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Biopharma in China: Insights into a market at a crossroads

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Biopharma in China is poised for change that will transform commercial and operating models, and require a step change in capabilities.

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China's biopharma market continues to grow at a healthy pace. Market growth has remained in mid-single figures over recent years, with total value reaching some $130 billion[1] in 2018, making China second only to the United States in world rankings. However, powerful trends are set to transform the industry over the next few years. On the one hand, the threat to mature brands has reached a tipping point driven by pressure from a combination of new policies; on the other hand, regulatory reform and broadening of market access provide a brighter outlook for innovative and patented products, although real uncertainties remain. Some observers say digital advances will have a major impact on

the industry, while others believe true digital transformations are still years away. Critically, companies find it harder than ever to identify, recruit, and retain the talent they need to compete.

We seek to shed light on an inflection point in the development of China's biopharma market. It draws both on our own observations and on a series of in-depth conversations with senior leaders of multinational pharma companies in China. Through our research, we identified five key insights into the industry's prospects for the next few years. We hope they will encourage debate, broaden stakeholders' thinking across the industry, and help companies plan wisely.

Insight 1: Generic-quality consistency evaluation and reimbursement reform exert pricing pressure on off-patent originator products, but they potentially release more funding for innovation and shift China toward a developed-market profile.

Mature products registered ten or more years ago are estimated to contribute to more than 85 percent of pharma multinationals' total revenues in China, and volumes continue to grow. But many executives are concerned about the impact of the rollout of generic-quality consistency evaluation (GQCE) and new tendering rules, which are likely to exert pricing pressure on mature portfolios.

By the fourth quarter of 2018, fewer than 10 percent of the 289 oral solid drugs on the original list published by the National Medical Products Administration (NMPA) had passed GQCE,[2] for reasons ranging from lack of bioequivalence testing sites to manufacturing capability gaps. Many generics manufacturers are now pursuing molecules outside this list

that have strong market potential. Overall, we estimate that some 60 percent of the top approximately 150 oral solid drugs by revenue will face GQCE competition in the near future, putting around $9 billion of revenue at risk for multinationals.[3]

When the GQCE policy was first published, pharma executives had mixed views on its likely impact. Today, almost every industry leader we spoke to believes that the policy will trigger convergence toward a developed-market profile for mature and off-patent brands —and that this will happen sooner than was expected just a few years ago.

"We're seriously considering whether to drop prices to capture volume or just retreat."

"For mature products, we're more pessimistic. We face significant challenges and we're under a lot of pressure. We're being forced to rethink investments and returns."

"Pricing will be an issue, especially as the reference pricing model comes to China. Some multinationals will restructure to raise profitability."

—Senior executives at multinational biopharma companies

The eventual impact of the GQCE will be shaped by how quickly the new tendering rules are applied and the approach that is followed. The "4+7" tendering results published in late 2018 created anxiety in the industry.[4] They revealed much lower tendering prices than companies had expected, with the highest discount exceeding 90 percent and an average discount of 55 percent across 25 molecules.[5]

Implementing the GQCE and new tendering rules will have implications for the whole industry. With generics passing GQCE, arguments for the quality of multinationals' off-patent originators will erode. Pricing pressures could spread to other cities and provinces, leading to intensified volume competition for off-patent originators as well as market

leaders in generics. Some executives from local as well as multinational pharma companies are concerned that implementing 4+7 more widely may reduce incentives for the industry to invest in GQCE and hit funding needed to support innovation.

That said, a volume guarantee gives the winner of a bid an opportunity to capture market share at speed. It could also enable the manufacturer to cut its distribution and commercial costs, reducing the impact of discounting on the bottom line. What is more, pockets of opportunity still exist outside guaranteed volumes, including the private and out-of-pocket market.

The mounting pressures on mature portfolios are prompting multinationals to reevaluate their returns on investment. As well as transforming their business models to improve productivity and sustain profitability, they are looking for additional opportunities to drive volume growth. Some multinationals are partnering with local companies not only to improve efficiency and sustain mature products but also to broaden their commercial reach, extend their market access, and allow the pursuit of a “second launch” strategy after national reimbursement inclusion, especially in lower-tier markets. They are also moving away from homogenous growth models to adopt more diversified strategies for different parts of their portfolios.

In the near future, we expect to see more outsourcing of off-patent originators from multinationals to partners, as exemplified in the recent Roche partnership with Ascletis for Pegasys and Eli Lilly and Company with 3SBio for human insulin. Companies will also reevaluate bottom lines and productivity, adopt innovative tools to drive sales-force efficiency, and shift investments in their portfolio more quickly.

Insight 2: Many multinationals are reorienting their portfolios toward innovative products, but the value of

innovation could be undermined by access constraints and aggressive reimbursement negotiations.

The external environment for innovation in China has never been more supportive. Having achieved a series of milestones since the implementation of NMPA reform (Exhibit 1), industry participants are optimistic that the reform will stay on course for the coming years and that its scope may expand to bring it into closer alignment with global regulatory practices and standards in pragmatic ways.

Exhibit 1

Meanwhile, market access has also improved significantly in the past few years: 181 drugs were added to the national reimbursement drug list (NRDL) in two rounds of updates since 2017; in addition, 187 were added to the essential drug list (EDL) in 2018, six years after the previous update. Drugs added to the EDL include important medicines for treating cancer and metabolic disorders such as Herceptin and Januvia. The leaders we spoke to were optimistic about the possibility of more frequent NRDL updates every year or two, and even more frequently at the level of patient groups or therapeutic areas, such as pediatrics or rare diseases.

In this increasingly favorable environment, multinationals are shifting the focus of their China portfolios from mature to innovative products. However, success is far from guaranteed, and expectations may be running ahead of reality. Despite recent progress, access conditions are still constrained, and companies may take time to develop the mind-set and capabilities needed for innovative product launches tailored to the China market context. Further, the number of innovative products to “absorb” by the market is

staggering. We estimate that about 100 new molecules have been approved in the 2016–18 period, with many more to come in the next few years. This creates challenges around funding capacity, access to hospitals, adaptation of clinical guidelines, and so on. How smooth the transition will be from mature to innovative product portfolios will depend partly on the speed and scale of the rollout of GQCE and new tendering rules, and whether some of the savings for public payers will be shifted to reimbursement of innovative molecules. Another important factor will be company-specific strategy and portfolio considerations, such as the number of new assets to be launched in the next three years, the concentration of mature brands in the business, and exposure to GQCE.

Some of the senior leaders we spoke to identified challenges that may slow this portfolio shift toward innovative products. One is the difficulty of understanding and predicting the direction of government policy, which has a critical impact on innovation. Another open question is whether government reimbursement negotiations will recognize the value of innovation, given the price cuts seen in recent rounds. Whether a value-based approach will be adopted in reimbursement assessments remains a key uncertainty—for instance, through the integration of independent clinical evaluations into price negotiations.

In a complex and rapidly developing environment for innovation, some companies are pushing to play a role in broader healthcare ecosystems. AstraZeneca has set up centers for chest pain, metabolic management, and pulmonary care, for example. By joining forces with government stakeholders, academic institutions, digital and tech companies, device manufactures, hospitals, and key opinion leaders, AstraZeneca is able to provide better integrated solutions for patients and clearer value propositions for hospitals and clinicians. In 2018, AstraZeneca achieved 25 percent growth in China, reaching some $3.8 billion in total sales.[6]

Insight 3: China is becoming more central to multinationals' strategies.

In recent years multinationals have made a number of major organizational moves in China. In 2019, Pfizer plans to reorganize into three businesses and base its leadership team for established medicines in China, while Sanofi is expected to establish a "China and emerging markets" business unit. The rising importance of the Chinese market to many, but not all, pharmaceutical multinational companies can also be seen by its rising contribution to global pharma revenues, which ranges between about 4 and 18 percent for top ten global multinationals, at an average of 8 percent. Though there is concern over the transition from a mature brands portfolio to an innovative one—and the shape of profits and losses associated with that—it is becoming clear that moving forward, the importance of China's market will not only be based on sales contribution but also on a series of other strategic considerations.

"Everyone is looking at China right now."

"China is so large and diverse; it's not just one country. We need to bring every CEO to China to see for themselves."

—Senior executives at multinational biopharma companies

In the future, as broadening of access accelerates, we expect to see increasing evidence of China becoming a "wave one" country for innovative product launches with companies pivoting toward an innovation-driven portfolio. In recognition of its overall strategic importance and the business opportunity, China needs to be elevated within pharmaceutical multinational companies' global development frameworks and strategic agenda. Whether it be including China in early-stage product development, inclusion of Chinese patients in global pivotal trails for simultaneous development, including China as part of global strategic branding team, or doubling down on strategic investments in the country, a significant amount needs to be done to fully capture China's 1.3 billion patient opportunity.

Another reason for China's increasing strategic importance is because it is becoming the proving ground for transformations involving healthcare analytics and ecosystem partnerships, driven by a few key factors. The current healthcare system is under significant pressure, with high levels of inefficiency, access inequality, and quality gaps—it's lagging in the establishment of modern medical practices. Just "scaling up" the current model will not work, and new solutions are acutely needed. Policy-wise, the government has laid out a road map[7] for transformation, in particular identifying the Internet of Things and digital as a strategic way to make significant advances and develop a sustainable model that can help fulfill the vision of universal access to quality healthcare at affordable cost.

Private digital players have accordingly prioritized healthcare in their long-term strategies, as seen in an explosion of new offerings and partnerships across the ecosystem over the past few years. At the same time, an innovation ecosystem has started to emerge, facilitated by reform from the China Food and Drug Administration and the opening up of capital markets to biotech start-ups in Hong Kong, with Shanghai to follow. Though still at an early stage, China could take a lead in these areas, providing opportunities and a testing ground for multinationals to radically rethink their healthcare delivery models in a fundamental way.

Insight 4: Biopharma companies are scrambling for talent as the market continues to expand.

With intensifying competition from Chinese biotech companies and new capability requirements (including the ability to manage uncertainty and ambiguity), multinationals face a tough talent challenge across all functions, skill sets, and parts of the ecosystem. Finding, recruiting, and retaining enough people with advanced skills will be key to

success in new product launches, pricing and reimbursement, medical affairs, and R&D. At the same time, capabilities in areas such as digital, pharmacoeconomics, and private health insurance will become more critical.

As a result, multinationals will need to rethink their talent strategies. This will involve articulating a clear talent-development structure and organizational plan, creating jobs with meaningful responsibilities that attract ambitious candidates, offering global rotation programs that allow promising individuals to gain an international perspective, and providing structured training programs that focus on the holistic skill sets needed to compete.

To fill their talent gaps, industry leaders are looking to new talent pools, including Chinese universities, whose graduates may lack experience but have vital technical skills. Another promising talent pool is provided by returnees from overseas, many of whom have much-needed experience as well as new skills. In the years ahead, leading Chinese companies may well need to share in the responsibility of developing talent for the industry, as this is a challenge affecting all participants in the ecosystem.

Insight 5: Digitization has yet to transform pharma, but digital touchpoints are becoming essential to customer engagement.

Pharma executives believe that China has the potential to lead the digitization of the industry because of its policy tailwinds, acute need for new solutions, and strong digital ecosystem. Leading private digital companies are already putting healthcare on their strategic agendas (Exhibit 2). However, the biopharma industry has yet to be transformed, and much trial and error will be needed before a new viable business model emerges.

“If we count WeChat-based interactions, the share of digital interactions will reach significant levels, perhaps more than half of all touchpoints.”

“Digital can enhance face-to-face relationships, but it is not replacing them yet.”

—Senior executives at multinational biopharma companies

Exhibit 2

The importance of digitization in driving commercial excellence and coverage efficiency will continue to grow. The price pressures faced by mature portfolios, coupled with rising talent costs, will force companies to find more efficient ways to sustain and broaden their coverage. Similarly, the increasingly competitive launch environment and complex treatment landscape call for more effective approaches to customer engagement. Over the next three years, digital touchpoints are likely to double or triple their share of customer interactions from less than 10 percent today to 20 or 30 percent for some multinationals. Digital initiatives are set to become part of the industry’s infrastructure in the years ahead. However, developing a digital ecosystem will require close collaboration between the industry and government; by themselves, biopharma companies are not in a strong position to drive progress.

Biopharma, like many other industries in China, is at a crossroads. Fundamental changes are on the horizon: a transformation in commercial and operating models, a reevaluation of investment strategies, step-changes in capabilities, and innovation on a scale that will allow leading multinationals to continue to thrive. In a country that continues to be a hot

spot for biopharma, the companies that make bold moves in the right direction today will successfully manage the transition from mature brands to innovative ones, in the process benefiting hundreds of millions of patients in China and around the world and delivering significant future returns to shareholders.

1. *IMS Market Prognosis 2017-2021: China*, QuintilesIMS, March 2017.
2. GBI Source database, October 2018, gbihealth.com.
3. GBI Source database, October 2018, gbihealth.com.
4. In November 2018, a new drug-tendering rule was officially piloted in 11 cities, called 4+7. The new rule stipulates that off-patent originator products will compete with GQCE-qualified generics in the same tendering group. The manufacturer with the lowest bidding price will win the tender for each molecule, with a guaranteed purchase volume in these 11 cities estimated at 60–70 percent of the molecule's volume from the previous year.
5. The price discount was calculated by comparing the 2018 tendering price for a molecule with the lowest purchasing price in pilot cities in 2017. See Shanghai Medical Procurement All-In-One, smpaa.cn.
6. *What science can do: AstraZeneca Annual Report and Form 20-F Information 2018*, AstraZeneca, February 2019, astrazeneca.com.
7. "Outline for Healthy China 2030," Central Committee of Communist Party of China and State Council, October 25, 2016.

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