RANZCO The Royal Australian and New Zealand College of Ophthalmologists
THE LEADERS IN COLLABORATIVE EYE CARE

12 May 2020

Medical Devices Reform Unit
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
Via e-mail: devicereforms@health.gov.au

Dear Sir / Madam,

RE: Scope of Regulated Software-Based Products

The Royal Australian and New Zealand College of Ophthalmologists (RANZCO) welcomes the opportunity to comment on the Draft Poisons and Therapeutics Goods Amendment Regulation 2020.

RANZCO'S mission is to drive improvement in eye health care in Australia, New Zealand, and the Asia Pacific Region through continuing exceptional training, education, research, and advocacy. Underpinning all the College's work is a commitment to best patient outcomes, providing contemporary education, training, continuing professional development, evidence-based decision making, collaboration, and collegiality. RANZCO also seeks to educate the general public in all matters relating to vision, the health of the human eye and advocates for accessible cost-effective ophthalmology services for patients.

Please see below our response to some of the questions posed in the consultation document:

What kinds of software-based products should be excluded from regulation by the TGA? What are they and why should they be excluded?

RANZCO is in favour of excluding unique in vitro diagnostic (IVD) medical device-related software products from regulation by the TGA. While TGA involvement might be useful in collecting data on accuracy and software reliability, the final decision on the interpretation of results and/or reports is in the scope of practice of the treating doctor. Moreover, the current medical device labelling obligations are sufficient. In essence, if the software has a disclaimer in its diagnostic report saying that it is meant to be a guide for interpretation by a physician, there is no need for TGA involvement. Therefore, RANZCO does not believe an additional layer of regulation is required.

Describe what evidence or product characteristics could be used to determine that particular types of software pose no potential for significant harm to an individual.

RANZCO believes that patient outcome registries are a useful characteristic that can help guide the TGA in determining types of software that pose no potential for individual harm. This is because these patient outcome registries do not produce any associated adverse events. Rather they promote 'optimisation' of patient outcomes. For instance, The Save Sight Registries contain modules that track outcomes of treatment of wet macular degeneration, diabetic macular oedema, branch retinal vein occlusion, keratoconus, glaucoma, ocular melanoma and uveitis. These modules have data entered at every patient visit to an ophthalmologist. The graphical outputs can be used to monitor treatment outcomes. Other Australian outcome registries include the Australian Corneal Graft Registry and PROGRESSA.

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In addition to the above responses, we have further questions that we recommend should be considered when amendments to the Scope of Regulated Software-Based Products are proposed. These are:

1. Does the IVD software include intra-ocular lens (IOL) power calculation formulae or a toric calculator?
2. Is the TGA involved with regulating IOL power calculation formulae presently?
3. Glaucoma progression analysis in the Humphrey Visual Field Analyser and OCT may also be classified as an IVD software. Should the machine analysis be reserved for interpretation by a physician, and not be regarded as a total diagnostic report?

[redacted]

Yours sincerely,

[redacted]

David Andrews

RANZCO CEO