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The Health Pod

Japan Medical Device Market – Healthcare Apps and Software as a Medical Device (SaMD)
Episode Guide

Overview of SaMD regulations in Japan

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Understanding how regulations apply to software as a medical device (SaMD) is critical to companies developing healthcare apps as it will significantly impact their business strategies. Before developing and launching a new product, companies should consider whether it will be treated as a regulated SaMD under the Pharmaceutical and Medical Devices Act (PMD Act). If a healthcare app is deemed to be an SaMD, strict regulations apply and regulatory approval or registration will be required to manufacture and sell it. On the other hand, however, if a healthcare app is deemed to be an SaMD, its developer can then apply for health insurance reimbursement in Japan. This episode will provide an overview of SaMD regulations in Japan and some specific examples.

1. Legal developments
   - In the past, only hardware was regulated under the PMD Act.
   - The PMD Act was expanded to cover software starting in 2014.
2. Software as a medical device
   - Any software used in the diagnosis, treatment or prevention of disease is treated as a medical device.
   - A case-by-case assessment has been established under the relevant court precedents and Ministry notifications to determine whether a particular healthcare app constitutes a medical device.
   - The Ministry of Health, Labour and Welfare (MHLW) has issued guidance on how to determine whether a software program constitutes a medical device.
3. Specific legal Issues in the SaMD business
   - Telemedicine SaMD is subject to the Japanese Medical Practitioners Act, which requires that the examination of patients be conducted in person, in principle.
4. Health insurance coverage for SaMD
   - For an SaMD to be eligible for health insurance reimbursement in Japan, the marketing authorization holder must submit an "application for health insurance reimbursement" (the "**Application**") to the MHLW and present the product to the relevant government officials.
   - The MHLW and an expert panel will hold a hearing and evaluate the Application. If they approve it, an outside advisory body called the Chu-I-Kyo will issue the approval and the applicant will negotiate the reimbursement price with the Chu-I-Kyo.
   - The first SaMD approved for reimbursement under the Japanese national insurance system is CureApp SC, a nicotine addiction treatment app developed by KK CureApp. KK CureApp has also developed other similar apps for which it is applying for insurance reimbursement.
5. Future outlook
   - Japan is the world's second-largest market for medical devices. The healthcare and pharmaceutical industry is one of the top-10 most funded sectors by Japanese VC firms. More investment and innovation will be seen in this area.

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