



# Life Sciences in China: the CEO's Perspective



2016

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# Foreword

The past decade has been a successful period for China's life sciences industry as the sector expanded at a faster rate than the economy as a whole. Between 2006 and 2011, the overall Chinese pharmaceutical market grew between 15 and 30 percent per year before tapering off slightly with growth dipping into the high teens in 2012-13.<sup>1</sup> The last two years have proven to be more challenging as revenue growth fell into single digits in 2015 and this decline looks set to continue. While some of this can be explained by the transition China's economy is undergoing, regulatory changes have also played a role, particularly the reforms to the drug tendering process that were introduced in mid-2015.

In spite of this fact, most of the executives interviewed by KPMG China for this report remain optimistic about the industry's long-term prospects in China. While those interviewed identified many hurdles such as the length of China's approval process for marketing drugs, ongoing price reforms and stricter, more complex local regulations, they also recognised that the opportunities for companies in China are manifold. The government is committed to increasing healthcare expenditure to meet the demands of an ageing and increasingly affluent citizenry. It has also demonstrated a willingness to open up the sector to market forces, which will mostly benefit multinationals as they remain at the vanguard of some of the most innovative developments in the healthcare sector.

We hope that you find this report both interesting and helpful. If you have any comments or queries, please feel free to reach out to either one of us or your current KPMG China contact.



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<sup>1</sup> National Bureau of Statistics of China, <http://data.stats.gov.cn/english/easyquery.htm?cn=C01>.

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# Key findings

**“** Last year, President Obama announced that the US government would invest USD 215 million in precision medicine in the 2016 budget. In comparison, China announced recently that in its next Five Year Plan it would include a commitment to invest USD 9 billion over the next 20 years. **”**

- Danny Yeung, CEO, Prenetics

- Healthcare remains a priority for China's government. Having featured prominently in the country's 12th Five Year Plan from 2011-2015, delivering effective care remains a key topic in the 13th Plan for the 2016-2020 period. Specific measures outlined in the latest plan include integrating the insurance schemes of rural and urban public hospitals and adopting cyber-medicine and other digitally optimised ways of managing resources.<sup>2</sup>
- While the long-term potential of China's life sciences market remains appealing, the short-term outlook is murky. Headquarter offices expecting high growth rates from their China operations to offset limited growth in other parts of the world should engage with local managers and possibly alter expectations and strategies accordingly.
- Reforms introduced in 2015 have created major disruptions for both the supply and delivery sides. Above all, new tendering processes have been a key reason for sales growth declining at some multinational pharmaceutical companies. While regulatory changes are not the sole cause of this decline, policy reforms are forcing many companies to rethink existing strategies and practices.
- Domestic companies continue to grow. Their share of China's pharmaceutical market has increased by 2.3 percent in the last seven years.<sup>3</sup> Thin margins, arising from a portfolio of mainly non-branded, generic drugs and price-based competition with other domestic players continue to stifle their development. Low margins also make it difficult for local players to allocate or raise funding for developing new products.
- The gulf in size and quality between multinationals and local companies has resulted in few major acquisitions occurring but opportunities do exist. This is especially true for companies specialising in niche products or those willing to take a long-term view on start-ups launched by Chinese nationals who have studied abroad and have significant commercial or R&D experience with international life sciences companies.
- The time required for new drugs to obtain approval from the China Food and Drugs Administration (CFDA) remains an issue, although recent changes have started to clear the backlog of applications. Over time the speed and transparency of the approval process should get better, while also driving improvements in drug quality and effectiveness.
- Advances in data analytics and other digital technologies are helping companies get a better handle on their business processes and are allowing new companies to disrupt the status quo. This is forcing regulators to play catch-up.
- Maintaining high standards of compliance remains a priority at all companies. From transparency in the supply and distribution chains through to relationships with hospitals and healthcare professionals, pharmaceutical companies remain focused on improving processes internally and with third parties.

<sup>2</sup> The State Council of the People's Republic of China, The Thirteenth Five-Year Plan for the Economic and Social Development of the People's Republic of China, [http://www.gov.cn/xinwen/2016-03/17/content\\_5054992.htm](http://www.gov.cn/xinwen/2016-03/17/content_5054992.htm).

<sup>3</sup> James Shen, Contemporary Trends and Outlook of the Chinese Pharma Industry and Market 2015/2016, p. 8.



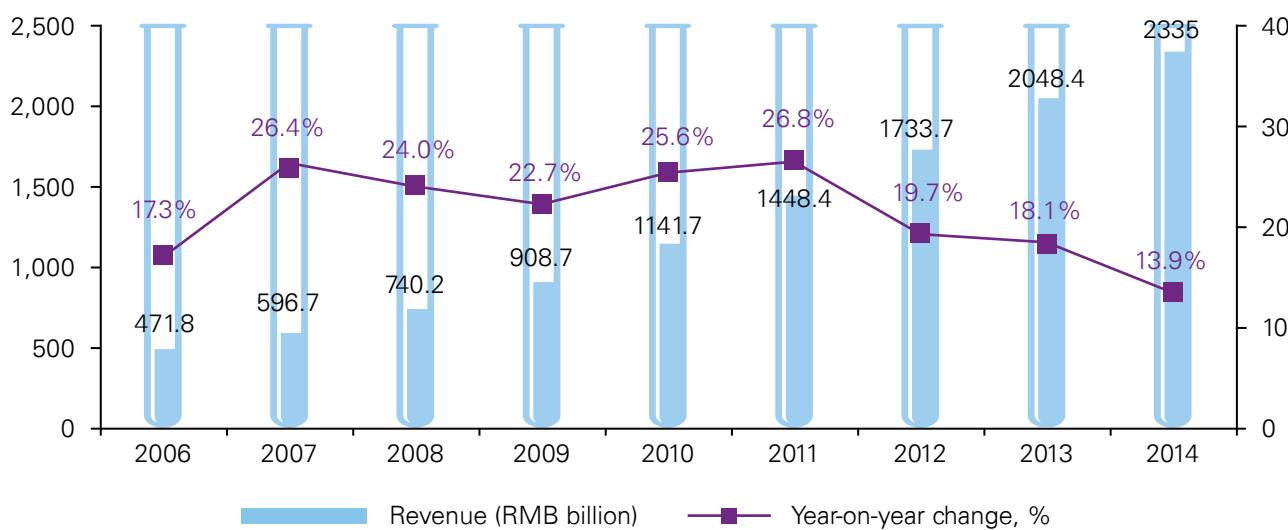
# China's burgeoning healthcare market

## Market overview

China remains one of the most compelling markets for life sciences and pharmaceutical companies globally. The twin effects of an ageing population and a burgeoning, urban middle class are placing strain on the country's public hospital system, which is pushing up demand for new products and services. This translates to opportunities for multinational pharmaceutical companies, which are currently unmatched by their local counterparts in both size and sophistication.

In spite of rising healthcare demand, revenues from pharmaceutical sales are starting to taper off following the double digit growth of the previous decade. This is due to increasing competition driving down the price of drugs as well as regulatory changes and stronger enforcement of existing regulations.

### Revenue from principle business of manufacture of medicines, China



Source: National Bureau of Statistics of China<sup>4</sup>

In spite of this, industry observers continue to predict that healthcare spending in China will rise. The Economist Intelligence Unit (EIU) forecasts that annual healthcare expenditure will reach RMB 4,780.4 billion (USD 680.4 billion) by 2018, which represents a 7.44 percent growth year-on-year.<sup>5</sup> This will be driven by rising incomes and the government's commitment to make the sector more responsive to market forces.

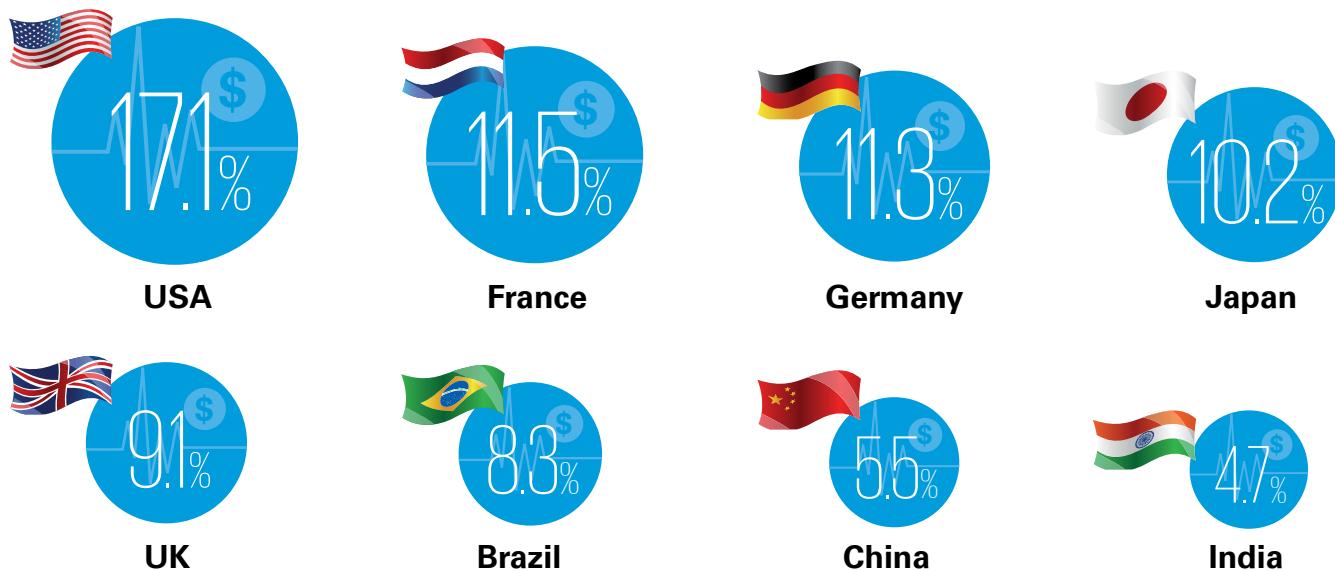
The EIU also predicts that spending per capita on healthcare in China will surpass USD 570 in 2020, double the figure for 2011. Although this is still quite small when compared with equivalent figures for the US, where spending is forecast to reach around USD 11,204 by 2020, China is on course to close the gap for total expenditure due to the size of its population. The EIU predicts that total expenditure on healthcare in China will increase from 14 percent to over 21 percent of the total for the US during the same period.<sup>6</sup> Even with total expenditure increasing, as a share of GDP, China's healthcare spending is still much lower than that of Japan as well as many European and North American countries.

4 National Bureau of Statistics of China, <http://data.stats.gov.cn/english/easyquery.htm?cn=C01>.

5 The Economist Intelligence Unit, China Healthcare, <http://www.eiu.com/industry/Healthcare/asia/china/article/1294268113/healthcare-spending/2016-05-30>.

6 The Economist Intelligence Unit, United States Healthcare, <http://www.eiu.com/industry/Healthcare/americas/united-states/article/1224072506/healthcare-spending/2016-03-30>.

## Healthcare expenditure as share of GDP, 2014



Source: World Bank<sup>7</sup>

For many of the world's largest pharmaceutical companies, China accounts for a significant proportion of global revenue. Executives interviewed by KPMG China expressed confidence about the long-term prospects for life sciences companies in China, especially those focused on treatments for age-related, chronic diseases. As the country's population ages, the chronic disease burden in China has grown exponentially. Incidences of diabetes have risen from around 90 million adults or 9.29 percent of the adult population in 2011 to 110 million in 2015 or 10.6 percent of the adult population in 2015 and are forecast to reach as many as 151 million by 2040.<sup>8</sup>

## Healthcare reforms

China's long-term goal of establishing a high-quality system of universal healthcare provision will take many years to realise, although the reforms introduced so far have been encouraging. A positive example is the increase in coverage under the government's Basic Medical Insurance (BMI) programme from a low coverage rate to 96 percent of the population in 2012.<sup>9</sup> Several issues still need to be resolved including the price of medication, the quality of medications available, lack of funding for hospitals and the lack of a competitive domestic pharmaceutical market.

In 2014, the government turned its attention to reforming its public hospitals as it sought to place more on a secure financial footing, boost compensation levels among medical staff and lower the dependence of hospitals on drug sales. Last year, officials also unveiled a number of measures aimed at lowering costs and improving the quality of pharmaceuticals. The government rescinded existing powers to cap prices for many drugs, introduced new measures aimed at improving procedures for evaluating and approving new drugs and issued a number of policies with the aim of encouraging innovation.

7 The World Bank, Healthcare Expenditure, <http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS>.

8 International Diabetes Federation, IDF Diabetes Atlas (7th edition), Brussels, Belgium.

9 World Health Organisation, The 12th Five-Year Plan for Health Sector Development, [http://www.wpro.who.int/health\\_services/china\\_nationalhealthplan.pdf](http://www.wpro.who.int/health_services/china_nationalhealthplan.pdf).

**“** We are devoted to bringing innovative drugs to Chinese patients. We are very pleased to see recently that the CFDA is stepping up efforts to accelerate the drug approval process. Although some details regarding how these reforms will be implemented are still unclear, the overall effect is very positive. **”**

**- Hong Chow, general manager, Shanghai Roche Pharmaceuticals**

“We understand and appreciate the government’s objective, which is to create a healthcare system that is affordable and accessible to all,” said Wei Jiang, executive vice president, commercial operations & APAC region managing director, Bayer Pharmaceuticals China. “However, striking a balance between the objectives of the reforms and ensuring the sustainable development of the industry will not be an easy task.”

While nearly all of the executives surveyed by KPMG China understood that these reforms were important to China’s long-term social development, many of those interviewed also said that pharmaceutical companies faced a period of great uncertainty. Our interviewees highlighted four key areas that posed major challenges to pharmaceutical and life sciences companies in China. These were:

- changes to the tendering process introduced in mid-2015,
- the approval procedure for new products,
- finding new markets and targeting portfolios,
- compliance with China’s anti-corruption regulations.

Each of these challenges also presents companies with opportunities and many are beginning to explore new business models in order to become more competitive.



# The effects of China's drug policy reforms



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## Medication prices

In June 2015, the National Development and Reform Commission (NDRC), China's top economic policy body, abolished Article 55 of the Drug Administration Law that grants government the authority to cap the price of most drugs. The NDRC's aim is to lower the price of most commonly available drugs by adopting a market based approach to setting prices. The NDRC said these reforms would "improve purchasing mechanisms, control medical insurance costs and allow the price of medicines to be set by the market."<sup>10</sup>

This is an important step towards China's goal of universal healthcare, although the benefits of these reforms may not be immediately obvious to patients, who remain burdened with the cost of paying for many of these drugs themselves. Roughly one third of healthcare costs are paid for by patients out-of-pocket and some treatments will remain unaffordable as many drugs are still not covered by China's BMI programme. The National Reimbursement Drug List (NRDL) provides a complete list of medicines eligible for reimbursement and the government has not updated this list since 2009. In the case of cancer treatments, many target therapies are not listed at all. This means that patients are left to bear a larger portion of the costs of treatment or are faced with relying on other therapies with poorer outcomes.

The abolition of price caps should benefit pharmaceutical companies in the long run by granting them greater flexibility to work with healthcare providers in establishing prices based on the effectiveness of treatment. This is also expected to reduce the costs of high volume common drugs. In the immediate term however, these reforms have created uncertainty for manufacturers of drugs as many struggle to navigate the approval procedures required to set regional prices with government and to negotiate purchase prices with hospitals.

"We expect intensified cost containment measures, especially for off-patent drugs, and price pressure from bidding across all levels: national, provincial, city and hospital level, which are unfortunately uncoordinated at the moment. Roche has made tremendous efforts to improve affordability through its negotiations with government, charity foundations and private insurance companies on reimbursement for a number of drugs," said Hong Chow, general manager, Shanghai Roche Pharmaceuticals.

Roche recently achieved an important breakthrough with one of its flagship products, Herceptin, a targeted therapy for treatment of Her2-positive breast cancer, which is also the company's largest product in China. Although Herceptin is not included in the NRDL, 11 regions so far have added it to their reimbursement list, potentially extending access to this form of treatment to around 350 million people. "The government has announced its goal to improve reimbursement coverage for critical illnesses, which will bring further opportunities," said Hong.

<sup>10</sup> National Development and Reform Commission, Question and Answers on Promoting Reform of Drug Prices, [http://www.ndrc.gov.cn/zcfb/zcfbtz/201505/t20150505\\_690664.html](http://www.ndrc.gov.cn/zcfb/zcfbtz/201505/t20150505_690664.html).

*Recent reforms at the CFDA are very positive. I'm certain that the length of time it takes for new drugs to be approved will be reduced.*

**- Tony Au, general manager, AbbVie China**

## Approval process

A major concern for pharmaceutical companies is the time needed to obtain approval for new drugs before they can come to market. "Clinical trial applications can take anywhere between 18 and 24 months," said Tony Au, general manager, AbbVie China. "If you are granted approval to proceed, it will normally take around six years to complete, although sometimes it can be longer."

Following clinical trials at the national level, new drugs have to be approved at the provincial or city level before they can be placed into formularies, a process that can take up to four or five years in some cases. As a result, many new medications remain unavailable for use for up to half of the life of the patent, denying patients access to potentially more effective forms of treatment for many years. "Other countries often get access to drugs much earlier because of the length of the approval process in China," said Au.

One reason often cited as a cause of the delay is China's Center for Drug Evaluation, which is widely viewed as being under-resourced. The centre employs slightly more than 130 staff to screen new drugs, whereas its equivalent in the US has over 5,000 staff responsible for overseeing the approval process.<sup>11</sup>

The government's efforts to reform the approval process have been positive. These reforms have helped increase the number of approvals and also helped weed out lower quality applicants. In 2015, the CFDA reviewed nearly 9,400 new applications, 90 percent more than in 2014.<sup>12</sup> The government also introduced measures in July 2015 to promote higher clinical trial standards. 1,622 applications were randomly selected by the CFDA from the 9,394 submitted in 2015. The selected applicants were subjected to a newly introduced self-check mechanism. This led to almost 1,200 of the sampled applicants withdrawing their submissions and most of these applications were from smaller, domestic companies for generic drugs.<sup>13</sup>

China's government remains committed to making further reforms to the approval process for new drugs. In August 2015, the State Council issued a publication entitled 'Opinions on Reforming Review and Approval Process for Drugs and Medical Devices', which listed a number of policies aimed at accelerating the approval process.<sup>14</sup> These include:

- launching a pilot programme to allow R&D organisations and academic researchers to apply for approval of new drugs and subsequently find commercial partners (only drug manufacturers can apply under existing regulations),
- streamlining the approval process for various types of innovative medications, especially those produced domestically or not yet available in other markets,
- allowing companies to conduct clinical trials in both China and overseas simultaneously and to use multicentre data for CFDA applications,
- increasing the resources of the CFDA.

<sup>11</sup> The State Council Information Office of the People's Republic of China, *Press Conference Regarding Work on Safety of Food and Drugs*, <http://www.scio.gov.cn/xwfbh/xwfbh/wqfbh/33978/34253/index.htm>.

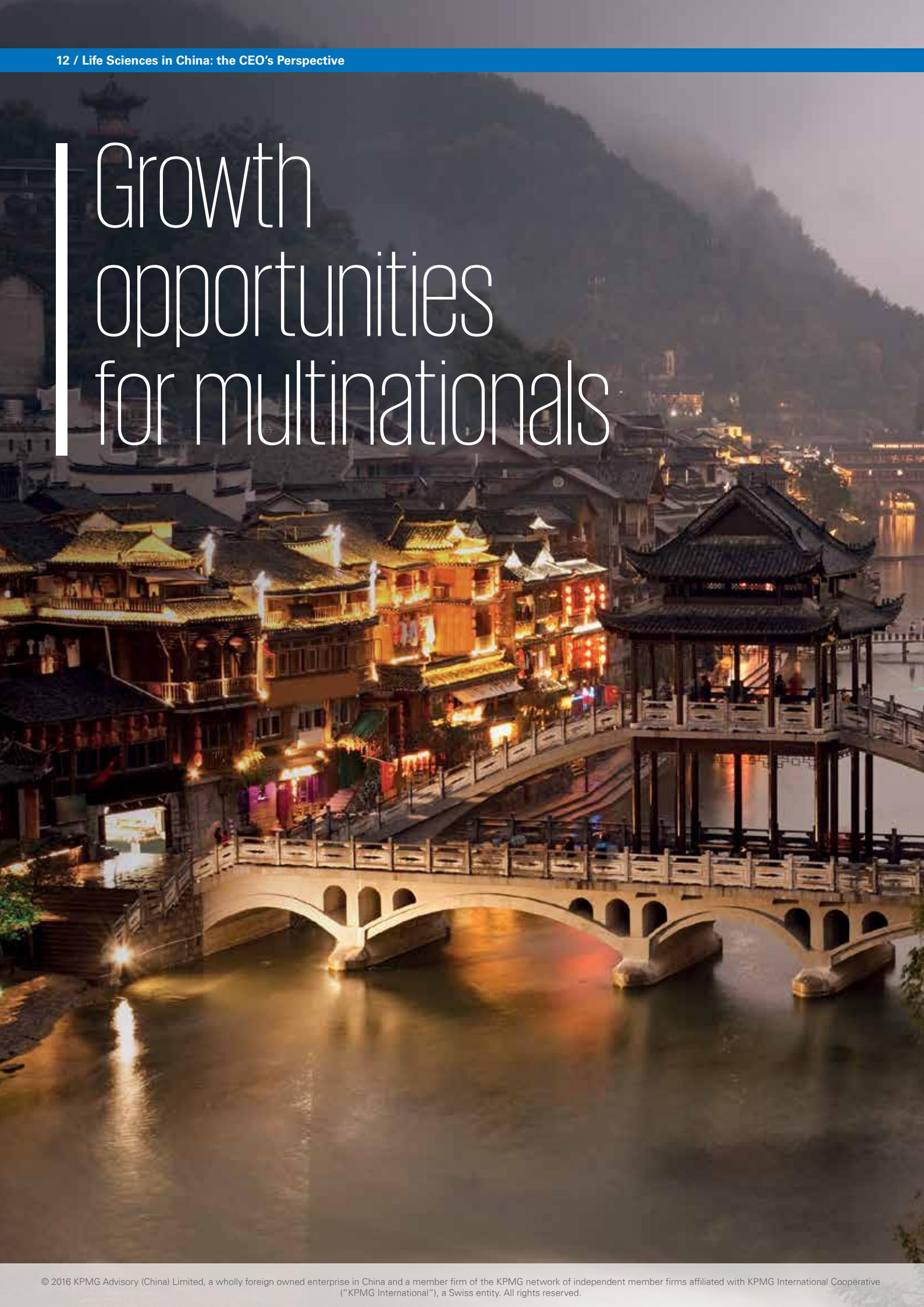
<sup>12</sup> China Food and Drug Administration, *National Food and Drug Supervision and Management Work Conference Held in Beijing*, <http://www.sfda.gov.cn/WS01/CL0050/142020.html>.

<sup>13</sup> China Food and Drug Administration, *National Food and Drug Supervision and Management Work Conference Held in Beijing*, <http://www.sfda.gov.cn/WS01/CL0050/142020.html>.

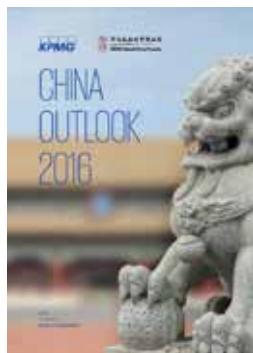
<sup>14</sup> The Central Government of the People's Republic of China, *Opinions on Reforming Review and Approval Process for Drugs and Medical Devices*, [http://www.gov.cn/zhengce/content/2015-08/18/content\\_10101.htm](http://www.gov.cn/zhengce/content/2015-08/18/content_10101.htm).



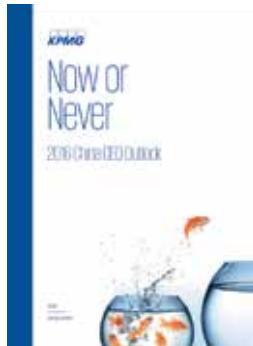
# Growth opportunities for multinationals



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## New markets

Whereas a few years ago multinationals may have focused their efforts exclusively in a handful of key markets such as Beijing, Shanghai and Guangzhou, many are now starting to pay greater attention to rural and lower tier urban markets due to the fierce competition that exists in China's major urban centres. If companies are able to manage this expansion process well, they are usually capable of achieving growth rates well above the industry average.

According to Jean-Christophe Pointeau, general manager of the pharmaceutical division at Sanofi China, the French headquartered firm was one the fastest growing multinational pharmaceutical companies in China in 2015. The Sanofi Group's annual report states that sales growth in the company's pharmaceuticals, vaccines and animal health divisions increased by 7.8 percent across emerging markets with growth in China up 19.5 percent.<sup>15</sup> Pointeau said that revenue at the company grew by around 20 percent with pharmaceutical sales increasing 15 percent and the company's vaccine business also experiencing high double digit growth. "There has been an industry slowdown since last year," said Pointeau. "However, I am optimistic about the market and our future development in China. We are only addressing a market of 400 to 500 million people in China, which means that there are still another billion to be reached."

Pointeau cites three factors as contributing to Sanofi's expansion in China. Firstly, the company has invested significantly in China having entered the mainland market 30 years ago. Secondly, the company has developed a strong portfolio of products to tackle some of China's biggest healthcare needs such as hypertension, diabetes, oncology and central nervous system related illnesses. Thirdly, Sanofi is expanding into county level markets outside of the major cities, where multinational companies traditionally focus their efforts. The company set up a dedicated unit in 2011 to communicate scientific information about Sanofi's products at the county level. Sanofi currently employs more than 1,100 staff in this division, which was established to respond to the government's renewed focus on primary care.

"The government wants to accelerate the growth of China's primary healthcare system. What I expect to see is more community healthcare centres and county hospitals opening up in rural areas and a general shift away from big hospitals towards these health centres for the provision of primary healthcare," said Pointeau.

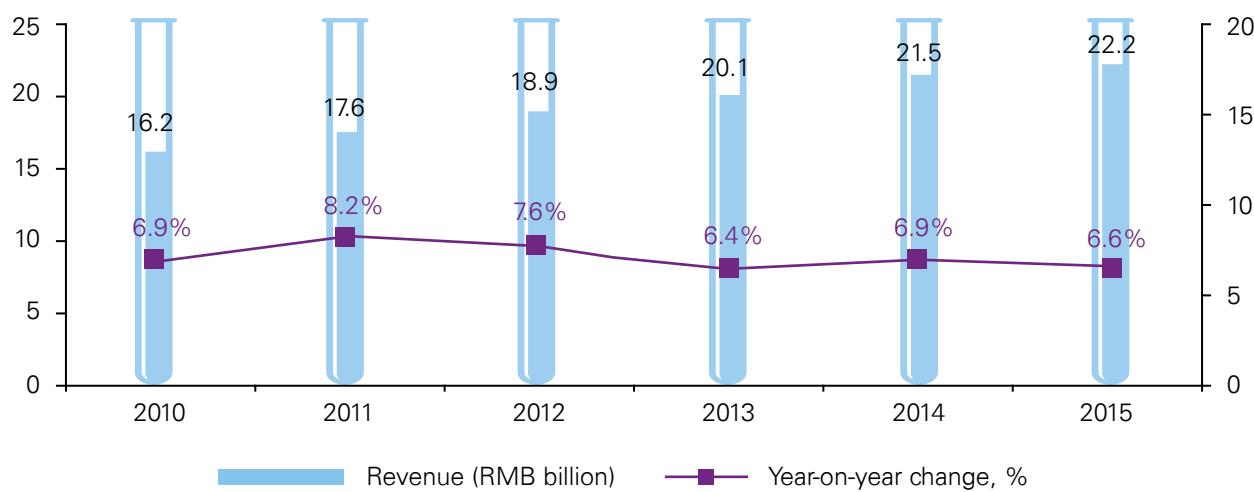
Recent government reforms, such as the relaxation of single-site practice for doctors, are expected to improve China's primary healthcare system. By allowing healthcare practitioners to work in multiple sites, this will enlarge the area of coverage by the same number of practitioners and reduce pressure on large hospitals. This flexibility, combined with various pilot schemes being rolled out for the reform of public hospitals, is part of the government's plan to improve efficiencies in the healthcare sector and distribute resources more effectively across the country.

<sup>15</sup> Sanofi Group, Document de Référence, [http://en.sanofi.com/Images/45885\\_Document\\_Reference\\_2015\\_V2.pdf](http://en.sanofi.com/Images/45885_Document_Reference_2015_V2.pdf)

## OTC sales

Over-the-counter (OTC) sales is another area of the healthcare industry often mentioned for its potential. So far it has proved elusive for multinationals, largely due to the preference among Chinese nationals for traditional Chinese medicines (TCM). Even today many of these medicines are sold through tiny outlets, where they are often prepared on the spot by TCM practitioners. In this fragmented market, even domestic companies have found it tough to grow and no single supplier holds more than a 10 percent market share.<sup>16</sup>

### Revenue from China's Over-the-counter Pharmaceutical Market



Source: Nicholas Hall DB6 Global OTC Database/James Shen, Contemporary Trends and Outlook of the Chinese Pharma Industry and Market<sup>17</sup>

Multinationals are exploring several different ways to develop a foothold in this market such as partnering with or acquiring established domestic companies and increasing their manufacturing capabilities within China. German pharmaceutical company Bayer is pursuing both strategies and recently acquired Yunnan-headquartered Dihon, a Chinese herbal medicine company that sells most of its products over-the-counter. Bayer is looking to expand its revenue from OTC sales through this acquisition and has also established a new facility in Yunnan province, which provides both western OTC products and traditional Chinese medicines.

For multinationals operating in China, the long-term opportunities from OTC medications are potentially significant. Chinese patients are used to paying directly for medications, either at hospitals or through vendors of traditional Chinese medicines, and companies marketing OTC medications can determine prices freely by building relationships directly with users, bypassing the more cumbersome approval process required for selling drugs to hospitals.

<sup>16</sup> Euromonitor International, *Consumer Health in China*.

<sup>17</sup> James Shen, *Contemporary Trends and Outlook of the Chinese Pharma Industry and Market 2015/2016*, p. 11.

**“** In distribution, innovation is taking a known idea from the US or Europe and applying it in China. Places are different, but not that different. **”**

**- Eric Zwisler, chairman, Cardinal Health China**

## M&A activity

Although China's pharmaceutical market is undergoing changes, the opportunities are still manifold. Many companies are reacting to the changes in China's healthcare sector by adapting their business models and looking for new ways of expanding revenue beyond traditional methods such as introducing new products or increasing the volume of existing products.

China's fragmented marketplace also offers opportunities to keep growth rates above average. With provinces and sometimes cities being served by local pharmaceutical or distribution companies, there are opportunities for multinationals to forge partnerships or acquire domestic companies. According to Mergermarket, an online intelligence service for the global M&A market, there were roughly 200 drug and biotech related mergers or acquisitions in China in the first three quarters of 2015 compared with 186 for the whole of the previous year.<sup>18</sup> The majority of these deals were between domestic companies since multinational companies remain cautious when looking at potential acquisition targets due to differences in strategy compared with local outfits.

One exception to this is Cardinal Health China, the Chinese arm of US pharmaceutical distributor Cardinal Health. The company was established when Cardinal bought Zuellig Pharma China, known locally as Yong Yu, a prominent distributor of imported drugs in China. Cardinal Health has so far acquired 18 companies in China, the majority of which sell directly to hospitals, and is now one of the largest pharmaceutical wholesale distributors in China.

Being able to manage acquisitions is an important skill as the parties involved may have significantly different business models or process maturities. "Companies need to put in place the correct systems to manage acquisitions," said Eric Zwisler, chairman, Cardinal Health China. "In spite of the differences between companies, market valuations remain high in China. Capital efficiency is a challenge. Many companies are paying large sums to acquire assets as they look to consolidate their supply chain, although they often struggle to get a good return on their investment."

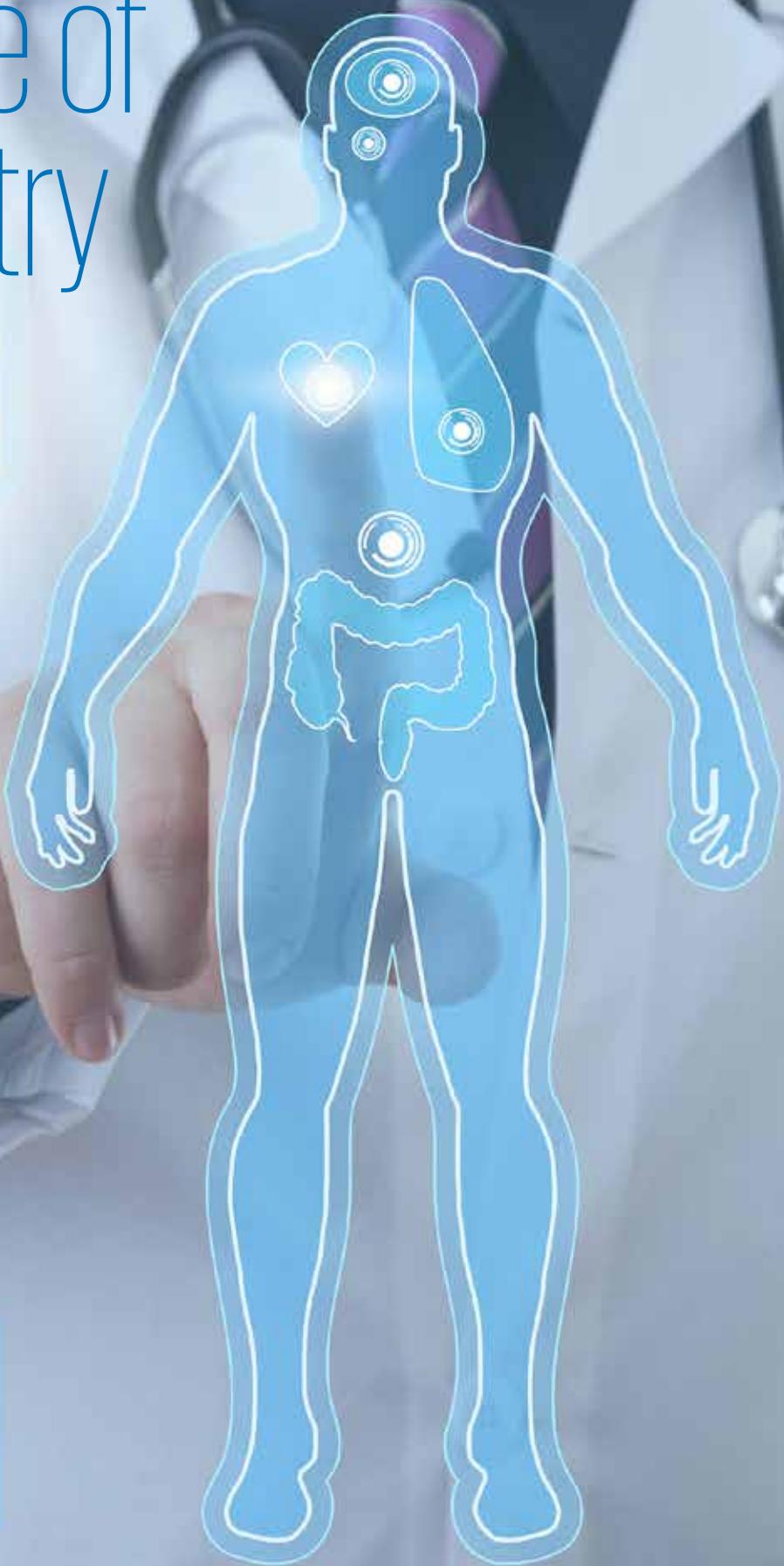
Multinationals are also forming partnerships with local companies. In February 2016, a large European pharmaceutical company signed two deals with a Shenzhen-based pharmaceutical company for a combined total of USD 500 million. These two deals grant the Chinese outfit the right to sell two drugs produced by the multinational company.

One other possibility for multinationals is to form joint ventures with large state-owned enterprises (SOEs). This has proven less popular so far compared with acquiring private firms but the potential could be enormous if SOEs are willing to open up to private capital and foreign companies are able to find suitable partners.

"State-owned enterprises can contribute hard assets, distribution networks, supply chains and huge sales forces, while multinationals can provide intellectual property, cash and sometimes products," said Mark Harrison, a Shanghai-based deal advisory partner at KPMG China. "For international companies, they gain access to new markets and a potentially large increase in scale, while domestic firms benefit from access to new technology and particular expertise."

<sup>18</sup> Mergermarket, *M&A News, Data & Trends*, <http://www.mergermarket.com/home.asp>.

# The future of the industry in China



**“**As an industry, we have invested heavily in China. The question now is: how can we continue to drive value for all our stakeholders? **”**

**- Wei Jiang,  
executive vice president,  
commercial operations & APAC  
region managing director,  
Bayer Pharmaceuticals China**

## Regulatory compliance

Since President Xi Jinping launched his anti-corruption campaign in 2012, compliance has become an important area of focus for pharmaceutical companies operating in China. “This isn’t just a passing phase. It’s the new normal,” said AbbVie’s Au. “Many companies, not just those in the life sciences sector, are trying to make sure that their business operations are properly aligned with the government’s view of this subject.”

Over the past several years, companies have continuously improved their compliance strategies to minimise risk. More mature record-keeping systems have evolved, which provide greater transparency into supply chains and distribution networks. Given that many companies work with hundreds of distributors and thousands of representatives, manual systems are less effective at scale. Life sciences companies are increasingly adopting analytics tools that combine analysis of risk indicators such as individual representatives with other data sources in order to generate profiles of their distributor populations. This allows companies to monitor compliance more thoroughly than ever before.

With the right processes and systems in place, companies are also able to track expenses and other forms of expenditure more closely, reducing the risk of employee or third-party fraud. Roche, for example, pays car hire firms directly through mobile phone apps such as taxi and private car ordering services. Other companies are investigating ways of applying predictive analytics, which can be used to pre-empt non-compliant behaviour.

Companies are also aware that working closely with officials allows both to gain a better understanding of each other’s needs, particularly with regards to tax auditing and transfer pricing matters (see box).



## Transfer pricing

With multinational pharmaceutical companies often opting to import large quantities of drugs for packaging in China, tax officials in the mainland are becoming more knowledgeable about the business operations of these companies and transfer pricing has emerged as a major tax issue.

“The tax challenge for pharmaceutical companies is how to balance the requirements of different government agencies,” said Grace Xie, a tax partner in the Life Sciences group at KPMG China in Shanghai. “Even though the NDRC is seeking to bring down the price of many different medicines significantly, tax officials still expect pharmaceutical companies’ profits to rise, while customs authorities want to know if the price of any imported drug or active pharmaceutical ingredient varies by 5 percent or more. Managing these different expectations can be a difficult balance.”

According to Sanofi’s Pointeau, more communication with authorities and stakeholders is needed to support the sustainability of China’s pharmaceutical markets as well as to improve the quality of care for 1.4 billion Chinese people.

**“** We urge the government to think about how to leverage funding to foster the connection between researchers, industry and the needs of the patients so that innovative solutions can truly impact society. **”**

**- Dong Wu, head, Johnson & Johnson Innovation, Asia Pacific Innovation Center**

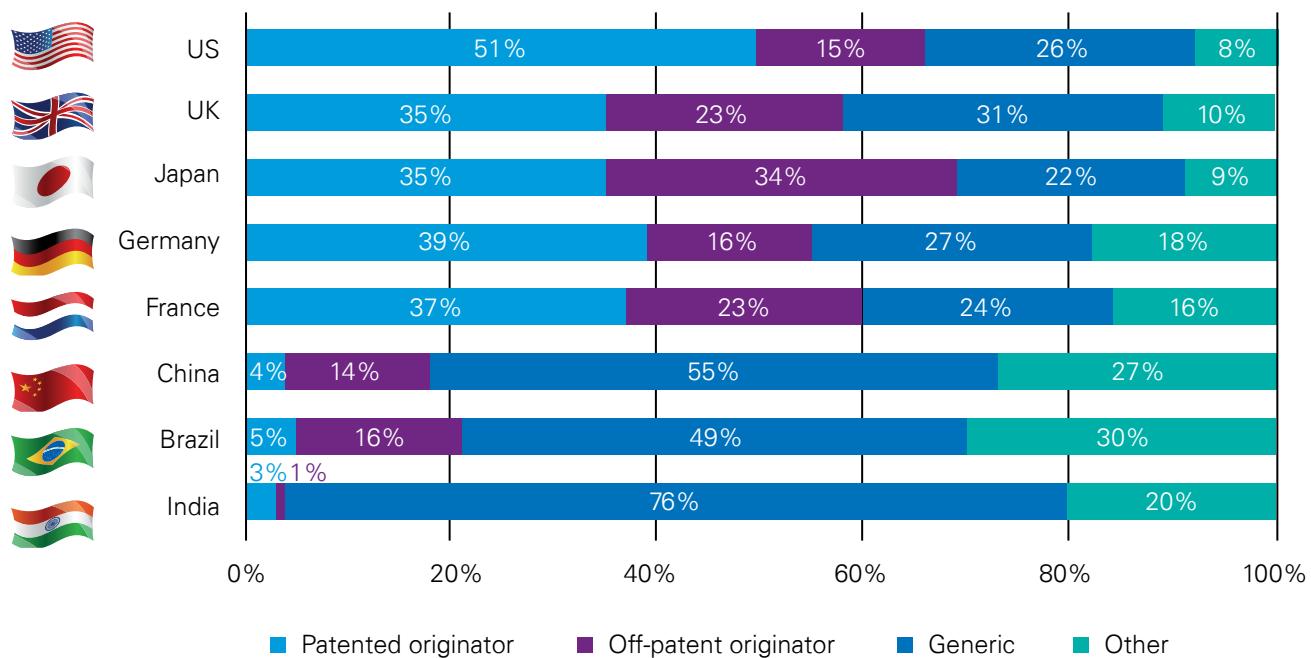
## Local innovation

Higher costs and thinner margins are encouraging domestic companies to focus their attention on raising the standard of their products and introducing more innovative processes. Before this happens, domestic firms have to overcome various obstacles including the lack of available talent in China's life sciences industry and the country's cumbersome approval process for new drugs. There are indications though that things are starting to change.

“There are signs that officials are accelerating the approval process. With the support of the government and a large number of returnees entering the talent market, many existing bottlenecks are being eased,” said Philip Cui, vice president, Fosun Pharma, the pharmaceuticals arm of the Shanghai-headquartered conglomerate Fosun Group. “Only by launching new products can pharmaceutical enterprises expect to maintain and improve their profits.”

Johnson & Johnson has invested in improving its product and service offering in China. The company launched its Asia Pacific Innovation Center in Shanghai in 2014 with the aim of finding new products and innovative practices at the earliest stage possible. “China's population is ageing like nowhere else other than Japan,” said Dong Wu, head, Johnson & Johnson Innovation, Asia Pacific Innovation Center. “The burden will be enormous so we need disruptive solutions for this. Nothing conventional will do.”

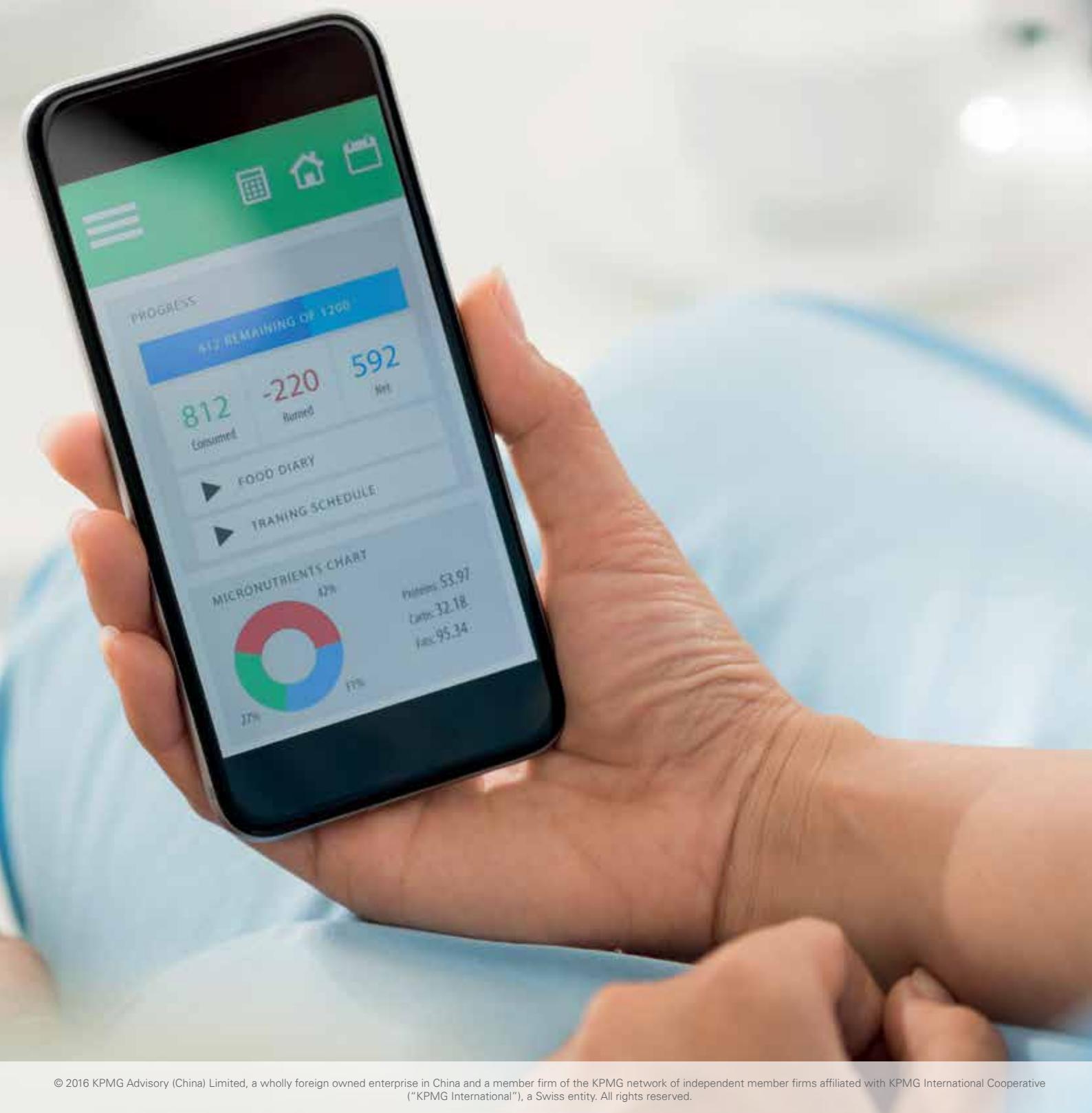
## Origin of drugs by share of sales, 2014



\* Includes OTC products and traditional Chinese medicines

Source: IMS<sup>19</sup>

19 Joseph Cho, *The Pathway for Developing An [sic] Sound Ecosystem for Drug Innovation in China*.



Traditionally, innovative drugs are launched in the United States or Europe first, due in part to the opportunity of much higher revenues. For China, this means that patient access to innovative drugs is typically years behind other markets. However, the number of scientists returning to China having been educated overseas has grown dramatically in recent years and they are seeking to make China an R&D hub for the life sciences. Many estimates suggest that there are several thousand start-ups in China launched by life sciences graduates educated overseas. "These are people who have trained for ten to fifteen years in the United States," said Wu. "They are bringing back the latest knowledge. This is where we see entrepreneurship happening." He added: "the Asia Pacific Innovation Center helps find seeds of innovation. As companies mature, we help them produce a plan to bring out their commercial potential at the earliest stage possible, opening the way for money and support."

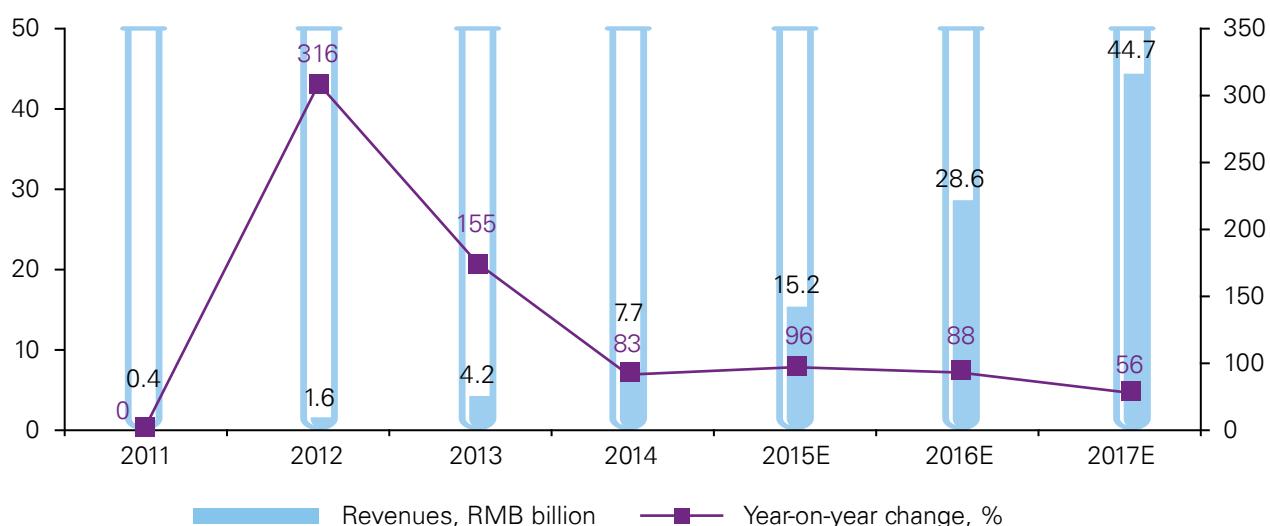
Roche is also looking to grow its R&D capabilities in China. "We will continue to invest in China and we have a long-term commitment to bring innovative medicines to Chinese patients," said Roche's Chow. At the end of 2015, Roche started construction on the Roche Innovation Center following an initial investment of RMB 860 million. The company hopes the new centre will allow for collaboration with local research institutions and attract top research talent to China. "Our aim is to develop outstanding innovative drugs for patients in Asia and around the world to address unmet medical needs and enhance our long-term commitment to R&D in China," said Hong.

## Digital healthcare

Many venture capital firms are investing heavily in China's digital healthcare sector by providing funding for new start-ups. "The eco-system is at a very early stage but it's growing rapidly," said Johnson & Johnson's Wu. "There is a gap with other countries but it's closing very quickly and we're seeing a tremendous entrepreneurial surge."

## China's online pharmacy B2C market

### Revenues, 2011-2017E



Source: Nicholas Hall DB6 Global OTC Database/James Shen, Contemporary Trends and Outlook of the Chinese Pharma Industry and Market<sup>20</sup>

20 James Shen, *Contemporary Trends and Outlook of the Chinese Pharma Industry and Market 2015/2016*, p. 13.

While many of these start-ups have emerged to fill a void that is not currently being met, a lot of established companies from other sectors of the economy have also begun to take an interest in healthcare and life sciences. The services provided by these companies include booking appointments online, online diagnostics tools and prescription drugs distribution. "These companies are very ambitious," said Andy Qiu, a deal advisory partner at KPMG China in Shanghai. "They want to totally replace hospitals even though this is not necessarily straightforward. Online diagnostics is not easy, patient follow-up is difficult and delivering medicines to patients outside of hospital channels can be challenging."



## Apricot Forest – mobile apps for doctors

There are approximately 2.9 million doctors in China as of 2014, a small number given the size of the country's population and this inevitably places a strain on the country's medical services.<sup>21</sup> Zhang Yusheng, a former doctor, founded Apricot Forest in 2012 to tackle this problem. The company supplies several free mobile apps, which help doctors review patient information remotely, obtain up-to-date information about new products and technologies and access a number of important medical journals.

Zhang said that 30 percent of doctors in China have already downloaded his apps and the number of users is growing at a rate of 1,000 per day. "Our business is focused on the physicians and is designed to be easy to use and to encourage collaboration between different practitioners," he said. Investors have so far committed USD 45 million in funding and the company employs roughly 200 staff, split almost evenly between the marketing and technical teams. Apricot Forest is currently present in more than 20 cities and is hoping to expand its coverage to reach more than half of China's doctors within the next year.



## iGenes – reducing insurance costs

Beyond being a source of new medicines and treatments, China is also known for pioneering new healthcare technologies that not only benefit patients but also help insurers and governments reduce their costs. Hong Kong based Prenetics has developed iGenes, a non-invasive test that allows doctors to prescribe the most effective dosages for a range of medications based on a patient's genetic profile. This type of precision medicine can also mitigate potentially dangerous drug reactions, which is a major issue in China and results in 190,000 deaths annually.<sup>22</sup>

The scale of this type of challenge is compelling for companies and investors. One large Chinese insurance company has already invested USD 10 million in the company in early 2016. Danny Yeung, Prenetics' CEO, said that the benefits offered by iGenes and other similar products extend beyond saving money on ineffective prescriptions. "We are entering a new era of healthcare, which is personalised, predictive and preventive. China is making the proper investments to be a pioneer in this field," he said.

<sup>21</sup> National Health and Family Planning Commission of the People's Republic of China, *Statistical Communique of the PRC on the 2014 National Development of Health and Family Planning*, <http://www.nhfpcc.gov.cn/guihuaxxs/s10742/201511/191ab1d8c5f240e8b2f5c81524e80f19.shtml>

<sup>22</sup> Katriina Aalto-Setala, A Systematically Combined Genotype and Functional Combination Analysis of CYP2E1, CYP2D6, CYP2C9, CYP2C19 in Different Geographic Areas of Mainland China – A Basis for Personalized Therapy, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3788764/>.

# Conclusion



China's government has set itself the ambitious target of providing affordable and effective healthcare for all its citizens, while at the same time fostering the development of the country's domestic life sciences industry so that it is capable of delivering high quality products and services. Over the next few years, the government is expected to continue with its programme of reforms to help achieve these goals. These reforms will centre on reducing the price of drugs, accelerating the approval process for new drugs, channelling more funding into R&D and allowing market forces to play a greater role in determining prices.

During our interviews, KPMG China heard repeatedly that the long-term prospects for China's life sciences sector are strong but exactly when growth will return is not as clear. "In the long-term, we believe the industry will grow in the right direction to become more robust. In the meantime, the impact and duration of the 'growing pains' remains to be seen," said Bayer's Wei.

Some executives believe the slowdown in China's healthcare growth rates will whittle down the competition. "China's pharmaceutical market will look more and more like that of every country. Companies that develop new products will find markets to sell to but those marketing generics will find life harder," said Cardinal Health's Zwisler.

To remain competitive, companies will need to start expanding into new geographies and different market segments, which will inevitably lead to many adopting more flexible operational structures. "You can't use one central strategy for the whole country," said AbbVie's Au. "You now have to deal with all 31 provinces and provincial level entities. With some provinces developing faster than others, all companies need local capabilities to cope with the many differences between them."

Pharmaceutical companies will also need to be sophisticated in managing their relationships with regulators. Those companies manufacturing drugs that meet China's most pressing medical needs will likely find themselves under the most pressure from government to lower prices. For these organisations, increasing volume while keeping costs low will have a higher priority than manufacturers of more niche products whose main focus will likely be finding ways of accelerating the approval process for new medicines.

Navigating this path will likely prove tough for a number of companies, while at the same time greater competition from domestic companies will add to the squeeze on margins. Some opportunities exist for multinationals to collaborate with domestic companies but many remain too risky for many multinational companies that need to maintain their reputation for probity above all else.

Although, China's pharmaceutical sector also presents multinationals with opportunities on a scale they cannot find elsewhere in the world. "I am still optimistic about our growth perspectives," said Roche's Chow. "First of all, market fundamentals such as growing wealth and an aging population are still very strong drivers. Despite all the challenges, companies with innovative portfolios and flexible business models will continue to thrive."

Regardless of many of the issues outlined, executives in the life sciences sector view the long-term trajectory for China as heading in only one direction: upwards.

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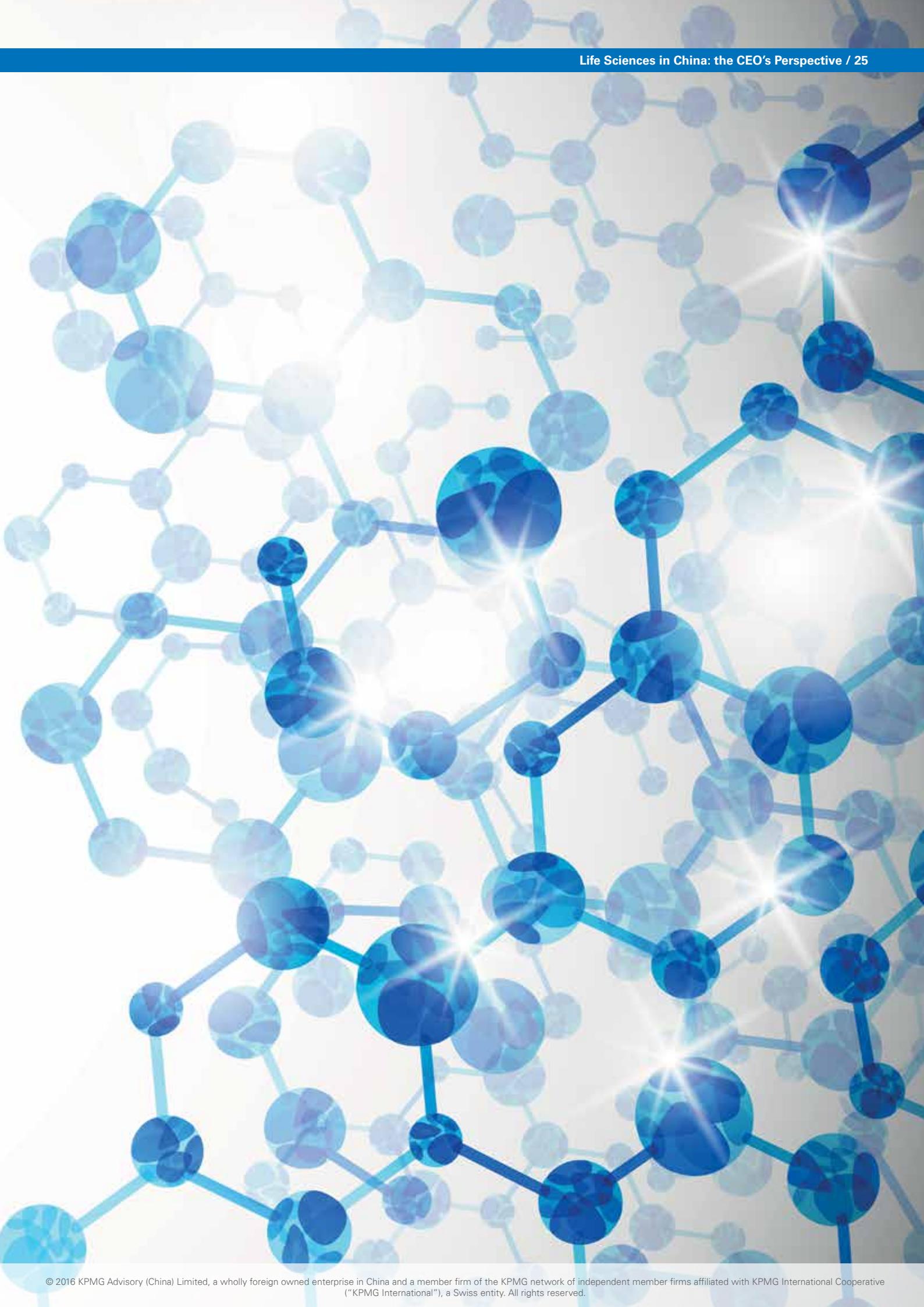
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