RACGP

Royal Australian College *of* General Practitioners

Submission to the Therapeutic Goods Administration's Consultation: Regulation of software, including Software as a Medical Device

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Contents

1. Executive summary

The RACGP welcomes the opportunity to provide written comment to Therapeutic Goods Administration's Consultation (TGA): Regulation of software, including Software as a Medical Device.

The RACGP is Australia's largest medical organisation, representing more than 40,000 members who provide more than 154 million general practice services each year to more than 24 million Australians.

The RACGP's mission is to improve the health and wellbeing of all people in Australia by supporting general practitioners (GPs), general practice registrars and medical students and promotes the potential of technology to deliver greater quality and safety to support improved patient health outcomes.

2. Key recommendations

The Royal Australian College of General Practitioners (RACGP):

- supports the regulation of software used as medical devices
- does not support the regulation of general practice clinical information systems by the TGA
- is well placed to provide regulation for clinical information systems and other tools used in general practice and these systems should not be regulated by the TGA
- recommends the definition of what is considered software as a medical device is strengthened to remove ambiguity
- has identified a number of areas where the proposed changes to regulation may have unintended consequences
- recommends software developers be restricted from sharing sensitive health information

3. Consultation response

Question 1. Do you support the proposal to change the way medical device software are regulated? Why or why not? If you do not support the proposal, do you have any suggestions for an alternative that would be acceptable to you?

The RACGP supports some of the proposed changes to the way medical device software is regulated. The changes have the potential to increase safety for consumers who use software as a medical device.

However, the RACGP recommends the definition of what is considered software as a medical device is strengthened to remove ambiguity. The current definition is vague, which could lead to issues in defining products as a medical device and cause some products being unnecessarily

regulated, including general practice clinical information systems and other support tools used in general practice.

Question 2. What do you consider to be the benefits and disadvantages of the particular proposals for change?

Benefits of the proposal include:

- potential increased safety to new and existing devices
- increased general practitioner and consumer confidence in software as a medical device knowing that it is subject to a regulatory process.

Disadvantages of the proposal include:

- the regulations may be onerous and difficult to keep up with, which may force some suppliers to no longer make their product available on the Australian market
- new products may never enter the Australian market if the regulations appear too costly and burdensome for developers
- point of care tools that assist GP decision making may be slow to come onto the market as developers go through the regulatory process, and improvements to existing software may be delayed or not occur
- there will be no incentive to innovate, fix or improve current software if changes are bound by regulatory oversight
- compliance requirements may increase the cost of software for GPs and patients.
- regulation enforcement costs will have to be considered and will increase costs to the community.

Question 3. Do you believe there will be any unintended consequences arising from the proposed changes?

The RACGP has identified a number of areas where the proposed changes to regulation may have unintended consequences.

General practice clinical information systems (CIS) and the decision making and assessment tools that sit within these systems may be affected by the proposed regulation changes. The RACGP recognises there is a need for clinical software to be regulated via a set of minimum requirements or standards, however, an onerous and costly regulation process might impede the development of new and improved tools. Increased costs, caused by regulation, could be passed on to general practices.

The RACGP has a key role in progressing the clinical usability and safety agenda for general practice clinical information systems. Through the development of standards and guidelines, the RACGP ensures Australian general practice remains at the forefront of safe, high quality primary healthcare delivery. The RACGP recommends all decision making/assessment tools currently found in general practice clinical software be evidence based to create trust and credibility in the systems

The RACGP has a strong history of advising governments and other stakeholders on what is reasonable, workable and useful for general practice. This includes promoting the potential of technology to deliver substantially greater quality, safety and efficiency benefits. If appropriately supported, the RACGP can further build on the *Minimum requirements for general practice clinical information systems to improve usability* report to develop a minimum set of standards and a supporting framework to regulate the technology used by general practice. This work would be done in collaboration with software developers and other key stakeholders to ensure a patient focused approach to improve usability and health outcomes

The RACGP does not support the regulation of general practice clinical information systems by the TGA.

The RACGP has concerns that the cost and time involved in the regulation process may reduce the ability of not-for-profit organisations or academic groups to develop and evaluate apps for specific purposes, e.g. physical activity or nutrition apps for specific cultural or language groups. An exception to the regulatory process should be made for researchers to develop and evaluate apps before they are widely marketed.

Finally, the criteria for class 11b in particular could be interpreted to include any program which makes a recommendation, such as common physical activity or nutrition apps. Apps of this nature are not intended and designed for people with specific medical conditions and should be excluded from the regulatory process.

4. Additional RACGP feedback

Software as medical device, particularly apps used by consumers, may hold sensitive medical data on its users. A recent *British Medical Journal study* on data sharing practices of medicines related apps showed that 79% of apps in the study shared user data with third or fourth parties[1]. The study revealed that this practice is not transparent to users of the app and the data, in some instances, could potentially be re-identified. This is a cause for concern and must be addressed in the regulation of software as a medical device. The RACGP recommends software developers be restricted from sharing sensitive health information, especially identifiable information, to third and fourth parties.

5. Final comments

The RACGP is a key stakeholder on this issue as it relates to patient safety and software commonly used and recommended by general practitioners. The Therapeutic Goods Association is encouraged to work with the RACGP on the further development of these regulations.