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TGA admits error in clinical trial tracking

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Singapore: Australia'sÃ?Â Therapeutic Goods Administration (TGA) has identified errors in its internal reports regarding the numbers of clinical trial conducted from July 1, 2009-to-December 31, 2012.

The error occurred when the TGA switched to a new database. A filter applied to automate reports discounted clinical trials notified to the TGA, if those clinical trials commenced outside the reporting period in which they were notified. For example, a trial notified in December, but commenced in January, was not counted.

These figures have not previously been made public on the TGA website, but they have been shared with key stakeholders, who may have used them for various purposes. The errors came to light when preparing to publish the data for the first time publicly. The filter has now been rectified and the data published from September this year will be correct, clarified TGA website.

TGA regulates clinical trials where unapproved therapeutic products are used, or approved therapeutic goods are used outside their marketing approval e.g. different indication.

Unapproved therapeutic goods for use in clinical trials conducted in Australia require either notification to the TGA under the Clinical Trials Notification (CTN) Scheme or approval from the TGA under the Clinical Trials Exemption (CTX) scheme. The TGA maintains a database of clinical trials conducted in Australia under the CTN and CTX schemes and provides data to the TGA Industry Consultative Committee (TICC) on the numbers of clinical trials via TGA half-yearly performance reports.

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