Submission to TGA consultation: Regulation of software, including Software as a Medical Device (SaMD)

March 2019

Our Credo

We believe our first responsibility is to the patients, doctors and nurses, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality. We must constantly strive to provide value, reduce our costs and maintain reasonable prices. Customers' orders must be serviced promptly and accurately. Our business partners must have an opportunity to make a fair profit.

We are responsible to our employees who work with us throughout the world. We must provide an inclusive work environment where each person must be considered as an individual. We must respect their diversity and dignity and recognize their merit. They must have a sense of security, fulfillment and purpose in their jobs. Compensation must be fair and adequate and working conditions clean, orderly and safe. We must support the health and well-being of our employees and help them fulfill their family and other personal responsibilities. Employees must feel free to make suggestions and complaints. There must be equal opportunity for employment, development and advancement for those qualified. We must provide highly capable leaders and their actions must be just and ethical.

We are responsible to the communities in which we live and work and to the world community as well. We must help people be healthier by supporting better access and care in more places around the world. We must be good citizens–support good works and charities, better health and education, and bear our fair share of taxes. We must maintain in good order the property we are privileged to use, protecting the environment and natural resources.

Our final responsibility is to our stockholders. Business must make a sound profit. We must experiment with new ideas. Research must be carried on, innovative programs developed, investments made for the future and mistakes paid for. New equipment must be purchased, new facilities provided and new products launched. Reserves must be created to provide for adverse times. When we operate according to these principles, the stockholders should realize a fair return.

Johnson & Johnson

Comments

On behalf of the Johnson & Johnson Family of Companies (herein referred to as Johnson & Johnson), we appreciate the opportunity to provide comments on the Therapeutic Goods Administration's (TGA) *Consultation: Regulation of software, including Software as a Medical Device (SaMD).*

It should be noted that we have contributed to and broadly support the submission made by the Medical Technology Association of Australia (MTAA). Our additional commentary is summarised below.

Overall, Johnson & Johnson support the TGA's proposal to develop a risk-based regulatory pathway for software as a medical device (SaMD). We also support the alignment of this approach with those outlined in the IMDRF documents "Software as a Medical Device: Possible Framework for Risk Categorisation and Corresponding Considerations" (N12)[1] and Software as a Medical Device (SaMD): Clinical Evaluation (N41)[2]. Digital technologies such as SaMD Digital technologies create new opportunities to transform health care and empower patients to make better informed decisions about their health. Regulatory approaches should facilitate access to these products, while balancing the need of protecting patient safety. Global harmonisation of requirements will further facilitate patient access by developing predictable and transparent regulatory pathways for software developers.

Risk Classification

Proposal: *We propose the TGA align with the IMDRF risk classification*

Following the publication of the final IMDRF SaMD document on Clinical Evaluation, jurisdictions across the globe have been able to consider harmonised approaches based on the risk classification as outlined in IMDRF document N12. We recommend that TGA consider the following points when finalising its document, as confusion has resulted with other regulatory authorities and within the medical device industry.

Traditional device risk classifications are generally linear in progression from low to high risk. The IMDRF SaMD classification, however, is two dimensional and considers the "State of healthcare situation or condition" and the "Significance of information provided by SaMD to the healthcare decisions;" this can be interpreted to how sick is the patient, and how reliant is the user on the information being provided. As patient population health declines and the user reliance increases,

[1] "Software as a Medical Device": Possible Framework for Risk Categorization and Corresponding Considerations, IMDRF, 18 September 2014: http://www.imdrf.org/workitems/wi-samd.asp

[2] Software as a Medical Device (SaMD): Clinical Evaluation, IMDRF, 5 August 2016: http://www.imdrf.org/docs/imdrf/final/consultations/imdrf-cons-samd-ce.pdf

the risk goes up. As the IMDRF risk classification is being implemented across the globe, it is becoming clear that in the context of cross walking the IMDRF classifications to country-specific risk classification, both concepts are being considered simultaneously (and as described in sections 7.2 and 7.3 of the IMDRF N12 document reproduced below).

7.2 SaMD Categories

State of healthcare situation or condition	*Significance of information provided by SaMD to healthcare decision*		
	Treat or diagnose	*Drive clinical management*	*Inform clinical management*
Critical	*IV*	*III*	*II*
Serious	*III*	*II*	*I*
Non-serious	*II*	*I*	*I*

7.3 Criteria for Determining SaMD Category

Criteria for Category IV –

i. SaMD that provides information to treat or diagnose a disease or conditions in a critical situation or condition is a Category IV and is considered to be of very high impact.

Criteria for Category III –

i. SaMD that provides information to treat or diagnose a disease or conditions in a serious situation or condition is a Category III and is considered to be of high impact.

ii. SaMD that provides information to drive clinical management of a disease or conditions in a critical situation or condition is a Category III and is considered to be of high impact.

Criteria for Category II –

i. SaMD that provides information to treat or diagnose a disease or conditions in a nonserious situation or condition is a Category II and is considered to be of medium impact.

ii. SaMD that provides information to drive clinical management of a disease or conditions in a serious situation or condition is a Category II and is considered to be of medium impact.

iii. SaMD that provides information to inform clinical management for a disease or conditions in a critical situation or condition is a Category II and is considered to be of medium impact.

Criteria for Category I –

i. SaMD that provides information to drive clinical management of a disease or conditions in a non-serious situation or condition is a Category I and is considered to be of low impact.

ii. SaMD that provides information to inform clinical management for a disease or conditions in a serious situation or condition is a Category I and is considered to be of low impact.

iii. SaMD that provides information to inform clinical management for a disease or

conditions in a non-serious situation or condition is a Category I and is considered to be of low impact.

The four categories (I, II, III, IV) are based on the levels of impact on the patient or public health where accurate information provided by the SaMD to treat or diagnose, drive or inform clinical management is vital to avoid death, long-term disability or other serious deterioration of health, mitigating public health.

Full consideration of both aspects of the risk categorisation is critical when determining how the Australian risk classifications should apply. For example, per IMDRF, low impact includes some "inform" and some "drive" software depending on the seriousness of the patient condition:

i. SaMD that provides information to drive clinical management of a disease or conditions in a non-serious situation or condition is a Category I and is considered to be of low impact.
ii. SaMD that provides information to inform clinical management for a disease or conditions in a serious situation or condition is a Category I and is considered to be of low impact.
iii. SaMD that provides information to inform clinical management for a disease or conditions in a non-serious situation or condition is a Category I and is considered to be of low impact.

Exempting of Low Risk Devices

Proposal: *We propose the TGA exempt low-risk devices from regulatory oversight based on recognised criteria.*

One jurisdiction (United States) has changed their definition of medical device to exclude low risk software and another is considering excluding low risk software from regulatory oversight (Health Canada). The following criteria is being proposed for the TGA to consider a similar exemption. Exemption could be appropriate because it would focus regulatory resources on higher-risk products. Once again, this approach should consider the balance between patient access, and patient safety.

Various types of SaMD may not be considered to meet the device definition when **all of the four criteria outlined in Table 1.** It would be helpful to include examples of such devices in an associated TGA guideline.

Table 1: Criteria for Exempting Low Risk Devices

Exclusion Criteria		Interpretation
1	Software that is not intended to acquire, process or analyse a medical image or a signal from an IVDD or a pattern /signal from a signal acquisition system.	• Software that acquires images and data from medical devices solely for the purpose of display, storage, transfer or format conversion is commonly referred to as Medical Device Data Systems (MDDS) software, which does not qualify as a medical device. • Information from in vitro diagnostic devices (IVDDs) includes qualitative and quantitative outputs and signals from instruments, tests and assays. • Physiological signals are those signals that require use of either an in vitro diagnostic device or signal acquisition system. In the context of an in vitro diagnostic device, a physiological signal is typically an electrochemical or photometric response generated by an assay and instrument that must be further processed by software to generate a clinical test result. A signal acquisition system is the electronic circuitry and control processor that receives, as inputs, signals from sensors that are within, attached to (e.g., EEG, ECG), or external to (e.g., CT, MRI) the human body or sample from the human body (e.g., digital pathology). The fidelity with which a physiologic signal is captured, processed, and analysed is often critical to the overall performance of a device.
2	Software that is intended to display, analyse, or print medical information about a patient or other medical information (such as demographic information, drug labelling, clinical guidelines, studies, or recommendations).	• Software that matches medical information to reference information routinely used in clinical practice would meet this criterion. This could include software that matches patient symptoms and test results with best practice treatment guidelines for common illnesses. • Software that provides a reference for health care professionals to identify possible drug interactions in order to prevent adverse drug events could be interpreted to prevent an abnormal physical state as per the medical device definition. However, Health Canada does not intend to regulate this type of software since the alert provided by the software functions as a convenient mechanism for health care professionals to match patient-specific information with reference information that is readily available to the medical community and routinely used in clinical practice.

Exclusion Criteria		Interpretation
3	Software that is intended to support a health care professional, patient, or nonhealthcare professional caregiver in making decisions about prevention, diagnosis, or treatment of a disease or condition.	• Generally, this includes Type I software, as defined by IMDRF as low impact (e.g. inform/non-serious, inform/serious, and drive/non-serious). *Note: Per IMDRF guidance N12, Type I products are considered low risk, taking into consideration both the state of the health care condition and significance of the information. This risk is not captured by software functionality alone and therefore, use of terms "inform" and "drive" in the HC interpretation inappropriately includes higher risk products (i.e. inform/critical) and excludes lower risk products (i.e. drives/non-serious). Referencing IMDRF Type I addresses this inconsistency and provides added clarity on which software is most appropriate to be considered low enough risk to be excluded.*
4	Software that is not intended to replace the clinical judgement of a health care professional to make a clinical diagnosis or treatment decision regarding an individual patient.	• The intended user is able to reach a recommendation independently without primarily relying on the software function. For example, software intended to provide a convenient way to perform various simple medical calculations, which are routinely used in clinical practice, would meet the fourth criterion as the software retains functionality that is similar to simple general purpose tools such as paper charts, spread sheets, timers or generic mathematical calculators, and is able to be independently validated. • The software should enable health care professionals, patients or non-healthcare professional caregivers to independently review the basis for the recommendations presented by the software.

Transitional arrangements

We currently estimate it may take 18 months to implement the proposed changes, however we would like the opportunity to consult further once the final details of the proposed regulatory changes have been confirmed i.e. when we can make an accurate assessment against the new classification rules and the additional Essential Principles that SaMD is required to meet.

Johnson & Johnson appreciates the ongoing engagement and opportunity for input to the TGA's framework for regulating SaMD. Should you have any questions regarding our consultation feedback, we welcome the opportunity to discuss further.