Foreword

QuintilesIMS 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 QuintilesIMS 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 Indonesia.

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 QuintilesIMS team
Market Overview and Forecasts

Market Synopsis

- The Chinese pharmaceutical market is forecast to grow at a compound annual growth rate (CAGR) of 6.9% (±2.5%) between 2016 and 2021, reaching RMB1,084.6 billion by 2021.

Business Environment

- Real gross domestic product (GDP) growth is forecast to slow to 6.2% in 2017, from 6.7% in 2016, as strong housing market activity and investment by state-owned enterprises slow, while private consumption remains relatively robust. Growth will slow to 4.2% in 2018 as the authorities move to bring debt levels under control, before recovering in 2020-2021, averaging 5.0%. Consumer prices will rise by 2.2% annually in 2017-2021, with upward price pressures stemming from higher levels of imported price inflation offset by downwards effects from slower GDP growth and excess-supply problems. The renminbi is forecast to depreciate against the US dollar until 2019, before strengthening again from 2020, to average RMB7.08:US$1 in 2021.

- China’s president, Xi Jinping, is the most powerful head of the ruling Chinese Communist Party (CCP) since Deng Xiaoping. Mr Xi’s ambition is to preserve the CCP’s political dominance by turning it into a more effective governing outfit, ensuring political stability in 2017-2021. The government’s policy agenda will focus on reducing government interference in the economy and allowing market forces a ‘decisive’ role in the allocation of resources by 2020, although many reforms have struggled to make headway. Social reforms, including the removal of the distinction between rural and urban household registration in smaller cities, will also be pursued.

Healthcare Provision

- Healthcare policy directions outlined in the 13th Five-Year Plan for 2016-2020 will focus on wider reform of hospital financing, the implementation of a tiered diagnosis and treatment system, improvements in the treatment of chronic diseases, a deepening of health insurance cover and encouragement of the private sector, with a view to achieving affordable and equitable basic healthcare for the whole of the Chinese population by 2020.

- Total healthcare expenditure as a percentage of GDP increased to 6.0% in 2015. The government’s goal is to see that figure reach between 6.5% and 7.0% by 2020. While patients still account almost 30% of total healthcare spending, that figure is gradually declining.

- The government will seek to improve cover under the three basic medical insurance schemes, while keeping budgets under control. Benefits will continue to improve and integration of the urban and rural residents’ schemes will seek to eliminate inequalities in cover. Cover for critical illnesses will be improved, and greater participation of commercial insurance in the healthcare system will be encouraged.

- Hospital numbers will continue to grow in line with the government’s health sector development plans for the period to 2020. Public hospital financing will be restructured in a bid to remove the profit motive from hospital drug sales and limit the drug budget as a percentage share of the total hospital budget. Further development of the private sector will be encouraged.
• Greater attention will be focused on improving primary care provision. Capacity in the sector will be expanded and a family doctor system will be established. This will pave the way for the development of a hierarchical diagnosis and treatment system, within which family doctors will manage referral to specialist care and hospital facilities in the longer term.

• Drug procurement will remain extremely complex as provinces operate different models for bidding. Pressure on prices will intensify as multinational companies face growing competition from domestic manufacturers for their off-patent brands, and as price transparency increases. Provincial demands for price cuts and the trend towards city-level or group purchasing organization (GPO) negotiations will remain features of the market.

Prescribing and Dispensing

• The long-awaited update of the National Reimbursement Drug List (NRDL) has seen 339 products added to the list, including 133 western medicines. The update will trigger the adjustment of provincial reimbursement lists. More frequent updates of the national list are expected going forward. A separate list of 45 high-priced specialty products, the ‘negotiation list’ or List C, has been announced, pending further negotiations.

• Prescribing choices will be influenced increasingly by hospital financing reforms, which aim to eliminate drug mark-ups and reduce the proportion of hospital budgets allocated to drugs. Efforts to reduce overprescribing will be stepped up. In the longer term, the implementation of diagnosis-related groups (DRGs), if rolled out more widely, could begin to impact prescribing practices.

• Hospitals will continue to dominate dispensing, but more prescriptions – especially for non-reimbursed products – are beginning to flow out of hospitals, as cost containment and rational drug use initiatives affect that segment of the market. Online sales of OTC drugs will continue to grow, but online sales of prescription drugs remain prohibited for the time being.

Pricing

• The new pricing system will ensure that drug prices remain under pressure despite the recent removal of price controls. The tendering system, national-level price negotiations for certain products, and a system of ‘reimbursement standards’ will all contribute to downward pressure on prices. Launch prices will be referenced under a proposed ‘price commitment’, while price supervision will also be stepped up.

• The government intends to create a national-level price negotiation mechanism for patented drugs. Price reductions in excess of 50% were secured for three products under a pilot of this approach in 2016, and national negotiations on other drugs are expected. Price negotiations are also expected for products contained in the new ‘negotiation list’ of the NRDL.

• The establishment of a ‘reimbursement standard’ reference pricing system for drugs reimbursed by the public health insurance schemes is expected, although no date for the implementation had been set as of early 2017. Standards are expected to be set by molecule for generics which have passed the quality consistency evaluation and the number of drugs subject to standards will expand gradually as more products pass the evaluation. The proposed system would have obvious negative implications for higher-priced products.

Regulatory Environment

• Reforms designed to speed up the drug approval process and tackle a substantial backlog of applications are beginning to have an impact. The establishment of a new fast-track approval
system will speed the approval of innovative new medicines, helping to reduce the long drug lag that has become a feature of the Chinese market.

- The introduction of simplified review procedures will reduce the time taken to approve clinical trial applications. Clinical trial data quality will improve following the China Food and Drug Administration’s (CFDA) campaign for self-inspection of study data and the ongoing inspection of trial sites. The regulatory framework for clinical trials is being tightened.

- Under the CFDA’s drive to raise the quality of generics, all generics on the market will have to undergo quality and consistency evaluation. The State Council’s five-year plan for drug safety for the period 2016-2020 requires 289 generic drugs on the essential drug list (EDL) to have passed the evaluation by 2020 at the latest.

- While a 20-year patent term is available under China’s patent law, patent erosion, regulatory data protection, patent linkage and patent enforcement remain key issues of concern for originators. Compulsory licensing, while not employed in China to date, will remain an option for the government to ensure access to patented drugs.

**Pharmaceutical Business Environment**

- The operating environment will remain challenging as the economy slows. Demand will remain strong, and approval times for innovative products will shorten, but aggressive purchasing practices and the intensification of hospital cost-containment measures will limit rates of increase in market value. The rollout of the new NRDL will have a positive impact over the next two years, but market growth will slow in the second half of the forecast period.

- Restructuring of the local industry will gather pace, driven in part by government policies designed to build economics of scale, improve quality standards, enhance innovation and fuel exports in the sector, which will strengthen the leading domestic players. With mature brands facing stronger competition from local generics, multinational companies will focus a growing proportion of their resources on the approval and commercialization of innovative drugs.

- The number of domestic companies conducting original research will grow. Multinationals will also step up research activity in China and R&D tie-ups between local companies and foreign partners will become more extensive, contributing to the emergence of a more innovative industry.

- China’s biosimilars market will expand rapidly, with a growing number of domestic companies targeting the development of biosimilars following the establishment of guidelines for the regulation of follow-on biologics.

- Drug distribution will be streamlined as the ‘two invoices’ system is rolled-out over the next two years, triggering consolidation of the sector as leading players increase their geographical coverage. Manufacturers will see an increase in the number of distributors with which they will engage.

- Some consolidation will be seen in the fragmented retail pharmacy sector as chains pursue expansion. Direct-to-patient pharmacies have begun to emerge as a channel for specialty products. The limited nature of outpatient drug benefits will continue to restrict wider retail sector sales of prescription drugs. The complex OTC market in China is characterized by high regulatory barriers and lengthy switching procedures, and will continue to be dominated by TCM products.

Further change to sales and promotion practices will be driven by the government’s push to establish a medical representative registration system, limiting representatives’ role to
‘academic promotion’ and ‘technical consultancy’. Greater focus will be given to delivering scientific and educational messages. Growing use will also be made of digital marketing platforms and e-detailing.
Total Market Forecasts 2017-2021

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 discounts are happening on a small 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 CHPA covers hospitals with more than 100 beds and was estimated to capture approximately 64% of the total pharmaceutical market in 2016.

Retail pharmacy sector data: The prognosis incorporates a projection of the audited retail pharmacy sector at prefecture city level and above, based on the QuintilesIMS PharmaTrend data, which is available from Q1 2012 onwards and which is estimated to account for approximately 60% of the total China retail pharmacy market (10% of the total market). For the purpose of this forecast, the PharmaTrend data has been projected using an exponential smoothing model, optimized using the Forecast Pro Expert system.

Unaudited sector projection: The forecast also incorporates an estimate of the value of the unaudited sectors, based on the latest China National Audit analysis conducted by QuintilesIMS China in 2016. The unaudited sector includes retail pharmacies at county level and below (estimated to account for approximately 40% of the total retail pharmacy market, or close to 7% of the total market), as well as small hospitals with less than 100 beds, community health centers, township health centers and clinics (together estimated to account for just over 19% of the total market).

For the purpose of this forecast, it is assumed that the unaudited retail pharmacy sector will grow in line with the audited retail pharmacy sector, while the unaudited small hospital sector has been projected independently.

The total pharmaceutical market is forecast to grow at a CAGR of 6.9% (±2.5%) during the period 2016-2021.

Key Issues Affecting Market Growth:

- Reimbursement coverage will improve following the long-awaited publication of the new National Reimbursement Drug List (NRDL) in February 2017, which adds 339 products, including 133 western medicines, to the list. A ‘negotiation list’ of high priced specialty products has also been announced, but has not been published yet. Some 45 expensive, but high clinical value products have been proposed for inclusion, with final listing depending on the outcome of further negotiations.

- Health insurance coverage will expand as coverage under the basic medical insurance schemes is broadened, critical illness cover is rolled out further and improved, and commercial insurance is encouraged. The integration of the urban and rural resident basic medical insurance (BMI) schemes is intended to improve access and coverage for rural residents.
• Further improvements will be made to the healthcare infrastructure and to medical services under the 13th Five-Year Plan, involving further increases in hospital bed numbers and healthcare personnel. Accelerating urbanization and reform of the hukou system of household registration will pave the way for better access to healthcare for eligible rural residents.

• New product launches will contribute to market growth as lengthy registration times improve following the reforms to the drug approval process and efforts to accelerate the approval of new innovative drugs.

• Pricing pressures in the tender system will increase. Demands for mandatory price cuts by provinces will remain a feature of the market and price transparency is set to increase further, while second-level price negotiations by cities or group purchasing organizations (GPOs) will become more common. Competition for off-patent originators will increase as a growing number of generics passes quality consistency evaluation.

• Hospital cost containment will intensify as budget controls are rolled out nationwide, with a view to reducing hospitals’ drug budgets to below 30% of total budgets and limiting annual budget growth to 10%.

**Change in the Prognosis**

The five-year outlook for China remains broadly similar to the previous forecast published in September 2016, but has been revised upwards in the short and medium term. The following changes have been made to the forecast:

**Baseline Changes**

• Higher than expected volume growth in the dominant large hospital sector in 2016 has lifted the volume baseline forecast.

• A stronger than expected decline in volume in the audited retail pharmacy sector in 2016 has resulted in a downward adjustment of the volume baselines for the sector in the short-medium term.

**Event Changes**

• **The event ‘Demographic changes’ is now expected to have a positive impact**, as population growth forecasts have been revised upwards by the EIU for the 0-15 age cohort following the relaxation of the ‘one child’ policy.

• **Following the publication of the new NRDL, the probability of the event has been revised upwards and its positive impact on volume raised**, although roll-out to the provinces is expected to take some time.

• **The impact of the event ‘Rapid increase in chronic diseases’ has been revised upwards**, as treatment has become a policy priority and a long-term national plan on the prevention and treatment of chronic diseases over the period 2016-2025 has been published, which will address cardio/cerebrovascular diseases, cancer, chronic respiratory diseases and diabetes.

• **The probability of the event ‘Increasing pricing pressures in the tender system’ has been revised downwards in the short term, and the negative impact reduced slightly**, as the system is expected to continue to allow a certain amount of flexibility in the short to medium term.