Medical Device Incident Reporting (MDIR) System

User Guide 2013

Version 1.0, July 2013
About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.

- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.

- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.

- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.

- To report a problem with a medicine or medical device, please see the information on the TGA website <http://www.tga.gov.au>.
## Version history

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<tr>
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Introduction

Welcome to the Medical Device Incident Reporting (MDIR) system. This is just one of a number of systems accessible from the TGA eBusiness Services (eBS) website.

This document is a user guide for the MDIR system. It outlines the initial steps to access the MDIR and then describes how to use the system, with step by step instructions and examples as required.

It is assumed that Users have a valid eBS username and password.

Medical Device Incident Reporting (MDIR) System

Overview

The Medical Device Incident Reporting (MDIR) system has been enhanced to enable Sponsors and Manufacturers to monitor and track device incident reports. Users are able to lodge reports as usual, but can now update previously reported incidents with additional information and view past reports.

Information is secure with users accessing the MDIR system using their eBS username and password.

Benefits

The system update enables sponsors to review the status of their reports and update initial and follow-up reports. All report updates are received immediately by the TGA and can be validated by users on demand.

Getting started

Navigating to the MDIR login screen

Use a web browser to navigate to the TGA reporting problems webpage (http://www.tga.gov.au/safety/problem.htm) and click on the ‘Sponsors/Manufacturers Medical Device Incident Report’ link. This link will navigate you directly to the Medical Device Incident Reporting (MDIR) login screen.
Alternatively, you can also access the Medical Device Incident Reporting (MDIR) login screen via the TGA eBusiness Services web page (https://www.ebs.tga.gov.au/).

If you have any issues accessing the TGA eBusiness Services system (including the creation of a new account) please contact the TGA eBS helpdesk on 1800 010 624.

Accessing the MDIR system via eBS

In eBS, access to the Medical Device Incident Reporting (MDIR) login screen is from a link within your eBS Portal. To access your eBS Portal click on the “Secure Login” link.
Enter your eBS user name and password and click on the ‘Login’ button.

Image 3 - TGA eBS login screen

Then click on the highlighted link to navigate to the MDIR system login screen from within your eBS Portal.

Image 4 - Medical Device Incident Reporting link within eBS Portal

Logging into the MDIR system

Enter your eBS username and password then click the ‘Login’ button to access the MDIR system.
New incident reports

Creating a new incident report

After logging in, you will see a summary of all Open incidents. Click the ‘New Report’ button located towards the top right of the screen to begin lodging a new incident report.

Entering incident details

You will be taken to the Medical Device Incident Report form for Sponsors/Manufacturers. Enter the report details as required.

All fields that are marked with a red asterisk * are mandatory – you will not be able to submit the report without filling them in.
Form tooltips

Some fields provide assistance to clarify what information is required. To view the help, hover your mouse pointer over the question mark symbol and further information is displayed underneath.

Attaching supporting information

You are also able to attach supporting documents, images, or other electronic files to the incident report using the 'Report Attachments' section located towards the end of the report. To add an attachment, click the 'Browse' button and select a file from your computer. Once you have selected a file, its name will be displayed on the form. Click the 'Add' button to add it to the report. Once a file has been added, you can continue to add more files to the report. To remove an attachment click on the paper clip symbol next to the title of the attachment you wish to remove.

There is a limit to the size of each attachment of 3MB and a limit to the total size of all attachments of 16MB. Attachments that are outside of the above limits should be sent to the TGA via email, to iris@tga.gov.au, citing the DIR number as a reference to the report.
Submitting the report

Once all the mandatory information has been entered, the report can be submitted to the TGA by clicking the ‘Submit to TGA’ button located at the bottom of the report.

You will receive a confirmation screen with the new report number for your reference. You can then return to the list of ‘Open’ reports by clicking the ‘Back to Summary’ button, start a new incident report by clicking the ‘New Report’ button or print the submitted report by clicking the ‘Print Report’ button.

You can also update the details in the initial report form you just submitted and submit it to the TGA as a follow-up or final report by clicking on the ‘Submit to TGA’.

To save a copy of the submitted report form you will need to:

- ensure that you have PDF creator on your computer, then
- click on the ‘Print Report’ button
- select PDF creator from the list in Select Printer
- click on the ‘Print’ button
- click on the ‘Save’ button in the PDF Creator pop up box
- select the location on your system where you want to save the document in the Save as pop up box
- then click on the ‘Save’ button.
Viewing/editing existing reports

Viewing a list of Open reports

Once you have logged into the MDIR system you will see a list of all your existing ‘Open’ reports that have been reported to the TGA.

![Image 11 - Location of the List Report Currently button](image)

The list of ‘Open’ reports can be ordered by any of the column headings, simply click on the column heading you wish to sort by. The default order is by date of adverse event (most recent first).

If you have many open reports, you can use the navigation bar located at the bottom of the page to view other pages/more reports.

![Image 12 - The Navigation bar within the MDIR system](image)

Viewing a list of Closed reports

You can change the table to display a list of all your ‘Closed’ reports using the ‘List Report Currently’ drop down which is located towards the top left of the page (Refer to Image 11). Click on the down arrow and select ‘Closed’, then wait for the page to reload to show a list of all relevant closed reports.

The list of ‘Closed’ reports can be ordered by any of the column headings, simply click on the column heading you wish to sort by. The default order is by date of adverse event (most recent first).
Searching for reports

You can also search using the ‘Search Results For’ box by entering part or all of the Report Number, Brand/Trade Name or Reporter’s Reference. Type the detail in the ‘Search Results For’ textbox located towards the top right of the page and press the Enter button on the keyboard to perform the search.

![Image 13 - Location of the Search Results For button](image)

Opening an existing report for editing

Reports in the ‘Open’ summary view with a type status of ‘Initial’ or ‘Follow-up’ can be opened for editing. Once you have located the report you would like to edit, hover the mouse over the report so it is highlighted and click once. The report will then open up for editing.

You are then able to update your information, including adding additional file attachments. Once you've updated your information, click the ‘Submit to TGA’ button towards the bottom of the page.

![Image 14 - The Submit Report to TGA section of a existing MDIR form](image)

You will then receive a confirmation message that the update has gone through, or a notification of the mandatory fields that you still need to update prior to a successful submission.
Logging out

It is important to log out of the system properly to ensure the security of your submitted information. Once your report has been submitted and you are finished reviewing your information, make sure to click the 'Log Out' button located towards the top right of the screen prior to closing your web browser.

Image 15 - Location of the Log Out button

Help

At present this user manual is available from the TGA website, eBS website and via email upon request.

If you are experiencing problems with the system, contact the Device Vigilance and Monitoring staff from the Office of Product review on:

- Email: iris@tga.gov.au
- Phone: 02 6232 8695
- Fax: 02 6203 1713