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China's Greater Bay Area Offers Medtech Harmonization Zone For Hong Kong

by Ashley Yeo

Medtech businesses in both Hong Kong and mainland China stand to gain from the Guangdong Hong Kong Macao Greater Bay Area plan, according to China's medtech regulator, the NMPA.

One of the outcomes of the China's Greater Bay Area initiative will be the creation of more mutual recognition of device regulatory approvals between mainland China and Hong Kong.

If a device is approved in Hong Kong – which still uses a system of voluntary approvals – it can also be sold in the Greater Bay Area of mainland China. It could be seen as a way reaching China by the back door, according to one local medtech regulatory expert.

In some ways it is an experiment to create faster progress in medtech regulation, which is an aim of China. The Greater Bay Area initiative might also be likened to an "ASEAN system for China" in its drive to create a region with harmonized regulatory principles.

Bay Area initiatives are now starting up in the wake of the drafting by ministers and national authorities in November 2020 of the Work Plan for the Innovative Development of the Regulation of Drugs and Medical Devices in the Guangdong-Hong Kong-Macao Greater Bay Area of China.

The plan enables Guangdong Province's Pearl River Delta cities (Guangzhou, Shenzhen, Zhuhai, Foshan, Huizhou, Dongguan, Zhongshan, Jiangmen and Zhaoqing) to use, in cases of urgent clinical need, devices and drugs already sold in Hong Kong and Macao. The regulatory oversight for this will be provided by the government of Guangdong Province, according to legal firm CMS' Law-Now portal.

Hong Kong Regulatory Activity Update

A recent activity update from Hong Kong's Medical Device Administrative Control System

(MDACS) confirmed that the deadlines of trial schemes for listing medical devices approved in China and South Korea had been extended.

Devices with marketing approvals obtained from China's National Medical Products Administration (NMPA) may continue to be used in Hong Kong until 30 June 2021. The same extended deadline also applies to products approved by South Korea's Ministry of Food and Drug Safety (MFDS).

These products enjoy quicker assessment, akin to a priority review, in Hong Kong under these trial schemes. Hong Kong already gives priority reviews to some CE marked and US Food and Drug Administration approved products.

The MDACS has also extended its trial scheme for the expedited approval of class II, III and IV general medical devices until 31 December 2021. The scheme now dispenses with requirementsor products entering the Hong Kong market that previously asked for: at least three years' in-country regulatory approval; and at least one substantially equivalent device being listed on the MDACS.

Hong Kong's system of device regulation remains voluntary, but a new bill is being refined that would make product registrations mandatory. However, at the current rate of progress, barring unforeseen events, the bill will not be passed for another two to three years, according to the local consensus.

Bay Area Aims In Health Care By 2022

CMS detailed the scope of on the Greater Bay Area initiative for devices and drugs in a recent *website article*. Among other things, the work plan aims by 2022 to:

- Set up cooperation in medical and health care services locally;
- Establish a system and mechanism for local medical institutions to use drugs and medical devices that are already sold on Hong Kong and Macao markets;
- Stimulate the development, production, circulation and use of drugs and medical devices locally; and
- Site device and drug production facilities in the Greater Bay Area to serve Hong Kong and Macao.

By 2035, the plan foresees a medical device supervision and coordination mechanism covering the whole Greater Bay Area. It is claimed that this will attract local and multinational healthtech companies that wish to expand in Hong Kong and the mainland China Greater Bay Area.

The MDACS received 1,747 applications for medical device approvals in 2020, 2% down on 2019. A total of 1,458 products were approved (+0.3%). New IVD applications were up by 161%, at 149 products, and IVD approvals were up by 54%, at 37.