

the Industry Status Quo Changed: Gresham's Law Disappearing

- Internationalization: CFDA join ICH;
- Consistency Evaluation of generics;
- Clinical data & manufacture specification verification;
- Approval of API

1

Improve Quality

Cost Control



2

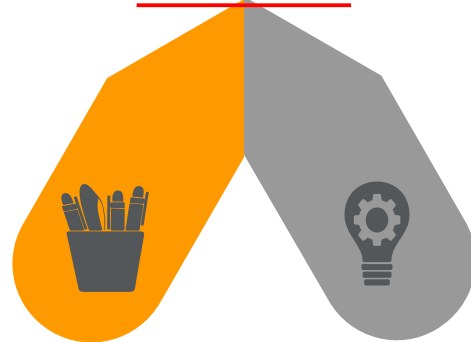
- Tendering & centralized procurement;
- GPO, the secondary price negotiation
- Expense control & reimbursement payment method change.
- Zero profit for hospital, control drug expenses in total healthcare cost

Deepening Reform

3

Compliance

Encourage Innovation



4

- Clinical trial management reform;
- Accelerate approval time ;
- Drug on the market list, IP link and IP protection;
- Implementation of MAH;
- Reimbursement list modification, in favor to to Innovation drugs.
- Data Protection elongation

- 2 invoice regulation implementation;
- Anti-commercial Bribe, anti-corruption & Sales forces register system.

**Eliminate out of date industry capacity
Supply better and cheaper medicines quickly !!!**



Price Cutting for Generic Drugs in Centralised Procurement in China: Harsh, but Justifiable !!

Unit: tablet/RMB	Dosage	Avg Price	“4+7” Tendering price	reduction	Europe price	USA price	Asia Price
Nifedipine	5mg	0.35	0.15	-57%	0.13	0.07	0.01
Atorvastatin	20mg	5.80	0.94	-84%	0.62	0.19	0.13

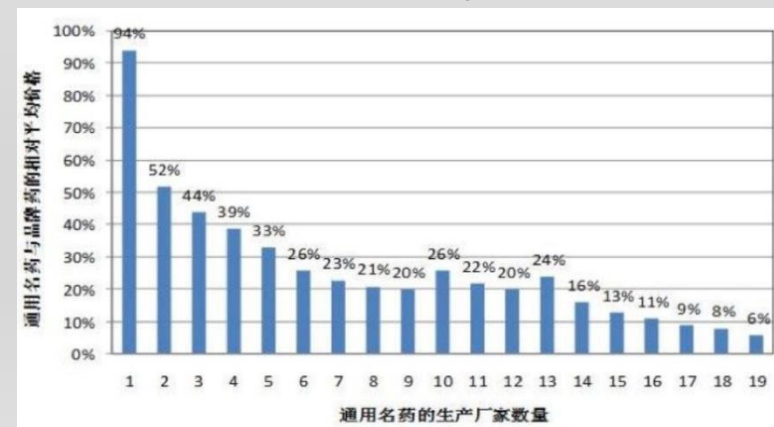
In comparison with USA Market

Highly consolidated procurement system:
buyer's market

Rank	Company	Market share
1	McKesson	35.20%
2	Cardinal Health	31.90%
3	Amerisource Bergen	27.50%
4	H.D. Smith	1.20%
5	Smith Drug	0.80%
6	Henry Schein	0.50%
7	RDC-Rochester Drug Cooperative	0.30%
8	Anda	0.30%

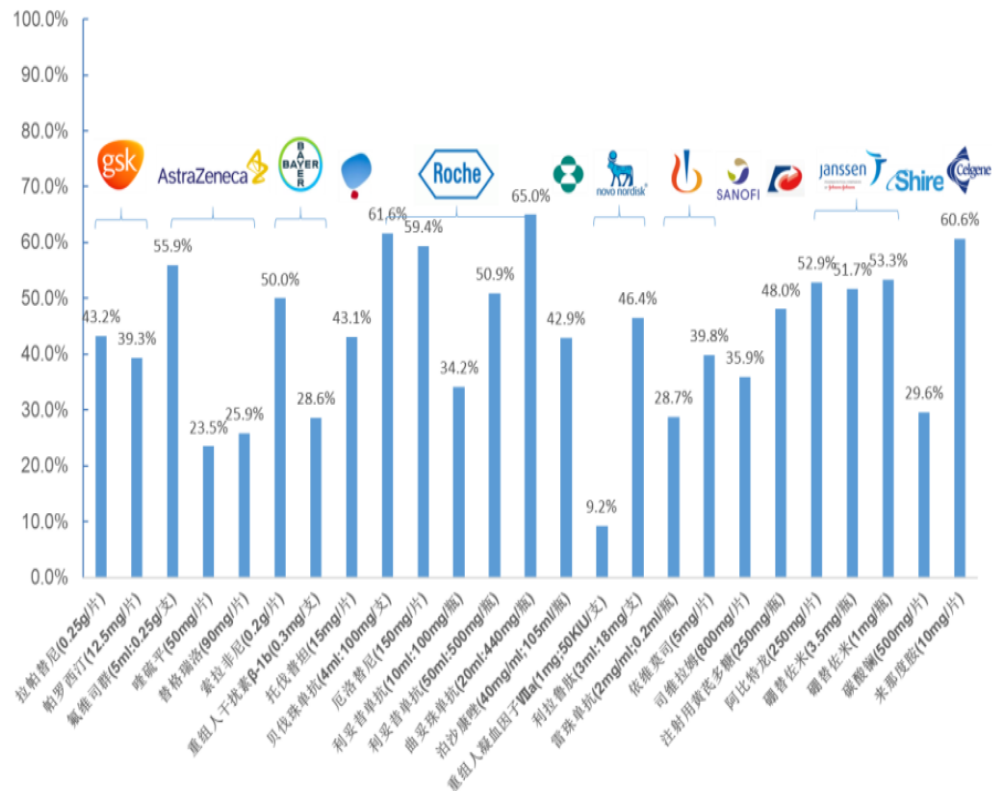
来源：公司年报、国金证券研究所

The Price is determined by the competition
Landscape

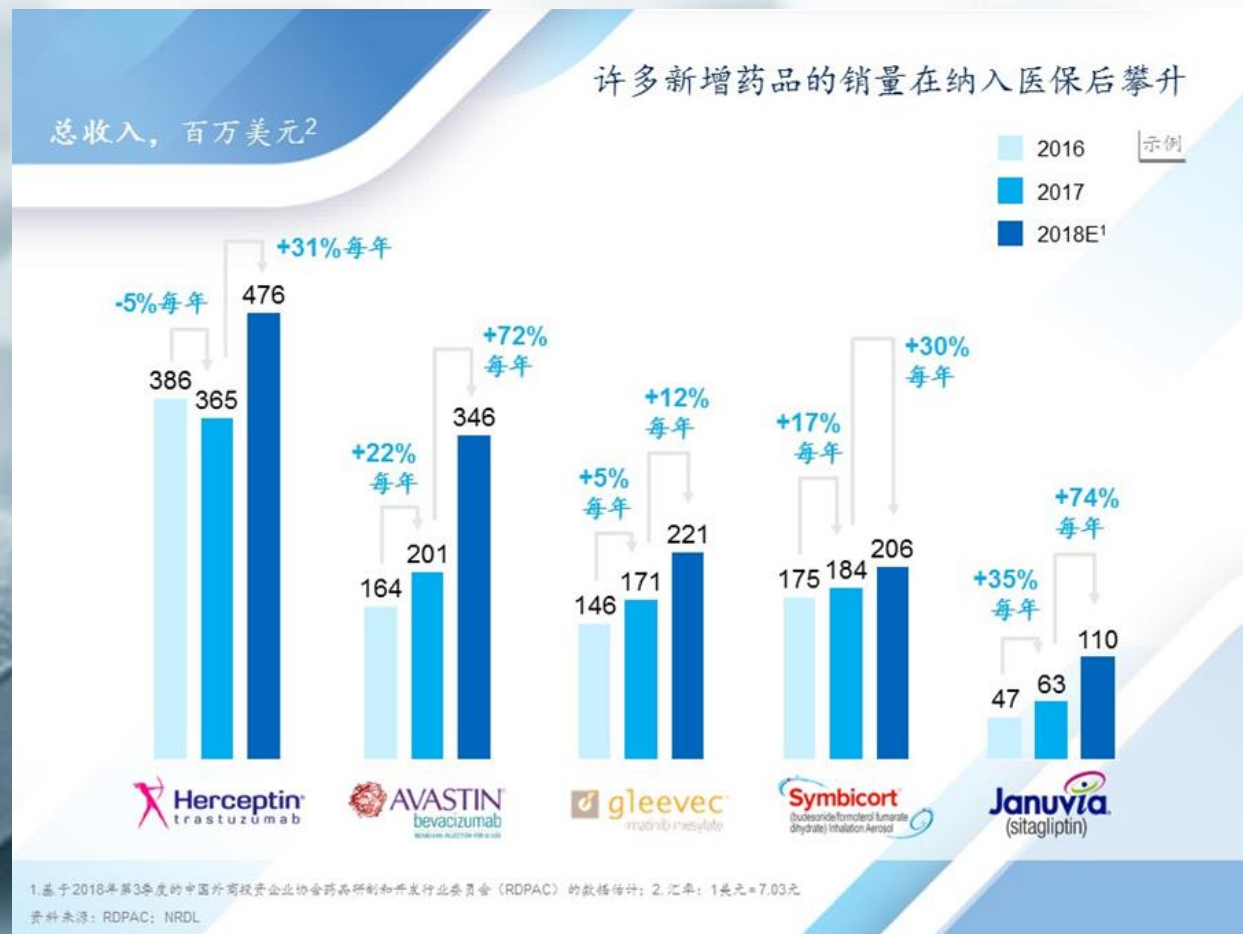


For Innovative Drugs- Price Cutting to Enter Reimbursement List Increases a Volume Sales

图 27、2017 年医保价格谈判的外资药品价格降幅

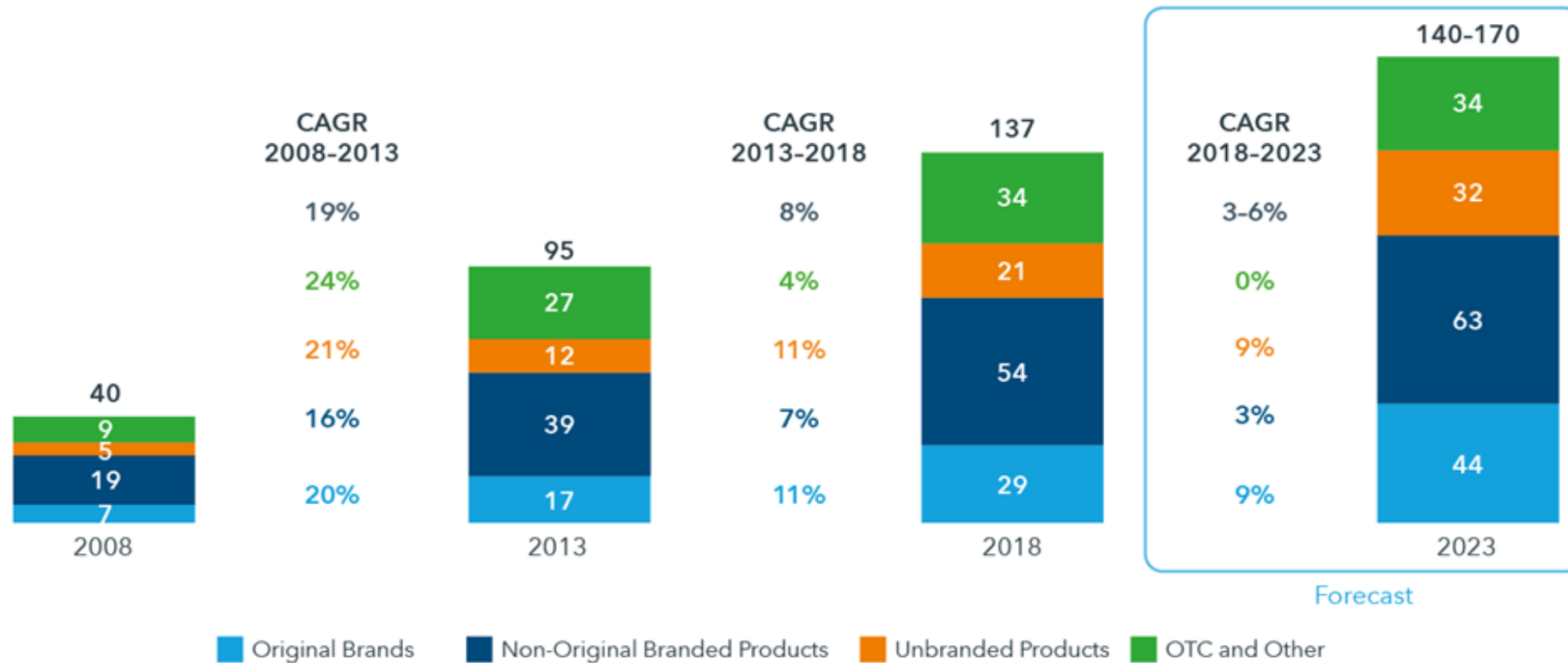


资料来源：国家医保局、药渡数据、药智数据、PDB 数据，兴业证券经济与金融研究院整理



Pharmaceutical Industry Structure is Changing

China Spending 2008-2023 and Compound Annual Growth Constant US\$Bn



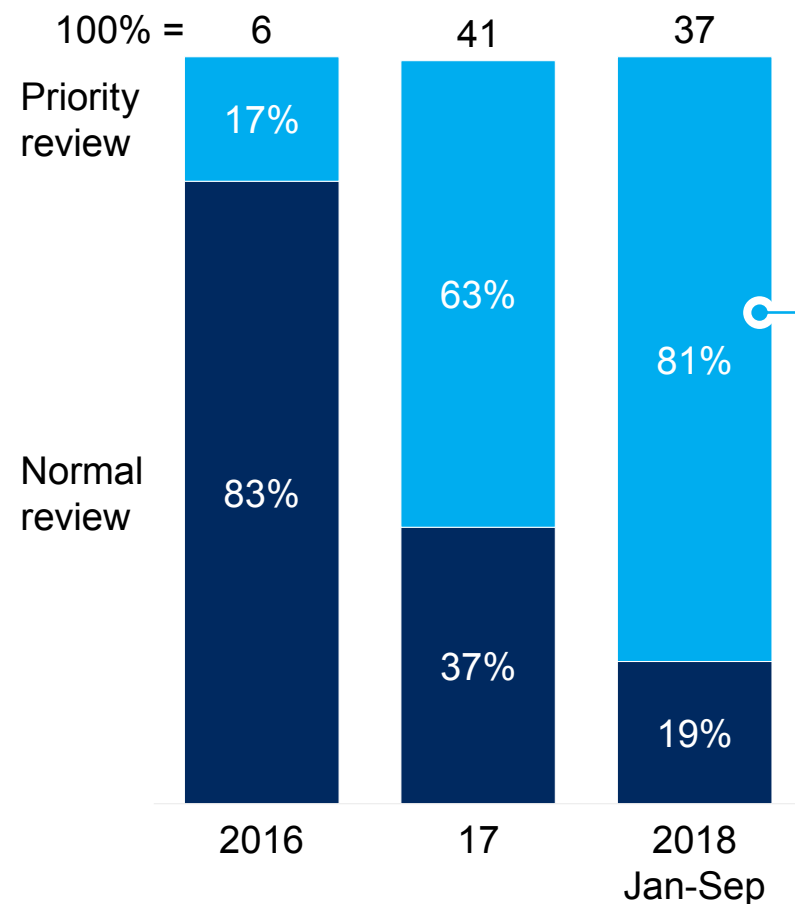
Source: IQVIA Market Prognosis, Sep 2018; IQVIA Institute, Dec 2018

Notes: OTC = Over-the-counter

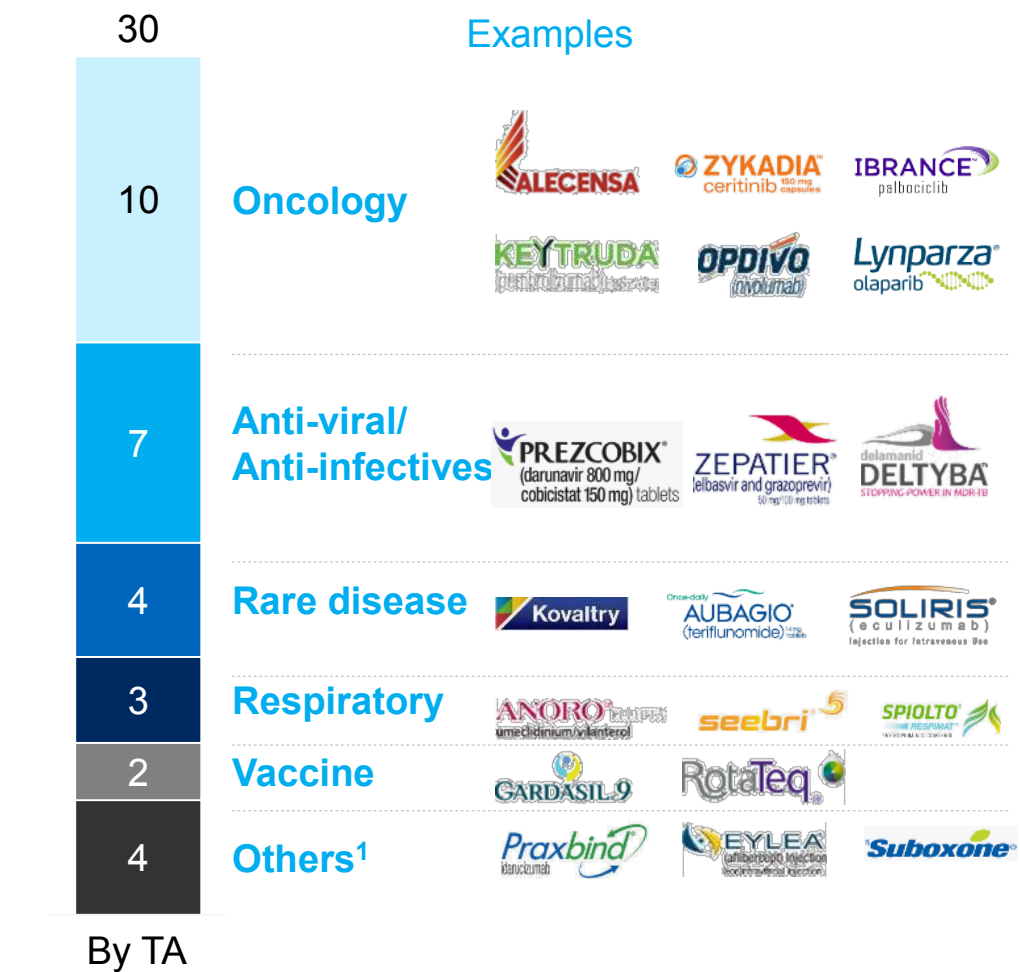
Report: The Global Use of Medicine in 2019 and Outlook to 2023. IQVIA Institute for Human Data Science, Jan 2019

Priority Review has Become a New Normal for Innovative Drugs

of priority review among new product launch since establishment in 2016, # of products



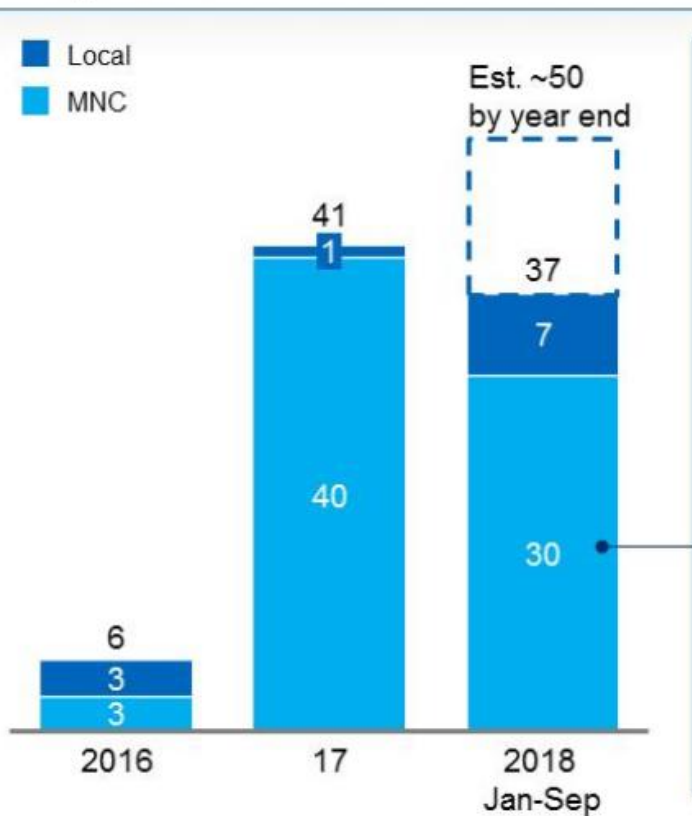
Priority review by TA, 2018 Jan-Sep, # of products



Drug Approval Time was Shorten and More Drugs were Approved

Pre-regulation change (2014-2016)		Post-regulation change (2017-)	
Company	NDA Timeline (months)	Company	NDA Timeline (months)
Boehringer Ingelheim	12	Bayer	3
Pfizer	14.5	AstraZeneca	2
Roche	11.5	Bristol-Myers Squibb	5.5
Novartis	16.5	GlaxoSmithKline	6.5
Celgene	28	Pharmacyclics	9.5
AbbVie	35	Janssen	9.5
Teva	41.5	AbbVie	6
Bayer	18	Gilead	6.5
Novo Nordisk	24	Boehringer Ingelheim	5.5
Allergan	17	Novartis	8.5
	21.8		6.25

of new drug approvals¹ in the past 3 years
of products



Examples

Local

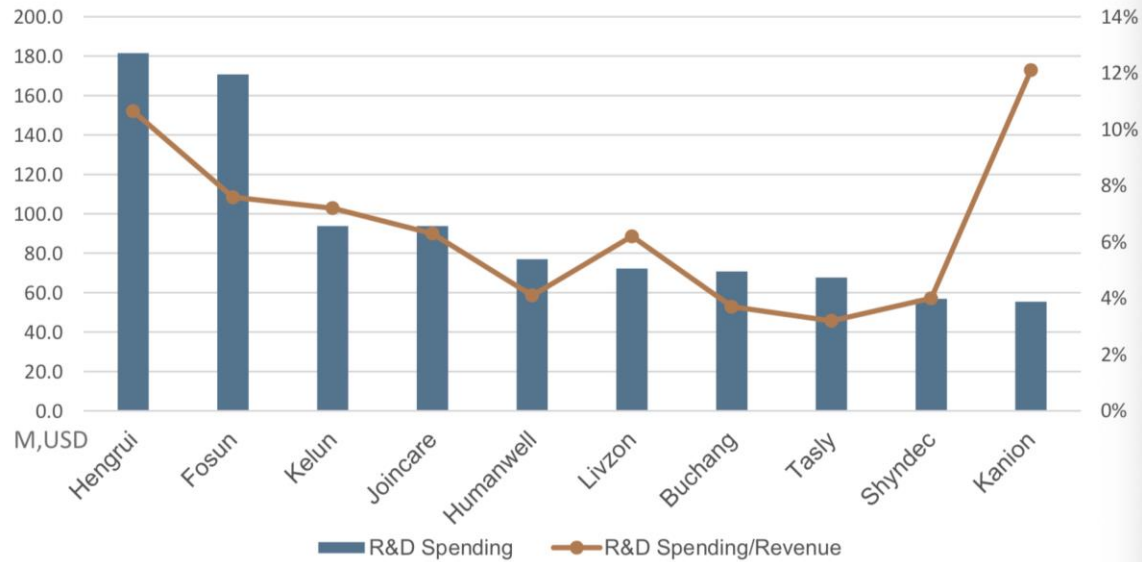
艾可宁 (Albuvirtide) 爱优特 (Fruquintinib)
 福可维 (Anlotinib) 艾瑞妮 (Pyrotinib)
 戈诺卫 (Danoprevir) 派益生 (Recombinant consensus interferon variant)
 乐复能 (Recombinant cytokine gene derived protein)

MNC

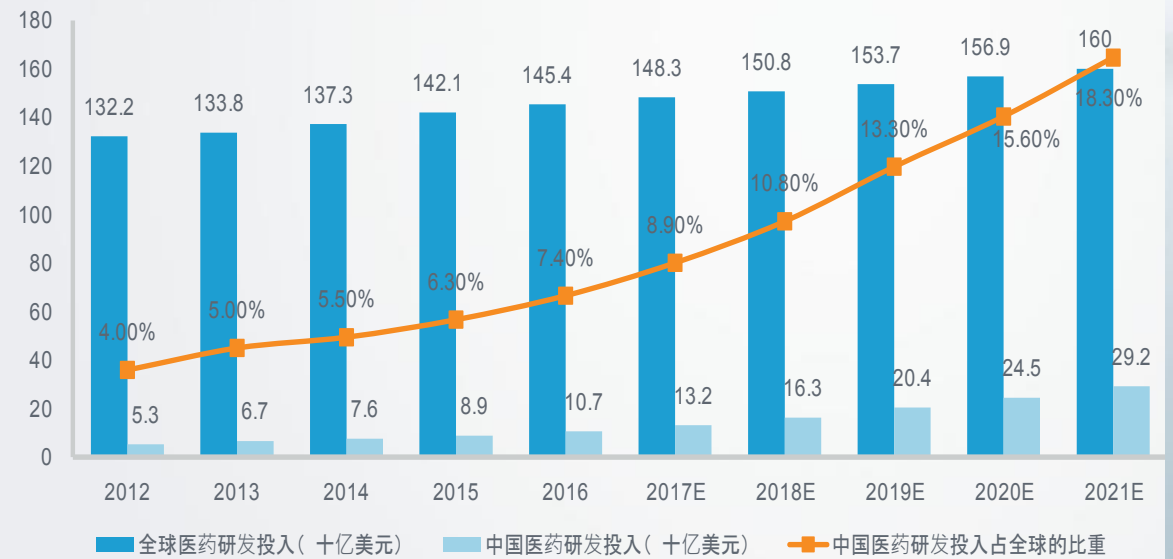


Chinese Pharmaceutical Companies Increasing their R&D spending

R&D Spending of the TOP 10 Domestic Public Pharmas in 2016



亿欧智库：全球医药研发投入及中国医药研发投入比较 (2012-2021E)



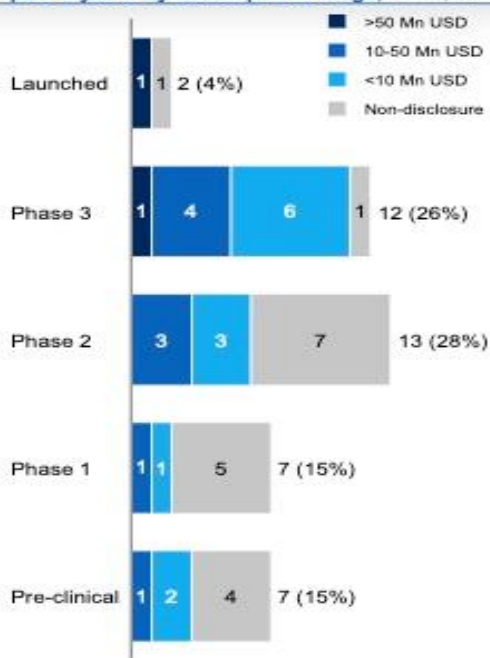
来源: Evaluatepharma

Active License-in in China

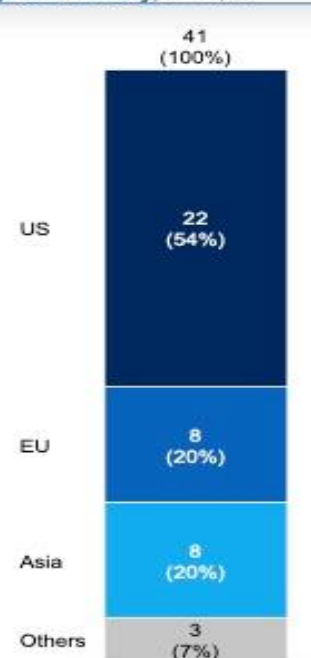


Most in-licensed assets are sourced at late clinical stage, originated from US/EU, and majority with China/Asia rights only NOT EXHAUSTIVE

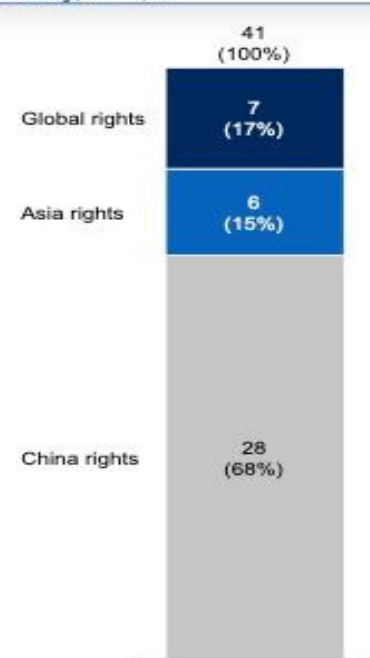
Breakdown of major licensing deals in the past 2 years by development stage, N=41, %



Breakdown of in-licensing assets by originator country, N=41, %



Breakdown of in-licensing assets by rights territory, N=41, %



SOURCE: Press search; team analysis

McKinsey & Company 21



Increase Accessibility of Medicine to Target Unmet Clinical Needs



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China to exempt import tariffs on all cancer drugs

Updated: Apr 13, 2018 11:06 AM Xinhua

BEIJING — China will exempt import tariffs on all cancer drugs and encourage the import of more innovative drugs, according to a statement released after an executive meeting of the State Council presided over by Premier Li Keqiang on April 12.

China to reduce taxes for rare-disease drugs

Xinhua | Updated: 2019-02-28 18:37



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[Photo/VCG]

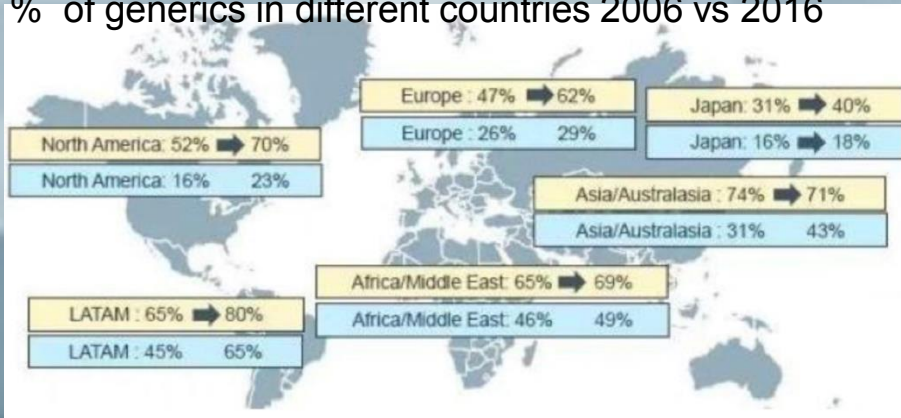
BEIJING -- A total of 21 rare-disease drugs and four active pharmaceutical ingredients will be the first to enjoy China's VAT reduction policy, which will take effect on March 1.



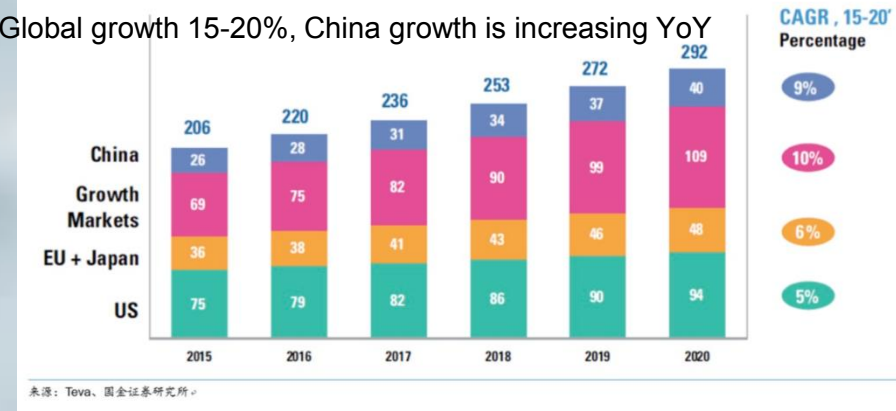
What about Generics?

- Always a main stream in the industry
 - the cornerstone for the country's healthcare
 - Address affordability and accessibility while new drugs for unmet clinical need
 - Growing industry globally, especially in China
 - a balance between innovative medicines and generics

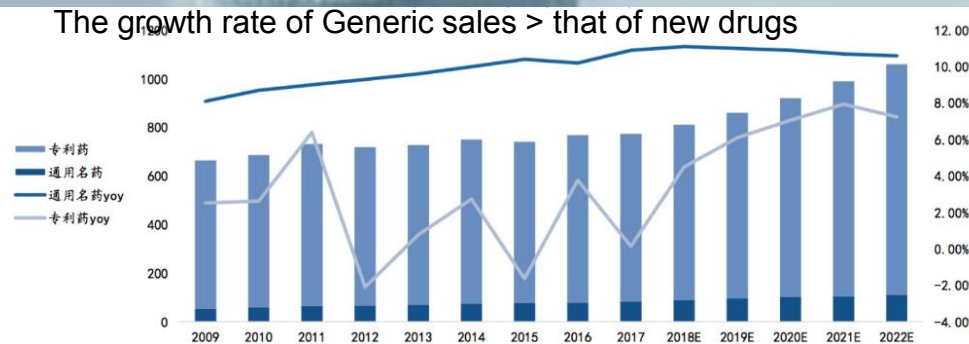
% of generics in different countries 2006 vs 2016

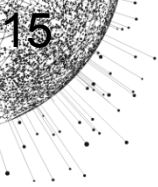


Global growth 15-20%, China growth is increasing YoY



The growth rate of Generic sales > that of new drugs





Future Profitability Model for Generic Drugs:

Price/unit X Volume X (1-CoG%-Sales Fee%)

Price and Volume: depending on government tendering and competition landscape

CoG: ++

Sales Fee: +/-

How to Make a Difference For Generic Players?

- R&D efficiency
- Quality
- Competitive price
- Stable and abundant manufacturing capacity
- Technology barriers- eg nanotech, microspheres, drug + device, difficult API

Highlights of 2019 Government Work Report- Medicine related

The 13th National People's Congress, China's national legislature -5/3,2019

- Encourage investment in hi-tech innovations including biotech medicines and tele-medicine.
- Improve social insurance systems for VAs, disables, poor income family etc.
- General care for old populations (250m >60 years old), disables and VAs
- Increase reimbursement of medicine for
 - The old populations
 - Chronic diseases like hypertension and diabetics
- Early diagnosis and treatment of serious diseases, like cancer
- Improve the quality of medicine and vaccines.
- Further hospital reform
 - Privatization of hospital system
 - set up a hierarchical medical system
 - Tele-medicine
 - Improve the quality of medical services



How to Bring Your Drugs into China?

Options for China and Asia market entry

