



# IMS Market Prognosis Summary China 2016-2020

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# Market Overview and Forecasts

## Market Synopsis

- The Chinese pharmaceutical market is forecast to grow at a compound annual growth rate (CAGR) of 6.9% ( $\pm 2.5\%$ ) between 2015 and 2020, reaching RMB1,003.9 billion by 2020.

### Business Environment

- Economic growth is forecast to slow to 6.5% in 2016, from 6.9% 2015, as private consumption growth decelerates. Over the medium term, real gross domestic product (GDP) growth will slow steadily, averaging 5.4% during 2017-2020, driven by a slowdown in investment, while private consumption should hold up better and government consumption will expand rapidly. Inflation will rise from 1.5% in 2015 to average 2.0% in 2016-2020, reflecting imported inflation as the renminbi depreciates against the relatively strong US dollar and global commodity prices increase. The renminbi is forecast to strengthen again in the longer term, to average RMB6.42:US\$1 in 2020.
- China's president, Xi Jinping, has secured his authority over the Chinese Communist Party (CCP) and emerged as a decisive, powerful leader. 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, with a view to creating the conditions for sustainable economic expansion and social stability. Social reforms, including the abolition of the one-child policy and 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 13<sup>th</sup> Five-Year Plan for 2016-2020 reinforce the goal of achieving affordable and equitable basic healthcare for the whole of the Chinese population by 2020. A five-year roadmap prioritizes further development of the healthcare infrastructure and personnel.
- Greater impetus will be given to the reform of hospital financing, implementation of a working referral system, encouragement of the private sector, deepening and broadening of health insurance cover, and improvements in access to healthcare in rural areas. While national policies will provide guidance, implementation will be driven by local authorities, contributing to an increasingly heterogeneous and fragmented market environment.
- Healthcare spending growth has slowed since 2011, but health expenditure as a percentage of GDP is still rising, reaching 5.6% in 2014. The government's goal is to see that figure reach between 6.5% and 7.0% by 2020. While patients still account for one-third of total healthcare spending, that figure is gradually declining.
- With over 95% of the population now covered by the three basic medical insurance schemes, the government will turn its attention to improving and harmonizing the benefits they offer, while keeping budgets under control. The proposed unification of the urban and rural residents' schemes will represent a significant step in that direction. Cover for critical illnesses will be improved, and greater participation of commercial insurance in the healthcare system will be encouraged, with the objective of achieving universal coverage of the population by 2020.

- A renewed push will be made for reform of the hospital sector, where progress to date has been limited. 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 hospital sector will be encouraged, with rules governing private and foreign investment in hospitals, as well as physician employment, being relaxed, although broader use of private facilities will depend on the implementation of measures enabling their participation in the basic medical insurance schemes.
- Strengthening primary care provision and the implementation of a working referral system is a key objective of the reform program. Attention will focus on improving community health centers, developing a general practitioner network and establishing a gatekeeper system.
- Drug procurement will remain extremely complex as provinces pilot different models for bidding under a new procurement framework. Multinational companies will face growing competition from domestic manufacturers as off-patent originators are grouped increasingly with high-end local generics in tenders. Pricing pressures will increase as more provinces and cities cross-reference prices, and as provinces continue to impose mandatory price cuts.

### Prescribing and Dispensing

- Prescribing choices will be influenced increasingly by policies designed to curb drug spending. The share of hospital budgets earmarked for spending on drugs will be reduced progressively to less than 30% under the hospital reforms, driving the introduction of measures to curtail prescription volumes and the imposition of prescribing quotas for high-cost products. Stricter reimbursement claim controls will act as an additional constraint on prescribing volumes, while anti-corruption compliance requirements will affect prescribing practice.
- Continued delays in the update of the 2009 National Reimbursement Drug List (NRDL) will complicate market access for new products. Publication of the list is expected in the second half of 2016, with roll-out to provinces expected to take an additional one-two years. The introduction of a national list of specialty products to guide provincial listing – the so-called ‘C List’ – is a possibility, although listing by provinces will not be obligatory.
- A growing number of new specialty products are gaining access to reimbursement at provincial level through local negotiations with provincial authorities. Patient assistant programs are becoming more important as a way to gain market access at provincial level.
- With reforms encouraging hospitals to reduce drug spending and preventing them from profiting significantly on the sale of drugs, more prescriptions will be released for dispensing in retail pharmacies, particularly where scripts are for non-reimbursed drugs. Draft regulations for the online sale of prescription drugs have been prepared, although concerns remain about ensuring quality and safety.

### Pricing

- Pricing reforms implemented in 2015 aim to establish a market-oriented system. Following the removal of price controls in 2015, the government is shifting its focus from price setting to price supervision and monitoring, while provincial authorities are assuming greater responsibility for pricing through the provincial tendering system. Strong downward pressure on prices will persist despite the relaxation of price controls, however.
- The government intends to create a national-level price negotiation mechanism for patented drugs. Under a pilot program, discounts of at least 50% were expected to be negotiated for

five patented drugs in early 2016. Companies remain concerned about the absence of volume or reimbursement guarantees under the pilot program.

- The establishment of a 'reimbursement standard' reference pricing system for drugs subsidized by the public health insurance schemes has been proposed, although no schedule for implementation had been set as of early 2016. With any difference between the reimbursement price and a higher priced brand to be paid by patients out-of-pocket, the proposed system would have obvious negative implications for higher priced products.

## **Regulatory Environment**

- The time taken to register new drugs will begin to decline as measures to reform the drug approval process and reduce the backlog of applications are implemented. This will benefit innovative new drugs, allowing for accelerated reviews of more new products that address unmet clinical needs, but will also incentivize the development of quality generics.
- The introduction of simplified review procedures will reduce the time taken to approve clinical trial applications. Simultaneous trials are allowed for new drugs which have not yet been marketed outside China, and multi-regional clinical trials will continue to be used to support the registration of imported drugs.
- As part of an overhaul of drug safety, the China Food and Drug Administration (CFDA) is seeking to re-evaluate the quality of all generics. New generic product submissions are already required to contain bioavailability and bioequivalence data, and all generics on the market will have to undergo quality and consistency assessment.
- While a 20 year patent term is available under China's patent law, effective patent terms have been eroded by the lengthy drug approval process. Regulatory data protection and patent enforcement remain key issues of concern for originators. Patent term erosion should be reduced if approval times are accelerated following the reform of the registration process.

## **Pharmaceutical Business Environment**

- The pharmaceutical industry operating environment will become more challenging as the economy slows and efforts to curb drug spending are stepped up. Demand will remain strong, while drug approval times for innovative products will improve, but more aggressive purchasing practices and the intensification of hospital cost-containment measures will limit market growth to rates significantly below historical levels.
- The domestic industry will become increasingly polarized between strong local players operating to high quality standards and smaller companies producing multiple versions of the same molecule. The quality gap between multinational brands and premium local products will narrow.
- The number of research and manufacturing partnerships between local companies and multinationals will grow, contributing to the emergence of an innovative industry in China. More domestic companies will begin to conduct original research, while multinationals will also enhance their R&D capabilities in China.
- While the generics market will remain crowded, the number of local generic manufacturers will decline as tighter quality standards are applied by regulators. Leading domestic players will become stronger, and will increase their market share. The publication of a regulatory guideline for biosimilars in 2015 has clarified the route to market for biologics that demonstrate similarity with the originator brand, although they will continue to be reviewed under the new drug approval process.

- Restructuring within the fragmented distribution sector slowed during 2015. Incremental consolidation of the sector will continue, however, as pressure on margins and costs associated with the implementation of new good supply practice standards squeeze distributor finances.
- The limited nature of outpatient drug benefits will continue to restrict retail sector sales of prescription drugs. While more prescription drugs are beginning to flow out of larger hospitals as a result of cost-containment pressures in that sector, most are being dispensed in community health centers (CHCs) – though some primary care, traditional Chinese medicine (TCM) and adjuvant prescription drugs are being sold more widely through retail pharmacies. High-value and non-reimbursed prescription products are being dispensed increasingly in specialized retail pharmacies.
- The complex over-the-counter (OTC) market in China is characterized by multiple channels, different product segments, and the inclusion of reimbursed medicines. The market will continue to be dominated by TCM products, which are driving growth.
- Sales and marketing practices are changing in the wake of the 2013 anti-corruption campaign, with companies adopting new approaches to product promotion. Access to doctors has become more difficult, and while sales reps will remain a key factor in maintaining and expanding market share, growing use will be made of digital marketing platforms and e-detailing.

# Total Market Forecasts 2016-2020

## 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 2015.

**Retail pharmacy sector data:** The prognosis incorporates a projection of the audited retail pharmacy sector at prefecture city level and above, based on the IMS PharmaTrend data, which is available from Q1 2012 onwards and which was estimated to account for approximately 56% of the total China retail pharmacy market in 2015. 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 IMS Health China. The unaudited sector includes retail pharmacies at county level and below (estimated to account for approximately 44% of the total retail pharmacy market in 2015), as well as small hospitals with less than 100 beds, community health centers, township health centers and clinics (together estimated to account for 19% of the total market in 2015).

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 at a rate above the audited hospital sector, to account for the comparatively less stringent cost-containment measures in smaller hospitals.

The total pharmaceutical market is forecast to grow at a CAGR of 6.9% ( $\pm 2.5\%$ ) during the period 2015-2020.

### Key Issues Affecting Market Growth:

- Health insurance coverage will expand as coverage under the three basic public health insurance schemes is deepened, critical illness cover is rolled out for the whole population, and commercial insurance is encouraged.
- An update of the NRDL is still expected, in the second half of 2016 at the earliest. A list of higher priced specialty products, List C, is expected to be published for guidance, but adoption by provinces will not be obligatory.
- 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.

- Further improvements will be made to the healthcare infrastructure and to medical services in line with a new five-year roadmap to 2020, which calls for a significant increase in hospital bed numbers and healthcare personnel. Reform of the *hukou* system of household registration will pave the way for better access to healthcare for eligible migrant workers.
- Controls of reimbursement claims using sophisticated claim processing software are being implemented more widely by the health insurance authorities; hospitals in response are tightening up monitoring of rational use of medicines, leading to a reduction in overprescribing, with traditional Chinese medicines (TCM) particularly affected.
- Pricing pressures in the tender system will increase further. Off-patent originators will be grouped increasingly with high-end local generics in tenders. Demands for mandatory price cuts by provinces will remain a feature of the market and price transparency is set to increase further, while city-level price negotiations will become more common.
- Hospital cost-containment will intensify as budget controls are rolled out nationwide over the next years, with a view to reducing hospitals' drug budgets to below 30% of total budgets by 2017.

### **Change in the Prognosis:**

The prognosis for China has been adjusted downwards slightly compared to the previous forecast published in September 2015. This is mainly due to:

- Slightly lower than expected volume and price growth in the audited hospital sector at year-end 2015, resulting in a slight downward adjustment of both baselines.