

Technical Alert

Important Information: TGA End of Financial Year Process

Dear CHC member,

The end of financial year is an important time to consider the financial aspects of your entries in the Australian Register of Therapeutic Goods. Annual charges for 2013-14 for entries in the Register will be generated in July 2013. All entries in the Register as at 1 July are subject to the full year's annual charge.

If you no longer require your product to be in the Register please complete the <u>TGA cancellation form</u> and submit it by the **end of May** to avoid the annual charge. The TGA highlights that the effective date of the cancellation isn't when you sign or send in the form – it is when the delegate in the TGA signs the 'decision letter' required by the legislation, cancelling the product/s from the Register. So please ensure you allow plenty of time for this to occur to avoid the 2013-14 annual charge for unwanted entries.

It is also important to consider, in relation to annual charges, the deadline for low value turnover (LVT) exemption applications. **Applications are due to TGA by 1 September and no late applications will be accepted**. Under the legislation it isn't necessary for the TGA to issue an annual charges invoice for you to submit your LVT application, however it is common practice to use the invoice to submit the LVT application. If you have not received an annual charges invoice from the TGA by the beginning of August we encourage you to follow up with the TGA. Please ensure that your LVT applications are signed by an approved person¹ and received by the TGA by 1 September 2013.

Please also note that early in the next financial year the TGA will conduct a validation process for LVT exemptions granted in 2012-13. When you submitted your LVT application during the year for <u>new</u> entries you would have had a client representative sign a declaration of estimated turnover. In order to now validate that information the TGA will ask you to have an 'approved person' sign a declaration of ACTUAL turnover for the year. This should not be confused with the 2013-14 LVT application process.

Key Dates	Action Required
31 May 2013	Submit requests for cancellations
	http://www.tga.gov.au/about/forms-artg-cancel.htm
	Any queries regarding cancellation should be emailed to ebs@tga.gov.au
July 2013	Annual charges invoices issued
1 September 2013	Lodgement of low value turnover (LVT) exemption applications
	http://www.tga.gov.au/about/fees-forms-low-value-applying.htm
	(applications received after this date will not be considered)
1 October 2013	Payment of 2013-14 annual charges

Please do not hesitate to contact the TGA accounts area by emailing accountsrec@tga.gov.au if you have any further queries regarding fees or charges.

¹ 'Approved person' means a person who is a qualified accountant under section 88B of the Corporation Act 2001, but does not include a person who is required to submit an exemption application or an employee of that person.