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China’s generic drug industry undergoes an overhaul

Pharmaceutical industry’s response to new regulatory reforms and potential strategies for both domestic and MNC firms.

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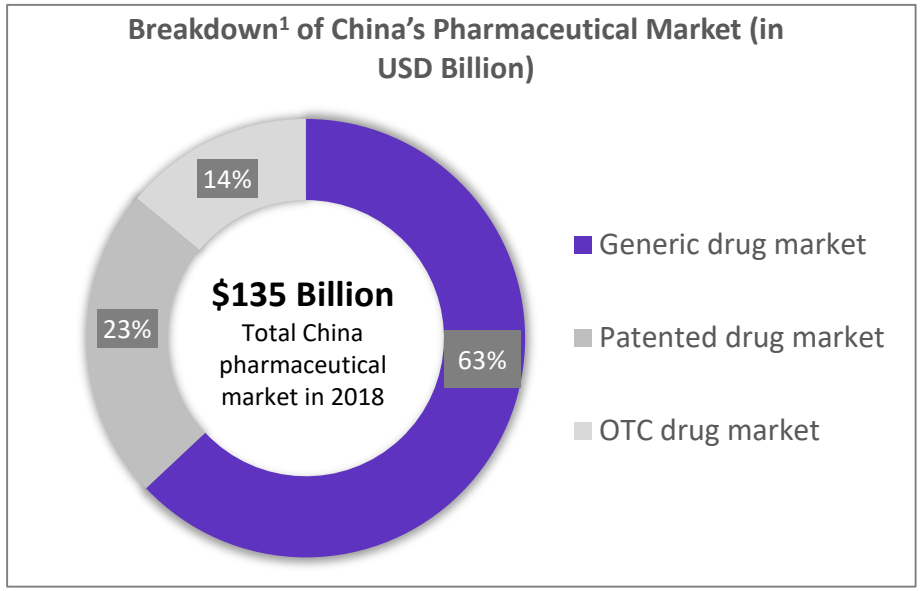
Generic drug market—the mainstay of Mainland China's pharmaceutical industry—faces critical challenges



$85 billion is the size of China's generic drug market

>90% of drugs registered in China are generic

Challenges associated with China's generic drug industry

Lack of regulatory supervision

No requirement of bioequivalence study against the originator drugs in China, prior to 2016.

Lower R&D investment

Outdated drug manufacturing technology hampered innovation in China's generic drug industry.

Unconsolidated market

Plethora of generic drug manufacturers in China who compromised quality to assure high profit margins, resulting in many, low quality generics in the market.

OTC: Over the counter; R&D: Research and development; USD: US Dollars

[1] Source: International Trade Administration; DRG analysis

China introduces decisive reforms to improve quality control, lower drug prices, and consolidate the generic drug industry

China introduced reforms / polices to guide the strategic development of its generic drug industry

Generic Quality Consistency Evaluation (GQCE)

Tax incentive for Generic Drug Manufacturers

Volume-Based Procurement Program (VBP)

May 2016

Mandatory requirement of bioequivalence testing against originator drugs to commercialize generics in China.

April 2018

Lower corporate tax rate of 15%, as opposed to 25% earlier, to encourage the development of generic drugs.

December 2018

Price negotiations through bidding process to win guaranteed volume-based contracts for public hospital procurement.

Source: DRG analysis

GQCE is reducing the quality gap between generic and originator drugs

Scope

Oral solid dosage drugs approved for marketing before October 1, 2007 and all approved injectables in China to undergo GQCE evaluations.

Implications

- Failure to pass GQCE testing leads to the revocation of registration licenses.
- Ineligibility for government tendering for hospital supply.

Progress

231 GQCE-approved drugs[1]

109 NMPA reviews completed[1]

429 under NMPA review[1]

Top Five Generic Drugs With Most GQCE Approvals[1]

1. Metformin (43)
2. Amlodipine (35)
3. Amoxicillin (20)
4. Entecavir (16)
5. Acetaminophen (16)

[1] As of September 2020

GQCE: Generic quality consistency evaluation; NMPA: National Medical Products Administration

Source: GBI SOURCE; DRG analysis

Volume-based procurement is consolidating generic-drug procurement and reducing drug prices at the national level

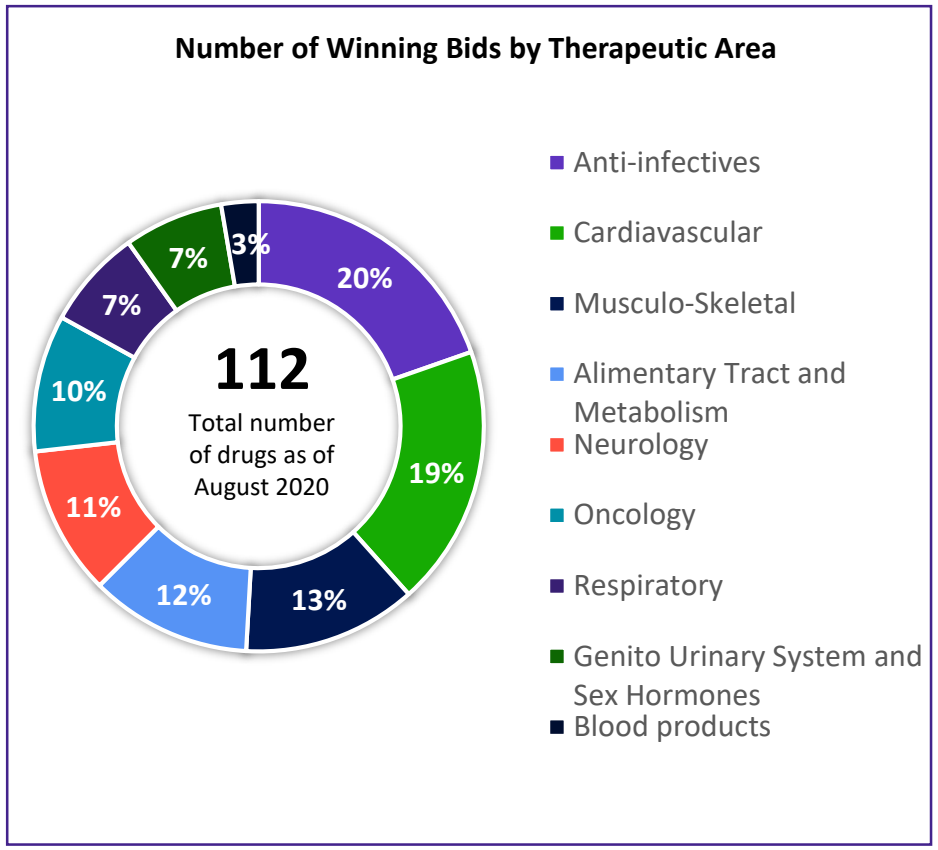
Started as 4+7 pilot program in 11 major cities (4 municipalities [Beijing, Tianjin, Shanghai, and Chongqing] and 7 provinces [Chengdu, Xi'an, Shenyang, Dalian, Xiamen, Guangzhou, and Shenzen]), and later got extended to the national level.

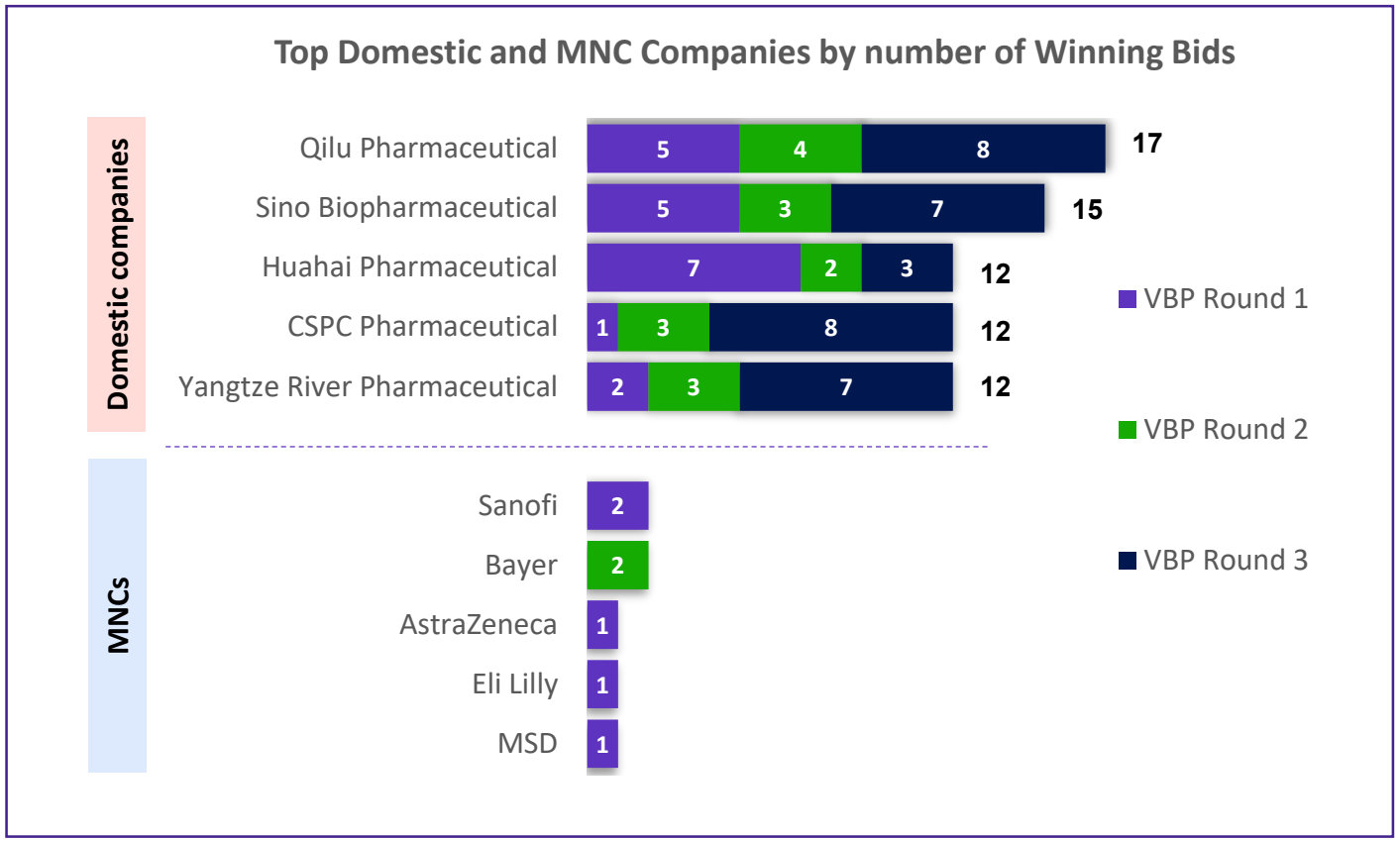
Parameters	4+7 Program	VBP Round 1	VBP Round 2	VBP Round 3
Tender date	December 8, 2018	September 24, 2019	January 17, 2020	August 20, 2020
Product negotiated	**25** products (only GQCE-passed)	Drugs included in the 4+7 program	**32** products (non-NRDL / GQCE-approved drugs)	**55** products (non-NRDL / GQCE-approved drugs)
Geographic scope	4 municipalities and 7 provinces	National[1]	National	National
Procurement contract Duration	12 months	≤ 2 bid winners: 1 year 3 bid winners: 2 years	1 winner: 1 year 2-3 winners: 2 years ≥ 4 winners: 3 years	1 or 2 winners: 1 year 3 winners: 2 years ≥ 4 winners: 3 years
Output				
Average price reductions	**52%**	**59%**	**53%**	**72%**
Total value of procurement	$0.3 billion	$0.6 billion	$1.3 billion	$2.2 billion
Total volumes[2]	1.6 billion	4.6 billion	12.4 billion	15.2 billion

[1] Excluding the 4+7 cities, Fujian, and Hebei
[2] In single-unit terms

GQCE – Generic quality consistency evaluation; NRDL: National reimbursement drug list; VBP: Volume-based procurement
Source: GBI SOURCE; DRG analysis

Domestic companies continue to strengthen their foothold in VBP while MNCs remain conspicuously absent

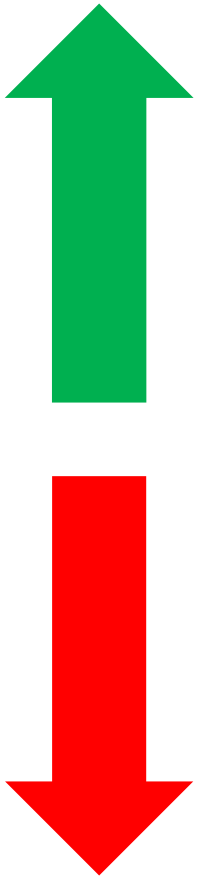




MNC : Multinational corporation; VBP: Volume-based procurement

Source: GBI SOURCE; DRG analysis

The early wave of reforms for the generic drug sector is yielding benefits but also raising profitability concerns for manufacturers



Eliminating drug manufacturers with uncertified generics

Most small-sized companies are struggling to gain GQCE certification, which led to the decline in total number of generic drug manufacturers from >5,000 in 2015 to 4,300 in 2018.

Significant reduction in overall healthcare cost

Chinese Government has saved an estimated $1.5 billion in healthcare spending following the third VBP round in August 2020.

Greater visibility of highly genericized therapeutic segments

40% of the total VBP drugs are from anti-infective and cardiovascular therapeutic segment in all VBP rounds.

MNCs de-prioritize VBP due to reduced profitability

Bayer, Sanofi, Novartis and Pfizer reported declining revenues for the VBP products, affecting profit margins for these firms.

Fear of long-term survival among domestic firms

Reduced profitability will hinder domestic firms to optimally invest in R&D. Companies losing bids will find it hard to sustain through retail channels only.

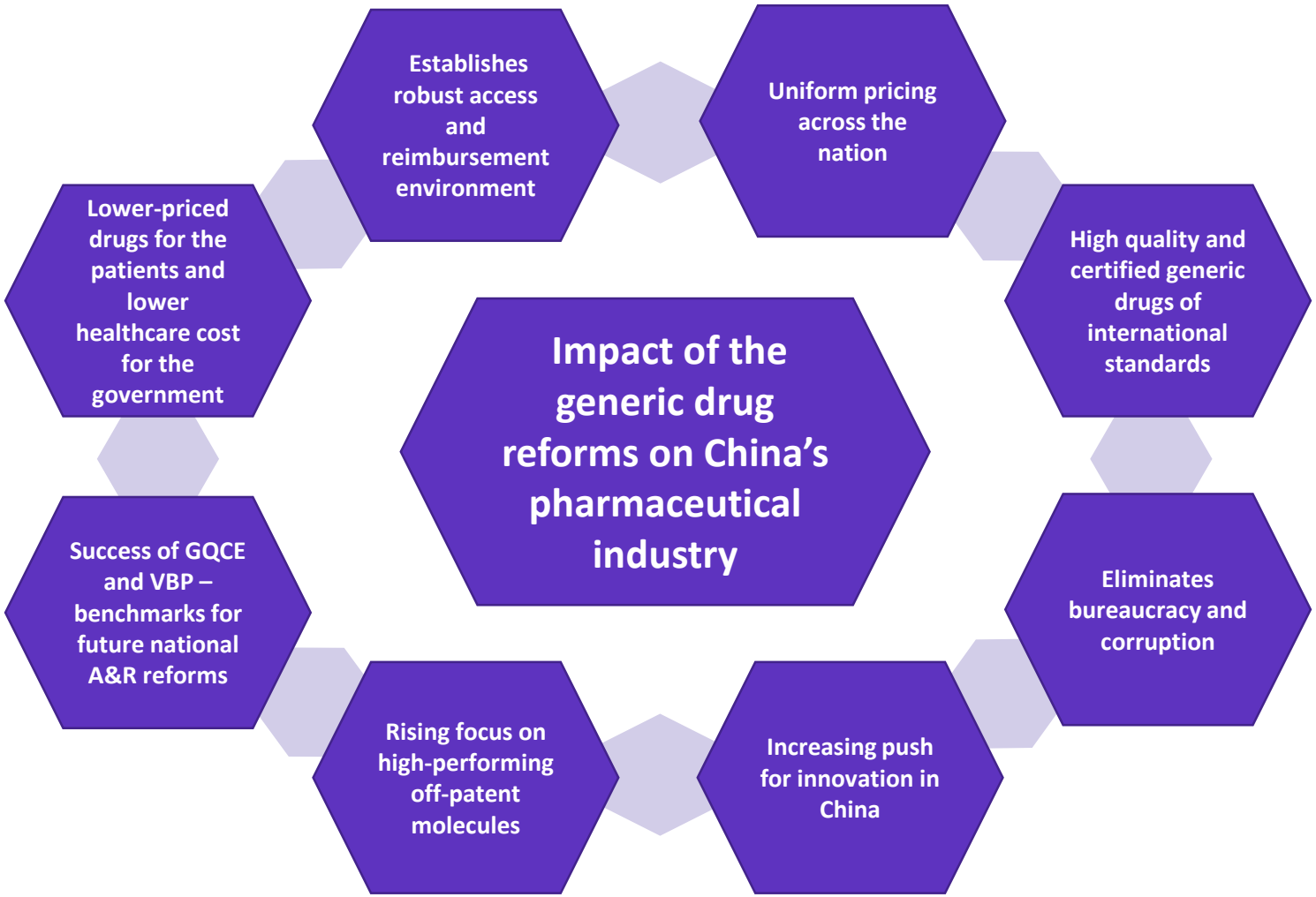
Unclear roadmap

Recently, VBP reform has been split into provincial and national VBP which may lead to confusion on the drug's accessibility from province to province.

GQCE: Generic quality consistency evaluation; R&D: Research and development; VBP: Volume-based procurement

Source: GBI SOURCE; DRG analysis

The reforms will allow China to achieve ultimate objective of high quality and affordable healthcare



A&R: Access and reimbursement; VBP: Volume-based procurement
Source: DRG analysis

Both domestic and MNC players must formulate robust strategies to survive in a highly competitive market space

Potential Strategies for Drug Manufacturers

- ***Boost R&D and manufacturing capabilities*** to foster innovation and develop high quality generics while maintaining low manufacturing cost.
- With guaranteed volume-based contracts, ***realign the sales force model*** to maximize the profit margins.
- ***Adapt omnichannel strategy*** to also focus marketing efforts on non-hospital channels such as retail, direct-to-patient, and online pharmacies to sustain business.
- ***Leverage past experiences*** to cash-in the $90 billion segment with the extension of GQCE and VBP program to injectables.
- ***Penetrate untapped rural retail pharmacy markets*** that present a potential opportunity for MNCs as healthcare goes digital.

GQCE: Generic quality consistency evaluation; R&D: Research and development; VBP: Volume-based procurement
Source: DRG analysis

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