



Summary of Fees and Charges At 1 July 2011

ABN: 40 939 406 804

PRESCRIPTION MEDICINES		
Evaluation Fees	Application Fee	Evaluation Fee
New Chemical Entity	39,800	159,200
Extension of indications	23,700	94,600
Major variations	15,400	61,600
New generic product	15,200	60,700
Additional trade name	2,500	10,000
Minor variations Change in formulation, composition, specifications or container [Therapeutics Goods Act 9D(1) or 9D(2)]	910	4,540
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 [Therapeutics Goods Act 9D(3) to which regulation 16D applies)	910	3,630
Changes to Product Information involving the evaluation of data	910	3,630
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
Changes to Product Information where no evaluation is required		1,400
Changes to Consumer Medicines Information		1,400
Variations to a Register entry involving the evaluation of only chemistry, quality control and manufacturing information		4,540
Notification of Self Assessable Changes		1,400
Safety Related Notification		1,400
Testing and provision of advice, requested from Pharmaceutical Benefits Program, prior to listing on Pharmaceutical Benefits Listing Program (*this item is inclusive of GST)		1,830 (2,013*)
Administrative Charges		Fee \$
Correction of a Register entry		1,400
Annual Charges		Fee \$
Biological Medicines (Biologics)		5,920
Non-Biologics		3,550
Clinical Trials		Fee \$
CTX 30 Days		1,440
CTX 50 Days		17,900
CTN		290
CTN – more than one trialing body		290

OVER THE COUNTER (OTC) MEDICINES including REGISTERED COMPLEMENTARY MEDICINES

Registration of Non Prescription (OTC) Medicines		Fee \$
Application fee		1,300
Additional /concurrent application fee		570
Processing fee (variation to an existing registration)		1,300
Annual Charge		1,210
Evaluation Fees if the documentation does not contain Clinical or Toxicological data - per submission		Fee \$
New product		8,680
Variation		3,130
New substance: CMEC, sunscreen Excipients, all other		8,680
Evaluation Fees based on total page count(s) of Clinical or Toxicological data per submission		Fee \$
New Product	1 - 50	8,680
	51 - 250	11,200
	251 - 500	15,200
	501 - 1000	20,300
	1001 - 2000	30,400
	2001 - 3000	40,500
	> 3000	60,700
Variations	1 - 50	3,130
	51 - 250	11,200
	251 - 500	15,200
	501 - 1000	20,300
	1001 - 2000	30,400
	2001 - 3000	40,500
	> 3000	60,700
New Substance	1 - 50	8,680
	51 - 250	11,200
	251 - 500	15,200
	501 - 1000	20,300
	1001 - 2000	30,400
	2001 - 3000	40,500
	> 3000	60,700
Multiple New Excipients in listed or registered good for dermal use	1 - 50	8,680
	51 - 250	11,200
	251 - 500	15,200
	501 - 1000	20,300
	1001 - 2000	30,400
	2001 - 3000	40,500
	> 3000	60,700
Assessment of Safety and Efficacy	1 - 50	8,680
	51 - 250	11,200
	251 - 500	15,200
	501 - 1000	20,300
	1001 - 2000	30,400
	2001 - 3000	40,500
	> 3000	60,700

LISTED MEDICINES		Fee \$
Application fee		680
Processing fee (variation to an existing listing)		340
Annual Charge		860
Evaluation Fees based on total page count(s) of Clinical or Toxicological data per submission		Fee \$
New Listable Medicines Substance	1 – 50	8,680
	51 – 250	11,200
	251 – 500	15,200
	501 – 1000	20,300
	1001 – 2000	30,400
	2001 – 3000	40,500
	> 3000	60,700
Assessment of safety information or documents submitted pursuant to Section 31 of the <i>Therapeutic Goods Act 1989</i>		6,610

LISTED MEDICINES – EXPORT ONLY		Fee \$
Application fee		680
Processing fee (variation to an existing listing)		340

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	1,090
	11 - 50	9,390
	51 - 100	20,900
	101 - 1000	28,000
	1001 - 3000	43,800
	3001 - 4000	58,200
	> 4000	70,900
GMP Audit of Manufacturers of Blood and Blood Components except Haematopoietic Progenitor Cells		Hourly rate per auditor \$
GMP audit of primary site		750
GMP audit of site other than primary site		550
Annual Licence Charge		Fee \$
Primary site		133,100
Additional fixed site (non-mobile)		6,550
GMP Audit of Manufacturers of Haematopoietic Progenitor Cells		Hourly rate per auditor \$
GMP audit fee		550
Annual Licence Charge		Fee \$
Manufacturing premises		5,730
GMP Audit of Manufacturers of Human Tissues		Hourly rate per auditor \$
GMP audit fee		550
Annual Licence Charge		Fee \$
Single step and single human tissue		5,730
Two or more steps		11,200

REGISTERED DEVICES			Fee \$
Application fee – high level registration			3,620
Additional/ concurrent – high level registration			1,810
Application fee – low level registration			1,210
Additional/ concurrent – low level registration			610
Processing fee – high level registration (variation to an existing registration)			370
Processing fee – low level registration (variation to an existing registration)			370
Annual Charge – therapeutic devices such as IVD's, tampons and disinfectants			1,360
Annual Charge			2,390
Device Clinical Trials			Fee \$
CTN			290
Clinical Trial – Other			2,270
Clinical Trial – Schedule 3 Part 1 Item 3			15,100
Evaluation Fees	Initial Application Fee \$	Concurrent Application Fee \$	Abridged Application Fee \$
High Level Registration – type of data			
Design / materials / testing	26,600	4,540	9,070
Manufacture / quality control	18,100	4,540	7,550
Biocompatibility / pre-clinical	18,100	4,540	7,550
Human clinical	30,400	4,540	30,400
Software	18,100	4,540	7,550
Confirmatory review of clinical information	n/a	n/a	7,550
Confirmatory review of overseas evaluation report	18,100	4,540	7,300
Low Level Registration – type of data			
Design / materials / testing	4,540	n/a	n/a
Manufacture / quality control	4,540	n/a	n/a
Biocompatibility / pre-clinical	4,540	n/a	n/a
Human clinical	4,540	n/a	n/a
Software	4,540	n/a	n/a
Diagnostic Goods Control Reagent	4,540	n/a	n/a
Disinfectants and diagnostic goods for in vitro use	15,100	n/a	n/a
Variation – High Level Registration – type of data			
Design / materials / testing	9,070	1,660	n/a
Manufacture / quality control	7,550	1,660	n/a
Biocompatibility / pre-clinical	7,550	1,660	n/a
Human clinical	30,400	1,660	n/a
Software	7,550	1,660	n/a
Confirmatory review of clinical information	7,550	n/a	n/a
Confirmatory review of overseas evaluation report	7,550	1,660	n/a
Variation – Low Level Registration – type of data			
Design / materials / testing	1,210	n/a	n/a
Manufacture / quality control	1,210	n/a	n/a
Biocompatibility / pre-clinical	1,210	n/a	n/a
Human clinical	1,210	n/a	n/a
Software	1,210	n/a	n/a
Diagnostic Goods Control Reagent	1,210	n/a	n/a
Disinfectants and diagnostic goods for in vitro use	3,040	n/a	n/a

LISTED DEVICES	Fee \$
Application fee	370
Processing fee (variation to an existing listing)	370
Application for exemption under Section 14	390
Annual Charge	1,210
Annual Charge – therapeutic devices such as IVD's, tampons and disinfectants	690
Evaluation Fees	Fee \$
Evaluation for assessing whether a listable or listed device is safe for the purposes for which it is to be used	15,100

LISTED DEVICES – EXPORT ONLY	Fee \$
Application fee	370
Processing fee (variation to an existing listing)	370
LISTED DEVICES – EXPORT CERTIFICATES	Fee \$
Export Certificate for listed/ listable device	130

INCLUDED DEVICES	
Medical Devices – Annual Charges	Fee \$
(a) Class AIMD medical device	1,090
(b) Class III medical device	1,090
(c) Class IIb medical device	840
(d) Class IIa medical device	840
(e) Class I medical device - sterile	550
(f) Class I medical device – measuring function	550
(g) Other Class I medical device	60
Conformity Assessment – All Procedures	Fee \$
Application for Conformity Assessment Certificate – All Procedures	820
Conformity Assessment – Initial Assessment	Fee \$
(a) Schedule 3, Part 1 – Full Quality Management System Audit; or	24,600
(b) Schedule 3, Clause 1.6 – Design Examination; or	48,500
(c) Schedule 3, Part 2 – Type Examination (including management of testing, analysis, and reporting on examination of the type); or	33,800
(d) Schedule 3, Part 3 – Verification (including management of testing, analysis, and reporting on verification tests); or	23,600
(e) Schedule 3, Part 4 – Production Quality Management System Audit; or	21,500
(f) Schedule 3, Part 5 – Product Quality Management System Audit	18,400
Conformity Assessment – Changes	Fee \$
(a) Schedule 3, Part 1 – Full Quality Management System Audit; or	14,800
(b) Schedule 3, Clause 1.6 – Design Examination; or	29,200
(c) Schedule 3, Part 2 – Type Examination (including management of testing, analysis, and reporting on examination of the type); or	20,400
(d) Schedule 3, Part 4 – Production Quality Management System Audit; or	12,900
(e) Schedule 3, Part 5 – Product Quality Management System Audit	11,200
Conformity Assessment Surveillance Audits	Fee \$
(a) Schedule 3, Part 1 – Full Quality Management System Audit; or	7,160
(b) Schedule 3, Part 4 – Production Quality Management System Surveillance Audit	7,160
(c) Schedule 3, Part 5 – Product Quality Management System Surveillance Audit	7,160

Conformity Assessment - Review of Certificate	Fee \$
(a) Schedule 3, Clause 1.6 – Design Examination re-assessment	43,900
(b) Schedule 3, Part 2 – Type Examination re-assessment (including management of testing, analysis, and reporting on examination of the type)	33,800
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	5,840
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 Therapeutic Goods Regulations 1990)	
Supplementary assessments to Items 1.2, 1.3, 1.9 or 1.10	\$340 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	\$340 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	3,330
Inclusion in the ARTG – Application for an inclusion in the Register	Fee \$
(a) Class AIMD medical device	1,090
(b) Class III medical device	1,090
(c) Class IIb medical device	840
(d) Class IIa medical device	840
(e) Class I medical device - sterile	840
(f) Class I medical device – measuring function	840
(g) Other Class I medical device	n/a
Inclusion in the ARTG – Application Audit Assessment	Fee \$
(a) Level 1 – verification of sponsor’s application and evidence of conformity	3,180
(b) Level 2 – Level 1 activities plus review of evidence of conformity	5,840
Considering submissions to the Secretary in relation to a proposed suspension of a kind of medical device from the Register	5,840
Variation to an ARTG inclusion entry if the entry is incomplete or incorrect	370
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	370
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)	290
Application for approval to use a specified kind of medical device solely for experimental purposes in humans – Clinical Trial eXemption Scheme (CTX)	15,100

IVD Devices	Fee \$
Application for conformity assessment certificate	820
Conformity Assessment – Initial Assessment	Fee \$
Schedule 3, Part 1 – Full Quality Management System Audit; or	24,700
Schedule 3, Clause 1.6 – Design Examination; or	52,700
Schedule 3, Clause 1.6 – Design Examination – immunohaematology reagent; or	12,900
Schedule 3, Clause 1.6 – Abridged Design Examination – previously registered IVDs; or	3,110
Schedule 3, Part 2 – Type Examination; or	34,100
Schedule 3, Part 4 – Product Quality Management System Audit	21,700
Conformity Assessment – Review of Certificate	Fee \$
Schedule 3, Part 1 – Full Quality Management System Audit; or	24,700
Schedule 3, Clause 1.6 – Design Examination; or	52,700
Schedule 3, Clause 1.6 – Design Examination – immunohaematology reagent; or	12,900
Schedule 3, Clause 1.6 – Abridged Design Examination; or	3,110
Schedule 3, Part 2 – Type Examination; or	34,100
Schedule 3, Part 4 – Product Quality Management System Audit	21,700
Conformity Assessment – Review of Certificate for IVD medical devices	Fee \$
Surveillance assessment for conformity assessment certificate under Schedule 3, Part 1 or 4	7,210
Inclusion in the ARTG – Application for an inclusion in the Register	Fee \$
IVD medical devices, including Class 4 in-house IVDs	840
Conformity Assessment – Additional Fees	Fee \$
Supplementary assessment in addition to assessment mentioned in item 1.2, 1.3, 1.9A or 1.10A	\$350 per assessor hour
Application audit assessment for Class 1, Class 2 and Class 3 IVDs	5,690
Initial and annual notification by a laboratory of its in-house IVDs	840
Considering submissions to the Secretary in relation to a proposed suspension of a conformity assessment certificate for an IVD	5,690
Annual charges for IVDs Class 1-4	Nil

GOOD MANUFACTURING PRACTICE (GMP)	Fee \$
Licence application fee (excluding Biologicals)	840
Australian Manufacturers – GMP Audit Fee ^{1,2}	Hourly rate per Auditor \$
All types of therapeutic goods	550
Annual Licence Charge ^{1,3}	Fee \$
Single step / single medicine / single type of therapeutic device	5,300
In-vitro diagnostic products	5,300
Ingredients or components	5,300
Herbal / Homeopathic medicinal products	5,300
Other types of therapeutic goods, including containers in which therapeutic goods are to be packed	10,300
<p><i>Note:</i></p> <ol style="list-style-type: none"> <i>Not applicable to blood, blood products, and human tissues, which appear on p3.</i> <i>GMP Audit fee is payable when an audit is undertaken before a licence is issued</i> <i>The following audit hours are included in the annual licence charges:</i> <ul style="list-style-type: none"> <i>Manufacturers with low level licence charges – total 16 auditor hours in 3 financial years</i> <i>Manufacturers with high level licence charges – total 48 auditor hours in 3 financial years</i> <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	1,130
Overseas Manufacturers – GMP Clearance Fees	Fee \$
Assessment of GMP evidence (per manufacturer, per site and per sponsor)	320
Obtaining evidence from overseas regulatory agency (per manufacturer, per site and per sponsor)	570
Reinstatement of expired GMP clearance approval (per manufacturer, per site and per sponsor)	970
Desk Audit (in-lieu of an overseas GMP audit)	1,720
GMP Certificates	Fee \$
Certificate of GMP Compliance	130
Quality Systems Certificate	130
Mutual Recognition Agreement Certificate	270
Certified copy of a certificate	40

MISCELLANEOUS	Fee \$
ARTG reinstatement application fee – registered medicines or devices – per invoice	550
ARTG reinstatement application fee – listed medicines or devices – per invoice	550
Processing fee for consent under Section 14 to waive compliance with standards for prescription, registered and listed medicines – per product/ARTG entry	390
ARTG information – Freedom of Information (FOI) charges apply – contact ARTG for advice	
The wholesale turnover level for reduction in the manufacturing licence charge is \$81,300	

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 threshold of sales used in calculation of Low Volume Turnover products for exemption of Annual Charges is 15 times that of the Annual Charge.	

ADVERTISING	
Fees for Advertisements in “Specified Media” other than “Broadcast Media”	Fee \$
Advertising processing time less than 1 hour and:	
• not more than 100 words	200
• more than 100 words	250
• more than 300 words (including advertorial)	390
• minor change to an approved advertisement sought more than 3 months after approval	90
• re-approval of an identical advertisement whose approval number has expired	50% of applicable fee
• approval of a variation to an advertisement whose approval number has not expired	50% of applicable fee
• classified advertisement	90
Each additional hour or part thereof	180
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	990
Television Commercial for a retail outlet that is intended to be broadcast on 1 regional station only in that station’s regional area	520
Television Advertorial greater than 150 seconds in length	750 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	360
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	260
Still Cinema Media including outdoor media:	
• not more than 100 words	200
• not more than 300 words	250
• more than 300 words	390
• minor change to an approved advertisement sought more than 3 months after approval	50% of applicable fee
• re-approval of an identical advertisement whose approval number has expired	50% of applicable fee
• approval of a variation to an advertisement whose approval number has not expired	50% of applicable fee
Each additional hour or part thereof	180

BIOLOGICALS	Fee \$
Annual Charges	Fee \$
Annual charge for Class 1 biological	550
Annual charge for Class 2,3,4 biological	5,550
Application and Notification Fees	Fee \$
Application for manufacturing licence	900
Application for variation	900
Application for inclusion of a Class 1,2,3,4 biological	900
Notification Fee for a biological (CTN)	280
Evaluation Fees	Fee \$
Variation Class 2	5,500
Minor Variation Class 3 and 4	14,500
Major Variation Class 3 and 4	28,500
Evaluation of an ingredient/component	19,400
Evaluation CTX	21,600
Inspection Fees	Fee \$
Domestic initial manufacturing audit	17,900
Domestic subsequent manufacturing audit	13,500
Overseas initial manufacturing audit	17,900
Overseas subsequent manufacturing audit	13,500
Inspection Fee - in addition to initial or subsequent inspection fee outside Australia	550