Review of fees payable under the Medicines Act 1981

Analysis of Submissions and Outcomes document

Medsafe

May 2018

Contents

About the consultation

In March 2018, the New Zealand Medicines and Medical Devices Safety Authority (Medsafe), a business unit of the Ministry of Health, released a consultation document proposing to increase the fees payable under the Medicines Act 1981.

The Medicines Act (the 'Act') provides for the charging of fees in relation to applications for licences and for the approval of new and changed medicines, related products, and clinical trials. The fees provide funding to Medsafe to conduct its statutory duties.

The last comprehensive fees review was completed in 2008 and implemented in 2009, which resulted in an average 12 percent reduction to fees (fees were last increased in 2006). At that time 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.

The proposed increases in fees are consistent with the Treasury's charging guidelines for cost-recovery. The proposed fees are targeted at cost-recovery levels because Medsafe's activities relating to the regulation of medicines, medical devices, related products, licensing, pharmacovigilance, investigations and surveillance contributes to the Ministry of Health's mission to improve the health of New Zealanders.

The new fees will be as listed in Appendix 1.

Submissions received

Medsafe has received and reviewed a total of 13 submissions in response to the consultation. Submissions that were not marked as containing commercially sensitive information are published on Medsafe's website. Personal information that can identify the submitter has been removed, where requested.

1. Anonymous
2. Medicines New Zealand
3. GlaxoSmithKline (NZ) Ltd
4. Roche Products (New Zealand) Limited
5. Pfizer New Zealand Limited
6. AbbVie Limited
7. Johnson & Johnson (New Zealand) Ltd
8. Amgen Australia Pty Ltd, on behalf of Amgen New Zealand Limited
9. New Zealand Self Medication Industry

Stakeholder representation

Ten submissions made were on behalf of a pharmaceutical company, and two were from a pharmaceutical industry association. The remaining submitter was anonymous, and did not identify themselves as belonging to any particular group.

Three submissions were from organisations based in Australia and the remainder were from New Zealand. No submissions were received from the public.

All of the submissions commented on the proposed increases in fees for new medicine applications and changed medicine notifications. There were no submissions on the increases to clinical trial application fees.

Medsafe thanks all the submitters who took the time to prepare a submission and provide helpful comments and suggestions.

Support for the proposed increase in fees

Ten submissions supported the proposed fees increases, with a few submitters considering these to be long overdue. Two of the ten submissions were from pharmaceutical industry associations submitting on behalf of their members. Several submitters said that they would support fee increases to improve Medsafe's performance in the evaluation of new medicine applications (NMAs) or changed medicine notifications (CMNs). One submission supported increasing fees by an additional 10 to 20 percent in order to improve performance. Another submission supported increasing the fees for full evaluations to a level that would allow Medsafe to gather sufficient resources to complete evaluations in a timely fashion. One submission voiced support for the review of fees, but opposed the new fee structure.

Two submissions did not mention either support or opposition to the proposed increases in fees. One of these submissions noted that the fees increases are being applied as a single increase of 15 percent that is an accumulation of Consumer Price Index (CPI) changes since 2008 and would not support an increase of this scale. However, the submitter would support annual adjustments that addressed changes to the CPI.

One submitter opposed increases in fees as they believed that there was a lack of transparency with respect to Medsafe's estimation of evaluation time, effort and resources. One submitter opposed fees increases unless these were linked Medsafe's performance. Submitters also commented on a number of other issues.

Medsafe appreciates the general support of the pharmaceutical industry for the fees increases.

Key issues raised

Timing for the new fees

Seven submitters questioned the date proposed for the implementation of the increased fees. Their main concern was the short period of notice, as most companies had already prepared their annual budgets well in advance of fiscal year 2018.

Submitters commented that the proposed implementation of the increases in fees before the end of 2018 is expected to cause delays in submission of NMAs and CMNs for the remainder of the 2018 calendar year, and an increase in such submissions in the first quarter of 2019. This was anticipated to affect Medsafe's regulatory workload and guideline timeline for evaluation of applications and notifications, leading to further unpredictability and uncertainty for pharmaceutical companies to plan their activities.

The general consensus from the submissions was to request delaying implementation of the new fees until 2019.

Medsafe comment

Medsafe acknowledges the difficulty that pharmaceutical companies face with the timing of the proposed increases. However, Medsafe does not have the ability to delay for another seven months. As a compromise, Medsafe has adopted two suggestions and will implement the following plan for new medicine applications.

Outcomes:

- Implementation of the new fees will proceed.
- Medsafe will delay implementation of the new fees from 1 June 2018 to 1 July 2018.
- Medsafe will give applicants the option of staggering the payment of the increased fee for new medicine applications (NMA). Under this option the new NMA (including applications for additional dose forms) fees will be applicable from 1 July 2018, however, this can be paid in two parts. From 1 July to 31 December 2018 it will be possible to select to pay the existing fee when the application is submitted, with the remaining balance being invoiced by Medsafe in January 2019. This option will be available until 31 December 2018.

Scale of the fees increases

Most submissions considered that the proposed fees increases were in line with the CPI movements since 2008, and apart from the proposed fees for abbreviated route high risk new medicine applications, accepted that the increases were not excessive.

Almost all submissions commented on the proposed new fee for abbreviated route for higher-risk NMAs (with no new active ingredients). These submissions pointed out that the proposed new fee ($51,000) for the abbreviated route for higher-risk

NMAs (with no new active ingredients) exceeded the fee for a full evaluation ($43,875).

Medsafe comment

Medsafe agrees with industry on this anomaly.

Outcome:

- Medsafe will align the fee for an abbreviated route higher-risk new medicine application (with no new active ingredients) with that of an abbreviated route intermediate-risk new medicine application. The new fee will be $21,940.
- All other fees will be increased as proposed.

Frequency of reviews of fees

Most submitters commented that they understood the reason why fees were being increased after a ten-year period of no fees increases, given increases in the consumer price index (CPI) over that time. However, some submitters stated that they would prefer annual adjustments, or at least, more regular reviews, in line with movements in the CPI. There was also concern expressed about the short time frame of the fees consultation, in effect, of only about ten weeks from consultation on the proposal to increase fees, to the implementation of the new fees.

Medsafe comment

Medsafe has been conducting fees reviews at three-year intervals, in keeping with an agreement with the Ministry's auditors, Audit New Zealand. At those reviews, an increase in fees was not justified as there remained a surplus in Medsafe's Memorandum account.

Medsafe acknowledges that this had not been communicated to the industry, and the industry should have been better informed of fees reviews.

Outcome:

- Medsafe will contact the industry for their input when the next fees review is scheduled and will better align review of fees with the industry's planning cycle.

Performance

Submitters were concerned that the target evaluation timelines were not being met. While there was overall support for the increases in fees, it came with the expectation that Medsafe's performance in relation to evaluation target timelines will improve.

Medsafe comment

Medsafe acknowledges that there is an expectation that a rise in fees would be accompanied by continuous improvement in regulatory practice, but notes that

meeting target evaluation times can be affected by a number of factors beyond capacity issues, such as complexity, urgency, and the quality of submissions.

Outcome:

- Continuous improvement processes are currently being identified and implemented.

Other Issues raised

Impact of increased fees on the community

Four submitters raised the concern that the proposed fees increases would restrict patient access to pharmaceuticals. Two particular issues were identified. These were that the general increases in fees would serve as a disincentive to submit new applications or notifications for new indications. An increased fee for the abbreviated H-NMA route in particular would serve as a disincentive for companies to choose this route. There would also be the possibility of products being withdrawn due to the proposed increases in fees applied to notification of changes to medicines. In each case, increases in fees would result in delays in the availability of new products. One submission requested discounts or waivers for orphan drugs and indications.

Medsafe comment

The fees have been adjusted only in accordance with guidelines for cost recovery set by the Treasury. Medsafe considers that the allocation of individual fees is reflective of the effort involved. Medsafe will continue to consider any request for a fee waiver in accordance with current fee waiver criteria.

Additional suggestions

A number of submitters made other suggestions that were not directly related to the proposed increases in fees. These suggestions relate to improving performance or reducing workload, introducing new fees or other increases in fees, or payment models to help reduce the impact of the increased fees.

Medsafe comment

Medsafe will adopt the suggestion of staggered fee payment for new medicine applications, and will discuss the other suggestions with the industry.

Summary of Outcomes

1. Medsafe will proceed to implement the new fees.
2. Medsafe will delay implementation of the new fees from 1 June 2018 to 1 July 2018.
3. Medsafe will give applicants the option of staggering the payment of the increased fee for new medicine applications (NMA). Under this option the new NMA (including applications for additional dose forms) fees will be applicable from 1 July 2018, however, this can be paid in two parts. From 1 July to 31 December 2018 it will be possible to select to pay the existing fee when the application is submitted, with the remaining balance being invoiced by Medsafe in January 2019. This option will be available until 31 December 2018.
4. Medsafe will align the fee for an abbreviated route higher-risk new medicine application (with no new active ingredients) with that of an abbreviated route intermediate-risk new medicine application. The new fee will be $21,940.
5. All other fees will be increased as proposed (Appendix 1).
6. Medsafe will work with industry to plan future fees reviews and their timing.

Implementation

The new fees will be implemented from 1 July 2018.

Enquiries

Any questions relating to this consultation should be directed via email to: askmedsafe@moh.govt.nz

APPENDIX 1: SCHEDULE OF FEES (effective from 1 July 2018)

- 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	***Existing fee ($)***	***New fee ($)***
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	***Existing fee ($)***	***New fee ($)***
New higher-risk medicine containing one or more new active substances	33,750	51,100
Any other new higher-risk medicine	33,750	21,940
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	***Existing fee ($)***	***New fee ($)***
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	***Existing fee ($)***	***New fee ($)***
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	***Existing fee ($)***	***New fee ($)***
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

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	***Existing fee ($)***	***New fee ($)***
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

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	***Existing fee ($)***	***New fee ($)***
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	***Existing fee ($)***	***New fee ($)***
Product name		
Product name, for each new name	720	830
Formulation/excipients		
Formulation − Grade 1	2,880	3,200
Formulation − Grade 2	720	830

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	***Existing fee ($)***	***New fee ($)***
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

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	***Existing fee ($)***	***New fee ($)***
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	***Existing fee ($)***	***New fee ($)***
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

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	***Existing fee ($)***	***New fee ($)***
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	***Existing fee ($)***	***New fee ($)***
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	***Existing fee ($)***	***New fee ($)***
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		