

## SCHEDULE OF FEES (effective from 1 July 2019)

- 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](http://www.medsafe.govt.nz/regulatory/forms.asp))

<b>New Medicines Application (NMA) Fees</b>	
<i>Type of application</i>	<i>New fee (\$)</i>
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 <b>same time</b> as the parent application	0
The following fees apply when the additions are <b>subsequent</b> 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

<b>New Medicines Application (NMA) Fees</b>	
<b><i>Type of application</i></b>	<b><i>New fee (\$)</i></b>
Additional strength – Grade 4	20,700
Additional strength – Grade 5	31,050
Additional flavour or type of sweetening	1,660

<b>New Medicines Application (Abbreviated Evaluation Process) Fees</b>	
<b><i>Type of application</i></b>	<b><i>New fee (\$)</i></b>
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, strengths, flavours and classifications must be notified at the same time as the parent application	

<b>New Related Product Application (NRPA) Fees</b>	
<b><i>Type of application</i></b>	<b><i>New fee (\$)</i></b>
New related product	5,500
Additional names, strengths, flavours and classifications notified at the <u>same time</u> as the parent application	0
<i>The following fees apply when the additions are <u>subsequent</u> to the parent application</i>	
Additional name – Grade 1	830
Additional name – Grade 2	1,660
Additional strength	1,660
Additional flavour or type of sweetening	1,660

<b>New Medicine Application Provisional Consent Fees</b>	
<b><i>Type of application</i></b>	<b><i>New fee (\$)</i></b>
Application for provisional consent to distribute a new medicine	8,437
Application for renewal of provisional consent	500

<b>Changed Medicine Notifications (CMN) Fees</b>	
<b>Non-Biological Medicine (CMN Form A)</b>	
<i>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</i>	
<b><i>Type of application</i></b>	<b><i>New fee (\$)</i></b>
<i>Product name</i>	
Product name, for each new name	830
<i>Formulation</i>	
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
<i>Active ingredient</i>	
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

<b>Changed Medicine Notifications (CMN) Fees</b>	
<b>Non-Biological Medicine (CMN Form A)</b>	
<i>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</i>	
<b>Type of application</b>	<b>New fee (\$)</b>
Active ingredient specifications/test methods – Grade 4, Type 2	1,660
<i>Excipient</i>	
Excipient specifications/test methods – Grade 1	415
Excipient specifications/test methods – Grade 2	830
Excipient specifications/test methods – Grade 3	830
<i>Finished product</i>	
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
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
<i>Product stability and packaging</i>	
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
<i>Indications and dosage</i>	
Indications/dosage – Grade 1	3,200
Indications/dosage – Grade 2	3,200
Indications/dosage – Grade 3	3,200

<b>Changed Medicine Notifications (CMN) Fees</b>	
<b>Non-Biological Medicine (CMN Form A)</b>	
<i>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</i>	
<b>Type of application</b>	<b>New fee (\$)</b>
Indications/dosage – Grade 4	830
Indications/dosage – Grade 5	830
Contraindications, Warnings and Precautions	3,200
<i>Data sheet</i>	
Data sheet – miscellaneous changes	415
Data sheet – format change (an administration fee applies if this is the sole change)	0
<i>Labelling</i>	
Labelling – Grade 1	415
Labelling – Grade 2	830
Labelling – Grade 3	830
Other	
Sponsor	415
Change in ownership	830
Self-assessable change(s)	415
Administration Fee	415

<b>Biological or Biotechnological Medicine (CMN Form B)</b>	
<i>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.</i>	
<b>Type of application</b>	<b>New fee (\$)</b>
<i>Product name</i>	
Product name, for each new name	830
<i>Formulation/excipients</i>	
Formulation – Grade 1	3,200

<b>Biological or Biotechnological Medicine (CMN Form B)</b>	
<i>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).</i>	
<i>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.</i>	
<b>Type of application</b>	<b>New fee (\$)</b>
Formulation – Grade 2	830
<i>Bulk active</i>	
Active ingredient manufacturing site	3,200
Active ingredient method of manufacture – Grade 1	3,200
Active ingredient method of manufacture – Grade 2	830
Active ingredient method of manufacture – grade 3	415
Finished product manufacturing site	3,200
Finished product secondary packing site	830
Finished product testing site	1,660
Finished product manufacturing process – Grade 1	3,200
Finished product manufacturing process – Grade 2	3,200
Finished product manufacturing process – Grade 3	830
Finished product manufacturing process – Grade 4	415
<i>Excipient</i>	
Excipient specifications/test methods – Grade 1	415
Excipient specifications/test methods – Grade 2	830
Excipient specifications/test methods – Grade 3	830
<i>Test methods and specifications</i>	
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
<i>Product stability and packaging</i>	
Shelf life/storage conditions – active ingredient and intermediate bulks	1,660
Shelf life/storage conditions – finished product	1,660
Shelf life/storage conditions – Reference standard – Grade 1	1660
Shelf life/storage conditions – Reference standard – Grade 2	415
Container/closure/packaging – Grade 1	1,660
Container/closure/packaging – Grade 2	3,200

<b>Biological or Biotechnological Medicine (CMN Form B)</b>	
<i>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).</i>	
<i>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.</i>	
<b>Type of application</b>	<b>New fee (\$)</b>
Container/closure/packaging – Grade 3	830
Container/closure/packaging – Grade 4	415
<i>Indications and dosage</i>	
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
<i>Labelling</i>	
Labelling – Grade 1	415
Labelling – Grade 2	830
Labelling – Grade 3	830
<i>Data Sheet</i>	
Data sheet – miscellaneous changes	415
Data sheet – format change (an administration fee applies if this is the sole change)	0
<i>Other</i>	
Sponsor	415
Change in ownership	830
Self-assessable change(s)	415
Administration fee	415

<b>Change Related Product Notification (CRPN) Fees</b>	
<i>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.</i>	
<b>Type of application</b>	<b>New fee (\$)</b>
<i>Product name</i>	
Product name	830
<i>Formulation</i>	
Formulation – Grade 1	1,245
Formulation – Grade 2	1,245
Formulation – Grade 3	2,490
<i>Active ingredient</i>	
Active ingredient specifications/test methods – Grade 1	415
Active ingredient specifications/test methods – Grade 2	830
<i>Finished product</i>	
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
<i>Product stability and packaging</i>	
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
<i>Indications and dosage</i>	
Indications/dosage – Grade 1	3,200
Indications/dosage – Grade 2	1,245
Indications/dosage – Grade 3	1,245
Indications/dosage – Grade 4	830
<i>Labelling</i>	
Labelling – Grade 1	415
Labelling – Grade 2	830
<i>Other</i>	
Sponsor	415
Self-assessable change(s)	415

<b>Change Related Product Notification (CRPN) Fees</b>	
<i>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.</i>	
<b>Type of application</b>	<b>New fee (\$)</b>
Administration fee	415

<b>Clinical Trial Application Fees</b>	
<b>Type of application</b>	<b>New fee (\$)</b>
Application for consent to conduct a clinical trial	7,500
Additional clinical trial for the <u>same</u> medicine, submitted at the <u>same</u> time	3,750
Application for consent to conduct a clinical trial – abbreviated approval process	415

<b>Licences and Other Fees</b>	
<b>Type of application</b>	<b>New fee (\$)</b>
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 (per statement)	178.25
Dietary Supplements – additional copy of original certificate 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 <ul style="list-style-type: none"> <li>• \$250 per hour (plus GST if applicable) for technical time</li> <li>• \$200 per hour for travel time (up to a maximum of 8 hours per day)</li> <li>• plus \$50 administration fee, plus disbursements</li> </ul>	