

Hainan Boao Lecheng Pilot Zone Introduction and New Policy Interpretation

博鳌乐城先行区介绍及新政策解读

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PART1

Boao Lecheng International Medical Tourism Pilot Zone Introduction 博鳌乐城国际医疗旅游先行区介绍

先行区成立的背景——应运而生

The background of Lecheng Pilot Zone



据不完全统计，2016年出国就诊60万人，全球健康业消费突破7000万美金，人们对生命健康有了更高的需求；

According to incomplete statistics, there are 600,000 people go abroad to access health care in 2016. Global health industry consumption exceeded 70 million dollars, people have a greater demand for life health.

国家希望能够有一个新的通道，提供高质量的医疗健康服务，提高全民健康生活水平。

Governments hope to creat a new channel to provide high-quality medical and health services and improve the health of the whole nation.

乐城先行区规划图（效果图）
Planning map of Lecheng Pilot Zone

先行区9家医疗机构投入运营 9 medical institutions are operating



The Pilot Zone start to operate
Medical system gradually improved



16 projects are already under construction



9 medical institutions are operating
and more institutions are during approval process

PART2

New Policies Interpretation 新政策解读

国务院“国九条” The Nine Preferential Policies

2013年2月28日遵照中央领导的批示精神，国务院发布《国务院关于同意设立海南博鳌乐城国际医疗旅游先行区的批复》

国务院批复的九条优惠政策可以概括为“四个特许”：

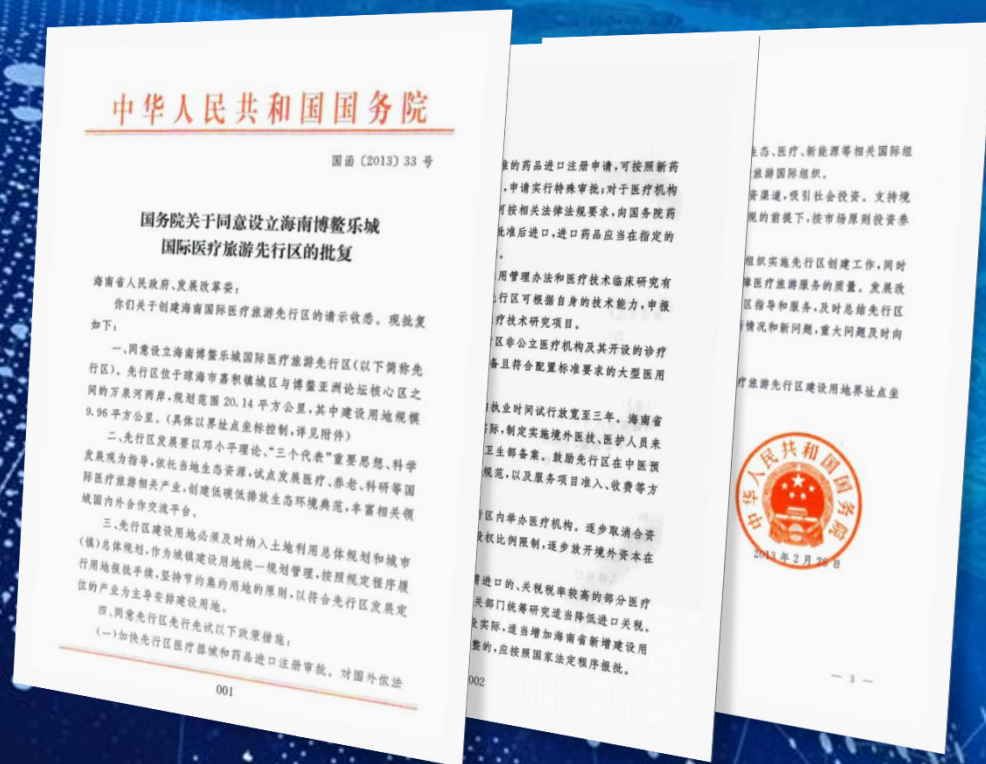
The nine preferential policies issued by the state council can be summarized as “Four special permissions”

1、特许医疗：医疗技术、医疗人才、医疗器械和药品特许进入
Franchise Medical Care : medical technology, medical talents, medical devices and drugs

2、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 Research : carry out research projects of advanced medical technologies such as stem cell clinical research

3、特许经营：放宽部分医疗审批权，允许境外资本进入和经营
Franchise Operation: relax some medical examination and approval rights, and allow foreign capital to enter and operate

4、特许国际医疗交流：特许国际交流医疗组织，承办医疗会议
Franchise International Communication: Chartered International Exchange medical organization, undertaking medical conference



四部委“新国九条”

The New Nine Preferential Policies Released by

2019年9月16日，经国务院同意，国家发改委、卫生健康委、中医药局、药监局联合印发《关于支持建设博鳌乐城国际医疗旅游先行区的实施方案》

On September 16, 2019, with the approval of the State Council, the national development and Reform Commission, the health and Health Commission, the Chinese medicine bureau and the Food and Drug Administration jointly issued “Implementation Plan for Supporting the Construction of Boao Lecheng International Medical Tourism pilot Zone ”



发布了多条政策支持，包括：

- ◆ 公立医院、商标、技术、管理等授权园区内机构使用；
- ◆ 干细胞等前沿医疗技术研究项目转化应用，加快国内注册；
- ◆ 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；
- ◆ 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；
- ◆ 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；
- ◆ 进口单克隆抗体等低风险类特殊物品实施“先入仓、后检验”；
- ◆ 世界知名医学院联合设立医学院校，科研院所设置分支机构；
- ◆ 先行区卫生系列高级专业技术职称评审实行社会化评价机制；
- ◆ 国有企事业单位医疗卫生、旅游专业人才在先行区兼职兼薪；
- ◆ 加大高端诊疗宣传力度，支持设立国家医疗旅游研究院；
- ◆ 国内顶尖医疗机构设立临床试验机构，依法依规开展临床试验；
- ◆ 等更多优惠政策

两大目标 Two Main Goals



技术
Technology

+



装备
Equipment

+



药品
Medicines

By 2025, significant breakthrough will be made in the pilot zone covering aspects such as establishment of advanced clinical medicine center, transformation base for cutting-edge medical technology. The zone will boast world -class medical technology, equipment and medicine

By 2030, Industrial cluster and brand effect will be fully formed. The pilot zone will turn into a world-class destination for international medical tourism and innovation platform for medical science and technology

亮点（一）政策效果初步显现 初步形成医疗“特区”

The initial effects of the policy have begun to emerge

① 患者可以在先行区内接受全球最好、最新的医疗服务

Patients can receive the world's best and latest medical services in the pilot zone.

② 允许外籍医疗专家在先行区内开展诊疗活动

Foreign medical experts carry out diagnosis and treatment activities are allowed.

③ 境外已上市、境内未上市药品、器械可以在先行区内落地应用

Drugs and devices listed overseas but unlisted domestic can be used in pilot zone

④ 有条件允许先行区医疗机构患者带合理自用量的进口药品离开先行区使用

Patients in medical institutions in pilot zone are allowed to leave with imported drug in reasonable self-dosage.

亮点（二）创新的医学模式---共享医院的共享模式 Innovative medical mode - shared hospital mode.

博鳌超级医院通过“1+X”的集群办医模式，引进了17个院士专家团队签约入驻，并**开展50余例国内首创手术**
Boao Super Hospital has adopted the "1 + X" cluster medical model, already have 17 academicians and industry experts teams sign in, and carried out more than 50 "National First Case" pioneered surgeries in domestic.

肾脏 Nephrology
皮肤 Dermatology
呼吸 Pneumology
心脏 Cardiology
肿瘤 Oncology



Otology 耳科
Pediatrics 儿科
Ophthalmology 眼科
Urinary Surgery 泌尿外科
Orthopaedics 骨科

亮点（三）创新药械使用---51个全国首例---心血管内科

Implement of innovative drug and medical devices

中国首台全程可视暨磁电双定位心脏手术

China First Full-Process Visualization and Magnetic-Electrical Dual-Positioning Cardiac Surgery

我国首例磁兼容心脏同步治疗心律转复除颤器植入手术

China's First MRI compatible cardiac resynchronization for cardioverter defibrillator implantation.

我国首例OPTIMIZER Smart心脏收缩力调节器

China's First Optimizer smart systolic force regulator

我国首例Micra TPS无导线心脏起搏器临床市场化植入

The first clinically marketed Implantation of Mirca TPS Wireless Pacemaker in China

亮点 (三) 创新药械使用---51个全国首例---耳鼻喉科

Implement of innovative drug and medical devices

奥地利MDE-EL Mi1200 SYNCHRONY耳蜗植入体
Austrian MDE-EL Mi1200 synchrony cochlear implant

美国AB公司Ultra 3D耳蜗植入体
Advanced Bionics ultra 3D cochlear implant

奥地利MDE-EL SONNET声音处理器
Austrian MDE-EL sonnet sound processor

科利耳CP950声音处理器
Cochlear CP950 sound processor

奥地利MDE-EL RONDO2声音处理器
Austrian MDE-EL rondo2 sound processor

科利耳CP1000声音处理器
Cochlear CP950 sound processor

美国AB公司Ultra 耳蜗植入体
Advanced Bionics ultra cochlear implant

科学利耳耳蜗N7处理器升级
Cochlear N7 processor upgrade

科利耳CI532耳蜗植入体
Collier Cochlear CI532 implant

亮点（三）创新药械使用---51个全国首例---眼视光眼科

Implement of innovative drug and medical devices

波士顿 I 型人工角膜移植手术

Boston Type I keratoprotheses implantation

波士顿II型人工角膜

Boston Type II keratoprotheses implantation

中国内地首例强生飞秒激光治疗白内障创新手术

The first innovative cataract surgery with Catalys femtosecond laser in mainland China

YUTIQ-氟轻松植入剂治疗葡萄膜炎

First Fluocinolone injection in China

中国首个微创青光眼引流管植入手术

First minimally invasive glaucoma drainage tube implantation in China

荷兰NKL巩膜镜

Netherlands NKL scleralscope

亮点（三）创新药械使用---51个全国首例---血管外科 Implement of innovative drug and medical devices

中国首个微创青光眼引流管植入手术

First minimally invasive glaucoma drainage tube implantation in China



国外上市时间

First launched abroad

2015年经FDA批准



乐城先行区实施时间

Conducted in Pilot Zone

2019年9月28日

亮点（三）创新药械使用---51个全国首例---皮肤科

Implement of innovative drug and medical devices

苏金单抗内地首针注射

The first licensed import of Sulfonizumab for Psoriasis Treatment, in mainland China



国外上市时间

First launched abroad

2015年经FDA批准



乐城先行区实施时间

Conducted in Pilot Zone

2018年6月22

特应性皮炎靶向生物制剂Dupixent中国内地首针注射

Injection of dupixen, a targeted biological agent for atopic dermatitis



国外上市时间

First launched abroad

2017年3月经FDA批准



乐城先行区实施时间

Conducted in Pilot Zone

2019年2月22

亮点（三）创新药械使用---51个全国首例---肿瘤科

Implement of innovative drug and medical devices

国内首次在博鳌乐城国际医疗旅游先行区使用Perjeta(Pertuzumab)

Perjeta(Pertuzumab) First use in Boao Lecheng International Medical Tourism Pioneer Area in China

国内首次在博鳌乐城国际医疗旅游先行区使用kadcyla(T-DM1)

First use in Boao Lecheng International Medical Tourism Pioneer Area in China

国内首次在博鳌乐城国际医疗旅游先行区使用(Ribociclib)

First use in Boao Lecheng International Medical Tourism Pioneer Area in China

免疫检查点抑制剂T药 (Tecentrip)

Immune checkpoint inhibitor (tecentrip)

亮点（三）创新药械使用---与国际药厂开展更深入的合作

Implement of innovative drug and medical devices

先行区与15家跨国药械厂商签订战略合作协议、备忘录及意向书的形式，后续将在更多创新药械的使用方面开展更深入、更广泛的合作。

In the form of strategic cooperation agreements, MOU and letters of intent signed between the pilot area and 15 international pharmaceutical manufacturers, more in-depth and extensive cooperation will be carried out in the use of more innovative medicine and devices in the future.



亮点（四）真实世界数据应用进入快车道

Trial application of Real World Clinical Evidence enter the highway

中国内地首个应用真实世界数据研究的先行区

Unique pilot zone
“Application of RWS”
in China mainland

From October 9th to 11th, trial application of real world clinical data seminar was held in the pilot zone jointly developed by the CFDA and the Hainan provincial FDA, this is the first on-site meeting of trial application of real world data, meaning for the real-world data application enter into the actual operation phase

亮点（四）真实世界数据应用进入快车道

Trial application of Real World Clinical Evidence enter the highway



2020年3月26日，美国艾尔建公司“青光眼引流管”经国家药监局审查，获批上市，成为首个使用境内真实世界数据成功上市的医疗器械，标志着真实世界临床数据应用试点工作取得阶段性成果。

On March 26, 2020, the "glaucoma drainage tube" of Allergan company was reviewed by the FDA and approved for listing, becoming the first medical device successfully listed using real world data in China, marking the phased achievement of real world clinical data application pilot work

亮点（四）真实世界数据应用案例——XEN®青光眼引流管

Trial application of Real World Clinical Evidence enter the highway

XEN®青光眼引流管

XEN® GLAUCOMA TREATMENT SYSTEM

XEN®青光眼引流管是2016年12月由FDA批准的一种由预装在注射器中的凝胶引流管所组成青光眼治疗系统。用于难治性青光眼患者，该系统只需要使用皮下注射针植入一个小的引流管进入眼内即可，可以让多余的液体流出。比目前的方法更快更安全，是近年来中重度青光眼治疗的重大突破。



该产品自申报真实世界数据应用，到完成FDA注册审批，未超过是通过真实世界数据应用加速国际新药中国上市的首个案例。



PART3

**Creating a New Highland in the
Medical Field**

打造医疗领域开放新高地



Pilot zone in **Hainan Free Trade Port**

自贸港的先行区

一、加快全球创新药械的引进

Speeding up the introduction of global innovative medicines

- From 2001 to 2016, 433 types of innovative new drugs were approved in developed countries, but only about 100 types have been approved in China, accounting for about 30%. According to incomplete statistics, in 2017, about 20 foreign companies and 39 innovative drugs were approved in China, including multinational companies such as Bayer, Novartis, Sanofi, Johnson & Johnson, AstraZeneca and so on. The treatment areas of the new drugs include tumors, hepatitis C, diabetes, Parkinson's disease, AIDS, hypertension, depression, etc. About 35% of them are anti-tumor drug.
- Professional service platform will be built with policy support on the pilot zone to accelerate the introduction of global innovative medicinal equipment from those well-known global pharmaceutical companies and those small and medium-sized innovative medicinal equipment enterprises.
- For example, low-risk special items like monoclonal antibody drugs can be imported first and then inspected. They can also be imported and placed in public bonded warehouses in advance.

二、建立特许药械追溯平台，确保用药数据安全

Establish traceability management platform for chartered drugs and medical devices



建立特许药械追溯管理平台，构建以法律法规为依据、监督网络为基础、信用体系为载体、信息技术为支撑的特许药械追溯管理平台，实现多部门业务的电子审批及特许药械来源可追溯、去向可查证、责任可追究。

三、提高审批速度，确保患者及时用药

Speed up approval process to ensure that patients can get the medicine in a timely manner.



强化保税仓公共属性
药械提前进到保税仓



深化极简审批改革
以方便患者为中心，优化审批流程



公开邀请符合条件专家进驻
自主申请使用特许药械

患者申请使用特许药械使用时间
缩短至3-7天

四、推进中外合作办学--爱丁堡大学和上海交大医学院

Promoting Chinese-foreign cooperative education --Edinburgh University and Shanghai Jiaotong University Medical College



The "Implementation Plan" clearly states to establish national medical education and scientific research bases. Encourage and support key scientific research institutes and medical schools, national key laboratories, and well-known enterprises domestic and overseas to set up branches in the pilot zone

五、建设中国第一个真正意义上的研究型医院 Building the first Research Hospital in China



The construction area is 90,270 square meters. This is mostly taken up by the medical function room, scientific research laboratory and other supporting rooms. After the project finished and the number of beds has reached 500 the total investment will be 870,000,000 RMB.

The project will be built into:

National Real World Clinical Data Research;
Center; National Clinical Medical Innovation Center;
National Medical Advanced Technology Research Center.

樂城

Boao Hope City

独乐乐不如众乐乐

Shareing Health, Shareing Happiness

六、打造国际新药械交流展示平台——“永不落幕”药械展

Building an international new Drug and Medical Devices display platform--"Everlast" Exhibition



Long term free space

import applications and
customs clearance

Promote the use of
Products on show

training venues provied

Carry out RWS

release conferences of
new products

Provide scientific research
transformation platform



Release by Lecheng Administration

Official web site: <http://lecityhn.com>



THANKS