Australian Traditional-Medicine Society Ltd
PO Box 1027 Meadowbank NSW 2114
Freecall 1800 456 855 Tel +61 2 9809 6800
Fax +61 2 9809 7570 info@atms.com.au
www.atms.com.au ABN 46 002 844 233

March 2019

The Australian Government
Department of Health
Therapeutic Goods Administration

Submission to the TGA from the Australian Traditional-Medicine Society (ATMS) on the consultation document, Regulation of Software, including Software as a Medical Device (SaMD)

ATMS is the peak professional membership body for practitioners of natural medicine in Australia. A significant number of members of ATMS use proprietary software to assist in clinical decision-making processes related to diagnosis and prescribing, in the treatment of their clients. For these reasons, ATMS and its members have a vested interest in ensuring that such software is properly constructed and fit for purpose, and the most effective means of ensuring that these goals are met is through appropriately designed regulation and appropriate third party oversight. ATMS believe that the TGA is the organisation best placed to design and administer such regulations and welcomes the opportunity to contribute to this consultation process.

ATMS Responses to the Consultation Document

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?

ATMS agrees that the classification of software under the current framework is often not in accordance with the level of risk it poses, although that risk is indirect, given that the information provided by the software generally used by ATMS members merely informs decision-making processes. However, because healthcare practitioners invest in this software on the basis that the guidance that it provides is complete and accurate, that guidance must be able to be relied upon. A failure of the software in these and other areas renders such software at best, unfit for purpose, and at worst, a significant risk to the

community. ATMS is of the view that appropriate regulation is required to ensure that such software can be relied upon to be fit for the purposes for which it is marketed, and that the risk categorisation system as proposed by the IMDRF, referred to in the consultation document, appears to be a suitable starting point for this process, though more detail will be required for a fully functional system that will meet the requirements of all stakeholders.

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

The primary benefit from these changes is expected to be a reduction in risk to the community from the use of poorly designed, incomplete or inaccurate healthcare software. More broadly, these changes should also contribute to a better quality of community health, through the use of better quality healthcare resources. The only significant foreseeable disadvantage that may occur as a result of the changes would be an increase in the cost of healthcare software due to the additional regulatory compliance costs for manufacturers.

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

As referred to above, the introduction of a new regulatory system for healthcare software will introduce new compliance costs for manufacturers. It may be that some software manufacturers will be able to bear this cost, and some will not. Some software packages used by ATMS members are manufactured and supplied by relatively small businesses that may not have the capacity to bear these additional compliance costs, even though they may be fully compliant with the proposed regulatory system, and cease trading as a result. The outcome from this may be the disappearance of what, to date, have been useful diagnostic or therapeutic tools that have been of benefit to the community.

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

ATMS does not deal in products, such as healthcare software, and so cannot comment on this directly, though a healthcare software manufacturer could reasonably be of the view that it may be difficult to respond to this without seeing more detail of the proposed regulatory system.

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.

ATMS does not deal in products, such as healthcare software, so cannot quantify the financial impact of the proposed changes or comment on this directly though it's conceivable that healthcare software manufacturers would have difficulty in making any financial assessment of the impact of the proposed changes without first knowing far more about the requirements of the proposed system, including the application, listing and registration costs that will be imposed on manufacturers by the TGA.

6. What period would be needed for your organisation to implement the proposed changes? This information will be used to inform any transitional arrangements.

Again, ATMS does not deal in products, such as healthcare software, so cannot comment on this directly, though a healthcare software manufacturer could reasonably be of the view that it may be difficult to reply to this without seeing more detail on the proposed regulatory system.

As a final comment, ATMS assumes that, once healthcare software becomes classified as a medical device and is regulated as such, this change will be accommodated in the Therapeutic Goods Advertising Code and Therapeutic Goods Regulations as required.

Yours sincerely

Charles Wurf
Chief Executive Officer