

Medical Device Regulation in Australia – 2021 and beyond

Medicines have been regulated in Australia since the first half of the twentieth century. The regulation of medical devices in Australia, however, only began in the mid 1980's using Customs regulations to control the importing of specific high risk devices.

In 1989 the Therapeutic Goods Act and subordinate regulations were introduced and the Therapeutic Goods Administration was created. However, the world of medical devices is constantly evolving and in 1994 discussions began with the regulated industry on the introduction of a new framework for the regulation of medical devices based on that being developed by the recently formed Global Harmonisation Task Force.

In late 2002, Australia introduced that new regulatory framework for medical devices and it was a full adoption of GHTF principles with the four pillars of essential principles of safety and performance, a risk based approach to regulation, quality management systems and postmarket monitoring.

Over the ensuing years, small changes were made to the regulations, but things never stand still, and in 2013 the Government announced a review of regulations which progressed through lengthy consultation and, coupled with rapid changes over the period and introduction of new diagnostic and treatment modalities culminated in significant changes introduced in 2019 with the *Therapeutic Goods Legislation Amendment (2019 measures) Regulations* incorporating elements of regulatory principles developed by the International Medical Device Regulatory Forum and alignment with the new EU Medical Device Regulations.

The amendments significantly impacted on up-classification of some devices, introduction of regulation of software as a medical device and new regulations for personalised medical devices.

This presentation will outline and discuss these changes, including the transition timelines for the changes, and outline some of the recently proposed changes announced and currently undergoing consultation with the industry.