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Editorial

More shoes of healthcare reform drop, while uncertainties remain with local implementations

James J. Shen

I have been in China for the past couple of weeks on a "pre-Christmas" tour to get some first-hand feel of the pharma industry following recent launches of critical healthcare reform policies.

The skies in Chinese cities worsened lately with more fog or smog, but once in city centers, it can easily be forgotten as you would be surrounded with Christmas lightings and music everywhere as if Jesus had been born in China. By comparison, I had lots of clean skies in New Jersey but less holiday feel when I left - nevertheless, thanks to Novo Nordisk, which is right next to my community in Princeton, for putting up a giant lit-up Christmas tree every year. On the other hand, if it is not too much to ask in this economic climate, would someone at Novo please help fix your treetop lights - the tree looks weird without it and could bring bad Fengsui (as if anyone cares).

More signs of China's rising global importance

Recently I had the chance to visit Pfizer China's new headquarters in Beijing, which is located in a fancy contemporary building. I felt like "*Granny Liu entering the Grand View Garden for the first time*" (the *Dream of Red Chambers*). I was trapped in the elevator scratching my head with agitation - there was no floor buttons there to press - luckily a real live "*Granny Liu*" came to my rescue and helped me set the floor number outside the elevator in the lobby. Well, I still prefer the old elevator arrangement, which I think is more effortless, but I guess anything new goes well in China - innovative Americans should have a great future in the country, for sure.

During this China trip, I also had chances to meet with some old friends who are or were high-flying MNC executives ¡- everyone is amazed at how fast the global pharmaceutical industry is changing and how important China has become lately. The rising importance of the market, it seems, is leading to some high level personnel reshuffles in MNCs in China. All of a sudden, China is no long a hardship location to many and may even be worth some salary cuts - One of my buddies told me he would not be surprised if some global headquarters move to China ten or 20 years down the road. Along with the rising importance and investments, everyone acknowledges that pressures to deliver higher growth is also mounting - for China CEOs, it will also mean more white hairs.

In the meantime, Eli Lilly told investors recently that the Chinese pharmaceutical market will be a top priority for the company, while GSK pledged to continue its acquisition drive in emerging markets, despite its resentments over the "unreasonable pricing" of some companies.

Though I also have no magic wand, industry friends kept asking me for referrals of good local acquisition targets in the pharma industry. Good candidates are tough to find and they are often unreasonably-priced, just like the real estates in the country. I guess the over-pricing reflects the scarcity of good candidates and does present a dilemma for MNCs.

With little progress made on the M&A side last month, MNCs focused on R&D investments in China. Merck Serono announced in late November a plan to invest US$223 million into its new Chinese R&D operation. Around the same time, Pfizer also reached a deal to expand its R&D operations in central and western China, in addition to its other deals for further joint research with Peking University, collaborative research of Asian cancers, co-marketing of Actos and production of penicillin products in China. On top of all these, rumors of Pfizer's interests in acquiring Glucocorticoid competitor Tianjin Tianyao Pharma have resurfaced after similar speculations last year failing to materialize. The speculated acquisition actually makes a lot of sense and Tianyao happens to be a very good candidate - what's the problem, price?

The acquisition path is not one way only and I heard last week that SinoPharm is one of the three frontrunners bidding for leading European generic drug

company Ratiopharm and the price tag is likely to be higher than US$3 billion. It is a milestone for Chinese pharma companies regardless if SinoPharm succeeds in winning the deal.

Shoes of healthcare reform finally dropped

A series of important healthcare reform policies have been launched in the past few weeks and in the spotlight are the *National Drug Reimbursement List* (NDRL) and the new policy for pharmaceutical pricing.

NDRL

The 2009 edition of NDRL added a total of 260 drugs including 53 Class A drugs. All of the newly added are new drugs launched in recent years with proven therapeutic efficacy and sound safety profiles.

Inclusion of these newer medicines, some of them exclusive products, will present significant growth opportunities for their manufacturers. Nevertheless, the prices of these drugs will most likely be reduced to relieve financial burdens of the basic medical insurance (BMI) programs. The trend is confirmed by an expert with the Ministry of Human Resources and Social Security (MoHRSS).

For very expensive innovative drug products, the new NDRL policy provides a new negotiation mechanism through which relevant BMI agencies and manufacturers can negotiate prices and terms for NDRL inclusion and partial reimbursement. The introduction of the mechanism is a landmark victory for R&D-based pharmaceutical companies and is the result of persistent government-industry communications.

I have been chased by some Wall Street analysts recently for latest developments over the negotiation mechanism and the likelihood for inclusion of certain expensive oncology drugs like Nexavar through this channel. In fact, the latest NDRL policy does not contain specific provisions for the negotiation mechanism and detailed rules are still under development. However, it is comforting to know that RDPAC is communicating closely with the MoHRSS on this subject and will present evidence-based information to support the Ministry's relevant policy development.

NEDL and clinical pathway management experiment

Despite its earlier promise to release Part II of the *National Essential Drug List* (NEDL) and relevant supporting policies before the end of November, the Ministry of Health (MOH) failed again to meet its goal. This makes one wonder how Part II of the NEDL, which is intended for urban hospitals, will fit in with policies of the NDRL and local healthcare reform implementation plans. There has been little news leaked from the MOH about the timeline of this release, but the delay is expected to amplify the complexity of its implementation and inter-agency policy integration.

Meanwhile, the Ministry of Health issued on December 8 an official plan to conduct experiment of clinical pathway management for 112 diseases in 50 large hospitals nationwide. This move is expected to lay the foundation for future introduction of cost-containment measures such as disease-based lump sum medical and drug expenditure reimbursements.

On the other hand, Health Minister Chen Zhu recently published an article citing insufficient government funding as a leading cause of hospitals becoming increasingly profit-driven. Boosting government funding is the only way to turn public hospitals back into true non-profit institutions, he argued. It is obvious Chen is fighting for more government financial support of the public hospitals, which are facing unprecedented reform. He is also seen as gathering public support, thereby pressing the Ministry of Finance and the MoHRSS for more financial support to the medical industry.

New policy on prices of drugs and medical services

Another shoe that dropped in late November is "*The Opinions on Reform of Formation Mechanisms for Drug and Medical Service Prices*". The NDRC-led policy attempts to strike a balance between government regulation and market forces, while upholding the government's commitments to both innovation and cost rationalization.

In the absence of a detailed implementation rule (currently under development), this new drug pricing policy delivers a number of key messages as follows:

- The government regulation centers on prices of essential drugs, reimbursable drugs and controlled substances. Other drug prices are market-driven but the government will seek to improve control of such prescription drugs with high consumption;
- The central government develops drug pricing policies and sets prices of drugs subject to government price control, while provincial level price authorities decide on prices of reimbursable OTC drugs and locally-added BMI reimbursable drugs;
- The basis of government drug pricing will continue to be "average social costs", but other evaluation models will play more important roles;
- Government sets guidance prices and manufacturers are allowed to price their drugs freely below them;
- Government drug pricing is on the basis of generic drug names, and differentiation ratios will be established for different dosage forms and specifications;
- The price gaps between individual priced products (including innovative category drugs) and regular generics will be narrowed. However, preferential pricing is allowed for drugs with significantly higher quality standards and encouraged by government policies. The bracket of the former innovative category is no longer used;
- Innovative products are allowed preferential margins within reasonable periods in accordance with their levels of innovativeness;
- The prices of first-to-copy generic drug products will be set referencing prices of their respective original drugs and the prices of follow-on products should be lower. Uniform prices will be adopted when the number of manufacturers for a given copy drug reaches a certain level;
- Essential drugs are priced by the government with minimal sales expenditure considerations and distributor margins;
- The distribution margins of drugs subject to government pricing will be gradually reduced with ceiling limits, and differentiated margins will be adopted for high-priced and low-priced drugs; and
- During the transition periods of reform, the drug sales margins of medical institutions (not to exceed 15%) will be reduced gradually and local governments are encouraged to introduce zero drug sales margin reform in public hospitals.

It is important to note that the new drug pricing policy continues to support drug innovation, so in principle premium pricing is allowed for innovative drugs. Despite elimination of the innovative bracket for off-patent drugs, R&D-based companies can continue to gain premium pricing through quality claims. Nonetheless, the gap between high quality drugs and regular

generics is expected to be narrowed gradually, thus resulting in chronic price cuts for off-patent innovative drugs.

However, the new policy needs to be further defined via its implementation rules. Important areas of concern include specific pricing models for patented innovative drugs and high quality products, timelines for premium pricing and methods of distributor margin differentiation. Industry communications with the government are critical and must not lose steam at this stage.

All eyes on local implementation of the latest healthcare reform policies

The healthcare reform policies launched so far provide substantial allowance and flexibility for implementation by the provincial-level governments in order to reflect regional differences in local social-economic environments. The provincial level governments have the following authorities as provided by healthcare reform policies in the areas of essential drugs, BMI drug reimbursement and drug pricing.

Essential drugs

Provincial level governments are authorized to add additional drugs to their local essential drug lists in accordance with clinical necessity, local fiscal affordability and level of local BMI funding. Such products should be selected from Category A of the National BMI Reimbursement List (NRL) and from Category B only if needed by special local diseases. Sales of these added drugs must not exceed 30% of the total essential drug sales.

NDRL

Provincial level governments are not authorized to adjust the Class A of the NDRL, but they are allowed to adjust Class B of the NDRL. Drugs listed in the NEDL and those exclusively listed under the OII can not be removed from the local DRLs. Payment limitations or scopes specified in the NDRL can be adjusted but not removed from local DRLs. Certain local participant co-payment ratios of Class B reimbursable drugs can be reset in accordance with affordability of regional BMI funds. Brand names can not be used or noted in the local DRLs.

All provincial level governments are banned from collecting any fees in the process of adjusting the local Class B drug reimbursement list. The total number of adjustments (including eliminations, additions and adjustments to payment limitations or scopes) should not exceed 243.

Provincial level governments should publish their local DRLs before March 31, 2010 and all BMI fund-raising regions are required to complete updates of relevant drug IT systems and databases before June 30, 2010.

Drug pricing

Provincial level governments should determine specific retail prices of essential drugs on the basis of their purchase prices, distribution expenses and drug margins determined in tenders. Local governments are encouraged to explore purchase models which further reduce prices of essential drugs and to explore the establishment of base prices for essential drugs to avoid irregular competition among producers.

Provincial level price authorities are in charge of setting prices of reimbursable OTC drugs (excluding national essential drugs) and locally-added BMI reimbursable drugs. They are also responsible for setting prices of non-profit hospital formulations.

Recent developments

Some provincial level governments have already introduced local implementation plans for healthcare reform and more provinces will follow soon. After releases of these plans, local governments are expected to work on development of their local lists, organizing local tenders and setting relevant prices. Pharmaceutical companies have a limited window of few months from now to lobby provincial level governments.

We are following developments of local implementations closely and will invite relevant experts to write on the subject in a few months when dusts settle at the provincial level.

Vision for the future

My recent conversations with industry executives and Wall Street analysts often touched on the subject of fundamental driver(s) for long term growth of the Chinese pharmaceutical market. Despite short term increase of government funding and expanded coverage of the basic medical insurance programs and the rural cooperative medical scheme, growth spurred by expansions of the NDRL and/or local DRLs will be brief and limited.

The ultimate fruit of the Chinese healthcare reform will be the creation of a healthy and streamlined healthcare environment under which patient needs can be better met by more robust and efficient delivery, management and insurance systems.

As China's healthcare expenditures only accounted for less than 5% of the country's GDP last year, the growth potential should be huge. The healthcare needs of the Chinese are clearly depressed under the present system and need to be released through a reformed healthcare model.

In addition to a universal basic medical insurance system, China needs a well-established commercial healthcare sector (with Chinese characteristics) to meet higher medical needs of its people. Global healthcare insurance companies have what China needs to develop this sector and they are beginning to lay necessary foundations in the country although they are not yet fully ready. Pharmaceutical companies and their trade associations are advised to take this development seriously and find ways to support and integrate with the plans of global health insurers.

Final words

ZS Associates and eyeforpharma conducted a survey of 70 senior pharma executives (66% of them working for MNCs) for their views on the Chinese healthcare reform in the last four months. The full survey findings and observations are in the Feature Articles section of this issue.

Generally executives are optimistic that reforms will be positive for the pharma industry despite some significant potential risks. Interestingly, respondents from the biggest MNCs are the most optimistic. This finding is supported by increased MNC maneuvers and investments in China lately.

The New Year is around the corner again. As hard as it is to believe, this editorial is last one for this decade. Looking back, this decade has witnessed so many industry challenges and critical healthcare policy shifts, but with efforts of many, the outcomes of these changes are by and large positive for the pharmaceutical industry, especially for MNCs.

So all of us who have worked hard for the development of the Chinese pharmaceutical industry and market deserve to enjoy and even indulge a bit in the upcoming holiday season. It also means subscribers will not receive our weekly e-alert in the last week of December as our editors will also take a few days off. As for myself, I will be sailing (... *on a cruise ship, of course*) to Bahamas with family and friends.

To all our readers and families, ***Merry Christmas and Happy New Year!***

News in Focus

Chinese government releases new reform policy for drug and medical service prices

Three government agencies, the National Development and Reform Commission (NDRC), the Ministry of Health (MOH) and the Ministry of Human Resources and Social Security (MoHRSS) jointly issued the long-anticipated reform policy, *The Opinions on Reform of Formation Mechanisms for Drug and Medical Service Prices*.

The following is a thorough summary of the document:

1. *Guiding Principles*

In accordance with the current development stage of the Chinese pharmaceutical industry and the special characteristics of the country's medical services, the price leverage should be fully utilized and the price level of drugs and medical services should be rationalized in order to promote healthcare services and healthy development of the pharmaceutical industry as well as meeting rising healthcare demands of its people.

2. *Basic principles*

a) Government regulation and market forces should be integrated - With the public welfare characteristics of healthcare, government regulation of drug and medical service prices should be strengthened, while the role of market mechanisms should be fully employed. Regulation of pharmaceutical manufacturers and distributors as well as medical institutions should be enhanced to form open, fair, just and orderly drug and medical service markets.

b) New drug innovation should be encouraged while the use of essential drugs & appropriate technologies is supported - The setting of prices should help provide motivation and power to enterprises and medical institutions for developing new products and technologies, protect and support development of traditional Chinese medicine (TCM), and raise competitiveness of the medical and pharmaceutical industry. At the same time, the current economic development level, basic medical insurance (BMI) standard and affordability of the public should be considered, and the use of essential drugs and appropriate technologies should be encouraged to relieve the public from irrational healthcare expenditure burdens.

c) The product quality and service standards of enterprises and medical institutions should be improved persistently - The drug and medical service prices set by the government should reflect differences in product quality, thus encouraging enterprises to enhance their product quality and medical institutions to improve their medical service environments and therapeutic technologies, and consequently satisfying the multi-layered drug consumption and medical service demands of the people.

d) The drug and medical service price reform will be implemented in coordination with the overall healthcare reform - The reform of drug and medical service pricing should help support the overall healthcare reform and should be in concert with the relevant healthcare reform policies. Interests of all stakeholders and affordability of the people should be fully considered and balanced for price adjustments, so that conflicts are resolved.

3. *Objectives and tasks*

- By 2011, the government drug pricing mechanisms will be further refined, pricing activities of enterprises and medical institutions will be relatively streamlined, the order of market prices will turn better, the prices of drugs will become more rational, and the structural problems of medical service prices will be alleviated visibly.
- By 2020, a medical/pharmaceutical price formation mechanism that meets the natural laws of healthcare industry development and integrates government price regulation and market correction mechanism will be established and fine-tuned; drug and medical service prices will timely and objectively reflect the changes of production and services as well as market supply and demands; the regulatory system of drug and medical service prices will be refined with scientific adjustment methods; and the order of drug and medical service prices will be reinforced and market competitive practices will be customary.

Main tasks between 2009 and 2011 are as follows:

- *Fine-tuning regulatory policies for drug and medical service prices* - The scope of drugs and medical service which are subject to government regulation will be adjusted and the relevant rules and regulations will be improved, in order to further refine the price decision making process and raise scientificness & transparency of price regulation.
- *Drug prices will be rationalized* - Based on comprehensive price reviews of all government-regulated drugs, the prices of unreasonably expensive drugs will be reduced while those of cheap products with substantial clinical demands will be raised. The prices of national essential drugs will be developed scientifically.
- *The pricing of different medical services will be rationalized* - On the basis of streamlining medical service pricing items, the prices of some medical services including clinical treatment, nursing, surgery and other services reflective of the value of healthcare professionals will be raised appropriately. At the same time, the prices of large medical equipment examination and treatment will be reduced. Price regulation for use of expensive medical devices, such as implantation and intervention category technologies or products, will be strengthened.

4. *Scope of drugs subject to government price regulation will be adjusted*

The focus of government drug price regulation is on national essential drugs, reimbursable drugs under the BMI programs and special drugs of which the production and distribution are monopolized. All other drugs adopt market prices, but the experiments will be conducted to explore effective ways for strengthening pricing regulation of those prescription drugs with widespread clinical consumption.

5. *Multi-level drug price regulation*

The price authority under the State Council is responsible for developing policies, principles and methods of drug pricing, and setting prices for national essential drugs, reimbursable prescription drugs under the BMI programs and special drugs of which the production and distribution are monopolized.

In accordance with the national policies, provincial level price authorities are responsible for setting prices for reimbursable OTC drugs under the BMI programs (excluding national

essential drugs) and locally-added BMI reimbursable drugs. They are also responsible for setting prices of non-profit hospital formulations, and for establishing relevant authorities and rules in accordance with local realities.

6. *Government sets and publishes drug guidance prices, while producers and distributors establish their own selling and purchase prices.*

Drugs subject to government price regulation, with the exception of drugs under the state immunization programs and state contraceptive programs, should adopt government guidance prices. The prices of narcotics and class I psychoactive drugs should also adopt government guidance prices, but maximum distributor margins will be established for these drugs.

Manufacturers and distributors can determine the selling and purchase prices of drugs under government regulation as long as they do not exceed the government guidance prices.

7. *Government sets drug prices on the basis of generic drug names in principle.*

In principle, the government sets prices on the basis of generic drug names disregarding manufacturers. Existing prices for products of individual manufacturers will be adjusted in the case if they have substantial price gaps (with generics) in order to narrow the price differences. However, differentiated pricing policies will be adopted for drugs which have significantly different quality standards and are covered under relevant government encouragement and supporting policies.

8. *Government price-setting should be on the average social cost basis with considerations of other relevant factors.*

In setting drug prices, the government should follow the basic principles of "compensating costs, allowing reasonable profits and reflecting supply & demand", and consider factors including the current economic development level, BMI standard, affordability of the people, national macro-economic and industrial development policies and clinical value of drugs. Prices can be raised for those clinically-demanded common medicines in short supply.

9. *Price differentiation ratios for different dosage forms and specifications should be established scientifically.*

Rules for price differential ratios among different drug dosage forms and specifications should be refined. Prices for the representative dosage form and specification of each drug should be developed first, and prices of other dosage forms and specifications of the same drug can be set according to relevant differentiation ratios and rules. Pharmaco-economics should gradually be introduced in the price-setting of substitutable drugs and innovative drugs, and reasonable differential ratios should be maintained for different types of drugs.

10. *Drug innovation encouraged.*

Provided drug costs can be reasonably verified, differentiated control on their sales margins will be adopted in accordance with their innovative levels. In order to encourage new drug innovation, relatively higher sales margins are allowed within reasonable periods for drugs with relatively higher innovativeness.

11. *Order in production and competition of copy drugs*

The prices of first-to-copy generic drug products will be set by referencing prices of their respective original drugs; if the original drugs are not marketed in China, the prices of such products will be set on the basis of their reasonable costs. The prices of follow-on copy drugs will be set at certain percentages lower than the first-to-copy drugs. When the number of manufacturers for a given copy drug reaches a certain level, uniform prices will be set for the copy drug according to social average costs and other factors.

12. *Essential drug production and supply encouraged.*

Retail guidance prices will be reasonably set for essential drugs on the basis of generic drug names disregarding manufacturers. In the development of such prices, sales expenditures should be strictly contained and their distribution margins should be suppressed. The prices of essential drugs should be kept relatively stable, and the normal production and supply of national essential drugs should be secured.

13. *Drug distribution margins should be controlled.*

The distribution margins of drugs subject to government guidance prices will be gradually reduced. Ceiling limits will be set for distribution margin rates (value), and differentiated margins will be adopted for high-priced and low-priced drugs -- the margins for high-priced drugs will be lower and those for low-priced drugs will be higher. M&As and reorganizations in the pharmaceutical distribution sector are encouraged through the price leverage, so that the scale of economy is achieved, costs reduced and distribution expenditures driven down.

14. *The policy for drug sales margins of medical institutions will be reformed.*

In accordance with the requirements of "separating medical institutions from drug sales", the compensation mechanisms for medical institutions will be reformed and the drug sales margins of medical institutions will be eliminated gradually. During the transition periods of reform, the drug sales margins of medical institutions will be reduced gradually. Such margins must not exceed 15% and differentiated margins will be applied to high-priced and low-priced drugs. When necessary, maximum margins (value) can be set on high-priced drugs. The margins for TCM crude drugs can be relaxed accordingly.

When integrated with the trials of public hospital reform, local governments are encouraged to introduce zero drug sales margin reform in public hospitals. The reduced revenues of public hospitals from drug sales can be compensated by measures including increased fiscal subsidies, raised medical service prices and introduction of the "pharmacy service fee".

15. Drug market price transactions will be streamlined.

Pharmaceutical distributors should reasonably establish their purchase and selling prices in accordance with the principles of honesty and trust. Industry self-discipline should be strengthened, price information should be open, and transparency of price formation should be improved. Price fraud, price monopoly, price discrimination and other practices damaging legal consumer rights are banned.

16. *Government guidance price and market prices should be integrated in the regulation of medical service prices.*

Government guidance prices should be implemented for basic medical services provided by non-profit medical institutions, while market prices should be implemented for all medical services of profit-oriented medical institutions and special need medical services of non-profit medical institutions.

17. *Uniform policies and multi-level administration will be adopted for the regulation of medical service prices.*

In association with other government departments, the price authority under the State Council is responsible for development of medical service pricing policies, items, principles and

methods, and for guiding and coordinating medical service pricing by local governments. The guidance prices of basic medical services should be developed by provincial level price authorities in association with health departments and human resource & social security departments at the same level.

18. *The prices of basic medical services must reflect the welfare nature of basic medical services.*

The prices of basic medical services should be established in accordance with the principles of "reasonably compensating costs, and meeting needs of the people and affordability of BMI programs". The reasonable costs, on which basic medical service prices are developed, should be calculated after deducting fiscal subsidies and net income from drug sales and medical devices (consumables).

19. *The medical service pricing methods should be reformed.*

In accordance with medical technology development and clinical needs, medical service price items will be rationalized and streamlined. Additions of new medical examination items under the names of new equipment, new reagents and new techniques will be strictly controlled. The pricing methods of medical services will be gradually reformed, and new methods, which can help contain costs and are transparent and easy to operate, will be actively explored. Personal medical services of community and rural township healthcare facilities can be priced on the basis of service time and frequency.

20. *Differentiated guidance prices can be developed for medical services of different grades of medical institutions and different ranks of physicians.*

Different guidance prices can be set on the basis of factors including medical institution grades, physician ranks and market demands. Price differentiations should be extended gradually in order to rationalize patient distribution.

21. *Prices of medical services with special techniques and labor values should be raised.*

According to requirements of reasonably compensating medical service costs and with considerations of government fiscal investments, the basic medical service prices of non-profit medical institutions should be reasonably adjusted, so that the prices of treatment, surgery, nursing and TCM services with special techniques and labor values can be gradually raised.

22. *The prices of major medical equipment examinations and therapies should be reduced.*

Surveillance of the prices of medical examination and therapeutic equipment will be strengthened. The verification of service costs will be improved, and the depreciation of medical examination and therapeutic equipment should be calculated on the basis of fixed workloads. The medical equipment examinations and therapies with high prices should have their prices reduced. Centralized use of such examinations and therapies should be enhanced.

23. *Prices of medical devices will be strengthened.*

The scope of medical devices which are individually-priced outside regular medical service price items should be rationalized. These products should be controlled under a product list. The prices of high value medical devices, especially implant (intervention) category products, should be guided and rationalized through controlling their distribution margins and publicizing their market price information.

24. *Price evaluation will be strengthened and the system of cost investigations and price surveillance will be improved.*

The evaluation system of drug and medical service prices will be improved, the capacity building for relevant price evaluation experts will be strengthened and the methods for calculating costs of drugs and medical service will be fine-tuned. The systems for relevant market price investigations, surveillance and information collection & analysis will be established and improved.

25. *The decision making processes of relevant prices will be further refined.*

The processes and methods of government price-setting should be open and increase transparency of their price decisions. Dynamic adjustment systems should be established for drug and medical service prices. Inter-regional information exchange and coordination mechanisms should be established for prices of drugs and medical services. The opinions of manufacturers, medical service providers, medical insurance agencies, consumers and relevant government departments should be heard thoroughly in the development and adjustment of relevant prices, and participations by all walks of the society in the regulation of drug and medical service prices should be mobilized.

26. *The negotiation mechanisms between supply and demand sides for drug and medical expenditures should be actively explored.*

On the basis of the government-set drug and medical service prices, the medical insurance reimbursement methods will be reformed, and reimbursement schemes by disease, by service units and by lump-sum prepayments will be gradually implemented.

The mechanisms under which medical insurance agencies negotiate with drug manufacturers and medical service providers (hospital associations) over reasonable drug and medical service expenditures as well as reimbursement models should be actively explored. Localities with appropriate conditions are encouraged to initiate trials of various reimbursement schemes and expenditure negotiation mechanisms.

27. *Price supervision and inspection will be strengthened.*

Transparency of drug and medical service prices will be strengthened. Schemes including public listing of medical service, medical device and drug prices as well as daily hospitalization expenditure statements will be fully implemented in medical institutions. Special inspections of drug and medical service prices will be conducted regularly. Long term mechanisms for supervision of drug and medical service prices should be explored and established to regulate pricing practices of pharma manufacturers & distributors and medical institutions.

MoHRSS releases the National Drug Reimbursement List

The Ministry of Human Resources and Social Security (MoHRSS) released the 2009 Edition of the *National Drug Reimbursement List (NDRL) under the Basic Medical Insurance (BMI), Occupational Injuries Insurance (OII) and Maternity Insurance (MI) Programs* on November 30 as scheduled (The document is dated on November 27, 2009).

The MoHRSS Notice for Publication of the NDRL

The following is a thorough summary of the *Notice for Publication of the NDRL* from MoHRSS:

- All provincial level human resource and social security departments are required to organize effective implementation of the new NDRL.
- The 2009 Edition of the NDRL is expanded on the basis of ensuring drug reimbursement policy continuity and in accordance with the drug consumption pattern changes of program participants.
- The new NDRL is divided into three volumes including Western medicines (WMs), formulated traditional Chinese medicines (TCMs) and herbal crude drugs. The WM and formulated TCM volumes of the NDRL adopt the "entry permit system" which specifies the drugs reimbursable by BMI funds. Reimbursable drugs under the BMI programs are classified into Class A and Class B, while reimbursable drugs under the OII and MI programs are not classified. The herbal crude drug volume of the NDRL adopts the "entry exclusion system" which specifies non-reimbursable drugs. Expenditures incurred by participants for reimbursable WMs and formulated TCMs as well as herbal crude drugs will be reimbursed in accordance with relevant rules of BMI, OII and MI programs.
- All therapeutic drugs under the *National Essential Drug List* (NEDL) are included in the Class A of the NDRL. BMI fund-raising regions should fully reimburse Class A reimbursable drugs in accordance with BMI requirements, and additional (local) participant co-payment ratios are not allowed. For Class B reimbursable drugs, certain (local) participant co-payment ratios can be set in accordance with affordability of regional BMI funds before they are reimbursed according to BMI rules. For AIDS/anti-HIV drugs, anti-tuberculosis drugs, anti-malaria drugs and antimony drugs freely supplied by the state, they will not be reimbursed by the BMI, OII and MI programs if participants consume such drugs and meet payment requirements under the public health system. However, if such consumptions do not meet payment requirements under the public health system, relevant expenditures should be reimbursed according to rules of BMI, OII and MI programs.
- All local governments are required to organize well the implementation of the NDRL. All provincial level governments should not adjust the Class A of the NDRL which must be implemented in all BMI fund-raising regions in December 2009. Class B of the NDRL can be implemented by BMI fund-raising regions after provincial level governments adjust their scope according to relevant rules. The minority medicine and herbal crude drug parts of the NDRL should be implemented according to existing policies. Provincial level governments should publish their local DRLs before March 31, 2010 and all BMI fund-raising regions are required to completed updates of relevant drug IT systems and databases before June 30, 2010.
- All provincial level governments are banned from requiring enterprises to submit applications for DRL listing and/or collecting any fees from enterprises in the process of adjusting the local Class B drug reimbursement list. Drugs listed in the NEDL and those exclusively listed under the OII should not be removed in the local DRLs. Payment limitations or scopes specified in the NDRL can be adjusted but not removed in the local DRLs. Brand names can not be used or noted in the local DRLs. Local DRL adjustments must be filed with the MoHRSS, and the total number of adjusted products (including eliminations, additions and adjustments to payment limitations or scopes) should not exceed 243.
- All BMI fund-raising regions must strictly implement the provincial level DRLs and update reimbursable hospital formulations added by designated medical institutions. Furthermore, DRLs must not be adjusted or re-developed under any names or purposes. According to the consumption patterns of reimbursable drugs by medical institutions and retail pharmacies within their territories, BMI fund-raising regions should conduct relevant drug name matches and update their IT systems/drug databases. Provincial level regions with appropriate conditions should conduct uniform updates of their drug databases. All drug reimbursements should be carried out on the basis of drug generic names and brand names are not allowed. Reimbursement of participant expenditures should not be rejected on the ground that relevant drug databases are not updated.
- All local governments should strengthen surveillance and analysis of DRL-listed drug consumptions. Surveillance and analysis systems of DRL-listed drug consumption should be gradually established with uniform drug codes and refined analytical parameters. Primary drug consumption data should be fully utilized in the analysis of all categories of drug consumption and insurance expenditures. Surveillance of drugs with high consumption volume and expenditures should be emphasized, and relevant focused and purpose-oriented regulatory measures should be developed to strengthen control of improper practices, such as drug abuse, in the healthcare process.
- All local governments should strengthen control of the DRL application in designated medical institutions and retail pharmacies. WM prescriptions by physicians must meet clinical/therapeutic principles of Western medicine while TCM prescriptions should follow the principles of Chinese medicine and drug composition. Drugs under the same minimal sub-category should not be duplicated (in a single physician prescription) in principle. There should be clear and corresponding penalties in (medical institution or retail pharmacy) designation agreements for irrational drug prescription practices, duplicate drug prescriptions and drug abuses, e.g. prescribing formulated TCMs under Western medicine diagnosis and Western drugs under TCM diagnosis. Measures should be adopted to encourage physicians to adopt the principles of prescribing Class A before Class B DRL drugs, oral formulations before injectable drugs, and regular release before slow (controlled) release formulations. Pharmacists are encouraged to dispense first the cheaper product among products with the same drug name and dosage form.
- Based on drug prescription regulations, medical operating guidelines, clinical therapeutic guidelines and clinical drug use guidelines developed by the health and other relevant departments, all local governments should strengthen supervision and inspection for rational consumption of drugs, further clarify drug reimbursement scope, refine drug reimbursement evaluation rules and strictly control drug expenditure consumption. The evaluation of DRL applications by designated medical institutions and retail pharmacies should be included in their designation agreements and service evaluations. Relevant evaluation parameters should be fine-tuned and supervision/inspection should be strengthened.
- All local governments should further improve the classified reimbursement of DRL-listed drugs. Maximum payment limits should be explored for NDRL-listed drugs with the same drug

name, dosage form and specification. Participant co-payment ratios can be raised appropriately for Class B reimbursable drugs which are of supplemental therapeutic roles, thus extending the reimbursement ratio gap between such drugs and other Class B drugs. Application processes and relevant evaluation mechanisms for drugs not-listed in the DRL but are needed by clinical emergency rescues and treatment of special diseases should be established for designated medical institutions. In principle, NDRL-listed drugs which can be used for self-medication are reimbursable by BMI programs during hospitalization only and such outpatient drug expenditures can be paid by personal medical expenditure accounts. Compound drugs (including IV solutions containing drugs) that are not listed in the NDRL but are made up by NDRL-listed drugs can be reimbursed as Class B reimbursable drugs if their prices are not higher than the sum of their ingredient drugs respectively. Specific rules for this provision should be developed locally.

- The DRL management should be well integrated with itemized management of medical services and expenditure settlement management. Radioactive isotope category drugs not listed in this edition of the NDRL should be included in the itemized management of medical services. Existing policies are still in force before local governments introduce specific rules for this provision. With regard to drugs for medical imaging and diagnosis, the evaluation of their reimbursement should be strengthened in accordance with itemized management of medical services. In regions where lump sum total expenditure settlement, reimbursement by disease type and preset fixed reimbursement schemes are implemented, relevant evaluation and management measures should be explored and fine-tuned from the perspective of ensuring necessary drug needs of participants, so that basic interests of participants are ensured while expenditures are contained, administration is strengthened and risks are shared.
- This NDRL does not include drugs to be included through negotiation. In association with other relevant government departments, MoHRSS will formulate relevant rules for the NDRL negotiation mechanism, establish relevant working organizations and systems, ascertain drug categories under the negotiation mechanism, organize BMI agencies and drug suppliers to initiate negotiations over the payment standards and methods of those drugs which have proven clinical efficacy and major innovative value, but are expensive and potentially risky to the BMI funds. Specific rules for this provision will be released separately.
- All local governments should report major issues in the process of adjustment and implementation of the NDRL.

Common Rules (凡例) of the NDRL

The NDRL is the reimbursement standards of BMI, OII and MI for drug expenditures. Prescriptions by physicians in accordance with medical situations and drug purchases and uses by participants are not limited by the NDRL.

The Common Rules refer to explanations and notes for NDRL contents including drug classification, numbering, names & dosage forms, and reimbursement scope limitations.

Composition of the NDRL

1. *The NDRL is divided into three volumes including Western medicines, formulated traditional Chinese medicines (TCMs) and herbal crude drugs.* Drugs listed in the Western medicine and formulated TCM volumes of the NDRL are reimbursable under the BMI, OII and MI programs. There are 1,140 Western medicines, 987 formulated TCMs and 45 minority medicines reimbursable by the BMI, OII and MI programs. Among the total, 20 Western medicines are only reimbursable under the OII and four Western medicines are only reimbursable under the MI.

Drugs listed in the herbal crude drug volume of the NDRL are not reimbursable by the BMI, OII and MI programs. 127 herbal crude drugs and one category of crude drugs are listed.

2. *Reimbursable drugs under WM and formulated TCM volumes of the BMI programs are classified into Class A and Class B.* There are 349 and 791 Western medicines in Class A and B respectively, while there are 154 and 833 formulated TCMs in Class A and B respectively. Reimbursable drugs under the OII and MI programs are not classified.

Serial numbering and classification

3. *Western medicines, formulated TCMs and minority medicines are numbered by drug products with one number for each product.* Whenever a product is repeated, "★" is added and product number is noted in brackets. The order of drug product numbers has no special meanings.

4. *Western medicines are classified according to clinical pharmacology and drug usage by medical specialties, while formulated TCMs are classified according to drug usage by medical specialties and therapeutic roles & indications.* The drug prescriptions by physicians of all medical specialties are not limited by the classifications of the NDRL.

Names and dosage forms

5. *Except drugs with "◆" in the notes, names of Western medicines (listed in the NDRL) adopt their Chinese generic drug names and English INN names to reflect their (main active) chemical ingredients.* The names do not include base & acid radical of drugs and notations such as "children", "child", "infant", "for children use", "pediatric" or "for infant use". Dosage forms are listed separately.

For formulated TCMs, Chinese generic names are adopted, and dosage forms are not listed separately. When their A and B classification as well as delivery routes are the same, different dosage forms of drugs with the same generic names are listed in parallel and the order has no special meanings.

6. *Western medicine dosage forms are grouped on the basis of the "formulation general principles" of the existing edition of the Chinese Pharmacopoeia.* Those dosage forms not grouped are as noted in the NDRL.

The "dry suspension" included in the "oral liquid dosage forms" (except "★" No.118, No.373 and No.1122) and "dry syrup" are reimbursable for pediatric use only.

Among formulated TCMs, the dosage form of pills includes water pill, honeyed pill, water honeyed pill, paste pill, concentrated pill and micro-pill, but does not include drop pill. Capsule refers to hard capsule and does not include soft capsule. Other dosage forms are not grouped.

7. *Explanations concerning names and dosage forms*.

- Western medicines with the chemical part of their generic names and dosage forms being the same as those listed in NDRL are covered by the list, even though they have different brand names, specifications and manufacturers.
- Western medicines with the chemical part of their generic names and dosage forms being the same as those listed in NDRL are covered by the list, even though they have different base or acid radical.

- Western medicines with the chemical part of their generic names and dosage forms being the same as those listed in NDRL and are noted "children", "child", "infant", "for children use", "pediatric" or "for infant use" in the front are covered by the list.
- Formulated TCMs with their generic names (excluding dosage forms) and their dosage forms being the same as those listed in NDRL are covered by the list, even though they have different brand names, specifications and manufacturers.

8. *Drugs with "◆" in the notes are grouped on the basis of their similar compositions and indications.* The names of these drugs are names for a sub-class of medicines.

Reimbursement scope limitations

9. *"Notes" in the NDRL establish scope limitations for reimbursement of certain drugs.* Such limitations restrict the reimbursement of participant drug expenditure by BMI, OII and MI programs to only stipulated situations. Relevant proofs must be checked before BMI agencies make payments for such expenditures.

- Drugs with "◆" in the notes are reimbursable by BMI programs during participant hospitalization only and such outpatient drug expenditures can be paid by personal medical expenditure accounts. This limitation does not apply to reimbursable drugs under OII and MI programs.
- Drugs noted as "OII only" are reimbursable by OII program only and are not reimbursable by BMI and MI programs.
- Drugs noted as "MI only" are reimbursable by MI program only and are not reimbursable by BMI and OII programs.
- Drugs noted as "*** and OII only" are reimbursable by BMI program under *** situations and OII program (without *** limitations) only.
- Drugs noted with certain indications are reimbursable only when participants fall into the scope of these stipulated limited indications and have relevant clinical symptoms, laboratory and supporting examination proofs as well as relevant clinical diagnosis. These limitations do not represent modifications to the legal package inserts of drugs. Physicians should prescribe these drugs in accordance with medical situations and legal drug package inserts.
- Drugs noted "limited to second line drug use only" are reimbursable only if frontline drugs are proven to have failed or have been intolerable.

10. *AIDS/anti-HIV drugs (Category 1.5 under Western medicine volume), which are freely supplied by the state, are only reimbursable by the BMI, OII and MI programs if participants do not meet state requirements for free AIDS/HIV treatments*.

Anti-tuberculosis drugs and antimony drugs (Category 1.3.1 and Category 2.1), which are funded by the state public health system, are only reimbursable by the BMI, OII and MI programs if participants do not meet public health payment requirements.

Others

Insulin and insulin analogues listed in the NDRL do not include supporting devices such as syringes.

"Musk" contained in some formulated TCMs listed in NDRL refers to artificial musk, while "bezoar" contained in some NDRL-listed formulated TCMs refers to artificial bezoar, internally-breeded bezoar and externally-breeded bezoar.

Full translation of the NDRL is available from Pharma China upon request, please email info@pharmachinaonline.com.

The Market

Chinese hospital market growth slowed in the first half

According to a recent industry conference presentation quoting data from the Chinese Pharmaceutical Association (CPA), growth of the Chinese hospital drug purchase slowed to 12. 67% in the first half of 2009, and the drug purchase by representative hospitals monitored by the CPA (257 hospitals in 16 major Chinese cities) was CNY 29,995 million. The annual growth rates were 24.65% in 2008 and 29.92% in 2007.

The Chinese hospital market growth in the first half by CPA's account was significantly lower than that recorded by IMS, which estimated the growth to be 25.1% in the first quarter and 24. 7% in the second quarter.

According to the CPA, the three therapeutic classes with the highest average annual hospital market growth between 2005 and 2009 are oncology and immuno-regulatory agents, nervous system drugs and digestive system and metabolism drugs with 26.94%, 26.57% and 20.29% respectively.

Hospital Drug Purchases by Representative Hospitals 2005-1H/2009 Unit: CNY Mlr

Therapeutic Category	2005	2006	2007	2008	1H/2009	CAGR
Systemic anti-infectives	7,519	7,967	10,558	13,082	7,147	+17.42%
Anti-cancers and Immuno-regulators	4,027	5,415	7,065	8,968	5,228	+26.94%
Cardiovasculars	4,789	4,529	5,714	7,134	4,012	+13.78%
Digestive system and metabolism drugs	3,675	4,171	5,423	6,734	3,847	+20.29%
Blood and blood making system	3,526	4,101	4,915	5,793	3,248	+16.51%
Nervous system	2,013	2,361	3,467	4,515	2,583	+26.57%
Overall	29,297	32,878	42,716	53,244	29,995	+19.62%

Source: Chinese Pharmaceutical Association

Leading 20 products by hospital purchase value in 2008

1H/2009 Rank	2008 Rank	Product
1	1	Chloride Sodium
2	2	Omeperazole
3	3	Ginkgo preparations
4	4	Docetaxel
5	10	Ganglioside
6	6	Paclitaxel
7	8	Human Albumin
8	7	Cefotiam
9	14	Thymic peptide alpha 1
10	12	Clopidogrel
11	5	Levofloxacin
12	13	Pantoprazole
13	15	Cefminox
14	11	Emulsion Fat
15	18	Oxaliplatin
16	21	Thymopentin
17	19	Cefamandole
18	20	Ambroxel
19	16	Glucose
20	9	Cefuroxime

Source: CPA

Hospital Drug Market Shares by TCs in 1H/2009

Therapeutic Category	Share
Systemic anti-infectives	24%
Anti-cancers and Immuno-regulators	17%
Cardiovasculars	13%
Digestive system and metabolism drugs	13%
Blood and blood making system	11%
Nervous system	9%
Others	13%
Total	100%

Source: Chinese Pharmaceutical Association

Among the leading 15 suppliers to the Chinese representative hospitals in 1H/2009, ten of them were MNC companies. Three companies with the highest growth in the period were Pfizer (+32.92%), AstraZeneca (+32%) and Shanghai Squibb (30. 70%). Sanofi Aventis, Dalian Pfizer, Shandong Qilu and GSK surged around 27%.

Leading 15 pharma suppliers by representative hospital sales in 1H/2009

Rank	Company	Value (CNY million)
1	AstraZeneca	887
2	Shanghai Roche Pharma	740
3	Pfizer	714
4	Hanzhou Sanofi-Aventis Minsheng	702
5	Bayer	659
6	Dalian Pfizer	617
7	Shandong Qilu Pharma	560
8	Jiangsu Hengrui Pharma	460
9	Hangzhou MSD Pharma	410
10	Harbin Pharma Group	365
11	Novartis Pharma	359
12	GlaxoSmithKline	331
13	Youngtze River Pharma	321
14	Shanghai Squibb Pharma	291
15	North China Pharma Corporation	271

Source: CPA

Overview of Chinese pharmaceutical retail market in 1H/2009

According to the China Retail Drug Monitoring System (RDM) of the Southern Medicine Economic Institute (SMEI), the market shares of Western medicines (WMs), formulated traditional Chinese medicines (TCMs) and health supplements in the retail sales of pharmaceutical related products were 42.2%, 29.2% and 9.6% respectively in the first half of 2009.

The market shares of Western medicines, Chinese crude drugs and medical devices were on the rise, while those of health supplements and formulated TCMs were falling.

Shares of Chinese pharmaceutical retail sales 2005-2009 (%)

Category	1H/2005	1H/2006	1H/2007	1H/2008	1H/2009
WMs	42.3	41.5	40.9	41.3	42.2
Formulated TCMs	29.3	33.4	34.7	29.8	29.2
Health supplements	12.7	10.1	10.4	10.1	9.6
Others	5.8	6.0	5.7	7.3	6.3
Chinese crude drugs	4.1	5.0	4.0	6.6	7.6
Medical devices	5.8	3.6	4.0	4.9	5.1

Source: SMEI

By therapeutic classes (TCs), the shares of circulatory system drugs and anti-cancers & immuno-regulatory agents in total retail sales of Western medicines grew in the first half of 2009, while shares of other TCs fell.

Retail market shares of Western medicines 2008-2009

Rank	Therapeutic Class	1H/2008	1H/2009
1	Digestive system and metabolism	29.1	28.4
2	Circulatory system	16.1	17.4
3	Systemic Anti-infectives	12.9	12.7
4	Respiratory system	11.0	10.3
5	Dermatology	7.4	7.1
6	Reproductive/urinary system and sex hormones	5.5	5.3
7	Oncology and immuno-regulatory agents	4.6	5.2
8	Muscle-skeletal system	4.0	3.9
9	Nervous system	3.2	3.4
10	Sensory system	3.3	3.1
	Others	2.9	3.2
Total		100.00	100.00

Source: SMEI

Rivalry intensifies in the Chinese market for monoclonal antibody drugs

Leading pharmaceutical companies are stepping up their competitive efforts to win larger shares of the Chinese market for monoclonal antibody oncology drugs, according to Bai Xianhong, Chairman of Biotech Pharmaceutical Co., Ltd. (BPL), a Sino-Cuban joint venture dedicated to monoclonal antibody and vaccines. The company markets Taixinsheng (Nimotuzumab), the first genetic recombination humanized monoclonal anti-epidermal growth factor receptor (EGFR) antibody, in China. The product is indicated for the treatment of epithelial original tumors, including head and neck cancer, glioma, colorectal carcinomas, pancreatic cancer and non small cell lung cancer.

Bai told the Chinese finance journal Caiji that the current Chinese market size of monoclonal antibody oncology drugs is around CNY 3 billion with all major global players present. Roche, which owns Genentech, is the market leader in the segment, but other leading players also have substantial sales. He estimated that Chinese sales of such drugs by Bayer, AstraZeneca and Merck should reach CNY 500 million, CNY 500 million and CNY 400 million respectively in 2009. Even late comer Pfizer is expected to have sales in tens of millions.

Chinese companies have small market shares at present although some of them have unique R&D strength in this market segment. They should expand production capacity and boost marketing efforts, Bai suggested.

Licensing-in is another option for Chinese companies to succeed in this segment. In June 2009, Shenzhen Wanle Pharmaceutical signed an agreement with Celltrion of South Korea for co-development of nine monoclonal antibody drug products in China targeting cancers and rheumatoid arthritis. Celltrion is the joint venture of Genentech and a Korean government-backed financial group.

China has nearly five million cancer patients currently and more than two million new cancer patients are added each year. As traditional chemotherapies lead to serious adverse drug reactions, more Chinese patients are expected to shift to monoclonal antibody drugs in future. Recent introduction of

the negotiation mechanism for BMI drug reimbursements of expensive drugs is likely to facilitate partial reimbursement of these oncology drugs. This will reduce financial burdens of patients and further strengthen the shift to monoclonal antibody oncology drugs.

Chinese market for drug-eluting stent estimated to grow over 20% in 2009

According to Millennium Research Group (MRG), a company specializing in medical technology market intelligence, healthcare reforms in China have supported rapid expansion of the Chinese drug-eluting stent market in 2009, and will continue to fuel growth in the coming years. MRG's new Asia Pacific Markets for Interventional Cardiology Devices 2010 report finds that initiatives undertaken by the Chinese government will allow the Chinese drug-eluting stent market to reach a value of more than US$900 million by 2014.

The potential Chinese patient population for coronary stenting has historically been under-penetrated due to the high cost of the devices. Despite a rising incidence of coronary artery disease in the country, many patients choose to forego a coronary intervention due to a lack of insurance coverage and an inability to privately finance these procedures. In April 2009, the Chinese government unveiled its plans for a universal health care plan, a component as part of its Healthy China 2020 plan, which was first announced in January 2008. The healthcare reforms will increase access to premium-priced procedures and will have huge implications for the drug-eluting stent market.

"This amount of funding earmarked for a public health care system will vastly expand the volume of drug-eluting stent procedures performed in China," says Dan Whalen, Analyst at MRG. "With more people able to afford the procedure, this market is expected to grow an average of nearly 20% per year over the next five years, which presents a huge opportunity for new and emerging drug-eluting stent manufacturers in the region."

Nicholas Hall reports 10% growth for the Chinese OTC analgesics market in MAT mid-2009

China's OTC analgesics market grew by 10% in the 12 months to June 2009, in line with the growth of other major OTC categories in the country, according to Nicholas Hall, a leading market research firm specializing in the global OTC drug market.

Systemic analgesics remained the largest category. This continued to grow and a rising trend of Chinese consumers moving towards Western medicine was observed. Price controls inhibited innovation as anything that added value for the consumer, such as newer delivery formats, ultimately ended up taking value from the manufacturer. Fenbid (TSKF/GSK) led the category with a share of around 20%. FenKa was launched recently as line extension to Fenbid.

The category of topical analgesics was dominated by traditional delivery formats, especially patches, with no signs of changes in consumer behavior. As a result, the leading brands were all local players.

Chinese OTC Analgesics Market Facts

OTC analgesics sales MAT mid-2009	**US$970.8 mn**
Index 2009/2008 (local currency):	110
Population:	1,324.7mn
Per capita spend:	US$0.73

Source: Nicholas Hall (www.nicholashall.com)

OTC Analgesics Market in China – 12 months to mid-2009

Category	**CNY mln**	**US$ mln**	**Index 2009/2008**
Systemic analgesics	3,991.2	583.7	110
Topical analgesics	2,647.1	387.1	111
TOTAL	6,638.3	970.8	110

Source: Nicholas Hall (www.nicholashall.com)

Industry News

CNMA release 2009 ranking of top 20 Chinese OTC drug manufacturers

The China Nonprescription Medicine Association recently released its rankings of Chinese OTC drug manufacturers by sales value.

Xiuzheng Pharmaceutical Group topped the list, followed by Xi'an Janssen, Harbin Pharmaceutical Group, Beijing Tongrentang, Sanjiu Pharmaceutical, Shandong Dongeejiao, Jiangzhong Group, GlaxoSmithKline China, and Bayer Healthcare.

Chinese and Brazilian drug companies form alliance

As part of a technology transfer deal signed on December 9 in Beijing, companies from Brazil and China plan to jointly manufacture the latest drugs.

The agreement, signed by EMS and two Shanghai laboratories (Biomabs and Guojian), is part of the Brazilian effort to "develop the pharmaceutical industry" and relieve Brazil's "high dependence" in this area, said Brazil's health minister, Jose Gomes Temporao.

The first product of the new partnership, which will be manufactured in Brazil within five years, is Etanercept, a drug mainly used to treat rheumatoid arthritis, a disease that affects some 850,000 Brazilians.

The agreement, according to its signatories, will be a "technological platform",which also includes production of other five drugs known as monoclonal antibodies.

Local company News

Hisun to establish a subsidiary in the United States

Zhejiang Hisun Pharmaceutical Co. Ltd., a leading Chinese pharmaceutical exporter, announced on November 25 that it

plans to invest US$1.5 million to open a subsidiary in the U.S., Hisun Pharmaceutical (USA) Inc. The company will be registered in the State of Delaware.

The subsidiary will handle businesses including new drug R&D, process research, partnerships and licensing, U.S. regulatory affairs, clinical research and sales of Zhejiang Hisun's chemical intermediates, APIs and drug formulations.

Sinoovac enters vaccine JV with Dalian Jingang

Sinovac Biotech Ltd. announced it had formed a joint venture with Dalian Jingang Group for R&D and manufacture of vaccines.

Sinovac will pay CNY 60 million, or about US$8.8 million, for a 30% stake while Dalian Jingang will make an asset contribution -- including factories, production lines and land-use rights -- valued at CNY 140 million. Sinovac agreed to raise its stake to 55% by paying CNY 50 million by the end of 2010.

The venture, called Sinovac (Dalian) Vaccine Technology Co., will be aided by Dalian's relatively low operating costs and its existing facilities, in setting up manufacturing platforms for live attenuated vaccines and vero cell cultured vaccines, according to Sinovac. The venture's pipeline is expected to include vaccines for rabies, mumps, varicella and rubellas. Operations will be led by Sinovac management.

Skystar Biopharma acquires aquaculture vaccine technology from FMMU

Skystar Bio-Pharmaceutical Company (SKBI) has purchased an exclusive aquaculture vaccine technology from and signed a collaborative research and development agreement with China's Fourth Military Medical University ("FMMU") for approximately US$1.2 million, granting Skystar exclusivity on the patent through 2012. The vaccine has been shown to be effective in treating and preventing bacterial infections in marine life without harmful side effects. The patented technology is designed to address the company-estimated US$150 million underserved aquaculture market opportunity in China.

Skystar will manufacture its aquaculture vaccine in its new 51,000 square foot veterinary vaccine facility along with other vaccine products presently produced by the company. To accommodate the new aquaculture vaccine line, Skystar now expects to complete the build-out of its new veterinary vaccine facility in the first quarter of 2010, rather than the fourth quarter of 2009 as previously anticipated. Based on the extended timeline, management currently expects full-year 2010 organic revenue to be between US$44.0 to US$46.0 million with gross margins between 48% and 54%.

Nuokang Biopharma IPO falls at debut

China Nuokang Bio-Pharmaceutical Inc (NKBP.O), a Chinese company focusing on hematological and cardiovascular drugs, launched its IPO on the NASDAQ but closed down 3.7% at US$8.67 on December 10.

China Nuokang sold 5 million American Depositary Shares for US$9 a piece a day earlier, raising about US$45 million. The company had expected the shares to sell for between US$10 and US$12 each.

Nuokang has a portfolio of 14 products, three of which it considers particularly important: Baquting for bleeding control, Aiduo, a cardiovascular stress imaging agent, and Aiwen, an anti-arrhythmic agent. An additional four products are in development, one to serve the bleeding control sector on which Nuokang depends, and the others for hematological, cardiovascular and cerebrovascular disease diagnosis, treatment and prevention.

The company has also signed an exclusive agreement to distribute Kaitong in China. Kaitong is an intravenous injectable lipid emulsion of a vasodilator that treats peripheral vascular diseases, cardiocerebral microcirculation disorders and post-surgery thrombosis.

Although it offers a diverse portfolio, 94% of the company's revenue in the first nine months of the year came from its clotting agent, Baquting. Nuokang launched the drug in 2001, and it now commands a 38% share of its market.

In 2008, Nuokang reported revenues of CNY 225 million (US$33 million) and net income of CNY 64 million (US$9.3 million), a margin of 28%. Revenues were up 50% from the year earlier, while profits almost doubled.

In the first nine months of 2009, the company reported its revenues to have climbed to CNY 200 million (US$29.3 million) and net income to CNY 42 million. It indicates that the company's sales rate was slowing down and net income would have a hard time matching the year earlier results.

SinoPharm participates in bids for Ratiopharm

According to a Bloomberg report, three drugmakers are the front-runners in the race for a deal. According to sources quoted by Bloombery, fellow generics maker Teva Pharmaceutical Industries, Chinese drugmaker Sinopharm, and French-based Big Pharma Sanofi-Aventis are leading contenders for the buyout.

Ratiopharm is on the block as the family of Adolf Merckle sells assets to pay off debt. Four to six potential buyers will be invited to continue negotiations, Bloomberg reports. Offers less than 2 billion euros (US$3 billion) are being rejected out of hand. Besides Teva, Sinopharm and Sanofi, other drugmakers who reportedly are still interested in all or part of Ratiopharm include Mylan, Watson Pharmaceuticals and Pfizer.

Simcere Pharma enters strategic alliance with TigerMed

Jiangsu Simcere Pharmaceutical R&D Ltd., the R&D subsidiary of Simcere Pharmaceutical Group, recently reached an agreement with TigerMed, a leading Chinese CRO, for strategic alliance.

The agreement calls for collaboration by the two companies for all aspects of new drug R&D including clinical studies.

Simcere Pharma is reported to possess a number of technological platforms and has 89 Chinese patents. It has ten first-to-copy or exclusive drug products.

Taiji Group likely to consolidate its pharma businesses

There have been speculations recently that Taiji Group, the parent company of publicly-listed Southwest Pharmaceutical Co. Ltd. and Tongjunge Pharmaceutical Co. Ltd., is likely to

consolidate the two companies into Taiji Enterprises (Group) Ltd., the core publicly-listed subsidiary of Taiji Group. If it does happen, both Southwest Pharma and Tongjunge Pharma will become valuable shell companies.

Taiji Group is the largest state-owned pharmaceutical enterprise in southwest China, and it owns 33.49% of Southwest Pharma and 54.73% of Tongjunge Pharma.

Chinese analysts suggest that three possible scenarios may arise if and after the speculated consolidation takes place: 1) Taiji Group will be merged into Huayi Group, a 100% state-owned conglomerate in Chongqing; 2) Taiji Group will bring in strategic investors; and 3) Taiji will continue to operate as an independent company.

Shanghai Pharma to build a biopharma industry park in Pudong

Shanghai Pharmaceutical Group (SPG) signed a strategic alliance agreement with the Shanghai's Pudong New Area Government on November 26 to build a biopharmaceutical industrial park in Pudong.

The industrial park will be situated on 1.5 square kilometers of land, and SPG plans to build on it a central formulation manufacturing facility, a new central antibiotic formulation facility, a modern pharmaceutical distribution and logistics center, a mid-scale industrialization pilot plant and an animal experiment center.

The site will be built in two phases. Phase I construction will begin in the third quarter of 2010, and total phase I investment is expected to be CNY 2 billion. Following its completion, phase I facilities are projected to generate CNY 10 billion in annual sales.

According to the company, the new manufacturing site will help upgrade its existing facilities and significantly expand manufacturing and distribution capacity.

Anhui company initiates recombinant human insulin production

Hefei Economic Development Zone Biopharmaceutical Co. (HEDZB) recently began production of genetically recombinant human insulin injection products in Hefei Life Science Park, thus making the company the third manufacturer of the product in China.

Approved by the SFDA for import, the active ingredients and relevant technologies used by HEDZB to manufacture the product are originated from BTG of Israel, according to local press reports. The product has been produced and marketed outside China for more than six years already.

Total investment of HEDZB for its insulin project is US$25 million, and the company hopes to supply its insulin products not only to the Chinese market, but also to other Asia-Pacific and European markets. It will be seeking GMP certifications from the Chinese and European authorities.

Nepstar to acquire six more retail pharmacy outlets in Beijing

China Nepstar Chain Drugstore, the largest drugstore chain in China based on the number of directly operated stores, announced an agreement to acquire all six retail pharmacy outlets of Beijing Xiang Yun Kang Drug Store. This acquisition will be China Nepstar's second acquisition in Beijing.

In the first ten months of 2009, the six drugstores being acquired generated unaudited revenues of approximately CNY 6 million. These stores have an average store size of 140 square meters, and are located in densely populated residential areas in Beijing. Together with the five stores acquired in July 2009, all Nepstar's Beijing stores will be serviced by its regional logistics center in Tianjin, where Nepstar has over 100 stores.

As of September 30, 2009, China Nepstar had 2,337 stores across 67 cities, one headquarter distribution center and 12 regional distribution centers in China.

First modern pharma distribution facility in Southwest China becomes operational

Western Worldbest Pharamceutical Co. Ltd., reportedly the first major modern pharmaceutical distribution and logistics facility in Southwest China, became operational in Suining City, Sichuan Province on November 24.

The facility is a joint venture of Anhui Worldbest Pharmaceutical Co. Ltd. and Sichuan Huatong Pharmaceutical Industries Co. Ltd. Anhui Worldbest operates China's largest pharmaceutical trading market in Taihe, Anhui Province.

With a total building area of 130,000 square meters, the facility's total investment reached CNY 370 million. Overall inventory capacity of the facility is 500,000 cases, while its maximum daily processing capacity can reach 25,000 cases and 50,000 orders. Its distribution coverage (with delivery lead time under 24 hours) includes Sichuan, Shaanxi, Yunnan and Guizhou provinces as well as Chongqing municipality.

Nanjing Pharma forms logistics JV

Nanjing Pharmaceutical Co. Ltd. (NPCL), the fourth largest pharmaceutical distributor in China, announced recently that it would establish a 50:50 joint venture company for pharmaceutical logistics related business, Nanjing Pharmaceutical Supply Chain Management Co. Ltd., with Nanjing Sanbao Science & Technology Co. Ltd.

The JV will be formed on the basis of Nanjing Pharmaceutical Sales Co. Ltd., a subsidiary of NPCL with CNY 45 million registered capital. Following the reorganization, the company will have a total registered capital of CNY 150 million equally contributed by the two JV partners. NPCL will inject an additional capital of CNY 30 million, while Nanjing Sanbao will inject CNY 75 million.

The joint venture will develop an IT platform for pharma supply chain information, according to a statement from the NPCL.

In a separate development, NPCL announced on December 12 that it had acquired 51% of Henan Jibaokang Pharmacy Service Co. from its parent company, Nanjing Pharmaceutical Industry (Group) Co. Ltd. The price tag of the acquisition is CNY 8.3 million. By acquiring Henan Jinbaokang, NPCL hopes to become a designated drug distributor and expand its pharmacy service and fast-distribution businesses in Henan province.

Shanghai Pharma expands national distribution and logistical capabilities

Expanding national pharmaceutical distribution and logistical capabilities has become the latest business priority of Shanghai

Pharmaceutical Co. Ltd., the second largest pharmaceutical distributor in China.

The company announced on December 8 that it plans to invest nearly CNY 37 million to expand its pharmaceutical distribution network in eastern and central China regions.

As a part of this plan, Shanghai Pharma will invest CNY 7.65 million to form a 51%-owned joint venture, Suzhou Shangyao Supply Chain Co. Ltd., with Suzhou Logistics Center Ltd. This deal will help Shanghai Pharma improve its pharmaceutical distribution capability in eastern China region.

Separately, Shanghai Pharma will spend CNY 18 million to acquire 40% of Shangqiu New Pioneer Pharma of Henan province from Shanghai New Pioneer Pharma. Following this, Shanghai Pharma will inject an additional CNY 11 million into Shangqiu New Pioneer Pharma so that its stake in the company will increase to 52%.

Shangqiu New Pioneer Pharma had revenue of CNY 569 million last year, and the company's revenue is expected to rise to CNY 1,136 million following the reorganization.

This deal is expected to strengthen Shanghai Pharma's pharma distribution capabilities in central China region.

Xinfu Pharma exits pharma business

Xinfu Pharmaceutical Co. Ltd. (002019) announced on December 7 that it would exit the pharmaceutical formulation and health food businesses and dispose relevant assets in these sectors. Early this year, the company signed an agreement with Hangzhou Tianmushan Pharma to sell its pharmaceutical manufacturing facilities.

The company said in a statement that its pharmaceutical and health food businesses have not been profitable since it entered the sectors in 2005. Consequently, the company decided to exit these businesses and refocus on the businesses of bio-chemicals and fine chemicals.

Xinfu Pharma is the largest producer of Vitamin B5 in the world.

Holley Pharma exits pharma distribution business

Holley Pharmaceuticals, a leading manufacturer of anti-malaria drug Artemisinin, recently disposed its 51% stake in Guangdong Meikang Wante Pharmaceutical Ltd. to Meikang Jiuzhou Pharmaceutical Ltd. at a price of CNY 13 million, thereby exiting pharmaceutical distribution business completely.

According to Holley Pharma, the move represents its attempt to concentrate resources on developing the company's core businesses.

Foreign company news

Roche seeks to take over AstraZeneca as the new oncology drug leader in China

Despite being a later comer than AstraZeneca in the Chinese oncology drug market, Roche has made significant advances with Chinese sales of Tarceva after it was launched one and half years ago.

Tarceva is the only anti-cancer drug in the world that is proven to substantially prolong life of non-small cell lung cancer patients, according to Roche. The product is now approved in 75 countries around the globe.

Because of this, Tarceva has now caught up with AstraZeneca's Iressa and taken over 30% of the market share within just one and half years, Wang Xinguang, Deputy General Manager of Shanghai Roche Pharmaceutical, told the Chinese press recently at a lung cancer awareness promotion event of the Chinese Anti-cancer Association.

Wang also disclosed that Roche is applying for registration of another oncology new drug in China, which was already approved in Europe in 2005. The drug is expected to be approved in the first half of 2010, adding further strength to Roche's oncology drug business in the country, he said.

AstraZeneca's Iressa was approved in China in early 2005 despite the outcome of a clinical trial (ISEL) in December 2004 suggesting the product to be ineffective in prolonging lifespan of non-small cell lung cancer patients in general, according to local press reports.

The product is more effective in Asian patients compared with their Western counterparts, said Wang Xiaolan, Public Relations Manager of AstraZeneca China. The product was already withdrawn from European markets and its sales were suspended in the U.S., but it is still marketed in almost all Asian markets, she added.

Currently the monthly treatment cost with Iressa is around CNY 16,500, while that of Tarceva is CNY 19,500.

China currently has more than 6.6 million cancer patients including over 1.6 million new patients every year. The country has the largest lung cancer patient population in the world.

The recent oncology drugs launched by MNC drug companies are all target-oriented anti-cancer drugs which do not damage healthy cells, said Zhi Xiuyi, Head of Capital Medical University's Lung Cancer Medical Center. Local pharma companies have yet to develop any similar products, he added.

These drugs are very expensive and not covered by basic medical insurance (BMI) at present. They are mostly used as supplements to chemotherapies and surgeries, according to Zhi. Nevertheless, he and his colleagues are now collecting more clinical data on these drugs and may recommend reimbursements of these drugs by the BMI system in future.

"We can not eat (inexpensive) pork with rice noodles and shy away from (expensive) sea foods forever," he concluded.

Merck Serono to invest US$223 million into R&D in Beijing

Merck is strengthening its global R&D capabilities of its Merck Serono division by establishing a global R&D center in Beijing.

Merck plans to invest more than US$223 million (Euro 150 million) and create more than 200 new qualified jobs over the next four years to set up its China R&D operation.

"The creation of the China R&D center marks a new milestone in Merck Serono's commitment to China, where there is a rising demand for more healthcare options," said Elmar Schnee, Executive Board Member with responsibility for the Pharmaceuticals business sector.

"China is a country with talented scientists and high-quality research," added Bernhard Kirschbaum, Executive Vice

President, Research and Development for Merck Serono. "We will recruit more R&D talent in China and build a world-class organization in China that will extend our global R&D expertise and capabilities."

The China R&D organization will become one of the key R&D hubs for Merck Serono worldwide. Key hubs so far are Germany, Switzerland and the United States.

The China team will lead drug development for China and other Asian countries, for local clinical trials as well as for the participation in global clinical trials. The team also will ensure the management of collaborations with research institutions in China and continue to look for partnerships with local academic institutions and companies. Research activities conducted in the China R&D center will mainly focus on biomarker research including pharmacogenomics and bioanalytics activities.

Merck Serono already has some research collaborations in China and plans to further develop its collaboration network and build its R&D strategy on more innovation opportunities by tapping into the Chinese scientific expertise.

Merck Serono China currently employs more than 1,000 persons nationwide.

Gilead, GSK to commercialize Viread in mainland China and other Asian markets

Gilead Sciences and GlaxoSmithKline have announced a licensing agreement to commercialize Viread (tenofovir disoproxil fumarate) for the treatment of chronic hepatitis B infection in adults in five markets in Asia.

The companies' combined commercialization activities will expand access to Viread for the treatment of HBV, once approved, to patients in Asia where the prevalence in most countries is greater than 8%. As part of the deal, Gilead will retain exclusive rights for commercialization of Viread for HBV in Hong Kong, Singapore, South Korea and Taiwan.

In mainland China, GSK will have exclusive commercialization rights and registration responsibilities for Viread for HBV. Each company will pay royalties to the other on sales of Viread for HBV in their respective Asian territories. The companies are working to expand this agreement to include Japan and other countries.

The Viread agreement modifies the terms of the April 2002 licensing agreement between Gilead and GSK under which GSK received exclusive rights to Hepsera (adefovir dipivoxil), Gilead's first hepatitis B treatment, in various territories including China, Japan, South Korea and Taiwan, as well as the right to commercialize Viread for the treatment of HBV under certain circumstances.

Pfizer expands and seeks to grow over 25% annually in China

Pfizer said it expects to boost Chinese sales at more than 25% a year as it takes advantage of stronger intellectual property right protection and a population increasingly suffering from the cardiovascular diseases and diabetes seen in developed countries, the Wall Street Journal reported.

Allan Gabor, Pfizer's regional president of North Asia highlighted the company's Lipitor cholesterol drug and Norvasc treatment for high blood pressure as potentially strong performers in China. Pfizer also announced this week that it would partner with Japan's Takeda Pharmaceutical to bring Actos, a drug for treating type-2 diabetes, to China.

Gabor said Pfizer's growth in China would be helped by its recent acquisition of Wyeth, which produces consumer products such as vitamin supplements and baby formula, but its market share remains low due to tough competition and unique challenges in this market.

The Chinese pharmaceutical market is highly fragmented, with thousands of small local players. Although Pfizer is the largest foreign pharmaceutical company in China, it has only around 2% market share, Mr. Gabor said, citing data from IMS.

IMS estimates that the total market for pharmaceuticals in China rose 27% in the third quarter of this year from a year earlier. It forecasts that the Chinese pharmaceutical market will grow by over 20% annually through 2013, and Mr. Gabor said Pfizer aims to beat that, thus gaining more market share.

Pfizer's acquisition of Wyeth, which closed in October, adds vaccines and consumer brands to its offerings in China. In particular, Mr. Gabor highlighted Prevnar, a vaccine to protect children from pneumococcal disease. According to Gabor, 12% of global cases of the disease occur in China.

Wyeth launched Prevnar in China last year, and again according to Mr. Gabor, it was "absolutely one of the most successful product launches in China history". It didn't provide actual sales number for Prevnar.

Pfizer sold its consumer-product division, which included products such as Listerine, to Johnson and Johnson in 2006. With the Wyeth acquisition, Pfizer once again offers consumer products, such as the popular vitamin supplement Centrum, which Mr. Gabor thinks will help give Pfizer a positive brand image in China. That is particularly helpful since it is illegal to advertise prescription drugs here, he said.

R&D expansion in central and western China

Pfizer announced on November 25 its plans to expand its research and development operations in central and western China as it strengthens its biomedical infrastructure throughout the country.

Pfizer (China) Research and Development Co Ltd will team up with its Chinese partner Wuhan National Bioindustry Base Construction and Management Office to establish a new Pfizer R&D center in Wuhan, expand its existing R&D facility in Shanghai and serve as a platform for global drug development and strategic biomedical alliances.

"With plans to be a state-of-the-art facility, the Wuhan center will be an integral part of Pfizer's global R&D operations while being closely aligned with the Chinese government's strategy on biopharmaceutical industry development in the region," Allan Gabor, the company's Regional President for North Asia, said in the statement.

Pfizer's R&D operations in Wuhan will support global clinical drug development programs, including Phase I-IV clinical trials, and will utilize the resources of local staff and industry to develop research collaboration on drug innovation and development. The number of employees in the facility will grow to 200 within three years, it said.

Shanghai will remain the operations hub of Pfizer's R&D in China. The company gave no further details on the investment.

Research collaboration deepened with Peking University

Pfizer and the Shenzhen Graduate School of Peking University (PKU) announced on December 1 a partnership to further

collaborate on life sciences and biomedical research with an aim to develop novel technologies for drug discovery.

As part of this initiative, Pfizer will not only provide funds to support projects of mutual interests, but also offer support to PKU in its endeavor to build a world class translational research and drug discovery center.

The Drug Discovery Center at PKU's Shenzhen campus will be dedicated to translating basic research and clinical observations into effective disease diagnostic, prevention and clinical intervention with emphasis on indigenous biomedical innovation. The immediate mission of the center is to focus on the development of novel therapies for three major disease areas including cardiovascular, metabolic, and neurodegenerative.

The research projects sponsored by Pfizer by this joint initiative will be selected and cooperatively developed by Pfizer scientists and PKU professors, including those in the PKU main campus and the Health Science Center in Beijing.

Pfizer and PKU have a long-term good cooperative relationship of academic research. In March this year, both sides announced to establish PKU-Pfizer Quantitative Pharmacology Education Center jointly, with the objective of supporting the talent cultivation of quantitative pharmacology, an extremely significant technical field of drugs development and research. The signing of this initiative adds PKU to Pfizer's network of strategic partnerships in biomedical research that includes the Scripps Research Institute, UCSF QB3, and the Shanghai Institutes for Biological Sciences.

"Pfizer is committed to establishing a mutually beneficial partnership with local outstanding research institutes. The collaboration with PKU is a clear demonstration for Pfizer to support scientific research capacity building of healthcare related R&D efforts in China," said Dr. Steve Yang, Vice President and Head of Asia R&D for Pfizer Pharma Therapeutics R&D.

Collaboration with Crown Bioscience for Asian cancers

Pfizer and Crown Bioscience have entered into a collaboration to research and develop novel therapeutics for Asian cancers. Specific treatments for Asian cancers represent an important unmet medical need as well as a significant market opportunity, according to a joint statement.

Crown will receive an upfront payment and research funding, as well as milestone payments based on the achievement of preclinical and clinical goals, but financial terms were not disclosed. The companies will work together to discover and advance multiple candidates for clinical development. The work will take place at Crown's new research facility located in Taicang, China, near Shanghai.

"I am delighted to be collaborating with Pfizer's exceptional oncology group," says Alex Wu, chief executive officer of Crown. "I am also very happy that Pfizer is focusing on and dedicating resources to address a very important unmet medical need for the Asian populations. This new collaboration extends an already very successful partnership between Crown and Pfizer and further demonstrates Crown's commitment to becoming an outstanding cancer research company in Asia."

Co-marketing Actos with Takeda in China

Takeda Pharmaceutical and Pfizer have entered into an agreement under which Pfizer China will co-promote Takeda's Actos (pioglitazone HCl) with Tianjin Takeda Pharmaceuticals. The exclusive co-promotion agreement will build on the current sales capability for Actos in China by increasing the number of medical representatives supporting the sales and marketing of the product and expanding the product reach utilizing the territory coverage of Pfizer, which is the largest multinational pharmaceutical company in China. Pfizer's Chinese affiliate will receive a fixed ratio of Actos net sales.

Actos, for the treatment of type 2 diabetes, has been sold in China since 2004 by Tianjin Takeda Pharmaceuticals, a joint venture of Takeda and Tianjin Lisheng Pharma.

Currently as the world's fifth largest pharmaceutical market, China is expected to be the third largest market by 2011. According to the International Diabetes Federation, the diabetes epidemic has the greatest potential to increase in China due to its population size, rapid urbanization and economic expansion.

China becomes a top priority for Eli Lilly

Eli Lilly recently said, in an annual review of its business plans, that the Chinese pharmaceutical market will be a top priority for the company. Lilly has reorganized its corporate structure and now one of its six units targets emerging markets, in particular China.

Lilly's China revenues toped US$200 million in 2008, ranking 11th among MNC pharma companies in China and its 2009 revenues are expected to be 20% higher. Lilly stated that it is taking additional steps to boost its presence in China.

The company also doubled its headcount in the country from 1,100 to about 2,200, and it is currently building a second manufacturing plant in Suzhou to produce insulin.

Lilly listed three initiatives that will help the company increase its impact in emerging markets in a press release:

- Maximize Lilly's core assets, including both patented and post-patent medicines. Two key tactics are to accelerate new product launches and to capitalize on longer product lifecycles in select countries such as China.

- Add select non-Lilly medicines to build upon core therapeutic areas, especially diabetes, oncology and neuroscience, to accelerate top-line growth. This could include product acquisitions and co-promotion or co-marketing agreements.

- Establish local alliances to more effectively access fast-growing market segments in select countries where its current infrastructure is not well suited to capture growth.

On the R&D front, Lilly has implemented a partnering strategy in China rather than establishing an in-house R&D facility.

It has developed risk sharing partnerships with local companies, including Shanghai ChemExplorer and a cancer/inflammation partnership with Chi-Med.

Suzhou Novartis became operational

Following more than three years of construction, Suzhou Novartis Pharmaceutical Technology Co. Ltd. became operational in Changshu Economic Development Zone, Jiangsu province. Novartis started construction of the facility in February 2006 and expects to begin using APIs and intermediates from it in 2010. Suzhou Novartis currently employs 340 staff. Total investment of the company exceeded US$250 million.

"It is a critical part of Novartis' global manufacturing and supply chain, and will become a global strategic supply center for intermediates and APIs of our experimental and approved drugs", commented Novartis CEO Dr. Daniel Versella.

According to Novartis, the Changshu site was chosen because of government support and a good talent pool.

The facility will synthesize small amounts of Novartis developmental APIs in its laboratories to support early-phase pre-clinical development activities (toxicology and formulation development work) in other Novartis sites in Europe and US. Another part of its goals is to optimize manufacturing technology of products, increasing production quality and quantity.

The plant will concentrate on producing Novartis drugs in the areas of hypertension (Rasilez/Tekturna, Esidrex), hepatitis B (Sebivo) and oncology (Glivec), all of which have a high incidence in China. It will also examine and manufacture chemicals used in drugs for leukemia, epilepsy and other diseases.

The R&D facility is 10,801 square meters in size. It consists of a 4,815 square meter pilot plant, plus labs, kilo labs and a safety lab spreading over the remaining 5,986 square meters. The site also houses three additional production buildings, each with an area of 9,682 square meters.

The manufacturing capacity of the Changshu site is reported to be equivalent to the existing facilities of Novartis in Grimsby, UK and Ringaskiddy, Ireland. Although the new site is only expected to supply less than 10% of the global needs of Novartis at present, the share will be raised to 25% eventually.

The existing annual production capacity of Suzhou Novartis is 340 tons (which can be stretched to 600 tons) and core products include 100 tons of intermediates for Gleevec and Sebivo.

Annual sales of Novartis China rose 40% to CNY 3.3 billion in 2008, according to a company official.

AlphaRx establishes corporate headquarters in HK and R&D facility in Shanghai

AlphaRx Inc. (OTCBB: ALRX), a specialty pharma company developing proven therapies by reformulating FDA approved and marketed drugs through the application of its site-specific drug delivery technology, announced on December 3 that it has selected locations in Hong Kong and Shanghai for its corporate headquarters and a new R&D facility respectively. This initiative will spearhead a major push into Greater China.

The R&D facility will be located in The State Biotech Pharmaceutical industrial base (Shanghai) which is situated on 740 acres of land in Zhangjiang High-Tech Park, Shanghai, also known as China's medicine valley.

In a separate development, AlphaRx Inc. announced on December 17 the signing of an agreement with VenturePharm that provides long-term supply of the active pharmaceutical ingredient (API) for ARX1088, an orally active interferon inducer intended for the adjunctive treatment of Hepatitis in China and other emerging markets. Under the agreement, Venturepharm will be the primary supplier of AlphaRx's worldwide requirements for the compound.

Service provider news

Milestone forms JV for injection technologies

Milestone Scientific Inc., a company specializing in advanced injection technologies, announced on December 3 that it would form a joint venture with China National Medicines Corporation Ltd. ("Sinopharm") and Yichang Humanwell Pharma to develop orthopedic and epidural drug delivery instruments.

Under an "agreement of intent", Milestone and its two Chinese partners will establish a new joint venture entity for this purpose in the first quarter of 2010 with an estimated US$1.4 million initial funding. The joint venture entity will utilize and adapt Milestone's proprietary, patented CompuFlo technology for use in orthopedic and epidural drug delivery instruments. Milestone will own 50% of the joint venture entity and the PRC parties will together own the remaining 50%.

Milestone's patented CompuFlo is a computer-controlled injection delivery technology that uses Dynamic Pressure Sensing for painless delivery and aspiration of all medicaments.

Agios Pharma and ChemPartner report outstanding cancer research achievements

Shanghai ChemPartner Co., Ltd., a leading Chinese CRO and a subsidiary of ShangPharma, announced that ChemPartner scientists have been involved in recent groundbreaking cancer research from Agios Pharmaceuticals through the companies' ongoing partnership. This breakthrough discovery by Agios scientists was recently published online on November 22 by Nature in an article entitled "Cancer-associated IDH1 mutations produce 2-hydroxyglutarate (2HG)".

"The important discovery by Agios and the publication of the Nature article solidifies Agios' leading role in cancer metabolism. ChemPartner has been providing integrated drug discovery research support in the areas of protein science, HTS, enzymology, cell biology, in vivo pharmacology, and DMPK to Agios' innovative R&D programs in the emerging field of cancer metabolism," said Mr Michael Hui, CEO of ChemPartner.

Medicilon/MPI expands to offer GLP-compliant preclinical services

Medicilon/MPI Preclinical Research-Shanghai has recently expanded its service offerings to provide sponsors with the ability to conduct studies that meet the FDA Good Laboratory Practice (GLP) regulations, at its Chuansha facility in Shanghai.

Dr Bob Sigler, a consulting toxicologic pathologist and President of Vet Pathology and IND Services, has validated qualifications of the Medicilon/MPI Preclinical Research-Shanghai facilities. "The lab is a state-of-the-art facility optimally designed for GLP toxicology-safety as well as efficacy studies. The talented staff are taking full advantage of having the onsite experienced MPI Research staff present for training and operations as well as integration of Standard Operating Procedures," said Dr Sigler.

Instem establishes office in Shanghai

Instem, a leading provider of early drug development software solutions, announced on December 11 the establishment of an office in Shanghai to provide local customer support, service delivery, client management, development and sales support to the Chinese pharma and wider life sciences R&D market.

"Instem was the first western Toxicology/Pathology software supplier to enter the Chinese market and we have added 3 new clients in just the last 12 months," stated Phil Reason, CEO at Instem.

The new offices of Instem are located in the Zhangjiang Hi-Tech Park in Shanghai. In addition to traditional on-site

deployments, Instem will be providing access to its software application over the Internet from a Shanghai-based data center. Professionally managed and recognized as a premier Tier 3 facility, the data center will enable Instem to deliver its Provantis preclinical solution as an all inclusive service to laboratories of any size with the highest levels of security, performance and support.

Regulatory News

SFDA news

SFDA investigates quality issues of rabies vaccine from Simcere's acquired subsidiary

China's State Food and Drug Administration (SFDA) has initiated a comprehensive investigation into quality issues regarding human use rabies vaccine (vero cell) manufactured by Jiangsu Yanshen Biological Technology Co, a newly acquired subsidiary of Simcere Pharmaceutical Group.

The SFDA has assigned investigation teams to oversee the provincial administrations' inquiry into the matter and has established a file on Jiangsu Yanshen. Four batches of the human use rabies vaccine manufactured by Jiangsu Yanshen between July and October 2008 have been found to have quality problems. The SFDA has ordered Jiangsu Yanshen to halt marketing and production of all products including human use rabies vaccine and has organized experts to provide an assessment of risks presented by the problem vaccine.

SFDA seeks public comments on second draft of the GMP regulation

The State Food and Drug Administration (SFDA) completed its second draft of the "Quality Control Standards for Drug Manufacturing" (GMP) and published it on December 7 for public comments.

All comments should be submitted to the Drug Safety Supervision Department of the SFDA via fax to 010-88363227 and via email to gmp2009@sda.gov.cn before December 20, 2009. Full text of the draft in Chinese can be downloaded from the SFDA website.

MOC and SFDA issue notice concerning the drug distribution sector

The Ministry of Commerce and the SFDA recently issued a notice calling for continuous upgrading of industry management, development of retail pharmacy chains, consolidation of the sector to improve scale of economy and prevention of market monopoly to ensure fair competition.

The notice also demands expedited development of "modernized pharmaceutical logistics", and encourages the growth of contract warehousing and distribution of pharmaceutical products by capable pharmaceutical distributors with modernized logistical infrastructures and technologies.

Six central government agencies agree to coordinate drug safety regulation

Six central government agencies, including the Ministry of Health (MOH), the Ministry of Industry and IT, the Ministry of Public Security, the General Administration of Industry and Commerce, the SFDA and the State Administration of Traditional Chinese Medicine, signed on December 11 a joint document, Opinions for Establishing the Inter-ministerial Coordination Mechanism for Focused Drug Safety Corrections, to coordinate their efforts in strengthening the regulation of drug safety.

The inter-ministerial coordination mechanism is led by the MOH and, in principle, relevant officials of the six agencies should meet at least every six months.

The Leaders Group for Focused Drug Safety corrections under the SFDA is responsible for collecting related information and reports from all six agencies, organizing them into appropriate formats, and disseminating them to all relevant agencies.

Beijing Institute for Control of Drugs opens office in BDA

Beijing Institute for Control of Drugs and Biological Products has officially opened a representative office in Beijing Economic-technological Development Area (BDA), that will provide drug testing services to pharmaceutical enterprises there.

The newly launched representative office is the institute's first in the country. It has been widely welcomed by the pharma enterprises in BDA because it can shorten the time needed for drug testing and reduce the management costs.

Reportedly, 65% of the drugs submitted for testing to the institute are products of pharma companies in BDA.

Legal / IPR News

SFDA issues new administrative protection announcements

The SFDA issued the No.143 Drug Administrative Protection Announcement on October 23, 2009, declaring the ending of drug administrative protection for Glaxo Wellcome Belgium S. A.'s Seretide Evohaler (salmeterol xinafoate/ fluticasone propionate inhalation aerosol).

The SFDA issued the No.144 Drug Administrative Protection Announcement on November 25, 2009, declaring the ending of drug administrative protection for Italy Schering-Plough's Aerius (desloratadine) tablets.

APIs / Bulk Drugs

Pfizer enters cooperation with Zhejiang Xinhua Pharma for penicillin products

According to a news report on SASAC's website, Pfizer initiated a cooperative project with Zhejiang Xinhua Pharma for penicillin line of products on November 3. No further details were offered.

Zhejiang Xinhua Pharma is a subsidiary of Sinochem Group,

one of the largest Chinese state-owned enterprises. The company is a manufacturer of pharmaceutical intermediates, bulk drugs and finished formulations.

Rumors die hard: Pfizer to acquire stake in Tianyao Pharma?

Rumors are circulating again recently that Pfizer is in close talks with Tianjin Tianyao Pharmaceutical Co. Ltd, the SHSE-listed core subsidiary of Tianjin Pharmaceutical Group, for acquisition of a stake in Tianyao Pharma.

The rumor was denied by Pfizer China, but a local securities firm recently cited inside sources who strongly suggested otherwise. Similar speculations were rampant in the second half of last year.

Both companies produce Glucocorticoid APIs. Pfizer is the largest producer of glucocorticoid API in the world, followed by Schering Plough and Tianjin Tianyao as the second and the third largest. Pfizer currently sources some of its glucocorticoid APIs from Tianjin Tianyao. In addition, Tianjin Tianyao currently controls 100% Chinese market of methylprednisolone API.

AZ to move more API production to China and other low cost countries

AstraZeneca plc plans to relocate production of its active ingredients (API) to low-cost countries, mainly to China, according to a spokesman for the company.

"Over the next several years we would seek to outsource all of our active ingredients," the spokesman told The Times of UK.

The company has already stopped producing APIs at its main UK plant in Macclesfield. At the same time, the company has been building up its production capacity in China.

EU authorities only inspect Chinese pharma factories after problems occur

European Union authorities only inspect pharmaceutical factories in China that make medicines for Western patients after something bad has happened, according to a policy paper published by a European Union rule-making body. European inspectors only visited non-Western drug factories 19 times in 2008, even though Western drug companies such as Pfizer (PFE), AstraZeneca (AZN), Eli Lilly (LLY) and Novartis (NVS) have hundreds of sites in China.

BNET reported last week that the U.S. FDA has just two inspectors working full time in China. It is not known how many inspectors Europe has in China.

The European Commission sought public comment on what it should do to beef up inspections of medicines made in China two years ago. The papers associated with that move don't give a number for inspectors in China, but many of them imply that no one knows how many are there, or if inspectors only show up after a scandal emerges, or if the number is zero. In 2008, EMEA (the European version of the FDA) inspected only 19 sites outside Europe or America, according to its annual report.

Baiyunshan Pharma and DSM enter strategic alliance

Guangzhou Baiyunshan Pharmaceutical General Works and DSM announced a strategic alliance agreement on December 8. Under the agreement, Guangzhou Baiyunshan Pharma will purchase Cephalexin and Cefadroxil bulk drugs manufactured by an environmental-friendly process of DSM. The two companies will also strengthen technical cooperation, the agreement provides.

The Chinese press reported that the pharmaceutical formulations with APIs from DSM's "green" production process have lower toxicity and adverse reaction rates.

Product and R&D News

Biolaxy gains Chinese IND approval for oral insulin

Shanghai Biolaxy Medical Science and Technology Co. Ltd. announced on November 24 that it had received the investigational new drug application (IND) approval from the SFDA for its oral insulin project (Nodlin), an innovative insulin formulation to treat diabetes. This IND approval allows Biolaxy to initiate its first phase I clinical study.

Nodlin is developed with NOD technology, a patented bio-adhesive nano-particle oral delivery technology, to overcome the barriers of oral insulin.

Shanghai Biolaxy is a wholly-owned subsidiary of US-based NOD Pharmaceuticals. The company is also developing Nodexen (preclinical phase), an oral Exenatide formulation in a capsule form based on enteric coated interferon nano-particles. Additionally, the company is reported to be researching on the oral formulations of interferon and human growth hormone.

SFDA approves recombinant insulin of United Labs

The United Laboratories International Holdings Limited (HKSE: 3933), a major pharmaceutical company in China, announced recently that it had received the approval for production and marketing of its recombinant insulin under the brand name of You Si Ling.

The approved product is indicated for type I and II diabetes. There are more than 100 million diabetes patients in mainland China with an annual market of CNY 4 billion growing between 20%-30% yearly.

SFDA approves Bayer Schering's Betaferon

Bayer Schering Pharma AG announced on December 2 that the SFDA has approved Betaferon (interferon beta-1b) therapy for patients with relapsing-remitting multiple sclerosis (MS). Bayer plans to launch Betaferon in China by mid 2010. Betaferon is available in more than 100 countries around the world.

The approval is based on established efficacy and safety data from pivotal Betaferon clinical trials, along with findings from a single-arm study designed to demonstrate the efficacy and safety of Betaferon among Chinese patients with relapsing-remitting MS. During the multi-center six-month study, Betaferon significantly decreased the number of newly active lesions on MRI in Chinese patients. The data in MS patients from China is comparable with data from Betaferon studies in different patient populations and with Bayer post-marketing experience.

General Health

MOH issues document for clinical pathway management experiment

The Ministry of Health issued on December 8 the "*Work Plan for Experiment of Clinical Pathway Management*". The document calls for trial introduction of clinical pathway guidelines for 112 diseases in 50 large hospitals nationwide.

The 50 hospitals are located in 12 Chinese provinces or central municipalities including Beijing, Liaoning, Jilin, Shanghai, Jiangsu, Shandong, Henan, Guangdong, Sichuan, Guizhou, Yunnan and Gansu.

The 112 diseases come from 22 medical specialties including common cardiovascular, gynecological and pediatric diseases, and diseases with high-prevalence and high treatment costs.

The experiment will be carried out between January 2010 and October 2011, and general hospitals should select at least two medical specialties as trial sites while specialized hospitals should select their specialty areas as trial sites, according to the document.

Seven hospitals in Beijing and six hospitals in Shanghai are included in the experiment.

MOH, CFHPC and Roche spotlight HCV surge in China

The Ministry of Health (MOH), the Chinese Foundation for Hepatitis Prevention and Control (CFHPC), and Roche jointly held a press briefing concerning the hepatitis C virus (HCV) in China.

New cases of HCV infection reached 120,000 in 2008 in China, a six-fold increase over incidence rates of five years prior, in 2003. According to HCV expert Hui Zhuang, HCV-related deaths are now the number five cause of death among all diseases in China. At present, there are approximately 38 million HCV carriers in China, about 3% of the population.

Public awareness of HCV is estimated to be as low as 1%, and less than 5% of the population has been tested for HCV. Physicians not specializing in infectious diseases were also found to have a low awareness of the disease - only 38% order an HCV test as part of regular blood work, and 85% are not familiar with HCV treatments.

Additionally, Roche announced to the press that its HCV drugs currently account for 80% of the market in China. The company's key HCV product, Pegasys (pegylated interferon alfa-2a), is currently marketed in China.

China's smoking death toll to double by 2020

Smoking deaths in China, home to the world's largest smoking population, will double to two million a year by 2020 if the country does not do more to reduce tobacco use, health experts predict.

Raising the price of tobacco products might help discourage smoking, but experts note that such a step could be tricky in China, where the government controls the industry.

China has 300 million smokers who consume a third of the world's cigarettes. Nearly 60 percent of men in China smoke, puffing an average of 15 cigarettes per day.

According to a study commissioned by the Paris-based International Union against Tuberculosis and Lung Disease, a million Chinese die each year from smoking-related illnesses, and that figure will increase to two million by 2020. The study was released at a conference on lung health hosted by the union on December 4 in Cancun.

Global health insurers look to China for future growth

Discovery Holdings Ltd. recently agreed to take over a 24.99% stake in Ping An Health Insurance Company of China, Ltd. in a bid to enter the Chinese market.

PICC Health Insurance Co., Ltd., which has a market share of 24%, recorded premium revenue of CNY 13.78 billion in 2008. The company was set up as the health insurance unit of Ping An Insurance (Group) Company of China, Ltd. (SHSE: 601318 and SEHK: 2318) in 2005 and saw sales rise over four times in the past four years.

Discovery was established in 1992 and is mainly engaged in providing health insurance. It made a combination between health management and traditional insurance in 2000 and became the biggest South African health insurance provider soon, with market share reaching over 40 percent locally.

It is the great potential of the Chinese health insurance sector that pushed Discovery to make such a decision and in addition to it, a list of foreign health insurance giants have cast eye to the sector.

MSH, one of the world's largest third-party administrators (TPA) of international health insurance, has entered into a partnership with Shanghai Tiecare Business Management Co., Ltd., a Shanghai-based company engaged in TPA of international health insurance.

US-based Wellpoint and UK-based Bupa plan to march into the sector, too. Wellpoint established a representative office in China in 2007 and will be qualified to set up a branch in the county soon. It plans to enter the sector via establishing a joint venture and is seeking partners now. Bupa established a representative office in the country two years ago and is seeking partners that have sharp edge in distribution and government relationship locally.

Statistics show that the coverage ratio of health insurance on sanitation fee averages at 40% in Western countries, but the ratio in China is only 4%. China's health insurance market size is expected by experts to hit CNY 300 billion in 2013 provided that the ratio is raised to an international average of 10%. The premium revenue from the market will exceed CNY 120 billion in 2015. All those figures indicate that the nation's health

insurance market, especially the new health and medical management sector, is full of potential. However, it is still on an initial growth stage.

Survey: 76% of urban white-collar workers suffer from sub-health problems

76% white-collar workers in Chinese mainland cities suffer from sub-health problems and nearly 60% are over-fatigued, according to the latest report, "White Paper on China's Urban White-collar Workers". Among high income employees aged between 35 and 50, their biological ages average ten years older than their actual ages, the report indicates.

The report was developed on the basis of a survey jointly conducted by the Chinese Medical Doctor Association, the Chinese Hospital Association, the Beijing Health Security Association and Ciming Health Checkup Group.

The survey found that nearly 80% of China's urban white-collar workers sleep irregularly and feel tired everyday; 23.7% do not eat breakfast regularly and over 20% eat fast food frequently without regular intake of fruit and vegetables; over 54.4% get insufficient sleep and 32.4% sleep poorly; and only 46% play sports occasionally. In addition, more than half of them feel irritable, 20% feel lonely and over 70% lack happiness and gratification.

Apart from work-related reasons, local experts believe that excessive internet surfing, over-frequent parties, unbalanced diet, irregular sleep, lack of exercise, family troubles and depression are important factors for causing the sub-health problems.

It is found that female urban white-collar workers are often threatened by cardiovascular and cerebrovascular diseases, while males frequently face the problems of sudden death, over fatigue and cancer.

People in the News

Recent executive moves

After Pfizer completed its acquisition of Wyeth in mid-November, the company appointed ***Dr. Xiaobin Wu***, former president and managing director of Wyeth Pharma China, as the General Manager of the new Pfizer China. Wu will report to Allan Gabor, President of North Asia, Emerging Markets, Pfizer Global Pharmaceuticals. Wu is the first local Chinese general manager of Pfizer China. ***Ahmet Esen***, former General Manager and Chairman of Pfizer China, has retired. But he will provide advices on the integration of Pfizer and Wyeth businesses in China.

Instem, a leading provider of early drug development software solutions, announced on December 11 the appointment of ***Penny Stockley*** as its General Manager for Asian Operations. She is based in Shanghai.

Rumors are circulating among industry insiders that ***James Deng***, CEO of Beijing Novartis Pharma, will be reassigned by Novartis to an overseas position. As a result of his departure, there are likely to be many mid- and senior-level management reshuffles within Beijing Novartis Pharma and Novartis China.

Liang Fang, a controlled operating entity of Lotus Pharma, appointed ***Jinzhong HAN*** to be General Manager of the Company's OTC Drug division.

AlphaRx Inc., a biopharmaceutical company specializing in proprietary drug delivery technology, has named ***Ruby Hui*** as President of China Operations.

Dr. Qin Maximilian Lue, who is the primary shareholder of Shanghai-based Mephax Holdings, was appointed the managing director of Alvogen China, the subsidiary of US-based Alvogen Pharmaceuticals.

Stop Press

MOH releases outcome of the first Chinese health awareness survey

The Ministry of Health (MOH) released on December 18 results of the first national health awareness survey, which indicates the overall health awareness of the Chinese to be only 6.48%. Health awareness refers to the ability to obtain and understand health related information by individuals.

79,542 full-time residents in 31 Chinese provinces (autonomous regions/central municipalities) aged between 15-69 were surveyed using a uniform questionnaire designed by the MOH.

The survey found that 14.97% of the surveyed residents had basic health knowledge and sense, 6.93% had healthy lifestyles and practices and 20.39% had basic health skills.

The lowest area of health awareness is chronic disease prevention, according to the survey. 29.97% of the survey participants had scientific health awareness, 18.70% had awareness for safety and first aid, 15.86% were aware of infectious disease prevention, 7.43% had basic medical awareness and only 4.66% had awareness for chronic disease prevention.

Health awareness of urban residents (9.94%) was much higher than that of rural residents (3.43%), the survey suggests. There were also regional differences in health awareness - the populations of eastern, central and western China regions had health awareness ratios of 7.03%, 7.67% and 5.23% respectively.

People aged between 55 and 69 are found to have the lowest health awareness at 3.81%, followed by the age group of 55 to 64 at 4.69%.

The survey assessed 71 health awareness parameters of respondents and among them six parameters were found to have the lowest scores including 1) correct understanding of the role of "four hazards" in spreading diseases (3.28%); 2) correct understanding of obesity (7.16%); 3) correct understanding of sedative analgesics (13.95%); 4) correct handling of bone-fracture patients (17.28%); 5) correct understanding of drug package inserts (18.70%); and 6) appropriate daily alcohol drinking by adults (18.79%).

Chinese experts urge elevated health promotion and education in order to improve general health awareness of the Chinese population.

Feature Articles

Data Exclusivity Rules in China

By Zhen (Katie) FENG and Julia PENG of Lovells (Shanghai)

Huge investments on risky R&D are the prices pharmaceutical companies pay to develop innovative or new drugs. The innovative pharmaceutical companies often resort to patents to protect their intellectual property rights formed in the innovation process. However, granting of patents may take several years in many countries. In such circumstances, what protection can the pharmaceutical companies seek to prevent others from enjoying the innovation benefits without cost?

One of the answers is data exclusivity. It refers to protection of research data such as clinical test data required to be submitted to a regulatory agency to prove safety and efficacy of a new drug, and prevention of generic drug manufacturers from relying on this data in their own applications.

Data exclusivity is available under the Chinese laws. This article provides a summary of the Chinese laws governing data exclusivity, followed by discussions on how to challenge breach of data exclusivity rules in China. Later part of this article highlights factors a pharmaceutical company should consider before it challenges the breach.

> ***Article 35, Implementation Regulation of Drugs Administration Law***
>
> The State protects undisclosed data of drug study and others which are independently acquired and submitted by drug manufacturers or sellers to obtain production or marketing approval of the drugs in question which contain new chemical entities. No one may make unfair commercial use of the said data.
>
> Within six (6) years from the date a drug manufacturer or seller obtains the approval documents for producing or marketing a drug containing new chemical entities, if any other applicant uses the data mentioned in the preceding paragraph to apply for approval for production or marketing of the drug in question without permission of the original applicant who has obtained the approval, no approval may be given to any other applicant by the drug regulatory department except that the data submitted are acquired independently.
>
> No drug regulatory department may disclose the data set forth in the first paragraph of this Article except:
>
> (1) for the need of public interests; or
>
> (2) where steps are taken to ensure that the data are protected against unfair commercial use.

What the Chinese laws say?

Answering to its WTO obligations under Article 39.3 of the TRIPs Agreement, China first incorporated the data exclusivity rule in Article 35 of the *Implementation Regulation of Drugs Administration Law*, promulgated by the State Council in 2002. The same rule was reinforced by the SFDA in its Administrative Measures for Drugs Registration.

According to the above laws, after a company submits to the SFDA or its local counterparts (collectively referred to as the "SFDA") test data and obtains a marketing or production approval (the "Approval") for a new drug, the SFDA should not, within 6 years from the Approval date, grant the Approval to others for the drug in question if others use such test data.

Exceptions to this are allowed in any of the following circumstances:

(a) the later applicants acquired the test data independently;

(b) the later applicants' use of the data is authorized by the original applicant who first submits the data;

(c) the drug in question is not a drug with a new chemical entity; or

(d) the data in question is not "undisclosed data".

What the Chinese laws do not say?

When applying the above laws in cases where breach of data exclusivity is alleged by foreign pharmaceutical companies, we found the Chinese laws leave a few issues in dark or at least in ambiguity.

As an example, the laws do not provide what constitutes acquiring the data "independently". When a company has its competitors' data, it is not difficult for it to produce same or similar test data in papers even if it has insufficient capacity to conduct clinical tests to generate such data. Should the SFDA find independence by looking at documents only or should it look deeper by examining the whole process of the alleged independent test?

In addition, there is no clear definition of a "new chemical entity". Our understanding is if a pharmaceutical company has applied for drug registration in China for a chemical substance that has never been found for pharmaceutical use, such drug should be deemed as a drug with "new chemical entity".

Moreover, it is not clear what "undisclosed" data means. If the company submitting the data only discloses it to the SFDA but for unknown reasons the data is later leaked to others despite of the great efforts made by the submitting company' to keep the data confidential, should the data be qualified as "undisclosed data"?

Clarification from the legislator or the SFDA is certainly needed to clarify the above issues.

How to challenge breach of data exclusivity?

What a pharmaceutical company can do if it has evidence showing others relied on its data to obtain Approvals from the SFDA on the same drug within the 6-year period? There is no statutory SFDA complaint procedure available now for this company to ask the SFDA to either revoke the Approval or refuse to grant the Approval.

Despite of this, we consider a complaint can still be made to the SFDA to make them aware of the breach of the data exclusivity. Our experience shows the complaint will likely result in the SFDA's investigation or enquiry into the complained Approval as well as the supporting data. Depending on what the SFDA (is willing to) finds out, the complaining company then can consider whether to formally request the SFDA to revoke the Approval or not to grant the Approval.

If the breach of data exclusivity also involves patent infringement, infringement of trade secrets or other proprietary information, the injured company may consider taking legal actions directly against the breaching party besides the complaint to the SFDA.

More than a legal issue

How to handle breach of data exclusivity can sometimes be a

very sensitive issue and requires consideration of commercial and public-relation factors. Therefore, few companies have made complaints to the SFDA based on data exclusivity rules.

Filing a complaint to the SFDA asserting data exclusivity protection could be mistakenly read as making criticism that SFDA is not careful enough in examining drug applications. Such misunderstanding is not the desired "side effect" for most pharmaceutical companies who have pending drug applications at the SFDA. To avoid or mitigate such side effect, we suggest engaging business and/or government-affair team to devise a suitable approach to bring the complaint, such as engaging pre-complaint meetings with the SFDA.

Any expected legislative development?

Developed countries with more mature pharmaceutical industries, such as the US, view data protection or data exclusivity a major concern from the standpoint of protecting their citizen's interests in China. On the 20th session of the Joint Commission on Commerce and Trade (JCCT) concluded on October 29 this year in Hangzhou, Zhejiang, the US and Chinese government again discussed data protection for pharmaceuticals but they did not reach agreement on this issue. They only agreed to continue the discussion. This suggests that China will unlikely make any immediate legislative move on data exclusivity issue in the short future.

Katie Feng ZHEN (zhen.feng@lovells.com) is the General Manager of Lovells (Shanghai) Intellectual Property Service Co., Ltd., and Julia PENG (julia.peng@lovells.com) is an associate of the firm. Lovells is one of few foreign law firms that have been granted an agency license in China. The domestic agency status allows it to undertake all trademark-related work directly. Lovells is also able to file directly enforcement actions including litigation for trademark and copyright in China.

Other News

Upcoming events

Event: Winning Pharmaceutical Product Marketing & Branding Strategy
Venue: Four Points By Sheraton, Shanghai, China
Dates: March 22-23, 2010
Contact: Lee Chew Wan
Tel: +603 2723 6748
Email: leec@marcusevanskl.com
Weblink: www.marcusevansassets.com/doc/pdfs/Ep_11434.pdf

Event: China Pharmaceutical Law Summit
Dates: April 8 and 9, 2010
Venue: TBD, Shanghai, China
Contact: Devashini Satiananden
Tel: +65 6835 5131
Email: devashini.s@informa.com

Webcast: Pharma Opportunities in China: Promises and Pitfalls
Date: Tuesday January 19, 2010 at 9:30am EST.
Contact: Seth Harlem, China Micro Finance
Email: seth.harlem@chinamacrofinance.com
Weblink: www.chinamacrofinance.com
Cost: By Jan. 4 (pre-registration) US$350. After Jan. 4, US$400.

Chinese bio-pharma sector becomes latest darling of venture capitalists

Spurred by the healthcare reform launched by the central government, healthcare has now become the hot destination for domestic and foreign venture capital (VC). The bio-pharmaceutical sector, which raised funds of nearly US$130 million in the first half of the year, is the hottest of all.

The sector accounted for 20% of the investment deals signed in China during the same period, according to a report by Zero2IPO, a leading domestic service provider for the venture capital and private equity industry.

"The ratio is pretty high. The passion (for bio-pharmaceuticals) has been ignited by the predictable growth potential in China's healthcare industry and the growing demand for biopharmaceuticals," said Zheng Yufen, senior manager for healthcare at the investment banking division of Zero2IPO.

"Talks are also on for a slew of other investment deals in the bio-pharmaceutical sector and hopefully they would be sewn up by the end of the year," she said.

In January, Kerry Bio-Science, a Zhejiang-based life science research pharmaceutical company, raised its second round offunding worth US$13 million from KPCB China and some institutional investors. The Kerry Bio-Science deal sparked a flurry of investment in the bio-pharmaceuticals sector. Macrostat, a clinical research data provider on bio-pharmaceuticals, got investment, with no details available, from Tigermed Consulting and Qiming Venture Partners. In May, KPCB China made its second investment this year, in Nanjing-based Genscript Corporation, a leading bio-pharmaceutical research outsourcing company, at a price of US$15 million, the largest this year.

With its strong talent pool, China is in a much better position to attract investment by international medical companies for R&D centers. In November, drug major Merck Serono and IBSA, a Switzerland-based bio-pharmaceutical company, announced plans to set up R&D centers in China.

This year, venture capital firms like IDG and SAIF are bolstering their teams and hiring more employees from hospitals and domestic bio-pharmaceutical companies. "Both the companies are in negotiations for deals of over US$10 million," said Zheng.

Stop Press

Alvogen establishes operation in Asia with HQ in Shanghai

Alvogen, a US-based pharmaceutical company, has established operations in Asia and has opened an office in Shanghai, China that will lead efforts to commercialize the company's products in the country. The Chinese market is said to represent a strategic gateway for future business development in Asia as the company aims to solidify its presence in the region.

Alvogen China will also serve as a global sourcing unit for active pharmaceutical ingredients and finished products that will be used throughout the company's regional business units that encompass North America, Europe and Asia.

China's Drug Registration & IPR Update and Strategies of MNCs

Huang Juhui, Vice President, RDPAC

MNC's capacity to bring new products to the Chinese market and to expand their life-span through IPR protection is one of the key factors for their continuing success in their traditional market in large hospitals.

To revise drug administration law (DAL) and to implement new GMP standards are on top of SFDA's agenda. DAL revision will provide a unique chance for MNCs to address their concerns on product registration and IPR protection. MNCs should motivate their government affairs, regulatory affairs and legal affairs teams to jointly monitor and input to the DAL revision in coming 1-2 years. A draft new GMP standard was circulated for public comments on Sept 25, 2009. The enforcement of new GMP standards is expected to improve drug quality, to create a level playing field for both multinational and local pharmaceutical companies, and to lift the bar for drug registration where SFDA is flooded with applications from generic manufacturers. Multinational companies should fully support SFDA to upgrade GMP standards as close as possible to cGMP standard currently adopted in developed countries.

On August 25, SFDA posted on its webpage the Rules for Registration of Technology Transfer of Drugs. This new regulation had been expected by the industry for quite a long time after the first draft for public comments issued on November 9, 2007 and the second one issued on April 09, 2009. Multinational companies will benefit from this regulation. More options are provided for local production of drugs with Import Drug License, while the technical review timeline at CDE will be 40 working days only, significantly shorter when compared with the previous practice. The new regulation is a positive move toward establishing a marketing authorization system in China, which will speed time to market for advanced medicines and ensure equal treatment and regulation of locally manufactured and imported products.

Currently Chinese law protects data submitted in the context of a registration application of a drug containing new chemical ingredient from unfair commercial use. However, certain key concepts such as "new chemical entity" (NCE) and "unfair commercial use" have been left undefined by the current Chinese law, leading to ambiguity in the enforcement.

An important step to improve the data protection environment would be to link China's data protection provisions to its drug registration regulations and close some of the loopholes in the latter relating to "reliance" on innovators' data. The industry would urge the government to revise the current drug registration regulations to ensure "exclusive" data protection for all NCE drugs as defined by major international markets. According to feedback from a recent Data Exclusivity (DE) workshop organized by US-China JCCT Pharmaceutical Taskforce, the Chinese Government showed some flexibility/ possibility to grant meaningful DE for category 1.1 drugs first. This will be a potential breakthrough for MNCs to pursue in 2010.

The prevalence of counterfeit drugs within and originating from China remains a substantial concern. Although pharmaceutical counterfeiting is subject to criminal, administrative and civil remedies under the Chinese Laws, the effectiveness of such remedies in practice is often undermined either by burdensome evidentiary requirements or ineffective enforcement. Another important factor contributing to the pervasiveness of drug counterfeiting is that Chinese chemical manufacturers are allowed to produce and advertise bulk active pharmaceutical ingredients (API) for "medicinal use" without having to adhere to the quality and safety measures administered by the SFDA.

The Chinese government issued a Judicial Interpretation (JI) Regarding the Production and Sale of Counterfeit & Substandard Drugs on May 26th, 2009. The new JI is expected to significantly enhance the criminal investigation and prosecution of drug-counterfeiting and related crimes in the future, for example, by providing per se harmful standards for the production of highly-dangerous drug products, including the injections and prescription drugs. Also, to "knowingly" supply "raw materials" (APIs) or advertise for a fake drug product will constitute offence as an "accomplice" to drug counterfeiting under the new J.I., which will certainly enhance the deterrence of reckless supply of API products and counterfeit drug-advertising in the future. However, it is important for MNCs to advocate the new J.I., and test it out by filing cases to court.

In conclusion, the China market has become one of the most important markets for pharmaceutical companies, which can be exemplified by frequent visits of senior executives of pharmaceutical companies to China, and more strategic and significant investments in China. Novartis just announced a US$1 billion investment in Shanghai to make China a third global pillar for its research and development. To realize their market potential in China, some companies have started to build up their sales force and distribution channels to access the fast growing grass root market. Some companies like Bayer, Pfizer, Sanofi-Aventis have acquired or showed interest to acquire local companies to expand their capacity in low cost production and distribution.

Besides business strategy actions, MNCs should make sure they have a seat in the tent to understand the policy directions and to influence new policies. To steer the company through a fast changing policy environment in a country with the size of China, MNCs should be able to figure out the key decision makers and policy influencers through government mapping exercise. A recent stakeholder mapping report on China healthcare reform conducted by RDPAC has been welcomed as a very valuable tool. MNCs should also try their best to collaborate with and align their position with local companies and industry associations. "Chinese government will never make a policy solely serving the interest of foreign pharma companies", said a SFDA deputy commissioner recently.

MNCs have done a good job so far in communicating with Chinese Government. James Shen commented in Pharma China Editorials on Aug 26, 2009: "*after reviewing the healthcare reform policies which have been released or proposed, I am quite convinced that research-driven pharmaceutical companies have done a good job presenting their interests and opinions to the Chinese government in the development process of these policies.*" Many MNCs are enhancing their government affairs teams with a focus shift from specific issue solving to strategic policy influence in order to be better equipped to face more challenges to come in China market.

Dr. Huang Juhui is currently serving as Vice President of government affairs and driving healthcare policy working group for RDPAC. He took several senior government affairs and business development roles in leading multinational life science companies before joining RDPAC. This article represents the author's personal observations and analysis only. He can be reached at Juhui.huang@163.com.

The Impact of Chinese Health Care Reforms - Survey Findings and Observations

Chris Arzt, Managing Principal, ZS Associates Shanghai

Introduction

Over the past few years the urgency for health care reforms in China has grown. After much deliberation, the government has now clarified the scope of reforms, and implementation in some areas is under way.

These reforms will have a significant impact on the health care system and thus on the business of pharmaceutical firms. As the reforms begin, the potential impacts on the pharma industry and companies' likely responses have begun to take shape.

While much is still unknown, and companies are still feeling their way to appropriate responses, now is a good time to take stock of the emerging direction. Accordingly, ZS Associates, in collaboration with eyeforpharma, asked 70 senior pharma managers and executives their views on health care reform over the last four months.

All participants were managers or executives in the pharma industry. 66% worked for MNCs. 38% worked for top 10 MNCs. 56% had responsibility for the whole of China, 22% for part of China, and 21% had regional or global responsibility.

We found that the industry is convinced that significant reforms are coming. Overall people are optimistic that reforms will be positive for the pharma industry, but do acknowledge some significant risks. Interestingly, respondents from the biggest multinationals (MNCs) are the most optimistic. Most respondents believe that reforms will lead companies to change the way they do business, in particular by expanding customer audiences and adapting more varied go-to-market strategies.

Health Care Reforms

The anticipated reforms are designed to broaden access to medical care while reducing the cost of basic care. They fall in five major categories:

- Creating and driving utilization of the new National Essential Drug List (NEDL) comprising cheap and broadly needed products. The NEDL is actually one part of a broader National Essential Drug System, which tentatively includes provisions for the selection, production and distribution of drugs deemed essential to the treatment of common medical conditions. The entire system is under the jurisdiction of the MOH. At this point only the NEDL (i.e. the drug selection) part of this system has been put into place. The other parts are in dispute.
- Increasing funding for medical insurance, leading in the future to universal medical insurance at somewhat higher levels of reimbursement.
- Strengthening and promoting the Community Health Care (CHC) system as a cheaper health care alternative, while building incentives to shift patients to CHC.
- Reform of public hospital management and financing, including removing the link between hospital profits and hospital funding.
- Reform of drug pricing policies, including an increased government role in setting prices.

These policies are already having an impact on the pharmaceutical business, and the impact will only increase as more reforms are implemented. The exact nature of reforms, the extent to which each will be carried out, and local variation in rolling out these reforms are all important but as yet unknown factors. Each will evolve as localities undertake experiments and implement their own policies.

Pharma Industry Beliefs

The pharma industry is taking these changes seriously. Almost all survey respondents (96%) are actively working to understand the impact on their business or have already done so. 60% think their global HQs have a good understanding of Chinese health care reforms.

Survey respondents believe that specific healthcare reforms are coming in the next five years, and respondents from the biggest companies believe so even more strongly. For example, respondents were asked whether:

- the government will require hospital bidding to be conducted directly by pharma companies and not by distributors? 64% say yes (80% of top 10 pharma MNC respondents).
- the pricing differential between off patent innovative drugs and local generics will be removed? 65% say yes.
- there will be significant consolidation of distributors? 74% say yes (85% of top 10 pharma MNC respondents).
- community health centers will play a significant role in their business? 68% say yes (77% of top 10 pharma MNC respondents).

Opportunities and Threats

Survey Answer

Survey respondents are quite positive about health care reforms. Not surprisingly, reforms involving increased government spending are overwhelmingly seen as opportunities. Hospital reform and the new NEDL received mixed reviews, while drug pricing reform is seen as a significant threat.

Reform	Opportunity	Threat	Neither/Unsure
Increased funding for Basic Medical Insurance	81%	4%	15%
Government investment in township hospitals	74%	6%	20%
Government investment in CHC	70%	6%	24%
Reform of public hospital management and financing	48%	16%	36%
New NEDL	46%	32%	22%
Drug pricing reform	22%	59%	19%

In general, respondents from pharma MNCs are about 10 percentage points more positive than the full industry averages above. The exceptions are for reform of public hospital management and financing (same as above) and for drug pricing reform (only 8% see it as an opportunity).

View from ZS Associates

The impact on pharma firms largely depends on policy and implementation details which have yet to be determined. Nonetheless, we can make predictions based on what is known so far.

Increased insurance funding can only be positive, although a significant portion of this spending will likely be for drugs on NEDL and especially in rural areas. MNCs with lower-priced products may stand to benefit; others may not be strongly impacted.

Investment in township hospitals should benefit pharma firms including some MNCs. For CHC hospitals the biggest opportunities are in therapeutic areas related to chronic

conditions such as diabetes, hypertension, etc. The beneficiaries will likely be lower-priced products, as we expect that in most places CHCs will primarily or exclusively prescribe products on NEDL. There is the risk for more expensive brands of erosion of both price (in order to gain access to CHCs, or to maintain share in the face of market changes driven by CHC prescriptions) and share (if CHC's can effectively switch prescriptions initiated in Tier 2 and 3 hospitals). Any changes are likely to be gradual and to vary dramatically by locality.

The most significant hospital financing reform regards drug markups. Currently hospitals may charge a markup of 15% on the price of any pharmaceutical, thus encouraging sales of more expensive products. Because government financing of hospitals is limited, this is an important funding source for hospitals. The proposed tradeoff is to prohibit markups on drug sales, while increasing government funding of hospitals. Making this change will require local governments to better fund hospitals, and so governments may take some time to implement this. If and when this happens, this should put pressure on sales of higher-priced products.

The new NEDL, along with various policies to drive usage of NEDL products, may help some brands and harm others. Companies with molecules on the NEDL must forecast the unique tradeoff for each brand between lower prices and increased unit sales. Brands with prices already not so far from NEDL ceilings or in markets where NEDL can drive significant share increase could stand to gain. Key factors which will determine the impact of NEDL include (1) whether brands with a price above the NEDL ceiling will still be reimbursed under BMI and (2) what mechanisms the government uses to drive sales of NEDL products. In scenarios where more expensive products are not reimbursed under BMI and NEDL usage is enforced, there could be a serious impact to products with innovator pricing. However, for several political and economic reasons this scenario is unlikely to emerge in the near term.

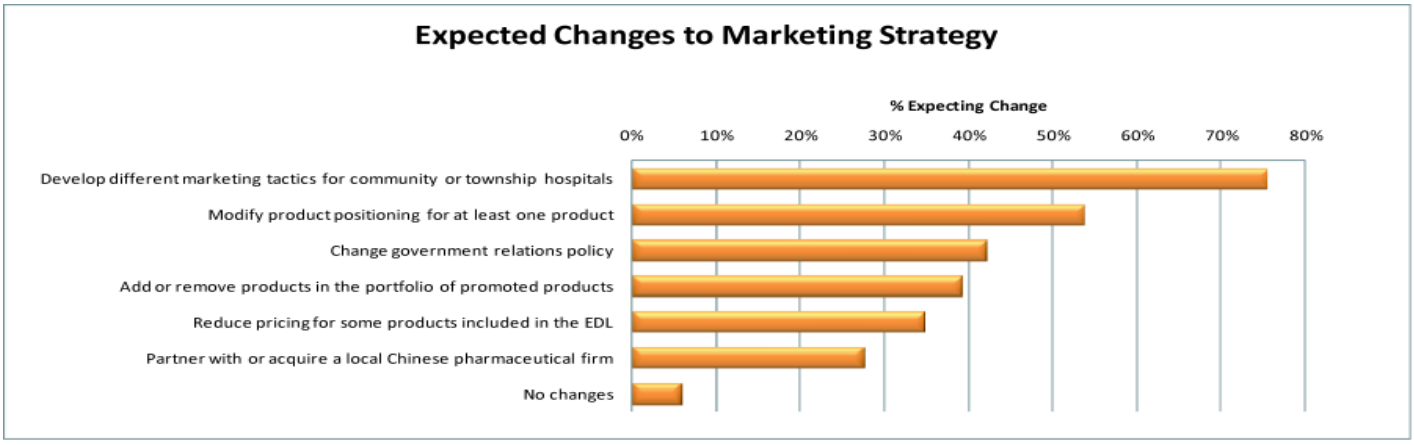
Finally, drug pricing reform encompasses a range of issues, many overlapping with other reforms. Examples include changes in the level and application of drug price controls, changes to price-setting mechanisms such as incorporating pharmaco-economics in price evaluations, reviewing the price premium for innovative drugs, etc. Each of these has its own impact, and while some seem risky, others (e.g., increased importance of pharmaco-economics) may be positive for the larger MNCs.

Pharma Industry Response

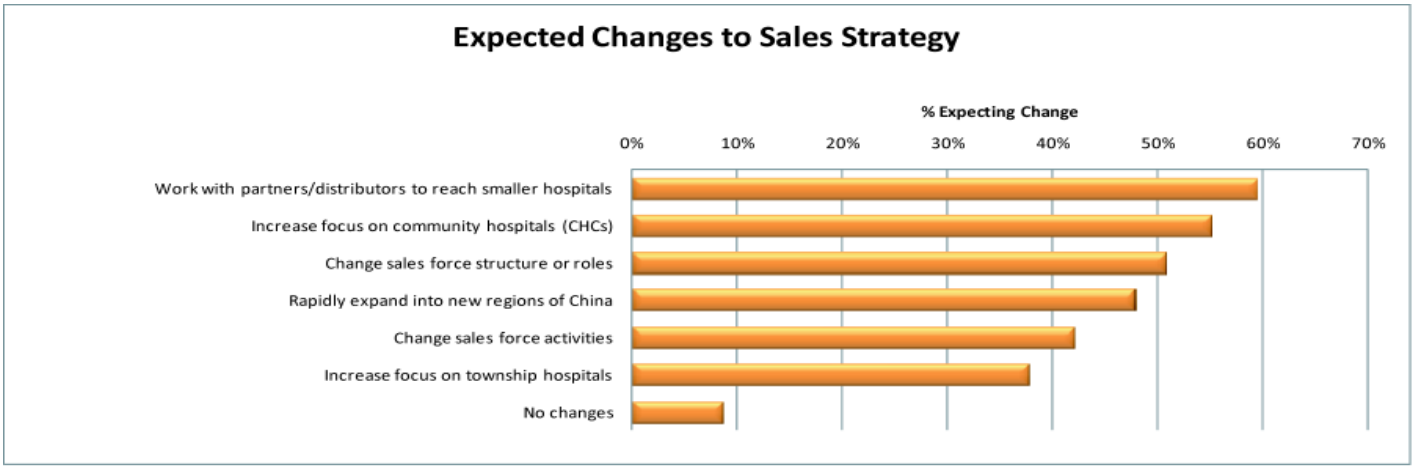
Survey Answers

Survey respondents believe that changes in sales and marketing strategy will be needed to compete in the new environment. About half believe that coverage across China will both broaden (new regions) and deepen (different hospital types).

Respondents believe that the most likely changes are an increased focus on CHCs and more partnerships to reach smaller hospitals. This shift in focus will require different marketing tactics, according to most survey respondents. Increased focus on township hospitals is seen as the least likely change.



Respondents from top 10 pharma MNCs show similar responses, except that they are 20% more likely to expect reduced pricing for NEDL and 9% less likely to expect partnerships with local firms.



Respondents from pharma MNCs are 10-20% more likely to expect more focus on CHCs and township hospitals, a rapid expansion in to new regions, and use of partnerships to reach smaller hospitals.

View from ZS Associates

Significant changes will likely be necessary to take advantage of health care reforms. In some cases changes will come quite quickly (e.g., pricing changes due to the new NEDL). In other cases changes will be slower (e.g., expanded promotion to CHCs).

In general, health care reforms will prompt many companies to diversify their customer base. This has been happening gradually for many years, as companies first focused on major hospitals in tier 1 cities then increasingly expanded to smaller hospitals and cities. Several current reforms may speed this trend:

- *Township hospitals* - Increased funding for township hospitals may drive greater geographic coverage by sales forces or via other marketing methods. The impact depends on the actual level of increased funding, and will vary depending on each company's product portfolio (e.g., funds for purchase of capital equipment may be more immediately significant than Rural Cooperative Medical System funding).
- *NEDL* - Companies with products priced within NEDL ceilings will find a broader market for their products. Some of this will be organic, as lower prices lead to increased opportunities in less-developed regions. Others will be driven by new policies promoting NEDL sales in CHC hospitals and elsewhere.
- *CHCs* - The increased importance of the CHC system will drive more attention from MNCs, especially (but not exclusively) from those with products priced within NEDL ceilings.

To cover this more diverse set of customers many companies will have a more diverse go-to-market strategy. Rather than one type of medical rep calling on all hospitals, companies may call on less profitable hospitals using different approaches. For example, companies may consider:

- *Different direct sales models* - This may include separate teams with different hiring profiles, job responsibilities, sales processes and compensation levels. This could include part-time or contract medical reps.
- *Companies will find many challenges in trying to successfully implement different models* - determining which customers are covered by this new type of rep, coordinating responsibilities across sales teams, defining the new selling process, determining hiring profiles, etc.
- *Indirect sales models* - An indirect model relies on distributors to cover customers in places which are unprofitable for pharma companies to cover directly. Companies will need to clearly define which accounts should receive indirect coverage, and what activities they want distributors to perform.

  This type of partnership with distributors is rare right now, both because most distributors lack capabilities and because pharma firms are not experienced managing these types of relationships. Building partnerships will require pharma companies to select distributors with the right skills and controls, to effectively train distributors, and to build and manage compensation programs which drive the right behavior.

Leading distributors are open to rethinking the relationship with pharma companies, including testing ideas such as fee for service and pay for performance. Pharma companies will need to craft appropriate strategies to take advantage of this.

Brands which reduce pricing to meet NEDL ceilings will have a broader physician and patient universe. Companies will therefore need to rethink product positioning to maximize value. They will also need to consider the best marketing tactics to effectively reach the new audience. For example, marketing in CHCs may rely less on detailing individual physicians and more on interactions with government officials and CHC heads for access, and on broad-based educational programs for pull-through. Also, a broader and more complex set of customers will cause companies to re-evaluate their market understanding. For example, marketers will pay more attention to switching within CHCs and referral patterns between tier 1/2 and CHCs.

Finally, companies must consider the impact of reforms on their product portfolio strategy. This could include a re-evaluation of the relative attractiveness of different therapy areas, or a desire for increased presence in generic markets. This may impact new registrations and the attractiveness of certain licensing or acquisition deals.

Summary

Significant health care reforms are underway, and pharma companies are carefully considering the impact on their businesses. While many of the changes are positive for the industry, others may be more troublesome. In truth, much depends on reform details still to be worked out. But regardless of the evolution of reform, it seems clear that pharma companies will need to change their operating models to succeed in the new environment.

About the Author

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ZS Associates is a global management consulting firm specializing in sales and marketing consulting, capability building and outsourcing. The firm has more than 1,000 professionals in 18 offices around the world, and has assisted more than 700 clients in 70 countries. ZS Associates' Shanghai office works with pharmaceutical firms on critical sales and marketing issues. Its team has served clients in China since 2004, combining deep local expertise with global experience.

This article is developed on the basis of a survey of 70 senior pharma executives which is jointly conducted by ZS Associates and eyeforpharma.

Stop Press

Astellas receives SFDA approval for Vesicare

Astellas Pharma China announced on December 5 that the SFDA approved the marketing of its Vesicare (solifenacin succinate) in China for overactive bladder (OAB). The company estimates that 100 million Chinese people suffer from this disease.

Vesicare is an oral anti-muscarinic agent which reduces smooth muscle tone in the bladder, allowing the bladder to hold greater volumes of urine as well as reducing urgency and incontinence episodes.