Description	TGA Task	Sponsor Task	Sponsor Time (Hours)	No of Sponsors Affected	Class	Sponsor Hourly Rate	Sponsor Total Cost	We do not cost option 1 as we cost CHANGE from stus quo. However, I have used these firgure as the deregulatory component of each of option 2 and 3 since they will no longer be required.	No. Sponsors Actual (RBM Use Only)		Cost Catego
A new therapeutic product is listed, registered or included on the Register. An ARTG number is assigned to the product The full year annual charge is incurred (per ARTG No.) effective from the date of listing, registration or inclusion on the Register TGA Financial Services issues a tax invoice to the sponsor for the applicable annual charge	Yes Yes Yes	No No	0.0 0.0 0.0	0	Not Applicable - TGA Only Not Applicable - TGA Only Not Applicable - TGA Only	0.00	\$0.00		1,29		
									75		#1
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	1.0	The second second	Managers (including accountants)	72.80			94		Notificati
Sponsor pays the annual charge for the entry. No further action is required.	No	Yes	1.0	0 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 involveing paying a charge.	94	8	Notificat
	Ma	V	1.0	225	Manager (Carlodina accounts to 1)	72.80	\$72.80		34		Notificat
Sponsor assesses that the estimated turnover of the new entry will be a low value turnover. (average 7 new entries per sponsor) 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 No	Yes	4.0		Managers (including accountants) Managers (including accountants)	72.80			34		Notificat
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	0.5	335	Clerical and Administrative Workers	53.20	\$26.60		34	2	
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	0.0	0	Not Applicable - TGA Only	0.00	\$0.00				
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	0.0	0	Not Applicable - TGA Only	0.00	\$0.00				
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	8.0	335	Managers (including accountants)	72.80	\$582.40		34	2	Notificat
The sponsor connot supply a statement of octual 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	100	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 inwriting 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	2	4	Notificati
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	0.0	280	Not Applicable - TGA Only	0.00	\$0.00		26	2	
The sponsor is notified by the TGA in writing that the exemption is confirmed and no further action is required.	Yes	No	0.0	D	Not Applicable - TGA Only	0.00	\$0.00				
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	0.0	o	Not Applicable - TGA Only	0.00	\$0.00				
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	1.0	45	Clerical and Administrative Workers	53.20	\$53.20		4	7	Notifical

0.00

Managers (including accountants)	\$72.80	Notification
Professionals	\$76.48	Education
Technicians and Trades Workers	\$58.10	Permission
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

The sponsor does not supply the statement of actual turnover by 1 September. The exemption is cancelled under regulation 43AAE.

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.

fication	126.00	119,448.00
cation	1152.20	394,052.40
nission		513,500.40
hadaa		

Not Applicable - TGA Only
10 Clerical and Administrative Workers

0.00 53.20

\$1,278.20

\$0.00 non-complicance is not costed \$53.20 thins is no longer part of LVT scheme - not costed. ??Can discuss.

	AWE May	Oncost	Hourly Ra	te
	2013 Hourly	Multplier	\$	
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 Adı	\$30.40	1.75	5 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	5 59	85
Not Applicable	0)	0

OPTION	2 - \$0 Turnover - Transitional Entries {Option 8}			-	-			
	Description	TGA Task	Sponsor Task	Sponsor Time	No of Sponsors	Class	Sponsor Hourly	
1	Entries on the Register before 1 July 2014 - To qualify for an NVT exemption, an entry which was listed, registered or included on the Register before 1 July 2014 must have been "approved for LVT exemption in 2013-14 and 2014-15 on the basis of 50 tut unrover (SOAT), signed by on approved person (a third party occountant) of the entry in 2012-13 (for approval of the 2013-14 LVT exemption) and 2013-14 (for the approval of the 2014-15 LVT exemption) and 2013-14 (for the approval of the 2014-15 LVT exemption) and 2013-14 (for the approval of the 2014-15 LVT exemption) and 2013-14 (for the approval of the 2014-15 LVT exemption) and 2013-14 (for the approval of the 2014-15 LVT exemption) and 2013-14 (for the approval of the 2014-15 LVT exemption) and 2013-14 (for the approval of the 2014-15 LVT exemption) and 2013-14 (for the approval of the 2014-15 LVT exemption) and 2013-14 (for the approval of the 2014-15 LVT exemption) and 2013-14 (for the approval of the 2014-15 LVT exemption approvals has been collected/analysed, with all eligible (pre-1 July 2014) and 30 11 July 2015 (for automatic NYT exemption when the subteme commences on 1 July 2015 in another the 2014-15 (for approval of the 2014-15 LVT exemption approvals has been collected/analysed, with all eligible (pre-1 July 2014) and 30 11 July 2015 (for approval of the 2014-15 LVT exemption in 2014-15 (for approval of the 2014-15 LVT exemption in 2014-15 (for approval of the 2014-15 LVT exemption when the 2014-15 LVT exemption in 2014-15 (for approval of the 2014-15 LVT exemption when 2014-15 (for approval of the 2014-15 LVT exemption will be subject to the findings of the validation review of 2014-15 LVT exemptions (due by 29 September 2015) as follows: The basis for the 2014-15 (LVT exemption was the sponsor's estimate of turnover for the remainder of 2014-15 (for approval of the 2014-15 (Yes	No	(Hours) 0.00	3,679	Not Applicable - TGA Only	Rate 0.00	\$0.00
	NVT exemption is renewed (or cancelled) following the next annual (turnover status) renewal declaration which is due by 22 July in the next financial year (i.e.22 July 2016)							
2	Transitional entry is not a 50 turnover entry: A full year annual product charge tax invoice will be issued to sponsors [for all non-NVT entries at 30] June in the previous year], in July. The sponsor is required to pay the invoice for the non-NVT entries by 1 October [as per current s46 of TG Act]	Yes	No	0.00	2,829	Not Applicable - TGA Only	0.00	\$0.00
3	The full year annual product charge for a non-NVF entry will be levied on 1 July each year thereafter until the entry is cancelled from the Register	N/a	N/a				0.00	\$0.00
4	The sponsor pays the applicable product charge invoice. No further action is required until the next full year annual product charge is incurred.	No	/Mes:	1.00	2,829	Clerical and Administrative Workers	53.20	\$53.20
5	The sponsor of an essential good applies for a waiver of the charge on the basis of (a) a public health risk arising from the potential cancellation of the entry by the sponsors because (b) the entry is not financially viable if an annual charge is leviled; and (c) there is no reasonably available	Yes	Yes	1.50	85	Managers (including accountants)	72.80	\$109.20
6	alternative to the product Transitional entry is a \$0 turnover entry: The sponsor will not receive a tax invoice for any entries which are '\$0 turnover'. The exemption will remain	No	Yes	1.00	.850	Clerical and Administrative Workers	53.20	\$53.20
7	In force until the sponsor subsequently advices an entry has commenced generating turnover (subject to the sponsors' annual (turnover status) renewal dedaration by 22 July in the next financial year that an entry continues to be "50 turnover". Sponsor will not provide the status of all "50 turnover" entries (i.e. a Sponsor will be required to dedare the turnover status of all "50 turnover" entries (i.e. a	No	fer	4.00		Managers (including accountants)	72.80	\$291.20
262	declaration of turnover (including 50 turnover) in the previous financial year) within 21 days from commencement of each subsequent financial year to ensure all eligible entries (i.e. 50 turnover entries) retain their annual charge exemption; while all ineligible entries (i.e. not 50 turnover entries) will incur the applicable annual charges.							
8	Audit and monitoring program of '50 turnover' entries (The program will seek to review 20% of sponsors' claims annually (for 100% coverage of claims every five years). The desk top audit and monitoring will be used to identify and short-list sponsors for on-site audit to verify the turnover status of '50 turnover' entries. The TGA will exercise powers in the Regulations to request information about a sponsors turnover of any/all entries on the Register	Yes	No	0.00	200	Not Applicable - TGA Only	0.00	\$0.00
9	Onsite audit of '50 turnover' Entries - The program will seek to conduct onsite audits with 2% of sponsors annually. Based on previous audit activity between 2007 and 2012, the costing assumes 3 Manager or equivalent sponsor participants in each audit.	Yes	Yes	12.00	20	Managers (including accountants)	72.80	\$2,620.80
10	Sponsor declaration of turnover - upon receiving the sponsors' advice that an entry has commenced generating turnover, the annual product charge exemption will cease and the full year product charge will be levied for the year in which turnover was generated (and, if applicable, any subsequent years).	Yes	No	0.00		Not Applicable - TGA Only	0.00	\$0.00
11	ANNUAL CHARGES INVOICING SCHEDULE Monthly invoices - 50 turnover entries generating turnover during a financial year Tax invoices will be issued (monthly) after a sponsors voluntary declaration (during the current financial year) that a \$0 turnover entry has commenced generating turnover in that financial year.	Yes	No	0.00		Not Applicable - TGA Only	9.00	\$0.00
	Example (Monthly trivolces): A 50 turnover entry commences generating turnover on 1 October. The sponsor declares by 22 October that the entry is not 50 turnover (Mote. 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 (Induding 80 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 renewal declaration in July), 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 invoiding on 7 November for payment by 7 December)							
	If a compulsory annual 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).							
12	Sponsor pays the applicable annual product charge invoice. No further action is required until the next full year annual product charge is incurred.	No	Ves	1.00	850	Clerical and Administrative Workers	53 20	\$53.20
		Contract of the Contract of th	-					\$3,180.80

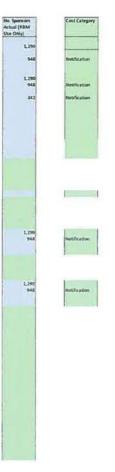
Managers (including accountants)	\$72.80	Not fication
Professionals	\$76.48	Education
Technicians and Trades Workers	\$58.10	Permission
Community and Personal Service Workers	\$55.48	Purchasing
Clerical and Administrative Workers	\$53.20	Record keeping
Sales Workers	\$47.60	Enforcement
Machinery Operators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

Cost Category

NO, D	8 - New Register Entries (up to 12 <u>MONTHLY INVOICES per sponsor per year)</u> - REFRESHED/CALCULATED BASED ON PY2013-14 DAT escription	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 ARIG number is assigned to the product	Yes	No	0.00	1560	Not Applicable - TGA Only	0.00	50.0
	ponsor assesses that the turnover of the new entry is not \$0 furnover and declares (not \$0 turnover) through the online portal or by paper	No	in.	1.00	1,225	Managers (including accountants)	72.80	572
Ti	arm. In this year annual charge is incurred (per ARTG No.) effective from the date of Insting, registration or inclusion on the Register OA Financial Service is issues a tax invoice to the sponsor for the applicable annual charge postor party the annual charge for the renty, No further action is required.	Yes Yes No	*	0.00 0.00		Not Applicable - TGA Only Not Applicable - TGA Only Clencal and Administrative Workers	0.00	\$0.
St 24	ponsor assesses that the estimated turnover of the new entry will be \$6 turnover, [swrape? new outries per aponous] porsor 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 plates a declearation within 22 days from registration, fisting or inclusion of the entry on the Registery of 50 turnover through the writer self- rence portal (or by paper form). Ye expended to the paper form) or a sponsor has reported (through the ordine portal or by paper form) that an entry is a 50 turnover try, the 50 turnover flag will result in an automatic annual product thange exemption. The sponsor will not receive a sax impose for any entries	No	Nan.	1.00	335	Managers (including accountants)	72.80	\$72.
11 51 54 54 64	hish are '50 tumover'. The annual spotch trape exemption will remain in force until the sponsor subsequently advises an entry has incurred tumover (subject to the possions' annual update (detailed below) within 21 days of commencement of the next financial year that an entry did not generate any tumover in we person are and therefore continues to be eligible for an NYT exemption, because of the previous and annual (tumover status) renewal declaration - to ensure continuity of the NYT exemption, the sponsor will be required to update to tumover status of all '50 tumover' entries by completing an ordine declaration that the entries did not generate tumover in the previous financial rate (by 22 Muly). He entries were 50 tumover, no further storon is required onlid the next namical update is required (the met financial layer), if the notices were 50 tumover, the NYT exemption will crase and the applicable annual charge for the full financial year in which the numover was mercetared will become playable	No	Yes	1.00	335	Managers (including accountants)	72.80	\$72
de	pensor does not provide an annual (turnover status) renewal declaration - if a sporoor fails to provide an annual (turnover status) renewal eclaration by 22 July in the next financial year, the annual charge exemption will cease and the applicable annual product charge will be payable on the beginning of the year to which the uplotted relater. (For example, an update required by 22 July 2016 interiors to 97016—11 to date to provide rugidate will inter the 2015-16 annual charge, and by detail will also incut the 2016-12 annual charge (as 16/17 commence on 1 Auf 2016).	No	-	9-00	NS INC.	Not Applicable - TGA Only	1.50	\$0.0
5	GA Financial Services insues a tax immice to the spoemor for the applicable annual charges peaner pays the annual charge(s) for any not \$0 turnover entries. No further action in required until the next full year annual product charge is curred.	Yes No	Yes	0.00 1.00		Not Applicable - TGA Only Clerical and Administrative Workers	0.00 53.20	
	ponsor declares an NVT exemption entry has incurred turnover "sporsors" will be required to declare within 21 days if an entry (subject to an NVT acmption) incun any turnover. Upon receiving the sporsors' advice that an entry has incurred turnover, the annual charge exemption will cease and while year charge will become payablot the year in which burnover was mixtured jam, if a placing, any subsequently years).	No	to	100	335	Clerical and Administrative Workers	51.20	\$53
5	IA Financial Services insues a tax imotice to the sponsor for the applicable annual charges peason pays the annual charge(s) for any not 50 turnover entries. No further action is required until the next full year annual product charge is curred.	No.	No	0.00 1.00	335	Not Applicable – TGA Only Clerical and Administrative Workers	9.90 53.20	
E P	INNUAL CHARGES INVOICING SCHEDULE Benthly involves - 50 turnover entries generating turnover during a financial year as invoices will be issued immotify a jober a sporsion voluntary declaration (during the current financial year) that a 50 turnover entry has somerence generating turnover in that financial year. sample (sidnotthly travidices): A 50 turnover entry commences generating turnover on 1 October. The sponsor declares by 22 October that the entry is 65 turnover light financial year. 65 turnover light financial year for the sponsor on volunturally declare the turnover width 12 days of the turnover being generated, the sponsor will be required to declare the turnover (Enchding 50 turnover if there was no turnover) of the entity in the next compulsiony annual (jurnover status) renewal citation due to 27 July in the next financial year).	Yes	No	6.00		Not Applicable - TUA Only	0.90	\$0.1
10	there a sponsor declaration of furnover is received during a financial year (i.e. at any other time than a compulsory an annual (turnover status) increased declaration by 22 May in the next financial year), an imotice for the applicable full year annual change will be issued in the next monthly obselve not (i.e. as year the example above, if turnover is recorded for a 50 turnover entry on 1 October, the sponsor may declare the turnover by 22 stober for invocting on 7 November for payment by 7 December)							
e	is computation annual faminore statis) reviewed destantion is all completed by 22 Mey in the next financial year, the Regulations will assume the rithy was not 50 turnore in the previous financial year and the applicable annual change will become psymble together with the change for the arent year (and each year therebyer will the early is canciled from the Register)							
E	nnual breaking "Not 50 turnover entries" Inties which are not 50 turnover on the next I July incur the full year annual charge. Annual innoices are insued in July for payment by 1 October (and gain each year intersaler until the expris carcelled from the Register).							

Managers (including accountants)	\$72.80
Professionals	576.48
Technicians and Frades Workers	558.10
Community and Personal Service Workers	555.43
Clerical and Administrative Workers	\$53.20
Sales Workers	\$47.60
Machinery Operators And Drivers	\$54.25
Labourers	\$46.55
All occupations	559.85
Not Applicable - TGA Only	50.00

Nortification 126.00 119,448.00 (ducation 305.20 104,378.40 Permission 305.20 104,378.40 Purchasing Record Leeping Enforcement Publication and documentation Procedual Delay Other



	AWE May	Oncost	- 1	Hourty Rate
	2013 Hourty	Multplier		
Managers	541 60		1.75	72.80
Professionals	543.70		1.75	76.43
Technicians and	533.20		1.75	\$8.10
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	\$34.70		1.75	59.85
Not Applicable	0		0	

tep No	Description	TGA Task	Sponsor Task	Particular - Control	No of Sponsors Affected	Class	Sponsor Hourly Rate	Sponsor Total Cost
			15 E	0.00		N. I		40.00
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
	the state of the s	103		0.00		not applicable for 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

Cost Catego	ory
Notification	i.
Notification	1

Managers (including accountants)	\$72.80	Notification
Professionals	\$76.48	Education
Technicians and Trades Workers	\$58.10	Permission
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

Summary report

		total number of entities within the	e segment.	
Proposal name		nover Exemption (LVT) Scheme		
Reference number	XXXXX			
Problem and objective				
Problem	The Therapeutic Goods Admi	nistration (TGA) is part of the Austr	ralian Government Do	partment of Health, and is responsible for regulating therapeutic goods including medicines,
Objective	The objectives of a proposed	scheme (to replace the current LV)	scheme) are as follo	ws: 1. The proposed scheme is consistent with the objectives of the Therapeutic Goods Act 198
Explanatory information				
Not applicable				
Segments affected				
Business				
Option 1				
Option name		heme to exempt (all) products which		
Option description		oonsor of a therapeutic good which	generates \$0 turnov	er will be exempt from the requirement to pay an annual charge in respect of that good. Optic
Business affected	3679			
	Business			
	Cost per	Total cost for		
	business	all business		
Start up cost	\$0		\$0	
Ongoing compliance				
cost per year	\$0	\$1,22	9 000	
Start up time	0 hr	71,22	0 hr	
Steam of the State	Jiii			
Ongoing compliance	12.5		01.	
ime per year	0 hr		0 hr	
Option 2				NAME OF THE PROPERTY OF THE PR
Option name		heme to exempt (all) products which		
Option description		oonsor of a therapeutic good which	generates \$0 turnov	er will be exempt from the requirement to pay an annual charge in respect of that good. Optio
Business affected	3679			
	Business			
	Cost per	Total cost for		
	business	all business		
Start up cost	\$0		\$0	
Ongoing compliance			***	
cost per year	64 000	****	0.000	
and the same of th	-\$1,000 0 hr	-\$4,19	0 hr	
Start up time	OIII		Oni	
Ongoing compliance				
time per year	0 hr		0 hr	
Option 3				
Option name	Option 3 - Cease the LVT Sche	eme - regulatory component		
Option description	Under option 3, all entries on	the Register would incur an annua	I product charge. No	annual charge exemptions would be available. Annual charge rates would be adjusted for all
Business affected	3679			
	Business			
	Cost per	Total cost for		
	business	all business		
Start up cost	\$0		\$0	
Ongoing compliance	- 50		7.	
	22	***	5 000	
cost per year	\$0	\$75	5,000	
Start up time	0 hr		0 hr	
Ongoing compliance			22	
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 sp	onsor of a therapeutic good not su	ipplied to the market	will be exempt from the requirement to pay an annual charge in respect of that good. Option
Business affected	3679		****	
	Business			
	Cost per	Total cost for		
	business	all business	1	
Start up east	S0 \$0	uii pusiiiess	\$0	
Start up cost	\$0		ŞÜ	
Ongoing compliance				
cost per year	-\$1,000	-\$4,19	The state of the s	
	0 hr		0 hr	1
Start up time	Unr		7.00	
Start up time Ongoing compliance	Unr		8.00	

Note

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.

ating therapeutic goods including medicines, ne objectives of the Therapeutic Goods Act 1989
n annual charge in respect of that good. Option
n annual charge in respect of that good. Option
in annual charge in respect of that good. Option
nnual charge rates would be adjusted for all
imuai charge races would be adjusted for all
annual charge in respect of that good. Option 2
simual charge in respect of that good. Option 2
deciding behavior relieves
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.

ep 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

Sponsors Actual M Use Only)	Cost Category
3550	
2599	Notification
2599	Notification
951	Notification
951	Notification
951	Notification
3550	Notification

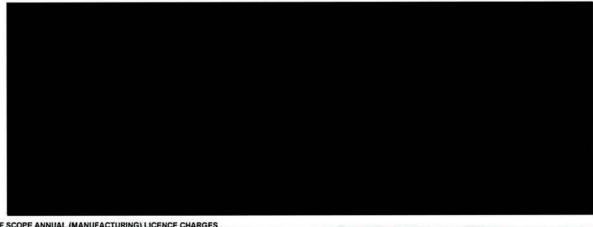
635.60 \$1,651,924.40 \$1,218.00 1,158,318.00 \$2,810,242.40

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

IN SC		NUAL 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	101009	\$1,180	371	\$437,780	65	\$76,700	306	\$361,080
ID1010	REIDPM	Included Devices	Device Class III Annual Charge	101010	\$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	101011	5920	6,092	\$5,604,640	1,332	\$1,225,440	4,760	\$4,379,200
ID1012	REIDPM	Included Devices	Device Class Ita Annual Charge	101012	\$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	101013	5600	2,000	\$1,200,000	387	\$232,200	1,613	\$967,800
ID1014	REIDPM	Included Devices	Device Class 1 Measuring Annual Charge	101014	\$600	460	\$276,000	107	\$64,200	353	\$211,800
Total Medical Medvices (excluding Class I other)						23,240	21,540,520	5,528	5,191,320	17,712	16,349,200
ID1015	RE DPM	Included Devices	Device Class 1 Annual Charge	101015	580	22,126	\$1,770,080	702	\$55,160	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 & Disinfe	LD1008	\$750	535	\$401,250	81	\$60,750	454	\$340,50
RD1005	REROPM	Registered Devices	Registered Devices Annual Charge - IVD, Tampons & Di	RD1005	\$1,480	71	\$105,080	8	\$11,840	63	\$93,24
RD1006	RERDPM	Registered Devices	Registered Devices	RD1006	\$2,590	9	\$23,310	4	\$10,360	5	\$12,95
Total Other Therapeutic Goods (OTG)					647	571,880	97	88,230	550	483,650	
LM1004	RELMPM	Listed Medicine	Listed Medicines Annual Charge	LM1004	5940	12,920	\$12,144,800	4,453	\$4,185,820	8,467	\$7,958,980
LM1005	RECMPM	Complementary Med	Registered Complementary Medicines	LM1005	\$1,320	199	\$262,680	47	\$62,040	152	5200,64
Total Lis	ted (Comple	mentary) 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 54858) Annual Charg	NP1003	\$1,320	3,352	\$4,424,640	1,258	\$1,660,560	2,094	\$2,764,08
NP1019	RECMPM	Complementary Med	Listed Medicines (Listed Non Prescription Medicine)	NP1019	5940	417	\$391,980	141	\$132,540	276	\$259,44
Total Re	gistered (O)	C) 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 Bis	ological Pres	cription 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	\$17,852,500
Total No	n-Biological	Prescription Medicines				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
				QA All LVT Total	-	77,591	100.477,640	21.830	49,931,000	55.761	50.546.64

RBM: Numbers of businesses affected	
ANNUAL CHARGES (ALL) [AVERAGE 21 ENTRIES/SPONSOR]	
No. of new & existing entries incurring annual charges	
No sponsors incurring 2013-14 annual charges	77,591 3,679
Average Entries Per Sponsor - Annual Charges Qty	3,073
=(77.591/3.679)	21
VT (ALL) [AVERAGE 27/ENTRIES/SPONSOR]	17
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) NOT LVT (ALL) [AVERAGE 21/ENTRIES/SPONSOR]	22
No of new and existing entries not approved for LVT	1000000
Sponsors not approved for LVT exemptions	55,761 2,678
Average Entries Per Sponsor - Not LVT (ALL)	2,076
(±55761/2,678)	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	2,073
=(67,848/3,679)	18
LYT (LVS - EXISTING ENTRIES) [AVERAGE 22 ENTRIES/SPONSOR]	
Existing entries approved for LVT (LVS)	19,355
Sponsors approved for existing entry LVT (LVS)	
Average No. of Entries Per Sponsor (LVS)	850
(=19,355/850)	23
NOT LYT (EXISTING ENTRIES) (AVERAGE 17	
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 (=/)	17
ANNUAL CHARGES (NEW ENTRIES) JAVERAGE 6	
ENTRIES/SPONSOR]	
No of new entries incurring annual charges No sponsors incurring annual charges for new entries	9,757
	1,560
Average No. of new entries per sponsor	
=(9,757/1,560) LVT (LVP - NEW ENTRIES) (AVERAGE 7	- 6
ENTRIES/SPONSOR]	
New entries approved for LVT (LVP) - validation review	1903
req. Sponsors approved for LVT exemptions - new entries	2,475
only	335
Average No. of Entries Per Sponsor (LVP) (=2,475/335)	
NOT LYT (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)	1,223
	- 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



BO2001	REBLPM	Blood Licences	Licence Charges - Primary Site	BD2001	\$144,700
302002	REBLPM	Blood Licences	Licence Charges - Secondary Site	BD2002	\$7,120
302003	REBLPM	Blood Licences	Single Step and Single Human Tissue	802003	\$6,230
802004	REBLPM	Blood Licences	Two or more steps of manufacture	BD2004	\$17.100
GM2005	REVEGM	GMP Licences	GMP Low Level Annual Licence	GM2005	\$0
GM2006	REVEGM	GMP Licences	GMP High Level Annual Licence	GAC:006	\$07///

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	Usted 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
LM 1005	RECMPM	Complementary Med	Registered Complementary Medicines
NP1003	RENPPM	Non Prescription Med	Registered Medicines (Other than S4&S8) Annual Charge
NP1019	RECMPM	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
101014	\$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	5200,640
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	C49 931 000	55.761	\$50 546 640

Item Annu QTY	S	Item LVT	QTY
ID1009	371	ID1009	65
ID1010	3271	ID1010	949
ID1011	6092	D1011	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

001	, 000	LEWINOWE	MANULACIONING/ EIGENGE CHANGES
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

BD2001	\$144,700			11/11	///	<u>///</u>	///			W	Ø	⅓						$\overline{\ell}$					8	₩					72	//		//		//			
BD2002	\$7,120					W.						Ø						Ł					Ø	∅					7							n	
BD2003	\$6,230	m				M					Ø	8						Ę					ğ	∅					Ž								
BD2004	\$12,100					<i>///:</i>		%			Ø	Ø						¥	测	$/\!\!/$			Ø	⅓					7	7							
GM2005	\$0					m,					Ø	\overline{y}	%					Ę					Ø						Ä	0	//	"	"	7		n	
GM2006	\$0						///				Ø	Ø	W					Ę					Ž						Ž			7					

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