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, medical devices, biologicals, blood and blood products. This Regulatory Burden Measure (RBM) has been prepared by the TGA. The purpose of this RBM is to inform a Regulatory Impact Statemen (RIS) which will assist Australian Government decision making on how to address problems that have been identified in relation to the Low Value Turnover Exemption Scheme (the LVT scheme) and determine the best option to address the problems. The RIS summarises the consultation process that has been undertaken with stakeholders to explore options that may address the problems that have been identified with the current policy. The TGA released theâ€˜Review of the Low Value Turnover Exemption Schemeâ€™ consultation paper in April 2104. The RIS concludes with a recommended proposal, outlining the proposed amendments to the requirements for Government consideration.
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 (the Act); 2. Those who create a need to regulate will bear the cost of regulation and the scheme is compliant with the Australian Government Cost Recovery Guidelines (the Guidelines); 3. The scheme is not inconsistent with the aims of the National Medicines Policy; 4. We are able to recover the total costs of specified pre and post market functions appropriately through annual product charges; 5. The scheme allows sponsors to keep their therapeutic goods on the Register without an annual charge until that good isâ€˜suppliedâ€™ to the market. This means that a therapeutic good (already registered/listed/included but not supplied to the market) can be supplied to the market at short notice in case of a need, as per one of the aims of the National Medicines Policy; 6. Simplifies the administrative process and its effectiveness; and 7. Reduces regulatory burden on industry. The implementation of policy option 2 would align with the majority of submissions from respondents to the consultation paper, noting that responses varied significantly, and would also be consistent with the above objectives.
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 2 is a combination of consultation options 2 and 3 (option 2 proposed to retain the LVT scheme, with some amendments to improve its efficiency; and option 3 proposed to replace the LVT scheme with one that only grants exemptions for Register entries that are not supplied to the Australian market), wherein annual product charges would not be levied on products that are not generating turnover in the Australian market. Under option 2, a therapeutic goods sponsor will not incur an annual product charge for a Register entry until the entry generates turnover (rather than the current requirement for sponsorsâ€™ turnover to be of â€˜low valueâ€™ before they can be exempted).The rationale for this option is that, as the product is $0 turnover, it is likely the product is not marketed or supplied, it requires minimal post-market surveillance and monitoring by the TGA. The change to exempt entries which are $0 turnover from annual product charges would be complemented by other amendments to improve the efficiency of the exemption scheme including:€¢ Sponsors will self-declare that an entry is $0 turnover and thus automatically qualify for an annual charge exemption. o Sponsorsâ€™ will be responsible for nominating which of their Register entries are $0 turnover. â€¢ No application fee will be prescribed for notifying turnover of an entry. o An online portal will be developed to allow sponsors to self-manage the turnover status of their entries [e.g.â€˜$0 turnoverâ€™ or â€˜>$0 turnover']. o As access to TGAâ€™s online systems is not a pre-requisite for a sponsor of a therapeutic good to list, register or include a therapeutic good on the Register, paper forms will be made available [via the TGA website] for sponsors who do not have access to online facilities (up to 11% of all active sponsors do not have access to TGA online systems). ï‚§ Of 7,517 active sponsors recorded in the TGAâ€™s Client Database, 844 do not have active e-Business Services (eBS) accountsï‚§ Less than 50% of active sponsors in the Client Database are Australian sponsors who have entries on the Register which incur annual charges. For example, only 3,679 active sponsors had entries on the Register which incurred annual charges in 2013-14. ï‚§ Anecdotally, the minority of Australian sponsors who have entries on the Register but do not have active eBS accounts, are currently utilising third party regulatory affairs agents or representatives to interact with the TGA on their behalf. €¢ The annual product charge exemption will apply until an entry commences generating turnover. €¢ To ensure accountability for any entries which are greater than $0 turnover but are not declared as greater than $0 turnover, the TGA would implement an audit program to detect any inadvertently or deliberately incorrect sponsor declarations. o The extent of the audit program would need to satisfy requirements set out by the ANAO in 2009 for greater scrutiny of financial benefits being obtained by sponsors.
Business affected	3679

	Business	
	Cost per business	**Total cost for all business**

Start up cost	$1,000	$2,143,000
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 2 is a combination of consultation options 2 and 3 (option 2 proposed to retain the LVT scheme, with some amendments to improve its efficiency; and option 3 proposed to replace the LVT scheme with one that only grants exemptions for Register entries that are not supplied to the Australian market), wherein annual product charges would not be levied on products that are not generating turnover in the Australian market. Under option 2, a therapeutic goods sponsor will not incur an annual product charge for a Register entry until the entry generates turnover (rather than the current requirement for sponsorsâ€™ turnover to be of â€˜low valueâ€™ before they can be exempted).The rationale for this option is that, as the product is $0 turnover, it is likely the product is not marketed or supplied, it requires minimal post-market surveillance and monitoring by the TGA. The change to exempt entries which are $0 turnover from annual product charges would be complemented by other amendments to improve the efficiency of the exemption scheme including:€¢ Sponsors will self-declare that an entry is $0 turnover and thus automatically qualify for an annual charge exemption. o Sponsorsâ€™ will be responsible for nominating which of their Register entries are $0 turnover. â€¢ No application fee will be prescribed for notifying turnover of an entry. o An online portal will be developed to allow sponsors to self-manage the turnover status of their entries [e.g.â$0 turnoverâ€™ or â€˜>$0 turnover']. o As access to TGAâ€™s online systems is not a pre-requisite for a sponsor of a therapeutic good to list, register or include a therapeutic good on the Register, paper forms will be made available [via the TGA website] for sponsors who do not have access to online facilities (up to 11% of all active sponsors do not have access to TGA online systems). ï‚§ Of 7,517 active sponsors recorded in the TGAâ€™s Client Database, 844 do not have active e-Business Services (eBS) accountsï‚§ Less than 50% of active sponsors in the Client Database are Australian sponsors who have entries on the Register which incur annual charges. For example, only 3,679 active sponsors had entries on the Register which incurred annual charges in 2013-14. ï‚§ Anecdotally, the minority of Australian sponsors who have entries on the Register but do not have active eBS accounts, are currently utilising third party regulatory affairs agents or representatives to interact with the TGA on their behalf. €¢ The annual product charge exemption will apply until an entry generates turnover. €¢ To ensure accountability for any entries which are not $0 turnover but not declared as not $0 turnover, the TGA would implement an audit program to detect any inadvertently or deliberately incorrect sponsor declarations. o The extent of the audit program would need to satisfy requirements set out by the ANAO in 2009 for greater scrutiny of financial benefits being obtained by sponsors.
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 therapeutic goods currently subject to LVT exemptions resulting in an overall decrease in charges across all types of therapeutic goods.
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 is a combination of consultation options 2 and 3 (option 2 proposed to retain the LVT scheme, with some amendments to improve its efficiency; and option 3 proposed to replace the LVT scheme with one that only grants exemptions for Register entries that are not supplied to the Australian market), wherein annual product charges would not be levied on products that are not supplied to the Australian or overseas market. Under option 2, a therapeutic goods sponsor will not incur an annual product charge for a Register entry until the entry is supplied (rather than the current requirement for sponsorsâ€™ turnover to be of â€˜low valueâ€™ before they can be exempted).The rationale for this option is that, as the product is not supplied, it requires minimal post-market surveillance and monitoring by the TGA. The change to exempt entries which are not supplied from annual product charges would be complemented by other amendments to improve the efficiency of the exemption scheme including: £¢ Sponsors will self-declare that an entry is not supplied and thus automatically qualify for an annual product charge exemption. o Sponsorsâ€™ will be responsible for nominating which of their Register entries are supplied. â€No application fee will be prescribed for notifying supply status of an entry. o An online portal will be developed to allow sponsors to self-manage the supply status of their entries [e.g.€œnot suppliedâ€™ or â€˜commencement of supply dateâ€™ or â€˜suppliedâ€™]. o As access to TGAâ€™s online systems is not a pre-requisite for a sponsor of a therapeutic good to list, register or include a therapeutic good on the Register, paper forms will be made available [via the TGA website] for sponsors who do not have access to online facilities (up to 11% of all active sponsors do not have access to TGA online systems). ï‚§ Of 7,517 active sponsors recorded in the TGAâ€™s Client Database, 844 do not have active e-Business Services (eBS) accountsï‚§ Less than 50% of active sponsors in the Client Database are Australian sponsors who have entries on the Register which incur annual charges. For example, only 3,550 active sponsors had entries on the Register which incurred annual charges in 2012-13. ï‚§ Anecdotally, the minority of Australian sponsors who have entries on the Register but do not have active eBS accounts, are currently utilising third party regulatory affairs agents or representatives to interact with the TGA on their behalf. £¢ The annual product charge exemption will apply (only) until the initial supply of an entry commences.€¢ A quarterly pro rata product charge will apply in the first year an entry is newly supplied. o Entries which are newly supplied in quarter 1 of a financial year will incur the full year annual product charge; while entries commencing supply in quarters 2, 3 or 4 will incur a pro rata product charge (calculated at 75%, 50%, and 25% of the annual product charge respectively).€¢ To ensure accountability for any entries which are supplied but not declared as supplied, the TGA would implement an audit program to detect any deliberately or inadvertently incorrect sponsor declarations. o The extent of the audit program would need to satisfy requirements set out by the ANAO in 2009 for greater scrutiny of financial benefits being obtained by sponsors.			
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.