Senate Support For Medical Device Reforms Welcomed

A senate committee report recommending the passage of legislation that changes the way the Therapeutic Goods Administration (TGA) regulates medicines and medical devices has been welcomed by the Australian Dental Industry Association (ADIA), the peak business organisation representing dental product manufacturers and suppliers.

“This Bill contains important reforms that will cut the red tape associated with introducing into the Australian market new and innovative patient treatment and diagnostic options,” said Troy Williams, ADIA Chief Executive Officer.

The Senate Community Affairs Legislation Committee handed down its report (dated 2 February 2018) on the Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017 which provides the legislative amendments that will allow the TGA to utilise the work of comparable overseas regulators in the course of making assessments of dental products and other medical devices.

“ADIA has been a long-standing proponent for this reform that will shorten the timeframe associated with gaining domestic market approval from the TGA for not only dental products, but most types of medical devices. In a practical sense, this is what a cut to red-tape looks like,” Mr Williams said.

This Bill also makes changes that supports amendments to the Therapeutic Goods Act 1989 (Cth) made in 2017. These reforms allows the TGA to authorise Australian companies to undertake conformity assessments, a significant departure from past practice where only the TGA could do this.

“This legislation, combined with the legislative changes made last year that ADIA also secured, creates a far more efficient system for dental product manufacturers to introduce new product to the Australian market. Whereas previously the TGA was the sole source of authority, the increasing use of overseas regulators and third-party Australian conformity assessment bodies will provide alternatives without compromising patient safety,” Mr Williams said.

ADIA is confident that the legislation will pass the Senate soon and, having been passed by the House of Representatives in December 2017, will soon become law. It delivers a long-standing legislative reform priority that ADIA, over nearly a decade, has been lobbying politicians of all political persuasions to deliver.

“ADIA has been pushing for these changes as it creates a regulatory framework for dental products that is based on a risk management approach designed to ensure public health and safety, while at the same time freeing industry from any unnecessary regulatory burden,” Mr Williams concluded.

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