MEDTECH INSIGHT
CITELINE COMMERCIAL

07 Jun 2024 | **News**

Greater Bay Area Device Adoption Can Be A Steppingstone To China Uptake

White Paper Says Innovative Products Stand To Benefit Most

by Ashley Yeo

Medical devices from Hong Kong and Macao selected for use in the Guangdong-Hong Kong-Macao Greater Bay Area may potentially be fast-tracked for adoption across mainland China, according to a new industry white paper.

A multi-sector initiative signed in 2017 in the presence of Chinese president Xi Jinping to set up the Guangdong-Hong Kong-Macao Greater Bay Area (GBA) is now increasingly being leveraged by medical device and drug companies with products listed for use in public hospitals in Hong Kong and Macao.

In 2021, the Guangdong Provincial Medical Products Administration (MPA) and the health commission of Guangdong Province introduced interim regulations setting up a system to cover urgent clinical needs in China. The GBA has a population of some 86 million. *(Also see "China's Greater Bay Area Offers Medtech Harmonization Zone For Hong Kong*" - Medtech Insight, 3 Jun, 2021.)

As of early 2024, at least 28 companies' devices had been designated as necessary by the GBA, according to a new white paper coordinated by the Asia Regulatory Professional Association (ARPA). The GBA comprises Guangdong province's nine municipalities, including Shenzhen and Guangzhou, as well as the "special administrative regions" of Hong Kong and Macao.

Yet to be officially released, the white paper shares experiences of device companies who view product usage in the GBA as a potential precursor to future approval by China's National Medical

Products Administration (NMPA), said ARPA secretary general Jack Wong. Nineteen designated GBA healthcare institutions can access products not yet available in China.

This brings opportunities to drive sales revenue, especially of high-value devices and drugs for treating and diagnosing of rare diseases. Companies can also collect real world data for establishing a platform for collaboration with mainland China. Other companies must use the standard NMPA application route.

The white paper seeks to raise awareness about the Greater Bay Area initiative. “There is a good perception about the ability of companies already in Hong Kong and China increasing their business and investment opportunities,” Jack said.

Getting Innovative Devices Into China

Using the Hong Kong route, especially, as a potential pathway into the GBA, could be particularly advantageous for overseas companies seeking to bring innovative devices into China, given that Hong Kong has voluntary device registration and no requirement for device listing, he noted.

The GBA health care institutions decide which products are needed, but the scheme is most relevant to innovative products. The intention is not to duplicate products already available in China.

For a product to qualify for consideration, the company must present approval documents showing listing, purchase and use in Hong Kong or Macao, as well as documents showing country of origin.

Among other requirements, the company must also submit risk assessments of racial difference, evaluation of the level of advancement of the technology and an evaluation of the clinical urgency and need locally.

The GBA’s review process typically takes 20-35 working days.

The ARPA white paper advises applicants to:

- Initiate an education/communication platform for medical staff;
- Grasp opportunities for incorporating real world data generated in GBA into supporting clinical evidence for an NMPA registration; and
- Optimize collaboration between regulatory affairs and medical affairs.

It also recommends that companies form taskforces to organize and coordinate their affairs from mainland China. Jack added: “With different regulations and standards between GBA cities, having a dedicated task force can ensure that companies comply with all necessary regulations and streamline the process.”

Moreover, different teams from the mainland, Hong Kong and Macao can organize regular discussions to help develop pharmacovigilance modules, risk minimization measures and product recall and quality complaints systems.

Committing to these and many other necessary measures will narrow the culture gap between mainland China and the two special administrative regions, Jack added. It will also enhance communication between the stakeholders of the region.

Jack Wong is a member of the editorial board of *In Vivo*, Medtech Insight's sister publication. He can be contacted about the white paper at *jack.wong@ARPAedu.com*