



中日医药领域双边合作： 加强合作，促进交流

China-Japan Bilateral Cooperation in the Healthcare Sector
Enhancing Collaboration, Promoting Exchanges

中国医药保健品进出口商会

2015年4月 日本东京

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全球及中国医药产业发展态势

Current development Status of the Chinese and Global 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

中日医药贸易及中国医药企业的关注

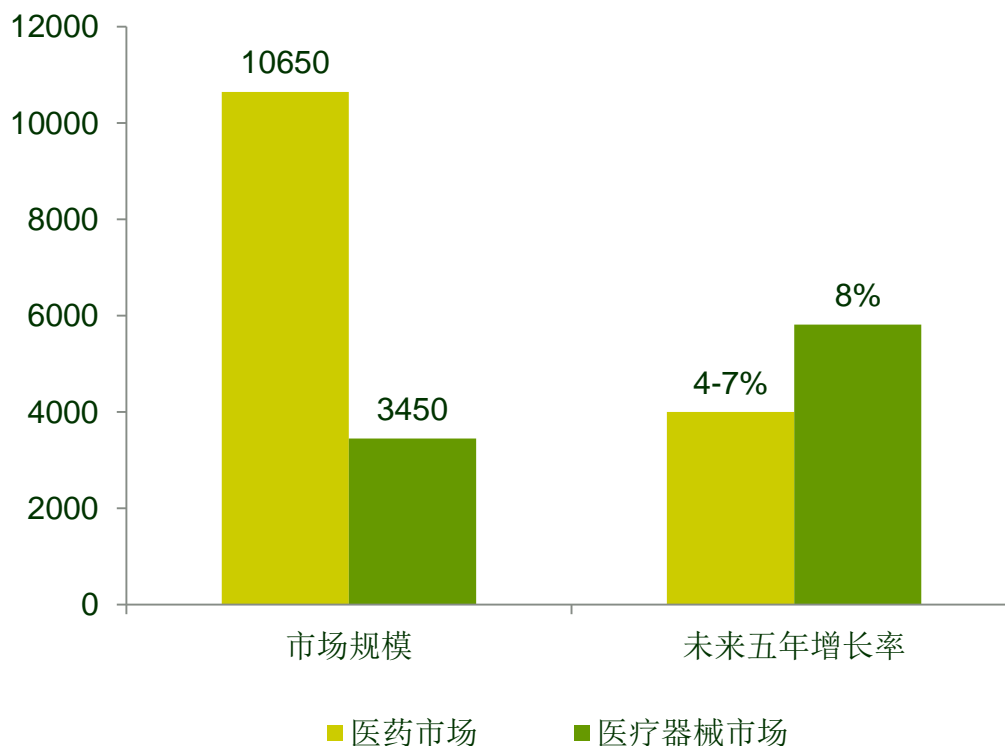
China-Japan Healthcare Trade and Interests of the Chinese Companies

一、全球及中国医药产业发展态势

Current Development Status of the Chinese and Global Healthcare Industry



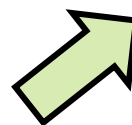
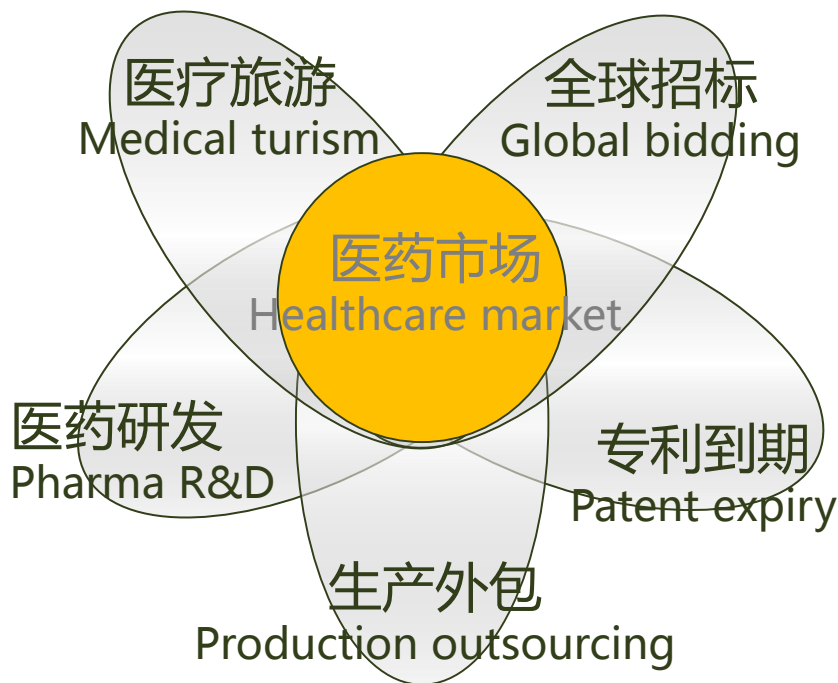
1. 全球医药市场 The global healthcare market



2014年全球医药市场形势 Global healthcare market in 2014

- 医药市场规模增速是GDP增速2-3倍
- Growth rate is 2-3 times that of GDP
- 新兴市场>发达市场
- Emerging markets> developed markets

1. 全球医药市场 The global healthcare market

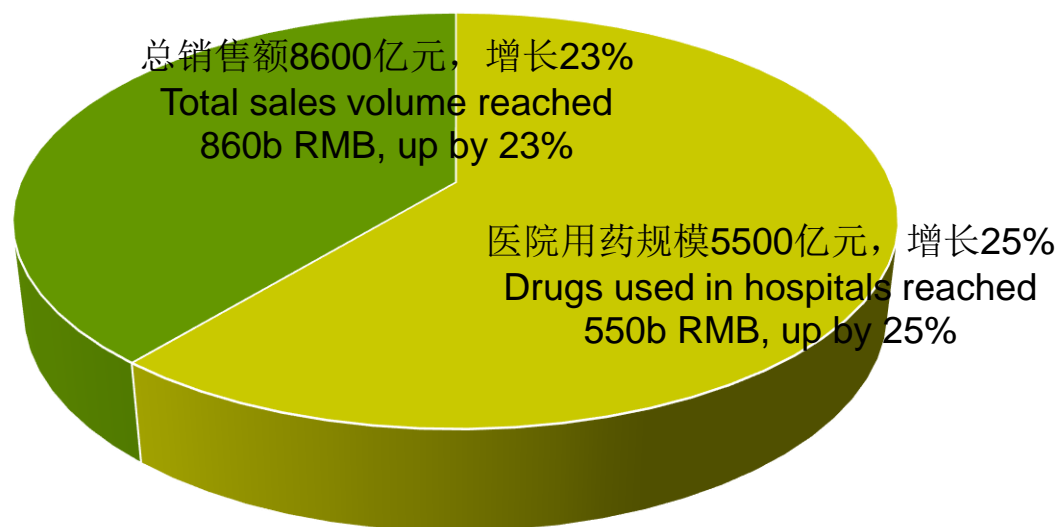


生物仿制药Biosimilar

- 2013年全球热销药物前十位中生物制品占据七个，抗体类药物独占鳌头
- In 2013, seven out of global top ten most popular drugs are therapeutic biologics, and antibodies have been leading the sales growth
- 预计2015年将有640亿美元生物药物专利到期
- By 2015, drugs worth 64 billion USD will reach expiry date
- 2020年生物仿制药市场将达200多亿美元，未来十年复合增长率56%。
- The biosimilar market value will reach over 20 billion USD by 2020 with CAGR of 56% in the next decade.

2. 中国医药产业发展现状 Current development status of the Chinese healthcare industry

2014年中国医药市场销售额 Drug sales in China in 2014



2. 中国医药产业发展现状 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。

China became the third largest pharmaceutical market in the world in 2013.

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

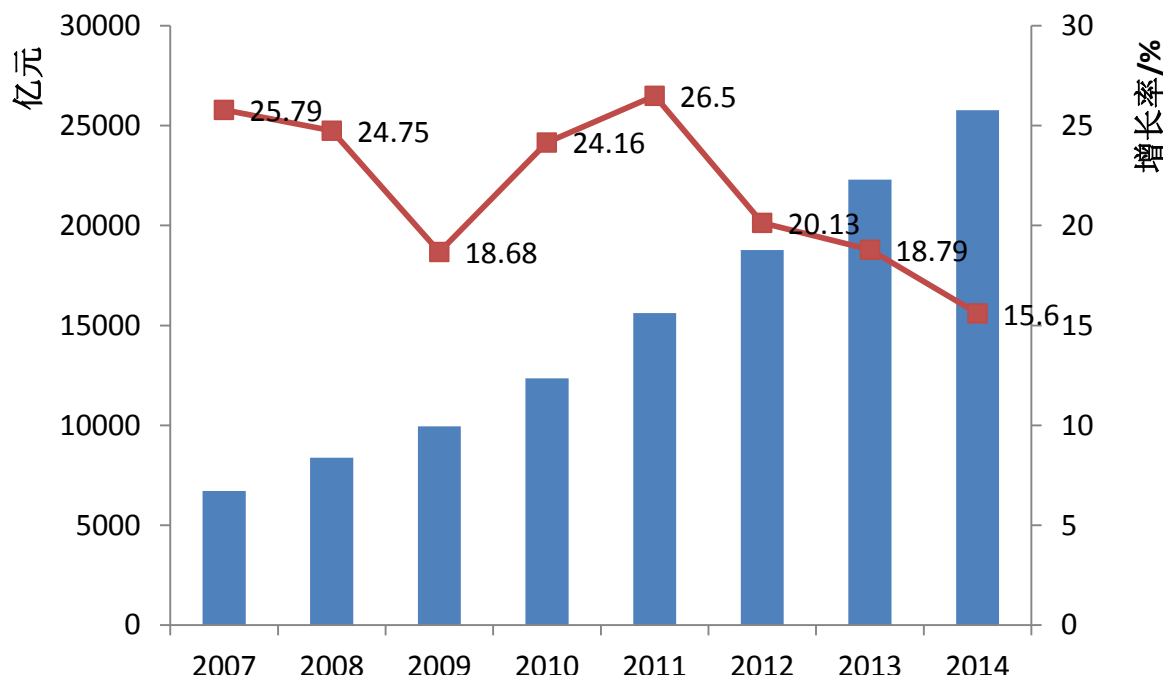
Rank	2013
1	United States
2	Japan
3	China
4	Germany
5	France
6	Italy
7	Brasil
8	UK
9	Canada
10	Spain
11	Australia
12	India
13	Russia
14	Turkey
15	Mexico

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

2. 中国医药产业发展现状 Current development status of the Chinese healthcare industry

2014年，中国医药工业总产值约2.5万亿元，同比增长15%。

In 2014, China's pharmaceutical and medical industry output reached around 2.5trillion RMB, up by 15%.



中国是世界上最大的原料药生产和出口国。

China is the world's largest producer and exporter of APIs.

- 化学原料药1500种，年产量200多万吨
- 青霉素、维生素、头孢菌素类等传统原料药
- 他汀类、普利类、沙坦类等特色原料药

- China is capable of producing more than 1500 types of APIs with an annual output of over 2 million tons.
- Conventional APIs such as Penicillins ,Vitamins, Cephalosporins.
- Specialized APIs such as Statins, Perindopriils and Sartans.

中国的制剂产能居世界第一。

China is producing more formulations than any other country in the world.

- 化药产业正在实现全面的转型升级
- 制剂出口十年翻了10倍，比重达到10%以上
- 60多个剂型4500多个品种

- The pharmaceutical industry is undergoing transformation.
- China's export of formulations has increased by 10 folds, and the volume accounts for more than 10% of the total export of pharmaceutical products..
- China is able to produce over 4500 different types of pharmaceutical formulations in more than 60 dosage forms.



生物医药制造能力获得了大幅提升。

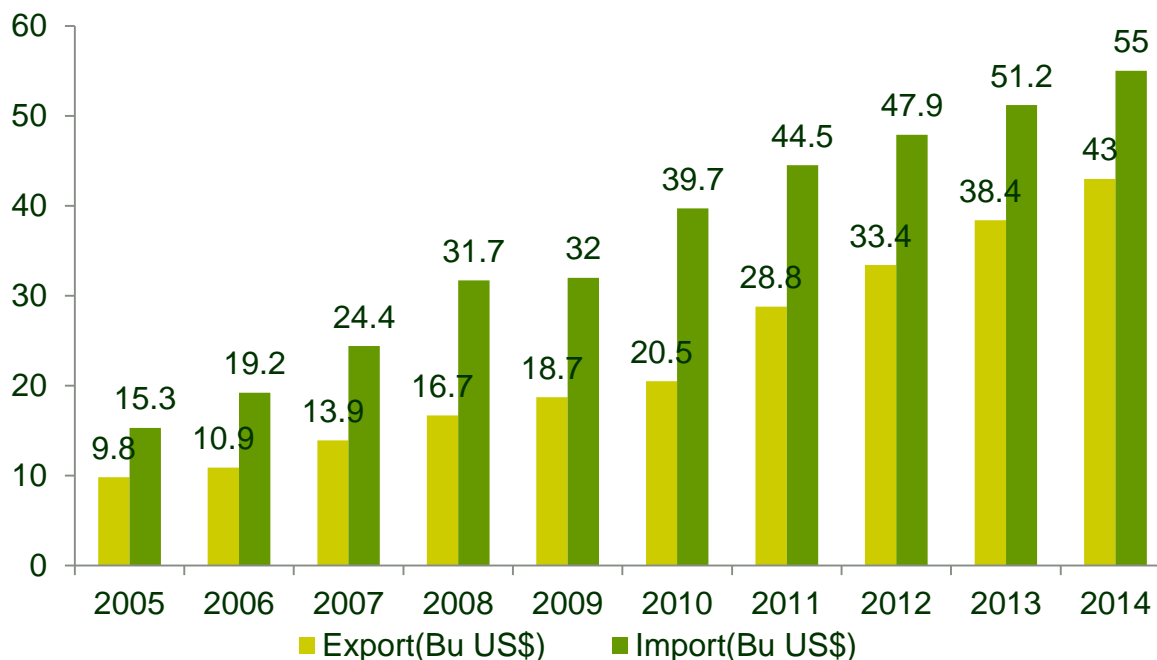
China's biopharmaceutical manufacturing capacity is also greatly improved.

- 肝素类产品出口到世界各地
- 人用疫苗、血液制品、胸腺类药物深受国外客户欢迎
- 生物医药工业产值比例仅占11%，发展空间大

- Heparin products are exported to all over the world.
- Human vaccines, blood products and thymus drugs are welcomed by clients overseas.
- The industrial output of biopharmaceutical industry only takes up 11% of the total for the time being, bigger progress could be expected.

3. 中国医药国际化态势 Internationalization of the Chinese medicinal products and devices

2014年，中国医药保健品进出口额达980.02亿美元，同比增长9.26%。
 In 2014, the export volume of China's health products (medicines and medical devices included) reached 98b USD, up by 9.26%.



3. 中国医药国际化态势 Internationalization of the Chinese medicinal products and devices

产业链逐渐由上游原料药向下游制剂一体化延伸

- 高附加值产品出口增幅高于原料类，比重增加

对新兴市场出口稳步增加

- 东盟、非洲、俄罗斯、中东等
- 出口增幅高达20%左右，远高于整体出口增幅
- 制剂类产品在发达国家市场所占份额逐年上升

中国医药市场快速扩容，进口增速大于出口

- 2014年，中国医药产品进口同比11.7%，高于出口4个百分点
- 贸易顺差缩小，平衡性增强

Industry chain extended from APIs to finished products

- Export of high value-added products takes a bigger share and grows faster than APIs

Export to emerging markets has seen steady growth

- ASEAN, Africa, Russia, Middle East, etc.
- Export rate of which increases by around 20%, much higher than the average export growth rate
- More and more export of finished products to developed markets annually

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

- In 2014, China's import of medicines and medical devices grew by 11.7%, 4 percentages points higher than the export rate
- Trade surplus is narrowing.

国际认证 International Certification

原料药企业 API companies	欧盟EDQM颁发的COS/CEP证书 The number of COS/CEPs from EDQM	>450
原料药企业 API companies	向美国FDA递交的DMF申请 The number of DMFs	1741
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	≈50
制剂企业 Formulations manufacturers	通过WHO PQ认证 The number of generics that were PQ qualified by WHO	>10
原料药或制剂企业 API or formulations manufacturers	在境外建立研发中心或生产基地的企业 The number of companies who set up R&D centers or production bases overseas	>50

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

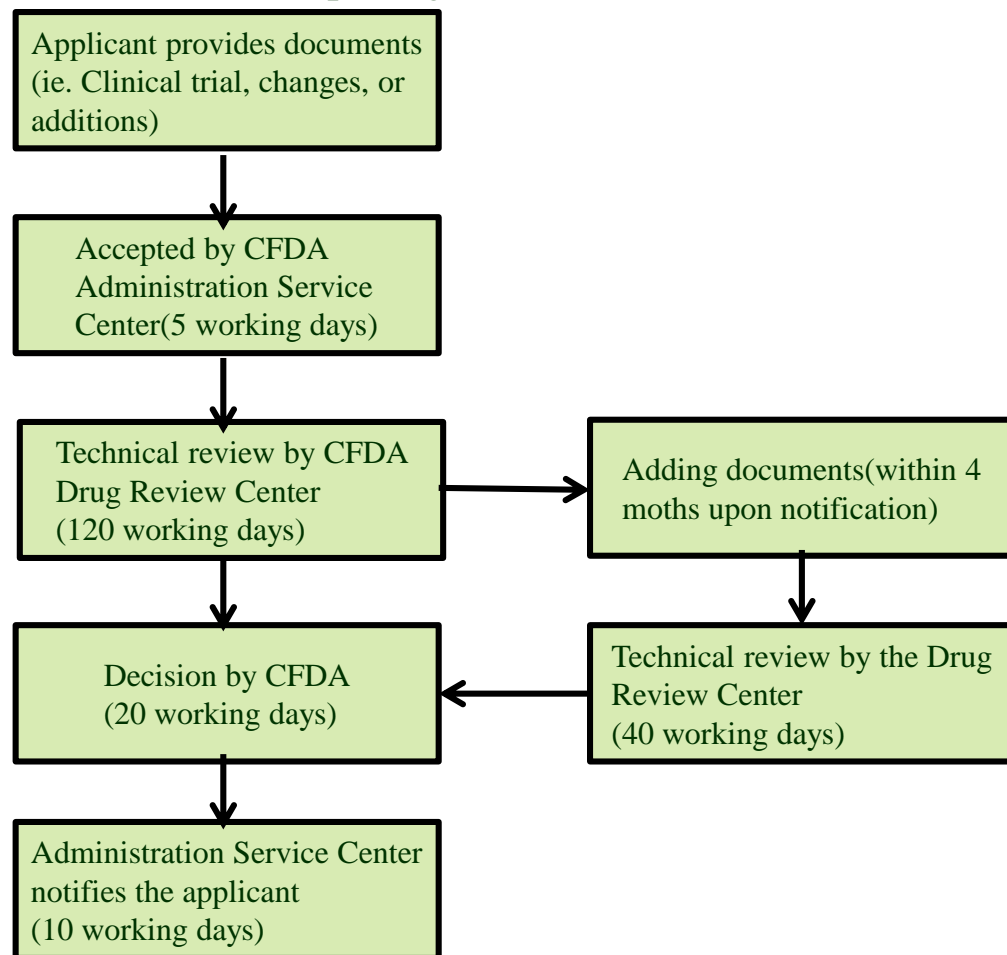
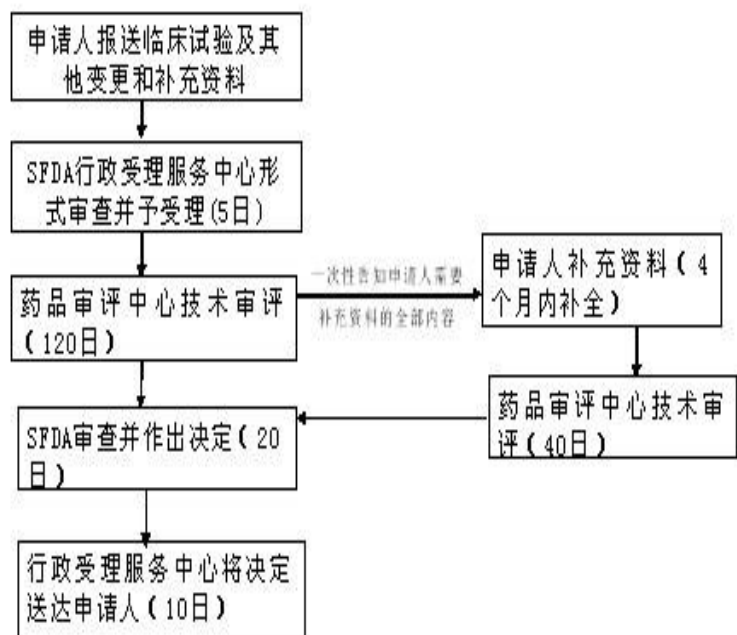
《药品管理法实施条例》
*Regulations for Implementation of The
Drug Administration Law*

《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

Registration Process of Imported Drugs (after completing clinical trial)

进口药品注册（完成临床试验后）的申办流程示意图



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

原料药GMP
实施现状
Implementati
on of GMP
for APIs

截止2015年1月，CFDA共批准原料药生产批文9760条，来自2234家生产企业。

By January 2015, CFDA approved the production of 9760 APIs from 2234 manufacturers.

颁发原料药相关GMP证书960份，无菌原料药相关GMP证书140份，抗肿瘤原料药GMP证书共36份。
960 GMP certificates were issued for APIs, 140 for sterile APIs, 36 for oncological drug APIs

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

无菌药品GMP
实施现状
GMP
implementation
for Sterile
medicinal
products

根据新修订药品GMP实施规划，血液制品、疫苗、注射剂等无菌药品的生产必须在2013年12月31日前达到新修订药品GMP要求。

According to the work plan, blood products, vaccines and injections were required to be GMP compliant before Dec.31,2013

截止2013年底，已有870家提出GMP认证申请，其中855家完成现场检查，通过检查并公告的企业有796家。

By the end of 2013, 870 companies applied for new GMP certificates, 855 of them were inspected and 796 passed the inspection and were announced compliant by CFDA with a public notice.

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

非无菌药品
GMP实施现状
GMP
Implementation
of Sterile
Medicinal
Products

我国共有非无菌药品生产企业5634家，预计92%的药厂可在今年年底前通过认证。
China has 5634 manufacturers of sterile medicinal products and it is expected that 92% of them will pass new GMP by the end of 2015.

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

- CFDA坚持高标准、严要求，及时颁布相关附件和认证检查指南，修订原有质量手册及34个程序文件，并新增4个文件，从制度方面进一步完善了药品GMP认证检查。
- CFDA is adherent to the highest standards and requirement, and has worked out relevant guidance, updated 34 quality related procedures, added 4 documents, and improved GMP inspection.
- 新版GMP为中国医药产业的优胜劣汰、兼并重组提供了历史性的机遇。
- The new GMP has offered an historic opportunity for 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，确保中国医药产品质量标准达到国际先进水平。
- The new GMP is in line with WHO rules to ensure that the qualities of Chinese products are geared to the international standards.

3. 最新变化 Latest changes



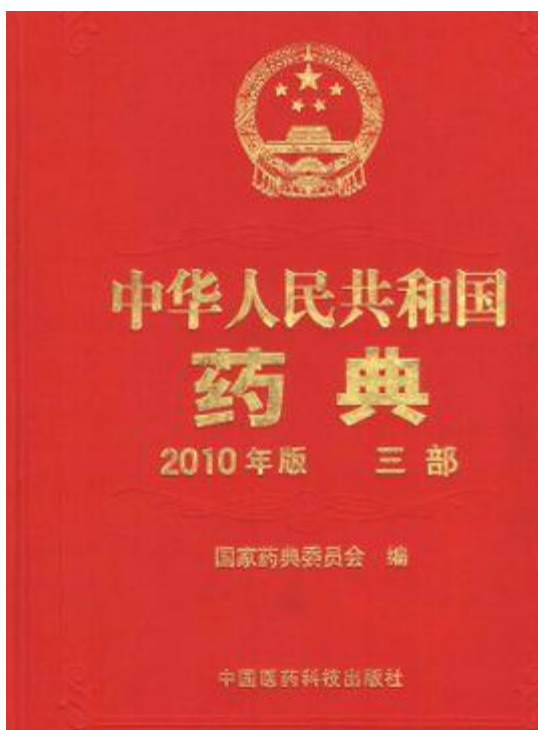
- 药品管理法修订列入十三届人大立法规划和2014年国务院法制办立法计划中。
- Revision of *Drug Administration Law* was listed into the 13th NPC law-making plan and the agenda of the legal office of the State Council.
- 2013年12月CFDA正式启动药品管理法修改工作，成立了修法领导小组和工作组，进行了相关任务分解。
- CFDA officially started the DAL revision work in December 2013, and has so far set up a steering group and laid out detailed working plans.



药品管理法修订思路 Principles underlying the Revision of DAL

I	强化监管，减少行政审批 Enhance regulation, streamline administrative approval	加强使用环节的监督 Enhance in-process supervision	加大违法者的处罚力度 Harsher punishment to the violators	
II	增加药品召回制度 Set up a drug recall system	增加药品出口管理规定 Set up the drug export management system	增加原辅料备案管理规定 Set up the filing procedure for APIs and excipients	增加电子监管和互联网药品交易监管内容 Set up an electronic supervision and on-line transaction management system
III	建立药害救济制度 Set up a drug ADR relief system	建立企业责任首负制度 CSR system	完善药品监管信息公开机制 Improve the information sharing system for drug regulation	

3. 最新变化 Latest changes



- 2015年版药典于2014年6月完成修订，并将于今年7月份正式实施。
- The revision of the *2015 Chinese Pharmacopoeia* was finalized in June 2014, and this version will be put into use from July 2015
- 新版药典拟收载品种5660个，增幅达26%，完成标准提高品种2917个，其中收载化学药品种数量为2617个，比日本多1276个
- The new Pharmacopoeia includes 5660 products, the number of which increases by 26%. 2917 more standards have been newly added. There are 2617 chemical drugs in the new pharmacopoeia, 1276 more than the Japanese pharmacopoeia.
- 药用辅料独立成卷，并增加到271个，同比增幅105%。
- Excipients are in a stand-alone volume, and number of products included have risen to 271, up by 105%.

3. 最新变化 Latest changes

- 针对化学药领域，加强了对杂质定性和定量测定方法的研究，实现对已知杂质和未知杂质的区别控制，优化抗生素聚合物测定方法；
 - 加强了对包括催化剂在内的无机杂质检测方法的研究与修订，提高方法的准确性。
-
- Regarding chemical drugs, qualitative and quantitative assays of impurities were emphasized so that known impurities and unknown impurities are controlled differently and improve testing method for antibiotics polymers.
 - Developed and updated testing method for inorganic impurities such as catalyzers to increase the accuracy of the method.

三、中日医药贸易及中国医药企业的关注

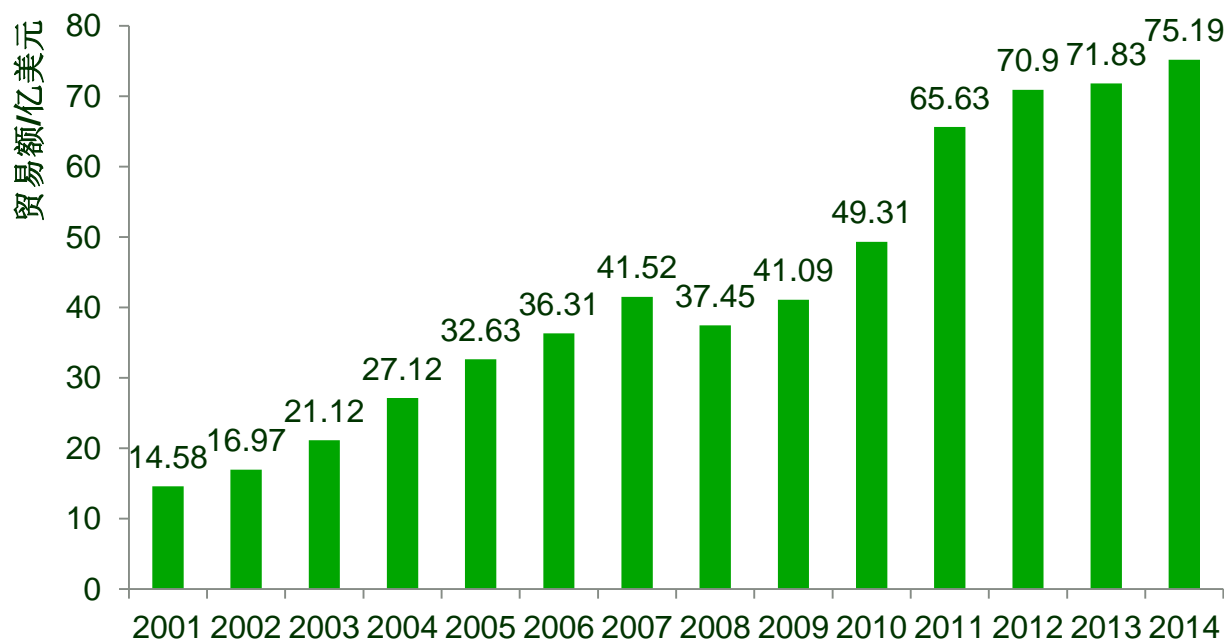
China-Japan healthcare trade and interests of the Chinese companies



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

中日医药进出口额从2001年的14.58亿美元增长到2014年的75.19亿美元，翻了五倍多，年均复合增长率达12.4%。

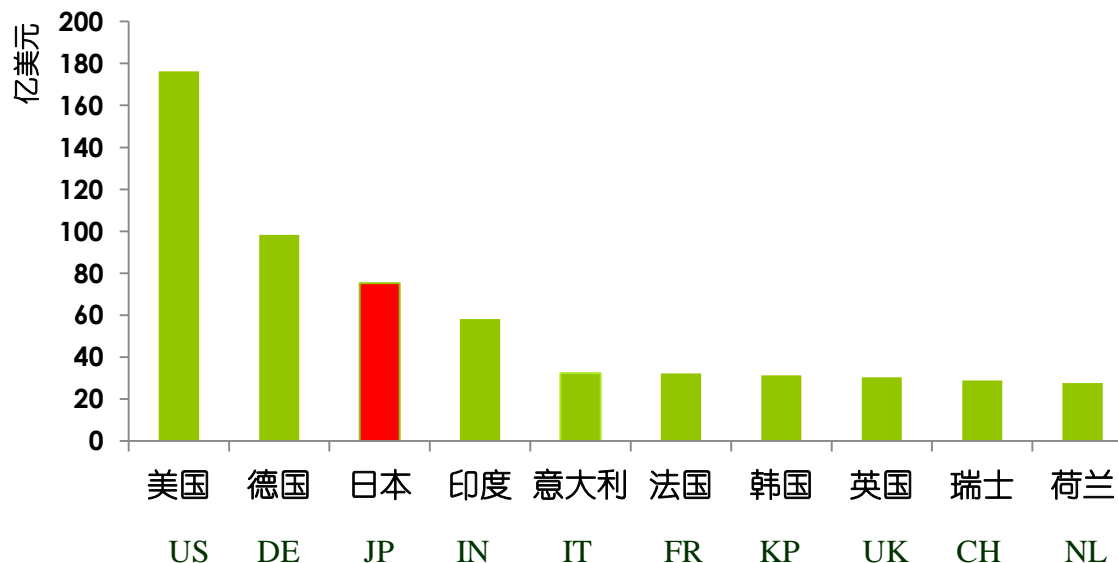
China-Japan healthcare import and export trade rose from 1.458b USD in 2001 to 7.519b USD in 2014, an increase of five times, and CAGR of 12.4%



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。2014年，对日贸易额占中国医药对外贸易总额的7.7%。

Japan has long been one of China's top three trading partner in the healthcare sector. In 2014, China-Japan healthcare trade took 7.7% of China's total foreign healthcare trade with the world.



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

- 日本在中国医药出口目的国榜单中位列前三。
- China is among China's top three exporting destinations.
- 2014年出口增幅10.63%，明显高于美、德、韩、英等主要出口目的国。
- Export growth stood at 10.63% in 2014, significantly higher than the other exporting destinations such as US, Germany, Korea, UK, etc.
- 日本在中国医药进口来源国榜单中也位居前三甲。
Japan is also among the top three importing sources of China.
- 近年来，进口增幅普遍高于出口增幅，顺差缩小，2013年出现逆差。
- Import growth from Japan has been obviously higher than export from China to Japan and the trade surplus has narrowed and trade deficit occurred in 2013.

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

2014年，中国对日本原料药出口金额达16.54亿美元，同比增长17.76%，高于对日医药出口总额增幅7.1个百分点，占比超过四成。

In 2014, China's API export volume to Japan reached 1.654b USD, up by 17.76%, higher by 7.1 percentage points than China's total healthcare export to Japan, accounting for more than 40% 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
Perindopril
- 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

中药类产品出口受欢迎。
TCM exports getting ever more popular.

2014年，我对日本出口中药类商品5.28亿美元，同比增长16.33%。
In 2014, China's total TCM export volume to Japan reached 5.28b USD, up by 16.33%.

中药材及饮片 TCM raw materials and prepared slices	植物提取物 Herbal extracts	中药保健品 TCM Health Products
<ul style="list-style-type: none">• 人参Ginseng• 半夏Pinellia ternata• 甘草Licorice• 茯苓Poria cocos• 白芍Paeonia lactiflora Pall• 当归:Chinese Angelica	<ul style="list-style-type: none">• 植物浸膏Concrete• 甘草酸盐 Glycyrrhetate• 芸香苷Rutin	<ul style="list-style-type: none">• 蜂王浆Royal jelly

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

- 原研药
- Originators

医疗器械
medical devices

- 光学射线仪器
- Spectroscopy devices
- 内窥镜
- Endoscopy
- X射线断层检查仪
- X-ray tomography instrument
- 彩超
- Ultrasound devices

中药保健品
TCM health products

- 汉方药
- Kampo medicine
- 卵磷脂
- Lecithin

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

- 中国经营医药原料药和中间体对日出口的企业有2000家，但集中度较差，出口额在1000万美元以上的企业仅30家，500万美元以上的68家。而经营对日成品药出口的本土制药企业仅有20多家。
- China has 2000 API and intermediate companies exporting to Japan, but the concentration is low and there are only 30 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.
- 2005年3月到2014年3月，中国企业共接受日本PMDA现场检查114次，海正药业、华北制药、海翔药业等一大批原料药企业通过日本GMP认证。
- From March 2005 to March 2014, PMDA had done 114 inspections on Chinese companies, and a lot of them, including Hisun, NCPC, Hisoar have got Japan GMP certificates.
- 仿制药方面，北京泰德制药、华北制药集团华民公司制剂车间先后通过日本GMP现场检查。
- Regarding generics, facilities of Beijing Tide and NCPC Hebei Huamin have passed Japan GMP inspections.

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.

生物药领域合作潜力大。

Great cooperation potential in therapeutic biologics.

日本
Japan

- 在生命科学方面具有雄厚的基础和有利的市场环境
- Solid foundation and favorable market environment in Japan's life science industry.
- 但在生物技术基础研究成果商业化方面并未走在世界前列，缺乏有效可行的政策培育。
- But is yet to be a global leader in commercializing those fundamental achievements because effective and viable policies are not in place

中国
China

- 出台了一系列鼓励生物医药发展的措施和政策
- A series of measures and policies have been adopted to encourage the development of the biopharmaceutical industry
- 企业引进技术和产品的积极性高
- Companies are highly interested in introducing new technologies and products to the Chinese market
- 庞大的医药市场
- Huge domestic market

商会简介

ABOUT CCCMHPIE

2014年医药进出口贸易额接近 **1000亿** 美元

Healthcare Import and Export volume approached **100 billion USD** in 2014.

2400多家 会员遍布全国

2400+ members

25年 不懈服务

25 years of experiences



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

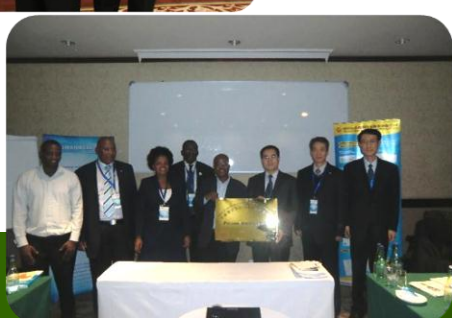
► 参与政府双边磋商

governmental dialogues and
negotiations



国际交流
International exchange

- 商会与英国、美国、俄罗斯、意大利、法国、东盟、非洲、中东欧等几十个国家和地区的医药业界保持着密切的往来
- 与十余个国家的药政管理当局、医药行业组织或贸促机构签署了长期合作协议。
- CCCMHPIE maintains close relationships with its counterparts across the globe, including those of UK, US, Russia, Italy, France, ASEAN, Africa, central and eastern Europe.
- It has long-term cooperation agreements with over 10 counterparts in the healthcare industry or trade





国际交流
International exchange

- 组织中国医药企业代表团分赴英国、瑞士、俄罗斯、爱沙尼亚、乌克兰、保加利亚、意大利、法国等国深度访问，开展交流与对接。
- CCCMHPIE has taken healthcare delegations to some countries like the UK, Switzerland, Russia, Estonia, Ukraine, Bulgaria, Italy, France for industry dialogues and match-makings with local companies.





中意医药开启高端对话，携手共谋产业国际化之路

China-Italy high level exchange program to seek for internationalization of the industry on both sides.



对话赛诺菲，嫁接中法双边产业合作交流平台
Dialogue with Sanofi to link up leading companies of China and France.



与英国、丹麦、印度、东南亚、非洲等国家建立战略合作机制

Strategic cooperation mechanisms are formed with UK, Denmark, India, Southeast Asia and Africa.etc.

商会个性化服务

CCCMHPIE providing customized services



认证

出具产品自由销售证书, 外办公证和外交部及外国驻华使馆认证

Issue Certificate of Free Sales, and are certified by Ministry of Foreign Affairs and foreign Embassies in China

技术引进

协助引进和转让技术

Assistance in technology introduction and transfer

注册

协助企业进行药品、保健品和医疗器械境内外注册

Assistance in domestic and overseas registration of drugs, health products and medical devices

企业战略发展规划

Corporate development strategies



Thank you!