SFDA Commissioner Yin Li met the delegation of Ministry of Industry, Trade and Labor of Israel

On May 29, 2012, Yin Li, Commissioner of SFDA met with the delegation led by Mr. Shalom Simhon, Minister of Industry, Trade and Labor of Israel. Both sides exchanged opinions on relevant issues related to medical devices. (May 30, 2012)

SFDA Commissioner Yin Li met Deputy Head of the State Administration of Ukraine on Medicinal Products

On May 17, 2012, Yin Li, Commissioner of SFDA, met with the visiting Mr. Andrii Zakharash, Deputy Head of the State Administration of Ukraine on Medicinal Products, and his entourage. Both sides signed a memorandum of understanding on bilateral cooperation, and exchanged views on strengthening cooperation in the future. Main director of SFDA’s Department of International Cooperation and relevant directors of Department of Drug Safety and Inspection, Department of Drug Registration attended the meeting. (May 18, 2012)

SFDA Commissioner Yin Li met WHO Representative in China Dr Michael O’Leary

On May 10, 2012, Yin Li, Commissioner of SFDA, met with the visiting Dr. Michael O’Leary, WHO Representative in China, and his entourage. SFDA Commissioner Yin Li reported the situation about Chromium-excessive pharmaceutical capsules. Both sides exchanged views on National Institutes for Food and Drug Control to apply to join the WHO Collaborating Centers on Standardization and Regulatory Evaluation of Vaccines and Biotherapeutic Products. (May 11, 2012)

SFDA Deputy Commissioner Wu Zhen met the delegation of Iran’s Ministry of Health and Medical Education

On May 15, 2012, Wu Zhen, Deputy Commissioner of SFDA, met with the delegation led by Mrs. Marzieh Vahid Dastjerdi, Minister of Health and Medical Education of Iran. Both parties exchanged views on enhancing exchange and cooperation in the supervision of traditional medicines. (May 16, 2012)

SFDA Chief of Discipline Inspection Group Yu Xiancheng visits the Netherlands Health Care Inspectorate and signs MOU

On April 19, 2012, Yu Xiancheng, Chief of Discipline Inspection Group of SFDA, signed the Memorandum of Understanding Between the State Food and Drug Administration of the People’s Republic of China and the Health Care Inspectorate of the Kingdom of the Netherlands with Mr. Gerrit van der wal, Inspector-General of the Netherlands Health Care Inspectorate, in The Hague, Netherlands. Both parties will strengthen cooperation in the field of drug and medical device supervision. (May 4, 2012)

SFDA Commissioner Yin Li Attended the Opening Ceremony of the ”National Professional & Technical Personnel Continuing Education Base” of SFDA Advanced Training Institute

On May 15, 2012, SFDA Commissioner Yin Li attended the Opening Ceremony of the ”National Professional & Technical Personnel Continuing Education Base” of SFDA Advanced Training Institute. Commissioner Yin Li stated that the National Professional & Technical Personnel Continuing Education Base is one of the important programs of National Professional & Technical Personnel Knowledge Updating Project, and it is an important platform and carrier to speed up the training of high level and backbone professional and technical personnel that are urgently needed in focus areas of economic and social development. The construction of the Base shall lay a solid foundation to comprehensively promote the continuing education of food and drug administration professional & technical personnel. The whole system of food and drug administration shall take full advantage of this platform of continuing education to reinforce the training on medium and high-level professional & technical administration personnel. (May 16, 2012)
On May 21, 2012, the “4th Drug Information Association (DIA) China Annual Meeting” was grandly opened in Shanghai, themed as "China and the World—Cooperation and Innovation". SFDA Commissioner Yin Li attended the opening ceremony and delivered a speech.

Commissioner Yin Li stated that in recent years, with the rapid development of globalization and information technology, drugs are closely related to not only public health and safety, but also to socio-economic development, and the importance of international pharmaceutical cooperation and innovation loomed large. It is therefore meaningful for the Annual Meeting to focus on cooperation and innovation, to discuss the future development of Chinese medicine and world medicine.

Commissioner Yin Li said that China’s drug administration departments attach great importance to and devote efforts to promoting cooperation and innovation in the pharmaceutical field. Over the years, SFDA continued to strengthen drug safety supervision, and improve the system of drug production and supply, at the same time, actively carried out strategic cooperation with other countries and regions, kept in close contact with international or regional organizations. A great deal of works has been performed to promote the healthy development of pharmaceutical economy, and improve the level of social and public health, and has achieved remarkable results.

Commissioner Yin Li pointed out that broader and closer cooperation, coupled with in-depth innovation, is the inevitable choice to seize the opportunity, deal with risks, solve problems and achieve development. China’s drug administration departments anticipate the synergy of our counterparts around the world to achieve the following four ideals.

1. Improve the ability to deal with drug safety risks. China’s drug administration departments have taken the enhancement of regulation capacity as an unremitting pursuit, in the next few years, greater efforts shall be made to accelerate the implementation of electronic supervision, fully implement the newly revised drug GMP, and strive to improve the technical capacity.

2. Promote innovation, and improve the protection level of drug safety. China’s drug administration departments shall give full play to the role of policy guidance, pharmaceutical R&D management and standards’ guidance, to speed up pharmaceutical R & D and innovation, and promote the improvement of drug quality.

3. Strengthen cooperation to jointly safeguard the public rights of drug use. SFDA will further improve the regulatory system and rules, the regulatory standards and technical levels. Continue to carry out in-depth exchange of drug R & D technology, drug regulatory experience, personnel training and other aspects, introduce foreign high-end technical methods, facilities and devices for testing, monitoring and evaluation. Support and guide the domestic pharmaceutical enterprises to participate in the international market competition, and to receive international certification & examination.

4. Achieve a win-win situation, promote the sustainable development of the pharmaceutical industry, and accelerate the formulation and implementation of regulatory policies that support the superior and eliminate the inferior enterprises, and promote industrial concentration, improve the market withdrawal mechanism to guide the industry to enhance its core competitiveness.

The Annual Meeting, jointly organized by DIA China and CCPIE (China Center for Pharmaceutical International Exchange), DIA Global Chairman Yves JUILLET and other guests attended and delivered speeches. The Annual Meeting has attracted a total of nearly 1,000 R&D-related guests, experts and scholars from major drug administration institutions, academia, clinical sites and business communities and academia of countries around the world, who shall exchange their experiences and share their research results with respect to new drug R&D, clinical research, GMP, drug safety, regulatory policies, data management and other topics.
SFDA Stresses to Further Implement the Requirements on Batch to Batch Testing on Pharmaceutical Gelatin Capsules and Capsule Drugs

On May 13, 2012, the State Food and Drug Administration issued a Notice requiring the further implementation of the requirements on batch-to-batch testing on pharmaceutical gelatin capsules and capsule drugs, to ensure the realization of the objectives of batch-to-batch inspection. Any manufacturers found with substandard drugs in self-testing must conduct voluntarily recall, and thereby can be exempted from administrative punishment; severe punishment measures shall be meted out on manufacturers that are reluctant to recall substandard drugs, or on manufacturers with substandard drugs successively spotted in sampling tests and supervision.

The Notice pointed out that any manufacturers who fail to complete the batch-to-batch testing should suspend the production of capsule drugs, and spared no efforts to ensure the completion of the testing tasks. Any drug batches that failed to complete the batch-to-batch testing by June 1 should be suspended from sales and use.

State Food and Drug Administration shall launch a nationwide quality assessment of marketed capsule drugs by the end of May, and extract a certain percentage of capsule drugs for test, through a comparison with the previous sampling test results, the status quo of the quality of drugs on the market can be evaluated, and chromium-excessive products shall be strictly and severely punished according to law.  

(May 13, 2012)

The Ministry of Health Issued the "Management Measures for the Clinical Application of Antibiotics"

On April 24, 2012, the Ministry of Health issued the "Management Measures for the Clinical Application of Antibiotics" (MOH Decree 84) (hereinafter referred to as the "Measures"), which shall enter into force as of August 1, 2012.

The "Measures" consists of 59 articles in 6 Chapters, including the General Principles, Organization and Responsibilities, the Management of Clinical Application of Antibiotics, Supervision and Management, Legal Responsibilities and Supplementary Articles, focusing on the requirements to establish a classified management system for the clinical application of antibiotics, clarify the whole process work mechanism for medical institutions to select, procure, apply, monitor with early warning, intervene and recall antibacterial drugs, reinforce the intervention on the phenomenon of irrational drug use, establish bacterial drug-resistance early warning mechanism, and clarify supervision and management accountabilities and legal responsibilities.

The Ministry of Health will continue to strengthen the management of clinical use of antibiotics, extensively publicize and implement the "Measures", to facilitate the implementation of various regulations; continue to carry out national special rectification activities on the clinical use of antibiotics, and intensify supervision and inspection; further strengthen the monitoring on rational use of antibiotics to guide the rational clinical application; and continue to carry out relevant nationwide trainings on the rational use of antibiotics. Improve the microbiological testing capacity and the rational use of antibiotics in primary health care institutions.  

(May 8, 2012)

国家食品药品监督管理局强调进一步落实药用明胶囊胶囊剂药品批批检要求

2012年5月13日，国家食品药品监督管理局发出通知，要求进一步落实药用明胶囊胶囊剂药品批批检要求，确保实现批批检工作目标。凡是企业自检发现不合格药品必须主动召回，对主动召回的可以免于行政处罚，对召回不力的，以及监督抽验中仍发现不合格药品的从严从重处罚。

通知指出，凡是不能按期完成批批检的企业暂停胶囊剂药品的生产，集中力量保证批批检任务的完成，凡是6月1日仍然没有完成批批检的药品批次，一律暂停销售使用。

国家食品药品监督管理局将于5月底在全国范围内开展一次市场胶囊剂药品质量评估工作，抽取一定比例的胶囊剂药品进行检验，通过与前期市场抽验情况的比对，以评估市场药品质量状况。若仍有铬限量超标的品种，依法从严从重处理。  

(2012年5月13日)

卫生部发布《抗菌药物临床应用管理办法》

2012年4月24日，卫生部发布了《抗菌药物临床应用管理办法》（卫生部84号令）（以下简称《办法》），《办法》自2012年8月1日起施行。

《办法》共6章59条，包括总则、组织机构和职责、抗菌药物临床应用管理、监督与管理、法律责任和附则，规定了建立抗菌药物临床应用分级管理制度、明确了医疗机构抗菌药物遴选、采购、临床使用、监测和预警、干预与退出全流程工作机制，加大对不合理用药现象的干预力度，建立细菌耐药预警机制、明确监督管理和法律责任等内容。

卫生部将继续加强抗菌药物临床应用管理工作，广泛开展《办法》的宣传贯彻工作，促进落实各项规定，继续开展全国抗菌药物临床应用专项整治活动，加大督导检查力度，进一步加强合理用药监测、指导临床合理使用抗菌药物，继续开展全国抗菌药物合理使用相关培训，提高基层医疗机构微细菌检测能力和抗菌药物合理使用水平。  

(2012年5月8日)
SFDA Revised the Packaging Insert for OTC Drugs Containing Amantadine Hydrochloride

In order to ensure drug safety in children, according to the provisions related to [Pediatric use] in the instructions of simple recipe amantadine hydrochloride preparations, on May 7, 2012, the State Food and Drug Administration revised the packaging insert for OTC drugs containing amantadine hydrochloride.

The revisions are: for Children-only Pediatric Anjin Huangmin Granules (Paracetamol, Amantadine Hydrochloride, Artificid Cow-bezar and Chlorphenamine Mdeate Granules), Pediatric Paracetamol and Amantadine Hydrochloride Granules, and Pediatric Compound Paracetamol and Amantadine Hydrochloride Tablets, the [precaution] in the instructions shall delete the Entry: "Medication for children under 1 year of age should be under the guidance of physicians", the [Contraindication] shall add the entry: “Due to the lack of safety and effectiveness data, newborns and infants under 1 year of age shall be prohibited from this medicine”.

For Paracetamol Amantadine Hydrochloride and Chlorphenamine Maleate Capsules that can be used for both children and adults, the Entry “medication for children under 5 should be under the guidance of physicians” shall be revised as "children under age 5 are not recommended to use this medicine", the [Contraindication] shall add the entry: “Due to the lack of safety and effectiveness data, newborns and infants under 1 year of age shall be prohibited from this medicine”.

For adults-only Compound Paracetamol and Amantadine Hydrochloride Tablets, the Entry of "medication for children under 5 can be used for both children and adults, and Pediatric Compound Paracetamol and Amantadine Hydrochloride Granules, the Entry: "medication for children under 1 year of age shall be prohibited from this medicine".

(May 16, 2012)

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SFDA Revised the Packaging Insert for Pioglitazone

To control the risk of drug use, on May 4, 2012, the State Food and Drug Administration decided to revise the packaging insert of pioglitazone according to the adverse drug reactions assessment results.

The revised packaging insert added in the entry of [Contraindication] the contents of “Contraindicated in patients currently have or previously had a history of bladder cancer, or patients with unexplained macroscopic hematuria”; added in the entry of [Adverse reactions] the contents of “long-term use of pioglitazone in patients of bladder cancer or diabetes may induce higher risks”; and added in the entry of [precaution] the contents of “Prior to the treatment, the physicians should give full explanation of the bladder cancer risks and other potential risks to the patients or their relatives”.

(May 4, 2012)
SFDA Revisited the Packaging Insert for Orlistat Tablets / Capsule OTC drugs

To control the risk of drug use, on April 24, 2012, the State Food and Drug Administration decided to revise the packaging insert for Orlistat tablets / capsule OTC drugs according to the adverse reactions assessment results, and required the food and drug administration departments of all provinces (autonomous regions, municipalities) to revise the relevant content in alignment with the packaging insert template of Orlistat, to notify the drug manufacturers within the administrative area to revise the packaging insert and labels promptly, and notify the revisions to relevant medical institutions, drug distribution enterprises, and other units. Related pharmaceutical manufacturers should take the initiative to track the safety information of clinical application of such products, and to collect and timely report adverse reactions as required. (May 7, 2012)

SFDA Issued the "Notice on Strengthening the Management on the Quality of Capsule Drugs and Related Products"

The recent events of chromium-excessive medicinal capsules have reflected the weak quality management in some pharmaceutical manufacturing enterprises, to ensure the quality and safety of drugs and health foods, strengthen the quality control and testing in manufacturers of pharmaceutical gelatin, medicinal capsules, capsule drugs and health foods, on April 28, 2012, the State Food and Drug Administration issued a Notice on related issues.

The Notice clarified relevant requirements on improving the quality management system in production enterprises, reinforce production quality management and testing of pharmaceutical gelatin, medicinal capsules, and capsule products, and regulate entrusted testing and control.

The Notice pointed out that the above requirements should be implemented from May 1, 2012. All enterprises that fail to reach the above requirements should stop the production of related products, and cannot resume production until conditions met. Food and drug administration departments at all levels should beef up the supervision, testing and sampling test on production enterprises of pharmaceutical gelatin, medicinal capsules, capsule drugs and health foods, and resolutely investigate and punish all enterprises found with illegal production. (April 28, 2012)

SFDA Revised the Packaging Insert for Orlistat Tablets / Capsule OTC drugs

To control the risk of drug use, on April 24, 2012, the State Food and Drug Administration decided to revise the packaging insert for Orlistat tablets / capsule OTC drugs according to the adverse reactions assessment results, and required the food and drug administration departments of all provinces (autonomous regions, municipalities) to revise the relevant content in alignment with the packaging insert template of Orlistat, to notify the drug manufacturers within the administrative area to revise the packaging insert and labels promptly, and notify the revisions to relevant medical institutions, drug distribution enterprises, and other units. Related pharmaceutical manufacturers should take the initiative to track the safety information of clinical application of such products, and to collect and timely report adverse reactions as required. (May 7, 2012)
SFDA Demands Strict Implementation of Batch to Batch Inspection on Pharmaceutical Gelatin Capsules and Capsule Drugs

To ensure the safe use of drugs, the State Food and Drug Administration decided that since May 1, 2012, all manufacturers of pharmaceutical gelatin, medicinal capsules and capsule drugs must conduct strict test on every variety and every batch of purchased raw materials, excipients, and outbound products, otherwise the production and sales of related products shall not be allowed.

Pharmaceutical manufacturing enterprises should perform chromium limits test on their capsule drugs produced and marketed before April 30, 2012 within designated time limit, the specific requirements are as follows: (A) The pharmaceutical manufacturing enterprises must be responsible for the quality of their marketed or used, and notify the testing results to the public. (B) The enterprises should voluntarily recall chromium-excessive drugs once they are found in the test. (C) The aforementioned works must be completed by May 31, 2012. (D) drug administration departments at all levels should supervise enterprises to implement the above requirements, reinforce the daily supervision & testing efforts and increase test frequency, and mete out severe punishment according to law on manufacturers still marketing chromium-excessive drugs. (April 27, 2012)

SFDA Issued Notice on Effective Utilization of ADR Monitoring Data

To achieve the effective utilization of ADR monitoring data, on April 16, 2012, the State Food and Drug Administration issued a notice on relevant issues.

The notice requires to conduct effective analysis, evaluation and utilization of ADR monitoring data, and organize ADR Monitoring institutions to feedback related data in an appropriate manner to pharmaceutical manufacturing enterprises, urge and guide manufacturers to analyze ADR data, timely and voluntarily improve the safety information in the drug packaging insert in accordance with the provisions, and take targeted measures to resolve the problems found in inspection, so as to reduce and prevent the recurrence of adverse drug reactions. In accordance with the law, the enterprises should be urged to find out the reasons, improve quality, and take control measures, where necessary, on the problematic drugs in a timely manner.

The drug administration departments at all levels shall take into account the adverse drug reaction monitoring, analysis & evaluation results, strengthen the supervision and inspection on pharmaceutical manufacturers, supervise and guide enterprises to strengthen pharmaceutical production quality management, and adopt effective measures to control the quality and safety risks in the pharmaceutical manufacturing process. (April 25, 2012)
**Ministry of Health Solicits Public Comment on “Good Drug Supply Practice (Revised Draft)” (Draft for comment)**

On April 25, 2012, the Ministry of Health issued the “Good Drug Supply Practice (Revised Draft)” (Draft for comment) (hereinafter referred to as "the new GSP Revised Draft"), which is open for public comments before May 27.

The new GSP Revised Draft has been expended to 201 articles, among which stipulations for “drug safety” are significantly enriched. The new GSP specifically mandated that pharmaceutical wholesale and retail enterprises should establish a quality management system, develop quality management system provisions for strict implementation. The new GSP Revised Draft significantly standardized and escalated the requirements on the team building, business environment, information management, quality management, and many other aspects of drug distribution enterprises. (April 25, 2012)

**SFDA Further Defines Time Limits for Ophthalmic Preparations to Meet the Requirements of Newly Revised GMP**

According to the provisions of SFDA “notice on the implementation of the Good Manufacturing Practice for Drugs (2010 Revision) (SFDA Department of Drug Safety & Inspection [2011] No. 101), the production of sterile drugs shall meet the requirements of the newly revised GMP before December 31, 2013. Sterile drugs refer to drugs that are subject to sterility test items as required in the official drug specifications, including sterile preparations and sterile drug substances. In accordance with the relevant provisions of the "Chinese Pharmacopoeia (2010 edition)", taking into account the particularity of the ophthalmic preparations, specific provisions are hereby provided: intraocular injections, ophthalmic insert agents, ophthalmic preparations used in surgery and treatment of wound and penetrating injury of cornea as well as ophthalmic liquid preparations should meet the requirements of the newly revised GMP before December 31, 2013; other ophthalmic preparations should meet the requirements of the newly revised GMP before December 31, 2015. All the other preparations and drug substances which are subject to sterility test items as required in the official drug specifications should meet the requirements of the newly revised GMP before December 31, 2013.

In vitro diagnostic reagents regulated as drugs should meet the requirements of the newly revised GMP before December 31, 2015.

While handling the affairs of previous "Drug GMP Certificates" for sterile drug substance, ophthalmic preparations and in vitro diagnostic reagents within valid continuation, Food and Drug Administration Departments of all Provinces should strictly abide by the requirements of the Notice, any inconsistencies with the Notice shall be corrected in time. (April 20, 2012)

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**衛生部就《药品经营质量管理规范（修订草案）》（征求意见稿）公开征求意见**

2012年4月25日，衛生部发布了《药品经营质量管理规范（修订草案）》（征求意见稿）（以下简称 “新GSP修订草案”），公开征求意见相关的，意见反馈截止日期为5月27日。

新版GSP修订草案扩容至201条。其中关于“药品安全”的表述显著增加，明确提出了药品批发和零售企业应当建立质量管理体系、制定并执行质量管理体系文件。新版GSP修订草案规范了药品经营企业人才队伍，经营环境，信息化管理，质量管理等多方面的要求。

(2012年4月25日)

**国家食品药品监督管理局进一步明确眼用制剂等产品实施新修订药品GMP期限**

国家食品药品监督管理局《关于贯彻实施〈药品生产质量管理规范（2010年修订）〉的通知》（国食药监安〔2011〕101号）规定，无菌药品的生产应在2013年12月31日前达到新修订药品GMP要求，无菌药品是指法定药品标准中列有无菌检查项目的药品，包括无菌制剂、无菌原料药。根据《中国药典（2010版）》有关规定，考虑到眼用制剂的特殊性，2012年4月20日，国家食品药品监督管理局发出通知，规定眼内注射液、眼内插入剂、术后、伤口、角膜穿透伤用的眼用制剂以及眼用液体体制剂应在2013年12月31日前达到新修订药品GMP要求，其他眼用制剂应在2015年12月31日前达到新修订药品GMP要求，其他法定药品标准中列有无菌检查项目的所有制剂和原料药均应在2013年12月31日前达到新修订的药品GMP要求。

在药品管理的体外诊断试剂应在2015年12月31日前达到新修订药品GMP要求。

各省食品药品监督管理局在以往办理无菌原料药、眼用制剂、体外诊断试剂的《药品GMP证书》有效期延续工作中，如有与本通知要求不一致的地方，一律按通知要求更正。

(2012年4月20日)
With the implementation of the National Key New Drug R&D Strategy and the globalization of drug R&D, it has become a top priority for China to establish an IND mechanism which complies with the law of innovative drug research and development. In recent years, SFDA Center for Drug Evaluation (CDE) has explored the possibility to establish a mechanism to encourage innovation and control the risk based on CDE’s review practice of innovative drug and mature experiences from other countries. On the one hand, CDE will promote the implementation of the following works according to their key functions: clinical trial data management, online registration of clinical trial program, monitoring of the clinical trial process, establishing of relevant clinical trial systems (Ethics Committee, Independent Data Monitoring Committee, etc.). In some specific therapeutic areas, CDE will open the door for concurrent global development, exploring EIH study to improve the capability of clinical trial design and risk management in China. On the other hand, CDE is exploring the possibility of differentiating the review strategy for IND application of chemical drug in each discipline, and harmonize the review practice by implement the review template, so as to make the technical requirements of evaluation comply with the general rules of drug R&D.

The depth and scope of innovative drugs studies are extending with R&D progress. Taking this into account, CDE is trying to establish the pathways of data submission and communication for IND application of chemical drug to improve the IND system for innovative drug. On May 10, 2012, the documents - “Chemical Drug IND Application (Phase I and II) CMC Data Summary sheet (Trial)” and “Chemical Drug IND Application Annual Report (Trial)”, which are related to the data submission - shall be released for your notice.

For applications under CDE IND evaluation procedure, applicant should submit related CMC data according to the following requirements since the publish date of this notice.

1. For Phase I and Phase II IND application, besides the CMC data required in the submission dossier, before the application enlist in the CDE monthly evaluation plan, applicant should submit the word version of “Chemical Drug IND Application (Phase I and II) CMC Data Summary” though the “Electronic Submission” channel on CDE website. The information in the CMC Data Summary sheet should be consistent with that in the submission dossier.

2. From the 1st IND approval date of the innovative drug on, applicant should submit the “Chemical Drug IND Application Annual Report” annually. As annual report provides very important data supporting subsequent clinical studies and NDA application, please make sure the information and data submitted in the annual report is complete and real. Currently, the annual report should be submitted to CDE by paper documents through the pathway of submission official documents. Submission of electronic documents. Submission of electronic
Any problem rising during the trial period, applicant can communicate with CDE through the “information feedback” pathway on CDE website.

(May 10, 2012)

Any problem rising during the trial period, applicant can communicate with CDE through the “information feedback” pathway on CDE website.

(May 10, 2012)

In order to enable the public to have access to field experience and understanding of the whole process of drug testing & control, enhance the communication and exchange between drug administration departments and the public, and facilitate face-to-face hearings of the comments and suggestions from the public on the work of drug administration, on May 16, 2012, the State Food and Drug Administration organized the Open Day Activities for Drug Testing & Control, and invited the public to visit the National Institutes for Food and Drug Control (NIFDC).

NIFDC is liable for the implementation of the registration testing & control, import testing, supervision and testing, safety evaluation of multi-field products encompassing drugs, biological products, medical devices, food, health food, cosmetics, laboratory animals, packaging materials etc., and the verification, approval and certificate issuance of biological products, NIFDC is responsible for the research, distribution and management the standards for national drugs and medical device, and bacterial and virus strains for production & test, and for carrying out research on relevant technologies. NIFDC annually tests nearly ten thousand items (batches) of various types of drugs, biological products, and medical devices etc. As of the end of April 2012, NIFDC boasts of 2226 testing & control items in 9 master categories that have passed the National Laboratory Qualification Accreditation and recognition, NIFDC’s product coverage and testing & control capabilities take the lead in the industry.

On the Open Day, the State Food and Drug Administration invited the public to visit the Antibiotics Room, the Chinese Medicine Herbarium, the Analysis and Test Rooms, Food and Cosmetics Test Rooms and the Drug Fast Test Vehicle.

During the visit, relevant SFDA staff answered questions of public concern, and listened to public comments and suggestions on the work of drug administration. In the next stage, the State Food and Drug Administration will hold from time to time Open Day Activities for the public in terms of drug review and approval, Adverse Drug Reaction Monitoring and re-evaluation of post-marketed drugs.

(May 17, 2012)

SFDA held the Open Day Activities for Drug Testing & control

国家食品药品监督管理局举办 药品检验检测开放日活动

为了让公众到现场感受和了解药品检验检测过程，加强药品监管部门与公众的沟通与交流，便于面对听取公众对药品监管工作的意见和建议，2012年5月16日，国家食品药品监督管理局举办药品检验检测开放日活动，邀请公众参观中国食品药品检定研究院。

中国食品药品检定研究院依法承担实施药品、生物制品、医疗器械、食品、保健食品、化妆品、实验动物、包装材料等多领域产品的审批注册检验，进口检验、监督检验，安全评价及生物制品批签发，负责国家药品、医疗器械标准物质和生产检定用菌毒种的研究，分发和管理，开展相关技术研究工作。每年检验各类药品、生物制品、医疗器械等近万件（批）。截至2012年4月底，通过国家实验室资质认定和国家实验室认可的检验检测项目9大类2226项。检验检测覆盖产品类别及检验检测能力在同行业处于首位。

开放日活动当天，国家食品药品监督管理局邀请公众参观了抗生素室、中药标本馆、分析测试室、生物制品检定所等四个室所以及药品快检车。

参观过程中，国家食品药品监督管理局相关人员对公众关注的问题进行了解答，并听取了公众对药品监管工作的意见和建议。下一阶段，国家食品药品监督管理局将针对药品审评审批、药品不良反应监测和药品上市后再评价等环节不定期举办开放日活动。

(2012年5月17日)
The Development Status of China’s Pharmaceutical Industry in the First Quarter of 2012

In the first quarter of 2012, China’s pharmaceutical industry has, in general, maintained a steady growth trend, the industrial output value grew rapidly along with high investment growth, the sales rebounded, but owing to the benefit downturn of chemical APIs and chemical preparations industry, the growth of cost effectiveness declined.

1. The output value grew rapidly

The pharmaceutical industry totaled 384.03 billion yuan of output value in the first quarter, up by 22.7% in equal terms, and declined by about 6% compared with that of the last year. Among them, chemical APIs totaled 71.4 billion yuan, an increase of 13.6% in equal terms; chemical preparations totaled 109.2 billion yuan, up by 21.8%; TCM herbal slices totaled 21.38 billion yuan, up by 32.7%; TCM patent drugs totaled 90.64 billion yuan, up by 30.2%; biological & biochemical drugs totaled 36.79 billion yuan, up by 18.1%; and medical devices totaled 31.97 billion yuan, an increase of 24.8%. In the first quarter, the industrial added value of pharmaceutical industry increased by 16.7%, 5.1% higher than the industry growth rate.

2. Rebounded sales

In the first quarter, the pharmaceutical industry realized a sales output value of 370.7 billion yuan, an increase of 24% in equal terms; the overall sales-output ratio was 96.5%, an increase of 0.5% over the same period last year. Compared with the same period last year, only the sales-output ratio of medical device and sanitary materials fell by 1.2% and 0.7%, respectively, the sales-output ratio of other sub-sectors all rose more than 1%.

3. Slow export growth

In the first quarter, the pharmaceutical industry realized an export delivery value of 32.33 billion yuan, an increase of 6.6% in equal terms, but lower than that of last year by nearly 10%. Among them, the chemical preparations, TCM slices

2012年一季度我国医药产业进展情况

2012年一季度，我国医药产业总体保持平稳增长的态势，总产值快速增长，销售有所回升，投资高速增长，受化学药品原料、化学药物制剂行业效益下滑影响，效益增速有所下降。

一、产值快速增长

一季度医药产业累计完成产值3840.3亿元，同比增长22.7%，较去年全年增幅下降约6个百分点。其中，化学药品原料714亿元，同比增长13.6%，化学药物制剂1092亿元，同比增长21.8%；中药饮片213.8亿元，同比增长32.7%，中成药906.4亿元，同比增长30.2%；生物生化药品367.9亿元，同比增长18.1%；医疗器械319.7亿元，同比增长24.8%。一季度，医药产业工业增加值增长16.7%，高出工业增速5.1个百分点。

二、销售有所回升

一季度，医药产业实现销售产值3707亿元，同比增长24%，整体销存率为96.5%，较去年同期增加0.5个百分点。与去年同期相比，除医疗器械产销率下降1.2个百分点，卫生材料下降0.7个百分点外，其他子行业的产销率上升幅度均超过1个百分点。

三、出口增长缓慢

一季度，医药产业实现出口交货值
processing and TCM patent drugs enjoyed faster growth rate of 24.8%, 24.2% and 41.3% respectively; but the exports of chemical APIs and medical devices, which accounting for a larger proportion of total exports, witnessed a stagnant growth, with year on year growth of merely 2.4%, and a decrease of 1.3%, respectively.

4. Declined growth of cost effectiveness
In the first two months, the pharmaceutical industry realized a core business income 323.3 billion yuan, lower than that of the last year by 12%; the sales income margin was 9.2%, down by 0.8% in equal terms.

5. Rapid investment growth
In the first quarter, driven by implementation of the new version of "Good Manufacturing Practice", the investment in the pharmaceutical industry maintained rapid growth, the accumulated investment was 43.11 billion yuan, an increase of 39.6% in equal terms, which was 15% higher than that of the manufacturing industry.

(May 3, 2012)

OTC market showed a steady upward trend

In 2010, the size of OTC retail market in China's 27 major cities was 21 billion yuan, in 2011, it grew to 25 billion yuan, and the annual growth rate of 2010 and 2011 was 14.9% and 17.3%, respectively. The 2011 market size of retail pharmacy in China's 27 major cities climbed to 46.1 billion yuan, an increase of 10.1% in equal terms. As the leader of the retail pharmacies, OTC sales in 2011 accounted for roughly 55% of the total sales of retail pharmacies, with about 17.3% year-on-year growth rate in 27 major cities, and a growth of 2.5% compared to that of 2010.

In 2011, in terms of OTC sales channels, large hospitals accounted for 15% of total sales, while the prefecture-level city pharmacies accounted for 42%, county-level city pharmacies accounted for 9%, rural pharmacies accounted for 15%, small hospitals, community hospitals and clinics accounted for 21% of total sales.

In 2010, the sales of OTC in the hospital market was 13 billion yuan, with a growth rate of about 16.7%; the sales in 2011 was 15 billion yuan, a growth rate of about 16.8%.

In the coming years, China's OTC market size is expected to retain around 15% growth rate.

(May 16, 2012)

OTC行情呈稳健上升趋势

2010年，全国27个主要城市零售OTC市场的容量为210亿元，2011年增长为250亿元，2010年增长率为14.9%，2011年增长率为17.3%。27个主要城市的零售药店市场规模攀升到461亿元人民币，同比增长了10.1%。作为零售药店的主导者，OTC2011年的销售额大致占总量的55%，在27个主要城市的同比增长率为17.3%，较2010年全年同比增长了2.5%左右。

2011年，在OTC销售渠道上，大型医院占据了15%的销售额，而地级市药店占据了42%，县级市药店占据了9%，县和农村的药店药店占据了15%，小医院、社区医院及诊所占据了21%。

2010年，OTC在医院市场的销售额为130亿元，增长率为16.7%；2011年销售额为150亿元，增长率为16.8%。

在未来几年内，中国OTC市场规模预测仍维持15%左右的上升速度。

(2012年5月16日)
Notes: • All Chinese information in Newsletter extracted from Newspapers and Internet.
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