On 3 April the State Council released a new guideline on research, development and adaptation of generic medicine as part of China’s healthcare system. Through ensuring the efficacy of domestically produced generic drugs, the reform aims to increase the quality of care and reduce the financial burden for patients. It is also expected to trigger consolidation in the industry that will ultimately raise profitability and promote research and innovation in the industry.

Leadership pledges reform on generics supply and distribution

On 3 April the State Council released a new update on adopting more widespread use of generics in China’s healthcare system. Titled “Opinions regarding reforming and perfecting policies in the supply and usage of generic drugs”, it highlighted fifteen deliverables to cut health care cost, meet public demand, and build a “healthy China”, the announcement reinforces the commitment to ensure the supply and distribution of high quality generic drugs, especially for the treatment of major contagious diseases, pediatric diseases, rare diseases, and public health outbreaks.

This is the latest supportive guideline to compliment the progress in China’s pharmaceutical sector reform to-date. The industry-wide overhaul of generic drug quality formally began two years ago, when the State Council announced the “Opinion on Conducting Consistency Evaluations of the Quality and Efficacy of Generic Drugs”, as part of Healthy China 2030 initiative which aims at raising the overall quality of China’s healthcare.

In fact, drug approval was specifically delegated to a new administration during the recent State Council structure reshuffle in March for more focused management, as the former China Food and Drug Administration (CFDA) is no longer a standalone agency. In our view, the latest updates indicates that reform on the pharmaceutical industry is going to fast-track in 2018.

Lackluster standard of generic drugs in the past

The Opinion in 2016 set forth retroactive requirements for generic consistency evaluations (GCE) on all oral solid preparations of generic drugs on the National Essential Drugs List (2012) approved before 1 October 2007. Before 2007, generic drugs only needed to show conformity with a "national standard" that was set with reference to the main chemical compositions of similar generic drugs. Significant discrepancies in approval requirements were also found across provinces.

As a result, as many as 95% of the generic drug approvals currently on the register of the former CFDA were approved before a government-led market consolidation in 2007. Despite being the world’s second largest manufacturer, with the obsolete standard, preference for generic drugs remains low among China’s healthcare practitioners and patients. According to a survey by Ding Xiang Yuan², an industry website, 87.5% of 2,185 healthcare professionals believe imported branded drugs are significantly superior in quality and safety compared to domestic generics.

Reliance on generic drugs is high in China despite low preference by healthcare practitioners

In most international markets, branded drugs suffer revenue loss due to price erosion or reduction of market share when a patent expires, due to competition from generics. However, a similar phenomenon, dubbed the "patent cliff", was found to be significantly less distinct in China³. The main reason for the difference is that off-patent branded drugs continue to be shielded from direct generic competition due to hospital procurement’s preference for branded drugs.

In its official explanatory document, the CFDA described GCE as crucial to "remedying the past" to fill in the quality gap between generic drugs and branded drugs. Specifically, the 2016 Opinion requires the generic drug to be evaluated against a reference product that is either the original branded drug or a generic import recognized by authorities in the Eurozone, US or Japan if the original was no longer available.

Raising the bar for efficacy evaluation

The bulk of essential drugs to complete evaluation in 2018

Under the proposed timeframe, 289 types of oral solid dosage drugs on the National Essential Drugs List approved before 1 October 2007 should complete the evaluation by end-2018, with delays allowed only for cases where clinical trials are necessary. For other generic drugs (around 2,700 types), the Opinion requires that after the first manufacturer completes GCE, other manufacturers of the same drug will have to complete the evaluation within three years. Failure to meet the deadline will lead to the revocation of registration. In this sense, the GCE process becomes a race among the generic pharmaceutical companies in China.

The first batch of generic drugs approved for GCE was released by the CFDA on 29 December 2017. Among the 24 types of drugs approved so far, only six belong to the National Essential Drugs List. In order to facilitate the process, the CFDA also simplified the clinical evaluation process, allowing more medical facilities to carry out the evaluation, but pharmaceutical companies will be held liable for any falsification on record. With most applications estimated to require around 7-10 months to prepare bioequivalence data before submission, the applications for GCE will surge in 2018 and beyond.

BE study data suggests that GCE application to surge in the coming months

![Bioequivalence tests chart]

Source: CFDA

Closer substitutes to branded medicine

With critical evaluation, China’s generic medicine could become a closer substitute to branded medicine, possibly at a fraction of the cost. It will also help to drive more significant price cuts for branded drugs when patents expire. To facilitate the substitution process, the name of drugs that have passed the GCE are posted on the CFDA website, and manufacturers can also put a special label on the packaging of the medicine.

The state-funded health insurance will also give preferential treatment to GCE-approved generic medicine, by putting them on equal ground as branded drugs. Except in special circumstances, physicians will not be allowed to write brand names on prescriptions, and even if they do, pharmacists will have the right to change to qualified generics. Additionally, the State Council announced that if more than three manufacturers are able to pass the evaluation, the remaining manufacturers will no longer be considered in centralized hospital medicine procurement.
An important step in China’s healthcare reform

In our view, improving the quality of domestically-produced generic drugs is a critical component in China’s healthcare reform. It also has significant implications on technology upgrades in China’s industries.

Reducing healthcare expenditure

Reform of the pharmaceutical industry constitutes part of the government’s drive to provide universal healthcare access by 2020. Previously, with fees for healthcare services remaining below cost due to government price control, hospitals turned to selling medicine at a significant mark-up and/or prescribing unnecessary medicine to subsidize their operations. In 2015, medicine fees accounted for 48.3% and 36.0% of total healthcare spending for out-patient and in-patient care respectively.

Drug sales constitute a significant share of hospital revenue

Drug sales

Source: National Health and Family Planning Commission

In order to improve China’s healthcare service, deregulation of fees for medical services began in 2017, when out-patient consultation fees rose by as much as 72.3%YoY at top tier hospitals in urban areas. To keep healthcare affordable to users, the government in turn would have to reduce the cost of medicine, ramp up the coverage of national health insurance, and increase fiscal expenditure to compensate for the shortfall.
In addition, to simplify the supply chain for medicine, the government has also announced plans to launch the “two invoice system” on a national level in 2018. Based on the pilot schemes so far, the policy allows only one layer of distributor between drug manufacturer and hospital. It helps to lower drug prices at user level through bypassing the multi-layered distribution channel that has become a breeding ground for speculation and corruption.

Under the “two invoice system”, we expect pharmaceutical manufacturers to have to expand their own distribution capabilities, with the possibility of more challenges regarding their collectibles. Meanwhile, distributors may either be squeezed out of the market or face pressure to reorganize themselves to become more comprehensive service providers, adopting a logistics distribution enterprise (LDE) model or a contract service organization (CSO) model.

The “two-invoice system” attempts to alleviate end-user drug burden through reduction of distribution cost

Source: EY

Significant increase in fees for healthcare services since 2017

Source: Wind

Consumer price index (CPI)
Steps to promote innovation and research

In the guideline on 3 April, the State Council allowed qualified generic drug makers to be eligible for corporate tax breaks designated for hi-tech companies, at 15% compared to 25% for regular companies. In addition, the regulator will regularly update a list of medicine, such as important drugs that are running scarce, that encourages production of generic versions. The policy also makes clear that China considers compulsory patent licensing a bona fide option during public health emergencies or shortages of key drugs.

Although the market for branded drugs may be increasingly challenged by generic producers, pharmaceutical companies with leading research capabilities are also earmarked for policy support. To balance the interests of patent holders with those of the general public, China will also aim to strengthen enforcement of intellectual property rights and establish “early warning” mechanisms to prevent generic drug producers from infringing patents.

Clinical studies of new drugs, meanwhile, are encouraged by simplified approval procedures and supportive policies for hospital participation. The CFDA also outlined a patent linkage scheme, which requires a generics applicant to make a non-infringement declaration to protect the interest of patent holders. These policies are paramount to the pharmaceutical industry where innovation is taking off, as the number of applications of new domestic drugs entering clinical trials in China has grown from 21 in 2011 to 69 in 2016.

The CFDA also started to accept foreign clinical data for new drug applications from October 2017, if they were consistent with Chinese requirements and accounted for ethnicity differences. Currently, Chinese clinical trials may only begin for a new drug that is at an advanced stage in an overseas trial, a requirement that has created a significant backlog in drug approval. This is expected to accelerate the approval process for foreign medicine in China.

Boosting competitiveness of the pharmaceutical industry

GCE will also help to eliminate excess and obsolete production capacity in the industry. It will likely lead to consolidation in China’s fragmented pharmaceutical industry, which currently consists of over 5,500 domestic businesses with the top 100 comprising just one-third of the market.

Through competition, leading generic manufacturers may enjoy higher profitability that is conducive to more innovative research, which also makes them eligible for incentive funding from the government. All in all, the reform could help trigger the transition of China’s pharmaceutical industry from generic-focused manufacturing to more innovative original research.