

TGA submission regarding regulation of software including software as a medical device

1. The proposed changes relate to improving the technical/security aspects of software that may be used for a range of purposes including diagnosis, monitoring and treatment advice for an unspecified range of medical conditions. It is not clear exactly what the specifications are for each app or device being considered under these proposals. What is the overlap between an app that allows a patient to conduct their own depression and anxiety assessment (DASS) and a downloadable form with exactly the same data that is not contained in an app? I don't think this legislation is proposing to cover downloadable forms.

2. Nothing in these changes specifically addresses the content accuracy or the applicability of any specific app to an individual patient. I am not sure how any legislation could address this and since patients constantly diagnose themselves using Google etc I am not sure that it is reasonable to try but I think that this limitation should be acknowledged in any proposed changes.

3. It may be that the practitioners who either recommend apps or are asked to act on data handed to them by patients with apps on their devices, are the ones that need to be protected. Who is liable if a practitioner acts upon inaccurate data presented to them in an app? Will these changes ensure that there is a warning associated with any app covered by the TGA that this coverage relates only to the technical data security, stability etc of the app and not to the veracity of the data supplied by the app?

4. I cannot comment on cost implications etc etc