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News in Focus

MOH Issues "Provisions for Drug Prescription" to Curb Abuse

The Ministry of Health (MOH) issued a new regulation, "Provisions for Drug Prescription", which will become effective on May 1. The new regulation is designed to restrict physicians from prescribing expensive drugs and over-prescribing, and to some extent to cut off the financial link between drugs sales and physicians & hospitals, according to Mao QunAn, the spokesperson for the MOH.

Mao indicated that China is likely to introduce a physician prescription fee system to compensate the work of physicians in prescribing.

The following is a summary of some important provisions of the new regulations:

1. All prescriptions must be written in generic drug name approved and published by drug regulatory authority, patent drug names of new chemical compounds, names of compound drug formulations, names of hospital formulations approved by provincial level health departments or drug regulatory authority, and common drug names published by the Ministry of Health.

2. Physicians are banned from coding drug products or using codes on prescription. Patients have the right to choose where to purchase the drugs, and use of codes in prescriptions will be penalized.

3. Each prescription is valid for three days, and in principle, the prescription should not exceed seven-day supply of drugs. Each prescription should not contain more than five drugs.

4. Pharmacists are responsible for validating the rationale of physician prescriptions. When irregular or erroneous physician prescriptions are found, pharmacists have the right to refuse dispensing, ask the physicians to re-prescribe, and record and report such incidents.

5. Medical institutions should establish prescription evaluation systems to monitor physician prescriptions and prevent abuse. Physicians who write irregular prescriptions without reasonable justifications for more than three times will be issued a formal warning with their prescription privilege restricted, and those who repeat this conduct twice more after the warning will have their prescription privilege withdrawn.

6. Medical institutions are only allowed to purchase a maximum of two injectable products and two oral dosage form products for a drug with the same generic drug name (products with the same active ingredient and similar clinical efficacy). They are also restricted to purchase between one to two products for compound drug formulations that have similar compositions.

7. Medical institutions that hire personnel without prescription privilege to write prescriptions or those without pharmacist qualification to dispense drugs will be fined up to CNY 5,000, and in serious cases, licenses held by these medical institutions will be withdrawn.

8. Physicians should prescribe based on the principles of clinical need, cost and safety.

If the new regulation is implemented and enforced, it will produce significant impacts on ways pharmaceutical companies will market their ethical drugs in hospitals.

The requirements outlined in No. 1 above practically bans the use of brand names (it is unclear what "patent drug names of new chemical compounds" means in this regulation and it is subject to further clarifications) in physician prescriptions. The provision, if implemented, will be disastrous

for brand name drug companies.

No.2 will help divert some of the prescriptions to be filled in at retail pharmacies, while No.3 and No.5 will help reduce and penalize over-prescription.

No.4 empowers pharmacists - "pharmacy professionals who have the pharmacy professional qualification", which technically should include licensed hospital and retail pharmacists.

No.6 will severely limit the range of products medical institutions can purchase, thus making the competition for drug entry into hospitals even more intensive.

No.7 targets mainly private hospitals where such practices are popular, while No.8 provides the principles by which physicians should write their prescriptions.

The regulation, if fully implemented and enforced, will indeed be very effective in curbing over-prescription and cutting drug sales revenues of medical institutions. However, without new revenue sources, it remains to be seen how medical institutions will fund themselves; and by the end of the day, this will determine if the regulation is feasible in the long run.

Proposed New "Provisions for Drug Registration" Aims to Close Loopholes

Following comprehensive research and consultations with the pharmaceutical industry and members of the National People's Congress and the Chinese People's Political Consultative Conference, the State Food and Drug Administration issued on March 9 the draft for its proposed revision of the "Provisions for Drug Registration".

A copy of the draft, which is in Chinese, can be downloaded from www.sfda.gov.cn. SFDA welcomes comments and feedbacks from the public for its draft, which can be sent to the agency online at the SFDA website, faxed to +86 10 88363236, or mailed to the agency at the following address:

Drug Registration Department, SFDA

A38 Beilishi Lu, Xicheng District

Beijing 100810, China

Provincial food and drug administrations are required by the SFDA to organize the pharmaceutical manufacturers and research institutions in their territories to discuss the draft and send their feedbacks to the SFDA before April 10, 2007. Other comments and feedbacks must be received by the SFDA before May 10, 2007.

Contact persons of SFDA for this matter are:

Hou Renping / Xia Junping

Tel: +86 10 88331213, 88331203

It is hoped that the revised "Provisions for Drug Registration" will be introduced before the end of 2007.

Following review of the draft, Pharma China noted a number of major differences between the current regulation and the proposed revisions:

1. Definition of "new drugs" – new specifications, dosage forms/administration routes, and indications of marketed products will no longer be classified as new drugs, although their registration application will still need to follow application processes for the "new drug" registration.

2. The registration applications for new dosage forms (without changing the route of administration) of marketed products must be made by holders of the existing registrations of the marketed products, with the exception of new dosage forms that involve the use of new technologies, new methods or new materials and have significant advantages in reducing toxic and side effects or production costs compared with the existing dosage forms.

3. Drug regulatory agencies are required to conduct field investigations to R&D and sample production sites of new drug products, to validate the truthfulness of new drug registration dossier, and organize the examination of samples.

These major changes in the proposed new "Provisions for Drug Registration" are mainly designed to block loopholes in the existing regulation that allow pharmaceutical companies to obtain new drug registrations through merely adding new but largely unnecessary specifications, changing dosage forms or delivery routes of existing products for the purpose of receiving government pricing advantages.

The changes also aim to strengthen the regulatory control over the process of drug R&D, preclinical and clinical research, and sample production in order to reduce fraud in the drug registration process and consequently improve safety and quality of registered drugs.

Official data shows that the SFDA accepted 10,009 new drug applications in 2004, compared with only 148 new drug registrations accepted by the USFDA in the same year. However, among the new drug applications SFDA accepted in 2004, only 22 are innovative new drugs with exclusive IP rights.

It is no secret to anyone that a large percentage of such new drug applications in China were filed by local pharmaceutical companies to fend off government price cuts and maintain their profit margin.

Despite the regulatory loopholes, approvals of such a large number of new drug applications, many of them on the basis of fraudulent dossiers, would not have been made possible without collaboration of corrupt SFDA officials.

In a related development, SFDA director general Shao Mingli said recently that the ongoing food and drug regulatory reshuffle will not end in the middle of this year as originally planned, but instead will be extended to the end of the year.

Shao said that the SFDA will strengthen:

- Collective decision-making to avoid power abuse by individual officials;
- Accountability for irregular activities in the drug registration process to hold relevant officials liable for their actions, and
- Publicizing identifies and responsibilities of drug approval officials to subject them to public supervision. He said that SFDA is likely to make the entire drug registration public through internet in order to increase transparency.

Editorial

Directionless Regulatory Corrections Corner the Pharma Industry

More Short-Term Contractions Ahead But Prospects Remain Encouraging for Some in the Long Run

James J. Shen

It is now a month after the Chinese New Year and as I am writing this editorial, the "two conferences" (National People's Congress or NPC and Chinese People's Political Consultative Conference or CPPCC) are dropping their curtains. The "*two conferences*" are becoming an increasingly significant political event as China moves forward on the long road towards a more transparent, democratic and law-upholding government system.

Officials face scrutiny at the "two conferences"

Representatives of the "two conferences", who come from all walks of the society, appear increasingly proactive in questioning government policies and submitting their own proposals. Senior officials of important central government agencies need to report on their work in the past year to the "two conferences" which are widely covered by the media. More ever than before, they have to take the heat from the representatives and the public for any poor performances.

Both Vice Premier Wu Yi (who is in charge of healthcare) and Health Minister Gao Qiang openly apologized at the recent "two conferences" for their responsibilities in the current chaos in drug regulation and healthcare. Given the fact that the Chinese political system has not yet advanced to the degree of holding senior officials accountable for such failures in their responsibilities, such open apologies are already considered a milestone which are well-received by the public.

Meanwhile, Shao Mingli, Director General of SFDA, has been in relatively low profile at the "two conferences", busy taking notes of comments from representatives and shying away from eager reporters. The only remark he was reported saying humbly was: "thank you for your comments and criticisms" and "we invite the public to supervise us". However, Shao's newly appointed deputy, Wu Zhen, who is in charge of drug registration, has been very active on the Chinese media, declaring various new measures to prevent future corruption, in attempts to rebuild the image and credibility of the SFDA.

Direction of healthcare reform still uncertain

While feeling comforted by the resolve recently displayed by the Chinese government to prevent corruptions and reform healthcare, my concerns over the timing and the transition process of the proposed new healthcare reform are nevertheless mounting.

It's alarming to see that various central government agencies have been busy launching new regulations and measures on areas they consider as of importance, before an overall healthcare reform plan or even direction have taken shape yet.

Information released from the "two conferences" has not reveal much concrete progress the government agencies have made on the country's healthcare reform plan. Little has been said about the issue of the healthcare financing model, which serves as the centerpiece of the healthcare reform.

It was reported earlier that a trial plan for the urban resident basic medical insurance system, which will cover urban residents who are not eligible for the existing urban employee medical insurance system, was submitted to State Council for approval. The system will be mostly funded by premium contributions of urban residents and supplemented by government funding designed to help the poor.

Health Minister Gao Qiang retreated from his earlier calls for a government-funded universal basic healthcare insurance, and said instead that the goal for such a system will need to be realized gradually over a long period of time. It seems the Ministry of Labor and Social Security had an upper hand in its debate with the MOH about the financing model of basic medical care.

However, the overall direction of the healthcare reform continues to be unclear. The Chinese government has contracted six different parties, including Chinese academic institutions, WHO and international private research institutions, to develop their respective proposals for the Chinese healthcare reform, according to Vice Minister of Health Chen Xiaohong. Although it is reassuring to know that such a process is beneficial to the development of a balanced and executable reform plan, the process may be long and intricate.

Other proposals addressing different segments within the healthcare sector are also coming from all directions during the "two conference" period. One proposal that won popular support was put forward by Zhu Qingsheng, a CPPCC representative and a former vice minister of health. This proposal calls for the establishment of an expanded Ministry of Health, which, in addition to its current responsibilities, will take over jurisdictions of SFDA, the State Administration of Traditional Chinese Medicine, and set up a proposed new state administration for medical insurance systems. The possible government reshuffle of its healthcare related agencies will inevitably impact the development of the future healthcare reform plan to some extent.

There have been talks from senior officials about a new national essential drug system, a physician prescription fee system, and an expansion of community healthcare networks.

Isolated regulatory corrections threaten bottom-line of the pharma industry in the transitional period

Various government agencies are launching succesively, ahead of a conclusive direction of the healthcare reform, isolated new measures and regulations within their own jurisdictions largely in efforts to demonstrate their competence to the public and the central government.

An English friend once asked me why there was so little historical architecture left in China despite its 5,000-year civilization. An intriguing question indeed. Now I found one possible clue to that - it is because to the Chinese, especially if he is the new Emperor, a newly-promoted Mandarin or a new landlord, the best way to disassociate and differentiate themselves is to destroy whatever that is associated with their predecessors (to show their hatred towards old sins) and replace them with the new ones of their own (to show their wisdom).

We had a corruption drug regulatory regime and a failing healthcare system. And now, we have a crowd of new Mandarins who are eager to demonstrate their difference – by way of introducing new regulations, I guess.

On the drug pricing end, we had another price cut in late February from NDRC – to the relief of Western pharmaceutical companies, this cut targeted only traditional Chinese medicines (TCMs). But note it is the largest cut ever on TCMs and NDRC is likely to launch more price cuts on pharmaceuticals, so stay alert.

Hospital drug purchase tendering system is also experiencing fast changes, with the entire country watching the experiments in Guangdong province that aim to slash prices over internet bidding on the basis of historical bids.

The SFDA published in March a draft for its new "Provisions for Drug Registration" which aims primarily to block pharmaceutical companies from using new drug registration as a route to gain new and preferential government pricing. The agency plans to change the classification of "new drug" to include almost nothing else but patented NCEs, while other new products (eg. new dosage forms or indications), though no longer classified as new drugs, will continue to be registered following the new drug registration process. In addition, SFDA announced that it would extend the period of its various regulatory corrections until the end of the year instead of previously planned mid-2007.

There has probably been too much attention on the SFDA in the past decade and the significance of the Ministry of Health (MOH) was somewhat overlooked by many. The wrath of MOH was finally released with the recent introduction of "Provisions for Drug Prescription" which will become effective on May 1, 2007. If implemented, it may be the last straw that breaks the back of the local pharmaceutical industry in China.

Concurrent with all these happenings, experiments began with drug supplies to urban community healthcare networks. Beijing Municipal Health Department launched the country's first government drug purchase tender for the city's urban community healthcare system in January, and banned such healthcare facilities from adding any profit margins on drug products. SFDA also announced in February a list of ten companies as the first group of designated suppliers for its "Essential Drug List for the Urban Community Healthcare System and Rural Areas".

All these moves are made independently by different government agencies designed to squeeze out the fat in drug sales. But the question that needs to be answered is: if successful, how will the hospitals be funded in future? Judging by what we heard from the senior officials, they are as clueless as we are at this stage.

Uprising of the pharmaceutical companies ahead?

Before China's healthcare reform puts in place a new healthcare financing model, it seems the pharmaceutical industry will be cornered indefinitely by various government measures and new regulations with no way out.

At the recent introduction of the "Provisions for Drug Prescription", a senior official of MOH asked physicians and hospitals to sacrifice their interests temporarily before a physician prescription fee system is installed. Ironically, rather than sacrificing their own interests, physicians and hospitals are more likely to force the potential losses on pharmaceutical companies.

However, signs show that desperate pharmaceutical companies are beginning to fight back. Here are some stories:

In February, Over 100 local pharmaceutical companies grouped under China Association of Pharmaceutical Enterprise Management, submitted an appeal letter to the State Council. The appeal letter sharply criticizes the existing healthcare financing model, the role of medical institutions in it, the turbulences created by the drug regulation regime, and the unfair competitive grounds created by the government between local and foreign companies. It calls for immediate termination of all isolated regulatory corrections before a full package of healthcare reform is introduced. China Association of Pharmaceutical Commerce also submitted a document calling for separation of pharmacies from hospitals.

Representatives of over 600 pharmaceutical companies gathered at the site of the Guangdong provincial hospital drug purchase tender to protest the heavy price reductions on government-priced drug products and the failure for 80% of such products to pass even the first round of the tendering.

Despite NDRC threats, many pharmaceutical companies stopped supply of a number of drug products that are priced too low after NDRC introduced its 21st round of price cut on January 26. One example is co-enzyme A (freeze-dried powder for injection), the supply of which was almost completely terminated due to heavy cut on its price. The result was devastating for medical institutions and patients, and NDRC was forced to make temporary compromises in unannounced forms.

What does the future hold for the pharma industry in China?

A recent industry research showed that 40% of Chinese pharma companies made losses in 2006 and 900 GMP-certified manufacturing facilities stopped production. It concluded that the pharmaceutical industry is now at the brinks of survival.

The research went on to say that 60% of the remaining profits of the pharmaceutical industry in 2006 went to a small number of multinational pharmaceutical companies (MPCs) and Sino-foreign joint ventures.

While MPCs, with pipelines of patent products, are somewhat less impacted than the local companies by recent turbulences, they also suffered huge setbacks in 2006. Revenues of Novartis China rose only 6% last year, against a 26% growth in 2005. The company, nevertheless, continues to be upbeat about its future in China with plans for more investments this year.

Indeed, why wouldn't the MPCs be optimistic when both time and money are on their side As one of the earliest Novartis employees in China in the 1980s, I remember vividly the painstaking years for the company to negotiate its first JV deal and to build its pharma plant in Beijing. We even wondered then if the company would ever be able to start selling in China. But now Novartis is rewarded for its persistence and investments with over CNY 2 billion in annual sales, and that makes it one of the largest pharmaceutical companies in the country. Nevertheless, this is only the beginning of its growth, much bigger rewards are yet to come.

When turbulences and transitional periods are over, which may take years in the worst scenarios, order and stability will regain ground. For a small number of companies that are fit enough to survive this long and harsh winter, many of whom are MPCs with patience and financial muscles, the spring will undoubtedly yield them enormous market growth with long-lasting prospects.

For existing smaller companies without niche and specialty, my advice is to cut the loss and get out of this business quickly before they are frozen in the winter blitzards yet to come. This winter will be too long for the weak to endure and when spring comes, the marketplace is more likely to be a game land for the dinosaurs with no space left for small players.

Those who have the reasons and resolve to stay on, beware that financial muscle will be needed to ride through this rough transition. Overseas stock listing is a popular route for fund raising but prospects dimmed somewhat following the recent crush of Shanghai Stock Market and Chinese concept stocks. Nonetheless, companies successful in raising substantial capital will be able to take advantage of the current industry weakness to gain fast growth through acquisition of good-quality assets and businesses.

Foreseeable threats ahead for MPCs

Despite many positive prospects for them, The MPCs should carefully observe and actively participate in the process of China's healthcare reform. One biggest single risk ahead is how the proposed national essential drugs system fits into the entire healthcare reform. Many proponents of the system suggest that the future national essential drugs list should merge with or replace the reimbursement list of the existing urban employee basic medical insurance system and the future urban resident basic medical insurance system.

The proposed national essential drug system, which may be based on WHO essential drug recommendations, is likely to provide huge drug expenditure savings to the Chinese government, and help revive many ailing large-scale state-owned pharmaceutical companies that have huge production capacity of such drugs. If successful, it may become the foundation for China to launch the universal basic medical coverage in future.

For research-based MPCs, however, it may mean slower market growth as people will have to pay for newer drugs out of their own pocket, while they can receive essential drugs free through basic medical coverage. MPCs may also experience shrinking market share for their off-patent brand name drugs under the same scenarios.

As prices for essential drugs come down, MPCs will face increasing pressure from the government for price cuts on both their off-patent and patented products.

China's intention to promote its community healthcare networks as the front line for healthcare may present additional challenges to MPCs, who have little marketing and sales coverage of such facilities now. How and if such coverage should be developed will again rest on the specifics of the future healthcare reform. What is sure now is that hospitals, where MPCs are strong traditionally, may lose a big chunk of their existing patient base to community healthcare facilities.

Current regulatory corrections over the use of brand names will produce, at the least, short term negative impacts or disruptions on the business of MPCs. Both SFDA and MOH now have regulations that ban the use of brand names on drugs other than NCEs, which need to be clarified.

At this critical moment, senior executives of MPCs in China are advised to make it a top priority to study and influence the undercurrents in the development of China's healthcare reform plan, which will affect the businesses of MPCs in this market for many years to come.

The Market

China's Import and Export of Medicines and Health Products Exceeded US$30 Billion in 2006

According to China Chamber of Commerce for Import and Export of Medicines and Health Products, the foreign trade of medicines and health products rose steadily in 2006, despite turmoil in the domestic pharmaceutical market.

Import and Export Statistics for 2006

Import and export of medicines and health products in 2006 reached US$30,670 million, up 20.4% over 2005. Among the total, export of medicines and health products was up by 26. 3% totaling US$19,610 million, while import of the same category was up by 11.2% totaling US$11,060 million.

Chinese Customs statistics show that import and export of Western medicines rose 21.3% in the year to US$18,730 million, accounting for 61.1% of total export of medicines and health products. Among this total, export of Western medicines reached US$11,650 million, up 24.3%, while import rose 16. 7% to US$7,080 million.

Import and export of APIs was US$15,350 million last year, up 21.6% compared with 2005. Export of APIs grew 25.6% reaching US$10,630 million.

Export of finished Western pharmaceutical products also rose 23.7% totaling US$500 million. They were exported to 162 countries and regions, and such export to Vietnam, Thailand, Malaysia and North Korea doubled during the period.

Export of biochemical drugs (biopharmaceuticals) also grew 11.9% totaling US$930 million in 2006, among which export was up 2.3% at US$520 million, while import was up by 27.0% at US$410 million. Export of heparin sodium had been on a steadily rise, while that of chondroitin sulfate fell sharply due to US regulatory changes.

Import and export of traditional Chinese medicines were up 23.9% reaching 1,390 million in 2006, among which export took up US$1,090 million. Export of herbal materials had been on a sharp rising trend, while that of formulated traditional Chinese medicines grew slowly.

China's Import & Export of Medicines and Health Products in 2006 Unit: US$ mil

Category	Import	+/-(%)	Export	+/-(%)
All	11,060	+11.2	19,610	+26.3
Western Medicines	7,080	+16.7	11,650	+24.3
APIs			10,630	+25.6
Finished Products			500	+23.7
Biochemical Drugs	410	+27.0	520	+2.3
Traditional Chinese Medicines	300		1,090	
Formulated TCMs			135	
Medical Devices	3,680		6,870	+28.6
Medical Dressings			2,230	+22.3
Medical Consumables			1,100	+30.0
Diagnostic & Med. Equipment			2,110	+36.7
Dental Equipment & Materials			870	+39.7

Source: Chinese Custom Statistics

Characteristics for Export Trade in 2006

Asia, Europe and North America continue to be the three biggest regional export markets for medicines and health products from

China, representing 40.2%, 28.0% and 21.2% respectively of the total export of medicines and health products.

Export sales of medicines and health products to the US market reached a new high of US$3,930 million last year, up by 20% compared with 2005.

Leading export markets of APIs from China in 2006 included US, India, Japan, Germany and the Netherlands, while that of finished Western pharmaceutical products were Japan, Hong Kong, Nigeria, Pakistan and Australia, and that of traditional Chinese medicines were Japan, Hong Kong, USA, South Korea, India and Germany. The increasing import of APIs from China by India in 2006 indicated the rising trend for the Indian pharmaceutical industry to rely on cheap Chinese raw materials from China for production of higher-value-added drug products.

APIs continue to be the core export product segment, accounting for 54% of the total export of medicines and health products. Chinese API exporters continue to control a substantial market share for a number of product categories including antibiotics, vitamins, hormonal drugs, analgesics & antipyretics, amino acids and alkaloid. An increasing number of Chinese API exporters have obtained FDA approvals or COS certifications.

Chinese Pharma Industry Growth Slowed in 2006

According to official statistics Pharma China obtained, the total revenues of China's pharmaceutical industry in 2006 was around CNY 520 billion (US$67 billion) with a total profit before taxes of CNY 41.5 billion (US$5.3 billion), up by 17% and 11% respectively compared with the same figures in 2005.

Despite its continued rise, the growth rate of the Chinese pharmaceutical industry slowed down significantly in 2006, and its profit margin fell by nearly 50%.

25.6% of the Chinese pharmaceutical companies were making losses, and their total losses rose 26.2% in 2006 compared with the same figure in 2005.

Pakistani Pharma Threatened by FTA with China

Pakistani pharmaceutical companies feel threatened by the potential flood of imported medicines, especially imports from China, according to Pakistani press reports.

Chinese pharmaceutical companies have signed about 250 inquires of different products following a Free Trade Agreement inked in November last year, most of their products are already produced locally. Pakstani pharma companies fear that the cheap prices of Chinese firms may force them out of the market or into heavy losses.

An anonymous pharmaceutical company official expressed that while the government was unable to stop Chinese products owing to the signing of FTA, it could endeavor to arrange export of medicines to China, which would balance the trade between the two sides.

He added that the Chinese markets can be lucrative for Pakistani pharmaceuticals if the products are exported, but the criterion, process and fees charged by China are the strong barriers for Pakistani companies.

Dr Farnaz Malik, Secretary Drug Control Authority said that inquiries relating to price and quality of Chinese and other foreign products are under process. She added that her government would not allow import of basic products being produced locally.

However, its pharmaceutical manufacturers said that the basic products are very limited in categories and restricting the import of these basic medicines could not protect the country's pharmaceutical sector. Chairman of Pakistan Pharmaceutical Manufacturer Kaiser Waheed suggested the government only allow import of medicines not manufactured in Pakistan instead of opening doors for foreign makers.

Asia Under Threat by "Epidemic of Counterfeits"

Asia is seeing an "epidemic of counterfeits" of life-saving drugs and the scale of the problem is escalating, experts said recently.

China, they say, is the main source of these drugs which are being produced on an industrial scale.

Malaria medicines have been particularly hard hit. In a recent sampling in Southeast Asia, 53% of the anti-malaria products bought were fakes. Counterfeits for bogus antibiotics, tuberculosis drugs, AIDS drugs and even meningitis vaccines have also been found.

Estimates of the deaths caused by fakes run from tens of thousands a year to 200,000 or more, according to the International Herald Tribune.

According to Dr Paul Newton from the Center for Tropical Medicine in Vientiane, Laos, a prime target of counterfeiters now is artemisinin, the newest miracle cure for malaria. His team found that more than half the malaria drugs it bought in Southeast Asia were counterfeit, and it also discovered 12 fakes being sold as artesunate pills made by Guilin Pharma of China. Many of the fake artesunate pills found by Dr Newton's team were "startlingly accurate" in appearance and much more devious in effect than investigators had suspected.

NDRC: Drug Expenditure Raised by Changes in Drug Consumption Pattern

NDRC released in late February its investigative report, "Sharp Rise of Antibiotics Expenditures Caused by Changes in Their Hospital Consumption Pattern and Volume", which concluded that the rapid growth of drug expenditures is related to increased purchase of expensive drug products by hospitals.

The report is based on research conducted by the Pricing Department of NDRC using hospital drug purchase audits of the Chinese Pharmaceutical Association.

The research team is composed of experts from the Medical School of Beijing University and the Chinese Pharmaceutical Association, who investigated, on behalf of NDRC, antibiotic drug purchases by 12 representative hospitals in Beijing between 1996 and 2005.

The research found that despite the fact that the hospital purchase prices of antibiotics by these representative hospitals fell by 50% between 1996 and 2005, hospital purchase value of antibiotics continued to rise sharply during the period. Both

volume increase and substitution of cheaper antibiotics with more expensive ones contributed to the rising hospital spending on antibiotics, but the latter is found to be a much more significant factor.

The result shows that the hospital purchase of expensive antibiotic drugs shot up sharply during the period, while that of cheap antibiotics fell steeply.

The situation is not only limited to antibiotics but also applies to all therapeutic categories, said Prof. Wu Song, Deputy Director of the Institute of Material Medica, Chinese Academy of Medical Sciences.

He commented to the local press that the rapidly expanded use of newer generations of expensive drugs is not driven by clinical needs, but rather by financial incentives.

Industry News

60% of Chinese Pharma Industry's Profits in 2006 Went to MPCs

According to a recent survey jointly conducted by Chinese Pharmaceutical Enterprise Competitiveness Project and China Social-Economic Investigation Center, 40% of Chinese pharmaceutical companies made losses in 2006, and the total profits of the Chinese pharmaceutical industry fell by 20% as a whole.

Furthermore, the survey found that 60% of the total profits of the Chinese pharmaceutical industry in 2006 went to wholly-owned foreign subsidiaries and Sino-foreign joint ventures.

900 GMP-certified local pharmaceutical manufacturers were forced to suspend their production in 2006, the research suggested.

Researchers say that the local pharmaceutical industry is facing unprecedented pressure for survival and development.

Pharmaceutical Ads Continue to Dominate Chinese Advertising Space

Advertising revenue in China continued to climb fast in 2006, according to Nielsen Media Research. The country's advertising market reached CNY 386.6 billion ($50 billion) last year, up 22% from 2005. Income was up in all media sectors, but magazines and TV in particular experienced dramatic growth of 27% and 26%, respectively. TV took the lion's share of the ad market, with 81% of the total revenue.

Pharmaceutical ads continue to dominate the advertising space, followed by cosmetics and toiletries and retail services. Four of the top five advertised brands in 2006 were Chinese, including telecom giant China Mobile and three pharmaceutical companies.

India's CIPI to Sign MOU with CPMA

In an effort to help small-scale Indian pharmaceutical manufacturers to develop business in China, the Confederation of Indian Pharmaceutical Industries (CIPI), the umbrella organization of small-scale pharma associations from different states, and the China Pharmaceutical Manufacturers Association (CPMA) will soon sign a MOU to explore joint ventures, contract manufacturing opportunities, joint research possibilities and technology transfer.

TS Jaishankar, chairman of CIPI, said the association was planning to enter into more similar tie-ups to help small-scale units expand overseas and survive in business.

The 6,000-odd small scale pharma units, which employ 100, 000 people and have an annual production value of about Rs 7,000 crore (US$1.6 billion), were mainly surviving by working as contract manufacturers for the major domestic companies and through government hospital supply orders.

CIPI is planning a delegation to China for exploring opportunities. The delegation hopes to explore the possibility of acting as suppliers to Indian pharma majors by roping in direct supply pacts with Chinese companies.

Small Indian companies can also bring Chinese drugs to the Indian market depending upon their core competent areas of manufacturing, said Jaishankar.

CSKI Enters Strategic Alliance with Takasima

China Sky One Medical, Inc. (OTCBB: CSKI), a producer and distributor of topical Chinese medicines in China, announced a strategic agreement with Takasima Industries in late February.

As a result of this agreement, Takasima has been engaged as the sole agent of CSKI's patch products in Malaysia. Takasima has commenced its efforts with CSKI's Slim Patch product line. The Slim Patch is a weight loss product that is currently sold in China under the "Tian Di Ren" brand. The Slim Patch will be repackaged and sold in Malaysia under the "Takasima" brand.

The strategic agreement requires Takasima to generate monthly sales revenue of approximately US$1.0 million. Since the signing of the agreement early this year, Takasima has fulfilled its monthly obligation. The agreement also provides that Takasima has the first right of refusal to become the sole distributor of the Slim Patch in all of Southeast Asia.

Bayer China to Complete Reorganization of Schering AG China by Mid-2007

Following Bayer's acquisition of its German rival Schering AG, Bayer Healthcare China is poised to re-organize Schering AG China and the integration is expected to complete by mid-2007.

"As a part of the reshuffle, some of our colleagues have been transferred to Bayer Healthcare's Beijing office. There are still a few uncertainties at the moment as some positions of our current staff will have to be redefined to avoid overlapping responsibilities," an official from Schering AG China said.

He said the current product lines of Schering AG China will still remain the same. "Our female health care products and diagnostic imaging products will supplement Bayer HealthCare China's current lines. These two departments will remain comparatively independent. But our oncology products will

have to be integrated into Bayer HealthCare China's oncology department. I don't think there will be big changes in the whole structure of Bayer HealthCare China," the official said.

He said that the business of Schring AG China is likely to be boosted by Bayer HealthCare's acquisition. Last year, sales revenues of Schering AG China rose more than 30% despite the current negative policies implemented by the government.

Schering AG China currently employs about 500 staff, which includes workers at its Guangzhou plant. It remains unclear if Schering AG China will lay off any employees.

"Many of Schering AG China's employees are awaiting the company's final decisions regarding the change, while some have chosen to leave the company," the official said.

ReceptoPharm Forms JV with Nanogene Biotech

Nutra Pharma Corp. (OTCBB: NPHC), a biotechnology company that is developing drugs for HIV and Multiple Sclerosis, announced on March 7 that its drug discovery division, ReceptoPharm, signed a nonbinding letter of intent with Zhong Xin Dong Tai Co., Ltd. (Nanogene Biotechnology), to create a joint venture in China aiming at developing the Company's antiviral drug, RPI-MN, for the Chinese market. RPI-MN is ReceptoPharm's lead drug candidate being researched for the treatment of HIV/AIDS and other viral disorders.

"We are excited about the opportunity to create this joint venture with such a well established Chinese company," explained Paul Reid, CEO of ReceptoPharm, Inc. "Nanogene Biotechnology's existing supply of raw material is sufficient to produce up to 200 million doses of RPI-MN, which we believe would be enough to treat everyone infected with HIV in China for one year. The joint venture will produce and market the antiviral drugs for the Chinese market," he added.

Under the proposed Joint Venture, Nanogene Biotechnology will provide drug raw material and the required financing, including the funding of clinical trials in China, necessary to meet all required Chinese governmental consents and approvals. ReceptoPharm will provide the Joint Venture with the bulk drug substance. Nanogene Biotechnology will have the controlling interest in the new entity. However, ReceptoPharm will retain ownership of all intellectual property, trade secrets and other confidential information relating to the drug and its manufacture.

IPO/Capital Related News Roundup

Tongjitang Seeks NYSE Listing

Tongjitang Chinese Medicines Co. Ltd., which owns one of China's well-known TCM brands, is seeking to list its stock at the New York Stock Exchange. It plans to raise up to US$168 million from its IPO.

Tongjitang describes itself as a vertically integrated specialty pharmaceutical company focusing on the development, marketing and sales of modern formulated traditional Chinese medicine – both prescription and OTC.

The company is offering 9.87 million American Depositary shares representing 29.5% of the company at a price between $15 and $17 apiece. This gives a total deal size of $148.0 million to $167.7 million, or a maximum of $192.9 million if the 15% overallotment option is exercised in full. The price range values the company at 18 to 20.5 times based on consensus 2007 earnings forecasts.

Merrill is also joint bookrunner for the offering together with UBS.

Between 2004 and 2006, the company achieved a bottom line compound annual growth rate of 243%, reaching a net profit of CNY 134.3 million (US$17.2 million) last year. Revenues grew at a CAGR of 43.8% in the same period, reaching CNY 485 million ($62.1 million) in 2006.

Wanxin Biotechnology Listed Through Merger with CDoor (SinoBiomed)

Wanxin Bio-Technology Limited ("Wanxin") recently became a US listed company through acquisition of a shell company, CDoor Corp., which is now named Sinobiomed Inc. (OTCBB: OBM).

Wanxin, through its subsidiary Manhing Enterprises Limited, owns 82% of Shanghai Wanxing Bio-pharmaceuticals Co., Ltd.

Shanghai Wanxing Bio-pharmaceuticals Co. Ltd. ("Shanghai Wanxing") specializes in the development of genetically engineered recombinant protein drugs and vaccines, and currently has 10 products approved or in development, which respond to a wide range of diseases, including malaria and hepatitis. The development of Shanghai Wanxing's malaria vaccine candidate is supported by the WHO and the Program for Appropriate Technology in Health's Malaria Vaccine Initiative. Shanghai Wanxing's candidate vaccine received a US patent in September 2006.

Lotus Pharma Completed US$3 Million Financing

Lotus Pharmaceuticals, Inc. (OTCBB: LTUS) announced it has completed a US$3 million financing with a U.S.-based investment fund. The proceeds will be utilized to expand its domestic markets, increase sales and to acquire additional drugs for its Beijing retail stores.

Skystar BioPharm Raises US$4.075 Million in Private Placement

Skystar Bio-Pharmaceutical Company (OTCBB: SKBI), a Chinese bio-pharmaceutical company, announced on March 7 that it raised gross proceeds of US$4.075 million in a private transaction with several institutional and accredited investors in the US. Pacific Ridge Capital, LLC acted as the placement agent for this transaction.

Jointown Group in talks with Itochu ahead of Hong Kong listing

Jointown Group (Jiuzhoutong), the third largest pharmaceutical distribution group in China, is believed to be in talks with a Japanese trading company Itochu Corp ahead of its planned Hong Kong initial public offering, according to the 21st Century Business Herald.

The newspaper, citing an unidentified source, said Itochu is

expected to be introduced as a strategic investor with an investment of CNY 300 million (US$38.5 million). Jointown is believed to be talking with other potential foreign investors.

Jointown Group had sales of CNY 13 billion (US$1.7 billion) in 2006, the third-largest in its sector, following state-owned China National Pharmaceutical Group Corp and Shanghai Pharmaceutical Group Co Ltd. The company is seeking Hong Kong listing in order to raise capital for expansion.

Frontier Biosciences Acquires Stake in Chinese CRO

Frontier Biosciences, a US preclinical research services provider, announced in early March that it has bought a majority stake in a China-based preclinical contract research organization (CRO) National Chengdu Center for Safety Evaluation of Drugs (NCCSED), which specializes in drug safety evaluation.

"We used to be in collaboration with the Chengdu Center but we have now a contractual partnership and we co-manage the facility," Beth Wong, assistant vice president of business development at Frontier said during an interview with Outsourcing-Pharma.com

"Instead of putting up our own facility we decided it was better to partner with an organization which has existing capabilities and a good track record in conducting preclinical studies."

Wong said the company will expand the existing facilities to bring its bio-analytical capacity to full-scale and will relocate its Chengdu-based primate breeding activity into the new facility in order to increase the size of its toxicology facility.

Frontier expects to complete the construction of its new facilities by early 2008.

Daiichi Beijing Receives Authorization to Promote Imported Drugs

Daiichi Sankyo announced in late February that Daiichi Pharmaceutical (Beijing) Co., Ltd., a subsidiary of Daiichi Pharmaceutical Co., Ltd., itself a wholly owned subsidiary of Daiichi Sankyo, has been granted permission to promote pharmaceutical products of its parent company within China.

The amended registration gives approval for the sales promotion of pharmaceuticals sold within China by parent company Daiichi Sankyo Pharmaceutical, headquartered in Tokyo. This is the first time that a Japanese company has been granted such permission.

Previously, Daiichi Pharmaceutical (Beijing) could only sell and promote products it had manufactured by itself, but the newly granted permission enables it to also promote products imported and sold by Shanghai Sankyo Pharmaceutical Co., Ltd, which had already acquired a pharmaceutical distribution license. This will broaden the sales scope of its medical representatives (MR) and should accelerate the synergies within the Daiichi Sankyo Group's pharmaceutical business in China.

Daiichi Pharmaceutical (Beijing) plans to focus its sales promotions on the anti-infectives franchise that includes Cravit and Tarivid.

Pfizer Consolidates Asia-Pacific Helpdesk Facilities to China

Through a new IT-outsourcing deal with HP, Pfizer is consolidating all its IT helpdesk operations in the Asia-Pacific to HP's new Global Solution Center in Dalian, China.

Over three stages, Pfizer's helpdesk facilities in now located in 14 countries/territories in Asia Pacific, including Japan, Thailand, Indonesia, Pakistan, Australia, New Zealand, Korea, Taiwan, Hong Kong, Malaysia, Singapore, Philippines and India, will be moved to the new Chinese site in Dalian. The move for Japan is already undergoing, which is expected to be operational by mid-2007.

The consolidation move will allow Pfizer to reduce costs and the number of staff required, in addition to benefiting from the use of shared facilities.

Pfizer's main pharmaceutical manufacturing facility in China is located in Dalian.

Novo Nordisk Establishes Research Foundation with CAS

Novo Nordisk and the Chinese Academy of Sciences (CAS) signed an agreement on March 5 to form a joint research foundation in China. The aim of Novo Nordisk–Chinese Academy of Science Research Foundation is to fund or co-fund activities of common interest within the fields of diabetes and biopharmaceuticals, including related disciplines and technologies such as protein chemistry, immunology, inflammation, toxicology, oncology, endocrinology and drug delivery.

In January 2002, Novo Nordisk established a world class R&D centre in Beijing, which is the first R&D centre in China established by international bio-pharmaceutical companies. After five years of R&D activity in China, Novo Nordisk decided to cooperate with CAS and provide a funding of US$2 million to support research in diabetes and biopharmaceuticals.

"This cooperation illustrates the great attention Novo Nordisk pays to China as well as our long-term commitment to help in further developing the Chinese healthcare system," says Dr Mads Krogsgaard Thomsen, Executive Vice President and Chief Science Officer of Novo Nordisk. He also emphasized that Novo Nordisk will continue to launch new products in China and increase the company's R&D presence in the country.

Walgreens Resists China Temptation

Despite recent movements by Alliance Boots, Europe's top retail pharmacy chain, to enter the Chinese market, leading US pharmaceutical retail chain Walgreens said on March 5 that it would not consider a market entry into China's retail pharmacy market at present, due to a completely foreign market environment and negative policies placed on the industry, according to Russian News Agency Interfax.

Earlier there had been rumors that Walgreens may line up with the Chinese retail giant Guomei for such a market entry into China.

Novartis Upbeat about Its Future in China Despite Lower Growth in 2006

This year will be a watershed for pharmaceuticals, but the sector is moving in a positive direction after intensive regulation in the past year, according to James Deng, president and CEO of Beijing Novartis Pharma Ltd.

He said on March 12 that the Chinese government's decision to announce its healthcare system reform plan within the year will create a clear and orderly environment for the industry.

The ongoing regulatory and market corrections in the Chinese pharma sector also have produced negative impacts on Novartis in China. Revenues of the company rose only 6% to CNY 2.13 billion (US$273 million) in 2006, compared with a growth of 26.3% in 2005.

Beijing Novartis Pharma, the flagship subsidiary of Novartis China, booked revenue of CNY 1.8 billion (US$231 million), ranking No.4 among the multinational pharmaceutical firms in the country. No details about the growth of its revenues were announced by Beijing Novartis Pharma. The company has five major products with over CNY 100 million in annual sales in the therapeutic areas of cardiovascular system, oncology and immuno-regulation/transplant.

Most of the growth in 2006, however, came from vaccines. Novartis China anticipated high growth for flu vaccines and rabbies vaccines in 2007. The company is now applying for a new production site in China for rabbies vaccine, in order to ease the current situation of short supply.

But with an expected improving market environment and increased investment in China, Jeffery Li, president of Novartis China, said his company would aim for growth of around 20% in China in 2007.

Li said that Novartis invested US$250 million in China in 2006, which is 350% of its investment in China in 2005. He said the company will continue to increase its investments in China in 2007.

Major new investment projects in 2006 include: Novartis (China) R&D Center, Suzhou Novartis Pharmaceutical Science and Technology Ltd., and a US$4.5 million collaborative research project with the Kuming Natural Plants Research Institute under the Chinese Academy of Sciences.

Suzhou Novartis Pharmaceutical Science and Technology Ltd., with a total investment of US$175 million, will become one of Novartis's largest API production sites globally. The site will be operational by the end of April 2007 and is an integral part of Novartis's global supply chain. The company will develop and produce APIs and intermediates of Novartis's new drugs in the therapeutic areas of leukemia, epilepsy, high blood pressure and others.

In addition, Novartis is also expanding its manufacturing facility in Changping, Beijing. The expansion is expected to be completed in the second half of 2007, and will double the plant's existing production capacity.

Sanjiu (999) Held Talks with Deutsche Bank over 40% Stake, But CRG Prevailed Eventually

Sanjiu Enterprise Group held talks with Deutsche Bank-consortium over a 40% stake in the group for CNY 4 billion in cash, according to the group's listed subsidiary, Sanjiu Pharmaceutical Co Ltd (SZA 000999).

Sanjiu Enterprises Group said in November 2006 that five potential investors - a Deutsche Bank-led consortium, a Shanghai Industrial Investment (Holding) Co Ltd consortium, a New World Group consortium, Fosun Group and China Resources Group - filed restructuring proposals for Sanjiu Group. It is believed that Fosun Group, New World Group consortium and Shanghai Industrial consortium have been left out of the shortlist due to low bids.

China Resources Group, another state-owned conglomerate which is currently restructuring China Worldbest Group, submitted a proposal to buy 70% stakes of Sanjiu Enterprises Group for CNY 3.9 billion yuan, and may have the support of SASAC, the state-owned asset regulator.

According to the bid requirements set by SASAC, Sanjiu Enterprises Group should still be controlled by the agency.

While the management of Sanjiu Enterprises Group may prefer to work with Deutsche Bank which has made a much higher offer and may leave the management intact after the investment, SASAC's attitude will be critical for the final decision.

Just before we close this issue, we learnt that SASAC announced on March 20 that it picked CRG to re-organize Sanjiu (999) Enterprises Group.

Largest Pharma Distribution Center in Southwest China to be Established in Chongqing

Shenzhen Neptune Group, Chongqing Jinguan Science & Technology Group and Chongqing Huabo Pharmaceutical Ltd. jointly announced in late February to found Chongqing Modern Pharmaceutical Distribution Center, which is anticipated to be the largest pharmaceutical distribution and logistics facility in Southwest China.

Total investment of the project is CNY 600 million (US$77 million) and the center is expected to become operational within five years.

The new distribution center is expected to cover Chongqing and surrounding areas, as well as Sichuan province and other parts of Southwestern China regions.

Over 100 Pharma Companies Join Hands to Demand Their Voices Heard over Healthcare Reform

Over 100 Chinese pharmaceutical companies grouped together in February under the China National Association of Pharmaceutical Enterprise Management in a bid to submit a document, "Suggestions for Supporting the Healthy Development of the Pharmaceutical Industry", to the highest level of the Chinese central government.

The document blames the current healthcare financing mechanism, which uses profits from drug sales to fund the country's medical system, and the widespread corruption in the medical system to be the culprits of drug abuse and rising medical expenditures in the country.

It also suggests that hospitals nationwide gain more than CNY

50 billion in profits from drug sales, and all types of PR fees and kickbacks to hospitals and physicians amount to another CNY tens of billions. In addition, hospitals use freely more than CNY 100 billion (US$12.8 billion) of the working capital of the Chinese pharmaceutical industry to maintain their operations.

It says that the dominating position of the medical sector in drug sales has suffocated the existence of the pharmaceutical industry, and has now forced the industry to the brinks of survival.

Under the present healthcare financing model, pharmaceutical enterprises, faced with repeated price cuts, can no longer absorb the rising costs of production and their survival are seriously threatened, the document stated.

The document also harshly criticizes the country's drug regulatory system which has produced constant turbulences, failed to foster development of the pharmaceutical industry, discouraged innovation, and created uneven ground for competition between foreign and local pharmaceutical companies.

It calls for termination of all types of superficial reform measures that do not change the current healthcare financing mechanism, which is the culprit of rising medical expenditures and related problems, saying these reform measures will only delay the pace for structural reform.

In addition, the document calls for the formation of a single central government agency that is in charge of the healthcare reform, which is independent from NDRC, the Ministry of Health and the SFDA.

It is reported that the highest level of the Chinese government already viewed the document and instructed the Ministry of Health and NDRC to work on this paper. Minister of Health Gao Qiang already met with representatives of the Association to communicate.

Meanwhile, China National Association of Pharmaceutical Commerce also prepared a carefully researched paper for the central government expressing its views on China's healthcare reform. The document emphasizes the importance of separating hospitals from drug sales as a critical solution for the challenges the Chinese healthcare sector currently faces.

Top Ten Retail Pharmacy Chains in 2006

The Retail Pharmacy Chain Branch of the China National Association of Pharmaceutical Commerce announced at the 2007 Annual Pharmaceutical Retailing Conference on March 5 the top 10 retail pharmacy chains in China in 2006 (by revenues). They are:

Rank	Retail Pharmacy Chain Operator
1	Hunan Laobaixing Pharmacy Chain Ltd.
2	Shenzhen Nepstar Pharmaceutical Ltd.
3	Liaoning Chengda Fangyuan Pharmacy Chain Ltd.
4	Hubei Tongjitang Pharmacy Ltd.
5	Chongqing Tongjunge Pharmacy Ltd.
6	Jiangxi Kaixinren Pharmacy Chain Ltd.
7	Chongqing Heping Pharmacy Chain Ltd.
8	Shanghai Huashi Pharmacy Ltd.
9	Harbin Remin Tongtai Pharmacy Chain Ltd.
10	Yunan Hongxiang Yixintang Pharmacy Chain Ltd.

Regulatory News

SFDA News Roundup

SFDA Proposes ADR Assistance System

The Drug Safety Supervision Department of SFDA has recently proposed to establish an adverse drug reaction (ADR) welfare system, under which sufferers of ADRs will be assisted and compensated financially.

The rising trend of adverse drug reactions in China, as highlighted by a number of recent high-profile substandard drug cases, is causing increasing social problems in the country due to the lack of relevant laws and regulations for resolution of ADR situations.

SFDA made following proposals in the areas of ADR welfare and resolution:

1. Setting up a system or mechanism for ADR assistance and resolution, and establish a lead government agency for this matter;

2. Improving the legal system dealing with ADR related damages, responsibilities, assistance, compensation and resolution. A mechanism for ADR assistance and resolution should be established by law, such as the ADR damage assistance fund adopted in Taiwan and Japan, or a drug product liability system.

3. The proposed ADR assistance system will help alleviate and diversify the high risks associated with ADR from individual companies to the pharmaceutical industry as a whole.

4. The ADR damage assistance fund should be financed through a levy on pharmaceutical manufacturers (including importers), medical institutions, and from government funding.

In the case of drug product liability system, the solution for pharmaceutical companies should be to purchase commercial product liability insurance policies.

5. The proposed ADR assistance system will cover only ADR cases involving legally approved drugs, cases where sufferers have exhausted other means of compensation, cases involving no improper use of medicines, no medical accidents, no emergency use, and no liability from pharmaceutical manufacturers, distributors, medical institutions or physicians, and cases causing substantial damages.

6. The coverage should include sufferer's medical and nursing fees, consequent income loss, etc. Those handicapped by ADRs should also be paid for their living assistance and supplements, etc. Those killed by ADRs shoud be paid for their funeral, and living expenses of their dependents, etc.

7. The government should designate a special agency regulating this area and providing official appraisal of relevant damages.

Although the SFDA's proposal is a preliminary move to regulate this area, it is important for the pharmaceutical industry to follow the development and become involved with the relevant legislation process at an early stage.

Legislations in this area may have a substantial impact on the cost structure of pharmaceutical products in China.

SFDA Announcements on Administrative Protection of Pharmaceuticals

Announcement #: 105

Date: February 14, 2007

Content: Pfizer's ZELDOX for injection (ziprasidone mesylate) proceed to substantive examination

Announcement #: 106

Date: February 25, 2007

Contents: Ending of drug administrative protection for Organon Teknika's Esmeron (rocuronium bromide)

SFDA Switches 57 Drugs to OTC Status

The State Food and Drug Administration recently issued a notice announcing the switch of minoxidil gel and other 56 drugs to OTC status.

This switch includes 13 pharmaceutical chemical drugs and 44 traditional Chinese medicines.

List of 13 Pharmceutical Chemicals Switched to OTC in January 2007

Product Name	Key Ingredients	OTC Class
Minoxidil gel	40 g/0.88 g	A
Compound miconazole nitrate cream	20 mg	A
Acetaminophen + pseudoephedrine sulfate + clemastine fumarate	0.335 mg + 500 mg + 30 mg	A
Acetaminophen + pseudoephedrine sulfate + dextromethorphan (day) / Acetaminophen + pseudoephedrine sulfate + dextromethorphan + chlorpheniramine maleate (night) tablets	325 mg + 30 mg + 10 mg / 325 mg + 30 mg + 10 mg + 2 mg	A
Acetaminophen + pseudoephedrine sulfate + + chlorpheniramine maleate chewable tablet	160 mg+15 mg+1 mg	A
Acetaminophen + pseudoephedrine sulfate + + chlorpheniramine maleate tablet	320 mg+30 mg+2 mg	A
Acetaminophen + pseudoephedrine sulfate + dextromethorphan + Phenol glycerylether	325 mg + 30 mg + 15 mg + 200 mg	A
Pirenoxine Sodium Eye Drops	0.8 mg	A
Iron protein succinylate oral liquid	800 mg	A
Acetaminophen dispersible tablet	100 mg	B
Loratadine dispersible tablet	10 mg	A
Tinidazole suppository	200 mg	A
Ibuprofen chewable tablet	50 mg	A

Source: SFDA

SFDA Adopts Tough Measures to Fend Off Corruption

In an attempt to prevent corruption and abuse of power in drug regulation and registration, the State Food and Drug Administration (SFDA) will adopt a collective liability system, said Wu Zhen, SFDA deputy director general during an online interview on February 27.

The collective liability system will be composed of four elements: 1) drug evaluation decisions will be made by evaluation officials collectively; 2) drug evaluation officials will be held liable for their wrongdoings; 3) information about drug evaluation officials will be made public to ensure public supervision; and 4) transparency of the drug evaluation process will be improved through continuous updates of SFDA's website and public information platform.

Wu said that it is a likely scenario that all future product registration submissions will be made through online applications.

"The goal is to prevent any single person from abusing his power," Wu said.

He said the SFDA would "leave no stone unturned" during investigations of any corruption in the agency.

Wu denied that the SFDA had suspended granting approval to new drugs amid all the corruption scandals and defended the national standard regime by saying that it would weed out substandard drugs. "Having a single standard is conducive to the supervision of drug safety," he said.

Wu also offered legal basis for the current move of SFDA to re-approve drug products. He indicated that the validity of all drug approvals is five years, and upon expiry they need to be re-approved in accordance with relevant regulations. Thus the approved drug products that need to be re-registered in 2007 are those renewed in 2002 and newly approved in 2003. However, he also said that not all approved drug products need to be re-registered.

In a separate move, SFDA announced that it barred its officials from owning stocks in pharmaceutical companies in an effort to clean up the scandal-plagued agency, according to Shao Mingli, Director General of SFDA.

"This kind of wrongdoing in the past should be corrected and those who violate the rules in future will be sacked," said Shao in a recent speech to the Chinese press.

Meanwhile, the Chinese central government is beginning to implement a policy that requires all levels of local governments to relieve their local drug administrative departments from their management duties over the local pharmaceutical industry, and to concentrate solely on drug regulation. The move is an attempt to avoid conflicts of interest for drug administrations when they play both the role of regulators of the pharmaceutical industry and that of industry promoters.

Prior to this, many local level drug administrations, including a few provincial level drug administrations such as Hainan Provincial Drug Administration, had such dual roles. Hainan Provincial Drug Administration is currently transferring its pharmaceutical industrial management duties to Hainan Provincial Industrial Administration.

Most of the provincial level drug administrations have already been relieved their industrial administrative duties.

SFDA Revokes Licenses of Bioyee and Kangliyuan

Guangdong Bioyee Pharmaceutical Company and Hainan Kangliyuan Pharm Company have had their GMP certifications revoked due to their GMP violations.

SFDA said recently the GMP violations of the two companies were found during a GMP audit in December 2006. SFDA demanded these two companies to recall related medicines and, at the same time, requested Guangdong Provincial Food and Drug Administration to further investigate the violations.

Bioyee produces blood products, and Kangliyuan is a manufacturer of freeze dried powder for injections, capsules, pills and other raw materials for manufacturing medicine. Kangliyuan is a close ally of Zheng Xiaoyu, corrupt former SFDA director general who was arrested at the end of 2006.

During 2006, SFDA conducted audits on 24 pharmaceutical

manufacturers, and the outcome was alarming: GMP certificates of 13 of those companies were revoked, nine companies were asked to make changes, and the remaining two were under investigation.

NDRC Launched 22nd Drug Price Cut on 278 TCMs

National Development and Reform Commission (NDRC) launched its 22nd drug price cut in March, and this round of cut targeted 278 formulated traditional Chinese medicines of more than 1,000 specifications. The cut is the largest price cut ever on traditional Chinese medicine products.

The average price reduction of this cut is 15%, with the highest cut at 81%. New prices will become effective on March 15.

NDRC said that it took into consideration the rising costs of raw materials of TCMs when cutting these prices. It also adopted preferential pricing for better-quality TCM products from selected manufacturers.

NDRC Sets Rules for Drug Price Regulators

Warned by the corruption in the SFDA, National NDRC issued a "Pharmaceutical Pricing Work Codes (Interim)" in late February that sets behavior codes for drug pricing regulators in the process of their work.

Effective from March 1, 2007, the new interim regulation requires the following:

A minimum of two investigators are requested to be present for all on-site investigations concerning cost structures of pharmaceutical products. Investigators are not allowed to charge pharmaceutical companies any fees or to attend dinner receptions by pharmaceutical companies.

- Drug regulators are banned from meeting pharmaceutical company personnel outside office hours or accepting invitations from pharma companies for overseas trips.
- Drug pricing evaluations should be carried out by external experts, who are randomly selected from databases on such experts.
- Drug price review plans must be approved collectively by relevant drug price regulators. Disciplinary officials should be invited to attend important meetings concerning drug price reviews.
- Job functions of drug price regulators should be rotated every five years.

APIs/Bulk Drugs

United Pharma (HK) Group Builds Major API Facilities in Inner Mongolia

United Pharmaceutical (HK) Group reached agreements with the local governments in Inner Mongolia to invest CNY 1,680 million (US$215 million) between 2007 and 2009 into the construction of a number of major API and raw material manufacturing facilities in the autonomous region.

The company will invest CNY450 million (US$61.5 million) into phase I project that includes a 6-APA plant with 5,000 tons of annual production capacity, a starch plant with 120,000 tons of annual production capacity, and manufacturing facilities for phenylacetic acid and feed additives. Phase II project, with CNY 600 million (US$76.9 million) investment, includes a plant for potassium clavulanate (600 tons in annual capacity) and a plant 7-ACA (800 tons in annual capacity). Phase III project will be a L-lactic acid plant involving another CNY 600 million (US$76.9 million) investment.

Construction of phase I project has already begun, and the 6-APA plant is expected to complete by October 2007.

United Pharmaceutical (HK) Group, through its subsidiary in Zhuhai, is the largest manufacturer of Amoxicillin finished products, and owns one of the well-known cough medicine brands in China.

Product and R&D

China Rivals Western Leading Nations in Nanotech R&D

China is expected to drive the global nanotechnology and catalysts market this year, a new report from research firm RNCOS claims. The report predicts that nanoscience will gain huge investment over the next twenty years, bringing about radical changes in the pharmaceutical industry.

Another report by Lux Research released in early March indicated that China increased its investment in nanotech R&D by double-digits in 2006, along with leading Western nations including U.S. and Japan. Russia and India have also stepped up their nano activity.

"China is moving up very rapidly in nanotech activity, almost to a point of being a peer of the United States and some of the top countries," Michael Holman, a senior analyst at Lux Research told United Press International.

The report says that, globally, government spending on nanotech grew 10% to US$6.4 billion in 2006 in total. The United States was on top, with US$1.78 billion, followed by Japan and Germany. But China actually ranks second when factoring in purchasing power parity. The nation's funding is the equivalent of US$906 million.

However, China's nanotech research is more focused on material science and electronics, rather than life sciences as other leading Western nations. In addition, China still lags behind in industrializing and commercializing its nano research.

Furthermore, "China could present a headache for companies in life sciences in terms of patent protection," Holman said.

The report suggests that corporate funding of nanotech research jumped 19% to $5.3 billion in 2006, with the United States again leading this category with $1.93 billion. China's corporate funding ranks significantly lower at $165 million, but this represents a 68% jump from 2005.

Sebivo Approved in China

Novartis announced in early March that the SFDA approved Sebivo (telbivudine) as a treatment for chronic hepatitis B, a

disease estimated to affect more than 100 million people in China and considered the second leading cause of death in the country. The decision came shortly after Sebivo was recommended for approval in the European Union.

Sebivo meets an urgent demand for effective therapies that can provide profound and sustained suppression of the hepatitis B virus, reducing the risk of liver disease and improving long-term outcomes for patients. Sebivo will be available in China as of April.

"Sebivo's demonstrated ability to rapidly and profoundly drive down virus levels within the first 24 weeks of treatment, in addition to its favorable safety profile, makes it a promising treatment option for patients with chronic hepatitis B", said Prof. Jidong Jia, Director of the Liver Research Center, Beijing Friendship Hospital, Capital Medical University, China.

Worldwide regulatory submissions of Sebivo have been based primarily on one-year data from the GLOBE study, the largest worldwide registration trial ever conducted in patients with chronic hepatitis B and the first to include patients from mainland China. The study results demonstrated that Sebivo provided greater viral suppression and significantly greater response on all virologic markers after one year compared to lamivudine, the most widely prescribed treatment. An additional Chinese phase III trial, involving 332 adult Chinese patients with CHB, corroborated these findings and supplemented the filing in China.

Sebivo, a once-daily oral treatment, is already approved in 12 countries including Switzerland and the US, where it is marketed as Tyzeka.

HUYA Licenses International Rights of Chidamide from China

HUYA Bioscience International LLC announced on March 7 that it exclusively licensed worldwide rights outside China of the cancer compound chidamide from Shenzhen Chipscreen Biosciences Ltd. Chidamide, is an investigational cancer compound currently approved for Phase I clinical trial in China.

Chidamide is an orally bioavailable histone deacetylase (HDAC) inhibitor derived from the benzamide class. Histone deacetylase inhibitors are a new class of cancer drugs that induce selective regulation of gene expression in cancer cells. Chidamide has exhibited preclinical efficacy and pharmacokinetic properties that may translate into a superior clinical profile over other HDAC inhibitors currently in development or being marketed.

HUYA will co-develop chidamide with Chipscreen through Phase I clinical trials to be initiated shortly in China. Thereafter, HUYA plans to file an Investigational New Drug application and commence clinical trials of chidamide/HBI-8000 in the United States and Europe. Financial terms of the transaction were not disclosed.

Mireille Gingras, HUYA's President and Chief Executive Officer, stated, "We are excited to complete what we believe is the first license and co-development deal of such an innovative investigational pharmaceutical from a China-based company. HUYA's mission is to comprehensively source proprietary late preclinical and early clinical drug candidates from China for development and commercialization in Western markets. This approach is significantly strengthened by partnership and cooperation on early stage clinical trials in China."

Kunming Pharma in Dispute with WHO over Malaria Treatment

Kunming Pharmaceutical Corp., a major Chinese pharmaceutical firm which co-developed the anti-malaria drug artemisinin, is reported to be engaged in an ongoing dispute with the WHO over the best way to fight malaria.

According to WHO, artemisinin should be used only in combination with other antimalarials to prevent malaria parasites from developing resistance to the drug, and the agency says that by manufacturing and selling its artemisinin monotherapy, Kunming is jeopardizing global health.

WHO has urged companies and governments to promote artemisinin-based combination therapies (ACTs), such as one made by Novartis AG of Switzerland, in hopes it will slow any growing resistance of the malaria parasite to the mono-therapy, according to the Wall Street Journal.

However, Kunming and other Chinese pharmaceutical companies have said that they believe WHO is "overestimating the risk of resistance and underestimating the urgent need for treatments", and "worries about resistance ... are not fully based on solid science", the Journal reports. In addition, Chinese companies "resent being boxed out of part of a market for a drug Chinese scientists invented," according to the Journal.

Kunming sells millions of doses of artemisinin in more than 30 countries annually. It doesn't deny the value of ACTs but says it should be permitted to phase in its own ACT, called Acro, on its own schedule, and does not want to pull out its artemisinin monotherapy while the drug is still selling well.

WHO officials say Acro is a promising drug and are encouraging Kunming to submit laboratory and clinical data so the drug can be prequalified by the agency and made eligible for purchase by U.N. agencies. However, Kunming wants to avoid the possibility of having to spend years trying to receive WHO approval for Acro and instead wants to continue distributing the drug through commercial channels.

General Health

WHO Says China Faces Serious Challenges in Improving Life Expectancy

A report by the prestigious Chinese Academy of Sciences released in Februray predicted that by the middle of this century, the Chinese would be living to an average age of 85, up from the current 72.

But Dr. Henk Bekedam, the WHO's representative in China, said the Chinese will not reach that goal unless they cut down on smoking, improve their diet, and exercise more. China has 350 million smokers, according to Bekedam, said were likely to die five to 10 years earlier than if they didn't smoke. He said a modern lifestyle of fast food and little exercise had led to 150 million Chinese suffering from chronic high blood pressure, 23% of the population being overweight, and 7% obese. China also has some of the most polluted cities and waterways in the world.

Bekedam said that despite the country's booming economy, average life expectancy had increased by only three years over

the last three decades. He said only the well-off had access to quality health care, and the government must provide better care for the poor.

Bekedam said China should adopt international standards for its medicines, and encourage more preventative health care.

Health Minister Pushes for National Essential Drug System

According to local press reports, Health Minister Gao Qiang recently expressed that the key issue for reducing sharply rising medical expenditures is to contain drug expenditures through the establishment of national essential drug system based on the principles that these essential drugs are "safe, clinically effective, demanded by medical institutions, and cheaply-priced".

He mentioned that the WHO recommends 300 to 400 essential medicines to all countries every year.

Under this system the government will organize, regulate and intervene the production, supply and purchase of these essential drugs to ensure their availability, safety and low price.

Gao revealed that relevant government agencies have now reached common understandings in terms of the guiding doctrines, essential principles, directions & goals, and main tasks of the healthcare reform following months of research and discussions. However, specifics of the healthcare reform, including the main contents of the healthcare reform, operating modes of medical insurance, government-funded medical security measures, contents of service providers, and ways of regulation, are still under discussion.

The trials of the urban resident basic medical insurance system will be initiated as soon as the State Council approves the submitted plans, he said.

Gao also admitted that the Ministry of Health has not paid sufficient attention to the area of occupational disease, and promised to step up efforts. According to incomplete statistics of the Ministry of Health, around 16 million workplaces in China are affected by toxic or occupational hazards causing health damages of different degrees to approximately 200 million employees. The ministry has made occupational hazards one of its five emphasized areas for regulation in 2007.

Healthcare Reform Plans to Come from Six Parallel Sources

According to a recent report by Vice Health Minister Chen Xiaohong to the Chinese People's Political Consultative Conference, the Chinese government has entrusted six organizations for development of healthcare reform proposals.

The six organizations include prestigious Chinese academic institution(s), international organization(s) including the WHO, research institution(s) under the State Council, and well-known international private research firm(s).

The government will compare the six proposals from different sources, and eventually decide on a final model for the healthcare reform.

Chen said that the Ministry of Health will push forward a number of reforms this year, including:

- Reallocating urban healthcare resources and restructuring some public hospitals into community healthcare facilities;
- Decentralizing the management of medical institutions to local governments;
- Strengthening public service of government-owned hospitals, and increasing funding to these hospitals in order to reform the current hospital financing mechanism through drug sales.

China and WHO Conduct Joint Research into Viability of Essential Drugs

In order to understand the viability of essential drugs in China, the China Office of WHO, the Ministry of Health and SFDA are now conducting a joint investigation into the availability and use of essential drugs in China, according to the SFDA.

An investigative forum on the availability of essential drugs in China was therefore held between March 7 and 8 in Jinan City, Shandong province.

Officials from SFDA and researchers from the Public Health Management School of Shanghai Fudan University met with representatives of local government departments responsible for drug administration, fiscal finance, price control and basic medical insurance, and representatives of pharmaceutical manufacturers, retailers, medical institutions and patients.

Subjects of discussion included China's drug policy, relationship between the existing essential drug list and the reimbursement list of the urban employee basic medical insurance system, and government's role in essential drug provision and use.

Eli Lilly Sponsors Survey on Sex Life of Chinese Couples

China will conduct its first-ever survey on the sex life of middle-aged couples this year, China News Service reported on February 15.

The survey, to be conducted by the China Population Communication Center and the pharmaceutical company Eli Lilly & Co, will ask couples if they are intimate and if their sex life is satisfactory. Eli Lilly is the maker of the Cialis, an erectile dysfunction drug.

CCA Survey Finds China's Medical Services Improved

A recent survey by the China Consumer Association (CCA) finds that more than 70% of patients are satisfied with the outpatient services provided by the country's medical institutions in recent months.

The survey, conducted from last September to November, covered 761 patients at outpatient clinics of 178 State and private hospitals in 11 provinces and cities. Survey results suggest that general medical services ha been upgraded, and the attitude of doctors toward patients had improved in recent months. The findings of the survey were released on March 2, 2007.

Statistics from the CCA show the nation's medical service sector has been receiving complaints and criticism since 2004. The survey finds high medical costs as the major complaint of the respondents.

Besides costs, the survey also finds the lax procedure for dispensing prescriptions to be a major concern to people. 56% of the doctors involved in the survey were willing to prescribe drugs without seeing the patient.

Urban Resident Basic Medical Insurance System to be Launched for Trial in March

According to reliable sources, three central government agencies, NDRC, the Ministry of Health and the Ministry of Labor and Social Security, have agreed on a detailed plan to expand the current urban employee basic medical insurance system to cover all urban residents.

The three agencies are believed to have submitted "Trial Plans for Urban Resident Basic Medical Insurance System" to the State Council for final approval, which may come in the month of March.

Currently the urban employee basic medical insurance system covers 130???? employees in urban areas, while the new rural cooperative medical care system is designed to cover rural residents. Urban residents who are not employees, such as children, migrant workers, students, and self-employed, are the only people without any form of medical security. The new system, under the name of urban resident basic medical insurance system, is designed to provide basic medical coverage to such urban residents.

The new system is expected to be launched in the second half of 2007 on a experimental basis, to be expanded in 2008, and fully-implemented nationwide in 2009.

It is proposed that the new system be funded by premium contributions from individuals and a combination of central and local government finance. It will be administered regionally in line with administrative structure of the current urban employee basic medical insurance system.

The new system will require insured patients to visit designated community healthcare facilities first for treatment and referral before visiting hospitals. There will be no personal medical spending accounts as under urban employee basic medical insurance system.

Morbidity Trends of 59 Types of Cancer in the Past Two Decades

According to a recent research report - Prevention and Analysis of Maglinant Tumor Epidemic Trends, the average morbidity of 59 types of cancers rose 50% in the past 20 years in China. The research was led by Dr Hao Xishan, President of Oncology Hospital, Tianjin Medical University.

The research studied 20-year data from a cancer-death monitoring system which included information on 5.2 million cancer-related deaths. It found the morbidity of cancers rising with age, and people over 65 represents 55% of all the cancer-related deaths.

The research predicts that, by 2010, the leading cancers will be lung cancer, liver cancer and colon cancer among males in China, while that among Chinese females will be breast cancer, lung cancer and colon cancer. The causes for changes in leading cancers include increased smoking, Westernization of food intake, rising obesity and falling physical exercises.

Future Expenditures for Kidney Dialysis and Transplant Predicted to be Astronomical

According to a recent large-scale epidemiology survey, the incidence rate of chronic nephronia among Beijing adult residents is 9.3%. 16,000 adult residents of Beijing were surveyed, among whom 13,925 met research requirements.

It is found that the incidence of albuminuria among valid survey participants is 3.5%, that of renal function degression is 1.7% and that of blood urine 3.5%. Leading causes of such conditions include aging, high blood pressure, diabetes, lipid metabolism disorder and intake of drugs with renal toxicity.

Based on the research, experts estimate that China now has at least 120 million chronic nephronia patients, among whom 1% will develop into renal failure.

Experts also predict that the future expenditures for kidney dialysis and kidney transplant will be astronomical.

Cancer Incidence Up Sharply Among Female Residents in Shanghai

According to information from Shanghai Municipal Disease Prevention and Control Center, the cancer incidence and death rates among female residents of Shanghai have risen significantly in the past two decades, and such rates has also been rising among younger females. Leading cancers among this population group include breast cancer, cervical cancer, ovarian cancer and endometrial cancer.

The center says there are now 134,000 surviving cancer patients in Shanghai, with females accounting for 54% of them. The morbidity of cancers among Shanghai females residents is 1%. Breast cancer is the most common among this group, representing 30% of all cancer patients from this group.

Currently females over the ages of 60 and 65 as the high risk groups, account for 21% and 16% of the total Shanghai population respectively. However, the number of cancer patients from females between the age of 40 and 59 is rising fast to a level similar to that of the over 60 age group.

People in the News

Former PhRMA President to Head US-China Strategic Economic Dialogue

US Secretary of the Treasury Hank Paulson announced in February the appointment of ***Alan Holmer*** to run the US-China strategic economic dialogue, as US-China bilateral talks intensify ahead of the next bilateral summit in May. Holmer

was formerly President and CEO of the Pharmaceutical Research and Manufacturers of America (PhRMA) and deputy US trade representative.

Chinese Official Appointments

Wang Guoqiang, formerly Vice Commissioner of National Population and Family Planning Commission, was appointed on March 1 as the Vice Minister of Health and Director General of State Administration of Traditional Chinese Medicine.

Wang PeiAn was appointed on the same date to take over Wang Guoqiang's former post as the Vice Commissioner of National Population and Family Planning Commission.

Bu Zhengfa and ***Hua Fuzhou*** were removed from their posts as the Vice Ministers of Labor and Social Security.

She Jing was removed from her post as the Vice Minister of Health and Director General of Traditional Chinese Medicine.

Another Former Senior Drug Regulator Detained over Corruption

Zheng Shangjin, former director of Zhejiang Provincial Food and Drug Administration, was detained Feb. 17 on charges of bribe-taking. Zheng was dismissed from his post in October 2006.

His arrest may be related with the ongoing investigation of the corruption ring of Zheng Xiaoyu, former director general of SFDA.

Only weeks before the arrest, Zhejiang Provincial Food and Drug Administration issued a statement denying Zheng Shangjin's connection with Zheng Xiaoyu, and suggested his departure from the agency in late 2006 was just normal retirement.

Other News

Upcoming Industry Events

Conference Title: **China 2007 R&D Summit**
Event Organizer: IBC Asia
Conference Date: June 04 - 06, 2007
Conference Venue: Grand Hyatt Hotel - Shanghai, China
Contact Person: Ms. Alison McInerney
Tel: +65 6835 5136
Fax: +65 6733 5087
Email: alison.mcinerney@ibcasia.com.sg

Conference Title: **Diagnostics & Therapeutics Innovation**
Event Organizer: Marcus Evans
Conference Date: May 28 - 29, 2007
Conference Venue: Meritus Mandarin Hotel, Singapore
Contact Person: Tan Peng Pheng
Tel: +603 2723 6614
Fax:+603 2723 6699
Email: tanp@marcusevanskl.com

Premier Wen Jiabao Outlines Four Major Tasks of the Government in Healthcare in 2007

During his govenment report to the recent 5th session of the Tenth National People's Congress, Premier Wen Jiabao outlined four major areas in the healthcare sector that the Chinese government will focus on in 2007:

1. Actively pushing forward the implementation of the new rural cooperative medical care system. The Chinese government will invest CNY 10.1 billion into this area, an increase of CNY 5.8 billion over 2006.

2. A new urban healthcare system will be established on the basis of community healthcare networks. Urban medical resources will be optimized and development of community healthcare services will be supported. The central government will provide appropriate funding to the central and western regions for this work.

3. Experiments of urban resident basic medical care system, funded primarily by premium contributions, will be initiated. The government will provide appropriate financial support to people with financial difficulties.

4. Prevention of major infectious diseases will be ensured. The central government will increase CNY 2.8 billion investment into this area to expand the national free immunization program to include an additional 15 vaccinations such as hepatitis B and epidemic meningitis.

According to Premier Wen, public health expenditures of the Chinese government were CNY 13.8 billion in 2006, up by 65. 4% over 2005.

Stop Press

TEDA Holdings to Reorganize Sihuan Pharma

Sihuan Pharmaceutical Shareholding Co. Ltd. (Sihuan), a major Chinese pharmaceutical company, announced in mid-March that TEDA Holdings reached agreement with its parent, Sihuan Biological Industries Group Ltd. to reorganize itself.

Sihuan Pharmaceutical Ltd. is a publicly-traded company on the Shenzhen Stock Exchange. The company has been heavily in debt and it made an estimated loss of CNY 57 million in 2006. In addition, the company was under investigations by Chinese securities regulators for irregular loan guarantees totaling CNY 100 million. Trade of the company's stock had been suspended until March 14.

It is believed that all the existing personnel, assets and liabilities of Sihuan will be transferred to its parent, Sichuan Biological Industries Group Ltd. before the reorganization takes place.

TEDA Holdings said earlier that it may inject selected assets of its own into Sihuan. Rumors have been circulating that TEDA Holdings plans to use Sihuan as a shell company for one of its subsidiaries, Bohai Securities, to gain stock listing. TEDA Holdings, whose primary businesses are real estate development and finance, has so far made no comments about its plan to reorganize Sihuan.

Commentaries

Despite Challenges with Worldbest Reorganization, CRG May Be Crowned King of Chinese Pharmaceuticals Afterall

While many outsiders may be under the impression that the re-organization of China Worldbest Group (Worldbest) is already history, CRG is in fact still struggling to push the re-organization forward.

One CRG senior official cautioned recently that there is still a long way to go before the end of Worldbest re-organization, and at present the company is only temporarily out of trouble after clearing parts of its debts.

Qiao Shibo, the new CEO of Worldbest, is frank about the current status of Worldbest. He indicated recently to local press that Worldbest is still in crisis, rather than post-crisis.

Despite clearing some of its debts, substantial equity/assets of Worldbest continue to be frozen or held by its debtors, thus prolonging the process and time of its restructuring.

The long re-organization time and process is now producing a ripple effect and instability among employees, mid-level managers, and subsidiaries. Representatives of core subsidiaries like Shanghai Pharmaceutical Group and Beijing Pharmaceutical Group are already questioning at least the direction of restructuring, if not the ability of CRG to handle this re-organization yet.

So far CRG has been tough in cutting the fat at the headquarters of Worldbest through a restructure of its management system. The number of Worldbest's corporate functional departments has been reduced from 15 to only 7, and the number of HQ employees has been cut to 66 from previously 190.

Worldbest's textile businesses are being integrated into CRG, while its other non-core assets and businesses are being disposed.

Re-organizing and integrating Worldbest's pharmaceutical businesses is probably the most important task of all, so that the new Worldbest will become efficient, competitive, and at the end of the day, a profitable business unit of CRG soon.

However, CRG is meeting some challenges in this respect, especially when it comes to the integration of Shanghai Pharmaceutical Group (SPG) into its reign.

Owning 40% of Shanghai Pharmaceutical Group (SPG) makes CRG the largest shareholder of the company, but nonetheless, does not warrant it to be a controlling shareholder. The rest of the 60% is owned by Shanghai Municipal State Asset Supervision and Administration Commission and other Shanghai government-owned concerns.

In addition, the management of SPG attempted to bring in strategic investors in preparation for an independent IPO in 2005 and 2006. A number of groups, such as Singapore's Temasek Holdings, Citibank, Goldman Sachs and Carlyle Group expressed their interests for a 25% stake in SPG. However, due diligence of these investors revealed a financial blackhole in CNY billions, scaring all of them away.

Despite of CRG's hope to increase its stake in SPG and its deep background in the central government, the Shanghainese seems undetered and unwilling to let SPG out of its realm. After all, SPG may be critical for Shanghai's plan to make pharma one of its pillar industries.

So far CRG even failed to appoint a new chairman to Shanghai Pharmaceutical Group, replacing Zhou Yucheng, who was the former chief of Worldbest and still chairman of SPG.

Parts of the trouble CRG has with gaining control of Shanghai Pharmaceutical Group, local experts suggest, might be related with the debts Worldbest owes to the state banks in Shanghai, the bulk of which is yet to be cleared.

Whatever the reasons for CRG's Waterloo in Shanghai, its battle to take over SPG will be critical for its successful restructure of Worldbest. Losing SPG may produce a domino effect on its other businesses, such as Beijing Pharmaceutical Group, which is 50%-owned by CRG.

Despite the difficulties in the Worldbest reorganization, CRG was one of the leading contenders for reorganization of another failed conglomerate, Sanjiu Enterprises Group (999). It is believed that CRG submitted a proposal to acquire 70% of Sanjiu for CNY 3.9 billion.

Latest development – CRG may be crowned the King of Chinese pharmaceuticals

As *Pharma China* anticipated, the State-owned Assets Supervision and Administration Commission (SASAC) announced on March 19 its final decision to select CRG to take over and reorganize the troubled state-owned pharmaceutical company Sanjiu (999) Enterprises Group, despite a much better deal from a consortium of investors led by the Deutsche Bank.

SASAC said that it had picked CRG to rescue the debt-laden Sanjiu in order to "protect the interests of the group's minority shareholders and ensure the healthy development of the company."

CRG's influence in the central government, which is best demonstrated in the above victory, must not be underestimated.

On the SPG front, we just learnt from reliable sources that CRG's bid to control SPG may end in a compromise between CRG and the Shanghai Municipal Government. It is believed that a deal may be struck between CRG and Shanghai Municipal Government, under which CRG/Worldbest will gain a 70% stake in SPG, while Shanghai Enterprises Group, a representative of Shanghai Municipal Government will hold the rest 30%. However, as a compromise, CRG will transfer the medical device business of SPG to Shanghai Enterprises Group, and hold only a minority interest in this business.

When all these deals and reorganizations finally draw to a close, CRG will have the control over five of the largest Chinese pharmaceutical companies, namely Worldbest, Sanjiu (999), SPG, Beijing Pharmaceutical Group and Shandong Dong'er Erjiao Group, under its wings. Consequently, it will become the undisputed King of Chinese pharmaceuticals by size, finally satisfying the dreams of an "aircraft carrier" in the Chinese pharmaceutical industry by many government agencies and Chinese *Mandarins*.

Development of Community Healthcare Sector Bottlenecked

Despite recent determination and pushes by the Chinese government to develop the country's urban community healthcare network as one of the primary solutions to contain rapid growth of medical expenditures, there are four major bottlenecks that hinder its rapid growth, according to Chen Lingfu, a member of the Chinese People's Political Consultative Conference (CPPCC).

- Although prior government policies already mandated the functions of the urban community healthcare facilities, including health education, disease prevention, healthcare, rehabilitation and family planning, such facilities have been severely under-funded, forcing community healthcare facilities to depend financially on profits from medical and drug revenues.
- Community healthcare facilities are currently poorly-equipped and its medical personnel severely under-qualified to cater for the healthcare needs of urban residents. For example, only 11.9% of healthcare professionals in urban community healthcare facilities in Jiangsu province are university graduates, and three to five healthcare professionals in some communities need to cater for around 10,000 residents.
- There are disconnections between the government goals and reality. For example, 40% of community healthcare facilities in Jiangsu province are not even listed by the urban employee basic medical insurance system for reimbursement.
- Coordination between hospitals and urban community healthcare facilities is poor. One large hospital investigated by Chen referred only three patients to community healthcare facilities in a month.

According to the Ministry of Health, 65% of outpatients and 77% of inpatients can be treated by community healthcare facilities, resulting in a saving of CNY 45 per outpatient, and CNY 990 per inpatient. Currently China has 23,036 community healthcare facilities.

The Chinese government is stepping up its efforts to boost the community healthcare sector. The Ministry of Fiscal Finance reported at the recent session of the National People's Congress that it has listed the healthcare reform as one of the most important areas for government investment and fiscal finance this year. The government plans to spend CNY 31, 276 million in healthcare this year, up by 86.8% compared with 2005.

Stop Press

New Drug Advertising Regulations Jointly Issued by SFDA and SAIC

SFDA and the State Administration of Industry and Commerce have jointly issued "Provisions for Evaluation of Drug Advertisements" and "Guidelines for Evaluation and Publication of Drug Advertisements". Both regulations will become effective as of May 1, 2007.

The new "Provisions for Evaluation of Drug Advertisements" is intended to further clarify the requirements and procedures for drug advertising, which puts special emphasis on the following two areas:

1. Advertisers of drugs who illegally change the contents of approved drug advertisements will have all their related drug advertising approvals withdrawn, and will be banned from applying for such drug advertisements within one year; and

2. Illegal drug advertisements which are found as inflating the indications of advertised drug products, exaggerating therapeutic efficacy, or deceiving and misleading consumers will have their sales of the related products suspended and will be ordered to remediate negative impacts produced by the illegal advertisements.

Drug advertisements will continue to be approved by the drug administrative agencies, while departments of industry and commerce will be responsible for enforcing and supervising the implementation of drug advertisement regulations.

The new "Guidelines for Evaluation and Publication of Drug Advertisements" replaces the old guideline which was issued in 1995. The new guidelines attempts to further clarify and strengthen regulation of the evaluation and publication of drug advertisements.

A detailed summary of the new "Guidelines for Evaluation and Publication of Drug Advertisements" is available at our website: www.pharmachinaonline.com.

Lenovo Acquisition of Shijiazhuang Pharma Confirmed

As we predicted in December 2006, Hony Capital, the private equity arm of Legend Holdings (parent of Lenovo) is going to acquire state-owned Shijiazhuang Pharmaceutical Group. The news was revealed on March 19 by Ji Chuntang, Mayor of Shijiazhuang City in Hebei province.