

## The Generic Drug Industry In China—An Overview<sup>1</sup>

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### Introduction

Of the 20,000+ drugs that are sold on markets around the world, the 2004 WHO list of drugs that are important in the management of disease that impacts public health amounts to 316. This suggests that there is a great deal of similarity in the drugs that are sold on the market for the treatment of disease. As a consequence the population is repeating similar medication. It is also recognized that close to 50 percent of all drugs that are used are ineffective. Moreover, 10 percent of all drugs sold worldwide are fake and the 2004 figure suggests this latter market is as big as US\$ 32 billion. These dilemmas negate the efforts of governments worldwide to fight disease effectively because these practices are believed to be an indirect cause responsible for the development of drug resistance.

Owing to a continued increase in health care costs, global governments are turning to finding more economical and safe medicine for their citizens. Consequently public health care policy tends to advocate:

- use of cheaper and proven generics in which an annual increase in consumption is expected to reach more than 20 percent.
- branded items (patent expired) not to be excluded from the medical service reimbursement scheme, and for the next five years the annual consumption increase is expected to be below 10 percent.

China is one of the most populated countries in the world with a population of 1.4 billion. The economic miracle created by the Chinese Government (9 percent average annual growth rate) over the past twenty years has defied the crystal ball of analysts and economists. With the emergence of affluence in the cities and a target to create a nationwide middle class by 2015, the issue of health care has been an important policy issue in China. The Chinese Government has set out medical service quality improvement and affordability as the two guiding principles in the reform of its health care system. However, these two objectives contradict each other. In a crusade to improve quality health care, hospitals install high quality equipments as well as prescribe high quality drugs. While hospitals are subject to a stringent quality compliance inspection, local drug

manufacturers must pass Good Manufacturing Practice (GMP) standards or their operation will be suspended. These regulatory requirements translate to increased operation costs for both hospital operations and local drug manufacturers and indirectly push up the cost of health care that is to be borne by the public.

To overcome the effect of increased health care cost as a result of enhanced quality, the Government has implemented policies to encourage the use of generic drugs. There is also a big movement to regularize and modernize Traditional Chinese Medicine (TCM).

In this paper, we made no attempt to dwell in detailed specific issues in the generic drug industry because of the highly sensitive market dynamics playing out in the market place in response to Chinese government health care reform policy. Rather, we have taken the approach of providing a general overview of the industry and offer some observation on its future growth dynamics.

### The Health Care Industry in China

The Chinese drug market is dominated by generics. The Chinese pharmaceutical industry has over the last 15 years sustained a double-digit average annual growth rate. A 2004 market study reveals that China's Over the Counter (OTC) drug market size is about 6 percent of the world market, ranking fourth after North America, Western Europe and Japan. The large but unsaturated pharmaceutical market is represented by the fact that drug and health product consumption in China accounts for less than 5 percent of consumption of its people, whereas in developed countries this figure is close to 20 percent. In 2004, the total market size of intellectual property (IP) protected pharmaceutical products, including those from Chinese corporations, did not exceed 30 percent of all drugs in circulation.

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1. A Life Science Committee Contribution

## Consumer Behavior and Expectation

Medical problems are attended to either at hospitals or small local clinics. Hospitals are monitored closely by authorities while local clinics are poorly regulated and the latter are perceived to provide less effective treatment. Consequently, the majority of the patient population (>75 percent) does not trust treatment provided at local clinics. A local survey indicates that over 50 percent of Chinese consumers will seek medical attention at hospitals and less than 10 percent seek medical attention at local clinics. Among those surveyed, 10 percent indicate a preference of using OTC/generics for treatment whereas another 30 percent will only go to hospital for major illness. Minor medical needs are attended to at local clinics or simply by the use of OTC.

At present, drugs reach patients through three routes:

- a) Sold directly to hospitals, which sell drugs to patients through prescription.
- b) Sold through distribution agents, who sell drugs to hospitals or drug stores. If a drug does not belong to the OTC category, a doctor's prescription is needed. There are approximately 10,000 distribution agents in China.
- c) Sold directly to patients.

Most patients will follow physicians' instructions when purchasing medication. This is because patients simply do not believe in drug advertisement by manufacturers. In making a purchasing decision, drug efficacy remains the most important issue, whereas brand equity is ranked lower in priority.

Another local survey indicates that over 85 percent of all patients believe that drugs purchased from hospital are the most reliable. While only 4 percent of all patients surveyed do not consider price as a major decision consideration in buying medication, there are still 25 percent who will buy medication from the attending hospital. The large majority of the consumers cannot afford the perceived safe and reliable medication sold in the hospital, but turn to pharmacy super chains for cheaper OTC.

However, consumers have two major reservations with hospital medical service. One concern is that pricing of medication in hospital is perceived to lack proper policing and that patients are always over charged. The other major concern is that doctors lack credibility when prescribing medication. Most patients believe that doctors prescribe additional medication unnecessarily. The over prescription is also compounded by the unhealthy medical insurance situation in China. Today's figure indicate that in

urban areas about 30 percent of the population has social or public insurance, less than 10 percent has private insurance and the rest are uninsured.

Owing to these credibility issues, a new brand of clinics has flourished on the Chinese medical service scene. Clinics are usually affiliated with prestigious institutions staffed by "Star" doctors that are prestigious academicians. Patients are willing to pay up to RMB 300 per visit despite a waiting period of just under two months.

## The Main Players in the Pharmaceutical Industry in China

### Multinational Corporations (MNCs)

Among the top international pharmaceutical companies such as Pfizer, Astra Zeneca, GSK, etc., Novartis-Sandoz and Ratipharm are the two most important players in the generic drug market in China. These strong foreign brands of OTC in the Chinese market create an extremely keen competition and crowded environment. For branded generics, the profit margin of 40-60 percent is much higher than the 8 percent of non-branded products. Selected branded products could exceed this high range. However, the markets for visible brand names are limited to big cities. Owing to poor brand equity and product quality, the participation of MNCs in the Chinese market has directly influenced local manufacturers to shift their battleground for the OTC market to 2nd or 3rd tier cities as well as the countryside.

### Local Companies

At present, there are more than 5,000 drug manufacturers in China. While 13 percent of the industry participants report sales revenue of more than RMB 0.1 billion and account for more than 72 percent of the national sales revenue, many others are small-sized operations with sales revenue between RMB 5 million to RMB 50 million. This latter category of manufacturers is often survived through one or few products that are plagued by low brand equity and poor quality. Relative to the entire industry, this category translates to 61 percent of total number of companies registered under the pharmaceutical industry and accounts for only 16 percent of the national sales revenue of the industry.

Most of these manufacturers also lack the understanding of the principles of retail business and goals. Almost without exception, they do not engage qualified professionals to conduct market studies to determine market factors and dynamics. This results in misguided application of resources and marketing methodology. To upgrade themselves, they will need to make significant improvements on management

skill, product quality, brand building and if possible introduce proprietary products.

## **Strength, Management New Breed and New Initiatives of Chinese Companies**

A unique strength that clearly stands out for the local pharmaceutical companies has been its long experience in the manufacture of generics. Leading experts in the Chinese Pharmaceutical industry are advocating and advising the industry leaders to model their corporate strategy after the Israel and Indian experience, that is to gain international market share through exporting, consolidate international business experience in the pharmaceutical industry and to create positive net cash flow for companies. Technically, this translates to improving the manufacturing and development capabilities in OTC/generics to a level acceptable by the regulatory authority of industrialized first world nations.

It follows that there is increased R&D and licensing activities with industry leaders. Companies are looking to license in proprietary technologies from local universities/companies as well as universities/companies outside of China. However, in most cases, the know-how of licensing activities has not yet reached a sophisticated level. It is not uncommon that an outright assignment is preferred over a license. The understanding of license clauses could be subject to different interpretation and could be problematic in latter day management. Milestones based on downstream R&D of the technologies could pose another challenge to the licensing professional. This is because the R&D capability and facility of a company may not be strong enough to meet these milestones. While consultancy would be subject to different consideration in the western community, this is not the case for licenses in China. Along with the license, there is often time a high expectation of consultancy or transfer of know-how of the technology at no extra cost. This is an acceptable arrangement between entities in China, and outside companies looking to license technologies to China are advised to manage this expectation as well as make sure that there is a mutual understanding of the license agreement. Finally, because of remittance control, companies would need a permit to remit money outside of China to pay for the license fees and other considerations. This is another issue that should be taken care of during license negotiation.

While few local companies venture into development of original products either through licensing or in-house development, the majority of the manufacturers in the industry do not have the capacity to follow this strategy. However, under the manage-

ment leadership of a new breed of well-trained and educated professionals that has emerged in the industry scene in the last decade, a number of Chinese pharmaceutical companies are executing this strategy. (See the table at the end of this section on major local pharmaceutical players in China.) These managers understand and are also equipped with modern business know-how to turn an aging non-profitable SOE (State Own Enterprise) into a profitable business.

## **Two Cases of New Management**

The Dong Sheng Group started as a branded tea product manufacturer with international product sales. It aspires to become a local biopharmaceutical giant. To achieve this goal, the Group formulated a strategy to leverage against Dong Sheng's manufacturing background in natural product. It focuses its activities on creating the right platform to access the capital market as means of raising funds to finance its business activities.

Today's Dong Sheng Pharmaceutical Co. Ltd. is the result of a series of merger and acquisition activities starting from 1996. At that time government regulation did not allow pharmaceutical company to be publicly listed. To overcome this hurdle, Dong Sheng acquired 28.92 percent of the Government owned Qinghai Tongwen Aluminum Factory Co. Ltd., a publicly listed company, and changed its name to Dong Sheng Technology Corporation the next year. This strategy immediately enabled Dong Sheng Technology Corporation to tap into the capital market and operate as a listed company. The business was further restructured and the Group eventually repositioned itself in the market place with a new business focus that aligned with its new image as a publicly listed biopharmaceutical corporation. In 2000, the Group acquired 80 percent of the share of the government owned QianJiang Pharmaceutical Co. Ltd. Through this acquisition, the Group had total control over at least two very well established product brands in the market. The Group completed its strategy by immediately penetrating the TCM health product market by acquiring 95 percent share of a TCM manufacturer with a strong brand.

To finance its debts and all its business activities, the Group strategically acquired 52.9 percent share of Qinghai Pharmaceutical Factory Co. Ltd, the largest and only anesthesia product manufacturer in China at the time. This successful acquisition provided the company with a reliable source of guaranteed cashflow—"the needed cash cow" because of its distinct advantage of a guaranteed market and its monopoly over the market place. The

business activities the Dong Sheng Group engaged in throughout this period has focused on achieving vertical integration capability through which it can position products of the Group to be recognized as the No. 1 supplier and manufacturer of OTC in China by 2007. The 2003 combined sales generated by the Group was RMB 8 billion. The long-term goal is to reach RMB 15 billion sales by 2009.

Another strong player in the Chinese health care market is Jiang Kang Yuan Group. It focuses its business on both conventional and TCM based Preventive Health Care Products. Based on this strategy, its acquisition goal is focused on acquiring strong brands to widen its own proprietary product lines. It utilizes strong branded products under its umbrella, for example, JOINCARE a top brand in female health care products on the Chinese market, to support the development of brand equity for other products in the chain. Unlike other health care companies in China, this Group engaged in the development of TCM proprietary products to compete in the high-end preventive health care and OTC market. The Group achieved a 146.25 percent growth in 2003 with total revenue of RMB 1.752 billion and a net profit of RMB 140 million. The contribution to the profit margin by its proprietary TCM based products is high, averaging 70 percent over 2002 to 2003.

This is a success story demonstrating that by properly managing the R&D focus and aligning the resources utilization to support the corporate strategy; the Jiang Kang Yuan Group is on track to becoming an upcoming giant in the industry. Moreover, it has demonstrated that cost effectiveness can be achieved in supporting a new product development strategy, which contrasts to the exceedingly high cost (US \$1 to 2 billion, 15-20 percent of sales) for new drug development experienced by MNCs in industrialize first world nations.

It is the goal of the Government to improve the social well being of the Chinese population. Self-care and health awareness management concepts are to be developed in the general public, as a means of overcoming high health care costs to the general public at large and to the public treasury. The consumers have responded positively to this self-care and health awareness initiative. These examples demonstrate that this new breed of managers leading Chinese pharmaceutical companies is highly skilled in their trade. Under their leadership, modern privately owned Chinese health care companies focus their business development activities in alignment with both government policy and consumer behavior.

## Initiatives from the Government

### National Goals

The Chinese Government has set out that by 2015, all Chinese nationals should enjoy affordable medical care that is higher than underdeveloped countries or equivalent to middle rank first world nations medical care bench mark. To achieve this new goal for the nation, the Government has begun the task of reforming the pharmaceutical industry over the last decade to create a comprehensive, competitive and market oriented health care industry in alignment with its economic and national policies. The ultimate long-term goal of the Government is to establish a modern industry that could compete in the global arena with its own human resources in disease treatment and management through modern biopharmaceutical discovery efforts. To deliver this national objective, privatization and consolidation of state owned companies has been the main interim vehicle to achieve quality and cost effectiveness, which is the core essence of this reform target.

### Laws Governing Technology Transfer Activities

The Patent Law, Technologies Contract Law and Regulations of the PRC on Technology Import and Export Administration govern technology transfer activities in China. These laws have been updated to align with the national goal for economic development. Naturally, these laws would also facilitate the modernization of the pharmaceutical industry. The Government has also relaxed restrictions on foreign ownership of enterprises thereby encouraging more direct investment into the country.

### On Improvement of Quality

Laws have been implemented to require that all pharmaceutical manufacturers have to reach China's GMP standard by June 30, 2004 and that no transition period is allowed. The State Food and Drug Administration (SFDA) instituted a proactive approach to GMP compliance inspection policy of drug manufacturers. SFDA will conduct annual pre-announced as well as unannounced GMP certification inspections. Failure of compliance will result in the revocation of the GMP status and the license to produce drugs will be terminated. Furthermore, the manufacturers in default are not allowed to out-source to a toll production facility for continued product production. Not only will the application for new drug approval be denied, approval for product sales will also be cancelled for manufacturers that have not obtained GMP approval for its products.

Quality assurance is also reflected in the drive to protect IPR through the establishment of laws and

## The Seven Major Local Pharmaceutical Groups in China (The Magnificent Seven):

Group	Company Name in Chinese	Company Name in English	Web Site
華源系 (Hua Yuen)	上海醫藥（集團）有限公司	Shanghai Pharmaceutical (Group) Co., Ltd.	<a href="http://www.pharm-sh.com.cn/cht/">www.pharm-sh.com.cn/cht/</a>
	上海華源制藥股份有限公司	Shanghai Worldbest Pharmaceutical Co., Ltd.	<a href="http://www.chinaworldbest.com/shangshigs/hyzhiyao.htm">www.chinaworldbest.com/shangshigs/hyzhiyao.htm</a>
復星系 (Fu Xing)	上海華源股份有限公司	Shanghai Worldbest Co., Ltd.	<a href="http://www.worldbest.sh.cn/files_cn/index.asp">http://www.worldbest.sh.cn/files_cn/index.asp</a>
	上海復星實業股份有限公司	Fosun Pharma	<a href="http://www.fosun.com.cn/">www.fosun.com.cn/</a>
	上海豫園旅遊商城股份有限公司	Yuyuan Tourist Mart	<a href="http://www.yuyuantm.com.cn/guanyu_gaikuang.htm">www.yuyuantm.com.cn/guanyu_gaikuang.htm</a>
	上海友誼集團股份有限公司		<a href="http://www.shfriendship.com.cn/gongsijianjie.php">www.shfriendship.com.cn/gongsijianjie.php</a>
健康元系 (Jian Kang Yuan)	天津天藥藥業股份有限公司	Tianjin Tianyao Pharmaceuticals Co., Ltd.	<a href="http://www.tygf-jy.com/gaikuang.asp">www.tygf-jy.com/gaikuang.asp</a>
	河南羚銳制藥股份有限公司	Henan Lingrui Pharmaceutical Company Ltd.	<a href="http://www.lingrui.com/script/gongsijianjie.php">www.lingrui.com/script/gongsijianjie.php</a>
	重慶藥友制藥有限責任公司	Yaoyou Pharmaceutical	<a href="http://www.yaoyou.cn/rencai.asp">www.yaoyou.cn/rencai.asp</a>
	廣西花紅藥業股份有限公司	Huahong Pharmaceutical	<a href="http://www.hhy.com/hhy/index.htm">www.hhy.com/hhy/index.htm</a>
	北京金象復星醫藥股份有限公司		<a href="http://www.kissun.com/">www.kissun.com/</a>
太極系 (Tai Ji)	深圳太太藥業股份有限公司	Shenzhen Taitai Pharmaceutical Company Ltd.	<a href="http://www.bioon.com/industry/Special/taitai/Index.html">www.bioon.com/industry/Special/taitai/Index.html</a>
	麗珠醫藥集團股份有限公司	LIVZON Pharmaceutical Group Inc.	<a href="http://www.livzon.com/">www.livzon.com/</a>
	健康元藥業集團股份公司	Joincare	<a href="http://www.joincare.com/">www.joincare.com/</a>
東盛系 (Dong Sheng)	太極集團	Taiji	<a href="http://www.taiji.com/">www.taiji.com/</a>
	桐君閣		
遠大系 (Yuan Da)	西南藥業股份有限公司	Southwest Pharmaceutical Co., Ltd.	
	東盛科技股份有限公司		
	潛江制藥股份有限公司	QianJiang Pharmaceutical Co. Ltd.	<a href="http://www.qjzy.com">www.qjzy.com</a>
	東盛科技啟東蓋天力制藥股份有限公司		<a href="http://www.gaitianli.com.cn/">www.gaitianli.com.cn/</a>
華立系 (Hua Li)	青海制藥廠有限公司	Qinghai Pharmaceutical Factory Co. Ltd.	<a href="http://www.qhzyjt.com/index.htm">www.qhzyjt.com/index.htm</a>
	華東醫藥股份有限公司	Hangzhou Huadong Medicine Group Co., Ltd.	<a href="http://www.eastchinapharm.com/english/about.asp">www.eastchinapharm.com/english/about.asp</a>
	連雲港如意集團股份有限公司	Lianyungang Ideal Group Co. Ltd.	<a href="http://www.idealgroup.com.cn/">www.idealgroup.com.cn/</a>
三九系 (San Jiu)	浙江醫藥股份有限公司	Zhejiang Medicine Co., Ltd.	<a href="http://www.xcpharm.com/">www.xcpharm.com/</a>
	華立控股股份有限公司	Holley Share Holding	<a href="http://www.cqhlkg.com/">www.cqhlkg.com/</a>
三九系 (San Jiu)	昆明製藥集團股份有限公司	Kuming Pharmaceutical Corp.	<a href="http://www.kpc.com.cn/">www.kpc.com.cn/</a>
	浙江華立科技股份有限公司	Holley Technology	<a href="http://www.holleykj.com/">www.holleykj.com/</a>
三九系 (San Jiu)	三九醫藥股份有限公司	Sanjiu Medical & Pharmaceutical Co. Ltd.	<a href="http://www.999.com.cn">www.999.com.cn</a>
	三九宜工生化股份有限公司		

enhancement of enforcement. IP litigation involving local drug companies as well as MNCs has increased. As copies dominate drugs being sold in the Chinese market, manufacturers who have no proprietary products are finding it difficult to survive.

Compulsory compliance to these regulatory policies is expected to impact the industry positively and minimize health care scams.

## **On Cost Sharing Health Care Policy**

In addition to social and public health care insurance, the Government is encouraging private health care insurance to participate in this process. Regulations established in the area of insurance reimbursement lists, price caps, marketing and advertising laws were all enacted as part of the overall health care reform package.

Owing to the need of a large population, reimbursement of branded OTC has not been excluded as part of the national health care policy. The Chinese Government is also rapidly moving towards a direction to ensure policy transparency. Necessary infrastructure has been developed to support the implementation of policy that would bring safe and quality medicine to the market in the most cost effective manner. For example, for raw materials that are imported for medicinal use that is already registered with the SFDA no clinical trial is needed. These government policies play a part in driving the growth of the OTC industry in China. They provide the necessary push and incentives for local manufacturers to upgrade so that they can be in a position to capture a market share.

## **Effects of the Reform Process—How the Market Responds to Governments' Initiatives**

According to the 2004 Government statistics, health care expenses account for the 3rd most important expenses of a household in China. The statistics further show that over 50 percent of such health care costs are drug related, whereas a similar figure in the developed country is just 8-12 percent. Is the reform derailing?

For local manufacturers, GMP compliance greatly increases capital investment. To compete with branded products on the open market and to try to achieve cost recovery resulting from GMP upgrading, some local manufactures engage in branding maneuvers to achieve price inflation. For example, one product previously sold on the market at RMB 2.20 under a trade (common) name would be retailed at RMB 7.10 using a scientific or academic name for the same product. Even affordable life saving OTC drugs that were previously available at the hospitals

cannot escape the fate of price inflation. Other manufacturers would embark on elaborate marketing effort, which often results in over expansion of retail outlets thereby substantially increasing the operation cost.

Thus, the reform process has indirectly resulted in exploding cost escalation in drug prices far exceeding the purchasing power of the vast majority. The situation created in the market place is politically unacceptable because only those with social and public insurance can readily afford expensive medicine. In response to this deteriorating atmosphere and the increasing bad publicity of overcharges in the hospital, the Government imposed price caps for 1,500 different generics. If a manufacturer finds that its product is among the list of generics that are under price control, it finds itself in a dire situation because prices become stagnant as a result of government interference.

## **Price Regulation—What Are the Real Issues?**

Unfortunately, when the Government regulates the price of drugs it creates a number of real challenges for the consumers and the entire industry. In setting regulation to impose price caps, the Government overlooks the vast spread in earnings and income across the population spectrum. It simply acts on highly inflated prices and set price to be uniform nationwide, therefore the pricing policy created is out of tune with market supply and demand principles. Moreover, Government authorities are often not up-to-date with their market intelligence. As a result the imposed price cap is misguided because it is based on an unrealistic assessment of the situation. The dramatic decrease in product price resulting from price regulation policy and the substantial increase in operation cost, which amounts to at least ten times that of pre-GMP operation, totally erodes profits for many local manufacturers. For some manufacturers, this is good sound business reason to stop manufacturing. As a consequence, there are less product choices available in circulation in the market place.

For consumers, the choices are limited. They are affected by the shortage of supply of good affordable drugs. On the other hand, because of the continuous hype on quality, they are reluctant to purchase cheaper products even if supply is available because of doubts on quality. For major hospitals, there is no choice but to switch to more expensive products. This emerging consumer culture and market environment has indirectly benefited big players like Novartis-Sandoz, Ratipharm, etc., in the market place. However, for the vast majority of consumers,

the average household income cannot withstand the continuous high cost, therefore the ultimate choice would be to purchase products priced between expensive brands and low end products from drug stores. While government interference with price has a positive effect on the consolidation of the industry, it also indirectly creates a supply shortage and further threatens the competitive position of an already fragile local industry.

## Competition from Traditional Chinese Medicine (TCM)

For centuries, Chinese have relied on TCM for the maintenance of health, treatment of ailments such as common cold, flu and sore throat, as well as for the management of disease, especially chronic diseases. Despite the impact of the major push for western medical practice and training in the medical universities in China, the TCM industry continues to grow steadily achieving RMB 89.16 billion in sales and RMB 8.95 billion in profit in 2004. These values represent an increase of 15.5 percent and 10.8 percent, respectively, over 2003 and an estimated profit rate of 44 percent, which is 4 percent higher than the chemical drug preparation industry.

Survey results conducted by local Chinese analysts indicate that the understanding in the use of non-prescription drugs has gone up by double digits averaging close to 45 percent of the population. For cities with a population of 3 million or more and GDP exceeding RMB 50 billion, the understanding rate exceeds 55 percent of the population. Moreover, for the segment of consumers with higher education training (67 percent) and age 64+ (49 percent) local consumer satisfaction survey data indicated that western generics or OTC do not have a unique competitive advantage over the use of traditional medicine products. Thus, the acceptance of TCM and understanding on its use do not have a clear age barrier factor, which is a very favorable environment for the development of TCM products.

To capitalize on the sentiment on TCM, industry leaders also advocate that the corporate wealth created should be channeled into making breakthroughs in the development of traditional medicine. This strategy allows the Chinese companies to apply their distinct market and knowledge competitive advantage over MNCs. For TCM products, there is little doubt that Chinese manufacturers hold the competitive edge on IP and the market.

While it is difficult to obtain patent protection for known natural products or formulation, patents related to TCM have been issued on extraction method, manufacturing process of formulation,

compositions comprising of active ingredients, and synthetic equivalence of active ingredient. TCM products are also known to rely heavily on trademark for protection and acquisition of market share. Patent application and trademark registration as well as issuance related to TCM have increased substantially over the years. Before 1992, the average number of TCM related patent application was 500/year. This number has increased to 2,000/year after 1994. For the year 2004, the number of TCM related applications has increased to 4,520, a nine fold increase within a short span of 12 years, signifying a serious effort of TCM manufacturers to upgrade their business practice.

While the MNC remains focused on the development and marketing of conventional drugs, the Chinese pharmaceutical manufacturers are busy developing a total product strategy to consolidate their business into three divisions; they are the OTC including TCM, proprietary TCM drugs and health products. This is in line with the world trend in the preference for complementary and alternative medicine (CAM), which includes TCM.

Data from the U.S. Government funded 2002 National Health Interview Survey indicated that there is an increase use of alternative medicine by the Americans. The establishment of a research grant by the National Institute of Health in the U.S., the various legislations in the U.S. and Europe on "traditional medicine" mark the beginning of the gradual acceptance that traditional medicine, herbology included, is becoming a way of life in these jurisdictions. More importantly, in the long run, the benefit to the industry and the public is the implicit requirement of statutory compliance through which a healthy standard can be established for an otherwise fragmented industry.

The Chinese Government has included in its national five-year development plan the modernization of TCM as one of the national priorities. This is because TCM typically provides a cheaper medical alternative for personal wellness and chronic disease management. With the support of the Government to modernize TCM, the initiative will in time provide scientific evidence to demonstrate the effectiveness of TCM. More importantly, this segment poses the greatest opportunity for enterprising Chinese manufacturers to capture a lion share of the developing markets in industrialized first world nations in the future.

## Outlook

### Short-Intermediate Term

Beginning 2005, the Chinese Government has

already moved to correct its policy in pricing regulation. As SFDA continues to fine-tune its pricing strategy to one that is closely determined by market forces, the pricing practice which led to the chaos in the market place is expected to correct itself.

Short term, the MNCs with their superior brand equity and focus business activities in the bigger first tier cities will continue to compete successfully in these markets. However, when the regulatory protection fades out, their market shares could erode rapidly. The local giants, with a superior distribution network extending beyond the first tier cities and a more competitive pricing schedule in line with the income distribution spread of the population of 2nd and 3rd tier cities, would seriously threaten the market position of MNCs. These 2nd and 3rd tiered markets are not to be overlooked as it is becoming increasingly clear that they will expand in line with income trends of these cities.

## Long Term

Beginning the second half of 2004, SFDA began the process of studying how the existing GMP certification, which is modeled after WHO specification, can be further improved to reach the same GMP standard as that of the industrial first world nations. SFDA has focused its study on developing more stringent quality control and management methods. This suggests that the industry would be expected to undergo further consolidation.

As China slowly dismantles its cradle to grave welfare system, the Government is increasingly looking to private health care insurance as a form of “managed care plans” for its citizens. In July 2006, the State Council pushed forward health care reform further by endorsing equity investments in medical facilities by commercial health insurance providers, and in August the China Insurance Regulatory Commission announced the declaration of the country’s first health insurance regulation. As more policy reforms could be expected from the Government, new players would be introduced thus fostering a highly dynamic market environment. Manufacturers with a vision and a fully aligned strategic marketing focus in delivering its product are anticipated to lead in this environment

Although the improved IP situation in China favors MNCs, it is expected that it will become increasingly difficult for MNCs to maintain a leading edge in China. The consolidation of the local industry that took place in the last decade has created new privately owned powerful local players in the market place. Long term, a well thought out business strategy and commitment to penetrate the remaining

70+ percent of the Chinese market is unavoidable. Moreover, the ability of manufacturers to innovate beyond the 20/80 rule and to seek out a reliable and credible distribution network, are two most important key success factors that would determine the real winner(s) in this contest because there is a vast geographical difference in market differentiation in China.

The medical education reform in full force in China focuses on training medical doctors in compliance with the global minimum essential requirements (GMER) medical education standards and to cultivate high-quality medical professionals. This development will alleviate the pressure on the operation of major hospitals in the future because patients will shift to seeking medical attention in credible small private clinics. Therefore, the current marketing strategy that focuses on selling to major hospitals by manufacturers will need to be re-visited and a new overall marketing strategy would need to be developed to also incorporate marketing to small clinics because of its emergence as a future market segment.

For smaller manufacturers, keeping up with GMP requirements has already stretched their resources to the limit. Therefore, as much as the Government encourages R&D and innovations, the resources needed to develop and maintain IPR protection dictated by the market is not available to small manufacturers. The survivors are those manufacturers who strived to develop or license in proprietary products for development. They would need to rely on this and lower production cost, an edge over the MNCs to survive. Another factor that favors the local company is that they are in a better position to understand the application process involved in the drug application process, which is often murky and subject to interpretation of the authority concerned.

Based on these assessments, the industry can expect more merger and acquisition activities as small manufacturers face increasing difficulty to keep up with Government’s GMP regulation while maintaining a low cost operation. The new entity could leverage on the local know-how and distribution network of the domestic companies and the R&D, IPR and financial capabilities of the MNCs.

## Conclusion

The market response to the action of the Chinese Government has created an impact on the economic reality of health care to the general public. This reality has created a pull-push effect in the market place fostering a gradual response to developing a self-care and health awareness management attitude within the population. As unfortunate as it is in the short

term, this misfortune is helping to shape a healthier growth of the generic drugs market in China.

TCM product is an area that generic manufacturers should watch out for. An excellent example of this threat closer to home is the popularity of the TCM based product COLD-fx by CV Technologies of Canada, a listed drug manufacturer in the Toronto Stock Exchange, with CAD\$ 400 million sales in 2004. As more scientific evidence is gathered for TCM, the market for TCM will pose a serious threat to an already crowded generic market.

A lot of MNCs are pushing a technology based implementation protocol of personalized medicine, which is a highly expensive form of medicine and would only be within reach of the wealthy population even in industrialized first world nations. On the other hand, the development of a wider and safer practice of herbology is a far cheaper form of personalized medicine accessible by the general population globally. Here, the powerful Chinese players, with their modern management practices, would have the unique advantage over the MNCs in becoming global players.

According to Ratipharm, Europe's number one biggest generic manufacturer, which also has a prominent presence in China, the three key success factors for a manufacturer of generics are good quality, competitive price and a broad range of products to lower marketing and production cost. However,

to be successful in China, we suggest that three additional elements are most important and that is making the right choice for a truly credible distribution network, seeking out the right know-how to manage the rapidly changing government regulatory process for drug manufacturing and marketing, and finally learning and developing a TCM product strategy. ■

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