



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Fees and charges: summary

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Introduction

The TGA is required to recover its costs for all activities that fall within the scope of the *Therapeutic Goods Act 1989* (the Act), including the TGA's public health responsibilities.

- A fee is charged for a service, such as a product evaluation.
- A charge is a form of tax on regulated industry and is applied annually based on a 1 July to 30 June financial year.

Go to:

- [Payment options](#) for information on how to pay
- [Information and notices about TGA fees and payments](#) for general information.

This guidance is a summary of fees and charges, which are in the Australian therapeutic goods legislation. This is not an exhaustive list.

For a complete list of all fees and charges and the exact legislative wording, please refer directly to the legislation.

Legislation links

- [Therapeutic Goods Act 1989](#)
- [Therapeutic Goods Regulations 1990](#)
- [Therapeutic Goods \(Medical Devices\) Regulations 2002](#)
- [Therapeutic Goods \(Charges\) Regulations 2018](#)

Prescription medicines

These fees apply to prescription medicines and other medicines evaluated as prescription medicines.

For clinical trials supplying unapproved medicines, go to [Clinical trials](#).

Annual charges for prescription medicines

Table 1: Annual charges for prescription medicines

| Type of prescription medicine | Charge | Regulation |
|---|----------|--|
| Biological medicine | \$8,573 | Item 7(1)(b)(i)(ii)(iii) Item 7(2)(b)(i)(ii)(iii) |
| Non-biological medicine (chemical entity) - subsection 3-10 of regulation 8 | \$4,876 | Item 8(2)(a) |
| Non-biological medicine (chemical entity) - otherwise | \$3,972 | Item 8(2)(b) |
| Provisionally registered biological medicine | \$19,343 | Item 9(1)(a) |
| Provisionally registered non-biological medicine | \$15,796 | Item 9(1)(b) |

These charges are in the [Therapeutic Goods \(Charges\) Regulations 2018](#)

More about chemical entities annual charges

Higher annual charges

Regulation 8 of the *Therapeutic Goods (Charges) Regulations 2018* states when the higher annual charge applies for prescription medicine chemical entities.

Briefly, for prescription medicine chemical entities, a higher annual charge applies:

- whatever the duration or registration, for medicines containing at least one specified active ingredient:
 - thalidomide
 - leflunomide
 - lenalidomide
 - mifepristone
 - clozapine
 - isotretinoin

- until eight years have passed since registration, following an application for:
 - new chemical entity
 - extension of indications
 - change to intended patient group

Annual charges following applications for other major variations will incur higher or lower charges depending on the parent good, for example:

- new formulation
- change of strength
- new dosage forms

Lower annual charges

The lower annual charge applies for:

- most generic prescription medicines
- most prescription medicines that are not biological medicines past the eighth anniversary of an application approval for a:
 - new chemical entity
 - extension of indications
 or
 - change to intended patient group.

Application and evaluation fees for prescription medicines

Standard prescription medicine processes

These applications have both an application fee and an evaluation fee.

Table 2: Standard prescription medicine processes

| Prescription Medicine Application Type | Application Fee | Evaluation Fee | Clause 3 of Schedule 9 |
|---|------------------------|-----------------------|-------------------------------|
| New chemical entity* | \$54,292 | \$217,598 | Item 2(ba) and Item 4(a) |
| Extension of indications* | \$32,381 | \$129,091 | Item 2(bd) and Item 4(b) |
| Major variations*^ | \$21,156 | \$84,189 | Item 2(bi) and Item 4(g) |

| Prescription Medicine Application Type | Application Fee | Evaluation Fee | Clause 3 of Schedule 9 |
|---|-----------------|----------------|-----------------------------|
| Minor variation applications applied for under section 23 of the Act (Change in formulation, composition, design specifications, type of container or change of trade name) ^ | \$1,241 | \$4,954 | Item 2(bj) and Item 4(h) |
| Application to register a vaccine for a new strain of COVID-19, respiratory syncytial virus or influenza, where the vaccine is closely related to an existing vaccine that is included in the Register in relation to the applicant | \$1,241 | \$4,954 | Item 2 (bcb) and Item 4(ac) |
| Variations to an ARTG entry involving the evaluation of clinical, pre-clinical or bio-equivalence data, applied for under 9D(3) of the Act. Includes applications for changes to Product Information involving the evaluation of clinical, pre-clinical or bio-equivalence data*^ | \$1,241 | \$4,954 | Item 2AC and Item 2C |
| Additional trade name^ | \$3,421 | \$13,600 | Item 2(bh) and Item 4(d) |
| New generic product* | \$20,939 | \$83,110 | Item 2(bg) and Item 4(c) |
| Extension of indications of a generic medicine to; maintain currency with indications already registered to the corresponding innovator product, and where clinical and/or bioequivalence data are not required | \$1,241 | \$4,954 | Item 2 (bk) and Item 4(bc) |

These fees are in Schedule 9, [Therapeutic Goods Regulations 1990](#)

'The Act' refers to the [Therapeutic Goods Act 1989](#)

n/a: not applicable

* the fees are the same for the standard process and the comparable overseas regulator report-based process

^ the fees are the same for registered and provisionally registered medicines

Priority review pathway for prescription medicines

These applications have both an application fee and an evaluation fee.

Table 3: Priority review pathway for prescription medicines

| Prescription Medicine Application Type | Application Fee | Evaluation Fee | Clause 3 of Schedule 9 |
|---|-----------------|----------------|----------------------------|
| Priority determination of a prescription medicine | \$14,140 | n/a | Item 1B |
| New prescription medicine in the priority pathway | \$57,530 | \$230,118 | Item 2(bca) and Item 4(ab) |
| New indications medicine in the priority pathway | \$34,215 | \$136,862 | Item 2(bfa) and Item 4(bd) |

These fees are in Schedule 9, [Therapeutic Goods Regulations 1990](#)

n/a: not applicable

Provisional approval pathway for prescription medicines

These applications have both an application fee and an evaluation fee.

Table 4: Provisional approval pathway for prescription medicines

| Prescription Medicine Application Type | Application Fee | Evaluation Fee | Clause 3 of Schedule 9 |
|--|-----------------|----------------|-----------------------------|
| Provisional determination of a prescription medicine | \$14,140 | n/a | Item 1AA |
| Extension of provisional determination | \$5,127 | n/a | Item 1AB |
| Provisional registration of a new prescription medicine | \$54,399 | \$283,870 | Item 1AC(a) and Item 1AD(a) |
| Provisional registration of a new indications medicine | \$32,489 | \$187,268 | Item 1AC(b) and Item 1AD(b) |
| Extension of provisional registration | \$19,537 | n/a | Item 1AG |
| Transition from provisional registration to full registration* | \$32,381 | \$136,538 | Item 1AE and Item 1AF |

These fees are in Schedule 9, [Therapeutic Goods Regulations 1990](#)

n/a: not applicable

* Fees for an application under Section 23 for registration of a medicine that is included in the part of the ARTG for goods known as provisionally registered goods, to be included in the part of the ARTG for goods known as registered goods.

Requests with single fee

These requests have a single fee, instead of an application fee and an evaluation fee.

Table 5: Requests with single fee

| Prescription medicine request | Fee | Schedule 9 |
|--|---------|---------------------|
| Variations to an ARTG entry, applied for under section 9D(3) of the Act, involving the evaluation of only chemistry, quality control or manufacturing data. Includes applications for changes to Product Information involving the evaluation of only chemistry, quality control or manufacturing information. | \$6,195 | Clause 3 Item 2B |
| Minor editorial changes: variations to an ARTG entry (requiring changes to Product Information) with no evaluation of data | \$1,900 | Part 2 Item 2A(a) |
| Correction to an ARTG entry | \$1,900 | Part 2 Item 2A(a) |
| Notification request | \$907 | Clause 3 Item 2CB |
| Self-assessable request with no evaluation of data | \$1,900 | Part 2 Item 2A(a) |
| Safety-related request with no evaluation of data | \$1,900 | Part 2 Item 2A(a) |
| Safety-related request with evaluation of data | \$6,195 | Clause 3 Item 2CA |
| Request for advice in relation to a prescription medicine for the purpose of listing the medicine as a pharmaceutical benefit | \$2,504 | Clause 3 Item 18 |
| Request for early scientific advice on a biowaiver justification | \$9,347 | Clause 3 Item 1ABA |
| Application for consent by the Secretary under sections 14 and 14A of the Act to the import, export or supply of therapeutic goods that do not comply with an applicable standard where the application relates to a single entry in the register. | \$540 | Clause 3 Item 1A(a) |

| Prescription medicine request | Fee | Schedule 9 |
|---|--|--|
| Application for consent by the Secretary under sections 14 and 14A of the Act to the import, export or supply of therapeutic goods that do not comply with an applicable standard where the application relates to two or more entries in the register. | \$540 for the first entry, plus \$108 for each additional entry | Clause 3 Item 1A(a) Additional entry Item 1A(b) |

These fees are in Schedule 9, [Therapeutic Goods Regulations 1990](#)
'The Act' refers to the [Therapeutic Goods Act 1989](#)

Medicines as components of devices

This table applies to prescription medicines used as an ancillary component of a medical device.

Table 6: Medicines as components of devices

| Application type | Application fee | Evaluation fee | Clause 3 of Schedule 9, |
|--|-----------------|----------------|--|
| New chemical entity of a medicine used as an ancillary medical component of a device - chemistry, quality control and manufacturing OR nonclinical studies | \$18,025 | \$72,641 | Item 2(bb) Item 4(aa)(i) and (ii) |
| New chemical entity of a medicine used as an ancillary medical component of a device - chemistry, quality control and manufacturing AND nonclinical studies | \$36,158 | \$144,742 | Item 2(bc) Item 4(aa)(iii) |
| Extension of indicators of a medicine used as an ancillary medical component of a device – chemistry, quality control and manufacturing OR nonclinical studies | \$10,761 | \$43,066 | Item 2(be)(i) Item 4(bb)(i) and (ii) |
| Extension of indications of a medicine used as an ancillary medical component of a device – chemistry, quality control and manufacturing AND nonclinical studies | \$21,695 | \$86,024 | Item 2(bf)(i) Item 4(bb)(iii) |
| Major variation of a medicine used as an ancillary medical component of a device – chemistry, quality control and manufacturing OR nonclinical studies | \$7,026 | \$27,955 | Item 2(be)(ii) Item 4(bb)(i) and (ii) |
| Major variation of a medicine used as an ancillary medical component of a device – chemistry, quality control and manufacturing AND nonclinical studies | \$14,032 | \$56,235 | Item 2(bf)(ii) Item 4(bb)(iii) |

These fees are in Schedule 9, [Therapeutic Goods Regulations 1990](#)

Non-prescription medicines

Non-prescription medicines include:

- listed medicines
- assessed listed medicines
- registered complementary medicines, and
- registered over the counter (OTC) medicines.

For clinical trials supplying unapproved non-prescription medicines, go to [Clinical trials](#).

Listed medicines

Listed medicines are medicines that are not registered, for example:

- [listed complementary medicines](#)
- [assessed listed medicines](#)
- [sunscreens](#)

For listed export-only medicines go to [Export of therapeutic goods](#).

Listing applications

The following fees and charges apply to medicines listed under section 26A of the Act.

Table 7: Listing applications

| Listed medicine fee or charge | Amount | Regulation |
|--|---------|--------------------------------------|
| Annual charge | \$1,339 | Item 7(1)(c)(i) Item 7(2)(c)(i) |
| Application fee | \$939 | Clause 3 of Schedule 9 Item 3(b) |
| Fee for a request for variation to an existing listing | \$474 | Part 2 of Schedule 9 Item 2A(b) |
| Application for consent by the Secretary under sections 14 and 14A of the Act to the import, export or supply of therapeutic goods that do not comply with an applicable standard where the application relates to a single entry in the register. | \$540 | Clause 3 of Schedule 9 Item 1A(a) |

| Listed medicine fee or charge | Amount | Regulation |
|---|---|---|
| Application for consent by the Secretary under sections 14 and 14A of the Act to the import, export or supply of therapeutic goods that do not comply with an applicable standard where the application relates to two or more entries in the register. | \$540 for the first entry plus \$108 for each additional entry | Clause 3 of Schedule 9 Item 1A(a) and Item 1A(b) |

These fees are in the [Therapeutic Goods \(Charges\) Regulations 2018](#) and the [Therapeutic Goods Regulations 1990](#)

'The Act' refers to the [Therapeutic Goods Act 1989](#).

Permitted indications

Applications for a new [permitted indication](#) have an application fee.

Table 8: Permitted indications

| Listed medicine fee or charge | Amount | Clause 3 of Schedule 9 |
|---|---------|------------------------|
| Application fee for a new indication to be added to the permitted indication list | \$1,176 | Item 7C |

These fees are in Schedule 9, [Therapeutic Goods Regulations 1990](#)

Permitted ingredients

The ingredient application pathway is available for applications related to ingredients (new or variations) in:

- listed medicines (under section 26A of the Act)
- assessed listed medicines (under section 26AE of the Act)

An application to vary the [permitted ingredients list](#) has both an application fee and an evaluation fee.

For information on application types, see [Applications for new substances in listed medicines](#).

Table 9: Permitted ingredients for listed medicines

| Application Category | Application fee | Evaluation fee | Clause 5 of Schedule 9 |
|----------------------|-----------------|----------------|------------------------|
| IN1 | \$1,209 | \$16,299 | Item 28 and Item 29 |
| IN2 | \$1,209 | \$16,299 | Item 30 and Item 31 |
| IN3 | \$3,205 | \$26,552 | Item 32 and Item 33 |
| IN4 | \$3,205 | \$26,552 | Item 34 and Item 35 |

These fees are in Schedule 9, [Therapeutic Goods Regulations 1990](#)

Assessed listed medicines

Annual charge for assessed listed medicines

Assessed listed medicines have an annual charge.

Table 10: Annual charge for assessed listed medicines

| Annual charge | Amount | Regulation |
|---------------|---------|------------------------------------|
| Annual charge | \$1,339 | Item 7(1)(c)(i) Item 7(2)(c)(i) |

These charges are in the [Therapeutic Goods \(Charges\) Regulations 2018](#)

Assessed listed applications

Applications for assessed listed medicines (under section 26AE of the Act) have both an application fee and an evaluation fee.

For information on application types, see [Assessed listed medicines evidence guidelines](#).

Table 11: Assessed listed applications

| Application Category | Application fee | Evaluation fee | Clause 5 of Schedule 9 |
|----------------------|-----------------|----------------|------------------------|
| L(A)1 | \$497 | \$1,889 | Item 22 and Item 23 |
| L(A)2 | \$2,040 | \$15,651 | Item 24 and Item 25 |
| L(A)3 | \$2,040 | \$15,651 | Item 26 and Item 27 |

These fees are in Schedule 9, [Therapeutic Goods Regulations 1990](#)

Variations to assessed listed medicines

Application made under section 23 of the Act to list a new medicine if:

- new medicine is a changed from existing listed medicine, and
- new and existing medicine are separate and distinct, but new medicine is part of same therapeutic group as existing medicine

For information on application types, see [Changing a listed or assessed listed medicine, Application types and changes tables](#).

Table 12: Section 23 applications

| Application type | Application fee | Evaluation fee | Clause 5 of Schedule 9 |
|------------------|-----------------|----------------|------------------------|
| L(A)CN | \$885 | n/a | Item 1F |
| L(A)C1 | \$1,026 | \$1,188 | Item 1D and 1G |
| L(A)C2 | \$1,026 | \$8,635 | Item 1E and 1H |

These fees are in the [Therapeutic Goods Regulations 1990](#)

n/a: not applicable

Request made under subsection 9D of the Act to **vary** information included in an entry in the ARTG for a listed medicine

For information on application types, see [Changing a listed or assessed listed medicine, Application types and changes tables](#).

Table 13: Section 9D applications

| Application type | Upfront fee | Refund if no evaluation | Clause 5 of Schedule 9 |
|-----------------------------|-------------|-------------------------|------------------------|
| L(A)CN notification request | \$885 | n/a | Item 1C |
| L(A)C1 application | \$2,212 | \$1,188 | Item 1A, Item 1G |
| L(A)C2 application | \$9,661 | \$8,635 | Item 1B, Item 1H |

These fees are in the [Therapeutic Goods Regulations 1990](#)

n/a: not applicable

Registered complementary medicines

Annual charges for registered complementary medicines

Registered complementary medicines have an annual charge.

Table 14: Annual charges for registered complementary medicines

| Charge | Amount | Regulation |
|---------------|---------|-------------------------------------|
| Annual charge | \$1,763 | Item 7(1)(a)(i) and Item 7(2)(a)(i) |

These charges are in the [Therapeutic Goods \(Charges\) Regulations 2018](#)

Application and evaluation fees for registered complementary medicines

Applications for registered complementary medicines have both an application fee and an evaluation fee.

For information on application types, see: [Applications for registered complementary medicines](#)

Table 15: Application and evaluation fees for registered complementary medicines

| Application Category | Application fee | Evaluation fee | Clause 5 of Schedule 9 |
|----------------------|-----------------|----------------|------------------------|
| RCM1 | \$615 | \$3,529 | Item 12 and Item 13 |
| RCM2 | \$2,212 | \$23,637 | Item 14 and Item 15 |
| RCM3 | \$2,212 | \$23,637 | Item 16 and Item 17 |
| RCM4 | \$2,925 | \$32,165 | Item 18 and Item 19 |
| RCM5 | \$3,205 | \$41,015 | Item 20 and Item 21 |

These fees are in Schedule 9, [Therapeutic Goods Regulations 1990](#)

Variations to registered complementary medicines

Section 23 applications

For applications to change registered complementary medicines made under section 23 of the *Therapeutic Goods Act 1989*, there is an application fee and an evaluation fee for RCMC2, RCMC3 and RCMC4 applications.

For information on application types, go to the [Australian Regulatory Guidelines for Listed Medicines and Registered Complementary Medicines \(ARGLMRCM\)](#).

Table 16: Section 23 application to change registered complementary medicines

| RCM change application category | Application fee | Evaluation fee | Clause 5 of Schedule 9 |
|---------------------------------|-----------------|----------------|------------------------|
| RCMC1 | \$1,609 | n/a | Item 5 |
| RCMC2 | \$842 | \$4,576 | Item 6 and Item 7 |
| RCMC3 | \$907 | \$7,167 | Item 8 and Item 9 |
| RCMC4 | \$928 | \$10,588 | Item 10 and Item 11 |

These fees are in Schedule 9, [Therapeutic Goods Regulations 1990](#)

n/a: not applicable

Section 9D applications

For applications to change registered complementary medicines made under section 9D of the *Therapeutic Goods Act 1989*, there is an application fee and a refund if no evaluation occurs for RCMC2, RCMC3 and RCMC4 applications.

For information on application types, go to the [Australian Regulatory Guidelines for Listed Medicines and Registered Complementary Medicines \(ARGLMRCM\)](#).

Table 17: Section 9D application to change registered complementary medicines

| RCM change application category | Upfront fee | Refund if no evaluation* | Regulation |
|---------------------------------|-------------|--------------------------|---|
| Notification requests | \$907 | n/a | Clause 3 of Schedule 9 Item 2CB and Item 2CC |
| RCMC1 | \$1,609 | n/a | Clause 5 of Schedule 9 Item 1 |
| RCMC2 | \$5,429 | \$4,576 | Clause 5 of Schedule 9 Item 2, and Paragraph 43ACA(2)(a)* |
| RCMC3 | \$8,063 | \$7,167 | Clause 5 of Schedule 9 Item 3, and Paragraph 43ACA(2)(b)* |
| RCMC4 | \$11,442 | \$10,588 | Clause 5 of Schedule 9 Item 4, and Paragraph 43ACA(2)(c)* |

These fees are in Schedule 9, [Therapeutic Goods Regulations 1990](#)

* refund amounts are in Division 2 Part 7, *Therapeutic Goods Regulations 1990*

Other fees

Table 18: Other fees for registered complementary medicines

| Type of fee or charge | Amount | Clause 3 of Schedule 9 |
|---|--------|------------------------|
| Application for consent by the Secretary under sections 14 and 14A of the Act to the import, export or supply of therapeutic goods that do not comply with an applicable standard where the application relates to a single entry in the register | \$540 | Item 1A(a) |

| | | |
|---|--|--|
| Application for consent by the Secretary under sections 14 and 14A of the Act to the import, export or supply of therapeutic goods that do not comply with an applicable standard where the application relates to two or more entries in the register. | \$540 for the first entry, plus \$108 for each additional entry | Item 1A(a) Additional entry Item 1A(b) |
|---|--|--|

These fees are in Schedule 9, [Therapeutic Goods Regulations 1990](#)
'The Act' refers to the [Therapeutic Goods Act 1989](#)

Registered OTC medicines

For guidance on OTC applications, go to the [Australian regulatory guidelines for OTC medicines](#).

Annual charges registered OTC medicines

Registered OTC medicines have an annual charge.

Table 19: Annual charges registered OTC medicines

| Medicine type | Charge | Regulation |
|-------------------------|---------|-------------------------------------|
| Registered OTC medicine | \$1,763 | Item 7(1)(a)(i) and Item 7(2)(a)(i) |

These charges are in Part 2 of the [Therapeutic Goods \(Charges\) Regulations 2018](#)

New registered OTC medicine applications

For information on application types, go to [OTC application categorisation framework](#).

Table 20: New registered OTC medicine applications

| Application type | Application fee | Evaluation fee | Clause 4 of Schedule 9 |
|--|-----------------|----------------|-------------------------|
| N1 application | \$1,835 | \$4,533 | Item 1(a) and Item 2(a) |
| N1 concurrent application per additional application | \$928 | \$4,533 | Item 3(d) and Item 2(a) |
| N2 application | \$1,835 | \$6,444 | Item 1(b) and Item 2(b) |
| N2 concurrent application per additional application | \$928 | \$6,444 | Item 3(e) and Item 2(b) |
| N3 application | \$2,947 | \$9,930 | Item 1(c) and Item 2(c) |

| Application type | Application fee | Evaluation fee | Clause 4 of Schedule 9 |
|---|-----------------|----------------|-------------------------|
| N3 concurrent application per additional application | \$1,479 | \$5,030 | Item 3(f) and Item 4(d) |
| N4 application | \$4,307 | \$16,514 | Item 1(d) and Item 2(d) |
| N4 concurrent application per additional application (as described in item 3 and 4 of Part 3 Schedule 9 of the Regulations) | \$1,479 | \$5,030 | Item 3(g) and Item 4(e) |
| N5 application | \$6,379 | \$24,285 | Item 1(e) and Item 2(e) |
| N5 concurrent application per additional application (as described in item 3 and 4 of Part 3 Schedule 9 of the Regulations) | \$1,479 | \$5,030 | Item 3(h) and Item 4(f) |

These fees are in Schedule 9, [Therapeutic Goods Regulations 1990](#)

Section 23 application to change registered OTC medicines

For applications to change registered OTC medicines made under section 23 of the *Therapeutic Goods Act 1989*, there is an application fee and an evaluation fee for C2, C3 and C4 applications.

For information on application types, go to [OTC application categorisation framework](#).

Table 21: Section 23 application to change registered OTC medicines

| Application type | Application fee | Evaluation fee | Clause 4 of Schedule 9 |
|-----------------------------|-----------------|----------------|-------------------------|
| C1 (section 23) application | \$1,835 | n/a | Item 1(f) |
| C2 (section 23) application | \$1,835 | \$4,533 | Item 1(g) and Item 2(f) |
| C3 (section 23) application | \$1,835 | \$7,609 | Item 1(h) and Item 2(g) |
| C4 (section 23) application | \$2,947 | \$9,930 | Item 1(i) and Item 2(h) |

These fees are in Schedule 9, [Therapeutic Goods Regulations 1990](#)

n/a: not applicable

Section 9D application to change registered OTC medicines

For applications to change registered OTC medicines made under section 9D of the *Therapeutic Goods Act 1989*, there is a fee and a refund if no evaluation occurs for C2, C3 and C4 applications.

For information on application types, go to [OTC application categorisation framework](#).

Table 22: Section 9D application to change registered OTC medicines

| Application type | Upfront Fee | Refund if no evaluation* | Regulation |
|--------------------------------------|-------------|--------------------------|--|
| CN (section 9D) notification request | \$907 | n/a | Clause 3 of Schedule 9 Item 2CB and Item 2CD |
| C1 (section 9D) application | \$1,835 | n/a | Clause 4 of Schedule 9 Item 5(a) |
| C2 (section 9D) application | \$6,379 | \$4,533 | Clause 4 of Schedule 9 Item 5(b) and Paragraph 43AC(2)(a)* |
| C3 (section 9D) application | \$9,455 | \$7,609 | Clause 4 of Schedule 9 Item 5(c) and Paragraph 43AC(2)(b)* |
| C4 (section 9D) application | \$12,844 | \$9,930 | Clause 4 of Schedule 9 Item 5(d) and Paragraph 43AC(2)(c)* |

These fees are in Schedule 9, [Therapeutic Goods Regulations 1990](#)

* refund amounts are in Division 2 Part 7, [Therapeutic Goods Regulations 1990](#)

n/a: not applicable

Other fees for registered OTC medicines

Table 23: Other fees for registered OTC medicines

| Registered OTC medicine request | Fee | Schedule 9 |
|--|---------|---------------------|
| Request for advice in relation to a registered OTC medicine for the purpose of listing the medicine as a pharmaceutical benefit that does not contain clinical data | \$1,802 | Clause 4 Item 7(a) |
| Request for advice in relation to a registered OTC medicine for the purpose of listing the medicine as a pharmaceutical benefit that contains clinical data or a justification as to why such data is not needed | \$9,240 | Clause 4 Item 7(b) |
| Application for consent by the Secretary under sections 14 and 14A of the Act to the import, export or supply a therapeutic good that does not comply with an applicable standard where the application relates to a single entry in the register. | \$540 | Clause 3 Item 1A(a) |

| | | |
|--|---|--|
| Application for consent by the Secretary under sections 14 and 14A of the Act to import, export or supply in Australia, a therapeutic goods that do not comply with an applicable standard where the application is for two or more therapeutic goods. | \$540 for the first entry, plus \$108 for each additional entry | Clause 3 Item IA(a) Additional entry Item 1A(b) |
|--|---|--|

These fees are in Schedule 9, [Therapeutic Goods Regulations 1990](#)
‘The Act’ refers to the [Therapeutic Goods Act 1989](#)

New substances

This is an old provision from 2005 that remains in the *Therapeutic Goods Regulations 1990* at R16GA that is now infrequently used. This pathway is still available for applications for:

- a new substance in a listed medicine
- a new substance for registered medicines
- multiple new excipients in listed or registered medicines for dermal use.

There are evaluation fees, but no application fees for new substance applications.

Table 24: New substances

| Pages of nonclinical and clinical data | Evaluation fee | Clause 3 of Schedule 9 |
|--|----------------|---|
| 0-50 | \$11,873 | Item 7A(a), Item 7A(b)(i), Item 7B(a) and Item 7B(b)(i) |
| 51-250 | \$15,327 | Item 7A(b)(ii) and Item 7B(b)(ii) |
| 251-500 | \$20,939 | Item 7A(b)(iii) and Item 7B(b)(iii) |
| 501-1000 | \$27,739 | Item 7A(b)(iv) and Item 7B(b)(iv) |
| 1001-2000 | \$41,555 | Item 7A(b)(v) and Item 7B(b)(v) |
| 2001-3000 | \$55,371 | Item 7A(b)(vi) and Item 7B(b)(iv) |
| >3000 | \$83,110 | Item 7A(b)(vii) and Item 7B(b)(vii) |

These fees are in Schedule 9, [Therapeutic Goods Regulations 1990](#)

Manufacturing medicines and OTGs

The section applies to the [manufacture](#) of:

- all medicines
- [other therapeutic goods \(OTGs\)](#), listed and registered

Annual charges for manufacturing licences

Manufacturing licences have an annual charge.

Table 25: Annual charges for manufacturing licences

| Annual charges for manufacturing licences | Charge | Regulations |
|---|---------|------------------------------|
| Manufacturing licence charge for medicines, ingredients, components, herbal and homeopathic preparations and containers | \$5,494 | Item 7(5)(a) to Item 7(5)(e) |

This charge is in the [Therapeutic Goods \(Charges\) Regulations 2018](#)

Manufacturing inspections

Australian manufacturing licences

Applications for Australian manufacturing licences have application, variation and inspection fees.

Table 26: Australian manufacturing licences

| Fees related to Australian manufacturing licences | Fee | Clause 3 of Schedule 9 |
|--|------------------------|------------------------|
| Australian manufacturing sites – application fee for a manufacturing licence | \$885 | Item 8(a) |
| Variation application for a manufacturing licence | \$885 | Item 8A to 8C |
| Australian manufacturing sites – inspection fee | \$1,101/hour/inspector | Item 9(a) |

These fees are in Schedule 9, [Therapeutic Goods Regulations 1990](#)

Overseas manufacturing site inspections

There is no application fee for GMP certification of overseas manufacturing sites.

Table 27: Overseas manufacturing site inspections

| Overseas manufacturing site inspections | Fee | Clause 3 of Schedule 9 |
|---|------------------------|------------------------|
| Overseas manufacturing sites – inspection fee | \$1,543/hour/inspector | Item 9(b) |

| Overseas manufacturing site inspections | Fee | Clause 3 of Schedule 9 |
|---|-------------------------------|------------------------|
| Inspection fees to cover costs and reasonable expenses by each inspector, including costs for accommodation and allowance outside Australia | Costs and reasonable expenses | |

These fees are in Schedule 9, [Therapeutic Goods Regulations 1990](#)

GMP clearance fees

There is no application fee for GMP clearance. See [GMP clearance guidance](#) for information on this process.

Table 28: GMP clearance fees

| GMP clearance of overseas manufacturers | Fee | Clause 3 of Schedule 9 |
|--|---------|------------------------|
| GMP clearance application processing fee (per manufacturer, per site, per sponsor) | \$723 | Item 6AA |
| Obtaining evidence from an overseas regulatory authority (per manufacturer, per site, per sponsor) | \$777 | Item 6AB |
| Compliance verification (in lieu of an overseas GMP inspection) | \$2,764 | Item 6ABA |
| Reinstatement of expired GMP clearance approval (per manufacturer, per site, per sponsor) – in addition to relevant fees above | \$1,306 | Item 6AC |

These fees are in Schedule 9, [Therapeutic Goods Regulations 1990](#)

Issuing manufacturing certificates

There are fees for issuing manufacturing certificates.

Table 29: Issuing manufacturing certificates

| Certificate | Fee |
|--|-------|
| Certificate of GMP compliance | \$195 |
| Mutual Recognition Agreement certificate | \$359 |
| Certified copy of: <ul style="list-style-type: none"> original GMP certificate certificate of GMP compliance | \$72 |

Export of therapeutic goods

This section references the fees and charges associated with export only therapeutic goods and export certification for therapeutic goods.

Export only medicines

There is an application fee and a processing fee for listed export only medicines.

Table 30: Export only listed medicines

| Export only applications | Fee | Schedule 9 |
|--|-------|--------------------|
| New export only medicine listing | \$939 | Clause 3 Item 3(b) |
| Grouping application for an existing export only medicine listing | \$939 | Clause 3 Item 3(b) |
| Variation application for an existing export only medicine listing | \$474 | Part 2 Item 2A(b) |
| Grouping application to add an export name to a registered product | \$939 | Clause 3 Item 3(b) |

These fees are in Schedule 9, [Therapeutic Goods Regulations 1990](#)

Export certification for medicines

Export certification is provided for medicines that are registered or listed in the Australian Register of Therapeutic Goods (ARTG).

Table 31: Export certification for medicines

| Certificate type | Fee | Clause 3 of Schedule 9 |
|---|-------|------------------------|
| Certificate of Pharmaceutical Product (CPP) | \$195 | Item 10 |
| Certificate of Listed Product (CLP) | \$195 | Item 10 |

These fees are in Schedule 9, [Therapeutic Goods Regulations 1990](#)

Medical device export certification

Export certification is provided for medical devices, including in-vitro diagnostic medical devices (IVDs) and Other Therapeutic Goods (OTGs).

Table 32: Export certification for medical devices

| Certificate type | Fee | Clause 3 of Schedule 9 |
|--------------------------|-------|------------------------|
| Certificate of Free Sale | \$195 | Item 10 |
| Export Certificate | \$195 | Item 10 |

These fees are in Schedule 9, [Therapeutic Goods Regulations 1990](#)

Export only devices

This fee applies to include a medical device, including IVD device, in the ARTG that is for export only.

Table 33: Export only devices

| Export only applications | Fee | Part 1 of Schedule 5 |
|--|------|----------------------|
| Application for inclusion into the ARTG of export only devices | \$92 | Item 1.5(f) |
| Application for inclusion into the ARTG of export only IVD devices | \$92 | Item 1.5(i) |

This fee is in the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#)

Biologicals

Below are the fees and annual charges for manufacturing and sponsoring biologicals.

The [Australian Regulatory Guidelines for Biologicals \(ARGB\)](#) provide information on the legal arrangements in Australia for the supply and use of human cell and tissue-based therapeutic goods (collectively defined as 'biologicals').

For clinical trials supplying unapproved biologicals, go to [Clinical trials](#).

Annual charges for manufacturing biologicals

There is no annual charge for a manufacturer who only manufactures biologicals (regulation 7(5)(j) [Therapeutic Goods \(Charges\) Regulations 2018](#)).

Manufacturing biologicals fees

There is an application fee and various inspection fees for manufacturing biologicals.

Table 34: Manufacturing biologicals fees

| Manufacturing biologicals | Fee | Part 2 of Schedule 9A |
|---|-------------------------------|-----------------------|
| Australian manufacturing sites – application fee for a manufacturing licence | \$1,231 | Item 3 |
| Initial manufacturing audit – inspection fee for Australian and overseas manufacturing sites | \$24,285 | Item 12 |
| Subsequent manufacturing audit – inspection fee for Australian and overseas manufacturing sites | \$18,457 | Item 13 |
| Inspection fee for each hour of preparation by each inspector for an inspection conducted outside Australia | \$755/hour/inspector | Item 14 |
| Inspection fees to cover costs and reasonable expenses by each inspector, including costs for accommodation and allowance outside Australia | Costs and reasonable expenses | Item 15 |

These fees are in Schedule 9A, [Therapeutic Goods Regulations 1990](#)

Annual charges for sponsoring biologicals

There are annual charges for including a biological in the ARTG.

Table 35: Annual charges for sponsoring biological, other than an export only biological

| ARTG inclusion of biologicals | Amount | Regulation |
|---|---------|--------------|
| Class 1 biological annual charge for ARTG inclusion | \$801 | Item 7(3)(a) |
| Class 2, 3, 4 biological annual charge for ARTG inclusion | \$7,966 | Item 7(3)(b) |

These charges are in the [Therapeutic Goods \(Charges\) Regulations 2018](#)

Fees for sponsoring biologicals

Table 36: Fees for sponsoring biologicals

| Sponsoring biologicals | Fee | Part 2 of Schedule 9A |
|--|-----------|-----------------------|
| Ingredient or component of a biological to be evaluated under regulation 16GF - evaluation fee | \$26,660 | Item 7 |
| Class 1 biological – application fee for inclusion in ARTG | \$1,231 | Item 1 |
| Class 2, 3, 4 biological – application fee for inclusion in ARTG | \$1,231 | Item 2 |
| Priority determination application fee for biological product | \$14,697 | Item 2A |
| Variation application fee – all classes | \$1,231 | Item 8 |
| Class 2 biological - priority evaluation fee for inclusion in ARTG | \$85,630 | Item 4a |
| Class 2 biological – evaluation fee for inclusion in ARTG | \$81,922 | Item 4b |
| Class 2 biological – evaluation fee for variation to ARTG entry | \$7,512 | Item 9 |
| Class 3 biological - priority evaluation fee for inclusion in ARTG | \$171,683 | Item 5a |
| Class 3 biological – evaluation fee for inclusion in ARTG | \$163,953 | Item 5b |
| Class 4 biological - priority evaluation fee for inclusion in ARTG | \$277,423 | Item 6a |
| Class 4 biological – evaluation fee for inclusion in ARTG | \$266,384 | Item 6b |
| Class 3 or 4 biological – evaluation fee for major variation to ARTG entry | \$38,857 | Item 11 |
| Class 3 or 4 biological – evaluation fee for minor variation to ARTG entry | \$19,752 | Item 10 |
| Safety related variations – evaluation of application | \$7,512 | Item 8A |

These fees are in Schedule 9A, [Therapeutic Goods Regulations 1990](#)

Blood, blood components and HPCs

Below are the fees and annual charges for human blood, blood components, haematopoietic progenitor cells (HPC) and human tissues not regulated as biologicals.

Manufacturing annual charges

Table 37: Manufacturing annual charges

| Therapeutic good being manufactured | Charge | Regulation |
|--|-----------|------------------|
| Blood and blood components (not HPCs) – primary manufacturing site | \$192,185 | Item 7(5)(f)(i) |
| Blood and blood components (not HPCs) – a fixed (non-mobile) manufacturing site | \$9,461 | Item 7(5)(f)(ii) |
| HPCs manufacturing site | \$8,276 | Item 7(5)(g) |
| single step in the manufacture of a single human tissue at manufacturing premises covered by the licence | \$8,276 | Item 7(5)(h) |
| licence for 2 or more steps in the manufacture of human tissues at manufacturing premises covered by the licence | \$16,186 | Item 7(5)(i) |

These charges are in the [Therapeutic Goods \(Charges\) Regulations 2018](#)
Only highest applicable charge is payable

Manufacturing fees

Table 38: Manufacturing fees

| Manufacturing fees | Fee | Clause 3 of Schedule 9 |
|--|------------------------|------------------------|
| Australian manufacturing sites – application fee for a manufacturing licence | \$1,155 | Item 8(b) |
| Blood and blood components (not HPCs) - Australian primary manufacturing site - inspection fee | \$1,026/inspector/hour | Item 9AB |
| Blood and blood components (not HPCs) - Australian manufacturing site other than the primary site – inspection fee | \$755/inspector/hour | Item 9AC |
| HPCs - Australian manufacturing site inspection fee | \$755/inspector/hour | Item 9AA |

| | | |
|---|----------------------|-----------|
| Human tissues that are not biologicals - Australian manufacturing site – inspection fee | \$755/inspector/hour | Item 9ACA |
|---|----------------------|-----------|

These fees are in Schedule 9, [Therapeutic Goods Regulations 1990](#)

Blood plasma and technical master files

The evaluation fee for blood plasma master files and blood technical master fees depends on the number of pages.

Table 39: Blood plasma and technical master files

| Pages | Fee | Clause 3 of Schedule 9 |
|-----------|----------|------------------------|
| 1–10 | \$1,490 | Item 9AD(a) |
| 11–50 | \$12,628 | Item 9AD(b) |
| 51–100 | \$28,494 | Item 9AD(c) |
| 101–1000 | \$38,317 | Item 9AD(d) |
| 1001–3000 | \$59,688 | Item 9AD(e) |
| 3001–4000 | \$79,548 | Item 9AD(f) |
| >4000 | \$97,033 | Item 9AD(g) |

These fees are in Schedule 9, [Therapeutic Goods Regulations 1990](#)

Miscellaneous fees

This fee applies to human blood, blood components and HPCs and human tissues not regulated as biologicals.

Table 40: Miscellaneous fees

| Application type | Fee | Clause 3 of Schedule 9 |
|--|-------|------------------------|
| Application for consent by the Secretary under sections 14 and 14A of the Act to the import, export or supply of therapeutic goods that do not comply with an applicable standard where the application relates to a single entry in the register. | \$540 | Item 1A(a) |

| | | |
|---|--|--|
| Application for consent by the Secretary under sections 14 and 14A of the Act to the import, export or supply of therapeutic goods that do not comply with an applicable standard where the application relates to two or more entries in the register. | \$540 for the first entry, plus \$108 for each additional entry | Item 1A(a) Additional entry Item 1A(b) |
|---|--|--|

This fee is in Schedule 9, [Therapeutic Goods Regulations 1990](#)
'The Act' refers to the [Therapeutic Goods Act 1989](#)

Medical devices

Medical devices are included (not listed or registered) in the ARTG.

- For IVDs, go to [IVD medical devices](#)
- For export information, go to [Device export certificates](#)
- For clinical trials supplying unapproved medical devices, go to [Clinical trials](#)
- For guidance on medical devices, go to the [Australian regulatory guidelines for medical devices](#).

Sponsoring medical devices

Annual charges

These charges are for inclusion of the following kinds of medical devices (other than medical devices produced for export) in the ARTG.

Table 41: Annual charges

| Class of medical device | Charge | Regulation |
|------------------------------|---------|--------------|
| AIMD | \$1,394 | Item 7(4)(d) |
| Class III | \$1,394 | Item 7(4)(d) |
| Class IIb | \$1,095 | Item 7(4)(c) |
| Class IIa | \$1,095 | Item 7(4)(c) |
| Class I – sterile | \$749 | Item 7(4)(b) |
| Class I – measuring function | \$749 | Item 7(4)(b) |
| Class I – other | \$103 | Item 7(4)(a) |

These charges are in the [Therapeutic Goods \(Charges\) Regulations 2018](#)

Application fees

These fees are to apply to include a medical device in the ARTG. Application audit assessment fees are often payable as well. Application fees for [export only devices](#) are not included in this section.

Table 42: Application fees

| Class of medical device | Application fee | Schedule 5 Part 1 |
|---|-----------------|-------------------|
| Class III | \$1,416 | Item 1.5(b) |
| Class IIb | \$1,098 | Item 1.5(c) |
| Class IIa | \$1,098 | Item 1.5(d) |
| Class I – sterile | \$575 | Item 1.5(e) |
| Class I – measuring function | \$575 | Item 1.5(e) |
| Class I – other (excluding export only devices) | \$575 | Item 1.5(g) |

These fees are in the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#)

Note: Refer to [export only device](#) application fees

Application for medical devices (priority applicant) determination

This fee is for applicants seeking priority applicant determination in relation to an application to include a medical device in the ARTG.

For guidance on how to seek priority consideration, go to [Priority applicant guidelines for medical devices \(including IVDs\)](#).

Table 43: Application for medical devices (priority applicant) determination

| Application type | Application fee | Schedule 5 Part 1 |
|--|-----------------|-------------------|
| Application for medical devices (priority applicant) determination in relation to a medical device inclusion | \$11,118 | Item 1.5A |

This fee is in the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#)

Application audit assessment fees

An application audit assessment fee is payable in addition to the application fee for the inclusion of some medical devices in the ARTG.

For guidance on medical device audits, go to [Auditing](#) of medical device, including IVD medical device, applications.

Table 44: Application audit assessment fees for medical devices (excluding IVD medical devices)

| Type of application audit | Assessment fee | Part 1 of Schedule 5 |
|---|----------------|----------------------|
| Level 1 – verification of sponsor’s application, evidence of conformity, and aspects of compliance against essential principles | \$4,350 | Item 1.13 |
| Level 2 – Level 1 activities, plus in-depth technical documentation review to determine compliance with Essential Principles - Class III medical devices (other than IVD medical devices) | \$16,000 | Item 1.14(a) |
| Level 2 – Level 1 activities, plus in-depth technical documentation review to determine compliance with Essential Principles - All other medical devices (other than IVD medical devices) | \$4,000 | Item 1.14(b) |

These fees are in the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#)

Variation fees

For guidance on variations go to [Varying entries in the ARTG – medical devices and IVDs](#).

Table 45: Variation fees

| Application type | Application fee | Part 2 of Schedule 9 |
|--|-----------------|----------------------|
| Variation to an ARTG inclusion entry - disinfectant | \$1,400 | Item 2A(c) |
| Variation to an ARTG inclusion entry – Class 3 or Class 4 IVD | \$1,750 | Item 2A(d) |
| Variation to an ARTG inclusion entry – IVD not a Class 3 or Class 4 IVD | \$1,000 | Item 2A(e) |
| Variation to an ARTG inclusion entry – medical device that is not an IVD | \$1,000 | Item 2A(f) |

| | | |
|--|--|------------|
| Variation to an ARTG inclusion entry – medical device that is not an IVD | \$190 per 10 entries (or part thereof) | Item 2A(g) |
|--|--|------------|

These fees are in Schedule 9, [Therapeutic Goods Regulations 1990](#)

Miscellaneous fees for medical devices

For guidance on consent to import, export, or supply non-compliant medical devices go to [Essential Principles](#) - consent for noncompliance

Table 46: Miscellaneous fees for medical devices including IVD medical devices

| Type of application | Fee | Part 1 of Schedule 5 |
|---|----------|----------------------|
| Considering submissions to the Secretary in relation to a proposed suspension of Class III medical devices (other than IVD medical devices from the ARTG (as described in item 1.6) | \$16,000 | Item 1.14(a) |
| Considering submissions to the Secretary in relation to a proposed suspension of all other medical devices (other than IVD medical devices from the ARTG (as described in item 1.6) | \$4,000 | Item 1.14(b) |
| Considering a submission to the Secretary in relation to a proposed suspension of a kind of IVD medical device, from the Register - Class 1 and Class 2 IVDs | \$7,387 | Item 1.14A(a) |
| Considering a submission to the Secretary in relation to a proposed suspension of kind of IVD medical device from a Register - Class 3 IVDs | \$22,387 | Item 1.14A(b) |
| Considering a submission to the Secretary in relation to a proposed suspension of a kind of IVD medical device from the Register - Class 4 IVDs, other than: (i) Class 4 IVDs that are immunohaematology reagent IVD medical devices; or (ii) devices to which item 1.14B or 1.14C applies; | \$22,387 | Item 1.14A(c) |
| Considering a submission to the Secretary in relation to a proposed suspension of a kind of IVD medical device from the Register - Class 4 IVDs that are immunohaematology reagent IVD medical devices | \$16,621 | Item 1.14A(d) |

| Type of application | Fee | Part 1 of Schedule 5 |
|---|---|---|
| Considering a submission to the Secretary in relation to a proposed suspension of a kind of medical device from the Register - Class 4 in house IVD medical devices | \$22,387 | Item 1.14B |
| Application for consent to export, supply, or import a medical device, including an IVD medical device, for a single entry in the ARTG or an application for inclusion in the ARTG, that does not comply with the Essential Principles | \$540 (for all the devices to which the application relates) | Item 1.15(a) |
| Application for consent to export, supply, or import a medical device, including an IVD medical device, for a two or more entries in the ARTG or applications for inclusion in the ARTG, that do not comply with the Essential Principles | \$540 for the first entry, plus \$108 for each additional entry | Item 1.15(a) Additional entry Item 1.15(b) |
| Application for consent to export, supply, or import medicals devices, including IVD medical devices that do not comply with the Essential Principles – specifically Essential Principle 13A relating to patient information materials | \$30 per ARTG entry or \$30 per Application for Inclusion in the ARTG within the application. | Item 1.15 and Clauses 13A.2 and 13A.3 of Schedule 1 |

These fees are in the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#)

Conformity assessment bodies designation determination

These applications have both an application fee and an assessment fee.

Table 47: Conformity assessment bodies designation determination

| Application type | Application fee | Assessment fee | Regulation |
|---|-----------------|----------------|-------------------------|
| Full designation conformity assessment body determination | \$5,083 | \$83,002 | Item 1.4A and Item 1.4D |
| Partial designation conformity assessment body determination (full QMS) | \$2,795 | \$59,580 | Item 1.4B and Item 1.4E |
| Partial designation conformity assessment body determination (partial QMS or partial devices) | \$2,795 | \$59,580 | Item 1.4C and Item 1.4F |

These fees are in the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#)

Manufacturing medical devices

Information about conformity assessment is in [Australian regulatory guidelines for medical devices](#).

Application for conformity assessment

Table 48: Application for conformity assessment

| All conformity assessment procedures | Fee | Part 1 of Schedule 5 |
|--------------------------------------|---------|----------------------|
| Application fee | \$1,416 | Item 1.1 |

This fee is in the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#)

Application for conformity assessment (priority applicant) determination

This fee is for applicants seeking priority applicant determination in relation to an application for TGA conformity assessment of a medical device. For guidance on how to seek priority consideration, go to [Priority applicant guidelines for medical devices \(including IVDs\)](#).

Table 49: Application for conformity assessment (priority applicant) determination

| Application type | Application fee | Part 1 of Schedule 5 |
|--|-----------------|----------------------|
| Application for conformity assessment (priority applicant) determination in relation to a medical device | \$10,568 | Item 1.1A |

This fee is in the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#)

Initial assessment of conformity assessment

In addition to the application fee, one or more of the following fees will apply to your kind of medical device. Conformity assessment procedures are legislated in Schedule 3, *Therapeutic Goods (Medical Devices) Regulations 2002*.

Table 50: Initial assessment of conformity assessment

| Type of conformity | Fee for initial assessment | Part 1 of Schedule 5 |
|--|----------------------------|----------------------|
| Full quality management system (described in Schedule 3, Part 1) | \$32,011 | Item 1.9(a) |
| Design examination (described in Schedule 3, Clause 1.6) | \$62,894 | Item 1.9(b) |
| Type examination (including management of testing, analysis, and reporting on examination of the type) (described in Schedule 3, Part 2) | \$43,810 | Item 1.9(c) |

| | | |
|---|----------|-------------|
| Verification (including management of testing, analysis, and reporting on verification tests) (described in Schedule 3, Part 3) | \$30,677 | Item 1.9(d) |
| Production quality management system (described in Schedule 3, Part 4) | \$28,010 | Item 1.9(e) |
| Product quality management system (described in Schedule 3, Part 5) | \$23,906 | Item 1.9(f) |

These fees are in Schedule 5 [Therapeutic Goods \(Medical Devices\) Regulations 2002](#)

Changes to conformity assessment

Conformity assessment procedures are legislated in Schedule 3, *Therapeutic Goods (Medical Devices) Regulations 2002*.

Table 51: Changes to conformity assessment

| Type of conformity | Fee for change | Part 1 of Schedule 5 |
|--|----------------|----------------------|
| Full quality management system (described in Schedule 3, Part 1) | \$19,289 | Item 1.10(a) |
| Design examination (described in Schedule 3, Clause 1.6) | \$37,962 | Item 1.10(b) |
| Type examination (including management of testing, analysis, and reporting on examination of the type) (described in Schedule 3, Part 2) | \$26,471 | Item 1.10(c) |
| Production quality management system (described in Schedule 3, Part 4) | \$16,621 | Item 1.10(d) |
| Product quality management system (described in Schedule 3, Part 5) | \$14,569 | Item 1.10(e) |

These fees are in Schedule 5 [Therapeutic Goods \(Medical Devices\) Regulations 2002](#)

Table 52: Additional assessment fees

| Assessment costs | Fee | Part 1 of Schedule 5 |
|--|---|----------------------|
| Supplementary assessment of a medical device is required, in addition to the assessment mentioned in item 1.2, 1.3, 1.9, 1.9A, 1.10 or 1.10A | \$474/hour/ assessor and/or auditor | Item 1.12 |

| | | |
|---|--|-----------|
| For assessment of the medicinal component of the device, (and in addition to the assessment mentioned in item 1.2, 1.3, 1.9, 1.10 or 1.10A) | Various based on the level of assessment under relevant item of Part 2 of Schedule 9 to the <i>Therapeutic Goods Regulation 1990</i> | Item 1.11 |
|---|--|-----------|

Surveillance assessment for conformity assessment certificates

Conformity assessment procedures are legislated in Schedule 3, *Therapeutic Goods (Medical Devices) Regulations 2002*.

Table 53: Surveillance assessment for conformity assessment certificates

| Type of surveillance audits | Fee | Part 1 of Schedule 5 |
|---|---------|----------------------|
| Full quality management system surveillance audit (described in Schedule 3, Part 1) | \$9,296 | Item 1.2(a) |
| Production quality management system surveillance audit (described in Schedule 3, Part 4) | \$9,296 | Item 1.2(a) |
| Product quality management system surveillance audit (described in Schedule 3, Part 5) | \$9,296 | Item 1.2(a) |

These fees are in Schedule 5 [Therapeutic Goods \(Medical Devices\) Regulations 2002](#)

Review of certificate of conformity assessment

Conformity assessment procedures are legislated in Schedule 3, *Therapeutic Goods (Medical Devices) Regulations 2002*.

Table 54: Review of certificate of conformity assessment

| Type of certificate being reviewed | Fee | Part 1 of Schedule 5 |
|--|----------|----------------------|
| Design examination re-assessment (described in Schedule 3, Clause 1.6) | \$56,840 | Item 1.3(a) |
| Type examination re-assessment (including management of testing, analysis, and reporting on examination of the type) (described in Schedule 3, Part 2) | \$43,810 | Item 1.3(b) |

These fees are in Schedule 5 [Therapeutic Goods \(Medical Devices\) Regulations 2002](#)

Additional assessment fees

For medical devices that incorporate a medicine, application and evaluation [fees apply for the medicine component](#) as well as fees related to assessing the device.

Table 55: Additional assessment fees

| Assessment costs | Fee | Part 2 of Schedule 5 |
|--|-------------------------------------|----------------------|
| Supplementary additional assessment in addition to assessment mentioned in item 1.2, 1.3, 1.9 or 1.10, Schedule 5 | \$474/hour/ assessor and/or auditor | Item 2.1(b) |
| Costs and reasonable expenses of travel by each assessor and / or auditor involved, including travel both in and outside Australia | Costs and reasonable expenses | Item 2.1(a) |
| Cost of testing incurred in purchasing, establishing and setting up the equipment to be used to conduct the tests and the direct costs of conducting the tests (including the cost of any consumables used to conduct the tests) | At cost | Item 2.2 |

Conformity assessment fees are in Schedule 5, [Therapeutic Goods \(Medical Devices\) Regulations 2002](#)

Issuing quality systems certificates

Table 56: Issuing quality systems certificates

| Certificate | Fee |
|---|-------|
| Quality systems certificate | \$195 |
| Certified copy of quality systems certificate | \$72 |

IVD medical devices

The TGA website has information about [IVD regulation basics](#).

- For export information, go to [Device export certificates](#)
- For clinical trials supplying unapproved IVD medical devices, go to [Clinical trials](#).

Sponsoring IVDs

Annual charges

Table 57: Annual charges

| Class of IVD | Charge | Regulation |
|--|--------|--------------|
| All classes of IVD (excluding Class 4 in-house IVDs) | \$807 | Item 7(4)(e) |
| Class 4 in-house IVDs | n/a | Item 7(4)(f) |

These charges are in the [Therapeutic Goods \(Charges\) Regulations 2018](#)
n/a: not applicable

Notification fee

Laboratories that manufacture Class 1, Class 2 or Class 3 in-house IVDs are required to provide a notification to the TGA. These in-house IVDs are not required to be included in the ARTG.

Table 58: Notification fee

| Class of IVD | Notification fee | Part 1 of Schedule 5 |
|---|------------------|----------------------|
| Notification by a laboratory of its Class 1, Class 2 or Class 3 in-house IVDs | \$1,155 | Item 1.17 |

These fees are in the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#)

Application fees

These fees are to apply to include an IVD in the ARTG. Application audit assessment fees are also often payable.

For guidance on variations go to [Varying entries in the ARTG – medical devices and IVDs](#).

Table 59: Application fees

| Application | Application fee | Part 1 of Schedule 5 |
|--|-----------------|----------------------|
| Application for inclusion into the ARTG of all classes of IVD, including Class 4 in-house IVDs (excluding export only IVD devices) | \$1,098 | Item 1.5(h) |

These fees are in the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#) and [Therapeutic Goods Regulations 1990](#)

Application for medical devices (priority applicant) determination

This fee is for applicants seeking Priority Review designation for an application to include an IVD in the ARTG.

Table 60: Application for medical devices (priority applicant) determination

| Application type | Application fee | Part 1 of Schedule 5 |
|---|-----------------|----------------------|
| Medical devices (priority applicant) determination in relation to a medical device (including an IVD) | \$11,118 | Item 1.5A |

This fee is in the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#)

Application audit assessment fees

An application audit assessment fee is payable in addition to the application fee for the inclusion of some medical devices in the ARTG.

Go to IVD guidance documents: [Application audit \(technical file review\)](#) and [Regulatory requirements for in-house IVDs](#) for more details.

Table 61: Application audit assessment fees

| Type of IVD | Assessment fee | Part 1 of Schedule 5 |
|--|----------------|----------------------|
| Class 1 and Class 2 IVDs | \$7,387 | Item 1.14A(a) |
| Class 3 IVDs | \$22,387 | Item 1.14A(b) |
| Class 4 IVDs, other than: (i) Class 4 IVDs that are immunochemistry reagent IVD medical devices; or (ii) devices to which item 1.14B or 1.14C applies; | \$22,387 | Item 1.14A(c) |
| Class 4 IVDs that are immunochemistry reagent IVD medical devices | \$16,621 | Item 1.14A(d) |
| Class 4 in house IVD medical devices (other than a device to which item 1.14C applies) | \$22,387 | Item 1.14B |

These fees are in the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#)

Manufacturing IVDs

Application for conformity assessment

Table 62: Application for conformity assessment

| All conformity assessment procedures | Fee | Part 1 of Schedule 5 |
|--------------------------------------|---------|----------------------|
| Application fee | \$1,416 | Item 1.1 |

These fees are in the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#)

Application for conformity assessment (priority applicant) determination

This fee is for applicants seeking priority applicant determination in relation to an application for TGA conformity assessment of an IVD. For guidance on how to seek priority consideration, go to [Priority applicant guidelines for medical devices \(including IVDs\)](#)

Table 63: Application for conformity assessment (priority applicant) determination

| Application type | Application fee | Part 1 of Schedule 5 |
|--|-----------------|----------------------|
| Application for conformity assessment (priority applicant) determination in relation to a medical device | \$10,568 | Item 1.1A |

This fee is in the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#)

Initial assessment of conformity assessment

In addition to the application fee, one or more of the following fees will apply to your kind of medical device.

Conformity assessment procedures are legislated in Schedule 3, *Therapeutic Goods (Medical Devices) Regulations 2002*.

Table 64: Initial assessment of conformity assessment

| Type of conformity | Fee | Part 1 of Schedule 5 |
|--|----------|----------------------|
| Full quality management system: described in Schedule 3, Part 1 | \$32,114 | Item 1.9A(a) |
| Design examination: described in Schedule 3, Clause 1.6 | \$68,434 | Item 1.9A(b) |
| Design examination – immunohematology reagent: described in Schedule 3, Clause 1.6 | \$16,621 | Item 1.9A(c) |

| Type of conformity | Fee | Part 1 of Schedule 5 |
|---|----------|----------------------|
| Type examination: described in Schedule 3, Part 2 | \$44,221 | Item 1.9A(e) |
| Production quality management system: described in Schedule 3, Part 4 | \$28,215 | Item 1.9A(f) |

These fees are in Schedule 5 [Therapeutic Goods \(Medical Devices\) Regulations 2002](#) Review of certificate of conformity assessment

Conformity assessment procedures are legislated in Schedule 3, *Therapeutic Goods (Medical Devices) Regulations 2002*.

Table 65: Review of certificate of conformity assessment

| Type of certificate being reviewed | Fee | Part 1 of Schedule 5 |
|--|----------|----------------------|
| Full quality management system: described in Schedule 3, Part 1 | \$32,114 | Item 1.3A(a) |
| Design examination: described in Schedule 3, Clause 1.6 | \$68,434 | Item 1.3A(b) |
| Design examination – immunohematology reagent: described in Schedule 3, Clause 1.6 | \$16,621 | Item 1.3A(c) |
| Type examination: described in Schedule 3, Part 2 | \$44,221 | Item 1.3A(e) |
| Production quality management system: described in Schedule 3, Part 4 | \$28,215 | Item 1.3A(f) |

These fees are in Schedule 5 [Therapeutic Goods \(Medical Devices\) Regulations 2002](#)

Other IVD conformity assessment fees

Table 66: Other IVD conformity assessment fees

| Other assessment for IVD conformity assessment | Fee | Part 1 of Schedule 5 |
|---|-------------------------------|----------------------|
| Supplementary additional assessment in addition to assessment mentioned in item 1.2, 1.3A, 1.9A or 1.10A [item 2.1(b) Part 2 of Schedule 5] | \$474/assessor hour | Item 1.12 |
| Costs and reasonable expenses of travel by each assessor / auditor involved, including travel both in and outside Australia | Costs and reasonable expenses | Item 2.1(a) |
| Surveillance assessment for conformity assessment certificate under Schedule 3, Part 1 or 4 | \$9,347 | Item 1.2(b) |

| Other assessment for IVD conformity assessment | Fee | Part 1 of Schedule 5 |
|--|----------|----------------------|
| Assessment of changes to IVD or QMS for applicable IVD – Full Quality Management System | \$19,268 | Item 1.10A(a) |
| Assessment of changes to IVD or QMS for applicable IVD – Design Examination | \$41,060 | Item 1.10A(b) |
| Assessment of changes to IVD or QMS for applicable IVD – Design Examination – Immunohaematology | \$9,973 | Item 1.10A(c) |
| Assessment of changes to IVD or QMS for applicable IVD – Abridged Design Examination – previously registered IVD | \$2,419 | Item 1.10A(d) |
| Assessment of changes to IVD or QMS for applicable IVD – Type Examination | \$26,533 | Item 1.10A(e) |
| Assessment of changes to IVD or QMS for applicable IVD – Production QMS | \$16,929 | Item 1.10A(f) |

Conformity assessment fees are in Schedule 5, [Therapeutic Goods \(Medical Devices\) Regulations 2002](#)

* for relevant [‘initial assessment’](#) fees

Other listed and registered therapeutic goods (OTGs)

Other listed and registered therapeutic goods (OTGs) include:

- [disinfectants and sterilant](#)
- [tampons and menstrual cups](#)

OTGs are the goods that meet the definition of a therapeutic good, but do not meet the definition of a medical device, a medicine or a biological.

In this section, we have only included fees and charges that directly apply to these goods.

For a complete list, go to the relevant legislation.

- For information about manufacturing OTGs, go to [Manufacturing medicines and OTGs](#)
- For export information, go to [Device export certificates](#)

Annual charges

Table 67: Annual charges

| Type of OTG | Charge | Regulation |
|-------------------------------|---------|---|
| Listed OTG: disinfectants | \$1,014 | Item 7(1)(c)(iii) and Item 7(2)(c)(iii) |
| Registered OTG: disinfectants | \$1,961 | Item 7(1)(a)(iii) and Item 7(2)(a)(iii) |

These charges are in the [Therapeutic Goods \(Charges\) Regulations 2018](#)

Listed OTG fees

Table 68: Listed OTG fees

| Listed OTG fee type | Fee | Schedule 9 |
|---------------------|---------|--------------------|
| Application fee | \$2,200 | Clause 3 Item 3(a) |
| Variation fee | \$1,400 | Part 2 Item 2A(c) |

These fees are in Schedule 9, [Therapeutic Goods Regulations 1990](#)

Miscellaneous fees

Application for consent by the Secretary under sections 14 and 14A of the Act to the import, export or supply of therapeutic goods that do not comply with an applicable standard

Table 69: Miscellaneous fees

| Application type | Fee | Clause 3 of Schedule 9 |
|---|--|--|
| Where the application relates to a single entry in the register. | \$540 | Item 1A(a) |
| Where the application relates to two or more entries in the register. | \$540 for the first entry, plus \$108 for each additional entry | Item 1A(a) Additional entry Item 1A(b) |

This fee is in Schedule 9, [Therapeutic Goods Regulations 1990](#)

Clinical trials

The Clinical Trial Notification (CTN) and Clinical Trial Approval (CTA) schemes provide two avenues for conducting [clinical trials](#) involving the use of unapproved therapeutic goods.

Unapproved medicines

These fees are for clinical trials of unapproved [medicines](#).

Table 70: Unapproved medicines

| Unapproved medicines | Fee | Clause 3 of Schedule 9 |
|---|----------|------------------------|
| Clinical trial notification (CTN) | \$410 | Item 14(a) |
| Clinical trial notification (CTN) - for each notification of one or more additional trial sites | \$410 | Item 14(b) |
| Clinical trial approval (CTA) - 30-day evaluation | \$1,954 | Item 1(a) |
| Variation – Medicines Clinical trial approval (CTA) - 30-day evaluation | \$537 | Item 1AAA(a) |
| Clinical trial approval (CTA) - 50-day evaluation | \$24,285 | Item 1(b) |
| Variation – Medicines Clinical trial approval (CTA) - 50-day evaluation | \$6,628 | Item 1AAA(b) |

These fees are in Schedule 9, [Therapeutic Goods Regulations 1990](#)

Unapproved biologicals

These fees are for clinical trials of unapproved [biologicals](#).

Table 71: Unapproved biologicals

| Biologicals | Fee | Part 2 of Schedule 9A |
|---|----------|-----------------------|
| Clinical trial notification (CTN) | \$410 | Item 17(a) |
| Clinical trial notification (CTN) – for each notification of one or more additional trial sites | \$410 | Item 17(b) |
| Clinical trial approval (CTA) | \$29,574 | Item 16 |
| Variation – Biologicals Clinical trial approval (CTA) | \$8,069 | Item 16AA |

These fees are in Schedule 9A, [Therapeutic Goods Regulations 1990](#)

Unapproved medical devices (including IVDs)

These fees are for clinical trials of unapproved [medical devices](#) and [IVDs](#).

Table 72: Unapproved medical devices (including IVDs)

| Unapproved medical devices (including IVD) | Fee | Part 1 of Schedule 5 |
|---|----------|----------------------|
| Clinical trial notification (CTN) | \$410 | Item 1.8 |
| Clinical trial approval (CTA) | \$20,723 | Item 1.7 |
| Variation – Medical Devices Clinical trial approval (CTA) | \$5,656 | Item 1.7A |

These fees are in the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#)

General fees

Transfer of sponsorship

There are no fees for the transfer of sponsorship. However, there are fees associated with some changes to therapeutic goods that occur because of sponsor transfer, such as changes to registered medicine labels or variation of ARTG entry following acceptance of a new Manufacturer Evidence.

Fees related to annual charge exemption (ACE) scheme

To maintain an [annual charge exemption](#), sponsors are able to self-declare that their product had no turnover. Self-declarations must be submitted to the TGA between 1 July and 22 July each year or it will be assumed that the product generated greater than \$0 turnover.

Late notice declarations made before 15 September under regulation 43AAE(2) of the *Therapeutic Goods Regulations 1990* attract a late notice declaration fee.

Table 73: Fees related to annual charge exemption (ACE) scheme

| Number of ARTG entries | Late notice declaration fee | Clause 3 of Schedule 9 |
|---|--|--|
| If the declaration relates to not more than 5 entries in the ARTG | \$474 | Item 3AB(a) |
| If the declaration relates to 6 or more entries in the ARTG | \$474 for first 5 entries, plus \$54 for each additional entry | Item 3AB(a) Additional entry Item 3AB(b) |

Fees are in the [Therapeutic Goods Regulations 1990](#)

Fees related to a request to revoke an ARTG entry cancellation

There are fees for the requests for revocation of:

- the voluntary cancellation of an ARTG entry by the sponsor
- the cancellation of an ARTG entry that was cancelled due to non-payment of the annual charge

Table 74: Fees related to a request to revoke an ARTG entry cancellation

| Number of ARTG entries | Fee for revocation of cancellation | Regulation |
|---|------------------------------------|--|
| If the request relates to one entry in the ARTG | \$173 | Part 2 of Schedule 9A Item 16A(a) and Item 16B(a) Clause 3 of Schedule 9 Item 6BA(a) and Item 6BB(a) |

| | | |
|---|---|---|
| If the request relates to more than one entry in the ARTG | \$173 for first entry, plus \$54 for each additional entry | Part 2 of Schedule 9A Item 16A(a) and (b) and Item 16B(a) and (b) Clause 3 of Schedule 9 Item 6BA(a) and (b) and Item 6BB(a) and (b) Additional entry Part 2 of Schedule 9A Item 16A(b) and Item 16B(b) Clause 3 of Schedule 9 Item 6BA(a) and (b) Item 6BB (a) and (b) |
|---|---|---|

Fees are in the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#) and [Therapeutic Goods Regulations 1990](#)

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Reference/Publication #