Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Fees and charges: summary

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Contents

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	$9,148	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	$5,203	Item 8(2)(a)
Non-biological medicine (chemical entity) - otherwise	$4,238	Item 8(2)(b)
Provisionally registered biological medicine	$20,641	Item 9(1)(a)
Provisionally registered non-biological medicine	$16,856	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 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*	$56,844	$227,825	Item 2(ba) and Item 4(a)
Extension of indications*	$33,903	$135,158	Item 2(bd) and Item 4(b)
Major variations*^	$22,150	$88,146	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)^	$1,299	$5,187	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	$1,299	$5,187	Item 2 (bcb) and Item 4(ac)

Prescription Medicine Application Type	Application Fee	Evaluation Fee	Clause 3 of Schedule 9
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*^	$1,299	$5,187	Item 2AC and Item 2C
Additional trade name^	$3,582	$14,239	Item 2(bh) and Item 4(d)
New generic product*	$21,923	$87,016	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	$1,299	$5,187	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	$14,805	n/a	Item 1B
New prescription medicine in the priority pathway	$60,234	$240,934	Item 2(bca) and Item 4(ab)
New indications medicine in the priority pathway	$35,823	$143,295	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	$14,805	n/a	Item 1AA
Extension of provisional determination	$5,368	n/a	Item 1AB
Provisional registration of a new prescription medicine	$56,956	$297,212	Item 1AC(a) and Item 1AD(a)
Provisional registration of a new indications medicine	$34,016	$196,070	Item 1AC(b) and Item 1AD(b)
Extension of provisional registration	$20,455	n/a	Item 1AG
Transition from provisional registration to full registration*	$33,903	$142,955	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.	$6,486	Clause 3 Item 2B
Minor editorial changes: variations to an ARTG entry (requiring changes to Product Information) with no evaluation of data	$1,989	Part 2 Item 2A(a)
Correction to an ARTG entry	$1,989	Part 2 Item 2A(a)

Prescription medicine request	Fee	Schedule 9
Notification request	$950	Clause 3 Item 2CB
Self-assessable request with no evaluation of data	$1,989	Part 2 Item 2A(a)
Safety-related request with no evaluation of data	$1,989	Part 2 Item 2A(a)
Safety-related request with evaluation of data	$6,486	Clause 3 Item 2CA
Request for advice in relation to a prescription medicine for the purpose of listing the medicine as a pharmaceutical benefit	$2,622	Clause 3 Item 18
Request for early scientific advice on a biowaiver justification	$9,786	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.	$565	Clause 3 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.	$565 for the first entry, plus $113 for each additional entry	Clause 3 Item 1A(b)(i) Additional entry Item 1A(b)(ii)
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 goods that do not have an entry in the register, and the way in which the goods do not conform with the standard applicable to the goods is the same for all the goods.	$3,712	Clause 3 Item 1A(c)
Fee for request from a sponsor to impose a new condition, or to vary or remove an existing condition, of registration for a therapeutic good specified in Part 1 of Schedule 10 to the Therapeutic Goods Regulations 1990, for the purposes of subsection 28(3A) of the Act.*	$2,879	Clause 3 Item 1AFA(a)

These fees are in Schedule 9, *Therapeutic Goods Regulations 1990*
'The Act' refers to the *Therapeutic Goods Act 1989*
* The fees prescribed under subsection 28(3A) of the Act will be further examined across the range of circumstances in relation to which such requests may be made.

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	$18,872	$76,055	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	$37,857	$151,545	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	$11,267	$45,090	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	$22,715	$90,067	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	$7,356	$29,269	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	$14,692	$58,878	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 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	$1,429	Item 7(1)(c)(i) Item 7(2)(c)(i)
Application fee	$983	Clause 3 of Schedule 9 Item 3(b)
Fee for a request for variation to an existing listing	$496	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.	$565	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.	$565 for the first entry plus $113 for each additional entry	Clause 3 of Schedule 9 Item 1A(a) and Item 1A(b)
Fee for request from a sponsor to impose a new condition, or to vary or remove an existing condition, of registration or listing for a therapeutic good other than a therapeutic good specified in Part 1 of Schedule 10 to the Therapeutic Goods Regulations 1990 (the TG Regulations), for the purposes of subsection 28(3A) of the Act (note that this means that this fee is not limited to medicines but to any registered or listed therapeutic goods other than a therapeutic good specified in Part 1 of Schedule 10 to the TG Regulations).*	$1,790	Clause 3 of Schedule 9 Item 1AFA(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.
* The fees prescribed under subsection 28(3A) of the Act will be further examined across the range of circumstances in relation to which such requests may be made.

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	$1,231	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 Understanding the application requirements for a new substance in listed medicines.

Table 9: Permitted ingredients for listed medicines

Application Category	Application fee	Evaluation fee	Clause 5 of Schedule 9
IN1	$1,266	$17,065	Item 28 and Item 29
IN2	$1,266	$17,065	Item 30 and Item 31
IN3	$3,356	$27,800	Item 32 and Item 33
IN4	$3,356	$27,800	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	$1,429	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 Understanding the application requirements for an assessed listed medicine.

Table 11: Assessed listed applications

Application Category	Application fee	Evaluation fee	Clause 5 of Schedule 9
L(A)1	$520	$1,978	Item 22 and Item 23
L(A)2	$2,136	$16,387	Item 24 and Item 25
L(A)3	$2,136	$16,387	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 an assessed listed medicine in the Australian Register of Therapeutic Goods (ARTG).

Table 12: Section 23 applications

Application type	Application fee	Evaluation fee	Clause 5 of Schedule 9
L(A)CN	$927	n/a	Item 1F
L(A)C1	$1,074	$1,244	Item 1D and 1G
L(A)C2	$1,074	$9,041	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
- Request made under subsection 28(3A) of the Act to **vary or remove** conditions of listing for a listed medicine

For information on application types, see Changing a listed or an assessed listed medicine in the Australian Register of Therapeutic Goods (ARTG).

Table 13: Section 9D and Subsection 28(3A) applications

Application type	Upfront fee	Refund if no evaluation	Schedule 9
L(A)CN notification request	$927	n/a	Clause 5 Item 1C
L(A)C1 application	$2,316	$1,244	Clause 5 Item 1A, Item 1G
L(A)C2 application	$10,115	$9,041	Clause 5 Item 1B, Item 1H

Application type	Upfront fee	Refund if no evaluation	Schedule 9
Fee for request from a sponsor to impose a new condition, or to vary or remove an existing condition, of registration or listing for a therapeutic good other than a therapeutic good specified in Part 1 of Schedule 10 to the Therapeutic Goods Regulations 1990 (the TG Regulations), for the purposes of subsection 28(3A) of the Act (note that this means that this fee is not limited to medicines but to any registered or listed therapeutic goods other than a therapeutic good specified in Part 1 of Schedule 10 to the TG Regulations).	$1,790	n/a	Clause 3 Item 1AFA(b)

These fees are in the *Therapeutic Goods Regulations 1990*
n/a: not applicable
The fees prescribed under subsection 28(3A) of the Act will be further examined across the range of circumstances in relation to which such requests may be made. *

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	$1,881	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: Submitting an application for a registered complementary medicine.

Table 15: Application and evaluation fees for registered complementary medicines

Application Category	Application fee	Evaluation fee	Clause 5 of Schedule 9
RCM1	$644	$3,695	Item 12 and Item 13
RCM2	$2,316	$24,748	Item 14 and Item 15
RCM3	$2,316	$24,748	Item 16 and Item 17
RCM4	$3,062	$33,677	Item 18 and Item 19
RCM5	$3,356	$42,943	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	$1,685	n/a	Item 5
RCMC2	$882	$4,791	Item 6 and Item 7
RCMC3	$950	$7,504	Item 8 and Item 9
RCMC4	$972	$11,086	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	$950	n/a	Clause 3 of Schedule 9 Item 2CB and Item 2CC
RCMC1	$1,685	n/a	Clause 5 of Schedule 9 Item 1
RCMC2	$5,684	$4,791	Clause 5 of Schedule 9 Item 2, and Paragraph 43ACA(2)(a)*
RCMC3	$8,442	$7,504	Clause 5 of Schedule 9 Item 3, and Paragraph 43ACA(2)(b)*
RCMC4	$11,980	$11,086	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.	$565	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.	$565 for the first entry, plus $113 for each additional entry	Item 1A(a) Additional entry Item 1A(b)
Fee for request from a sponsor to impose a new condition, or to vary or remove an existing condition, of registration or listing for a therapeutic good other than a therapeutic good specified in Part 1 of Schedule 10 to the Therapeutic Goods Regulations 1990 (the TG Regulations), for the purposes of subsection 28(3A) of the Act (note that this means that this fee is not limited to medicines but to any registered or listed therapeutic goods other than a therapeutic good specified in Part 1 of Schedule 10 to the TG Regulations).*	$1,790	Item 1AFA(b)

These fees are in Schedule 9, *Therapeutic Goods Regulations 1990*
'The Act' refers to the *Therapeutic Goods Act 1989*
* The fees prescribed under subsection 28(3A) of the Act will be further examined across the range of circumstances in relation to which such requests may be made.

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	$1,881	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	Clause 4 of Schedule 9
N1 application	$1,921	$4,746	Item 1(a) and Item 2(a)
N1 concurrent application per additional application	$972	$4,746	Item 3(d) and Item 2(a)
N2 application	$1,921	$6,747	Item 1(b) and Item 2(b)
N2 concurrent application per additional application	$972	$6,747	Item 3(e) and Item 2(b)
N3 application	$3,086	$10,397	Item 1(c) and Item 2(c)
N3 concurrent application per additional application	$1,549	$5,266	Item 3(f) and Item 4(d)
N4 application	$4,509	$17,290	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)	$1,549	$5,266	Item 3(g) and Item 4(e)
N5 application	$6,679	$25,426	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)	$1,549	$5,266	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	$1,921	n/a	Item 1(f)
C2 (section 23) application	$1,921	$4,746	Item 1(g) and Item 2(f)
C3 (section 23) application	$1,921	$7,967	Item 1(h) and Item 2(g)
C4 (section 23) application	$3,086	$10,397	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	$950	n/a	Clause 3 of Schedule 9 Item 2CB and Item 2CD
C1 (section 9D) application	$1,921	n/a	Clause 4 of Schedule 9 Item 5(a)
C2 (section 9D) application	$6,679	$4,746	Clause 4 of Schedule 9 Item 5(b) and Paragraph 43AC(2)(a)*
C3 (section 9D) application	$9,899	$7,967	Clause 4 of Schedule 9 Item 5(c) and Paragraph 43AC(2)(b)*

Application type	Upfront Fee	Refund if no evaluation*	Regulation
C4 (section 9D) application	$13,448	$10,397	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	$1,887	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	$9,674	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.	$565	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.	$565 for the first entry, plus $113 for each additional entry	Clause 3 Item IA(a) Additional entry Item 1A(b)
Fee for request from a sponsor to impose a new condition, or to vary or remove an existing condition, of registration or listing for a therapeutic good other than a therapeutic good specified in Part 1 of Schedule 10 to the Therapeutic Goods Regulations 1990 (the TG Regulations), for the purposes of subsection 28(3A) of the Act (note that this means that this fee is not limited to medicines but to any registered or listed therapeutic goods other than a therapeutic good specified in Part 1 of Schedule 10 to the TG Regulations).*	$1,790	Clause 3 Item 1AFA(b)

These fees are in Schedule 9, *Therapeutic Goods Regulations 1990*
'The Act' refers to the *Therapeutic Goods Act 1989*
* The fees prescribed under subsection 28(3A) of the Act will be further examined across the range of circumstances in relation to which such requests may be made.

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.

Multiple new excipients

'Multiple new excipient' fee is ONLY applicable to applications under regulation 16GA(1)(b), being excipients already in use in listed or registered medicines subject to a specific condition under section 28 of the Act.

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	$12,431	Item 7A(a), Item 7A(b)(i), Item 7B(a) and Item 7B(b)(i)
51-250	$16,047	Item 7A(b)(ii) and Item 7B(b)(ii)
251-500	$21,923	Item 7A(b)(iii) and Item 7B(b)(iii)
501-1,000	$29,043	Item 7A(b)(iv) and Item 7B(b)(iv)
1001-2,000	$43,508	Item 7A(b)(v) and Item 7B(b)(v)
2001-3,000	$57,973	Item 7A(b)(vi) and Item 7B(b)(iv)
>3,000	$87,016	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	$5,840	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	$927	Item 8(a)
Variation application for a manufacturing licence	$927	Item 8A to 8C
Australian manufacturing sites – inspection fee	$1,153/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	$1,616/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)	$757	Item 6AA
Obtaining evidence from an overseas regulatory authority (per manufacturer, per site, per sponsor)	$814	Item 6AB
Compliance verification (in lieu of an overseas GMP inspection)	$2,894	Item 6ABA
Reinstatement of expired GMP clearance approval (per manufacturer, per site, per sponsor) – in addition to relevant fees above	$1,367	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	$204
Mutual Recognition Agreement certificate	$376
Certified copy of: • original GMP certificate • certificate of GMP compliance	$75

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

Table 30: Export only listed medicines

Export only applications	Fee	Schedule 9
New export only medicine listing	$983	Clause 3 Item 3(b)
Grouping application for an existing export only medicine listing	$983	Clause 3 Item 3(b)
Variation application for an existing export only medicine listing	$496	Part 2 Item 2A(b)
Grouping application to add an export name to a registered product	$983	Clause 3 Item 3(b)
Fee for request from a sponsor to impose a new condition, or to vary or remove an existing condition, of registration for a therapeutic good specified in Part 1 of Schedule 10 to the Therapeutic Goods Regulations 1990, for the purposes of subsection 28(3A) of the Act	$2,879	Clause 3 Item 1AFA(a)
Fee for request from a sponsor to impose a new condition, or to vary or remove an existing condition, of registration or listing for a therapeutic good other than a therapeutic good specified in Part 1 of Schedule 10 to the Therapeutic Goods Regulations 1990 (the TG Regulations), for the purposes of subsection 28(3A) of the Act (note that this means that this fee is not limited to medicines but to any registered or listed therapeutic goods other than a therapeutic good specified in Part 1 of Schedule 10 to the TG Regulations).*	$1,790	Clause 3 Item 1AFA(b)

These fees are in Schedule 9, *Therapeutic Goods Regulations 1990*
* The fees prescribed under subsection 28(3A) of the Act will be further examined across the range of circumstances in relation to which such requests may be made.

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)	$204	Item 10
Certificate of Listed Product (CLP)	$204	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	$204	Item 10
Export Certificate	$204	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	$96	Item 1.5(f)
Application for inclusion into the ARTG of export only IVD devices	$96	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	$1,289	Item 3
Initial manufacturing audit – inspection fee for Australian and overseas manufacturing sites	$25,426	Item 12
Subsequent manufacturing audit – inspection fee for Australian and overseas manufacturing sites	$19,324	Item 13
Inspection fee for each hour of preparation by each inspector for an inspection conducted outside Australia	$790/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	$855	Item 7(3)(a)
Class 2, 3, 4 biological annual charge for ARTG inclusion	$8,500	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	$27,913	Item 7
Class 1 biological – application fee for inclusion in ARTG	$1,289	Item 1
Class 2, 3, 4 biological – application fee for inclusion in ARTG	$1,289	Item 2
Priority determination application fee for biological product	$15,388	Item 2A
Fee for request from a sponsor to vary or remove conditions of inclusion of biologicals in the Register, for the purposes of subsection 32EE(2) of the Act.*	$2,010	Item 2B
Variation application fee – all classes	$1,289	Item 8
Class 2 biological - priority evaluation fee for inclusion in ARTG	$89,655	Item 4a
Class 2 biological – evaluation fee for inclusion in ARTG	$85,772	Item 4b
Class 2 biological – evaluation fee for variation to ARTG entry	$7,865	Item 9
Class 3 biological - priority evaluation fee for inclusion in ARTG	$179,752	Item 5a

Sponsoring biologicals	Fee	Part 2 of Schedule 9A
Class 3 biological – evaluation fee for inclusion in ARTG	$171,659	Item 5b
Class 4 biological - priority evaluation fee for inclusion in ARTG	$290,462	Item 6a
Class 4 biological – evaluation fee for inclusion in ARTG	$278,904	Item 6b
Class 3 or 4 biological – evaluation fee for major variation to ARTG entry	$40,683	Item 11
Class 3 or 4 biological – evaluation fee for minor variation to ARTG entry	$20,680	Item 10
Safety related variations – evaluation of application	$7,865	Item 8A

These fees are in Schedule 9A, *Therapeutic Goods Regulations 1990*
* The fees prescribed under subsection 32EE(2) of the Act will be further examined across the range of circumstances in relation to which such requests may be made.

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	$204,297	Item 7(5)(f)(i)
Blood and blood components (not HPCs) – a fixed (non-mobile) manufacturing site	$10,057	Item 7(5)(f)(ii)
HPCs manufacturing site	$8,798	Item 7(5)(g)
single step in the manufacture of a single human tissue at manufacturing premises covered by the licence	$8,798	Item 7(5)(h)
licence for 2 or more steps in the manufacture of human tissues at manufacturing premises covered by the licence	$17,206	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	$1,209	Item 8(b)
Blood and blood components (not HPCs) - Australian primary manufacturing site - inspection fee	$1,074/inspector/hour	Item 9AB
Blood and blood components (not HPCs) - Australian manufacturing site other than the primary site – inspection fee	$790/inspector/hour	Item 9AC
HPCs - Australian manufacturing site inspection fee	$790/inspector/hour	Item 9AA

Manufacturing fees	Fee	Clause 3 of Schedule 9
Human tissues that are not biologicals - Australian manufacturing site – inspection fee	$790/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	$1,560	Item 9AD(a)
11–50	$13,222	Item 9AD(b)
51–100	$29,833	Item 9AD(c)
101–1,000	$40,118	Item 9AD(d)
1001–3,000	$62,493	Item 9AD(e)
3001–4,000	$83,287	Item 9AD(f)
>4,000	$101,594	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.	$565	Item 1A(a)

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 two or more entries in the register.	$565 for the first entry, plus $113 for each additional entry	Item 1A(a) 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	$1,521	Item 7(4)(d)
Class III	$1,521	Item 7(4)(d)
Class IIb	$1,195	Item 7(4)(c)
Class IIa	$1,195	Item 7(4)(c)
Class I – sterile	$804	Item 7(4)(b)
Class I – measuring function	$804	Item 7(4)(b)
Class I – other	$111	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	$1,483	Item 1.5(b)
Class IIb	$1,150	Item 1.5(c)
Class IIa	$1,150	Item 1.5(d)
Class I – sterile	$602	Item 1.5(e)
Class I – measuring function	$602	Item 1.5(e)
Class I – other (excluding export only devices)	$602	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	$11,641	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	$4,554	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	$16,752	Item 1.14(a)
Level 2 – Level 1 activities, plus in-depth technical documentation review to determine compliance with Essential Principles – other medical devices (other than IVD medical devices	$4,188	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	$1,466	Item 2A(c)
Variation to an ARTG inclusion entry – Class 3 or Class 4 IVD	$1,832	Item 2A(d)
Variation to an ARTG inclusion entry – IVD not a Class 3 or Class 4 IVD	$1,047	Item 2A(e)
Variation to an ARTG inclusion entry – medical device that is not an IVD	$1,047	Item 2A(f)

Application type	Application fee	Part 2 of Schedule 9
Variation to an ARTG inclusion entry – medical device that is not an IVD	$199 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)	$16,752	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)	$4,188	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	$7,734	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	$23,439	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;	$23,439	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	$17,402	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	$23,439	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	$565 (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	$565 for the first entry, plus $113 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	$31 per ARTG entry or $31 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	$5,322	$86,903	Item 1.4A and Item 1.4D
Partial designation conformity assessment body determination (full QMS)	$2,926	$62,380	Item 1.4B and Item 1.4E
Partial designation conformity assessment body determination (partial QMS or partial devices)	$2,926	$62,380	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	$1,483	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	$11,065	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)	$33,516	Item 1.9(a)
Design examination (described in Schedule 3, Clause 1.6)	$65,850	Item 1.9(b)
Type examination (including management of testing, analysis, and reporting on examination of the type) (described in Schedule 3, Part 2)	$45,869	Item 1.9(c)

Type of conformity	Fee for initial assessment	Part 1 of Schedule 5
Verification (including management of testing, analysis, and reporting on verification tests) (described in Schedule 3, Part 3)	$32,119	Item 1.9(d)
Production quality management system (described in Schedule 3, Part 4)	$29,326	Item 1.9(e)
Product quality management system (described in Schedule 3, Part 5)	$25,030	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)	$20,196	Item 1.10(a)
Design examination (described in Schedule 3, Clause 1.6)	$39,746	Item 1.10(b)
Type examination (including management of testing, analysis, and reporting on examination of the type) (described in Schedule 3, Part 2)	$27,715	Item 1.10(c)
Production quality management system (described in Schedule 3, Part 4)	$17,402	Item 1.10(d)
Product quality management system (described in Schedule 3, Part 5)	$15,254	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	$496/hour/ assessor and/or auditor	Item 1.12

Assessment costs	Fee	Part 1 of Schedule 5
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 *Therapeutic Goods Regulation 1990*	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)	$9,733	Item 1.2(a)
Production quality management system surveillance audit (described in Schedule 3, Part 4)	$9,733	Item 1.2(a)
Product quality management system surveillance audit (described in Schedule 3, Part 5)	$9,733	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)	$59,511	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)	$45,869	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	$496/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	$204
Certified copy of quality systems certificate	$75

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)	$867	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	$1,209	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)	$1,150	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)	$11,641	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	$7,734	Item 1.14A(a)
Class 3 IVDs (other than Class 3 IVDs to which item 1.14AA applies)	$23,439	Item 1.14A(b)

Type of IVD	Assessment fee	Part 1 of Schedule 5
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	$23,439	Item 1.14A(c)
Class 4 IVDs that are immunohaematology reagent IVD medical devices	$17,402	Item 1.14A(d)
Class 3 IVD medical devices or Class 4 IVD medical devices (other than devices to which paragraph (d) of item 1.14A, or item 1.14C, applies), where the devices are not subject to laboratory testing as part of the auditing of the application	$14,865	Item 1.14AA
Class 4 in house IVD medical devices (other than a device to which item 1.14C applies)	$23,439	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	$1,483	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	$11,065	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	$33,623	Item 1.9A(a)
Design examination: described in Schedule 3, Clause 1.6	$71,650	Item 1.9A(b)
Design examination – immunohematology reagent: described in Schedule 3, Clause 1.6	$17,402	Item 1.9A(c)
Type examination: described in Schedule 3, Part 2	$46,299	Item 1.9A(e)
Production quality management system: described in Schedule 3, Part 4	$29,541	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	$33,623	Item 1.3A(a)
Design examination: described in Schedule 3, Clause 1.6	$71,650	Item 1.3A(b)
Design examination – immunohematology reagent: described in Schedule 3, Clause 1.6	$17,402	Item 1.3A(c)
Type examination: described in Schedule 3, Part 2	$46,299	Item 1.3A(e)
Production quality management system: described in Schedule 3, Part 4	$29,541	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]	$496/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	$9,786	Item 1.2(b)
Assessment of changes to IVD or QMS for applicable IVD – Full Quality Management System	$20,174	Item 1.10A(a)
Assessment of changes to IVD or QMS for applicable IVD – Design Examination	$42,990	Item 1.10A(b)
Assessment of changes to IVD or QMS for applicable IVD – Design Examination – Immunohaematology	$10,442	Item 1.10A(c)

Other assessment for IVD conformity assessment	Fee	Part 1 of Schedule 5
Assessment of changes to IVD or QMS for applicable IVD – Abridged Design Examination – previously registered IVD	$2,533	Item 1.10A(d)
Assessment of changes to IVD or QMS for applicable IVD – Type Examination	$27,780	Item 1.10A(e)
Assessment of changes to IVD or QMS for applicable IVD – Production QMS	$17,725	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	$1,078	Item 7(1)(c)(iii) and Item 7(2)(c)(iii)
Registered OTG: disinfectants	$2,085	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	$2,303	Clause 3 Item 3(a)
Variation fee	$1,466	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.	$565	Item 1A(a)
Where the application relates to two or more entries in the register.	$565 for the first entry, plus $113 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)	$429	Item 14(a)
Clinical trial notification (CTN) - for each notification of one or more additional trial sites	$429	Item 14(b)

Unapproved medicines	Fee	Clause 3 of Schedule 9
Clinical trial approval (CTA) - 30-day evaluation	$2,046	Item 1(a)
Variation – Medicines Clinical trial approval (CTA) - 30-day evaluation	$562	Item 1AAA(a)
Clinical trial approval (CTA) - 50-day evaluation	$25,426	Item 1(b)
Variation – Medicines Clinical trial approval (CTA) - 50-day evaluation	$6,940	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)	$429	Item 17(a)
Clinical trial notification (CTN) – for each notification of one or more additional trial sites	$429	Item 17(b)
Clinical trial approval (CTA)	$30,964	Item 16
Variation – Biologicals Clinical trial approval (CTA)	$8,448	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)	$429	Item 1.8a
Clinical trial notification (CTN) – for each notification of one or more additional trial sites	$429	Item1.8b
Clinical trial approval (CTA)	$21,697	Item 1.7

Unapproved medical devices (including IVD)	Fee	Part 1 of Schedule 5
Variation – Medical Devices Clinical trial approval (CTA)	$5,922	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	$496	Item 3AB(a)
If the declaration relates to 6 or more entries in the ARTG	$496 for first 5 entries, plus $57 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	$181	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	$181 for first entry, plus $57 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*

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication for the financial year 1 July 2024 to 30 June 2025	Regulatory Engagement Branch	June 2024
V2.0	Publication to include fees and charges commencing 1 January 2025	Regulatory Engagement Branch	December 2024

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

Reference/Publication #