

# CHINA UPDATES

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### **Season's Greetings from U.S.-China HPA**

On behalf of the association, I wish you all a very Happy Holiday Season and Healthy Prosperous New Year.

As we approach 2013, the global dietary supplement and overall natural health products industry is in great shape. China's developing dietary supplement industry continues to move forward and represents some wonderful opportunities for those that know where to look. If you haven't already begun plans to enter the China market, you should make it a priority in 2013. More and more foreign companies have landed and domestic companies are springing up.

U.S.-China HPA is here on the ground and looking forward to working with your team to make your entry a successful one. So as a New Year's resolution and sound investment, I suggest you all join the U.S. – China HPA and reap the rewards in 2013.

Hope to see you at Expo West March 8-10, 2013 – Jeff Crowther

China Updates is a service provided by U.S.-China Health Products Association. The Newsletters are issued three times a month. China Updates provides news on regulatory environment, new legislation, association activities and any information related to China's natural health products industry.



## U.S. Ambassador to China Discusses China Relations

The United States and China have "got to figure out how they can get along," says Gary Locke, the U.S. Ambassador to China. "There will be continuity in the U.S.-China relationship," Locke told a standing-room-only crowd at Asia Society in New York on Monday evening. "So much of the world's economy is in the Asia-Pacific arena. Almost 60 percent of the world's GDP is in the Asia-Pacific region. And we are so economically intertwined as two countries. ... So many of the problems facing the world today will only be solved with the United States and China cooperating and collaborating together." Locke was joined on stage by moderator George Stephanopoulos, of ABC News, and Asia Society's own Orville Schell, who heads up the Center on U.S.-China Relations. To see the discussion with Ambassador Locke click [HERE](#). (Source: Asia Society)

## Drug Makers Finding Opportunities with Chinese Herbs

The world's biggest drugmakers are turning to ancient Chinese remedies to boost product pipelines.

GlaxoSmithKline Plc is testing botanicals -- compounds extracted from plants -- for immune disorders, Sanofi plans to turn traditional Chinese medicines into alternative diabetes and cancer therapies, and Nestle SA (NESN) teamed last month with billionaire Li Ka-Shing to develop a drug derived from ancient Chinese approaches to cure inflammatory bowel disease.

The confluence of China's growing middle class and pharmaceutical companies' need to find new revenue have combined to give Western drugmakers an increasingly open mind about a 2,500 year-old form of medicine they once scoffed at.

"You have 1.3 billion people, many of whom cannot afford Western medicines and who believe that traditional Chinese medicines are good enough," said Bloomberg Industries analyst Sam Fazeli. "If they can manufacture it on a meaningful scale, and do it with the stamp of a Glaxo or a Sanofi on it, perhaps the consumer will be more interested in buying it than something that's boiled up in a vat somewhere."

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China's market for traditional drugs, excluding raw herbs and highly purified compounds extracted from herbs, was \$13 billion in 2011 and could grow 14 percent annually over the next five years, according to consultancy McKinsey & Co. Of last year's total, \$6 billion came from medicines sold over the counter, accounting for almost half of China's market for non-prescription drugs, the consultancy said.

### Ancient Recipes

Less stringent U.S. rules for approving plant-based treatments may give drugmakers a quicker path to creating medicines, with more than 500 applications to test treatments lodged with the Food & Drug Administration. Previous attempts to break down herbal medicines into single ingredients failed to yield major breakthroughs so Western drugmakers now target mixtures inspired by ancient recipes to sell globally and in China, where many are raised to trust traditional methods.

Combining Western science with traditional cures is an approach that already extends to Glaxo's research center in Shanghai. Sick workers can tap an alternative Chinese therapy using suction cups made of glass, as well as the pharmaceuticals that generate most of the Brentford, U.K.-based company's \$44 billion of annual sales.

## Botanical Treatments

"Traditional medicine has been practiced for thousands of years but it has always been based on clinical experience and not so much on clinical evidence like Western medicine," said Zang Jingwu, Glaxo's head of China research and development. "Our strategy is to integrate existing traditional knowledge of diseases with modern drug discovery technology."

The U.S. FDA introduced new guidelines for botanical treatments in 2004, applying less strict conditions to those imposed on chemical and biological drugs seeking approval. That opened up a new avenue for producers to replenish their medical research pipelines and replace expiring patents.

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It's no longer essential to identify the active constituents of botanical drugs, while products legally used as dietary supplements in the U.S. with no known safety issues may provide "markedly reduced" information on their toxicology, according to the U.S. regulator.

"Almost all botanicals are complex natural mixtures that are difficult to have full chemical characterization and will need flexibility in regulatory approaches," said Shaw Chen, who leads the FDA's botanical review team. The guidelines are "intended to facilitate more development of new treatments, especially for unmet medical needs," he said.

## Scaly Skin

The agency has received more than 500 applications to test drugs under the guidelines, most of which were approved for human trials, Chen said in an e-mailed response to questions. Many are in phase three trials, typically the last hurdle to qualify for approval, with a handful soon to make the final application to become an allowed drug, he said, declining to be more precise.

Glaxo's herbal drugs efforts will focus initially on immune disorders such as psoriasis, a chronic disease that causes scaly skin, and drugs that treat inflammation of the digestive system, according to Zhang Xun, Shanghai-based head of research and development for the company's global natural products unit.

"We want to get quickly into the clinical development stage by collaborating with domestic companies," said Zhang, adding that the company will "soon" have a product in development with a Chinese partner without being more specific.

## 'Good Baby'

Sanofi (SAN), France's largest drugmaker, is in talks with the Hong Kong University of Science and Technology to come up with "modernized" versions of traditional medicines.

These could be used to treat chronic diseases such as diabetes and cancer, said Frank Jiang, the company's head of Asia Pacific research and development. The Paris-based company wants to first register new drugs in China to target local patients before aiming for the global market through approvals in the U.S.

"If you have a very well-designed clinical trial, with evidence to show the mixture is better than a placebo in treating the disease, then in traditional medicine you may have less issues with getting approved," Jiang said.

Sanofi has already added traditional Chinese therapies to its consumer health portfolio after agreeing to buy Beijing-based BMP Suntone Corp. for \$520.6 million in October 2010. The purchase added the Ha Wa Wa, or Good Baby, brand of children's medicines that includes a cough mixture containing ephedra, or mahuang, a herb that has been boiled into a soup to treat asthma for thousands of years.

## Growing Market

China's pharmaceuticals market is expected to grow as much as 18 percent annually to \$165 billion by 2016 to make it the world's second-largest market after the U.S., according to consultancy IMS Health Inc. Companies such as Novo Nordisk A/S (NOVOB) and Merck & Co. (MRK) are spending millions and hiring hundreds of scientists to study diseases prevalent in China such as diabetes and cancer. Initial attempts by Western scientists to develop workable drugs by extracting single components from herbs failed to yield major results because much of traditional medicine works as a mixture of ingredients, said Gao Sihua, president of the Beijing University of Chinese Medicine. Combining the scientific standing of western drugmakers with Chinese methods may overcome consumer doubts about the value of botanical treatments. The most prominent success came from artemisinin, which is extracted from sweet wormwood and is one of the most effective medicines against malaria.

## Thunder God

Chinese scientist Tu Youyou received the Lasker Award for medical research last year for her work with artemisinin. Novartis AG (NOVN) gained FDA approval to sell the drug in the U.S. under the brand name Coartem in 2009.

"Western doctors may feel Chinese medicines are not scientific enough, but we should look at what's the aim," said Gao, who trains aspiring doctors on how to integrate Chinese and Western practices. "As long as it heals the patient and doesn't have strong side effects, then it should be scientific."

In October, a drug made from a plant known as "thunder god vine," or lei gong teng, that has been used in traditional Chinese medicine, wiped out pancreatic tumors in mice, researchers at the University of Minnesota's Masonic Cancer Center said, and may soon be tested in humans.

## 50,000 Extracts

Vevey, Switzerland-based Nestle and Hutchison China Meditech Ltd. (HCM), a drugmaker controlled by Li Ka-shing, agreed Nov. 28 to form an alliance to develop gastrointestinal treatments based on Chinese herbal medicines. The collaboration gives Nestle's Health Science unit exclusive access to Chi-Med's botanical library of more than 1,500 purified natural products and 50,000 extracts from medicinal plants. Chi-Med will begin third phase trials next year for a herbal extract aimed at treating inflammatory bowel disease.

Tianjin-based Tasly Pharmaceutical Group has already started the third phase of trials for its Danshen Dripping Pill, a combination of salvia and notoginseng extracts with synthetic borneol, according to Henry Sun, Tasly's vice president. The drug, used to treat chronic chest pains, passed the second phase of trials in 2010.

"I don't think we can make a good impact in the world until the day we have 10 to 20 different products from traditional Chinese medicine research, offering clinical benefits with low toxicity profiles," Sun said. "By that time, the image of traditional medicines will be different." (Source: Bloomberg News)

## **Chongqing to Establish Rating System for Health Food and Cosmetics**

According to Chongqing Municipal People's government, Chongqing will implement a rating system for the health food and cosmetic industries. The system will have four grades A-D. Companies that are rated as "D" will be publicized throughout the media as a discreditable enterprise.

In accordance with the Management System of Credit Rating for Health Food Operators (Trial), the health food and cosmetics operators in Chongqing will be divided into the following four categories: A (creditable), B (faithful), C (warning), and D (discreditable).

After being graded, each of the four groups will be treated differently in supervision and management. Companies that belong to Group A will be awarded by the supervision and management departments of Chongqing Food and Drug Administration. Besides the once a year on-site inspection, the supervision for Group A companies would mainly be off-site inspections such as written examinations and telephone checks. For the Group B companies, the supervision will follow the conventional routine. For Group C, in addition to increasing the frequency of on-site inspections, their legal representatives will be interviewed by regulatory officials, who will also pay return visits to the companies to check their existing problems. For Group D, in addition to the measures taken to deal with Group C, they will be informed to relevant departments of industry and commerce, taxation, and public security, etc. For those whose credits are rated as D for two consecutive years, they will be publicized through mass media. (Source: CQTV News)

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## **2013 Bohai Rim Health Product Exhibition to be Held in Tianjin**

The 2013 China (Tianjin) International Health Food and Medicine Exhibition (IHFME), which is one of the largest industry events in the Bohai Economic Rim in 2013, will be held on May 23-26 next year in Tianjin Binhai International Convention and Exhibition Center. The exhibition will be co-hosted by Tianjin's government authorities, industry associations, and professional exhibition institutions. IHFME will use nine exhibition halls in the Tianjin Binhai International Convention and Exhibition Center with an exhibition area of over 40,000 square meters to show thousands of well-known products and services. Meanwhile, hundreds of thousands of visitors at home and abroad will be invited, especially those who are interested in the market of Tianjin and the Bohai Rim region. It is estimated that there will be over 50,000 professional participants from more than 30 countries. IHFME will provide a great opportunity for them to make purchases, exchange thoughts, and get to know the target market and consumers better.

Besides exhibition, IHFME will also hold a series of events such as the Industry Summit Forum, a variety of large-scale health promotion activities, demonstrations of health service companies, and lotteries, etc. So far IHFME has won the support of more than 20 domestic and international professional organizations. Over 200 media institutions also promise to deliver tracking reports on the Exhibition. (Source: Foodmate.net, ihfme.chinacihif.com)

## Health Products May Have Violated the Law

Many health food companies, after studying the consumer psychology of the patients with high blood pressure and high blood lipid, make advertisements claiming that their health products can 100% lower the blood pressure and blood lipid. In view of this situation, experts at Shenzhen Food and Drug Administration once again reminded the public of the health food safety knowledge: Health food can only play a supporting role in lowering blood pressure; it is not a substitute for drugs.

An expert told reporter that high blood pressure and high blood lipid are important factors in causing cardiovascular and cerebrovascular diseases. In accordance with recent relevant laws and regulations, health food can only play a supporting efficacy in lowering blood pressure and other related diseases. In June this year, the State Food and Drug Administration issued the Adjustment Plan for the Function Range of Health Food (Exposure Draft), and four formerly functions of the health food, i.e., "to improve body growth and development, to prevent radiation hazards, to help lower blood pressure, and to adjust skin oil", were intended to be canceled. When the exposure draft passes, health food shall no longer claim to have auxiliary hypotensive efficacy. However, most health food in the market now still claim to have the effect of lowering blood pressure, and some even claim to be substitutes for drugs. This is obviously not just an exaggeration in advertising, but a violation of the relevant laws and regulations. If consumers see these kinds of products in the market, they should not only avoid them, but also take the initiative to report to the SFDA. The expert repeated that health food does not have a therapeutic effect; if it is used as a drug alternative, it not only has no health benefit, but also may cause exacerbations with potential health risks.

Also, the expert warned the public that the main component of the health food that claims to lower blood pressure and blood lipids is unsaturated fatty acids. Excessive intake of it may lead to obesity. In addition, some health products that lower blood pressure in China also contain a lot of sugar and additives, which may also lead to obesity. When purchasing health food, consumers should pay more attention to the ingredient statements and the effectiveness of the products. (Source: Shenzhen Evening News)

**If you have China related news that you would like to share with the association for publication in its newsletter please contact us at:**

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