

Healthcare Policy Updates & Mega Trends

Prepared by PwC
Aug 2022



Speaker Intro



Mr. Cai Jingyu is PwC S& China Consulting Partner focusing on pharmaceutical and life science sector. He has more than 16 years combined industry and consulting experience.

Mr. Cai has accumulated profound experience in strategy development and execution, business model transformation, and operation optimization. Moreover, he has led many global and domestic pharma M&A cases.

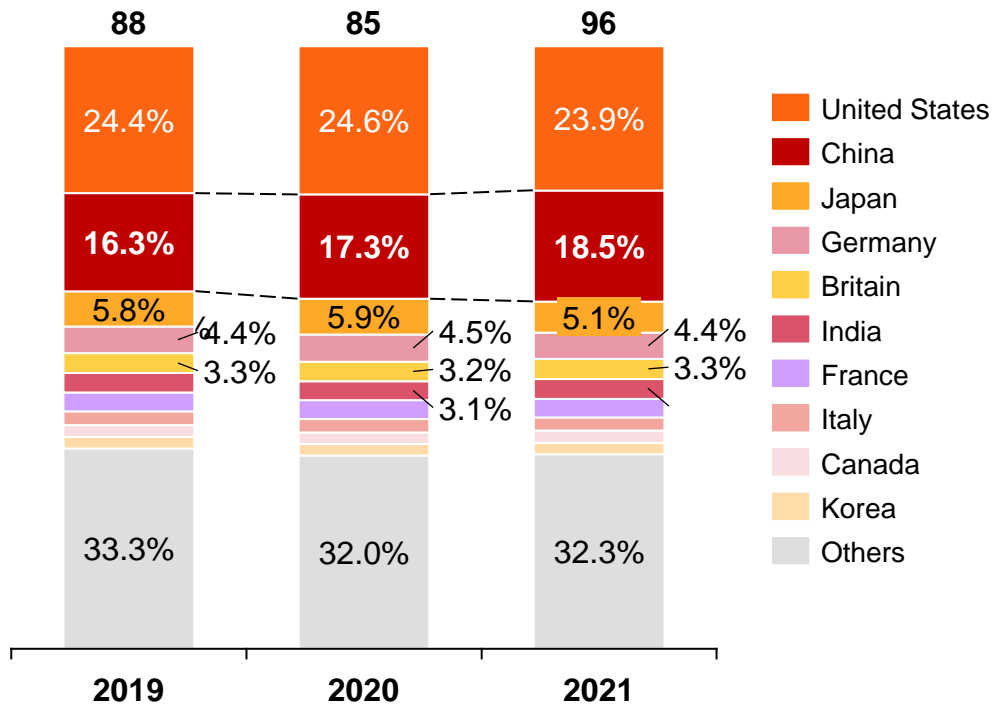
Mr. Cai led PwC team to serve China government authorities, thus had insights on the regulatory trends and implementations to pharma companies' business transformation.

Jinyu Cai 蔡景愚

Partner | Healthcare Industry | PwC Strategy&

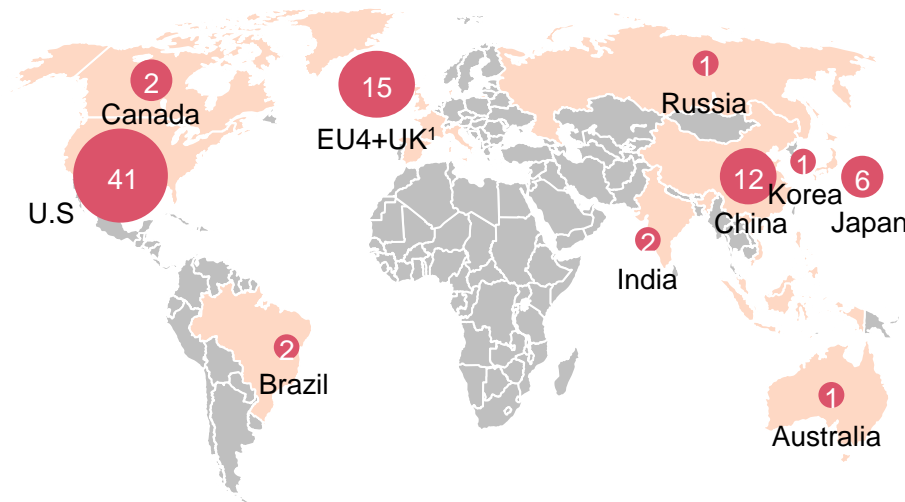
China pharma market has been growing along with macroeconomic growth

Share of total global GDP (USD trillion, %)



- In 2021, China accounts for **18% of global GDP**

Share of global pharmaceuticals market size (2021, %)

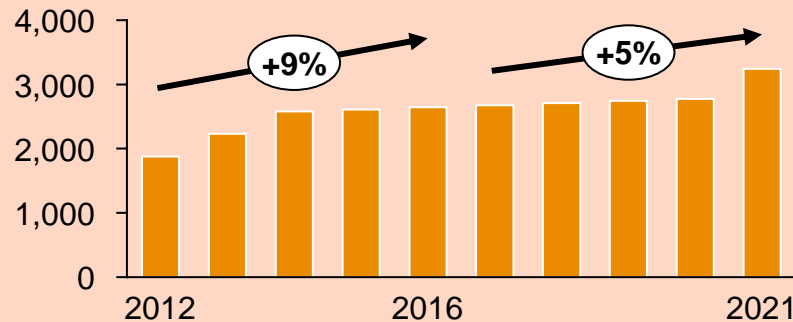


- The United States and EU4+UK¹ countries account for 56% of the global pharmaceuticals (hospital) market, followed by China , **accounting for 12% of global pharma market**

The growth potential is driven by regulatory reform, increased spending on healthcare, big patient base with unmet clinical need

Steady Growth of healthcare sector

Pharma industry gross production²
(RMB Bn)



Favorable Policies promoting industry development

Innovation

- **Publish** the new *Drug Administration Law*
- **Promote** bio-economy in selected regions
- **Reform** new drug registration
- **Join** ICH and encourage MRCT

Production

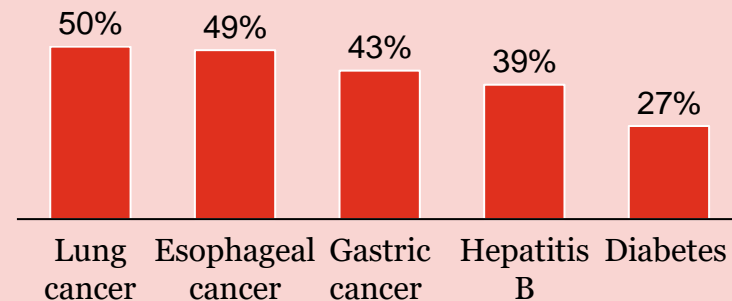
- **Propose** to join PIC/S
- **Encourage** CMO model under MAH
- **Provide** financial support for local manufacturing

Access

- **Expand** BMI coverage
- **Promote** commercial insurance
- **Enhance** county-level hospitals and CHC

Big patient base and unmet need

Proportion of Chinese patients among global patients (2018)



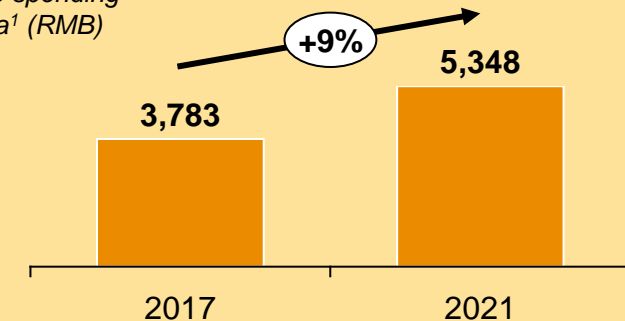
Clinical unmet need

Oncology as example

- Increasing drug resistance
- Decreasing response
- Low survival rate
- High risk of recurrence and metatheses

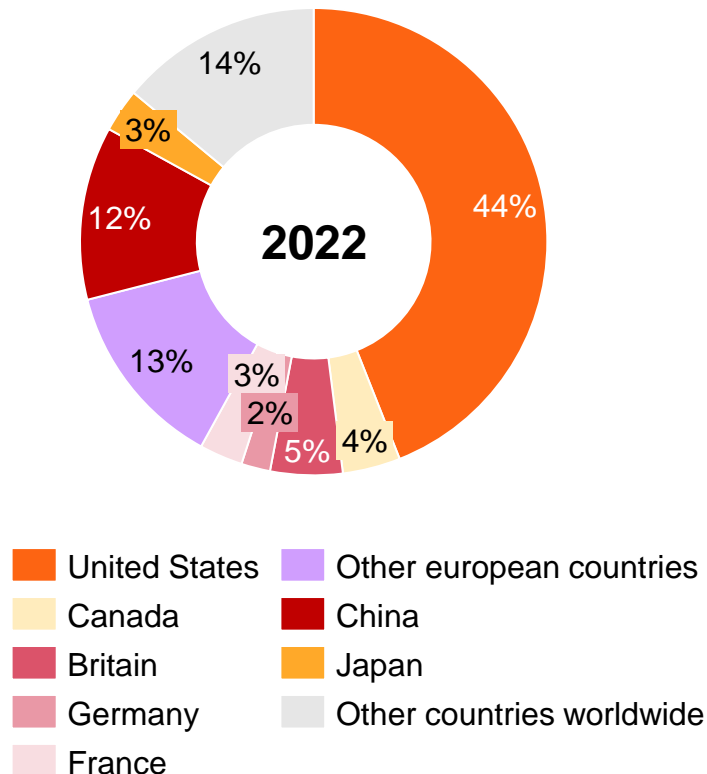
Increased Spending on healthcare

Healthcare spending
per capita¹ (RMB)

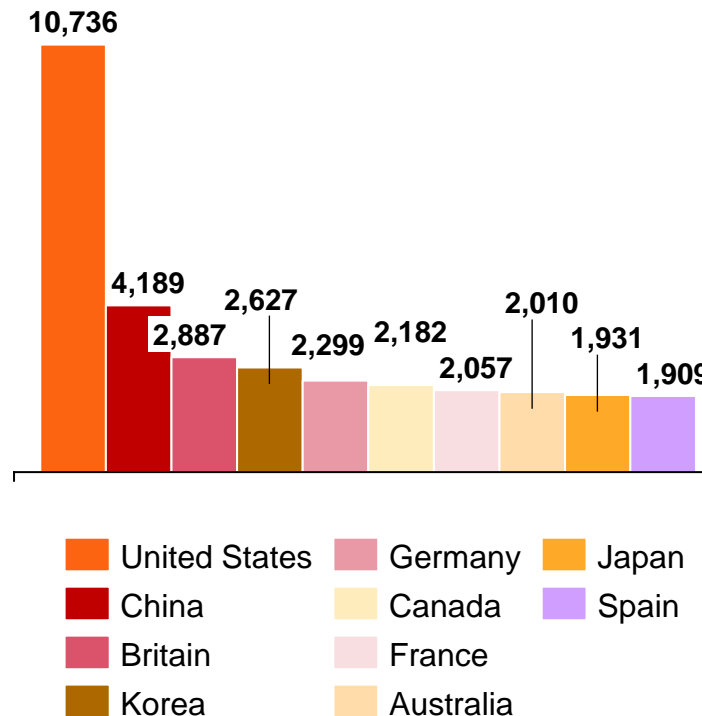


From 2015, Chinese innovation started to stand on global stage

Distribution of company with innovative drug pipeline (2022, %)



Top 10 countries with most # of drug pipelines (2022)



Companies with most # of New drug pipelines (2022)

2022 Rank (2021)	Company	# of pipeline, 2022	# of new drug pipeline, 2022
1 (1)	NOVARTIS	213	129
2 (2)	Roche	200	120
3 (3)	Takeda	184	68
4 (4)	Bristol-Myers Squibb	168	98
5 (6)	Pfizer	168	101
6 (9)	AstraZeneca	161	89
7 (5)	MERCK	158	77
8 (7)	Johnson & Johnson	157	86
16 (37)	恒瑞医药 (Hengrui Medicine)	89	80
23 (66)	FOSUNPHARMA (复星医药)	68	48

- China R&D capability has been elevated by encouraging policies towards innovative drug companies: # of innovative drug company in China has increased from 522 to 792 (+43%), accounting for 12% of the world

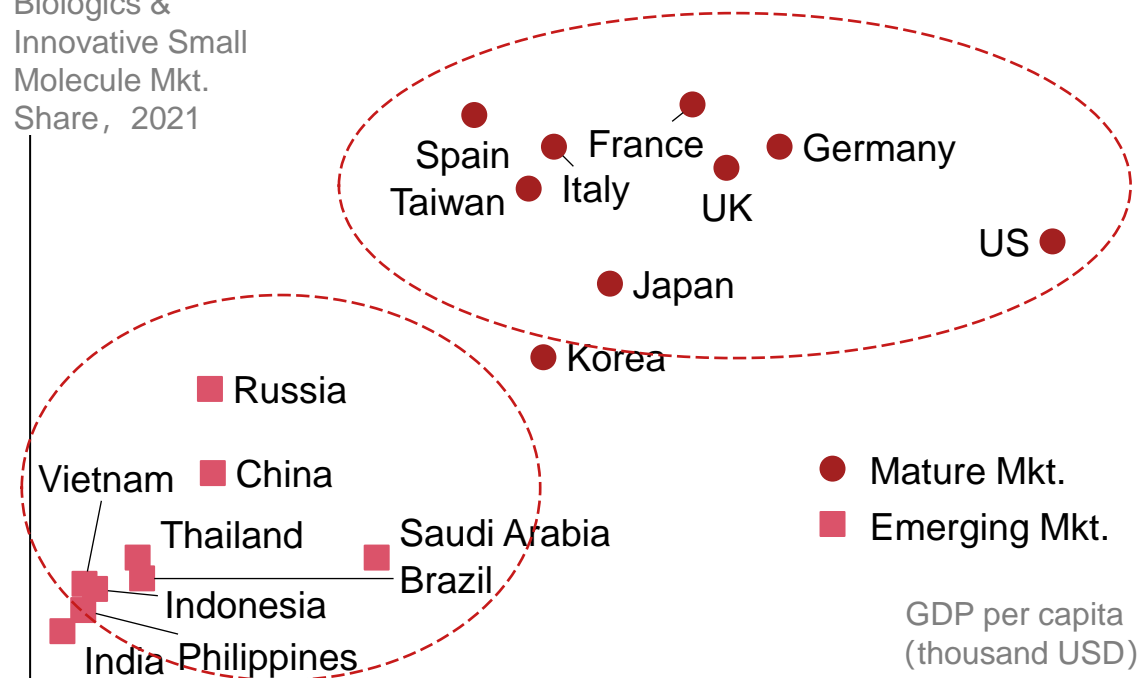
- Chinese innovative drug companies FOSUN and Heng Rui made to Top 25 for the 1st time

Looking forward, China target to transform from Gx-dominant market to innovation-driven market, but it does not mean Gx is not important

Mature markets with higher share of innovative drugs

Significant difference in medicine spending between mature and emerging markets

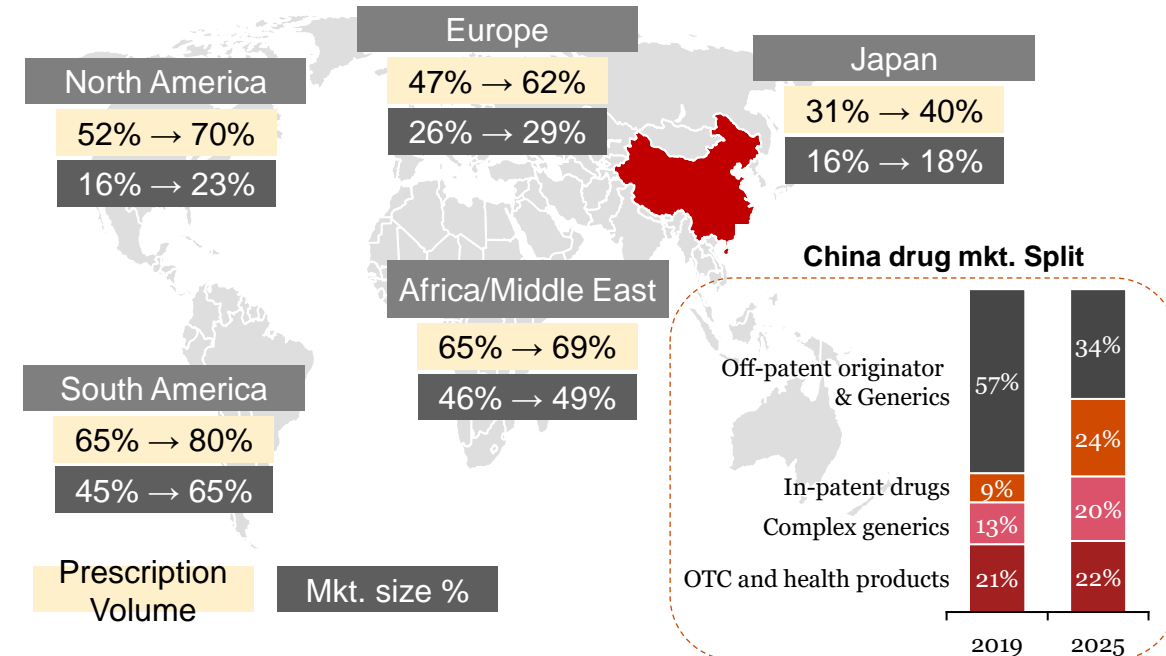
Biologics & Innovative Small Molecule Mkt. Share, 2021



- Innovative drugs from MNC are at dominate place in mature market, with higher % in Oncology and Nervous System

Emerging market dominated by Gx.

Trends in global Gx. prescription volume & mkt. share, 2006~2016



- Gx. from leading local companies dominate the market with high prescription volume
- Emerging markets, such as China, are gradually transitioning to innovative drugs

1

“Ice & Fire” of innovative drug

创新药的“冰火两重天”

2

Innovative business model with compliance

商业模式创新的合规要求

3

Blue Ocean in consumer healthcare

消费医疗的新蓝海

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Local production – “to be” or “not to be”

地产化策略的“是与非”

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“Acceleration” should be the key word for innovative drug companies

Policy highlights encouraging drug innovations

Accelerating drug approval

New drugs with important clinical value will enjoy priority approval

Adopting international standards on evaluation and registration

In 2017, China joined ICH and started to keep in line with international standards for domestic drug evaluation and registration

Implementing MAH

Separation of drug marketing license and production license

Significant reduction of application durations

IND process

27 months
(Average duration in 2015)



60 work days
(After reform)

NDA process

26 months
(Average duration in 2014)



12-18 months
(After reform)

China/US launch time gap

5-7 years
(Average duration in 2015)

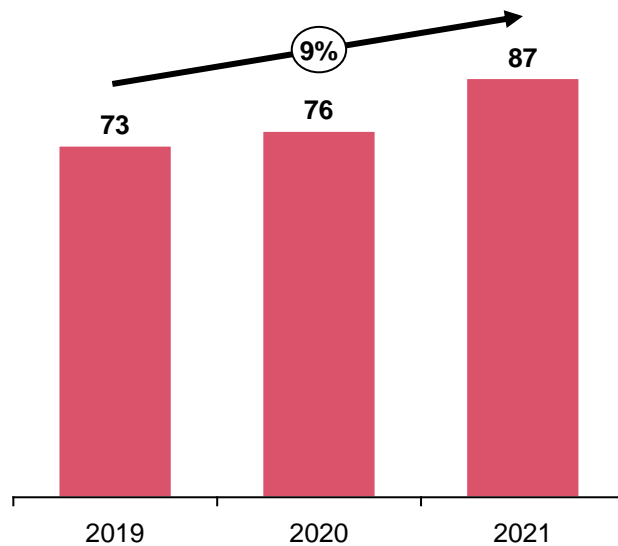


Gradually simultaneous
(After reform)

MNCs are enhancing clinical trial design (like MRCT) and operation to achieve simultaneous global launch with China in the first wave...

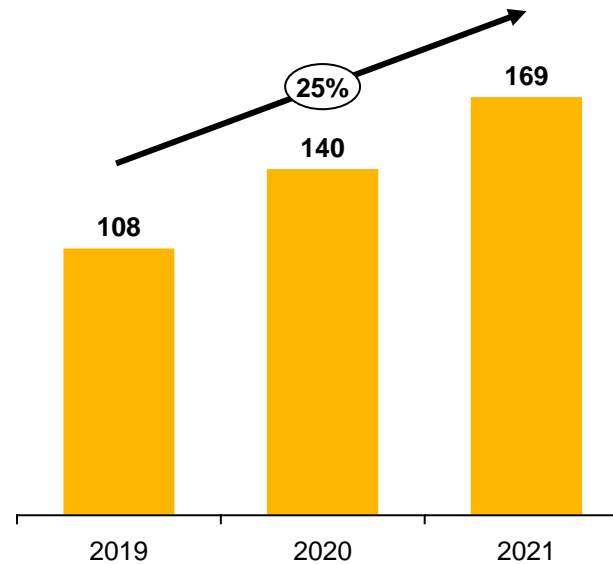
MNCs are actively conducting clinical trials in China

Number of MNCs' clinical trial in China



MNCs are involving China into MRCT for global launch

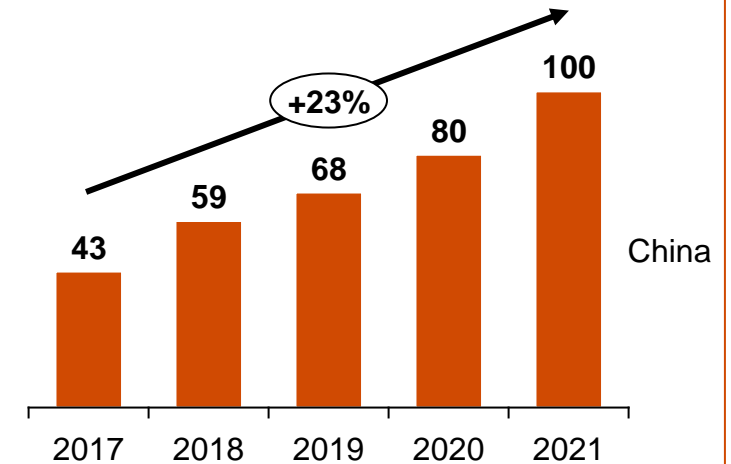
Number of MNCs' MRCT in China



CRO is growing rapidly in China, attracting collaboration with MNCs

China CRO market (2017-2021)

Unit: Bn RMB



Leading CROs in China have also attracted MNCs to collaboration on local clinical trials

...And also collaborate with local partners to expand pipelines faster

Type of collaboration

Samples

Collaboration mode



Partnership with VC/PE



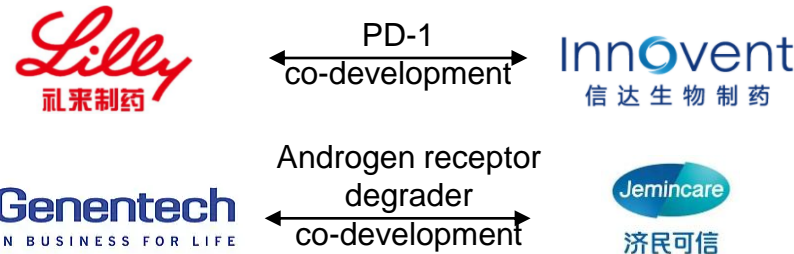
- AZ as GP and managing partner, setting up a fund and is responsible for the operation



- Sanofi as LP, directly invest in Cathay Capital



Collaboration with biotech



- Project-based strategic collaboration
- License-in / license-out
- Support China companies to enter into overseas countries



Open innovation platform



- Set up open innovation as a department or an independent legal entity
- Accelerator and incubator for local start-ups with capital and relevant resource support

China pharma companies have taken “fast follower” strategy, which results in overheated industry and poor commercialization

Level of innovation to be lifted



Mostly **fast-follow** of large and small molecules



Starting with **mature mechanisms/targets**, with insufficient innovation capability

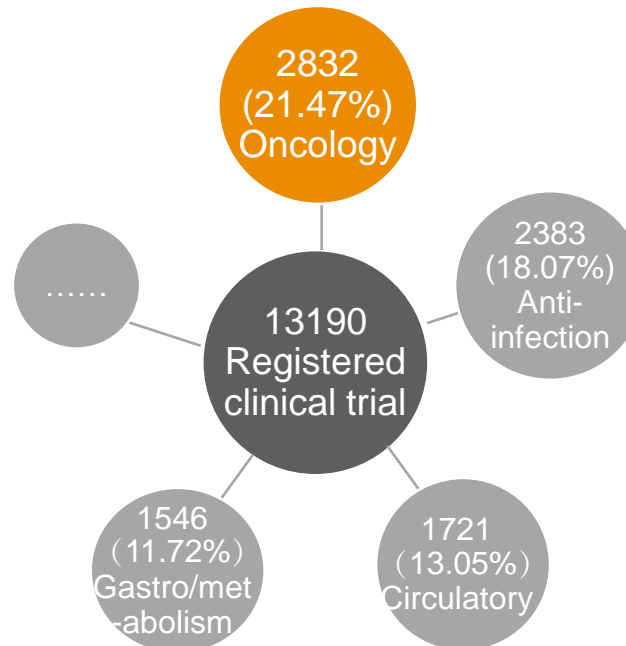


of INDs kept ~50% growth per year, while **FIC only accounts for 17%**

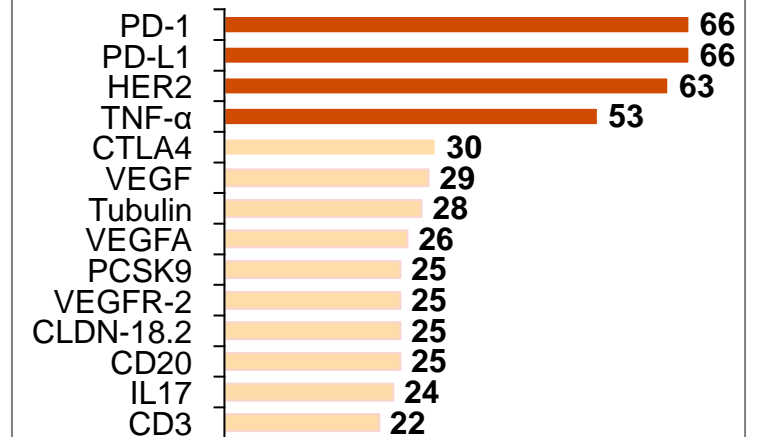
Crowded in certain areas

Oncology being the hottest area*

Clinical trial statistics by TA



PDx being the hottest target

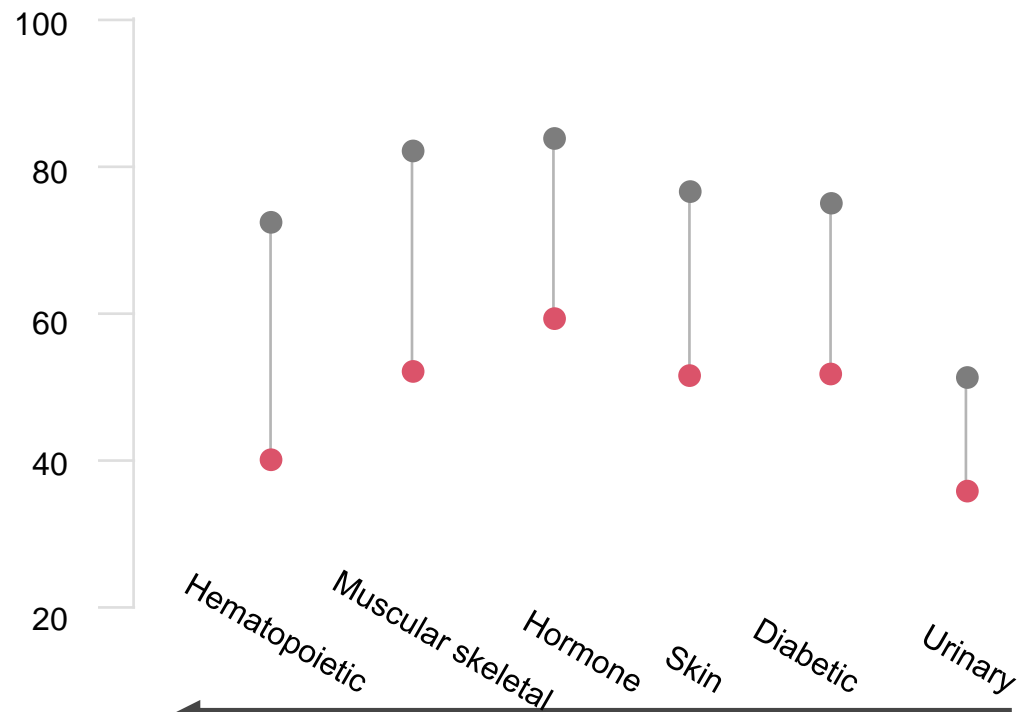


- Only 8% of new class I drugs launched in China (2017~2020) have original mechanisms of action
- Currently China only covers 20% of the global developing targets, ~50% of products focus on the top nine popular targets worldwide¹

Meanwhile, leading local biotech companies' innovation is catching up with the US

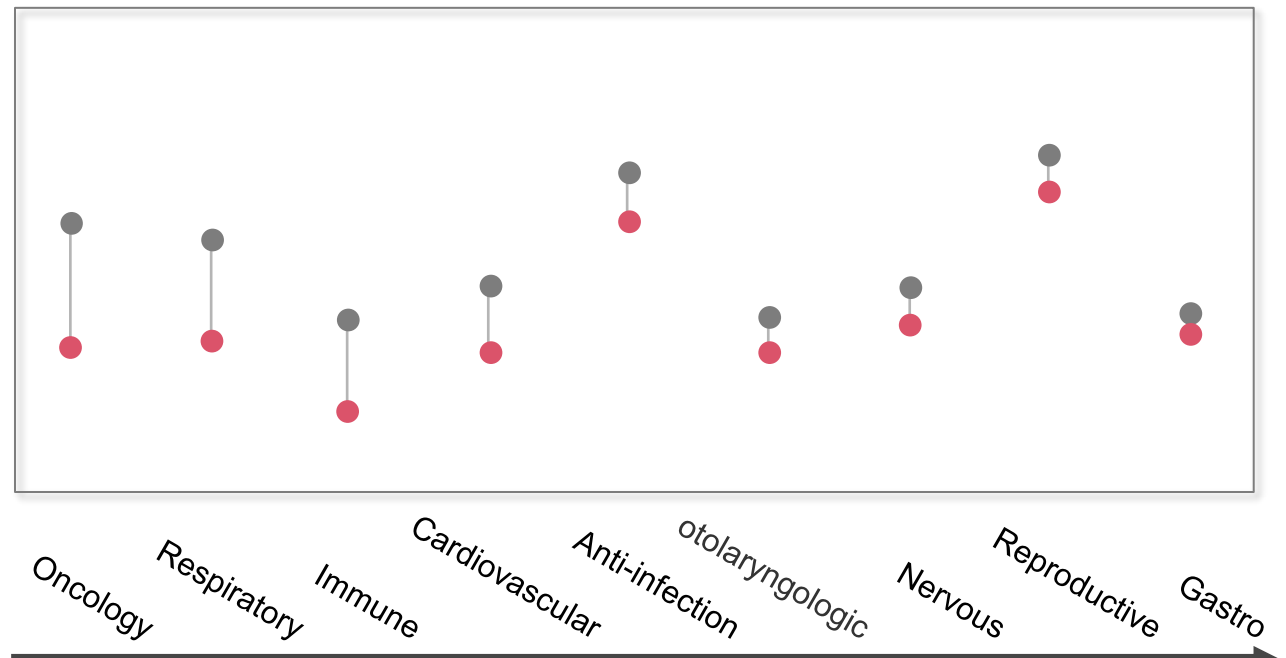
% Proportion of clinical trials with validated targets¹ in all clinical trials

● US
● China



China is behind the US in exploring unlisted targets/mechanisms

China is close to the US in exploring unlisted targets/mechanisms

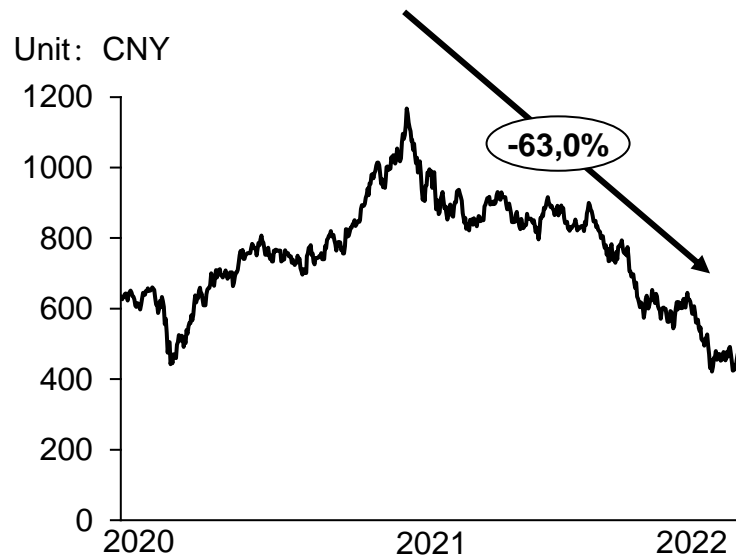


China is close to the US in exploring unlisted targets/mechanisms

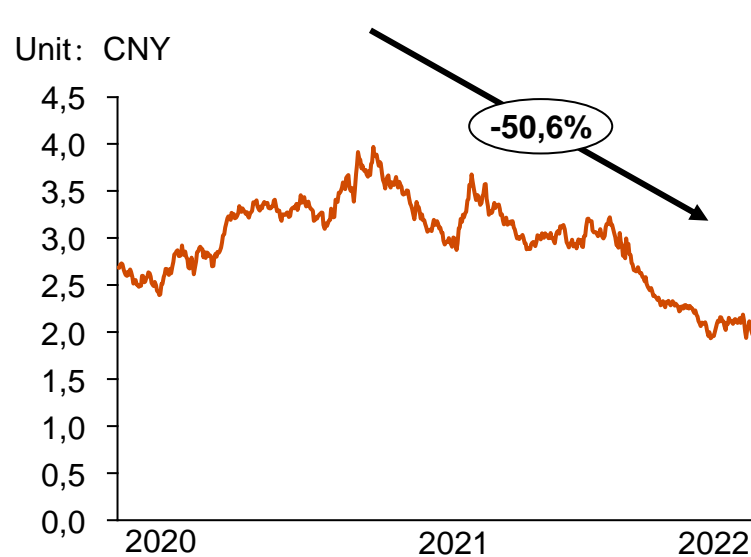
From 2H of 2021, China pharma industry is cooling down, and local biotech companies are facing challenges to survive

- Affected by policy and macroeconomic environment changes, the value of domestic and US pharmaceutical sector began to slump in 2021
- From 2019 to 2021, 90.9%, 87.9% and 100% of A-share listed pharmaceutical companies were traded below IPO price in the 1st month of listing

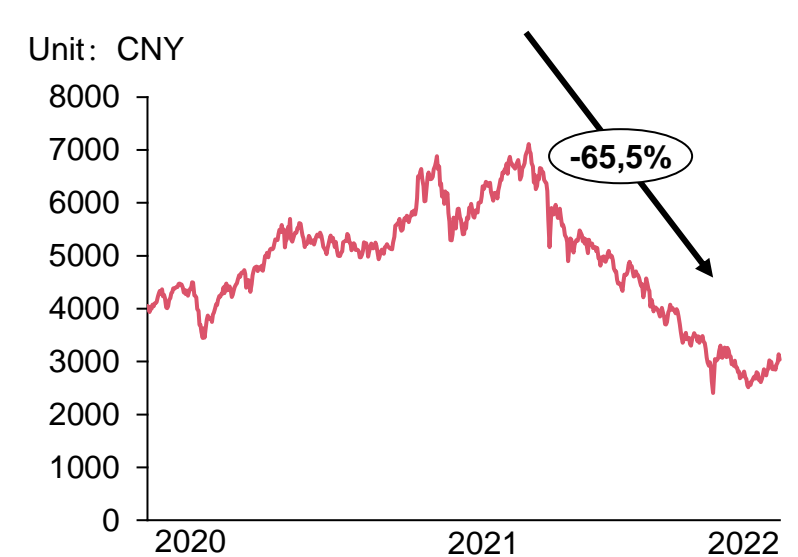
US¹pharma. sector value



China A-share² pharma. sector value

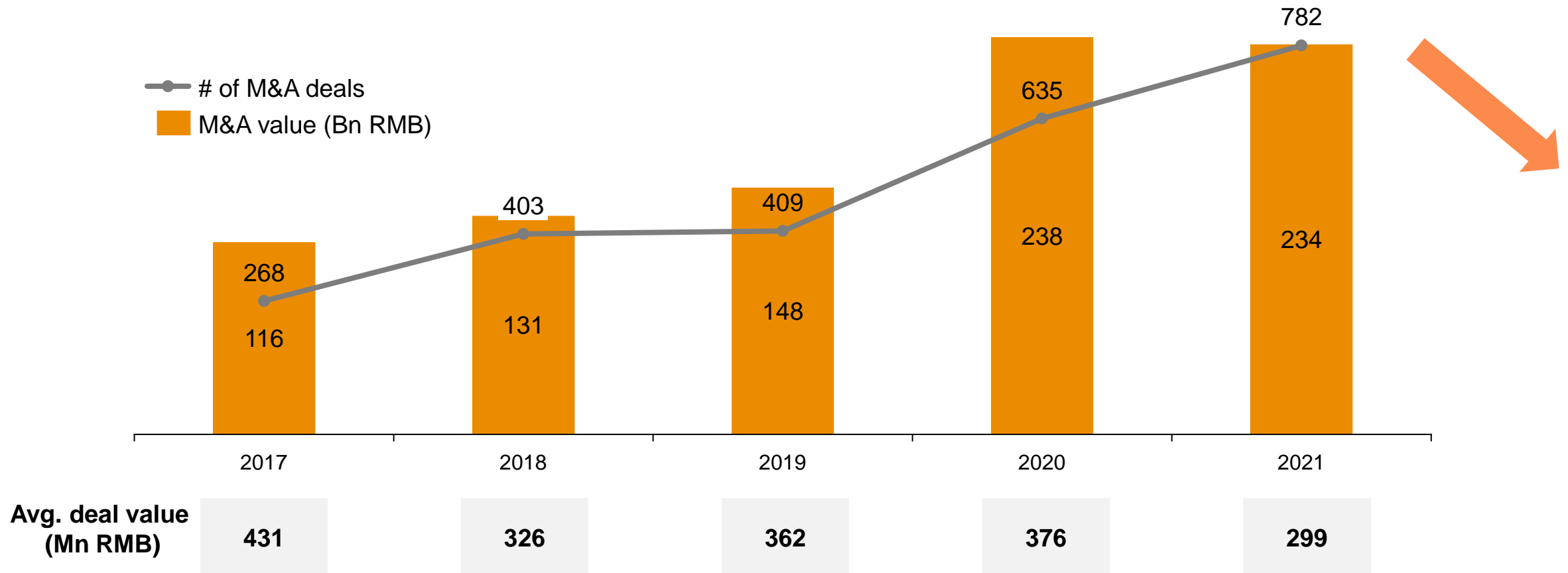


HKX³pharma. sector value



M&A cases are likely to shrink in 2022. When assets are being re-evaluated, it may indicate a better for valuable deals

Total # and size of M&A deals in China's pharmaceutical & life sciences industry¹



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Blue Ocean in consumer healthcare

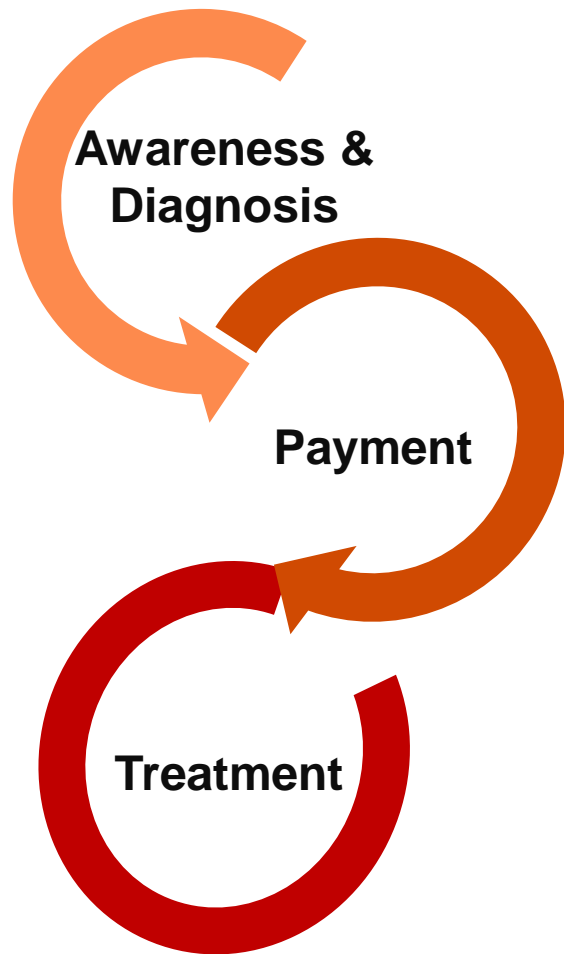
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Local production – “to be” or “not to be”

地产化策略的“是与非”

New business models are explored along the patient journey, while redlines need to be aware of



<i>Pain Point</i>	<i>Solution</i>	<i>Redline to aware</i>
<ul style="list-style-type: none"> ▪ Low awareness and diagnosis ▪ High cost on patient education and conversion 	<ul style="list-style-type: none"> ▪ O2O platform / Internet hospital for disease education, potential patient consultation and offline conversion 	<ul style="list-style-type: none"> I Patient and physician's private data protection II Constraint to leverage commercial insurance to cut drug price ▪ Lower compliance requests towards CSO ▪ Illegal activities to promote targeting therapy without diagnosis results ▪ False reimbursement ▪ Direct-to-patient promotion online
<ul style="list-style-type: none"> ▪ Disease burden from high / innovative price drug 	<ul style="list-style-type: none"> ▪ Mult-tier payment scheme with innovative payment models 	
<ul style="list-style-type: none"> ▪ Limited accessibility for better care ▪ Treatment incompliance 	<ul style="list-style-type: none"> ▪ Hierarchical healthcare system and internet hospital for integrated and broader HCP engagement ▪ Disease management via digital tool 	

Multi-tier payment system will continue to forge, as increasing importance of innovative payment models

Multi-level payment system

Individual payment / out-of-pocket:

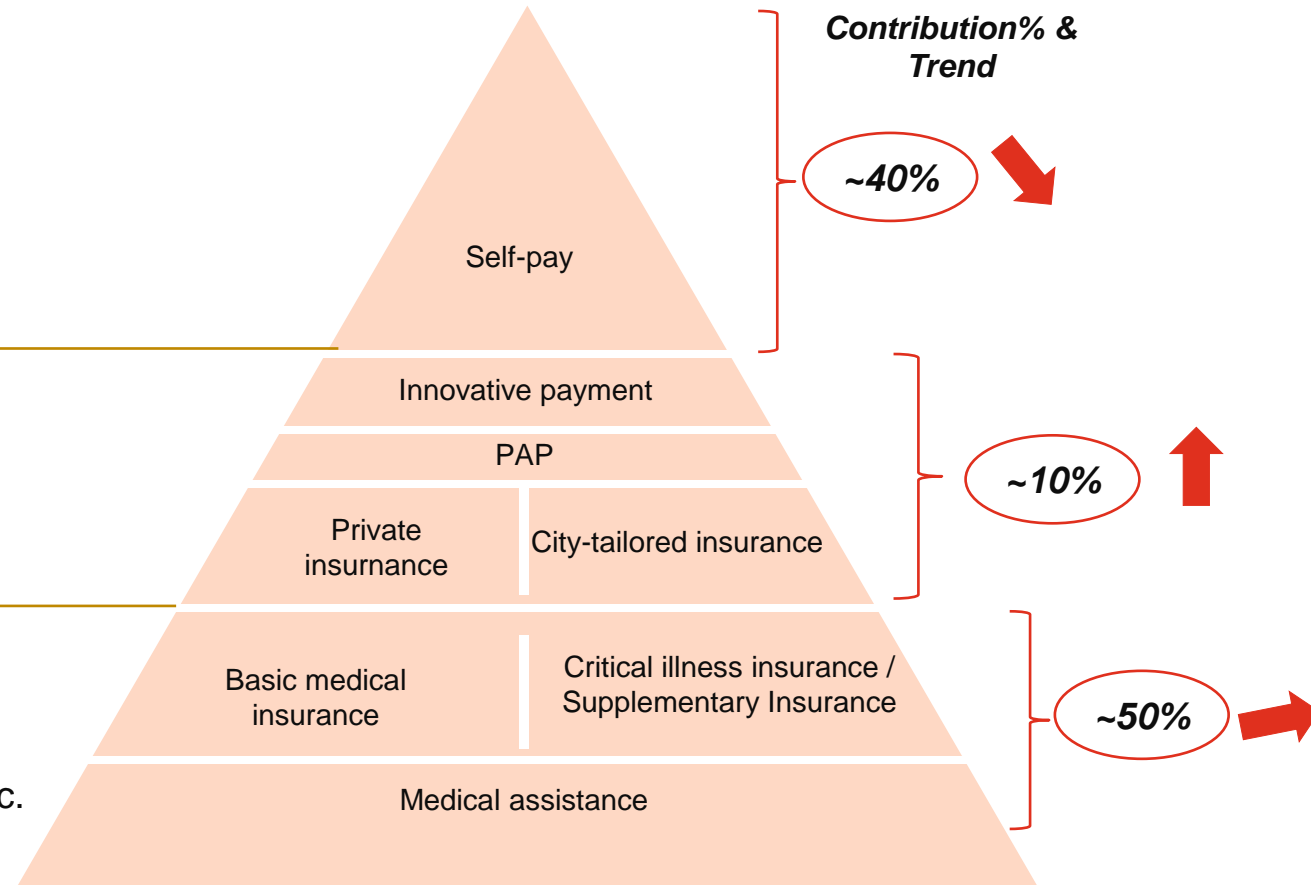
- Self-pay burden of patient is still high (diagnosis & treatment)

Social supplementary payment program:

- City-tailored insurance (Huiminbao, etc.)
- Pharmaceutical companies led programs (e.g. outcome-based insurance, PAP, etc.)

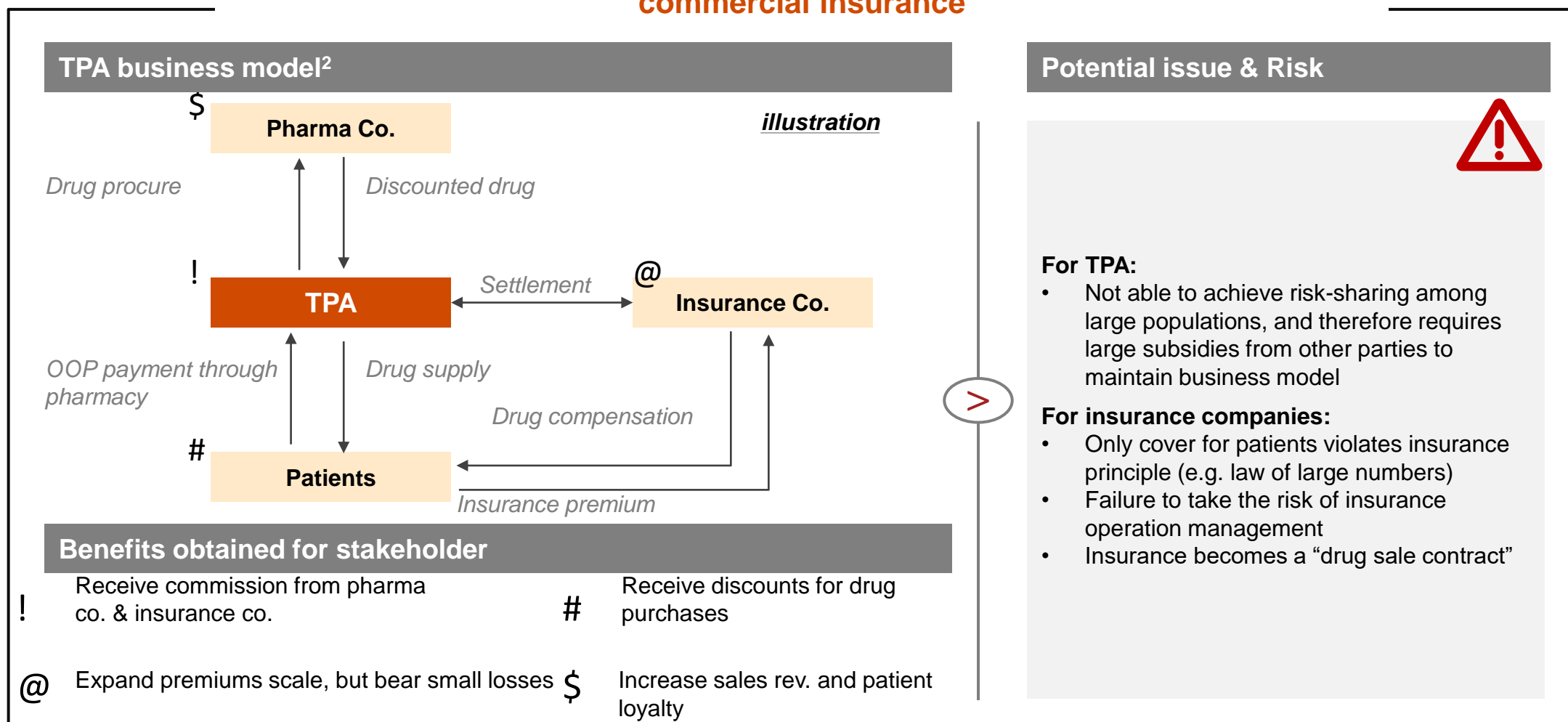
Public health insurance / Basic Medical Insurance (BMI)

- 99% citizens covered by BMI (urban / rural)
- Broad coverage and addressing basic needs via NRDL, CII, etc.



China government authorities just alarm the incompliant TPA model which is widely used by innovative drugs

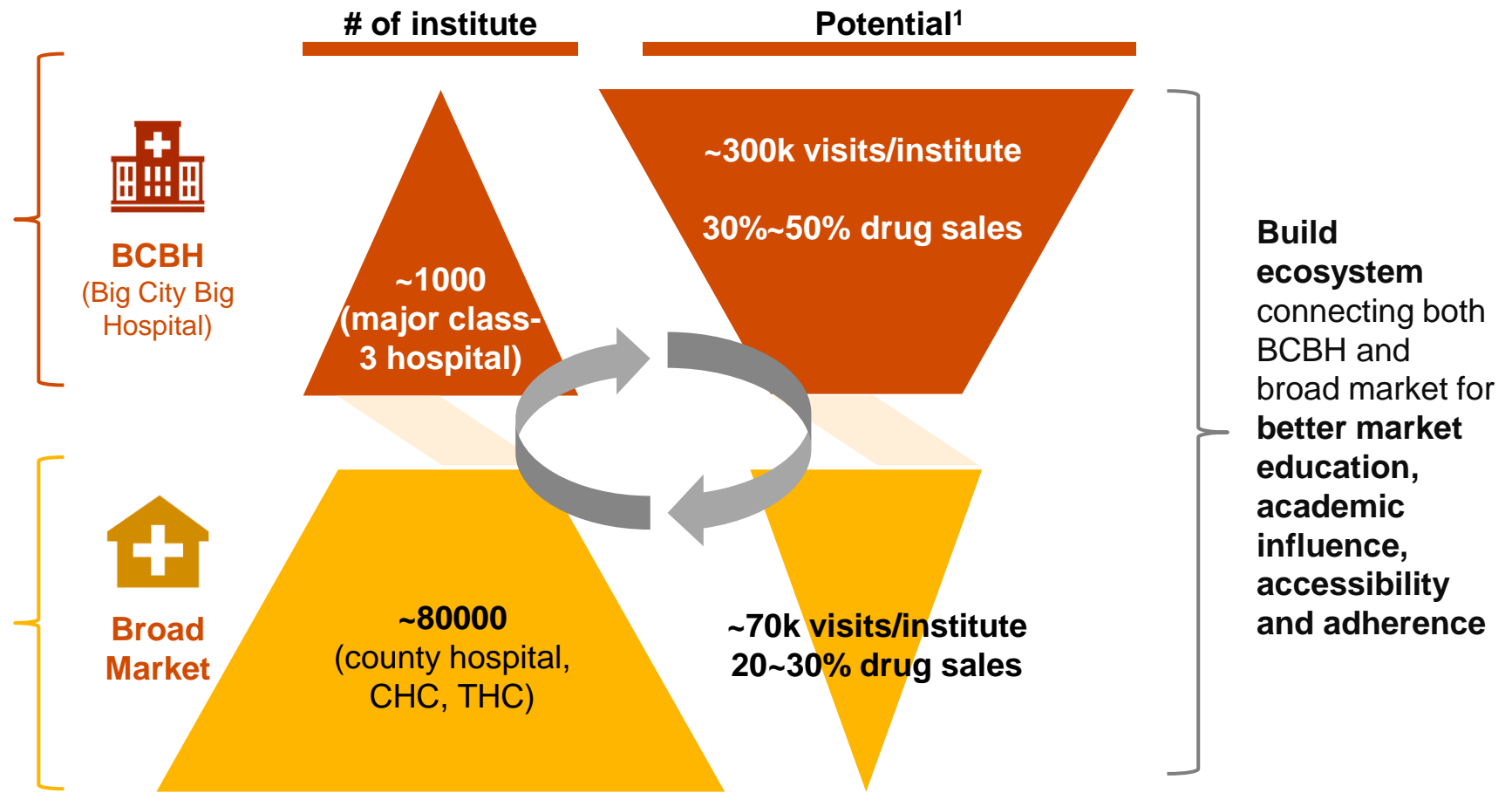
The popular “Pharma-TPA¹-Patient” model is hit by recent regulation on commercial insurance



BCBH is must-win territory and broad market looks attractive, while only integrated ecosystem could maximize market potential

Main battle field for innovative drug coverage and prescription, where **market potential and level of competition are high**, **medical evidence based clinical value** and **KOL network** are the key to success

Improving treatment capability and increasing needs for better care, but **fragmented, lower ROI, lagging in treatment mindset change**, partnership and sales behaviour management are critical






Recent regulation on data protection highlights importance of compliance in new model implementation and practice

Recent policy to regulate

2021.11 *Personal Information Protection Law (PIPL)*

2021.9 *Data Security Law*

Type of data collected	Data collection scenarios	Key considerations
 Patient Data	<ul style="list-style-type: none"> ▪ Clinical trial ▪ Pharmacovigilance ▪ Patient management 	<ol style="list-style-type: none"> 1. Obtain consent from respective party 2. Info. should only be collected for “specific purpose” 3. Plan info. storage duration thoughtfully 4. Clarify Info. sharing and access permission 5. Understand cross-border info. localization storage requirements
 HCP Data	<ul style="list-style-type: none"> ▪ HCP-visit record ▪ Meeting/Event Compensation 	
 Employee Data	<ul style="list-style-type: none"> ▪ Employment info. (e.g. gender, age, payroll) 	
...		

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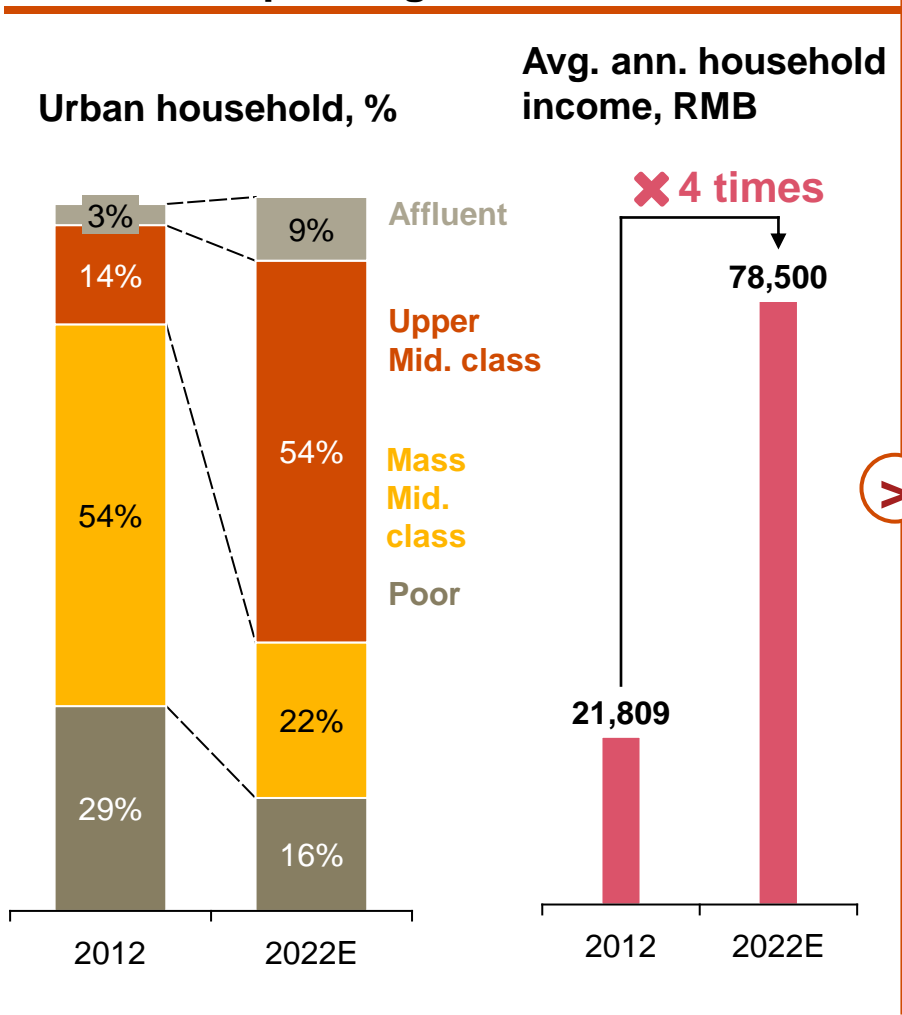
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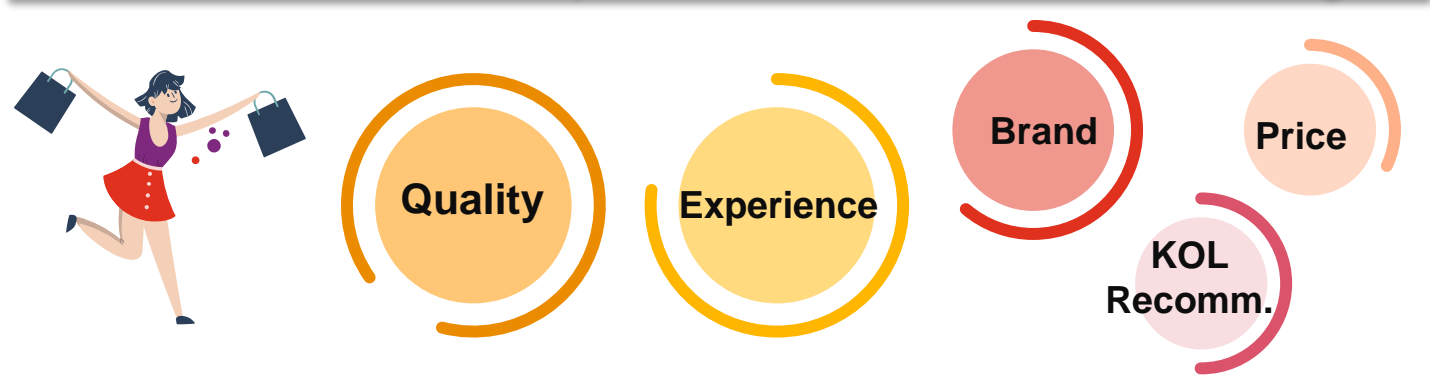
地产化策略的“是与
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Expanding middle class lays out foundation for the growth of consumer healthcare in China

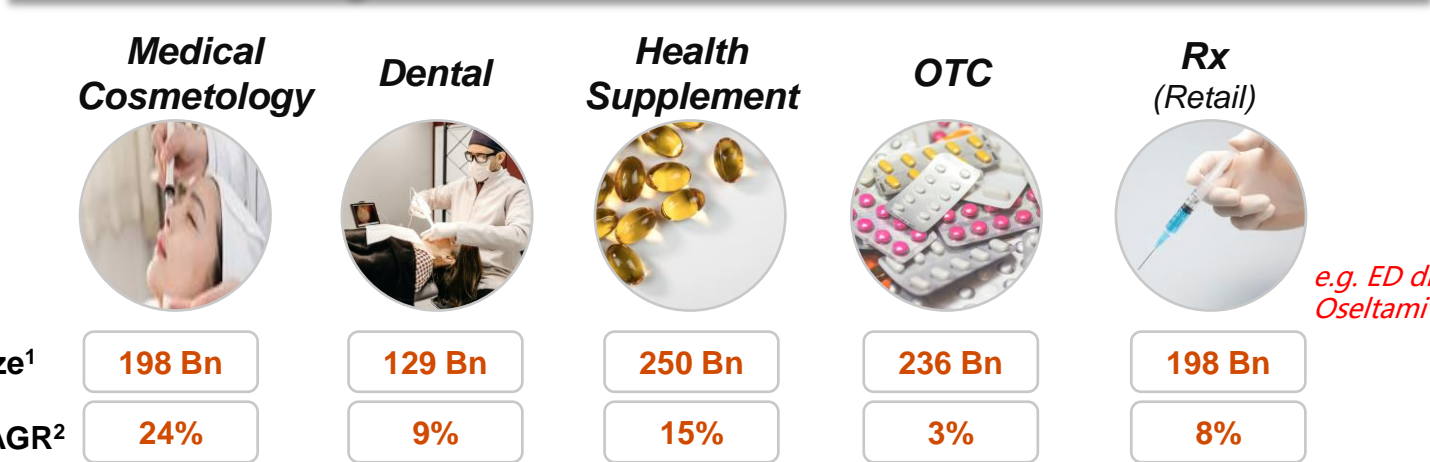
Expanding middle class



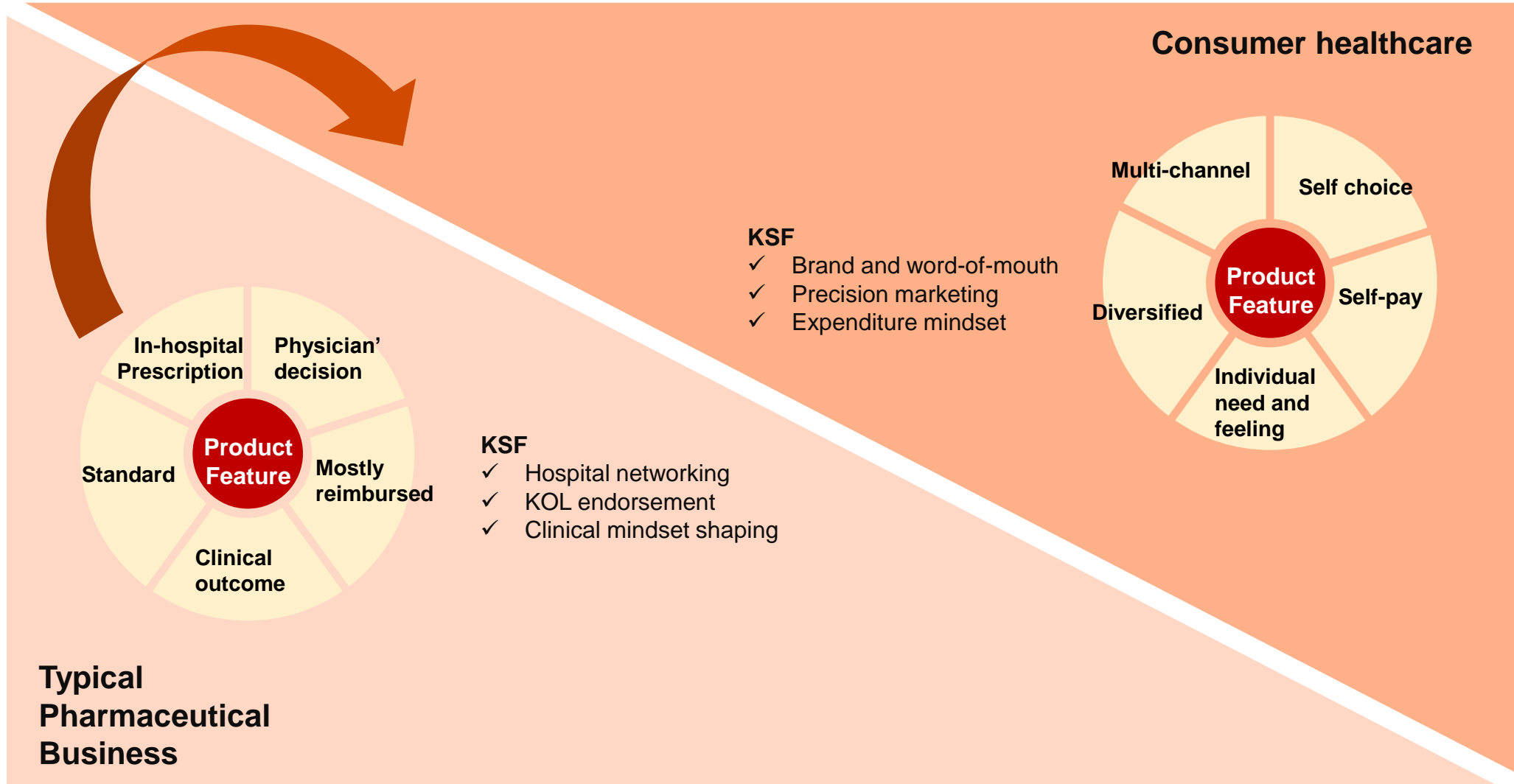
Centered around “me” - Top selection criteria in decision making



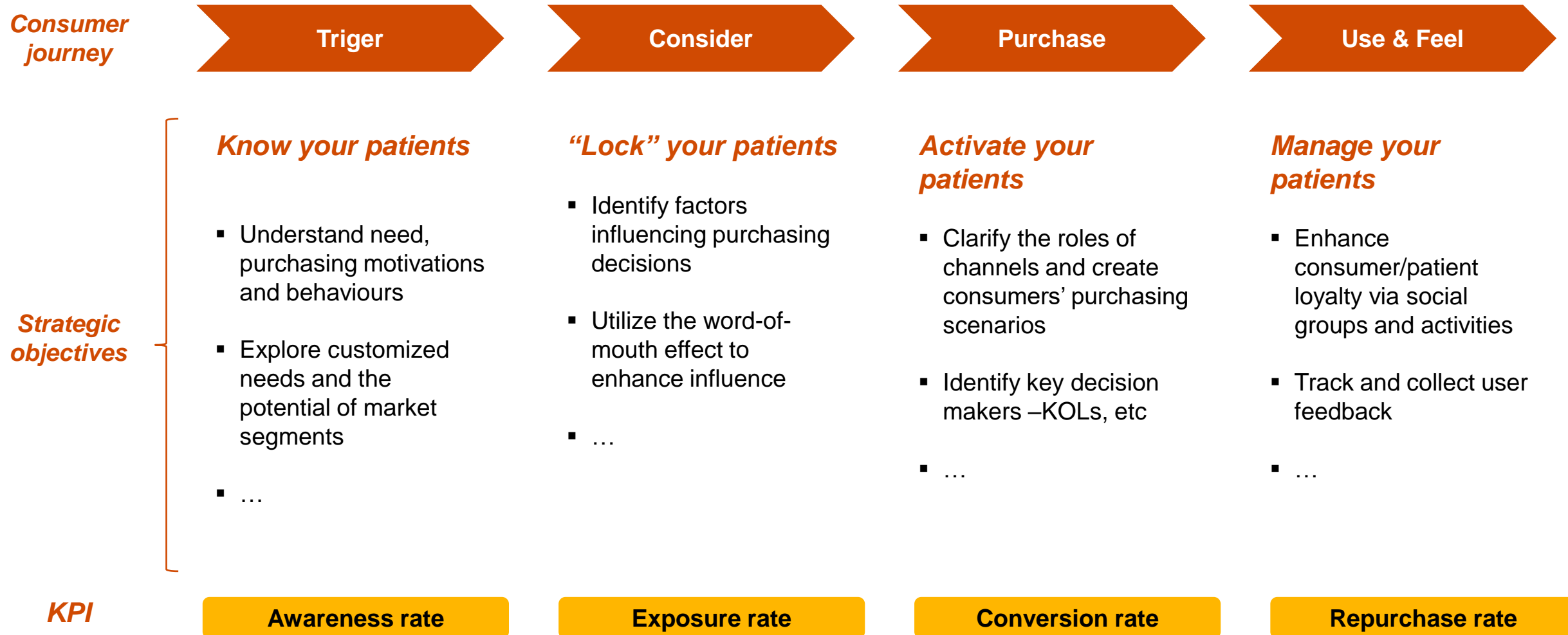
Diversified categories for “me”



Pharma companies need to switch mindset from “patient centric” to “consumer centric” for consumer healthcare business...



... and deploy initiatives along the consumer journey on the basis of in-depth understanding of consumer behaviour



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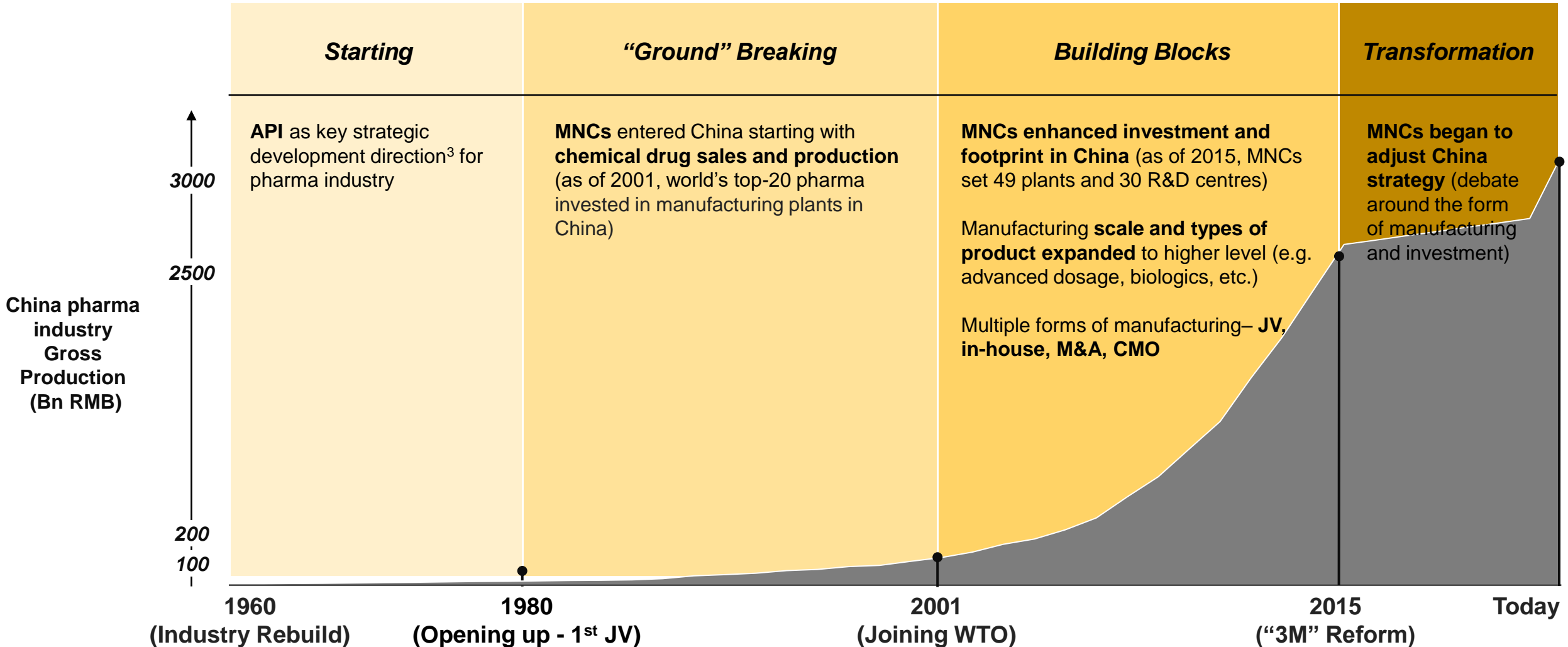
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China pharma production has entered a new phase, when MNCs are revisiting their China strategy

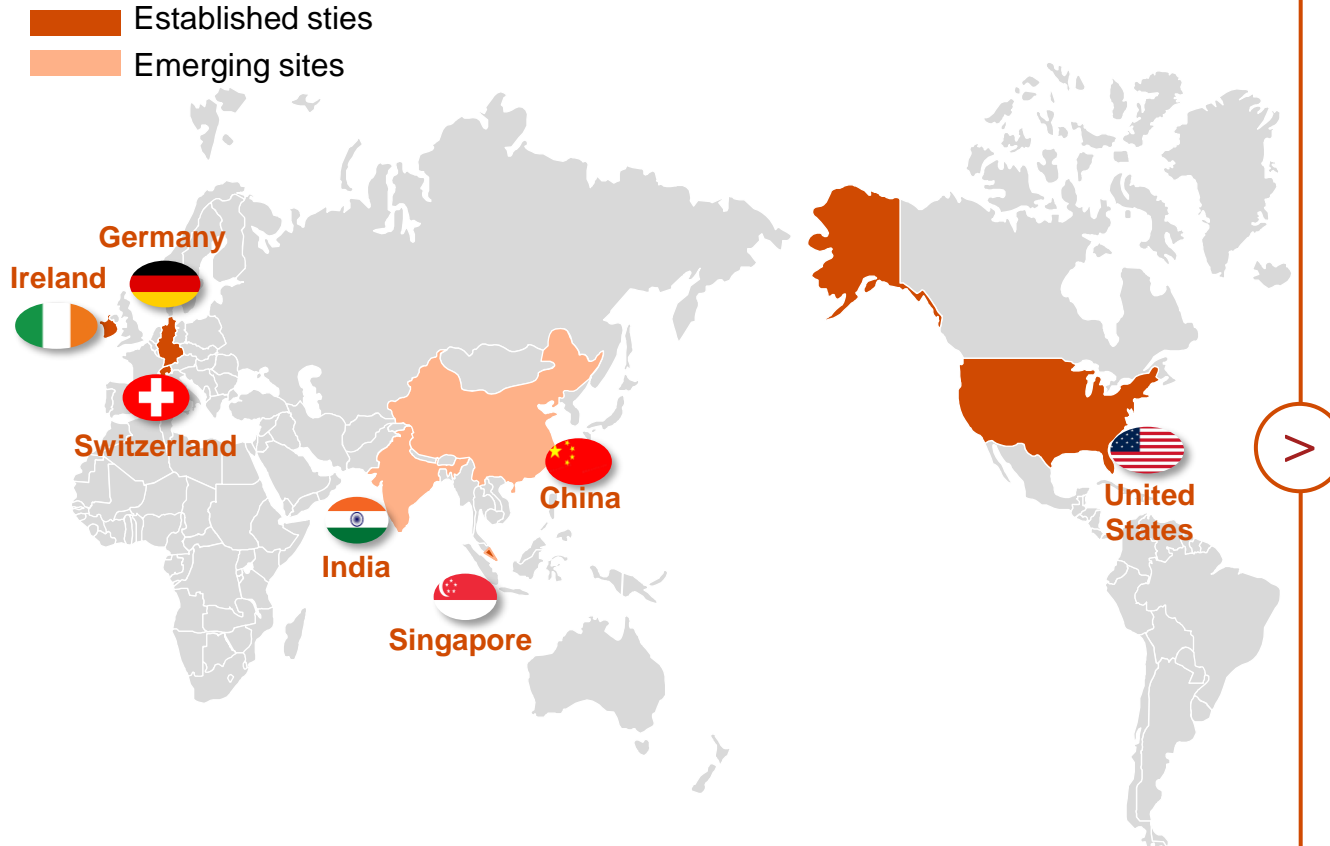


MNCs enhanced manufacturing footprint in recent 5 years mostly for 2 rationales

	Product	Mode	Examples
 Specific regulatory requirement	 Cell therapy products(CTP)	JV	<ul style="list-style-type: none"> Kite set up JV with FOSUN to enter China market
	 Plasma developed Therapy (PDT)	Local plant acquisition	<ul style="list-style-type: none"> CSL 2017 \$352 Mn acquire China PDT manufacturer Ruide to enter the market
 Cost efficiency & market supply	 Small-molecule	CMO	<ul style="list-style-type: none"> Pfizer 2022 partnered with Huahai as CMO
		Self-built plant	New plant <ul style="list-style-type: none"> Janssen Xi'an 2019 \$397 Mn Merck Nantong 2016 €170 Mn AstraZeneca Taizhou 2014 \$230 Mn
			Expansion <ul style="list-style-type: none"> Novartis Beijing 2022 \$100 Mn Santen Suzhou 2021 N.A. Takeda Tianjin 2019 \$110 Mn Bayer Beijing 2016 €100 Mn

Imagine what will happen when “made in China” drugs enter into global market?

Established & emerging sites¹ as global production hub



Rationale / Key Criteria

Representative Nation

Favourable policies



Switzerland

Logistic hub



Singapore



Germany

Talent resource



Ireland

API supply & cost advantages



China



India

Close to demand



United States



China

MNCs should address some strategic questions for local production



In summary, it is the time for us to revisit China strategy in response to the fast-changing environment



Innovative Business Model

- Increase market coverage with affordable cost
- Implement multi-channel strategy
- Enhance market access capability
- Improve effectiveness of promotion activities by satisfy HCP unmet needs
- Reshape patient journey with digital solutions

- Focus on key therapeutic areas
- Optimize product portfolio through in-house R&D and deals
- Consider the possibility to integrate Rx with consumer health products

Integrated Operation

- Integrate cross-functional resources in business plan and execution
- Improve business analysis & intelligence capability
- Align with government authorities in disruptive therapy and new business model
- Save cost in manufacturing & supply chain

Last but not the least, what could be the top priorities for medical device companies in China?



Innovative Business Model

- Increase market coverage with affordable cost
- Enhance market access capability
- **Direct and indirect sales model transformation after VBP**
- Reshape **HCP experience** or patient journey with digital solutions
- **Commercialization of digital therapy**

Focused Product Portfolio

- Focus on key therapeutic areas **and core tech platforms**
- Optimize product portfolio through in-house R&D and deals
- **Accelerate product design for China market in a fast way**

Integrated Operation

- Integrate cross-functional resources in business plan and execution
- Improve business analysis & intelligence capability **with dealers**
- **Determine and implement the local production strategy**
- **Compliance to implement digital solutions in China**

Promote technology enabled new business model, and build leading practice in China healthcare industry



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