

## CHINA PHARMACEUTICAL UPDATE

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While China's economy maintained a healthy growth rate during the Asian Economic Crisis of 1997-1998, the country's transition to a free-market system has exposed and created serious economic problems. Bad government loans have made the bank system unviable, leading to the spiraling decline of the backbone of the economy: State-Owned Enterprises (SOEs). Unemployment has reached record levels both in rural and urban areas. This, along with the income discrepancy between the city and the countryside, has caused widespread, but thus far containable, social unrest. While most outside analysts agree that the Chinese leadership will be able to reform the country's economic structure in the long run, the next 5-10 years will be crucial for the PRC. Despite its systemic problems, however, the country has reportedly maintained steady growth in recent years.

China's new market economy has rendered its previous pharmaceutical laws and regulations obsolete.<sup>1</sup> In order to combat this problem, the Chinese government created the State Drug Administration (SDA) in 1998. The SDA consolidates the functions of several former agencies, streamlining law enforcement and inspection activities, and separating regulatory control from business operations in the pharmaceutical industry. While it is too soon to tell what effect the SDA will have upon the industry, its creation is a sign that the Chinese government is modernizing its approach to government-business relations.

Health care reform has been an important part of China's efforts to wrestle its unwieldy economy. Recent changes have shifted some of the burden off the government, allowing the cost of medical expenses to be shared with employees. A new classification system allows pharmaceutical products to be sold over the counter in drug stores, creating a boom in retail sales – from 5% of the total market a few years ago to 15% today. The pharmaceutical market grew to \$22.5 billion in 1998, with a projected 14% growth rate for 1999. Already twenty of the world's twenty-five multinational pharmaceutical corporations have entered the Chinese market.

The booming pharmaceutical market is not only due to systemic changes and foreign investment, but also in large part to China's unprecedented elderly population. In several of China's larger cities such as Shanghai, Beijing and Tianjin as well as in a number of provinces like Zhejiang, Jiangsu, Shangdong, Hunan, Guangdong, Guagxi and Sichuan, people over the age of 65 make up 7% of the total population. Of all the pharmaceuticals taken in China, over 75% are consumed in cities, with the three largest cities - Beijing, Shanghai and Guangzhou - accounting for approximately 12% of total consumption. China's total population is expected to increase to 1.3 billion by the year 2000, a figure that renders the elderly population a formidable consumer.

## INCREASED DRUG SUPERVISION

The SDA's plans to clean up the national medicine market have been disrupted by increased entry of counterfeit and substandard medicines. A 1998 selective inspection of some major categories of medicines showed that 13% of the products tested failed to satisfy national standards and posed potential threats to the health of the people. The SDA has since ordered stricter legal measures to confront this problem. For example, the SDA will soon begin to penalize the manufacturer of the *Wei Ge Kai Tai* capsule (an anti-impotency drug). These capsules were taken off the shelf in the Chinese pharmaceutical market in April 1999 after a legal dispute with Pfizer, the maker of Viagra, which claimed the rights to the name "Wei Ge." According to authorities, *Wei Ge Kai Tai* is a counterfeit drug that entered China illegally, a violation of the Drug Control Law. So far in 1999, 25 factories have had their production licenses for 19 types of medicines revoked, and 35 companies have been punished for the production of fake medicines.

In August 1999, the SDA issued a request asking its local branches to tighten up the inspection of production facilities and medicine vendors. The majority of current Chinese pharmaceutical production does not meet quality standards, a problem that has not been reduced by previous annual inspections. For example, in Leshan, a small city in Sichuan Province, 1996, 1997 and 1998 inspections discovered 24% of 8,000 batches did not meet industry standards.

Although China approves 800-900 new drugs for further testing each year, the majority of these are not unique and do not present much scientific value. Research and development has not been helped by the tremendous lack of coordination among researchers.<sup>ii</sup> To encourage innovative pharmaceuticals, the government adopted a "closed door" policy during a national pharmaceutical working conference in February 1999. When a new drug has been approved for clinical trials, no similar medicines may be considered for approval.

In addition, the State Administration for the Supervision and Management of Medicine established stricter punishments for drug research, declaration, and registration violations, beginning in September 1999. Violations include: forging or altering research or registration documents; plagiarizing research; providing fake samples; allowing inconsistencies between actual prescription, production technology and application materials; failing to perform human testing; and interfering with the drug evaluation process. The sequence of events following a violation is:

1. Warning;
2. Termination of examination and appraisal;
3. Establishment of bad record;
4. Registration suspended for 3-5 years. For more than one violation, the registration application will be permanently revoked and the guilty party will not

- be granted any applications for the manufacture of new drugs for the next 3 - 5 years;
5. Punishments as provided in the Drug Management Law of the People's Republic of China;
  6. Cancellation of approval document numbers, certificates for new drugs, or corresponding registration numbers.
  7. Criminal punishment by a judiciary body.<sup>iii</sup>

## **GOOD MANUFACTURING PRACTICES (GMP)**

GMP guidelines define standards for the pharmaceutical manufacturing process to reduce the possibility of contamination errors.

The World Health Organization (WHO) initiated the GMP system in the 1960s, and China adopted it in the early 1980s. The Chinese government issued its own GMP standards in 1988, followed with two sets of revisions, the most recent in 1999. Under new GMP management guidelines, pharmaceutical producers must set up special administrative offices to supervise production and product quality. Administrative personnel must be pharmaceutical professions with prior experience, and technicians responsible for quality testing must receive professional training.

The State Administration for the Supervision and Management of Medicine issued the "Quality Control Convention in Drug Production" in September 1999. This convention provides guidelines for various kinds of drug manufacture in keeping with GMP standards. It states provisions concerning drug verification and authentication, including facility and equipment installation, operation, property and products. GMP certification for powder injections, large capacity injections and genetically engineered products will be completed by the end of the year 2000. Enterprises that fail to meet GMP specifications will be restricted or banned from production.<sup>iv</sup>

Difficulty in GMP enforcement has allowed inefficient production and substandard quality to persist in the majority of pharmaceutical factories, despite the government's regulations. Fund shortage, rigid operation mechanisms, and ideological resistance among some producers have contributed to the continuing problem, although local governments are working to initiate change. In Hangzhou, the capital of Zhejiang Province, the municipal Drug Supervision and Management Bureau has aided 18 of the city's 77 pharmaceutical manufacturers to reach GMP standards. Nationally, only 5% of enterprises have received GMP certification.

A shortage of qualified personnel in China's pharmaceutical enterprises further delays national GMP implementation. Substandard companies find a lack of senior managers who are aware of GMP, as well as difficulty in finding well-trained GMP inspectors that are able to give a fair, objective and accurate appraisal of GMP results. Augmenting the problem, companies have discovered some ambiguity in their interpretations of GMP standards issued by the Chinese Ministry of Public Health. The government has

undertaken the slow process of educating these companies, leading to a slight rise in production and quality control levels.<sup>v</sup>

## **PATENTS**

A loophole in China's Intellectual Property (IP) protection allows Chinese drug companies to copy drugs with foreign patents. When foreign pharmaceutical firms apply to the SDA for administrative protection and approval, drug specifics are made available to Chinese companies to discover any overlap with drugs already in the local market.

For example, Eli Lilly and Co.'s Prozac competes against local generic versions, which sell for approximately 40% less than Prozac. When the State Pharmaceutical Administration, SDA's predecessor, did not respond to U.S. government lobbying efforts, Lilly took the matter to court. A lower Chinese court ruled against Lilly, a decision then upheld by the Beijing Intermediate People's Court. Lilly plans to appeal to the Chinese Supreme Court. Most foreign companies, however, are hesitant to fight existing laws, fearing the government may respond by withholding approval for their drugs.<sup>vi</sup>

In May 1999, the SDA began extending patent protection periods for pharmaceutical companies in an attempt to give small-scale producers an incentive to develop new drugs. Of the 1,500 new drugs developed in China in the first half of the 1990s, only 70 met international standards and only two were actually original products with unique chemical structures.

The "Measures Governing the Examination and Approval of New Medicine" have increased the drug patent protection period. Class I drug protection has been extended from 8 years to 12 years; Class II drugs, 6 years to 8 years; Class III drugs, 4 years to 8 years; Class IV drugs, 3 years to 6 years; and Class V drugs' period has been extended by 5 years.

In addition, the new regulations will accelerate new medicine testing procedures, especially for traditional Chinese medicines and medicines for serious illnesses. Innovative companies will receive more support during testing and registration periods.<sup>vii</sup>

## **OVER-THE-COUNTER AND PRESCRIPTION DRUG CLASSIFICATION**

The SDA plans to enforce a regulation on prescription (Rx) and non-prescription (OTC) drug classification, effective January 1, 2000. The new system was created to bring Chinese practices closer to international standards, and to allow the public to make informed consumer choices. In July 1999, the SDA commented that there were several problems with drug labeling in China and that some form of standardization was urgently needed in order to meet the requirements and provisions of formal label management laws. Currently, some of the labels on drugs conceal the batch number

and validity period inside the sealing points or inside the packages. Some drugs have obscure terms of validity and the batch number of some drugs is not consistent with that on the outer packaging. In other cases the required information is altogether absent. Efficient labeling is essential to ensure the quality of pharmaceuticals and the welfare of users. The new Rx and OTC classification system will place even greater pressure on the necessity to provide accurate, clear and informative labeling for all drugs.<sup>viii</sup>

The SDA released the new classification system and an initial list of approved OTC drugs in July 1999, stating that both Rx and OTC medicines may only be produced by licensed enterprises, and every drug must be registered with the SDA. Other regulations concerning Rx and OTC drugs include the following:

- Manufacturers of both Rx and OTC products must be licensed for drug production. All products, regardless of classification, must be approved by the SDA.
- OTC drug labels and instructions must be approved by the SDA, and should be clearly printed on the product's packaging in clear, simple language.
- OTC product logos must be clearly printed on the product's packaging.
- OTC drugs are characterized into Class A and Class B drugs. Vendors require a special license to sell Class A drugs, and those selling Class B drugs need only SDA authorization.
- Prescribed medicines may only be advertised in professional medical journals with the SDA's approval. OTC drugs may be freely advertised in any media and such advertising does not require any approval.<sup>ix</sup>

The SDA plans to release more regulations concerning OTC drug approval and distribution in the near future.<sup>x</sup>

## **INSURANCE AND HEALTHCARE**

Based upon its findings at the November 1998 national work conference on health insurance, the State Council issued its Decision on Basic Health Insurance for City and Town Workers in December 1998. The decision addressed issues relating to group-owned private enterprises and government organizations, but not those of individually owned businesses and township and village enterprises. The document also gives the Ministries of Labor and Social Security, Finance, and Health the responsibility of setting medicine and service limits, determining which diagnostic tests and services will be covered, and selecting hospitals whose services will be eligible for reimbursement.

The government plans to implement this new insurance plan by the end of 1999. The new system requires both employers and employees to contribute to insurance premiums. Under the previous arrangement, employers were required to cover all of their employees' medical expenses. The new system requires employers to contribute an amount equal to 6% of the employee's salary, and employees to contribute 2% of the same figure towards medical expenditures. These percentages may be adjusted in the

future along with economic development. The new system is an attempt to guarantee basic healthcare to all workers.

The new insurance system gives each employee two distinct accounts, a personal account and a social fund account. The personal account will cover small expenditures and outpatient service fees, while the social fund account will cover major medical expenses and hospitalization fees. The social fund account will be limited by an indicated deductible and a payment ceiling.

The new system grants some exceptions. For example, large companies with offices nationwide and those that offer railroads, power, and ocean shipping services will be allowed to pool their own medical funds. In addition, retired veterans who joined the armed forces before 1949 and seriously handicapped veterans will preserve their former coverage. Retirees will not be required to contribute to medical insurance premiums and their out-of-pocket expenditures will be subsidized.

The reforms will also introduce two significant changes for the country's healthcare management system. First, hospitals and pharmacies will separate their management and accounting. Under the old system, every hospital managed its own pharmacy, providing incentives for abuses, such as prescribing unnecessary prescriptions to increase revenue. Secondly, the new plan will use "market competition" to place a reasonable ceiling on pharmaceutical prices. Because medical insurance administrators will select hospitals to join their health plan, hospitals will need to compete for the new insurance groups. Proponents of the new system believe that this will force hospitals to streamline operations, cut costs and dramatically improve their services.<sup>xi</sup>

## PRICING

Cost containment has consistently served as a crucial element in China's healthcare reform program. Drug manufacturers, distributors and hospitals in China have all been criticized for taking advantage of weaknesses within the price control system, leading to unreasonably high pharmaceutical prices.

At the end of 1998, the Chinese government took a variety of measures to better regulate drug cost. These measures were designed to bring some semblance of order to drug pricing in China. In December 1998, China's State Development Planning Commission (SDPC) announced the following measures:

- The SDPC will reduce the cost of medicines that it determines are priced too high. Government-set prices will be reviewed every two years.
- Retail prices must correspond with wholesale prices, i.e. drugs bought at a low price must be sold at a low price.
- Marketing expenses incurred by pharmaceutical manufacturers will be regulated to better determine a reasonable product price.

- Price restrictions will be relaxed to compensate hospitals and other medical service organizations for pharmaceutical sale losses.
- Pharmaceutical manufacturers may give a maximum discount of 5% on wholesale prices. In the current system, doctors receive kickbacks in the form of discounts from the manufacturer in exchange for prescribing its product.

In addition, the SDPC has relaxed profit margin restrictions for some high-tech pharmaceutical companies, to encourage new medicine R&D and technological innovation. These companies are those that meet international quality standards, that have contributed new Chinese medicines, and in a limited number of cases, those whose new medicine protection period has expired.<sup>xii</sup>

## CONCLUSION

China is engaged in a variety of measures to bring its pharmaceutical sector to a level where it can compete effectively in the world market. Regulations taking effect on January 1, 2000 will for the first time draw the dividing line between prescription and non-prescription drugs, a step that will allow consumer choice. Although safety is an important element of the reforms taking place, the main objective is to shift responsibility from the state to the consumer. Additionally, the shift to a more commercial retail pharmaceutical market will create opportunities for drug manufacturers and advertising companies.<sup>xiii</sup>

China's developing economy and higher living standards have made consumers more health conscious. Under these circumstances, pharmaceutical companies must educate prospective consumers and introduce new ideas in order to create a demand for products that previously did not exist. As China's laws are changing, foreign companies can shift their attention from battling red tape and cultivating connections to focusing on market competition and consumer demand.<sup>xiv</sup>

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