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)

Staggered payment option of New Medicines Application (NMA) Fees – *effective 1 July 2018 to 31 December 2018 only*

The new fee effective from 1 July 2018 is applicable. Applicants can opt to pay the total fee at once or in two parts. Please make your selection clear on the relevant application form. For the two part option, the initial fee can be paid when the application is submitted, with the balance to be invoiced by Medsafe in January 2019. This option is only available until 31 December 2018.

	Initial fee ($)	***Balance due Jan-19 ($)***	***Total Applicable Fee ($)***
New higher-risk medicine containing one or more new active substances	88,875	13,335	102,210
New intermediate-risk medicine – non-prescription medicine	7,650	2,570	10,220
New lower-risk medicine	7,650	2,570	10,220
Additional dose form – intermediate-risk non-prescription medicine – Grade 1 or 2	7,650	2,570	10,220
Additional dose form – lower-risk medicine – Grade 1 or 2	7,650	2,570	10,220
Abbreviated evaluation process - New higher-risk medicine containing one or more new active substances	33,750	17,350	51,100
Abbreviated evaluation process - New intermediate-risk medicine – prescription medicine	16,875	5,065	21,940

New Medicines Application (NMA) Fees	
Type of application	***New fee ($)***
New higher-risk medicine containing one or more new active substances	102,210
Any other new higher-risk medicine	43,875
New intermediate-risk medicine – prescription medicine	43,875
New intermediate-risk medicine – non-prescription medicine	10,220
New lower-risk medicine	10,220
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	10,220
Additional dose form – lower-risk medicine – Grade 1 or 2	10,220
New combination pack containing two or more currently approved products	3,680
Additional names, strengths, 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	830
Additional name − Grade 2	1,660
Additional classification (with/without new name)	830
Additional strength − Grade 1	2,490
Additional strength − Grade 2	3,320
Additional strength − Grade 3	6,640
Additional strength − Grade 4	20,700
Additional strength − Grade 5	31,050
Additional flavour or type of sweetening	1,660

New Medicines Application (Abbreviated Evaluation Process) Fees	
Type of application	***New fee ($)***
New higher-risk medicine containing one or more new active substances	51,100
Any other new higher-risk medicine	21,940
New intermediate-risk medicine – prescription medicine	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	***New fee ($)***
New related product	5,500
Additional names, strengths, 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	830
Additional name − Grade 2	1,660
Additional strength	1,660
Additional flavour or type of sweetening	1,660

New Medicine Application Provisional Consent Fees	
Type of application	***New 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/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	830
Formulation	
Formulation − Grade 1, Type 1	1,660
Formulation − Grade 1, Type 2	2,490
Formulation − Grade 2, Type 1	1,660
Formulation − Grade 3, Type 1	2,075
Formulation − Grade 4, Type 1	2,490
Formulation − Grade 4, Type 2	3,200
Active ingredient	
Active ingredient manufacturing site	830
Active ingredient manufacturing process − Grade 1, Type 1	830
Active ingredient manufacturing process - Grade 1, Type 2	830
Active ingredient manufacturing process − Grade 2, Type 1	3,200
Active ingredient manufacturing process − Grade 2, Type 2	3,200
Active ingredient manufacturing process − Grade 3, Type 1	830
Active ingredient manufacturing process − Grade 3, Type 2	830
Active ingredient specifications/test methods − Grade 1	415
Active ingredient specifications/test methods − Grade 2	830
Active ingredient specifications/test methods − Grade 3	830
Active ingredient specifications/test methods − Grade 4, Type 1	830
Active ingredient specifications/test methods − Grade 4, Type 2	1,660
Excipient	
Excipient specifications/test methods − Grade 1	415
Excipient specifications/test methods − Grade 2	830
Excipient specifications/test methods − Grade 3	830
Finished product	
Finished product packing site − Grade 1	830
Finished product packing site − Grade 2	1,660
Finished product manufacturing process − Grade 1, Type 1	1,660

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

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 ($)***
Labelling − Grade 2	830
Labelling − Grade 3	830
Other	
Sponsor	415
Change in ownership	830
Self-assessable change(s)	415
Administration Fee	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	***New fee ($)***
Product name	
Product name, for each new name	830
Formulation/excipients	
Formulation − Grade 1	3,200
Formulation − Grade 2	830
Bulk active	
Bulk active manufacturing site	3,200
Bulk active methods of manufacture	3,200
Change in site of lyophilisation	1,660
Revalidation of lyophilisation process	1,660
Active ingredient method of manufacture	830
Finished product manufacturing site	3,200
Finished product secondary packing site	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	***New fee ($)***
Finished product manufacturing process − Grade 1	3,200
Finished product manufacturing process – Grade 2	3,200
Finished product manufacturing process	830
Test methods and specifications	
Test methods and specifications − Grade 1	3,200
Test methods and specifications − Grade 2	3,200
Test methods and specifications − Grade 3	3,200
Test methods and specifications − Grade 4	1,660
Test methods and specifications − Grade 5	1,660
Test methods and specifications − Grade 6	415
Product stability and packaging	
Shelf life/storage conditions − bulk actives and intermediate bulks	1,660
Shelf life/storage conditions − finished product	1,660
Container/closure/packaging − Grade 1	1,660
Container/closure/packaging − Grade 2	3,200
Container/closure/packaging − Grade 3	415
Indications and dosage	
Indications/dosage − Grade 1	3,200
Indications/dosage − Grade 2	3,200
Indications/dosage − Grade 3	3,200
Indications/dosage − Grade 4	830
Indications/dosage − Grade 5	830
Contraindications, Warnings and Precautions	3,200
Labelling	
Labelling − Grade 1	415
Labelling − Grade 2	830
Labelling − Grade 3	830
Data Sheet	
Data sheet − miscellaneous changes	415
Data sheet − format change (an administration fee applies if this is the sole change)	0

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 ($)***
Other	
Sponsor	415
Change in ownership	830
Self-assessable change(s)	415
Administration fee	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	***New fee ($)***
Product name	
Product name	830
Formulation	
Formulation − Grade 1	1,245
Formulation − Grade 2	1,245
Formulation − Grade 3	2,490
Active ingredient	
Active ingredient specifications/test methods − Grade 1	415
Active ingredient specifications/test methods − Grade 2	830
Finished product	
Finished product packing site	830
Finished product manufacturing site − Grade 1	830
Finished product manufacturing site − Grade 2	2,490
Finished product manufacturing process − Grade 1	1,660
Finished product manufacturing process − Grade 2	2,490
Finished product specifications/test methods	830
Product stability and packaging	
Shelf life/storage conditions − Grade 1	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	***New fee ($)***
Shelf life/storage conditions − Grade 2	1,660
Container/closure/packaging − Grade 1	415
Container/closure/packaging − Grade 2	830
Container/closure/packaging − Grade 3	1,660
Indications and dosage	
Indications/dosage − Grade 1	3,200
Indications/dosage − Grade 2	1,245
Indications/dosage − Grade 3	1,245
Indications/dosage − Grade 4	830
Labelling	
Labelling − Grade 1	415
Labelling − Grade 2	830
Other	
Sponsor	415
Self-assessable change(s)	415
Administration fee	415

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	250

Licence to Manufacture Medicines	13,750
Licence to Pack Medicines	845
GMP Certificates	178.25
Medical Devices – Regulatory Statements to Foreign Governments (per statement)	178.25
Dietary Supplements - Regulatory Statements to Foreign Governments (first statement)	178.25
Dietary Supplements – additional copies issued at the same time (per statement)	25.00
New Zealand Based − Auditing of Non-Licensed Manufacturers − per hour, plus $50 administration fee, plus disbursements	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	