IQVIA™ MARKET PROGNOSIS 2018-2022

Asia/Australia – China

Published March 2018

IQVIA
210 Pentonville Road
London
N1 9JY, UK
Tel: +44 (0)20 3075 5888, Fax: +44 (0)20 3075 5999
mpenquiries@uk.imshealth.com
www.iqvia.com

Published: March 2018

Foreword

IQVIA and CPhI are pleased to bring you our co-branded special Market Prognosis report sharing our view of the future of the China 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 5.5% (±2.5%) between 2017 and 2022, reaching RMB1,081.2 billion by 2022.

Business Environment

- Real GDP growth is forecast to moderate from 6.9% in 2017 to 6.4% in 2018, with tighter credit conditions in 2017 having a lagged impact on investment, and consumption growth set to soften as regulators tighten controls over household loans. Growth will slow gradually thereafter to average 5.8% in 2019-2022. Consumer price growth will quicken to 2.4% in 2018 as food price inflation accelerates, and will average 2.8% annually in 2019-2022. The renminbi is forecast to strengthen against the US dollar in 2018, before depreciating over the remainder of the forecast period to average RMB7.10: US$1 in 2022.
- The 19th national congress of the Chinese Communist Party in October 2017 confirmed the political dominance of China's president, Xi Jinping. In his speech, Mr Xi set out an ambitious vision of establishing China as a 'leading global power', making it clear that he envisages himself as a transformative leader set to remain on the political scene for years to come. In the coming years, the authorities will look to proof the economy against economic risks associated with China's considerable debt by enhancing financial regulation. Mr Xi has also committed to eliminating all rural poverty by 2020.

Healthcare Provision

- Further reform of China's hospital-led healthcare system will be pursued in a bid to improve the availability and quality of provision, and to manage the growing threat – to both patient health and healthcare finances – posed by chronic non-communicable diseases. Efforts will focus on the establishment of a tiered diagnosis and treatment system, relieving pressure on the country's major hospitals and making more effective, efficient use of available healthcare resources.
- National expenditure on healthcare will rise at rates below those witnessed in the early part of this decade, but will continue to outpace economic growth. Spending in the sector is now equivalent to 6.2% of GDP, but the government has said it wants to see the figure reach between 6.5% and 7.0% by 2020. The share of total expenditure accounted for by patient payments has declined to below 30% in line with government targets.
- With health insurance coverage now more or less complete, attention will focus on improvements in the range of benefits available to affiliates of the three basic medical insurance schemes, and on the harmonization of benefit packages. This will be pursued initially through integration of the urban and rural residents' schemes, but could eventually be overseen by a single body responsible for administering all three schemes if plans for the creation of a new Medical Reimbursement Agency go ahead. Greater participation of commercial insurance in the healthcare system will be encouraged.

- Hospital numbers will continue to rise, but structural change within the sector will accelerate as a tiered diagnosis and treatment system is rolled out. Partnerships will be established between leading hospitals and grassroots facilities to optimize resources and improve medical services at grassroots level. Provider payment reforms and the imposition of more restrictive caps on hospital drug budgets will encourage more rational, cost-effective treatment in the sector.
- Primary care provision will be strengthened through improvements in the range and quality of services available at grassroots facilities, and by the establishment of a family doctor system. The longer-term objective is for GPs to manage referrals to specialist care and hospital facilities.
- Drug procurement under the tender system will become more complex as price negotiations at sub-provincial level become more common. Price transparency, which is increasing with the establishment of 'sunshine procurement platforms' at provincial level will drive procurement prices down. Multinationals will face growing competition from domestic manufacturers of generics that have proven bioequivalence following quality consistency evaluation (QCE).
- Recognizing healthcare big data as a strategic national resource, the government has called for the creation of interconnected public health information and national drug procurement platforms by 2020.

Prescribing and Dispensing

- Hospital financing reforms, which aim to reduce the proportion of hospital budgets allocated to drugs, will have a growing influence on prescribing choices. Efforts to reduce overprescribing will be stepped up, while the introduction of new prospective payment models for providers will also encourage more cost-effective prescribing.
- Restrictions on the prescription of drugs that do not feature on the Essential Drug List (EDL) in community health centers (CHCs) have been relaxed in a bid to encourage more widespread use of primary care facilities. The prescription of EDL products will be encouraged where possible in both primary and secondary care, however.
- The long-awaited update of the National Reimbursement Drug List (NRDL), which took place in 2017, has triggered significant improvements in the accessibility and affordability of new drugs launched since the beginning of this decade. More frequent updates of the list are anticipated in future, while provinces will update their own reimbursement lists more rapidly in the wake of NRDL revisions.
- Gaining access to hospital formularies will remain a lengthy, often challenging process – even for products added to the NRDL. Formulary access may become even more difficult for expensive new drugs as caps on hospital drug budgets are reduced, and as hospital drug mark-ups have been eliminated.
- Stricter controls on hospital drug budgets and the elimination of mark-ups on hospital drugs will drive the release of more prescriptions for dispensing in retail pharmacies. The ban on online sales of prescription drugs is unlikely to be lifted in the foreseeable future. Direct-to-patient pharmacies have begun to emerge as a sales channel for specialty products.

Pricing

- The State Council has called for the establishment of a new Medical Reimbursement Agency (MRA), which would replace the National Development and Reform Commission (NDRC) as the body responsible for drug price regulation. The MRA would also be responsible for pricing and reimbursement policy making, and would also oversee the centralized procurement of medicines.
- Pressure on prices will intensify, driven by the tendering system, the growing threat posed by bioequivalent-certified generics to sales of patent-expired brands, and the impact of national negotiations on the price of innovative new drugs seeking inclusion on the NRDL.
- National negotiations secured an average reduction of 44% in the price of the 36 innovative new drugs added to the NRDL in July 2017. The negotiation procedure will be adjusted and refined in light of early experience gained with the mechanism, which will be used to manage the financial impact of listing more innovative new drugs over the next five years.
- Reference pricing, through the establishment of so-called 'reimbursement standards', will begin to affect the price of multi-source drugs. Fujian province has already begun to set reference prices for certain high-volume molecules, but the adoption of reimbursement standards on a more widespread basis will be gradual process, with uptake reflecting the relative availability of bioequivalent-certified generics.
- Shortages of data and expertise will need to be addressed before health technology assessments (HTAs) begin to play a major role in pricing and reimbursement procedures. The government is keen to pursue a more rounded approach to listing decisions, however, and has begun to lay the foundations for broader use of HTAs.
- The gap between ex-manufacturer and consumer prices will reduce following the elimination of hospital drug mark-ups, and as the 'two invoice' system is rolled out in a bid to eliminate excessive profit margins and increase levels of price transparency in the distribution chain.

Regulatory Environment

- Plans to restructure responsibility for the oversight of rules governing the development, manufacture, pricing, distribution and sale of medicines were unveiled by the State Council in March 2018. As well as enabling more effective policing of standards in the sector, the plans may help to drive further improvements in regulatory efficiency.
- A further reduction in drug approval times will be witnessed, while originators will benefit from the establishment of a fast-track review procedure for innovative new drugs – some of which may be granted conditional approval on the back of promising clinical trial data.
- Foreign trial data will be accepted more widely in support of drug approvals, while changes to regulations governing the approval and conduct of local studies will render China a more attractive location for investment in clinical trial activity.
- Revision of the Drug Administration Law (DAL) will pave the way for nationwide rollout of a marketing authorization holder (MAH) system. This is expected to encourage new drug R&D and would also benefit foreign companies that do not possess manufacturing capabilities in China.

- China's accession to the International Council on Harmonization (ICH) will hasten moves towards the implementation and enforcement of higher standards governing the development, manufacture, distribution and sale of medicines. Improving the quality of generics through the application of the ongoing QCE initiative will remain a priority.
- Proposals unveiled towards the end of 2017 could pave the way for the establishment of a more robust intellectual property protection framework. The proposals envisage the introduction of a patent linkage mechanism, improved regulatory data protection, and trial patent term restoration to compensate for regulatory delays encountered by new drugs.

Pharmaceutical Business Environment

- Reforms implemented since 2015 have begun to create a regulatory environment that is more conducive to innovation. The rollout of the new NRDL will also benefit originators, but patent-expired brands will face growing competition from bioequivalent-certified generics, which will be the main beneficiaries of rising demand for medicines. Pressure on prices will remain intense, limiting rates of increase in market value.
- The structure of the Chinese pharmaceutical industry will continue to change, reflecting the impact of regulatory and pricing policy developments on both local manufacturer and multinational strategies. Multinationals will focus their resources increasingly on a smaller core of innovative products, while consolidation of the domestic industry will see the emergence of fewer, larger players – a growing number of which will possess the resources to invest in R&D and pursue the expansion of their businesses beyond the Chinese market.
- The QCE initiative will drive a period of substantial restructuring in the generics market, strengthening the hand of leading domestic manufacturers. China's biosimilars market will expand rapidly as a growing number of domestic and multinational companies enter the sector.
- Drug distribution will be streamlined as the 'two-invoice' system is rolled out, triggering consolidation in the sector as leading players pursue broader geographical coverage. Manufacturers will need to engage directly with a growing number of distributors.
- Further consolidation of the retail pharmacy market will also be witnessed, with chains expected to control well over half of all outlets by the end of this decade. Prescription drug dispensing opportunities for community pharmacies will remain modest, however, constrained by the relative absence of reimbursement and the ability of patients to purchase many drugs more cheaply in hospitals and CHCs. Traditional Chinese medicine (TCM) products will continue to dominate the OTC market.
- Promotional strategies will be refined further in the face of close regulatory scrutiny. The introduction of a medical representative registration system, limiting the role of reps to 'academic promotion' and 'technical consultancy', will impact promotional activity, reducing face-to-face interaction between reps and doctors and driving growing use of digital marketing platforms and e-detailing.

Total Market Forecasts 2018-2022

Analysis of Rebates and Discounts

The China Hospital Pharmaceutical Audit (CHPA) reports the market at weighted average purchase prices at which the panel hospitals purchase products from wholesalers, distributors and manufacturers. For Market Prognosis, hospital purchase prices are converted into ex-manufacturer prices.

While discounting occurs on a modest scale, there are no significant off-invoice rebates or discounts causing distortion of these price levels in China for the time being.

Summary of the Prognosis

All values shown are in local currency.

The China Hospital Pharmaceutical Audit (CHPA) covers hospitals with more than 100 beds, estimated to account for approximately 64% of the total pharmaceutical market in 2017.

A retail pharmacy sector forecast has now been fully integrated in the Market Prognosis China forecast. The forecast is based on the China Retail Pharmacy Audit held on the IQVIA MIDAS database, covering sales of prescription-only products through retail pharmacies at prefecture level and above, and estimated to account for approximately 5% of the total pharmaceutical market in 2017 (see also Forecasting Data and Methods).

Unaudited hospital sector projection: The forecast incorporates an estimate of the value of the unaudited hospital sector, based on the latest China National Audit analysis conducted by IQVIA China in 2017. This includes small hospitals with fewer than 100 beds, community health centers, township health centers and clinics (together estimated to account for close to 20% of the total market in 2017).

For the purpose of this forecast, the unaudited hospital sector has been projected independently, at a growth rate above that of the CHPA, to account for faster growth in the segment as the tiered diagnosis and treatment system is rolled out.

Other retail pharmacy segments projection: The prognosis also incorporates a projection of the value of retail pharmacy market segments not held on MIDAS, which are estimated to account for approximately 11.0% of the total pharmaceutical market in 2017.

These segments, which together make up approximately 69% of the total retail pharmacy market, include OTC drugs (western medicines and TCMs) sold through retail pharmacies in prefecture-level cities and above, as well as sales through retail pharmacies in county-level cities (which are estimated to account for approximately 40% of the total retail pharmacy market).

For the purpose of this forecast, it is assumed that the market shares of these segments will remain stable from 2017 onwards, growing at rates in line with those in the audited retail pharmacy sector.

The total pharmaceutical market is forecast to grow at a CAGR of 5.5% (±2.5%) during the period 2017-2022.

Key Issues Affecting Market Growth

- Reimbursement coverage is improving following the significant update of the National Reimbursement Drug List (NRDL) in February 2017, and the inclusion of an additional 36 high-cost drugs in July 2017. While most provinces added newly-listed drugs to their provincial lists promptly, inclusion of newly-listed drugs in hospital formularies will take more time. More frequent updates of the NRDL are expected in future.
- Health insurance coverage will continue to expand as coverage under the basic medical insurance schemes (BMI) is deepened, critical illness cover is improved, and commercial insurance is encouraged. The integration of the urban and rural resident BMI schemes is intended to improve access and coverage for rural residents, while government subsidies and personal contributions under the scheme are being raised.
- Reforms to the drug approval process and efforts to accelerate the approval of innovative new drugs have begun to reduce lengthy registration times, allowing new drugs to reach the market faster and reducing China's drug lag. China's accession to the International Council for Harmonization (ICH) is expected to contribute to further acceleration of the drug review and approval process.
- Reform of hospital financing, involving the accelerated abolition of hospital drug mark-ups nationwide by September 2017, moves to limit hospital drug budgets to 30% or less of total budgets, and the implementation of prospective provider payment systems – including disease-based and diagnosis-related group (DRG)-based, as well as capitation-based payment regimes – will constrain hospital sector growth.
- The establishment of a tiered diagnosis and treatment system, featuring a family doctor system designed to reduce reliance on tier 3 (tertiary) hospitals, has begun to drive a shift of patients to smaller hospitals. Primary care capacity is being strengthened, differentiated service charges and tiered reimbursement are being implemented, and the Essential Drug List (EDL) system has been relaxed, allowing for a wider selection of drugs to be used at community health centers (CHCs). Grassroots facilities will increasingly take on the management of chronic diseases.

Change in the Prognosis

The five-year outlook for China has been adjusted downwards compared to the previous forecast published in September 2017. The following changes have been made to the forecast:

Baseline Changes

- **Hospital sector:** A sharper than expected slowdown in both volume and price growth in 2017 has led to a downward adjustment of the baseline forecasts. The slowdown is largely attributed to the implementation of hospital financing reforms, as the government seeks to reduce hospital drug budgets to 30% or less of total hospital budgets, while the roll-out of the tiered system is also contributing to the slowdown. While the baseline forecasts expect a rebound in 2018, the projections for both volume and price growth have become more conservative.

- **Retail sector:** The retail sector forecast is now based on the IQVIA MIDAS retail pharmacy audit, and as such is not directly comparable to the previous forecast, which was based on IQVIA PharmaTrend data. As in the previous forecast, retail sector baseline forecasts assume a continuing but gradually lessening decline in volume, and strong but slowing price growth.

Event Changes

- **The negative impact of the event 'Hospital financing reform and tighter controls of hospital drug budgets', has been increased.** This is to account for the growing attention to cost containment under the ongoing hospital financing reforms, including the reduction in the share of hospital drug budgets, reforms of provider payments and the implementation of prospective payment systems, such as disease-based, DRG-based and capitation based payments.
- **A new event 'Acceleration of the drug approval process' has been included,** to account for the higher number of innovative new drugs expected to gain marketing approval in the short-medium term, following ongoing reform of the drug review and approval process.