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China Life Sciences and Health Care Industry Alert

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China Briefing - October 2011 (November 22, 2011)

Pharmaceutical Devices, Health Care & Life Sciences

News

- ***SFDA Issues 2010 Annual Report on Drug Registration and Approval (State Food and Drug Administration 2011-10-09) – October 10, 2011***
  The State Food and Drug Administration (SFDA) recently issued its 2010 annual report. The report comprises six chapters covering major drug registration and administration measures issued in 2010, the production and sale of approved drugs in 2010, the clinical research status of approved drugs, key approved drug categories, and trends and changes in registration applications. In 2011, SFDA will continue to improve its operating procedures, researching and implementing new registration review methods, improving review efficiency, and strictly controlling risks related to drugs on the market. (See detailed summary, as our featured report below.)

- ***CCTV to Restrict Advertisement of Alcohol, Medical Institutions (Caijing 2011-10-11) – October 12, 2011***
  As of January 1, 2012, CCTV 1 will no longer broadcast advertisements for medical institutions after 6 p.m. CCTV 1 Hong Kong, CCTV 2, CCTV 13, CCTV 9, CCTV 15, CCTV 4 and CCTV foreign language channels will be prohibited from broadcasting advertisements for medical institutions, including plastic surgery institutions, at any time. Also starting Jan. 1, only 12 wine enterprises may advertise their products in prime-time advertising slots. Other wine enterprises may broadcast the advertisements, but these ads will not be allowed to include the words "bottle" or "glass," among others.

- ***MOH Requires Improvement of the Reward and Penalty System for Antibacterial Drug Administration (China News Service 2011-10-17) – October 17, 2011***
  The Vice Minister of Health emphasized on a working conference that all medical institutions shall establish and improve the rewards and penalty system for antibacterial drug administration, and shall enhance the penalty on responsible personnel of irrational use of antibiotics. The Ministry of Health will continue the special rectification actions for clinical application of antibacterial drugs.

- ***Draft Mental Health Law Submitted to NPC Standing Committee for First Deliberation (Xinhua News Agency 2011-10-25) – October 26, 2011***
  The draft focuses on hospitalization, diagnosis, medical treatment, referral and identification of mental patients. The following two kinds of patients shall be hospitalized for medical treatment: (i) patients who have hurt themselves or have potential to hurt themselves; and (ii) patients who have hurt others or have potential to hurt others. In order to prevent the compulsory mental health treatment, the draft defines two referral approaches and two identification systems.

- ***SFDA: All Drugs on Market to Have E-ID by End of 2015 (China Legal Information Center 2011-10-25) – October 26, 2011***
  The Director of the State Food and Drug Administration (SFDA) said on the ASEAN Drug Safety Summit that China will further enhance the supervision in the drug market and will conduct electronic supervision on all the drugs on the market by the end of 2015, which means the manufacturing, distribution and use of drugs will be monitored and traced. Currently, China has completed the electronic supervision on high-risk drugs such as narcotic drugs, psychotropic drugs, blood products, vaccines, and traditional Chinese medicine injections. China is working on the electronic supervision on national essential drugs.

- ***SFDA Releases 3rd Batch of Illegal Drugs, Medical Devices and Health Food Advertisements in 2011 (State Food and Drug Administration 2011-10-31) ---October 31, 2011***
  The State Food and Drug Administration (SFDA) recently released the third batch of illegal drugs, medical devices and health food advertisements in 2011. From this past June to September, provincial food and drug administrations investigated 12,902 illegal drug advertisements, 2,030 illegal medical device advertisements, and 3,382 illegal health food advertisements. Ten drug advertisement approval numbers and eight health food advertisement approval numbers were revoked. The authorities took 381 administrative measures to suspend the sales of products in the illegal advertisements.

Regulations

- ***Notice on Release and Delivery of GMP Certification Announcement – October 12, 2011***
  The State Food and Drug Administration (SFDA) issued the Notice in accordance with Article 27 and Article 38 of the Administrative Measures on Drug Production GMP. The SFDA's provincial counterparts shall release GMP certification, certificate revocation, certificate renewal and certificate cancellation announcements on their websites in the various formats provided in Annexes I and III, and deliver them to the central SFDA in the format provided in Annexes II and III.

- ***Notice concerning Circulation of the Administrative Measures on Drug Supervision in Medical Institutions (for Trial Implementation) – October 14, 2011***
  The State Food and Drug Administration (SFDA) issued the Measures that are applicable in drug quality supervision and administration of domestic medical institutions. The drug purchase, storage, preparation and use in medical institutions shall be subject to the Measures. Medical institutions shall establish a special department or appoint special personnel to take the responsibilities of daily management of drug quality. Medical institutions are also required to deliver their annual reports regarding the drug quality manamgent to local drug administrations before December 31 of each year.

Detailed Summary of SFDA 2010 Annual Report on Drug Registration and Approval

- The State Food and Drug Administration ("SFDA") recently released the 2010 Annual Report on Drug Registration Approval. The Annual Report comprises six sections, summarizing the major measures of the SFDA to strengthen the drug approval administration, detailing the status of drug production and marketing approval, the status of drug clinical trial approval as well as the status of approval of drugs used in key therapeutic areas and, analyzing the trend and change in drug registration application in 2010. We summarize the salient points of the Annual Report below.

- To strengthen the management of drug quality, the SFDA issued the Guidelines for Ethic Review of Drug Clinical Trials. Several other relevant regulations are in the pipeline, including the Administrative Provisions on Pharmaceutical Raw Materials and Excipients Registration and Filing, the Administrative Measures on Drug Standards, the Guidelines for Management of Phase I Drug Clinical Trial, etc. The SFDA is undertaking the development of various technical guiding principles for drug research. The SFDA (together with other authorities) also issued the Opinion on Strengthening the Management of Traditional Chinese Medicine Prepared by Medical Institutions.

- To improve the efficiency, fairness and transparency of drug registration review, the SFDA constructed data bases of drugs in market circulation, pharmaceutical excipients, etc, introduced electronic application for chemical generic drug registration, adopted various methods (such as expert consulting meeting, third party verification, expert voting) to conduct technical review for drug registration, enhanced the technical review standards for high risk drugs (such as vaccine and blood products), new drugs of long term use and antibiotics and, enhanced the transparency of review work by publishing the review report, hosting open-day and consultation day, etc.

- To strengthen the regulation of drug research process, the SFDA emphasized on-site inspection for drug registration, conducted good laboratory practice ("GLP") and good clinical practice ("GCP") certification for drug research institutions and medical institutions. In 2010, 10 drug research institutions and 38 medical institutions passed the GLP certification and GCP certification respectively. The SFDA also conducted pilot electronic supervision of drug clinical trials conducted by 6 hospitals in Tianjin.

- In 2010, a total of 1000 drug registration applications were approved by the SFDA, which represents an increase by 26.2% from year 2009. Chinese domestic drug registration accounts for 88.6% of the total and foreign drug import registration accounts for 11.4%. 889 chemical drugs (domestic and foreign) were approved, accounting for 88.9% of the total approved drug registration, while only 30 biological products (3% of the total) were approved. The remaining 81 approvals were for Traditional Chinese Medicine. The top 5 indications are anti-infection, diabetes, cardiovasular, respiratory system and anti-tumor.

- In 2010, a total of 916 clinical trials were approved, among which 780 were for chemical drugs, 81 for biological products and 55 for Traditional Chinese Medicine.

- In 2010, the total accepted registration applications were 6294 among which 3066 were new registration applications and 3228 were supplementary applications; and domestic applications represent 80% of the total and foreign applications represent 20%. Same with the approved registration, over 80% of the total accepted applications were for chemical drugs and about 10% and 8% were for Traditional Chinese Medicine and biological products respectively.

- The Annual Report shows the SFDA has been and will continue improving the drug registration work to enhance the quality of drugs, the efficiency and transparency of drug registration. The data contained in the Annual Report also indicate the pharmaceutical industry will grow further.

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