

Pharmaceuticals China Bimonthly Report

Vol.1 Issue 01 2012



Copyright © CCM International Limited



Publication date: 15 February 2012

Contents

Editor's Note.....	III
Headlines of Pharmaceuticals China Bimonthly Report.....	III
Regulatory & Policies	1
MOH announces progress on public hospitals expenditures control.....	1
NDRC updates essential drugs tendering system & healthcare reform.....	2
SFDA ensures essential drugs safety and supply	3
SFDA strengthens control on internet drug selling	3
Market & Industry Dynamics	4
Major therapeutic classes market review	
-- Cancer market review	4
Antibiotic control impact	5
SFDA requested recall of Caelyx and Velcade	5
Chinese pharmaceuticals received FDA approval	6
Business & Companies Dynamics.....	6
BMS and Simcere expand strategic cooperation	6
Simcere launches Iremod for active rheumatoid arthritis	7
AstraZeneca expands local manufacturing.....	7
Boehringer Ingelheim expands Shanghai factory.....	7
MSD sets up Asia R&D center in Beijing	8
Global CRO targets China market	8
Research & Development	9
HBV therapeutic vaccine Phase III trial continues	9



Editor's Note

Welcome to the first issue of Pharmaceuticals China Bimonthly Report.

Healthcare reform will continue to be the hottest issue in 2012. It has important implications not only for the general public, but also hospital administrators, doctors, pharmaceutical companies and healthcare investors. Healthcare reform targets at many areas. In this issue, we review two of these based on the recent government announcements: they are hospital expenditure control and drug safety.

The general public is watching closely at how hospital expenditure control can lessen their medical expense burden through strengthening the implementation of reimbursement drug list and improving the pharmaceuticals tendering system. We will take a closer look at how difficult the process is and suggest reasons behind. Drug safety becomes the focus of the government recently with the continuous discoveries of counterfeit drugs in different provinces of the country. We will review the news and actions from the government to tackle the problem.

We review the cancer market and discuss the major classes of cancer drugs and their sales performance. We selected this special therapeutic area due to its rapid market growth and product development. Discussion of other therapeutic classes will be covered in future issues.

Multi-National pharmaceutical companies' strategies are more aggressive in China as seen in recent announcements by some of the global pharmaceutical companies regarding their expansion in local manufacturing and R&D. There are also more partnerships with local pharmaceutical companies in product development and commercialization. Even though each of these cases may have different objective, it is a clear signal of their commitment to China market. We will try to explain the motives and predict the possible outcomes in these cases.



Headlines of Pharmaceuticals China Bimonthly Report 1201

- MOH makes progress on the public hospitals' expenditure control through the control over drug consumption, especially the expensive drugs.
- NDRC updates essential drugs tendering system and healthcare reform, to make health systems more transparent and standardized.
- The implementation of Essential Drug List (EDL) is expected to expand to higher tier hospitals, SFDA announced the specific regulations to cope with the issues related to safety and supply.
- SFDA strengthens the control on internet drug selling to prevent the incorrect information delivered to the public and the selling of unapproved or counterfeit drugs through the internet.
- China is the second highest cancer-incidence country in the world with over 2.2 million new cancer cases every year.
- The sales of pharmaceutical companies with antibiotic drugs as their core products will be affected due to "Control over clinical use of antibiotics".
- SFDA requested recall of Caelyx and Velcade due to European Medicines Agency regarding the shortcomings in quality assurance of Johnson & Johnson manufacturing facilities, which will have a negative impact on both sales and reputation of the company.
- Jiangsu Hengrui received the approval for its Irinotecan injection, a new kind of colon cancer drug, from the FDA.
- BMS and Sincere entered into a partnership to develop a preclinical drug used in cardiovascular diseases, which has benefits for both companies.
- In order to lower the cost of goods and ensures the competitiveness, AstraZeneca expands their second manufacturing facilities in China.
- Boehringer Ingelheim expands the current manufacturing facilities in Shanghai, suggesting its aggressive strategy in China.
- MSD sets up their Asia R&D center in Beijing, due to the huge market opportunity and the lower cost in China.
- China's CRO market expanded rapidly as a result of the speeding up of product launch from pharmaceutical companies to capture potential market.
- Preliminary result of a study for a kind of therapeutic vaccine for type B hepatitis (YIC), YIKE, is optimistic.

Regulatory & Policies

MOH announces progress on public hospitals expenditures control

According to the State Council's document released in February 2011 on the Public Hospital Reform, public hospital expenditure control is a key focus. This was in response to the extensive media coverage of complaining the heavy healthcare burden on general public. A press conference organized by the Ministry of Health (MOH) on Dec. 13, 2010 announced the progress on the public hospitals' expenditure control. Figures released in Oct. 2011 reflected: the expenditure growth in the past four years reaches 5% in each consecutive year in both out-patient and in-patient departments of tier-2 and tier-3 hospitals; however, the out-patient department sees only a 0.3% increase while the in-patient department even encounters a 0.1% decrease in the first half of 2011. The achievement was based on a series of actions including the implementation of a mandate expense control which links to the performance appraisal of hospital management, strengthened management training, lowered overall expenditure by improving drugs-and-equipments tender process, improved monitoring and surveillance system of control, and the rational use of medical services by encouraging patients to lower tier hospitals.

For healthcare spending, according to TABLE 1, total health expenditure as a proportion of GDP for 2010 from World Health Databook of Euromonitor, China ranks significantly lower than other countries do; the 5.2% of GDP spending is much lower than that of other major pharmaceutical markets such as the US, Japan, Germany and France. It is also lower than other BRIC countries (except for India). The financial funding from Chinese government is insufficient to support the healthcare services that are carried out primarily by public hospitals.

Public hospitals provide over 90% of medical services. Over 40-50% income of hospitals is from drugs. The hospital expenditure control is fundamentally the control of drug consumption, especially the expensive drugs. This is not a new idea; Shanghai Health Bureau had implemented the mandate hospital expenditure control in 1996, a policy penalized hospitals with drug income growth exceeding 15% over the previous year. An obvious effect on control of the soaring growth is observed. The overall hospital income growth of Shanghai in 1994 was over 50% before it decreased to 20% in 1996, while the percentage of drug income in Shanghai hospitals' total income had dropped from over 60% in 1994 to less than 50% in 1996.

It is not surprising a similar result with the Ministry of Health control on hospital expenditure will be expected from the past experience of the Shanghai Health Bureau. What important is the reality that drug income is still critical for hospitals. The government is still struggling with the conflict of controlling the hospital expenditures without financial compensation to hospitals. Chinese hospitals are under government's control but operating based on market, so they have to obtain profit to survive. Controlling their income will have a negative impact on the hospitals' operation. In the long run, the success of these governmental policies will be limited without considering the market driven hospital system.

Another interesting observation is the figures of hospital expenditure growth reported by MOH seem to be very low. Based on the fact that drug income contributes to about 40-50% of hospitals' income, the 5% growth of the income is contradictory to the drug market growth rate of over 25%. It may be due to the increased drug sales from self-pay market and lower tier health centers. This is in line with some big pharmaceutical players' strategies; a good example is the proactive over 50% price cut of Zocor, a cholesterol lowering drug under EDL from Merck aiming at the penetration to lower tier market.

TABLE 1: Proportion of total health expenditure in GDP, 2010

Country	Total healthcare expenditure % in GDP
United States	17.4%
Germany	12.6%
France	14.0%
Japan	7.6%
Russia	7.5%
Brazil	8.5%
China	5.2%
India	3.9%

Source: World Health Databook, 4th edition, Euromonitor International Limited



NDRC updates essential drugs tendering system & healthcare reform

Essential drugs tendering system: Healthcare Reform Office of National Development and Reform Commission (NDRC) updated the status of drugs-tender system of Essential Drug List (EDL) on Nov. 22, 2011. Officers reviewed the implementation of 2011 provincial tendering; about 2/3 of the provinces have completed the tender process according to the EDL tender guidelines released in Nov. 2010. The guidelines aimed at solving the five main problems related to EDL tender system. The problems and the guidelines to solve these are:

1. The poor efficiency due to the lack of coordination between the provincial and regional tender offices. Tenders are open to manufacturers and distributors. Too many negotiations in tender procedures increase costs.

Simplify the tender process; tender only award to manufacturers.

2. Cost of the suppliers used to be high and resulted in higher bidding price. This was because of the unspecified quantities of drugs, poor payment and extra cost in negotiation with local tender offices.

Specify quantity in tender; centralize payment system to reduce cost of suppliers.

3. The quality of drugs in the low-level health centers was questionable due to the difficulty in logistics monitoring; counterfeit drugs, expired or nearly expired drugs were common.

Companies need to meet quality standard to be eligible for tender bidding.

4. Bribery was still an issue in the tender process.

Illegal transaction is minimized by centralized payment to break the financial links between suppliers and medical institutes; cash flow of companies is ensured at the same time.

5. Under the fact that drugs-oriented hospital income resulted in expensive drugs prescriptions from doctors, there was some pressure to push to use low-price drugs.

Increase the monitoring of tender process; disqualify companies who did not comply with the tender policy.

The guidelines basically address all specific problems in the tender process except to solve the hospital income from drugs; this is more than a tender problem. In fact, it is a central problem of the rapid increase from hospital expenditure.

Essential Drug List (EDL) was formulated in 2009

to establish the rational use of basic and inexpensive drugs. With the mandate use of essential drugs in basic health institutes through tender, basically all 50,000 basic health institutes had adopted the use of essential drugs after two years' implementation.

The huge achievement is critical to the improvement and lowering of the medical services' cost in basic health institutes, and it also creates a model to non-profit service providers in public hospital sectors.

Healthcare Reform: The Chief of Healthcare Reform Office under NDRC, Mr. Sun zhigang, released the 2012 three key objectives of healthcare reform in an interview. These included firstly the increase of financial subsidies for basic medical insurance up to RMB240 per capita, secondly the increase of patient reimbursement to an average of 70%, thirdly the implementation of EDL to reduce general public's healthcare financial burden and, last but perhaps the most difficult one, the public hospital reform to change the "Drugs profit hospital" to "social welfare hospital".

The transformation from "Drugs profit hospital" to "social welfare hospita" began from 2009 among the basic health institutes while the central government had allocated over RMB47 billion to improve facilities and development of county hospitals and health centers. EDL was the key initiative; it was implemented in these institutes at cost so that no profit is made from drugs; finally, a significant improvement in services and cost reduction is observed. However, extending this to tier 2 and tier 3 hospitals in cities is challenging. Figures show that drugs in EDL contributed a relatively small proportion of the total drug consumption. For instance, in Shandong Province, the percentage of EDL drugs is only 16.8% and 32.4% for tier 3 and tier 2 hospitals respectively. These hospitals' incomes mainly come from non EDL drugs, and financial compensation with these hospitals will be tremendous if no profit from drugs is allowed. Based on the average revenues of the tier 3 and tier 2 hospitals, a conservative estimation of no less than RMB 50 billion per year is needed to compensate the loss income from drugs.

SFDA ensures essential drugs safety and supply

The implementation of Essential Drug List (EDL) is expected to expand to higher tier hospitals, SFDA announced the specific regulations to cope with the issues related to safety and supply.

In Dec. 20 2010 during a SFDA food and drug safety meeting in Beijing, Head of SFDA, Mr. Zhao Mingli announced that all companies supplying essential drugs have to establish electronic code to track the products by the end of Feb. 2012. Those unable to comply with it will be delisted from the tender suppliers. This policy was proposed last year, setting a deadline for companies to demonstrate the determination to enforce essential drug safety monitoring and surveillance.

Prices for essential drugs have been lowering through tender process and thus some pharmaceutical companies supplying essential drugs are not profitable and even losing money. According to Medicine Economic News, the average cost to set up the electronic tracking is about USD31,696 (RMB200,000) for one production line. This is significant for those smaller manufacturers with low profit and multi-production lines. Nevertheless, with the economy of scale, large pharmaceutical companies will be less affected. This is in line with the SFDA's objective to ensure quality essential drugs from bigger pharmaceutical manufacturers.

Besides essential drug safety, SFDA is also concern with their steady supply. The inadequate supply of Protamine Sulfate injection, the only drug used for heart surgery, is widely covered by media. This addressed the issue that many pharmaceutical companies are unwilling to produce drugs with low profit margin and small market size. Some other essential drugs encounter the similar supply issue. SFDA announced the proposal during the food and drug safety meeting on the policy of "Centralized production, tendering, distribution and storage".

Details of the proposal are not disclosed but it is clear that the government will be more involved regarding shortage of essential drug. Possible mechanism may be prone to centralized tender negotiation with qualified manufacturers and distributors for specific products on price and quantity. This is good news for those companies supplying essential drugs since the policy will probably allow better pricing for these products.

SFDA strengthens control on internet drug selling

The use of internet by pharmaceutical companies is phenomenal in the last decade, ranging from product information, advertisement to drug selling. Monitor and control over internet drug promotion and selling are universal problems. China, with no exception, is concerned with the incorrect information delivered to the public and the selling of unapproved or counterfeit drugs through internet. SFDA becomes more aggressive in view of the increasing events of internet drug selling, especially the safety issues of counterfeit drugs. A campaign initiated in 2008 made regular disclosure of websites violating the regulations through SFDA website so as to inform and educate people regarding the risk of on-line drug purchase. Furthermore, SFDA works with other relevant departments such as Ministry of Health, Ministry of Information Industry and Ministry of Public Security to take legal actions to eradicate illegal on-line drug selling. SFDA reported the results on 29 Dec. 2011: 1,350 websites were confirmed to be illegal, among which 788 were prosecuted and 350 were hosted oversea; 1,800 counterfeit drug manufacturing sites were identified and uprooted. SFDA expressed the determination to strengthen the control through taking more legal

actions.

There is no official data on how many on-line drug stores in China, so the figures from the report illustrate the tip of the iceberg. It is a long, challenging and difficult task to achieve. From the pharmaceutical industry perspective, multi-national and famous local companies will continue to increase on-line activities mainly in product promotion and education. Their brand and image protect them from negative image of internet drug promotion. Smaller companies are more prompt to be questioned and checked. In terms of legal on-line drug selling, there are official channel for license approval by SFDA. The requirements of application are demanding; the process takes an average 3-4 years. The companies must have a brick-and-mortar pharmacy. Until now there are only 43 licenses approved. It is natural that most companies are not keen on the application of a license full of difficulties and restriction. The development of official on-line drug selling is still limited in the near future.

Market & Industry Dynamics

Major therapeutic classes market review -- Cancer market review

According to International Agency for Research on Cancer under WHO (2008 data), China is the second highest cancer-incidence country in the world with over 2.2 million new cancer cases every year. The figures are even higher from Chinese Cancer Registry Annual Report 2009 (3.6 million). The ten leading cancers and their prevalence in China are listed in TABLE 2. Cancer drugs contribute to 10% of the total prescription drug market in China, and grow at an annual rate of 25% which is higher than the overall pharmaceutical market growth of 18%. The total cancer market is about USD4 billion. Cancer market is attracting pharmaceutical companies and we are seeing a clear trend for them to make more efforts to capture the potential.

TABLE 2: Ten leading cancers in China

Rank	Cancer types	Incidence rate*	Cases	Mortality rate*	Death
1	Lung	49.7	653,510	44.2	580,574
2	Gastric	35.0	460,486	26.1	342,936
3	Colon-rectal	29.1	382,274	13.4	175,137
4	Liver	26.6	349,823	25.8	339,624
5	Breast	21.1	274,106	9.1	59,647
6	Esophageal	18.8	247,130	15.3	200,706
7	Pancreas	7.5	98,013	7.0	22,975
8	Bladder	6.9	90,022	2.4	32,075
9	Lymphoma	6.4	84,525	3.6	47,792
10	Brain	6.4	84,039	4.1	53,686
	Others	66.2	874,593	24.7	454,267
	Total	273.7	3,598,521	175.7	2,309,419

Note: *number of cases or deaths per 100,000 person per year

Source: Chinese Cancer Registry Annual Report 2009

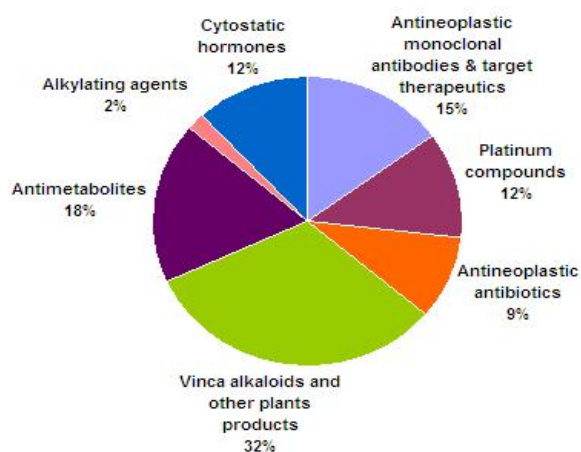
Cancer drugs are classified generally based on their mechanism of action.

- Alkylating agents
- Platinum compounds
- Antimetabolites
- Natural plant derivatives
- Antineoplastic antibiotics
- Antineoplastic monoclonal antibodies and target therapeutics
- Cytostatic hormones
- Adjuvant drugs
- Traditional Chinese medicines

Natural plant derivative drugs have the biggest market share while monoclonal-and-target-therapeutics drugs and hormonal drugs have the highest growth rates.

Local generic drugs are dominating the market with over 70% of the market share by value.

FIGURE 1: Different classes of cancer drugs and their market share in China



Note: *Other therapeutic class including cardiovascular, infectious diseases, metabolic and endocrinology, central nervous system, respiratory and gastrointestinal will be covered for subscribers.

Source: IMS data 2010



Antibiotic control impact

The release of the document for seeking of public opinions on the "Control over clinical use of antibiotic" (the "Control") in Sep. 2011 indicated the determination of the Ministry of Health to eliminate the over-use of antibiotics. The industry regarded it as "the most severe control over antibiotics in the history". Public opinions were received and the details are expected to be released very soon. Though there are different points of view on the degree of impact, it is generally agreed that sales of pharmaceutical companies with antibiotic drugs as their core products will be affected.

Antibiotics rank the top in all therapeutics classes in China with estimated market size of about USD12.70 billion (RMB80 billion), contributing to about 25% of the total pharmaceutical market. This is exceptional compared to other countries. The over-use of antibiotics not only increases the burden of healthcare and patients, but also poses serious risks to patients due to the development of highly resistance bacteria. The "Control" mandates all tier 2 level or above hospitals to establish antibiotic committee to oversee the purchase and use of antibiotics. The "Control" set clear requirements for hospitals, and the key one that

affects pharmaceutical companies is: only 2 brands of antibiotics for each presentation can be purchased for the same class. Small local companies with generic antibiotics will be likely to be kicked out from the hospitals compare to those branded products from foreign or larger local companies.

Some municipalities or provinces such as Beijing, Jiangsu and Sichuan had already started the control over the number of antibiotic drugs in pharmacies and their consumption.

According to the General Manager of a local pharmaceutical company with antibiotics as its major products, "some municipalities and provinces like Beijing are more proactive with the control of antibiotics' usage and have already started some sort of control such as deleting some antibiotics that are not used frequently; hospitals also limited the share of antibiotics in total drug expenses; pharmaceutical companies started lobbying work to minimize the negative impact."

The impact of the "Control" may vary with different companies, and financial analysts and industry experts generally predict a market shrinkage of 20-30%.

SFDA requested recall of Caelyx and Velcade

Based on the recommendations from the European Medicines Agency regarding the shortcomings in quality assurance of Johnson & Johnson manufacturing facilities (Ben Venue Laboratories) in the US at the end of Nov. 2011, SFDA requested drug recall of the two products affected on Dec. 8. For Caelyx, as there are two products with the same ingredient available, SFDA recommended replacing Caelyx with these products. For Velcade, since Ben Venue Laboratories is the only approved manufacturing site, SFDA called off the product selling immediately.

To ensure drug safety, the latest revision of regulation regarding pharmaceuticals' recall was released in 2007. The regulation classified three levels of recall, from first level that drugs recalled within 24 hours due to serious irreversible health threat to third level within 72 hours that the recalled drugs will not have significant harm. Recall can be mandatory, initiated by SFDA or through manufacturers' voluntariness. This is similar to the US FDA recall mechanism. Most recalls in the US

are voluntary, while those in China are frequently mandated by SFDA. Fine up to three times of the drugs sales value will be imposed to manufacturers for delay in recall and non-compliance. For serious violation and non-cooperation, the manufacturing license can be cancelled.

According to Johnson & Johnson, the recall of the two products was a third-level recall, and it was recalled voluntarily. SFDA did not comment on whether the recall is voluntary. In any case, the recall of the two products will have a negative impact on both sales and reputation. The recall involved two of their three products namely Caelyx, Velcade and Dacogen.



Chinese pharmaceuticals received FDA approval

On Dec. 17 2011, Jiangsu Hengrui Medicine Co., Ltd. (Jiangsu Hengrui), a Shanghai-listed company focusing on cancer drugs, received the approval for its Irinotecan injection, a new kind of colon cancer drug, from the FDA. According to Jiangsu Hengrui, it is the first Chinese pharmaceutical company receiving FDA approval for an injection formulation.

Although many Chinese pharmaceutical companies are interested in expanding their overseas market, especially the US and the EU markets, there are relatively few drugs from Chinese pharmaceutical companies with FDA or EU approval. The reasons behind this are: on one hand, the manufacturing facilities can not meet the requirements; on the other hand, many companies are not experienced in the application process. We do see a promising trend in FDA approval to Chinese pharmaceutical companies in 2011. In addition to Jiangsu Hengrui's Irinotecan, Zhejiang Huahai Pharmaceutical Company also received the FDA approval for the generic version of Boehringer Ingelheim's nevirapine for the treatment of AIDS.

The two approvals are for generic drugs, and thus the market potential is limited. We doubted that whether the two companies have the experience and the infrastructure to market their drugs in the US. Therefore, it seems impossible that the two companies will launch the products in the US on their own. Nevertheless, the approvals do enhance their image and establish the sense of high-quality products.



Business & Companies Dynamics

BMS and Sincere expand strategic cooperation

Bristol-Myers Squibb (BMS) and Sincere Pharmaceutical Group (Sincere, a Nanjing-based, New York Stock-listed company) entered into a partnership to develop a small molecule--BMS-795311. It is a preclinical drug used as an inhibitor of the cholesteryl ester transfer protein that can increase HDL, a good cholesterol, so as to prevent cardiovascular diseases. This is the second agreement between the two companies. Sincere's focus is in oncology market and the first partnership involved the co-development of a preclinical small molecule MET/VEGFR-2 inhibitor with potential cancer indications in Nov. 2010. For both agreements, Sincere has received the exclusive rights of research & development and commercialized operation for the products in China and is responsible for the funding of the relevant clinical development in China. BMS will retain the rights for all other markets.

The cooperation may be a signal of Sincere's strategy to enter the cardiovascular diseases market. Since the product is only in the preclinical stage, near term positive impact on Sincere's income will not be expected. For BMS, partnering with a strong local company like Sincere may leverage the clinical and commercialization strength. It is common for foreign multi-national pharmaceutical companies to cooperate with local companies with products that are not their top priorities in China.

BMS is not the only pharmaceutical multinational that Sincere has partnered with. Merck and Sincere established a joint venture in July 2011 with a partnership, aiming at combining the two companies' resources and expertise. The focus of the partnership is the branded pharmaceutical products for cardiovascular and metabolic diseases.

Sincere was set up in 1995; the company became more aggressive in terms of product development and acquisitions in the last few years. The launch of Endu, the company's first class-one new drug for treatment of lung cancer, signifies its transformation from a traditional generic company to a specialized biopharmaceutical company. Endu quickly becomes the company's key product. In August 2011, the SFDA approved another class-one new drug of Sincere, Iremod, for the treatment of active rheumatoid arthritis.

Sincere is an excellent model of how a struggling local pharmaceutical company with proper financial funding, visionary leadership and advanced management transforms to a successful innovative company.



Simcere launches Iremod for active rheumatoid arthritis

Simcere Pharmaceutical Group (Simcere), announced the launch of its class-one new drug, Iremod, for the treatment of active rheumatoid arthritis on 8 Jan. 2012. In fact, Simcere applied for the clinical trial to SFDA in 2008 and the approval was released last August.

Iremod was developed by Tianjin Institute of Pharmaceutical Research back in 2003; it is a new drug

in the category of Disease Modifying Anti-rheumatic Drugs ("DMARDS") for the treatment of active rheumatoid arthritis. Clinical studies demonstrate that Iremod can significantly alleviate symptoms caused by active rheumatoid arthritis. It is the second class-one new drug for Simcere. The first one is Endu for lung cancer. The market size for active rheumatoid arthritis in China is about USD634 million. (For more detailed information, please refer to therapeutics classes in the next issue.)

AstraZeneca expands local manufacturing

Momentum of sales slows down in many major cities. In order to increase the penetration to lower tier cities, many pharmaceutical companies increase the local manufacturing. On January 5, 2012, AstraZeneca announced the start of the construction for their second manufacturing facilities in China. The plant is located in Taizhou, Jiangsu province. It is their biggest plant worldwide. Total investment is USD230 million. The increase in local manufacturing can lower the cost of goods which is important for the market penetration of the lower-tier cities that are more price-sensitive. It also ensures the competitiveness during the tender process and price cut.

This is another aggressive plan to increase local manufacturing after the acquisition of Guangdong Pei Kang Pharmaceutical Company. The company is a private manufacturer of generic drugs, mainly antibiotics.

Besides capturing potential market of the second and third tier cities, the increasing trend of local manufacturing for multinational pharmaceutical companies is also due to the pressure of patent expiration.

According to the Research Based Pharmaceutical Association Committee (RDPAC), Over 70% of their members manufacture their drugs in China with 50 production plants. Many multi-national pharmaceutical companies are targeting good acquisition or partnering opportunities. The partnerships between Pfizer and Zhejiang Hisun Pharmaceutical Co., Ltd., and Merck and Simcere Pharmaceutical Group are good examples. AstraZeneca is taking the lead in this local manufacturing strategy.

Boehringer Ingelheim expands Shanghai factory

On Dec. 14, 2011, Boehringer Ingelheim announced the expansion of the current manufacturing facilities in Shanghai Zhangjiang High Tech Park with the total investment of about USD91.78 million. Besides ensuring supply for the expected demand from China market, the new facilities will also be responsible for other Asian countries. Besides, the company will increase investment to support the R&D center in Shanghai.

The investments has two important implications. First, it lowers production cost for both China and oversea market. Second, the increase in R&D reflects the long term commitment to China.

Boehringer Ingelheim's major business in China is respiratory and gastrointestinal drugs. Besides the prescription market from hospitals, OTC market is also an important focus for the company. Compared to other large multi-national players, Boehringer Ingelheim's strategy in China was relatively conservative. Since the company built its China manufacturing plant in Shanghai in 2002, there were few major investments except the set up of the USD13.11 million R&D center in Shanghai. With a new China President and CEO, Mr. David Preston on Board in 2009, who came with experience from other large pharmaceutical companies in China, there would be a more aggressive strategy. The major investment in the Shanghai plant would be a signal of the change.



MSD sets up Asia R&D center in Beijing

MSD announced on December 6, 2011 to invest USD1.5 billion in R&D in China, including the set up of their Asia R&D center in Beijing. The new center will focus on new drug development, clinical trials and registration. This is perhaps the biggest R&D investment for foreign pharmaceutical companies in China after Novartis invested USD1 billion in its R&D center in Shanghai in 2009.

The trend for multi-national pharmaceutical companies moving their Research and Development Centers into China seems irreversible. Starting from a small investment in setting up a medical division to co-ordinate global clinical trials; from small R&D facility as a symbol to commitment in China, to large and full R&D facility and finally an Asia, regional and even global R&D center. All these took place only in 10 years. All the global top 10 pharmaceutical companies have established their R&D centers in China.

There are two important reasons behind. First, all big foreign pharmaceutical companies focus on China as it is the faster growing market. The growth of other traditional big markets is slowing down and China pharmaceutical market is growing at over 25% per year. These foreign companies started to look at products that are specific for China population. Diseases like lung cancer, and hepatitis B carry huge potential in China but not in western countries. Setting up R&D facilities in China can serve the need and capture the potential market. Second, another reason for setting up R&D center in China is cost: it is much cheaper in expenses for the scientists and researchers; the cost to conduct clinical trials is much cheaper than that in western countries such as the US.

It may be too early to determine whether these R&D centers will generate new drugs for the companies since the development of a new drug takes at least 10-12 years. These investments do help the companies foster a better corporate image which is invaluable.



Global CRO targets China market

The world's fifth biggest Contract Research Organization (CRO), ICON announced the acquisition of BeijingWits Medical Consulting Company, the Chinese CRO, on Dec. 12, 2011. With the success of the deal, ICON will play a more active role in China business. This is the first acquisition of a local CRO by a foreign company. Charles River Laboratories International Inc. failed to buy WuXi AppTech last year. Now most of the top global CROs such as Quintiles, Covance, Parexel and PPD have presence in China.

According to the PricewaterhouseCoopers analysis on CRO industry, the total market of medical outsourcing in China in 2010 was approximately USD430 million and expected to grow at 20-25% per year due to the increasing R&D investments and the speeding up of product launch by pharmaceutical companies.

The history of CROs in China reflects the change of product development strategies by pharmaceutical companies. Quintiles, the world's largest CRO, set up the China office in 1997 which is the first CRO's presence in China; its customers are mostly multi-national pharmaceutical companies; the main focus of the business is to conduct bridging tests on behalf of the customers for their product approval (bridging tests is the product-approval clinical trials for foreign drugs to test the drug efficiency and safety; it is the same as those approvals oversea). Covance, a CRO from the US, established its Shanghai office in 2007. The market expanded rapidly as a result of the speeding up of product launch from pharmaceutical companies to capture potential market. More global trials were conducted; their business model is the partnership with local CROs and laboratories. With the local experience from BeijingWits, the acquisition reflects ICON's strategy to target the research outsourcing market with local pharmaceutical companies. It is expected that there will be more similar deals in the near future, and thus the CRO market may become less segmented than it used to be when high-end market is dominated by foreign CROs and the lower-end market is captured by their local counterparts.

Research & Development

HBV therapeutic vaccine Phase III trial continues

Shanghai Medical College of Fudan University and Institute of Biological Products of Beijing announced the preliminary result of a study on the effect of a kind of therapeutic vaccine for type B hepatitis (YIC) in Nov. 2011. The principle investigator of the trial is Prof. Xu Daozhen from Beijing Ditan Hospital. Prof. Xu is a leading figure in the field of hepatitis.

Preliminary result of a study for a therapeutic vaccine, YIKE, showed that the viral load became clinical negative in 59.8% of the patients and 84.4% of the patients have improved liver function in the treatment group. Since there still exists positive results, the study will proceed with larger number of patients to confirm the efficacy and safety.

Most industry experts and financial analysts are cautiously optimistic for the product with the announcement of the preliminary result. The result of clinical trial for another HBV therapeutic vaccine from Chongqing Beer Company was released recently; but the HBV therapeutic vaccine did not demonstrate any clinical improvement and thus the product development was terminated.

According to a Marketing Director of a pharmaceutical company in the field of hepatitis, "The key issue is whether the drug is better than the existing products like interferon and nucleosides or improves efficacy by combination therapy. Further study is needed to confirm these."

Hepatitis B market is attractive; the total market value for nucleosides and interferon in China is at least USD800 million based on the estimate from a leading hepatologist in Shanghai.



CCM's Market Reports Announcement

For more details, please contact CCM at econtact@cnchemicals.com

- Survey of PAP and Paracetamol in Asia Pacific
- Benchmarking on Paracetamol Production in China
- The para-Amino Phenol Industry in China

Choose Type of Subscription:

Single user license: 1 year CNY9,100 USD1,300
 2 years CNY15,470 USD2,210
Corporate license: 1 year CNY 22,750 USD3,250
 2 years CNY38,675 USD5,525

Print

Send

***All the above prices exclude tax, and additional 8% of each price should be charged as tax.**

* The price is based on CNY. CCM reserves the right to adjust the rate of other currencies if the exchange rate fluctuation exceeds 3%.

Your Details:

First Name: _____ Surname: _____
Job Title: _____ Department: _____
Company: _____
Address: _____
Postcode/Zip Code: _____ E-mail: _____
Telephone: _____ Fax: _____

Payment Method:

Wire Transfer

Bank Account:

A/C NO.: 3602008109200235331 (CNY) 3602008129200315969(USD)
BENEFICIARY NAME: CCM
BANK NAME: ICBC GAOXIN SUB-BR
BANK ADDRESS:NO.41, West ZhongShan Ave, Tian He, Guangzhou, China
BANK SWIFT CODE: ICBKCNBJGDG

Please send your completed order to us by

Online at www.cnchemicals.com
Post to Guangzhou CCM Information Science & Technology Co., Ltd.: 17th Floor, Huihua Commercial & Trade Building, No.80, Xianlie Zhong Road, Guangzhou 510070, P.R.China
Tel: +86-20-37616606
Fax: +86-20-37616968
E-mail: econtact@cnchemicals.com

CCM's legal disclaimers

1. CCM guarantees that the information in the report is accurate and reliable to the best of its knowledge and experience. CCM defines the report as a consulting product providing information and does not guarantee its information is completely in accordance with the fact. CCM shall not have any obligations to assume any possible damage or consequences caused by subscribers' any corporate decisions based upon subscribers' own understanding and utilization of the report.
2. The complete copyright of the report is and will be held by CCM. Subscribers shall not acquire, or be deemed to acquire the copyright of the report.
3. The report provided by CCM shall be only used as source of subscriber's internal business decisions and shall not be used for any other purposes without CCM's prior written consent, unless stated and approved in license contract signed by both parties. Subscribers shall not distribute, resell and disclose the whole report or any part of the report to third parties and shall not publish any article or report by largely or directly copying or citing the information or data based on CCM's report without the prior written consent of CCM.
4. Single User License means that there shall be only ONE person to receive, access and utilize the report. Subscriber can present the content of the report that marked the source from CCM to their internal colleagues for their internal communication and utilization, but cannot share the whole report to other individuals. Any citation, distribution, reselling and disclosure of the report as well as its partial content to any third party are prohibited, including but not limited to their parent companies or subsidiaries.
5. Corporate License means that subscriber shall not cite, distribute, resell the report or disclose information of the report to any third party without CCM's prior written consent, except subscribers' affiliates controlled with ownership of more than 50% of shares.

Signature : _____

Date: _____

Writer: Rick Woo

Reviser: Jack Lin, Zanhua Guo, Emily Chen

Editor: Feng Xu

Chief Editor: Norman Lai, Hongxiang Du

Publisher: CCM International Limited

Disclaimer

1. CCM International guarantees that the information in the report is accurate and reliable to the best of its knowledge and experience. CCM International defines the report as a consulting product providing information and does not guarantee its information is completely in accordance with the fact. CCM International shall not have any obligations to assume any possible damage or consequences caused by subscribers' any corporate decisions based upon subscribers' own understanding and utilization of the report.

2. The complete copyright of the report is and will be held by CCM International. Subscribers shall not acquire, or be deemed to acquire the copyright of the report.

3. The report provided by CCM International shall be only used as source of subscriber's internal business decisions and shall not be used for any other purposes without CCM International's prior written consent, unless stated and approved in license contract signed by both parties. Subscribers shall not distribute, resell and disclose the whole report or any part of the report to third parties and shall not publish any article or report by largely or directly copying or citing the information or data based on CCM International's report without the prior written consent of CCM International.

4. "Single User License" means that there shall be only ONE person to receive, access and utilize the report. Subscriber can present the content of the report that marked the source from CCM International to their internal colleagues for their internal communication and utilization, but cannot share the whole report to other individuals. Any citation, distribution, reselling and disclosure of the report as well as its partial content to any third party are prohibited, including but not limited to their parent companies or subsidiaries.

5. "Corporate License" means that subscriber shall not cite, distribute, resell the report or disclose information of the report to any third party without CCM International's prior written consent, except subscribers' affiliates controlled with ownership of more than 50% of shares.

CCM International Limited

17th Floor, Huihua Commercial & Trade Building, No.80 Xianlie
Zhong Road Guangzhou, 510070, P.R.China

Tel: +86-20-37616606

Fax: +86-20-37616968

E-mail: econtact@cnchemicals.com

Website: www.cnchemicals.com