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Vietnam: Overview of the national rule for Software of Medical Devices (SaMD)

Asia Newsletter

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I Introduction

As innovation in the life sciences continues worldwide, Asian countries are seeing an increase in the number of new business launches utilizing technologies in the digital health and life sciences fields, as well as acquisitions, reorganizations, venture investments, and licensing transactions targeting such businesses.

In May 2023, the Japanese Ministry of Health, Labour and Welfare issued "Guidance for Appropriate and Prompt Approval and Development Based on the Characteristics of Software as Medical Devices"[1/2] (the "Guidance"). The Guidance outlines the current pharmaceutical affairs approval system based on the characteristics of Software as Medical Devices ("SaMD"), as well as a new concept to further accelerate the launch of new products. This guidance is only available in Japanese.

This newsletter focuses on SaMD and provides an overview of the relevant legislation in Vietnam, a country that has been attracting increasing attention in recent years among Asian countries, focusing on the medical device status of SaMD and their classification of medical devices.

II Overview of medical device regulation

1. What is a medical device?

In accordance with Article 2.1 of Decree 98/2021/ND-CP ("Decree 98"), a medical device is defined as any instrument, implant, apparatus, material, in-vitro reagent or calibrator, or software that satisfies all of the following requirements:[3]

a) It is intended, by the medical device owner, to be used, whether separately or in combination, for human beings for one or more of the following purposes:
   (i) To diagnose, prevent, monitor, treat or reduce disease, or to make up for injury or trauma;
   (ii) To investigate, replace, modify or support the anatomy or a physiological process;
   (iii) To support or sustain life;
   (iv) To control conception;

1 https://www.mhlw.go.jp/hourei/doc/tsuchi/T230530I0080.pdf

2 The term "Software as a Medical Device (SaMD) is defined by the International Medical Device Regulators Forum (IMDRF) as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device." (IMDRF "Final Document: Software as a Medical Device (SaMD): Key Definitions" (December 9, 2013))
https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf

3 Article 2.1 of Decree 98 of the Government dated 08 November 2021 on management of medical devices, as amended by Decree 07/2023/ND-CP.

(v) To disinfect medical devices; or,

(vi) To provide information serving diagnosis, monitoring or treatment through examination of specimens derived from the human body.

b) It does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means to serve the purposes mentioned in item (a) as above.

2. The regulation on medical devices

The following key procedures shall be carried out for the distribution of medical devices in Vietnam.

- Carrying out the classification of medical devices in accordance with Article 5 of Decree 98. The Classification has four (4) categories; class-A, class-B, class-C, and class-D. The classification of medical devices must be carried out by the entity whose name is specified in the declaration of applied standards or certificate of circulation of medical devices.

- Carrying out the procedure for declaration of applied standards for class-A or class-B medical devices by submitting an application to the Department of Health ("DOH") in accordance with Article 28 of Decree 98 if the medical device is classified as a class-A or class-B medical device; or the procedure for registration of circulation by submitting an application to the Ministry of Health ("MOH") in accordance with Article 32 of Decree 98 if the medical device is classified as a class-C or class-D medical device; or import license if the medical device falls within the scope of Article 48 of Decree 98.[4]

III SaMD can be qualified as a medical device in Vietnam?

As mentioned above, the definition of medical devices under Decree 98 includes software. Other than this, there is no specific guidance or further definition on which software shall be considered as satisfying of the above criteria and will then be considered as a medical device. Therefore, in Vietnam, even SaMD will be regulated as a medical device if it meets the above requirements for a medical device.[5]

IV Classification of medical device in Vietnam

Article 5.5 of Decree 98/2021/ND-CP says that "the Minister of Health shall provide detailed guidelines on classification of medical devices in accordance with ASEAN's treaties on classification of medical devices to which Vietnam is a signatory." In this regard, the Minister of Health issued Circular No. 05/2022/TT-BYT dated August 1, 2022 detailing a number of articles of Decree 98/2021/ND-CP which, however, fails to provide sperate rules applicable specifically to medical device software.

V Consultation service to classify medical devices

There is no consultation service provided officially by the Vietnamese authorities. Alternatively, for professional consultation service concerning medical device classifications, there are several consultation service providers in Vietnam.[6]

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4 Article 22.1(a) of Decree 98.

5 Please note further that there is no legal provision guiding the method/criteria to determine a SaMD under current regulations.

6 Please refer to the entity specified under the following link (only available in Vietnamese): https://dmec.moh.gov.vn/cong-khai-phan-loai-ttbyt?p_p_id=vanbancongkhaipl_WAR_trangthietbiyteportlet&p_p_lifecycle=0&p_p_state=normal&p_p_mode=view&p_p_col_id=column-1&p_p_col_count=1&_vanbancongkhaipl_WAR_trangthietbiyteportlet_jspPage=%2Fhtml%2Fttbyte%2Fportlet%2Fvanbancongkhaipl%2Fview.jsp

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This newsletter has basically focused on the qualification and classification of SaMD in Vietnam. We will continue to cover trends in regulations for Software of Medical Devices in other countries and regions, as well as an overview of regulations that may require attention in new digital health and life science-related businesses. Should you need further detailed information on this topic, please contact us directly.

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