

TGA to get adverse medtech events report online

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Singapore: Sponsors and manufacturers of medical devices are now able to update adverse event reports that they have submitted to the Therapeutic Goods Administration (TGA) online.

Online reporting of medical device adverse events through the TGA's Incident Reporting and Investigation Scheme (IRIS) has been in place since November 2011. However, until now follow-up and final reports still had to be submitted by email, fax or mail.

Medical device sponsors and manufacturers can now update their reports by logging into the Medical Device Incident Reporting (MDIR) system using their eBS user name and password.

The MDIR system allows users to submit initial, follow-up and final reports and to review reports already submitted to the TGA.

The TGA expects that sponsors and manufacturers of medical devices will find the improved reporting system a valuable resource.