



2021-22 TGA Financial and Important Dates

Important Information for Sponsors

Communications Update #3 of 2020-21

Dear Sir / Madam

Most goods that are registered, listed or included in the Australian Register of Therapeutic Goods (ARTG), *excluding export only goods*, are subject to Therapeutic Goods Administration (TGA) annual charges.

2021-22 TGA Annual Charges

The next financial year commences on Thursday, 1 July 2021, meaning that the next TGA annual charges will shortly be incurred for all:

- (i) Active registered, listed or included entries on the ARTG, unless the entries are exempt under the TGA's annual charge exemption ([ACE](#)) scheme; and
- (ii) Active manufacturing licences.

Annual product charges will be invoiced in the first week of August 2021 (after the ACE declaration period has closed on 22 July) and will be due and payable by **15 September 2021**.

Annual manufacturing licence charges will be invoiced in the first week of July 2021 and will be due and payable by **1 October 2021**.

Annual Charge Exemption (ACE) Scheme

A declaration of \$0 turnover for entries which meet legislated criteria for [exemption from annual charges](#) (2020-21) must be made [online](#) via the TBS Portal **between 1 July and 22 July 2021**.

Cancelling ARTG entries

If your product is no longer supplied, you can request to cancel the entry. If the reason for cancelling the entry is (only) to avoid incurring the next financial year annual charge, you **must** ensure your cancellation request is received by the TGA before or by **30 June 2021**.

- You can make your request by using either our online form (encouraged); or you can submit the request in a [paper-based form](#).

Full information and instructions about how to [Request to cancel an entry from the ARTG](#) is available on the TGA website.

Request to revoke a manufacturing licence

If a manufacturer no longer requires a manufacturing licence for the upcoming financial year 2021-22, please submit an application to revoke the GMP Licence via the [TGA Business Services \(TBS\) Portal](#) as soon as practical and before **15 June 2021** to ensure that an annual licence charge for financial year 2021-22 is not invoiced to your organisation.

Instructions for submitting a licence revocation application can be found on our [website](#).

If you require any further assistance or advice about how to request to revoke a manufacturing licence, please contact the TGA's Manufacturing Quality Branch (directly) by email to gmp@health.gov.au or telephone 1800 020 653.

Do you require access to the TGA Business Services (TBS) Portal?

The [TBS Portal](#) is the online system that TGA uses to engage with industry stakeholders and is the platform that regulated industries use to make submissions in relation to therapeutic goods, manufacturing, clinical trials and more, including ACE declarations.

- If you need to obtain your existing log in details for the TBS Portal, please contact the TBS Helpdesk by email to ebs@health.gov.au or telephone 1800 010 624.

Is your TBS Portal account password current?

If you currently have access to the TBS Portal, you should seek to login to the account to confirm the currency of your account password - it is prudent to check your password and access before 1 July as this will help to ensure you are able to (for example) lodge your declaration of \$0 turnover for any ARTG entries which were ACE in 2020-21 without delay or disruption when the declaration period opens on 1 July 2021.

Please ensure you log in **prior** to 1 July 2021 to ensure you are able to successfully gain access.

If you require assistance with resetting your password, please contact the TBS Helpdesk by email to ebs@health.gov.au or telephone 1800 010 624.

Note. You can only reset your password **once** every 24 hours. If you attempt more than once you will lock your account for 24 hours.

If you require a new user account to be created, please contact the administrator of your organisation. In circumstances where the administrator is required to be updated, please complete and return an [Updating organisation administrator](#) form. Log in details will then be provided to the new administrator.

Update your billing details

Correct billing details enables the TGA to send invoices, statements of account and other important billing and related information to you in a timely and easy manner.

Noting that the 2021-22 annual charge invoices will be issued in July for manufacturing licences and August for ARTG entries, we highly recommend that you take the opportunity to review and, if required, update your billing email and postal addresses.

***** Important *****

Please note that maintenance of billing and related contact information is the responsibility of each sponsor or manufacturer.

Your information can be reviewed and, if required, updated through the TBS Portal by the person who holds the administrator role for your account.

Payment of annual product charges is a **mandatory** condition to maintain an entry on the ARTG; likewise the payment of an annual licence charge in respect of a manufacturing licence.

The non-receipt of important notices (including annual charges invoices) due to, *for example*, out dated contact information recorded in our systems, is not accepted as a valid reason for a late payment, or (worse) non-payment of annual charges.

Furthermore, non-payment of said charges will result in the cancellation of your entries or manufacturing licence [non-payment of the annual product or licence charges is grounds for cancellation of an ARTG entry or revocation of a manufacturing licence].

Additional information and instructions about how to update your details is available on the TGA website. [Questions and answers for TBS administrators](#) refers.

Notification of a change in sponsorship

If your organisation is required to submit a notification of transfer of sponsorship and you wish the transfer to be processed and completed before the end of financial year 2020-21 (to avoid incurring financial year 2021-22 annual charges for the entry or entries), your completed [notification form](#) must be received before or by the TBS Helpdesk by **30 June 2021**.

All requests received after 30 June 2021 will not be processed until after the annual charges have been issued, and therefore the charges will be issued to the sponsor whom the products are recorded as at 1 July 2021.

Note. The TGA is not responsible for mediating between a relinquishing and accepting sponsor about who is liable for any charges owing in respect of an ARTG entry, this is (and always will be) a matter between the two third parties who are agreeing to exchange and transfer sponsorship of an entry or entries.

Deactivation of your organisations TGA Business Services account

As your organisation is currently active in our database, you will continue to receive further general financial correspondence from the Product Billing and Industry Assistance Section.

If your organisation is no longer required to be registered with the TGA and you wish to have your account deactivated, please send your deactivation request to the TBS Helpdesk at ebs@health.gov.au. An organisation will only be deactivated once the TBS Helpdesk are satisfied there are no ongoing or future liabilities (regulatory or financial) arising in respect of the organisation.

Further assistance or advice

Please contact us at your earliest opportunity if you have any questions in relation to the upcoming annual charges. We will promptly respond to any relevant TBS Portal or annual charge billing matters. Similarly, enquiries about the ACE scheme or Manufacturing licenses should be sent directly to the relevant teams for their attention.

Contact details for each are set out below.

TBS Portal Enquiries:	ebs@health.gov.au	1800 010 624
Financial / Billing Enquiries:	accountsrec@health.gov.au	1800 241 615
ACE Scheme Enquiries:	ace.scheme@health.gov.au	02 6289 4639
Manufacturing Quality Branch Enquiries:	gmp@health.gov.au	1800 020 653

Yours sincerely



Phillip Cooley
Director (A/g)
Product Billing and Industry Assistance Section
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