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Aus, NZ focus on quality use of medical devices

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Singapore: In an effort to help support the quality use of medical devices and therapeutic products, regulatory bodies from both Australia and New Zealand have launched certain initiatives.

The Australian Therapeutic Goods Administration (TGA) and the New Zealand Medicines and Medical Devices Safety Authority (Medsafe) have both implemented these initiatives. TGA initially launched the database of Adverse Event Notifications (DAEN) for medical devices, which incorporates data on adverse events reported to the TGA from a wide range of sources, including from members of the public, GPs, other health professionals and from the therapeutic goods industry.

The database is a step towards forming the regulatory body - Australia New Zealand Therapeutic Products Agency (ANZTPA), a regulatory body that would link the TGA with its New Zealand counterpart. The database that will be updated monthly includes reports dating back to January 1971. It is being made available to the members of the public as part of TGA's initiatives to be more transparent regarding its activities and to help stimulate the reporting of adverse events.

The second project of TGA and Medsafe is the development of an early warning system to communicate potential safety concerns with therapeutic products. Both regulatory authorities will apply the agreed upon procedures independently to communicate potential safety concerns identified with therapeutic products through their existing therapeutic product vigilance processes.