Baker McKenzie.

The Health Pod

Japan Medical Device Market – Distinguishing Features and Industry Practice

Episode Guide

Overview of the medical device industry in Japan

Overview of the medical device industry in Japan

Japan is widely regarded as the No. 2 market for medical devices in the world after the US and is very much a growth market. The below is a snapshot of the Japanese medical device industry.

1. NHI System
   - Japan has a universal health insurance scheme (National Health Insurance; "NHI"), under which all Japanese citizens and residents must be enrolled in and pay premiums for national health insurance. The NHI contributes to the delivery of high-quality medical services and products to patients in Japan.
   - Under the NHI system, the price which will be reimbursed by the NHI is determined on a per-product or per-procedure basis. This is also the basis for the pricing of medical device products to be sold by medical device companies to wholesalers.
2. Supply chains
   - In Japan, medical devices are very frequently supplied to hospitals through distributors often called "dealers."
   - Medical device dealers in Japan play an important role in providing a wide range of technical support for healthcare professionals in collaboration with medical device manufacturers.
3. Regulatory framework
   - The marketing authorization holder for a medical device is primarily responsible for its quality control and post-sale safety management.
   - Regulatory approval is required for each medical device to be distributed in Japan. The necessary procedure is determined based on a device's category (i.e., Class I, II or III).
   - Clinical trials are required if the efficacy and safety of a product cannot be verified solely based on non-clinical studies or performance tests.
   - The MHLW has been trying to shorten the regulatory evaluation period in recent years. Medical device approvals are currently being granted approximately six months to one year from receipt of the application.
4. Market entry strategy
   - Foreign medical device companies can enter the Japan market by establishing (i) a Japanese entity which will hold the Marketing Authorization, (ii) a distributorship relationship with a Japanese distributor which will hold the Marketing Authorization or (iii) a D-MAH framework under which the foreign manufacturer will hold the Marketing Authorization and retain a Japanese D-MAH entity which will be responsible for regulatory matters.
5. Digital transformation
   - Many companies are making significant investments in digitalization of various aspects of their businesses.
   - This new trend has given rise to a number of new issues, including data privacy and regulatory issues.

Baker McKenzie.

The Health Pod

Speakers

Chris Hodgens

chris.hodgens
@bakermckenzie.com

Partner | Tokyo

Ryosuke Tateishi

ryosuke.tateishi
@bakermckenzie.com

Partner | Tokyo

Wabi Tanaka

wabi.tanaka
@bakermckenzie.com

Associate | Tokyo