



# 中日医药健康产业的合作 现状与前景

Current Status and Prospect of  
China-Japan healthcare Cooperation

**China Chamber of Commerce for Import & Export  
of Medicines & Health Products**

April 2016

# 主要内容 Content



一

## 中国医药健康产业发展态势

Current development Status of the Chinese Healthcare Industry

二

## 中国医药监管制度及最新变化

Overview and Latest Changes of the Chinese Regulatory System

三

## 中日医药合作现状及未来合作前景

China-Japan Healthcare Trade and Prospect of Future Cooperation

# 一、中国医药健康产业发展态势

## Current Development Status of the Chinese Healthcare Industry



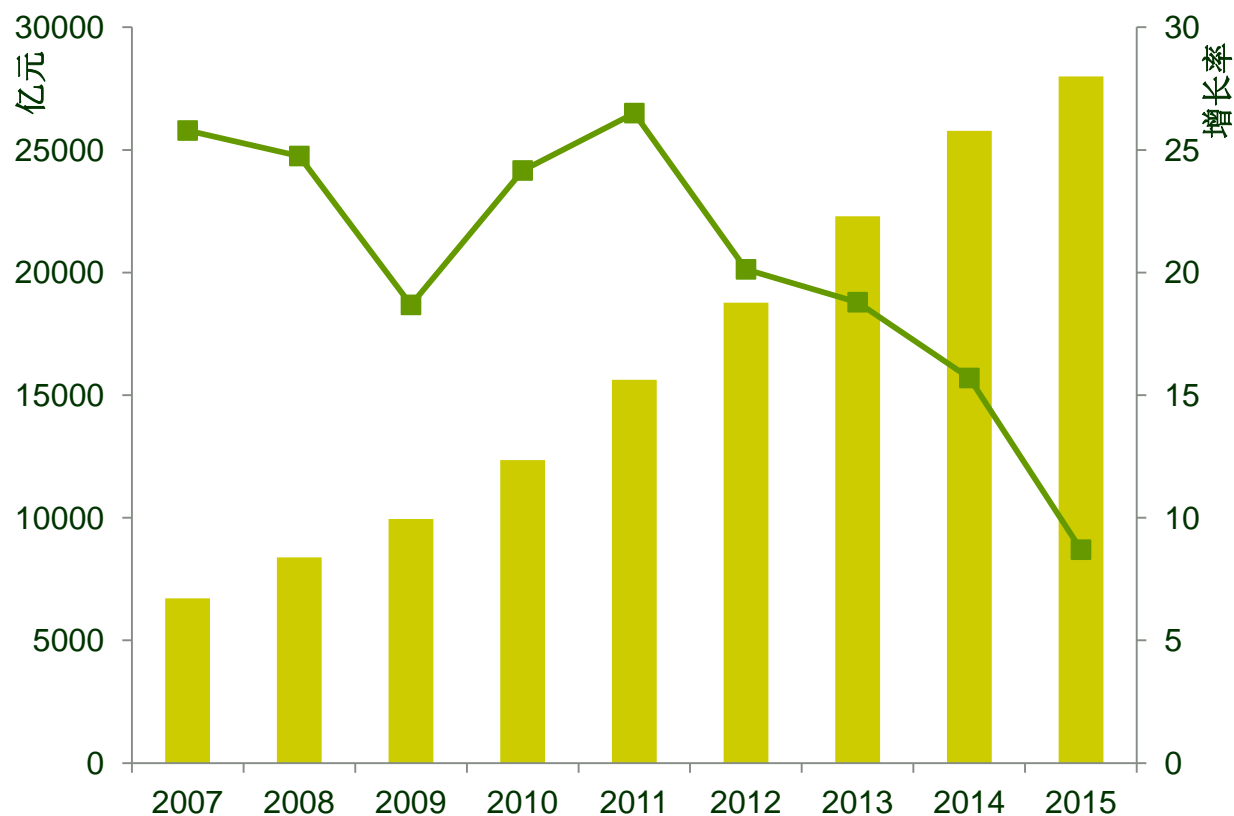
2013年，中国医药市场规模已经跃居到世界第三位。2015年中国医药市场规模达2200亿美元，同比增长11.5%。

China became the third largest pharmaceutical market in the world in 2013. In 2015, Chinese pharmaceutical market value reached over 220 billion USD, up by 11.5%.

Rank	2005	Rank	2013	Rank	2017
1	United States	1	United States	1	United States
2	Japan	2	Japan	2	China
3	Germany	3	China	3	Japan
4	France	4	Germany	4	Brasil
5	Italy	5	France	5	Germany
6	UK	6	Italy	6	France
7	Spain	7	Brasil	7	Italy
8	Canada	8	UK	8	Russia
9	China	9	Canada	9	UK
10	Mexico	10	Spain	10	Canada
11	South Korea	11	Australia	11	India
12	Brasil	12	India	12	Spain
13	Turkey	13	Russia	13	Mexico
14	Australia	14	Turkey	14	South Korea
15	India	15	Mexico	15	Australia

2015年，中国医药工业总产值约2.8万亿元（4400亿美元），同比增长15.7%。

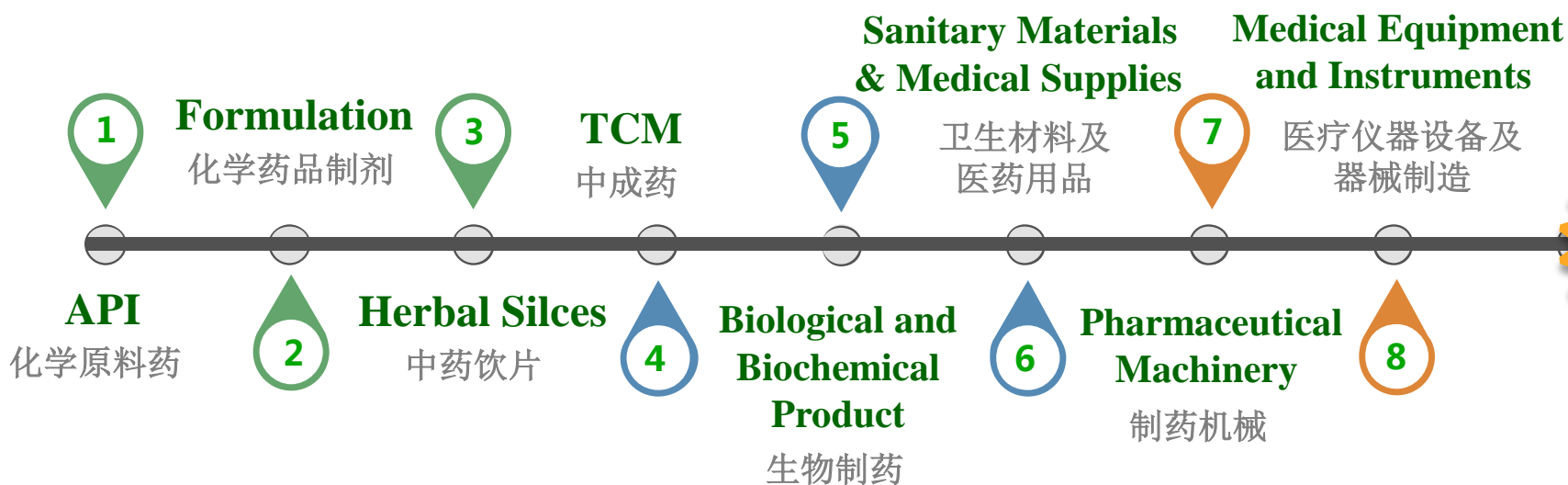
In 2015, China's pharmaceutical and medical industry output reached around 2.58trillion RMB (440 billion USD), up by 15.7%.



# Chinese Pharmaceutical Industry

Compound growth rate **20%**

**\$ 4400** 亿



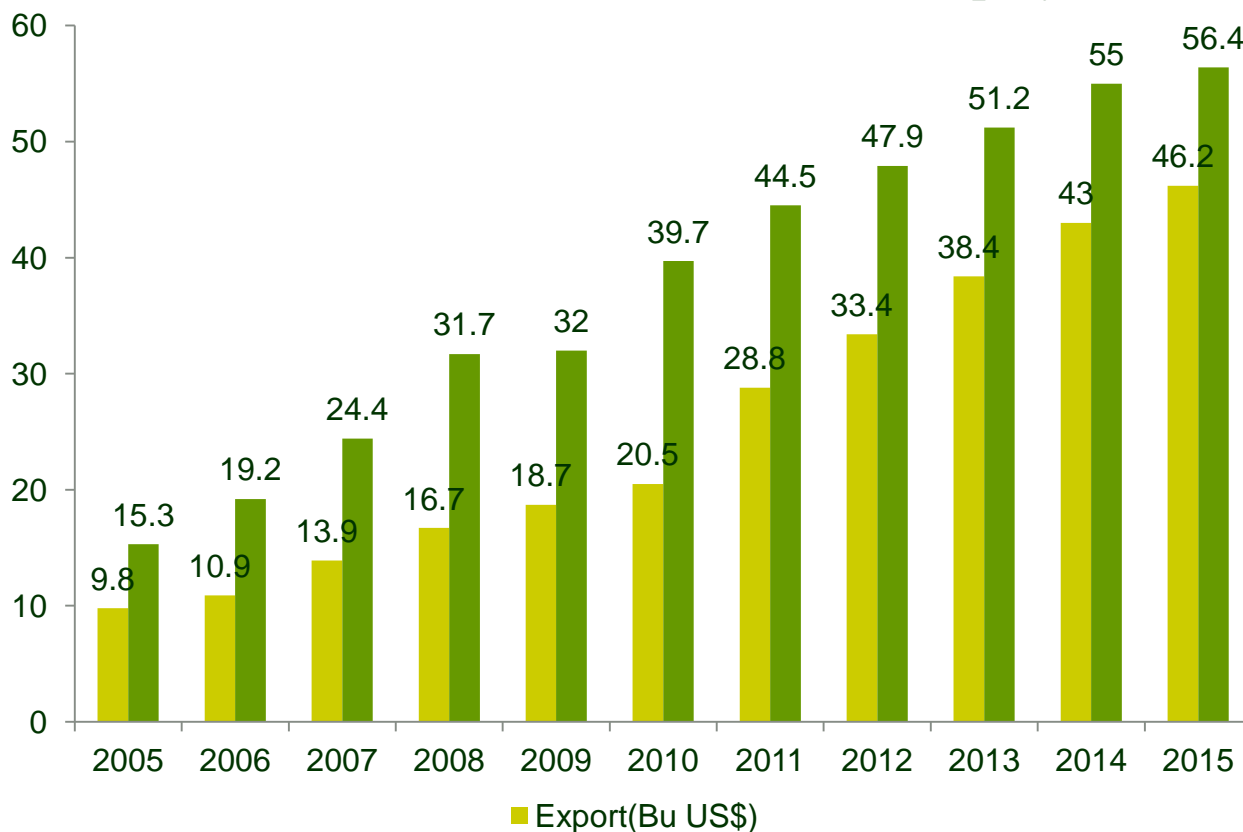


Chinese Medicinal Industry

**Made in China**



2015年，中国医药保健品进出口额达1026亿美元，同比增长4.73%。  
 In 2015, the trade volume of China's health products (medicines and medical devices included) reached 102.6b USD, up by 4.73%.





1、产业链逐渐由上游原料药向下游制剂一体化延伸

●Industry chain extended from APIs to finished products

2、对新兴市场出口稳步增加

●Export to emerging markets has seen steady growth

3、中国医药市场快速扩容，进口增速大于出口

●China's market keeps on expanding, and import grows faster than export

4、生物医药、体外诊断等新领域发展迅猛

●Rapid Development in new areas such as biopharmaceuticals and IVD

5、一批优秀的本土医药国际化先导企业和品牌正在脱颖而出

●An array of leading Chinese local companies and brands are developed

6、注重研发投入，一批国际领先的高技术产品相继推出

●Increasing investment on R&D helps to bring about a number of internationally leading technologies and products

7、境外投资并购增多，境外营销网络已现雏形

●Preliminary overseas distribution network has been set up as a result of M&As



## 8、国际注册认证步伐加快

### Paces of international registration are accelerated

原料药企业 API companies	欧盟EDQM颁发的COS/CEP证书 The number of COS/CEPs from EDQM	>600
原料药企业 API companies	获得美国DMF文件 The number of DMFs	>1400
制剂企业 Formulations manufacturers	通过欧美日等的GMP认证 The number of companies that were GMP- certified by US, EU countries and Japan	>50
制剂企业 Formulations manufacturers	获得美国ANDA申请 The number of ANDAs that were filed with US FDA	>40
医药企业 Pharmaceutical manufacturers	通过WHO PQ认证 The number of generics that were PQ qualified by WHO	APIs: 28 FDF: 16 Vaccine: 3

## 二、中国医药监管制度及最新变化

Overview and latest changes of the Chinese regulatory system



### 1. 中国医药监管制度 Drug Management System

CFDA

《药品管理法》  
*Drug Administration Law*

《药品管理法实施条例》  
*Regulations for Implementation of The  
Drug Administration Law*

《药品注册管理办法》  
*Methods on the Administration of Drug  
Registration*

- 4200多个进口药品文号
- more than 4200 imported drugs

## 2. 中国新版GMP实施现状 Implementation of new Chinese GMP

2010年新  
版GMP  
New GMP  
adopted in  
2010

1. 明确要求企业建立和完善质量管理体系  
Companies to establish and improve Quality Management System
2. 提高企业从业人员资质要求  
Enhance qualification of personnel
3. 细化操作规程、生产记录等文件管理规定  
Better documentation such as operating procedures and production records
4. 提高无菌药品生产环境标准  
Raise production standards of sterile medicinal products
5. 围绕质量风险管理增设一系列新制度  
New procedures added to quality risk management

## 2. 中国新版GMP实施现状 Implementation of new Chinese GMP

- 修订34个程序文件，新增4个文件，进一步完善药品GMP认证检查
- Updated 34 quality related procedures, added 4 documents, and improved GMP inspection.
- 推动中国医药产业优胜劣汰、兼并重组。
- Made weaker companies to be phased out, and the industry to conduct mergers and acquisitions.
- 新版GMP基本与WHO的规则相一致，达到国际先进水平。
- The new GMP is in line with WHO rules to ensure that the qualities of Chinese products are geared to the international standards.

## 2. 中国新版GMP实施现状 Implementation of new Chinese GMP

- 新版GMP认证截止：2015年12月31日。
- Deadline for enterprises passing the new GMP inspection: Dec. 31, 2015.
- 截止去年底，CFDA共颁发GMP证书：约7000张。
- By the end of last year, about 7000 GMP certificates were issued by CFDA.
- 2015年CFDA通过飞行检查收回了144张GMP证书，涉及140家药企
- In 2015, CFDA withdrew 144 GMP certificates from 140 companies by unannounced inspection.

### 3. 中国药品法规最新变化 Latest changes of the Chinese Regulatory System



1

中国《药品管理法》修订施行。

**Implementation of *the Drug Administration Law*.**



中华人民共和国  
药品管理法

中国民主法制出版社

2015年4月24日，中国《药品管理法》修订后公布。加强使用环节的监督制度，调整药品定价思路，将药品价格“市场化”。

**On April 24, 2015, the revised Drug Administration Law was publicized.**

**It has strengthened supervision during the use of drugs, adjusted thinking on drug pricing.**

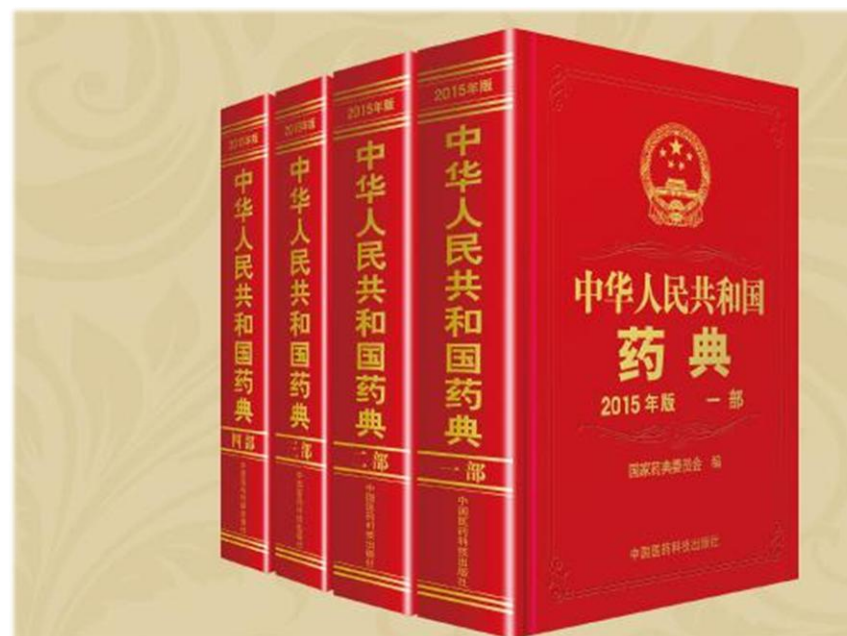
2

2015版《中国药典》修订发布。

**Release of the Chinese Pharmacopeia 2015.**

新版药典已于去年12月1日起实施，进一步扩大药品品种的收载和修订，收载品种达到**5608种**。

**The Chinese Pharmacopeia 2015 edition has been implemented since December 1, 2015. The new edition expanded the scope of products to be **5608 types.****



### 3 新《环境保护法》的修订实施。 **Implementation of *the new Environmental Protection Law.***

2015年1月1日，新修订的《环境保护法》正式实施，中国“**史上最严环保法**”。对于原料药行业影响重大。环保改造成本上涨，出口价格上涨。



**On January 1, 2015, the newly revised Environmental Protection Act, “the strictest environmental protection law in Chinese history”, was put into formal effect. It has a great influence on the API industry.**



# 4

新修订了医疗器械、体外诊断试剂等注册管理办法。  
**Revising registration procedures for medical devices and in-vitro diagnostic reagents.**



## 食品药品监管总局关于实施《医疗器械注册管理办法》和《体外诊断试剂注册管理办法》有关事项的通知

食药监械管〔2014〕144号

2014年08月01日 发布

各省、自治区、直辖市食品药品监督管理局：

《医疗器械注册管理办法》（国家食品药品监督管理总局令第4号）和《体外诊断试剂注册管理办法》（国家食品药品监督管理总局令第5号）（以下统称《办法》）已发布，自2014年10月1日起施行。为做好《办法》实施工作，现将有关事项通知如下：

5

药品上市许可持有人制度开始试点。

**Pilot of MAH system in China.**



2015年11月，药品上市许可持有人制度开始在国内十个省市试点。促进药品创新，激发市场活力，优化资源配置。

In November 2015, **MAH system** began to be tested in 10 provinces of China. The system would facilitate innovation, boost market vitality, increase quality management and optimize resource allocation.



# 6

仿制药一致性评价新政即将落地。

Policy of consistency evaluation of generic drugs will implement.



## 总局办公厅公开征求关于落实《国务院办公厅关于开展仿制药质量和疗效一致性评价的意见》的有关事项的意见

2016年04月01日

根据《国务院关于改革药品医疗器械审评审批制度的意见》（国发〔2015〕44号）、《国务院办公厅关于开展仿制药质量和疗效一致性评价意见的通知》（国办发〔2016〕8号）的有关要求，食品药品监管总局组织起草了《关于落实〈国务院办公厅关于开展仿制药质量和疗效一致性评价的意见〉的有关事项（征求意见稿）》。现向各省级食品药品监督管理部门、社会各界公开征求意见。请将修改意见于2016年4月20日前通过电子邮件反馈至国家食品药品监督管理总局仿制药质量一致性评价办公室。

电子邮件：[fzy@nifdc.org.cn](mailto:fzy@nifdc.org.cn)

附件：关于落实《国务院办公厅关于开展仿制药质量和疗效一致性评价的意见》的有关事项（征求意见稿）

食品药品监管总局办公厅

2016年3月31日

中国的政策及制度改革方向。

**The direction of China's policy and system reform.**



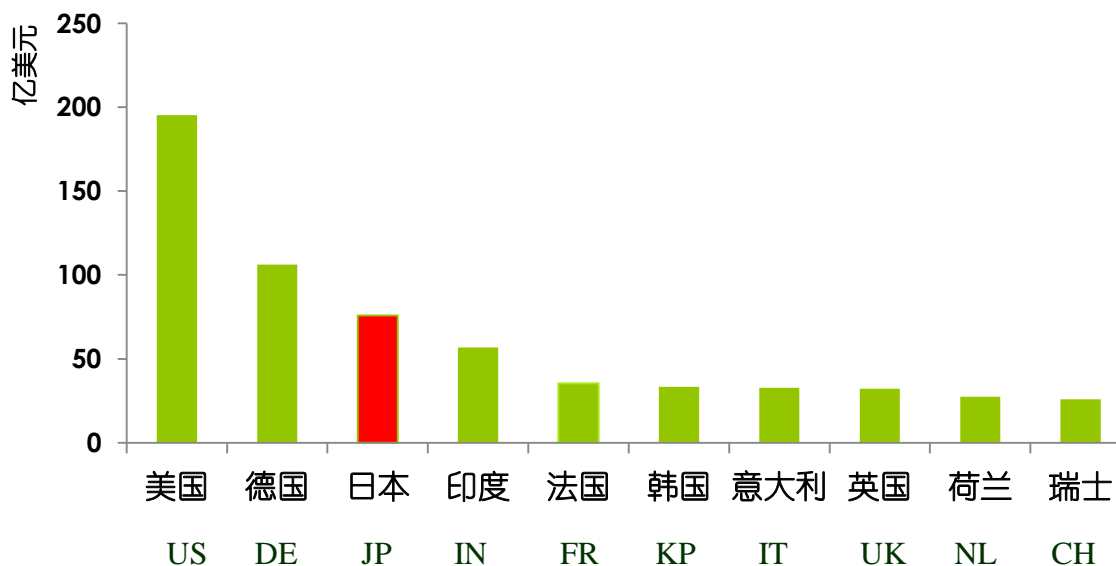
# 三、中日医药贸易及未来合作前景

China-Japan Healthcare Trade and the Prospect of Future Cooperation



## 1. 中日医药贸易状况 China-Japan healthcare trade

- 日本常年稳居中国医药伙伴前三名。2015年，对日贸易额占中国医药对外贸易总额的7.4%。
- Japan has long been one of China's top three trading partner in the healthcare sector. In 2015, China-Japan healthcare trade took 7.4% of China's total foreign healthcare trade with the world.



**原料药出口为主。  
APIs are the main exported products.**

2015年，中国对日本原料药出口金额达16.93亿美元，占比43%。  
In 2015, China's API export volume to Japan reached 1.693b USD,  
accounting for 43% of the total.

大宗原料药  
APIs

- 柠檬酸Citric acid
- 维生素Vitamins
- 氨基酸Amino Acid

特色原料药  
Specialized APIs

- 沙坦类Statins
- 普利类Perindopriils
- 他汀类
- Sartans

生化原料药APIs for  
biochemical drugs

- 蛋白胍衍生物  
protein-derivatives
- 酶类enzyme
- 肝素类heparin

**医疗器械和中药类产品出口受欢迎。  
Medical devices and TCM exports getting  
ever more popular.**

2015年，中国对日本出口医药诊断与治疗设备6.72亿美元。  
In 2015, China's total Hospital diagnostic and treatment devices export  
volume to Japan reached 0.672b USD.

医药诊断治疗设备

Hospital diagnostic  
& treatment devices

- X射线断层检查仪  
X-ray tomography  
instrument
- 核磁共振设备  
MRIs
- 医用家具Medical  
Furniture

保健康复用品

Rehabilitation  
products

- 按摩器具Massage  
equipment
- 残疾人用车  
Assistive Devices  
Support disabled
- 视力矫正设备  
Vision correction  
equipment

植物提取物

Herbal extracts

- 植物浸膏Concrete
- 甘草酸盐  
Glycyrrhetate
- 芸香苷Rutin

进口以成品药和医疗器械为主。

**Finished formulations and medical devices are the main imported products.**

成品药

FDF

- 抗感染Anti-infective
- 激素类Hormone drugs

医疗器械

Medical devices

- 光学射线仪器  
Spectroscopy devices
- 内窥镜  
Endoscopy
- 显微镜  
Microscope

原料药

APIs

- 蛋氨酸  
Methionine
- 维生素Vitamin



## 2. 中国医药企业关注 Interests of the Chinese companies

- 原料药和中间体对日出口企业2154家，出口额1000万美元以上28家，500万美元以上68家。成品药对日出口的本土制药企业仅有20多家。
- 2154 API and intermediate companies exporting to Japan, only 28 companies with an annual export volume of over 10 million USD and 68 companies with an annual export volume of more than 5 million USD. Only 20 Chinese local companies are exporting finished products to Japan.
- 近十年间，中国企业接受日本PMDA现场检查130余次，海正药业、华北制药、亚邦药业等通过日本GMP认证。
- In last ten years, PMDA had done more than 130 inspections on Chinese companies, and a lot of them , including Hisun, NCPC, Yabang have got Japan GMP certificates.
- 华北制药集团，哌拉西林钠、无菌头孢曲松等原料药，头孢曲松粉针剂生产线通过了PMDA的检查。
- NCPC's Piperacillin Sodium and Sterile Ceftriaxone APIs and Sterile Powder of Ceftriaxone for Injection manufacturing line were certified by PMDA.

## 2. 中国医药企业关注 Interests of the Chinese companies

- 中日双方在医药健康领域具有很强的互补性。
- 日本：拥有颇具规模的研发机构群和完善的监管体系，研发资金密集度较高，在原研产品开发和制造方面具有独特的优势。
- 中国：世界最大的原料药生产和出口商，仿制药开发潜力巨大，医疗器械工业基础雄厚。

-China and Japan are highly complementary in the healthcare sectors.

-Japan: well-established R&D facilities and an advanced regulatory system, research funding is focused, and is uniquely competitive in developing and manufacturing original products.

-China: the largest producer and exporter of APIs, with huge potential in generics, and solid foundation of medical devices.

中日医药产业合作。

**China and Japan forging industry collaboration.**

将中国原料药生产能力、研发和生产外包能力与日本的创新能力和制剂生产能力有效结合，不仅可以打造整体生产链优势，而且可以有效节约成本，促进两国制药业的发展壮大。

China's capacities in API production, R&D and outsourcing combining with Japan's strengths in innovation and formulations not only helps to build competitiveness along the whole production chain, but also helps to cut cost, and thrive the pharmaceutical industries of the two countries.

- 2014年和2015年，中国医药健康企业代表团连续两次访问日本，开展交流对接活动
- In 2014 and 2015, Chinese healthcare delegation visited Japan twice to hold Exchange and Business Match-making Program.



# Introduction to CCCMHPIE

## 中国医药保健品进出口商会介绍



### For 企业

► 咨询指导

consulting services and guidance

► 反映诉求

representing interests of companies

► 政策建议 policy recommendations

► 平台搭建 platform building

### For 政府

► 决策参考

policy suggestions

### For 行业

► 参与行业政策制订

industry policy making

► 参与政府双边磋商

governmental dialogues and negotiations

誠信為本 服務為先  
為中國醫葯保健品進出口商會  
創立廿周年題言  
李春法

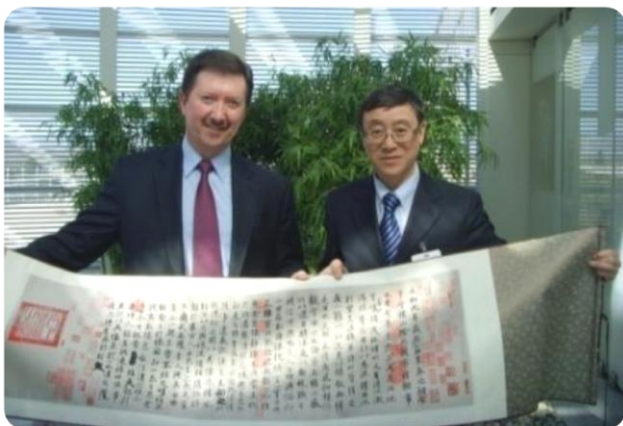
# Introduction to CCCMHPIE

中国医药保健品进出口商会介绍



## International Exchange

国际交流



# Introduction to CCCMHPIE

中国医药保健品进出口商会介绍



## International Exchange

国际交流





**Thank you!**