

OPTION 1 - New Register Entries (average 3 actions [MONTHLY INVOICES] per sponsor per year) - REFRESHED/CALCULATED BASED ON FY2013-14 DATA on 20 November 2014)

Step No.	Description	TGA Task	Sponsor Task	Sponsor Time (Hours)	No of Sponsors Affected	Class	Sponsor Hourly Rate	Sponsor Total Cost	Comments from RIA team	No. Sponsors Actual (RBM Use Only)	Cost Category
1	A new therapeutic product is listed, registered or included on the Register. An ARTG number is assigned to the product	Yes	No	0.00	1,560	Not Applicable - TGA Only	0.00	\$0.00	We do not cost option 1 as we cost CHANGE from stus quo. However, I have used these figure as the deregulatory component of each of option 2 and 3 since they will no longer be required.	1,290	
2	The full year annual charge is incurred (per ARTG No.) effective from the date of listing, registration or inclusion on the Register	Yes	No	0.00	1,560	Not Applicable - TGA Only	0.00	\$0.00		1,290	
3	TGA Financial Services issues a tax invoice to the sponsor for the applicable annual charge	Yes	No	0.00	1,560	Not Applicable - TGA Only	0.00	\$0.00		1,290	
4	Sponsor assesses that the estimated turnover of the new entry will not be a low value turnover. (average 6 new entries per sponsor)	No	Yes	1.00	1,225	Managers (including accountants)	72.80	\$72.80		948	Notification
5	Sponsor pays the annual charge for the entry. No further action is required.	No	Yes	1.00	1,225	Clerical and Administrative Workers	53.20	\$53.20	Would it really take 1 hour to pay the charge? This applied to all tasks involving paying a charge.	948	Notification
6	Sponsor assesses that the estimated turnover of the new entry will be a low value turnover. (average 7 new entries per sponsor)	No	Yes	1.00	335	Managers (including accountants)	72.80	\$72.80		342	Notification
7	Sponsor prepares an LVT application for the new entry which must be accompanied by (a) a statement of the estimated turnover of the therapeutic good for the current financial year and signed by the person liable to pay the charge; and (b) payment for the LVT application fee.	No	Yes	4.00	335	Managers (including accountants)	72.80	\$291.20		342	Notification
8	The sponsor submits the completed LVT application to the TGA. The application must be received at least 21 days before the date for payment of the applicable annual charge.	No	Yes	0.50	335	Clerical and Administrative Workers	53.20	\$26.60		342	
9	The TGA Delegate assesses the LVT application. If approved, a letter is issued to the sponsor with a credit note for the exempted charge. As a new entry LVT exemption, the approval is conditional that the sponsor must provide by 1 September in the following year, a statement, signed by an approved person, detailing the actual turnover of the entry in the year the entry was a new entry.	Yes	No	0.00		Not Applicable - TGA Only	0.00	\$0.00			
10	Validation reviews of new entry LVT exemptions commences on 1 July in the following year. The validation review entails the TGA writing to all affected sponsors to remind them their obligations to supply a statement of actual turnover by 1 September.	Yes	No	0.00		Not Applicable - TGA Only	0.00	\$0.00			
11	The sponsor extracts the actual turnover of the entry from (e.g.) their sales/ finance system and records it on a 'statement of actual turnover' form (approved by the Secretary) and then must have the actual turnover verified by an approved person. If satisfied, the approved person signs a declaration that the turnover reported is the actual turnover of the entry. The sponsor sends the completed statement to the TGA by 1 September 2014	No	Yes	8.00	335	Managers (including accountants)	72.80	\$582.40		342	Notification
11.1	The sponsor cannot supply a statement of actual turnover by 1 September and applies in writing for an extension (up to 28 days). If received before 1 September, the TGA approves the extension to 29 September (23 out of 334 sponsors (or 7%) applied for extensions in 13-14)	Yes	Yes	1.00	24	Managers (including accountants)	72.80	\$72.80	Non-compliance is not costed (or inability to comply). DISAGREE - This not non-compliance - there is a legit provision in the Regulations which allows the sponsors additional time to supply a statement of actual turnover (on the basis the request is rec'd in writing prior to 1 Sept)- while only a small number of sponsors use the provision each year does not make it a non-compliance issue - Dereg Response (thru Heidi) is that we do not impose the extension on the sponsor so should not include it - REMOVAL AGREED	24	Notification
12	The TGA Delegate assesses the actual turnover of the new entry was a low value turnover. The exemption is confirmed under regulation 43AAF.	Yes	No	0.00	280	Not Applicable - TGA Only	0.00	\$0.00		262	
13	The sponsor is notified by the TGA in writing that the exemption is confirmed and no further action is required.	Yes	No	0.00		Not Applicable - TGA Only	0.00	\$0.00			
14	The TGA Delegate assesses the actual turnover of the new entry was not a low value turnover. The exemption is cancelled under regulation 43AAF.	Yes	No	0.00		Not Applicable - TGA Only	0.00	\$0.00			
15	The sponsor is notified by the TGA in writing that the exemption is cancelled and the annual charge is (now) payable by 31 October. The sponsor pays the tax invoice for the annual charge.	Yes	Yes	1.00	45	Clerical and Administrative Workers	53.20	\$53.20		47	Notification
16	The sponsor does not supply the statement of actual turnover by 1 September. The exemption is cancelled under regulation 43AAE.	Yes	No	0.00		Not Applicable - TGA Only	0.00	\$0.00	non-compliance is not costed		
17	The sponsor is notified in writing that the exemption is cancelled under regulation 43AAE for failure to give information and the annual charge is (now) payable by 31 October. The sponsor pays the tax invoice for the annual charge.	Yes	Yes	1.00	10	Clerical and Administrative Workers	53.20	\$53.20	this is no longer part of LVT scheme - not costed...??Can discuss.	33	Notification
								\$1,278.20			

Managers (including accountants)	\$72.80	Notification	126.00	119,448.00
Professionals	\$76.48	Education	1152.20	394,052.40
Technicians and Trades Workers	\$58.10	Permission		513,500.40
Community and Personal Service Workers	\$55.48	Purchasing		
Clerical and Administrative Workers	\$53.20	Record keeping		
Sales Workers	\$47.60	Enforcement		
Machinery Operators And Drivers	\$54.25	Publication and documentation		
Labourers	\$46.55	Procedural		
All occupations	\$59.85	Delay		
Not Applicable - TGA Only	\$0.00	Other		

	AWE May 2013 Hourly	Oncost Multiplier	Hourly Rate \$
Managers	\$41.60	1.75	72.80
Professionals	\$43.70	1.75	76.48
Technicians and	\$33.20	1.75	58.10
Community and	\$31.70	1.75	55.48
Clerical and Ad	\$30.40	1.75	53.20
Sales Workers	\$27.20	1.75	47.60
Machinery Ope	\$31.00	1.75	54.25
Labourers	\$26.60	1.75	46.55
All occupations	\$34.20	1.75	59.85
Not Applicable	0	0	0

OPTION 2B - New Register Entries (up to 12 MONTHLY INVOICES per sponsor per year) - REFRESHED/CALCULATED BASED ON FY2015-16 DATA as 30 November 2014

Step No.	Description	TGA Task	Sponsor Task	Sponsor Time (Hours)	No of Sponsors Affected	Class	Sponsor Hourly Rate	Sponsor Total Cost
	A new therapeutic product is listed, registered or included on the Register. An ARTG number is assigned to the product	Yes	No	0.00	1,540	Not Applicable - TGA Only	0.00	\$0.00
	Sponsor assesses that the turnover of the new entry is not \$0 turnover and declares (not \$0 turnover) through the online portal or by paper form.	No	Yes	1.00	1,225	Managers (including accountants)	72.80	\$72.80
	The full year annual charge is incurred (per ARTG No.) effective from the date of listing, registration or inclusion on the Register	Yes	No	0.00		Not Applicable - TGA Only	0.00	\$0.00
	TGA Financial Services issues a tax invoice to the sponsor for the applicable annual charge	Yes	No	0.00		Not Applicable - TGA Only	0.00	\$0.00
	Sponsor pays the annual charge for the entry. No further action is required.	No	Yes	1.00	1,225	Clerical and Administrative Workers	53.20	\$53.20
	Sponsor assesses that the estimated turnover of the new entry will be \$0 turnover. (Average 7 new entries per sponsor)	No	Yes	1.00	335	Managers (including accountants)	72.80	\$72.80
	Sponsor assesses there is no turnover forecast for the entry in the current year so the entry will not incur an annual charge provided the sponsor makes a declaration (within 21 days from registration, listing or inclusion of the entry on the Register) of \$0 turnover through the online self-service portal (or by paper form).							
	NVT exemption - Entry is a \$0 turnover entry. Once a sponsor has reported (through the online portal or by paper form) that an entry is a \$0 turnover entry, the \$0 turnover flag will result in an automatic annual product charge exemption. The sponsor will not receive a tax invoice for any entries which are \$0 turnover.							
	The annual product charge exemption will remain in force until the sponsor subsequently advises an entry has incurred turnover (subject to the sponsor's annual update (detailed below) within 21 days of commencement of the next financial year that an entry did not generate any turnover in the previous year and therefore continues to be eligible for an NVT exemption).							
	Sponsor provides an annual (turnover status) renewal declaration - to ensure continuity of the NVT exemption, the sponsor will be required to update the turnover status of all \$0 turnover entries by completing an online declaration that the entries did not generate turnover in the previous financial year (by 22 July). If the entries were \$0 turnover, no further action is required until the next annual update is required (the next financial year). If the entries were not \$0 turnover, the NVT exemption will cease and the applicable annual charge for the full financial year in which the turnover was generated will become payable....	No	Yes	1.00	335	Managers (including accountants)	72.80	\$72.80
	Sponsor does not provide an annual (turnover status) renewal declaration - If a sponsor fails to provide an annual (turnover status) renewal declaration by 22 July in the next financial year, the annual charge exemption will cease and the applicable annual product charge will be payable from the beginning of the year to which the update relates. (For example, an update required by 22 July 2016 relates to FY2015-16 - failure to provide an update will incur the 2015-16 annual charge, and by default will also incur the 2016-17 annual charge (as 16/17 commences on 1 July 2016).	No	No	0.00		Not Applicable - TGA Only	0.00	\$0.00
	TGA Financial Services issues a tax invoice to the sponsor for the applicable annual charges	Yes	No	0.00		Not Applicable - TGA Only	0.00	\$0.00
	Sponsor pays the annual charge(s) for any not \$0 turnover entries. No further action is required until the next full year annual product charge is incurred.	No	Yes	1.00	335	Clerical and Administrative Workers	53.20	\$53.20
	Sponsor declares an NVT exemption entry has incurred turnover - Sponsors will be required to declare within 21 days if an entry (subject to an NVT exemption) incurs any turnover. Upon receiving the sponsor's advice that an entry has incurred turnover, the annual charge exemption will cease and the full year charge will become payable for the year in which turnover was incurred (and, if applicable, any subsequent years).	No	Yes	1.00	335	Clerical and Administrative Workers	53.20	\$53.20
	TGA Financial Services issues a tax invoice to the sponsor for the applicable annual charges	Yes	No	0.00		Not Applicable - TGA Only	0.00	\$0.00
	Sponsor pays the annual charge(s) for any not \$0 turnover entries. No further action is required until the next full year annual product charge is incurred.	No	Yes	1.00	335	Clerical and Administrative Workers	53.20	\$53.20
	ANNUAL CHARGES INVOICING SCHEDULE Monthly invoices - \$0 turnover entries generating turnover during a financial year Tax invoices will be issued (monthly) after a sponsor's voluntary declaration (during the current financial year) that a \$0 turnover entry has commenced generating turnover in that financial year. Example (Monthly Invoicing): A \$0 turnover entry commences generating turnover on 1 October. The sponsor declares by 22 October that the entry is not \$0 turnover. (Note - If the sponsor does not voluntarily declare the turnover within 21 days of the turnover being generated, the sponsor will be required to declare the turnover (including \$0 turnover if there was no turnover) of the entry in the next compulsory annual (turnover status) renewal declaration due by 22 July in the next financial year.) Where a sponsor declaration of turnover is received during a financial year (i.e. at any other time than a compulsory annual (turnover status) renewal declaration by 22 July in the next financial year), an invoice for the applicable full year annual charge will be issued in the next monthly invoice run (i.e. as per the example above, if turnover is recorded for a \$0 turnover entry on 1 October, the sponsor may declare the turnover by 22 October for invoicing on 7 November for payment by 7 December) If a compulsory annual (turnover status) renewal declaration is not completed by 22 July in the next financial year, the Regulations will assume the entry was not \$0 turnover in the previous financial year and the applicable annual charge will become payable together with the charge for the current year (and each year thereafter until the entry is cancelled from the Register). Annual Invoicing 'Not \$0 turnover entries' Entries which are not \$0 turnover on the next 1 July incur the full year annual charge. Annual invoices are issued in July for payment by 1 October (and again each year thereafter until the entry is cancelled from the Register).	Yes	No	0.00		Not Applicable - TGA Only	0.00	\$0.00
\$431.20								

Managers (including accountants)	\$72.80	Notification	126.00	119,448.00
Professionals	\$76.43	Education	305.20	104,378.40
Technicians and Trades Workers	\$58.10	Permission		
Community and Personal Service Workers	\$53.48	Purchasing		
Clerical and Administrative Workers	\$53.20	Record Keeping		
Sales Workers	\$47.60	Enforcement		
Machinery Operators And Drivers	\$44.25	Publication and documentation		
Labourers	\$46.55	Procedural		
All occupations	\$59.85	Other		
Not Applicable - TGA Only	\$0.00			

No. Sponsors Actual (RBM Use Only)	Cost Category
1,290	
948	Notification
1,290	
948	Notification
342	Notification
1,290	
948	Notification
1,290	
948	Notification

AWR May 2013 Hourly	Discount Multiplier	Hourly Rate \$
Managers	0.41	72.80
Professionals	0.41	76.43
Technicians and Trades Workers	0.41	58.10
Community and Personal Service Workers	0.41	53.48
Clerical and Administrative Workers	0.41	53.20
Sales Workers	0.41	47.60
Machinery Operators And Drivers	0.41	44.25
Labourers	0.41	46.55
All occupations	0.41	59.85
Not Applicable	0	0

OPTION 3 - Cease the Scheme (Up to 13 actions [ANNUAL INVOICE + MNTHLY INVOICES] per year) - REFRESHED/CALCULATED BASED ON FY2013-14 DATA on 20 November 2014)								
Step No.	Description	TGA Task	Sponsor Task	Sponsor Time (Hours)	No of Sponsors Affected	Class	Sponsor Hourly Rate	Sponsor Total Cost
1	Existing Register entry (at 1 July): If the entry is an existing on the Register at 1 July, the full year annual charge is incurred.	Yes	No	0.00		Not Applicable - TGA Only	0.00	\$0.00
2	The TGA Accounts Team issues the sponsor an existing entry annual charge invoice for the applicable annual charge in July for payment by 1 October.	Yes	No	0.00		Not Applicable - TGA Only	0.00	\$0.00
3	The sponsor pays the applicable annual charge. No further action is required until the next full year annual charge is incurred on the (next) 1 July.	No	Yes	1.00	3,679	Clerical and Administrative Workers	53.20	\$53.20
4	New Register entry: If the entry is a new entry in the Register, the full year annual charge is incurred for the year the entry is a new entry.	Yes	No	0.00		Not Applicable - TGA Only	0.00	\$0.00
5	The TGA Accounts Team issues the sponsor a new entry annual charge invoice for the applicable annual charge. New entry annual product charges invoices are issued to sponsors' on a monthly basis.	Yes	No	0.00		Not Applicable - TGA Only	0.00	\$0.00
6	The sponsor pays the applicable annual charge. No further action is required until the next full year annual charge is incurred on the (next) 1 July.	No	Yes	1.00	1,560	Clerical and Administrative Workers	53.20	\$53.20
								<u>\$106.40</u>

Cost Category
Notification
Notification

Managers (including accountants)	\$72.80
Professionals	\$76.48
Technicians and Trades Workers	\$58.10
Community and Personal Service Workers	\$55.48
Clerical and Administrative Workers	\$53.20
Sales Workers	\$47.60
Machinery Operators And Drivers	\$54.25
Labourers	\$46.55
All occupations	\$59.85
Not Applicable - TGA Only	\$0.00

- Notification
- Education
- Permission
- Purchasing
- Record keeping
- Enforcement
- Publication and documentation
- Procedural
- Delay
- Other

Summary report

Cost per entity equals total cost per segment divided by total number of entities within the segment.

Proposal name	Review of the Low Value Turnover Exemption (LVT) Scheme		
Reference number	XXXXX		
Problem and objective			
Problem	The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating therapeutic goods including medicines,		
Objective	The objectives of a proposed scheme (to replace the current LVT scheme) are as follows: 1. The proposed scheme is consistent with the objectives of the Therapeutic Goods Act 1989		
Explanatory information			
Not applicable			
Segments affected			
Business			
Option 1			
Option name	Option 2: Vary the current scheme to exempt (all) products which are \$0 turnover - regulatory component		
Option description	Option 2 proposes that the sponsor of a therapeutic good which generates \$0 turnover will be exempt from the requirement to pay an annual charge in respect of that good. Option		
Business affected	3679		
	Business	Cost per business	Total cost for all business
Start up cost		\$0	\$0
Ongoing compliance cost per year		\$0	\$1,229,000
Start up time		0 hr	0 hr
Ongoing compliance time per year		0 hr	0 hr
Option 2			
Option name	Option 2: Vary the current scheme to exempt (all) products which are \$0 turnover - deregulatory component		
Option description	Option 2 proposes that the sponsor of a therapeutic good which generates \$0 turnover will be exempt from the requirement to pay an annual charge in respect of that good. Option		
Business affected	3679		
	Business	Cost per business	Total cost for all business
Start up cost		\$0	\$0
Ongoing compliance cost per year		-\$1,000	-\$4,190,000
Start up time		0 hr	0 hr
Ongoing compliance time per year		0 hr	0 hr
Option 3			
Option name	Option 3 - Cease the LVT Scheme - regulatory component		
Option description	Under option 3, all entries on the Register would incur an annual product charge. No annual charge exemptions would be available. Annual charge rates would be adjusted for all		
Business affected	3679		
	Business	Cost per business	Total cost for all business
Start up cost		\$0	\$0
Ongoing compliance cost per year		\$0	\$755,000
Start up time		0 hr	0 hr
Ongoing compliance time per year		0 hr	0 hr
Option 4			
Option name	Option 3 : Cease LVT scheme deregulatory component		
Option description	Option 2 proposes that the sponsor of a therapeutic good not supplied to the market will be exempt from the requirement to pay an annual charge in respect of that good. Option 2		
Business affected	3679		
	Business	Cost per business	Total cost for all business
Start up cost		\$0	\$0
Ongoing compliance cost per year		-\$1,000	-\$4,190,000
Start up time		0 hr	0 hr
Ongoing compliance time per year		0 hr	0 hr

Notes

1. An assessment of compliance costs in itself do not provide an answer to the most effective and efficient regulatory proposal. Rather, it provides information that needs to be considered alongside other factors when deciding between policy options.

2. Negative dollar figures present a cost saving.

3. If 'See PV' appears in a cell you can refer to the present value report for more information.

OPTION 1 - Existing Register Entries (One action [ANNUAL INVOICE] per year) - REFRESHED/CALCULATED BASED ON FY2013-14 DATA on 20 November 2014)

Step No.	Description	TGA Task	Sponsor Task	Sponsor Time (Hours)	No of Sponsors Affected	Class	Sponsor Hourly Rate	Sponsor Total Cost
1	All existing entries on the Register on 1 July incur the applicable full year annual charge(s)	Yes	No	0.00		Not Applicable - TGA Only	0.00	\$0.00
2	TGA Financial Services issues a tax invoice to the sponsor for the applicable annual charge(s).	Yes	No	0.00	3,679	Not Applicable - TGA Only	0.00	\$0.00
3	Sponsor assesses that the actual turnover of the existing entry was not a low value turnover. (average 17 existing entries per sponsor)	No	Yes	8.00	2,829	Managers (including accountants)	72.80	\$582.40
4	Sponsor pays the annual charge(s) for any non-LVT entry/entries. No further action is required.	No	Yes	1.00	2,829	Clerical and Administrative Workers	53.20	\$53.20
5	Sponsor assesses that the actual turnover in the previous year of an existing entry was a low value turnover. The sponsor extracts the actual turnover of the entry from (e.g.) their sales/ finance system and records it on a 'statement of actual turnover' form (approved by the Secretary) and then must have the actual turnover verified by an approved person. If satisfied, the approved person signs a declaration that the turnover reported is the actual turnover of the entry. (average 23 existing entries per sponsor)	No	Yes	8.00	850	Managers (including accountants)	72.80	\$582.40
6	Sponsor prepares an LVT application for the existing entry which must be accompanied by (a) the statement of the actual turnover, signed by an approved person, and (b) payment for the LVT application fee (\$150 per entry in 12-13, to a maximum fee of \$15,000 for 100 or more LVT exemptions).	No	Yes	8.00	850	Managers (including accountants)	72.80	\$582.40
7	The sponsor submits the completed LVT application to the TGA. The application must be received before 2 September.	No	Yes	1.00	850	Clerical and Administrative Workers	53.20	\$53.20
7.1	The sponsors LVT application is not received before 2 September. The LVT application cannot be approved. (Go directly to Step 9)	N/a	N/a	0.00			0.00	\$0.00
8	The TGA Delegate assesses the LVT application. If approved, a letter is issued to the sponsor with a credit note for any exempted charge(s).	Yes	No	0.00		Not Applicable - TGA Only	0.00	\$0.00
9	Sponsor pays the annual charge(s) for any non-LVT entry/entries. No further action is required.	No	Yes	1.00	850	Clerical and Administrative Workers	53.20	\$53.20
								\$1,906.80

No. Sponsors Actual (RBM Use Only)	Cost Category
3550	
2599	Notification
2599	Notification
951	Notification
951	Notification
951	Notification
3550	Notification

Managers (including accountants)	\$72.80
Professionals	\$76.48
Technicians and Trades Workers	\$58.10
Community and Personal Service Workers	\$55.48
Clerical and Administrative Workers	\$53.20
Sales Workers	\$47.60
Machinery Operators And Drivers	\$54.25
Labourers	\$46.55
All occupations	\$59.85
Not Applicable - TGA Only	\$0.00

Notification		
Education	635.60	\$1,651,924.40
Permission	\$1,218.00	1,158,318.00
Purchasing		\$2,810,242.40
Record keeping		
Enforcement		
Publication and documentation		
Procedural		
Delay		
Other		

IN SCOPE ANNUAL PRODUCT CHARGES				2013-14	Rate	Est ANN QTY	Est ANN \$	Est LVT QTY	Est LVT \$	Est NET QTY	Est NET \$
ID1009	REIDPM	Included Devices	Device Class AIMD Annual Charge	ID1009	\$1,180	371	\$437,780	65	\$76,700	306	\$361,080
ID1010	REIDPM	Included Devices	Device Class III Annual Charge	ID1010	\$1,180	3,271	\$3,859,780	949	\$1,119,820	2,322	\$2,739,960
ID1011	REIDPM	Included Devices	Device Class IIb Annual Charge	ID1011	\$920	6,092	\$5,604,640	1,332	\$1,225,440	4,760	\$4,379,200
ID1012	REIDPM	Included Devices	Device Class IIa Annual Charge	ID1012	\$920	11,046	\$10,162,320	2,688	\$2,472,960	8,358	\$7,689,360
ID1013	REIDPM	Included Devices	Device Class 1 Sterile Annual Charge	ID1013	\$600	2,000	\$1,200,000	387	\$232,200	1,613	\$967,800
ID1014	REIDPM	Included Devices	Device Class 1 Measuring Annual Charge	ID1014	\$600	460	\$276,000	107	\$64,200	353	\$211,800
Total Medical Devices (excluding Class I other)						23,240	\$1,540,520	5,528	\$,191,320	17,712	\$1,349,200
ID1015	REIDPM	Included Devices	Device Class 1 Annual Charge	ID1015	\$80	22,126	\$1,770,080	702	\$56,160	21,424	\$1,713,920
Total Class I other Medical Devices						22,126	\$1,770,080	702	\$56,160	21,424	\$1,713,920
LD1007	RELDPM	Listed Device	Listed Devices Annual Charge	LD1007	\$1,320	32	\$42,240	4	\$5,280	28	\$36,960
LD1008	RELDPM	Listed Device	Listed Devices Annual Charge - IVD, Tampons & Disinf	LD1008	\$750	535	\$401,250	81	\$60,750	454	\$340,500
RD1005	RESRDPM	Registered Devices	Registered Devices Annual Charge - IVD, Tampons & D	RD1005	\$1,480	71	\$105,080	8	\$11,840	63	\$93,240
RD1006	RESRDPM	Registered Devices	Registered Devices	RD1006	\$2,590	9	\$23,310	4	\$10,360	5	\$12,950
Total Other Therapeutic Goods (OTG)						647	\$71,880	97	\$8,280	590	\$63,600
LM1004	RELMPM	Listed Medicine	Listed Medicines Annual Charge	LM1004	\$940	12,920	\$12,144,800	4,453	\$4,185,820	8,467	\$7,958,980
LM1005	RECHPM	Complementary Med	Registered Complementary Medicines	LM1005	\$1,320	199	\$262,680	47	\$62,040	152	\$200,640
Total Listed (Complementary) Medicines						13,119	\$12,407,480	4,500	\$4,247,860	8,619	\$8,159,620
NP1003	RENPPM	Non Prescription Med	Registered Medicines (Other than S4B58) Annual Charge	NP1003	\$1,320	3,352	\$4,424,640	1,258	\$1,660,560	2,094	\$2,764,080
NP1019	RECHPM	Complementary Med	Listed Medicines (Listed Non Prescription Medicine)	NP1019	\$940	417	\$391,980	141	\$132,540	276	\$259,440
Total Registered (OTC) Medicines						3,769	\$4,816,620	1,399	\$1,793,100	2,370	\$3,023,520
PR1001	REPMPM	Prescription Med	Prescription Medicines - Biologics	PR1001	\$6,430	1,038	\$6,674,340	577	\$3,710,110	461	\$2,964,230
Total Biological Prescription Medicines						1,038	\$6,674,340	577	\$3,710,110	461	\$2,964,230
PR1002	REPMPM	Prescription Med	Prescription Medicines - Non -Biologics	PR1002	\$3,860	13,652	\$52,596,720	9,027	\$34,844,220	4,625	\$17,752,500
Total Non-Biological Prescription Medicines						13,652	\$52,596,720	9,027	\$34,844,220	4,625	\$17,752,500
Total						77,591	\$100,477,640	21,830	\$49,931,000	55,761	\$50,546,640
QA All LVT Total						77,591	\$100,477,640	21,830	\$49,931,000	55,761	\$50,546,640

BBM Numbers of businesses effected	
ANNUAL CHARGES (ALL) [AVERAGE 21 ENTRIES/SPONSOR]	
No. of new & existing entries incurring annual charges	77,591
No. sponsors incurring 2013-14 annual charges	3,679
Average Entries Per Sponsor - Annual Charges Qty =(77,591/3,679)	21
LVT (ALL) [AVERAGE 22 ENTRIES/SPONSOR]	
No. of new and existing entries approved for LVT	21,830
Sponsors approved for LVT exemptions	1,001
Average Entries Per Sponsor - LVT Exemptions (ALL) =(21,830/1,001)	22
NOT LVT (ALL) [AVERAGE 21 ENTRIES/SPONSOR]	
No. of new and existing entries not approved for LVT	55,761
Sponsors not approved for LVT exemptions	2,678
Average Entries Per Sponsor - Not LVT (ALL) =(55,761/2,678)	21
ANNUAL CHARGES (EXISTING ENTRIES) [AVERAGE 18 ENTRIES/SPONSOR]	
No. of existing entries incurring annual charges	67,834
No. sponsors incurring annual charges for existing entries	3,679
Average No. of existing entries per sponsor =(67,834/3,679)	18
LVT (EXISTING ENTRIES) [AVERAGE 22 ENTRIES/SPONSOR]	
Existing entries approved for LVT (LVS)	19,355
Sponsors approved for existing entry LVT (LVS)	850
Average No. of Entries Per Sponsor (LVS) =(19,355/850)	23
NOT LVT (EXISTING ENTRIES) [AVERAGE 17 ENTRIES/SPONSOR]	
Existing entries not approved for LVT (LVS)	48,479
Sponsors not approved for existing entry LVT (LVS)	2,829
Average No. of Entries Per Sponsor Not LVT (LVS) =(48,479/2,829)	17
ANNUAL CHARGES (NEW ENTRIES) [AVERAGE 6 ENTRIES/SPONSOR]	
No. of new entries incurring annual charges	9,757
No. sponsors incurring annual charges for new entries	1,560
Average No. of new entries per sponsor =(9,757/1,560)	6
LVT (NEW ENTRIES) [AVERAGE 7 ENTRIES/SPONSOR]	
New entries approved for LVT (LVP) - validation review req.	2,475
Sponsors approved for LVT exemptions - new entries only	335
Average No. of Entries Per Sponsor (LVP) [(2,475/335)]	7
NOT LVT (NEW ENTRIES) [AVERAGE 6 ENTRIES/SPONSOR]	
New entries not approved for LVT	7,282
Sponsors not approved for LVT exemptions - new entries only	1,225
Average No. of Entries Per Sponsor [(7,282/1,225)]	6
LVT & OTHER RELATED STATS	
LVT Application Fees Paid	2,086,860
Number of LVT Applications (LVS and/or LVP)	1,652
Average No. of LVT Appl Per Sponsor (LVS & LVP) =(1,652/1,001)	2

OUT OF SCOPE ANNUAL (MANUFACTURING) LICENCE CHARGES					
BO2001	REBLPM	Blood Licences	Licence Charges - Primary Site	BO2001	\$144,700
BO2002	REBLPM	Blood Licences	Licence Charges - Secondary Site	BO2002	\$7,120
BO2003	REBLPM	Blood Licences	Single Step and Single Human Tissue	BO2003	\$6,230
BO2004	REBLPM	Blood Licences	Two or more steps of manufacture	BO2004	\$12,100
GM2005	REVEGM	GMP Licences	GMP Low Level Annual Licence	GM2005	\$0
GM2006	REVEGM	GMP Licences	GMP High Level Annual Licence	GM2006	\$0

IN SCOPE ANNUAL PRODUCT CHARGES

ID1009	REIDPM	Included Devices	Device Class AIMD Annual Charge
ID1010	REIDPM	Included Devices	Device Class III Annual Charge
ID1011	REIDPM	Included Devices	Device Class IIb Annual Charge
ID1012	REIDPM	Included Devices	Device Class IIa Annual Charge
ID1013	REIDPM	Included Devices	Device Class 1 Sterile Annual Charge
ID1014	REIDPM	Included Devices	Device Class 1 Measuring Annual Charge
ID1015	REIDPM	Included Devices	Device Class 1 Annual Charge
LD1007	RELDPM	Listed Device	Listed Devices Annual Charge
LD1008	RELDPM	Listed Device	Listed Devices Annual Charge - IVD, Tampons & Disinfectants
RD1005	RERDPM	Registered Devices	Registered Devices Annual Charge - IVD, Tampons & Disinfectants
RD1006	RERDPM	Registered Devices	Registered Devices
LM1004	RELMPM	Listed Medicine	Listed Medicines Annual Charge
LM1005	RECMPPM	Complementary Med	Registered Complementary Medicines
NP1003	RENPPM	Non Prescription Med	Registered Medicines (Other than S4&S8) Annual Charge
NP1019	RECMPPM	Complementary Med	Listed Medicines (Listed Non Prescription Medicine)
PR1001	REPMPM	Prescription Med	Prescription Medicines - Biologics
PR1002	REPMPM	Prescription Med	Prescription Medicines - Non - Biologics

2013-14	Rate	Est ANN QTY	Est ANN \$	Est LVT QTY	Est LVT \$	Est NET QTY	Est NET \$
ID1009	\$1,180	371	\$437,780	65	\$76,700	306	\$361,080
ID1010	\$1,180	3,271	\$3,859,780	949	\$1,119,820	2,322	\$2,739,960
ID1011	\$920	6,092	\$5,604,640	1,332	\$1,225,440	4,760	\$4,379,200
ID1012	\$920	11,046	\$10,162,320	2,688	\$2,472,960	8,358	\$7,689,360
ID1013	\$600	2,000	\$1,200,000	387	\$232,200	1,613	\$967,800
ID1014	\$600	460	\$276,000	107	\$64,200	353	\$211,800
ID1015	\$80	22,126	\$1,770,080	702	\$56,160	21,424	\$1,713,920
LD1007	\$1,320	32	\$42,240	4	\$5,280	28	\$36,960
LD1008	\$750	535	\$401,250	81	\$60,750	454	\$340,500
RD1005	\$1,480	71	\$105,080	8	\$11,840	63	\$93,240
RD1006	\$2,590	9	\$23,310	4	\$10,360	5	\$12,950
LM1004	\$940	12,920	\$12,144,800	4,453	\$4,185,820	8,467	\$7,958,980
LM1005	\$1,320	199	\$262,680	47	\$62,040	152	\$200,640
NP1003	\$1,320	3,352	\$4,424,640	1,258	\$1,660,560	2,094	\$2,764,080
NP1019	\$940	417	\$391,980	141	\$132,540	276	\$259,440
PR1001	\$6,430	1,038	\$6,674,340	577	\$3,710,110	461	\$2,964,230
PR1002	\$3,860	13,652	\$52,696,720	9,027	\$34,844,220	4,625	\$17,852,500
Total		77,591	\$100,477,640	21,830	\$49,931,000	55,761	\$50,546,640

Item Annu QTY	Item LVT	QTY
ID1009	371 ID1009	65
ID1010	3271 ID1010	949
ID1011	6092 ID1011	1332
ID1012	11046 ID1012	2688
ID1013	2000 ID1013	387
ID1014	460 ID1014	107
ID1015	22126 ID1015	702
LD1007	32 LD1007	4
LD1008	535 LD1008	81
RD1005	71 RD1005	8
RD1006	9 RD1006	4
LM1004	12920 LM1004	4453
LM1005	199 LM1005	47
NP1003	3352 NP1003	1258
NP1019	417 NP1019	141
PR1001	1038 PR1001	577
PR1002	13652 PR1002	9027

OUT OF SCOPE ANNUAL (MANUFACTURING) LICENCE CHARGES

BD2001	REBLPM	Blood Licences	Licence Charges - Primary Site
BD2002	REBLPM	Blood Licences	Licence Charges - Secondary Site
BD2003	REBLPM	Blood Licences	Single Step and Single Human Tissue
BD2004	REBLPM	Blood Licences	Two or more steps of manufacture
GM2005	REVEGM	GMP Licences	GMP Low Level Annual Licence
GM2006	REVEGM	GMP Licences	GMP High Level Annual Licence

Item	Rate	Est ANN QTY	Est ANN \$	Est LVT QTY	Est LVT \$	Est NET QTY	Est NET \$
BD2001	\$144,700						
BD2002	\$7,120						
BD2003	\$6,230						
BD2004	\$12,100						
GM2005	\$0						
GM2006	\$0						

RBM number of business affected (required for regulatory and deregulatory assumptions for cost impositions and savings)	
Sponsors incurring 2013-14 annual charges QTY	3,679
Sponsors approved for LVT exemptions QTY	1,001
Existing entries approved for LVT	19,355
New entries approved for LVT (subject to validation review)	2,475
Sponsors not approved for LVT QTY	2,678
Sponsors approved for LVT exemptions - new entries only QTY (RBM Validation Review)	
LVT Application Fees	\$2,086,860
Number of LVT Applications (LVS and/or LVP)	1,652