IS PROUD TO PRESENT

IQVIA MARKET PROGNOSIS 2020-2024

China

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FOREWORD

IQVIA and CPhI are pleased to bring you our special Market Prognosis report sharing our view of the future of the Chinese pharma market. Both CPhI and IQVIA consider that such information is key for the growth and development of the pharma industry and believe that this report will provide valuable insight as you look to develop your business in China.

The report provides an evidence-based outlook for China based on the knowledge of our country experts who carry out extensive research into key business and healthcare events and apply this to a gold standard historical view of the market.

We are excited to share this valuable country information with you and look forward to welcoming you to CPhI China.

CPhI and IQVIA team

MARKET OVERVIEW AND FORECASTS

Market Synopsis

- The Chinese pharmaceutical market is forecast to grow at a CAGR of 4.4% (±1.5%) between 2019 and 2024, reaching RMB1,215.1 billion by 2024.
- The COVID-19 pandemic has posed unprecedented challenges in understanding pharmaceutical market trends and building reliable forecasts. While Market Prognosis has leveraged IQVIA data assets as well as IQVIA in-house expertise to compile the country forecasts, there remains significant uncertainty about the evolution of the COVID-19 pandemic and its impact on pharmaceutical markets.
- Having first emerged in Wuhan in late 2019, the COVID-19 outbreak accelerated rapidly in January, with Wuhan and the surrounding Hubei province most affected. A strict lockdown was implemented in Wuhan from 23 January, followed by other cities in Hubei, while many other cities, districts and counties across China implemented varying levels of restrictions of movement. Daily new infections continued to increase through February, before peaking in late February. As daily new infections continued to slow, strict lockdowns in affected areas were relaxed from mid-March, with Wuhan lifting its lockdown on 8 April. Occasional small outbreaks over the spring and summer were rapidly contained. By early September, the virus had infected over 90,200 people and killed over 4,700 people in China. While further localized outbreaks cannot be ruled out, local prevention and control measures, alongside large-scale testing campaigns, will be sufficient to avoid the introduction of nationwide lockdown measures in the event of future waves.

Business Environment

- Real GDP is forecast to slow to 1.4% in 2020, from 6.1% in 2019, although economic momentum will accelerate in the second half of 2020. Private consumption has been most affected by the pandemic, reflecting the impact on jobs and income alongside lockdown and social distancing measures in the first half of the year. Investment is proving more resilient, with the government providing support for infrastructure spending to jumpstart the economic recovery. A rebound is expected in 2021, on a low base, and GDP is forecast to expand by an annual average of 5.9% in 2021-2024. Consumer price inflation is forecast to average 3.7% in 2020, driven in part by rising food prices, but will slow thereafter to average 2.9% in 2021-2024. The renminbi will weaken in the short term, before strengthening again from 2023, to be valued at RMB6.86 : US$1 in 2024.
- The position of China’s president, Xi Jinping, and the ruling Chinese Communist Party (CCP) will remain secure. Having brought the COVID-19 outbreak under control successfully, the authorities will focus on engineering an economic recovery. The bulk of a modest fiscal stimulus package in 2020 will be spent on job creation, income subsidies and (especially digital-related) infrastructure building. To stimulate consumption, the government will provide subsidies for car purchases and accelerate policies to phase out energy-intensive household appliances and vehicles. The next

political reshuffle will begin in late 2022, when the 20th CCP national congress will be held. Mr Xi is expected to retain his leadership of the party, military and state.

Healthcare Provision

- Building on the healthcare reforms implemented over the past decade, policymakers will pursue further improvements in the quality and availability of healthcare provision. This will strengthen measures for the prevention and effective treatment of chronic non-communicable diseases (NCDs) – notably cancer – and will drive further improvements in key health indicators. Methods for monitoring infectious disease will be improved and an early warning system will be developed.
- The healthcare reforms have driven a progressive rise in healthcare spending, which reached 6.6% of GDP in 2018, and which is expected to exceed 7.0% of GDP by the end of the forecast period as funding for the sector continues to outpace economic growth. Efforts to rein in costs and improve the efficiency of healthcare provision will be stepped up, however. This will have implications for a range of stakeholders, including pharmaceutical manufacturers.
- The National Healthcare Security Administration (NHSA) will oversee efforts to boost coverage and harmonize benefits under the basic medical insurance (BMI) schemes, although considerable variation in the extent of subsidies available to beneficiaries will persist, reflecting local economic conditions. Rapid growth is expected to continue in the private health insurance sector.
- Further significant reform of the hospital sector will be witnessed as the government pursues further increases in capacity, especially outside the main cities, and more efficient use of resources. Hospital management will be overhauled, while a diagnosis-related groups (DRG)-based hospital payment model will be trialed in 2020 with a view to national rollout from 2021.
- Strengthening primary care provision is a major target of healthcare reform. The government will push ahead with the implementation of a tiered diagnosis and treatment system designed to relieve pressure on major public hospitals and expand the range of services provided by primary care facilities. Teleconsultations and e-health services were boosted by the COVID-19 outbreak and are growing rapidly.
- More drugs will be procured through centralized volume-based procurement (VBP) contracts – both at national and at provincial level – as part of a broader cost-containment drive. Early rounds of VBP have driven substantial reductions in procurement prices, with cuts averaging in excess of 50%. A third round of VBP was implemented in August 2020, resulting in price cuts averaging 53% for 55 molecules, and further rounds are expected.

Prescribing and Dispensing

- Encouraging rational prescribing and reducing overprescribing will remain key objectives. The expansion of centralized VBP will increasingly favor the prescribing of generics procured under VBP contracts, while the gradual implementation of DRGs will begin to impact prescribing in the medium term.
- The government is firmly committed to the development of a stronger, more effective essential drugs system. The Essential Drug List (EDL) will be managed more dynamically in future, with an

update expected in the early part of the prognosis period, while the use of drugs on the list will be prioritized and encouraged.

- The National Reimbursement Drug List (NRDL) will also be updated on a more regular basis, with annual updates now expected. The latest update, incorporating 70 high-cost drugs following national price negotiations, was published in November 2019. As with previous recent updates, drugs for use in the treatment of cancer, other critical and rare diseases, and NCDs were prioritized. The next update is expected in late 2020. Full compliance with the national list is now required at provincial level.
- The share of dispensing handled by retail pharmacies is expected to grow. The COVID-19 outbreak in early 2020 led to a shift of dispensing of some chronic treatments to retail pharmacies, while reimbursement was extended to retail pharmacies in some cities to facilitate access to treatment. This is expected to stay in place, and further expansion is likely. Regulations governing online drug sales have been clarified under the revised Drug Administration Law (DAL), paving the way for online sales of prescription drugs.

Pricing

- A growing number of innovative new drugs is gaining access to reimbursement following national price negotiations. Manufacturers are being forced to cede substantial ground on price in return for NRDL listings, however, with the NHSA levering price cuts averaging almost 61% during the November 2019 update. This reflects the pursuit of a more strategic approach by regulators, which has seen them pit competing products against each other. In parallel, the agency has begun to re-negotiate the price of listed drugs, securing further price reductions, which averaged 26% during the November round.
- While formal health technology assessments (HTAs) are not yet a feature of the pricing and reimbursement environment, a value-based approach to the evaluation of medicines for inclusion in the reimbursement system is beginning to emerge as the NHSA demands the submission of pharmacoeconomic data before commencing price negotiations with manufacturers. The impact of that data and the agency's capacity to evaluate it effectively remain issues of concern for the industry.
- Prices secured under centralized VBP tenders have begun to function as reference prices for affected molecules. While the further expansion of centralized VBP and national price negotiations will be employed to drive prices down, the implementation of an explicit reference pricing mechanism is still expected in the medium-longer term. This will impose a defined limit on the reimbursement price of products that fail to secure VBP contracts or that do not participate in VBP tenders, and products falling outside the scope of VBP.

Regulatory Environment

- The National Medical Products Administration (NMPA) is implementing fast-track reviews and clinical trial waivers for priority medicines, including orphan drugs, products for the treatment of serious, life-threatening conditions, and products that target unmet needs. The agency is handling

an increasing number of new drug applications and investigational new drug applications. Real-world evidence is being incorporated into regulatory pathways.

- While safety concerns and ethical issues have triggered the introduction of tighter clinical trial regulations, trial approval procedures are being expedited and local trial waivers issued for priority new drugs. A significant number of clinical trials involving biosimilars have been authorized, presaging an anticipated surge in biosimilar approval submissions during the forecast period.
- The amended DAL came into effect on 1 December 2019, paving the way for a marketing authorization holder (MAH) system, as well as the introduction of drug traceability and pharmacovigilance systems, a simplified clinical trial approval process, and measures that will expedite the approval of priority medicines with limited clinical trial data.
- The number of generics achieving generic quality consistency evaluation (GQCE) accreditation is rising gradually. GQCE-accredited products benefit from preferential reimbursement and procurement terms, but the cost of generating required data, the limited nature of bioequivalence testing capacity, and a high failure rate have slowed progress.
- Proposals issued by the National People's Congress in July 2020 aim to improve intellectual property provisions. The introduction of a supplemental protection period (SPP) of a maximum of five years would allow manufacturers to apply for the extension of the standard 20-year protection period granted for innovative products under certain circumstances, while a proposed patent linkage system would enable patent holders to challenge market authorizations for generic versions before they come to market.

Pharmaceutical Business Environment

- The dynamics of the Chinese pharmaceutical market have shifted dramatically over the past five years. This is driving significant changes in the strategies being employed by both local manufacturers and multinationals, and will have major implications for the structure of the domestic industry.
- Multinationals are beginning to divest mature brands, focusing their resources on innovative new drugs that can be approved more quickly and are more likely to gain reimbursement in the wake of recent reforms – albeit at significantly lower prices. Rising regulatory compliance costs and falling prices will squeeze local manufacturer margins, triggering significant consolidation of the domestic industry, but encouraging the emergence of larger companies with the resources to invest in original research.
- Regulators will encourage the rapid approval of new generics and will pursue the expansion of GQCE certification. The NMPA has published a list of over 30 'urgently needed' medicines (either nearing patent expiry, or patent-expired but with no available generics) that will benefit from priority review and fast-track approval.
- A wave of biosimilar approvals is expected at an early stage in the prognosis period, following the authorization of China's first 'true' biosimilars by the NMPA in 2019. The inclusion of biosimilars in centralized VBP tenders in the medium term will trigger a sharp decline in the price of some biologics, enabling more widespread consumption.

- The COVID-19 outbreak had a significant impact on promotional activity in the first quarter of 2020. Face-to-face sales representative visits to hospitals were prohibited. Promotional activity through digital channels, while discouraged during the outbreak, saw a major increase. While face-to-face detailing remains a critical part of marketing strategies, other promotional channels will be explored more actively. A new campaign to crack down on illegal activities involving medical reps was launched in June 2020, while a proposed law aims to register all sales reps.

Total Market Forecasts 2020-2024

The total pharmaceutical market is forecast to grow at a CAGR of 4.4% (±1.5%) during the period 2019-2024.

Key Issues Affecting Market Growth

Key Drivers	Key Constraints
Improving access to innovative new drugs. National price negotiations represent a major opportunity for innovators seeking improved market access in China. Another 70 products were added to the NRDL in November 2019, with oncology therapies and drugs treating rare or severe chronic diseases featuring heavily among the newly added drugs; the next round of negotiations is expected by end 2020.	**COVID-19 outbreak.** The COVID-19 outbreak has had a significant impact on demand for healthcare services and pharmaceutical sales. As hospitals suspended services and patients stayed away from hospitals for fear of infection or due to lockdowns, hospital sales declined sharply. While retail pharmacies saw an increase in demand for certain chronic treatments, overall retail sales also declined.
Growing attention to the treatment of chronic diseases. Reductions in mortality rates associated with chronic, non-communicable diseases – and with cancer in particular – are key policy goals, with preventative measures and improved access to more effective treatment set to play a major role. Efforts to tackle rare diseases and address age-related health issues will also be pursued.	**Expansion of volume-based procurement.** Centralized volume-based procurement (VBP) will drive down prices for patent-expired molecules. Following nationwide expansion of VBP tendering in 2019, two further rounds were held in January and August 2020, each resulting in price cuts averaging 53% for the 33 and 55, respectively, commonly-used molecules involved. Further expansion is expected.
New product launches. New product launches will drive growth in the market, facilitated by improvements to the drug approval process implemented over the past five years.	**Implementation of a tiered diagnosis and treatment system.** Strengthening primary care provision is a major target for healthcare reform. The aim is to relieve pressure on top-tier public hospitals by shifting basic primary care provision into urban community health centers and rural township health centers, and to limit costs through more effective management of key diseases.

Source: IQVIA