

中日医药健康领域合作与中国医药监管制度改革

China-Japan Healthcare Cooperation and Chinese Drug Regulatory System Reform

China Chamber of Commerce for Import & Export

of Medicines & Health Products

Meng Dongping

Vice President

April 2017



主要内容 Content





中国医药健康产业发展态势

Current development Status of the Chinese Healthcare Industry



中国医药监管制度改革

Chinese Regulatory System Reform



中日医药合作现状及未来合作前景

China-Japan Healthcare Trade and Prospect of Future Cooperation

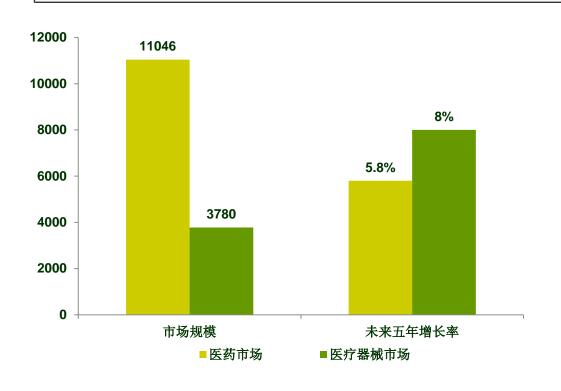


一、中国医药产业发展态势



Current Development Status of the Chinese Healthcare Industry

1. 全球医药市场 The global healthcare market



2016年全球医药市场形势 Global healthcare market in 2016

- ●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

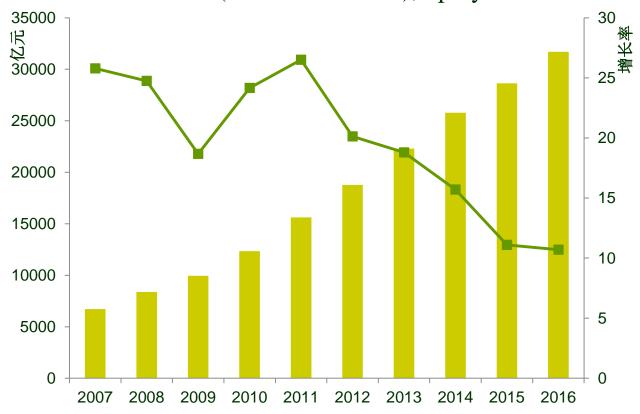


2. 中国医药产业态势Chinese healthcare industry



2016年,中国医药工业总产值约3.17万亿元(4600亿美元),同 比增长10.7%。

In 2016, China's pharmaceutical and medical industry output reached around 3.17trillion RMB (460 billion USD), up by 10.7%.







Chinese Medicinal Industry

Made in China





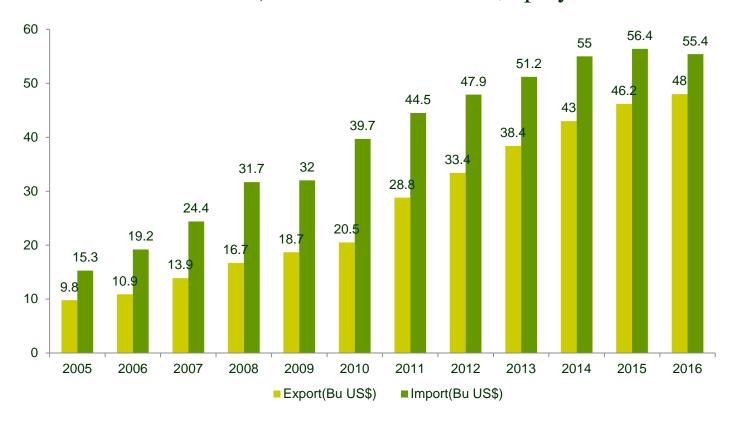








2016年,中国医药保健品进出口额达1034亿美元,同比增长0.73%。 In 2016, the trade volume of China's health products (medicines and medical devices included) reached 103.4b USD, up by 0.73%.



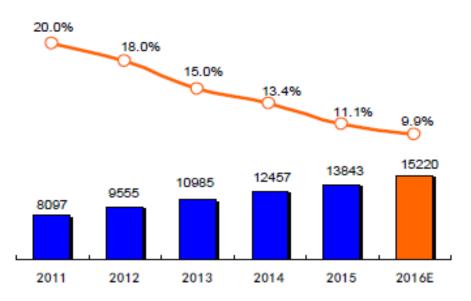




3. 中国医药市场 Chinese healthcare market

2015年,我国药品市场终端销售额为13843亿元,2016年预计为15220亿元,同比增长9.9%。In 2015, Drug sales in China reached 1384.3bn RMB, and will reach 1522bn RMB in 2016, up by 9.9%.

药品终端市场销售额(亿元)



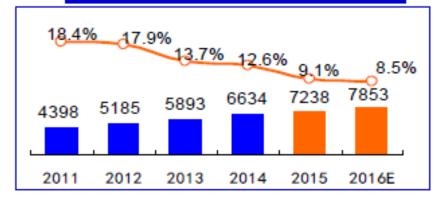
- ●第一终端: 医院终端——城市医院、县 级医院;
- •First terminal: Hospital, city and County level hospitals
- ●第二终端: 药品零售终端——实体药店、纯电商渠道;
- Second terminal: Pharmacies, e-commerce channel without drug stores
- ●第三终端:基层医疗机构终端——城市社区医疗机构、乡镇卫生院及村卫生所等。
- Third Channel: Basic medical institutions such as community hospital and rural clinics

2015年中国医院市场药品销售额9517亿元,占中国药品市场销售额的68.8% HPIE 2016年预计销售额10421亿元,同比增长9.5%。

In 2015, drug used in hospital reached 951,7bn RMB, accounting for 68.8% of the total drug sales and will reach 1042.1bn RMB, up by 9.5%.

中国27587家医院市场药品销售额(亿元) 21,7% 14.8% 13,7% 10.7% 9.5% 10421 9517 8596 7558 6584 5562 2011 2012 2015 2016E 2013 2014

14513家城市医院药品销售额(亿元)



13047家县级医院药品销售额(亿元)



2015药品零售市场销售额为3125亿元, 药品零售市场销售额占总体药品市场销售额的22.6%。 2016年销售额约为3443亿元,增长约10.2%。

In 2015, drug sales in retail market reached 312.5bn RMB, accounting for 22.6% of the total drug sales, and will reach 344,3bn RMB, up by 10.2%.

2015年药品零售市场规模3125亿元,分解如下

中国药品零售市场销售额(亿元) 15.0% 13.4% 12.8% 10.5% 10.6% 10.2% 3443 3125 2828 2558 2268 2000 2011 2015 2016E 2012 2013 2014

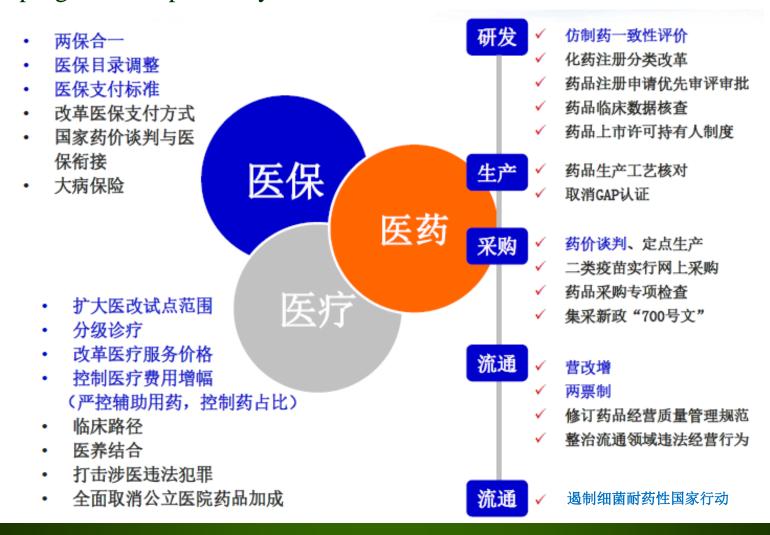
	实体药店	网上药店
数量	448057家 连锁门店204895家 单体药店243162家	A证: 40 B证: 217 C证: 639
药品销售额 (亿元)	3000	125
占药品零售市 场销售额比重	96%	4%
占总体药品市 场销售额比重	21.7%	0.9%





三医联动的政策进展

The progress of tripartite System reform







4. 中国医药国际化态势 International status of the Chinese healthcare industry

- 1、中国医药市场快速扩容, 进口增速大于出口
- 2、生物医药、体外诊断等新 领域发展迅猛
- 3、中医药产品和服务走出去 步伐加快
- 4、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

- •China's market keeps on expanding, and import grows faster than export
- •Rapid Development in new areas such as biopharmaceuticals and IVD
- TCM products and services speed up to walk out
- An array of leading Chinese local companies and brands are developed





5、医药产业并购 整合进一步加剧

More and more Merger and Integration cases happens in the Pharmaceutical industry.

2011年-2016年中国医药行业并购案例数量及金额







6、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	>560
原料药企业 API companies	获得美国DMF文件 The number of DMFs	>1500
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	>60
制剂企业 Formulations manufacturers	获得美国ANDA申请 The number of ANDAs that were filed with US FDA	>70
医药企业 Pharmaceutical manufacturers	通过WHO PQ认证 The number of generics that were PQ qualified by WHO	APIs: 32 FDF: 18 Vaccine: 3



7、中国企业展 开国际合作形 式高潮迭起 Paces of international collaboration are accelerated

注重研发,新药国际转让越来越多。

Focused on R&D, international transfers on new drugs are increasing.

- ●中国的研发型制药企业已增加到147家,超过日韩,成为亚洲最大,全球第四大新药研发国。
- •R&D oriented pharmaceutical companies being increased to 147 in China, which became the Asia leading and world's fourth new drug R&D country.
- ●越来越多中国企业从境外购买成熟产品,同时将自主产品 授权给跨国药企。
- •A growing number of Chinese companies buy mature products from abroad and authorize their own products to multinational pharmaceutical companies.

境外投资并购增多。

Overseas Investment and acquisition are increasing.

- ●设立子公司或合资公司:海正、天士力、悦康。
- •Established subsidiaries or joint ventures: Hisun, Tasly, Youcare
- ●并购国外企业:人福、绿叶、上药。
- •Acquisitions of overseas enterprises: Humanwell, Luye pharma, Shanghai Pharma.



二、中国医药监管制度改革

Chinese regulatory system Reform





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。原料药企业被要求搬迁、停限产、倒闭的情况时有发生。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.







化学药品注册分类调整。

New classification system for registration of chemical drugs

- ●2016年3月,CFDA发布《关于发布化学药品注册分类改革工作方案的公告》,对化学药品注册分类进行调整,对于创新药、改良新药、仿制药及对应原料药的分类和要求均有变化。
- •In Mar. 2016, CFDA issued reform plan for chemical drug registration classification, put forward new requirements for innovative drugs, me-better drugs, generic drugs and their APIs.
- •对原料药杂质研究、长期稳定性试验等的要求更加严格
- •More strict requirement for impurities, long-term stability test and so on.
- •与国内的核查要求更加衔接,与国际要求更加接轨。
- •More integrate with domestic inspection and international requirement





药品上市许可持有人制度开始试点。

Pilot of MAH system in China.



2016年5月,《药品上市许可持有人制度试点方案》出台,在国内十个省市试点启动。促进药品创新,激发市场活力,优化资源配置。申报超过270件,齐鲁制药获得首个文号。

In May 2016, 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.







仿制药一致性评价新政正式实施。

Implementation of Policy of quality consistency evaluation of generic drugs.



- ●"十三五"《医药工业发展规划指南》中,一致性评价列入产品质量升级工程。
- •In the "Thirteen-Five" Pharmaceutical Industry development Planning Guidence, consistency evaluation is included in the product quality upgrade project.
- ●CFDA成立一致性评价办公室,推出多项指导和鼓励措施。
- •CFDA established the Consistency Evaluation Office and launches a number of guidance and incentives.
- ●我国现有化药品种5743个,首批期限完成评价的仅占5%。
- •We have 5,743 pharmaceutical varieties in China, only 5% has finished evaluation during the first term.
- ●制药行业大洗牌, 1/3品种将被淘汰?
- The pharmacy industry will reshuffle, 1/3 drug approval number will be eliminated?







建立优先审评审批制度。

Establish drug review and approval priority system.

- ●2016年2月, CFDA出台实行优先审评审批制度的意见。
- •In Feb 2016, CFDA implemened review and approval priority system.
- ●2016年底,193件注册申请纳入优先审评,57件完成优先审评。
- •By the end of 2016, 193 application has been reviewed as priority and 57 of them has finished the procedure.
- ●加快创新药和临床急需药的上市速度。
- Speed up appoval process of innovative drugs and clinical urgently needed drugs.





进口药品注册管理改革, 提速进口药上市步伐。

Import drug registration management reforms to speed up their approval process.



国家食品药品监督管理总局 CFDA

China Food and Drug Administration

总局公开征求《国家食品药品监督管理总局关于调整进口药品注册管理有 关事项的决定(征求意见稿)》意见的通知

2017年03月17日 发布

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)要求,为鼓励境外未上市新药经 批准后在境内外同步开展临床试验,缩短境内外上市时间间隔,满足公众对新药的临床需求,国家食品药品监督管理总 局起草了《国家食品药品监督管理总局关于调整进口药品注册管理有关事项的决定(征求意见稿)》,现向社会公开征 求意见。有关单位和社会各界人士可于2017年4月20日前,通过以下方式提出意见: 同步上市?
Simultaneous
Approval?



《药品经营质量管理规范》重新修订。 GSP re-revised.

- ●2016年7月,新修订的《药品经营质量管理规范》公布。
- ●In July 2016, new revision of GSP is published.
- ●主要涉及药品追溯体系建设、疫苗批 发经营及配送等内容。
- •Mainly related to drug traceability system, vaccine wholesale management and distribution.





CFDA发布《体外诊断试剂注册管理办法修正案》。 Revising registration procedures for in-vitro diagnostic reagents.



- ●2017年2月, CFDA发布《体外诊断试剂注册管理办法修正案》, 更好地分类管理, 强化风险动态管理。
- •In Feb 2017, CFDA published registration procedures for in-vitro diagnostic reagents to enhance classification management and risk control.



中医药政策法规全面落实。

TCM Policies are fully implemented.

- ●《中医药发展战略规划纲要(2016-2030)》
- •Strategic planning outline of TCM development 2016-2030
- ●《中医药"一带一路"发展规划(2016-2020年)》
- ●TCM "One belt one road" development plan 2016-2020
- ●《中医药法》、《中国的中医药》白皮书
- ●TCM Law and TCM in China White Book
- ●中药材外贸基地认证
- Foreign Trade Base Certification
- ●提取物国际商务标准、"植物提取物优质供应商"认证(GEP认证)
- •International business standards for extract, "Plant extract quality Supplier" Certification
- 中药材流通追溯体系建设
- The development of Chinese medicinal herbs circulation tracing system







食品安全立法更严。

Food Policy legislation is stricter.

- ●2015年10月1日,新《食品安全法》正式实施,对保健食品加强监管。
- •October 1, 2015, the New Food Safety Act was formally enforced, and the regulation of health food was intensified.
- ●2016年, CFDA出台《保健食品注册与备案管理办法》和《保健食品注册审评审批工作细则》。
- ●2016, CFDA introduced the "Health food registration and filing management method" and "Health food Registration review approval work rules."





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。2016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 2016, 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.

2016年,中国对日本原料药出口金额达17.22亿美元,占比45%。 In 2016, China's API export volume to Japan reached 1.722b USD, accounting for 45% 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Perindoprils
- 他汀类
- Sartans

生化原料药APIs for biochemical drugs

- 蛋白胨衍生物 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.

2016年,中国对日本出口医药诊断与治疗设备6.33亿美元。 In 2016, China's total Hospital diagnostic and treatment devices export volume to Japan reached 0.633b 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Antiinfective
- 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. 中日医药合作前景及机遇 the Prospect of China-Japan Healthcare Future Cooperation







跨境电商促进中 日医药贸易。

Cross-border electronic business promote Sino-Japan pharmaceutical trade.

医药成为中日投资新增长点。

Medicine becomes a new growth point of Sino-Japanese investment.

第三方市场合作迎契机。

Cooperation of third-party market has opportunities.





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

- 日本政府致力于不断提升仿制药使用比例,今年目标70%。
- Japanese government are doing efforts to expand the use of generic drugs, the objective is accounting for 70% by the end of this year.
- 中国是世界最大的原料药生产和出口商,能够稳定地供应高品质的原料药。 仿制药质量也不断提高,并已进入欧美市场。
- China is the largest producer and exporter of APIs, can provide stable supply of high-quality APIs, the quality of generic drugs is better and better with access to the EU and USA market.
- 原料药和中间体对日出口企业2186家,出口额1000万美元以上30家,500万美元以上72家。成品药对日出口的本土制药企业仅有20多家。
- 2186API and intermediate companies exporting to Japan, only 30 companies with an annual export volume of over 10 million USD and 72 companies with an annual export volume of more than 5 million USD. Only 20 Chinese local companies are exporting finished products to Japan.





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

- ●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.

4. 药品进入中国市场策略 Strategy of Drugs Access to Chinese Market









药品注册问题 Problems of Drug Registration

- ●申报资料不完整,不符合CFDA要求。
- Incomplete file, inconsistent with CFDA requirements.
- ●产品立题目的与依据不充分。
- The purpose and basis of the project is insufficient.
- ●中方合作伙伴的技术能力问题。
- Technical incompetence of Chinese partners.
- ●外方企业不熟悉中国法律法规,又没有专业顾问为其提供支持,造成进口药品注册延迟。
- •Foreign enterprises are neither familiar with Chinese laws and regulations, nor supported by professional consultants, causing the delay of import drug registration.



- 2014-2016年,中国医药健康企业代表团连续三次访问日本,开展交流对接活动
- In 2014-2016, Chinese healthcare delegation visited Japan trice 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

我信信為本 為中國長持保徒品達出了商会 為中國長持保徒品達出了商会

Introduction to CCCMHPIE

中国医药保健品进出口商会介绍





International Exchange

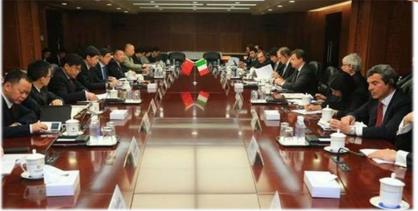
国际交流















Thank you!