RACGP
Royal Australian College of General Practitioners

Healthy Profession.
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15 May 2020

Medical Devices Reform Unit
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

To whom it may concern,

RE: Submission to the Therapeutic Goods Administration's Consultation: Scope of regulated software based products

The Royal Australian College of General Practitioners (RACGP) welcomes the opportunity to provide written comment to Therapeutic Goods Administration's (TGA) Consultation: Scope of regulated software based products. The RACGP has a keen interest in technology and its role in supporting the delivery of high quality and safe health care. Our submission addresses:

1. Exclusion of general practice clinical information systems from regulation by the TGA
2. Exclusion or exemption criteria for clinical decision support

1. Exclusion of general practice clinical information systems from regulation by the TGA

We feel satisfied the issues raised in our submission of April 2019 to the Regulation of software, including Software as a Medical Device consultation, have been addressed. The RACGP supports the TGA's position that general practice clinical information systems used for electronic patient records, management of prescription information, clinical workflow and administrative support for health care facilities are not considered medical devices and should, therefore, be excluded from regulatory oversight by the TGA.

As noted in our previous submission, whilst the RACGP believes this type of software should be excluded from regulation as a medical device by the TGA, we believe some oversight is warranted from a body such as the RACGP. There is a need for general practice clinical information systems software to be regulated via a set of minimum requirements or standards. The RACGP has already produced work in this space with the *Minimum requirements for general practice clinical information systems to improve usability* report, which could be developed further to include a minimum set of requirements and a supporting framework to regulate technology use by general practice.

2. Exclusion or exemption criteria for **clinical decision support**

General practice clinical information systems contain decision making and assessment tools that sit within these systems. As the name suggests, these tools are designed to support GPs to make clinical decisions. GPs must still apply their expertise and clinical judgement to make appropriate decisions relating to the care of their patients.

As such, we consider this type of software low risk to individuals or public health and agree with the TGA that it should be excluded or exempted from TGA regulation.

We believe this exclusion or exemption should extend to devices that input data into general practice clinical information software. For example, those devices that record blood pressure, heart rate, temperature, and oxygen saturation, as these types of software do not provide any interpretation of the data.