



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

# Review of the low value turnover exemption scheme

## Consultation paper

Version 1.0, April 2014

**TGA** Health Safety  
Regulation

Historical consultation document

## About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <<http://www.tga.gov.au>>.

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## Version history

Version	Description of change	Author	Effective date
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Historical consultation document

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# Executive summary

The Therapeutic Goods Administration (TGA) levies annual charges on entries in the Australian Register of Therapeutic Goods (the Register) to recover the costs of regulatory functions which cannot be reasonably assigned to individual businesses, or where such assignment would act as a deterrent to the effective regulation of therapeutic goods.

Annual charges fund post-market regulatory activities such as the monitoring of product safety and of sponsor compliance with regulatory obligation. The Therapeutic Goods (Charges) Regulations 1990 (the Charges Regulations) prescribe varied levels of charges for different classes of therapeutic goods, based on product risk.

The low value turnover exemption scheme (the LVT scheme) allows sponsors to seek an exemption from payment of annual charges for entries where the annual turnover is less than or equal to 15 times the annual charge for that Register entry.

The LVT scheme was introduced in 1990 and, as such, predates both the National Medicines Policy established in 1999 and the introduction of full cost recovery for the TGA in 1998.

There is no extant statement of policy to guide the LVT scheme. This makes objective assessment of the scheme's effectiveness very difficult. In 2009, ANAO recommended that tighter controls be applied to verifying product eligibility for the scheme. In response, the TGA introduced additional requirements related to independent certification of product turnover values. While this has improved governance of the scheme, the certification process also triggers complaints from industry every year – especially from small business sponsors who claim it is an unnecessary administrative burden.

The LVT scheme also attracts a range of other complaints from across the therapeutics goods industry. Key areas of concern include the inflexible timing for annual LVT applications, the level and determination of key financial parameters and the magnitude of difference in outcome between products that are marginally eligible, compared to those that are marginally ineligible.

With the above factors in mind, the TGA has commenced a policy and operational review of the LVT scheme. The first stage is the release of this consultation-discussion paper.

## Some of the essential questions to be considered include:

- Is there a contemporary policy need for an LVT scheme (i.e. is there a problem to be solved by an LVT scheme);
- Are there other policy options available to address the policy need;
- Is there a problem with the operation of the current LVT scheme;
- What are the policy options and what is the net benefit of each of those options;
- How compatible is each option with other Government policy such as the Australian Government Cost Recovery Guidelines and competition policy.

Research traces the establishment of the LVT scheme to a policy objective of supporting manufacturers of small volume products, small start-up companies, herb growers and small companies making medical appliances whose turnover on a number of product lines might only be a few hundred or a few thousand dollars<sup>1</sup>.

Examining the current operation of the LVT scheme, it is hard to trace the benefits of the scheme back to those original motivations. Evidence of the current operation of the scheme indicates that by order of gross annual charges, the top 20 (of a total of 3,550) sponsors, received more than 50% of LVT exemptions. The three largest beneficiaries of LVT exemptions, by dollar value, are companies that specialise in the manufacture of generic medicines.

The TGA is a fully cost recovered regulator. This means that fee exemptions under the LVT scheme result in distortion of fees across non-LVT categories (i.e. LVT reductions are 'recovered' by setting a higher level for annual charges). This impact is a form of cross subsidy and it is likely to be inconsistent with the Australian Government Cost Recovery Guidelines.

The cross-subsidy means that beneficiaries of LVT exemptions are not contributing towards the cost of post-market monitoring and compliance at a level commensurate with their share of such activities. The cross subsidy could also be operating contrary to some of the original policy motivators if small businesses are paying full fees while large multinational companies are claiming LVT exemptions.

Removing this cross subsidy fully (i.e. by discontinuing the LVT scheme) would see annual charges across products fall by up to 62%.

The LVT scheme also presents a degree of administrative complexity with sponsors frequently complaining about the complexity, administrative burden and inflexibility of the processes involved. Some sponsors report the cost of preparing and submitting a claim for an LVT exemption outweigh the value of the exemption.

This paper does not seek to answer all of the questions identified above. It is primarily a discussion paper. It raises questions, posits a range of answers and opens dialogue with the therapeutics industry.

Given the potential impact on a broad range of charges, sponsors and products, it is important that every sponsor consider the impact of the current LVT scheme on their product/s and the potential impact of changes to the LVT scheme.

As part of the review the following options for the future of the scheme are presented for comment, with possible variations:

- Option 1: Retain the LVT scheme in its current form
- Option 2: Retain the LVT scheme, with some amendments to improve its efficiency
- Option 3: Replace the LVT scheme with one that only grants exemptions for Register entries which are not supplied to the Australian market
- Option 4: Replace the LVT scheme with one that only grants exemptions for Register entries where the sponsor is a small business
- Option 5: Cease the LVT scheme completely.

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<sup>1</sup><<http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;db=CHAMBER;id=chamber%2Fhansards%2F1990-12-20%2F0218;query=id%3A%22chamber%2Fhansards%2F1990-12-20%2F0000%22>>

The TGA is seeking stakeholders' comments on these options as well as other feedback for the future operation of the scheme. **The closing date for submissions to the consultation is 5:00pm, Friday, 23 May 2014.**

At the close of the consultation period the TGA will collate and analyse submissions on matters that are within the scope of the consultation. An update on the progress of the review will be provided on the TGA website after the close of the consultation period. The TGA will then prepare advice for the consideration of Government.

# About this consultation

## What are the objectives of the consultation?

The primary objective of this consultation paper is to seek stakeholders' views on the operation of the LVT scheme, including suggestions for any future operations. Options for amendments are presented to generate this feedback. It is acknowledged that changes to the scheme would have varying impacts across sponsors.

Feedback received from stakeholder groups (both from individual sponsors and representative organisations) will be used to decide what, if any, changes to make to the scheme and to develop an appropriate strategy to implement the chosen option in a way that addresses the challenges arising with the operation of the current scheme, with consideration of the impacts on stakeholders.

### Through this consultation process the TGA would like:

- To identify issues and the financial impact that might be faced by sponsors and stakeholder groups as a result of each of the options;
- Feedback on whether the removal, or changes to, the LVT scheme would limit your ability to enter or maintain goods on the Register;
- Feedback on whether the implementation of any of the options presented could lead to cessation of supply of essential therapeutic goods, causing potential public health risks;
- Feedback on other options which may achieve the objectives but that may not have been considered; and
- To use the feedback received to arrive at the outcome of the review and to help devise appropriate mechanisms to implement changes, if any.

## What is outside the scope of the consultation?

The following matters are outside the scope of the proposed changes outlined in this paper:

- Annual licence charges currently levied on manufacturers of therapeutic goods; and
- Any other matter that is not directly related to the operation of the LVT scheme and the options proposed in this paper.

Any submissions received that are outside of scope will not be considered as part of the consultation. They may be noted for future reference.

## Have your say

Interested stakeholders are encouraged to provide a response, prompted by the questions posed in the text box above as well as the questions relating to each of the options. Stakeholders may respond to as many or as few of the questions as they wish and may provide additional information on the scheme not covered by the questions.

Responses should include:

- Which option(s) you support and why. If you do not support any option you may make suggestions for an alternative which is acceptable to you and provide a rationale.
- An assessment of how the proposed options will affect you or your business (either positively or negatively). Please attempt to quantify this (e.g. financial impacts).

Submissions should be lodged electronically to [lvtconsultation@tga.gov.au](mailto:lvtconsultation@tga.gov.au). The closing date for submissions is **5:00pm, Friday, 23 May 2014**.

## What will the TGA do with your comments?

Submissions will be acknowledged as they are received. All submissions will be placed on the TGA website, unless marked confidential. Any confidential material should be provided under a separate cover and clearly marked **IN CONFIDENCE**.

For submissions made by individuals, all personal details other than your name will be removed from your submission before it is published on the TGA website.

In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must request this in the space provided on the submission coversheet.

At the close of the consultation period, the TGA will collate and analyse submissions on matters that are within the scope of this consultation. An update on the progress of the review and expected timeframes for our response will be provided on the TGA website after the close of the consultation period.

The TGA may make amendments to the proposed options as appropriate and the outcome of the review will be published on the TGA website.



# Introduction

## Cost recovery at the TGA

The TGA is part of the Australian Government Department of Health, and is responsible for regulating therapeutic goods including medicines, medical devices, blood and blood products.

A therapeutic good must be listed, registered or included in the [Australian Register of Therapeutic Goods \(the Register\)](#) before it can be supplied in Australia.

The TGA undertakes a number of pre market functions, including evaluation of high risk therapeutic goods, before a therapeutic good is entered on the Register (pre market) and monitors products once they are on the market (post market). The TGA also assesses the suitability of medicines and medical devices for export from Australia. In addition, the TGA regulates manufacturers of therapeutic goods to ensure they meet acceptable standards of manufacturing quality.

The full cost of these regulatory services is recovered from industry. The legal authority for the fees and charges is prescribed in the *Therapeutic Goods Act 1989* (the Act), the *Therapeutic Goods (Charges) Act 1989* (the Charges Act) and subordinate regulations.

The cost recovery arrangements broadly cover regulatory activities in relation to:

- Prescription medicines;
- Non-prescription medicines / over the counter (OTC) medicines;
- Complementary medicines;
- Medical devices, including in-vitro diagnostic (IVD) devices;
- Compliance with Good Manufacturing Practice (GMP);
- Blood and blood products; and
- Biologicals.

Fees are charged for applications for inclusion in the Register and for assessment of the data in support of the application. The revenue from these fees primarily funds the costs of pre-market assessment services. The fees, prescribed in the Therapeutic Goods Regulations 1990 (the Regulations), are reviewed annually to ensure they reflect the underlying costs of providing these services in accordance with the Australian Government Cost Recovery Guidelines (the Guidelines).

Annual charges to maintain an entry on the Register are levied to recover costs that cannot be reasonably assigned to individual sponsors, or where such assignment would act as a deterrent to the effective delivery of the TGA's post market function. These charges fund post-market regulatory activities such as the monitoring of product safety and of sponsor compliance with regulatory obligations. The Charges Regulations prescribe varied levels of charges for different classes of therapeutic goods, based on the level of risk of the type of good.

Post market compliance and monitoring functions include the following activities:

- Management and processing of adverse drug reaction reports;

- Management and processing of recalls of therapeutic goods, including recalls for product correction;
- Testing of therapeutic goods by the TGA laboratories;
- Post-market compliance reviews for listed complementary medicines and class 1 medical devices;
- Management of advertising and complaints resolution functions; and
- Other regulatory costs which cannot be easily assigned to individual sponsors or products.

## Annual charges

All therapeutic goods are required to be entered on the Register before they are supplied in or exported from Australia, unless exempted by the Act.

Sponsors are required to pay an annual charge to maintain their entries on the Register, other than for entries which are specifically exempted (such as export only entries).

Table 1 illustrates the rate of annual charge for each type of therapeutic good, determined by the Charges Regulations and based on the level of risk for the type of good.

**Table 1: 2013-14 Annual charges**

Type of Therapeutic Good	Annual Charge \$
Prescription Medicines – Biologics	6,430
Prescription Medicines – Non-Biologics	3,860
Registered Non Prescription (OTC) Medicines	1,520
Listed (Complementary) Medicines	940
Medical Device Class I	80
Medical Device Class I Measuring	600
Medical Device Class I Sterile	600
Medical Device Class IIa	920
Medical Device Class IIb	920
Medical Device Class III	1,180
Medical Device Class AIMD	1,180
Other Listed Therapeutic Devices (e.g. IVD's, tampons and disinfectants)	750
Other Registered Goods (e.g. IVD's, tampons and disinfectants)	1,480

**Notes:**

A good entered on the Register at any time during a financial year incurs a full year's annual charge, unless an exemption is granted on the basis of low value turnover.

There is currently no annual charge for export only goods.

The annual charge for in-vitro diagnostic (IVD) devices that were not included in the Register prior to the commencement of the new regulatory framework on 1 July 2010 has been set at zero for the period to 1 July 2014, which covers transition to new regulatory arrangements.

## Low value turnover exemption

### History and objectives of the LVT exemption scheme

The LVT exemption scheme (previously known as the low value low volume (LVLV) scheme), has been operating since 1990.

The scheme is established by provisions in the Regulations<sup>2</sup> which allow sponsors to apply for an exemption from the annual charge for a Register entry if the turnover of that entry in a financial year is of low value. The Parliamentary debates surrounding the introduction of the original exemption reveal that the Parliament was seeking to address concerns of the therapeutic goods industry including:

- Manufacturers of small volume products;
- Small start-up companies which may eventually have high volume sales but have very large development costs;
- Herb growers and small companies making medical appliances whose turnover on a number of product lines might only be a few hundred or a few thousand dollars.

The therapeutic goods industry has changed significantly since the 1990s. For example, in the early 1990's the complementary medicines industry in Australia was small, with the regulatory framework covering not only producers of finished products, but also herb growers. The current domestic market for complementary medicines is estimated to be worth nearly \$2 billion<sup>3</sup>.

At the time of the LVT scheme's implementation, the overall fee setting strategy was to avoid linking the annual charges to a company's gross turnover. Consequently, charges were linked to individual Register entries without any limitation as to the number of entries or the company's size.

The threshold for exempting a sponsor from the payment of an annual charge was initially set at 2% of the value of the turnover of the therapeutic good to which the annual charge related. The threshold was subsequently raised to 5% in 1993 and then gradually increased to 6.8% in 2003. To simplify administration of the scheme, the threshold is now expressed as 15 times the applicable annual charge for the relevant Register entry.

In order to ensure full cost recovery of post market regulation, charges must be set taking into consideration the value of the exemptions to be granted (47% in 2012-13 and increasing each year as take up of the scheme increases, thereby putting pressure on increases to the rates of annual charges).

### Applying for an exemption

The process for applying for an LVT exemption is prescribed in the Regulations. A sponsor must submit a completed application within a prescribed timeframe, together with a prescribed application fee (currently \$150 per Register entry, subject to a maximum application fee of \$15,000 per financial year per sponsor). Of note is that the cost of processing LVT applications does not decrease after 100 products (the application fee cap). Each product must be individually assessed for low value turnover.

<sup>2</sup> As per annexure A

<sup>3</sup> <[Complementary Health Council Annual Report 2012](#)>

A completed LVT application comprises:

- *For new Register entries:* an LVT application detailing an **estimate of turnover** of the entry in the current financial year.
  - This estimate is verified at the beginning of the following year, through provision of a statement of actual turnover, signed by a third party accountant (an approved person). If this information is not provided within the prescribed timeframe (by 1 September), or the turnover for the year was above the relevant threshold, the full annual charge for the prior year becomes payable.
  - The Secretary or their delegate may grant an extension of up to 28 days for providing the statement of actual turnover for the prior year.
- *For existing Register entries (entries on the Register at 1 July):* an LVT application containing a **statement of actual turnover** of the entry in the previous financial year.
  - The statement is required to be signed by a third party accountant (an approved person) to certify the reported turnover and is to be received by the TGA before 2 September.
  - No extension to this timeframe is available.

Applications are required to be made by the specified deadline for each financial year. If the deadline is missed for any reason, the sponsor must pay the full annual charge for entries on the Register irrespective of whether the goods have been included in the Register for the full or part financial year. Subsequent cancellation of the entry from the Register does not void the debt. Where the deadline has been missed this has created unplanned financial impact on some sponsors.

### **Current operation of the exemption**

In 2012-13 the TGA invoiced a total of 3,550 sponsors for annual charges relating to 73,831 Register entries - totalling \$90.941 million.

Of these, 974 sponsors applied for, and received, LVT exemptions (relating to 20,027 Register entries), totalling \$42.925 million.

The exemptions resulted in net annual charge revenue of \$48.016 million – only 53% of the invoiced annual charges in that year.

In addition, in 2012-13, sponsors paid a total of \$1.923 million in LVT application fees.

Table 2 below provides a summary of the actual 2012-13 gross annual charges, LVT exemptions and net annual charge revenue, based on the rates of annual charges that were applicable for the 2012-13 financial year.

**Table 2: 2012-13 Actual annual charges revenue and LVT exemptions**

	Annual Charges	LVT Exemptions	Net Annual Charges	Annual Charges Revenue	LVT Exemptions	Net Annual Charge Revenue
Type of Therapeutic Good	Number of Units			\$		
Prescription Medicine – Biologics	1,011	555	456	6,318,750	3,468,750	2,850,000
Prescription Medicine – Non-Biologics	12,413	7,713	4,700	46,502,550	28,892,150	17,610,400
Non Prescription (OTC) Medicines	3,506	1,269	2,237	4,485,370	1,622,290	2,863,080
Listed (Complementary) Medicines	13,116	4,541	8,575	11,926,510	4,128,160	7,798,350
Medical Device Class I	21,262	707	20,555	1,487,010	49,470	1,437,540
Medical Devices – Other than Class I	21,841	5,141	16,700	19,637,830	4,671,870	14,965,960
Other Therapeutic Goods (OTG)	682	101	581	583,320	92,230	491,090
<b>Total</b>	<b>73,821</b>	<b>20,027</b>	<b>53,804</b>	<b>90,941,340</b>	<b>42,924,920</b>	<b>48,016,420</b>

## Observations on the current LVT exemption scheme

While a number of amendments have been made to the LVT eligibility threshold and application requirements since the introduction of the scheme, the general nature of the scheme and its primary criteria for eligibility (i.e. annual turnover) has remained the same.

Over the years, a number of challenges have arisen with the operation of the scheme which are discussed below.

### The scheme is no longer consistent with stated objectives

The original objectives of the LVT scheme, sourced from the parliamentary debate, were to provide exemptions to the therapeutics industry which manufacture small volume products, and address the concerns of herb growers and small companies making medical appliances whose turnover on a number of product lines might only be a few hundred or a few thousand dollars.

However, in the absence of any specific criteria about the size of the sponsor responsible for the Register entry for which the exemption is claimed, the benefit extends to companies of all sizes,

and not only to those small companies whose turnover on a number of product lines is low as per the objective of the LVT exemption scheme.

Table 3 below illustrates a summary of the gross annual charges, LVT exemptions and net annual charges for the top 20 sponsors (by gross annual charges, that is, annual charges invoiced before any exemption is applied) in 2012-13. As demonstrated by the figures below, the top 20 sponsors now account for more than 50% of all LVT exemption benefits. Furthermore, 11 of the top 20 sponsors pay less than 50% of the gross annual charges they each incur.

In contrast, a large number of small business sponsors, who generally only hold a few entries on the Register, did not receive LVT exemptions. The contrast may result, among other reasons, from small businesses not having dedicated regulatory compliance officers/advisers. In one case reported to us, a small business did not apply because they didn't have an accountant. In other cases it is because their financial records do not produce financial information by Register entry.

For sponsors of class I medical devices (other than those in the sterile or measuring function categories) the annual charge is much less than the LVT application fee.

The sole criterion to access the current LVT scheme is that the value of the turnover of the individual Register entry is below the threshold value. This criterion doesn't take into account total turnover of the sponsor or the company size.

**Table 3: Top 20 Sponsors by gross annual charges revenue in 2012-13**

	Gross Annual Charges		LVT Exemptions		Net Annual Charges	
	QTY	\$	QTY	\$	QTY	\$
Top 20 Sponsors	12,225	36,832,610	6,532	22,290,810	5,693	14,541,800
Remaining 3,530 Sponsors	61,606	54,108,730	13,495	20,634,110	48,111	33,474,620
<b>Total</b>	<b>73,831</b>	<b>90,941,340</b>	<b>20,027</b>	<b>42,924,920</b>	<b>53,804</b>	<b>48,016,420</b>
Top 20 Sponsors	17%	41%	33%	52%	11%	30%
Remaining 3,530 Sponsors	83%	59%	67%	48%	89%	70%
<b>Total</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

### Lack of a clear, contemporary policy objective

To reform, or refine, the LVT scheme to meet the needs of the modern therapeutic goods industry, it is essential to articulate a clear policy objective.

Possible policy objectives include:

- Assisting small business;
- Supporting provision of essential therapeutic goods that might otherwise not be viable in the market; and/or
- Supporting therapeutics goods manufactured in Australia for the export market.

### Administrative complexity and sponsor understanding of the processes

On the recommendation of the Australian National Audit Office (ANAO), the scheme was amended in 2009 to require sponsors to obtain third party certification of the reported turnover of Register entries for which an LVT exemption was sought, to ensure the eligibility of claims for exemption.

To overcome administrative difficulties faced by both the TGA and sponsors in implementing the new requirements, further amendments were made to the scheme in December 2011 and June 2012. These amendments respectively provided sponsors with more time to submit their LVT applications for new entries, and an additional opportunity to meet their obligations in relation to the 2009-10 and 2010-11 LVT exemptions for new entries.

Despite the amendments, issues remain in relation to sponsor compliance with certification requirements.

Eight validation processes were conducted between 2008 and 2013 to examine sponsor records relating to sales revenue and the mapping of these to Register entries to determine LVT eligibility. The validation processes comprised desk top reviews of sponsor records, and, for



select sponsors, were complemented by on-site validation meetings where further cross verification of LVT related records was conducted. During these meetings, the TGA identified repeat examples where sponsors had experienced difficulties in recording and accurately reporting the actual turnover of individual Register entries.

Small businesses were disproportionately affected by these difficulties, given their generally smaller resource base and reporting system support. Sponsors do not necessarily capture turnover by Register entry, other than to meet the requirements of the LVT scheme.

The process for new entries is more complex than for existing entries as this requires sponsors to initially submit their applications on the basis of **estimated turnover for the current financial year**; and then subsequently submit a statement of **actual turnover**, signed by a third party accountant, in the following financial year. These two separate processes for new and existing entries, with similar information requirements, have been confused as being part of a single process.

As a result the TGA has received informal feedback that some sponsors do not seek an LVT exemption because they consider the LVT exemption process to be administratively difficult, with the cost of preparing and submitting an LVT application outweighing the value of the exemption in some cases.

Of some concern to sponsors has been the strict deadline outlined in the legislation for LVT applications for existing entries. If the deadline for submission of the LVT application is missed, the full annual charge becomes payable. This deadline is very important for minimising the administrative burden of the LVT scheme and to provide greater certainty of revenue estimates for planning purposes, but has resulted in unexpected charges for sponsors who were planning to apply for an LVT exemption.

### **Compliance with cost recovery principles**

In 2002, the government introduced a Cost Recovery Policy (the Policy) and issued the Australian Government Cost Recovery Guidelines July 2005 (the Guidelines)<sup>4</sup>. As a cost recovered operation, the TGA is required to establish and maintain a system of fees and charges that comply with the Guidelines.

The Guidelines aim to ensure that fees and charges applied for government services:

- Are legally applied;
- Are cost effective to implement;
- Are cost reflective of the services performed;
- Do not impede competition or innovation; and
- Avoid cross subsidisation.

The LVT exemption provisions were introduced in 1990, much earlier than the Guidelines.

Under current annual charge settings a significant number of Register entries which are subject to TGA's post market activities are not paying their share of the costs associated with the performance of these functions – these costs are paid disproportionately by sponsors of Register entries for which the exemption is not claimed. Therefore, the current take up of the LVT scheme could lead it to be inconsistent with the Guidelines.

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<sup>4</sup> <[http://www.finance.gov.au/publications/finance-circulars/2005/docs/Cost\\_Recovery\\_Guidelines.pdf](http://www.finance.gov.au/publications/finance-circulars/2005/docs/Cost_Recovery_Guidelines.pdf)>

Table 4 below details the portion of LVT benefit as a percentage of gross annual charge revenue.

In addition, the benefit provided by the scheme seems to differ between groups of therapeutic goods - the table below shows that the proportion of LVT benefit as a percentage of gross annual charge revenue varies significantly from one group of therapeutic products to another. For example, LVT benefits claimed are only 24% of expected total gross annual charges revenue in relation to medical device Register entries; while for non-biological prescription medicines the value is much higher at 62%.

**Table 4: 2012-13 Annual Charge Revenue and LVT Exemption by Type of Therapeutic Good**

Type of Therapeutic Good	Annual Charge Revenue	LVT Benefit Received	Fees After LVT Benefit	LVT as a % of Gross Revenue
	\$	\$	\$	\$
Prescription Medicines – Biologics	6,318,750	3,468,750	2,850,000	55%
Prescription Medicines – Non-Biologics	46,502,550	28,992,150	17,610,400	62%
Registered Non-Prescription (OTC) Medicines	4,485,370	1,622,290	2,863,080	36%
Listed (Complementary) Medicines	11,926,510	4,128,160	7,798,350	35%
Medical Device Class I	1,487,010	49,470	1,437,540	3%
Medical Device – Other than Class I	19,637,830	4,671,870	14,965,960	24%
Other Therapeutic Goods (OTG)	583,320	92,230	491,090	16%
<b>Total</b>	<b>90,941,340</b>	<b>42,924,920</b>	<b>48,016,420</b>	<b>47%</b>

### LVT exemption and small business

As outlined earlier in this paper, one of the stated objectives of the scheme was to assist small businesses, including those making medical appliances whose turnover on a number of product lines might only be a few hundred or a few thousand dollars upon introduction of regulation. However, the legislation does not include any restriction for medium and large businesses to seek LVT exemption. The data suggests large and medium sized companies (and not necessarily small businesses) are the major beneficiaries of the current scheme.

Whilst some 75% of TGA sponsors have 10 or fewer entries on the register (and assuming these sponsors are small businesses) they claim only 3% of total LVT benefit. It is estimated that the average number of entries for which small business (those who claim an exemption) claim LVT

exemption is two. Despite this number being low, a small business is subject to the same level of compliance with the LVT application and validation requirements, and as mentioned, small businesses are disproportionately affected by these compliance requirements, given their generally smaller resource base and reporting system support.

The Productivity Commission has released a draft consultation paper '[Regulator Engagement with Small Business](#)' on how to address the key challenges small businesses face in complying with regulations and to appropriately balance the needs of small business and the interests of the broader community.

The paper advocates the principles of taking a risk based approach to reduce regulatory burden for small business. TGA's risk based regulatory framework allows automatic listing/inclusion of low risk complementary medicines and class 1 medical devices. A large proportion of TGA sponsors with 10 or fewer entries are in the business of complementary medicines and class I medical devices, and may represent small business. Given the low risk associated with these entries, the cost of regulation is generally lower and that is the reason they attract lower fees and a lower annual charge.

The consultation paper also discusses differential treatment for small business where it would maximise the net benefit to the community. If the current scheme continues, the differential treatment the TGA could offer to small business is to not require the validation process for new entries or to accept a declaration that does not require an approved person (an accountant) to sign the declaration. However, this would make the process more complex and costly to run e.g. one process for small business and another for others, and may not be considered of net benefit to the community.

# Options

The TGA is seeking feedback on the following options for the future operation of the scheme:

- Option 1:** Retain the LVT scheme in its current form
- Option 2:** Retain the LVT scheme, with some amendments to improve its efficiency
- Option 3:** Replace the LVT scheme with one that only grants exemptions for Register entries which are not supplied to the Australian market
- Option 4:** Replace the LVT scheme with one that only grants exemptions for Register entries where the sponsor is a small business
- Option 5:** Cease the LVT scheme completely.

Each of the above options, with possible variations, is discussed below.

## Option 1: Retain the LVT scheme in its current form

Concerns around the current LVT scheme, outlined in this paper, include ineffectiveness in meeting its policy objectives, inequity, administrative burden and inconsistency with the Guidelines. So, it is not desirable to continue the scheme in its current form.

### Issues relating to Option 1

1. Do you support the option of continuing with the LVT scheme in its current form?
2. Is your business a beneficiary of the current LVT scheme? If you are currently claiming any LVT exemptions, how do the exemptions provide a benefit to your business?
3. If you're not currently claiming any LVT exemptions, please explain the reasons for this, particularly if you have entries which could qualify as low value turnover entries.
4. What do you see as the broader benefits of the current LVT scheme?
5. What do you see as the drawbacks of the current LVT scheme?

## Option 2: Retain the LVT scheme with some amendments

As discussed earlier, one of the primary objectives of the introduction of the LVT scheme was to provide relief to small businesses upon the introduction of therapeutic goods regulation.

Whilst it is noted that there are challenges with the current LVT scheme in achieving that intended objective, given the widespread use of the scheme, one option would be to continue the scheme, with some amendments to improve its administration and efficiency.

Possible changes to the current scheme include but are not limited to:

- Provide further clarification of the definition of 'turnover';
- Provide provision in the Regulations for an extension of the deadline for submitting an LVT exemption application, possibly with a late lodgement fee, or remove the option for

extension of the deadline for submitting validation information for new entries in the prior year so that the deadlines for these two processes cannot be confused;

- Accept self-declaration from small businesses of the turnover of their products; and
- Remove the annual cap of \$15,000 for LVT application fees for greater alignment with the Cost Recovery Guidelines as there are no administrative efficiencies gained on applications with a higher number of products.

#### Issues relating to Option 2

1. Do you support the option of continuing with the LVT scheme in its current form but amended as above? Please provide detail on why you hold this view.
2. What do you see as the broader benefits of this option?
3. What do you see as the drawbacks of this option?
4. If you could improve the way the LVT scheme operates, what changes would you introduce?

### Option 3: Replace the LVT scheme with one that only grants exemptions for Register entries which are not supplied to the Australian market

Another option under consideration is restriction of the LVT scheme to only those Register entries which are not supplied to the Australian market.

The rationale for this option is that, as these products are not marketed in Australia they require minimal post-market surveillance and monitoring by the TGA. Given the low post market cost of these Register entries, another option could be to establish a lower charge for these entries and remove the LVT scheme.

For example, if a product has not been marketed in Australia, the TGA is not required to undertake activities related to domestic recalls, product testing or adverse drug reactions for the vast majority of these products, but it must retain the capacity to do this. There are minimal administrative costs in relation to maintaining the entry on the Register and for compliance, monitoring and review. However, some high risk medicines or medical devices, though not supplied in Australia, may require limited monitoring if products are being supplied outside Australia.

Under this option, all Register entries reporting annual turnover in excess of zero (largely those products which are actively marketed in Australia, and which therefore are subject to post market monitoring and compliance), would contribute to the costs of post-market functions.

This option would better align the operation of the scheme with the Guidelines, as those who create the need for post market activities would bear the costs of such activities, whilst still providing some relief to sponsors who have products with zero turnover.

It is estimated that of the 974 sponsors who receive LVT exemptions in 2012-13, 600 sponsors would continue to receive LVT exemptions under this model (approximately 62%).

In the case of prescription medicines, the proportion of Register entries reporting zero annual turnover is much higher than the average at around 75% (relating to approximately 5,000 entries).

Given that annual charges would be paid across a broader number of Register entries, it is expected that under this option, the annual charge for individual entries on the Register would be reduced. However, it is also expected that some sponsors will choose to cancel some entries on the Register where they are no longer eligible for the exemption.

The small business consultation paper discussed earlier in this paper also highlights, where possible, not collecting information that doesn't already exist, and sharing information that has already been collected. A weakness of the current scheme is that as part of the application and validation process sponsors are required to provide the TGA with the turnover of each entry in respect of which an LVT exemption is claimed though most businesses wouldn't normally capture and report this information. Under this option, sponsors will be in a better position to make this declaration.

Table 5 below illustrates the potential decreases in annual charge rates for individual Register entries under this option, taking into account the cancellation by sponsors of some Register entries which would no longer be eligible for the exemption.

These forecasts suggest that annual charges for each Register entry could be reduced by up to 37%, depending on the proportion of Register entries cancelled by sponsors.

**Table 5: Potential reductions in annual charges, based on historic data, if access to LVT is limited to zero turnover entries**

Type of Therapeutic Good	Annual Charge Revenue Forecast	Potential decrease in annual charge rates if the below % of LVT entries are withdrawn from the Register				
		0%	25%	50%	75%	100%
Prescription Medicines – Biologics	2,847,910	30%	24%	17%	9%	0%
Prescription Medicines – Non-Biologics	17,169,862	37%	31%	23%	13%	0%
Registered Non-Prescription (OTC) Medicines	2,707,921	18%	14%	10%	5%	0%
Listed (Complementary) Medicines	7,284,671	18%	14%	10%	5%	0%
Medical Device Class I	1,421,694	1%	1%	1%	0%	0%
Medical Device – Other than Class I	15,207,735	10%	7%	5%	3%	0%
Other Therapeutic Goods (OTG)	497,243	8%	6%	4%	2%	0%
<b>Total</b>	<b>47,137,036</b>	-	-	-	-	-
Number of sponsors affected	374					
Total number of sponsors	3,550					

This option has the following benefits:

- Around 62% of current LVT exemptions would be expected to continue;
- Administrative processes would be relatively simpler as sponsors would be required to provide a 'no supply' declaration to claim the exemption from annual charges;
- The annual charge for individual Register entries is likely to be reduced;
- The operation of the LVT scheme would be more closely aligned with the Guidelines, with a stronger relationship between those creating a need for post market regulatory activities and those paying for them;
- This option would provide relief from TGA annual charges to sponsors until a good is launched in the Australian market. Existing entries could likewise remain on the Register without any annual charge, until they are marketed in Australia; and

- More zero turnover entries would remain on the Register (by comparison with Option 4 below) resulting in a quicker time to market for those products.

The disadvantages of this option include:

- Administrative costs of compliance would remain as a validation process for actual supply would still be required (exemptions would be granted on the basis of expectations). This validation process should apply equally to new entries added to the Register during the year, and existing entries on the Register at 1 July, to ensure that an annual charge becomes payable for entries that have been marketed during the year but for which an exemption was granted at the beginning of the year; and
- Small businesses that report low turnover of their products will not receive an exemption, and the original intent of the LVT scheme is deviated from.

### Issues relating to Option 3

1. Do you support the option of confining eligibility of annual charge exemptions to only those Register entries which are not supplied in Australia or establish a low or annual charge for such entries? Please mention which option (LVT for zero turnover products or lower annual charge) you prefer and detail why you hold this view and any variations to this option that could improve its operation.
2. How would this change impact your business? Would these changes be largely positive or negative, taking into account the expected benefits and disadvantages? Please include financial impacts, changes to marketing of products etc.
3. If this change was implemented, would this impact on your supply of products into the Australian market? If yes, please provide more detail on these expected impacts.
4. What do you see as the broader benefits of this option?
5. What do you see as the drawbacks of this option?

## Option 4: Replace the LVT scheme with one that only grants exemptions for Register entries where the sponsor is a small business

Implementing the original policy intent of assisting small business, with a better targeted and lower-burden scheme, is another option.

Providing relief from regulatory charges to small businesses in the early stages of regulation of a particular industry is not uncommon. The United States Food and Drug Administration (USFDA)<sup>5</sup> have a scheme under which the pre-market application fee for a new medical device is reduced by 50% for qualified small businesses. Health Canada<sup>6</sup> provides for remission of a portion of the review fee when the application fee exceeds 2.5% of the actual gross revenues during the fee verification period for the medical device for which a licence application or licence amendment application has been made.

One option is to replace the current LVT scheme with a scheme restricted to small business.

<sup>5</sup> <<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAlII/UCM314389.pdf>>

<sup>6</sup> <[http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/guidedoc\\_feesmd\\_docorient\\_fraisim-eng.php](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/guidedoc_feesmd_docorient_fraisim-eng.php)>



This option would be guided by business turnover rather than product turnover. The scheme would be limited to businesses that met the same small business definition used by the Australian Taxation Office (ATO) - aggregate turnover of less than \$2 million per annum.

Eligibility for, and administration of, this scheme would be simplified. At the beginning of each financial year sponsors would identify themselves as having met the small business definition applied by the ATO (aggregate turnover of less than \$2 million per annum) in the past financial year and identify the products that they have in the Register. Those sponsors would be exempt from annual charges for the financial year.

Sponsors whose businesses grew sufficiently during the financial year as to exceed the small business threshold would not lose their exemption entitlement until the commencement of the following financial year.

Rather than providing financial returns certified by an authorised person (an accountant), as required under the current LVT scheme, sponsors would authorise the TGA to match data with the Australian Taxation Office to confirm eligibility for the small business exemption.

The TGA does not currently seek information regarding the size of sponsors. However, we have formed assumptions for modelling purposes based on the number of products a sponsor has on the Register and the level of LVT benefit the sponsor receives. For example, it might be reasonable to assume that sponsors who received an LVT benefit of more than \$50k in a year were likely to be large businesses. 85% of the total LVT benefit is currently received by such businesses. It might also be reasonable to assume that sponsors who have less than 10 product entries are likely to be small businesses. These receive only 3% of the total LVT benefit.

For the purpose of this review we have assumed that 3% of the total LVT benefit is currently received by small businesses. Hence, by replacing the current LVT scheme and limiting exemptions to small business, the revenue foregone due to LVT exemptions can be reduced by 97%.

Table 6 below illustrates the potential decreases in annual charge rates arising from Option 4 (after taking into account various levels of withdrawal of entries from the Register).

**Table 6: Potential reductions in annual charges if access to LVT is restricted to small business**

Type of Therapeutic Good	Annual Charge Revenue Forecast	Potential decrease in annual charge rates if the below % of LVT entries are withdrawn from the Register				
		\$	0%	25%	50%	75%
Prescription Medicines – Biologics	2,847,91	52%	45%	35%	22%	0%
Prescription Medicines – Non-	17,169,8	61%	54%	44%	28%	0%
Registered Non-Prescription (OTC)	2,707,92	37%	30%	22%	13%	0%
Listed (Complementary) Medicines	7,284,67	37%	31%	23%	13%	0%
Medical Device Class I	1,421,69	3%	2%	2%	1%	0%
Medical Device – Other than Class I	15,207,7	22%	17%	12%	6%	0%
Other Therapeutic Goods (OTG)	497,243	18%	14%	10%	5%	0%
<b>Total</b>	<b>47,137,0</b>	-	-	-	-	-
Reductions in costs – savings of LVT	-	\$1.73m	\$1.73m	\$1.73m	\$1.73m	\$1.73m
Number of sponsors affected	408					
Total number of sponsors	3,421					

It should be noted that this option reflects a deliberate policy decision to support small business sponsors. This would be a deliberate departure from a pure cost recovery model whereby all sponsors contribute to the cost of post market compliance by paying annual charges (varied by category based on risk). In this respect, this option would not align with the Guidelines and would need to be implemented as a specific Government policy decision.

It is also worth noting that, under this option, low volume unique products (e.g. for unusual medical conditions) sponsored by larger business will no longer be exempt from annual charges. This may result in the products not being financially viable. Sponsors may wish to consider removing these products from the Register and making them available under the Special Access Scheme instead. This would negate the financial consequence for those sponsors.

This option has the following benefits:

- It supports the viability and growth of Australian small business;
- The annual charge for individual Register entries is likely to be reduced for prescription medicines, over the counter medicines and complementary medicines;
- Administrative processes would be clearer and simpler; and
- The burden of producing evidence to prove eligibility would be reduced to virtually nil

The disadvantages of this option include:

- The cost of post market compliance will be subsidised by sponsors who do not meet the small business definition; and

- Low volume unique products (e.g. for unusual medical conditions) sponsored by larger business will no longer be exempt from annual charges. Sponsors may consider removing these products from the Register and making them available under the Special Access Scheme instead.

#### Issues relating to Option 4

1. Do you support the option of confining eligibility of annual charge exemptions to small business?
2. How would this change impact your business? Would these changes be largely positive or negative, taking into account the expected benefits and disadvantages? Please include financial impacts, changes to marketing of products etc.
3. If this change was implemented, would this impact on your supply of products into the Australian market? If yes, please provide more detail on these expected impacts.
4. What do you see as the broader benefits of this option?
5. What do you see as the drawbacks of this option?

### Option 5: Cease the scheme completely

This option would involve the cessation of the LVT scheme at the commencement of the 2015-16 financial year, subject to Regulation changes.

Under this option, it is expected that a high portion of sponsors would benefit from 'across the board' decreases in annual charge rates for individual Register entries.

However, in the short term, a smaller portion of sponsors could be adversely affected by the cessation of the scheme, as they would be required to pay annual charges for all Register entries for which they are responsible.

In 2012-13, 47% of annual charges became exempt due to LVT. Recovering post market monitoring and vigilance costs from all Register entries would be expected to result in a significant reduction of the annual charge per Register entry, as detailed in Table 7 below.

Cessation of the scheme would also reduce regulatory burden and red tape for sponsors. As all product entries on the Register would attract a (reduced) annual charge, based on the risk of the product and the post market monitoring costs associated with the product type, cross subsidisation is avoided.

An important consideration of this option would be the expected cancellation by sponsors of some or all Register entries which would no longer be eligible for the exemption. As the number of entries removed would be the decision of individual sponsors, and difficult to predict exactly, this table considers potential results using a range of withdrawal rates.

It should be noted that the estimates assume that reductions are uniform across product groupings. In practice the TGA is aware that the withdrawal rates are likely to vary from sponsor to sponsor based on individual commercial decisions.

**Table 7: Potential reductions in annual charges, based on historic data, if LVT is discontinued**

Type of Therapeutic Good	Annual Charge Revenue Forecast	Potential decrease in annual charge rates if the below % of LVT entries are withdrawn from the Register				
		\$	0%	25%	50%	75%
Prescription Medicines – Biologics	2,847,910	53%	46%	36%	22%	0%
Prescription Medicines – Non-Biologics	17,169,862	62%	55%	45%	29%	0%
Registered Non-Prescription (OTC) Medicines	2,707,921	37%	31%	23%	13%	0%
Listed (Complementary) Medicines	7,284,671	38%	31%	23%	13%	0%
Medical Device Class I	1,421,694	3%	3%	2%	1%	0%
Medical Device – Other than Class I	15,207,735	22%	18%	12%	7%	0%
Other Therapeutic Goods (OTG)	497,243	18%	14%	10%	5%	0%
<b>Total</b>	<b>47,137,036</b>	-	-	-	-	-
Number of sponsors affected	974					
Total number of sponsors	3,550					

The variability currently associated with forecasting revenue due to LVT exemptions, and therefore the difficulty in setting annual charge rates, would be eliminated, improving TGA's ability to forecast revenue and tie charges to operational costs. This would also assist sponsors with their budget planning providing a lot more certainty and predictability around annual charges.

As the costs of post market functions would be recovered across all products (based on product risk), TGA's cost recovery arrangements would be aligned with the Guidelines.

The TGA recognises that the following negative impacts may arise if this option were implemented:

- Some sponsors may choose to cancel Register entries with low or no turnover, possibly resulting in the removal of some therapeutic goods from the Australian market;
- There will be no relief from the cost of regulation for small business or in relation to new therapeutic goods entering the market (which may, initially, have low annual turnover). (Although there is evidence to suggest that small businesses are not the primary beneficiaries of the current scheme and may in fact benefit from lower annual charges.); and

- Low volume unique products (e.g. for unusual medical conditions) sponsored by larger business will no longer be exempt from annual charges. Sponsors may consider removing these products from the Register and making them available under the Special Access Scheme instead.

#### Issues relating to Option 5

1. Do you support the cessation of the LVT scheme? Please detail why you hold this view.
2. How would this change impact your business? Would this change be largely positive or negative, taking into account the expected benefits and disadvantages? Please include financial impacts, changes to marketing of products etc.
3. If this change was implemented, would this impact on your supply of products into the Australian market? If yes, please provide more detail on these expected impacts.
4. What do you see as the broader benefits of this option?
5. What do you see as the drawbacks of this option?

## Annexure A - Legislative references

### ***Therapeutic Goods Act 1989***

#### **44A Exemptions from liability to pay charges**

**Subsection 44A** (1) states that the regulations may make provision for and in relation to:

- a. exempting a person from liability to pay annual registration charge, annual listing charge or annual charge for inclusion in the Register for a financial year (the *current year*) if the person's turnover of the therapeutic goods concerned for the financial year specified in the regulations is of low value;
- b. the making of an application for an exemption and requiring payment of that charge for the current year if the application is refused; and
- c. cancelling an exemption and requiring payment of that charge for the current year.

### **Therapeutic Goods Regulations 1990**

#### **Regulation 43AAB: Definitions**

##### ***Approved person***

Approved person means a person who is a qualified accountant under section 88B of the *Corporations Act 2001*, but does not include:

- A person who is required to submit a statement signed by an approved person; or
- An employee of that person.

**Existing entry**

Existing entry, for a therapeutic good (other than a biological), means an entry for registration, listing or inclusion of the therapeutic good (other than a biological) in the Register that is not a new entry.

**Low value turnover (LVT)**

Low value turnover means a turnover of not more than 15 times the annual registration charge, the annual listing charge, or the annual charge for inclusion in the Register (other than the annual charge for inclusion of a biological under Part 3-2A of the Act) payable for a financial year.

**New entry**

New entry, for a therapeutic good (other than a biological), means an entry for registration, listing or inclusion of the therapeutic good (other than a biological) in the Register that commenced in the financial year.

**Turnover (Therapeutic Good)**

Turnover, for a therapeutic good (other than a biological), means gross dollar receipts (excluding GST) from sales of the therapeutic good (other than a biological) in Australia for a financial year, including retail and wholesale sales.

**Turnover (aggregated turnover for small business eligibility)**

Aggregated turnover means the total gross income or proceeds of your business plus the total gross income or proceeds of any business you are connected with or that is your affiliate. It does not include any goods and services tax (GST) amounts charged on sales. This is the same definition used by the Australian Taxation Office. <<http://www.ato.gov.au/Business/Small-business-entity-concessions/>>.

**Regulation 43AAC: Application requirements**

**Subregulation 43AAC (1)** states that for section 44A of the Act, the person liable to pay the annual registration charge, annual listing charge or the annual charge for inclusion of a therapeutic good (other than a biological) in the Register may apply to the Secretary for an exemption from liability to pay the charge for the current financial year on the ground that the turnover of that good for the applicable financial year is a low value turnover.

**Subregulation 43AAC (2)** states that the application must be:

- a. In writing, in a form approved by the Secretary; and
- b. Accompanied by:
  - i. For an existing entry – a statement of actual turnover of the therapeutic good for the previous financial year, signed by an approved person; or
  - ii. For a new entry – a statement of estimated turnover of the therapeutic good for the current financial year; and
  - iii. Subject to regulation 45A, the fee payable; and
- c. Received by the Secretary:
  - i. For an existing entry – before 2 September of the financial year; and

- ii. For a new entry – at least 21 days before the date for payment of the charge mentioned in regulation 43AAA.

**Subregulation 43AAC (3)** states that the statements mentioned in subregulations 43AAC (b) (i) and (ii) must be in a form approved by the Secretary.

#### **Regulation 43AAD: Decision by the Secretary – exemption application**

**Subregulation 43AAD (1)** states that within 21 days after receiving an application under subregulation 43AAC (1), the Secretary must:

- a. Decide whether to grant the exemption; and
- b. Give written notice to the person of the decision; and
- c. If the decision is a refusal, the reasons for the decision.

**Subregulation 43AAD (2)** states that if the Secretary refuses to grant the exemption, the applicant must pay the charge for which exemption was sought:

- a. For an existing entry – within the later of:
  - i. 14 after the notice is given under subregulation 43AAD (1) (b); or
  - ii. The date mentioned in paragraph 44 (1) (b) of the Act; and
- b. For a new entry – within the later of:
  - i. 14 days after the notice is given under subregulation 43AAD (1) (b); or
  - ii. The date mentioned in regulation 43AAA.

#### **Regulation 43AAE: Actual turnover – new entries in the Register**

**Subregulation 43AAE (1)** requires that if an exemption has been granted under sub regulation 43AAD (1) for a new entry in the Register based on the estimated turnover of a therapeutic good (other than a biological) for a financial year (the **current year**), the person must give to the Secretary by 1 September in the following financial year (the **following year**):

- a. Details, in writing in a form approved by the Secretary, of the actual turnover of the therapeutic goods (other than a biological) for the current year; and
- b. A statement, signed by an approved person, in a form approved by the Secretary, of the actual turnover of the therapeutic good (other than a biological) for the current year.

**Note.** If the current year is financial year 2013-14, the following year is financial year 2014-15. The statement, signed by an approved person, detailing the actual turnover of the new entry in 2013-14 would therefore need to be received by 1 September 2014.

**Subregulation 43AAE (2)** states that before 1 September in the following year, the person may apply in writing for, and the Secretary may agree to, an extension of up to 28 days after the time mentioned in Regulation 43AAE (1) for giving the information.

**Subregulation 43AAE (3)** states that if the person does not give the information to the Secretary within the time mentioned in Regulation 43AAE (1) or within the extended time agreed to by the Secretary under Regulation 43AAE (2):

- a. The exemption is taken to be cancelled on 30 September in the following year; and

- b. The person must pay the charge for which the exemption was granted by 31 October of the following year.

### **Regulation 43AAF: Decision based on actual turnover**

**Subregulation 43AAF (1)** states that the Secretary must within 21 days after receiving the information from a person under subregulation 43AAE (1):

- a. Decide whether the actual turnover of the therapeutic goods was low value; and
- b. Give the person notice of:
  - i. the decision; and
  - ii. if the decision is that the actual turnover was not a low value turnover – the reasons for the decision.

**Subregulation 43AAF (2)** states that if the Secretary decides that the turnover of the therapeutic good for the financial year was not a low value turnover and gives the person a notice under subregulation 43AAF (1) (b), then:

- a. The exemption is cancelled; and
- b. The person who receives the notice mentioned in subregulation 43AAF (1) (b) must pay the charge for which that exemption had been granted by 31 October of the following year.

## **Glossary of terms**

Definitions of key terms used in this consultation paper are provided in this section to facilitate a common understanding of the key issues and proposed options.

**Australian Register of Therapeutic Goods (the [Register](#)):** The Register is the publicly accessible reference database of the therapeutic goods available in Australia. The Register is available online <<https://www.ebs.tga.gov.au>>. It provides information on therapeutic goods that can be supplied in Australia and includes the product and sponsor name and other basic information about the goods. It is not intended to provide guidance, advice or recommendations on those goods.

**Therapeutic goods:** Therapeutic goods include prescription, over the counter and complementary medicines, medical devices and blood and biological goods that are required to be entered on the Register.



Historical consultation document

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