



Summary of Fees and Charges At 10 July 2009

ABN: 40 939 406 804

PRESCRIPTION MEDICINES		
Evaluation Fees Category 1 and 2 Submissions	Fee \$ - 100%	Fee \$ - 75%
New Chemical Entity	187,900	141,000
Extension of indications	111,700	83,800
Major variations New strength New dosage form New route of administration Change in patient group Change in dosage	72,800	54,600
New generic product	71,700	53,900
Additional trade name	11,800	8,870
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	4,290	3,210
Changes to Product Information involving the evaluation of data	4,290	3,210
Changes to Product Information where no evaluation is required	1,320	990
Changes to Consumer Medicines Information	1,320	990
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	4,290	
Notification of Self Assessable Changes	1,320	
Safety Related Notification	1,320	
Testing and provision of advice, requested from Pharmaceutical Benefits Program, prior to listing on Pharmaceutical Benefits Listing Program (*this item is inclusive of GST)	1,730 (1,903*)	
Administrative Charges	Fee \$	
Withdrawal of a submission prior to acceptance of the submission	20% of evaluation fee to a maximum of 7,600	
Withdrawal of a submission after the evaluation process is taken to be complete	Full fee	
Correction of a Register entry	1,320	
Annual Charges	Fee \$	
Biologics	5,600	
Non-Biologics	3,350	
Clinical Trials	Fee \$	
CTX 30 Days	1,360	
CTX 50 Days	16,900	
CTN	270	
CTN – more than one trialing body	270	

OVER THE COUNTER (OTC) MEDICINES		
Registration of Non Prescription (OTC) Medicines		Fee \$
Application fee		1,230
Additional /concurrent application fee		540
Processing fee (variation to an existing registration)		1,230
Annual Charge		1,140
Evaluation Fees if the documentation does not contain Clinical or Toxicological data - per submission		Fee \$
New product		8,190
Variation		2,960
New substance: CMEC, sunscreen Excipients, all other		8,190
Evaluation Fees based on total page count(s) of Clinical or Toxicological data per submission		Fee \$
New Product	1 - 50	8,190
	51 - 250	10,500
	251 - 500	14,400
	501 - 1000	19,100
	1001 - 2000	28,700
	2001 - 3000	38,300
	> 3000	57,300
Variations	1 - 50	2,960
	51 - 250	10,500
	251 - 500	14,400
	501 - 1000	19,100
	1001 - 2000	28,700
	2001 - 3000	38,300
	> 3000	57,300
New Substance	1 - 50	8,190
	51 - 250	10,500
	251 - 500	14,400
	501 - 1000	19,100
	1001 - 2000	28,700
	2001 - 3000	38,300
	> 3000	57,300
Multiple New Excipients in listed or registered good for dermal use	1 - 50	8,190
	51 - 250	10,500
	251 - 500	14,400
	501 - 1000	19,100
	1001 - 2000	28,700
	2001 - 3000	38,300
	> 3000	57,300
Assessment of Safety and Efficacy	1 - 50	8,190
	51 - 250	10,500
	251 - 500	14,400
	501 - 1000	19,100
	1001 - 2000	28,700
	2001 - 3000	38,300
	> 3000	57,300

COMPLEMENTARY MEDICINES		
Registration of Non Prescription (Complementary) Medicines		Fee \$
Application fee		1,230
Additional /concurrent application fee		540
Processing fee (variation to an existing registration)		1,230
Annual Charge		1,140
Evaluation Fees if the documentation does not contain Clinical or Toxicological data - per submission		Fee \$
New product		8,190
Variation		2,960
New substance: Complementary Medicines Substance, sunscreen Excipients, all other		8,190
Evaluation Fees based on total page count(s) of Clinical or Toxicological data per submission		Fee \$
New Product	1 - 50	8,190
	51 - 250	10,500
	251 - 500	14,400
	501 - 1000	19,100
	1001 - 2000	28,700
	2001 - 3000	38,300
	> 3000	57,300
Variations	1 - 50	2,960
	51 - 250	10,500
	251 - 500	14,400
	501 - 1000	19,100
	1001 - 2000	28,700
	2001 - 3000	38,300
	> 3000	57,300
New Substance	1 - 50	8,190
	51 - 250	10,500
	251 - 500	14,400
	501 - 1000	19,100
	1001 - 2000	28,700
	2001 - 3000	38,300
	> 3000	57,300
Multiple New Excipients in listed or registered good for dermal use	1 - 50	8,190
	51 - 250	10,500
	251 - 500	14,400
	501 - 1000	19,100
	1001 - 2000	28,700
	2001 - 3000	38,300
	> 3000	57,300
Assessment of Safety and Efficacy	1 - 50	8,190
	51 - 250	10,500
	251 - 500	14,400
	501 - 1000	19,100
	1001 - 2000	28,700
	2001 - 3000	38,300
	> 3000	57,300

LISTED MEDICINES		Fee \$
Application fee		640
Processing fee (variation to an existing listing)		320
Annual Charge		810
Evaluation Fees based on total page count(s) of Clinical or Toxicological data per submission		Fee \$
New Listable Medicines Substance	1 – 50	8,190
	51 – 250	10,500
	251 – 500	14,400
	501 – 1000	19,100
	1001 – 2000	28,700
	2001 – 3000	38,300
	> 3000	57,300
Assessment of safety information or documents submitted pursuant to Section 31 of the <i>Therapeutic Goods Act 1989</i>		6,240

LISTED MEDICINES – EXPORT ONLY		Fee \$
Application fee		640
Processing fee (variation to an existing listing)		320

LISTED MEDICINES – EXPORT CERTIFICATES		Fee \$
Certificate of Pharmaceutical Product		130
Certificate of Listed Product		130
Certificate of Exempt Product		130

BLOOD, BLOOD COMPONENTS, AND HUMAN TISSUES		
Evaluation Fees – per submission		Fee \$
Page Counts – Blood Plasma Master File & Blood Technical Master File	1 - 10	1,030
	11 - 50	8,870
	51 - 100	19,700
	101 - 1000	26,500
	1001 - 3000	41,400
	3001 - 4000	55,000
	> 4000	67,000
GMP Audit of Manufacturers of Blood and Blood Components except Haematopoietic Progenitor Cells		Hourly rate per auditor \$
GMP audit of primary site		710
GMP audit of site other than primary site		520
Annual Licence Charge		Fee \$
Primary site		125,700
Additional fixed site (non-mobile) associated with a primary site		6,180
GMP Audit of Manufacturers of Haematopoietic Progenitor Cells		Hourly rate per auditor \$
GMP audit fee		520
Annual Licence Charge		Fee \$
Manufacturing premises		5,410
GMP Audit of Manufacturers of Human Tissues		Hourly rate per auditor \$
GMP audit fee		520
Annual Licence Charge		Fee \$
Single step and single human tissue		5,410
Two or more steps		10,500

REGISTERED DEVICES			Fee \$
Application fee – high level registration			3,420
Additional/ concurrent – high level registration			1,710
Application fee – low level registration			1,140
Additional/ concurrent – low level registration			580
Processing fee – high level registration (variation to an existing registration)			350
Processing fee – low level registration (variation to an existing registration)			350
Annual Charge – therapeutic devices such as IVD's, tampons and disinfectants			1,290
Annual Charge			2,260
Device Clinical Trials			Fee \$
CTN			270
Clinical Trial – Other			2,150
Clinical Trial – Schedule 3 Part 1 Item 3			14,300
Evaluation Fees	Initial Application Fee \$	Concurrent Application Fee \$	Abridged Application Fee \$
High Level Registration – type of data			
Design / materials / testing	25,100	4,290	8,560
Manufacture / quality control	17,100	4,290	7,130
Biocompatibility / pre-clinical	17,100	4,290	7,130
Human clinical	28,700	4,290	28,700
Software	17,100	4,290	7,130
Confirmatory review of clinical information	N/a	N/a	7,130
Confirmatory review of overseas evaluation report	17,100	4,290	7,130
Low Level Registration – type of data			
Design / materials / testing	4,290	N/a	N/a
Manufacture / quality control	4,290	N/a	N/a
Biocompatibility / pre-clinical	4,290	N/a	N/a
Human clinical	4,290	N/a	N/a
Software	4,290	N/a	N/a
Diagnostic Goods Control Reagent	4,290	N/a	N/a
Disinfectants and diagnostic goods for in vitro use	14,300	N/a	N/a
Variation – High Level Registration – type of data			
Design / materials / testing	8,560	1,570	N/a
Manufacture / quality control	7,130	1,570	N/a
Biocompatibility / pre-clinical	7,130	1,570	N/a
Human clinical	28,700	1,570	N/a
Software	7,130	1,570	N/a
Confirmatory review of clinical information	7,130	N/a	N/a
Confirmatory review of overseas evaluation report	7,130	1,570	N/a
Variation – Low Level Registration – type of data			
Design / materials / testing	1,140	N/a	N/a
Manufacture / quality control	1,140	N/a	N/a
Biocompatibility / pre-clinical	1,140	N/a	N/a
Human clinical	1,140	N/a	N/a
Software	1,140	N/a	N/a
Diagnostic Goods Control Reagent	1,140	N/a	N/a
Disinfectants and diagnostic goods for in vitro use	2,870	N/a	N/a

LISTED DEVICES	Fee \$
Application fee	350
Processing fee (variation to an existing listing)	350
Application for exemption under Section 14	370
Annual Charge	1,140
Annual Charge – therapeutic devices such as IVD's, tampons and disinfectants	650
Evaluation Fees	Fee \$
Evaluation for assessing whether a listable or listed device is safe for the purposes for which it is to be used	14,300

LISTED DEVICES – EXPORT ONLY	Fee \$
Application fee	350
Processing fee (variation to an existing listing)	350
LISTED DEVICES – EXPORT CERTIFICATES	Fee \$
Export Certificate for listed/ listable device	130

INCLUDED DEVICES	
Conformity Assessment All Procedures	Fee \$
Application for Conformity Assessment Certificate – All Procedures	770
Medical Devices – Annual Charges	Fee \$
(a) Class AIMD medical device	1,030
(b) Class III medical device	1,030
(c) Class IIb medical device	790
(d) Class IIa medical device	790
(e) Class I medical device - sterile	520
(f) Class I medical device – measuring function	520
(g) Other Class I medical device	60
Conformity Assessment – Initial Assessment	Fee \$
(a) Schedule 3, Part 1 – Full Quality Management System Audit; or	23,200
(b) Schedule 3, Clause 1.6 – Design Examination; or	45,800
(c) Schedule 3, Part 2 – Type Examination (including management of testing, analysis, and reporting on examination of the type); or	31,900
(d) Schedule 3, Part 3 – Verification (including management of testing, analysis, and reporting on verification tests); or	22,300
(e) Schedule 3, Part 4 – Production Quality Management System Audit; or	20,300
(f) Schedule 3, Part 5 – Product Quality Management System Audit	17,400
Conformity Assessment – Changes	Fee \$
(a) Schedule 3, Part 1 – Full Quality Management System Audit; or	14,000
(b) Schedule 3, Clause 1.6 – Design Examination; or	27,500
(c) Schedule 3, Part 2 – Type Examination (including management of testing, analysis, and reporting on examination of the type); or	19,200
(d) Schedule 3, Part 4 – Production Quality Management System Audit; or	12,200
(e) Schedule 3, Part 5 – Product Quality Management System Audit	10,500
Conformity Assessment Surveillance Audits	Fee \$
(a) Schedule 3, Part 1 – Full Quality Management System Audit; or	6,760
(b) Schedule 3, Part 4 – Production Quality Management System Surveillance Audit	6,760
(c) Schedule 3, Part 5 – Product Quality Management System Surveillance Audit	6,760

Conformity Assessment - Review of Certificate	Fee \$
(a) Schedule 3, Clause 1.6 – Design Examination re-assessment	41,500
(b) Schedule 3, Part 2 – Type Examination re-assessment (including management of testing, analysis, and reporting on examination of the type)	31,900

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	,5,520

Conformity Assessment – Additional Fees	Fee \$
Assessment of a medicinal component of a device*	As per TG Regs Items 4(bb), 5(b), and 5(d)
*(Refer to Items 4(bb), 5(b), and 5(d) of Part 2 of Schedule 9 of the <i>Therapeutic Goods Regulations 1990</i>)	
Supplementary assessments to Items 1.2, 1.3, 1.9 or 1.10	\$320 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	\$320 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	3,140

Inclusion in the ARTG – Application for an inclusion in the Register	Fee \$
(a) Class AIMD medical device	1,030
(b) Class III medical device	1,030
(c) Class IIb medical device	790
(d) Class IIa medical device	790
(e) Class I medical device - sterile	790
(f) Class I medical device – measuring function	790
(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	3,010
(b) Level 2 – Level 1 activities plus review of evidence of conformity	5,520
Considering submissions to the Secretary in relation to a proposed suspension of a kind of medical device from the Register	5,520
Variation to an ARTG inclusion entry if the entry is incomplete or incorrect	350
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	350
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)	270
Application for approval to use a specified kind of medical device solely for experimental purposes in humans – Clinical Trial eXemption Scheme (CTX)	14,300

GOOD MANUFACTURING PRACTICE (GMP)	Fee \$
Licence application fee	790
Australian Manufacturers – GMP Audit Fee ^{1,2}	Hourly rate per Auditor \$
All types of therapeutic goods	520
Annual Licence Charge ^{1,3}	Fee \$
Single step / single medicine / single type of therapeutic device	5,010
In-vitro diagnostic products	5,010
Ingredients or components	5,010
Herbal / Homeopathic medicinal products	5,010
Other types of therapeutic goods, including containers in which therapeutic goods are to be packed	9,700
<p><i>Note:</i></p> <ol style="list-style-type: none"> 1. Not applicable to blood, blood products, and human tissues, which appear on p3. 2. GMP Audit fee is payable when an audit is undertaken before a licence is issued 3. 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	1,060
Overseas Manufacturers – GMP Clearance Fees	Fee \$
Assessment of GMP evidence (per manufacturer, per site and per sponsor)	300
Obtaining evidence from overseas regulatory agency (per manufacturer, per site and per sponsor)	540
Reinstatement of expired GMP clearance approval (per manufacturer, per site and per sponsor)	920
Desk Audit (in-lieu of an overseas GMP audit)	1,620
GMP Certificates	Fee \$
Certificate of GMP Compliance	130
Quality Systems Certificate	130
Mutual Recognition Agreement Certificate	250
Certified copy of a certificate	40

MISCELLANEOUS	Fee \$
ARTG reinstatement application fee – registered medicines or devices – per invoice	520
ARTG reinstatement application fee – listed medicines or devices – per invoice	520
Processing fee for consent under Section 14 to waive compliance with standards for prescription, registered and listed medicines – per product/ARTG entry	370
ARTG information – Freedom of Information (FOI) charges apply – contact ARTG for advice	
The wholesale turnover level for reduction in the manufacturing licence charge is \$76,800	

LOW VALUE LOW VOLUME (LVLV) EXEMPTIONS	Fee \$
Application fee for Declaration that Annual Turnover is of Low Value and Low Volume – per product (to a maximum of \$13,000)	130
The percentage of sales used in calculation of low volume and low value products for exemption from Annual Charge is 6.8%	

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 	190
<ul style="list-style-type: none"> • more than 100 words 	230
<ul style="list-style-type: none"> • more than 300 words (including advertorial) 	370
<ul style="list-style-type: none"> • minor change to an approved advertisement sought more than 3 months after approval 	90
<ul style="list-style-type: none"> • re-approval of an identical advertisement whose approval number has expired 	50% of applicable fee
<ul style="list-style-type: none"> • approval of a variation to an advertisement whose approval number has not expired 	50% of applicable fee
<ul style="list-style-type: none"> • classified advertisement 	90
Each additional hour or part thereof	170
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	940
Television Commercial for a retail outlet that is intended to be broadcast on 1 regional station only in that station’s regional area	490
Television Advertorial greater than 150 seconds in length	710 for the first minute plus 200 per minute or part minute after that
Radio Advertisement including up to 6 variants of the one concept, for the same product	340
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	240
Still Cinema Media including outdoor media:	
<ul style="list-style-type: none"> • not more than 100 words 	190
<ul style="list-style-type: none"> • not more than 300 words 	230
<ul style="list-style-type: none"> • more than 300 words 	370
<ul style="list-style-type: none"> • minor change to an approved advertisement sought more than 3 months after approval 	50% of applicable fee
<ul style="list-style-type: none"> • re-approval of an identical advertisement whose approval number has expired 	50% of applicable fee
<ul style="list-style-type: none"> • approval of a variation to an advertisement whose approval number has not expired 	50% of applicable fee
Each additional hour or part thereof	170