## **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 Stateme (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 the Review of the Low Value Turnover Exemption Scheme' consultation paper in April 210. 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 annuly product charges; 5. The scheme allows sponsors to keep their therapeutic goods on the Register without an annual charge until that good is€ supplied' 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 Nation 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.				
<b>Explanatory informati</b>	on				
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 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 an ot 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 turno (rather than the current requirement for sponsors turnover to be of †low value†before they can be exempted). The rationale for this option is that, as the product is \$0 turnover 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: \$6 Sponsors will self-declare that an entry is \$0 turnover and thus automatically qualify for an annual charge exemption. o Sponsors ** will be responsible for nominating which of their Register entries are \$0 turnover. \$6 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€350 turnover. \$6 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€350 turnover. \$6 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£350 turnov				
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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 sch	eme to exempt (all) products which are \$0	turnover - deregulatory component
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Ongoing compliance time per year	0 hr	0 hr			
Option 4					
Option name	Option 3 : Cease LVT scheme deregulatory component				
Option description Business affected	combination of consultation of scheme with one that only granot supplied to the Australian than the current requirement requires minimal post-market amendments to improve the scharge exemption. o Sponsors entry. o An online portal will bâ€~supplied']. o As access will be made available [via the active sponsors recorded in the Australian sponsors who have 13. ī,§ Anecdotally, the minori representatives to interact will product charge will apply in the entries commencing supply in accountability for any entries	options 2 and 3 (option 2 proposed to retain ants exemptions for Register entries that are for overseas market. Under option 2, a therefor sponsorsæ™ turnover to be of â€"low var surveillance and monitoring by the TGA. The efficiency of the exemption scheme including sa€™ will be responsible for nominating which are developed to allow sponsors to self-manato TGA's online systems is not a pre-reque TGA website] for sponsors who do not have entries on the Register which incur annual sity of Australian sponsors who have entries the the TGA on their behalf. ₤¢ The annual properties that the the the the the the the the the th	the market will be exempt from the requirement to pay an annual charge in respect of that good. Option 2 is a the LVT scheme, with some amendments to improve its efficiency; and option 3 proposed to replace the LVT not supplied to the Australian market), wherein annual product charges would not be levied on products that are peutic goods sponsor will not incur an annual product charge for a Register entry until the entry is supplied (rather before they can be exempted). The rationale for this option is that, as the product is not supplied, it is change to exempt entries which are not supplied from annual product charges would be complemented by other is £€ Sponsors will self-declare that an entry is not supplied and thus automatically qualify for an annual product the of their Register entries are supplied. € No application fee will be prescribed for notifying supply status of an age the supply status of their entries [e.g.€ā not supplied' or †"commencement of supply date' or isite for a sponsor of a therapeutic good to list, register or include a therapeutic good on the Register, paper forn is access to online facilities (up to 11% of all active sponsors do not have access to TGA online systems). 7,§ Of 7,517 excive e-Business Services (eBS) accounts 7,§ Less than 50% of active sponsors in the Client Database are harges. For example, only 3,550 active sponsors had entries on the Register which incurred annual charges in 20:.2 on the Register but do not have active eBS accounts, are currently utilising third party regulatory affairs agents or oduct charge exemption will apply (only) until the initial supply of an entry commences. €€ A quarterly pro rata ries which are newly supplied in quarter 1 of a financial year will incur the full year annual product charge; while ct charge (calculated at 75%, 50%, and 25% of the annual product charge respectively). €€ To ensure lied, the TGA would implement an audit program to detect any deliberately or inadvertently incorrect sponsor direments set out by the ANAO		
Business affected	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.