

The Rise of China: Implications for Pharma and Pharma Librarians

Pharmaceutical & Health Technology Division Special Libraries Association March 20, 2012





Agenda

- Why China?
- China's Healthcare System
- China Healthcare Reform
- Things To Watch For In 2012 & Beyond
- Sources Of Information On China



- Patent Cliff
- R&D Productivity Crisis
- Demonstrating Real-World Outcomes
- FDA



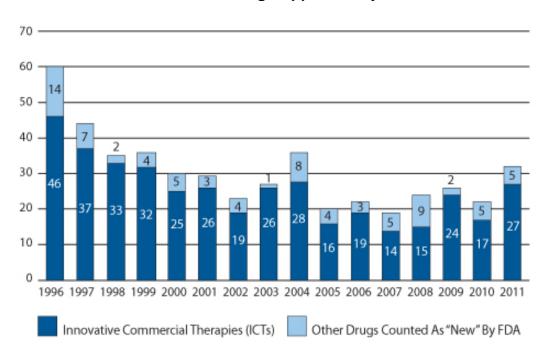
Big pharma patent expiry risk over next 3 years (data based on FY 2011 estimates)

big pilatilia patent expiry fisk over hext o years (data based on 1 1 2011 estillates)							
	WW Pharma Sales in 2011 (\$bn)	Patent expired sales (\$bn)	Patent expiry within 3 years (\$bn)	% Portfolio at risk within 3 years			
Eli Lilly	21.5	7.2	8.0	71%			
AstraZeneca	32.2	7.5	15.2	71%			
Takeda	16.3	4.0	6.9	67%			
Pfizer	54.7	24.6	11.7	66%			
Bayer	18.6	9.5	2.3	63%			
Johnson & Johnson	24.9	8.4	6.0	58%			
Bristol-Myers Squibb	17.1	0.7	8.5	54%			
GlaxoSmithKline	39.2	18.8	2.1	53%			
Merck & Co	43.2	8.5	10.2	43%			
Novartis	50.1	9.6	12.0	43%			
Sanofi	45.6	8.4	7.3	34%			
Abbott Laboratories	22.6	4.0	1.6	25%			
Roche	36.7	3.9	2.4	17%			

Source: Evaluate Pharma (2/9/12)



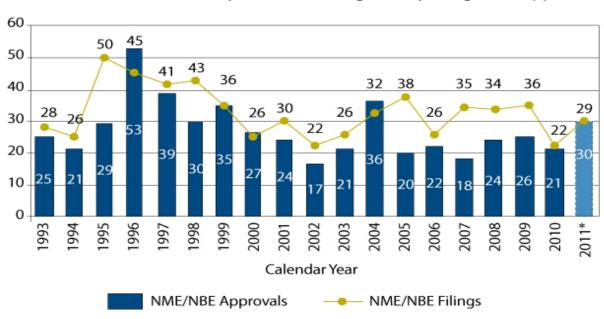




Source: RPM Report/Elsevier (January 2012)



CDER New Molecule Entity And New Biologic Entity Filings And Approvals



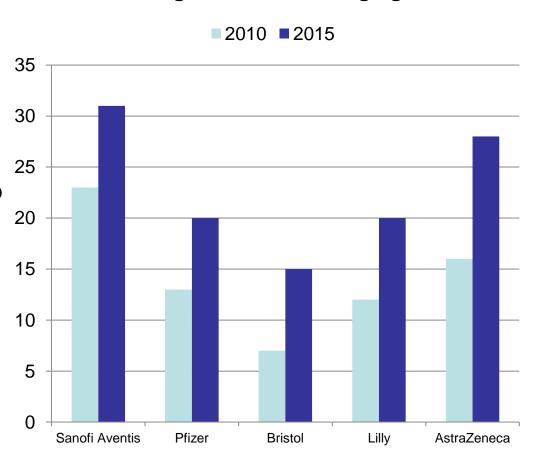
Source: RPM Report/Elsevier (January 2012)



Tomorrow's Growth: Emerging Markets

% of drug sales from Emerging Markets

- Squeezing revenue from legacy brands: Emerging Markets may be less profitable (40% avg. operating margins) but brands are "stickier"-- less exposed to steep revenue drop on patent expiry
- ➤ Take *Lipitor*: 9% of sales come from EM today; by 2015 this will be 54%, with sales up 60% in those areas





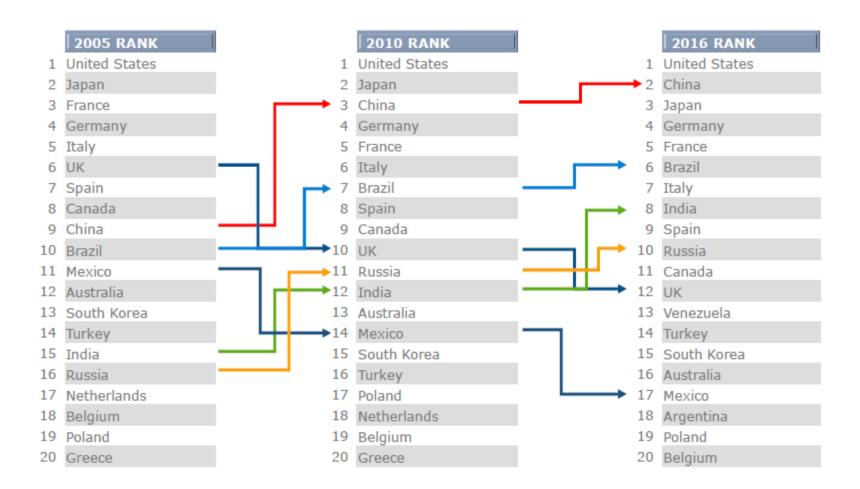


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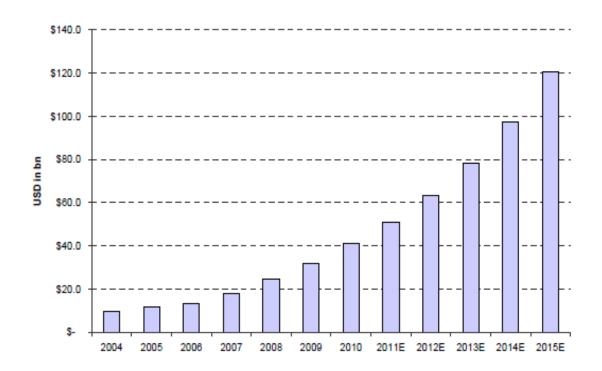
China's Pharma Market



Source: IMS Health, Market Prognosis, Sept. 2011



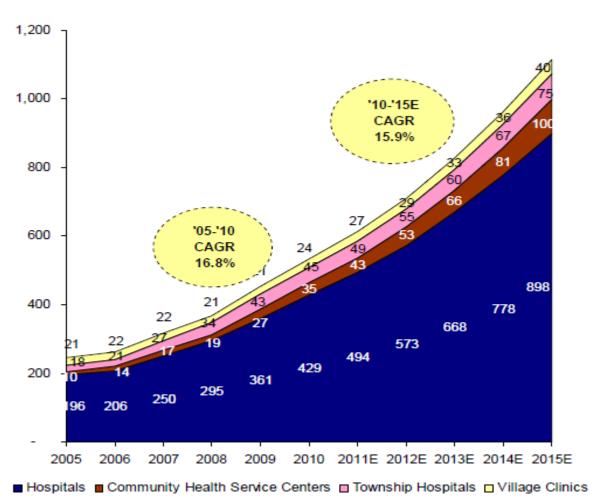
China's Pharma Market



Source: Cowen & Co, IMS Health, 08/11



China's Pharma Market



Source: Citi Investment Research, 12/11

China Demographics – Fueling Pharma Growth

Aging Population

- Percent of Population Age 60+:

10% in 2000 13% in 2010 (~178 million – 50 million larger than Japan's total population) 23% in 2030 (est.)

Rising Income Levels

- Personal disposable income predicted to grow 9% in 2010-2015
- 170 million can now afford modern medicine, rising to 380 million by 2016 (DB estimate).

Lifestyle Changes Leading To Western Diseases

cardiovascular, obesity, diabetes, cancer

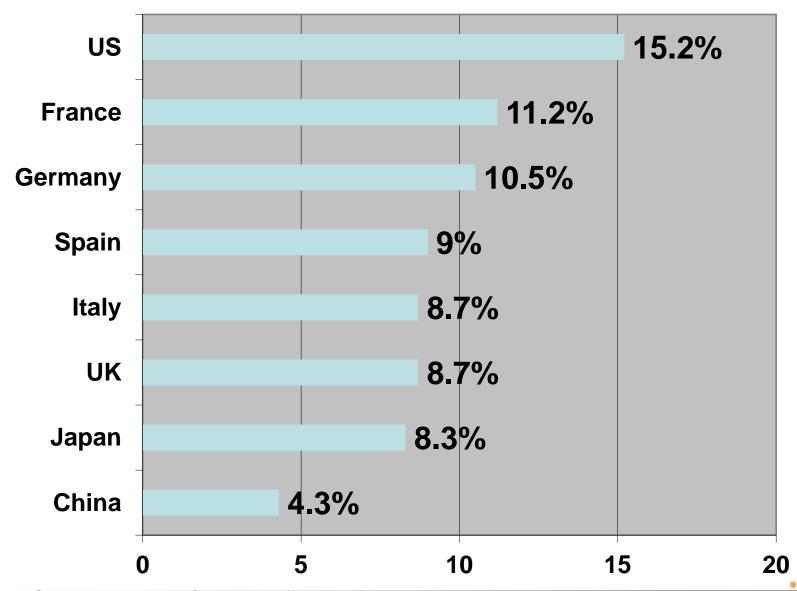
China Now #3 Pharma Market (~\$67 billion)

- Will soon surpass Japan (projected 17% CAGR 2011-15, reaching \$127 billion by 2015)

Source: World Health Organization, Macquarie Research, Deutsche Bank, IMS Health

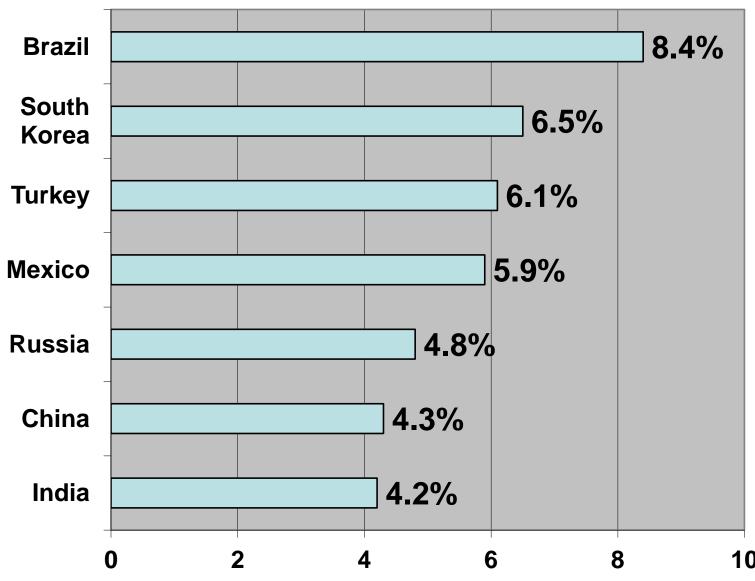


Total Expenditure On Health As % Of GDP – China vs. US/EU5/Japan



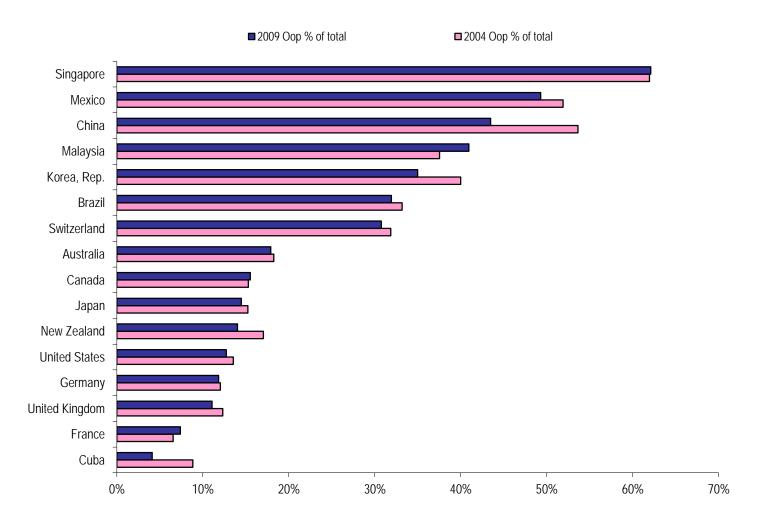


Total Expenditure On Health As % Of GDP – China vs. BRICS-MT





Out-of-pocket Health Expenditures (% of Total Expenditures on Health)



Source: Citi Investment Research & Analysis

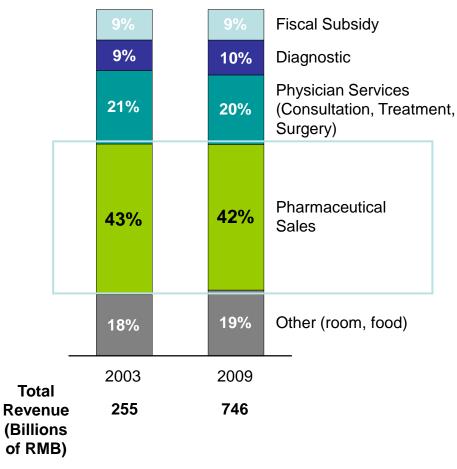
China's Healthcare System

- China traditionally has not had a primary care system
 - Patients go to hospitals for treatment (overcrowded top-tier hospitals)
 - Most drugs prescribed/dispensed by hospitals (which rely on drug sales for profits)
- China is primarily a generics (branded generics) market
- Government reimbursement rather than commercial/private reimbursement
 - China has become the world's largest single-payer system (1.3 billion people)
- Reimbursement for healthcare products/services set by government
 - No negotiation between payers (insurance) and providers (hospitals)
 - Drug reimbursement is set by the government (EDL/NRDL)
 - 31 provinces, each with own reimbursement list/negotiation
- Highly fragmented drug distribution system



Due to lack of public funding, public hospitals rely heavily on selling pharmaceuticals to finance operations

Revenue Structure of Government Hospitals



- Government-owned hospitals, despite being public and non-profit, are in reality profit-seeking entities, due to severe shortage of public funding.
- These hospitals rely heavily on pharmaceutical sales as the most important source of revenue and profitability.
 - They are allowed to charge a 15% markup on pharmaceuticals dispensed in hospital pharmacies.
 - The combination of prescription and dispensing created distorted incentive for hospitals to drive up drug utilization, in some cases excessive.
- This reliance on pharmaceutical is deemed one of the root causes of health care expenditure inflation in China, and one of the most difficult areas to reform.
 - From 2003 to 2009, despite a tripling of total sector revenue, the structure of income barely changed.



- China market is highly fragmented Pfizer is the top company with roughly 3% of the market.
- Most Big Pharma have concentrated on off-patent drugs (branded generics) roughly 60-80% of China sales for MNCs are branded generics, according to Monitor Group
- Branded generics from Big Pharma are generally reimbursed with a premium price, but are increasingly subject to price cuts
- Many innovative products (eg, targeted oncologics) are paid for out-of-pocket by patients as these drugs are not on government reimbursement lists.
- Patient assistant programs increasingly popular tactic by Big Pharma to help with affordability while preserving global pricing power
- Big Pharma looking to partnerships/acquisitions to increase sales in second-tier cities and lower manufacturing costs (Pfizer/Hisun, Merck/Simcere, Sanofi/BMP)
- Most Big Pharma focusing on diversified strategy Rx drugs, OTCs, vaccines
- Most Big Pharma are increasing R&D in China looking to get more innovative drugs on the market

Big Pharma In China – Recent Headlines (PharmAsia News)

- Pfizer and China's Hisun To Explore Branded Generics JV For China And The Globe (Feb. 22, 2012)
- Novo Nordisk Signs MOU With China's Health Ministry To Launch Patient Education Programs (Feb. 2, 2012)
- After Januvia And Onglyza, Novartis Launches Galvus In China; Lucentis Receives SFDA Nod (Jan. 19, 2012)
- **Boehringer** Doubles Down On China With €70 Million Plant Upgrade, Sets Sights On Biosimilars In Shanghai (Dec. 22, 2011)
- China's Hua Medicine Licenses Worldwide Rights To Roche Diabetes Compound, More Deals On The Way (Dec. 20, 2011)
- Merck Unveils \$1.5 Billion Expansion In China With New Beijing R&D Center; Plans To Double R&D Team By 2014 (Dec. 11, 2011)
- As AstraZeneca Cuts Back In The U.S., It's Full Steam Ahead In China (Dec. 8, 2011)
- Could "Calculated Risks" In China Help Solve Global R&D Challenges? **Bayer** Thinks So (Oct. 18, 2011)



Big Pharma In China - Top Companies

	2009	2010	2011 (6-8 months)
1.	Pfizer	Pfizer	Pfizer
2.	AstraZeneca	AstraZeneca	Sanofi
3.	Bayer	Sanofi	AstraZeneca
4.	Sanofi	Bayer	Bayer
5.	Jiangsu Yangzijiang	Jiangsu Yangzijiang	Kelun
6.	Roche	Kelun	Roche
7.	Kelun	Roche	Jiangsu Yangzijiang
8.	Shandong Qilu	Shandong Qilu	Shandong Qilu
9.	Jiangsu Hengrui	Jiangsu Hengrui	Jiangsu Hengrui
10.	Harbin Pharma	Novartis	Merck

Source: Deutsche Bank, IMS Health



Big Pharma In China - PAPs

Figure 2: The Existing Long-Term Patient Assistance Programs in China

NGO	Drug	Molecule	Company	Indication	Retail price	Admin	PAP Scheme for Non-Low Income Patients
CCF1	Glivec	Imatinib	Novartis	CML, GIST	\$3,984/mo	Oral	If on RDL: Buy 6 months + 6 months free; If not on RDL: Buy 3 months + 9 months free drugs
CCF	Tasigna	Nilotinib	Novartis	CML	\$5,625/mo	Oral	Buy 3 months + 9 months free drugs
CCF	Iressa	Gefitinib	AstraZeneca	NSCLC	\$2,578/mo	Oral	Buy 6 months + free drugs
CCF	Tarceva	Erlotinib	Roche	NSCLC	\$3,080/mo	Oral	Buy 5 months + free drugs
CCF	Nexavar	Sorafenib	Bayer	RCC, HCC	\$7,873/mo	Oral	Buy 3 months + free drugs
CFC ²	Sutent	Sunitinib	Pfizer	RCC, GIST	\$6,780/mo	Oral	Buy 3 months + free drugs
CFC	Herceptin	Trastuzumab	Roche	HER2+ breast cancer	\$4,703/month	IV	Buy 6 vials + 8 vials of free drugs
CCF	Exjade	Deferasirox	Novartis	Chronic iron overload	\$1,477/mo	Oral	Buy 13 weeks + 39 weeks free drugs
CCF	Ventavis	lloprost	Bayer	PAH	\$9,688/mo	Inhaled	Buy 1 month + 5 months free drugs, then buy 1 month + 11 months free drugs
CCF	Tracleer	Bosentan	Actelion	PAH	\$4,328/mo	Oral	Buy 2 months + 3~4 months free drugs
CCF	Cerezyme	Imiglucerase	Genzyme	Gaucher's disease	\$19,531/mo	IV	Free of charge to patients

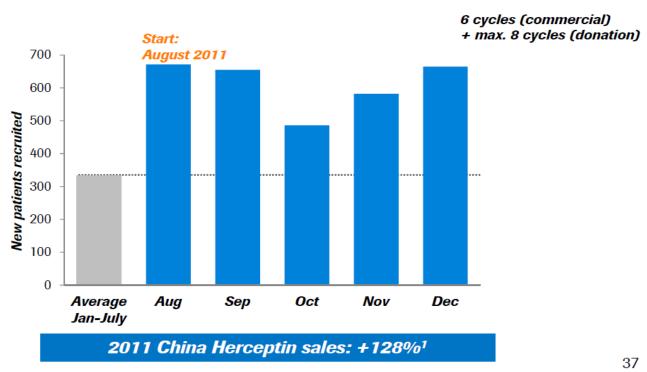
¹ CCF: China Charity Foundation 2 CFC: Cancer Foundation of China



Big Pharma In China - Roche Herceptin PAP

Roche

Patient Assistance: Herceptin program in China Creating platform for public reimbursement

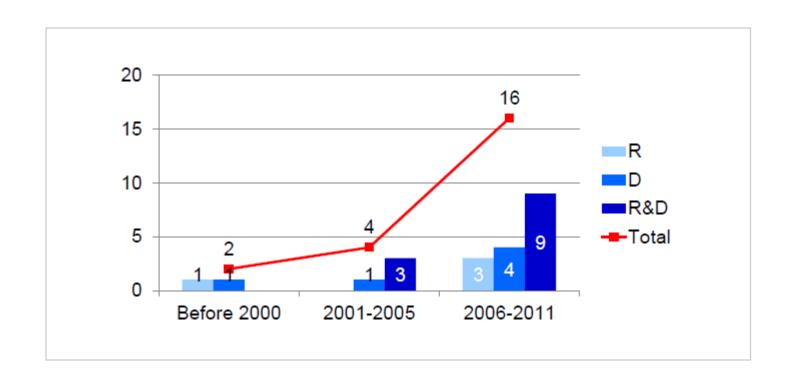


¹ CER = Constant Exchange Rates

Source: Roche Annual Results - 2011 Presentation (Feb. 1, 2012)



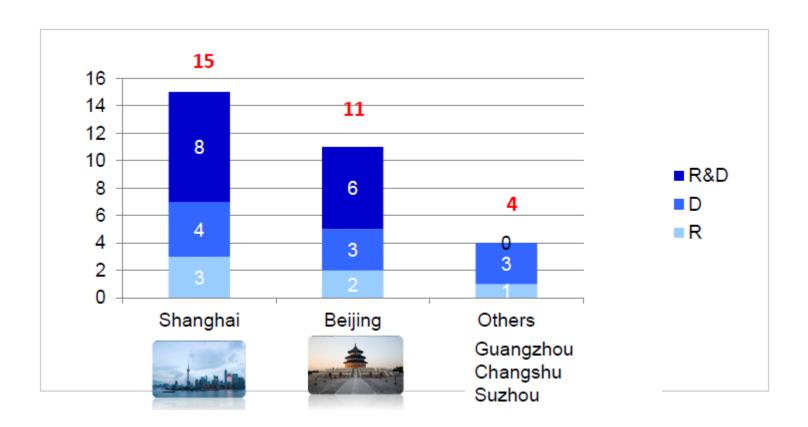




Number of New MNC R&D Centers in China

Source: RDPAC

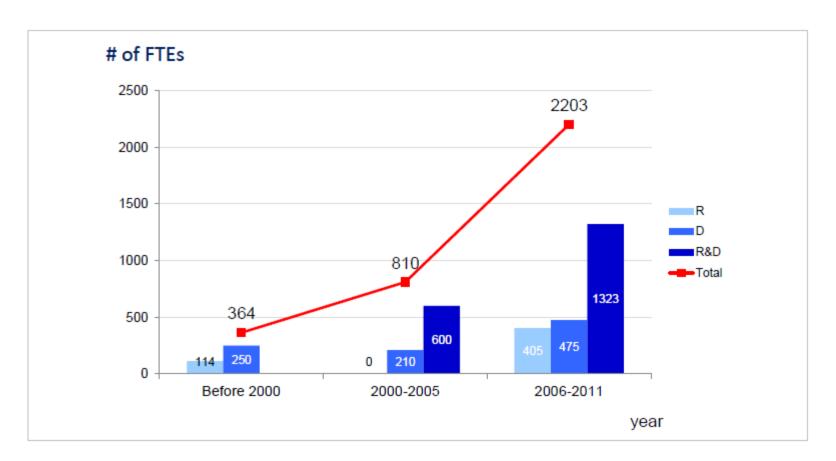




Location of MNC R&D Centers in China

Source: RDPAC





Number of New FTEs at MNC R&D Centers in China

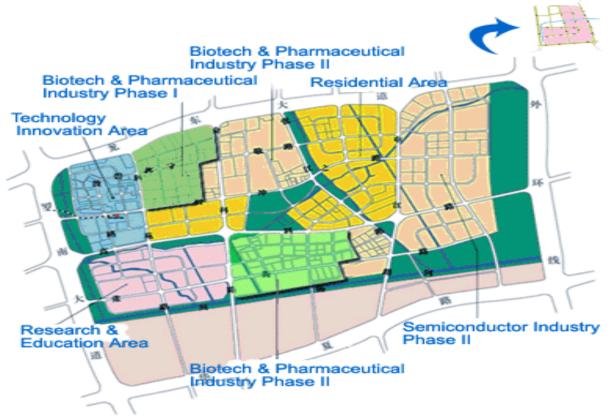
Source: RDPAC





AstraZeneca R&D Center (Shanghai)





Zhangjiang Hi-Tech Park (Shanghai)





Pfizer R&D Center (Wuhan)

"Sea Turtles"

- Roughly 80,000 Western-trained PhDs have returned to China
- Predicted two-thirds of Chinese life sciences professionals currently in the U.S. will return to China or shuttle back and forth between the countries (Source: Monitor Group)
- "1,000 Talents Program" Government provides research funding, salaries, RMB 1 million relocation package. Goal is to lure back 2,000 scientists over next 5-10 years.



Example: Steve Yang, PhD, VP, Head of R&D Asia & Emerging Markets, AstraZeneca



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China Healthcare Reform



Tongren Hospital (Beijing), 6 am

China Healthcare Reform

- First Phase (2009-11) RMB 850 billion (\$124 billion) government investment
 - Primary Goal: Access To Affordable Healthcare For All Citizens (1.3 billion people)
- Five Areas Of Reform
- Universal Medical Insurance
- 2) Reform Basic Drug System (Essential Drug List)
- 3) Improve Basic Healthcare Infrastructure
- 4) Promote Equity in Basic Health Services
- 5) Reform Public Hospitals

Universal Medical Insurance

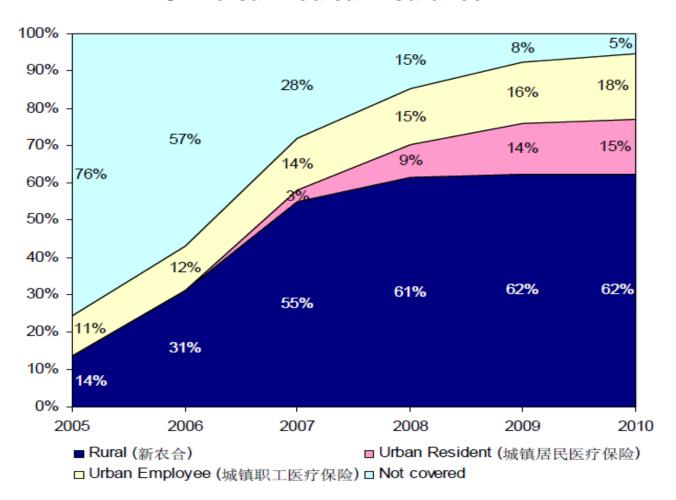
- Goal: 90% of population should have basic medical insurance by 2011
- Goal: Virtually 100% of population should have basic medical insurance by 2020
- Analysts estimate that 96% of population will have insurance by end of 2011
- "Basic" Limited coverage compared to the U.S. (much higher out-of-pocket spending)
 - Government plans to increase subsidies in coming year to help reduce out-of-pocket spending
 - Insurance target is 70% of inpatient costs for urban residents and rural cooperative residents
 - By 2015, Macquarie estimates out-of-pocket spending will be down to 25% on average from ~45% now
- Long Term supplementary commercial insurance?

Source: Macquarie Research





Universal Medical Insurance



Source: Citi Investment Research

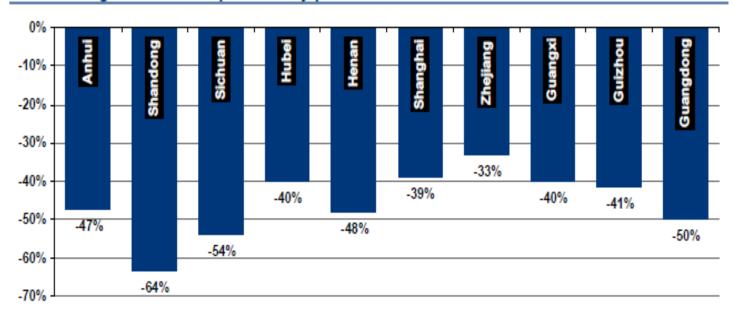
Reform Basic Drug System

- Essential Drug List (EDL) established to provide a national basic drug system that is affordable (price controls)
- 307 drugs included (Western and TCMs) on national EDL, with additional drugs added by provinces
- EDL drugs are 100% reimbursed
- Western drugs are older generic/off-patent medications (eg., old-line antibiotics) and MNCs have largely stayed away from this market (save for testing the water, e.g., Zocor)
- All community hospitals must purchase EDL drugs and provide to patients at zero markup (compared to traditional 15% drug markup for hospitals) – has led to drug shortages as some centers are no longer stocking.
- Price controls/tenders Many complaints about price trumping quality in the provincial EDL tenders (Anhui Model)
- Government expected to more than double the number of drugs on the EDL in 2012



Reform Basic Drug System

Chart 4: Magnitude of EDL price cut by province



Source: BoA Merrill Lynch

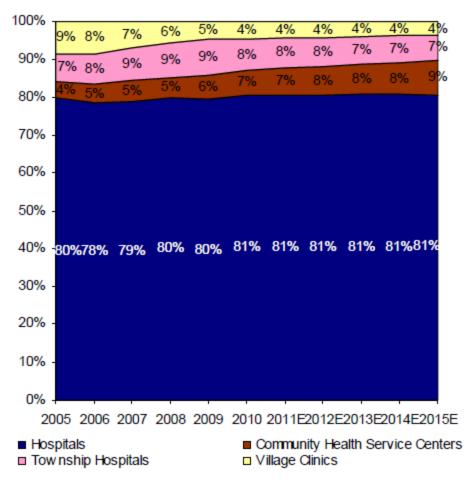
Improve Basic Healthcare Infrastructure

- Goal #1: Improve medical service system by improving infrastructure
- Goal #2: Encourage patients to seek primary care outside of big hospitals
- Construction Boom: grassroots-level hospitals, township hospitals, urban community health centers
- Improve quality of healthcare professionals at village clinics/township hospitals (training, recruitment)



Improve Basic Healthcare Infrastructure





Source: Citi Investment Research



Promote Equity in Basic Health Services

- Goal: Ensure urban and rural areas receive equal public health services
- Standardize electronic health records
- Annual check ups for seniors
- Vaccine drive for children

Reform Public Hospitals

- Goal: Reform hospitals so they can run efficiently and be financially independent
- Challenge: Transition from a cost-based reimbursement system to one based on quality of care/health outcomes
- Current system encourages hospitals/doctors to prescribe higher priced drugs (15% mark up), recommend additional tests/services to generate revenue.
- Drug sales contributed to 62% of hospital profits in 2009
- Many provincial pilot projects now underway
 - Examples: DRG Payment System; Universal Budgeting
- Long term: Insurance providers (government medical insurance) negotiating directly with service providers (public hospitals)?
- Long term: Private hospitals encouraging reform in public hospitals?
- Long term: Raise doctor salaries/medical service fees?

Source: Cowen & Co.



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Looking Ahead

Healthcare Reform Will Continue

- State Council Healthcare Reform Group is led by Vice Premier Li Keqiang, who is likely to be China's next premier
- Access, Affordability AND Innovation
- Changes To EDL/Community Health Centers, Continued Hospital Reform
- Further controls on hospital expenditures

• China's 12th Five-Year Plan (2011-15)

- Biotechnology is one of seven "Strategic Emerging Industries"
- Goal: Grow seven industries from 5% of GDP in 2010 to 8% in 2015 to 15% by 2020
- Central government will spend ~\$2.16 trillion over next five years to achieve this target
- Additional support via finance, tax and other local policies



Looking Ahead

Drug Safety

- Heparin, vaccines, melamine controversies
- New GMPs
- Industry consolidation on the way

Regulatory Reforms

- Speed up clinical trial approvals
- Speed up drug approvals
- Increase training and expertise
- Increase size of SFDA?



Where Do Our Drugs Come From?



Source: Wall Street Journal

Key Questions

- Will China create a system to reimburse novel therapeutics (eg., targeted oncologics)?
- Will China eliminate premium pricing for branded generics (off-patent drugs)?
- Will Big Pharma participate in EDL?
- Will China encourage commercial insurance options to supplement basic government insurance?
- How will government funding of the life sciences industry impact R&D?
- Will China pursue a different regulatory path to encourage innovation and meet huge unmet medical needs?



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Sources Of Information – Tips For Librarians

- Many websites have a Chinese and English version, with more comprehensive information in Chinese.
- Most Chinese news sources (eg, China Daily) are government-owned, not independent.
- Several websites are blocked in China (Facebook, You Tube, Twitter), although there are workarounds (eg, VPN).
- The top search engine in China is Baidu NOT Google.
- Social media (eg, Sina Weibo) is now the go-to place for Chinese citizens to learn about and discuss news and other developments.
- Big Pharma executives in China are often unaware of entitlement rights for global site licenses purchased via headquarters.
- When educated about entitlements, many of these executives are anxious to get access
 a major need exists for reliable business/regulatory intelligence both about China and the global markets.
- Due to the "Sea Turtles" and the need to communicate with global colleagues, most Big Pharma executives in China speak and read English.

Sources Of Information

Government Web Sites

- SFDA A. English: http://eng.sfda.gov.cn
 - B. Chinese: http://sfda.gov.cn
 - C. Center for Drug Evaluation: http://www.cde.org.cn
 - D. Chinese Pharmacopoeia: http://www.chp.org.cn
 - E. National Institute for Food and Drug Control: http://www.nicpbp.org.cn
 - F. Center for Drug Reevaluation and National Center for ADR Monitoring: http://www.cdr.gov.cn
- NDRC A. English: http://en.ndrc.gov.cn
 - B. Chinese: http://www.ndrc.gov.cn
- MOH http://www.moh.gov.cn
- Ministry of Human Resources and Social Security- http://www.mohrss.gov.cn
- Ministry of Science and Technology- A. English: http://www.most.gov.cn/eng/
 - B. Chinese: http://www.most.gov.cn/
- Central Gov't A. English: http://english.gov.cn/
- Central Gov't B. Chinese: http://www.gov.cn/
- Links to other Chinese Ministries: http://english.gov.cn/links.htm#1



State Food and Drug Administration, P.R. China



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What's New

<u>Food and Cosmetics Supervision (Interim)</u> (2011-12-27)

- National Food and Drug Regulatory Working Conference held in Beijing (2011-12-21)
- China's Cabinet approves plan to strengthen drug safety (2011-12-09)



■ ABOUT SFDA



- Mission
- Organization

REGULATORY GUIDE



- Drug Registration
- Medical Device Registration
- Health Food Registration
- Administrative Protection

more>>

E LAWS & REGULATIONS



- Drug Administration Law of the People's Republic of China
- Regulations for Implementation of the Drug Administration Law of the People's Republic of China
- Regulations for Supervision and Administration of Medical Devices
- Regulations on Administrative
 Protection for Pharmaceuticals

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SFUI 国家食品约曲面自己生产 State Food and Drug Administration 国家食品药品监督管理局



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邵明立局长会见古巴政府部长会议副主席 卡布里萨斯一行

最新动态

工作动态

新闻发布

全国药品安全专项整治工作总结电视电话会议召开(2011-12-29)

热点追踪

- 2012年全国食品药品医疗器械检验工作电视电话会议在京召开... (2011-12-29)

■ 国家食品药品监督管理局对外用药苯佐卡因等三种药品说明书进行... (2011-12-29)

- 国家药品监管信息系统一期工程监理项目公开招标中标公告(2011-12-28)
- 邵明立局长会见古巴政府部长会议副主席卡布里萨斯一行(2011-12-27)
- 国家食品药品监督管理局印发《保健食品化妆品监督行政执法文书... (2011-12-26)
- 国家食品药品监督管理局通报表扬全国食品药品监管系统打击侵犯...(2011-12-26)
- 国家食品药品监督管理局提醒关注维生素K1注射液的严重过敏反...(2011-12-26)
- 国家食品药品监督管理局曝光"健力邦裕丰胶囊"等8种假冒保健...(2011-12-23)

更多图片

■ 边振甲副局长带队督查广东省 学校食堂食品安全工作

 边振甲副局长出席江苏省第五 届打假保名牌工作会议和广东省 第六届石龙食品药品打假协作论 坛并讲话

局领导

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邵明立 局长 副局长 吴 浈 副局长 李继平

副局长 边振甲

地方动态

- 天津市食品药品监督管理局部署开展保健食品违法违规专项检查(2011-12-30)
- 福建省食品药品监督管理局多举措强化化妆品生产日常监管 (2011-12-30)
- 甘肃、新疆两省区食品药品监督管理局安排部署2012年元旦春节食品药品监管工... (2011-12-30)
- 江苏省食品药品监督管理局举办药品广告监测系统操作培训班(2011-12-30)
- 安徽省食品药品监督管理局获评全省政府法制系统先进集体(2011-12-30)
- 福建省福州市食品药品监督管理局入驻福州市行政服务中心 (2011-12-30)

更多











Sources Of Information

Industry Web Sites

RDPAC (PhRMA of China) - http://www.rdpac.org

SINO – PHIRDA (China Pharma R&D) - http://www.phirda.com (Chinese)

Chinese Pharmaceutical Enterprises Association - http://www.cpema.org (Chinese)

U.S.-China Business Council - https://www.uschina.org/

EU Chamber of Commerce in China - http://www.europeanchamber.com.cn

Stock Market Web Sites

Hong Kong Stock Exchange - http://www.hkexnews.hk/

Shanghai Stock Exchange - http://www.sse.com.cn/sseportal/en/home/home.shtml

Shenzhen Stock Exchange (ChiNext) - http://www.szse.cn/main/en/

Sources Of Information

General News Websites

China Daily - http://www2.chinadaily.com.cn/ (government owned)

South China Morning Post (HK) - http://www.scmp.com

Financial Times China Page - http://www.ft.com/intl/world/asiapacific/china

Wall Street Journal China Real Time Report - http://blogs.wsj.com/chinarealtime/

Interesting Insights

China Law Blog - http://www.chinalawblog.com/

China Knowledge at Wharton - http://www.knowledgeatwharton.com.cn/

Monitor Group's China Life Sciences 2020 Report - http://bit.ly/yKYXOv

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Pfizer Inc. (PFE) News - The New York Times

News about Pfizer Inc. Commentary and archival information about Pfizer Inc. from The New York Times.

topics.nytimes.com/top/news/business/.../pfizer inc/index.html - 网页快照 - 类似结果

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