



NORDIC LIFE SCIENCE PLATFORM

- Fast-track China Entry
Medtech, Healthtech, and Drugs

www.nlsp.dk

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NLSP – China Entry Barriers

- Although China is the **world's second largest market** for both medical devices & drugs, many foreign companies hold back from doing business in China mainly due to lack of market knowledge and real/perceived **entry barriers** and therefore consider it too **difficult and risky**.
- This **uncertainty and doubt** include among others:
 - ❖ Geopolitical tensions
 - ❖ Language barriers
 - ❖ Poor IPR protection
 - ❖ Forced technology transfer
 - ❖ Unfair local competition
 - ❖ Growing/hidden protectionism
 - ❖ Unfamiliar payment & reimbursement models
 - ❖ Complex registration procedures
 - ❖ Unclear public procurement rules
 - ❖ Unknown distribution channels
- To **lower the entry barriers and reduce risks**, NLSP presents a team of professionals with many years of know-how and experience from supporting foreign companies in China.

NLSP – Purpose & Mission

- To give foreign life science companies a **safer, easier, and faster access** to the Chinese healthcare market by taking advantage of the preferential policies and opportunities at:
 - Hainan Boao Lecheng International Medical Tourism Pilot Zone (HBL)
 - Guangdong-Hong Kong-Macao Great Bay Area (GBA)
- To **match the demand** for innovative medtech, healthtech, and drugs by the hospitals at HBL & GBA **with the supply** of foreign life science companies to help them develop and access new sales/export opportunities in China.



NLSP – Geographical Area



Guangdong - Hong Kong - Macao Great Bay Area (GBA)



Hainan Boao Lecheng International Medical Tourism Pilot Zone (HBL)





Hainan Boao Lecheng – Background

National Medical Destination & Cluster

- On 10 September 2019, the State Council approved the “Implementation Plan for Supporting the Construction of Boao Lecheng International Medical Tourism Pilot Zone”.
- HBL granted **preferential policies and incentives** to create a world-class international medical destination & cluster for **advanced medical diagnosis, treatment, rehabilitation, R&D, and technological innovation** in China.

Status & Future Development

- Currently, a total of **31 private + 2 public general hospitals (Tier 3)** are in operation with another 10-15 planned or underway.
- Total construction cost estimated at RMB 100 billion (USD 14 billion).
- When completed by **2035**, it will cover 20 km² with 3 km² of constructed land, offer **12,000 hospital beds** and **employ 28,500 medical personnel**.
- In 2025, HBL received, **865,460 medical tourists** (+109.2%, Y-on-Y).

Hainan Boao Lecheng – Key Preferential Policies

Fast-Track Approval

- Makes it easier & quicker for the hospitals to procure, register, import, and use **innovative medical products** without the need for an NMPA approval.
- **Fast Review & Approval: 10 working days.**
- As of January 2026, **540 medical products** have been approved by Hainan MPA for exclusive use at HBL.

Main Eligibility Criteria

1. Product cannot have been approved in mainland China but needs **CE/FDA/PMDA/ICH member registration.**
2. Product shall be **innovative** and cannot be replaced by already approved predicate in mainland China.
3. **Sales agreement** for medical product to be signed first with HBL hospital applying for its specific use.

Real-World Data Study

First place in China where it is possible to conduct **RWD/RWE Studies** of the use of medical devices & drugs imported under the fast-track approval procedure that can supplement the application for the **NMPA registration** and **accelerate the approval process** to sell in all of mainland China.

Hainan Boao Lecheng – Other Preferential Policies

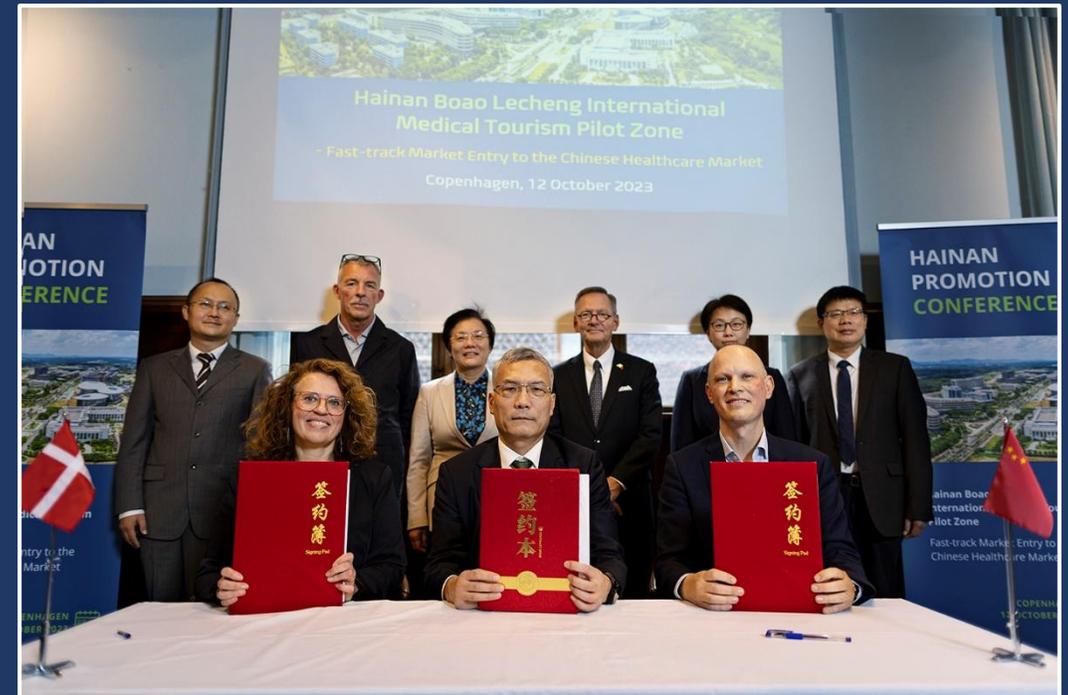
- 1) Medical institutions with an independent registered entity at HBL are **exempt from import duties and import VAT** on medical devices and drugs.
- 2) HBL allows the set-up of **wholly foreign-owned and JV medical institutions**.
- 3) HBL allows **foreign doctors and nurses** to practice at the hospitals for three years.
- 4) Products that have undergone a RWS at HBL can be included in the **national healthcare insurance reimbursement list**.
- 5) Qualified medical institutions and foreign-invested enterprises at HBL can engage in the development and application of **human stem cells, gene diagnostics, and therapy technologies** for product registration and manufacturing.
- 6) Overseas approved **Health Foods (dietary supplements) & Food for Special Medical Purposes** can be introduced and used at HBL without mainland China approval. (As of January 2026, 10 health foods and 3 specialty foods have been approved).

NLSP – Strategic Cooperation Agreement

On 12 October 2023, Nordic Life Science Platform, Danish Life Science Cluster, and the Lecheng Administration signed a Strategic Cooperation Agreement in Copenhagen, Denmark during a high-level medical delegation visit headed by Ms. XIE Jing, Vice Governor of Hainan Province.



Ms. XIE Jing, Vice Governor of Hainan Province.



Front from left to right: Ms. Diana Arsovic Nielsen, CEO of DLSC, Mr. JIA Ning, Director of Lecheng Administration, and Mr. Noam David Stern, Co-founder & Director of NLSP.

Great Bay Area – Background

National Development Plan

- On 18 February 2019, the State Council published the latest "Outline Development Plan for the Guangdong-Hong Kong-Macao Greater Bay Area".
- GBA is a designated geographical and economically integrated area including HK, Macao, and the nine-mainland cities of Dongguan, Foshan, Guangzhou, Jiangmen, Huizhou, Shenzhen, Zhaoqing, Zhongshan, and Zhuhai in Guangdong Province.

Status & Future Development

- As of 10 December 2025, the GBA consists of 71 designated hospitals (Tier 3) in Guangdong.
- As of 10 December 2025, 140 medical products have been approved by the Guangdong MPA for exclusive use at the designated GBA hospitals.

Great Bay Area – Key Preferential Policies

Fast-Track Approval

- Makes it **easier and quicker** for the designated GBA hospitals in Guangdong to procure, register, import, and use medical devices & drugs without the need of an NMPA approval.

Main Eligibility Criteria

- 1) Product cannot be replaced by a similarly approved product in mainland China.
- 2) Product needs HK or Macao registration.
- 3) Product needs to have been procured and used by a public hospital in HK or Macao.
- 4) Product shall be used for a specific medical purpose at designated GBA hospital.

Real-World Data Study

- GBA also offers the opportunity to conduct Real-World Data Studies that can supplement the application for the **NMPA registration** and accelerate the approval process to sell in all of mainland China.

NLSP – Step-by-Step Market Entry Program

- NLSP delivers a **Step-by-Step Market Entry Program** that supports companies all the way from exploring, entering, and/or expanding in the Chinese healthcare market with the option to stop after each step of the process to determine the next step.



NLSP – One Stop Service Platform

- NLSP reduces the challenges and time-to-market by offering **expert advice and supporting services** that are part of the different steps in the process such as:

- ❖ Project Management
- ❖ Legal Advice & Assistance
- ❖ IPR Protection
- ❖ Medical Expert Review
- ❖ Hospital Matchmaking
- ❖ Contract Negotiations
- ❖ Fast-track Product Approvals
- ❖ CRO Appointment & RWD Study Pre-communication
- ❖ RWD Study Implementation & New Medical Product Application
- ❖ NMPA Product Registrations
- ❖ Contact to Potential Distributors
- ❖ Contact to Potential Investors

- NLSP also cooperates closely with the hospitals and Chinese **national distributors of medical products** that can open doors to the mainland China market.

NLSP – Expert Advise & Support



Noam David Stern
Co-founder & CEO,
China & Denmark



Daisy Du
Legal Advisor
China



Sharon Xu
Medical Project Manager,
China & Germany



Peter Ølbye
Co-founder & Advisor,
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