TGA Consultation – Regulation of software including Software as a Medical Device

The Discipline of Clinical Ophthalmology at the University of Sydney has developed two medical apps (SaMDs) and has two more in development. We appreciate the opportunity by the TGA to provide feedback on the document: *Consultation: Regulation of software, including Software as a Medical Device (SaMD) Feb 2019.* As background to our feedback, the two currently available apps our department has developed are:

1. The Ophthalmic Pharmacopoeia Sydney Eye Hospital. Free App downloaded >1000 times
2. The Eye Manual lead by ACI NSW. Free app downloaded >1000 times

In development:

1. The University of Sydney Eye Examination (uSEE) app to assist clinicians in performing a range of eye tests.
2. The Eye Donor Oz app which aims to educate patients about corneal transplants and organ and tissue donation.

Overall, this is a very well-written framework to advance standards within the SaMD sphere. The principles espoused are important and patient safety with the SaMD apps is critical. However, the adoption of this regulation will have an impact on the SaMD projects we have undertaken in our department.

1. Do you support the proposal to change the way medical device software is 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?

We do not support the proposed changes as, under the new proposal, our apps would be classified as Class IIa devices which would incur significant costs. The costs of registering our apps as Class IIa devices would be prohibitive and we would no longer be able to innovate in this area. As the aim of the apps we develop is to benefit patients and clinicians, the result of our withdrawal from this area due to cost would have a negative impact on patients and their doctors.

Instead, we suggest that SaMDs remain a Class I device. Developers should be required to self-report online to provide details relating to any adverse events. Developers should also be required to provide details on software updates, number of downloads, user feedback, who is responsible for reviewing updated versions and whether an app has been discontinued.

The proposed new regulations are correctly concerned with the potential for patient harm that may be caused by SaMDs as there is a risk of miscalculation or causing errors in patient care. The risks posed must be balanced by the potential benefit an SaMD may have in preventing harm to patients. For example, our Eye Emergency app assists doctors in making the correct diagnosis through well-known diagnostic trees and images. Pages 8 to 19 of this app would be classified as Class IIa as it aids clinicians in making a diagnosis. The cost of premarket product assessment, manufacturer assessment and certification would be prohibitive and would result in the department having to withdraw this tool from clinicians. As a way of mitigating the risk, we propose that developers of SaMDs be required

to submit documentation showing how the SaMD benefits patients. For example, developers could conduct a small controlled study to test if using the app improves rates of correct diagnoses and thus reduces risk and harm to patients. If this is clearly demonstrated to the TGA, then they can conclude that the SaMD provides a relative reduction in risk to the patient rather than any absolute risk. We propose that if this is clearly demonstrated by the developer, their SaMD will qualify as a Class I device. As a result, developers of SaMDs would ensure that their products meet the expected standards for evidence-based medicine and will provide the preassessment evaluation relevant for the uptake of an SaMD. If developers are unable to demonstrate that their SaMD reduces harm, then they will be forced into alternative categories. Adopting this approach would enhance the quality of apps available to medical professionals and patients.

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

The four benefits outlined on page 11 of 19 are to be lauded and maintained. However, we again submit that for many SaMDs that assist in patient care, the high cost of administration and compliance for Class II or above would be prohibitive and would result in potentially valuable products being removed from the market. Forcing smaller developers and those with less access to funding for this type of project such as University departments, will potentially reduce expertise and innovation in this area. Development of SaMDs would become the territory of big pharma companies with the budgets to support software development. This will also drive up end-user costs as the motivation for SaMDs development will be based on profit margins rather than innovation and patient care.

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

The administrative and compliance cost of developing SaMDs to assist clinicians will result in little or no local SaMD development. As a result, in the tech-savvy world we live in, medical professionals will be downloading and using unregulated and untested SaMDs developed elsewhere. In effect, the proposed framework will increase the use of unregulated SaMDs and result in an increased risk to patients. The TGA correctly identified this issue in the background and problem sections of the document. The regulations need to take this unintended consequence more seriously as, if the new proposals are implemented, this risk will result. It is in the interests of patients that the TGA supports and encourages local developers and innovators to create SaMDs that can be properly regulated, classified and safely recommended to clinicians and patients.

4. What changes would you need to make (if any) to meet the new arrangements? If not, what are the impediments?

With the proposal as it stands, we would need to apply for Class IIa listing for all our apps. Realistically, the cost of this would be prohibitive and we would need to source funding to cover these costs. The Eye Manual app had NSW health support so would likely continue. The Pharmacopoeia app and uSEE app have no funding beyond development and would need grants to support TGA approval and product launch. If grants are not forthcoming, neither of these apps would be made available for download. This would be a disappointing outcome for medical professionals as our evidence shows that both these apps will provide significant benefits for patient care and risk reduction. Many years of development and approximately $20,000 development costs would be lost. Further, the expertise within the department for specific and unique SaMD development will also be lost.

5. What financial impact (both costs and savings) would implementing the proposed amendments have for you? If possible, please provide a breakdown of the impacts. This information will be used to quantify the financial impact to all affected stakeholders.

The financial impact of classifying our apps at class II or above would most likely result in the withdrawal of our products from development and the market. Currently, the cost for developing an app is approximately $10,000. We have received grants and support from the University of Sydney and NSW Health to support these projects.

If we are required to pay conformity assessment fees as well as application and annual fees, it would make it impossible for us to continue to provide and develop these apps which are offered free of charge. We wish to continue to be able to provide these apps at free or very low cost to reach the largest audience possible and increase the benefits to patients.

6. What period would be needed for your organisation to implement the proposed changes?

At least 12 months to comply if funding is found. An option to remain at class I for those that meet set criteria such as evidence-based research that demonstrates a reduced risk of harm to patients. This would have the added benefit of encouraging high-quality development of innovative software to support medical professionals in Australia in delivering exceptional care to patients.