Review of Fees payable under the Medicines Act 1981

Analysis of Submissions and Outcomes Document

Medsafe

May 2022

Contents

About the Consultation

In 2021, Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, released a consultation document proposing to increase the fees payable under the Medicines Act 1981 (the Act).

The proposed increase in fees is consistent with the Treasury's charging guidelines for cost-recovery. The proposed fees are targeted at cost recovery levels in accordance with a cost recovery model.

The cost model used was review by PwC who concluded that the model used by Medsafe was logical, robust, and consistent with the Treasury and Office of the Audit General frameworks.

Submissions Received

Medsafe received and reviewed a total of 31 submissions in response to the consultation.

Submissions were received from the following stakeholder groups:

- Pharmacies - 5
- Clinical trial centres - 1
- Pharmaceutical industry organisations – 2
- Pharmacy organisation – 1
- Individual pharmaceutical companies - 22

Medsafe thanks all those submitters who took the time to prepare a submission. The feedback was considered and reasonable and represented a range of views from stakeholders.

Structure of Document

This document is arranged in the order of the consultation questions. Many respondents provided general feedback (for example relating to Medsafe performance or operation generally) throughout the consultation questions. Where relevant, this feedback has been grouped and addressed at the appropriate consultation question.

The document summarises the most relevant and significant responses received and provides Medsafe comments. It does not detail our review and response to all feedback. In many cases, we have taken on board feedback and made changes to our fees schedule accordingly. In some cases, we have not made changes following specific feedback. Minor errors and discrepancies or irregularities noted in the consultation document have been corrected in the schedule of fees.

Significant changes to the fees schedule are outlined in the document, and a final list fees is included as Appendix 1.

Summary of submissions and Medsafe response

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

Of respondents, 77% agreed with the drivers of the fees review, with 20% disagreeing (some did not answer this question).

Most pharmacies that commented disagreed with the drivers, particularly noting the increase to pharmacy licence fees. Pharmacy feedback generally did not comment on fees relating to medicine applications.

Submitters recognised that Medsafe has an obligation to address the trends in its memorandum account but wanted to raise the option of having a greater balance between Crown funding and third-party fees. Some concern was expressed about a third-party / cost recovery revenue model in general.

Submitters recognised increases in costs, highlighting the importance of adequate staff resourcing, training and retention; and improvement in technology such as continuing the electronic transfer system in improving Medsafe's delivery of its regulatory functions.

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

Submitters suggested the following additional drivers. The following points are listed in approximately descending order with most common suggestions near the top of the list:

a) Improvement of service levels

Improvement in service levels and putting in place a full suite of key performance indicators were the most common suggestions. Submitters commented that predictability of evaluation timeframes was an important driver.

b) Crown Funding

Some respondents commented that Crown funding should be sufficient to resource those activities that are not directly related to medicines regulation. Examples noted included medical devices regulation, and advisory support provided by Medsafe to support public health work such as the COVID-19 response.

The rationale for these opinions seemed to be that these activities benefit not only the medicines industry, but also other stakeholders and the public. Feedback was also that the Crown should fund capital expenditure relating to upgrading technologies for infrastructure costs.

c) Medical need and clinical context

There were suggestions that incentives (such as lower fees) should be put in place to encourage companies to submit applications for products with high clinical benefit but low potential sales or revenue volume (e.g., 'orphan drugs'). There were also comments that fees increases could delay timing of innovative medicines being marketed in New Zealand. Other comments were that stability and security of New Zealand's medicines supply should be considered (for example the importance of having 'back up' medicines available should PHARMAC funded medicines be out of stock).

d) Impacts and unintended consequences

There was concern that Medsafe does not "over-correct" in terms of fees for specific types of applications, and concern that increased fees for certain categories would impact forecasted application volumes.

Medsafe response

Medsafe's intention is to continually improve the efficiency and effectiveness of our operations. The proposed fee changes are expected to enable Medsafe to make improvements in technology to assist stakeholders, ensure adequate staffing levels to carry out its regulatory functions as well as resource process improvement projects such as the review of its regulatory guidelines, and contribute to improved performance metrics.

Medsafe is currently funded through both Crown funding for activities not subject to fees under the Medicines Act such as medical device regulation and enforcement and by 3rd party revenue from fees.

Medsafe carries out regular fee reviews, with independent review of its costing model to ensure that Medsafe's cost recovery is aligned with best practice guidance issued by the Treasury and Office of the Controller and Auditor-General and that any over or under correction in the fee levels can be identified and corrected.

There is no change in Medsafe's policy to offer both fee waivers and priority assessments in response to clinical need and supply issues.

Question 3: How important are these drivers?

In general, the drivers were considered to be equally important, although some of the costs that Medsafe incurs, such as the ESR contract for medicine testing, and the CARM contract for adverse event monitoring, were considered to be of less importance.

The suggested additional drivers (detailed in responses to question 2) were considered significant.

Question 4: Do you think the forecast numbers of the applications are accurate?

Three quarters of submitters thought that the forecast application numbers were inaccurate. The opinion was that a retrospective look at trends did not accurately reflect future trends. It was suggested that Medsafe should look at international applications, especially the Australian Therapeutic Goods Administration. There was concern that Option 3 would result in behavioural changes from fee payers which would have a negative impact on forecasted application volumes.

The opinion of some submitters was that increases to fees for API grade 1 and 2 may not support the ongoing registration of some generics leading to portfolio rationalisation, particularly for products without current PHARMAC funding and generic products for which these changes are relatively common.

There was also feedback that sponsors may choose not to submit applications to extend or add new indications due to the increased cost and uncertainty about subsequent PHARAMC funding. This would lead to a negative impact on early access to medicines for patients.

Submitters also thought the increase in fees for provisional consent could decrease the number of applications, as these medicines are often for a relatively small population.

Medsafe response

It is acknowledged that retrospective trend analysis may not produce completely accurate numbers, analysing international trends is also problematic. Submissions to other regulators has shown to be inaccurate for New Zealand submissions due to the influence of PHARMAC funding decisions.

In response to specific feedback provided in relation to volume estimates for API grade 1 and 2 changes and new and extended indication changes, volume estimates have been reduced by 25%. This has resulted in a drop in predicted revenue.

Due to the low number of applications for provisional consent no changes have been made to predicted volumes for these applications.

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

Submitters raised the following views relating to the review of fees:

Feedback	Medsafe response
Medsafe should consider recognising Certificates of Pharmaceutical Product which would lead to faster approvals and lower costs overall.	Accepting Certificates of Pharmaceutical Product is not a feature of a comprehensive and world class regulator. CPPs were designed to help regulators without the ability to undertake quality assessments.
Reducing the complexity of the fees schedule should have been included.	Medsafe acknowledges that a cost structure that is easy to interpret is important. Some parts of the industry prefer the flexibility of the current fees structure. In the current consultation, several items of feedback supported a more flexible fee structure or requested further separation of fee categories. The proposed new therapeutics legislation would provide a better opportunity to explore the fee structure.
Medsafe should analyse efficiency improvements to reduce cost, for example move to a cloud-based system rather than paper/CDs.	Moving to a cloud system is not without cost and paper files, CDs and cloud storage need to be funded. In addition, copying CDs and scanning paper file will require one off costs of conversion.
Medsafe further breakdown the time costs on various application types to support the proposed fees (for example to quantify how many hours go into evaluation of CMNs API grade 1 and 2 changes). This data was considered necessary to justify fee increases.	We acknowledge that collecting data on time taken on various evaluations may have provided additional data. However, this is resource intensive, and the additional insight is limited, particularly given to the variability in the resource required for individual applications. We believe the approach taken was most suitable. This relied on experienced staff to estimate the relative average evaluation effort for each application type.

2020 data should have been included in the analysis.	Data from 2020 was not included in the analysis, as we anticipated that this may not be reliable, due to the impact of COVID-19.
An application fee cap for CMNs	Fee caps for CMNs are effectively the corresponding New Medicine Application fee. This is described in CMN application forms. We reiterate a fundamental principle of Medsafe's fees model review is to ensure that fees are equitably allocated relative to the evaluation effort for evaluation of certain medicine applications.

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

Half of submitters felt that the cost recovery principles were not accurate or complete but felt that there was not enough information provided for them to comment further. Others felt reassured by the independent review by PwC.

Question 7: Do you agree with these proposals?

Three quarters of submitters did not agree with the proposals as outlined in the consultation document, although the majority did agree with the overall direction. Concerns were raised about details of the proposals, and some indicated that amendments of these details would result in a more positive assessment by industry. In particular:

Automatic referral of some changed medicine notifications (CMNs) under section 24(5) of the Act.

Submitters felt that the proposal to impose automatic referrals for some CMNs would:

- not support the ongoing registration of some generic medicines leading to product rationalisation and decreased access to medicines for New Zealanders,
- discourage sponsors from submitting applications to extend or add new indications.

Medsafe response

A fundamental principle of Medsafe's fees model is that costs are equitably allocated relative to the time spent on evaluation of certain medicine applications. Most of the CMNs referred under section 24(5) require substantially more resource than is reflected in their current fee of $3200.

To provide clarity, the scope of applications that will be automatically under section 24(5) will be limited to:

- Active Pharmaceutical Ingredient (API) manufacturing process Grade 2 (for active ingredients used in prescription medicines[1]) other than biological or biotechnological (i.e., CMN form A); AND
- API manufacturing process Grade 1 (biological or biotechnological (i.e., CMN form B).
- Grade 1 and Grade 2 dosage/indication changes. Grade 3 changes will remain as CMN fees.

In response to feedback Medsafe has made changes to the fee structure provided as Appendix 1.

[1] API manufacturing process Grade 2 only applies to prescription medicines (i.e., does not include over the counter medicines).

For API manufacturing process grade 1 and 2, a flat fee structure will be employed, as it is considered the effort to evaluate these applications is similar regardless of the risk category. The fee will be 20% of the New Medicine Application (MNA) high risk New Chemical Entity (NCE) fee, refer to fee table.

Other changes in API manufacturing process (e.g., CEP updates) will remain as CMN fees:

- API manufacturing process Grade 1 (other than biological or biotechnological (i.e., CMN form A); AND
- API manufacturing process Grade 2 (biological or biotechnological (i.e., CMN form B)

For indication changes, fees will not differentiate between new (Grade 1) and extended (Grade 2) indication applications, as both can involve similar clinical evaluation work. There will be a tiered fee structure, with higher risk category medicines attracting a higher fee. This is because it is considered that more evaluation effort is required for clinical evaluation of higher risk medicines. The fee will be 35% of the risk category, refer to fee table.

Provisional consent

Feedback was that proposed increases to provisional consent fees were too high and would discourage applications.

There was feedback that provisional consent fees for out-of-stock situations could lead to sponsors being reluctant to submit applications due to cost, instead relying on supply of unapproved medicines under section 29 of the Medicines Act.

There was also feedback that in some instances, these fees should be funded or subsidised by either the Ministry of Health or PHARMAC.

Medsafe response:

Medsafe reiterates that there is an expectation that provisional consent is primarily intended as a pathway to enable early access of approved medicines where clinical data is still being generated. There is an expectation that additional data will be provided within two to four years and full consent under section 20 will be sought. The fee structure is designed to ensure consistency between costs of section 20 (full consent) medicine applications and section 23 (provisional consent) applications that are later converted to full consent.

We also appreciate that there is a necessary balance between encouraging participation in the regulatory system, and of ensuring that cost recovery is based on evaluation effort. We have refined the fee structure slightly based on feedback, refer to Appendix 1.

Contrary to some feedback, renewal of provisional consent is not solely an administrative function, though we have reviewed this fee. The evaluation effort required for individual provisional consent renewals can vary significantly, therefore it may be reasonable in some cases for applicants to request a partial fee waiver for a provisional consent renewal application.

Question 8: Do you agree with these other proposals?

Many submitters felt that the proposal to charge for administrative fees for self-assessable notifications when submitted with a CMN was reasonable but that the full administrative fee of $415 was not, as there should be an efficiency when submitted in this way.

For similar reasons, the proposal for an administrative fee for multiple names, strengths and dosage forms was questioned

Medsafe response

Medsafe agrees to trial an administrative cap of four SACN category fees for each assessable or non-assessable submission. However, if we find this does not cover administrative effort, we will reconsider this option.

Where non-assessable changes are consequential to an assessable change notified by CMN, and notified with that CMN, these will continue to not incur a fee.

The proposed administration fee for additional names will remain. Where sponsors have difficulty determining the appropriate fee (for example if there are multiple strengths supported by a single bioequivalence study) Medsafe will be happy to discuss the appropriate fees to accumulate.

Question 9: Do you agree with the status quo?

The majority of submitters agreed with the description of the status quo.

Question 10: Would you support retaining the status quo?

The majority of submitters did not support the status quo as there is dissatisfaction with the current situation, particularly the likelihood of further exacerbation of evaluation timeframes.

Question 11: Do you agree with the flat fee only increase?

The majority of stakeholders strongly disagreed with a flat fee option, as it was acknowledged there was a variability in the evaluation effort between applications. This option is considered inequitable and would increase costs inappropriately across the range of applications.

One company supported this option suggesting it was equitable but suggested modifications such as fee caps, while others supported this option rather than have increases in the fee for section 24(5) CMNs. Some indicated that they believed that Option 2 was preferred as the increase to costs of their own portfolio would be 19% while they calculated that the impact of Option 3 on their own portfolio would be closer to 30%.

One submitter noted that a benefit of the flat fee increase was that sponsors have experience with the current fee structure, so a flat fee increase may be simpler to implement.

Question 12: Do you agree with the mix of targeted cost recovery and CPI increase?

Most submitters supported this option but indicated there were concerns about the details of the proposal. Concerns are detailed earlier in this document.

Question 13: Are these all the potential options?

Some submitters suggested the following potential options:

Suggestion	**Medsafe response**
A mix of Option 2 and Option 3 – a higher flat fee and a moderation of the cost recovery proposals.	This has been considered by Medsafe. Due to the changes made to fees following consultation, Medsafe will monitor revenue and expenses and if required may need to review fees again sooner than anticipated.

Higher fees but with the capping of fees.	A higher initial fee and then capping the fees is administratively complex and may drive submission behaviours that result in inefficiencies.
Annual product fees (feedback here was mixed).	Annual product fees cannot be implemented as the current Medicines Act does not allow for annual fees.

Question 14: Do you agree with the impacts stated?

Most companies agreed with the impact analysis but were concerned that the impacts do not explicitly call out the potential behaviour changes and the flow on effect to Medsafe's revenue.

There was also concern that the proposals would have an impact on the submission of innovative applications, which in turn could impact on the supply of generics into the market.

Both points are discussed earlier in this document.

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

Most companies agreed that the split fee should be offered again.

Medsafe response:

Although this option was only used by a few companies with the last fees review, Medsafe will offer this again.

Outcome

Decision on fee increases

Medsafe concludes from this consultation that Option 3:

- Applying a 4.2% fee increase across all fees and an increase on targeted fees that had fallen out of step with cost recovery mechanisms would be implemented:

but with several changes to the original proposal as detailed in the table below:

Changes made following consultation

Change	Consultation document	Fee post consultation	Comments
Automatic referrals for section 24(5) applications; indications Grade 1 and Grade 2	66% of risk category for new indications ($35,146 - $70,292) 50% of risk category for extended indications ($26,626 - $53,252)	35% of risk category ($18,638 - $37,276)	Fees reviewed and lowered following feedback and reassessment. Volume estimates for forecasting were also lowered by 25%. Grade 3 changes are excluded from automatic referrals fees, rather will remain as CMN fees.
Automatic referrals for section 24(5) applications; active ingredient manufacture grade 1 and 2[2]	35% of risk category ($15,976 - $31,951)	Flat fee structure, 20% of High risk (NCE) ($21,301)	Fees reviewed and lowered following feedback and reassessment. Volume estimates for forecasting were also lowered by 25%.
Provisional consent due to clinical need	80% of risk category ($63,902 - $85,202)	66% of risk category ($52,719 - $70,292)	Initial fee payment reduced from 80% to 66% of risk category following feedback and reassessment. Note that the corresponding fee for conversion of provisional consent to full consent increases from 20% to 33% of risk category.
Provisional consent due to stock shortage	20% of risk category	20% of risk category for the corresponding NMA ($10,650 - $21,301)	Note that there are very few provisional consent applications for lower risk medicines. Note that the corresponding fee for conversion of provisional consent to full consent increases to 80% of the risk category.
Provisional consent renewals	35% of NCE or other high risk ($27,957 - $37,276)	15% of other high risk ($11,982)	Fees lowered following feedback and reassessment. Refer to 7(c) for further details.

[2] Note that the change to fees only applies to large applications in this category; refer to the response to 7(a), and the final fees table.

SACN Fees	SACN charged at administration fee ($415)	SACN charged at administration fee ($415), with a cap of four SACNs change fees per CMN ($1,660).	The cap of four SACNs will be reviewed by Medsafe following initial implementation.

The list of fees in Appendix 1 has been amended to reflect these changes.

Changes required to the Medicines Regulations

The following changes to the Medicine Regulations will be made:

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	$79,877
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

It is important to note that the fees specified in the regulations are the maximum level of fees that can applied. Regulation 61A provides for a fee waiver to be applied and will be used to implement the fees listed in Appendix 1.

Implementation of the fee increases

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

The implementation date is 1 July 2022. 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.

Medsafe will publish this document on our website, along with updated application forms and guidance documents.

Appendix 1: Fee Schedule – to be implemented 1 July 2022

Type of application	**New fee ($)**
New Medicine Application Fees	
New higher-risk medicine containing one or more new active substances (NCE)	106,503
Any other new higher-risk medicine, including biosimilars	79,877
New intermediate-risk medicine – prescription medicine	53,251
New intermediate-risk medicine – non-prescription medicine	26,626
New lower-risk medicine	10,649
Additional dose form – higher-risk medicine – Grade 1 or 2	53,252
Additional dose form – intermediate-risk prescription medicine – Grade 1 or 2	53,252
Additional dose form – intermediate-risk non-prescription medicine – Grade 1 or 2	26,626
Additional dose form – lower-risk medicine – Grade 1 or 2	10,649
New combination product – novel combination of approved active ingredients	70,292
New combination pack containing two or more currently approved products	3,835
The following fees apply when the additional products are applied for at the same time as the parent product[3]	
Additional name − Grade 1	432
Additional name − Grade 2	865
Additional classification (with/without new name)	432
Additional strength − Grade 1	1,298
Additional strength − Grade 2	1,730
Additional strength − Grade 3	3,460
Additional strength − Grade 4	10,785

[3] Fees for this category are cumulative. This is, an applicable fee is charged for each additional name, strength, etc.

Additional strength − Grade 5	16,177
Additional flavour or type of sweetening	865
The following fees apply when the additional products are subsequent to approval of the parent product (i.e., when additional product applications are submitted after approval of the parent product). [4]	
Additional name − Grade 1	865
Additional name − Grade 2	1,730
Additional classification (with/without new name)	865
Additional strength − Grade 1	2,595
Additional strength − Grade 2	3,459
Additional strength − Grade 3	6,919
Additional strength − Grade 4	21,569
Additional strength − Grade 5	32,354
Additional flavour or type of sweetening	1,730
New Medicines Application (Abbreviated Evaluation Process) Fees	
New higher-risk medicine containing one or more new active substances (NCE)	53,251
Any other new higher-risk medicine	39,939
New intermediate-risk medicine – prescription medicine	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	5,731
Additional names, strengths, flavours and classifications notified at the same time as the parent application	0
The following fees apply when the additional products are subsequent to approval of the parent product (i.e., when additional product applications are submitted after approval of the parent product).	

[4] Fees for this category are cumulative. This is, an applicable fee is charged for each additional name, strength, etc.

Additional name − Grade 1	865
Additional name − Grade 2	1,730
Additional strength	1,730
Additional flavour or type of sweetening	1,730
New Medicine Application Provisional Consent Fees	
Provisional consent to distribute a new medicine (clinical need) High risk NCE	70,292
Provisional consent to distribute a new medicine (clinical need) High risk other	52,719
Provisional consent to distribute a new medicine (stock shortage) High risk other	15,975
Provisional consent to distribute a new medicine (stock shortage) Intermediate risk	10,650
Provisional consent to distribute a new medicine (stock shortage) Low risk	2,130
Provisional conversion to full approval (clinical need) High risk NCE	35,146
Provisional conversion to full approval (clinical need) High risk other	26,359
Provisional conversion to full approval (stock shortage) High risk other	63,902
Provisional conversion to full approval (stock shortage) Intermediate risk	42,601
Provisional conversion to full approval (stock shortage) Low risk	8,176
Application for renewal of provisional consent [5]	11,982
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	865

[5] In some cases, where significantly less work is required to evaluate a renewal, it may be appropriate for applicants to apply for a fee waiver.

Formulation	
Formulation – Grade 1, Type 1	1,730
Formulation – Grade 1, Type 2	2,595
Formulation – Grade 2, Type 1	1,730
Formulation – Grade 3, Type 1	2,162
Formulation – Grade 4, Type 1	2,595
Formulation – Grade 4, Type 2	3,334
Active ingredient	
Active ingredient manufacturing site	865
Active ingredient manufacturing process – Grade 1, Type 1	865
Active ingredient manufacturing process - Grade 1, Type 2	865
Active ingredient manufacturing process – Grade 2, Type 2	See 24(5) referral fee
Active ingredient manufacturing process – Grade 3, Type 1	865
Active ingredient manufacturing process – Grade 3, Type 2	865
Active ingredient specifications/test methods – Grade 1	432
Active ingredient specifications/test methods – Grade 2	865
Active ingredient specifications/test methods – Grade 3	865
Active ingredient specifications/test methods – Grade 4, Type 1	865
Active ingredient specifications/test methods – Grade 4, Type 2	1,730
Excipient	
Excipient specifications/test methods – Grade 1	432
Excipient specifications/test methods – Grade 2	865
Excipient specifications/test methods – Grade 3	865

Finished product	
Finished product packing site − Grade 1	865
Finished product packing site − Grade 2	1,730
Finished product manufacturing process − Grade 1, Type 1	1,730
Finished product manufacturing process − Grade 1, Type 2	2,595
Finished product manufacturing process − Grade 2, Type 1	2,595
Finished product manufacturing process − Grade 2, Type 2	3,334
Finished product specifications/test methods − Grade 1	432
Finished product specifications/test methods − Grade 2	432
Finished product specifications/test methods − Grade 3	432
Finished product specifications/test methods − Grade 4	865
Finished product specifications/test methods − Grade 5, Type 1	865
Finished product specifications/test methods − Grade 5, Type 2	1,730
Product stability and packaging	
Shelf life/storage conditions − Grade 1	432
Shelf life/storage conditions − Grade 2	1,730
Container/closure/packaging − Grade 1	432
Container/closure/packaging − Grade 2	865
Container/closure/packaging − Grade 3	1,730
Container/closure/packaging − Grade 4	2,595
Container/closure/packaging − Grade 5	3,334
Indications and dosage	
Indications/dosage − Grade 1	See 24(5) referral fee

Indications/dosage − Grade 2	See 24(5) referral fee
Indications/dosage − Grade 3	3,334
Indications/dosage − Grade 4	865
Indications/dosage − Grade 5	865
Contraindications, warnings and precautions	3,334
Data sheet − miscellaneous changes	432
Data sheet − format change (an administration fee applies if this is the sole change)	
Labelling	
Labelling − Grade 1	432
Labelling − Grade 2	865
Labelling − Grade 3	865
Sponsor	432
Change in ownership	865
Administration Fee	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	865
Formulation/excipients	
Formulation − Grade 1	3,334
Formulation − Grade 2	865
Bulk active	

Active ingredient manufacturing site	3,334
Active ingredient method of manufacture – Grade 1	See 24(5) referral fee
Active ingredient method of manufacture – Grade 2	865
Active ingredient method of manufacture – Grade 3	432
Finished product manufacturing site	3,334
Finished product secondary packing site	865
Finished product testing site	1,730
Finished product manufacturing process − Grade 1	3,334
Finished product manufacturing process – Grade 2	3,334
Finished product manufacturing process – Grade 3	865
Finished product manufacturing process – Grade 4	432
Excipient	
Excipient specifications/test methods – Grade 1	432
Excipient specifications/test methods – Grade 2	865
Excipient specifications/test methods – Grade 3	865
Test methods and specifications Test methods and specifications − Grade 1	3,334
Test methods and specifications − Grade 2	3,334
Test methods and specifications − Grade 3	3,334
Test methods and specifications − Grade 4	1,730
Test methods and specifications − Grade 5	1,730
Test methods and specifications − Grade 6	432
Product stability and packaging	
Shelf life/storage conditions − active ingredient and intermediate bulks	1,730

Shelf life/storage conditions − finished product	1,730
Shelf life/storage conditions – Reference standard – Grade 1	1,730
Shelf life/storage conditions – Reference standard – Grade 2	432
Container/closure/packaging − Grade 1	1,730
Container/closure/packaging − Grade 2	3,334
Container/closure/packaging − Grade 3	865
Container/closure/packaging – Grade 4	432
Indications/dosage − Grade 1	See 24(5) referral fee
Indications/dosage − Grade 2	See 24(5) referral fee
Indications/dosage − Grade 3	3,334
Indications/dosage − Grade 4	865
Indications/dosage − Grade 5	865
Contraindications, warnings and precautions	3,334
Labelling	
Labelling − Grade 1	432
Labelling − Grade 2	865
Labelling − Grade 3	865
Data sheet − miscellaneous changes	432
Data sheet − format change (an administration fee applies if this is the sole change)	432
Sponsor	432
Change in ownership	865
Administration fee	432
Section 24(5) – automatic referrals	

Indications/dosage – Grades 1 and 2, high risk (NCE)	37,276
Indications/dosage – Grades 1 and 2, high risk other	27,957
Indications/dosage – Grades 1 and 2; intermediate risk	18,638
Active ingredient manufacturing process • Active ingredient manufacturing process − Grade 2, Type 2 • Active ingredient method of manufacture – Grade 1, Type 3	21,301
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	865
Formulation	
Formulation − Grade 1	1,297
Formulation − Grade 2	1,297
Formulation − Grade 3	2,595
Active ingredient	
Active ingredient specifications/test methods − Grade 1	432
Active ingredient specifications/test methods − Grade 2	865
Finished product	
Finished product packing site	865
Finished product manufacturing site − Grade 1	865
Finished product manufacturing site − Grade 2	2,595
Finished product manufacturing process − Grade 1	1,730
Finished product manufacturing process − Grade 2	2,595
Finished product specifications/test methods	865
Product stability and packaging	

Shelf life/storage conditions − Grade 1	432
Shelf life/storage conditions − Grade 2	1,730
Container/closure/packaging − Grade 1	432
Container/closure/packaging − Grade 2	865
Container/closure/packaging − Grade 3	1,730
Indications and dosage	
Indications/dosage − Grade 1	3,334
Indications/dosage − Grade 2	1,297
Indications/dosage − Grade 3	1,297
Indications/dosage − Grade 4	865
Labelling	
Labelling − Grade 1	432
Labelling − Grade 2	865
Sponsor	432
Administration fee	432
Clinical Trial Application	
Application for consent to conduct a clinical trial	7,500
Additional clinical trial for the same medicine, submitted at the same time	3,750
Other fees	
Appeal to the Medicines Review Committee	9,000
Issue of a Certificate of Pharmaceutical Product	261
Licence to Manufacture Medicines	14,328
Licence to Pack Medicines	880

GMP Certificates	186
Licence to Sell Medicines by Wholesale	1,123
Licence to Sell Medicines by Retail	900
Licence to Hawk Medicines	900
Licence to Operate Pharmacy	1,097
Medical Devices – Regulatory Statements to Foreign Governments (per statement)	186
Dietary Supplements - Regulatory Statements to Foreign Governments (per statement)	186
Dietary Supplements – additional copy of original certificate issued at the same time (per statement)	26
New Zealand Based − Auditing of Non-Licensed Manufacturers − per hour, plus $50 administration fee, plus disbursements	186 per hour