HERBERT SMITH FREEHILLS

A ‘NEW NORMAL’ WHEN IT COMES TO THE TGA REGULATION OF MEDICAL DEVICES?

11 March 2021 | Australia
Legal Briefings – By **Emma Iles and Helen Cousins**

KEY POINTS:

- In Australia responding to the urgent need for Covid-related medical devices the TGA implemented a number of emergency measures to bring medical devices to market faster.
- The emergency regulatory measures have proven agile, flexible and successful with the potential risks to the public well managed.
- The regulatory measures have potential utility beyond the pandemic – and could be harnessed to get fast moving medical device technology to market more quickly.

INTRODUCTION

The Covid-19 public health emergency has mobilised the pharmaceutical and medical devices industries like never before. The TGA in particular has played a pivotal role in Australia’s response to the pandemic; including implementing a number of emergency measures to **accelerate the registration** of medical devices or **to exempt them from registration** in certain circumstances.

Almost a year on, some of the emergency regulatory measures are being rolled back. The TGA has identified that it will, as a priority, 'respond proactively to emerging public health issues'[1] and it is seemingly now well prepared for future public health emergencies. But do some of these emergency regulatory measures potentially have broader application beyond public health emergencies? Specifically, rather than rolling back all of these measures, could some remain and have broader applicability to address the rapid rate of innovation in technology to get fast moving medical device technology to market more quickly? Once the fires of Covid-19 are extinguished, and planned regulatory regime changes that were delayed because of the pandemic take effect, this would be worthy of consideration.

MEDICAL DEVICES AND THE TGA

Broadly, a 'medical device' is any product, equipment or software that has a physical or mechanical effect on the human body or is used to measure or monitor the human body and its functions.[2] Unless a valid exemption applies, medical devices must be included in the ARTG, the reference database of the TGA, in order to be imported, supplied in, or exported from Australia. Ventilators, IVDs used for Covid-19 diagnosis, thermometers and any PPE presented or claiming to be for therapeutic use, such as masks intended to reduce or prevent the transmission of disease, are considered 'medical devices'.

The TGA regulates all therapeutic goods that are supplied in Australia so as to ensure their safety, efficacy, quality and timely availability. It adopts a 'risk-based' approach to regulation whereby the level of regulation is intended to be commensurate with the risks posed by the therapeutic good.

THE 'RELAXING' OF REGULATION TO ADDRESS THE PANDEMIC

In responding to the urgent need for Covid-related medical devices the TGA implemented a number of emergency measures to bring medical devices to market faster. This included:

- An automatic **expedited assessment process** for *all* medical devices associated with the detection, prevention and treatment of Covid-19[3] (distinct from the existing Priority Review Pathway under which a TGA 'front of queue' priority applicant determination requires sponsors to submit an application and satisfy specific criteria).[4] Additionally, for Covid-19 IVDs, the expedited assessment process is based on the information and data available at the time of application for ARTG inclusion.[5]

- Additional **non-standard conditions** applied to Covid-19 IVDs on the ARTG via the expedited assessment pathway, including the provision of additional evidence to support the ongoing safety and performance of the device within 12 months of approval.

- Medical devices approved via the expedited pathway being subject to **robust post-**

market validations including:

    - post-market review of all Point of Care and Laboratory tests intended to detect Covid-19;[6]
    - an on-going review of the overall performance of serology-based Point of Care tests by the Peter Doherty Institute;[7] and
    - post-market review of all filtering face piece respirators and face masks.[8]

- Instituting **emergency exemptions** to facilitate the supply of certain medical devices, such as Australian-made ventilators, without prior-inclusion in the ARTG (i.e. without TGA review of their safety and performance) if the devices demonstrated compliance with minimum technical requirements and were supplied only to Australian hospitals.[9] Another exemption applied to PPE[10] and to Covid-19 diagnostic tests when supplied to accredited pathology laboratories.[11]

- The TGA has established an **expedited recall pathway** to ensure that products that are found not to meet the requirements of the exemptions, or are faulty, can be removed quickly from the market.[12]

HOW HAS THE ‘RELAXED’ REGULATION FAIRED?

The flexible offerings of the TGA were clearly attractive to industry and well utilised. Remarkably, 3,000 new medical devices were included in the ARTG in less than two months in 2020. In comparison, a total of 2651 medical device applications for inclusion on the ARTG were completed in the 6 months from July to December 2019.[13] And while just 22 assessments of Class 3 IVDs (the class in which most Covid-19 tests fall) were completed from July to December 2019, 123 COVID-19 tests have been approved for inclusion in the ARTG since the pandemic began.[14]

However, post-market review of Covid-19 serology tests has raised some discrepancies regarding the performance of these medical devices. Approximately 40 COVID-19 serology tests are currently undergoing post-market review.[15] The post-market validation performed by the Doherty Institute to date indicates that manufacturers have claimed a better sensitivity for detecting Covid-19 antibodies than that observed by the Institute, although the sensitivity of tests was found to improve with increasing duration between sample collection and symptom onset.[16] Consequently the TGA has adjusted requirements for manufacturers' clinical performance studies and the instructions for use provided with the devices. Notwithstanding the Institute's findings, potential risks associated with the performance of these Covid-19 serology tests is managed practically - they can only be supplied to medical practitioners, accredited pathology laboratories and the Department of Health who can be expected to correctly advise patients about testing limitations and interpretation of results. Suspension or cancellation from the ARTG is also an option for non-compliant or poor performing tests.

WHAT CHANGES MIGHT REMAIN POST-COVID-19?

The emergency regulatory measures introduced are Covid-19 specific and the roll-back has already commenced.

While the measures provide a good framework for future public health emergencies, they could have potential application more generally. The expedited assessment framework, that does not require the submission of a priority application and is based on information and data available at the time of application for inclusion in the ARTG could, for example, be harnessed for fast-moving technologies such as software (including software as a medical device itself and software-related medical devices[17]) to ensure the availability of contemporary, innovative medical devices in the Australian market. Any associated risks with such an expedited assessment framework could be ameliorated with the requirement of non-standard conditions and robust post-market validations of a kind adopted for Covid-19 related medical devices.

The application of such an expedited assessment process for fast-moving technologies, is worthy of consideration, particularly given a focus of the TGA for 2021 is on supporting emerging medical technologies. The Covid-19 regulatory measures implemented by the TGA have proven agile, flexible and successful with the potential risks to the public well managed. Whether this success inspires further regulatory reforms to support emerging medical technologies will no doubt be of keen interest to industry.

ENDNOTES

1. TGA Business Plan 2020-21, page 8 (https://www.tga.gov.au/sites/default/files/tga-business-plan-2020-21.pdf).

2. Section 41BD *Therapeutic Goods Act 1989* (Cth) defines medical device. IVDs are a

subset of medical devices. In general, IVDs are 'pathology tests (and related instrumentation) used to carry out testing on human samples, where the results are intended to assist in clinical diagnosis or in making decisions concerning clinical management.'

3. https://www.tga.gov.au/expedited-covid-19-medical-device-application-process, viewed 25 February 2021.

4. https://www.tga.gov.au/sites/default/files/priority-applicant-guidelines-medical-devices-including-ivds.pdf.

5. https://www.tga.gov.au/legal-supply-covid-19-test-kits.

6. https://www.tga.gov.au/ability-covid-19-tests-detect-emerging-genetic-variants-sars-cov-2.

7. https://www.tga.gov.au/post-market-review-covid-19-point-care-tests.

8. https://www.tga.gov.au/behind-news/regulation-personal-protective-equipment-and-covid-19

9. The *Therapeutic Goods (Medical Devices—Ventilators) (Covid-19 Emergency) Exemption 2020* commenced on 8 April 2020 and ceased on 31 January 2021. Hospitals can however continue to use ventilators acquired under the exemption.

10. *Therapeutic Goods (Medical Devices—Face Masks and Other Articles) (Covid-19 Emergency) Exemption 2020* commenced on 22 March 2020 and ceased on 31 January 2021.

11. *Therapeutic Goods (Medical Devices—Accredited Pathology Laboratories) (Covid-19 Emergency) Exemption.*

12. https://www.tga.gov.au/behind-news/expedited-recall-system-faulty-or-unauthorised-covid-19-devices.

13. TGA Half Yearly Performance Snapshot 1 July to 31 December 2019, Table 21, page 29.

14. https://www.tga.gov.au/covid-19-test-kits-included-artg-legal-supply-australia (current as at 19 February 2021).

15. https://www.tga.gov.au/post-market-review-covid-19-point-care-tests.

16. https://www.tga.gov.au/post-market-evaluation-serology-based-point-care-tests.

17. Reforms to the regulation of software as a medical device and software-based medical devices were implemented on 25 February 2021 and include new classification rules for such devices (excluding IVDs).

KEY CONTACTS

If you have any questions, or would like to know how this might affect your business, phone, or email these key contacts.

EMMA ILES
PARTNER, MELBOURNE
+61 3 9288 1625
emma.iles@hsf.com

REBEKAH GAY
PARTNER AND JOINT GLOBAL HEAD OF INTELLECTUAL PROPERTY, SYDNEY
+61 2 9225 5242
Rebekah.Gay@hsf.com

SHAUN MCVICAR
PARTNER, MELBOURNE
+61 3 9288 1587
Shaun.McVicar@hsf.com

LEGAL NOTICE