THE NEXT DECADE OF OPPORTUNITY—AND JEOPARDY—IN CHINA'S PHARMA MARKET

By Frank Jia, Baiping Chen, and John Wong

Fundamental changes are underway in China's pharmaceuticals market, with significant implications for both multinational companies (MNCs) and domestic players. After more than a decade of emphasizing improved patient access and overall cost management, China has shifted the focus of its health care policy to innovation and quality, with the goal of speeding patient access to innovative drugs and making them more affordable.

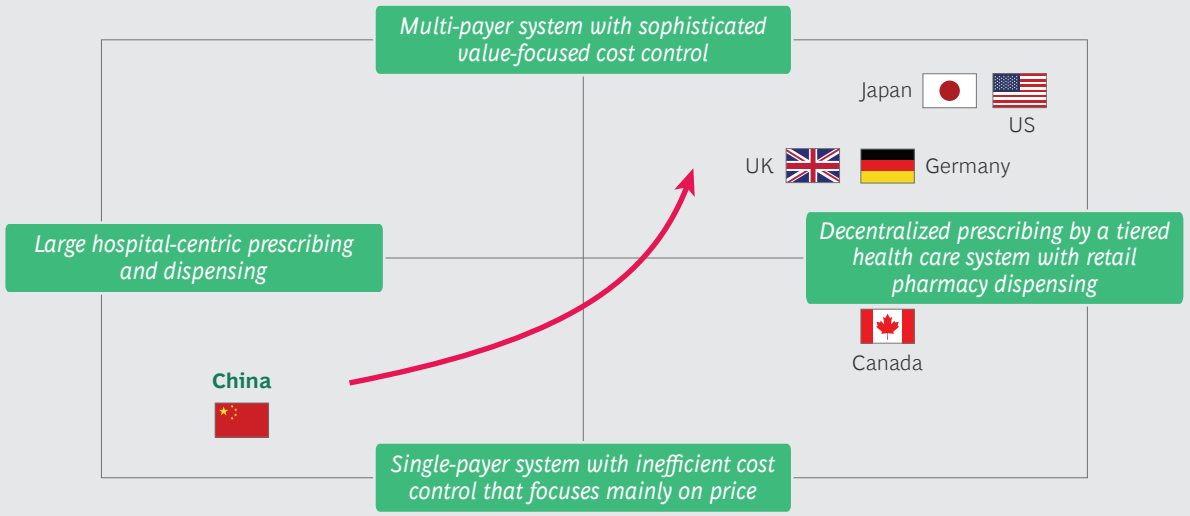
These new policies promise big changes in the marketplace. Manufacturers of originator LOE (loss of exclusivity) products will face much more direct competition from generics and, over the next couple of years, significantly lower reimbursement prices than those they have enjoyed for nearly two decades. At the same time, a greater number of innovative products will be available in the market and eligible for reimbursement.

All companies will need to rethink their drug portfolios, their R&D, and particularly their marketing and sales activities for both LOE and innovative products. The stakes are high: China is now the second largest drug market in the world, and even though its growth recently slowed, the market is still expanding at a rate of about 10% per year.

A Clear Change in Direction

LOE and generic drugs today make up the vast majority of pharmaceutical sales in China. While the market is likely to retain this balance for a while, we believe the recent policy changes will dramatically increase the proportion of innovative treatments, speed up their time to market, and increase their access to national reimbursement. (See Exhibit 1.) Among the specific changes that companies can look forward to are streamlined approval processes for new drugs, which will cut time to market from years to months, and much faster reviews of the reimbursement status for these treatments, so more of them can be added to the national reimbursement list. At the same time, as the government seeks to free up funding for innovative therapies,

EXHIBIT 1 | China Is Moving Toward a Tiered Provider System



Source: BCG analysis.

companies can expect actions that heighten competition among LOE and generic products. These actions will include combining LOE and generic quality consistency evaluations (GQCEs), setting new tendering and bidding procedures, and establishing new reimbursement rules. In addition, the government is delayering the distribution system by allowing expanded roles for retail pharmacies and other, emerging channels. (See Exhibit 2.)

The reforms will affect all product categories—mature, new, and pipeline. As MNCs begin to feel increased pricing pressure on their LOE portfolios, they will need to make the difficult transition from portfolios with high reimbursement prices to a product mix that is more in line with the government's policy of emphasizing new and innovative drugs and cheap LOE and generic products. For local companies, the challenges will be to determine where they can most effectively play—in generics or in innovative products—and to retool their operations where necessary for quality and efficiency. Deals and partnerships are likely to rise in importance for all players.

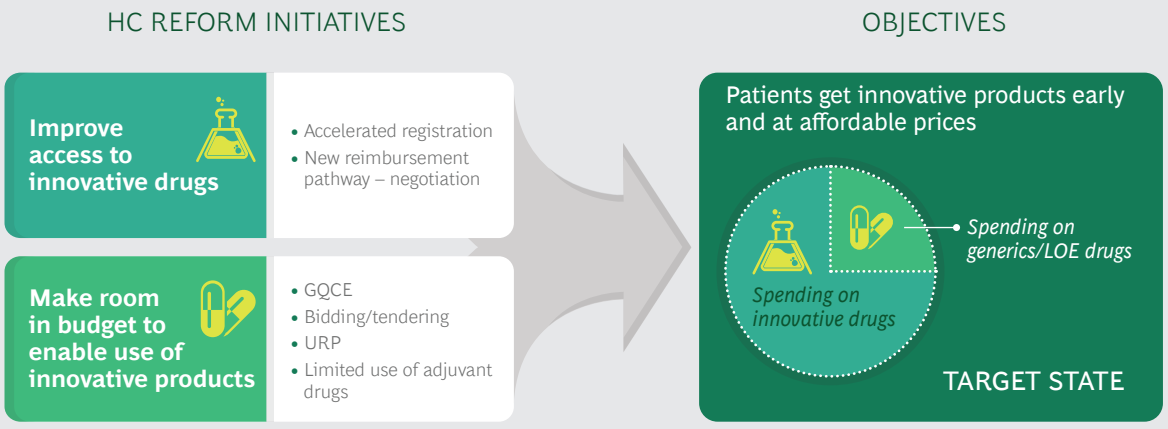
The New Game for MNCs

For the average large MNC in China, LOE products account for 80% to 95% of the sales mix. When LOE premiums to generic pricing were 50% or more (sometimes as high as 1,000%) and hospitals made 70% of their profits from dispensing drugs, the MNCs were able to build large LOE-based businesses. But premiums are already coming under growing pressure as the number of GQCE-qualified generics for many molecules increases and hospitals can no longer achieve dispensing margins that favor the more expensive LOEs. Adding to the strain is the fact that a molecule-based uniform reimbursement payment standard (RPS) will likely become more widely applied at the provincial level. The RPS will ultimately take hold as a key pricing mechanism for negotiation and purchase by hospitals and government purchasing organizations.

The MNCs need to ask themselves several questions:

- How can we shift our portfolio away from LOE products but still maintain growth?
- Should we adjust our allocation of resources in light of changing LOE pricing and the RPS?
- What do the policy shifts mean for our organization's LOE and innovative businesses?
- Should we now think differently about partnerships?

EXHIBIT 2 | Government's Actions Increasingly Reflect China's Health Care Objectives



Source: BCG analysis.
Note: GQCE = generic quality consistency evaluations; URP = Universal Reimbursement Payment.

Mature Products. Managing their portfolios of mature LOE products is the biggest single challenge facing MNCs in the near to medium term. Two questions loom large: How do MNCs maximize these products' value amid shrinking margins, and how do they adjust their commercial strategies as the marketplace transitions from a sales- and marketing-driven model to an access-driven model?

Increased generics competition, changing provincial tendering rules, and new reimbursement programs and procedures will have a quick and negative impact on LOE sales. Most provinces have already placed GQCE generics and LOE originators in the same quality band, with the expected impact on price. MNCs have seen moderate price cuts in provinces that have price negotiation mechanisms, and major price reductions—down to generics levels—in provinces that have direct price bidding mechanisms. New RPS mechanisms will affect patient out-of-pocket payments and ultimately reduce sales volumes if LOE prices remain higher than those of GQCE molecules. A key challenge for MNCs will be adapting their go-to-market models for LOE products. As pricing pressures gain traction and margins shrink, it will be increasingly difficult to sustain existing sales promotion activities.

There is no "one size fits all" solution; MNCs will need to explore product-specific solutions for each mature drug in their portfolios. Among the criteria they should screen against are the following:

- **Competition:** How many GQCE molecules are in the pipeline?
- **Entry barriers:** How difficult is it to manufacture the compound at competitive cost?
- **Reliance on the product:** How big a factor is the product in the company's mix? How soon can the company ramp up new products?
- **Price:** How much price pressure will the product feel from related drugs, shifting reimbursement policies, and the current price differential versus other GQCE-approved products?

In November 2018, the government initiated a tender process in large cities (known as the 4+7 cities—four big urban areas and seven large provincial centers) by which it sought significantly lower prices for leading LOE products and their respective generics. This initiative highlights the government's willingness to pit LOE products and their GQCE equivalents against one another in competitive tenders for guaranteed volumes. The winners were decided largely on price—with average reductions of 50% to 60%.

This new practice of linking specific volume guarantees to price is a significant, though expected, change from the previous practice of negotiating price without a volume commitment, and the approach is likely to expand to more provinces and cities. For each of their highest-selling products, MNCs will need to calculate carefully the value (if any) from a share gain at a lower price versus the potential value hit from a product being excluded (at least partially) from China's largest markets. "Successful" bidders must also factor in the price-cut spillover effect in various channels outside of affected cities and provinces, because they will be required to match the bid price nationwide.

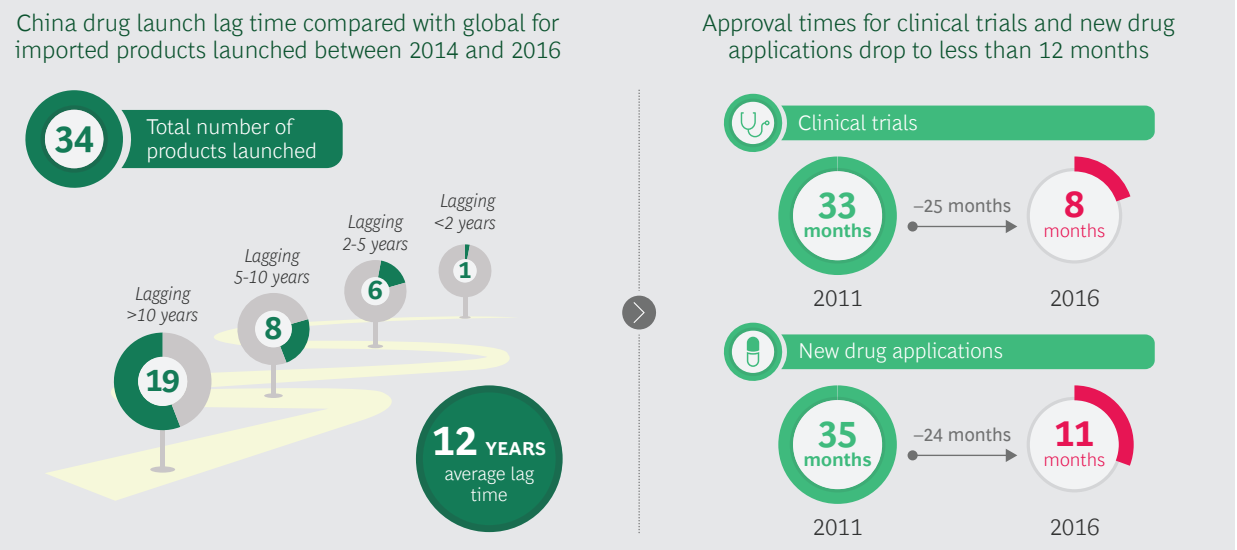
In addition to an immediate revenue impact, the new bidding practices will have far-reaching ramifications for MNCs' commercial infrastructure and supply chains. Each company will face a complex puzzle calling for different calculations and strategic choices for each of its major products. Among the many possible choices are embracing a low-margin/high-volume model, retreating to maintain margins, and developing a hybrid model to the extent possible.

For lower priority products, or drugs that have only moderate growth or heightened generics competition to look forward to, companies must also determine whether an alternative commercial model is better suited to the changing market circumstances. Options include reorienting the sales effort, partnering with local pharma companies or contract sales organizations, partnering with distributors, outsourcing selling rights, or outright divestiture.

New Products. As the importance of new and innovative treatments rises, MNCs face a more complicated challenge: how to accelerate registration and profitably launch their innovative drugs in a market that now provides faster access but also greater competition.

Consistent with a policy that pushes innovation, the speed of review and approvals is already comparable to that in advanced economies such as the US. Our analysis of 34 drugs launched in the first half of 2018 found that 12 had review times of less than half a year, and 16 had review times of a year or less—much different than the consistent multiyear review periods of the past. (See Exhibit 3.) The approvals included in our analysis spanned all major treatment areas: oncology, immunology, infectious diseases, metabolism, respiratory ailments, and others. At the same time, changes to the reimbursement model will require companies to rethink how they

EXHIBIT 3 | Recent Reforms Speed Approvals



Source: BCG analysis.

launch, price, and market new treatments. For example, the timing of reimbursement reassessments is likely to move from historically lengthy rounds (often measured in years) to a more dynamic system with shorter cycles.

Our analysis of 31 drugs (from multiple treatment areas) that were recently subject to National Reimbursement Drug List (NRDL) price negotiations revealed an average price cut of 44%. MNCs may want to plan pricing and pricing concession strategies differently going forward, including new launch sequencing and new factors for price discounts. Some companies are already exploring alternative pricing and funding models, including patient financing programs, private insurance, and outcome-based payment.

Speed is a priority. In this evolving environment, MNCs need to execute effectively and efficiently. As product approvals accelerate, the window of opportunity for any product is much narrower than it used to be. Obtaining approval and going to market are now much more time-sensitive—how quickly a drug becomes available can make or break its prospects.

For products that are still patented and eligible for government reimbursement, companies now need to think about whether, when, and how to expand outside their core hospital market. We expect a big shift in the importance of distribution channels in the coming years, and it will be important for new products to quickly establish themselves beyond large hospitals. Aggressive expansion will require upfront investment, but establishing the right products in the right channels early could result in substantial profits over time. Among the factors that companies need to take into account on a product-by-product basis are the competitive outlook (determined by the number of players and their products' competitive advantages) and how quickly a tiered approach to treatment is expected to take hold in each therapeutic area.

Pipeline Products. The size of the Chinese market, combined with its newfound emphasis on fast approvals for innovative treatments, all but mandates that MNCs review how they approach and manage their pipelines. Early movers stand to benefit. The priority assigned to innovation and products with the ability to address unmet clinical needs is having a marked effect on the approval process. The number of new drug applications reviewed jumped from 36 in 2015 to 76 in 2016. More than 50 applications were reviewed in the first half of 2018.

A high priority for most MNCs will be adopting the most effective model for managing their pipelines. We see three options:

- **Global for China.** China becomes involved early in proof of concept and global R&D decision making and strategy.
- **China for China.** Companies focus on products for China only, to meet China's unmet medical needs.
- **China for Global.** China takes the lead in developing new products with global potential, as the newly named National Medical Products Administration (NMPA) opens the door for being first in human studies.

MNCs taking the first approach will find ample opportunities to accelerate approval timelines in China, but taking advantage will require that their global organizations recognize China's new potential and include the market early in priority-setting and decision-making processes. Historically, China's lengthy clinical approval timelines undermined its inclusion in global priority setting. Given the regulatory changes now underway, it makes sense to take China's market needs into consideration and, if appropriate, to include China in global trials. Strong communication channels with the NMPA and operational excellence in seeking approvals and going to market will also be essential success factors.

Pursuing the Chinese market for its own sake also involves recognition that China

has different disease patterns than other countries—and thus different unmet medical needs. For example, the rates of gastric, liver, and esophageal cancer are much higher in China than in the United States; these diseases represent a distinct local opportunity. In planning global investments, it is important to consider funding potential China-only (or China-predominant) treatments.

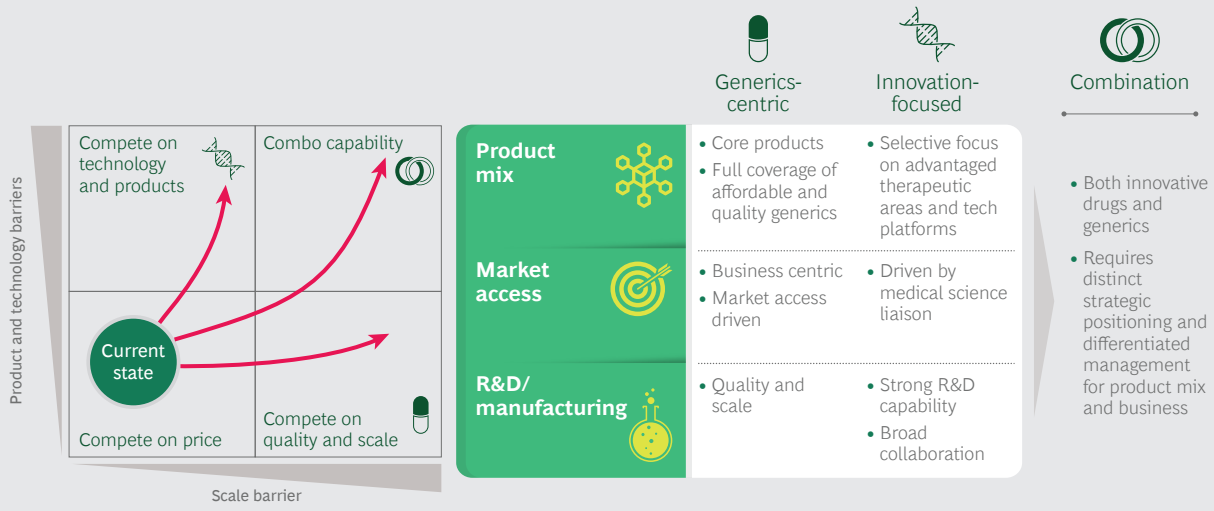
China's market characteristics make it a potential source of innovation. MNCs can look to leverage local innovators and develop new treatments for both China and the global market. MNCs will want to assess the development opportunities for both their early-stage and their later-stage pipeline products through a China lens. Early-stage treatments may offer some big opportunities (as well as risks), but they will likely require time and the building out of a local R&D capability. It will be relatively easy to examine the business potential of later-stage drugs, but moving forward will require close coordination with headquarters on the realities and requirements of the evolving Chinese market. Some MNCs may uncover global opportunities from their China activities, particularly when treatments developed in China complement a global pipeline gap or when circumstances in China allow for a quicker time to market than in other countries.

Changes for Local Companies

The changes underway in China are no less significant for local players, who will also find long-standing models disrupted and need to find new ways to compete and win. (See Exhibit 4.) As is the case with MNCs, these companies face critical strategic choices that will determine how they invest, conduct R&D, market their products, and organize for the next decade and beyond. There are two primary strategic avenues for the future, each with its own set of resource requirements: (1) competing on technology and innovative products and (2) competing on quality and scale. Some local players may transition over time into a comprehensive model that encompasses both approaches.

Generics-Centric. There are about 6,000 pharma companies operating in China, most of them competing in the broad generics market. Some shakeout is inevitable; indeed, current government policies are designed in part to drive consolidation among weaker, lower-quality players. Firms that want to survive will select or develop a core group of products, prioritize the molecules to be registered as GQCE, and determine how to compete effectively against companies with LOE or other GQCE-approved products. And they will build sales capabilities that fit the new commercial models, such as packaged

EXHIBIT 4 | Structural Changes Require Local Players to Find New Ways to Win



Source: BCG analysis.

deals involving multiple drugs and volume-based purchasing.

They will also plan in phases. The near term (the next few years) is about the core portfolio, making volume gains through 4+7 programs (where possible), maintaining sales coverage by treatment area in channels and areas that have not yet implemented volume-committed tenders, and improving quality control and manufacturing management. In the medium and longer term, companies can build comprehensive portfolios that cover multiple therapeutic areas, develop volume-based purchasing models (including data-driven pricing capabilities), and improve efficiencies and cut costs through economies of scale.

Innovation-Focused. Local companies that focus on newer drugs will need to determine which therapeutic areas to concentrate on and how best to accelerate development and build their pipelines. Pharma R&D in China is a nascent activity, with companies working mostly serendipitously and taking economic advantage of the clinical work done by others. Local players tend to invest in mechanisms of action and molecules that show positive clinical results overseas, to license and develop deprioritized pipeline assets from leading MNCs for the China market, or to develop me-too products for well-established disease targets.

To compete across the full value chain, local companies must develop deep expertise in selected areas that are both promising and compatible with their current competitive advantage. They need to acquire new technology, build R&D efficiency and competitiveness, and develop core innovation capabilities. The latter requires making a transition from follower to leader in the lab and improving R&D management capabilities with respect to basic research, target identification, and clinical trial design and execution. Three models are viable. One is going it alone—developing a full in-house R&D capability, probably focused on organic growth in treatment areas that currently have limited competition. A second is partnering with a contract research organization to share costs and develop innovative products. The third model, reflecting their different goals and resource requirements, keeps the new research initiatives and the existing organization separate by establishing an independent entity to focus on R&D.

China's quickly evolving pharma market will look very different in just a few years. All companies, multinational and local, must move fast in assessing what the shifts in access and competition mean for each product in their portfolios, and in adapting those portfolios to the changes. Companies that move expeditiously to maintain market access and adjust their go-to-market models to the new realities can establish strong future-oriented positions for their LOE and generic products, although the new procedures will be tricky to navigate. Companies that retool R&D and new product development to take advantage of the government's shift in emphasis toward innovative treatments can also achieve significant success. The companies that do not start to shape their futures now will soon find themselves staring at a much more complex and difficult challenge.

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