March 16, 2019

TO THE TGA

DEPARTMENT OF HEALTH | AUSTRALIAN GOVERNMENT

This submission was written after attending the National mHealth Apps Collaborative Workshop in Brisbane February 13, as a representative of the Royal Australian and New Zealand College of Psychiatrists, in my capacity as Chair of the RANZCP's eLearning Advisory Group (eLAG). The eLAG advises the RANZCP on the development of online resources to maintain the clinical and professional standards of psychiatrists in Australia and New Zealand. This submission is informed by my involvement in that process, but it is a personal submission that has not been considered or sanctioned by the RANZCP.

I broadly support the proposals for reform of the "Therapeutic Goods (Medical Devices) Regulations 2002", as outlined in the "Consultation: Regulation of software, including Software as a Medical Device (SaMD)" document (here). I would like to make a specific recommendation that the reform revise the "Essential principles" to include the principle that SaMD apps provide a minimum set of information, in a predictably accessible location within the software, to allow medical professionals to quickly understand the nature and implications of the SaMD. The required information would be a subset of the information already required, but its inclusion in a standard format and in a standardised and accessible location within each app would allow doctors to quickly find and assess the relevant information and incorporate that knowledge in their care for and advice to their patients.

I would recommend that the standardised access to the information would be provided in all apps in a top-level menu item labelled "Information for doctors" or similar, in a location similar to menu items "About" and "Contact us". I would recommend that the standardised set of information include at a minimum:

- Intended population(s)

- Intended health/wellbeing outcomes
- Mechanisms of change (eg how the software achieves the outcomes listed)
- Log of changes to software affecting health mechanisms (eg similar to logs of software patches advising of bug fixes, but instead recording changes to how the app affects health behaviours, monitoring, or diagnosis/alerts)

Standardising access to this information would allow the relevant professional bodies responsible for the continuing professional development of medical professionals to educate their members about how to find, interpret, and communicate accurate information about mHealth apps to patients. Once standardised, it will also be possible to engage in continuous quality improvement to refine what information is provided.

As the impact of any changes to these regulations will be vitally affected by the understanding and awareness of medical professionals, I would also recommend that changes should incorporate an understanding of the structure and practice of continuing professional development by medical professionals by formal consultation with the medical colleges. The Royal Australian and New Zealand College of Psychiatrists, the Royal Australian College of General Practitioners, and the Royal Australasian College of Physicians were represented at the Brisbane workshop, and have collaborated on cross-discipline public health projects before, and would be a suitable advisory group for this current purpose.

SINCERELY,

DR ANDREW AMOS
FELLOW OF THE ROYAL AUSTRALIAN AND NEW ZEALAND COLLEGE OF PSYCHIATRISTS