

## TGA changes to annual charges and LVT 2011-12

The following information relates to the payment of annual charges for therapeutic goods that are registered, listed or (in the case of medical devices) included in the Australian Register of Therapeutic Goods (the ARTG), and the exemption from such charges on the grounds of low value turnover.

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### **Payments**

From 2011-12, the TGA will no longer offer the option of paying annual registration or listing charges or annual charges for inclusion in the Register by instalments.

Instead, it will be necessary for sponsors to pay these annual charges for the 2011-12 financial year for existing ARTG entries (that is, for therapeutic goods that are registered, listed or included in the Register before the commencement of financial year 2011-12) in full by 1 October 2011. This requirement is consistent with Section 44 of the Therapeutic Goods Act 1989 and the requirements of the Therapeutic Goods Regulations 1990 (the Regulations).

In the case of a new ARTG entry, paragraph 44(1)(a) of the Act and regulation 43AAA, taken together, require the annual charge associated with that entry to be paid (in full) no later than the last day of the month immediately following the month when the goods were entered in the ARTG.

It is important to note that the registration or listing of therapeutic goods in the ARTG may, under paragraph 30(2)(f) of the Act, be cancelled (or, under paragraph 29D(1)(b) of the Act, suspended) if the annual registration or listing charge in relation to the goods is not paid within 28 days of the charge becoming payable. The inclusion of a kind of medical device in the ARTG may, under subsection 41GL(f) of the Act, be cancelled (or, under paragraph 41GA(1)(b) of the Act, suspended) if the annual charge payable in relation to the kind of medical device is not paid within 20 working days after the charge becomes payable.

In addition, all requests by sponsors for the cancellation of their therapeutic goods must be received by the TGA before 1 July 2011 in order to avoid an annual charge for the 2011-12 financial year.

Requests by sponsors for the Secretary to cancel the registration or listing of the sponsor's goods, or to cancel the entry relating to the sponsor's kind of the medical device, can be made in writing using the relevant forms on the TGA Website, and queries may be directed to 02 6232 8888.

## **Low value turnover exemptions**

Sponsors are also reminded that they are able to apply for an exemption from liability to pay an annual registration or listing charge or an annual charge for inclusion in the Register on the basis of the product's low value turnover (LVT). More information about LVT exemptions is set out on the TGA website.

Applications for LVT exemptions for 2011-12 in relation to existing ARTG entries must be received by the TGA by 2 September 2011. For new ARTG entries, LVT applications must be received at least 21 days before the last day of the month immediately following the month the goods were entered in the ARTG. Applications must be submitted together with (where applicable) the relevant fee for such an application and the 'statement of actual turnover<sup>1</sup>', signed by an 'approved person<sup>2</sup>'.

Please note that it is not possible for the TGA to consider late applications. This is in accordance with Regulation 43AAC of the Regulations.

Applications must be made on the '[Application for an exemption from payment of annual charges due to low value turnover](#)' form available on the TGA website.

## **References**

1. The 'statement of actual turnover' form can be found on the TGA website under Fees/payments - forms.
2. An 'approved person' is defined in Therapeutic Goods Regulations 1990 - reg. 43AAB.

## **Queries**

Please direct all enquiries regarding arrangements for 2011-12 annual charges to the TGA Accounts Manager 02 6232 8264, or in writing by either email to [accountsrec@tga.gov.au](mailto:accountsrec@tga.gov.au) or by letter to TGA Accounts, TGA, PO Box 100, Woden ACT 2606.

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