The Strengthening of Food and Drug Safety Incorporated into the Government Work Report

On the morning of March 5, the Fifth Session of the Eleventh National People's Congress opened in Beijing, Premier Wen Jiabao delivered the Report on the Work of the Government. The strengthening of drug safety, and the improvement of food safety levels are incorporated into the Report.

The Report stated retrospectively that in 2011, China has actively yet prudently carried out reform and development of medical and health care services. Basic medical insurance coverage was further expanded, 1.3 billion urban and rural residents had been covered, and a medical insurance system covering the whole population has been emerging gradually. While deploying the major tasks of 2012, the Report pointed out that the development and reform of medical and health care services shall be promoted vigorously. Improvement of the medical insurance system covering the whole population shall be accelerated, the coverage of basic medical insurance shall be consolidated and expanded, and the capability to provide and manage basic medical services shall be enhanced. Subsidies for medical insurance for urban residents and the New Rural Cooperative Medical Care System will be raised to 240 yuan per person per year. Serious illness insurance covering uraemia and seven other major diseases will be fully introduced, and lung cancer and 11 other major diseases will be covered in the pilot program to provide insurance and assistance for the treatment. Improvement of essential drugs system and primary medical and health care system will be consolidated. The reform of public hospitals will be pushed forward, to make sure that medical care is separated from pharmacy operations, government management is separated from hospital operations, and the practice of drug-maintaining-medicine shall be ended. Nongovernmental investment in hospitals shall be encouraged and guided, and the establishment of the system with the control of drug safety shall be tightened. The development of traditional Chinese medicine and the medical practices of ethnic minorities shall be supported and promoted.

The Report also requires that the food safety monitoring and the food safety level shall be improved. It shall be given high priority to strengthening the monitoring and inspection on food and drug prices as well as charges for medical, communications, and educational services. (March 6, 2012)
In accordance with related requirements, the SFDA released the Notice on Implementing Electronic Supervision in All Production and Distribution Enterprises of Essential Drugs. This notice was issued on February 29, 2012, in Beijing. The conference summarized the performance of the whole-cover electronic supervision on essential drugs in the year 2011, promulgated the 2011-2015 Work Plan for Electronic Supervision of Drugs, and deployed the forthcoming works in 2012. SFDA Deputy Commissioner Wu Zhen attended the meeting and delivered an important speech.

At the meeting, SFDA Deputy Commissioner Wu Zhen stated that drug electronic supervision is scientific in system design, and multifunctional in anti-counterfeiting, cracking down on fake products, traceability controlling, and resolving anti-channel conflicts. The implementation of drug electronic supervision is a general and prospective trend, as well as a powerful means for scientific drug administration. Becoming aware of the important role of drug electronic supervision, the enterprises also begin to voluntarily accept electronic supervision. Administrative departments at all levels should effectively implement the plan to accumulate substantial experience, strengthen their confidence and determination to unswervingly push forward drug electronic supervision. In the future, more efforts should be put to deepen the system application, lay a solid foundation, strengthen supervision and inspection, and improve the level of information technology.

SFDA requires to incorporate drug electronic supervision into the daily supervision on drug production and distribution, availing the newly revised GMP, GSP that have been implemented or to be implemented, to enable enterprises to conduct reforms commensurate with the electronic supervision at the earliest date. (March 2, 2012)

On February 29, 2012, the SFDA issued the Notice on Effectively Implement the Electronic Supervision of Essential Drugs in 2011 (Shi Yao Jian Ban [2011] No. 100), by the end of February 2012, all the national essential drugs produced by enterprises in all provinces, autonomous regions and municipalities directly under the central government have been completed the coding. Since March 1, 2012, those enterprises devoid of the capacity of registration & cancellation verification of essential drugs are unqualified for the production and distribution. (March 2, 2012)
SFDA Issues 2011–2015 Work Plan for Electronic Supervision of Drugs

To further strengthen drug electronic supervision, continuously improve the level of drug safety, promote social harmony and stability, and realize the whole process supervision of all varieties of drugs, in accordance with the relevant policies of the CPC Central Committee and State Council and the 12th Five-Year Plan on National Drug Safety, on February 27, 2012, SFDA promulgated the 2011-2015 Work Plan for Electronic Supervision of Drugs, which defines the guidelines, objectives, main tasks, work arrangements and guarantee measures for the electronic supervision of drugs.

The overall objectives of the plan are, by the end of 2015, whole-process electronic supervision shall be applied to all varieties of drugs, to ensure drug safety in the whole process of drug production, distribution, and application; fight against counterfeit and substandard drugs to most extent, trace and recall substandard drugs most efficiently, maximally protect the legitimate interests of the enterprises, and ensure drug safety for the people.

The work arrangements are:

(a) Complete the construction of the platform for national drug electronic supervision in 2012

(b) From 2012 to 2015, realize whole-coverage electronic supervision on all varieties of pharmaceutical preparations (including imported drugs)

1. Realize the whole-coverage electronic supervision on all varieties of essential drugs before February 29, 2012;

2. Realize the whole-coverage electronic supervision on all varieties of essential drugs supplemented in local areas, and start whole-coverage electronic supervision on all varieties of pharmaceutical preparations before February 28, 2013;

3. Realize the whole-coverage electronic supervision on all varieties of pharmaceutical preparations by the end of 2015.

(c) By the end of 2015, realize the whole-coverage electronic supervision on all varieties of drugs

Extend the electronic supervision from manufacturers and distributors to end-users such as retailers and medical institutions, etc.

1. Work arrangements for electronic supervision of drugs in wholesale enterprises

By the end of 2012, all wholesale enterprises shall carry out drug electronic supervision according to relevant regulations, to verify the registration and cancellation of all encoded drugs, and to achieve Compulsory Scanning of Drug Codes”.

2. Work arrangements for electronic supervision of drugs in retail pharmacies

(1) In the first half of 2012, complete the unified bidding and infrastructure instruction of drug electronic supervision hardware and software equipment in some retail pharmacies (a total of 47595 pharmacies) in 12 western provinces;

(2) By the end of 2012, realize the electronic supervision in some retail pharmacies in 12 western provinces;

(3) By the end of 2013, on the basis of summing up the pilots in retail pharmacies, expand the scope of the pilots in this respect;

(4) By the end of 2015, realize the electronic supervision in all retail pharmacies nationwide.

3. Work arrangements for electronic supervision of drugs in medical institutions

中华人民共和国国家食品药品监督管理总局

国家食品药品监督管理局印发
《2011—2015年药品电子监管工作规划》

为进一步加强药品电子监管工作，不断提高公众用药安全水平，促进社会和谐稳定，实现药品全过程监管，2012年2月27日，国家食品药品监督管理局现依据党中央、国务院有关方针政策和《国家药品安全“十二五”规划》，制定了《2011—2015年药品电子监管工作规划》，对电子监管工作的指导思想、工作目标、主要任务、工作安排和保障措施等进行了明确。

《2011—2015年药品电子监管工作规划》总体目标是，2015年年底前实现药品全品种全过程电子监管，保障药品在生产、流通、使用各环节的安全，最有力地打击假劣药品行为，最快捷地实现问题药品的追溯和召回。最大化地保护企业的合法利益，确保人民群众用药安全。

工作安排为：

（一）2012年完成国家药品电子监管平台建设

（二）2012—2015年实现药品制剂（含进口药品）全品种电子监管

1. 2012年2月29日前完成基本药物全品种电子监管实施工作；

2. 2013年2月28日前完成地方增补基本药物电子监管实施工作，并启动药品制剂全品种电子监管；

3. 2015年年底前完成药品制剂全品种电子监管。

（三）2015年年底前实现全过程电子监管

在生产企业和批发企业已实现电子监管的基础上，向零售药店、医疗机构等末端流通使用环节延伸。

1. 批发企业药品电子监管工作安排

2012年年底前，所有批发企业按规范开展药品电子监管实施工作，对所有赋码药品进行核注核销，做到“见码必扫”。

2. 零售药店电子监管工作安排

（1）2012年上半年完成西部12省部分零售药店（共47595家）药品电子监管软硬件设备的统一招标和配备工作。

（2）2012年年底前完成西部12省部分零售药店的电子监管实施工作。

（3）2013年年底前在总结零售药店试点工作的基础上，扩大零售药店试点范围。

（4）2015年年底前完成全国所有零售药店电子监管的实施工作。

3. 医药机构电子监管工作安排

按照卫生部的总体部署，开展医疗机构
Teleconference on Nationwide Concentrated Rectification of Drug Production and Distribution Convened

On February 24, the Teleconference on Nationwide Concentrated Rectification of Drug Production and Distribution was convened in Beijing. SFDA Commissioner Yin Li, Deputy Commissioner Wu Zhen attended the meeting and delivered speeches, Deputy Commissioner Bian Zhenjia presided over the meeting.

The conference pointed out that the concentrated rectification, which has been carried out for a period of four months, is an important measure taken by SFDA on the basis of drug special rectification in the past few years, to address some outstanding problems that still exist in the field of drug production and distribution. The rectification shall concentrate our efforts during a specific period of time to focus on resolving the outstanding problems in the field of drug production and distribution, crack down on illegal activities of manufacturing and selling counterfeit and substandard drugs, strictly rectify the illegal behaviors in drug production and distribution, and eliminate the possibility and facility for illegal activities of manufacturing and selling counterfeit and substandard drugs.

The concentrated rectification shall be divided into two stages: publicity and education, enterprises' self-checking and rectification, and concentrated inspection and preliminary summary.

The conference stressed that concentrated rectification shall severely correct the outstanding problems in drug production and distribution on the one hand, and promote the ethics and work style on the other hand, to reflect and enhance the systematicness, effectiveness and authority of supervision.

SFDA Issues the Notice on the Work Plan for Nationwide Concentrated Rectification of Drug Production and Distribution

To fight against illegal and criminal activities such as manufacturing or selling counterfeit and substandard drugs, and regulate drug production and distribution order, SFDA decided to conduct nationwide concentrated rectification of drug production and distribution, which will take four months from late February to late June 2012. On February 15, SFDA issued the Notice on the Work Plan for Nationwide Concentrated Rectification of Drug Production and Distribution (hereinafter referred to as "Notice"), which elaborated the work objectives, priorities, steps, and requirements of rectification. The "Notice" requires food and drug administration departments of all provinces (autonomous regions and municipalities) to evaluate the actual conditions, carefully organize the implementations. Through the concentrated rectification, to resolve the outstanding problems in the field of drug production and distribution, investigate and severely punish illegal behaviors in this process, crack down on illegal and criminal activities such as manufacturing and selling counterfeit and substandard drugs, continuously improve the

(d) Timely start electronic supervision pilot projects on high-risk medical devices, and explore the electronic supervision on APIs. (February 29, 2012)

SFDA Issues the Notice on the Work Plan for Nationwide Concentrated Rectification of Drug Production and Distribution (February 24, 2012)

Teleconference on Nationwide Concentrated Rectification of Drug Production and Distribution Convened (February 24, 2012)


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order of drug production and distribution, as well as drug quality and safety protection levels, to ensure drug safety for the people and that the concentrated rectification achieve tangible results.

In the field of drug production, we shall focus on the rectification of the enterprises’ productions that are not in strict accordance with the prescription and process specifications, the material balance problems, or the behaviors of using inferior or insufficient materials in the production process; the enterprises’ acceptance of unauthorized entrustment of drug processing or behavior of leasing plants and equipment; the loopholes of the sources of raw materials, using industrial chemicals to substitute approved APIs, and poor quality medicinal chemicals instead of qualified ones, and the purchasing of extracts with unguaranteed quality for the production of preparations.

In the field of drug wholesale, we shall focus on the rectification of the enterprises’ illegal "Substituting", "Affiliation" behaviors of leasing and transferring licenses and certificates; the lax qualification examination of the purchasers and suppliers; the loose audit of purchase & sales notes, records and inventory of drugs, the inconsistent flows of purchase & sales funds and notes, and the inconsistency of VAT invoice with the purchase and sale records and drugs. Enterprises who have been involved in the cases of purchase and sale of counterfeit drugs and corruptive practices in compound preparations containing special drugs shall be inspected in particular.

In the drug retail sector, we will focus on rectifying the following aspects: loopholes in source control resulting in purchasing from illegal channels; selling prescription drugs, compound preparations containing special drugs, the whereabouts of product sales is unclear; the purchase and sale qualification file is incomplete, and the enterprises operate beyond the category and scope as prescribed; the inconsistency of purchase & sale notes with in-kind goods, as well as the falsified purchase & sale notes and records. The Focus of the inspection shall cover retail pharmacies in urban and rural fringe areas, as well as individual pharmacies with insufficient managements.

SFDA shall timely organize inspection teams to carry out spot checks or supervision on the concentrated rectification in some areas.

(February 6, 2012)

SFDA Issues the Notice on the Follow-Up Investigation and Classified Guidance on the Implementation of the Newly Revised Drug GMP in Pharmaceutical Manufacturing Enterprises

To fully understand the existing problems and accelerate the implementation progress of the newly revised drug GMP, SFDA decided to organize food and drug administration departments of all provinces (autonomous regions, municipalities) to conduct follow-up investigation and classified guidance on the implementation of the newly revised drug GMP in pharmaceutical manufacturing enterprises.

The Notice requires food and drug administration departments of all provinces (autonomous regions, municipalities) to attach great importance to this end with careful deployment, organize special work teams to conduct follow-up investigation on the implementation of the newly revised drug GMP in pharmaceutical manufacturing enterprises in local areas, and on this basis, propose specific works deployments, plans and work objectives for the implementation of the newly revised drug GMP in the administrative area, which are to be reported to the local provincial people's government.
of technical personnel to withdraw or perform mergers and restructuring with advantageous enterprises; and organize on-site investigations and supervision on key enterprises, and enterprises whose GMP implementation status are difficult to grasp.

(February 16, 2012)

**Activity Brief**

**The Pandemic Influenza Project of NIFDC Wins the Second Class Prize of 2011 National Science and Technology Progress Award**

In the morning of February 14, the National Science and Technology Awards Conference was held in the Great Hall of the People, 45 medical and health scientific & technological achievements were granted the 2011 Annual National Science and Technology Awards. The “Innovation and Application of Key Evaluation Technologies for Pandemic Influenza Vaccines and Diagnostic Reagents Project”, led by the China National Institute for Food and Drug Control, won the Second Class Prize of 2011 National Science and Technology Progress Award. The project has established a key technology system, covering all aspects of the evaluation of pandemic influenza vaccines and diagnostic reagents, to solve various technical problems in the research and development. Among them, the H1N1 vaccine peer recognition at home and abroad, and high appraisal of the World Health Organization.

(February 16, 2012)

**China's Pharmaceutical Manufacturing Industry Saw a Year-on-Year Increase Around 30% in 2011**

According to the pharmaceutical manufacturing data recently released by the National Bureau of Statistics, in 2011, the accumulated sales revenue of China’s pharmaceutical manufacturing industry amounted to 1.4522 trillion yuan, up by 29.37% over the previous year, with a highest growth rate in the history; the accumulated total profit was 149.4 billion yuan, up by 23.50%. While the growth rate of revenue & profits of industrial enterprises had witnessed a gradual decline in the same period.

As for pharmaceutical market in 2012, some experts believe that as the growth rate of investment is likely to decline in the future. Compared with a few years ago, the year of 2012 will be an "Adjustment Year" for the transformation and upgrading of the pharmaceutical industry, the growth of pharmaceutical economy may slow down due to public hospitals’ control of drug expenditure, changes of payment models of medical insurances and other reasons.

(Febuary 15, 2012)
Ivabradine (Corlentor®), the first selective If channel inhibitors in the world, has been approved the third indication in chronic heart failure with systolic dysfunction in Europe on February 9 2012. The approval of the new indication is based on the results of SHIFT trial published in 2010. Around the world, including China, totally 6500 patients in chronic heart failure with systolic dysfunction, Who have heart rates >70 bpm, are eligible for participation in this large-scale randomised, double-blind, placebo-controlled, parallel-group study in 3.5years. The outcomes show that Ivabradine (Corlentor®) significantly reduces the primary endpoint (composites of cardiovascular death or hospitalization for worsening heart failure) by 18% and the death for heart failure by 26%. Ivabradine, is originally developed by SERVIER, specifically reduces the heart rate by blocking If channels of sinus node. There are no side effects on myocardial contractility and cardiac conduction system. According to INITIATIVE and ASSOCIATE trials in 2005 and 2009, the European Medicines Agency (EMA) has approved Ivabradine in symptomatic treatment of chronic stable angina pectoris in coronary artery disease. The indications are in adults unable to tolerate or with a contraindication to the use of beta-blockers.

(February 29, 2012)

China Accelerated New Drug Innovation

China’s key science and technology projects of “Significant New Drug Development” progressed smoothly, currently 137 new drugs are in clinical trials, the quality of which is significantly improved.

China has accelerated in recent years the R&D of major new drugs, through the support of National Science and Technology Key Projects, the “863 High-Tech Development Plan” and other projects, 18 drug varieties have obtained the New Drug Certificate, 22 varieties submitted new drug application for registration, and 137 new drugs are in clinical trials. Meanwhile, the transformation of major drug varieties is progressing smoothly, 36 good curative effect, big demand, high market share, growth potential and high added value drug varieties have been selected and supported for technological transformation, and this has played an effective role to address the difficulty and expensiveness of drugs. China has also supported 15 comprehensive drug R&D technology platforms, and a good momentum has been witnessed with respect to new drugs R & D, candidate drug screening and other aspects of drug R & D capacity building.

[Provided by Servier (Tianjin) Pharmaceutical Co., Ltd.

Special column

New Indication of Ivabradine Approved in EU

伊伐布雷定片新适应症在欧洲获得批准

全球第一个选择性If通道抑制剂伊伐布雷定片（可兰特®）于2012年2月9日在欧洲获得新适应症的批准，用于治疗伴有收缩功能不全的慢性心力衰竭。

该适应症的批准是基于2010年公布的SHIFT研究结果，包括中国在内的全球共6500例心率大于70次/分的伴有收缩功能不全的慢性心力衰竭患者参与了该项为期3.5年的随机双盲安慰剂对照的大型国际多中心研究。结果显示伊伐布雷定片能显著降低主要复合终点（心血管死亡和因心衰恶化住院）达18%，心衰死亡显著降低26%。

伊伐布雷定片由法国施维雅公司自主研发，通过特异性阻断If通道从而单纯降低心率，对心肌收缩力以及心脏传导系统无副作用。2005年和2009年基于冠心病领域的INITIATIVE和ASSOCIATE大型研究，欧洲药品监督管理局分别批准伊伐布雷定片用于对β受体阻滞剂不耐受或有禁忌的冠心病患者，以及和β受体阻滞剂联合使用治疗稳定性冠心病。]
or in combination with beta-blockers in patients inadequately controlled with an optimal beta-blocker dose. This new indication represents a major step forward in the management of patients with chronic heart failure. In practice, Corlentor * should be prescribed in all patients with stable coronary artery diseases and chronic heart failure with systolic dysfunction, thus providing these patients with symptomatic relief, better quality of life and further morbidity and mortality reduction beyond therapy they already received.

伊伐布雷定片新适应症的批准优化了目前慢性心衰的临床治疗方案。在临床实践中，伊伐布雷定片可以应用于慢性稳定性冠心病伴有收缩功能不全的慢性心力衰竭的患者。伊伐布雷定片可以更好的缓解病人临床症状，改善生活质量，并进一步降低稳定性冠心病和慢性心功能不全的临床发病率和死亡率。

Notes: • All Chinese information in Newsletter extracted from Newspapers and Internet. All English articles are the translations from the Chinese version.
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