SCHEDULE OF FEES Payable under the Medicines Act 1981 (Effective from 1 July 2022)

- 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/regulatory/forms.asp).

Contents

New Medicines Application (NMA) Fees

Type of application	New fee ($)
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[1]	
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
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 (ie, when additional product applications are submitted after approval of the parent product).[2]	

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

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

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

Type of Application	**New fee ($)**
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

Type of Application	New fee ($)
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 (ie, when additional product applications are submitted after approval of the parent product).	
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

Type of Application	New fee ($)
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[3]	11,982

[3] 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.

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	New fee ($)
Product name	
Product name, for each new name	865
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)	432
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.

Type of Application	New fee ($)
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

Type of Application	New fee ($)
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

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	New fee ($)
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 Fees

Type of Application	**New fee ($)**
Application for consent to conduct a clinical trial	7,500
Additional clinical trial for the **same** medicine, submitted at the **same** time	3,750
Application for consent to conduct a clinical trial – abbreviated approval process	415

Licences and Other Fees

Type of Application	New fee ($)
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

Information on the following Licences:

- Licence to Sell by Wholesale
- Licence to Sell Medicines by Retail
- Licence to Hawk Medicines
- Licence to Operate a Pharmacy
- Licence to deal in Controlled Drugs
- Licence to possess Controlled Drugs
- Licence to import Controlled Drugs
- Licence to export Controlled Drugs

can be obtained by contacting Medicines Control:

www.health.govt.nz/about-ministry/contact-us/groups/medicines-control-contacts.