# Boao Lecheng platform for the Turkish Pharmaceutical Industry October 11 2023 Webinar

Embassy of Turkey, China
IEIS
IKMIB
BOAO Lecheng Hengjun Business Services Co Ltd

# 1. There Is A Huge Demand in Chinese Medical Market

- 1.1. Aging Problems
- 1.2. Chinese tend to go abroad for medical need

# Age Composition and Dependency Ratio of Population

(10 000 persons)

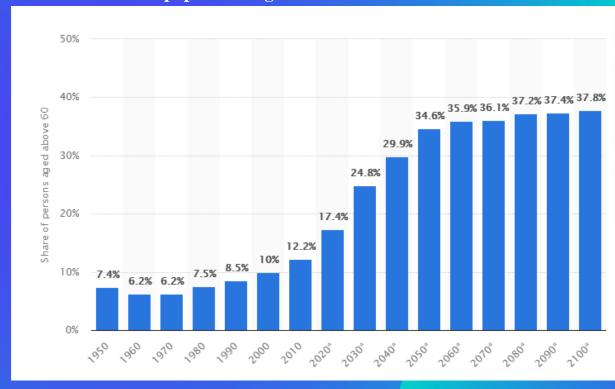
Source: China Statistical Yearbook 2020 (10 000 persons)														)
	Total	By Age								Gross	Gross Children		Elderly	
Year	Population	Aged	0-14	Aged	15-64		Aged 65	and Over Proportion		Dependency	Dependency	Depe	ndency	
	(year-end)	Population	Proportion	Population	Proportion	Po	pulation			Ratio(%)	Ratio(%)	Ratio(%)		
2010	134091	22259	16.6	99938	74.5		11894		8.9	34.2	22.3		11.9	
2011	134735	22164	16.5	100283	74.4		12288		9.1	34.4	22.1		12.3	
2012	135404	22287	16.5	100403	74.1		12714		9.4	34.9	22.2		12.7	
2013	136072	22329	16.4	100582	73.9		13161		9.7	35.3	22.2		13.1	
2014	136782	22558	16.5	100469	73.4		13755		10.1	36.2	22.5		13.7	
2015	137462	22715	16.5	100361	73.0		14386		10.5	37.0	22.6		14.3	
2016	138271	23008	16.7	100260	72.5		15003		10.8	37.9	22.9		15.0	
2017	139008	23348	16.8	99829	71.8		15831		11.4	39.2	23.4		15.9	
2018	139538	23523	16.9	99357	71.2		16658		11.9	40.4	23.7		16.8	
2019	140005	23492	16.8	98910	70.6		17603		12.6		Vindov <sub>23:8</sub> 置"以激活 Wind	ows.	17.8	

# **Aging Population**

In 2020, the total number of elderly people aged 60 and above in the mainland will be 264 million, already accounting for 18.7% of the total population.

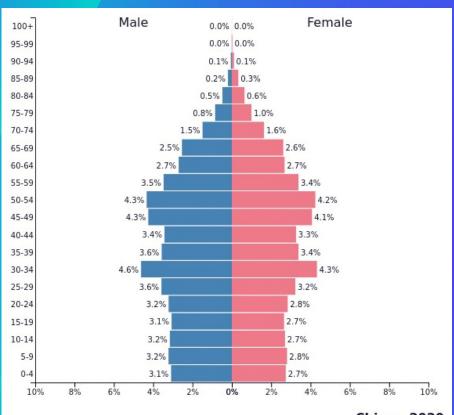
The graph shows the population share aged 60 and older in China from 1950 to 2010, with a forecast up until 2100.

### Share of population aged 60 and older in China 1950-2100



(Source: Office of the Leading Group for the Seventh National Census of the State Council)

### BOAO Lecheng Hengjun Business Services Co Ltd



PopulationPyramid.net

According to the data of the 7<sup>th</sup> National Population Census, the proportion of population aged 65 and above in China reached 13.50%, and the degree of population aging has been higher than the world average (9.3% of population aged 65 and above), but lower than the average of developed countries (19.3% of population aged 65 and above).

China - 2020 Population: 1,439,323,774

# 10 Common Chronic Conditions for Adults 65+



80% have have at least 1 chronic



68% have 2 or more chronic conditions



Hypertension (High Blood Pressure) 58%



**High Cholesterol** 47%



Arthritis 31%



Ischemic Heart Disease (or Coronary Heart Disease)



Diabetes 27%

29%



Chronic Kidney Disease 18%



Heart Failure 14%



Depression 14%



and Dementia 11%



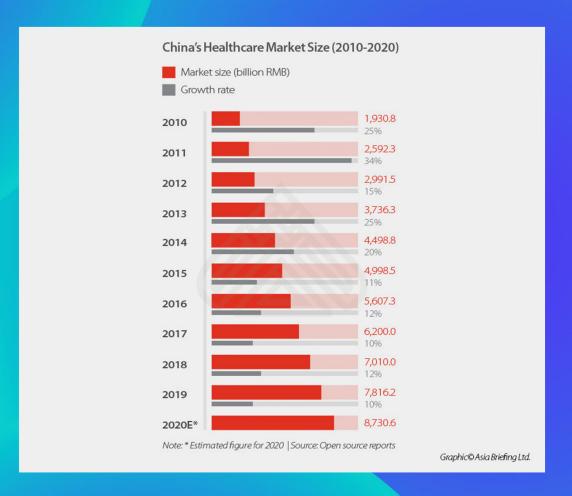
Alzheimer's Disease Chronic Obstructive **Pulmonary Disease** 11%

Common conditions in older age include hearing loss, cataracts and refractive errors, back and neck pain and osteoarthritis, chronic obstructive pulmonary disease, diabetes, depression, and dementia.

Furthermore, as people age, they are more likely to experience several conditions at the same time.

(Source: National Council on Aging)

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China healthcare industry is currently ranked the second largest in the world behind the US.

The market has grown at a consistently rapid rate in the past five years, and in 2019, the market reached RMB 7.82 trillion (US\$1.1 trillion), an increase of 10 percent when compared to that from the previous year.

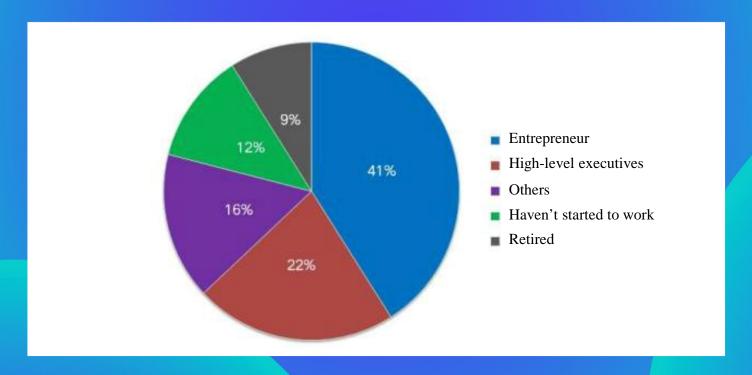
(Source: Open Source Report)

# 1. There Is A Huge Demand in Chinese Medical Market

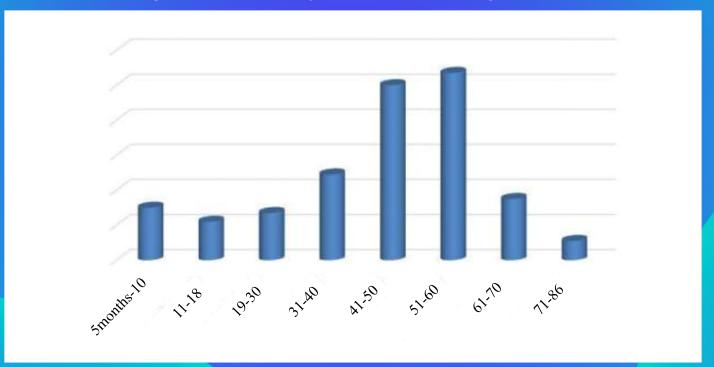
- 1.1. Aging Problems
- 1.2. Chinese tend to go abroad for medical need

- Since 2010, the demand of China's affluent class go abroad for medical treatment has increased dramatically. According to statistics, the size of China's overseas medical market has now reached US\$100 billion.
- In the United States, for example, Massachusetts General Hospital, affiliated with Harvard Medical School, received about 40 cases of Chinese patients in 2012, but the number jumped to about 100 cases in 2013.
- Statistics from industry information and consulting center Booz Data Research Center show that the number of patients receiving overseas medical treatment in China each year has grown from 20 million in 2006 to more than 50 million in 2014. According to this growth rate, the number of overseas medical visits has exceeded 60 million per year.

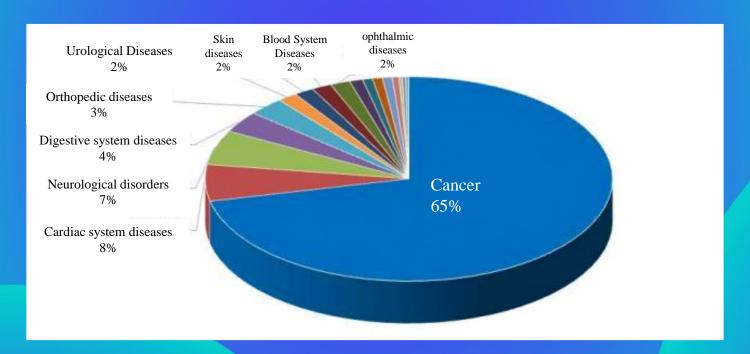
The patients who decide to go abroad are mostly of the affluent class.



The patients who decide to go abroad are mostly at their late middle age.



The patients who decide to go abroad are mostly suffering from cancer.



# Boao Lecheng International Medical Tourism Zone

- Target to serve foreign companies
- Express channel to bring in foreign pharmaceuticals and medical equipments
- Allow Chinese to access the latest treatments and medical technology within months after approval from overseas

# Geographical Advantages: Hainan is an island in the south of China

**Location: Only 25 minutes' drive from the permanent site of Boao Forum for Asia** 

The Hainan Boao Lecheng International Medical Tourism Pilot Zone is located between Qionghai City and the core area of the Boao Forum for Asia, along both banks of the Wanquan River. The planned land plot is 20.14 square kilometers, 9.96 square kilometers of which is designated for construction. It is within a 10-minute drive from Boao Airport, Boao High-speed Railway Station, Wenbo Expressway, and the East Line Expressway



Hainan Free Trade Port

# Chinese Government created Boao Lecheng Medical Zone in 2013

## Policy 1.0

On February 28, 2013, the State Council approved the establishment of the Boao Lecheng International Medical Tourism Pilot Zone in Hainan and issued nine unique and unprecedented supportive policies for it. Opening the "second chapter" of the Boao Forum for Asia.

The nine preferential policies of the state can be summarized as "4 special approvals"

# 

国际医疗旅游先行区的批复 海南省人民政府、发展改革委: 你们关于创建海南国际医疗旅游先行区的请示收悉。现我复

一。 网络彼立海南博鳌乐城园际医疗旅游先行区(以下简称 先行区)。 先行区位于城海市寨积镇城区均博鳌至湖地北核市区 之间的万泉河两岸。 规划范围20.14平方公里、其中建设用地规模 9.96平分分里。 (具体区影社点坐标包制、详见附件)

二。先行区发展要以邓小平理论。"三个代表"重要思想。 科学发展观为指导、依托当地生态资源,结点发展医疗。养老、 特研客国际医疗旅游相关产业。创建低碳低排放生态环境典范。 丰富相关规划国内外合作交流产台。

三、 先行区建设用地必须及时的人土地利用总体规划和城市 (镇) 是体级划,作为城镇建设用地批一规划管理,按照规定程 序履行用地级批子维、坚持节约集约用地的原则,以符合先行区 发展发促的产业力主导安持建设用地。

四。 同應先行区先行先试以下政策措施: (一) 加快先行区医疗器械和药品进口注册审批。对国外依法 批准上市、未获得我国注册批准的药品进口注册申请,可按照 新药注册特殊事批管理规定的要求,申请实行特殊审批;对于 医疗机构团临床免需型止少量药品的。可被每关法律法规要 求,向国务院药品监督管理部门提出申请,经批准后进口,进 口商品应占在每岁的部件组由规一并参写帐件目的。

(二)按照医疗技术临床应用管理办法和医疗技术临床研究有关规定实施医疗技术准入。先行区可根据自身的技术能力,申报开展干细胞临床研究等前沿医疗技术研究项目。

(三)卫生部门在审批先行区非公立医疗机构及其开设的 诊疗科目时,对其执业范围内实配各且符合配置标准要求的大 型医用设备可一并审批。

(四)境外医师在先行区内执业时间试行效宽至三年。海 南省人民政府可结合先行区自央实际,制定实施境外医校、医 护人员来先行区执业的相关办法,并假卫生郑备案;鼓励先行 区在中医预防循锁机构和人员准入。服务规范,以及服务项目 准入,效费等分割条行法点。

(五)允许境外资本在先行区内举办医疗机构。逐步取消合资或合作医疗机构的遗外资本股权比例限制。逐步放开境外资本在先行区设立轻资医疗机构。

(六)对于今后先行区靖雷进口的、关税税率较高的部分 医疗器械和药品,财政部要会同有关部门统筹研究适当降低进 口差程。

(七) 根据先行区开发建设实际,送当增加海南省新增建 设用地计划指标,涉及基本农田调整的。应按照国家法定程序 报款。 (八)支持并指导先行区引入生态。医疗、新能源等相关国际组织、采办国际会议。探索创建健康旅游国际组织。

(九) 鼓励先行区利用多种融资灌道, 吸引社会投资。支持 境内保险资金等长期资金在依法合规的前提下, 按市场原则投资 非安保和医疗机构。

海南省人民政府要积股税妥组织实施先行区创建工作。同时 如張市场管理,规范市场秩序。保障医疗旋游服务的质量。发展 改革要要每两有关部门加强对先行区指导和服务。及时应结先行 区建设中的经验、是善新法出现的新情况和新问题。重大问题及 即由但是各型组合

附件:海南博鳌乐城国际医疗旅游先行区建设用地界址点坐 标本



- 3 -



# 特许医疗

医疗技术、医疗人才、医疗器械和药品特许准入



# 特许经营

放宽部分医疗审批权, 允许境外资本进入和经营



# 特许国际交流

特许国际交流医疗组织,承办医疗会议



# 特许研究

开展干细胞临床研究等前沿医疗技术研究项目

- > Franchise Medical Care
- Franchise Operation
- > Franchise Research
- > Franchise International Communication

# Unique policies approved in 2019

国有企事业单位医疗卫

or tourism specialists from

力度。支持设立国家医

Promote high-end diagnosis

up medical tourism research

events and support to set

疗旅游研究院

### 公立医院品牌、商标、 技术、管理等授权区内 医疗机构使用

Use of brand, trademark, technology and other resources of public hospitals under franchise agreement.

### 干细胞等前沿医疗技术 研究项目转化应用、加 快国内注册

Accelerate domestic registration on products transformed from frontier medical researches

### 国外上市国内未上市药 品、医疗器械在园区医 疗机构使用

Permit use of drugs or medical devices that are foreign listed but domestic unlisted.

### 区内医疗机构患者带合 理自用量的进口药品离 开先行区使用

Allow patients to take reasonable units of imported drugs for self-use when leaving the zone;

### 真实世界临床数据应 用,设进口药品与医疗 器械审评分中心

Apply clinical real world data and set up evaluation center for imported drugs and medical devices.

### 先行区进口药品、医疗 器械临床使用数据用于 进口注册申请

Registration on imported drug or medical device using clinical data from medical institutions of pilot zone.

# 进口境外上市境内未上 加大高端诊疗宣传推介

Allow foreign listed but domestic unlisted healthcare products such as dietary supplement, health device and

调剂使用国内院内制

等实施备案管理

Deploy drugs from other

medicine on record rule.

剂, 中药制剂委托配制

hospitals and process designated traditional Chinese

先行区卫生系列高级专

业技术职称评审试行社

title for advanced workers in

health field applying market

会化评价机制

mechanism.

市保健食品、保健器材、

特医食品等

### 进口单克隆抗体等低风 险类特殊物品实施"先 入仓,后检疫" 新床试验机构,依法规 开展临床试验

"Entry first, inspection later" Top dor policy for low-risk imported instituti medical items like monoclonal conduct

Top domestic medical institutions set up labs and conduct clinical trials following legal regulations.

### 外籍患者及家属申请医 疗服务期私人事务类签 证或居留许可

Foreign patients and their families apply for visa or residence permit for their stay in the zone.

# the zone.

外籍医、护、技等人员 申请与工作期限一致工 作类居留许可

Foreign staff of doctors, nurses, technicians apply for residence permit to the extent of working period.

### 生、旅游专业人才在先 行区兼职兼薪 Part-time participation and World-famous medical schools

World-famous medical school jointly set up colleges and research institutions set up branches.

世界知名医学院联合设

### 区内医疗、研发机构等 牵头多中心临床试验视 为省部级课题

Clinical trial led by medical institutions of the pilot zone is regarded as provincial-level project.

### 引进和培育医疗类国际 组织和交流平台, 举办 博整健康论坛

Introduce the exchange platform with international medical institutes, hold annual Boao Health Forum.

### 开展国际药品及医疗器 械展销,设立境外厂商 售后服务中心

Undertake exhibition of international medical items, set up after-sales service center for foreign manufacturers.

### 取消健康险、人身险外 資限制,支持设立健康 和养老保险机构

No restriction on foreign investment in health or life insurance, support the health or pension insurance institution.

## Policy 2.0

In 2019, the National Development and Reform Commission, the National Health Commission, the National Administration of Traditional Chinese Medicine, and the National Medical Products Administration jointly issued the *Implementation Plan for Supporting the Construction of the Boao Lecheng International Medical Tourism Pilot Zone*.

- Special operation of public hospitals in the zone
- Real World Data application for NMPA registration
- > Imported Foods for Special Medical Purpose (FSMP) allowed for use
- > Patients can take medicines out of the zone for subsequent use
- Allow foreign doctors, nurses or technicians to practice in the zone ( 3 years)
- > Support foreign patients to apply for visa or residence service
- Lift the restriction of foreign direct investment on health and personal insurance
- Display of international medical products and establishment of aftersales service branch office

# More Unique Policies approved in 2021

### Policy 3.0

In 2021 With the approval of the CPC Central Committee and the State Council, the National Development and Reform Commission and the Ministry of Commerce release the *Opinions on Relaxing Market Access to Support Construction of Hainan Free Trade Port* 

- Supporting the sale of prescription drugs online: Establishing the Hainan Electronic
   Prescription Center in the Lecheng Pilot Zone
- Fully relaxing the market access restrictions for Contract Research Organizations (CROs)
- Supporting the innovative development of domestic high-end medical equipment in Hainan
- Supporting development of the high-end medical aesthetics industry in Hainan: Encouraging
  renowned medical aesthetics institutions to settle in the Lecheng Pilot Zone, where they are allowed
  to use large quantities of medical aesthetics products already marketed in countries or regions such as
  the US, the EU and Japan
- Optimizing the access and development environment for transplantation science across the board:
   Establishing an International Transplantation and Rehabilitation Center in the Lecheng Pilot Zone
- Establishing a mixed ownership reform fund for the development of the Hainan medical and health industry



# **Boao Lecheng Policy Summary**

- Drugs and medical equipment approved for use in Europe, United States, Japan and many countries are allowed to skip clinical trial and be used in Boao Lecheng. Approval time averages 6 months.
- Allow foreign doctors, nurses or technicians to practice in the zone
- Visa Free for Citizens of countries with China diplomatic relations
- Patients can take medicines out of the zone for subsequent use
- Doctors from Mainland China can bring patients to use the medicine
- Government insurance policy for use only in Boao Lecheng

# 26 Medical Institutions Up & Running 24 more under construction...

**Boao Research Hospital** 



**Boao International Hospital** 





**Boao Lecheng Aier Eye** Hospital



**Ruida Health Medicell International Health** 



Yingyi International Medical Center

Boao Evergrande International Hospital



Lecheng Shulan Hospital



Hainan Qiyan Stem Cell Anti Aging Hospital



China Stem Cell Group Hainan Hainan Xinshengquan Boao Affiliated Stem Cell International Cell **Boao Affiliated Stem Cell Hospital** 



Therapy Hospital



**Hainan Boao International Optometry** and Ophthalmology Hospital



**Raffles Hospital** 





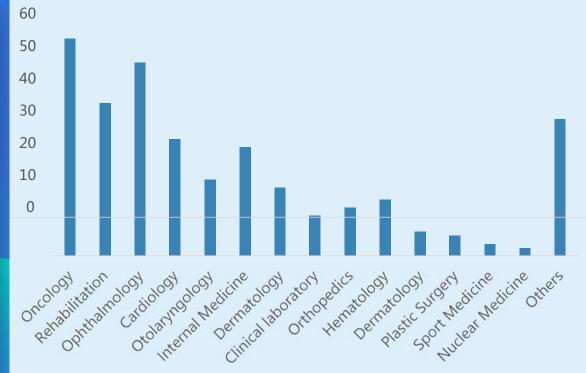




# **Excellent Track Record of Approving Medical Products**

As of August 2023, the Lecheng Pilot Zone had brought in 341 specially approved medical products, comprising 118 drugs and 223 medical devices, and has established partnerships with 120 multinational drug and medical device companies.







# Country source of products approved for sale in Boao Lecheng

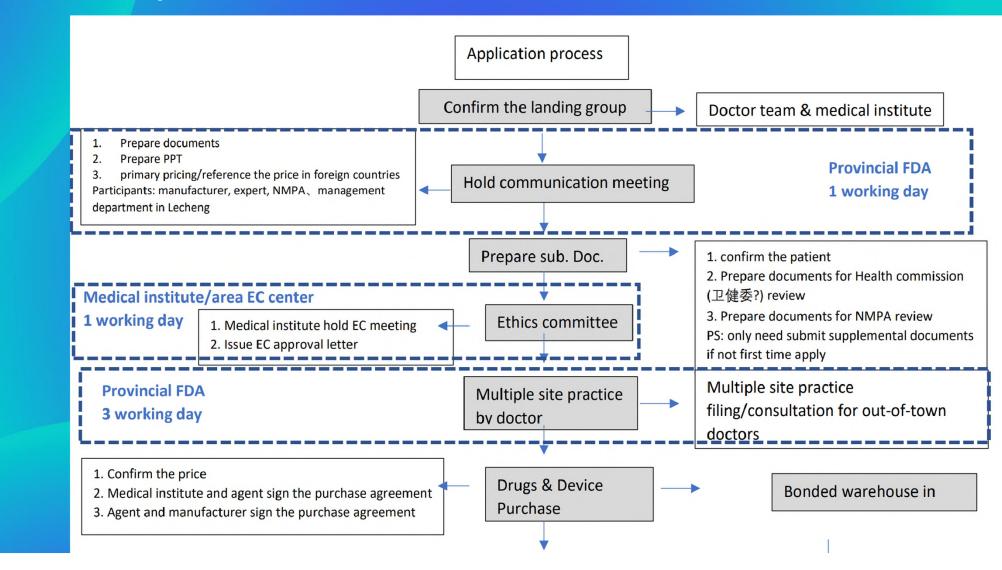


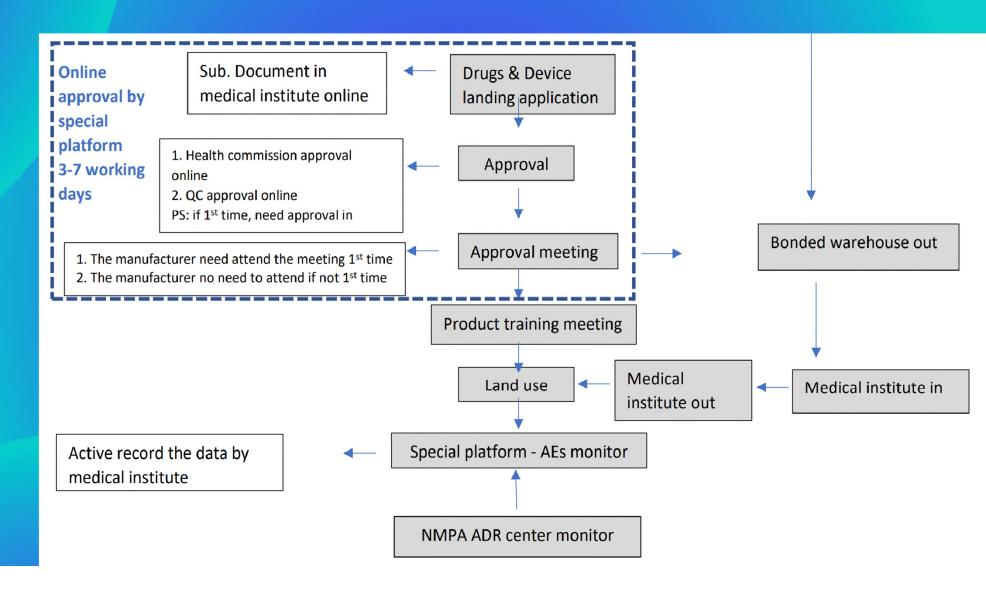
# How to get products approved for use in Boao Lecheng

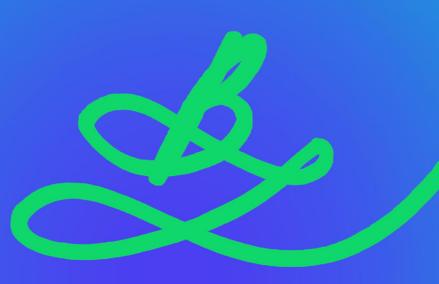
1. Special licensed medical product application process



# **Application and Aproval Process**







海南博鳌乐城恒俊商务服务有限公司 Hainan BOAO Lecheng Hengjun Business Services Company Ltd. We recognize that many overseas pharmaceutical companies find it difficult to market their products to BOAO Lecheng even with all the special and streamlined polices. Issues these companies face include but not limited to:

- Lack of funding to set up an office in BOAO Lecheng to hire local staffs to manage the approval process and market the products
- Unfamiliar with the approval process for new drugs and medical instruments
- No sales and distribution channels to market their products in BOAO Lecheng

### BOAO Lecheng Hengjun Business Services Co Ltd

Hainan BOAO Lecheng Hengjun Business Services Company Ltd. (AKA 海南博鳌乐城恒俊商务服务有限公司) jointly owned and managed by the BOAO Lecheng Administration (this is the government agency that oversees BOAO Lecheng) was set up with the mission to provide:

- A one stop end to end service for overseas pharmaceutical company who want to get their products approved and marketed to all the hospitals for use in BOAO Lecheng
- Services include:
  - Setting up the doctor team and medical institute needed to review the documentation for the drug. Manage all the needed communication and meetings with relevant parties. NO clinical trial is needed.
  - Working with the pharmaceutical company to :
    - Prepare for documents and PPT, including primary pricing / reference the price in foreign countries. This involves the manufacture, experts, NMPA and different departments within BOAO Lecheng Administration.
    - Prepare and submit final approval documents to BOAO Lecheng Health Commission and Ethics Committee for final approval
    - Confirm the final price desired by the pharmaceutical company
    - Help set up:
      - Inventory at the BOAO Lecheng bonded warehouse
      - Sales contract with individual hospitals

Hainan BOAO Lecheng Hengjun Business Services Company Ltd. will also help manage ongoing sales of the products:

- Together with the pharmaceutical company, hold online product introduction and training to the doctors of the relevant hospitals
- Manage the sales process by facilitating:
  - Hospitals to place purchase order with the pharmaceutical company. The Pharmaceutical company will sign sales agreement with logistics company and hospital detailing the payment terms
  - Logistics company will wire payment directly to the pharmaceutical company

Hainan BOAO Lecheng Hengjun Business Services Company Ltd. will sign an Exclusive Product Application Agreement with the pharmaceutical company to get her products approved for sales within BOAO Lecheng, and where appropriate within China (once the products are approved for sale within Mainland China).

- Stage 1A: Gather all the needed documents for submission. This includes reviewing
  existing documents from pharmaceutical company and advising what else is needed for
  submission. Securing hospital to sponsor the submission and also securing the approved
  logistics company for importing the products.
- Stage 1B: Submit the product application to the Hainan Government's NMPA for approval and answer any questions from the approval committee regarding the products.
- Stage 1C: Product is approved for sale in Boao Lecheng hospitals.

# The design of this partnership between Hainan BOAO Lecheng Hengjun Business Services Company Ltd. and each pharmaceutical company is to:

- Minimize the investment and time needed by the pharmaceutical company in entering the Chinese market
  - Average time from start of engagement with the company to product approval is 6 months
- Allow a foreign pharmaceutical company to get her products approved and start to sell in Boao
   Lecheng without having to set up an office, or sales team, or even visiting China.
- Once sales started in Boao Lecheng, if desired, start the application for sales in Mainland China.

# **Path Forward**

- Contact us at Executive.Offices@ChinaGlobalCapital.com
- We will work with you to:
  - Assess the demand of your products in Boao Lecheng and Mainland China.
  - Decide how best to get your products approved for sale in Boao Lecheng
  - Agree on how we will work together to get your products approved for sale in Boao Lecheng

# **Thank You**

Our Contact: Executive.Offices@ChinaGlobalCapital.com

http://www.boaolechengglobalinvestmentfund.com/