Australian Government
Department of Health
Therapeutic Goods Administration

Fees and charges: summary

From 1 July 2016

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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.

Annual charges

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

Type of prescription medicine	Charge
Biological medicine	$6,875
Non-biological medicine (chemical entity) – higher amount	$3,920
Non-biological medicine (chemical entity) – lower amount	$3,180

For prescription medicines that are not biological medicines (chemical entities), a higher annual charge applies:

- for goods 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 for relevant goods, which include:
  - new chemical entity
  - extension of indications
  - change to intended patient group

Other major variations will incur higher or lower charges depending on the parent good, for example:

- new formulation
- change of strength
- new dosage forms.

The lower annual charge applies for:

- most generic prescription medicines
- relevant goods past the eighth anniversary.

Prescription medicine 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
New chemical entity	$46,100	$185,100
Extension of indications	$27,500	$109,900
Major variations	$18,000	$71,600
Minor variations (Change in formulation, composition, design specifications, type of container or change of trade name) Category 3, Section 23 only	$1,060	$4,215
Additional trade name	$2,910	$11,700
New generic product	$17,800	$70,600
Extension of indicators 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	$1,060	$4,215
Variations to a Register entry involving the evaluation of clinical, pre-clinical or bio-equivalence data, but not included in another fee category. Includes applications for changes to Product Information involving the evaluation of clinical, pre-clinical or bio-equivalence data.	$1,060	$4,215

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
Variations to an ARTG entry 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. Category 3, 9D(3) only	$5,270
Minor editorial changes: variations to an ARTG entry (requiring changes to Product Information) with no evaluation of data	$1,625
Self-assessable request with no evaluation of data	$1,625

Prescription medicine request	Fee
Safety related request with no evaluation of data	$1,625
Safety related request with evaluation of data	$5,270
Request for advice in relation to a prescription medicine for the purpose of listing the medicine as a pharmaceutical benefit	$2,130
Correction to an ARTG entry	$1,625
Registration fee for applications made within 30 days of cancellation from the ARTG, when cancellation was due to failure to pay the annual charge (item 2AA, Part 2, Schedule 9)	$645
Section 14 and 14A application for exemption	$450

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
New chemical entity of a medicine used as an ancillary medical component of a device (item 4(aa)(i) and 4(aa)(ii))	$15,300	$61,800
New chemical entity of a medicine used as an ancillary medical component of a device (item 4(aa)(iii))	$30,800	$123,200
Extension of indicators of a medicine used as an ancillary medical component of a device – chemistry, quality control and manufacturing or pre-clinical studies	$9,160	$36,600
Extension of indicators of a medicine used as an ancillary medical component of a device – documentation mentioned in subparagraphs (i) and (ii)	$18,400	$73,200
Major variation of a medicine used as an ancillary medical component of a device – chemistry, quality control and manufacturing or pre-clinical studies	$5,975	$23,700
Major variation of a medicine used as an ancillary medical component of a device – documentation mentioned in subparagraphs (i) and (ii)	$12,000	$47,900

Clinical trials: prescription medicines

There are two schemes under which clinical trials involving unapproved therapeutic goods may be conducted.

Prescription medicine clinical trial	Fee
Clinical trial notification (CTN)	$345
Clinical trial notification (CTN) – more than one trialling body	$345
Clinical trial exemption (CTX) - 30 day evaluation	$1,665
Clinical trial exemption (CTX) - 50 day evaluation	$20,800

Non-prescription medicines

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

Listed medicines

Listed medicines include listed complementary medicines and sunscreens.

For listed export-only medicines go to Export.

Listed medicine fee or charge	Amount
Annual charge	$1,005
Application fee	$790
Processing fee (variation to an existing listing)	$400
Listing fee for applications made within 30 days of cancellation from the ARTG, when cancellation was due to failure to pay the annual charge (item 2AA, Part 2, Schedule 9)	$645

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.

Pages of nonclinical and clinical data	Evaluation fee
0-50	$10,100
51-250	$13,000
251-599	$17,800
501-1000	$23,500
1001-2000	$35,300
2001-3000	$47,100
>3000	$70,600

Listed medicine section 31 requests for more information	Evaluation fee
For listed medicines only: fee for evaluating documents and other information, relating to the safety of a medicine, obtained under paragraph 31(2)(f) of the Act (other than an evaluation to which item 6D applies)	$7,675

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 medicine.

Charges and application and processing fees

Type of fee or charge	Amount
Annual charge	$1,410
Application fee	$1,510
Additional or concurrent application fee	$665
Processing fee for variation	$1,510

Evaluation fees for registered complementary medicines

These evaluation fees are for registered complementary medicines.

Pages of nonclinical and clinical data	Fee
0-50 pages for a new product	$10,100
0-50 pages for a variation under section 9D(1), 9D(2) or 9D(3) of the Act	$3,645
51-250	$13,000
251-599	$17,800
501-1000	$23,500
1001-2000	$35,300
2001-3000	$47,100
>3000	$70,600

Registered OTC medicines

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

Annual charges

Medicine type	Charge
Registered OTC medicine	$1,410

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
N1 application	$1,565	$3,865
N1 concurrent application per additional application (described in item 3, Part 3, Schedule 9 of the Regulations)	$780	$3,865
N2 application	$1,565	$5,480
N2 concurrent application per additional application (described in item 3 of Part 3 Schedule 9 of the Regulations)	$780	$5,480
N3 application	$2,505	$8,455
N3 concurrent application per additional application (described in item 3 and 4 of Part 3 Schedule 9 of the Regulations)	$1,255	$4,280
N4 application	$3,655	$14,000
N4 concurrent application per additional application (described in item 3 and 4 of Part 3 Schedule 9 of the Regulations)	$1,255	$4,280
N5 application	$5,430	$20,800
N5 concurrent application per additional application (described in item 3 and 4 of Part 3 Schedule 9 of the Regulations)	$1,255	$4,280

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
C1 (section 23) application	$1,565	n/a
C2 (section 23) application	$1,565	$3865
C3 (section 23) application	$1,565	$6,470
C4 (section 23) application	$2,505	$8,455

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
C1 (section 9D) application	$1,565	n/a
C2 (section 9D) application	$5,430	$3865
C3 (section 9D) application	$8,035	$6,470
C4 (section 9D) application	$10,960	$8,455

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
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	$1,530
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	$7,860

Manufacturing medicines and OTGs

The section applies to the manufacture of:

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

Annual charges: manufacturing licences

	Charge	Therapeutic Goods (Charges) Regulations 1990
Low level manufacturing licence charge	$6,160	subregulations 3(2)(c), 3(2)(d), 3(2)(e), 3(2)(f), 3(2)(g), 3(2)(h)
High level manufacturing licence charge	$12,000	subregulations 3(2)(a), 3(2)(b)

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

Manufacturing inspections

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

GMP manufacturing inspections	Fee	Schedule 9
Australian manufacturing sites – application fee for a manufacturing licence	$980	item 8
Australian manufacturing sites – inspection fee	$645/hour/inspector	item 9(a)
Overseas manufacturing sites – inspection fee	$1305/hour/inspector	item 9(b)

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	Schedule 9
Assessment of GMP evidence (per manufacturer, per site, per sponsor)	$380	item 6AA
Obtaining evidence from an overseas regulatory agency (per manufacturer, per site, per sponsor)	$665	item 6AB
Compliance verification (in lieu of an overseas GMP inspection)	$2,000	item 6ABA
Reinstatement of expired GMP clearance approval (per manufacturer, per site, per sponsor) – in addition to relevant fees above	$1,125	item 6AC

Issuing certificates

Certificate	Fee
Certificate of GMP compliance	$165
Quality systems certificate	$165
Mutual Recognition Agreement certificate	$315
Certified copy of: · original GMP certificate · certificate of GMP compliance · quality systems certificate	$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.

Certificate type	Fee
Certificate of pharmaceutical product	$165
Certificate of listed product	$165
Certificate of exempt product	$165

Listed export-only medicines

Export only applications	Fee
Application fee	$790
Processing fee (variation to an existing listing)	$400

Device export certificates

You can apply for an export certificate for a medical device, IVD or OTG.

Certificate type	Fee
Certificate of free sale	$165
Export certificate	$165

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').

Manufacturing biologicals: annual charges

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

Manufacturing biologicals: fees

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

Manufacturing biologicals	Fee
Australian manufacturing sites – application fee for a manufacturing licence	$1,050
Initial manufacturing audit – inspection fee for Australian and overseas manufacturing sites	$20,800
Subsequent manufacturing audit – inspection fee for Australian and overseas manufacturing sites	$15,700
Inspection fee for each hour of preparation by each inspector for an inspection conducted outside Australia	$645/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

Sponsoring biologicals: annual charges

ARTG inclusion of biologicals	Amount	Legislation
Class 1 biological annual charge for ARTG inclusion	$645	subregulation 3(1AA)(a) *Therapeutic Goods (Charges) Regulations 1990*
Class 2, 3, 4 biological annual charge for ARTG inclusion	$6,395	subregulation 3(1AA)(b) *Therapeutic Goods (Charges) Regulations 1990*

Sponsoring biologicals: fees

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

Sponsoring biologicals	Fee	Schedule 9A
Ingredient or component of a biological to be evaluated under regulation 16GF - evaluation fee	$22,600	item 7
Class 1 biological – application fee for inclusion in ARTG	$1,050	item 1
Class 2, 3, 4 biological – application fee for inclusion in ARTG	$1,050	item 2
Variation application fee – all classes	$1,050	item 8
Class 2 biological – evaluation fee for inclusion in ARTG	$69,700	item 4
Class 2 biological – evaluation fee for variation to ARTG entry	$6,395	item 9
Class 3 biological – evaluation fee for inclusion in ARTG	$139,400	item 5
Class 4 biological – evaluation fee for inclusion in ARTG	$226,600	item 6
Class 3 or 4 biological – evaluation fee for major variation to ARTG entry	$33,100	item 11
Class 3 or 4 biological – evaluation fee for minor variation to ARTG entry	$16,800	item 10
Safety related variations – evaluation of application under section 9D(3AA)	$6,395	Item 8A

Clinical trials: biologicals

Biologicals clinical trials	Fee	Legislation
Clinical trial notification (CTN)	$345	item 17 Schedule 9A *Therapeutic Goods Regulations 1990*
Clinical trial exemption (CTX) evaluation	$25,200	item 16 Schedule 9A *Therapeutic Goods Regulations 1990*

Blood, blood components and HPCs

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

Manufacturing annual charges

Therapeutic good being manufactured	Charge	Therapeutic Goods (Charges) Regulations 1990
Blood and blood components (not HPCs) - primary manufacturing site	$154,700	subregulation 3(2)(j)(i)
Blood and blood components (not HPCs) – a fixed (non-mobile) manufacturing site	$7,615	subregulation 3(2)(j)(ii)
HPCs manufacturing site	$6,660	subregulation 3(2)(ja)

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

Manufacturing fees

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

Manufacturing fees	Fee	Schedule 9
Australian manufacturing sites – application fee for a manufacturing licence	$980	item 8
HPCs - Australian primary manufacturing site – inspection fee	$870/hour/inspector	Item 9AB
HPCs - Australian manufacturing site other than the primary site – inspection fee	$645/hour/inspector	Item 9AA
Blood and blood components (not HPCs) - Australian manufacturing site – inspection fee	$645/hour/inspector	item 9AC
Human tissues that are not biologicals - Australian manufacturing site – inspection fee	$645/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	Schedule 9
1–10	$1,265	item 9AD(a)
11–50	$10,800	item 9AD(b)
51–100	$24,200	item 9AD(c)
101–1000	$32,600	item 9AD(d)
1001–3000	$50,800	item 9AD(e)
3001–4000	$67,700	item 9AD(f)
>4000	$82,500	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	Schedule 9
Section 14 and 14A application for exemption	$450	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 guidance on medical devices go to the Australian regulatory guidelines for medical devices.

Sponsoring medical devices

Annual charges

Class of medical device	Charge
AIMD	$1,200
Class III	$1,200
Class IIb	$930
Class IIa	$930
Class I - sterile	$645
Class I – measuring function	$645
Class I - other	$80

Application fees

These fees are to apply to include a medical device in the ARTG. Application audit assessment fees are often payable as well.

Class of medical device	Application fee
AIMD	$1,265
Class III	$1,265
Class IIb	$980
Class IIa	$980
Class I - sterile	$980
Class I – measuring function	$980
Class I - other	n/a

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 Part 2 of Australian regulatory guidelines for medical devices for more details.

Type of application audit	Assessment fee
Level 1 – verification of sponsor's application and evidence of conformity	$3,700
Level 2 – Level 1 activities plus review of evidence of conformity	$6,790
Considering submissions to the Secretary in relation to a proposed suspension of a kind of medical device from the ARTG	$6,790
Variation to an ARTG inclusion entry	$430

Miscellaneous

Type of application	Fee
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	$430

Clinical trials: medical devices

Medical device clinical trial scheme	Fee
Clinical trial notification (CTN)	$345
Clinical trial exemption (CTX) evaluation	$17,600

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

All conformity assessment procedures	Fee
Application fee	$960

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
Full quality management system inspection: Schedule 3, Part 1	$28,600
Design examination: Schedule 3, Clause 1.6	$56,300
Type examination (including management of testing, analysis, and reporting on examination of the type): Schedule 3, Part 2	$39,300
Verification (including management of testing, analysis, and reporting on verification tests): Schedule 3, Part 3	$27,400
Production quality management system inspection: Schedule 3, Part 4	$25,100
Product quality management system inspection: Schedule 3, Part 5	$21,400

Changes to conformity assessment

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

Type of conformity	Fee
Full quality management system inspection: Schedule 3, Part 1	$17,200
Design examination: Schedule 3, Clause 1.6	$33,900
Type examination (including management of testing, analysis, and reporting on examination of the type): Schedule 3, Part 2	$23,600
Production quality management system inspection: Schedule 3, Part 4	$14,900
Product quality management system inspection: Schedule 3, Part 5	$13,000

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
Full quality management system surveillance inspection: Schedule 3, Part 1	$8,320
Production quality management system surveillance inspection: Schedule 3, Part 4	$8,320
Product quality management system surveillance inspection: Schedule 3, Part 5	$8,320

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
Design examination re-assessment: Schedule 3, Clause 1.6	$50,900
Type examination re-assessment (including management of testing, analysis, and reporting on examination of the type): Schedule 3, Part 2	$39,300

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
Supplementary additional assessment conducted outside Australia in addition to assessment mentioned in item 1.2, 1.3, 1.9 or 1.10, Schedule 5 [item 2.1(b), Schedule 5]	$400/assessor hour
Costs and reasonable expenses of travel by each assessor involved, including travel both in and outside Australia	costs and reasonable expenses
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) (item 2.2, Schedule 5).	At cost

IVD medical devices

The TGA website has information about IVD regulation basics.

For export information go to Device export certificates.

Sponsoring IVDs

Annual charges

There are currently no annual charges for sponsoring IVDs. Please note that there will be annual charges, beginning 1 July 2017.

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.

Class of IVD	Notification fee
Notification by a laboratory of its Class 1, Class 2 or Class 3 in-house IVDs	$980

Application fees

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

Class of IVD	Application fee
All classes of IVD, including Class 4 in-house IVDs	$980

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.

Type of IVD	Application audit assessment fee
Class 1, Class 2 and Class 3 IVDs	$6,610
Class 4 in-house IVDs	$61,200
Class 4 in-house immunohaematology reagent IVD	$14,900

Manufacturing IVDs

Application for conformity assessment

All conformity assessment procedures	Fee
Application fee	$960

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
Full quality management system inspection: Schedule 3, Part 1	$28,700
Design examination: Schedule 3, Clause 1.6	$61,200
Design examination – immunohaematology reagent: Schedule 3, Clause 1.6	$14,900
Type examination: Schedule 3, Part 2	$39,600
Production quality management system inspection: Schedule 3, Part 4	$25,300

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
Full quality management system inspection: Schedule 3, Part 1	$28,700
Design examination: Schedule 3, Clause 1.6	$61,200
Design examination – immunohaematology reagent: Schedule 3, Clause 1.6	$14,900
Type examination: Schedule 3, Part 2	$39,600
Production quality management system inspection: Schedule 3, Part 4	$25,300

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
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]	$400/assessor hour
Costs and reasonable expenses of travel by each assessor involved, including travel both in and outside Australia	costs and reasonable expenses
Surveillance assessment for conformity assessment certificate under Schedule 3, Part 1 or 4	$8,375
Assessment of changes to IVD or QMS for applicable IVD	$17,200
Considering a submission to the Secretary in relation to a proposed suspension of a conformity assessment certificate	$6,610

Other listed and registered therapeutic goods (OTGs)

Other listed and registered therapeutic goods (OTGs) include:

- disinfectants and sterilants
- tampons and menstrual cups

OTGs are referred to in the legislation as 'therapeutic devices'. There are many fees associated with therapeutic devices because medical devices used to be regulated as therapeutic devices. In this section, we have only included fees and charges that have been used in the last few years. 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

Type of OTG	Charge
Listed devices: tampons and disinfectants	$805
Listed devices - other	$1,410
Registered devices - disinfectants	$1,580
Registered devices - other	$2,765

Listed OTG fees

Listed OTG fees	Fee
Application fee	$430
Variation fee	$430
Fee for evaluating documents and information relating to the safety of a listed therapeutic device	$17,600

Registered OTG fees

Registered OTG fee type	Fee
Low level registered device – application fee	$1,410
Low level registered device – disinfectant initial evaluation fee	$17,600
Low level registered device – variation processing fee	$430
Low level registered device – disinfectant variation initial evaluation fee	$3,530
Clinical trial notification (CTN)	$345
High level registered device – application fee	$4,200
High level registered device – variation processing fee	$430
High level device – variation manufacturing and/or quality control – initial evaluation	$8,770
High level registered device – variation manufacturing and/or quality control – concurrent evaluation	$1,925

Miscellaneous fees

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

Application type	Fee	Schedule 9
Section 14 and 14A application for exemption	$450	item 1A

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*.

Type of advertisement in specified media	Fee
Advertisement* intended for publication in the classified advertisements column of a newspaper or other printed publication	$120
Advertisement* of 100 words or less	$235
Advertisement* of more than 100 words but of 300 words or less	$285
Advertisement* of more than 300 words (including an advertorial)	$450
Moving cinema advertisement* of 150 seconds or less in length, with up to 3 variations of the advertising concept, for the same product.	$1,155
Still cinema advertisement* (including outdoor media) of 100 words or less	$235
Still cinema advertisement* (including outdoor media) of more than100 words but of 300 words or less	$285
Still cinema advertisement* (including outdoor media) of more than 300 words.	$450
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
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
Advertisement* for re-approval of an identical advertisement whose approval number has expired	50% of applicable fee

Type of advertisement in specified media	Fee
Advertisement* for approval of a variation to an advertisement whose approval number has not expired.	50% of applicable fee
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.	$205

* 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*.

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

Type of advertisement in broadcast media	Fee
Television advertisement* of 150 seconds or less in length with up to 3 variations of the advertising concept for the same product	$1,155
Television advertisement* for a retail outlet that is intended to be broadcast on 1 regional station only in that station's regional area	$610
Television advertorial* greater than 150 seconds in length	$870 for first minute of script $245 for each additional minute or part minute
Radio Advertisement* including up to 6 variations of the advertising concept for the same product	$420
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	$295
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
Advertisement* requiring re-approval of an identical advertisement whose approval number has expired.	50% of applicable fee
Advertisement* requiring approval of a variation to an advertisement whose approval number has not expired	50% of applicable fee

Type of advertisement in broadcast media	Fee
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.	$205

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

General fees

Fees related to annual charges exemption (ACE) scheme

	Number of ARTG entries	Amount
Fee for a late declaration under sub regulation 43AAE(2) relating to an exemption from liability to pay an annual charge for a financial year (Schedule 9, Part 2, item 3AB and Schedule 9A, Part 2, item 3A)	a. if the declaration relates to not more than 5 entries in the ARTG	$400
	b. if the declaration relates to 6 or more entries in the ARTG	$400 for first 5 entries + $50 for each additional entry

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.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication replacing *Summary of fees and charges From 1 January 2016*	Regulatory Services and Improvement Branch, Therapeutic Goods Administration	01/07/2016
V1.1	Revised publication replacing V1.0 Minor amendments made	Regulatory Services and Improvement Branch, Therapeutic Goods Administration	August 2016
V1.2	Revised publication replacing V1.1 Minor amendments made to descriptions of Prescription medicine fees	Regulatory Services and Improvement Branch, Therapeutic Goods Administration	September 2016
V1.3	Revised publication replacing V1.2 Minor amendments made to description of fees in items 2AA and 3AA New table: Registered OTC medicines – requests with single fee	Regulatory Services and Improvement Branch, Therapeutic Goods Administration	November 2016
V1.4	Revised publication replacing V1.3 Correction of description in table of annual charges for 'Other listed and registered therapeutic goods (OTGs)'	Medical Devices Branch, Therapeutic Goods Administration	February 2017

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