Australian Government
Department of Health
Therapeutic Goods Administration

Fees and charges: summary

From 1 July 2017

Version 1.0, June 2017

TGA Health Safety Regulation

Contents

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 imposed on the 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 is a summary of fees and charges, which are in the Australian therapeutic goods legislation. For a complete list of all fees and charges and the exact legislative wording, please refer directly to the legislation.

Prescription medicines

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

For clinical trials supplying unapproved medicines, go to Clinical trials.

Annual charges

These charges are in the *Therapeutic Goods (Charges) Regulations 1990*.

Type of prescription medicine	Charge	Regulation
Biological medicine	$6,990	3(1)(b) and 3(1A)(b)
Non-biological medicine (chemical entity) – higher amount	$3,980	4(9)
Non-biological medicine (chemical entity) – lower amount	$3,230	4(9)

More about annual charges for chemical entities

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.

Higher annual charges

Regulation 4 of the *Therapeutic Goods (Charges) Regulations 1990* states when the higher annual charge applies for prescription medicine chemical entities.

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

1. for medicines containing at least one specified active ingredient, whatever the duration of registration:
   - 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.

Prescription medicine application and evaluation fees

These applications have both an application fee and an evaluation fee. These fees are in Schedule 9, *Therapeutic Goods Regulations 1990*.

Prescription medicine application type	Application fee	Evaluation fee	Item in Schedule 9, Part 2
New chemical entity	$46,900	$188,200	Items 2(ba) and 4(a)
Extension of indications	$28,000	$111,700	Items 2(bd) and 4(b)
Major variations	$18,300	$72,800	Items 2(bi) and 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)	$1,080	$4,280	Items 2(bj) and 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.	$1,080	$4,280	Items 2AC and 2C
Additional trade name	$2,960	$11,900	Items 2(bh) and 4(d)
New generic product	$18,100	$71,800	Items 2(bg) and 4(c)

Prescription medicine application type	Application fee	Evaluation fee	Item in 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	$1,080	$4,270	Items 2(bk) and 4(bc)

n/a: not applicable; 'The Act' refers to the *Therapeutic Goods Act 1989*.

Requests with single fee

These requests have a single fee, instead of an application fee and an evaluation fee. These fees are in Schedule 9, *Therapeutic Goods Regulations 1990*.

Prescription medicine request	Fee	Item in 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.	$5,360	Item 2B
Minor editorial changes: variations to an ARTG entry (requiring changes to Product Information) with no evaluation of data	$1,650	Item 2A(a)
Correction to an ARTG entry	$1,650	Item 2A(a)
Self-assessable request with no evaluation of data	$1,650	Item 2A(a)
Safety-related request with no evaluation of data	$1,650	Item 2A(a)
Safety-related request with evaluation of data	$5,360	Item 2CA
Request for advice in relation to a prescription medicine for the purpose of listing the medicine as a pharmaceutical benefit	$2,170	Item 18
Application fee for registration applications under paragraph 23(2)(a) of the Act made within 30 days of cancellation from the ARTG, when cancellation of registration was due to failure to pay the annual charge	$660	Item 2AA

Prescription medicine request	Fee	Item in 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.	$460	Item 1A

'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. Items refer to Schedule 9, *Therapeutic Goods Regulations 1990*.

Application type	Application fee	Evaluation fee	Item in Schedule 9, Part 2
New chemical entity of a medicine used as an ancillary medical component of a device	$15,600	$62,800	Items 2(bb), 4(aa)(i), 4(aa)(ii)
New chemical entity of a medicine used as an ancillary medical component of a device	$31,300	$125,200	Items 2(bc), 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	$9,310	$37,200	Items 2(be)(i), 4(bb)(i)(a), 4(bb)(ii)(a)
Extension of indications of a medicine used as an ancillary medical component of a device – chemistry, quality control and manufacturing AND nonclinical studies	$18,700	$74,400	Items 2(bf)(i), 4(bb)(iii)(a)
Major variation of a medicine used as an ancillary medical component of a device – chemistry, quality control and manufacturing OR nonclinical studies	$6,070	$24,100	Items 2(be)(ii), 4(bb)(i)(b), 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	$12,200	$48,700	Items 2(bf)(ii), 4(bb)(iii)(b)

Non-prescription medicines

Non-prescription medicines include complementary medicines, sunscreens and over-the-counter (OTC) medicines.

For clinical trials supplying unapproved non-prescription medicines, go to Clinical trials.

Listed medicines

Listed medicines include listed complementary medicines and sunscreens.

For listed export-only medicines go to Export.

Listed medicine fee or charge	Amount	Legislation
Annual charge	$1,020	*Therapeutic Goods (Charges) Regulations 1990*, regulations 3(1)(c)(i) and 3(1A)(c)(i)
Application fee	$800	*Therapeutic Goods Regulations 1990*, Schedule 9, Part 2, Item 3(b)
Processing fee (variation to an existing listing)	$410	*Therapeutic Goods Regulations 1990*, Schedule 9, Part 2, Item 2A(c)
Listing fee for applications made under paragraph 23(2)(a) of the Act within 30 days of cancellation from the ARTG, when cancellation was due to failure to pay the annual charge	$660	*Therapeutic Goods Regulations 1990*, Schedule 9, Part 2, Item 3AA

'The Act' refers to the *Therapeutic Goods Act 1989*.

New substances

There is no application fee for a new substance.

The evaluation fees below apply to:

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

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

Pages of nonclinical and clinical data	Evaluation fee	Item in Schedule 9 Part 2
0-50	$10,300	Items 7A(a), 7A(b)(i), 7B(a), 7B(b)(i)
51-250	$13,200	Items 7A(b)(ii), 7B(b)(ii)
251-500	$18,100	Items 7A(b)(iii), 7B(b)(iii)
501-1000	$23,900	Items 7A(b)(iv), 7B(b)(iv)
1001-2000	$35,900	Items 7A(b)(v), 7B(b)(v)
2001-3000	$47,900	Items 7A(b)(vi), 7B(b)(vi)
>3000	$71,800	Items 7A(b)(vii), 7B(b)(vii)

Registered complementary medicines

Refer to the Australian Regulatory Guidelines for Complementary Medicines (ARGCM) for information on the data package required for an application for a registered complementary medicine.

Charges and application and processing fees

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

Type of fee or charge	Amount	*Therapeutic Goods Regulations 1990*
Annual charge	$1,430	Regulation 3(1)(a)(i)
Application fee	$1,530	Schedule 9 Part 2 Item 2(a)
Additional or concurrent application fee	$680	Schedule 9 Part 2 Item 2(f)
Processing fee for variation	$1,530	Schedule 9 Part 2 Item 2A(b)

Evaluation fees for registered complementary medicines

These evaluation fees are for registered complementary medicines. These fees are in Schedule 9, *Therapeutic Goods Regulations 1990*.

Pages of nonclinical and clinical data	Evaluation fee	Item in Schedule 9 Part 2
0-50 pages for a new product	$10,300	Items 5(a) and 5(b)(i)
0-50 pages for a variation under section 9D(1), 9D(2) or 9D(3) of the *Therapeutic Goods Act 1989*	$3,710	Items 5(c) and 5(d)(i)
51-250	$13,200	Items 5(b)(ii) and 5(d)(ii)
251-500	$18,100	Items 5(b)(iii) and 5(d)(iii)
501-1000	$23,900	Items 5(b)(iv) and 5(d)(iv)
1001-2000	$35,900	Items 5(b)(v) and 5(d)(v)
2001-3000	$47,900	Items 5(b)(vi) and 5(d)(vi)
>3000	$71,800	Items 5(b)(vii) and 5(d)(vii)

Registered OTC medicines

For guidance on OTC applications, go to Australian regulatory guidelines for OTC medicines.

Annual charges

These charges are in the *Therapeutic Goods (Charges) Regulations 1990*.

Medicine type	Charge	Regulation
Registered OTC medicine	$1,430	Regulations 3(1)(a)(i) and 3(1A)(a)(i)

New registered OTC medicine applications

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

For information on application types, go to OTC application categorisation framework.

Application type	Application fee	Evaluation fee	Item in Schedule 9 Part 3
N1 application	$1,590	$3,930	Items 1(a) and 2(a)
N1 concurrent application per additional application (as described in item 3, Part 3, Schedule 9 of the Regulations)	$790	$3,930	Items 3(d) and 2(a)
N2 application	$1,590	$5,570	Items 1(b) and 2(b)
N2 concurrent application per additional application (as described in item 3 of Part 3 Schedule 9 of the Regulations)	$790	$5,570	Items 3(e) and 2(b)
N3 application	$2,550	$8,590	Items 1(c) and 2(c)
N3 concurrent application per additional application (as described in item 3 and 4 of Part 3 Schedule 9 of the Regulations)	$1,280	$4,350	Item 3(f) and 4(d)
N4 application	$3,720	$14,200	Items 1(d)and 2(d)
N4 concurrent application per additional application (as described in item 3 and 4 of Part 3 Schedule 9 of the Regulations)	$1,280	$4,350	Items 3(g)and 4(e)
N5 application	$5,520	$21,100	Items 1(e) and 2(e)
N5 concurrent application per additional application (as described in item 3 and 4 of Part 3 Schedule 9 of the Regulations)	$1,280	$4,350	Items 3(h) and 4(f)

Changes: applications under section 23

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.

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

For information on application types, go to OTC application categorisation framework.

Application type	Application fee	Evaluation fee	Item in Schedule 9 Part 3
C1 (section 23) application	$1,590	n/a	Item 1(f)
C2 (section 23) application	$1,590	$3,930	Items 1(g) and 2(f)
C3 (section 23) application	$1,590	$6,580	Items 1(h) and 2(g)
C4 (section 23) application	$2,550	$8,590	Items 1(i) and 2(h)

n/a: not applicable

Changes: applications under section 9D

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.

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

For information on application types, go to OTC application categorisation framework.

Application type	Fee	Refund if no evaluation	*Therapeutic Goods Regulations 1990*
C1 (section 9D) application	$1,590	n/a	Schedule 9 Part 3 Item 5
C2 (section 9D) application	$5,520	$3,930	Schedule 9 Part 3 Item 6(a) Regulation 43AC (2)(a)
C3 (section 9D) application	$8,170	$6,580	Schedule 9 Part 3 Item 6(b) Regulation 43AC (2)(b)
C4 (section 9D) application	$11,140	$8,590	Schedule 9 Part 3 Item 6(c) Regulation 43AC (2)(c)

n/a: not applicable

Requests with single fee

These requests have a single fee, instead of an application fee and an evaluation fee. These fees are in Schedule 9, *Therapeutic Goods Regulations 1990*.

Registered OTC medicine request	Fee	Item in 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	$1,560	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	$7,990	Item 7(b)

Manufacturing medicines and OTGs

The section applies to the manufacture of:

- all medicines
- other listed and registered therapeutic goods (OTGs).

Annual charges: manufacturing licences

These charges are in the *Therapeutic Goods (Charges) Regulations 1990*.

Annual charges for manufacturing licences	Charge	*Therapeutic Goods (Charges) Regulations 1990*
Low level manufacturing licence charge	$6,260	Regulation 3(2)(c-h)
High level manufacturing licence charge	$12,200	Regulation 3(2)(a)(b)

Only one charge applies and that is the greatest applicable charge [regulation 3(3) *Therapeutic Goods (Charges) Regulations 1990*].

Manufacturing inspections

Australian manufacturing licences

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

Fess related to Australian manufacturing licences	Fee	Item in Schedule 9 Part 2
Australian manufacturing sites – application fee for a manufacturing licence	$1,000	Item 8
Australian manufacturing sites – inspection fee	$660/hour/inspector	Item 9(a)

Overseas manufacturing site inspections

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

Overseas manufacturing site inspections	Fee
Overseas manufacturing sites – inspection fee	$1,330/hour/inspector
Inspection fees to cover costs and reasonable expenses by each inspector, including costs for accommodation and allowance outside Australia	costs and reasonable expenses

GMP clearance fees

There is no application fee for GMP clearance. These fees are in Schedule 9, *Therapeutic Goods Regulations 1990*.

GMP clearance of overseas manufacturers	Fee	Item in Schedule 9 Part 2
GMP clearance application processing fee (per manufacturer, per site, per sponsor)	$390	Item 6AA
Obtaining evidence from an overseas regulatory authority (per manufacturer, per site, per sponsor)	$680	Item 6AB
Compliance verification (in lieu of an overseas GMP inspection)	$2,030	Item 6ABA
Reinstatement of expired GMP clearance approval (per manufacturer, per site, per sponsor) – in addition to relevant fees above	$1,140	Item 6AC

Issuing manufacturing certificates

Certificate	Fee
Certificate of GMP compliance	$170
Mutual Recognition Agreement certificate	$320
Certified copy of: • original GMP certificate • certificate of GMP compliance	$60

Export

The *Therapeutic Goods Act 1989* applies to both the supply of therapeutic goods in Australia and the export of therapeutic goods from Australia.

Medicine export certificates

You can apply for an export certificate for any medicine. These fees are in Schedule 9, *Therapeutic Goods Regulations 1990*.

Certificate type	Fee	Item in Schedule 9 Part 2
Certificate of pharmaceutical product	$170	Item 10
Certificate of listed product	$170	Item 10
Certificate of exempt product	$170	Item 10

Listed export-only medicines

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

Export only applications	Fee	Item in Schedule 9 Part 2
Application fee	$800	Item 3(b)
Processing fee (variation to an existing listing)	$410	Item 2A(c)

Device export certificates

You can apply for an export certificate for a medical device (including IVD devices) or OTG. These fees are in Schedule 9, *Therapeutic Goods Regulations 1990*.

Certificate type	Fee	Item in Schedule 9 Part 2
Certificate of free sale	$170	Item 10
Export certificate	$170	Item 10

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.

Manufacturing biologicals: annual charges

There is no annual charge for a manufacturer who only manufactures biologicals [regulation 3(2)(m) *Therapeutic Goods (Charges) Regulations 1990*].

Manufacturing biologicals: fees

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

Manufacturing biologicals	Fee	Item in Schedule 9A Part 2
Australian manufacturing sites – application fee for a manufacturing licence	$1,070	Item 3
Initial manufacturing audit – inspection fee for Australian and overseas manufacturing sites	$21,100	Item 12
Subsequent manufacturing audit – inspection fee for Australian and overseas manufacturing sites	$16,000	Item 13
Inspection fee for each hour of preparation by each inspector for an inspection conducted outside Australia	$660/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

Sponsoring biologicals: annual charges

These charges are in the *Therapeutic Goods (Charges) Regulations 1990*.

ARTG inclusion of biologicals	Amount	Therapeutic Goods (Charges) Regulations
Class 1 biological annual charge for ARTG inclusion	$660	Regulation 3(1AA)(a)
Class 2, 3, 4 biological annual charge for ARTG inclusion	$6,500	Regulation 3(1AA)(b)

Sponsoring biologicals: fees

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

Sponsoring biologicals	Fee	Item in Schedule 9A Part 2
Ingredient or component of a biological to be evaluated under regulation 16GF - evaluation fee	$23,000	Item 7
Class 1 biological – application fee for inclusion in ARTG	$1,070	Item 1
Class 2, 3, 4 biological – application fee for inclusion in ARTG	$1,070	Item 2
Variation application fee – all classes	$1,070	Item 8
Class 2 biological – evaluation fee for inclusion in ARTG	$70,900	Item 4
Class 2 biological – evaluation fee for variation to ARTG entry	$6,500	Item 9
Class 3 biological – evaluation fee for inclusion in ARTG	$141,700	Item 5
Class 4 biological – evaluation fee for inclusion in ARTG	$230,300	Item 6
Class 3 or 4 biological – evaluation fee for major variation to ARTG entry	$33,600	Item 11
Class 3 or 4 biological – evaluation fee for minor variation to ARTG entry	$17,100	Item 10
Safety related variations – evaluation of application under section 9D(3AA)	$6,500	Item 8A

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

These charges are in the *Therapeutic Goods (Charges) Regulations 1990*.

Therapeutic good being manufactured	Charge	*Therapeutic Goods (Charges) Regulations 1990*
Blood and blood components (not HPCs) – primary manufacturing site	$157,300	Regulation 3(2)(j)(i)
Blood and blood components (not HPCs) – a fixed (non-mobile) manufacturing site	$7,740	Regulation 3(2)(j)(ii)
HPCs manufacturing site	$6,770	Regulation 3(2)(ja)

Only one charge applies and that is the greatest applicable charge [regulation 3(3) *Therapeutic Goods (Charges) Regulations 1990*].

Manufacturing fees

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

Manufacturing fees	Fee	Item in Schedule 9 Part 2
Australian manufacturing sites – application fee for a manufacturing licence	$1,000	Item 8
Blood and blood components (not HPCs) - Australian primary manufacturing site - inspection fee	$880/hour/inspector	Item 9AB
Blood and blood components (not HPCs) - Australian manufacturing site other than the primary site – inspection fee	$660/hour/inspector	Item 9AC
HPCs - Australian manufacturing site inspection fee	$660/hour/inspector	Item 9AA
Human tissues that are not biologicals - Australian manufacturing site – inspection fee	$660/hour/inspector	Item 9ACA

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

Pages	Fee	Item in Schedule 9 Part 2
1–10	$1,290	Item 9AD(a)
11–50	$11,000	Item 9AD(b)
51–100	$24,600	Item 9AD(c)
101–1000	$33,100	Item 9AD(d)
1001–3000	$51,600	Item 9AD(e)
3001–4000	$68,800	Item 9AD(f)
>4000	$83,900	Item 9AD(g)

Miscellaneous fees

This fee in Schedule 9, *Therapeutic Goods Regulations 1990* applies, to human blood, blood components and HPCs and human tissues not regulated as biologicals.

Application type	Fee	Item in 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.	$460	Item 1A

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 in the *Therapeutic Goods (Charges) Regulations 1990*.

Class of medical device	Charge	*Therapeutic Goods (Charges) Regulations 1990*
AIMD	$1,140	Regulation 3(1B)(d)
Class III	$1,140	Regulation 3(1B)(d)
Class IIb	$880	Regulation 3(1B)(c)
Class IIa	$880	Regulation 3(1B)(c)
Class I - sterile	$610	Regulation 3(1B)(b)
Class I – measuring function	$610	Regulation3(1B)(b)
Class I - other	$80	Regulation3(1B)(a)

Application fees

These fees are to apply to include a medical device in the ARTG. Application audit assessment fees are often payable as well. These fees are in the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Class of medical device	Application fee	Item in Schedule 5 Part 1
AIMD	$1,290	Item 1.5(a)
Class III	1,290	Item 1.5(b)
Class IIb	$1,000	Item 1.5(c)

Class of medical device	Application fee	Item in Schedule 5 Part 1
Class IIa	$1,000	Item 1.5(d)
Class I - sterile	$1,000	Item 1.5(e)
Class I – measuring function	$1,000	Item 1.5(e)
Class I - other	n/a	n/a

n/a: not applicable

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

Type of application audit	Assessment fee	Item in Schedule 5 Part 1
Level 1 – verification of sponsor's application and evidence of conformity	$3,760	Item 1.13
Level 2 – Level 1 activities plus review of evidence of conformity	$6,900	Item 1.14

Variation fees

These fees are in Schedule 9, *Therapeutic Goods Regulations 1990*. For guidance on variations go to Varying entries in the ARTG – medical devices and IVDs.

Application type	Application fee	Item in Schedule 9 Part 2
Variation to an ARTG inclusion entry	$440	Item 2A(g)

Miscellaneous

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

Type of application	Fee	Item in Schedule 5 Part 1
Application for consent of Secretary to importation into Australia, supply for use in Australia, or exportation from Australia of a medical device that does not conform to the essential principles	$440	Item 1.15
Considering submissions to the Secretary in relation to a proposed suspension of a kind of medical device from the ARTG	$6,900	Item 1.6

Manufacturing medical devices

Information about conformity assessment is in Part 1, Australian regulatory guidelines for medical devices. Fees are in *Therapeutic Goods (Medical Devices) Regulations 2002*.

Application for conformity assessment

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

All conformity assessment procedures	Fee	Item in Schedule 5 Part 1
Application fee	$980	Item 1.1

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* and the fees are in Schedule 5.

Type of conformity	Fee for initial assessment	Item in Schedule 5 Part 1
Full quality management system inspection: Schedule 3, Part 1	$29,100	Item 1.9(a)
Design examination: Schedule 3, Clause 1.6	$57,200	Item 1.9(b)
Type examination (including management of testing, analysis, and reporting on examination of the type): Schedule 3, Part 2	$39,900	Item 1.9(c)
Verification (including management of testing, analysis, and reporting on verification tests): Schedule 3, Part 3	$27,900	Item 1.9(d)
Production quality management system inspection: Schedule 3, Part 4	$25,500	Item 1.9(e)

Type of conformity	Fee for initial assessment	Item in Schedule 5 Part 1
Product quality management system inspection: Schedule 3, Part 5	$21,800	Item 1.9(f)

Changes to conformity assessment

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

Type of conformity	Fee for change	Item in Schedule 5 Part 1
Full quality management system inspection: Schedule 3, Part 1	$17,500	Item 1.10(a)
Design examination: Schedule 3, Clause 1.6	$34,500	Item 1.10(b)
Type examination (including management of testing, analysis, and reporting on examination of the type): Schedule 3, Part 2	$24,000	Item 1.10(c)
Production quality management system inspection: Schedule 3, Part 4	$15,100	Item 1.10(d)
Product quality management system inspection: Schedule 3, Part 5	$13,200	Item 1.10(e)

Surveillance inspections - conformity assessment

Conformity assessment procedures are legislated in Schedule 3, *Therapeutic Goods (Medical Devices) Regulations 2002* and the fees are in Schedule 5.

Type of surveillance inspection	Fee	Item in Schedule 5 Part 1
Full quality management system surveillance inspection: Schedule 3, Part 1	$8,460	Item 1.2(a)
Production quality management system surveillance inspection: Schedule 3, Part 4	$8,460	Item 1.2(a)
Product quality management system surveillance inspection: Schedule 3, Part 5	$8,460	Item 1.2(a)

Review of certificate of conformity assessment

Conformity assessment procedures are legislated in Schedule 3, *Therapeutic Goods (Medical Devices) Regulations 2002* and the fees are in Schedule 5.

Type of certificate being reviewed	Fee	Item in Schedule 5 Part 1
Design examination re-assessment: Schedule 3, Clause 1.6	$51,700	Item 1.3(a)
Type examination re-assessment (including management of testing, analysis, and reporting on examination of the type): Schedule 3, Part 2	$39,900	Item 1.3(b)

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.

Conformity assessment fees are in Schedule 5, *Therapeutic Goods (Medical Devices) Regulations 2002*.

Inspection costs	Fee	Paragraph in 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	$410/assessor hour	Paragraph 2.1(b)
Costs and reasonable expenses of travel by each assessor involved, including travel both in and outside Australia	costs and reasonable expenses	Paragraph 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	Paragraph 2.2

Issuing quality systems certificates

Certificate	Fee
Quality systems certificate	$170
Certified copy of quality systems certificate	$60

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

These charges are in the *Therapeutic Goods (Charges) Regulations 1990*.

Class of IVD	Charge	Regulation
All classes of IVD excluding Class 4 in-house IVDs	$660	3(1B)(e)
Class 4 in-house IVDs	n/a	3(1B)(f)

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.

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

Class of IVD	Notification fee	Item in Schedule 5 Part 1
Notification by a laboratory of its Class 1, Class 2 or Class 3 in-house IVDs	$1,000	Item 1.17

Application fees

These fees are to apply to include an IVD in the ARTG. Application audit assessment fees are often payable as well. These fees are in the *Therapeutic Goods (Medical Devices) Regulations 2002* and *Therapeutic Goods Regulations 1990*.

For guidance on variations go to Varying entries in the ARTG – medical devices and IVDs.

Application	Application fee	Item in Schedule 5 Part 1
Application for inclusion into the ARTG of all classes of IVD, including Class 4 in-house IVDs	$1,000	Item 1.5(f), Schedule 5 Part 1 *Therapeutic Goods (Medical Devices) Regulations 2002*
Variation to an ARTG inclusion entry	$440	Item 2A(g) Schedule 9 Part 2 *Therapeutic Goods Regulations 1990*

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.

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

Type of IVD	Assessment fee	Item in Schedule 5 Part 1
Class 1, Class 2 and Class 3 IVDs	$6,720	Item 1.14A
Class 4 in-house IVDs	$62,200	Item 1.14B
Class 4 in-house immunohaematology reagent IVD	$15,100	Item 1.14C

Manufacturing IVDs

Application for conformity assessment

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

All conformity assessment procedures	Fee	Item in Schedule 5 Part 1
Application fee	$980	Item 1.1

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* and the fees are in Schedule 5.

Type of conformity	Fee	Item in Schedule 5 Part 1
Full quality management system inspection: Schedule 3, Part 1	$29,200	Item 1.9A(a)
Design examination: Schedule 3, Clause 1.6	$62,200	Item 1.9A(b)
Design examination – immunohaematology reagent: Schedule 3, Clause 1.6	$15,100	Item 1.9A(c)
Type examination: Schedule 3, Part 2	$40,300	Item 1.9A(e)
Production quality management system inspection: Schedule 3, Part 4	$25,700	Item 1.9A(f)

Review of certificate of conformity assessment

Conformity assessment procedures are legislated in Schedule 3, *Therapeutic Goods (Medical Devices) Regulations 2002* and the fees are in Schedule 5.

Type of certificate being reviewed	Fee	Item in Schedule 5 Part 1
Full quality management system inspection: Schedule 3, Part 1	$29,200	Item 1.3A(a)
Design examination: Schedule 3, Clause 1.6	$62,200	Item 1.3A(b)
Design examination – immunohaematology reagent: Schedule 3, Clause 1.6	$15,100	Item 1.3A(c)
Type examination: Schedule 3, Part 2	$40,300	Item 1.3A(e)
Production quality management system inspection: Schedule 3, Part 4	$25,700	Item 1.3A(f)

Other IVD conformity assessment fees

Conformity assessment fees are in Schedule 5, *Therapeutic Goods (Medical Devices) Regulations 2002*.

Other assessment for IVD conformity assessment	Fee	Item or paragraph in 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]	$410/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	Paragraph 2.1(a)
Surveillance assessment for conformity assessment certificate under Schedule 3, Part 1 or 4	$8,510	Item 1.2(b)
Assessment of changes to IVD or QMS for applicable IVD	$17,500	Item 1.10A
Considering a submission to the Secretary in relation to a proposed suspension of a conformity assessment certificate	$6,720	Item 1.14A

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 either a definition of a medical device or 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
- For clinical trials involving unapproved OTGs, go to Clinical trials.

Annual charges

These charges are in the *Therapeutic Goods (Charges) Regulations 1990*.

Type of OTG	Charge	Regulation
Listed OTG: tampons and disinfectants	$820	Regulation 3(1)(c)(iii) Regulation 3(1A)(c)(iii)
Registered OTG - disinfectants	$1,610	Regulation 3(1)(a)(iii) Regulation 3(1A)(a)(iii)

Listed OTG fees

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

Listed OTG fees	Fee	Item in Schedule 9 Part 2
Application fee	$440	Item 3(a)
Variation fee	$440	Item 2A(f)
Fee for evaluating documents and information relating to the safety of a listed therapeutic device	$17,900	Item 9C

Registered OTG fees

These fees are in *Therapeutic Goods Regulations 1990*.

Registered OTG fee type	Fee	Item in Schedule 9 Part 2 OR, the regulation
Low level registered device – application fee	$1,430	Item 2(b),(g)
Low level registered device – disinfectant initial evaluation fee	$17,900	Item 5B
Low level registered device – variation processing fee	$440	Item 2A(d)
Low level registered device – disinfectant variation initial evaluation fee	$3,590	Item 6B
Clinical trial notification (CTN)	$350	Item 14A
High level registered device – application fee	$4,270	Item 2(c)
High level registered device – variation processing fee	$440	Item 2A(e)
High level device – variation manufacturing and/or quality control – initial evaluation	$8,910	Item 7(b)
High level registered device – variation manufacturing and/or quality control – concurrent evaluation	$1,960	Regulation 45(11)(a-e)

Miscellaneous fees

This fee is in Schedule 9, *Therapeutic Goods Regulations 1990*.

Application type	Fee	Item in 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.	$460	Item 1A

Clinical trials

The Clinical Trial Notification (CTN) and Clinical Trial Exemption (CTX) schemes provide two avenues for conducting clinical trials involving the use of unapproved therapeutic goods.

Unapproved medicines

These fees for clinical trials of unapproved medicines are in Part 2, Schedule 9, *Therapeutic Goods Regulations 1990*.

Unapproved medicines	Fee	Item in Schedule 9 Part 2
Clinical trial notification (CTN)	$350	Item 14(a)
Change or transfer of clinical trial sponsor of a CTN already notified by another clinical trial sponsor	$350	Item 14(a)
Clinical trial notification (CTN) - for each notification of one or more additional trial sites	$350	Item 14(b)
Clinical trial exemption (CTX) - 30 day evaluation	$1,690	Item 1(a)
Clinical trial exemption (CTX) - 50 day evaluation	$21,100	Item 1(b)

Unapproved Biologicals

These fees for clinical trials of unapproved biologicals are in Part 2, Schedule 9A, *Therapeutic Goods Regulations 1990*.

Biologicals	Fee	Item in Schedule 9A Part 2
Clinical trial notification (CTN)	$350	Item 17(a)
Change or transfer of clinical trial sponsor of a CTN already notified by another clinical trial sponsor	$350	Item 17(a)
Clinical trial notification (CTN) – for each notification of one or more additional trial sites	$350	Item 17(b)
Clinical trial exemption (CTX)	$25,600	Item 16

Unapproved medical devices (including IVDs)

These fees for clinical trials of unapproved medical devices and IVDs are in the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Unapproved medical devices (including IVD)	Fee	Item in Schedule 5 Part 1
Clinical trial notification (CTN)	$350	Item 1.8
Change or transfer of clinical trial sponsor of a CTN already notified by another clinical trial sponsor	$350	Item 1.8
Clinical trial exemption (CTX)	$17,900	Item 1.7

Unapproved other therapeutic goods

These fees for clinical trials of unapproved other therapeutic goods are in Part 2, Schedule 9, *Therapeutic Goods Regulations 1990*.

Unapproved other therapeutic goods	Fee	Item in Schedule 9 Part 2
Clinical trial notification (CTN)	$350	Item 14A(a)
Change or transfer of clinical trial sponsor of a CTN already notified by another clinical trial sponsor	$350	Item 14A(a)
Clinical trial notification (CTN) – for each notification of one or more additional trial sites	$350	Item 14A(b)
Clinical trial exemption (CTX) - with no clinical studies to demonstrate safety and effectiveness	$2,690	Item 1(d)
Clinical trial exemption (CTX) - with clinical studies to demonstrate safety and effectiveness	$17,900	Item 1(c)

Advertising

The fees for an application for pre-approval of an advertisement for therapeutic goods under Regulation 5F of the *Therapeutic Goods Regulations 1990* are set out in items 17 and 17A in Schedule 9 of the regulations. Each approved advertisement is given an approval number on the date of approval. The approval number expires two years from the date it is given under regulation 5J.

The fee includes up to one hour of processing time for each application. Any additional time beyond one hour is charged at the rate of $205/hour or part of an hour for those advertisements marked (*) in the tables below.

Specified media excluding broadcast media

'Specified media' is defined in section 42B of the *Therapeutic Goods Act 1989*. Fees are in in Schedule 9, *Therapeutic Goods Regulations 1990*.

Type of advertisement in specified media	Fee	Item in Schedule 9 Part 2
Advertisement* intended for publication in the classified advertisements column of a newspaper or other printed publication	$120	Item 17 (a)(iv)
Advertisement* of 100 words or less	$240	Item 17 (a)(i)
Advertisement* of more than 100 words but of 300 words or less	$290	Item 17 (a)(ii)
Advertisement* of more than 300 words (including an advertorial)	$460	Item 17 (a)(iii)
Moving cinema advertisement* of 150 seconds or less in length, with up to 3 variations of the advertising concept, for the same product.	$1,170	Item 17A (a)(i)
Still cinema advertisement* (including outdoor media) of 100 words or less	$240	Item 17A(a)(vi)(A)
Still cinema advertisement* (including outdoor media) of more than100 words but of 300 words or less	$290	Item 17A(a)(vi)(B)
Still cinema advertisement* (including outdoor media) of more than 300 words.	$460	Item 17A(a)(vi)(C)
Still cinema advertisement* (including outdoor media) for a minor change to an approved advertisement sought more than 3 months after the date the approval number was given. (There is no charge when sought 3 months or less.)	50% of applicable fee	Item 17A(c)

Type of advertisement in specified media	Fee	Item in Schedule 9 Part 2
Advertisement that is a minor change to an approved advertisement sought more than 3 months after the date the approval number was given. (There is no charge when sought 3 months or less)	$120	Item 17(c)
Advertisement* for re-approval of an identical advertisement whose approval number has expired	50% of applicable fee	Item 17(d)
Advertisement* for approval of a variation to an advertisement whose approval number has not expired.	50% of applicable fee	Item 17(e)
Each additional hour or part thereof after the first processing hour, in addition to the specified fee for the advertisements marked with an asterisk (*) in this table.	$210	Item 17(b)

* Any additional time beyond one hour is charged at the rate of $205/hour

Broadcast media

'Broadcast media' is defined in section 42B of the *Therapeutic Goods Act 1989*.

Certain broadcast media, for example the internet and certain mobile communications, are excluded from this definition for pre-approval of advertisements for therapeutic goods, by Regulation 5BA, *Therapeutic Goods Regulations 1990*. Fees are in Schedule 9 to the *Therapeutic Goods Regulations 1990*.

The term "commercial" and "advertorial" can be used in place of "advertisement" in relation to broadcast media.

Type of advertisement in broadcast media	Fee	Item in Schedule 9 Part 2
Television advertisement* of 150 seconds or less in length with up to 3 variations of the advertising concept for the same product	$1,170	Item 17A (a)(i)
Television advertisement* for a retail outlet that is intended to be broadcast on 1 regional station only in that station's regional area	$620	Item 17A (a)(ii)
Television advertorial* greater than 150 seconds in length	$880 for first minute of script $250 for each additional minute or part minute	Item 17A (a)(iii) (A)(B)

Type of advertisement in broadcast media	Fee	Item in Schedule 9 Part 2
Radio Advertisement* including up to 6 variations of the advertising concept for the same product	$430	Item 17A (a)(iv)
Radio Advertisement* that is intended to be broadcast in a regional area only including up to six variations of the advertising concept for the same product	$300	Item 17A (a)(v)
Advertisement* that is a minor change to an approved advertisement sought more than 3 months after the date of approval. (There is no charge when sought 3 months or less.)	50% of applicable fee	Item 17A (c)
Advertisement* requiring re-approval of an identical advertisement whose approval number has expired.	50% of applicable fee	Item 17A (d)
Advertisement* requiring approval of a variation to an advertisement whose approval number has not expired	50% of applicable fee	Item 17A (e)
Each additional hour or part thereof after the first processing hour, in addition to the specified fee for the advertisements marked with an asterisk (*) in this table.	$210	Item 17A (b)

* Any additional time beyond one hour is charged at the rate of $205/hour

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 need to occur as a result 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 charges 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 declarations made before 15 September under regulation 43AAE(2) of the *Therapeutic Goods Regulations 1990* attract a late declaration fee.

Number of ARTG entries	Late declaration fee	Item in schedule of *Therapeutic Goods Regulations 1990*
If the declaration relates to not more than 5 entries in the ARTG	$410	Schedule 9 Part 2 Item 3AB (a) Schedule 9A Part 2 Item 3A (a)
If the declaration relates to 6 or more entries in the ARTG	$410 for first 5 entries + $50 for each additional entry	Schedule 9 Part 2 Item 3AB (b) Schedule 9A Part 2 Item 3A (b)

Fees related to a request to revoke an ARTG entry cancellation

There are fees for the revocation of the voluntary cancellation of an ARTG entry by the sponsor.

Number of ARTG entries	Fee for revocation of cancellation	Legislation
If the request relates to one entry in the ARTG	$150	Schedule 5 Part 1 Item 1.6A(a) *Therapeutic Goods (Medical Devices) Regulations 2002* Schedule 9 Part 2 Item 6BA(a) *Therapeutic Goods Regulations 1990* Schedule 9A Part 2 Item 16A(a) *Therapeutic Goods Regulations 1990*

Number of ARTG entries	Fee for revocation of cancellation	Legislation
If the request relates to more than one entry in the ARTG	$150 for first entry + $50 for each additional entry	Schedule 5 Part 1 Item 1.6A(b) *Therapeutic Goods (Medical Devices) Regulations 2002* Schedule 9 Part 2 Item 6BA(b) *Therapeutic Goods Regulations 1990* Schedule 9A Part 2 Item 16A(b) *Therapeutic Goods Regulations 1990*

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication for the financial year July 2017 to June 2018	Regulatory Services and Improvement Branch	01/07/2017

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