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REGULATORY REFORM FOR SOFTWARE-BASED CONSUMER HEALTH - CAN RULES KEEP UP WITH REALITY?

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Legal Briefings – By **Emma Iles and John Lao**

As Australia moves to liberalise oversight of mobile health apps, we ask if such reforms can keep up with changing technology

- Mobile health apps and devices ("mHealth") are a rapidly growing sector of consumer technology. These products are able to measure increasingly complex physiological functions.
- Recent regulatory reforms clarify that "consumer health products", including most mHealth products, are not medical devices and therefore not regulated by the TGA.
- The simplified regulatory landscape should allow Australian consumers faster access to the newest and most advanced mHealth technology.
- Continual review of the regulatory framework will help the regulations keep pace with technological advancements in mHealth to ensure that the classification of "consumer health products" remains fit for purpose.

THE MHEALTH LANDSCAPE

Consumer technology has seen an explosion in mobile health and fitness products. There were over 250,000 "mHealth" apps available for download in Australia in 2018,[1] with the current figure likely to be significantly higher. In 2021, Australians became the highest users of mHealth apps per capita globally.[2]

Manufacturers have also continued to advance the capabilities of mHealth devices – complex physiological functions such as heart rate, blood oxygen saturation levels and sleep patterns, can now be measured on many popular consumer devices such as smart phones and 'wearables' produced by the likes of Apple, Fitbit and Garmin. With these capabilities, mHealth technology has straddled a grey area between medical device and consumer product regulation. However, recent regulatory reforms for medical devices – explored below – have been aimed at providing some much needed clarity on where mHealth products fall within the regulatory landscape.

REGULATORY REFORM

A "medical device" is any product, including 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.[3] The TGA oversees the safety and efficacy of medical devices by requiring their registration on the ARTG.[4]

On 25 February 2021, the TGA released a suite of regulatory reforms for software-based medical devices. Chief amongst these was the exclusion of all "consumer health products" from medical device regulation.[5] The intention being to reduce or remove unnecessary regulatory burden by not regulating products where:

- there is no significant risk to safety; and
- suitable frameworks for product or system oversight are already in place.

Consumer health products, described as "prevention, management and follow up devices that do not provide specific treatment or treatment suggestions",[6] were considered sufficiently "low risk" as to fall within the exclusions. The existing consumer law regulatory framework and oversight provided by the ACCC were considered apt for regulating these products.

CLARITY FOR MHEALTH PRODUCTS: "INTENTION" IS KEY

Most mHealth products now fall squarely under the oversight of the ACCC and the consumer law framework.[7] The exclusion of consumer health products from medical device regulation provides suppliers, manufacturers and developers with clearer guidance on whether ARTG registration for their mHealth products is required by drawing a "bright line" between TGA-regulated medical devices and ACCC-regulated consumer health products.

Whether an mHealth product is a “consumer health product” is determined by the manufacturer’s intended uses for the product and whether this is for a medical purpose.[8] Using this “intention test” TGA regulation can be avoided if intended uses all fall within prescribed “consumer health product” functions. These functions include, for example, software intended to be used “for the self-management of an existing disease” or to “improve general health or wellness by coaching”.[9] In general terms, uses limited to monitoring and tracking of fitness or health are excluded from regulation, while uses relating to diagnosis or treatment of diseases are unlikely to be excluded.[10]

Overall, along with reducing the burden on the TGA, the changes should have the effect of avoiding unnecessary regulatory requirements for mHealth products that are clearly of low risk. This should allow consumers faster access to the latest and most advanced technologies.

TIPS FOR MHEALTH MANUFACTURERS AND DEVELOPERS

Manufacturers wishing to exclude their products from TGA regulation will need to make sure any representations they make about a product’s features do not stray outside the excluded “consumer health product” functions. Failing to do so could risk an action from the TGA for not registering the product on the ARTG. Representations that are limited to a product's monitoring or tracking capabilities are unlikely to attract the TGA’s attention, while claims about diagnostic capabilities or serious diseases will.

For example, an app promoted as being able to “measure a user’s blood-oxygen saturation” would likely be excluded from the TGA’s regulation. However, representations that the measured data may be used to monitor or diagnose respiratory disorders (such as asthma) could be considered a “medical use” and invite serious attention from the TGA if no ARTG registration for the functionality had been obtained.[11]

Regardless of whether the mHealth product is subject to TGA regulation or not, the product will inevitably be subject to ACCC oversight. Manufacturers therefore also need to ensure claims made about a product’s features are true and accurate. Using the above example, if the app is not able to provide accurate and consistent measurements so that it can actually be relied on to monitor or diagnose a user’s respiratory disease, this could lead to action by ACCC under the Australian Consumer Law.[12] So, while the TGA’s reforms aim to exclude consumer health products from its regulatory ambit, there remains the potential for parallel actions for the same or related conduct under medical device and consumer law regulatory regimes.

IS THE LEGISLATION FUTURE-PROOF?

While the current capabilities of consumer health products are considered to be of low enough risk not to require TGA regulation, this may not hold true as the functions mHealth products continue to advance. This could potentially lead to mismatches between:

the “low risk” uses a manufacturer *intends* for the product’s functions; and

the “higher risk” uses *enabled* by the products functions, which consumers may rely on – for example, a user might rely on the physiological functions measured by an app to decide when to take life-saving medication.

Where such mismatches occur, the current regulatory framework could prove less than satisfactory at mitigating risks to consumers. In particular, as consumer products, the onus will fall entirely on consumers to bring complaints about adverse events to the ACCC. This differs from the reporting requirements for TGA-approved medical devices, with sponsors of such products having obligations when an adverse event, such as serious injury to or death of a patient, comes to their attention.[13] These reporting obligations can apply regardless of whether the use of the medical device leading to the adverse event is contrary to the use intended by the sponsor.[14] Moreover, the TGA would undoubtedly be better placed to investigate efficacy of devices in medical treatments compared to the ACCC.

Ultimately, while one of the TGA’s reasons for excluding consumer health products was to “avoid regulating products where there is no significant risk to safety”,[15] that assumption will need to be revisited in the future as the technology it relates to develops.

ENDNOTES

https://www.abc.net.au/news/2018-05-17/mhealth-apps-wellness-and-fitness-apps-not-always-proven-to-work/9758720

‘Health App Index: Which countries track their health the most?’ https://www.uswitch.com/mobiles/health-app-index/

Section 41BD Therapeutic Goods Act 1989 (Cth) defines medical device. See also A 'new normal' when it comes to the TGA regulation of medical devices? for more discussion on medical devices regulation by the TGA.

Registration on the ARTG allows importation into, supply in and export from Australia. See *Therapeutic Goods (Medical Devices) Regulations 2002.*

Therapeutic Goods (Excluded Goods) Amendment (Software-based Products) Determination 2021, which was incorporated into the *Therapeutic Goods (Excluded Goods) Determination 2018* on 25 February 2021.

'Regulatory changes for software based medical devices' https://www.tga.gov.au/resource/regulatory-changes-software-based-medical-devices, p 5.

The Explanatory Statement to the *Therapeutic Goods (Excluded Goods) Amendment (Software-based Products) Determination 2021*, p 2.

Therapeutic Goods (Excluded Goods) Determination 2018, Schedule 1 14A – 14E.

Ibid, Schedule 1 14A and 14C.

To further assist manufacturers, the TGA has released various publications with examples of regulated and unregulated (excluded) software-based medical devices – see: https://www.tga.gov.au/resource/examples-regulated-and-unregulated-software-excluded-software-based-medical-devices; https://www.tga.gov.au/resource/my-software-regulated.

See: 'Examples of regulated and unregulated software (excluded) software based medical devices', p 13 https://www.tga.gov.au/resource/examples-regulated-and-unregulated-software-excluded-software-based-medical-devices.

For example, ss 18 (misleading or deceptive conduct), 29 (false or misleading representations) and 33 (misleading conduct as to nature of goods) *Australian Consumer Law.*

Failing to report an adverse event for a TGA-approved medical device may attract criminal and/or civil penalties – see *Therapeutic Goods Act 1989*, ss 41MP and 41MPA; See Therapeutic Goods (Medical Devices) Regulations 2002, r 5.7 for timeframes on adverse event reporting. See also 'Adverse event reporting' at https://www.tga.gov.au/adverse-event-reporting https://www.tga.gov.au/medical-devices-safety for further information on types of adverse events and the TGA's reporting regime.

Therapeutic Goods Act 1989, ss 41MP(2)(a)(iii) and 41MPA(2)(a)(iii).

'Regulatory changes for software-based medical devices', p 5
https://www.tga.gov.au/resource/regulatory-changes-software-based-medica...

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