TGA Fees and Charges Comparison

October 2022 – July 2023

October 2022

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	$1,241	Item 7(4)(d)
Class III	$1,241	Item 7(4)(d)
Class IIb	$975	Item 7(4)(c)
Class IIa	$975	Item 7(4)(c)
Class I – sterile	$667	Item 7(4)(b)
Class I – measuring function	$667	Item 7(4)(b)
Class I – other	$92	Item 7(4)(a)

These charges are in the *Therapeutic Goods (Charges) Regulations 2018*

July 2023

Sponsoring medical devices

Annual charges

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

Table 41: Annual charges

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

These charges are in the *Therapeutic Goods (Charges) Regulations 2018*

Application fees

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

Table 42: Application fees

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

These fees are in the *Therapeutic Goods (Medical Devices) Regulations 2002*
Note: Refer to export only device application fees

Application for medical devices (priority applicant) determination

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

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

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

Application type	Application fee	Schedule 5 Part 1
Application for medical devices (priority applicant) determination in relation to a medical device inclusion	$10,568	Item 1.5A

This fee is in the *Therapeutic Goods (Medical Devices) Regulations 2002*

Application fees

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

Table 42: Application fees

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

These fees are in the *Therapeutic Goods (Medical Devices) Regulations 2002*
Note: Refer to export only device application fees

Application for medical devices (priority applicant) determination

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

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

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

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

This fee is in the *Therapeutic Goods (Medical Devices) Regulations 2002*

Application audit assessment fees

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

For guidance on medical device audits, go to Auditing of medical device, including IVD medical device, applications.

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

Type of application audit	Assessment fee	Schedule 5 Part 1
Level 1 – verification of sponsor's application, evidence of conformity, and aspects of compliance against essential principles	$4,135	Item 1.13
Level 2 – Level 1 activities, plus in-depth technical documentation review to determine compliance with Essential Principles	$7,582	Item 1.14

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

Application audit assessment fees

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

For guidance on medical device audits, go to Auditing of medical device, including IVD medical device, applications.

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

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

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

Variation fees

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

Table 45: Variation fees

Application type	Application fee	Schedule 9 Part 2
Variation to an ARTG inclusion entry	$482	Item 2A(c)

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

Variation fees

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

Table 45: Variation fees

Application type	Application fee	Part 2 of Schedule 9
Variation to an ARTG inclusion entry - disinfectant	$1,400	Item 2A(c)
Variation to an ARTG inclusion entry – Class 3 or Class 4 IVD	$1,750	Item 2A(d)
Variation to an ARTG inclusion entry – IVD not a Class 3 or Class 4 IVD	$1,000	Item 2A(e)
Variation to an ARTG inclusion entry – medical device that is not an IVD	$1,000	Item 2A(f)
Variation to an ARTG inclusion entry – medical device that is not an IVD	$190 per 10 entries (or part thereof)	Item 2A(g)

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

Miscellaneous fees for medical devices

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

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

Type of application	Fee	Schedule 5 Part 1
Considering submissions to the Secretary in relation to a proposed suspension of a kind of medical device from the ARTG (as described in item 1.6)	$7,582	Item 1.14
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	$513 (for all the devices to which the application relates)	Item 1.15(a)

Type of application	Fee	Schedule 5 Part 1
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	$513 for the first entry, plus $103 for each additional entry	Item 1.15(b)
Application for consent to export, supply, or import medicals devices, including IVD medical devices that do not comply with the Essential Principles – specifically Essential Principle 13A relating to patient information materials	$30 per ARTG entry or $30 per Application for Inclusion in the ARTG within the application.	Item 1.15 and Clauses 13A.2 and 13A.3 of Schedule 1

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

Miscellaneous fees for medical devices

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

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

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

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

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