COVINGTON

China Launches New Product Pathways in Hainan Special Zone

March 4, 2019

Food, Drugs, and Devices

On December 29, 2018, the State Council (China's chief executive agency) opened a new pathway for drugs to come into China through a special zone in southern China. It suspended certain central regulations in the Bo Ao Lecheng International Medical Tourism Pilot Zone in Hainan Province ("Pilot Zone") and permitted local authorities to make marketing decisions for the Pilot Zone, pursuant to the "Decision of the State Council on Tentatively Adjusting the Implementation of the 'Regulations on the Implementation of the Drug Administration Law' in the Bo Ao Lecheng International Medical Tourism Pilot Zone, Hainan Province" ("Drug Decision").

The Hainan Province People's Government ("Hainan") can now approve a patient's application submitted through a medical institution in the Pilot Zone for special importation of a small amount of unapproved chemical and biological drugs (excluding vaccines) offered by a foreign manufacturer. The drug must be necessary to meet urgent clinical needs.[1] The authority to approve special importation of unapproved drugs has previously belonged exclusively to the National Medical Products Administration ("NMPA").

Hainan can also independently approve devices that meet this criteria. Previously, NMPA (and its predecessor, the China Food and Drug Administration) reviewed these drug and device applications for the Pilot Zone on an expedited basis. Therefore, these changes will likely greatly improve the efficiency of importing medical devices and drugs in Hainan.

This alert highlights the key aspects of this development and of the Pilot Zone generally that have occurred over the last six years.

Establishment of the Pilot Zone

The Pilot Zone is located in Qionghai, Hainan, in the southernmost region of China. The Pilot Zone was first established in 2013 and included fast-track approval for new drugs and medical devices, extended the time foreign physicians to practice medicine in China (one to three years), relaxed the restriction on foreign investment and ownership in medical institutions, and reduced tariffs on certain drugs and medical devices.

[1] 国务院关于在海南博鳌乐城国际医疗旅游先行区暂时调整实施《中华人民共和国药品管理法实施条例》有关规定的决定, http://www.nhc.gov.cn/bgt/gwywj2/201901/b59a557f208d4dbfab51c3b4082cbf47.shtml.

Hainan also issued a Ten-Year Medical Industry Development Plan for the Pilot Zone in 2015, aimed at making the Pilot Zone a leading healthcare and wellness tourist destination within next decade through a series of preferential policies and projects.[2]

China accelerated the development of the Pilot Zone beginning in 2017 by launching dozens of medical institutions. The Pilot Zone currently provides services in the areas of oncology, assisted reproduction and *in vitro* fertilization ("IVF"), stem cell therapy, plastic surgery, and anti-aging and medical cosmetology. Even before the issuance of the Drug Decision, several drugs had already received expedited approval from NMPA for use in the Pilot Zone.

The central government significantly advanced the regulatory regime for the Pilot Zone in 2018. The State Council issued two documents, the "Decision of the State Council on Suspending the Implementation of the 'Medical Device Administration Rules' in the Bo Ao Lecheng International Medical Tourism Pilot Zone" (Medical Device Decision),[3] and the most recent Drug Decision. These documents gave Hainan the power to approve the use of unregistered foreign medical devices and drugs described above for urgent clinical use. This program is the first of its kind in China.

Specifics of Special Approval of Imported Drugs and Medical Devices

These decisions on special approvals for imported drugs and medical devices partially fill a gap that has existed for a long time in China's regulations for a named-patient exception to normal drug and device approval procedures.

Prior legislation has been implemented only narrowly or not at all. For example, China's Drug Administration Law ("DAL") contains an urgent clinical needs exemption, but it has been used in a very limited fashion, such as when there is an outbreak of disease. An expedited pathway also exists for "emergency devices" with similar criteria, and does not provide relief for one or a limited number of patients.

NMPA issued a draft proposal for a compassionate use and expanded access pathway in 2017, but it has not been finalized. The new Drug Decision and Device Decision have opened the door for the Pilot Zone much wider than these prior exemptions and streamlining the approval process to make it more accessible and efficient.

Special Approval of Medical Devices

The Medical Device Decision granted Hainan special approval power for Class II and III devices, which must normally be approved by the NMPA after a technical review by the Center for Medical Device Evaluation.[4] Hainan may approve imported medical devices marketed

---

[2] 海南博鳌乐城国际医疗旅游先行区医疗产业发展规划纲要（2015-2024 年), http://xxgk.hainan.gov.cn/hi/HI0101/201504/t20150403_1543452.htm.

[3] 国务院关于在海南博鳌乐城国际医疗旅游先行区暂停实施《医疗器械监督管理条例》有关规定的决定, http://www.gov.cn/gongbao/content/2018/content_5283176.htm.

[4] The Medical Device Decision suspended Article 11 of the Medical Device Supervision and Administration Regulation, which requires pre-approval of imported Class II and III devices.

abroad that are urgently needed for clinical use for patients receiving treatment in certain medical institutions in the Pilot Zone.

The application for qualifying devices must be submitted by a licensed medical institution in the Pilot Zone.[5] The medical institution must be a Class A / Level Three hospital, the top tier of hospital in China, and one with advanced medical technology and personnel to manage the risks associated with more complex products and procedures.

Although the medical institutions submit the applications, most of the documents must be provided by the foreign manufacturer. The foreign manufacturer must enter into a supply contract with the medical institution and provide documentation related to the device's marketing outside of China, including information about the manufacturer itself, evidence of foreign approval and other safety and effectiveness information from abroad, i.e., clinical study reports, an evaluation of differences in the ethnic makeup of the subject population, design specifications and manufacturing information, post-market safety reports and product and label samples.

Medical institutions submit these materials first to the Hainan's Provincial Health Commission to evaluate the medical institution and the patient's urgent clinical need for the medical device. The health administration's review opinion then goes to the Hainan Provincial Food and Drug Administration ("HPFDA"). At this time, among other documentation, the institution must also submit a written commitment to use the device in accordance with the declared purpose. The HPFDA will review the application and make the final decision.

The manufacturer can use the data collected through the use of the device in the Pilot Zone to support the device's application with NMPA for nationwide marketing.

Special Approval of Drugs

Similar to the Device Decision, the Drug Decision suspended certain existing drug regulations,[6] which require that special importation applications be submitted to NMPA. A patient may submit an application through a medical institution in the Pilot Zone. Hainan has not yet issued specific procedures for the application process, including how the manufacturer and institution cooperate on a patient's application.

Hainan will implement traceability systems for specially imported drugs and supervise their use. To that end, it has established a "special approval drugs supervision platform." Every imported drug has its own unique tracking code.

Hainan has also established a bonded warehouse for foreign drugs in the Pilot Zone to facilitate the importation of these drugs. Specially approved imported drugs are stored in the bonded warehouse in advance of their use, and patients can obtain the drugs promptly after they have received the approval of their special application for their use.

---

[5] 海南省人民政府关于印发海南博鳌乐城国际医疗旅游先行区临床急需进口医疗器械管理暂行规定的通知, http://hifda.hainan.gov.cn/zwgk/tzgg/ylqxgg/201805/t20180514_2625948.html.
[6] Article 36 of the Regulations for the Implementation of the Drug Administration Law.

Drug and device companies should continue to monitor developments in the Pilot Zone, including those related to the application procedures associated with the Drug Decision.

If you have any questions concerning the material discussed in this client alert, please contact the following China-focused members of our Food, Drugs, and Devices practice:

John Balzano	+1 212 841 1094	jbalzano@cov.com
Aaron Gu	+86 21 6036 2607	agu@cov.com
Muyun Hu	+86 21 6036 2519	mhu@cov.com