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China Life Sciences and Health Care Industry Alert

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Pharmaceuticals, Devices, Health Care & Life Sciences

Regulatory and Policy Changes

- ***Catalogue of Class II Medical Devices Exempted from Submitting Clinical Trial Materials (for Trial Implementation) Issued (State Food and Drug Administration 2011-11-30)***
  On November 24, 2011, the State Food and Drug Administration (SFDA) issued the Catalogue that identifies Class II medical devices that can be exempt from certain features of clinical trials. Medical device manufacturers may submit a written application for exemption from submitting clinical trial materials when registering the medical devices listed in the Catalogue, and shall submit an explanation that compares the devices to similar devices that have been sold in the market. Clinical trial materials are not required for certain testing and diagnostic medical devices that are not listed in this Catalogue, but in the Annex 12 of the Administrative Measures on Registration of Medical Devices.

- ***Notice concerning Circulation of Guiding Principles of Phase I Clinical Trial Management of Drugs (for Trial Implementation) (State Food and Drug Administration 2011-12-05)***
  The State Food and Drug Administration issued the Notice December 2 to require local counterparts to organize clinical trial institutions in their jurisdiction to follow the guiding principles. The Notice includes 14 chapters covering responsibility requirements for medical trial sponsors, clinical trial condition, quality guarantee, risk management, trial contracts and agreements, clinical trial programs, management of trials, management of drugs for clinical trial, biological samples management and analysis, data management, statistics and analysis, summary report, etc.

- ***Notice on Soliciting Comments on Revisions of the Good Supply Practice for Pharmaceutical Products (State Food and Drug Administration 2011-12-23)***
  The State Food and Drug Administration (SFDA) issued the draft for comments of the revised Good Supply Practice for Pharmaceutical Products December 23, 2011. The draft includes articles on quality management of wholesales and retails of drugs in the areas including quality management system, organization responsibilities, staffs and training, documentation, facilities and equipments, calibration and inspection, computer system, drug purchase, drug receiving, drug storage, drug delivery, sales, drug return, drug transportation, and after-sales management. The comment period will end January 13, 2012.

- ***China Adopts Drug Safety Plan: All Drugs to be Qualified by 2015 (Beijing Times 2011-12-08)***Premier Wen chaired the executive meeting of the State Council yesterday, on which the National Drug Safety Plan (2011-2015) was adopted. By 2015, drug manufacturers shall be 100 percent compliant with the newly revised "Good Manufacturing Practice" requirements. Meanwhile, seven major tasks in drug safety are determined in the meeting as follows:

  1. Improving the national standards
  2. Improving the inspection and testing system
  3. Enhancing the management of drug and medical device quality
  4. Enhancing the safety monitoring and early warning

5. Improving the supply capability of national essential drugs
6. Establishing the long-term drug safety supervision mechanism
7. Deepening the reform and improving the legislative system

- ***NDRC Issues Rules on Drug Price Parity to Prevent Disguised Price Hikes (China Legal Information Center 2011-12-02)***
  The National Development and Reform Commission decided to issue and officially implement the Rules on Drug Price Parity that have been trialed for several years, requiring that drugs with same active ingredients shall not be priced differently for different names, different packaging, etc. The Rules clarify the price-fixing principle and the measure for the ceiling of the retail price for same drugs in different formulations, specifications or packaging, and clarify the price parity among drugs in different contents, amounts, and packaging quantities. The Rules also clarify the price parity among the formulations commonly used in clinical in order to prevent enterprises from raising prices through change of the formulations.

- ***Guangdong Issues Drug Price Adjustment Program: 307 Western Drugs' Price have a 22 percent Reduction in Average (Guangzhou Daily 2011-12-16) [See list of drugs at the end of this alert]***
  On December 15, the Guangdong Provincial Price Bureau released a price adjustment program involving the price adjustments of 441 Western drug products, 307 of which are price cuts, with an average decreased price rate of 22 percent. This is the second wave of drug price cuts this year after November 22, when the Bureau reduced the prices of more than 500 traditional Chinese medicines. These differential pricing policies aim to lower the "artificially high" prices of some drugs and reduce the financial burden of the public. The approved prices are set by clinical physicians, pharmacists, and experts in related fields based on surveys of drug prices at different stages. The regulation involved a total of 99 species of Western drugs, the majority of which are over-the-counter drugs whose price-setting is state-authorized or province-authorized. Among these drug types, drugs relating to immune function saw the sharpest decline in price.

- ***Shenzhen Public Hospitals to Revoke Drug Price Addition by the End of 2012 (Xinhua News Agency 2011-12-28)***
  The drug price addition system will be revoked in the public hospitals in Shenzhen by the end of 2012. The local health authority will take the following measures to achieve the goal: charging the medical service fee that will be covered by the social medical insurance; promoting the reform of the medical service payment system; adjusting the prices of some medical services; and providing fiscal subsidies to losses of the hospitals because of the implementation of the reform measures.

News/Notices

- ***Notice concerning Strict Investigation into Illegal and Criminal Behaviors of Pharmaceutical Manufacturing and Distribution Enterprises in Production and Sales of Fake Drugs (State Food and Drug Administration 2011-12-21)***
  The State Food and Drug Administration (SFDA) recently cooperated with the Ministry of Public Security in crackdown on crimes in production and sales of fake drugs. SFDA requires local counterparts to revoke the drug manufacturing permits and drug distribution permits of pharmaceutical manufacturing and distribution enterprises that have been verified in production and sales of fake drugs. In addition, the local counterparts shall conduct inspection on pharmaceutical manufacturing enterprises within their jurisdictions, and the inspection will focus on use of raw material, commissioned production and processing, factories and facilities leasing, purchase and sales channels, and management of invoices and permits.

- ***China busts counterfeit drug racket (Xinhua News Agency 2011-12-30)***
  According to the State Food and Drug Administration (SFDA), Chinese authorities broke up more than 1,800 dens that made or sold counterfeit drugs in cases that involved 3.35 billion yuan ($530 million) in a two-year crackdown. During the campaign, 13 government departments mobilized more than 1 million law enforcement workers to combat the sale of fake drugs via ***online advertising or consignment, seizing more than 5,000 kinds of illegal products.***

- ***Pharmaceutical Sector Eyes 20 Percent Yearly Growth (Xinhua News Agency 2011-11-30)***
  China is likely to publish a plan before the end of this year for the development of its pharmaceutical industry during the 12th Five-Year Plan (2011-2015) to help realize 20 percent year-on-year growth in total output value, China Securities Journal reported Wednesday. Wang Xuegong, an official with the pharmaceutical department of the Ministry of Industry and Information Technology (MIIT), said Tuesday that the planning also set a goal of 16 percent year-on-year growth in the added value of the industry during the period.

- ***GE Healthcare adding to staff, budget for R&D (China Daily 2011-12-21)***
  GE Healthcare, a division of General Electric Co., said it plans to employ another 200 Chinese engineers next year to support local research and development work, along with a higher investment budget, to further expand its market share in second- and third-tier cities. Rachel Duan, president and CEO of GE Healthcare China, said that more than 40 new products are scheduled to be introduced to China in the next three years, with 80 percent to be sold to local hospitals and clinics.

- ***Notice from the Ministry of Health concerning Approval and Administration of Establishment of Specialized Hospitals (Ministry of Health 2011-12-21)***
  According to the Notice, provincial health administrations may plan and set up the specialized hospitals. Apart from the basic requirements for common medical institutions, the following conditions are required for establishment of specialized hospitals: (i) the current medical resources can't satisfy the demand for specialized medical service; (ii) the medical institutions establishment plan includes planning for such kinds of specialized hospitals; (iii) the name meets the naming rules of medical institutions; (iv) the hospitals to be established shall be above Class II scale and the service can cover certain areas; (v) the hospitals to be established shall have experts and technology teams to provide specialized medical services; and (vi) the specialized medical service is supported by a complete and scientific basic theory system, the relevant technologies are mature and safe, and the services shall meet medical ethics. The Notice has taken effect as of December 5, 2011.

- ***Hospitals in Beijing to Share Prescription as of Next Year (Beijing Morning Post 2011-12-15)***
  The Beijing Municipal Human Resources and Social Security Bureau announced yesterday that 1,823 designated medical institutions have set up the computer program of "Doctor Station." The e-prescriptions can be automatically transferred to the cashiers and can be transferred to medical insurance administration. Beijing will initiate the phase II construction of "Doctor Station" next year, which will realize the information-sharing among designated hospitals in order to avoid repeated prescription in different hospitals.

- ***Tighter Regulations to Ensure TCM's Safety (China Daily 2011-12-12)***
  China will strengthen the regulation of traditional Chinese medicine (TCM) to ensure its quality and to assist the country's plans to provide universal health care. The initiative in the national drug safety plan approved by the State Council came after TCM scandals, such as where dealers smoked TCM raw materials with sulfur to make them look better. Such scandals aroused public concerns over safety. In response to those concerns, the production and processing of Chinese herbal medicines will be standardized in the next five years, according to the plan. A system to track these medicines to their origin will also be established.

Detailed List of Drugs in the Guangdong Drug Price Adjustment Program (Summary of background above)

- Gentamicin
- Clindamycin Phosphate
- Cefazolin Pentahydrate
- Metronidazole
- Tinidazole
- Clotrimazole
- Miconazole
- Terbinafine
- Trochisci Piperazini Phosphatis
- Pyrantel Pamoate
- Ibuprofen
- Paracetamol
- Compound Paracetamol
- Naproxen
- Glucosamine
- Compound Chlorzoxazone
- Paracetamol and Pseudoephedrine Hydrochloride
- Paracetamol, Pseudoephedrine Hydrochloride and Dextromethorphan Hydrobromide Tablets II
- Paracetamol, Amantadine Hydrochloride, Artificial Cow-bezoar and Chlorphenamine Meleate Granules
- Paracetamol Caffeine Guaifenfsin and Chlorphenamine Naleate Solution
- Compound Pseudoephedrine Hydrochloride Capsules
- Compound Paracetamol and Amantadine Hydrochloride
- Compound Asiatic Moonseed, Paracetamol and Chlorphenamine Maleate Tablets
- Compound Bulbus Fritillariae Cirr Hosate and Ammonium Chloride Tablets
- Compound Licorice Fritillary Bule and Ammonium Chloride Tablets
- Compound Clorprenaline Hydrochloride Tablets
- Compound Loguat and Ammonium Chloride
- Compound Forsythia, Paracetamol and Chlorphenamine Maleate Capsules
- Salicylamide, Paracetamol, Caffeine, Phenylephrine and Brompheniramine Tablets
- Paracetamol Pseudoephedrine Hydrochloride and Dextromethorphan Hydrobromide
- Paracetamol, Caffeine, Cow-bezoar and Chlorphenamine Maleate Oral Solution
- Dextromethorphan Hydrobromide and Guaifenesin Syrup
- Guaifenesin, Pentoxyverine Citrate and Chlorphenamine Maleate Tablets
- Sulfogaiacol, Pentoxyverine and Promethazine Granules
- Compound Guaifenesin and Pseudoephedrine Hydrochloride
- Guaifenesin and Dextromethorphan Hydrobromide
- Nicotinic Acid
- Calcium Carbonate
- Calcium Carbonate D3
- Spirulina
- Decloxizine
- Dimenhydrinate
- Ketotifen
- Chlormezanone Dextromethorphan
- Diprophylline
- Beclometasone
- Budesonide

Detailed List of Drugs in the Guangdong Drug Price Adjustment Program (Summary of background above)

- Fluticasone
- Bismuth Potassium Citrate
- Bismuth Aluminate
- Hydrotalcite
- Glycerol
- Live Bacillus Licheniformis Preparation
- Live Bifidobacterium Preparation
- Lactulose
- Phenylpropanol
- Compound Carraghenates
- Dimethicone
- Compound Ranitidine Compound Aucklandia, Aluminum and Magnesium
- Compound Allantoin
- Compound Vitamin U
- Compound Digestive Enzyme
- Medicated Leaven, Rhubarb, Sodium Bicarbonate and Aluminum Hydroxide
- Vitamin U, Belladonna and Aluminum
- Ferrous Fumarate
- Ferrous Succinate
- Benzoyl Peroxide
- Crotamiton
- Ciclopirox Olamine Ointment
- Bifonazole
- Ketoconazole
- Econazole
- Selenium Sulfide Lotion
- Coal Tar Lotion
- Hydrocortisone Butyrate Cream
- Mometasone Furoate Cream
- Ethacridine
- Sulfacetamide Sodium
- Dobesilate
- Oxymetazoline
- Xylometazoline
- Cetylpyridinium Chloride
- Compound Zedoary Turmeric Oil
- Medicinal Charcoal
- Cefamandole
- Enteral Nutritional Suspension
- Xuesaitong Soft Capsule
- Trivitamins B
- Compound Diclofenac Sodium Chlorphenamine Maleate
- Compound Captopril
- Triamcinolone Acetonide Acetate and Miconazole Nitrate and Neomycin Sulfate Cream
- Compound Indometacin Cream
- Josamycin
- Lentinan for Injection
- Thymopentin for Injection
- Streptococcus A Group Injection

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