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## MTAA submission to TGA consultation paper:

# Scope of regulated software-based products

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# 1. Introduction and background

This submission provides MTAA's feedback to the TGA public consultation: *Scope of Regulated Software based products*, published on 25 March 2020. As stated by the TGA, the purpose of this consultation is "*to clarify the boundary for software-based products that are captured under the regulatory framework for medical devices in Australia" and also "to ensure that sponsors and manufacturers of software-based products are not subject to unnecessary regulatory oversight".*

This consultation follows the previous public consultations and workshops on regulation of software, including *Software as a Medical Device (SaMD)* that closed on 31 March 2019. These previous consultations and workshops highlighted the fact that there was confusion among stakeholders over what was considered a medical device. Consequently, it was considered important to clarify this in consultation with stakeholders prior to the commencement of the regulatory changes.

MTAA welcomes the opportunity to provide comments to the TGA proposed classification boundaries for health-based products which are crossing and/or blending traditional boundaries of therapeutic product definitions. Software-based products that do not fall under the definition of medical device should be specifically excluded from regulation by the TGA.

MTAA is broadly supportive of the proposed TGA proposal outlined in this consultation. Responses to the questions asked in the public consultation documents and any additional comments are provided below.

# 2. MTAA responses to questions

### *2.1 What kinds of software-based products should be exempted from inclusion in the ARTG? What are they and why should they be exempted?*

Software-based medical devices that pose no significant threat of harm to a patient should be exempted from regulation by the TGA. Regulatory controls for exempted therapeutic goods are adequate for software-based products that are intrinsically low-risk due to their intended purpose or if they fail to perform. Although inclusion in the ARTG is not required for exempt products, the following are still required:

- Compliance with relevant essential principles of safety and performance
- Reporting of adverse events
- Compliance with the Advertising Code

The TGA consultation paper lists the following categories of software-based products that pose no potential for significant harm to a patient or consumer:

- Software used by consumers intended to:
  - help patients self-manage a specific disease/ condition
  - help patients manage stress for mental health
  - monitor a mild or self-limiting condition

- Software used by health professionals intended to:
  - provide "class-based analyses" rather than patient-specific diagnosis or management, for common trends or diagnostic indicators

MTAA agrees that above categories of software-based products are low-risk and pose no potential for significant harm to a patient or consumer. We acknowledge the fact that exempting software-based products with a particular intended purpose while non-software medical devices with the same intended purpose are not exempted will create inconsistencies in the way regulations are applied. This could be managed by mandating appropriate cautions/ warnings aimed at users of the software-based products.

Software-based products do not pose risks associated with physical products such as electric shock hazards, mechanical hazards etc., therefore we believe it is appropriate to exempt low-risk software-based products even if this creates an apparent inconsistency in how regulation is applied.

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

*Please provide details:*

- *of any existing regulatory oversight that you consider would negate the need for the TGA to regulate particular software-based products; or*
- *describe what evidence or product characteristics could be used to determine that particular types of software pose no potential or significant harm to an individual.*

The TGA consultation paper has a comprehensive list of software products used in healthcare that do not fall under the definition of a medical device and therefore not subject of therapeutic goods regulations. It includes software products for the following intended purposes:

- Administrative support of a healthcare facility
- Management of prescription information
- Medication adherence (treatment regimens)
- Electronic patient records and record keeping
- Clinical workflow and support
- Education, training and guidance
- Data processing and data displaying
- Communication tools
- Health information management/ database systems
- Maintaining or encouraging a healthy lifestyle
- Extracting data from clinical trial records or patient records
- Monitoring or management of health IT systems
- Medi-alerts
- Standard (consumer) IT equipment without therapeutic claims
- Travel medicine tools
- Predictive analysis
- Archetype editor

Some clinical procedures might use software that integrates recording of patient information and setting therapy parameters. To assist software developers better navigate through regulatory requirements, it would be helpful if TGA included wording in the relevant software guidance advising health software developers to modularise and identify which software modules fall under the definition of medical device and which don't.

Software-based medical devices for which adequate alternative mechanisms of oversight exist should be excluded from regulation by the TGA, such as software-based products that are embedded in the delivery of a health service. Excluded products, while still subject to relevant consumer laws, are:

- not required to be included in the ARTG;
- not required to be assessed in any way by the TGA before they are made available in Australia,
- not monitored for ongoing safety by the TGA after they are made available, i.e. no reporting of adverse events to the TGA, and
- exempt from compliance with the Advertising Code.

The TGA consultation paper provides the following examples of software-based products for which adequate alternative mechanisms of oversight already exist:

- Lab support software intended to be used in an accredited pathology laboratory
- Clinical decision support software that is:
  - not intended to acquire, process, or analyse a medical image or a signal from a hardware medical device or an IVD, and
  - intended to display, analyse, or print medical information about a patient or other medical information (e.g., peer-reviewed clinical studies and clinical practice guidelines), and
  - intended for the purpose of supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition, and
  - intended for the purpose of enabling such health care professional to independently review the basis for such recommendations that such software presents, and not intended to be primarily relied upon for clinical diagnosis or treatment decision regarding an individual patient.

### *2.3 Which approaches from international jurisdictions, if any, should be used to inform the Australian approach to this issue?*

Considering that the majority of medical devices supplied in Australia are developed overseas, including software-based products, the carve-out and regulatory treatment should align as much as possible with the rules in the major established markets – the EU and U.S.

We should avoid situations where a software-based product category is not a medical device in the EU and/or U.S., but is regulated as medical device that is neither excluded nor exempt in Australia.

MTAA would like to thank the TGA for its continuous and constructive engagement with industry and other stakeholders in shaping an effective and sensible regulatory framework for software-based products in Australia.