The Royal College of Pathologists of Australasia
ABN 52 000 173 231

Durham Hall 207 Albion Street Surry Hills NSW 2010 Australia
Telephone 61 2 8356 5858 Facsimile 61 2 8356 5828

RCPA
The Royal College of Pathologists of Australasia

28 March 2019

Therapeutic Goods Administration
Department of Health
Australian Government

devicereforms@tga.gov.au

Dear Sirs,

Re: Consultation: Regulation of Software, including Software as a Medical Device

Thank you for inviting the College to comment on the above consultation document.

The RCPA has written to the TGA on two previous occasions and also provided a letter (attached) from the International Liaison of Pathology Presidents (representing Pathology Colleges and Association from English speaking countries around the world) expressing serious concerns on the issue of regulating software as a medical device for pathology.

The College is strongly of the view that pathology software should be regulated via existing accreditation systems (ie ISO standards) and not have another level of regulation imposed.

The College considers that as this is an international issue the views of the other pathology Colleges and Societies in USA, Canada, UK, Ireland, Hong Kong, Malaysia, South Africa and Australia should be taken seriously.

The College has reviewed the Consultation draft and notes the following:

The current draft does not address the issues previously raised by the ILPP in the previously provided letter, in particular ILPP's comment that "a better approach may be to use one analogous to that used in some countries for assessment of In-House testing by using a quality systems approach monitored through a laboratory accreditation framework."

It would be particularly concerning If internal systems that aided a pathologist in reaching a diagnosis, say image analysis obtained separately from digital pathology hardware or spreadsheets used to suggest chemistry comments to add, could not be covered under the now accepted NATA IVD approach but needed a separate path of sponsorship and accreditation.

It is worth noting using digital pathology as an example, drafting and/or implementation of regulatory/validation/accreditation guidelines for laboratories are already underway in many parts of the world including Australia. Development of separate regulatory guidelines specifically for software associated with pathology diagnosis would seem counter-productive, detracting from the existing resources that are already devoted to such quality and validation efforts.

Effect of Disclaimers

Also some systems have gone down the in-house IVD route when their importation is for "Research Purposes Only". This disclaimer may appear on what would otherwise be SaMD items. A Canadian expert committee notes "The same product may be considered a device if

the labelling claims are falling under the definition and not be considered a device if labelling does not indicate any of the claims covered by the definition. There is a lot of room for interpretation." https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/activities/scientific-expert-advisory-panels/software-medical-device/record-proceedings-2018-01-26.html

Overly simplified wording
The consultation seems to be trying to simplify the language used in the IMDRF referenced documents but ends up missing some of the finer points of the documents.

In Section 5 of the IMDRF Technical Document "5.0 Factors Important for SaMD Characterization" the document draws out differences between "Treating and Diagnosing" and "Informing Clinical Management" but this differentiation seems missing in the TGA consultation document. This is an important distinction as 'diagnosis and treatment' implies "the SaMD will be used to take an immediate or near-term action" while "Informing Clinical Management" implies "information provided by the SaMD will not trigger an immediate or near term action." This would have been an important distinction to make explicit in the TGA document.

Also, the consultation refers to the IMDRF Technical Document which talks about software 'used for the specific medical purpose of diagnosis' but TGA then talks about softwares that "make a diagnosis" as if a medical professional is not there to coordinate software advice with clinical circumstances.

LIS and EMR add-ons
In the past, a subsystem within a LIS that automatically adds comments has been exempt from being considered a SaMD and although the College expects this will continue this is not explicitly addressed by the TGA document. Also, more third-party LIS middlewares and add-ons are becoming available and their use may fall into a grey zone by the current consultation wording. Some jurisdictions, such as Canada have discussed this (see above link).

Translations available
In Europe, supplying coverage of multiple languages can be required of patient focused apps but the applicability of this approach to Australia is not addressed in this document.

The College would appreciate an opportunity to meet with the TGA to discuss this very important issue. Please contact me on [redacted].

Yours sincerely

[redacted]