

MASSARI, Brooke

From: Jocelyn McDonald <Jocelyn.McDonald@tga.gov.au> on behalf of ACE Scheme
Sent: Tuesday, 26 May 2015 10:54 AM
Subject: Upcoming sponsor communication on the proposed new annual charge exemption scheme (ACE) [SEC=UNCLASSIFIED]

Dear Mr Williams,

Upcoming sponsor communication on the proposed new annual charge exemption scheme (ACE)

Thank-you for your ongoing interest in the changes to the LVT scheme and new ACE scheme.

The new scheme is expected to be approved by the Federal Executive Council on Thursday 28 May 2015 and commence on 1 July 2015. Very soon we will send an email to all active sponsors who have a general sponsor email address or billing email address noted in TBS (TGA Business Services, or previously eBS). Please find attached, for your advance information, the draft email that I propose to send on **29 May 2015, subject to ExCo endorsement** of the changed regulations. Sponsors with no recorded general email address will be able to view the invitation to the ACE information sessions on the TGA website, though we will also be writing to all sponsors who have pre-qualified entries.

We have posted ACE information, including a [Q and A page](#) on the TGA website. You may like to bring this information to the attention of your members.

If you have any further questions please email ACE.scheme@tga.gov.au

Kind regards,

Jocelyn

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Good morning/afternoon

In April 2014 we released a consultation paper as part of a review of the low value turnover (LVT) annual charge exemption scheme. From the review findings, we developed a Regulation Impact Statement (RIS). This has been endorsed by the Assistant Minister for Health and is available on the TGA website. The RIS outlines a proposed new exemption scheme which, if implemented, will replace the LVT scheme.

Annual charge exemption (ACE) scheme

The proposed annual charge exemption (ACE) scheme will commence on 1 July 2015 if the Federal Executive Council approves the amendment of the regulations in one of its meetings before 1 July 2015. Information about the proposed ACE scheme is available on the TGA website.

Pre-qualified entries

Under the new scheme all new entries in the Australian Register of Therapeutic Goods (ARTG) on or after 1 July 2015 would automatically qualify for an ACE until the entry first generates turnover. Existing entries in the ARTG at 30 June 2015 would qualify for exemptions in 2015-16 if they had been granted LVT exemptions in 2013-14 and 2014-15 and had \$0 turnover in those years.

Based on the information submitted by you when seeking LVT exemptions in 2013-14 and/or 2014-15, we have identified those entries on the ARTG that would pre-qualify for an ACE in 2015-16, using the following criteria:

The product:

- was entered in the ARTG in 2013-14 or earlier, you applied for and were granted LVT exemptions for 2013-14 and 2014-15, and your product had \$0 turnover in 2013-14 which was certified by a third party accountant; or
- was entered in the ARTG between 1 July 2014 and 30 April 2015, you applied for and were granted an LVT exemption on the estimated turnover for 2014-15.

In addition, all entries first entered in the ARTG in May or June 2015 would prequalify without any action on your part.

If you have a pre-qualified ARTG entry, you will receive a letter in June 2015 from the TGA advising which of your ARTG entries pre-qualifies for an ACE exemption. If you believe you have entries that qualify for ACE and do not receive a letter by 12 June 2015, please notify us by email ace.scheme@tga.gov.au.

Information sessions

In June the TGA is conducting ACE information sessions for interested sponsors in Melbourne, Sydney and Brisbane. There will be two sessions (morning and afternoon) in Melbourne and Sydney and a morning session in Brisbane. Each session will be approximately 1.5 hours in length, depending on the time required for all Q&A's.

A representative from your company is invited to attend one of these sessions. To register, please email ace.scheme@tga.gov.au with the following information:

- Full name
- Position
- Company
- Phone number
- Preferred session time and location

Registrations close Thursday 11 June 2015. Spaces are limited. We cannot guarantee a place at your preferred session, so please register early.

| City | Date | Time* | Venue |
|-----------|----------------------|--------------------------------|--|
| Melbourne | Monday 15 June 2015 | 10 am – 12 noon 2 pm – 4 pm | Victoria University Convention Centre, City Flinders Campus, 12/300 Flinders street Melbourne |
| Sydney | Tuesday 16 June 2015 | 10 am – 12 noon 2 pm – 4 pm | Northside Conferences, Cnr of Oxley street and Pole Lane, Crows Nest |
| Brisbane | Friday 19 June 2015 | 10 am – 12 noon | Christie Conference Centre, 320 Adelaide Street Brisbane |

* Time is dependent on time required for Q&A's. Approx. 1.5 hours is estimated for each session.

More information

More information about these sessions and updates on the ACE scheme will be placed on the TGA website. Please keep an eye on the website for this information.

If you have a question that is not answered by the material on the website, the enquiry email address is ace.scheme@tga.gov.au.

Kind regards,

Nicole McLay
Assistant Secretary
Regulatory Business Services