TGA THERAPEUTIC GOODS ADMINISTRATION

Proposed Fees and Charges commencing 1 July 2005

ABN: 40 939 406 804

PRESCRIPTION MEDICINES

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 from, or on behalf of, another sponsor is a separate submission.

Evaluation Fees Category 1 and 2 Submissions	**Fee $ - 100%**	**Fee $ - 75%**
New Chemical Entity	185,600	139,200
Extension of indications	110,400	82,800
Major variations (new strength, new dosage form, new route of administration, change in patient group, change in dosage)	71,900	53,900
New generic product	65,000	48,800
Additional trade name	11,600	8,700
Minor variations (change in formulation, composition, specifications or container) and 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.	4,230	3,200
Changes to Product Information involving the evaluation of data	4,230	3,200
Changes to Product Information where no evaluation is required	1,300	1,000
Changes to Consumer Medicine Information	1,300	1,000

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 or 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	4,230
Notification of Self Assessable Changes	1,300
Safety Related Notification	1,300
Testing and provision of advice, requested from Pharmaceutical Benefits Program, prior to listing on Pharmaceutical Benefits Listing Program (*this item is inclusive of GST)	9,945 (10,940)*

Administrative Charges	**Fee $**
Withdrawal of submission prior to acceptance of the submission	20% of evaluation fee to a maximum of $6,030
Withdrawal of submission after the evaluation process is taken to be complete	Full fee
Correction of a Register entry	1,300

Annual Charges	**Fee $**
Biologics	3,690
Non-Biologics	2,230

Clinical Trials	**Fee $**
CTX 30 Days	1,240
CTX 50 Days	15,300
CTN	240
CTN-more than one trialing body	240

REGISTRATION OF NON-PRESCRIPTION MEDICINES (OTC & COMPLEMENTARY MEDICINES)	**Fee $**
Application fee	800
Additional /concurrent application fee	350
Processing fee (variation to an existing registration)	800
Annual charge	740
EVALUATION FEES per submission if the evaluation documentation does not contain Clinical or Toxicological data	**Fee $**
New product	5,350
Variation	1,930
New substance: CMEC, sunscreen excipients, all other	5,350
EVALUATION FEES - page counts	
New product – total page count of Clinical or Toxicological data per submission	**Fee $**
1-50	5,350
51-250	6,850
251-500	9,340
501-1000	12,500
1001-2000	18,700
2001-3000	25,000
>3000	37,300
Variations – total page count of Clinical or Toxicological data per submission	**Fee $**
1-50	1,930
51-250	6,850
251-500	9,340
501-1000	12,500
1001-2000	18,700
2001-3000	25,000
>3000	37,300

Non-prescription medicines (cont) **New Substance** - – total page count of Clinical or Toxicological data per submission	**Fee $**
1-50	5,350
51-250	6,850
251-500	9,340
501-1000	12,500
1001-2000	18,700
2001-3000	25,000
>3000	37,300
Multiple new excipients in listed or registered good for dermal use	**Fee $**
1-50	5,350
51-250	6,850
251-500	9,340
501-1000	12,500
1001-2000	18,700
2001-3000	25,000
>3000	37,300
[redacted]	[redacted]
1-50	5,350
51-250	6,850
251-500	9,340
501-1000	12,500
1001-2000	18,700
2001-3000	25,000
>3000	37,300

[redacted]	[redacted]
Application fee	510
Processing fee (variation to an existing listing)	250
Annual charge	550
Evaluation fee for assessing information or documents relating to the safety of goods for the purposes for which they are to be used.	4,980

BLOOD, BLOOD COMPONENTS, AND HUMAN TISSUES

EVALUATION FEES - per submission

Page counts	**Fee $**
1 - 10	910
11 - 50	7,720
51 - 100	17,100
101 - 1000	23,100
1001 - 3000	36,100
3001 - 4000	47,900
> 4000	58,500
[redacted]	**Hourly rate per auditor $**
GMP audit of primary site	620
GMP audit of site other than primary site	440
Annual Licence Charge	**Fee $**
Primary site	101,300
Additional fixed site (non-mobile) associated with a primary site	5,390
[redacted]	[redacted]
GMP audit fee	440
[redacted]	[redacted]
Manufacturing premises	4,360
[redacted]	[redacted]
GMP audit fee	440
Annual Licence Charge	**Fee $**
Single step and single human tissue	4,360
Two or more steps of manufacture	8,460

REGISTERED DEVICES	Fee $
Application fee - high level registration	2,990
Additional concurrent - high level registration	1,490
Application fee - low level registration	990
Additional/concurrent - low level registration	510
Processing fee - high level registration (variation to an existing registration)	990
Processing fee - low level registration (variation to an existing registration)	510
Annual Charge - therapeutic devices such as IVD's, tampons and disinfectants	1,130
Annual charge	1,970
Device Clinical Trials	
CTN	260
Clinical Trial - other	1,880
Clinical Trial - Sched 3 Pt1 Item 3	12,500

EVALUATION FEES	Initial Application Fee $	Concurrent Application Fee $	Abridged Application Fee $
High Level Registration -type of data			
Design materials/testing	22,000	3,740	7,460
Manufacture/quality control	14,900	3,740	6,230
Biocompatibility/pre-clinical	14,900	3,740	6,230
Human clinical	25,000	3,740	25,000
Software	14,900	3,740	6,230
Confirmatory review of clinical information	N/A	N/A	6,230
Confirmatory review of overseas evaluation report	14,900	3,740	6,230
Low Level Registration -type of data			
Design/materials/testing	3,740	N/A	N/A
Manufacture/quality control	3,740	N/A	N/A
Biocompatibility/pre-clinical	3,740	N/A	N/A

Registered Devices (cont.):

EVALUATION FEES (cont.)	Initial Application Fee $	Concurrent Application Fee $	Abridged Application Fee $
Human clinical	3,740	N/A	N/A
Software	3,740	N/A	N/A
Diagnostic Goods Control Reagent	3,740	N/A	N/A
Disinfectants and diagnostic goods for in vitro use	12,500	N/A	N/A
Variation - High Level Registration - type of data			
Design/materials testing	7,460	1,370	N/A
Manufacture/quality control	6,230	1,370	N/A
Biocompatibility/pre-clinical	6,230	1,370	N/A
Human clinical	25,000	1,370	N/A
Software	6,230	1,370	N/A
Confirmatory review of clinical information	6,230	N/A	N/A
Confirmatory review of overseas evaluation report	6,230	1,370	N/A
Variation – Low Level Registration – type of data			
Design materials/testing	990	N/A	N/A
Manufacture/quality control	990	N/A	N/A
Biocompatibility/pre-clinical	990	N/A	N/A
Human clinical	990	N/A	N/A
Software	990	N/A	N/A
Diagnostic Goods Control Reagent	990	N/A	N/A
Disinfectants and diagnostic goods for in vitro use	2,500	N/A	N/A

LISTED DEVICES	Fee $
Application fee	310
Processing fee (variation to an existing listing)	310
Application for exemption under Section 14	310
Annual Charge	990
Annual Charge - therapeutic devices such as IVD's, tampons and disinfectants	550
Evaluation Fees	
Evaluation for assessing whether a listable or listed device is safe for the purposes for which it is to be used.	12,500

INCLUDED DEVICES	
Conformity Assessment – All Procedures	**Fee $**
Application for Conformity Assessment Certificate – All Procedures	690
Medical Devices – Annual Charges	**Fee $**
(a) Class AIMD medical device;	910
(b) Class III medical device;	910
(c) Class IIb medical device;	690
(d) Class IIa medical device;	690
(e) Class I medical device - sterile;	690
(f) Class I medical device - measuring function;	690
(g) Other Class I medical device	60
Conformity Assessment – Initial Assessment	**Fee $**
(a) Schedule 3, Part 1- Full Quality Management System Audit; or	20,200
(b) Schedule 3, clause 1.6 - Design Examination; or	40,000
(c) Schedule 3, Part 2 - Type Examination (including management of testing, analysis, and reporting on examination of the type); or	27,800
(d) Schedule 3, Part 3 - Verification (including management of testing, analysis, and reporting on verification tests); or	19,500
(e) Schedule 3, Part 4 - Production Quality Management System Audit; or	17,700
(f) Schedule 3, Part 5 - Product Quality Management System Audit	15,300
Conformity Assessment – Change	**Fee $**
(a) Schedule 3, Part 1- Full Quality Management System Audit; or	12,200
(b) Schedule 3, clause 1.6 - Design Examination; or	24,000
(c) Schedule 3, Part 2 - Type Examination (including management of testing, analysis, and reporting on examination of the type); or	16,700
(e) Schedule 3, Part 4 - Production Quality Management System Audit; or	10,600
(f) Schedule 3, Part 5 - Product Quality Management System Audit	9,160
Conformity Assessment Surveillance Audit	**Fee $**
(a) Schedule 3, Part 1 - Full Quality Management System Surveillance Audit; or	5,900
(b) Schedule 3, Part 4 - Production Quality Management System Surveillance Audit	5,900
(c) Schedule 3, Part 5 - Product Quality Management System Surveillance Audit	5,900
Conformity Assessment – Review of Certificate	**Fee $**
(a) Schedule 3, clause 1.6 - Design Examination re-assessment	36,200
(b) Schedule 3, Part 2 - Type Examination re-assessment (including management of testing, analysis, and reporting on examination of the type)	27,800
Conformity Assessment – Components - Initial	**Fee $**
(a) Schedule 3, Part 1- Full Quality Management System Audit; or	20,200
(b) Schedule 3, clause 1.6 - Design Examination; or	40,000
(c) Schedule 3, Part 2 - Type Examination (including management of testing, analysis, and reporting on examination of the type); or	27,800
(d) Schedule 3, Part 3 - Verification (including management of testing, analysis, and reporting on verification tests); or	19,500

(e)	Schedule 3, Part 4 - Production Quality Management System Audit; or	17,700
(f)	Schedule 3, Part 5 - Product Quality Management System Audit	15,300
Conformity Assessment – Components – Changes		**Fee $**
(a)	Schedule 3, Part 1- Full Quality Management System Audit; or	12,200
(b)	Schedule 3, clause 1.6 - Design Examination; or	24,000
(c)	Schedule 3, Part 2 - Type Examination (including management of testing, analysis, and reporting on examination of the type); or	16,700
(e)	Schedule 3, Part 4 - Production Quality Management System Audit; or	10,600
(f)	Schedule 3, Part 5 - Product Quality Management System Audit	9,160
Considering submission to the Secretary in relation to a proposed suspension of conformity assessment certificate		**Fee $**
Considering a submission to the Secretary in relation to a proposed suspension of a conformity assessment certificate		4,810
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		$290 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		$290 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.		2,750
INCLUSION IN THE ARTG – Application for inclusion in the Register		**Fee $**
(a)	Class AIMD medical device;	910
(b)	Class III medical device;	910
(c)	Class IIb medical device;	690
(d)	Class IIa medical device;	690
(e)	Class I medical device - sterile;	690
(f)	Class I medical device - measuring function;	690
(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		2,630
(b) Level 2 – Level 1 activities plus review of evidence of conformity		4,810
Considering submissions to the Secretary in relation to a proposed suspension of a kind of medical device from the Register		4,810
Variation to an ARTG inclusion entry if the entry is incomplete or incorrect		310

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.	310
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)	260
Application for approval to use a specified kind of medical device solely for experimental purposes in humans - Clinical Trial eXemption Scheme (CTX)	12,500

GOOD MANUFACTURING PRACTICE (GMP)	Fee $
Licence application fee	690
Australian Manufacturers - GMP Audit Fee [1,2]	**Hourly rate per Auditor $**
All types of therapeutic goods	440
Annual Licence Charge [1,3]	
Single step single medicine/single type of therapeutic device	4,360
In-vitro diagnostic products	4,360
Ingredients or components	4,360
Herbal/homeopathic medicinal products	4,360
Other types of therapeutic goods, including containers in which therapeutic goods are to be packed	8,460

Note:

1. *Not applicable to blood, blood products, and human tissues, which appear on p 4.*
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:*
   - *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.*

   GMP audit fee for Australian manufacturers is applicable once the above number of hours is exceeded.

Overseas Manufacturers - GMP Audit Fee	**Hourly rate per Auditor $**
All types of therapeutic goods	930
Overseas Manufacturers - GMP Clearance Fees	**Fee $**
Assessment of GMP evidence (per manufacturer, per site and per sponsor)	260
Obtaining evidence from overseas regulatory agency (per manufacturer, per site and per sponsor)	230
Reinstatement of expired GMP clearance approval (per manufacturer, per site and per sponsor)	800
GMP Certificates	
Certificate of GMP Compliance	100
Quality Systems Certificate	100
Mutual Recognition Agreement Certificate	210
Certified copy of a certificate	40

MISCELLANEOUS	Fee $
Export Certificate	100
ARTG reinstatement application fee - registered medicines or devices - per invoice	690
ARTG reinstatement application fee - listed medicines or devices - per invoice	350
Processing fee for consent under Section 14 to waive compliance with standards for prescription, registered and listed medicines - per product/ARTG entry	310
Application for Declaration that Turnover is Low Volume and Low Value – per product ($11,700max.)	100
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 charges is 6.8%.	
The wholesale turnover level for reduction in the manufacturing licence charge has increased from $65,000 to $67,100.	

ADVERTISING	Fee $
FEES FOR ADVERTISEMENTS IN "SPECIFIED MEDIA" OTHER THAN "BROADCAST MEDIA"	
Advertising processing time less than 1 hour and - not more than 100 words	150
- more than 100 words	190
- more than 300 words (including advertorial)	320
- minor change to an approved advertisement sought more than 3 months after approval	80
-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	80
Each additional hour or part thereof	130
FEES FOR ADVERTISEMENTS IN "BROADCAST MEDIA"	
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.	830
Television Commercial for a retail outlet that is intended to be broadcast on 1 regional station only in that station's regional area	420
Television Advertorial greater than 150 seconds in length.	620 for first minute plus 150 per minute or part minute after that
Radio Advertisement Including up to 6 variants of the one concept, for the same product.	300
Radio Advertisement that is intended to be broadcast in a regional area only, including up to 6 variations of the concept for the same product	200
Still Cinema Media including outdoor media **Not more than 100 words** **Not more than 300 words** **More than 300 words**	 150 190 320
- 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	130