New Healthcare Reform in a New Era
Challenges for Multinational Pharmaceutical Companies and Corresponding Countermeasures to be Taken
February 2018
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Introduction

The pharmaceutical industry, is considered by China’s 13th Five Year Plan as a pillar industry that will fuel economic growth in the future, and is expected to maintain medium to high growth rates due to the increasing medical demand. At the same time, with a slower growing domestic economy and deep reforms into China’s social protection system, Beijing has been focused on medical cost control through a policy mix that includes tendering and medical insurance, encouraging the usage of cheaper domestically-produced drugs over higher priced imported ones. As a result, multinational pharmaceutical companies (MPCs) will face a more challenging environment going forward, as described in greater detail hereafter.
Growth of MPCs’ sales in China has slowed down

MPCs have experienced a less robust sales growth in China. According to data from QuintilesIMS, the total sales volume of MPCs from hospitals (with more than 100 beds) grew at the rate of 8.5% in 2016, while the growth rates in 2012 and 2013 were 11.5% and 12.2% respectively. Furthermore, only three MPCs performed better than the average growth rate of all the domestic and multinational companies (8.1%) in 2016.

Pharmaceutical sales in Chinese hospital market and top 20 players in 2016

The decreasing growth rate of MPCs’ sales is closely related to China’s healthcare reform focused on cost control. Currently, China’s basic healthcare insurance system covers more than 95% of the total population. Furthermore, China’s health expenditure represents 5.9% of GDP, with a growth rate exceeding the one of the economy. The rapidly rising health expenditure has put pressure on the healthcare insurance fund, resulting in a policy focus of the current healthcare reform on cost control. The priority measures taken by the Chinese government include: adopting a series of policies to control drug prices, reducing hospitals’ reliance on drug sales as well as imposing more rigorous compliance requirements on the entire healthcare industry.
Rapidly rising health expenditure has put pressure on healthcare insurance fund

**The growth rate of health expenditure has exceeded the one of GDP**

**Increasing income and expenditure of basic healthcare insurance fund in urban areas**


Brand-Name Drugs have lost the advantage of high premium

MPCs’ profits are mainly generated by their brand-name drugs (i.e. imported drugs whose patent protection periods in many cases have actually expired), which are being sold at premium prices. The Chinese government introduced several measures, trying to reduce drug prices and resulting in downward pressure on brand-name drugs’ profit margins.

In the second half of 2015, increased pressure on the “price ceiling” at the bidding stage, forced most MPCs to substantially lower their prices. At the same time, since most provincial biddings referred to the national minimum-winning bid, companies hesitated to adopt low-price strategies. If a negotiated price was too low, pharmaceutical companies would be forced to abandon the bidding in order to secure their bids in other provinces. In 2015, during Hunan’s centralized procurement for drugs, the overall bid price dropped significantly, achieving a maximum price reduction of 50% after two bidding rounds and consequently forcing Bayer, AstraZeneca and other MPCs to abandon their bids.

Moreover, the government has launched an evaluation of generic drugs’ consistency. Generic drugs that have passed the evaluation can theoretically take part in the bidding process alongside brand-name drugs, resulting in further downside pressure on brand-name drugs’ profit margins.

Over the past ten years, brand-name drugs experienced rapid growth, partly owing to a favorable government policy. However, decreasing drug prices and strict regulations will make it difficult for brand-name drugs to maintain the high premium – requiring a change of MPCs’ traditional, brand oriented business model.
In addition to a centralized procurement process, the government has organized national price negotiations with regard to certain brand-name drugs. In May 2016, the National Health and Family Planning Commission announced the results of the first series of national drug price negotiations, resulting into prices reduction for products such as Tenofovir Disoproxil, Ektinib and Gefitinib (see graph).

However, during the implementation process, achieving a “trade price for market” turned out to be easier said than done. As of December 23, 2016, only 23 provinces had included the negotiated drugs in the coverage of the healthcare insurance system. Different management structures over the healthcare insurance system make it difficult to achieve agreement over drug price negotiations and health insurance. While the National Health and Family Planning Commission leads the drug price negotiations, it is up to the Ministry of Human Resources and Social Security to decide if the drugs can be included in the healthcare insurance system. Furthermore, the fundraising capacity varies from province to province. However, for MPCs to accept a considerable cut in their profit margin, an inclusion of their negotiated drugs in the healthcare insurance system is key, allowing an increase in sales that can potentially compensate the effects of the price reduction.

### Results of National Drug Price Negotiations in 2015

<table>
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<tr>
<th>Drug</th>
<th>Before Negotiation</th>
<th>After Negotiation</th>
</tr>
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<tbody>
<tr>
<td>Tenofovir Disoproxil</td>
<td></td>
<td>67%</td>
</tr>
<tr>
<td>Ektinib</td>
<td></td>
<td>54%</td>
</tr>
<tr>
<td>Gefitinib</td>
<td></td>
<td>55%</td>
</tr>
</tbody>
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Data: National Health and Family Planning Commission, Deloitte Analysis

"Trade price for market" negotiations have failed to achieve desired results.
New Healthcare Reform in a New Era
Looming trend towards replacement of imported drugs with home-made drugs

Against the background of stricter cost controls, many regions are encouraging the use of less expensive domestically produced generic drugs over imported brand-name and generic drugs.

Furthermore, two major measures were implemented to reduce hospital prescriptions of expensive brand-name medicine, which had resulted from a malfunctioning incentive mechanism for medical institutions. In May 2015, the Government published the “Guiding Opinions on Urban Public Hospital Comprehensive Reform Pilot”, with the aim to lower the percentage of medicine sales in revenues of pilot public city-level hospitals to around 30% by 2017. This measure will have a significant impact on sales of imported drugs that are sold at premium prices.

On the other hand, the scope of the implemented reform of the payment method, i.e. payment according to DRGs (Diagnosis Related Groups), is expanding. The payment according to DRGs, as a method of payment in advance, is more efficient in controlling healthcare insurance costs – compared to the original method of payment in arrears, such as payment according to projects. This new payment method will effectively restrain hospitals from prescribing more expensive medicine, thus encouraging medical institutions to use domestic products with similar curative effects but lower prices.

All these abovementioned measures are likely to restrict hospitals’ use of expensive brand-name drugs and drive doctors to domestic generic drugs that are more cost-effective. However, price considerations are not the only matter related to generic drugs, since assuring drug quality is crucial. Therefore, the Chinese government is taking multi-pronged approaches to enhance the competitiveness of domestic pharmaceutical companies as well as to improve the quality of domestically produced generic drugs by adopting consistency evaluation and a new edition of GMP (Good Manufacturing Practice). Thus, the quality difference between products of domestic pharmaceutical companies and those of MPCs will gradually be reduced.
Operating pressure pushes pharmaceutical companies to adjust their business arrangements

The main focus of the healthcare reform is price reduction. Therefore, MPCs are facing a challenging environment, potentially slowing down future growth. As a result of a series of government policies, including strict regulation of drug prices and cancellation of drug mark-up policy, MPCs’ drug prices have significantly decreased and their market share has also declined. Due to the high cost structure of MPCs, keeping all low-profit projects is not suitable anymore. One of the responses to the government policies, a few MPCs have started to review their current product portfolio, reinforcing and strengthening competitive products while selling or reducing weaker internal product lines. For instance, Bristol-Myers Squibb – under its mature product life cycle management strategy – has successively divested its diabetes, tumor and cardiovascular departments, using a cost control approach to increase its profits. Furthermore, Bristol-Myers Squibb has shifted its focus to biological and innovative medicines.

Bristol-Myers Squibb adjusted its business layout in 2016

- Laid off both Taxol and Paraplatin product groups within tumour department
- Abandoned diabetes market, transferred Glucophage to product co-promoter Merck
- Transferred the HIV drug R&D line to Viiv Healthcare
- Abandoned cardiovascular department
- Laid off the entire OTC business in China, ceased all marketing for OTC products

Data: Public Information, Deloitte Analysis
## Overview of MPCs’ transfers of business to domestic pharmaceutical companies in 2016

Such strategic resetting of product portfolios, and allocation of internal resources, is demonstrated through certain transfers or collaboration models with domestic companies initiated by MPCs in 2016.

Finally compliance focus, increased by stronger regulation has also put pressure on MPCs same as their domestic counterparts. More recent marketing compliance issues, such as those reported by a CCTV report on Chinese doctors receiving kickbacks, broadcasted in December 2016 – have led to tighter regulation. Thus, compliance and business risk management in the healthcare sector will remain a major focus.

Under this context, many pharmaceutical companies have begun to readjust their marketing strategy. Steering away from their past relationship marketing, MPCs introduce the functioning, use and effects of their drugs during professional academic forums and seminars and conduct interactive information exchange with doctors via digital platforms. These marketing methods do not only help to strengthen compliance, but can also reduce costs. Moreover, pharmaceutical companies have implemented a series of compliance measures on drugs marketing, such as: reducing sales expenses, optimizing marketing-related systems and procedures for reimbursement and conferences, and adopting more precise cost control methods in order to lower catering, transportation and administrative costs.

<table>
<thead>
<tr>
<th>Date</th>
<th>Multinational Pharmaceutical Companies</th>
<th>Transferring Business</th>
<th>Domestic Pharmaceutical Companies</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 2016</td>
<td><em>Bayer</em></td>
<td>Commercial operating rights of White&amp;Black, Canesten, Mycospor, Redoxon and Saridon in China</td>
<td><em>SPH</em></td>
</tr>
<tr>
<td>March 2016</td>
<td><em>AstraZeneca</em></td>
<td>Right to sell Plendil in China, global asset (besides US) of Imdur</td>
<td><em>CMS</em></td>
</tr>
<tr>
<td>May 2016</td>
<td><em>Novartis</em></td>
<td>Injections and sprays of Miacalcic</td>
<td><em>N</em></td>
</tr>
<tr>
<td>July 2016</td>
<td><em>gsk</em></td>
<td>Full ownership of Nanjing MeiRui Pharma, including the manufacturing site at Nanjing and its urology products</td>
<td><em>Trade Star</em></td>
</tr>
<tr>
<td>October 2016</td>
<td><em>AstraZeneca</em></td>
<td>Commercial license of Byetta and Bydureon in China</td>
<td><em>SanPharm</em></td>
</tr>
<tr>
<td>November 2016</td>
<td><em>Lilly</em></td>
<td>Rights to sell Ceflor and Vancocin</td>
<td><em>EDDING</em></td>
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Data: Public Information, Deloitte Analysis
A strategic transition has become essential

The new round of healthcare reform is a multi-dimensional reform. MPCs that hold on to their past development model will inevitably suffer a decelerated future growth. To counter this scenario, a readjusted suitable marketing strategy is crucial.

How can MPCs succeed under the new circumstances in China?

Conducting localized production and R&D

China’s pharmaceutical market, maintaining double-digit growth rates is obviously considered very attractive among MPCs. Moreover, MPCs’ future growth goes hand in hand with their business arrangements in China. In order to reduce production costs, better serve China’s market demand, and reduce the time to market for new medicines, MPCs are considering more often to switch from an import-oriented to a local-oriented business model.

Localizing brand-name drugs production brings further advantages, such as an increased reaction time to local markets, the possibility to win over favorable bidding policies, and the opportunity to develop and expand local markets.

Then, quite a few MPCs have also established wide ranging and sophisticated research centers in China, such as Novo Nordisk, Roche, Pfizer, Johnson & Johnson, AstraZeneca, and GlaxoSmithKline.
As the Chinese government continuously publishes new price reduction policies, MPCs may lower costs by localizing production. While China is losing its cheap labor advantage, in many industrial parks, local governments have launched policies to attract investments, including preferential taxes, rent, financing, etc.

Furthermore, due to differences of ethnicity and disease spectrum, developing new drugs specifically for the Chinese market becomes increasingly crucial. In the past, research centers in China were restricted solely to assisting tasks for research centers abroad, conducting clinical trials and making new drug applications. As China’s market grows rapidly, this situation is changing. Also conducting R&D in China helps accelerating the launch process of new drugs in China and at the same time extends the earning cycle of a drug. So far, China’s contribution of new drug launches has been relatively low, compared to other countries, see figure below. According to China’s existing drug approval regulations, for a foreign new drug to be licensed in China, clinical trials need to be re-conducted, which takes at least 3 to 5 years, deferring the treatment of patience over a long period of time. However, according to the reform of the drug approval process published by the Chinese government in February 2016, applications for innovative drugs that have not been sold in or out of China or whose production has been moved to China can be examined and approved as priorities. Thus, conducting R&D in China helps accelerating the launch process of new drugs in China and at the same time extends the earning cycle of a drug.

### MPCs increased investments in local R&D in 2016

<table>
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<tr>
<th>Date</th>
<th>MPCs</th>
<th>Investment in R&amp;D</th>
<th>Investment Amount</th>
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<tbody>
<tr>
<td>March 2016</td>
<td>GSK</td>
<td>Announced it will form a new public health institute in Beijing - Help China tackle the health threats posed by antibiotic resistance and infectious diseases.</td>
<td>Over 20 million GBP (plan)</td>
</tr>
<tr>
<td>April 2016</td>
<td>AstraZeneca</td>
<td>Establish development and launch facility and the China Commercial Innovation Center (CCIC) in Wuxi - Support the development and manufacture of innovative small molecules, the CCIC is expected to attract more cross-border partners to carry out the AstraZeneca’s 3-D strategy (Diagnostics, Device and Digital)</td>
<td>50 million USD</td>
</tr>
<tr>
<td>June 2016</td>
<td>Novartis</td>
<td>The Biomedical Research &amp; Development center in Shanghai became fully operational – New medicine research focuses on diseases with high incidence rate in China and Asian region, including cancer and liver diseases</td>
<td>1 billion USD</td>
</tr>
<tr>
<td>June 2016</td>
<td>Pfizer</td>
<td>Will establish a Global Biotechnology Center in Hangzhou – Localized Biopharmaceutical base integrating development and manufacture, with focus on cancer-related biological medicines</td>
<td>0.35 billion USD</td>
</tr>
</tbody>
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Data: Public Information, fDi Markets, Deloitte Analysis
Some MPCs, rather than establishing their own local research centers, are making use of local talents by cooperating with local pharmaceutical companies. For instance, innovative and research-driven local companies may take over MPCs’ early-stage projects and conduct further localized development, tailored to the needs of Chinese patients.

There was a wave of Sino-foreign joint ventures in 2012, e.g. Merch joined force with Simcere Pharmaceutical, and Pfizer teamed up with Hisun Pharmaceutical. However, it seems that this round of joint ventures has ended in failure, showing that – after a trial for more than three decades – the business model of establishing joint ventures still needs further exploration and adjustments.

**Proportion of global innovative drugs’ first launched markets (2007-2015)**

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**Medicine market arrangement at the grassroots level**

In recent years, government’s support and investment led to abundant opportunities in county- and community-level hospitals and other grassroots markets. According to data from QuintilesIMS, the grassroots pharmaceutical market has great development potential, as the drug sales in community hospitals will rise rapidly at the rate of 18%, with a growth rate higher than at 2nd and 3rd -class hospitals. With the implementation of hierarchical diagnosis and treatment, the integration of new rural cooperative medical systems with urban resident basic health insurances, and stricter cost control policies implemented by major hospitals, a move of the medicine market towards the grassroots level is inevitable.

Under this context, MPCs may consider arranging their business towards the grassroots, including county-level hospitals, community health service centers and retail outlets. So far, quite a few pharmaceutical companies have already made their moves. In 2011, Sanofi took the lead and established the Primary Care Business Unit to reach out to China’s county-level markets. Its product arrangement included diabetes, cardiovascular, central nervous system and tumor products, – thus, products with a strong demand in grassroots markets. Moreover, Sanofi’s grassroots market coverage is part of its annual strategic priority in 2016, and it is planning to expand more community medical centers and retail pharmacy businesses. Furthermore, in order to expand market channels, companies like Merck and Pfizer have also increased their investment in retail pharmacy.
However, it is worth noting that due to regional and demographic factors, the county-level markets face a low ratio of market investment to medicine sales volume – an issue that MPCs need to overcome. Moreover, since mainly domestic pharmaceutical companies, whose medicine structure primarily focuses on essential medicines, dominate the grassroots markets, opportunities also exist for MPCs, adopting new strategies to face the high-volume but low-margin bottom markets.

**China's pharmaceutical sales by terminal**

Data: QuintilesIMS, Deloitte Research
In this regard, MPCs need to have an overall understanding of the particularity of each market, when choosing their targets. They may prioritize grassroots markets with a more advanced economy, higher population density, and better development potentials. Moreover, an adjustment of the marketing model is to be considered: instead of solely relying on sales representatives visiting clients, companies may apply more effective and economic methods, especially considering the fact that doctors in grassroots markets need more education on diseases and products as well as scientific dialogues and information about the curative and cost effects of the products.

Thus, pharmaceutical companies need to enhance their marketing personnel training, turning them into sales representatives covering the entire product catalog. At the same time, they may use digital channels, medical personnel, interactive seminars and trainings to encourage doctors to participate in conversations about topics they are most interested in.

### Exploring new business models and overall solutions

With patients focusing strictly on curative effects of the drugs, MPCs may explore new business models, providing overall health solutions for patients. Such new business model should allow MPCs to differentiate themselves from competitors, ensuring consumer stickiness and enabling growth in the long term. In foreign mature markets (such as the U.S.) such attempts have already been explored. Pharmaceutical companies have launched user-based mobile medical devices, improving patient medication adherence and participation. For instance, Johnson & Johnson gathered comprehensive user data by upgrading their devices; Sanofi and GlaxoSmithKline launched products that target specific diseases and used them to follow the entire progression of the targeted diseases.

Among various new business models, many MPCs applied the so-called "Internet+" model.

As the Internet medical wave is spreading across the world, "Internet+" brings various advantages to MPCs, including information dissemination among doctors – offsetting the weakness of marketing coverage –, improved communication between doctors and patients, as well as the implementation of disease management platforms to increase patient stickiness.
Additionally, collaborations with insurance companies are becoming increasingly significant. In 2012, Roche and Swiss Reinsurance Company collaborated with five Chinese insurance companies on promoting cancer insurance in China. This collaboration project allows Roche to lower drug prices for insured patients, and thus to increase drug sales volume; in return, Roche can provide cancer statistics to insurance companies allowing them to design better insurance products based on treatment risk and cost calculation. On the one hand, collaborations give pharmaceutical companies the opportunity to expand their sales and even production chains. On the other hand, insurance companies may obtain more comprehensive data to manage their product risks. Thus, collaborations have great commercial potential, especially in the field of chronic disease management.
As the healthcare reform progresses, MPCs are facing an increasingly challenging environment. Strict regulations of the entire medicine industry, with a focus on cost control and compliance are key components of the health care reform and put considerable pressure on MPCs’ profit rates. More precisely, cost control measures, including a capped total healthcare insurance expenditure, controlled drug sales proportion and a strict centralized procurement policy, will make it more and more difficult for MPCs to keep their overall margin at the current level.

Still, with the healthcare reform, MPCs will also benefit from a more standardized industry environment. For instance, compliant MPCs with a self-managed sales team benefit from the implementation of a two-invoice system, since it restrains certain domestic generic drug manufacturers from conducting rebate sales. Furthermore, the inelastic market demand caused by an ageing society and urbanization will stimulate the industry, and the multi-dimensional policies will ensure a healthy growth of the market.

Yet, there is room for MPCs to grow in China’s market. A market with the greatest growth potential in the world, and perhaps the biggest market that is yet to be developed. Hence, despite the pressure caused by the healthcare reform, MPCs have plenty of room to develop their business in China. If MPCs achieve to adapt to China’s policies and market trends and reconstruct their strategies accordingly, they will still be able to seize market opportunities and develop new competitive advantages. Conducting localized production and R&D and developing business in the grassroots medicine markets will help MPCs to lower costs, better serve Chinese patients’ needs and increase their market share. Furthermore, collaboration with other related industries at a deeper level will help MPCs to establish an ecosystem and product chains – and to finally achieve a successful transition in China’s reforming medicine market.

Conclusion
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