

Understanding the Preferential Policies and Opportunities at Hainan Boao Lecheng International Medical Tourism Pilot Zone, China

By Noam David Stern, Co-founder & Partner at **Nordic Life Science Partners** (30 March 2023)



Chinese Healthcare Reforms

On **11 March 2021**, China published its **14th Five-Year Plan (2021-2025)** that among others presents a detailed national strategic development plan to build a strong public healthcare system in China in which the government will further promote the **“Healthy China 2030”** plan and deepen the reform of the healthcare system by expanding the supply of high-quality medical resources.

Moreover, with the released plan for the [Hainan Free Trade Port](#) on **1 June 2020** and the latest **“Catalogue of Encouraged Industries in Hainan FTP”** issued on **27 January 2021**, special incentives are granted to companies within e.g., “Health services such as high-end professional medical care, rehabilitation and nursing” and the “Application of high-end medical equipment and new medicines”.

Hainan Boao Lecheng International Medical Tourism Pilot Zone

On **28 February 2013**, the State Council approved the establishment of the Hainan Boao Lecheng International Medical Tourism Pilot Zone (HBL), but it was not before **16 September 2019** that the **“Implementation Plan for Supporting the Construction of Boao Lecheng International Medical Tourism Pilot Zone”** was released.

With the Implementation Plan, HBL was granted **preferential policies and incentives** with the aim to create a world-class international medical destination and cluster for advanced medical treatment, professional rehabilitation, medical R&D, and technological innovation in China.

Layout and Capacity

HBL is planned to cover 25 km² with a total of 3 km² of constructed land. Currently, 13 hospitals and 5 medical service centers are in operation with 8 new hospitals opening in 2023, and ten more planned. Total construction costs are estimated at **RMB 100 billion (USD 16 billion)**.

When completed, it will provide 12,000 hospital beds, employ 28,500 medical personnel including 3,500 R&D staff, and receive up to 300,000 patients annually. In 2022, a total of 189,300 medical tourists were welcomed.

Location – Getting There

- Lies 7.3 kilometers from Boao Airport, and 3.7 kilometers from Boao Railway Station with high-speed train links. The driving distance by train or car from Haikou is 1 hour and 15 minutes.
- Flying time from Beijing to Haikou is 4 hours while it is 2 hours and 45 minutes from Shanghai and 1 hour and 15 minutes from Guangzhou, Shenzhen, and Hong Kong. Direct flights between Shanghai and Boao Airport take 3 hours and 20 minutes.



Special Policies for Fast-track Approval Procedure of Medical Devices and Medicines in HBL

On **17 September 2021**, the Hainan Provincial Medical Product Administration, Health Commission of Hainan Province, and Haikou Customs jointly issued the **“Several Measures to Further Optimize Regulatory Services to Support the High-Quality Development of Hainan Boao Lecheng International Medical Tourism Pilot Zone”**.

They aim was to simplify and speed up the examination and approval process of imported medicines and medical devices and improve the effectiveness of regulatory services.

On **15 October 2021**, the Hainan NMPA published the “**Guidelines for the Declaration of Urgently Needed Imported Drugs and Medical Devices in the Boao Lecheng International Medical Tourism Pilot Zone of Hainan Free Trade Port**”.

They outline the detailed application procedures and materials needed to get imported medical devices and medicines in urgent need approved for use by the individual hospitals in HBL.

On **25 March 2023**, the People’s Government of Hainan Province issued the “**Notice on ... the Administrative Regulations on Imported Drugs and Medical Devices Urgently Needed for Clinical Purposes in Boao Lecheng International Medical Tourism Pilot Zone of Hainan Free Trade Port**” that takes effect on **1 May 2023**.

It outlines the approval procedures and responsibilities for the import and use medical devices and medicines that have not yet been registered in China but approved overseas.

Qualification Criteria

To qualify, the medical device or medicine 1) Cannot have been approved for registration in China but approved overseas for sale with CE mark, FDA license or PMDA approval, 2) Cannot be replaced by an already approved predicate in China, and 3) Shall be used for a specific medical purpose at designated medical institution.

The **special fast-track approval procedure** makes it easier and quicker to register, import, sell, and test medical devices and medicines in urgent need for use by the individual hospitals in HBL.

Real-World Evidence Studies

HBL is also the only place in China that allows the collection of Real-World Data (RWD) from the use of medical devices and medicines imported under the fast-track approval procedure that can supplement the application for the NMPA registration which can accelerate the approval process for selling in the rest of mainland China.

Nordic Life Sciences Platform

The Nordic Life Science Platform ApS (NLSP) aims to give Nordic life science companies a more safe, efficient, and easier access to the China’s healthcare market and to take advantage of the preferential

policies and opportunities at HBL that can serve as a gateway and stepping stone to the mainland China market. NLSP has offices in Copenhagen and Shanghai.

NLSP is a **one-stop service platform** that delivers a **Step-by-Step Market Entry Model** with supporting services that helps Nordic companies to explore and enter China's healthcare market but also give them the option to stop or wait with the next step during the process.

To explore these market opportunities closer, NLSP has established a Partnership with the Danish Life Science Cluster, Innovation Center Denmark in Shanghai, and The Trade Council China with the support of Medtech Denmark.

To learn more, please visit www.nlsp.dk and contact us.