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NEWS

SFDA Releases Notice on Electronic Supervision of Entire Range of Essential Drugs From March 31, 2010, all bid-winning enterprises producing essential drugs should join the electronic drug supervision network. On May 24, the SFDA released a notice calling for the implementation of electronic supervision of the entire range of essential drugs. According to the provisions, before delivery from the factories of the range of essential drugs, manufacturing enterprises must additionally print (or paste) electronic monitoring codes for the drugs, with unified logos, on the minimum sales packages of marketed products.

According to the provisions, beginning from April 1, 2011, without exception, any variety that has been included in the essential drugs list but has not accessed the network and has not used the unified code logo for electronic drug supervision shall not participate in the open tender for essential drugs. Enterprises manufacturing and supplying essential drug ranges must carry out supervision code information collection and reporting according to the provisions.

The SFDA implements electronic supervision of the entire range of essential drugs. This is an important measure to implement the specific requirements of the State Council for deepening medical and health system reform and safeguarding food and drug safety for the people. It is also demanded by the transformation of supervision methods with modernized means and the improvement of supervision efficiency. (May 26, 2010)

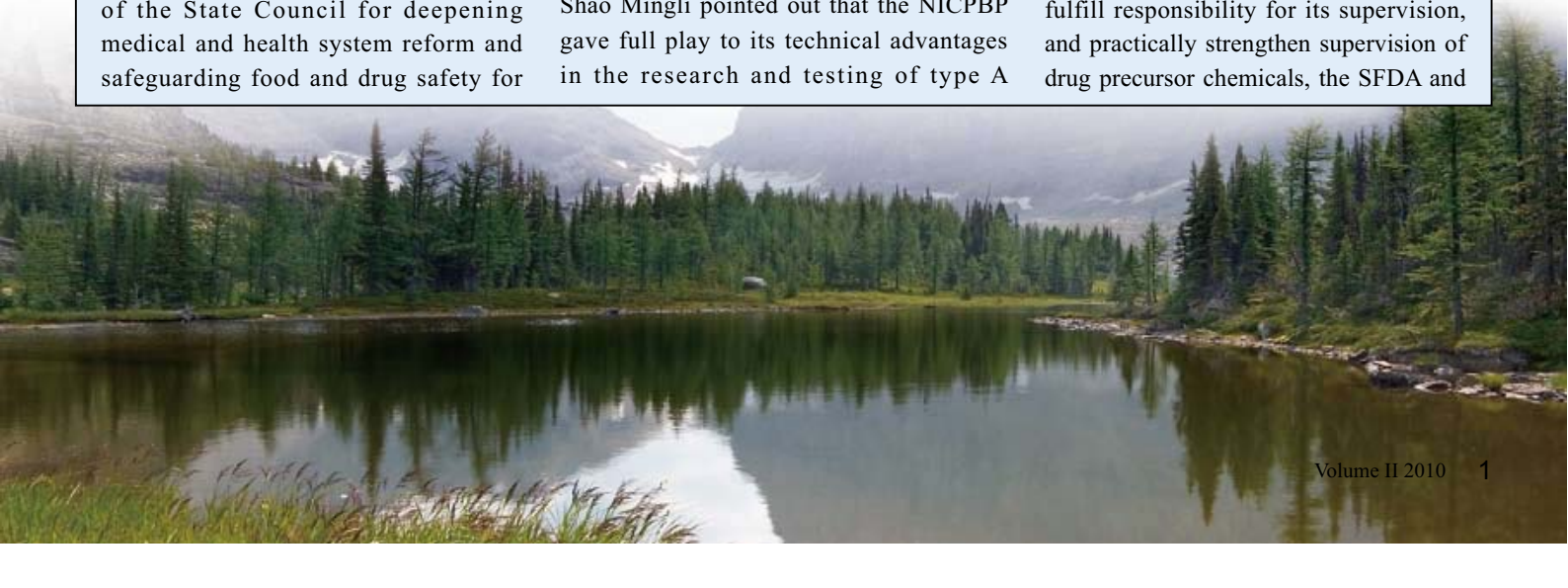
Chen Zhu and Shao Mingli Attend the Phase Summary and Award Conference of the NICPBP on Type A H1N1 Influenza Vaccination and Diagnostic Reagent Testing The National Institute for the Control of Pharmaceutical and Biological Products (NICPBP) convened the phase summary and award meeting on Type A H1N1 influenza vaccination and diagnostic reagent testing in Beijing on May 14, 2010. The Minister of Public Health, Chen Zhu, and the SFDA Director-General, Shao Mingli, attended the meeting and each delivered important speeches.

Chen Zhu pointed out that under the leadership of the Party Central Committee (PCC) and the State Council, China has achieved periodic victories in the prevention and control of type A H1N1 influenza, which has been applauded by all walks of life and recognized by the international community. The NICPBP has made outstanding achievements in type A influenza, especially in the research and development and quality supervision of type A influenza vaccination, and played a very important and irreplaceable role.

Shao Mingli pointed out that the NICPBP gave full play to its technical advantages in the research and testing of type A influenza vaccination and the testing of relevant rapid-test reagents, and made an outstanding contribution to the prevention and control of type A influenza. During this process, the NICPBP maintained a strong sense of political responsibility, demonstrated stronger scientific and technological innovative capability, conducted meticulous and highly-efficient organization and coordination, demonstrated the spirit of conquering new heights, and made important contributions to the safety, efficiency, and quality control of type A influenza vaccination.

Relevant leaders from the Ministry of Health, the Ministry of Science and Technology, the SFDA, relevant departments and bureaus and subordinate units of state commissions and administrations, experts in type A influenza joint prevention and control, and other related units and individuals attended the meeting. (May 14, 2010)

SFDA and Ministry of Public Security Ask for Effective Implementation of Management Measures for the Control of Drug Precursor Chemicals Management Measures for the Control of Drug Precursor Chemicals (MOH decree No.72) takes effect from May 1, 2010. In order to implement these measures, carefully fulfill responsibility for its supervision, and practically strengthen supervision of drug precursor chemicals, the SFDA and



NEWS

the MPS (the Ministry of Public Security) recently jointly issued a notice calling for effective implementation of Management Measures for the Control of Drug Precursor Chemicals.

The notice calls for adequate realization of the importance of implementing these measures and making great efforts to carry out their study, publicity and training. The food and drug administrative departments and departments (or bureaus) of public security of all provinces, autonomous regions, and municipalities directly under the central government should combine the implementation with strengthening the supervision of special drugs and implementing the responsibility for supervision, further perfect the supervision mechanism and system, intensify the inspection on daily supervision, and put in place the requirements for the control of drug precursor chemicals; and further, improve the sense of responsibility and sensitivity. Any evidence found of illegal acts should be investigated and settled by public security bodies. Those persons concerned should be turned over to the public security body for tending to in a timely manner and severely punished according to the law, thus ensuring standardized production and operation of drug precursor chemicals and taking strict precautions to prevent them from entering illegal channels. (April 30, 2010)

Director-General Shao Mingli Meets EU Enterprise and Industry Director-General Zollick On March 26, 2010, Shao Mingli, the SFDA Director-General, met Heintze Zollick, the visiting EU Enterprise and Industry Committee Director-General. The two directors reviewed the good cooperation since the establishment of the negotiation and cooperation mechanism in October 2007 and communicated on issues concerning cooperation between China and Europe in the supervision of drugs, medical devices, and cosmetics. (March 26, 2010)

SFDA issued Drug Production and Distribution Supervision Work Plan

To strengthen administration on drug production and distribution links, SFDA recently printed 2010 Drug Production Supervision Work Plan and 2010 Drug Distribution Supervision Work Plan.

2010 Drug Production Supervision Work Plan makes the following requirements: Firstly, to supervise daily drug production; Secondly, to coordinate drug GMP certification examination work; Thirdly, to strengthen basic drug production supervision; Fourthly, to implement all work requirements concerning drug production links in drug safety rectification campaigns; Fifthly, to strengthen vaccine production supervision; Sixthly, to strength supervision on controlled drugs; Seventhly, to earnestly implement e-monitoring code at drug production link; Eighthly, to strengthen drug ADR monitoring and reevaluation work; Ninthly, to continue on TCM injection reevaluation work.

2010 Drug Distribution Supervision Work Plan makes requirements as follows: Firstly, to strengthen daily supervision at drug distribution links; Secondly, to implement all work requirements concerning drug distribution links in drug safety rectification campaigns; Thirdly, to strengthen supervision at basic drug distribution links; Fourthly, handle well rural drug two-network building to promote drug safety model county campaign; Fifthly, to earnestly implement e-monitoring code at drug distribution link; Sixthly, to enhance supervision at drug use links; Seventhly, to earnestly conduct vaccine supervision work; Eighthly, to conduct drug distribution credit system building.

国家食品药品监督管理局印发药品生产和经营监管工作计划

为加强药品生产经营环节监管，近日，国家食品药品监管局印发了《2010年药品生产监管工作计划》和《2010年药品经营监管工作计划》。

《2010年药品生产监管工作计划》要求，一是药品生产日常监督管理；二是统筹药品GMP认证检查工作；三是强化基本药物生产监管；四是落实药品安全专项整治中涉及药品生产环节的各项工作要求；五是加强疫苗生产监管；六是强化特殊药品监管；七是认真做好药品生产环节电子监管码实施工作；八是加强药品不良反应监测和再评价工作；九是继续抓好中药注射剂再评价工作。

《2010年药品经营监管工作计划》要求，一是强化对药品经营环节的日常监督检查工作；二是落实药品安全专项整治中涉及药品经营环节的各项工作要求；三是强化基本药物经营环节的监督管理；四是做好农村药品“两网”建设，推动药品安全示范县创建活动；五是认真做好药品经营环节电子监管码实施工作；六是加强药品使用环节的监督管理；七是切实做好疫苗的经营监管工作；八是开展药品经营信用体系建设工作。

国家食品药品监督管理局要求各级食品药品监管部门根据2010年药品生产和经营监管工作计划的部署，加强组织领导，全面落实监管责任，认真履行职责，建立协作机制和长效机制，强化督促检查和信息及时上报，做好生产、经营环节的药品安全监管工作，加强药品生产经营的日常监管，加大检查力度，提高监管效率，确保药品质量安全。(2010-04-08)

SFDA requires all local food &drug authorities, in accordance with arrangements in 2010 Drug Production Distribution Supervision Work Plan, under enhanced leadership, comprehensively implement supervision responsibilities and seriously implement duties & responsibilities through establishing long-term and coordination mechanism to strengthen inspection and information reporting so as to handle well drug safety supervision work at production and distribution links. Efforts shall be made to enhance daily supervision on drug production and distribution with more weight and higher supervision efficiency to ensure drug quality & safety. (April 8th, 2010)

SFDA Publishes 2009 Annual National Report on Surveillance of Adverse Reactions to Drugs

On April 22, the SFDA promulgated the 2009 National Drug Adverse Reaction Surveillance Report. This report comprehensively details the data collection and utilization during surveillance on adverse reactions to drugs in China, from the following main aspects:

I. Drug Adverse Reaction Reporting System Maturing Day-to-Day

In 2009, the Chinese national drug adverse reaction surveillance network received a total of 638996 copies of the Drug Adverse Reaction/Event Report Form.

Beginning in 1999, the quantity of drug adverse reaction/event reports collected has increased rapidly, and that reflected the constant improvement in the reporting system. After 2008, the growth of reported cases slowed down. Compared to 2008, the quantity of Drug Adverse Reaction/Event Report Forms received by the National Center for Drug Adverse Reaction Surveillance in 2009 remained essentially stable.

II. Sources of Drug Adverse Reaction/Event Reports Become Increasingly Rational

Calculated by source, the numbers of drug adverse/event reports in 2009 were 540,717 copies from medical institutions, accounting for 84.6%; 78,665 copies from drug manufacturing and operating enterprises, representing 12.3%; and 19,614 copies from individuals, representing 3.1%. The proportion of reports from enterprises increased constantly.

III. Coverage of the National Drug Adverse Reaction Surveillance Network Becomes Increasingly Extensive

In 2009, the surveillance network added 5459 grassroots users, among which were included 2919 medical institution users, 2189 enterprise users, 228 surveillance institution users, and 123 individual and other users. As of December 31, 2009, there were a total of 33878 online grassroots users of the national drug adverse reaction surveillance network, which included 18215 medical institution users, accounting for 53.8%; 12881 enterprise users, representing 38.0%; 2414 surveillance institution users, representing 7.1%; and 368 individual and other users, representing 1.1%.

Key Words to Interpret the 2009 National

国家食品药品监督管理局公布2009年国家药品不良反应监测年度报告

4月22日，国家食品药品监管局发布了《2009年国家药品不良反应监测报告》，报告全面反映了2009年我国药品不良反应监测数据收集和利用情况。具体体系在：

一、药品不良反应报告系统日臻成熟

2009年全国药品不良反应监测网络共收到《药品不良反应/事件报告表》638996份。

自1999年开始，我国药品不良反应/事件报告收集的数量迅速增加，充分体现了报告系统不断完善的规律。特别是2008年后，报告数量增长趋缓，2009年国家药品不良反应监测中心收到《药品不良反应/事件报告表》数量与2008年的报告数量基本持平。

二、药品不良反应／事件报告来源日趋合理

2009年药品不良反应/事件报告按照来源统计，来自医疗机构540,717份，占84.6%；来自药品生产经营企业78,665份，占12.3%；来自个人19,614份，占3.1%。企业报告的比例不断提高。

三、 全国药品不良反应监测网络的覆盖面越来越广泛

2009年新增网络基层用户5459个，其中医疗机构用户2919个，企业用户2189个，监测机构用户228个，个人及其他用户123个。截至2009年12月31日，全国药品不良反应监测网络在线基层用户共33878个，其中医疗机构用户18215个，占53.8%；企业用户12881个，占38.0%；监测机构用户2414个，占7.1%；个人及其他用户368个，占1.1%。

《2009年国家药品不良反应监测报告》解读关键词：

数量：与2008年基本持平

提示：药品不良反应监测进入平稳发展期

重点：新的严重的报告增幅较大

Drug Adverse Reaction Surveillance Report:

Quantity: Roughly the same as in 2008

Notes: Drug adverse reaction surveillance have entered a stable state of development

Key point: Drastic increase in new serious reports

Notes: The quality of drug adverse reaction reports should be improved further;

Source: Medical institutions represent 84.6%

Notes: Consciousness of reporting by drug manufacturing enterprises should be enhanced

Variety: Anti-infection (antibiotic) drug takes the lead

Notes: Abuse of anti-infective (antibiotic) drugs is a key concern

Dosage form: 59% are by injection

Notes: Injection remains the key point for drug adverse reaction surveillance.

Route of administration: 57.9% are intravenous injection

Notes: The route of administration by intravenous injection has a higher risk.

(April 22, 2010)

提示：药品不良反应报告质量进一步提高

来源：医疗机构占84.6%

提示：药品生产经营企业报告意识有待加强

品种：抗感染药占首位

提示：抗感染药的不合理使用应重点关注

剂型：59%为注射剂

提示：注射剂仍是药品不良反应监测的重点

给药途径：57.9%为静脉注射

提示：静脉注射的给药途径风险较高

（2010-04-22）

Guideline for Compulsory Techniques in Drug-induced Carcinogenesis Test be Issued

Drugs with expected continuous clinical drug use exceeding 6 months shall go through carcinogenesis test.

To guide drug R&D activities, SFDA recently issued Guideline for Compulsory Techniques in Drug-induced Carcinogenesis Test. The Guideline expounded on under which situation drug-induced carcinogenesis test should be conducted to avoid unnecessary use of laboratory animals, human resources and material resources; suggested that drugs with expected continuous clinical use exceeding 6 months normally shall go through carcinogenesis test. The Guideline made it clear that if some drugs cause potential cancer-inducing concerns, carcinogenesis test might be necessary. As for anti-tumor drugs used for whole body tumor of advanced stage, carcinogenesis test might not be necessary. When an anti-tumor drug is intended for long-term use in adjunctive therapy or non-tumor indication on non-tumor patients, carcinogenesis test might normally be conducted. If metabolism and systematic exposure amounts are similar under different administration route, carcinogenesis test could be conducted under one administration route. Local application (such as cutaneous and ophthalmic might require carcinogenesis test. Local application with small systematic exposure amount doesn't need by-mouth administration to assess its potential carcinogenesis role to internal organ; With potential photo carcinogenesis concerns, carcinogenesis test might be required; Except with obvious full exposure or related concerns, carcinogenesis test administered through eye might not be necessary; Endogenous peptide or protein as well as their similarities chemically synthesized, extracted and purified from animal or human issues, or produced with biotechnical methods (such as recombinant DNA techniques) might require special consideration. As for endogenous materials for substitute therapy (with concentration at physiological level), especially when similar products (such as growth hormone and calcitonin derived from animal insulin and hyposysis) already have clinical use

药物致癌试验必要性技术指导原则发布

预期临床用药期至少连续6个月的药物应进行致癌试验

为指导药物研究开发，国家食品药品监管局日前印发了《药物致癌试验必要性的技术指导原则》。《指导原则》阐述了何种情况下需要进行药物致癌试验，以避免实验动物资源、人力资源和物力资源的不必要使用。提出预期临床用药期至少连续6个月的药物一般应进行致癌试验。《指导原则》明确，如果某些药物存在潜在致癌的担忧因素，可能需要进行致癌试验。用于晚期全身肿瘤的抗肿瘤药物，通常不需要进行致癌试验。当抗肿瘤药物拟用于非带瘤患者的辅助治疗或非肿瘤适应证长期使用时，通常需要进行致癌试验。如果不同给药途径下代谢及系统暴露量相似，可采用其中一种给药途径开展致癌试验。局部用药（如皮肤和眼科用药）可能需要进行致癌试验。系统暴露量非常小的局部用药不需要以经口给药途径来评价其对内脏器官的潜在致癌作用；若有潜在光致癌性担忧，可能需要进行皮肤给药致癌试验。除非有明显的全身暴露或相关担忧，经眼给予的药物通常不需要进行致癌试验。经化学合成、从动物或人体组织中提取纯化或生物技术方法（如重组DNA技术）生产的内源性肽类或蛋白质及其类似物，可能需要特殊考虑。对于替代治疗的内源性物质（浓度在生理水平），尤其是当同类产品（如动物胰岛素、垂体来源的生长激素和降钙素）已有临床使用经验时，通常不需要进行致癌试验。《指导原则》明确，当需要进行致癌试验时，通常

records, carcinogenesis test normally shall not be conducted. The Guideline specifies that carcinogenesis test, if necessary, normally shall be conducted before market application. With special concerns for patient population, carcinogenesis test for rodent animals shall be conducted before large sample clinical trial. When developing drugs for some serious diseases (such as AIDS), animal carcinogenesis test might not be necessary before applying for market authorization while after being listed on market, these testes shall be conducted. The Guideline is applicable for relevant chemicals in Drug Registration Regulation with fundamental principles applicable for TCMs, natural drugs and biologics.

(April 14th, 2010)

Vaccine Circulation and Cold Chain Management shall be strengthened----Vaccines not stored and transported under standard cold conditions shall be destroyed

Ministry of Health and SFDA co-issued notice, requiring all local food and drug authorities to strengthen supervision on vaccine manufacturers and wholesalers to enhance vaccine circulation and cold chain management and handle well ADR monitoring, reporting and disposal work for suspected preventative inoculation to ensure safety and efficiency of vaccine use.

All local authorities shall remind vaccine manufacturers and wholesalers to strictly manage vaccines in accordance with Regulation on Administration of Circulation and Vaccination of Vaccines and Regulation on Administration of Storage and Transportation of Vaccines to strengthen infrastructure building and to continually elevate cold chain assurance capacity through all distribution links. It is required to substantially enhance supervision and conduct on-site inspection. For those quality assurance capacity such as low-temperature storage, cold chain transportation, etc, not up to standard, those not with established real and complete vaccine purchasing, sale, storage and transportation temperature record as specified and those not conducting e-supervision code as specified, they shall be demanded to stop distribution and rectify within regulated periods, exceeding which or with serious nature shall be disqualified with its distribution license ,

Disease prevention and control institutes and inoculation unites shall handle well qualification check and approval of vaccine manufacturers and wholesalers and vaccine exit-entry registration, gradually conducting e-monitoring code management to ensure cold smooth operation at vaccine storage, transportation and use links.

All local health administrations and food &drug authorities shall enhance supervision on all links like vaccine distribution, storage, transportation and inoculation links, punishing based on law those vaccine manufacturers or wholesalers, disease prevention and control institutions and inoculation units if they wouldn't store and transport vaccines under standard cold conditions and destroy those vaccines under question. Meanwhile, all local authorities shall handle well ADR monitoring and reporting management of suspected preventative inoculation, timely organizing expert panels to conduct investigation and diagnosis to reported cases; As for ADR cases, compensation capital shall go to concerned subjects as regulated. All health administrations and food &drug authorities shall strengthen inspection to all links like vaccine manufacturing, distribution and inoculation links, conducting periodic supervision and campaigns to detect any problem for quick solutions so as to promote health and continuous development of preventative inoculation. Ministry of Health and SFDA shall conduct nation-wide inspection activities sooner to ensure safety and efficiency of vaccine use.

(April 13rd, 2010)

疫苗流通和冷链管理需强化——未在规定冷藏条件下储存运输的疫苗应销毁

卫生部、国家食品药品监管局联合下发通知，要求各地食品药品监管部门加大对疫苗生产和批发企业的监督力度，强化疫苗流通和冷链运转管理，做好疑似预防接种异常反应监测、报告与处置工作，确保疫苗使用安全有效。

各地食品药品监管部门要督促疫苗生产和批发企业严格按照《疫苗流通和预防接种管理条例》、《疫苗储存和运输管理规范》经营疫苗，强化基础设施建设，不断提升各经营环节冷链保障能力。切实加强监督，认真开展现场检查。凡检查发现疫苗低温贮存、冷藏运输等质量保障能力达不到规定的，未按规定建立真实、完整的疫苗购销、储运温度记录，未按要求实施电子监管码管理工作的企业，责令其暂停经营行为并限期整改，逾期仍达不到要求或情节严重的必须依法取消其经营资质。

疾病预防控制机构和接种单位要做好疫苗生产企业、疫苗批发企业的资质查验、审核等工作，做好疫苗出入库登记，逐步实施电子监管码管理，保障疫苗储存、运输和使用各个环节的冷链运转。

各地卫生行政部门、食品药品监管部门应加大对疫苗流通、储存运输及接种等各个环节的监管力度。对疫苗生产或批发企业、疾病预防控制机构和接种单位，未在规定冷藏条件下储存、运输疫苗的，依法严肃处罚，并按规定对所储存、运输的疫苗予以销毁。同时，各地要做好疑似预防接种异常反应病例的监测和报告管理，及时组织调查诊断专家组对报告的病例进行调查诊断；对于预防接种异常反应病例，应按照有关规定积极落实补偿资金。各级卫生行政部门、食品药品监管部门要加强对疫苗生产、流通和预防接种各个环节的督导检查，开展经常性监督和专项检

应在申请上市前完成。若对患者人群存在特殊担忧，在进行大样本临床试验之前需完成啮齿类动物的致癌试验。对于开发用于治疗某些严重疾病（如艾滋病）的药物，申请上市前可不必进行动物致癌试验，但在上市后应进行这些试验。《指导原则》适用于《药品注册管理办法》中的相关化学药，其基本原则也适用于中药、天然药物和生物制品。（2010-04-14）

Guidelines for Impurity Control and Research of Antibiotics

The implementation of Drug Registration Regulation (New Version) has put forward new requirements to relevant techniques in drug registration, especially high-risk products like antibiotics with an aim to comprehensively elevate quality of registered drugs for being listed on market.

Impurity research is an important item in drug quality control and research. As for antibiotics, mostly semi-fermentation and semisynthesis products, categories and contents of impurities are more complicated than normal synthesized chemicals; Meanwhile, with wider range of application, antibiotics face more prominent safety issues. Therefore, impurity research& control is a key item in impurity quality control & research.

As for similarities of antibiotics categories already marketed at home and abroad, in accordance with basic technical requirements for generics, modeled drugs shall be selected for systematic comparative study to ensure consistency in quality.

In terms of impurity research, the following requirements shall be made according to relevant technical requirements and coordinating with history and reality of antibiotics production and R&D activities,:

1. Impurities Detection Method

Science and Applicability of impurities detection method is key in impurity control. During research, we shall pay high attention to whether this product is listed in pharmacopoeia of ICH member states, differentiations between detection methods and that in Chinese Pharmacopoeia or approved standard methods, and also we shall conduct systematic comparative research and regular methodology verification, on which to choose scientific, applicable and efficient detection method.

2. Control Samples for Impurity Research

As for generics for antibiotics already marketed at home and abroad, for the sake of quality guarantee, the following principles are suggested to conduct relevant research:

(1) Priority on innovative products, by which if products already imported into China, innovative imports could be applied;

(2) Without access to innovative products or imports, products marketed in ICH member states could be applied, i.e., generics for similar categories of products in US, EU or Japan. If products in these countries already enter into Chinese market, imports could be applied.

(3) If domestic enterprises apply asepsis raw materials from the above places of origin to conduct subpackaging for asepsis powder needles, products of these enterprises could be applied to serve as control sample for impurity research. As for other preparations, adjuvant and solvent in use are more complicated, some heat-making production process could be applied. Even applying preparations made from imported raw materials, their impurity spectrum could be different from samples at home and abroad. As for above-mentioned preparations, it is suggested to apply control sample referred in category Ⅰor Ⅱ.

(4) If generics are marketed in member states mentioned in Category Ⅰwhile applicants don't apply marketed products as control samples for impurity research but samples from other places of origin (including domestic products), generally it would not be recommended.

(5) If this generic is not marketed in above-mentioned member states, i.e., enterprises could not have access to foreign samples, imported samples or domestic-making samples living up to above requirements, it is suggested under the precondition of fully rationality consideration, based on technical requirements ob impurity research for new drugs, preparations marketed in multiple countries are applied to conduct in-depth impurity research and control. Quality of newly-reported products shall not go under that of most domestic enterprises.

(6) If this drug is already listed in prevailing international pharmacopoeia like EP、BP、USP、JP, etc., and under sound control according to pharmacopoeia standards, for example, Azithromycin involved in BP identifies limitation of 16 known impurities, under which methods in pharmacopoeia could be referred to apply for control on related drug materials, but origination and related proof documents of control samples (or impurity positioning reference solution) shall be provided.

3.Comparison of Categories and Contents of Impurities

Currently, applicants mostly apply HPLC method to conduct comparison of in-study products and marketed products. Since most antibiotics are mostly semi-fermentation, semisynthesis products, categories and content of contained impurities are complicated than normal synthesized chemicals, for example, Azithromycin involved in BP identifies 16 known impurities and Cefuroxime sodium identifies 9 known impurities, under which mere application of HPLC is difficult to judge similarities and differences between in-study products and marketed products. Generally speaking, it is suggested to apply multiple methods such as LC/MS、diode array monitor as well as mixed sample injection with in-study products and marketed products to make comprehensive judgement from different perspectives and reflect research results all-roundly with tabulation ways to analyze differences in categories and contents of contained impurities between them to assess quality differences. Based on above standard research, relevant technical guidelines shall be coordinated to draw down scientifically rational impurity limitation;

Impurity research and control is a key indicator in antibiotics quality control, especially for generics of drugs already marketed at home and abroad, which base its safety and efficient on research results of innovative enterprises and systematic comparative study with innovative products. Drug developers shall refer to above thinking and methods, conduct comprehensive and in-depth research and efficient control on product impurities; During technical evaluation of registration process, we shall focus on scientificity and regularity of above research to ensure quality of above marketed products and realize the goal of its quality above that of innovative products.

(April 7th, 2010)

查，及时发现问题，尽早解决，促进预防接种工作健康持续发展。卫生部和国家食品药品监管局将于近期开展全国性的督导检查活动，确保疫苗使用安全有效。

（2010-04-13）

抗生素类药物杂质控制研究的技术要求

为了全面提升注册上市药品的质量和品质，新版《药品注册管理办法》，对于药品的相关技术特别是抗生素类高风险产品的相关技术提出了新的要求。

杂质研究是药物质量控制研究的重要项目。对抗生素而言，由于其多为半发酵、半合成产品，所含的杂质种类与杂质含量都比普通合成化学药物复杂；同时由于国内抗生素使用范围较广，面临的安全性问题更为突出，因此，杂质研究和杂质控制更是抗生素质量控制研究的关键项目。

对于仿制国内外已上市抗生素的品种，根据仿制药的基本技术要求，应选择被仿药物进行系统的质量对比研究，以保证其质量的一致性。

在杂质研究方面，根据相关技术要求，结合我国抗生素生产和研发的历史以及现实情况，提出如下要求：

1. 杂质检查方法

杂质检查方法的科学、适用性是杂质控制的关键。在研究过程中应该高度关注该产品是否在ICH成员国药典有无收载，其检查方法与国内药典或已批准标准方法的差异，并进行系统的比较研究和规范的方法学验证，在此基础上，选择科学、适用、高效的检查方法。

2. 杂质研究对照用样品

对于仿制国内外已上市产品的抗生素，为了保证仿制药的质量，在杂质研究对照用样品问题上，建议按以下原则开展相关研究：

（1）首选原研产品，如果原研企业产品已经进口中国，可采用原研进口品；

（2）如果无法获得原研产品或者原研进口产品，可以采用ICH成员国的上市产品，即美国、欧盟或日本等国的同品种仿制产品。如果上述国家产品已经进口中国，可采用进口品。

（3）如果国内企业采用上述产地的无菌原料，进行分装的无菌粉针，也可采用该企业产品作为杂质研究对照样品。对于其他制剂，因可能采用的辅料、溶剂比较复杂，并使用可能产热的某些工艺，即使采用进口原料制得的制剂，其杂质谱也可能与国外样品有差异，对于上述制剂，仍建议采用上述第(1)、(2)种研究对照样品。

（4）如果该仿制药品仍在上述ICH成员国上市，申请人未采用其上市品作为杂质研究对照样品，而采用其他产地的样品（包括国内产品）作为杂质研究对照样品，一般不予认可。

（5）如果该仿制药品未在上述ICH成员国上市，即企业无法获得符合上述要求的国外样品、进口样品或者国产样品时，则建议充分考虑立题合理性的前提下，按照新药的杂质研究的技术要求，采用多家国内上市制剂，进行深入的杂质研究和控制，新报产品的质量应不低于多数国内企业产品的质量。

（6）如果该药物已收载于EP、BP、USP、JP等国际通用药典，且该药典标准中对有关物质进行了良好的控制，例如英国药典纳入的阿奇霉素明确了16种已知杂质的限度，此种情况下可参考药典方法进行申报药品有关物质的控制，但需提供杂质对照品（或杂质定位对照液）的来源和相关证明。

3、杂质种类和含量的比较

目前，申请人多采用HPLC法对在研品与上市产品进行杂质比对。由于抗生素多为半发酵、半合成产品，所含的杂质种类与杂质含量都比普通合成化学药物复杂，如英国药典纳入的阿奇霉素明确了16种已知杂质、头孢呋辛钠明确了9种已知杂质，在此情况下，仅采用简单的HPLC相对保留时间的方法难以判断在研品与上市产品杂质的异同。一般而言，建议采用LC/MS、二极管阵列监测器，以及在研品与研究对照产品混合进样等多种方法从不同侧面综合判断，并以列表方式全面反映研究结果，综合分析二者所含杂质种类和含量的差异，进而评价其质量的差异。在上述规范研究的基础上，结合相关技术指导原则，制定科学合理的杂质限度。

杂质研究和控制是抗生素质量控制的关键指标，特别是仿制国内外已上市的药品，其安全有效性的认识是建立在原研企业的研究结果，以及与原研产品系统比较研究的基础上。药品研发者应参照上述思路和方法，对研究产品杂质进行全面的深入研究和有效控制；在注册过程中技术审评时，应重点关注上述研究的科学规范性，以保证上市产品的质量，并努力实现其质量不低于原研产品质量的目标。（2010-04-07 选自CED网站）

Q&A 知识问答

Q&A on Electronic Submission of Applications for Drug Registration

关于药品注册申请电子提交的问与答

The SFDA Center for Drug Evaluation released the Announcement on Issues Concerning Cancellation of Quality Standard Checking and Instructions to Applicants about Current Evaluation Procedures and the Notice on Further Strengthening Early Electronic Submission of Registration Application Materials. The frequently asked questions are answered as follows:

Q: Should all electronic materials for applications for registration be submitted through the CDE website at one time?

A: In principle, applicants for registration should submit quality standards, instructions, packing labels, processes, summaries, and other documents together with the early electronic submission; during the evaluation process, the registration applicant may submit related documents several times according to the requirements of the evaluation team.

Q: What are the requirements for early electronic submission?

A: Before the end of the work of the evaluation team but after the center receives your application for evaluation of registration, the item may be submitted by e-submission; after the end of the evaluation, e-submission will not be accepted during the recheck\examination and signing and issuance or document production by the management and coordination department. Therefore, the registration applicant may find out in good time about the state of evaluation of the registration application through the CDE website "follow-up inquiry" and conduct the early e-submission of the declaration materials in a timely manner.

Q: E-submission has been done according to requirements during the professional evaluation before registration application. After completion of comprehensive evaluation, the center sends a notice about supplementary materials. Should the applicant still conduct e-submission after sending supplementary materials?

A: In case of any changes to such contents as quality standards, drug operating instructions, packing labels, and process materials, e-submission of the above materials should be conducted when submitting supplementary materials to the center for drug evaluation.

Q: What are the requirements for e-submission of clinical test databases and human pharmacokinetics maps?

A: Please submit these according to the requirements of the Notice on Submission of Clinical Test Statistical Databases and All Maps of Human Pharmacokinetics (February 16, 2009).

Q: What is the requirement for the format of the summary items in the Summary and Evaluation of Main Research Results in the e-submission?

A: The e-submission template of various summary materials provided on the CDE website was extracted from the appropriate guidelines released by the SFDA. Registration applications therefore differ in research contents and scope. Registration applicants should refer to specific research contents according to the actual situation when organizing and preparing the related declaration materials.

国家食品药品监督管理局药品审评中心近期发布了《关于取消现行审评程序中提请申请人校核质量标准、说明书事宜的公告》以及《关于进一步加强注册申请资料早期电子提交工作的通知》，常见问题的解答如下：

问：注册申请电子资料是否需要一次性全部通过CDE网站进行提交？

答：原则上注册申请人应在早期电子提交时一并将质量标准、说明书、包装标签、工艺、综述等文件一次性提交；在审评过程中,注册申请人可以根据审评团队的要求,多次提交相关文件。

问：早期电子提交时间有什么要求？

答：在我中心收到您的注册申请审评任务后到审评团队的工作结束前，品种是可以进行电子提交的；当审评岗位的工作结束后，如复核\审核签发或管协部制件阶段，则不能进行电子提交。因此请注册申请人通过CDE网站“进度查询”及时获知注册申请的审评状态，及时进行申报资料的早期电子提交工作。

问：注册申请之前已经在专业审评阶段按照要求进行了电子提交，综合审评结束后中心发出补充资料通知，申请人完成补充资料工作后是否仍需进行电子提交？

答：若涉及质量标准、药品使用书、包装标签和工艺资料等内容的变化，则需要在补充资料提交药审中心时,将上述资料进行电子提交。

问：临床试验数据库和人体药代动力学图谱的电子提交要求？

答：请按照《关于提交临床试验统计数据库和人体药代动力学全部图谱的通知》（2009年2月16日）的要求进行提交。

问：电子提交中“对主要研究结果的总结与评价”综述资料项目有何格式要求？

答：CDE网站提供的各项综述资料电子提交模板系在SFDA发布的相应指导原则基础上进行梳理而成，因各类注册申请在研究内容和范围上有所不同，注册申请人在组织和撰写相关申报资料时应根据具体研究内容的实际情况进行参考。

问：生产工艺确认书签字盖章后如何提交？是否需要邮寄纸制资料？还是扫描后保存到word文件中？

答：早期电子提交时无需提交电子版生产工艺确认书，待注册申请人收到中心发出的具体通知时根据通知具体要求进行纸质资料和电子文档的提交。

问：注册申请在做完生物等效性试验后申请生产，是否需要重新提交电子信息？如果需要，通过什么渠道提交？

答：做完生物等效性试验后报生产的注册申请需在CDE网站进行电子提交，提交资料项目为：质量标准、药品使用说明书、包装标签、工艺资料、起草/修订说明等，综述资料可以不再进行电子提交。提交操作和途径同注册申请早期电子提交。

问：提交文档错了或文档更新怎么办？

答：当品种处于审评岗位时，CDE电子提交系统允许注册申请人多次提交。当发生提交文档错误或文档有更新的时候，可以再次提交，如需再次提交,请提前与审评团队沟通。

问：电子提交的文件必须是用word编辑的吗？

答：为了便于审评人员修订电子提交的文档，目前电子提交系统统一采用WORD2003兼容的格式的文件进行提交。对于使用WORD2007版本的注册申请人应将文档存储为WORD2003格式进行提交。

问：包装标签和说明书涉及到商标，防伪标识等，都是用制图软件设计的，用word则会非常不方便。不知道早期提交的包装标签等是否可以用word格式中插入图片吗？

答：电子提交文档中的文字内容是需要审评人员进行修订的，因此文字部分必须在WORD中是可以编辑的。对于标签等文件中涉及商标防伪标识等图形文件，我中心一般情况下不进行修改，故注册申请人可按原稿的形式进行插入编排。

问：为什么提交的时候提示当前阶段不能进行电子提交？

答：目前电子提交系统仅允许处于审评岗位的品种提交文档,当审评岗位的工作结束后，如复核\审核签发或管协部制件阶段，则不能进行电子提交。

（2010-04-15,05-24）

Q: How to submit letters of confirmation of production processes after they have been signed and sealed? Should paper-based materials be mailed, or saved as WORD files after scanning?

A: It is unnecessary to submit electronic versions of letters of confirmation for production processes in early e-submissions. Paper-based materials and electronic files should be submitted according to the specific requirements of notices after the registration applicants receive the specific notices from the center for drug evaluation.

Q: If an applicant applies for production after completing a biological equivalent test, should electronic information be resubmitted? If yes, which channel should be used?

A: Registration applications for production submitted after completing biological equivalent tests should be submitted via e-submission on the CDE website. Items to be submitted include quality standards, drug operating instructions, packing labels, process materials and drafting/revision descriptions; summary materials may not be submitted by e-submission. The operation and route for submissions are the same as those of early e-submissions for registration applications.

Q: How to handle submission of wrong files or file updates?

A: When the item is in the process of evaluation, the CDE e-submission system allows the registration applicant to submit materials many times; when errors occur in the submission of files or file updates, resubmission is allowed. If resubmission is necessary, please communicate with the evaluation team in advance.

Q: Must files submitted by e-submission be WORD documents?

A: In order to assist the evaluation personnel to revise files submitted by e-submission, the current e-submission system has uniformly adopted the use of files for submission which are compatible with WORD 2003. For registration filed edited with WORD 2007, applicants should save the files in the WORD 2003 format for submission.

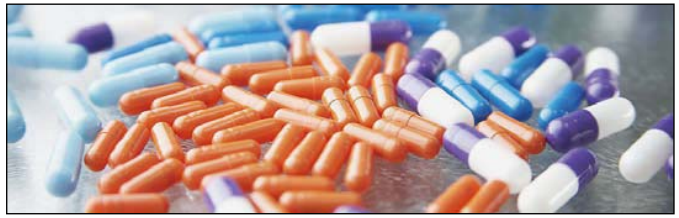
Q: Packing labels and instructions involve trademarks and anti-counterfeiting marks, which are designed using CAD software, so it is very inconvenient to use WORD. I want to know how packing labels and the like, submitted early, can be inserted as pictures in the WORD format.

A: The literal contents of files submitted by e-submission will be revised by the evaluation personnel. Therefore, literal parts must be editable in WORD. For graphic files involving trademarks and anti-counterfeiting marks on labels and other files, the CDE will generally not modify the files, so registration applicants may insert and edit these in the original format.

Q: Why can the system prompting e-submission not be done during the current stage when I submit a file?

A: Currently, the e-submission system only allows files for items under evaluation to be submitted. When the evaluation process has been completed, e-submission cannot be done during recheck/examination and approval signing and issuing or document production by the management and coordination department.

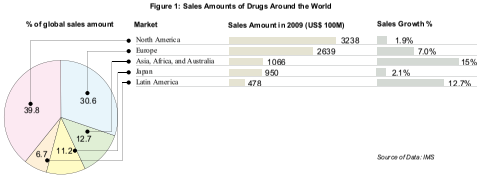
(April 15, May 24, 2010)



Sales Amounts of Drugs Around the World in 2009

According to the statistics of Pharmaceutical Manager, as shown in Figure 1 (sales amounts of drugs around world in 2009), North America and Europe remain the leading pharmaceutical markets around the world, dominating 70% of the sales on the global drug market. The emerging drug markets in Asia, Africa, Australia, and Latin America continue to maintain strong growth momentum of more than two digits and are becoming the leading driving force for growth in the global drug market. The Japanese market remains sluggish, registering a growth rate of 2% for two consecutive years.

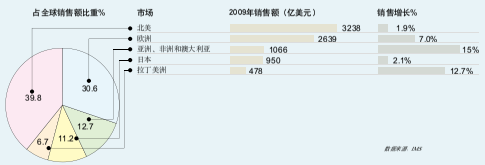
Figure 1: Sales Amounts of Drugs Around the World



2009年全球各地区药品销售额

据美国《制药管理者》杂志统计，2009年全球各地区药品销售额(图1)显示，北美和欧洲仍然是全球主要的药品市场，占据了全球药品市场中70%的销售额，亚洲、非洲、澳大利亚和拉丁美洲等新兴药品市场继续保持着两位数以上的强劲增长势头，成为全球药品市场增长的主要驱动力。日本市场则继续表现疲软，连续两年的增长率为2%。

图1 2009年全球各地区药品销售额



Top 15 Global Sales Amounts of Therapeutic Prescribed Drugs in 2009

As indicated in Figure 2 (the top 15 therapeutic drugs, in terms of sales amounts, of global prescribed drugs in 2009), the global sales amounts of anti-tumor drugs are the most excellent of all therapeutic drugs. The therapeutic drugs ranked third through fifth are respiratory drugs, anti-diabetic drugs, and anti-ulcer drugs.

Figure 2 Top 15 Products in Sales Amount of Global Prescribed Drugs in 2009

Rank	Name of Product	Therapeutic Action	Sales Amount in 2009 (US$100M)
1	Lipitor	hypolipidemic	132.88
2	Plavix	anticoagulant	91.00
3	Nexium	used for stomach	82.36
4	Seretide	treats asthma	80.99
5	Seroquel	treats psychiatric disorders	60.12
6	Enbrel	treats arthritis	58.63
7	Remicade	treats arthritis	54.53
8	Crestor	Lowers blood lipids	53.83
9	Zyprexa	treats psychiatric disorders	53.57
10	HUMIRA	treats arthritis	50.32
11	Avastin	antitumor drug	50.15
12	Singulair	treats asthma	49.86
13	Magnavox	antitumor drug	46.81
14	Abilify	treats psychiatric disorders	46.73
15	Lovenox	anticoagulant	45.72

Source of Data: IMS

2009年全球处方药销售额前15名治疗类别药品

2009年全球处方药销售额前15名治疗类别药品（图2）显示，抗肿瘤药物的全球销售额在所有治疗类别中表现突出，排名三至五位的治疗类别分别为呼吸系统用药、抗糖尿病药和消化性溃疡药。

图2 2009年全球处方药销售额前15名产品

	产品名	治疗作用	2009年销售额（亿美元）
1	立普妥	降血脂	132.88
2	波立维	抗凝血	91.00
3	耐信	治疗胃病	82.36
4	舒利迭	治疗哮喘	80.99
5	思瑞康	抗精神病	60.12
6	恩利	治疗关节炎	58.63
7	类克	治疗关节炎	54.53
8	可定	降血脂	53.83
9	再普乐	抗精神病	53.57
10	修美乐	治疗关节炎	50.32
11	安维汀	抗肿瘤	50.15
12	顺尔宁	治疗哮喘	49.86
13	美罗华	抗肿瘤	46.81
14	Abilify	抗精神病	46.73
15	Lovenox	抗凝血	45.72

数据来源：IMS

Second DIA China Annual Meeting Convened in Beijing on May 16

The Second DIA China Annual Meeting, co-sponsored by the DIA and the CCIPE, was held in Beijing on May 16, 2010. The theme of this meeting was leading drug innovation and development in China from strategy to practice. Nearly 100 speakers from drug administration institutions, scientific research and academic institutions, and business circles from around the world provided the latest updates on global drug development. The SFDA deputy director general Wu Zhen delivered the keynote speech entitled "Strengthen Administration, Encourage Innovation, and Promote Health Development of the Pharmaceutical Industry". The annual meeting included laws and regulations administrative affairs, clinical studies, pharmaceutical vigilance, clinical data management and statistics, non-clinical safety evaluation, CMC, and other topics. In total, more than 500 professionals related to drug research and development attended the meeting. (May 18, 2010)

药物信息协会（DIA）第二届中国年会于5月16日在京隆重召开

由药物信息协会（DIA）和中国医药国际交流中心共同举办的药物信息协会（DIA）第二届中国年会于2010年5月16日在北京隆重开幕，此次会议的主题是：从战略到实践，引领中国药物创新和开发。来自世界各国药物监管机构、科研学术机构和企业界的近100位讲演人将提供有关全球药物开发的最新动态。国家食品药品监督管理局副局长吴浈发表题为"加强监管，鼓励创新，促进医药产业健康发展"的主题报告。年会包括法规监管事务、临床研究、药物警戒、临床数据管理与统计、非临床安全评估、CMC等议题，共有500多名与药物研发有关的专业人士参加了会议。 (2010-05-18)

Special Focus

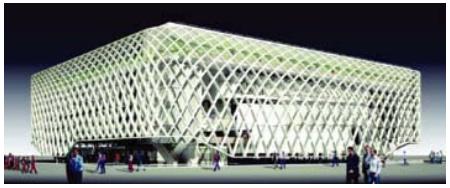
业界专题

French Medical Day on World Expo 2010

世博会"法国医学日"

The 2010 French Medical Day, co-hosted by the Chinese Ministry of Health and the French Ministry of Health and undertaken by the French Embassy and Servier (Tianjin) Pharmaceutical Co., Ltd, among enterprises, was held on May 15th in the France Pavilion of World Expo 2010, Shanghai. With the theme on preventing and treating chronic diseases for a better Life, hundreds of experts from China and France shared experiences on the prevention and treatment of chronic diseases, particularly diabetes, cardiovascular diseases and cancers.

The prevention and regular examination of chronic diseases, cardiovascular diseases in particular, have become one of the most important issues in modern society, and concern both China and France. The data released on the French Medical Day shows that nearly 150 million French people are suffering from various chronic diseases, accounting for about 20% of the total population in France. In view of such an increasingly daunting situation, France takes a variety of measures in terms of national planning, disease prevention, and patient education etc. to improve the living quality of patients with chronic diseases. "In fact, the prevalent chronic diseases in China allow little optimism either," said Kong Lingzhi, Deputy DG of Ddiseases Control, the Chinese Ministry of Health. The latest National Health Service Survey reveals that the prevalence of chronic diseases in the surveyed regions averages 20.0%. It is further estimated that cases of chronic diseases diagnosed by doctors may be 260 million. Facing this severe challenge, the Chinese Ministry of Health formally launched in 2008 the "Healthy China 2020"strategy



由中法两国卫生部合办，法国大使馆及法国施维雅（天津）制药有限公司等多家企业承办的2010年度"法国医学日"5月15日在上海世博会法国馆成功举行，来自中法两国的百余名专家围绕"防治慢性病，生活更美好"的主题，分享了两国在慢性病防治，尤其是糖尿病、心血管疾病和癌症预防和治疗方面的经验。

慢性病，尤其是心血管疾病的预防与定期检查成为了现代社会的重中之重，在这一点上，中法两国面临着同样的问题。会上公布的数据显示，在法国，约1500万人罹患各种慢性疾病，这一人数占全法人口的将近20%。面对日益严峻的慢性病形势，法国从国家规划、疾病预防及患者教育等方面，多管齐下，旨在提供慢性病人更高的生活质量。"事实上，中国的慢性病发病情况同样不容乐观。"卫生部疾病预防控制局副局长孔灵芝表示。根据最近一次国家卫生服务调查的数据，调查地区居民慢性病患病率为20.0%。以此推算，全国有医生明确诊断的慢性病病例数达到2.6亿。面对这一严峻挑战，2008年，卫生部正式提出"健康中国2020"战略，针对人民群众最关心的健康问题和影响健康的危险因素，积极采取经济有效的干预措施和适当的卫生策略，努力提高全民健康水平。

为支持两国医学专家的深入交流，促进中国医疗水平的进一步发展，施维雅中国分公司邀请了包括中华医学会心血管分会主任委员胡大一教授在内的80位全国知名专家参加了本次"法国医学日"的活动，总经理

for better health across the Chinese population through economical and effective interventions and appropriate health care policies targeted at health issues the general public concerns most and the risk factors on health.

To facilitate in-depth communication between Chinese and French medical experts and promote healthcare development in China, Servier China invited 80 well-known Chinese experts including Prof. Hu Dayi, President of the Cardiovascular Committee of the Chinese Medical Association, to participate in the French Medical Day. Mr. LU Anbang, General Manager of Servier China,attended the meeting and said, on behalf of Servier China in press release afterwards, that "As the second largest pharmaceutical company in France and one of the first foreign pharmaceutical companies which entered the Chinese market, Servier has been always the champion of its enterprise spirit of Life through Discovery and dedicated to promote health care in China. Servier's contact with the Chinese medical community started from 1979 on its entering China. Since 1980 when the first program was co-initiated with the Chinese Medical Society, Servier China has held 29 Sino-French Medical Exchanges. .In 2009, Servier China celebrated its 30th anniversary with its great development in the fields of cardiology, endocrinology, neurology, and psychiatry and its contribution to healthcare in China. Servier will continue to strengthen the exchange and cooperation with the Chinese medical circle, dedicate itself to bringing innovative drugs into China, and provide more comprehensive and better health care services for doctors and patients.

The meeting on the French Medical Day has been well covered by a number of media including the People's Daily, the Wen Wei Po, and the NetEase and is widely acclaimed among top Chinese medical figures.

Servier sponsored also the French Medical Day-Cardiovascular Expert Symposium, which provided a platform for deeper communication between Chinese and French cardiovascular experts. Chaired by Prof. Shen Weifeng with the Rui Jin Hospital in Shanghai. the symposium featured presentations from Prof. Pascal GUERET with the Paris Creteil Hospital in France, President of Cardiovascular committee of French Medical Association, and Prof. Sun Ningling with the People's Hospital of Peking University on "ACEi and CAD" and "the Role and Significance of Fixed Dose Combination Antihypertensives in Hypertension Treatment" among other hot topics on the treatment of cardiovascular diseases and hypertension respectively.

卢安邦先生也亲临会议现场，并代表施维雅中国分公司在会后的新闻发布会中发言，卢安邦先生讲道：作为法国第二大制药企业，也是第一批进入中国的外国医药公司，施维雅一直秉承"不断探索、生机勃勃"的企业精神，致力于中国的医疗事业。施维雅从1979年进入中国时就开始了与中国医药界的接触。1980年，与中华医学会合作创办了中国第一个中法医学交流项目，目前已成功举办了29届。2009年施维雅中国分公司迎来了三十岁生日，三十年来施维雅在心血管，内分泌，神经及精神等领域取得了长足的发展，并为中国的医疗事业做出了应有的贡献。未来，施维雅仍将继续加强与中国医学界的交流与合作，致力于把创新药品引入中国，为广大医生和患者提供更全面，更优质的医疗服务，为中国的医疗事业做出更大的贡献。

包括人民日报，文汇报，网易等多家媒体在第一时间对本次会议进行了全面的报道，会议得到了众多医药界权威人士的高度赞扬！

此外，施维雅公司还赞助举行了"法国医学日-心血管领域专家研讨会"，为两国心血管领域专家提供了更深层次交流的平台。会议由上海瑞金医院沈卫峰教授主持，来自法国巴黎Creteil医院（法国医学会心血管分会主席）Pascal GUERET教授和来自北京大学人民医院的孙宁玲教授分别就心血管及高血压疾病治疗领域的热点话题，如"血管紧张素转化酶抑制剂与冠状动脉疾病"、"固定复方降压药在高血压治疗中的地位和意义"作了精彩的报告。

SERVIER

Notes: All Chinese information in Newsletter extracted from Newspapers and Internet.
备注：Newsletter中所有中文信息摘自报刊及网络。

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