APACMed
The voice of MedTech

GUIDANCE ON SaMD REGULATIONS - LIFECYCLE APPROACH

An APACMed India Digital Health Centre of Excellence initiative

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CONTENT

1 Introduction

The Medical Device Regulations (MDR2017) established under Drugs and Cosmetics Act, 1940 (23 of 1940) apply to all medical devices imported or commercialized in India. The regulations utilize risk-based approach to regulate products within the scope.

Due to fast evolving and emerging technology platforms, software is becoming increasingly important and omnipresent in healthcare. Given the availability of a variety of technology platforms, software is playing increasingly important role in medical devices.

This guidance is the recommendation from APACMed to CDSCO on the regulatory approach for software based medical devices. CDSCO to continue to adapt its policy approach to Software as Medical Devices (SaMD) with emergence of new software related technologies and evolving risks

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Scope

CDSCO uses the definition developed by the International Medical Device Regulators Forum (IMDRF) to help determine whether software is a medical device in conjunction with the definition of a medical device as stipulated under Medical Device Rules 2017.

As per IMDRF, SaMDis a software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device. This means the software has its own intended use and may also be referred to as "independent" or "standalone" Software.

- Software as a Medical Device ranges from smartphone apps that calculate insulin doses based on a patient's blood glucose levels to Computer-Aided Detection (CAD) software that performs image post-processing to help detect breast cancer.
- Software that calculates the risk of prostate cancer from ultrasound images, patient and laboratory parameters.

3 Definitions

1. **Medical device**" means,-

a. substances used for in vitro diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant covered under sub-clause (I), of clause (b) of section 3 of the Act

b. substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified in the Official Gazette under sub-clause (ii), of clause (b) of section 3 of the Act

c. devices notified from time to time under sub-clause (iv) of clause (b) of section 3 of the Act

2. Software as a Medical Device - The term "Software as a Medical Device" (SaMD) is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device

Notes:

a. SaMD is a medical device and includes in-vitro diagnostic (IVD) medical device.

b. SaMD is capable of running on general purpose (non-medical purpose) computing platforms

c. "without being part of" means software not necessary for a hardware medical device to achieve its intended medical purpose;

d. Software does not meet the definition of SaMD if its intended purpose is to drive a hardware medical device.

e. SaMD may be used in combination (e.g., as a module) with other products including medical devices;

f. SaMD may be interfaced with other medical devices, including hardware medical devices and other SaMD software, as well as general purpose software

g. Mobile apps that meet the definition above are considered SaMD

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Guidance for Implementation

1. SaMD - Inclusion Criteria

a. The term Software as a Medical Device (or SaMD) refers to software that can function on, for example, a laptop computer, smartphone or tablet, and has an intended purpose consistent with the definition of a medical device. The interpretation of the intended use is a key consideration in the determination of SaMD. This could be any kind of software, including but not limited to: computer programs and applications, mobile apps, software as a service (cloud based), websites and browser delivered products.

b. Software would generally be a medical device if it is intended to be used for:

   i. Diagnosis, prevention, monitoring, prediction, prognosis or treatment of a disease, injury or disability

   ii. Compensation for an injury or disability

   iii. Investigation of the anatomy or of a physiological process

   iv. Supporting or sustaining life

   v. To control conception

   vi. Providing information for diagnostic, monitoring or compatibility purposes by means of in vitro examination of specimens derived from the human body

   vii. Provide means and suggestions for mitigation of disease

   viii. Provide information for determining compatibility, detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities

   ix. Be an aid to diagnosis, screening, monitoring, determination of predisposition; prognosis, prediction, determination of physiological status

2. SaMD - Exclusion Criteria

a. The medical purposes enlisted in the device definition can apply to a wide range of products. However, software that is not intended for the diagnosis, treatment, or management of an individual's disease, disorder, abnormal physical state or symptoms would not be subject to the regulations (e.g. a mobile app intended to monitor daily calorie intake and energy expenditure to allow an individual to self-manage their weight or an app intended by the manufacturer only to measure and display a person's heart rate for fitness purposes).

b. The below listed software do not meet the definition of medical device and are therefore not subject to regulation:

   i. Software intended for administrative support of a healthcare facility, such as Laboratory Information Systems (LIS)

   ii. Software that enables clinical communication and workflow including patient registration, scheduling visits, voice calling, video calling

   iii. Software intended for maintaining or encouraging a healthy lifestyle, such as general wellness apps

   iv. Software intended to serve as electronic patient records or tools to allow a patient to access their personal health information

   v. Software intended for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory tests or devices, unless the software is intended to interpret or analyze clinical laboratory test or other device data, results, and findings

c. Non-medical device clinical decision support software must meet all the following four criteria in order to be excluded from the medical device definition:

	Exclusion Criteria	Clarification
1	Software that is not intended to acquire, process, or analyze a medical image and is intended to process medical information1 from a hardware medical device, an in vitro diagnostic device, or other sources such as an electronic health record "medical information" can be described as outputs from medical or in vitro diagnostic devices that are well understood and could be found in an electronic health record. Such outputs are discrete results that are clinically meaningful. An example of medical information would be a potassium test result from an in vitro diagnostic assay/instrument.	■ Software that acquires images and data from medical devices solely for the purpose of display, storage, transfer or format conversion does not qualify as a medical device.
2	Software that is intended to display, analyze, 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 or self-care 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, CDSCO 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	Clarification
3	Software that is only intended to support a health care professional, patient or non healthcare professional caregiver in making decisions about prevention, diagnosis, or treatment of a disease or condition	■ Generally, software intended to inform clinical/patient management can be interpreted to fit this criterion. Informing clinical/patient management infers that the information provided by the software will not trigger an immediate or near term action. ■ Software that is used to treat, diagnose or drive clinical management does not generally fit under this criterion. Treatment or diagnosis infers that the information provided by the SaMD will be used to take an immediate or near term action
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 should have access to the basis for the software's recommendation, so the user can independently review and rely on their own judgement and reach a recommendation 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

5 Classification of SaMD

Upon determination of software being a medical device, classification must also be determined. There are several factors involved in SaMD classification but intended use will be fundamental in the determination of its classification. The intended use of SaMD is normally reflected in various sources such as the manufacturer's labelling, including instructions for use manuals, websites, promotional material, and other information provided by the manufacturer. The manufacturer should describe the intended use of the software, as well as any conditions, diseases that it's intended to treat and/or diagnose, including a description of the following factors:

1. Significance of information provided by SaMD to healthcare decision

a. The intended use of the information provided by SaMD in clinical management has different significance on the action taken by the user

   i. To treat or to diagnose - Treating and diagnosing infers that the information provided by the SaMD will be used to take an immediate or near term action

      1. To treat/prevent or mitigate by connecting to other medical devices, medicinal products, general purpose actuators or other means of providing therapy to a human body

      2. To diagnose/screen/detect a disease or condition (i.e., using sensors, data, or other information from other hardware or software devices, pertaining to a disease or condition).

   ii. **To drive clinical management** - Driving clinical management infers that the information provided by the SaMD will be used to aid in treatment, aid in diagonsis, to triage or identify early signs of a disease or condition will be used to guide next diagnostics or next treatment interventions

      1. To aid in treatment by providing enhanced support to safe and effective use of medicinal products or a medical device

2. To aid in diagnosis by analyzing relevant information to help predict risk of a disease or condition or as an aid to making a definitive diagnosis

3. To triage or identify early signs of a disease or conditions

iii. **To Inform clinical management** - Informing clinical management infers that the information provided by the SaMD will not trigger an immediate or near term action

1. To inform of options for treating, diagnosing, preventing, or mitigating a disease or condition

2. To provide clinical information by aggregating relevant information (e.g., disease, condition, drugs, medical devices, population, etc.)

2. Healthcare Situation or Condition

a. Critical situation or condition - Situations or conditions where accurate and/or timely diagnosis or treatment action is vital to avoid death, long-term disability or other serious deterioration of health of an individual patient or to mitigating impact to public health. SaMD is considered to be used in a critical situation or condition where the type of disease or condition is:

i. Life threatening state of health, including incurable states.

ii. Requires major therapeutic interventions.
Sometimes time critical, depending on the progression of the disease or condition that could affect the user's ability to act upon the output information.

b. Serious situation or condition - There are situations or conditions where accurate diagnosis or treatment is of vital importance to avoid unnecessary interventions (e.g. biopsy) or timely interventions are important to mitigate long-term irreversible consequences to an individual's patient's health condition or public health. SaMD is considered to be used in a serious situation or condition when:

i. The type of disease or condition is:

1. Moderate in progression, often curable,

2. Does not require major therapeutic interventions,

3. Intervention is normally not expected to be time critical in order to avoid death, long-term disability or other serious deterioration of health, whereby providing the user an ability to detect erroneous recommendations

c. **Non-serious situation or condition** - There are situations or conditions where an accurate diagnosis and treatment is important but not critical for interventions to mitigate long-term irreversible consequences on an individual patient's health condition or public health. SaMD is considered to be used in a non-serious situation or condition when

i. The type of disease or condition is:

1. Slow with predictable progression of disease state (may include minor chronic illnesses or states),
2. May not be curable; can be managed effectively,
3. Requires only minor therapeutic interventions, and
4. Interventions are normally noninvasive in nature, providing the user the ability to detect erroneous recommendations.

3. **Description of the SaMD's core functionality** - The description of the SaMD's core functionality identifies the critical features/functions of the SaMD that are essential to the intended significance of the information provided by the SaMD to the healthcare decision in the intended healthcare situation or condition. This description should include only the critical features

4. **SaMD Classification** - The below chart provides an illustration on SaMD classification based on the factors described above and identified in the SaMD intended use statement. This approach applies IMDRF's N12 SaMD Risk Categorization Framework to the CDCSO medical device classification system.

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	D	C	B
Serious	C	B	A
Non-Serious	B	A	A

6 General Considerations for SaMD

Developing SaMD that are safe entails identifying risks and establishing measures that give confidence that the risks are acceptable.

IEC 62304 is a standard for life-cycle development of medical device software. The standard specifies a risk-based decision model, defines some testing requirements, and highlights three major principles that promote safety relevant to SaMD:

- Risk management;
- Quality management; and
- Methodical and systematic systems engineering according to best industry practices.

IEC 62366 specifies a process for manufacturer to analyse, specify, develop and evaluate the usability of medical device with relation to safety. The process permits the manufacturer to analyze and minimize risks associated with the normal use of the medical device. It also enables the manufacturer to identify the risks associated with the abnormal use of the device.

The combination of these concepts allows SaMD manufacturers to follow a clearly structured and consistently repeatable decision-making process to promote safety for SaMD.

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Quality Management System (QMS) for Software Medical Devices

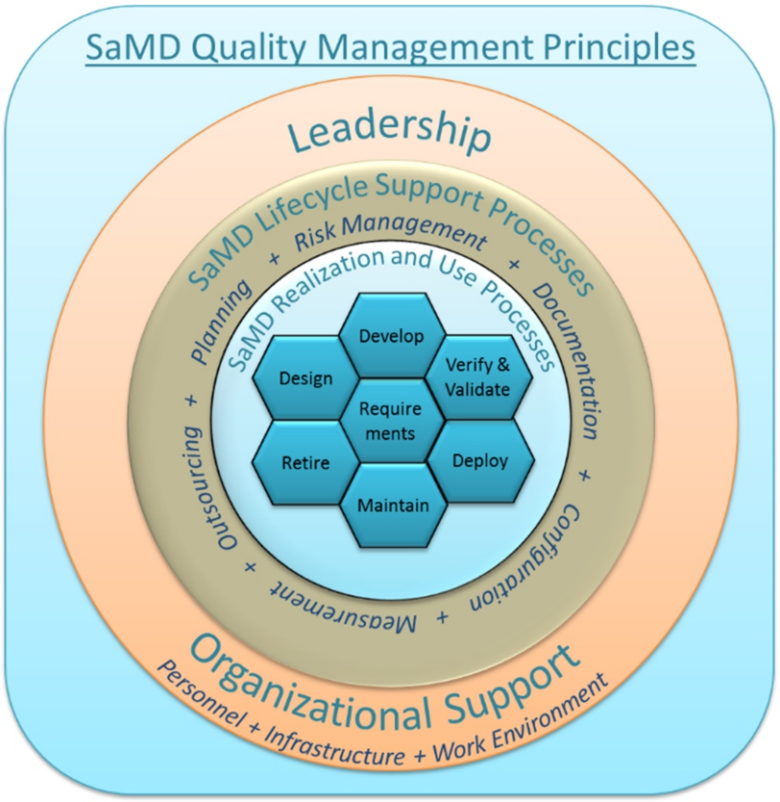
In medical devices sector, QMS requirements are the controls used to minimize and manage unintentional outcomes related to patient safety. QMS requirements for medical devices are defined in the international standard ISO 13485-Medical Devices-Quality Management Systems- Requirements for Regulatory Purposes.

In the software industry, good software quality and engineering practices are used to control the quality of software products. These practices may readily align with the general principles of medical device QMS requirements, as described in IMDRF's N23 guidance, "Software as a Medical Device (SaMD): Application of Quality Management System."

An effective QMS for SaMD should include the following principles:

- **Leadership and Organization** - An organizational structure that provides leadership, accountability, and governance with adequate resources to assure the safety, effectiveness, and performance of SaMD (outer circle in Figure 1);
- **Life Cycle Supported Processes** - A set of SaMD lifecycle support processes that are scalable for the size of the organization and are applied consistently across all realization and use processes (middle circle in Figure 1); and
    - Product Planning
    - Risk Management
    - Document and Record Control
    - Configuration Management and Control
    - Measurement, Analysis and Improvement
    - Outsource Management

- Product Realization Activities - A set of realization and use processes that are scalable for the type of SaMD2 and the size of the organization; and that takes into account important elements required for assuring the safety, effectiveness, and performance of SaMD (innermost circle in Figure 1).
    - Defining requirements
    - Design and Development
    - Verification and Validation
    - Deployment or Implementation
    - Maintenance and Servicing
    - Decommissioning



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Pre-Market Product Registration Requirement

Product registration application for medical devices must be prepared in line with the requirements of MDR2017 (Medical Device Rules). When applying for the software medical devices, there may be specific requirements which can be covered under the below listed sections:

- Essential Principles for safety and performance of medical devices
- Labelling requirements
- Software versioning and traceability
- Software verification and validation
- Clinical evidence
- Risk management
- Supporting documents for cybersecurity

9 Changes to a Registered Software

A software medical device undergoes a number of changes throughout its product life cycle. The changes are typically meant to

- correct faults
- improve the software functionality and performance to meet customer demands and
- ensure safety and effectiveness of the device is not compromised (e.g. security patch).

Proactive Approach to Anticipated Software Modifications SaMD Products

Due to their iterative nature, there is a need to streamline change management approaches for SaMD products to ensure that safe and effective updates can be rolled out to patients and healthcare professionals in a timely manner. The predetermined change control plan concept is designed to enable such an approach.

In such a plan, a software developer outlines the modifications it plans to make to future versions of its software and the methods it will utilize to achieve and appropriately control the risks associated with those modifications. The developer then includes this information (a predetermined change control plan) as a part of its regulatory submission and, when the licencing authority approves the product for commercialization, the predetermined change control plan is also approved. This enables the software developer to make significant changes to its SaMD product postmarket as long as the changes made are within the scope of the agreed upon predetermined change control plan.

Additional details on the predetermined change control plan, and its recommended contents, are provided below.

- **Predetermined change control plan** enables responsible performance enhancements in SaMD and AI/ML-based technologies. The predetermined change control plan should include the types of anticipated modifications - SaMD Pre-Specifications - based on the

retraining and model update strategy, and the associated methodology - Algorithm Change Protocol - being used to implement those changes in a controlled manner that manages risks to patients.

SaMD Pre-Specifications (SPS): A SaMD manufacturer's anticipated modifications to "performance" or "inputs," or changes related to the "intended use" of the SaMD. These are the types of changes the manufacturer plans to achieve when the SaMD is in use. The SPS draws a "region of potential changes" around the initial specifications and labeling of the original device. This is "what" the manufacturer plans to change in a SaMD product in the future. The key information contained within an SPS may include:

- The motiviation for the change describing why the developer desires to implement the change in the future.
- A technical description of the change.
- An impact assessment of the change, evaluating possible new risks associated with the change, as well as planned mitigations and planned objective evidence in relation to those risks.
- An overview of the anticipated labeling changes associated with the change.
- A comparison table to compare/contrast the intended purpose, performance and claims, and technical specifications of the software before and after implementation of the anticipated change.

Algorithm Change Protocol (ACP): Specific methods that a manufacturer has in place to achieve and appropriately control the risks of the anticipated types of modifications described in the SPS. The ACP provides an overview of the procedures to be followed so that the modification achieves its goals and the device remains safe and effective after the modification. This is "how" the manufacturer plans to implement the anticipated changes in a safe and effective manner. The key information contained within an ACP may include:

- A data management plan, including a data management protocol, risk assessment plan, new data collection protocols, and quality assurance process.
- A performance evaluation and monitoring plan, describing assessment metrics, a statistical analysis plan, assessment frequency, performance targets, and postmarket monitoring overview.

- An algorithm retraining plan (if applicable) to described retraining objectives, methods that will be employed to improve algorithm performance, the approach to performance evaluation, and potential impacts to intended purpose.

- A software update plan, describing version tracking, verification and validation methods, update triggers, update procedures, and approaches to transparently communicating updates to end users.

- A rollback plan, describing triggers, backup and recovery procedures, and communication to users.

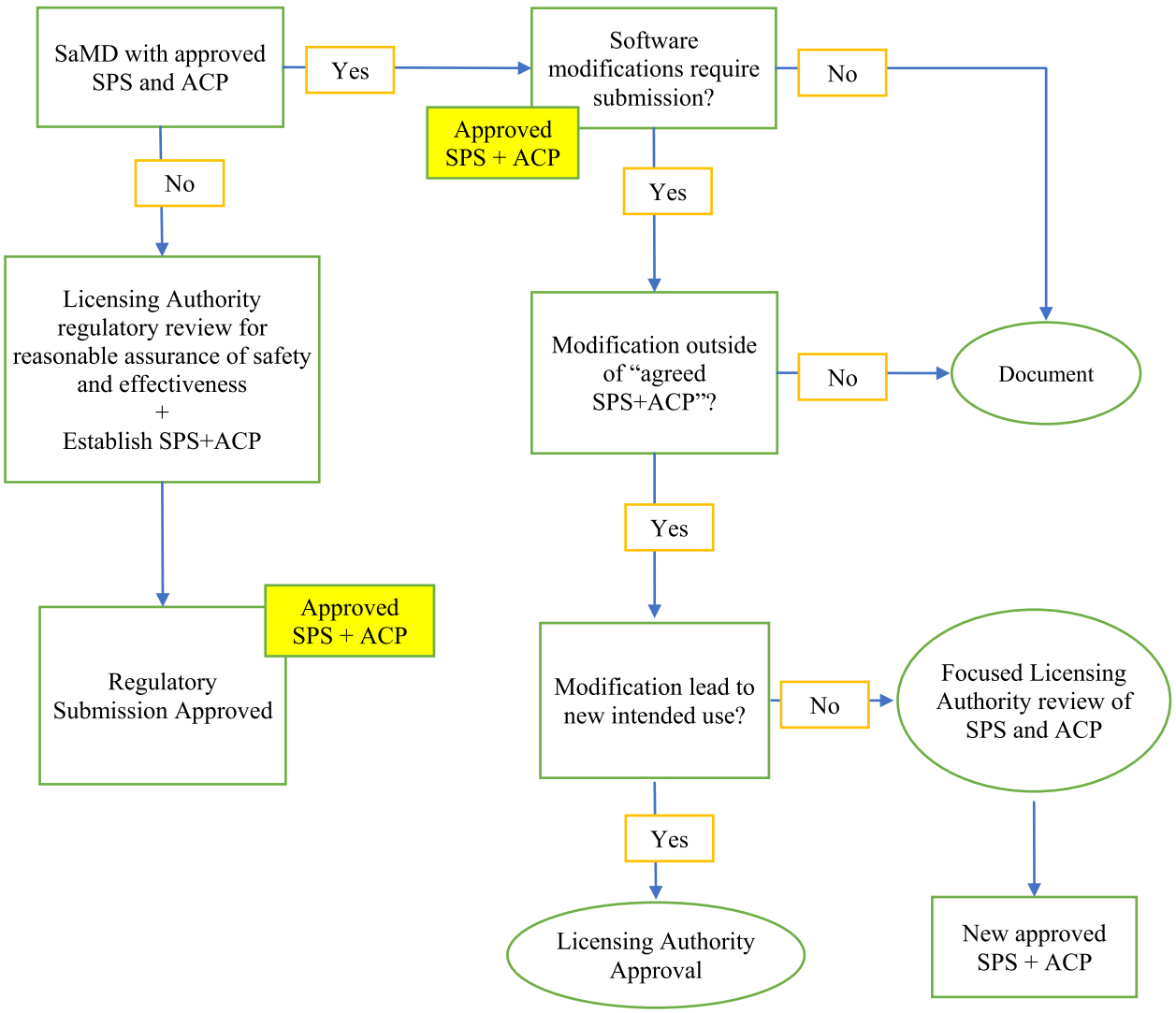
The following are example scenarios that illustrate the general concept of establishing an appropriate SPS and its corresponding ACP:

- Changes that involve improvements in performance, or changes in input, without affecting the intended use of the SaMD, may be accomplished with an appropriate level of pre-specification and an appropriate ACP that provides reasonable assurance that performance will be improved or maintained. The ACP may include the basis of validation and methods to adequately monitor and control for significant degradation in performance or introduce risks to patients.

" Certain changes related to the intended use, in particular, an increase in the significance of the information provided to the user for the same healthcare situation or condition. Using the IMDRF risk framework as the basis for an example, a SPS may include a modification related to the intended use within "drive clinical management," which may shift the intended use from "identify early signs of a disease or conditions" to "aid in making a definitive diagnosis" for the same healthcare situation or condition. An appropriate ACP might be developed, reviewed, and agreed by CDSCO and the manufacturer to adequately improve the performance to a level that increases the confidence in its ability to be used as an aid in making a definitive diagnosis.

- Certain changes related to the intended use, in particular, the "indications for use." For example, a manufacturer may intend to expand the use of their SaMD to a new patient population for which there had been insufficient evidence available to initially support that indication for use. In some cases, an appropriate reference standard may initially not be available for the new patient population; a manufacturer's ACP may include a characterization plan for the reference standard in the disease population to assure it provides a meaningful representation of the disease. In other cases, an input data type used

by the AI/ML-based SaMD may not normally be available for the patient population; a developer's ACP may include a demonstration of the clinical association between the disease and input data type in the new patient population, as well as a plan for data collection and algorithm testing in the patient population.



10 Approaches to Regulatory Review for Digital Health Solutions

There can be three evaluation routes for Class B and Class C SaMD:

- Full Evaluation Route
- Abridged Evaluation Route
- Immediate Class B Registration (IBR) Evaluation Route / Immediate Class C Registration (ICR) Evaluation Route

The abridged and immediate evaluation routes are set out according to a confidence based approach, leveraging the approvals by reference regulatory agencies and/or prior safe marketing history. The types of approvals that qualify for the abridged and immediate evaluation routes are those approved by the following reference regulators:

- Australia Therapeutic Goods Administration (TGA) Device Registration Licence
- Health Canada (HC) Device Registration Licence
- Japan Ministry of Health, Labour and Welfare
- US Food and Drug Administration (US FDA)
- European Union Notified Bodies (EU NB) via EC certificates issued according to
  - Regulation (EU) 2017/745 on medical devices (MDR)
  - Medical Device Directive 93/42/EEC
  - Regulation (EU) 2017/746 on In Vitro medical devices (IVDR)
  - In Vitro Device Directive 98/79/EC
- Ministry of Food and Drug Safety, South Korea
- Health Science Authority, Singapore

- **Full Evaluation Route** - A SaMD that has not obtained any prior approval from any of CDSCO's reference regulatory agencies at the point of application will be subject to the full evaluation route

- **Abridged Evaluation Route** - A SaMD that has obtained at least one reference regulatory agency approval for a labelled use identical to that intended for marketing in India at the point of submission will qualify for the abridged evaluation route

- **Immediate Class B Registration (IBR) Evaluation Route** - A Class B SaMD may qualify for registration via the IBR route if it fulfils the following conditions at the point of submission:
  - Obtained approval from at least one of independent reference regulatory agency for a labelled use identical to that intended for marketing in India;
  - No safety issues globally associated with the use of the medical device(s) when used as intended by the product owner, in the last three years or since market introduction of the medical device(s), globally, defined as
    - no reported deaths;
    - no reported serious deterioration in the state of health of any person; and
    - no open field safety corrective actions (including recalls) at the point of submission.
  - No prior rejection/withdrawal of the medical device by/from any reference regulatory agency/foreign jurisdiction(s) or CDSCO/India due to quality, performance/efficacy or safety issues. This includes non-registration such as refusal to register specific models in an application.

- **Immediate Class C Registration (ICR) Evaluation Route** - A Class C standalone medical mobile application may qualify for registration via the ICR route if it fulfils the following conditions at the point of submission:
  - Obtained approval from at least one of the reference regulatory agencies referred above for a labelled use identical to that intended for marketing in India;
  - No safety issues globally associated with the use of the SaMD when used as intended by the product owner, in the last three years, defined as
    - no reported deaths;
    - no reported serious deterioration in the state of health of any person; and no open field safety corrective actions (including recalls) at the point of submission.
  - No prior rejection/withdrawal of the SaMD by/from any reference regulatory agency/foreign jurisdiction(s) or by the licencing authority in India due to quality, performance/efficacy or safety issues. This includes non-registration such as refusal to register specific models in an application.

11
Software with Multiple Function

Software products with multiple functions may break down into a significant number of applications that include functions with a medical device intended use and functions without a medical device intended use. In such instances, the Licencing authority shall evaluate the intended use of each function independently, as the various functions may have different functionality even when residing on the same platform. Licencing authority shall only exercise regulatory oversight over those functions with an intended use that fulfills the medical device definition. However, Licencing authority may assess the impact that non-medical device functions have on medical device functions when assessing the safety and effectiveness of a multiple function software product.

12
Post-Market Management of Software Medical Devices

Field Safety Corrective Action

- A FSCA may be initiated when the manufacturer/ becomes aware of certain risks associated with use of the medical device through post-market monitoring and surveillance, such as through tracking of product complaints / feedback.
- For software medical devices, the commonly encountered issues are listed below:
  - Inaccurate or incorrect test results e.g. mixed up of patient results and demographics
  - Failure to deliver therapy e.g. failure to deliver defibrillation in certain software modes
  - Potential clinical misdiagnosis and/or mistreatment e.g. uploading of incorrect treatment plan during exportation
  - Calibration errors resulting in incorrect patient positioning
  - Improper interface with external devices and/or other software components or modules e.g. with Laboratory Information Systems (LIS)
  - Incorrect display of images e.g. flipped images when exported; display errors such as screen blank-outs or frozen screens
  - Errors in calculation e.g. software algorithm error resulting in wrong dose calculation for radiation therapy
  - Configuration errors e.g. unit measurements not properly configured resulting in erroneous results reporting
  - Alarm errors e.g. software bug causing incorrect alarm messages to be sent out

- Usability errors e.g. Graphical User Interface (GUI) related issues
- Input of incorrect, incomplete or inconsistent requirements and specifications
- Incomplete or lack of validation of software prior to initial release
- Failure to examine the impact of changes during software upgrades or bug fixes
- Incorrect configuration e.g. failure to upgrade accompanying operating system
- Incompatibility with 3rd party installed program
- Software does not properly interface with external devices or other software components/modules

Adverse Events

- The objective of AE reporting and investigation is to reduce the likelihood of, or prevent recurrence of the AE and/or to alleviate consequences of such recurrence.
- Adverse events involving software medical devices may directly or indirectly, have an impact on patients and users. For example, failure of software-controlled devices such as insulin pumps, which senses blood sugar levels periodically and injects insulin to maintain normal levels of blood sugar, may result in hypoglycaemia that can be life-threatening when left undetected. Indirect harm to patients may occur in AEs involving devices such as IVD analysers that include software that control and manage their performance. Software errors may lead to incorrect or inaccurate patient results and consequently, result in wrong diagnosis and potentially incorrect treatment for the patient
- AEs for software medical devices may arise due to:
  - Shortcomings in the design of the software
  - Inadequate verification and validation of the software code
  - Inadequate instructions for use
  - Software bugs introduced during implementation of new features

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Regulatory Considerations for Artificial Intelligence (AI)/Machine Learning–Based SaMD

- Artificial Intelligence has been broadly defined as the science and engineering of making intelligent machines, especially intelligent computer programs. Artificial intelligence can use different techniques, including models based on statistical analysis of data, expert systems that primarily rely on if-then statements, and machine learning.
- Machine Learning is an artificial intelligence technique that can be used to design and train software algorithms to learn from and act on data. Software developers can use machine learning to create an algorithm that is 'locked' so that its function does not change, or 'adaptive' so its behavior can change over time based on new data. Some real-world examples of artificial intelligence and machine learning technologies include:

    - An imaging system that uses algorithms to give diagnostic information for skin cancer in patients.
    - A smart sensor device that estimates the probability of a heart attack.

Conventionally, Licencing Authority reviews medical device applications through appropriate regulatory pathways such as License (Form 5/Form 9/Form 14). Licencing authority also reviews and clears modifications to medical devices, including software as a medical device, depending on the significance or risk posed to patients of the modifications. Licencing authority's regulatory pathway shall be designed for adaptive artificial intelligence and machine learning technologies. The ability for AI/ML software to learn from real-world feedback (training) and improve its performance (adaptation) makes these technologies uniquely situated among software as a medical device (SaMD) and a rapidly expanding area of research and development.

For the AI/ML based SaMD (both those that leverage "locked" and "adaptive" algorithms), the manufacturer can submit a plan for modifications during initial health authority review based on the principles of the previously described "Predetermined Change Control Plan". The predetermined change control plan would include the types of anticipated modifications - SaMD Pre-Specifications - based on the retraining and model update strategy, and the associated methodology - Algorithm Change Protocol - being used to implement those changes in a controlled manner that manages risks to patients. For more information, please review Section 9.0.

About Asia Pacific Medical Technology Association (APACMed)

Founded in 2014 and headquartered in Singapore, APACMed represents manufacturers and suppliers of medical equipment, devices and in vitro diagnostics, industry associations and other key stakeholders associated with the medical technology industry in Asia Pacific.

Providing a unified voice for the medical devices and in-vitro diagnostics industry in Asia Pacific, with an active presence in India as well, APACMed works proactively with bilateral, regional and local government bodies to shape policies, demonstrate the value of medical technology and promote regulatory harmonization. We strive to promote digital health innovation and impact policy that advances healthcare access for patients by engaging with medical device associations and companies in Asia Pacific.

APACMed is also host to the annual Asia Pacific MedTech Forum.

www.apacmed.org

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