MAY, 2020

MEDTECH IN AUSTRALIA LAW VS. SCIENCE?

INTRO >

MEDTECH ON EITHER SIDE OF THE PACIFIC

Controversial 2018 documentary *The Bleeding Edge* was **quickly denounced** by the Medical Technology Association of Australia, but there are some clear differences between the two Medtech industries on either side of the Pacific.

WHAT IS > MEDTECH?

What is MedTech? In Australia it's regulated under the Therapeutic Goods Act 1989 (Cth), and the Therapeutic Goods (Medical Devices) Regulations 2002. Under the former it can be broadly considered any device that addresses health issues that doesn't achieve its main purposes through biological means (eg: ingestion). The MedTech definition is a consistently evolving one. For example, **Corrs Chambers Westgarth** anticipated issues in late 2019 regarding the increasing regulatory definition gap for MedTech start-ups with software products - which was shortly followed by regulation of **Software as a Medical Device** (SaMD).

< AUSTRALIAN MEDTECH

MedTech consultancy Emergo **praised the Australian** domestic market for its "well-formed regulatory" system, and receptivity to new products (of which 80% are imported from overseas). However, Emergo doesn't see a high-likelihood of success for entrants into the market, due to low profit margins, and the market's drop in value in the mid-2010s. In comparison, **AusBiotech** sees a lot of potential for growth in exports – Australia's highly-skilled workforce is in a prime position to take advantage of the increasing affluence of South-East Asia.

But has this translated into success?

INDUSTRY > REGULATION

The **Australian Register of Therapeutic Goods** (ARTG) catalogues 90,000+ products that can be lawfully supplied in Australia. Certain exceptions are provided to some products that don't sit comfortably within that registry, sometimes on the grounds of special request, or clinical trial.

Exceptions on the grounds of clinical trials make a compelling financial argument – alone they're estimated to contribute $**1 billion to the Australian economy** annually.

A malleable regulatory framework was long fought for - in 2018, Professor Steve Webb, Deputy Chair of the Australian Clinical Trials Alliance (ACTA) **led a push for streamlining of clinical trial regulatory frameworks**. Webb noted that the regulatory framework was "frustrating enough, on occasion, to prevent getting (research) going in the first place", regaling industry anecdotes of:

> *"We will encourage the states and territories to adopt mandatory standards."*

While it might seem like it's a system that suffered under the auspices of a restrictive legal environment, this change was preceded by the Pinnacle LITE Pelvic Floor Kit scandal in August 2017. The urogynaecological surgical mesh implant was discontinued for use from the Australian market by the ARTG; after horrific stories surfaced of **patients' experiences** more than half a decade after their surgeries.

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In comparison, the American Food and Drug Administration (FDA) **ordered Boston Scientific** to stop selling and distributing their Pelvic Floor Repair Kit in May 2019. Two years after the ARTG's announcement.

Health Minister Greg Hunt issued a national apology for those affected, and after patient advocacy groups pushed for compulsory reporting of side-effects from any implantable device – **Minister Hunt agreed**, but said it was outside federal powers to do so:

> *We will encourage the states and territories to adopt mandatory standards.*

By the end of 2018, ACTA's lobbying efforts began to include rhetoric that "Australia's attractiveness as a preferred location for clinical trials" was diminishing due to the inefficiency of the regulatory framework. The **Clinical Trials Governance Framework** created a national standard with a parallel structure between states.

Fortunately, this was implemented in the months just before COVID-19. A more agile and aligned method of clinical trial research has brought a sensible balance, as seen in a **set of guidelines** released by the National Health and Medical Research Council (NHRMC):

> *Compliance with... regulations...policies and other standards remains necessary. However, interpretation of research responsibilities in the context of a crisis such as COVID-19 should be informed by* ***flexibility, consultation and good sense.***

But is it as simple as the archetypical Australian finger-pointing at the regulatory 'nanny state'?

A recent report by Deloitte found that 84% of MedTech companies believe that skills gaps have adversely impacted their business. The report advocated that addressing what many respondents believed to be an increasing trend in skills gaps could actually increase revenue in the industry by $1.5 billion in the next half-decade.

ASX commentator Stockhead **recently opined** that it's likely not the red tape of regulation that's letting down Australian biotech, but a lack of any product's suitability for the market. Listing a large number of recent failures, some were admittedly delayed entry to the market by ARTG, but: "they were never able to prove that it would save the ultimate users time, or save the people who would have to pay for it".

Although the ARTG's regulatory framework has been at times restrictive, we can see a useful case study with the FDA's **lack of checks and balances** for medical devices, and the effect that this can have on patients. Overall, it's clear that the opportunities for growth in the region are clear, but the source of the impediment isn't.