



ABN: 40 939 406 804

PRESCRIPTION MEDICINES		
<p>From July 2003 a new fee structure applies to therapeutic goods evaluated by the Drug Safety and Evaluation Branch of TGA. Fees will vary according to the type of evaluation undertaken and are on a per submission basis. A submission is one or more applications from the same sponsor, with the same active ingredient, submitted at the same time. A concomitant application form, or on behalf of, another sponsor is a separate submission.</p>		
Evaluation Fees Category 1 and 2 Submissions	Fee \$ - 100%	Fee \$ - 75%
New Chemical Entity	170,200	127,700
Extension of indications	101,200	75,900
Major variations New strength New dosage form New route of administration Change in patient group Change in dosage	65,900	49,400
New generic product	65,000	48,800
Additional trade name	10,700	8,030
Minor variations Change in formulation, composition, specifications or container Variations to a Register entry involving the evaluation of chemistry, quality control and manufacturing information, and clinical, pre-clinical or bio-equivalence data, but not included in another fee category	3,880	2,910
Changes to Product Information involving the evaluation of data	3,880	2,910
Changes to Product Information where no evaluation is required	1,200	900
Changes to Consumer Medicines Information	1,200	900
Evaluation Fees – Other Submissions	Fee \$	
Fees for the evaluation of the quality (chemical, quality control and manufacturing information) and/or the non-clinical (animal toxicology) data of a new chemical entity incorporated as an ancillary component of a medical device of therapeutic device, are each 1/3 of the respective fee for a prescription medicines.	various	
Variations to a Register entry involving the evaluation of only chemistry, quality control and manufacturing information	3,880	
Notification of Self Assessable Changes	1,200	
Safety Related Notification	1,200	
Testing and provision of advice, requested from Pharmaceutical Benefits Program, prior to listing on Pharmaceutical Benefits Listing Program (*this item is inclusive of GST)	1,560 (1,716*)	
Administrative Charges	Fee \$	
Withdrawal of a submission prior to acceptance of the submission	20% of evaluation fee to a maximum of 6,880	
Withdrawal of a submission after the evaluation process is taken to be complete	Full fee	
Correction of a Register entry	1,200	
Annual Charges	Fee \$	
Biologics	5,070	
Non-Biologics	3,030	
Clinical Trials	Fee \$	
CTX 30 Days	1,240	
CTX 50 Days	15,300	
CTN	250	
CTN – more than one trialing body	250	

REGISTRATION OF NON-PRESCRIPTION MEDICINES

OTC & Complementary Medicines			Fee \$
Application fee			990
Additional /concurrent application fee			440
Processing fee (variation to an existing registration)			990
Annual Charge			920
Evaluation Fees per submission if the evaluation does not contain Clinical or Toxicological data			Fee \$
New product			6,570
Variation			2,370
New substance: CMEC, sunscreen Excipients, all other			6,570
Evaluation Fees – Page Counts			Fee \$
New Product			
Total page count of Clinical or Toxicological data per submission:	1 - 50		6,570
	51 - 250		8,420
	251 - 500		11,500
	501 - 1000		15,400
	1001 - 2000		23,000
	2001 - 3000		30,700
	> 3000		46,000
Variations			
Total page count of Clinical or Toxicological data per submission:	1 - 50		2,370
	51 - 250		8,420
	251 - 500		11,500
	501 - 1000		15,400
	1001 - 2000		23,000
	2001 - 3000		30,700
	> 3000		46,000
New Substance			
Total page count of Clinical or Toxicological data per submission:	1 - 50		6,570
	51 - 250		8,420
	251 - 500		11,500
	501 - 1000		15,400
	1001 - 2000		23,000
	2001 - 3000		30,700
	> 3000		46,000
Multiple New Excipients			
In listed or registered good for dermal use	1 - 50		6,570
	51 - 250		8,420
	251 - 500		11,500
	501 - 1000		15,400
	1001 - 2000		23,000
	2001 - 3000		30,700
	> 3000		46,000
Evaluation Fees for Safety and Efficacy			
Total page count of Clinical or Toxicological data per submission:	1 - 50		6,570
	51 - 250		8,420
	251 - 500		11,500
	501 - 1000		15,400
	1001 - 2000		23,000
	2001 - 3000		30,700
	> 3000		46,000

LISTED MEDICINES	Fee \$
Application fee	540
Processing fee (variation to an existing listing)	270
Annual Charge	690
Evaluation fee for assessing information or documentation relating to the safety of goods for the purposes for which they are to be used	5,270

LISTED MEDICINES – EXPORT ONLY	Fee \$
Application fee	540
Processing fee (variation to an existing listing)	270

LISTED MEDICINES – EXPORT CERTIFICATES	Fee \$
Certificate of Pharmaceutical Product	120
Certificate of Listed Product	120
Certificate of Exempt Product	120

BLOOD, BLOOD COMPONENTS, AND HUMAN TISSUES	
Evaluation Fees – per submission	Fee \$
Page Counts – Blood Plasma Master File & Blood Technical Master File	
1 - 10	960
11 - 50	8,200
51 - 100	18,200
101 - 1000	24,500
1001 - 3000	38,300
3001 - 4000	50,900
> 4000	62,000
GMP Audit of Manufacturers of Blood and Blood Components except Haematopoietic Progenitor Cells	Hourly rate per auditor \$
GMP audit of primary site	660
GMP audit of site other than primary site	480
Annual Licence Charge	Fee \$
Primary site	107,500
Additional fixed site (non-mobile) associated with a primary site	5,290
GMP Audit of Manufacturers of Haematopoietic Progenitor Cells	Hourly rate per auditor \$
GMP audit fee	480
Annual Licence Charge	Fee \$
Manufacturing premises	4,630
GMP Audit of Manufacturers of Human Tissues	Hourly rate per auditor \$
GMP audit fee	480
Annual Licence Charge	Fee \$
Single step and single human tissue	4,630
Two or more steps	8,980

REGISTERED DEVICES			Fee \$
Application fee – high level registration			3,170
Additional/ concurrent – high level registration			1,580
Application fee – low level registration			1,050
Additional/ concurrent – low level registration			540
Processing fee – high level registration (variation to an existing registration)			330
Processing fee – low level registration (variation to an existing registration)			330
Annual Charge – therapeutic devices such as IVD's, tampons and disinfectants			1,200
Annual Charge			2,090
Device Clinical Trials			Fee \$
CTN			250
Clinical Trial – Other			1,990
Clinical Trial – Schedule 3 Part 1 Item 3			13,200
Evaluation Fees	Initial Application Fee \$	Concurrent Application Fee \$	Abridged Application Fee \$
High Level Registration – type of data			
Design / materials / testing	23,300	3,970	7,920
Manufacture / quality control	15,800	3,970	6,600
Biocompatibility / pre-clinical	15,800	3,970	6,600
Human clinical	26,500	3,970	26,500
Software	15,800	3,970	6,600
Confirmatory review of clinical information	N/a	N/a	6,600
Confirmatory review of overseas evaluation report	15,800	3,970	6,600
Low Level Registration – type of data			
Design / materials / testing	3,970	N/a	N/a
Manufacture / quality control	3,970	N/a	N/a
Biocompatibility / pre-clinical	3,970	N/a	N/a
Human clinical	3,970	N/a	N/a
Software	3,970	N/a	N/a
Diagnostic Goods Control Reagent	3,970	N/a	N/a
Disinfectants and diagnostic goods for in vitro use	13,200	N/a	N/a
Variation – High Level Registration – type of data			
Design / materials / testing	7,920	1,460	N/a
Manufacture / quality control	6,600	1,460	N/a
Biocompatibility / pre-clinical	6,600	1,460	N/a
Human clinical	26,500	1,460	N/a
Software	6,600	1,460	N/a
Confirmatory review of clinical information	6,600	N/a	N/a
Confirmatory review of overseas evaluation report	6,600	1,460	N/a
Variation – Low Level Registration – type of data			
Design / materials / testing	1,050	N/a	N/a
Manufacture / quality control	1,050	N/a	N/a
Biocompatibility / pre-clinical	1,050	N/a	N/a
Human clinical	1,050	N/a	N/a
Software	1,050	N/a	N/a
Diagnostic Goods Control Reagent	1,050	N/a	N/a
Disinfectants and diagnostic goods for in vitro use	2,650	N/a	N/a

LISTED DEVICES	Fee \$
Application fee	330
Processing fee (variation to an existing listing)	330
Application for exemption under Section 14	340
Annual Charge	1,050
Annual Charge – therapeutic devices such as IVD's, tampons and disinfectants	600
Evaluation Fees	Fee \$
Evaluation for assessing whether a listable or listed device is safe for the purposes for which it is to be used	13,200

LISTED DEVICES – EXPORT ONLY	Fee \$
Application fee	330
Processing fee (variation to an existing listing)	330
LISTED DEVICES – EXPORT CERTIFICATES	Fee \$
Export Certificate for listed/ listable device	120

INCLUDED DEVICES	
Conformity Assessment All Procedures	Fee \$
Application for Conformity Assessment Certificate – All Procedures	710
Medical Devices – Annual Charges	Fee \$
(a) Class AIMD medical device	960
(b) Class III medical device	960
(c) Class IIb medical device	730
(d) Class IIa medical device	730
(e) Class I medical device - sterile	480
(f) Class I medical device – measuring function	480
(g) Other Class I medical device	60
Conformity Assessment – Initial Assessment	Fee \$
(a) Schedule 3, Part 1 – Full Quality Management System Audit; or	21,400
(b) Schedule 3, Clause 1.6 – Design Examination; or	42,400
(c) Schedule 3, Part 2 – Type Examination (including management of testing, analysis, and reporting on examination of the type); or	29,500
(d) Schedule 3, Part 3 – Verification (including management of testing, analysis, and reporting on verification tests); or	20,700
(e) Schedule 3, Part 4 – Production Quality Management System Audit; or	18,800
(f) Schedule 3, Part 5 – Product Quality Management System Audit	16,100
Conformity Assessment – Changes	Fee \$
(a) Schedule 3, Part 1 – Full Quality Management System Audit; or	12,900
(b) Schedule 3, Clause 1.6 – Design Examination; or	25,500
(c) Schedule 3, Part 2 – Type Examination (including management of testing, analysis, and reporting on examination of the type); or	17,800
(d) Schedule 3, Part 4 – Production Quality Management System Audit; or	11,300
(e) Schedule 3, Part 5 – Product Quality Management System Audit	9,710
Conformity Assessment Surveillance Audits	Fee \$
(a) Schedule 3, Part 1 – Full Quality Management System Audit; or	6,250
(b) Schedule 3, Part 4 – Production Quality Management System Surveillance Audit	6,250
(c) Schedule 3, Part 5 – Product Quality Management System Surveillance Audit	6,250

Conformity Assessment - Review of Certificate	Fee \$
(a) Schedule 3, Clause 1.6 – Design Examination re-assessment	38,400
(b) Schedule 3, Part 2 – Type Examination re-assessment (including management of testing, analysis, and reporting on examination of the type)	29,500
Conformity Assessment – Components - Initial	Fee \$
(a) Schedule 3, Part 1 – Full Quality Management System Audit; or	21,400
(b) Schedule 3, Clause 1.6 – Design Examination; or	42,400
(c) Schedule 3, Part 2 – Type Examination (including management of testing, analysis, and reporting on examination of the type); or	29,500
(d) Schedule 3, Part 3 – Verification (including management of testing, analysis, and reporting on verification tests); or	20,700
(e) Schedule 3, Part 4 – Production Quality Management System Audit; or	18,800
(f) Schedule 3, Part 5 – Product Quality Management System Audit	16,100
Conformity Assessment – Components - Changes	Fee \$
(a) Schedule 3, Part 1 – Full Quality Management System Audit; or	12,900
(b) Schedule 3, Clause 1.6 – Design Examination; or	25,500
(c) Schedule 3, Part 2 – Type Examination (including management of testing, analysis, and reporting on examination of the type); or	17,800
(d) Schedule 3, Part 4 – Production Quality Management System Audit; or	11,300
(e) Schedule 3, Part 5 – Product Quality Management System Audit	9,710
Considering a submission to the Secretary in relation to a proposed suspension of a conformity assessment certificate	Fee \$
Considering a submission to the Secretary in relation to a proposed suspension of a conformity assessment certificate	5,110
Conformity Assessment – Additional Fees	Fee \$
Assessment of a medicinal component of a device	See Schedule 9 of the TG Regs Items 4, 5(b),(d)
Supplementary assessments to Items 1.2, 1.3, 1.9 or 1.10	\$300 per assessor hour
Reasonable travel, accommodation and allowance costs including travel both in and outside Australia	At Cost
Assessor preparation for assessments conducted outside Australia	\$300 per assessor hour
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
Conformity Assessment – Abridged Fee	Fee \$
Conformity assessment where assessment has already been undertaken by the TGA for the EU or EFTA Mutual Recognition Agreement and there is sufficient information to allow the assessment to be abridged	2,910
Inclusion in the ARTG – Application for an inclusion in the Register	Fee \$
(a) Class AIMD medical device	960
(b) Class III medical device	960
(c) Class IIb medical device	730
(d) Class IIa medical device	730
(e) Class I medical device - sterile	730
(f) Class I medical device – measuring function	730
(g) Other Class I medical device	Nil

Inclusion in the ARTG – Application Audit Assessment	Fee \$
(a) Level 1 – verification of sponsor’s application and evidence of conformity	2,790
(b) Level 2 – Level 1 activities plus review of evidence of conformity	5,110
Considering submissions to the Secretary in relation to a proposed suspension of a kind of medical device from the Register	5,110
Variation to an ARTG inclusion entry if the entry is incomplete or incorrect	330
Other Fees	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	330
Notification of intention to sponsor a clinical trial of a medical device to be used solely for experimental purposes in humans – Clinical Trial Notification Scheme (CTN)	250
Application for approval to use a specified kind of medical device solely for experimental purposes in humans – Clinical Trial eXemption Scheme (CTX)	13,200

GOOD MANUFACTURING PRACTICE (GMP)	Fee \$
Licence application fee	730
Australian Manufacturers – GMP Audit Fee ^{1,2}	Hourly rate per Auditor \$
All types of therapeutic goods	480
Annual Licence Charge ^{1,3}	Fee \$
Single step / single medicine / single type of therapeutic device	4,630
In-vitro diagnostic products	4,630
Ingredients or components	4,630
Herbal / Homeopathic medicinal products	4,630
Other types of therapeutic goods, including containers in which therapeutic goods are to be packed	8,980
<p><i>Note:</i></p> <ol style="list-style-type: none"> Not applicable to blood, blood products, and human tissues, which appear on p3. GMP Audit fee is payable when an audit is undertaken before a licence is issued The following audit hours are included in the annual licence charges: <ul style="list-style-type: none"> Manufacturers with low level licence charges – total 16 auditor hours in 3 financial years Manufacturers with high level licence charges – total 48 auditor hours in 3 financial years <p><i>GMP audit fee for Australian manufacturers is applicable once the above number of hours is exceeded</i></p>	

Overseas Manufacturers – GMP Audit Fee	Hourly rate per Auditor \$
All types of therapeutic goods	980
Overseas Manufacturers – GMP Clearance Fees	Fee \$
Assessment of GMP evidence (per manufacturer, per site and per sponsor)	280
Obtaining evidence from overseas regulatory agency (per manufacturer, per site and per sponsor)	500
Reinstatement of expired GMP clearance approval (per manufacturer, per site and per sponsor)	850
Desk Audit (in-lieu of an overseas GMP audit)	1,500
GMP Certificates	Fee \$
Certificate of GMP Compliance	120
Quality Systems Certificate	120
Mutual Recognition Agreement Certificate	230
Certified copy of a certificate	40

MISCELLANEOUS	Fee \$
ARTG reinstatement application fee – registered medicines or devices – per invoice	480
ARTG reinstatement application fee – listed medicines or devices – per invoice	480
Processing fee for consent under Section 14 to waive compliance with standards for prescription, registered and listed medicines – per product/ARTG entry	340
Application for Declaration that Turnover is Low Volume and Low Value – per product (\$12,400max)	120
ARTG information – Freedom of Information (FOI) charges apply – contact ARTG for advice	
The percentage of sales used in calculation of low volume and low value products for exemption from Annual Charge is 6.8%	
The wholesale turnover level for reduction in the manufacturing licence charge is \$71,000	

ADVERTISING	
Fees for Advertisements in “Specified Media” other than “Broadcast Media”	Fee \$
Advertising processing time less than 1 hour and: <ul style="list-style-type: none"> • not more than 100 words • more than 100 words • more than 300 words (including advertorial) • minor change to an approved advertisement sought more than 3 months after approval • re-approval of an identical advertisement whose approval number has expired • approval of a variation to an advertisement whose approval number has not expired • classified advertisement 	170 210 340 90 50% of applicable fee 50% of applicable fee 90
Each additional hour or part thereof	150
Fees for Advertisements in “Broadcast Media”	Fee \$
Advertising processing time less than 1 hour and :	
Television or Cinema Commercial up to and including 150 seconds in length with up to 3 variations of the one concept for the one product	870
Television Commercial for a retail outlet that is intended to be broadcast on 1 regional station only in that station’s regional area	450
Television Advertorial greater than 150 seconds in length	660 for the first minute plus 180 per minute or part minute after that
Radio Advertisement including up to 6 variants of the one concept, for the same product	320
Radio Advertisement that is intended to be broadcast in a regional area only, including up to six variations of the one concept for the same product	220
Still Cinema Media including outdoor media: <ul style="list-style-type: none"> • not more than 100 words • not more than 300 words • more than 300 words • minor change to an approved advertisement sought more than 3 months after approval • re-approval of an identical advertisement whose approval number has expired • approval of a variation to an advertisement whose approval number has not expired 	170 210 340 50% of applicable fee 50% of applicable fee 50% of applicable fee
Each additional hour or part thereof	150