Fees payable under the Medicines Act 1981

(effective from 1 October 2010)

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	***Fee***
New higher-risk medicine containing one or more new active substances	88,875
Any other new higher-risk medicine	43,875
New intermediate risk medicine – prescription Medicine	43,875
New intermediate risk medicine – non-prescription Medicine	7,650
New lower-risk medicine	7,650
Additional dose form – higher-risk medicine – Grade 1 or 2	43,875
Additional dose form – intermediate-risk prescription medicine – Grade 1 or 2	43,875
Additional dose form – intermediate-risk non-prescription medicine – Grade 1 or 2	7,650
Additional dose form – lower-risk medicine – Grade 1 or 2	7,650
New combination pack containing 2 or more currently approved products	3,200
Additional names, strengthens, flavours and classifications notified at the same time as the parent application	0
The following fees apply when the additions are subsequent to the parent application	
Additional name - Grade 1	720
Additional name - Grade 2	1,440
Additional classification (with/without new name)	720
Additional strength - Grade 1	2,160
Additional strength - Grade 2	2,880
Additional strength - Grade 3	5,760
Additional strength - Grade 4	18,000
Additional strength - Grade 5	27,000
Additional flavour or type of sweetening	1,440

New Medicines Application (Abbreviated Evaluation Process) Fees	
Type of application	***Fee***
New higher-risk medicine containing one or more new active substances	33,750
Any other new higher-risk medicine	33,750
New intermediate risk medicine – prescription medicine	16,875

Additional names, strengthens, flavours and classifications must be notified at the same time as the parent application	0

New Related Product Application (NRPA) Fees	
Type of application	***Fee***
New related product	5,500
Additional names, strengthens, flavours and classifications notified at the same time as the parent application	0
The following fees apply when the additions are subsequent to the parent application	
Additional name - Grade 1	720
Additional name - Grade 2	1,440
Additional strength	1,440
Additional flavour or type of sweetening	1,440

New Medicine Application Provisional Consent Fees	
Type of application	***Fee***
Application for provisional consent to distribute a new medicine	8,437
Application for renewal of provisional consent	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/CRPN fee for a single product exceed the fee for a new medicine application for a product of the same type	
Type of application	***Fee***
Product name	
Product name, for each new name	720
Formulation	
Formulation - Grade 1, Type 1	1,440
Formulation - Grade 1, Type 2	2,160
Formulation - Grade 2, Type 1	1,440
Formulation - Grade 3, Type 1	1,800
Formulation - Grade 4, Type 1	2,160
Formulation - Grade 4, Type 2	2,880
Active ingredient	
Active ingredient manufacturing site	720
Active ingredient manufacturing process - Grade 1, Type 1	720
Active ingredient manufacturing process - Grade 1, Type 2	720
Active ingredient manufacturing process - Grade 2, Type 1	2,880
Active ingredient manufacturing process - Grade 2, Type 2	2,880
Active ingredient manufacturing process - Grade 3, Type 1	720
Active ingredient manufacturing process - Grade 3, Type 2	720
Active ingredient specifications/test methods - Grade 1	360
Active ingredient specifications/test methods - Grade 2	720
Active ingredient specifications/test methods - Grade 3	720
Active ingredient specifications/test methods - Grade 4, Type 1	720
Active ingredient specifications/test methods - Grade 4, Type 2	1,440
Excipient	
Excipient specifications/test methods - Grade 1	360
Excipient specifications/test methods - Grade 2	720
Excipient specifications/test methods - Grade 3	720

Finished product	
Finished product packing site - Grade 1	720
Finished product packing site - Grade 2	1,440
Finished product manufacturing process - Grade 1, Type 1	1,440
Finished product manufacturing process - Grade 1, Type 2	2,160
Finished product manufacturing process - Grade 2, Type 1	2,160
Finished product manufacturing process - Grade 2, Type 2	2,880
Finished product specifications/test methods - Grade 1	360
Finished product specifications/test methods - Grade 2	360
Finished product specifications/test methods - Grade 3	360
Finished product specifications/test methods - Grade 4	720
Finished product specifications/test methods - Grade 5, Type 1	720
Finished product specifications/test methods - Grade 5, Type 2	1,440
Product stability and packaging	
Shelf life/storage conditions - Grade 1	360
Shelf life/storage conditions - Grade 2	1,440
Container/closure/packaging - Grade 1	360
Container/closure/packaging - Grade 2	720
Container/closure/packaging - Grade 3	1,440
Container/closure/packaging - Grade 4	2,160
Container/closure/packaging - Grade 5	2,880
Indications and dosage	
Indications/dosage - Grade 1	2,880
Indications/dosage - Grade 2	2,880
Indications/dosage - Grade 3	2,880
Indications/dosage - Grade 4	720
Indications/dosage - Grade 5	720
Contraindications, Warnings and Precautions	2,880
Data sheet	
Data sheet - miscellaneous changes	360
Labelling	
Labelling - Grade 1	360
Labelling - Grade 2	720
Labelling - Grade 3	720
Other	
Sponsor	360
Self-assessable change(s)	360
Administration Fee	360

Biological or Biotechnological Medicine (CMN Form B)	
Notifying a material change (including self-assessable changes) to an approved Type III (biological or biotechnological) product (i.e., 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	***Fee***
Product name	
Product name, for each new name	720
Formulation/Excipients	
Formulation - Grade 1	2,880
Formulation - Grade 2	720
Bulk Active	
Bulk Active manufacturing site	2,880
Bulk Active methods of manufacture	2,880
Change in site of lyophilisation	1,440
Revalidation of lyophilisation process	1,440
Active ingredient method of manufacture	720
Finished product manufacturing site	2,880
Finished product secondary packing site	720
Finished product manufacturing process - Grade 1	2,880
Finished product manufacturing process – Grade 2	2,880
Finished product manufacturing process	720
Test methods and specifications	
Test methods and specifications - Grade 1	2,880
Test methods and specifications - Grade 2	2,880
Test methods and specifications - Grade 3	2,880
Test methods and specifications - Grade 4	1,440
Test methods and specifications - Grade 5	1,440
Test methods and specifications - Grade 6	360
Product stability and packaging	
Shelf life/storage conditions - Bulk Actives and Intermediate Bulks	1,440
Shelf life/storage conditions - Finished Product	1,440
Container/closure/packaging - Grade 1	1,440
Container/closure/packaging - Grade 2	2,880
Container/closure/packaging - Grade 3	360
Indications and dosage	
Indications/dosage - Grade 1	2,880
Indications/dosage - Grade 2	2,880
Indications/dosage - Grade 3	2,880
Indications/dosage - Grade 4	720
Indications/dosage - Grade 5	720
Contraindications, Warnings and Precautions	2,880
Labelling	
Labelling - Grade 1	360
Labelling - Grade 2	720
Labelling - Grade 3	720
Data Sheet	
Data sheet - miscellaneous changes	360
Other	
Sponsor	360
Self-assessable change(s)	360
Administration Fee	360

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	***Fee***
Product name	
Product name	720
Formulation	
Formulation - Grade 1	1,080
Formulation - Grade 2	1,080
Formulation - Grade 3	2,160
Active ingredient	
Active ingredient specifications/test methods - Grade 1	360
Active ingredient specifications/test methods - Grade 2	720
Finished product	
Finished product packing site	720
Finished product manufacturing site - Grade 1	720
Finished product manufacturing site - Grade 2	2,160
Finished product manufacturing process - Grade 1	1,440
Finished product manufacturing process - Grade 2	2,160
Finished product specifications/test methods	720
Product stability and packaging	
Shelf life/storage conditions - Grade 1	360
Shelf life/storage conditions - Grade 2	1,440
Container/closure/packaging - Grade 1	360
Container/closure/packaging - Grade 2	720
Container/closure/packaging - Grade 3	1,440
Indications and dosage	
Indications/dosage - Grade 1	2,880
Indications/dosage - Grade 2	1,080
Indications/dosage - Grade 3	1,080
Indications/dosage - Grade 4	720
Labelling	
Labelling - Grade 1	360
Labelling - Grade 2	720
Other	
Sponsor	360
Self-assessable change(s)	360
Administration Fee	360

Clinical Trial Application Fees	
Type of application	***Fee***
Application for consent to conduct a clinical trial	6,525
Additional clinical trial for the same medicine, submitted at the same time	3,263

Licences and Other Fees	
Type of application	***Fee***
Appeal to the Medicines Review Committee	9,000
Issue of a Certificate of Pharmaceutical Product	250
Licence to Manufacture Medicines	13,750
Licence to Pack Medicines	845
GMP Certificates	135
Medical Devices – Regulatory Statements to Foreign Governments (per statement)	135
Dietary Supplements - Regulatory Statements to Foreign Governments (first statement)	135
Dietary Supplements – additional copies issued at the same time (per statement)	22.50
Auditing of Non-Licensed Manufacturers - $138 per hour, plus $50 Admin fee, plus disbursements	