

Questions

- **What kinds of software-based products should be exempted from inclusion in the ARTG? What are they and why should they be exempted?**
 - Electronic patient/health records e.g. Cerner, Epiq may be excluded. This is not definitive if functions of Cerner/Epiq are utilised to determine deteriorating patient based on information collected from bedside devices. Can be used to provide information to the health professional and also screening/diagnosing/alerts.
 - Educational software, including medical device simulator. E.g. Apps designed to emulate devices for clinical staff training. Such applications/software/web pages do not provide treatment/intervention for a condition of a patient. They are only used for training where physical devices are not available.
 - Archetype editor. E.g. LabVIEW often used for research, design and device control by clinicians.
 - Consequence of loss of information or result of denial of service attack/ransom ware attached should be taken into account when attempting to classify software-based medical devices, for both inclusion and exclusion. Often software-based apps are used control of devices or for alarm review. E.g. insulin pump control or Philips CareEvent. Initial oversight or redundancy may exist, though over time healthcare professionals become more reliant on apps. Denial of service may lead to adverse events or outcomes.

- **What kinds of software-based products should be excluded from regulation by the TGA? What are they and why should they be excluded?**
 - Consumer applications used for control/monitor/data retrieval of personal fitness trackers. Information obtained from such apps and devices can be used for screening to determine if future treatment/intervention is required. Future treatment/intervention is then determined by dedicated medical devices. Such devices are often proposed to be used by health professions, though they should not be used as they do not have TGA registration and also provide numerous issues for use in healthcare environments e.g. proper cleaning between patients.
 - Software that encourages a healthy lifestyle, e.g. Stop, Breathe, Think, Mindfulness app or similar. Software that encourages healthy lifestyle can be excluded from the TGA registration. Though I would suggest consideration be given to software apps/web sites that are used a screening tool to recommend learning modules. Often disclaimers used by such software is consult with a medical professional before/during undertaking these modules.

- **Which approaches from international jurisdictions, if any, should be used to inform the Australian approach to this issue?**

Due to previous experience with cyber security in addition to many software based products produced in USA and Europe, I would be considering their approaches to manage software-based device. Though in the current age of application based small devices, e.g. Philips now have an ultrasound probe that can be used with a Smartphone. The landscape is constantly changing and software developers are more readily available than in the past.