The effect of red tape on health services

MTAA Submission - January 2018

Medical Technology
ASSOCIATION OF AUSTRALIA

Level 12, 54 Miller St,
North Sydney
NSW 2060 Australia
P (+612) 9900 0600
F (+612) 9900 0655

E mtaa@mtaa.org.au

The Medical Technology Association of Australia (MTAA) is the national association for the medical technology industry. MTAA has been invited by the Senate Select Committee on Red Tape (the Committee) to provide comments to the inquiry into the effect of red tape on the economy and the community, in particular the effect of red tape on health services. We thank the Committee for the opportunity to share our views on this matter.

The Australian medical technology industry is highly innovative with significant investment in research, development and high-end manufacturing. Australia has many of the right attributes to grow a strong domestic industry - a significant health and research capability, quality health system, highly skilled manufacturing workforce, stable financial system and access to the growing middle-class markets of Asia.

The MedTech industry is also well placed to respond to the needs of an ageing population in a challenging fiscal environment, in particular, by developing remote monitoring technologies to keep elderly people in their homes longer and out of the hospital system reducing considerable strain on the health budget. In addition, we are also well placed to respond to increasing comorbidity health problems amongst younger demographics of the Australian population.

In 2016 the Australian Government released its response to the Review of Medicines and Medical Devices Regulation (the Review) and accepted most of its recommendations. The Review identified ways to improve access to therapeutic goods for consumers and remove unnecessary red-tape for industry whilst maintaining the safety of therapeutic goods in Australia.
MTAA acknowledges the Review including recent changes that encompass the introduction of SME Assist, implementation of notification scheme SAS Category C, reform of processes for minor or low-risk variations, new analytics capabilities for event report data and the reduction and streamlining of the number of advisory committees from eleven to seven.

MTAA has participated actively in the extensive TGA consultation process that resulted in a range of improvements in the regulatory space (see Table 1. A first tranche of changes has already been implemented in legislation by the *Therapeutic Goods Amendment (2016 Measures No. 1) Act 2017* (Cth). A second tranche of regulatory reforms is expected to be implemented when the *Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017* (Cth) and the *Therapeutic Goods (Charges) Amendment Bill 2017* (Cth) will be enacted in law.

Table 1: Regulatory reform consultations

Consultations on regulatory reform	Consultation closed
Designation of Australia conformity assessment bodies for medical devices	December 2016
Accelerated assessment of medical devices – priority review pathway	December 2016
The regulatory framework for advertising therapeutic goods	December 2016
Changes to accessing unapproved therapeutic goods through the Authorised Prescriber (AP) and Special Access Schemes (SAS)	May 2017
Options for the future regulation of 'low risk' products	May 2017
Enhancing sanctions and penalties in the Therapeutic Goods Act 1989	May 2017
Comparable overseas regulators for medical devices	June 2017
Alignment with European medical device regulatory framework; Up-classification of surgical mesh, Patient implant cards	August 2017
Therapeutic Goods Advertising Code	October 2017
Proposed regulatory changes related to personalised and 3D printed medical devices	October 2017
Therapeutic Goods Amendment (2016 Measures #1) Bill 2016	March 2017
Therapeutic Goods Amendment (2017 Measures #1) Bill 2017	January 2018

Of relevance too, is the cost of running clinical trials in Australia. MTAA encourages Government to support initiatives such as the R&D Tax Incentive, establishment of nationally-consistent processes and entities for clinical trials, and measures to increase patient participation in clinical trials. On this point, MTAA acknowledges (and supports) the recent efforts on the part of the NHMRC to streamline ethics approvals for clinical trials, and notes the advantages and value of conducting clinical trials in Australia, particularly the improvements in efficiency that increased patient recruitment would bring about.[1]

The MTAA reiterates our commitment to working strategically with Government agencies to create an efficient business environment for the medical technology industry, establishing innovative manufacturing as a thriving sector of the economy.

[1] L.E.K. Consulting and MTP Connect, 'Clinical Trials in Australia: The economic profile and economic advantage of the sector' (June, 2017).