Australian Government
Department of Health
Therapeutic Goods Administration

AEMS guidance for sponsors

Adverse Event Management System

Version 1.1, December 2018

TGA Health Safety Regulation

Contents

Accounts

Setup

Sponsors can access the Adverse Event Management System (AEMS) by using their TGA Business Services (TBS) account.

The TBS account username will be in the following format: **'xxxxx_xxxxx' ('personal ID number'_'organisation ID number')**. The number of characters will vary depending on the organisation's client ID.

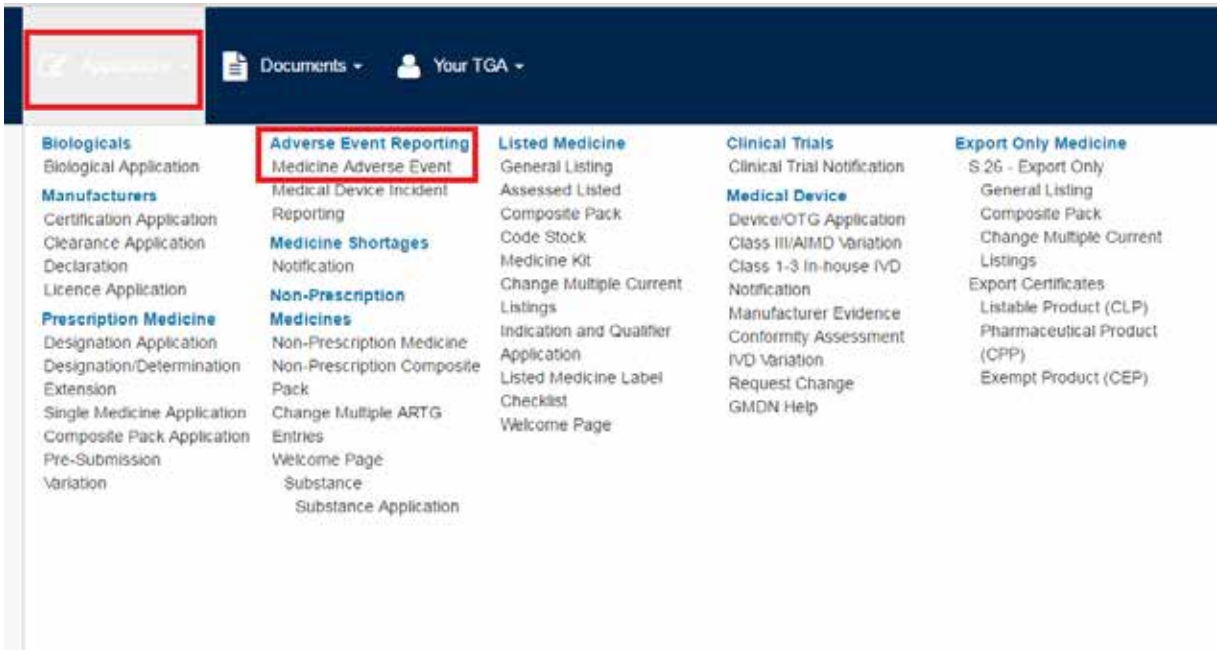
If an individual user does not have their own TBS credentials they will need to get in contact with their organisation's TBS administrator who can create a new user profile.

Access

Once a new user profile has been created it cannot be used to access AEMS until the next day.

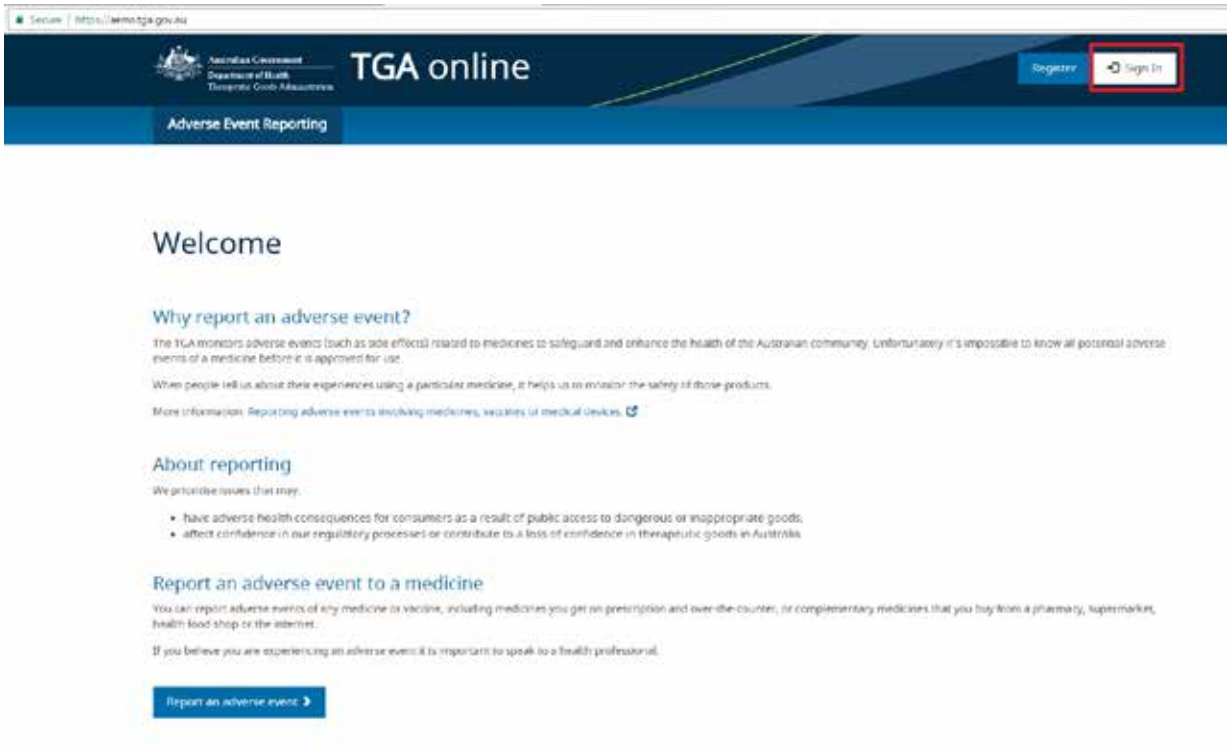
To access AEMS sponsors can login to the TBS portal and follow the links to the AEMS portal as demonstrated below:

From the top menu bar, select **Applications>Adverse Event Reporting>Medicine Adverse Event**.



From the left menu bar, select **Create Applications & Submissions>Adverse Event Reporting>Medicine Adverse Event**.

Sponsors can also access the AEMS portal by going directly to the AEMS site and selecting sign in.



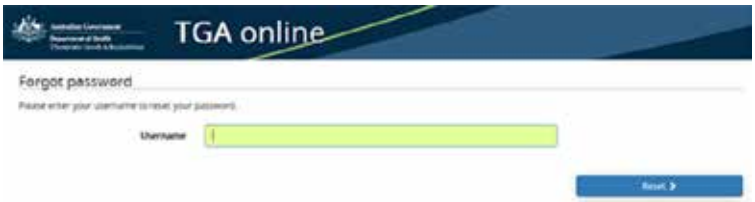
Password resets

AEMS passwords will expire every 90 days. After expiry system users will need to reset their password.

If system users need to reset an expired password or they have forgotten their password and cannot sign in they reset it as follows:

1. From the TBS portal login screen select the 'Forgotten your password?' link:

2. Enter their username and select 'Reset':



3. A password reset email will be sent to the email address associated with the account:

4. Once the password reset email has been received click the provided link. The user will be required to enter a new password:

Technical difficulties

In the event that the AEMS portal is unavailable for a period that affects the sender's ability to meet regulatory reporting timeframes, the sender must contact the TGA for advice on how to submit their report (ADR.reports@health.gov.au). In reviewing regulatory reporting timeframe compliance the TGA will consider relevant periods of unavailability of the service and the advice given by the TGA to the sender.

The TGA will email registered users to notify them that the AEMS Portal is not available, and again once it becomes available. The TGA will also advise users in advance if the AEMS portal will be unavailable for scheduled maintenance.

AEMS Reporting Dashboard

All users will have a Reporting Dashboard in AEMS that displays information specific to adverse event reports that they, or other colleagues within their organisation, have drafted or submitted via the system. There are two tabs which will display draft reports and submitted reports.

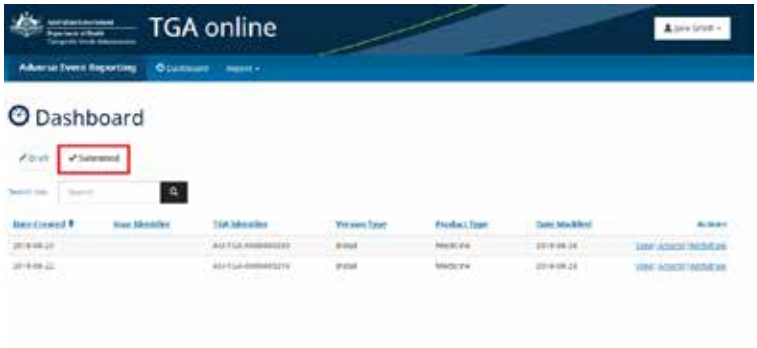
Draft reports

Draft reports are saved when a user has entered information as part of a new adverse event report but has not yet submitted this to the TGA. A draft report can be accessed from the Reporting Dashboard's 'Draft' tab at any point prior to submission.

Submitted reports

All adverse event reports that have been submitted via the AEMS portal will appear under the 'Submitted' tab. From the 'Submitted' tab, users can:

- generate a PDF summary of an adverse event report
- provide follow-up information (by selecting 'Amend')
- withdraw a report
- see reports submitted by other colleagues in their organisation.



Adverse event reporting form

To report an adverse event from the AEMS portal, the user must select '**Report > An adverse event of a medicine or vaccine**' from the menu bar.

The reporting form consists of a series of seven steps. All mandatory fields are marked with a red asterisk.

Step 1 – Sender details

This step will display the reporter and their organisation's name and contact details. This is prepopulated from the information stored in their TBS profile.

This prepopulated information cannot be changed in the reporting form. To change these details the organisation's administrator will need to make updates through the TBS portal.

The TGA identifier for the report will be displayed in the top right-hand corner and will be displayed on each step of the form. This identifier should be used in any correspondence with the TGA.

Step 2 – Case administration details

On Step 2, the sponsor is required to provide some preliminary information about the report including:

- whether it was a spontaneous report, a report from a study or another type of report
- when the report was first received from the source
- who was the source of the report, for example:
  - physician
  - pharmacist
  - other health professional
  - lawyer
  - consumer or other non-health professional.

The 'Your case identifier' field should be populated with the internal case identifier used by your organisation.

Step 3 – Patient details

On Step 3, the reporter should record all relevant details they have relating to the patient.

Please note, the 'ethnicity' dropdown has been populated from the Australian Bureau of Statistics' Australian Standard Classification of Cultural and Ethnic Groups.

Step 4 – Product details

On Step 4, the reporter should add all products that have been administered to the patient leading up to the adverse event. At least one product must be added and suspected.

Once a product has been added, further information such as dosage and indication details can be entered by selecting the 'View, add and edit items' link under the 'Dosage and reason for use' column.

Step 5 – Reaction details

On Step 5, the reporter should add all reactions experienced by the patient. A 'MedDRA LLT' value and an 'outcome' must be provided for each reaction.

Step 6 – Further information

On Step 6, the full case narrative must be included. A reference to an attachment, e.g. 'see CIOMS' is not sufficient. Other relevant information and supporting documents (e.g. X-rays, medical reports, test reports, photographs and literature citations) should also be added.

Step 7 – Summary report

On Step 7, the reporter can generate a summary of the adverse event report. A PDF document will be created that displays all recorded information. This document can be saved or printed by the reporter.

This is the final step and, once completed, the reporter can select 'Submit report'. The reporter will then be taken to a confirmation page where they can then navigate back to their Reporting Dashboard.

Submitting follow-up information

If the initial report was submitted using the AEMS online reporting form, follow-up information can be added via the online portal. From the 'Submitted' view on your Reporting Dashboard locate the relevant report and select 'Amend'. You will then be able to add any follow-up information and submit it to the TGA.

If the initial report was submitted via any other method such as by email or the decommissioned ADRS service then follow-up reports cannot be submitted using the AEMS online reporting form. These follow-up reports will need to be submitted via email to adr.reports@health.gov.au.

Accessing the decommissioned Adverse Drug Reaction System (ADRS)

The ADRS is still accessible in a read-only format. Users can view their historical reports but will not be able to submit any new reports using this system. Users can login to the system by entering their ADRS credentials on the TGA Business Services login page.

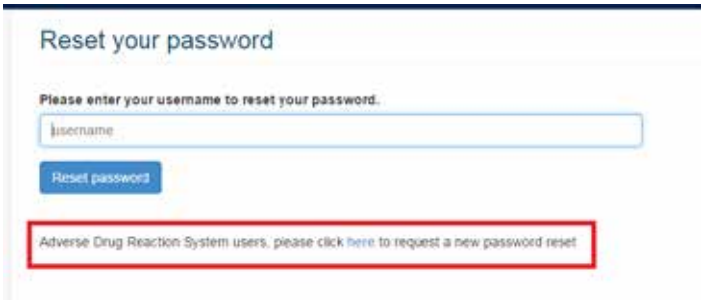
These accounts cannot be used to login to the AEMS Portal. To continue reporting adverse events to the TGA you will need to access the AEMS Portal.

ADRS password resets

If you have forgotten your ADRS password or it has expired then you can reset your password by using the following steps:

1. From the login page selecting 'Forgotten your password?':

2. Then selecting the link to the ADRS password reset:



3. The user can then enter their User ID and a password reset email will be sent to the email address associated with that account.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Pharmacovigilance and Special Access Branch	07/11/2018
V1.1	Minor update to correct errors	Pharmacovigilance and Special Access Branch	17/12/2018

Therapeutic Goods Administration

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Reference/Publication #