



## CHINA'S LIFE SCIENCE INDUSTRY 5-6/10

Dear Friends and Colleagues,

Only two years after the SFDA's Commissioner, Mr. Zheng Xiaoyu, was sentenced to death following a bribery scandal, a new corruption investigation involving high level officials in the healthcare industry, including Zhang Jingli, the Vice-Commissioner of the SFDA, was now launched in China. Recent reports suggest that pharma giant Johnson & Johnson is amongst the companies involved in this corruption case.

Critics may highlight the seriousness of these allegations in this sensitive industry. A more refreshing view emphasizes China's policy-shift from covering up cases of bribery or simply ignoring signs of corruption to a sincere battle against these phenomena.

From the industry's point of view, there is only one drawback: industry executives express their concern that the crackdown's repercussions will manifest themselves in the SFDA's growing scrutiny of ongoing and future drug and device registrations, making an already long process – uneconomical. On the bright side, with increasing local demand for new technologies to satisfy China's growing needs for improved health services, a balance will probably be stricken between the regulator and the public.

  
Eyal Harel  
Co-CEO

### **POLICY**

#### ***China Likely to Nullify Rx/OTC Dual Status of Drugs***

According to a report in the 21st Century Business Herald of June 10, 2010, China's State Food and Drug Administration (SFDA) is to nullify the current Rx/OTC dual status of drugs. The report quoted sources from the China Nonprescription Medicines Association (CNMA) and undisclosed drug firms.

The Rx/OTC dual status refers to drugs that exist as both prescription and over-the-counter medicines. There are currently more than 2300 drugs with Rx/OTC dual status in China.

### **NEWS FROM THE INDUSTRY**

#### ***Tasly: Influenza Subunit Vaccine Gets SFDA Approval***

On April 30, 2010 Tasly Ginna Biotechnology (Tianjin) Co., Ltd. received SFDA approval for its influenza virus subunit vaccine.

Due to technical difficulties, Tasly is only the second domestic company to date that managed to achieve SFDA approval for a subunit vaccine.

According to global statistics, the annual number of influenza cases ranges between 120 million to 600 million cases. Global vaccine sales are expected to reach \$3.7 billion by 2010. However, the

worldwide capacity for influenza vaccine production reaches only 2.8 to 3.0 million doses per year, just 14% of the actual global demand. The growth opportunities for this market are evident. In China, influenza annually occurs in about 8% of the general population – roughly 100 million cases per year.

#### ***Qiming Venture Partners to Invest RMB 100 Million in GanLee Pharmaceuticals***

GanLee Pharmaceutical Company Limited announced on May 19, 2010 that it has received an investment of RMB 100 million from Qiming Venture Partners. For GanLee, which is dedicated to the development and marketing of human recombinant insulin and insulin analog products, this is the first round of financing.

Insulin production technologies can be divided into three generations. The first generation is animal insulin, which is gradually becoming obsolete. The second generation is human insulin, which is currently more popular. The third generation is insulin analog. To date, GanLee and Sanofi-Aventis are the only two companies in the world with patented technologies to produce insulin analog.

In 2009, China's domestic insulin sales totaled 6 billion RMB. At present, the Chinese market is dominated by Novo, Lilly and Sanofi-Aventis.

#### ***Beijing Genomics Institute Sets its Headquarter in Copenhagen***

On May 17, 2010, the Beijing Genomics Institute (BGI) signed an agreement to open its European headquarters in Copenhagen, Denmark.

BGI will invest \$10 million in the project to recruit 20 to 50 employees at the site in the first year. As a second step, BGI will establish a sequencing platform necessitating the employment of another 50-100 staff.

BGI is considered one of the world's major genomic sequencing centers. It has completed a large number of projects, including sequencing 1% of the human genome for the International Human Genome Project, contributing 10% to the International Human HapMap Project, carrying out research to combat SARS, etc.

In conjunction with carrying out these projects, BGI has established its own technical platforms based on large-scale genome sequencing, efficient bioinformatics analyses and innovative genetic health care initiatives.

#### ***Hepalink Sets the Highest Issue Price in A-Share Market***

Shenzhen Hepalink Pharmaceutical Co Ltd ("Hepalink" - 002399.SZ) has achieved a record-high A-shares IPO price when listing on the Shenzhen Stock Exchange (China's Nasdaq-style market) on May 6. The company raised a total of RMB 5.9 billion from selling 40.1 million of its shares, representing a company value of RMB 42.6 billion (\$6.2 billion), which is 73 times the company's reported earnings in 2009.

Hepalink's IPO price of RMB 148 per share rose to the intraday high of RMB 188 per share, putting the company's value at about 70 billion RMB (US\$10 billion).

Hepalink manufactures the cGMP-certified blood-thinning Heparin API

(active pharmaceutical ingredient) with Sanofi-Aventis and Novartis as its clients. While Hepalink's IPO prospectus claimed Hepalink was the only Chinese FDA-accredited Heparin API manufacturer, it was clarified later by the FDA that in fact some 5 other Chinese companies are FDA-certified manufacturers of Heparin API.

### ***Chinese Stomach Vaccine May Stop Gastric Cancer***

Chongqing Kangwei Biotech has developed a vaccine that prevents infection by *Helicobacter pylori*. *Helicobacter pylori* is a bacterium that lives in the stomach and causes duodenal and gastric ulcers which was also linked to stomach cancer.

The vaccine against *Helicobacter pylori* (Hp) has obtained a drug certificate last year (SFDA) and is the world's first vaccine against Hp. The drug is expected to begin commercialization by 2011.

Clinical studies with some 6,000 participants showed that the vaccine can make the mucous membrane in the stomach immune to *Helicobacter pylori* and stop 72 percent of infections.

In China, about 200,000 people die from stomach cancer every year. Today, patients resort to antibiotics to combat Hp. Antibiotics are not only costly and cause serious side-effects, but also do not prevent the infection from reoccurring. It is expected that the vaccine will cost between 200 to 300 RMB, only 20-30% of the current treatment cost.

### ***Pfizer's China Swine Vaccine Unit Sold To Harbin Pharmaceutical Group***

Pfizer Inc is said to have sold its swine vaccine unit in China to Harbin

Pharmaceutical Group.

According the report, Pfizer will sell its RespiSure and RespiSure-One swine mycoplasma *hyopneumoniae* (MH) vaccines to Harbin Bio-Vaccine, an animal health unit of Harbin Pharmaceutical for US\$ 50 million.

Pfizer is required to divest its swine flu business in China as a condition by the Chinese antitrust authorities for Pfizer's last year \$68 billion merger with Wyeth.

Harbin Pharmaceutical, which counts Warburg Pincus among its major shareholders, manufactures and distributes generic antibiotics in China.

### ***Dehaier Medical Expands Product Line with a Series of Exclusive Distribution Agreements***

Dehaier Medical Systems Ltd. (Nasdaq: DHRM), an emerging leader in the development, assembly, marketing and sale of medical products in China, has announced the closing of 3 exclusive distribution agreements in China for the following products:

1. New York based Welch Allyn's two patient monitors, the Propaq®CS and the Atlas which are used for continuous bedside monitoring of vital signs such as ECG, NIBP, temperature, respiratory functions, blood pressure and other indications;
2. Cumulus, manufactured by the German company Heyer, which is suitable for the treatment of respiratory tract conditions such as asthma, bronchitis, chronic respiratory infections and others;
3. UK-based Penlon's Prima SP Anesthesia System which is a sophisticated anesthesia product (North China only).

***Mindray and Pulsion sign Licensing Agreement***

June 10, 2010: Shenzhen Mindray Bio-Medical Electronics Co. Ltd., a leading developer, manufacturer and marketer of medical devices worldwide, and Pulsion Medical Systems AG, a leading specialist in minimal invasive critical care and cardiovascular patient monitoring, have reached an agreement on a worldwide non-exclusive license according to which Mindray will integrate Pulsion's PiCCO and CeVOX technologies into their patient monitoring systems.

The signing of this license agreement marks an important milestone in both Mindray's and Pulsion's strategies to penetrate global markets with their advanced monitoring technologies.