43,875 | 53,252 |
| Additional dose form – intermediate-risk prescription medicine – Grade 1 or 2 | 43,875 | 53,252 |
| Additional dose form – intermediate-risk non-prescription medicine – Grade 1 or 2 | 10,220 | 26,626 |
| Additional dose form – lower-risk medicine – Grade 1 or 2 | 10,220 | 10,649 |
| New combination pack containing two or more currently approved products | 3,680 | 3,835 |
| ***The following fees apply when the additions are notified at the same time as the parent application*** |  |  |
| Additional name − Grade 1 | 0 | 432 |
| Additional name − Grade 2 | 0 | 865 |
| Additional classification (with/without new name) | 0 | 432 |
| Additional strength − Grade 1 | 0 | 1,298 |
| Additional strength − Grade 2 | 0 | 1,730 |
| Additional strength − Grade 3 | 0 | 3,460 |
| Additional strength − Grade 4 | 0 | 10,785 |
| Additional strength − Grade 4 | 0 | 10,785 |
| Additional strength − Grade 5 | 0 | 16,177 |
| Additional flavour or type of sweetening | 0 | 865 |
| ***The following fees apply when the additions are subsequent to the parent application*** |  |  |
| Additional name − Grade 1 | 830 | 865 |
| Additional name − Grade 2 | 1,660 | 1,730 |
| Additional classification (with/without new name) | 830 | 865 |
| Additional strength − Grade 1 | 2,490 | 2,595 |
| Additional strength − Grade 2 | 3,320 | 3,459 |
| Additional strength − Grade 3 | 6,640 | 6,919 |
| Additional strength − Grade 4 | 20,700 | 21,569 |
| Additional strength − Grade 4 | 20,700 | 21,569 |
| Additional strength − Grade 5 | 31,050 | 32,354 |
| Additional flavour or type of sweetening | 1,660 | 1,730 |
| **New Medicines Application (Abbreviated Evaluation Process) Fees** |  |  |
| New higher-risk medicine containing one or more new active substances | 51,100 | 53,252 |
| Any other new higher-risk medicine | 21,940 | 39,939 |
| New intermediate-risk medicine – prescription medicine | 21,940 | 26,626 |
| *Additional names, strengthens, flavours and classifications must be notified at the same time as the parent application* |  |  |
| **New Related Product Application (NRPA) Fees** |  |  |
| New related product | 5,500 | 5,731 |
| Additional names, strengths, flavours and classifications notified at the same time as the parent application | 0 | 0 |
| ***The following fees apply when the additions are subsequent to the parent application*** |  |  |
| Additional name − Grade 1 | 830 | 865 |
| Additional name − Grade 2 | 1,660 | 1,730 |
| Additional strength | 1,660 | 1,730 |
| Additional flavour or type of sweetening | 1,660 | 1,730 |
| **New Medicine Application Provisional Consent Fees** |  |  |
| Application for provisional consent to distribute a new medicine – clinical need | 8,437 | **63,902 (or 85,202 if NCE)** |
| Application for provisional consent to distribute a new medicine – stock shortage | 8,437 | **15,975 (or 21,301 if NCE)** |
| **Provisional conversion to s20 – clinical need** | **-** | **15,975 (or 21,301 if NCE)** |
| **Provisional conversion to s20 – stock shortage** | **-** | **63,902 (or 85,202 if NCE)** |
| Application for renewal of provisional consent | 500 | **27,957 (or 37,276 if NCE)** |
| **Changed Medicine Notifications (CMN) Fees**  **Non-Biological Medicine (CMN Form A)**  *Notifying a material change (including self-assessable changes) to an approved Type I product (lower- risk medicine) or a Type II product (intermediate- or higher-risk medicine other than a biological or biotechnological product − but including antibiotics and like substances derived from micro-organisms). Note: In no case will the CMN/Change Related Product Notification (CRPN) fee for a single product exceed the fee for a new medicine application for a product of the same type* | | |
| **Product name** |  |  |
| Product name, for each new name | 830 | 865 |
| **Formulation** |  |  |
| Formulation − Grade 1, Type 1 | 1,660 | 1,730 |
| Formulation − Grade 1, Type 2 | 2,490 | 2,595 |
| Formulation − Grade 2, Type 1 | 1,660 | 1,730 |
| Formulation − Grade 3, Type 1 | 2,075 | 2,162 |
| Formulation − Grade 4, Type 1 | 2,490 | 2,595 |
| Formulation − Grade 4, Type 2 | 3,200 | 3,334 |
| **Active ingredient** |  |  |
| Active ingredient manufacturing site | 830 | 865 |
| Active ingredient manufacturing process − Grade 1, Type 1 | 830 | 865 |
| Active ingredient manufacturing process - Grade 1, Type 2 | 830 | 865 |
| Active ingredient manufacturing process − Grade 2, Type 1 | 3,200 | 3,334 |
| Active ingredient manufacturing process − Grade 2, Type 2 | 3,200 | 3,334 |
| Active ingredient manufacturing process − Grade 3, Type 1 | 830 | 865 |
| Active ingredient manufacturing process − Grade 3, Type 2 | 830 | 865 |
| Active ingredient specifications/test methods − Grade 1 | 415 | 432 |
| Active ingredient specifications/test methods − Grade 2 | 830 | 865 |
| Active ingredient specifications/test methods − Grade 3 | 830 | 865 |
| Active ingredient specifications/test methods − Grade 4, Type 1 | 830 | 865 |
| Active ingredient specifications/test methods − Grade 4, Type 2 | 1,660 | 1,730 |
| **Excipient** |  |  |
| Excipient specifications/test methods − Grade 1 | 415 | 432 |
| Excipient specifications/test methods − Grade 2 | 830 | 865 |
| Excipient specifications/test methods − Grade 3 | 830 | 865 |
| **Finished product** |  |  |
| Finished product packing site − Grade 1 | 830 | 865 |
| Finished product packing site − Grade 2 | 1,660 | 1,730 |
| Finished product manufacturing process − Grade 1, Type 1 | 1,660 | 1,730 |
| Finished product manufacturing process − Grade 1, Type 2 | 2,490 | 2,595 |
| Finished product manufacturing process − Grade 2, Type 1 | 2,490 | 2,595 |
| Finished product manufacturing process − Grade 2, Type 2 | 3,200 | 3,334 |
| Finished product specifications/test methods − Grade 1 | 415 | 432 |
| Finished product specifications/test methods − Grade 2 | 415 | 432 |
| Finished product specifications/test methods − Grade 3 | 415 | 432 |
| Finished product specifications/test methods − Grade 4 | 830 | 865 |
| Finished product specifications/test methods − Grade 5, Type 1 | 830 | 865 |
| Finished product specifications/test methods − Grade 5, Type 2 | 1,660 | 1,730 |
| **Product stability and packaging** |  |  |
| Shelf life/storage conditions − Grade 1 | 415 | 432 |
| Shelf life/storage conditions − Grade 2 | 1,660 | 1,730 |
| Container/closure/packaging − Grade 1 | 415 | 432 |
| Container/closure/packaging − Grade 2 | 830 | 865 |
| Container/closure/packaging − Grade 3 | 1,660 | 1,730 |
| Container/closure/packaging − Grade 4 | 2,490 | 2,595 |
| Container/closure/packaging − Grade 5 | 3,200 | 3,334 |
| **Indications and dosage** |  |  |
| Indications/dosage − Grade 1 | 3,200 | 3,334 |
| Indications/dosage − Grade 2 | 3,200 | 3,334 |
| Indications/dosage − Grade 3 | 3,200 | 3,334 |
| Indications/dosage − Grade 4 | 830 | 865 |
| Indications/dosage − Grade 5 | 830 | 865 |
| Contraindications,Warnings and Precautions | 3,200 | 3,334 |
| Data sheet Data sheet − miscellaneous changes | 415 | 432 |
| Data sheet − format change (an administration fee applies if this is the sole change) | 0 |  |
| **Labelling** |  |  |
| Labelling − Grade 1 | 415 | 432 |
| Labelling − Grade 2 | 830 | 865 |
| Labelling − Grade 3 | 830 | 865 |
| Other Sponsor | 415 | 432 |
| Change in ownership | 830 | 865 |
| Self-assessable change(s) | 415 | 432 |
| Administration Fee | 415 | 432 |
| *Biological or Biotechnological Medicine (CMN Form B) Notifying a material change (including self-assessable changes) to an approved Type III (biological or biotechnological) product (ie, a vaccine, recombinant product, monoclonal antibody or variant thereof, or a medicinal product derived from blood or plasma). Note: In no case will the CMN/CRPN fee for a single product exceed the fee for a new medicine application for a product of the same type.* |  |  |
| **Product name** |  |  |
| Product name, for each new name | 830 | 865 |
| **Formulation/excipients** |  |  |
| Formulation − Grade 1 | 3,200 | 3,334 |
| Formulation − Grade 2 | 830 | 865 |
| **Bulk active** |  |  |
| Active ingredient manufacturing site | 3,200 | 3,334 |
| Active ingredient method of manufacture – Grade 1 | 3,200 | 3,334 |
| Active ingredient method of manufacture – Grade 2 | 830 | 865 |
| Active ingredient method of manufacture – grade 3 | 415 | 432 |
| Finished product manufacturing site | 3,200 | 3,334 |
| Finished product secondary packing site | 830 | 865 |
| Finished product testing site | 1,660 | 1,730 |
| Finished product manufacturing process − Grade 1 | 3,200 | 3,334 |
| Finished product manufacturing process – Grade 2 | 3,200 | 3,334 |
| Finished product manufacturing process – Grade 3 | 830 | 865 |
| Finished product manufacturing process – Grade 4 | 415 | 432 |
| **Excipient** |  |  |
| Excipient specifications/test methods – Grade 1 | 415 | 432 |
| Excipient specifications/test methods – Grade 2 | 830 | 865 |
| Excipient specifications/test methods – Grade 3 | 830 | 865 |
| Test methods and specifications Test methods and specifications − Grade 1 | 3,200 | 3,334 |
| Test methods and specifications − Grade 2 | 3,200 | 3,334 |
| Test methods and specifications − Grade 3 | 3,200 | 3,334 |
| Test methods and specifications − Grade 4 | 1,660 | 1,730 |
| Test methods and specifications − Grade 5 | 1,660 | 1,730 |
| Test methods and specifications − Grade 6 | 415 | 432 |
| **Product stability and packaging** |  |  |
| Shelf life/storage conditions − active ingredient and intermediate bulks | 1,660 | 1,730 |
| Shelf life/storage conditions − finished product | 1,660 | 1,730 |
| Shelf life/storage conditions – Reference standard – Grade 1 | 1,660 | 1,730 |
| Shelf life/storage conditions – Reference standard – Grade 2 | 415 | 432 |
| Container/closure/packaging − Grade 1 | 1,660 | 1,730 |
| Container/closure/packaging − Grade 2 | 3,200 | 3,334 |
| Container/closure/packaging − Grade 3 | 830 | 865 |
| Container/closure/packaging – Grade 4 | 415 | 432 |
| Indications and dosage Indications/dosage − Grade 1 | 3,200 | 3,334 |
| Indications/dosage − Grade 2 | 3,200 | 3,334 |
| Indications/dosage − Grade 3 | 3,200 | 3,334 |
| Indications/dosage − Grade 4 | 830 | 865 |
| Indications/dosage − Grade 5 | 830 | 865 |
| Indications/dosage − Grade 5 | 830 | 865 |
| Contraindications, Warnings and Precautions | 3,200 | 3,334 |
| **Labelling** |  |  |
| Labelling − Grade 1 | 415 | 432 |
| Labelling − Grade 2 | 830 | 865 |
| Labelling − Grade 3 | 830 | 865 |
| Data Sheet Data sheet − miscellaneous changes | 415 | 432 |
| Data sheet − format change (an administration fee applies if this is the sole change) | 0 |  |
| Other Sponsor | 415 | 432 |
| Change in ownership | 830 | 865 |
| Self-assessable change(s) | 415 | 432 |
| Administration fee | 415 | 432 |
| **Section 24(5) – automatic referrals only** |  |  |
| New indication – NCE | 3,200 | 70,292 |
| New indication – other high risk | 3,200 | 52,719 |
| New indication – intermediate risk | 3,200 | 35,146 |
| Extended indication – NCE | 3,200 | 53,252 |
| Extended indication – other high risk | 3,200 | 39,939 |
| Extended indication – intermediate risk | 3,200 | 26,626 |
| Active ingredient manufacturing process Grades 1 and 2– NCE | 3,200 | 31,951 |
| Active ingredient manufacturing process Grades 1 and 2– other high risk | 3,200 | 23,963 |
| Active ingredient manufacturing process Grades 1 and 2– intermediate risk | 3,200 | 15,976 |
| **Change Related Product Notification (CRPN)**  *Fees Notifying a material change (including self-assessable changes) to an approved related product. Note: In no case will the CMN/CRPN fee for a single product exceed the fee for a new medicine application for a product of the same type.* |  |  |
| **Product name** |  |  |
| Product name | 830 | 865 |
| **Formulation** |  |  |
| Formulation − Grade 1 | 1,245 | 1,297 |
| Formulation − Grade 2 | 1,245 | 1,297 |
| Formulation − Grade 3 | 2,490 | 2,595 |
| **Active ingredient** |  |  |
| Active ingredient specifications/test methods − Grade 1 | 415 | 432 |
| Active ingredient specifications/test methods − Grade 2 | 830 | 865 |
| **Finished product** |  |  |
| Finished product packing site | 830 | 865 |
| Finished product manufacturing site − Grade 1 | 830 | 865 |
| Finished product manufacturing site − Grade 2 | 2,490 | 2,595 |
| Finished product manufacturing process − Grade 1 | 1,660 | 1,730 |
| Finished product manufacturing process − Grade 2 | 2,490 | 2,595 |
| Finished product specifications/test methods | 830 | 865 |
| **Product stability and packaging** |  |  |
| Shelf life/storage conditions − Grade 1 | 415 | 432 |
| Shelf life/storage conditions − Grade 2 | 1,660 | 1,730 |
| Container/closure/packaging − Grade 1 | 415 | 432 |
| Container/closure/packaging − Grade 2 | 830 | 865 |
| Container/closure/packaging − Grade 3 | 1,660 | 1,730 |
| **Indications and dosage** |  |  |
| Indications/dosage − Grade 1 | 3,200 | 3,334 |
| Indications/dosage − Grade 2 | 1,245 | 1,297 |
| Indications/dosage − Grade 3 | 1,245 | 1,297 |
| Indications/dosage − Grade 4 | 830 | 865 |
| **Labelling** |  |  |
| Labelling − Grade 1 | 415 | 432 |
| Labelling − Grade 2 | 830 | 865 |
| Other Sponsor | 415 | 432 |
| Self-assessable change(s) | 415 | 432 |
| Administration fee Licences and Other Fees | 415 | 432 |
| **Clinical Trial Application** |  |  |
| Application for consent to conduct a clinical trial | 7,500 | 7,500 |
| Additional clinical trial for the same medicine, submitted at the same time | 3,750 | 3,750 |
| Application for consent to conduct a clinical trial – abbreviated approval process | 415 | 415 |
| Investigator-led Clinical Trial | $1,000 | $1000 |
| Clinical Trial Amendments (new site new investigator) |  | $415 |
| **Other fees** |  |  |
| Appeal to the Medicines Review Committee | 9,000 | 9000 |
| Issue of a Certificate of Pharmaceutical Product | 250 | 261 |
| Licence to Manufacture Medicines | 13,750 | 14,328 |
| Licence to Pack Medicines | 845 | 880 |
| GMP Certificates | 178.25 | 186 |
| Licence to Sell Medicines by Wholesale | 1,077.42 | 1,123 |
| Licence to Sell Medicines by Retail | 863.78 | 900 |
| Licence to Hawk Medicines | 863.78 | 900 |
| Licence to Operate Pharmacy | 1,052.89 | 1,097 |
| Medical Devices – Regulatory Statements to Foreign Governments (per statement) | 178.25 | 186 |
| Dietary Supplements - Regulatory Statements to Foreign Governments (per statement) | 178.25 | 186 |
| Dietary Supplements – additional copy of original certificate issued at the same time (per statement) | 25 | 26 |
| New Zealand Based − Auditing of Non-Licensed Manufacturers − per hour, plus $50 administration fee, plus disbursements | 178.25 per hour | 186 |

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*. [↑](#footnote-ref-1)
2. Treasury Circular 2011/10: *Guidance on the Operation of Departmental Memorandum Accounts* [↑](#footnote-ref-2)
3. New Zealand’s Crown Research Institute specialising in science for communities [↑](#footnote-ref-3)
4. The Treasury (2017), *Guidelines for Setting Charges in the Public Sector*. [↑](#footnote-ref-4)
5. Office of the Controller and Auditor-General (2008), *Charging Fees for Public Sector Goods and Services*. [↑](#footnote-ref-5)
6. <https://www.medsafe.govt.nz/regulatory/Performance.asp>; <https://www.medsafe.govt.nz/medicines/regulatory-timelines.asp> [↑](#footnote-ref-6)