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China Pharma Market Access (CPMA)

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Since the establishment of the China National Medical Insurance Bureau in 2018, the goal has been to strengthen public health and medical service levels, achieve maximum utilisation of the national medical insurance fund, and to enhance the strategic purchasing capability of medical insurance funds. Significant tools in achieving this are the National Reimbursement Drug List (NRDL) and drug Volume Based Procurement (VBP), which have opened a new chapter in China's medical reform. Meanwhile, the new drug registration process is improved, simplified, and accelerated.

Pharmaceutical companies face new challenges and opportunities in the Chinese pharmaceutical market, and the most critical among these is **market access**. To support pharmaceutical companies in formulating forward-looking strategies and building long-term competitive advantages, Deallus has, based on years of insights and project experience, authored this whitepaper.

Pharmaceutical market access generally refers to the stages involved in the entry of drugs into the market. With the changes in policies in recent years pharmaceutical market access planning have increasingly focused on themes such as the **National Reimbursement Drug List (NRDL)**, **Volume Based Procurement (VBP), and Hospital Drug Listing (HDL)**. Deallus proposes a more broad-based Chinese pharmaceutical market access model to support pharmaceutical companies in understanding market access and to provide a solid foundation for long-term company objectives and strategic intentions.

Key points:

- ✓ Deallus' Chinese pharmaceutical market access model revolves around the following five aspects: company's vision and objectives, drug discovery innovation, registration for approval, National Reimbursement Drug List (NRDL), Volume-based procurement (VBP) and pricing, Hospital Drug Listing (HDL) and physician perception building.
- ✓ A company's vision and strategy should determine its market access strategy, either of its pipeline selection, market coverage, or indication priority.
- ✓ New technologies, such as AI will lead pharmaceutical companies to accelerate drug discovery and accelerate market access excellence.
- ✓ Regulatory overhaul since 2016 has significantly encouraged innovation and new product in approval in China and will continue to accelerate introduction of more 'made-in-China' innovation.
- ✓ NRDL & VBP will continue to be the most critical factors to influence drug price.
- ✓ HDL and physician perception building is the final critical step in the market access for the patient.

Deallus' Chinese pharmaceutical market access model revolves around the following aspects: company's vision and objectives, drug discovery innovation, registration for approval, NRDL & VBP and pricing, and HDL and physician perception building.

Figure 1: Market Access Framework

1. Company vision and strategy

A company's vision and strategy should determine its market access strategy, either of pipeline selection, market coverage, or indication priority.

The company's vision and objectives determine the emphasis on different aspects of market access in subsequent stages, for example, whether a company chooses to focus on developing innovative drugs or producing generic drugs, will impact the market access strategy.

Let's see Roche's objective and strategy as an example.

Roche is a global leading biotechnology company headquartered in Switzerland, with a 125-year history. Roche is a committed innovator, investing 20% of its total revenue in research and development every year. For more than 50 years, Roche has been at the forefront of cancer research and treatment, with drugs for treating breast cancer, skin cancer, colon cancer, ovarian cancer, lung cancer amongst others. Roche showcased several new oncology products at the China International Import Expo in 2022, is accelerating the benefits for Chinese patients. Among them, Polivy, the world's first ADC (Antibody-Drug Conjugate) targeting CD79b, has experimental data that surpasses the first-line treatment gold standard of the past 20 years, and is expected to revolutionise the treatment landscape of diffuse large B-cell lymphoma (DLBCL). In the field of breast cancer, Roche will introduce Phesgo, the world's first HER2-targeted subcutaneous combination formulation for breast cancer, which is about to be launched in China. It can be administered through a single subcutaneous injection, significantly reducing the administration time, and providing patients with a faster and less invasive new treatment option. Roche's focus on the oncology field, particularly the continuous introduction of innovative products to the Chinese market, will provide advantages in drug pricing and clinical adoption. Introduction of innovative oncology drugs that will provide improved patient survival outcome is aligned with government priorities outlined in the 'Healthy China 2030' guideline, and at the same time, introducing high-value innovative therapies is also in line with the Medical Reform philosophy, at which replacing old treatments with next-gen innovation would effectively address local unmet needs.

AI-powered acceleration

New technologies such as AI will lead pharmaceutical companies to accelerate drug discovery and accelerate market access excellence.

Over recent years, many pharmaceutical giants have embraced AI-powered technology to accelerate drug discovery, either by themselves or by collaborating with AI drug discovery start-up companies. Different companies may focus on different fields, such as biologics, rare diseases, or chronic disease medications, and for which subsequent market access strategies may differ.

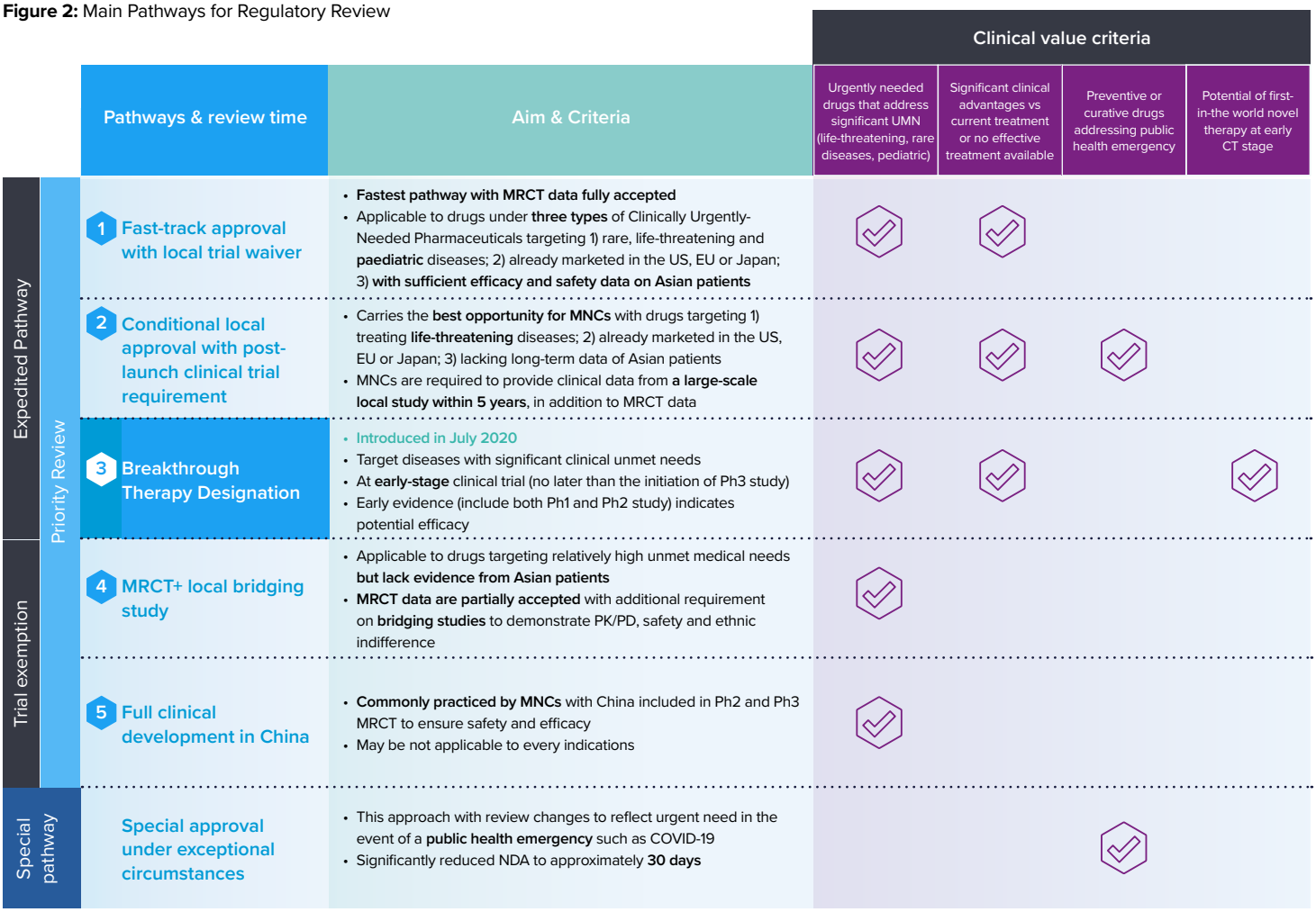
AI has been very powerful across all stages of preclinical R&D for pharmaceuticals, spanning target identification, molecular design, molecule screening, and small molecule synthesis. Moreover, AI capability during the clinical development of drug candidates also include biomarker identification, clinical trial planning and patient recruitment, and most importantly at a faster speed with significantly higher success rates and less cost.

Deallus has found several collaboration trends between MNCs (multi-national companies) with local AI-based solution providers focusing on small-molecule-centric target identification (preclinical), and solutions optimising diagnosis and patient recruitment. MNCs and biotechs are increasingly partnering with AI start-ups, such as the Hong Kong-based R&D solution provider Insilico Medicine, that has been a favored provider for many pharmaceutical companies. For instance, Sanofi's multi-year, multi-target strategic research agreement with Insilico focuses on leveraging the proprietary platform, Pharma.AI, to advance drug development candidates for up to six new targets.

It is anticipated that AI solutions will become an integral part of China's healthcare and life sciences R&D and add significant economic value in terms of faster drug discovery, as well as optimisation of clinical trials and decision-making, accelerating truly first-in-class or best-in-class therapeutics and transforming the current R&D and future treatment landscape.

Deallus – Medical Insights Capability Model (MICM)

Figure 2: Main Pathways for Regulatory Review



3. Registration for approval

Regulatory overhaul since 2016 has significantly encouraged innovation and new product approval in China and will continue to accelerate introduction of more 'made-in-China innovation.

Regulatory approval is the first step to ensure market access success in China. Shortening the registration and approval time and launching the drug to the market as early as possible, are one of the key drivers for all manufacturers. The strategic choices at this stage will also have a significant impact on the progress of drug approval and business outcome, particularly for competing with generic drugs that are approved for market launch.

The introduction of Medical Reform in 2015, represents the commitment of the China government to establish an efficient and inclusive regulatory system as a major pillar of Healthy China 2030. New measures introduced by the regulatory body National Medical Products Administration (NMPA) led to significantly improved efficiency on the regulatory review timeframe, as compared to pre-reform era and international standards.

Since reform, an open-minded data review policy of the regulator on accepting overseas data and implementation of the ICH (International Conference on Harmonization) policies have been effectively addressing the increased demand of innovative and effective healthcare treatment in China for chronic and life-threatening diseases such as oncology, CVRM and immunology. For example, the introduction of a 60-day review period for IND (Investigational New Drug) application means that pharma could carry out local trials if no comments raised by CDE (Center for Drug Evaluation) within 60 days. Clearly defined regulatory pathways and designations also encourage faster access of innovative therapies. Benchmarking to FDA, the NMPA revised the definition and data requirement of the Priority Review, Conditional Approval and introduced the Breakthrough Therapy Designation (BTD) (Figure 2). This also means that the approval efficiency has been greatly elevated with the cost for pharma players to run clinical trials in China reduced.

For example, Pfizer's and Merck's antiviral drugs for COVID-19, Paxlovid and molnupiravir respectively, have demonstrated huge performance differences in the Chinese market. While Paxlovid was approved for registration by NMPA in January 2022, there were not many patients with COVID-19 in Mainland China due to strict quarantine policies, and when the quarantine policy was suddenly lifted, over 900 million people were infected with COVID-19. Paxlovid became a life-saving drug, and its market price rocketed to more than RMB 20,000 ($2,766) per box on the black market. Paxlovid has achieved an astonishing RMB 400 million ($55 million) sales in its first year (2022), let alone the sales generated in January 2023 when the first wave of COVID-19 hit the population after lifting of Zero-COVID policy. On the other hand, molnupiravir was approved on December 29, 2022, but it missed the best opportunity for channel distribution and physician education. The significant difference in sales performance of Paxlovid and molnupiravir illustrate that drug registration process, as an important part of market access, is crucial to brand performance.

4. NRDL & VBP and pricing

NRDL and VBP will continue to be the most critical factors to influence drug pricing.

Since the introduction of the new stage of medical reform, NRDL and VBP have become two major tools for controlling drug expenses, relieving medical insurance costs, and influencing drug prices. When setting the price for a drug, pharmaceutical companies need to fully consider the impact of NRDL and VBP on drug price reductions. Based on the past experiences of NRDL and VBP, for imported innovative drugs, there are often significant price reductions of 50%-60% while entering the NRDL and VBP drug list. However, through a price-for-quantity strategy, companies can gain higher market shares in the public hospital markets, for example Eli Lilly's (in partnership with domestic biotech Innovent) PD-1 product Tyvyt (sintilimab), as the first PD-1/PDL-1 product with NRDL listing, recording product sales of over RMB 1,000 million ($138 million) in the first year of launch, and gaining significant advantage over the in-class products from benchmark companies such as Junshi, Hengrui, and BeiGene.

4.1 NRDL (National Reimbursement Drug List): NRDL is one of the greatest market access opportunities for pharmaceutical companies in China

As part of the Medical Reform, China has significantly increased market access opportunities for innovative drugs via frequent NRDL updates, the introduction of negotiation schemes, and Dual-Channel schemes to ensure on-the-ground patient accessibility.

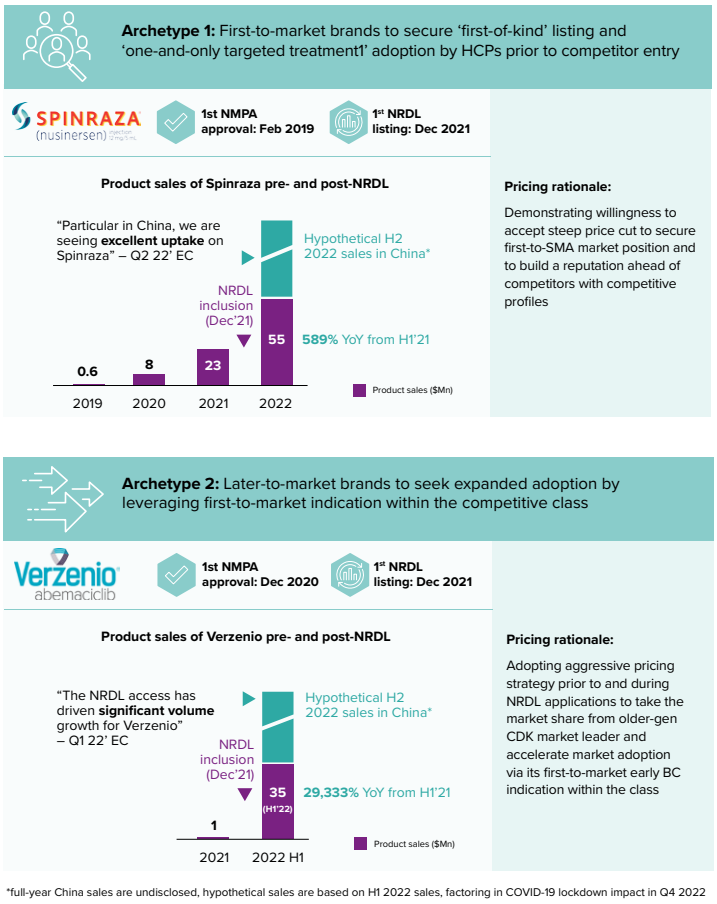
The NRDL negotiations, which started in 2017 and have undergone six rounds so far, takes place once a year, and have led to an average price reduction of between 44% and 62%. It is anticipated that the payer NHSA (National Healthcare Security Administration) has and will, continue to set strict requirements for price concessions to enter NRDL.

Deallus has observed the following archetypes of NRDL strategies by pharma players to respond with agility (Figure 3).

Both strategies have demonstrated that NRDL listing remains a critical growth driver and top priority for pharma players. As entry into NRDL is a prerequisite for subsequent hospital listings, major multinational pharmaceutical companies actively participate in NRDL negotiation upon approval.

In the latest round of NRDL negotiations in 2022, Novartis had 14 innovative drugs and new indications included in the national reimbursement list and renewed contracts as well. Eli Lilly also had multiple products and new indications included in the NRDL, including two new first-line indications for the PD-1 inhibitor sintilimab, two new indications for Trulicity, and renewals for Basaglar and Humalog.

Figure 3: Archetypes of agile NRDL strategies by pharma players in China



*full-year China sales are undisclosed, hypothetical sales are based on H1 2022 sales, factoring in COVID-19 lockdown impact in Q4 2022

4.2 Volume-Based Procurement (VBP): VBP has been the most influential factor for the pharmaceutical industry during last five years and which has reshaped several key therapeutic areas

VBP is an approach used by the Chinese government to negotiate drug prices and promote cost-effective healthcare. It aims to achieve lower drug prices for off-patent originators and generics by leveraging the purchasing power of the government and consolidating demand from various healthcare institutions. Since 2018, the NHSA has successively carried out eight rounds of VBP bidding, covering several key therapeutic areas, including diabetes, hypertension, coronary heart disease, anti-infection, cancer, digestive tract diseases, psychiatric, etc., covering a total of 333 drug varieties, and achieving remarkable results (Figure 4).

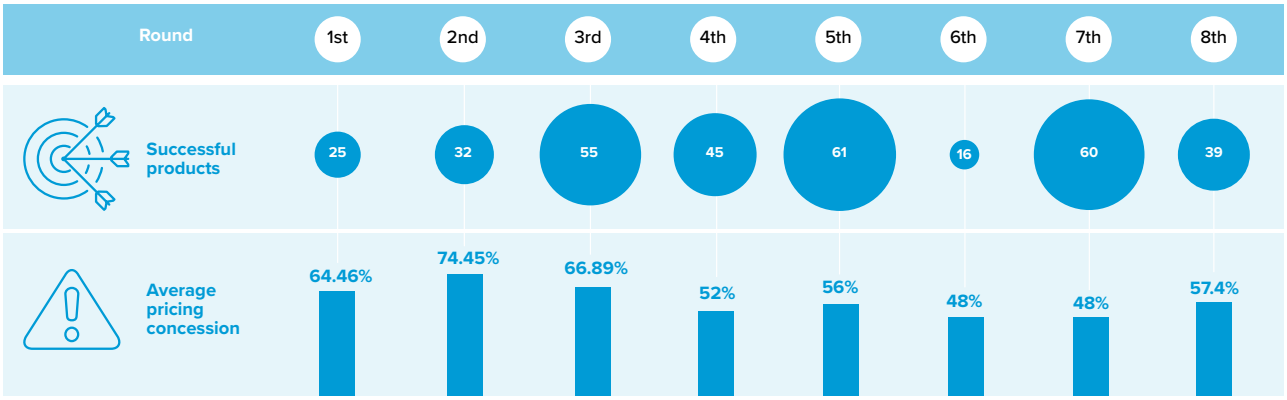


Figure 4: Evolution of VBP bidding rationale and change of success rate and average pricing concession

Priority has transferred from clinical physicians to listing stakeholders e.g., pharmacy dept after VBP. Before VBP execution, the main working content of sales representative is physician education. After VBP implementation, the focus has changed to ensure hospital listing, as the impact of physician education on influencing their prescription behavior is limited after VBP execution.

After VBP execution, pharma companies sacrifice price for volume, and face the sharp market size contraction brought by considerable price cuts. There are two choices: maintain market share or to maintain price. Domestic leading companies choose the former, while MNCs mainly choose the latter. After target completion of the specified volume, e.g., 50%-70% of the overall procurement volume, the remaining market shares would be occupied by branded drugs with high market awareness.

4.3 Pricing

Pricing strategies can range from premium price setting to low price setting, depending on the circumstances. Newly launched innovative drugs with unique mechanisms of action and significant efficacy tend to adopt a premium pricing strategy, while generic drugs often use a low pricing strategy.

Recent NRDL and VBP policies have had a significant impact on drug pricing strategies. Based on the last eight rounds of national volume-based procurement, the average price reduction for each round has been between 48% and 59%, with the highest price reduction being as much as 98%. MNC pharma companies' products also tend to see price reductions of between 40% and 60%. As an example, for the sixth round of insulin national VBP, Eli Lilly's Humalog saw a decrease in price of over 73%.

Pharmaceutical companies in the VBP and NRDL market environment hopes to achieve sales revenue through dramatically increased volume sales with significantly reduced price. However, the success of "price for volume" depends on accurate calculations, economies of scale, cost structure of the company, and other factors, such as the company's organisational structure, team execution, market access capabilities, and brand influence.

Figure 5: Key Stakeholders' Influence on Supplier Selection

Key Considerations	Clinical Deptartment	Hospital Management Team	Pharmacy department: Procurement	Pharmacy department: Supply Chain
	• Product quality • Innovation	• Product quality • Innovation	• Product quality • Price • Communication • Contract terms	• Order management • Delivery time • Breakage rate
Influence Power on New Supplier Selection	★★	★★★★	★★★	★★
Influence Power on Prescription	★★★★	★★	★★	★

★★★★ Strong influence power ★ Weak influence power

5. HDL and physician perception building is the final step in market access for patient

5.1 Hospital drug listing (HDL)

The final step in the market access of drugs (mainly referring to prescription drugs) is to enter the hospital's drug list and then to obtain a prescription from a physician. Hospitals prefer VBP tendered drugs and drugs within NRDL listing, to complete targets of hospital assessment. KA (key account) teams and sales team of pharmaceutical companies are under tremendous pressure to obtain access to hospital listings, especially for public hospitals in cities with standard listing process. There are over 1,600 level A tertiary hospitals nationwide.

For hospital listing in public hospitals in cities, clinical departments raise purchasing requests, for the whole year. Qualified vendors will be selected by the Pharmacy Administration Committee, consisting of (vice) president, procurement, finance, and pharmacy department after public bidding, which typically takes place once a year. Different from public hospitals in cities with standard listing process, private hospitals mainly consider profit or rebates in supplier selection. Vice president and chief of pharmacy are the key decision makers of drug listing in county hospitals. Community health centers (CHC) follow policies or large hospitals in hospital listing, and the decision may also be made by the hospital president directly.

Hospital management team, including (vice) president and chief of pharmacy, are the key decision maker in new supplier selection, and clinical department is the key decision maker in prescription. Product quality and innovation are key considerations for the clinical department, whereas the hospital management team mainly cares about feedback of related departments, business relations and policies (Figure 5).

Meanwhile, major pharmaceutical companies also use various traditional and innovative activities to obtain the support of physicians/hospital management teams, to establish the concept of favored perception, including but not limited to academic sponsorship, publication of literature, or digital marketing approach.

5.2 Physician perception building

Physician perception building plays a crucial role in ensuring the successful adoption and utilisation of medications. The following are Deallus' key recommendations for physician perception building:

Key Opinion Leaders engagement: Engage and collaborate with influential opinion leaders in the field, who have high credibility and can help disseminate information, address concerns, and advocate for the medication's use.

Continuing Medical Education (CME) Programs: These should be delivered through various channels, including seminars, workshops, webinars, and online platforms, to reach a wider audience and accommodate different learning preferences.

Peer-to-Peer Education: Facilitate interactions among physicians to share experiences, best practices, and success stories related to the medication through forums, case discussions, or collaborative research projects.

Engage in Scientific Exchanges: Participate in scientific conferences, symposia, and workshops to present clinical data, research findings, and expert opinions, to establish credibility, engage in scientific discussions, and build relationships with physicians.

Continuous Support and Access: Provided to physicians, including access to medical information, updates on clinical studies, safety alerts, and any emerging data related to the medication. Maintain open communication and provide a dedicated medical affairs team to address queries and provide timely support.

Patient Education: Collaborate with physicians to develop patient education materials. Well-informed patients are more likely to engage in discussions with their physicians and actively participate in their treatment decisions. Additionally, patient education can be facilitated through effective physician perception education, during which, physicians' knowledge and engagement would be further enhanced.

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In summary, market access in the Chinese pharmaceutical market is a complicated system. Pharmaceutical companies are required to perform well at every access point to gain competitive advantage and become winners. Meanwhile, balancing access in China with global access, especially in price management, requires close consideration by multinational pharmaceutical companies.

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Get in touch

At Deallus China, we have significant experience in supporting organisations from multinational corporates to biotech in achieving market access excellence in China. Our project expertise covers the product lifecycle, ranging from establishing pricing and reimbursement strategies, key stakeholder mapping, pre-launch activity support, and innovative payment model prototyping. Oncology, neuroscience, rare diseases, and biologics are leading areas of our expertise. We have also established extensive networks with various stakeholders in China, including company sources, partners, ex-regulator/payor, HCP, academia, and patient groups. We would be happy to talk about the work we have done and how we can support you better understand the full picture of the competitive environment and opportunities in your Market Access journey.

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