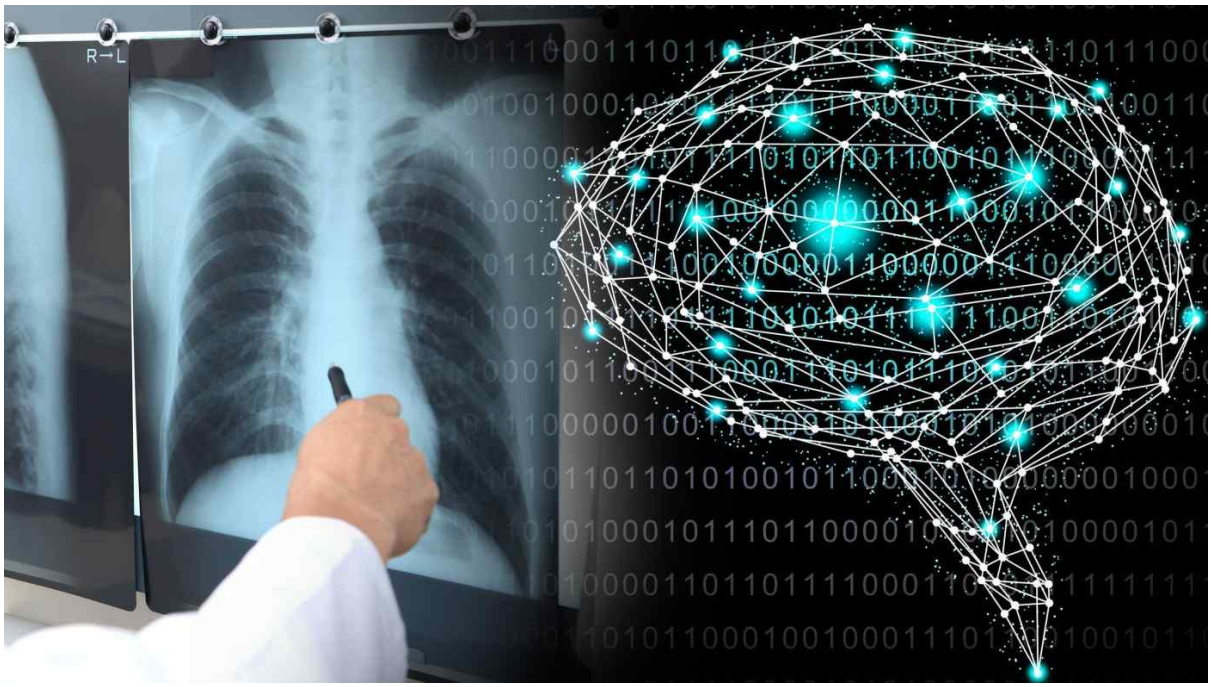
Japan to ease regulations on medical AI software

Government to allow updates without regulatory approval, shorten review process



Japan plans to allow companies to update medical artificial intelligence software without regulatory approval by the end of 2022.

TOKYO -- The Japanese government is planning to ease regulations for medical artificial intelligence software to boost the domestic market, Nikkei has learned.

The government is considering cutting the need for regulatory approval to update such software as early as by the end of 2022. This will make it easier for companies to improve software performance and to detect diseases more quickly. The medical software market is dominated by foreign companies, and the deregulation is aimed at helping the domestic market recover.

The software, known as software as a medical device or SaMD, uses technologies such as AI to help doctors diagnose diseases. For example, it is used to detect shadows and lesions from X-ray images of a patient's chest, or predict the presence of tumors from endoscopic images of the colon.

The domestic market for diagnosis and medical treatment support AI is expected to expand from 300 million yen ($2.6 million) in 2019 to 10 billion yen in 2025, according to a report by Yano Research Institute in December 2020.

The number of software approved in Japan is around 20, below one-sixth that of the U.S. and under half that of South Korea. Japan considers and examines every software update as if it were a new product, but the regulatory change will eliminate that process. It is also planning to shorten initial product reviews.

It often takes two to three months in Japan to start the review process after authorities receive an application. The review itself can take several more months. This is in addition to the re-examination for renewal. The Ministry of Health, Labor and Welfare is considering announcing the areas it focuses on during the review process, as well as the evaluation criteria for safety and efficacy.

The health ministry is also reviewing a rule that requires hands-on management of software by a technical supervisor. This rule makes it difficult for such staff to work away from the office.