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Department of Health
Therapeutic Goods Administration

Fees and charges: summary

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TGA Health Safety Regulation

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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*, 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* (the Act)
- *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	$7,490	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	$4,260	Item 8(2)(a)
Non-biological medicine (chemical entity) - otherwise	$3,470	Item 8(2)(b)

Type of prescription medicine	Charge	Regulation
Provisionally registered biological medicine	$16,900	Item 9(1)(a)
Provisionally registered non-biological medicine	$13,800	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	Schedule 9, Part 2
New chemical entity*	$50,300	$201,600	Item 2(ba) and Item 4(a)
Extension of indications*	$30,000	$119,600	Item 2(bd) and Item 4(b)
Major variations*^	$19,600	$78,000	Item 2(bi) and Item 4(g)
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)^	$1,150	$4,590	Item 2(bj) and Item 4(h)
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*^	$1,150	$4,590	Item 2AC and Item 2C
Additional trade name^	$3,170	$12,600	Item 2(bh) and Item 4(d)
New generic product*	$19,400	$77,000	Item 2(bg) and Item 4(c)

Prescription Medicine Application Type	Application Fee	Evaluation Fee	Schedule 9, Part 2
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	$1,150	$4,590	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	Schedule 9, Part 2
Priority determination of a prescription medicine	$13,100	n/a	Item 1B
New prescription medicine in the priority pathway	$53,300	$213,200	Item 2(bca) and Item 4(ab)
New indications medicine in the priority pathway	$31,700	$126,800	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	Schedule 9, Part 2
Provisional determination of a prescription medicine	$13,100	n/a	Item 1AA
Extension of provisional determination	$4,750	n/a	Item 1AB
Provisional registration of a new prescription medicine	$50,400	$263,000	Item 1AC(a) and Item 1AD(a)

Prescription Medicine Application Type	Application Fee	Evaluation Fee	Schedule 9, Part 2
Provisional registration of a new indications medicine	$30,100	$173,500	Item 1AC(b) and Item 1AD(b)
Extension of provisional registration	$18,100	n/a	Item 1AG
Transition from provisional registration to full registration*	$30,000	$126,500	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, Part 2
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.	$5,740	Item 2B
Minor editorial changes: variations to an ARTG entry (requiring changes to Product Information) with no evaluation of data	$1,760	Item 2A(a)
Correction to an ARTG entry	$1,760	Item 2A(a)
Notification request	$840	Item 2CB
Self-assessable request with no evaluation of data	$1,760	Item 2A(a)
Safety-related request with no evaluation of data	$1,760	Item 2A(a)
Safety-related request with evaluation of data	$5,740	Item 2CA
Request for advice in relation to a prescription medicine for the purpose of listing the medicine as a pharmaceutical benefit	$2,320	Item 18

Prescription medicine request	Fee	Schedule 9, Part 2
Request for early scientific advice on a biowaiver justification	$8,660	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.	$500	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.	$500 for the first entry, plus $100 for each 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	Schedule 9, Part 2
New chemical entity of a medicine used as an ancillary medical component of a device - chemistry, quality control and manufacturing OR nonclinical studies	$16,700	$67,300	Item 2(bb) Item 4(aa)(i) Item 4(aa)(ii)
New chemical entity of a medicine used as an ancillary medical component of a device - chemistry, quality control and manufacturing AND nonclinical studies	$33,500	$134,100	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	$9,970	$39,900	Item 2(be)(i) Item 4(bb)(i) Item 4(bb)(ii)

Application type	Application fee	Evaluation fee	Schedule 9, Part 2
Extension of indications of a medicine used as an ancillary medical component of a device – chemistry, quality control and manufacturing AND nonclinical studies	$20,100	$79,700	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	$6,510	$25,900	Item 2(be)(ii) Item 4(bb)(i)(b) Item 4(bb)(ii)(b)
Major variation of a medicine used as an ancillary medical component of a device – chemistry, quality control and manufacturing AND nonclinical studies	$13,000	$52,100	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	$1,170	*Therapeutic Goods (Charges) Regulations 2018* Item 7(1)(c)(i) and Item 7(2)(c)(i)
Application fee	$870	*Therapeutic Goods Regulations 1990*, Schedule 9 Part 2 Item 3(b)
Processing fee (variation to an existing listing)	$440	*Therapeutic Goods Regulations 1990*, Schedule 9 Part 2 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.	$500	*Therapeutic Goods Regulations 1990*, Schedule 9, Part 2 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.	$500 for the first entry plus $100 for each additional entry	*Therapeutic Goods Regulations 1990*, Schedule 9, Part 2 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	Schedule 9, Part 2
Application fee for a new indication to be added to the permitted indication list	$1,090	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	Schedule 9, Part 4
IN1	$1,120	$15,100	Item 28 and Item 29
IN2	$1,120	$15,100	Item 30 and Item 31
IN3	$2,970	$24,600	Item 32 and Item 33
IN4	$2,970	$24,600	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	$1,170	Part 2 Item 7(1)(c)(i) Part 2 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	Schedule 9, Part 4
L(A)1	$460	$1,750	Item 22 and Item 23
L(A)2	$1,890	$14,500	Item 24 and Item 25
L(A)3	$1,890	$14,500	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	Schedule 9 Part 4
L(A)CN	$820	n/a	Item 1F
L(A)C1	$950	$1,100	Item 1D and 1G
L(A)C2	$950	$8,000	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	Schedule 9 Part 4
L(A)CN notification request	$820	n/a	Item 1C
L(A)C1 application	$2,050	$1,100	Item 1A, Item 1G
L(A)C2 application	$8,950	$8,000	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	$1,540	Item 7(1)(a)(i) and Item7(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	Schedule 9, Part 4
RCM1	$570	$3,270	Item 12 and Item 13
RCM2	$2,050	$21,900	Item 14 and Item 15
RCM3	$2,050	$21,900	Item 16 and Item 17
RCM4	$2,710	$29,800	Item 18 and Item 19
RCM5	$2,970	$38,000	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	Schedule 9, Part 4
RCMC1	$1,490	n/a	Item 5
RCMC2	$780	$4,240	Item 6 and Item 7
RCMC3	$840	$6,640	Item 8 and Item 9
RCMC4	$860	$9,810	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	$840	n/a	Part 2 Item 2CC Part 2 Item 2CB
RCMC1	$1,490	n/a	Part 4 Item 1
RCMC2	$5,030	$4,240	Part 4 Item 2, and Paragraph 43ACA(2)(a)*
RCMC3	$7,470	$6,640	Part 4 Item 3, and Paragraph 43ACA(2)(b)*

RCM change application category	Upfront fee	Refund if no evaluation*	Regulation
RCMC4	$10,600	$9,810	Part 4 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	Schedule 9 Part 2
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	$500	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.	$500 for the first entry, plus $100 for each 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	$1,540	Item 7(1)(a)(i) and Item7(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	Schedule 9 Part 3
N1 application	$1,700	$4,200	Item 1(a) and Item 2(a)
N1 concurrent application per additional application (as described in item 3, Part 3, Schedule 9 of the Regulations)	$860	$4,200	Item 3(d) and Item 2(a)
N2 application	$1,700	$5,970	Item 1(b) and Item 2(b)
N2 concurrent application per additional application (as described in item 3 of Part 3 Schedule 9 of the Regulations)	$860	$5,970	Item 3(e) and Item 2(b)
N3 application	$2,730	$9,200	Item 1(c) and Item 2(c)
N3 concurrent application per additional application (as described in item 3 and 4 of Part 3 Schedule 9 of the Regulations)	$1,370	$4,660	Item 3(f) and Item 4(d)
N4 application	$3,990	$15,300	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)	$1,370	$4,660	Item 3(g) and Item 4(e)
N5 application	$5,910	$22,500	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)	$1,370	$4,660	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	Schedule 9 Part 3
C1 (section 23) application	$1,700	n/a	Item 1(f)
C2 (section 23) application	$1,700	$4,200	Item 1(g) and Item 2(f)
C3 (section 23) application	$1,700	$7,050	Item 1(h) and Item 2(g)
C4 (section 23) application	$2,730	$9,200	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	$840	n/a	Part 2 Item 2CB and Part 2 Item 2CD
C1 (section 9D) application	$1,700	n/a	Part 3 Item 5(a)
C2 (section 9D) application	$5,910	$4,200	Part 3 Item 5(b) and Paragraph 43AC(2)(a)*
C3 (section 9D) application	$8,760	$7,050	Part 3 Item 5(c) and Paragraph 43AC(2)(b)*
C4 (section 9D) application	$11,900	$9,200	Part 3 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 Part 3
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	$1,670	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	$8,560	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.	$500	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.	$500 for the first entry, plus $100 for each 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	Schedule 9, Part 2
0-50	$11,000	Item 7A(a), Item 7A(b)(i), Item 7B(a) and Item 7B(b)(i)
51-250	$14,200	Item 7A(b)(ii) and Item 7B(b)(ii)
251-500	$19,400	Item 7A(b)(iii) and Item 7B(b)(iii)
501-1000	$25,700	Item 7A(b)(iv) and Item 7B(b)(iv)
1001-2000	$38,500	Item 7A(b)(v) and Item 7B(b)(v)
2001-3000	$51,300	Item 7A(b)(vi) and Item 7B(b)(iv)
>3000	$77,000	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	$4,820	Item 7(5)(a), Item 7(5)(b), Item 7(5)(c) and 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	Schedule 9 Part 2
Australian manufacturing sites – application fee for a manufacturing licence	$820	Item 8(a)
Variation application for a manufacturing licence	$820	Item 8A
Australian manufacturing sites – inspection fee	$1,020/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	Schedule 9 Part 2
Overseas manufacturing sites – inspection fee	$1,430/hour/inspector	Item 9(b)
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	Schedule 9 Part 2
GMP clearance application processing fee (per manufacturer, per site, per sponsor)	$670	Item 6AA
Obtaining evidence from an overseas regulatory authority (per manufacturer, per site, per sponsor)	$720	Item 6AB
Compliance verification (in lieu of an overseas GMP inspection)	$2,560	Item 6ABA
Reinstatement of expired GMP clearance approval (per manufacturer, per site, per sponsor) – in addition to relevant fees above	$1,210	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	$180
Mutual Recognition Agreement certificate	$350
Certified copy of: • original GMP certificate • certificate of GMP compliance	$70

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 Part 2
New export only medicine listing	$870	Item 3(b)
Grouping application for an existing export only medicine listing	$870	Item 3(b)
Variation application for an existing export only medicine listing	$440	Item 2A(b)
Grouping application to add an export name to a registered product	$870	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	Schedule 9 Part 2
Certificate of Pharmaceutical Product (CPP)	$180	Item 10
Certificate of Listed Product (CLP)	$180	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	Schedule 9 Part 2
Certificate of Free Sale	$180	Item 10
Export Certificate	$180	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	Schedule 5 Part 1
Application for inclusion into the ARTG of export only devices	$90	Item 1.5(f)
Application for inclusion into the ARTG of export only IVD devices	$90	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	Schedule 9A Part 2
Australian manufacturing sites – application fee for a manufacturing licence	$1,140	Item 3
Initial manufacturing audit – inspection fee for Australian and overseas manufacturing sites	$22,500	Item 12
Subsequent manufacturing audit – inspection fee for Australian and overseas manufacturing sites	$17,100	Item 13
Inspection fee for each hour of preparation by each inspector for an inspection conducted outside Australia	$700/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

ARTG inclusion of biologicals	Amount	Regulation
Class 1 biological annual charge for ARTG inclusion	$700	Item 7(3)(a)
Class 2, 3, 4 biological annual charge for ARTG inclusion	$6,960	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	Schedule 9A Part 2
Ingredient or component of a biological to be evaluated under regulation 16GF - evaluation fee	$24,700	Item 7
Class 1 biological – application fee for inclusion in ARTG	$1,140	Item 1
Class 2, 3, 4 biological – application fee for inclusion in ARTG	$1,140	Item 2
Variation application fee – all classes	$1,140	Item 8
Class 2 biological – evaluation fee for inclusion in ARTG	$75,900	Item 4
Class 2 biological – evaluation fee for variation to ARTG entry	$6,960	Item 9
Class 3 biological – evaluation fee for inclusion in ARTG	$151,900	Item 5
Class 4 biological – evaluation fee for inclusion in ARTG	$246,800	Item 6
Class 3 or 4 biological – evaluation fee for major variation to ARTG entry	$36,000	Item 11
Class 3 or 4 biological – evaluation fee for minor variation to ARTG entry	$18,300	Item 10
Safety related variations – evaluation of application under section 9D(3AA)	$6,960	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	$168,600	Item 7(5)(f)(i)
Blood and blood components (not HPCs) – a fixed (non-mobile) manufacturing site	$8,300	Item 7(5)(f)(ii)
HPCs manufacturing site	$7,260	Item 7(5)(g)

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	Schedule 9 Part 2
Australian manufacturing sites – application fee for a manufacturing licence	$1,070	Item 8(b)
Blood and blood components (not HPCs) - Australian primary manufacturing site - inspection fee	$950/inspector/hour	Item 9AB
Blood and blood components (not HPCs) - Australian manufacturing site other than the primary site – inspection fee	$700/inspector/hour	Item 9AC
HPCs - Australian manufacturing site inspection fee	$950/inspector/hour	Item 9AA
Human tissues that are not biologicals - Australian manufacturing site – inspection fee	$700/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	Schedule 9 Part 2
1–10	$1,380	Item 9AD(a)
11–50	$11,700	Item 9AD(b)
51–100	$26,400	Item 9AD(c)
101–1000	$35,500	Item 9AD(d)
1001–3000	$55,300	Item 9AD(e)
3001–4000	$73,700	Item 9AD(f)
>4000	$89,900	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	Schedule 9 Part 2
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.	$500	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.	$500 for the first entry, plus $100 for each additional entry	Item 1A(b)

This fee 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	$1,210	Item 7(4)(d)
Class III	$1,210	Item 7(4)(d)
Class IIb	$950	Item 7(4)(c)
Class IIa	$950	Item 7(4)(c)
Class I – sterile	$650	Item 7(4)(b)
Class I – measuring function	$650	Item 7(4)(b)
Class I – other	$90	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
AIMD	$1,380	Item 1.5(a)
Class III	$1,380	Item 1.5(b)
Class IIb	$1,070	Item 1.5(c)
Class IIa	$1,070	Item 1.5(d)
Class I – sterile	$1,070	Item 1.5(e)
Class I – measuring function	$1,070	Item 1.5(e)
Class I – other (excluding export only devices)	$560	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 review designation for an application to include a medical device in the ARTG.

For guidance on how to seek priority review, 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
Medical devices (priority applicant) determination in relation to a medical device	$10,300	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.

Table 44: Application audit assessment fees

Type of application audit	Assessment fee	Schedule 5 Part 1
Level 1 – verification of sponsor's application and evidence of conformity	$4,030	Item 1.13
Level 2 – Level 1 activities plus review of evidence of conformity	$7,390	Item 1.14

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	Schedule 9 Part 2
Variation to an ARTG inclusion entry	$470	Item 2A(g)

These fees are in Schedule 9, *Therapeutic Goods Regulations 1990*

Miscellaneous

Table 46: Miscellaneous

Type of application	Fee	Schedule 5 Part 1
Considering submissions to the Secretary in relation to a proposed suspension of a kind of medical device from the ARTG (as described in item 1.6)	$7,390	Item 1.14
Application for consent of Secretary to importation into Australia, supply for use in Australia, or exportation from Australia of a medical device, including an IVD medical device, for a single entry in the register	$500 (for all the devices to which the application relates)	Item 1.15(a)
Application for consent of Secretary to importation into Australia, supply for use in Australia, or exportation from Australia of a medical device, including an IVD medical device, for a two or more entries in the register	$500 for the first entry, plus $100 for each additional entry	Item 1.15(b)

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	$4,710	$76,900	Item 1.4A and Item 1.4D
Partial designation conformity assessment body determination (full QMS)	$2,590	$55,200	Item 1.4B and Item 1.4E
Partial designation conformity assessment body determination (partial QMS or partial devices)	$2,590	$55,200	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	Schedule 5 Part 1
Application fee	$1,050	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 review designation for an application for TGA conformity assessment of a medical device.

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

Application type	Application fee	Schedule 5 Part 1
Conformity assessment (priority applicant) determination in relation to a medical device	$10,300	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	Schedule 5 Part 1
Full quality management system inspection (described in Schedule 3, Part 1)	$31,200	Item 1.9(a)
Design examination (described in Schedule 3, Clause 1.6)	$61,300	Item 1.9(b)
Type examination (including management of testing, analysis, and reporting on examination of the type) (described in Schedule 3, Part 2)	$42,700	Item 1.9(c)
Verification (including management of testing, analysis, and reporting on verification tests) (described in Schedule 3, Part 3)	$29,900	Item 1.9(d)
Production quality management system inspection (described in Schedule 3, Part 4)	$27,300	Item 1.9(e)
Product quality management system inspection (described in Schedule 3, Part 5)	$23,300	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	Schedule 5 Part 1
Full quality management system inspection (described in Schedule 3, Part 1)	$18,800	Item 1.10(a)
Design examination (described in Schedule 3, Clause 1.6)	$37,000	Item 1.10(b)
Type examination (including management of testing, analysis, and reporting on examination of the type) (described in Schedule 3, Part 2)	$25,800	Item 1.10(c)

Type of conformity	Fee for change	Schedule 5 Part 1
Production quality management system inspection (described in Schedule 3, Part 4)	$16,200	Item 1.10(d)
Product quality management system inspection (described in Schedule 3, Part 5)	$14,200	Item 1.10(e)

These fees are in Schedule 5 *Therapeutic Goods (Medical Devices) Regulations 2002*

Surveillance inspections - conformity assessment

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

Table 52: Surveillance inspections - conformity assessment

Type of surveillance inspection	Fee	Schedule 5 Part 1
Full quality management system surveillance inspection (described in Schedule 3, Part 1)	$9,060	Item 1.2(a)
Production quality management system surveillance inspection (described in Schedule 3, Part 4)	$9,060	Item 1.2(a)
Product quality management system surveillance inspection (described in Schedule 3, Part 5)	$9,060	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 53: Review of certificate of conformity assessment

Type of certificate being reviewed	Fee	Schedule 5 Part 1
Design examination re-assessment (described in Schedule 3, Clause 1.6)	$55,400	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)	$42,700	Item 1.3(b)

These fees are in Schedule 5 *Therapeutic Goods (Medical Devices) Regulations 2002*

Additional inspection 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 54: Additional inspection fees

Inspection costs	Fee	Schedule 5 Part 2
Supplementary additional assessment conducted outside Australia in addition to assessment mentioned in item 1.2, 1.3, 1.9 or 1.10, Schedule 5	$440/hour/ assessor	Item 2.1(b)
Costs and reasonable expenses of travel by each assessor 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 55: Issuing quality systems certificates

Certificate	Fee
Quality systems certificate	$180
Certified copy of quality systems certificate	$70

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 56: Annual charges

Class of IVD	Charge	Regulation
All classes of IVD (excluding Class 4 in-house IVDs)	$700	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 57: Notification fee

Class of IVD	Notification fee	Schedule 5 Part 1
Notification by a laboratory of its Class 1, Class 2 or Class 3 in-house IVDs	$1,070	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 58: Application fees

Application	Application fee	Regulation
Application for inclusion into the ARTG of all classes of IVD, including Class 4 in-house IVDs (excluding export only IVD devices)	$1,070	*Therapeutic Goods (Medical Devices) Regulations 2002*, Schedule 5 Part 1, 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 59: Application for medical devices (priority applicant) determination

Application type	Application fee	Schedule 5 Part 1
Medical devices (priority applicant) determination in relation to a medical device (including an IVD)	$10,300	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 60: Application audit assessment fees

Type of IVD	Assessment fee	Schedule 5 Part 1
Class 1, Class 2 and Class 3 IVDs	$7,200	Item 1.14A
Class 4 in-house IVDs	$66,700	Item 1.14B
Class 4 in-house immunohaematology reagent IVD	$16,200	Item 1.14C

These fees are in the *Therapeutic Goods (Medical Devices) Regulations 2002*

Manufacturing IVDs

Application for conformity assessment

Table 61: Application for conformity assessment

All conformity assessment procedures	Fee	Schedule 5 Part 1
Application fee	$1,050	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 Review designation for an application for TGA conformity assessment of an IVD.

Table 62: Application for conformity assessment (priority applicant) determination

Application type	Application fee	Schedule 5 Part 1
Conformity assessment (priority applicant) determination in relation to a medical device (including an IVD)	$10,300	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 63: Initial assessment of conformity assessment

Type of conformity	Fee	Schedule 5 Part 1
Full quality management system inspection: described in Schedule 3, Part 1	$31,300	Item 1.9A(a)
Design examination: described in Schedule 3, Clause 1.6	$66,700	Item 1.9A(b)
Design examination – immunohematology reagent: described in Schedule 3, Clause 1.6	$16,200	Item 1.9A(c)
Type examination: described in Schedule 3, Part 2	$43,100	Item 1.9A(e)
Production quality management system inspection: described in Schedule 3, Part 4	$27,500	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 64: Review of certificate of conformity assessment

Type of certificate being reviewed	Fee	Schedule 5 Part 1
Full quality management system inspection: described in Schedule 3, Part 1	$31,300	Item 1.3A(a)
Design examination: described in Schedule 3, Clause 1.6	$66,700	Item 1.3A(b)
Design examination – immunohematology reagent: described in Schedule 3, Clause 1.6	$16,200	Item 1.3A(c)
Type examination: described in Schedule 3, Part 2	$43,100	Item 1.3A(e)
Production quality management system inspection: described in Schedule 3, Part 4	$27,500	Item 1.3A(f)

These fees are in Schedule 5 *Therapeutic Goods (Medical Devices) Regulations 2002*

Other IVD conformity assessment fees

Table 65: Other IVD conformity assessment fees

Other assessment for IVD conformity assessment	Fee	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), Schedule 5]	$440/assessor hour	Item 1.12
Costs and reasonable expenses of travel by each assessor 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	$9,110	Item 1.2(b)
Assessment of changes to IVD or QMS for applicable IVD	60% of the relevant 'initial assessment' fee* under item 1.9A	Item 1.10A
Considering a submission to the Secretary in relation to a proposed suspension of a conformity assessment certificate	$7,200	Item 1.14A

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 sterilants
- 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 66: Annual charges

Type of OTG	Charge	Regulation
Listed OTG: disinfectants	$890	Item 7(1)(c)(iii) and Item 7(2)(c)(iii)
Registered OTG: disinfectants	$1,720	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 67: Listed OTG fees

Listed OTG fee type	Fee	Schedule 9 Part 2
Application fee	$470	Item 3(a)
Variation fee	$470	Item 2A(ba)
Evaluation fee (if an evaluation is necessary) for assessing, whether a disinfectant is not safe for the purposes for which it is to be used	$19,200	Item 9B

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 68: Miscellaneous fees

Application type	Fee	Schedule 9 Part 2
Where the application relates to a single entry in the register.	$500	Item 1A(a)
Where the application relates to two or more entries in the register.	$500 for the first entry, plus $100 for each 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 69: Unapproved medicines

Unapproved medicines	Fee	Schedule 9 Part 2
Clinical trial notification (CTN)	$380	Item 14(a)
Clinical trial notification (CTN) - for each notification of one or more additional trial sites	$380	Item 14(b)
Clinical trial approval (CTA) - 30 day evaluation	$1,810	Item 1(a)
Clinical trial approval (CTA) - 50 day evaluation	$22,500	Item 1(b)

These fees are in Schedule 9, *Therapeutic Goods Regulations 1990*

Unapproved biologicals

These fees are for clinical trials of unapproved biologicals.

Table 70: Unapproved biologicals

Biologicals	Fee	Schedule 9A Part 2
Clinical trial notification (CTN)	$380	Item 17(a)
Clinical trial notification (CTN) – for each notification of one or more additional trial sites	$380	Item 17(b)
Clinical trial approval (CTA)	$27,400	Item 16

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 71: Unapproved medical devices (including IVDs)

Unapproved medical devices (including IVD)	Fee	Schedule 5 Part 1
Clinical trial notification (CTN)	$380	Item 1.8
Clinical trial approval (CTA)	$19,200	Item 1.7

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 72: Fees related to annual charge exemption (ACE) scheme

Number of ARTG entries	Late notice declaration fee	Schedule 9 Part 2
If the declaration relates to not more than 5 entries in the ARTG	$440	Item 3AB(a)
If the declaration relates to 6 or more entries in the ARTG	$440 for first 5 entries, plus $50 for each 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 73: 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	$160	*Therapeutic Goods (Medical Devices) Regulations 2002*: Schedule 5, Part 1 Item 1.6A(a) and Item 1.6B(a) *Therapeutic Goods Regulations 1990*: Schedule 9, Part 2 Item 6BA(a) and Item 6BB(a) *Therapeutic Goods Regulations 1990*: Schedule 9A, Part 2 Item 16A(a) and Item 16B(a)

Number of ARTG entries	Fee for revocation of cancellation	Regulation
If the request relates to more than one entry in the ARTG	$160 for first entry, plus $50 for each additional entry	*Therapeutic Goods (Medical Devices) Regulations 2002*: Schedule 5, Part 1 Item 1.6A(b) and Item 1.6B(b) *Therapeutic Goods Regulations 1990*: Schedule 9, Part 2 Item 6BA(b) and Item 6BB(b) *Therapeutic Goods Regulations 1990*: Schedule 9A, Part 2 Item 16A(b) and Item 16B(b)

Fees are in the *Therapeutic Goods (Medical Devices) Regulations 2002* and *Therapeutic Goods Regulations 1990*

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