Review of fees payable under the Medicines Regulations 1984

Consultation document

Medsafe

March 2018

Contents

INTRODUCTION

Purpose and scope

The purpose of this consultation paper is to:

- explain why the Ministry of Health is reviewing the fees payable under the Medicines Act 1981 and specified in the Medicines Regulations 1984
- detail proposed changes to those fees
- seek comment on the proposed changes by **5pm Friday 27 April 2018.**

This consultation paper explains the reasons for the fees review, provides a summary of financial information and sets out proposals for changes to the fees.

Background

Medsafe is responsible for administering the Medicines Act 1981 and Medicines Regulations 1984. Its functions in relation to this legislation are funded from a mixture of Crown funding and third party revenue collected from fees set under the Medicines Act 1981.

The Medicines Act provides for charging fees in relation to applications for licences and for the approval of new and changed medicines, new and changed-related products, and clinical trials. The schedule of fees payable is contained in regulation 61 of the Medicines Regulations 1984.

Regulation 61A of the Medicines Regulations 1984 provides that the Director-General of Health may waive or refund, in whole or in part, a fee otherwise payable under regulation 61. 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.

Medsafe is proposing a fee increase by adjusting the standard waiver applied to the fees contained under regulation 61.

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 in order to recognise the reduced time required to consider the application. For example, a partial waiver is routinely applied to applications for approval of new non-prescription medicines. A partial fee waiver is also available for applications made under the abbreviated process for new prescription medicines already approved by a recognised overseas regulator.

The current 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 are the fees being reviewed at this time?

The last comprehensive fees review was completed in 2008 and implemented in 2009, which resulted in an average 12% reduction to fees (fees were last increased in 2006). At that stage there was a surplus in the Medsafe memorandum account and industry was notified that fees would not increase until the surplus was cleared. The memorandum account balance has now been cleared. As a result of this, it is proposed to introduce the new fee schedule by 1 June 2018 so that Medsafe achieves cost recovery on an annual basis in future years.

There have been periodic reviews of fees since 2009 (including absorbing the increase of GST from 10% to 15% in 2010, an effective 2% reduction in fees charged), but with a continued surplus in the memorandum account it was recommended to leave the fees unchanged.

The proposed fees would incorporate increased costs to Medsafe since 2008, with the cost increase being in line with the Consumer Price Index (CPI) movement from 2008 to 2017 (14.4% from Quarter 2 in 2008 to Quarter 4 in 2016).

Scope of the fees review

Medsafe has undertaken a review to identify the level of fees needed to achieve cost recovery. The review covers:

- fees to accompany applications for approval of new and changed medicines and related products (made under sections 20 to 24 of the Medicines Act 1981 and administered by Medsafe), and for approval of clinical trials (made under section 30 of the Medicines Act 1981 and administered by Medsafe)
- fees for the auditing of non-licensed manufacturers
- fees for the issue of regulatory statements and certificates.

METHODS USED TO CALCULATE FEES

Medsafe has undertaken a review to identify the level of fees needed to achieve cost recovery while maintaining consistency with the:

- *Guidelines for Setting Charges in the Public Sector*, issued by the NZ Treasury in April 2017
- *Charging Fees for Public Sector Goods and Services*, issued by the Audit Office in 2008.

The 2018 fees review has been completed by updating the methodology used in the 2008 review and has been reviewed by The Treasury. The cost model used in 2008 was independently reviewed at the time by Deloitte. The cost model is based on:

- estimating the annual expenditure requirement for Medsafe in 2017/18
- 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 effort involved. For example, an intermediate-risk new medicine application (NMA) is costed at 40% of a higher-risk NMA, and a lower-risk NMA is costed at 10% of a higher-risk NMA.

The effort involved for an abridged application process has been estimated at 50% of a full process for both the higher-risk NMA and the intermediate-risk NMA.

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. 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 2017/18 is $10.9 million (GST exclusive), of which $9.6 million is budgeted to come from fees charged to industry, assuming the proposed fee changes are implemented.

The $10.9 million 2017/18 expenditure forecast is an increase of 1.2% over the 2016/17 budget. The increase is mainly due to increased personnel costs, which are a combination of an annual increase in salaries (1.9%) and budgeting for a full establishment of staff.

The main drivers of increased costs for Medsafe have been;

- wage growth (this is in line with the Ministry's 1.9% annual increase salary growth in recent years, with FTE numbers remaining static)
- an increase in the cost of the drug testing programme (which moved from $500,000 to $835,000 under the new Science Purchasing Contract the Ministry entered into with ESR)[1].

Proposed changes to fees

To achieve cost recovery, Medsafe is proposing a 15% increase to new medicine application (NMA), changed medicine application (CMN) and clinical trial application (CTA) fees. The 15% increase is in line with the CPI movement from 2008 to 2017 (14.4% from Quarter 2 in 2008 to Quarter 4 in 2016).

The exception is a proposed no change to the intermediate-risk NMA fee, as the current fee is approximately 40% of the proposed higher-risk NMA fee, which aligns with the estimated effort involved for this activity.

It is proposed to set the abridged fee for both the higher-risk NMA and intermediate-risk NMA at 50% of the equivalent full fee, based on the effort involved for evaluating these applications, rather than the 30% estimated when the fee was first introduced.

Forecast expenditure

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

Table 1: Forecast expenditure, by expense type, for Medsafe

Expense type	**2017/18 forecast expenditure ($million)**
Personnel costs	4.61
Operating costs	3.66
Corporate overheads	2.60
Total	**10.87**
Total industry-funded activities	9.60
Total Crown-funded activities	1.27
Total	**10.87**

[1] Institute of Environmental Science and Research.

Table 2: Forecast expenditure, by industry output, for Medsafe	
Output	**2017/18 forecast cost ($million)**
New medicine applications – medicine containing a new drug substance	2.19
New medicine applications – prescription medicine not containing a new drug substance	1.86
New medicine applications – non-prescription medicine	0.29
Changed medicine notifications	3.91
Clinical trial applications	0.69
Manufacturing assessment (manufacturer and packer licensing)	0.66
Total industry-funded activities	**9.60**

Memorandum account balance

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.

Note: The actual expenditure since 2014/15 has been approximately $0.9 million lower than the $9.6 million forecast expenditure for 2017/18. This is due to two factors:

- Medsafe personnel costs have been lower in recent years because several senior management positions have been vacant and covered by internal secondments at a lower cost. These positions have now been recruited on a permanent basis and the 2017/18 forecast is based on a full establishment of staff.

- Recognising the full costs of the therapeutic drug testing programme: the contract (which is part of the wider Ministry of Health Science Purchasing Contract) has had a pricing review, which involved ESR updating its costing model and allowed ESR to achieve a 6% rate of return. This has led to the costs of drug testing rising from $505,000 in 2008 to $835,000 in the current contract. The 2017/18 year will be the first year that Medsafe has incurred the full costs.

Table 3: Movement in the Medsafe memorandum account					
($000)	**2012/13**	**2013/14**	**2014/15**	**2015/16**	**2016/17**
Opening balance	4,875	4,046	3,059	2,636	1,288
Revenue	7,739	8,218	8,318	7,427	7,646
Expenditure	–8,568	–9,205	–8,741	–8,775	–8,928
Closing balance	4,046	3,059	2,636	1,288	6

Application volumes

For the purpose of the fees review, a five-year average of application volumes has been used in the calculations. The volumes for the last five calendar years, and the five-year average used for the fees calculation, are detailed in Table 4.

Table 4: Application volumes, by fee type

	2012	2013	2014	2015	2016	5-year average
New medicine applications						
New higher-risk medicine containing one or more new active substances	12	11	8	9	9	**10**
Any other new higher-risk medicine	4	5	3	13	7	**6**
Abridged new higher-risk medicine containing one or more new active substances	12	26	33	32	26	**26**
New intermediate-risk medicine – prescription medicine	32	26	25	17	16	**23**
New intermediate-risk medicine – non-prescription medicine	-	10	1	2	1	**3**
Abridged new intermediate-risk medicine – prescription medicine	54	77	41	40	51	**53**
New lower-risk medicine	28	45	32	28	18	**30**
Changed medicine applications						
CMN applications	1468	1457	1566	1434	1466	**1478**
Self-assessable CMN applications	1105	1182	1278	1131	1003	**1140**
Clinical trial applications						
Application for consent to conduct a clinical trial	112	107	110	133	95	**111**
Additional clinical trial for the same medicine, submitted at the same time	13	7	10	12	8	**10**

PROPOSED NEW FEES

The proposed new fees schedule, by fee type, is detailed below. A complete proposed fee schedule is attached as Appendix 1. Note: fees are prescribed in legislation as the fee inclusive of GST. All fees listed below are inclusive of the 15% Goods and Services Tax.

New medicine containing a new drug substance (higher-risk)

A 15% increase in the fee for a new higher-risk medicine containing one or more new active substances is proposed, to reflect the rise in costs since the last fees review in 2008.

The fee for an abbreviated application based on the evaluation reports of a recognised overseas evaluator was previously set at 30% of the fee for a full evaluation. It is proposed that this be adjusted to 50% to reflect the evaluation time and resources required to assess this type of application.

Fee	Current fee	Proposed fee
New higher-risk medicine containing one or more new active substances	$88,875	$102,210
Any other new higher-risk medicine	$43,875	$43,875
Abridged new higher-risk medicine containing one or more new active substances	$33,750	$51,100
Abridged any other new higher-risk medicine	$33,750	$51,100

Intermediate-risk and lower-risk medicine applications

There is no proposed increase in the fee for a new intermediate-risk (prescription) medicine, as the current fee is approximately 40% of the proposed higher-risk NMA fee, which aligns with the estimated effort involved for this activity.

The fee for an abbreviated application based on the evaluation reports of a recognised overseas evaluator was previously set at 30% of the fee for a full evaluation. It is proposed that this be adjusted to 50% to reflect the evaluation time and resources required to assess this type of application.

It is proposed that fees for a new intermediate-risk (non-prescription) medicine and a new lower-risk medicine be set at 10% of the proposed higher-risk NMA fee, which aligns with the estimated effort involved for this activity.

Fee	Current fee	Proposed fee
New intermediate-risk medicine – prescription medicine	$43,875	$43,875
Abridged new intermediate-risk medicine – prescription medicine	$16,875	$21,940
New intermediate-risk medicine – non-prescription medicine	$7,650	$10,220
New lower-risk medicine	$7,650	$10,220

Changed medicine applications

A 15% increase in the fees for changed medicine notifications and for self-assessable change notifications is proposed to reflect the rise in costs since the last fees review in 2008.

The full list of changed medicine application (CMN) fees is given in Appendix 1.

Fee	Current fee	Proposed fee
CMN fee	From $720 up to $2,880	From $830 up to $3,200
Self-assessable changes	$360	$415

Clinical trial applications

A 15% increase in the fee for applications to conduct a clinical trial is proposed to reflect the rise in costs since the last fees review in 2008.

Fee	Current fee	Proposed fee
Application for consent to conduct a clinical trial	$6,525	$7,500
Additional clinical trial for the same medicine, submitted at the same time	$3,263	$3,750
Application for consent to conduct a clinical trial – abbreviated approval process	$360	$415

Other fees

It is proposed that the hourly fee for auditing non-licensed manufacturers will move from $138 per hour to $178 per hour. This is based on deriving an hourly cost from the annual cost of the Good Manufacturing Practice (GMP) function within Medsafe. A separate fee schedule for Medsafe to undertake auditing of overseas manufacturers is detailed in the full list off fees in Appendix 1.

Regulatory statements or certificates are based on taking one hour of effort to complete, and are set at the $178 per hour fee rate.

Fee	Current fee	Proposed fee
Auditing of non-licensed manufacturers – per hour	$138	$178
Regulatory statements or certificates	$135	$178

HOW TO MAKE A SUBMISSION

Please complete the Medsafe consultation submission form. Submissions must include full personal or organisation contact details (including address, telephone number or email address).

2018 Medsafe Fees Review Consultation Submission Forms (Adobe pdf 69 KB, 3 pages)

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Electronic submissions are preferred and should be emailed to medsafeapplications@moh.govt.nz and should include '**Medsafe Fees Review**' in the subject line of the email.

Alternatively, hard copy submissions may be posted to:

Fees Review
Medsafe
PO Box 5013
Wellington 6140

The closing date for submissions is 5pm Friday 27 April 2018.

Medsafe is particularly interested in how the proposed changes will affect the operation of organisations and individuals involved in the industry.

Please ensure that you provide an email address to which acknowledgement of receipt of your submission and feedback on the analysis of submissions can be sent.

Submissions may be released under the Official Information Act 1982. Any information you do not want made public should be sent separately and clearly marked CONFIDENTIAL.

Once the analysis of submissions has been completed and a recommendation made, the outcome will be notified on the Medsafe website. To subscribe to an automatic email notification of website updates, please register here.

Implementation date

It is proposed to introduce the new fee schedule by 1 June 2018 so that Medsafe achieves cost recovery on an annual basis for future years.

Appendix 1: Medsafe 2018 Fees Review – Proposed Fees Payable under the Medicines Act

NOTE

- All fees listed are **GST Inclusive**
- More detailed descriptions of the type of application or change to which a fee applies can be found on the relevant application form (available at www.medsafe.govt.nz/forms)

New Medicines Application (NMA) Fees		
Type of application	**Current fee ($)**	**Proposed fee ($)**
New higher-risk medicine containing one or more new active substances	88,875	102,210
Any other new higher-risk medicine	43,875	43,875
New intermediate-risk medicine – prescription medicine	43,875	43,875
New intermediate-risk medicine – non-prescription medicine	7,650	10,220
New lower-risk medicine	7,650	10,220
Additional dose form – higher-risk medicine – Grade 1 or 2	43,875	43,875
Additional dose form – intermediate-risk prescription medicine – Grade 1 or 2	43,875	43,875
Additional dose form – intermediate-risk non-prescription medicine – Grade 1 or 2	7,650	10,220
Additional dose form – lower-risk medicine – Grade 1 or 2	7,650	10,220
New combination pack containing two or more currently approved products	3,200	3,680
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	720	830
Additional name − Grade 2	1,440	1,660
Additional classification (with/without new name)	720	830
Additional strength − Grade 1	2,160	2,490
Additional strength − Grade 2	2,880	3,320

Additional strength − Grade 3	5,760	6,640
Additional strength − Grade 4	18,000	20,700
Additional strength − Grade 5	27,000	31,050
Additional flavour or type of sweetening	1,440	1,660

New Medicines Application (Abbreviated Evaluation Process) Fees		
Type of application	**Current fee ($)**	**Proposed fee ($)**
New higher-risk medicine containing one or more new active substances	33,750	51,100
Any other new higher-risk medicine	33,750	51,100
New intermediate-risk medicine – prescription medicine	16,875	21,940
Additional names, strengthens, flavours and classifications must be notified at the same time as the parent application		

New Related Product Application (NRPA) Fees		
Type of application	**Current fee ($)**	**Proposed fee ($)**
New related product	5,500	5,500
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	720	830
Additional name − Grade 2	1,440	1,660
Additional strength	1,440	1,660
Additional flavour or type of sweetening	1,440	1,660

New Medicine Application Provisional Consent Fees		
Type of application	**Current fee ($)**	**Proposed fee ($)**
Application for provisional consent to distribute a new medicine	8,437	8,437
Application for renewal of provisional consent	500	500

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		
Type of application	***Current fee ($)***	***Proposed fee ($)***
Product name		
Product name, for each new name	720	830
Formulation		
Formulation − Grade 1, Type 1	1,440	1,660
Formulation − Grade 1, Type 2	2,160	2,490
Formulation − Grade 2, Type 1	1,440	1,660
Formulation − Grade 3, Type 1	1,800	2,075
Formulation − Grade 4, Type 1	2,160	2,490
Formulation − Grade 4, Type 2	2,880	3,200
Active ingredient		
Active ingredient manufacturing site	720	830
Active ingredient manufacturing process − Grade 1, Type 1	720	830
Active ingredient manufacturing process - Grade 1, Type 2	720	830
Active ingredient manufacturing process − Grade 2, Type 1	2,880	3,200
Active ingredient manufacturing process − Grade 2, Type 2	2,880	3,200
Active ingredient manufacturing process − Grade 3, Type 1	720	830
Active ingredient manufacturing process − Grade 3, Type 2	720	830
Active ingredient specifications/test methods − Grade 1	360	415
Active ingredient specifications/test methods − Grade 2	720	830
Active ingredient specifications/test methods − Grade 3	720	830
Active ingredient specifications/test methods − Grade 4, Type 1	720	830
Active ingredient specifications/test methods − Grade 4, Type 2	1,440	1,660
Excipient		
Excipient specifications/test methods − Grade 1	360	415
Excipient specifications/test methods − Grade 2	720	830
Excipient specifications/test methods − Grade 3	720	830

	Current fee ($)	***Proposed fee ($)***
Finished product		
Finished product packing site − Grade 1	720	830
Finished product packing site − Grade 2	1,440	1,660
Finished product manufacturing process − Grade 1, Type 1	1,440	1,660
Finished product manufacturing process − Grade 1, Type 2	2,160	2,490
Finished product manufacturing process − Grade 2, Type 1	2,160	2,490
Finished product manufacturing process − Grade 2, Type 2	2,880	3,200
Finished product specifications/test methods − Grade 1	360	415
Finished product specifications/test methods − Grade 2	360	415
Finished product specifications/test methods − Grade 3	360	415
Finished product specifications/test methods − Grade 4	720	830
Finished product specifications/test methods − Grade 5, Type 1	720	830
Finished product specifications/test methods − Grade 5, Type 2	1,440	1,660
Product stability and packaging		
Shelf life/storage conditions − Grade 1	360	415
Shelf life/storage conditions − Grade 2	1,440	1,660
Container/closure/packaging − Grade 1	360	415
Container/closure/packaging − Grade 2	720	830
Container/closure/packaging − Grade 3	1,440	1,660
Container/closure/packaging − Grade 4	2,160	2,490
Container/closure/packaging − Grade 5	2,880	3,200
Indications and dosage		
Indications/dosage − Grade 1	2,880	3,200
Indications/dosage − Grade 2	2,880	3,200
Indications/dosage − Grade 3	2,880	3,200
Indications/dosage − Grade 4	720	830
Indications/dosage − Grade 5	720	830
Contraindications, Warnings and Precautions	2,880	3,200
Data sheet		
Data sheet − miscellaneous changes	360	415
Data sheet − format change (an administration fee applies if this is the sole change)	0	0
Labelling		
Labelling − Grade 1	360	415
Labelling − Grade 2	720	830
Labelling − Grade 3	720	830

Other		
Sponsor	360	415
Change in ownership	720	830
Self-assessable change(s)	360	415
Administration Fee	360	415

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.*		
Type of application	***Current fee ($)***	***Proposed fee ($)***
Product name		
Product name, for each new name	720	830
Formulation/excipients		
Formulation − Grade 1	2,880	3,200
Formulation − Grade 2	720	830
Bulk active		
Bulk active manufacturing site	2,880	3,200
Bulk active methods of manufacture	2,880	3,200
Change in site of lyophilisation	1,440	1,660
Revalidation of lyophilisation process	1,440	1,660
Active ingredient method of manufacture	720	830
Finished product manufacturing site	2,880	3,200
Finished product secondary packing site	720	830
Finished product manufacturing process − Grade 1	2,880	3,200
Finished product manufacturing process – Grade 2	2,880	3,200
Finished product manufacturing process	720	830
Test methods and specifications		
Test methods and specifications − Grade 1	2,880	3,200
Test methods and specifications − Grade 2	2,880	3,200
Test methods and specifications − Grade 3	2,880	3,200
Test methods and specifications − Grade 4	1,440	1,660
Test methods and specifications − Grade 5	1,440	1,660
Test methods and specifications − Grade 6	360	415
Product stability and packaging		
Shelf life/storage conditions − bulk actives and intermediate bulks	1,440	1,660

Shelf life/storage conditions − finished product	1,440	1,660
Container/closure/packaging − Grade 1	1,440	1,660
Container/closure/packaging − Grade 2	2,880	3,200
Container/closure/packaging − Grade 3	360	415
Indications and dosage		
Indications/dosage − Grade 1	2,880	3,200
Indications/dosage − Grade 2	2,880	3,200
Indications/dosage − Grade 3	2,880	3,200
Indications/dosage − Grade 4	720	830
Indications/dosage − Grade 5	720	830
Contraindications, Warnings and Precautions	2,880	3,200
Labelling		
Labelling − Grade 1	360	415
Labelling − Grade 2	720	830
Labelling − Grade 3	720	830
Data Sheet		
Data sheet − miscellaneous changes	360	415
Data sheet − format change (an administration fee applies if this is the sole change)	0	0
Other		
Sponsor	360	415
Change in ownership	720	830
Self-assessable change(s)	360	415
Administration fee	360	415

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.		
Type of application	***Current fee ($)***	***Proposed fee ($)***
Product name		
Product name	720	830
Formulation		
Formulation − Grade 1	1,080	1,245
Formulation − Grade 2	1,080	1,245
Formulation − Grade 3	2,160	2,490
Active ingredient		
Active ingredient specifications/test methods − Grade 1	360	415
Active ingredient specifications/test methods − Grade 2	720	830
Finished product		
Finished product packing site	720	830
Finished product manufacturing site − Grade 1	720	830
Finished product manufacturing site − Grade 2	2,160	2,490
Finished product manufacturing process − Grade 1	1,440	1,660
Finished product manufacturing process − Grade 2	2,160	2,490
Finished product specifications/test methods	720	830
Product stability and packaging		
Shelf life/storage conditions − Grade 1	360	415
Shelf life/storage conditions − Grade 2	1,440	1,660
Container/closure/packaging − Grade 1	360	415
Container/closure/packaging − Grade 2	720	830
Container/closure/packaging − Grade 3	1,440	1,660
Indications and dosage		
Indications/dosage − Grade 1	2,880	3,200
Indications/dosage − Grade 2	1,080	1,245
Indications/dosage − Grade 3	1,080	1,245
Indications/dosage − Grade 4	720	830
Labelling		
Labelling − Grade 1	360	415
Labelling − Grade 2	720	830
Other		
Sponsor	360	415

Self-assessable change(s)	360	415
Administration fee	360	415

Clinical Trial Application Fees		
Type of application	***Current fee ($)***	***Proposed fee ($)***
Application for consent to conduct a clinical trial	6,525	7,500
Additional clinical trial for the same medicine, submitted at the same time	3,263	3,750
Application for consent to conduct a clinical trial – abbreviated approval process	360	415

Licences and Other Fees		
Type of application	***Current fee ($)***	***Proposed fee ($)***
Appeal to the Medicines Review Committee	9,000	9,000
Issue of a Certificate of Pharmaceutical Product	250	250
Licence to Manufacture Medicines	13,750	13,750
Licence to Pack Medicines	845	845
GMP Certificates	135	178.25
Medical Devices – Regulatory Statements to Foreign Governments (per statement)	135	178.25
Dietary Supplements - Regulatory Statements to Foreign Governments (first statement)	135	178.25
Dietary Supplements – additional copies issued at the same time (per statement)	22.50	25.00
New Zealand Based − Auditing of Non-Licensed Manufacturers − per hour, plus $50 administration fee, plus disbursements	138.00 per hour	178.25 per hour
Overseas Auditing of Manufacturers • $250 per hour (plus GST if applicable) for technical time • $200 per hour for travel time (up to a maximum of 8 hours per day) • plus $50 administration fee, plus disbursements		