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NEWS

The State Council Issues the "Twelfth Five-Year Plan for National Drug Safety"

On February 13, 2012, the State Council issued the "Twelfth Five-Year Plan for National Drug Safety" (hereinafter referred to as the "Plan"). The "Plan" indicates that the "12th Five-Year Plan" Period is a critical period to build a moderately prosperous society, and an important period of opportunities to promote the healthy and rapid development of the pharmaceutical industry. We must further enhance drug safety to provide effective protection for people's health.

The Overall Goal of the "Plan" is: with five years' efforts, drug standards and drug quality shall witness a dramatical improvement; drug supervision system shall be further consolidated; drug R&D, production, circulation and application shall be further standardized; drug safety assurance capabilities shall keep abreast of or close to the international advanced levels; drug safety levels and the people's drug safety satisfaction shall be significantly enhanced.

The indicators of the "Plan" are: 1. All the standards of chemicals, biological products shall keep abreast of or close to international standards, the standards for traditional Chinese medicine shall lead the international standard-setting. More than 90% of the medical devices shall adopt international standards. 2. The quality of national essential drugs and commonly used clinical drugs of the generic drugs approved for production prior to the implementation of the Provisions for Drug Registration revised in 2007 shall reach international advanced levels. 3. Pharmaceutical production shall ensure 100% compliance with the "Good Manufacturing Practice for Drugs" as revised in 2010; the production of sterile and implantable medical devices shall ensure 100% compliance with the "Good Manufacturing Practice for Medical Devices". 4. Drug Supply shall ensure 100% compliance with the "Good Supply Practice for Drugs". 5. All newly opened retail pharmacies must have a licensed pharmacist. By 2015, all retail pharmacies and hospital pharmacies must have licensed pharmacists to guide the rational use of drugs.

The nine major tasks of the "Plan" are: 1. Improve the overall national drug standards. 2. Strengthen the Whole Process Quality supervision of drugs. 3. Improve drug inspection and testing system. 4. Improve drug safety monitor and vigilance levels. 5. Crack down on the manufacturing and sales of counterfeit and substandard drugs in accordance with the law. 6. Improve drug safety emergency treatment system. 7. Strengthen the infrastructure construction for drug administration. 8. Accelerate the construction of drug administration information system. 9. Enhance the quality of human resources. (February 14, 2012)

国务院发布《国家药品安全"十二五"规划》

2012年2月13日，国务院发布《国家药品安全"十二五"规划》（以下简称《规划》）。《规划》指出，"十二五"时期是我国全面建设小康社会的关键时期，也是促进医药产业健康快速发展的重要机遇期，必须进一步加强药品安全工作，为人民群众健康提供有力保障。

《规划》总体目标：经过5年努力，药品标准和药品质量大幅提高，药品监管体系进一步完善，药品研制、生产、流通秩序和使用行为进一步规范，药品安全保障能力整体接近国际先进水平，药品安全水平和人民群众用药安全满意度显著提升。

规划指标：一是全部化学药品、生物制品标准达到或接近国际标准，中药标准主导国际标准制定。医疗器械采用国际标准的比例达到90%以上。二是2007年修订的《药品注册管理办法》施行前批准生产的仿制药中，国家基本药物和临床常用药品质量达到国际先进水平。三是药品生产100%符合2010年修订的《药品生产质量管理规范》要求；无菌和植入性医疗器械生产100%符合《医疗器械生产质量管理规范》要求。四是药品经营100%符合《药品经营质量管理规范》要求。五是新开办零售药店均配备执业药师。2015年零售药店和医院药房全部实现营业时有执业药师指导合理用药。

《规划》九项主要任务：一是全面提高国家药品标准。二是强化药品全过程质量监管。三是健全药品检验检测体系。四是提升药品安全监测预警水平。五是依法严厉打击制售假劣药品行为。六是完善药品安全应急处置体系。七是加强药品监管基础设施建设。八是加快监管信息化建设。九是提升人才队伍素质。（2012年2月14日）

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SFDA Releases the "Notice on Enabling New Official Seals for Administrative Licensing Acceptance, Document sign-receiving and Cosmetics Licensing"

On February 7, 2012, SFDA issued a Notice to enable, since February 9, 2012, the new SFDA Administrative Licensing Acceptance Official Seals (30 Seals), the Administrative Licensing Document sign-receiving Official Seals (30 Seals), and Cosmetics Licensing Official Seals (1 Seal), the pattern of the Seals was announced in the meantime. The original Official Seals for Administrative Licensing Acceptance, Document sign-receiving and Cosmetics Licensing shall be repealed simultaneously. (February 7, 2012)

国家食品药品监督管理局发布《关于启用新行政许可受理专用章和资料签收专用章、化妆品许可专用章的通知》

2012年2月7日，国家食品药品监督管理局发布通知，自2012年2月9日起，启用新的国家食品药品监督管理局行政许可受理专用章（30枚）、行政许可资料签收专用章（30枚）、化妆品许可专用章（1枚），印章式样同时公布。原行政许可受理专用章和资料签收专用章、化妆品许可专用章同时废止。（2012年2月7日）

State Food and Drug Administration Further Strengthened the Management of Clenbuterol Hydrochloride

On January 9, 2012, the State Food and Drug Administration issued a notice requiring food and drug administrations at all levels to further strengthen the management of clenbuterol hydrochloride, perform focused monitoring on enterprises in production (distribution) of clenbuterol hydrochloride APIs. Manufacturers having ceased production of clenbuterol APIs should be supervised and prohibited from unauthorized resuming of production.

In September 2011, the State Food and Drug Administration issued a notice to halt the production, sales and application of clenbuterol hydrochloride tablets in China. To further enhance the management of clenbuterol hydrochloride APIs, aerosols, and compound preparations etc., on January 9, 2012, the State Food and Drug Administration once again issued a notice requiring the regulation of the production, distribution channels and diagnosis & treatment behavior of clenbuterol hydrochloride.

The notice requires to regulate clenbuterol production and strengthen the management of the production and application of APIs; regulate the distribution channels to ensure the traceability of drug circulation; regulate diagnosis & treatment behavior, and conduct strict prescription management; reinforce supervision and inspection, implement regulatory responsibilities; strictly inspect and punish production and sales behaviors that violate laws and regulations. (January 19, 2012)

国家食品药品监督管理局进一步加强盐酸克仑特罗管理工作

2012年1月9日，国家食品药品监管局发出通知，要求各级食品药品监管部门进一步加强盐酸克仑特罗管理，对盐酸克仑特罗原料药在产（销）企业应当实施重点监管。对已停产的原料药企业，应监督企业不得擅自恢复生产。

国家食品药品监督管理局2011年9月下发通知要求停止盐酸克仑特罗片剂在我国的生产、销售和使用。为进一步加强盐酸克仑特罗原料药及气雾剂、复方制剂等的管理，2012年1月9日，国家食品药品监督管理局要求规范盐酸克仑特罗生产行为、流通渠道及诊疗行为。

通知要求，要规范生产行为,加强对原料药生产和使用的管理；规范流通渠道，确保药品流向可追溯；规范诊疗行为，严格处方管理；强化监督检查，落实监管责任；严肃查处违法违规生产销售行为。

（2012年1月19日）

SFDA Requires Further Improving the Electronic Supervision of Certain Compound Preparations Containing Special Drugs

SFDA notice on the Implementation of Electronic Supervision of Certain Compound Preparations Containing Special Drugs (Guo Shi Yao Jian Ban [2010] No. 484) has clearly required the implementation of electronic supervision

国家食品药品监督管理局要求进一步做好部分含特殊药品复方制剂电子监管工作

国家食品药品监督管理局《关于对部分含特殊药品复方制剂实施电子监管工作的通

on ephedrines-containing compound preparations (exclusive of Chinese patent medicine containing ephedra), codeine-containing compound oral solution, diphenoxylate-containing compound preparations and other compound preparations containing special drugs as of December 31, 2011. To effectively implement the electronic supervision of the above-mentioned products, on January 10, 2012, the State Food and Drug Administration issued the "Notice on Further Improving the Electronic Supervision of Certain Compound Preparations Containing Special Drugs," and the relevant affairs are notified as follows:

The aforementioned compound preparations containing special drugs produced as of January 1, 2012 must be encoded, registered or canceled after verification, and un-coded products shall not be permitted into market.

All Provincal (Automomous regional, Municipal) Food and Drug Administrations should strengthen supervision and management, within their respective administrative areas urge pharmaceutical manufacturers to encode the above-stated compound preparations containing special drugs, drug distributors to verify the registration and sales of the encoded products, and to realize data upload through the electronic supervision network. If abnormal flow of drug sales is spotted, the sales must be suspended immediately, and the case must be reported to local food and drug administration departments. The Food and drug administration departments should immediately check the situation and invite food and drug administration in the destination areas of drugs to conduct a coordinated investigation, and the latter should cooperate actively. During the inspection, if the drugs were suspected to be distributed to illegal channels, the cases should also be immediately reported to public security department at the same level. (January 13, 2012)

知》（国食药监办〔2010〕484号）已明确要求，在2011年12月31日前，对含麻黄碱类复方制剂（不包括含麻黄的中成药）、含可待因复方口服溶液和含地芬诺酯复方制剂等含特殊药品复方制剂实施电子监管。为切实做好上述品种电子监管工作，2012年1月10日，国家食品药品监督管理局发布《关于进一步做好部分含特殊药品复方制剂电子监管工作的通知》，将有关事宜通知如下：

自2012年1月1日起生产的上述含特殊药品复方制剂，必须赋码并核注核销，未赋码的一律不得销售。

各省（区、市）局要切实加强监督管理，督促行政区域内药品生产企业对所生产的上述含特殊药品复方制剂进行赋码，药品经营企业对所经营的赋码产品进行核注核销，并通过电子监管网实现数据上传。发现药品销售流向异常时，应当立即暂停销售，并向所在地食品药品监管部门报告。食品药品监管部门应当立即进行核查，并请药品流入地食品药品监管部门进行协查，药品流入地食品药品监管部门应积极予以配合。核查中发现涉嫌流入非法渠道的，还应立即通报同级公安机关。

（2012年1月13日）

Center for Complaint and Reporting, SFDA Enters into Formal Operation

On January 16, 2012, Center for Complaint and Reporting, SFDA (hereinafter referred to as the CCR) entered into formal operation, and formally initiate accepting Complaints & Reporting via mails and Internet.

SFDA requires all Provincal (Automomous regional, Municipal) Food and Drug Administrations to pay great attention to the problems reflected through Complaint & Reporting, and provide strong support to CR in accordance with the “Provisions for Food and Drug Complaint and Reporting (interim)”, implement the work principles of territorial management, unified leadership and graded accountabilities, to speed up the construction of Complaint & Report institutions. Open as soon as possible the National Food and Drug Administration Complaint and Reporting Hotline “12331”, handle timely the complaints and reports within the administrative area, to further regulate food and drug production and distribution, strengthen the power to crack down on food and drug illegal activities, and protect food and drug safety for the public. Complaint Report URL: www.12331.org.cn

(January 16, 2012)

国家食品药品监督管理局投诉举报中心正式运行

2012年1月16日，国家食品药品监督管理局投诉举报中心（以下简称投诉举报中心）开始运行，并正式受理信件和互联网渠道的投诉举报。

国家食品药品监督管理局要求各省（区、市）食品药品监督管理部门要高度重视投诉举报反映的问题，大力支持投诉举报中心开展工作，按照《食品药品投诉举报管理办法（试行）》的规定，落实属地管理、统一领导、分级负责的工作原则，加快投诉举报机构建设，尽快开通全国食品药品监督管理部门投诉举报电话“12331”，及时办理本行政区域的投诉举报，进一步规范食品药品生产经营行为，加大对食品药品违法行为的打击力度，保障公众饮食用药安全。投诉举报网址：www.12331.org.cn，（2012年1月16日）

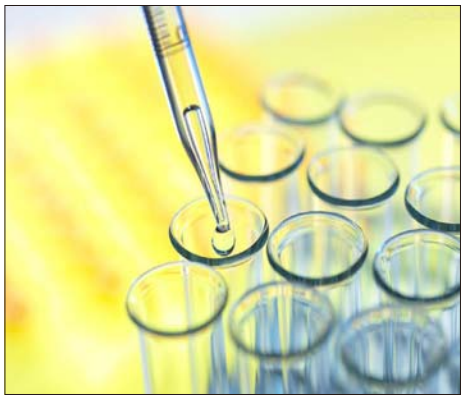
State Food and Drug Administration Calls for Strengthening the Implementation of the Revised Drug GMP

On January 6, 2012, the State Food and Drug Administration issued the "Notice on the Strengthening of the Implementation of Good Manufacturing Practice for Drugs (2010 Revision)," which called for strengthening the implementation of "Good Manufacturing Practice for Drugs (2010 Revision)" (hereinafter referred to as the newly revised Drug GMP), and adhering to the consistency of certification standards, and indicated that the cases of discrepancy and step-down of standards shall never be tolerated.

Since the newly revised Drug GMP came into force on March 1, 2011, food and drug administration at all levels and pharmaceutical manufacturers have actively organized its implementation, the overall work has been stable and orderly, but the progresses differ in different areas. To promote the implementation of the newly revised Drug GMP, the State Food and Drug Administration issued a Notice requiring food and drug administration at all provincial levels to strengthen the construction of food and drug supervision & inspection teams, and drug certification & inspection institutions. Where conditions permit, explorations should be actively made on the professionalization of drug GMP inspectors, and certification should be performed by specially designated full-time staff. The State Food and Drug Administration shall gradually develop standards of professional inspectors and conduct specialized training for them, to ensure work quality and further enhance the effectiveness of drug inspection & certification. Food and drug administration at all levels should strengthen drug quality supervision in the process of technological upgrading of enterprises, reinforce supervision, verification and follow-up inspection efforts to prevent product quality problems as a result of the comitant production with technological upgrading in the transitional period.

The State Food and Drug Administration require urging the pharmaceutical manufacturers to improve their quality management system, and attach importance to technical upgrading. Meanwhile, in the implementation process of the newly revised Drug GMP, enterprises are encouraged to put into effect the “Guidance on Speeding up the Structure Adjustment of the Pharmaceutical Industry” jointly issued by the Ministry of Industry and Information Technology, Ministry of Health and State Food and Drug Administration, establish win-win partnership between enterprises, conduct mergers and acquisitions, adjust the industrial structure, eliminate backward production capacity, promote industrial upgrading and accelerate the development of advantageous enterprises. The manufacturers (plants), which produce blood products, vaccines, injection agents and other sterile drugs that fail the certification as of December 31, 2013, and others that fail the certification as of December 31, 2015 must stop production.

(January 6, 2012)



国家食品药品监督管理局要求加强新修订药品GMP实施工作

2012年1月6日，国家食品药品监督管理局发布《关于加强<药品生产质量管理规范（2010年修订）>实施工作的通知》，要求加强《药品生产质量管理规范（2010年修订）》（以下简称新修订药品GMP）实施工作，坚持认证标准前后统一，绝不允许出现前紧后松，标准降低的情况。

新修订药品GMP自2011年3月1日实施以来，各级食品药品监管部门和药品生产企业积极组织开展实施，总体工作稳定有序，但各地进度不一。为推进新修订药品GMP实施工作，国家食品药品监督管理局发出通知，要求各省级食品药品监管部门要加强药品监督检查队伍和药品认证检查机构建设。有条件的地方，要努力探索实行药品GMP检查员职业化，认证工作由专职人员进行。国家食品药品监督管理局将逐步制定职业检查员标准，对职业检查员进行专门培训，保证工作质量，进一步提升药品检查认证工作的有效性。各级食品药品监管部门要加强对企业技术改造过程中的药品质量监管，加大监督检查和跟踪检查力度，防止在过渡期间因企业改造与生产同步造成产品质量问题。

国家食品药品监督管理局提出，要督促药品生产企业完善质量管理体系，重视技术升级改造。同时，鼓励企业在实施新修订药品GMP过程中，贯彻落实工业和信息化部、卫生部、国家食品药品监督管理局联合下发的《关于加快医药行业结构调整的指导意见》，开展企业间的强强联合、兼并重组，调整产业结构，淘汰落后产能，促进产业升级和优势企业做大做强。2013年12月31日后没有通过认证的血液制品、疫苗、注射剂等无菌药品以及在2015年12月31日后未能通过认证的其他药品生产企业（车间），必须停止生产。

(2012年1月6日)

"Guideline on Management of Phase I Clinical Trial of Drugs (Interim)"

(To continue)

Chapter VII Contracts and Agreements

Article 27 Prior to the trial, the sponsor and investigators should sign a commission contract with legal binding of Chinese law. The contract should clarify the content and progress of the trials, the responsibility and obligation of the two sides, the amount of commissioned research funding, and furthermore, special attention should be paid to confidentiality principle, subjects insurance, subjects' compensation or redress principles, trial suspension and termination principles, accountability, definition of intellectual property rights, and thesis publication policies, etc.

Article 28 Research offices or laboratories should not subcontract the clinical trials; If part of the work cannot be completed, commission contract should be signed in advance between sponsor and other related institution(s).

Article 29 Research offices or laboratories should not add any contents or change the trial methods without authorization. If the Sponsor requires additional services, the two sides should sign additional agreements before the start of the trial under the premise that the additional work does not conflict with the clinical trial protocol, and does not damage the rights or safety of the subjects.

Chapter VIII The clinical trial protocol

Article 30 The clinical trial protocol should be developed prior to the start of Phase I trial, signed to confirm by the sponsor and the investigators upon consensus, and reported to the Ethics Committee for implementation after review and approval.

Article 31 Phase I trial protocol should be developed with reference to relevant technical guidelines based on a scientific nature and the protection of the subjects' rights.

Article 32 During the trails, should the Phase I trial protocol need to be amended, the new one must be approved by the Ethics Committee or filed for record. In case of emergency medical event or serious adverse events, the investigators can take necessary emergency measures beyond the trial protocol to ensure the safety of the subjects.

Chapter IX Subjects Management

Article 33 Phase I trial must protect the rights and safety of the subjects, the recruitment methods of which should be reviewed by the Ethics Committee.

Article 34 The majority of the Phase I trial subjects should be healthy adults, if special populations are required for recruitment, such as children, the elderly, pregnant women, patients or other vulnerable groups, justifiable reasons should be provided, and appropriate security measures should be taken.

Article 35 Prior to the start of the trial, the subjects should be fully informed and sign an informed consent; during the implementation of the trials, good communication should be maintained

《药物Ⅰ期临床试验管理指导原则（试行）》

（接上期）

第七章　合同和协议

第二十七条　试验之前，申办者和研究方应签署具有中国法律约束力的委托合同。在合同中明确试验内容和进度、双方责任和义务、委托研究经费额度，此外还应关注保密原则、受试者保险、受试者补偿或赔偿原则、试验暂停和终止的原则和责任归属、知识产权界定、发表论文方式等。

第二十八条　研究室或实验室不可将试验工作转包；如果不能完成部分工作，应事先由申办者与其他相关机构签署相关委托合同。

第二十九条　研究室或实验室不应擅自增加试验内容和改变试验方法。申办者如要求进行附加服务，双方应于相关工作开始之前签署附加协议，并承诺额外的工作不与临床试验方案相冲突、不损害受试者的权益与安全。

第八章　试验方案

第三十条　Ⅰ期试验开始前应制订试验方案，该方案由申办者与研究者达成共识并签署确认，报伦理委员会审查批准后实施。

第三十一条　Ⅰ期试验方案应在符合科学性和保障受试者权益的基础上，参照相关技术指导原则制定。

第三十二条　试验过程中，Ⅰ期试验方案如需要修改，修改后的试验方案必须经伦理委员会审批或备案。如试验中发生紧急医学事件或严重不良事件，研究者可以采取临床试验方案以外的必要紧急措施，以确保受试者安全。

第九章　受试者管理

第三十三条　Ⅰ期试验必须保障受试者的权益与安全，受试者招募方式应经伦理委员会审查。

第三十四条　Ⅰ期试验受试者多为健康成人，如需选择特殊人群，如儿童、老年人、孕期妇女、患者或其他弱势群体等进行研究，应有合理的理由，并采取相应保障措施。

with the subjects in order to enhance their compliance, and timely detect adverse events. During the trials, should the informed consent form need to be amended, the revised informed consent form must be approved by the Ethics Committee. A new informed consent should be obtained from the research subjects.

Article 36 In Phase I trial, subjects often receive no significant treatment benefits, the sponsor should give the subjects reasonable economic compensation. For subjects experience damages due to participation in the trials, the sponsor should be liable for corresponding treatment costs and reasonable compensations.

Chapter X Investigational drug administration

Article 37 The sponsor is responsible to provide investigational drugs, and should be liable for their quality.

Article 38 Clinical trial institutions should set up clinical trial pharmacy, with qualified storage facilities and equipment for study drug.

Article 39 An appropriate individual should be assigned to manage the investigational drugs, the receipt, storage, distribution, use, recovery, and return of the test drugs should be administered in accordance with Investigational Drugs Management System and SOP, and relevant records should be well kept. The preparation of investigational drugs should be in line with the requirements of trial protocol. The weighing, dilution and aseptic preparation of investigational drugs must comply with relevant regulations.

Article 40 The investigators are responsible for the use of investigational drugs, they should use investigational drugs in light of the trial protocol and random table, ensure that the subjects receive drugs on scheduled time and dosage, and make good records.

Article 41 The investigational drugs may not be used for other purposes, or sold publicly or covertly.

Chapter XI Management and Analysis of Biological Samples

Article 42 The collection, processing and preservation of biological samples should be in accordance with the clinical trial protocol and SOP. The labelling of the sample containers should have sufficient information, identifiable and unique.

Article 43 The transportation and preservation of biological samples should meet the requirements of the trial protocol and related SOP, to ensure that their integrity and activity are not affected, and records should be taken accordingly.

Article 44 During the trial, the identification and traceability of biological samples should be ensured, the records of the labeling, transportation and preservation of samples should be well kept, the sample storage archive should be established.

Article 45 Before the start of the analysis, a detailed test protocol for the analysis of biological samples should be developed according to the requirements of the trial protocol, which will enter into force with the signatures of laboratory directors, project leaders and the sponsor.

Chapter XII Data Management and Statistical Analysis

Article 46 The original Phase I trial data (including electronic data) is the first-hand information collected during the

第三十五条 试验开始前，应使受试者充分知情并签署知情同意书；试验实施中，应保持与受试者良好沟通，以提高受试者的依从性，及时发现不良事件。试验过程中，知情同意书如需要修改，修改后的知情同意书必须经伦理委员会审批，并再次获得受试者的知情同意。

第三十六条 在Ⅰ期试验中，受试者通常未获得治疗利益，申办者应给予受试者合理的经济补偿，对因参加试验而受到损害的受试者，申办者应承担相应的治疗费用和合理补偿。

第十章 试验用药品管理

第三十七条 申办者负责提供试验用药品，并对其质量负责。

第三十八条 药物临床试验机构应设临床试验药房，具备合格的试验用药品储存设施和设备。

第三十九条 试验用药品应有专人管理，按照试验用药品管理制度和SOP进行试验用药品接收、保存、发放、使用、回收、返还，并保留相关记录。试验用药品的准备要符合方案的规定。如需对试验用药品称重、稀释、无菌条件下的配制等，均要符合相关规定。

第四十条 试验用药品的使用由研究者负责，研究者应按试验方案和随机表使用试验用药品，确保受试者按时按量用药，并做好记录。

第四十一条 试验用药品不得他用、销售或变相销售。

第十一章 生物样本管理和分析

第四十二条 按照临床试验方案和SOP采集、处理和保存临床试验生物样本。样本容器的标识应有足够的信息量，易于识别和具有唯一性。

第四十三条 生物样本转运和保存应符合试验方案和相关SOP的要求，保证其完整性和活性不受影响，并做好记录。

第四十四条 在试验过程中，应保证生物样本的标识性和可溯源性，建立样本标识、移交和保存等相关记录和样本的储存档案。

第四十五条 在分析工作开始之前，应根据试验方案要求，制订生物样本分析详细的实验方案，并由实验室负责人、项目负责人及申办者签署后生效。

trials, whose authenticity, accuracy and completeness should be ensured. The data-generating devices, equipment and methods must be validated.

Article 47 The computer system refers to the information system that is used, directly or indirectly, for data reception, collection, processing, reporting and storage, or a system integrated in the automation equipment, including one or more hardware units and software. The computer system for clinical trial data management and statistical analysis must be validated, and have traceability automatically generated by the system, all changes to the data are automatically recorded; the original data should be saved timely during system upgrading, to prevent data loss or alteration. The application of computer systems should set strict log-in permissions and password management system.

Article 48 The verification measures (such as double entry, automatic system logic checks. etc.) should be performed for data entry to avoid data entry errors. The data verification and lock process should be recorded in detail, and data modifications should have appropriate supportive documentations.

Article 49 The statistical analysis staff shall develop statistical analysis protocol after the trial protocol is determined, refine and confirm the data before they are locked; the statistical analysis must adopt recognized statistical software and appropriate statistical

methods; the statistical analysis procedures must be programmed, the program source code should be readable to facilitate verifications; and the results of statistical analysis should be expressed in professional, objective and standardized terms.

Article 50 The statistical analysis of Phase I trials should focus on the impact of dosage on safety indicators, pharmacokinetic parameters, pharmacodynamic index and its variation patterns.

Chapter XIII Summary Report

Article 51 After the Phase I trial completion, the Summary Report of Phase I trial (hereinafter referred to as the Summary Report) should be drafted integrating all the clinical trial data. The Summary Report shall be signed and confirmed by the sponsor and principal investigators, and stamped with the seals of sponsors and clinical trial institutions. The biological sample analysis report should be signed by the Laboratory Director and stamped with the seal of the research institution.

Article 52 The structure and content of the Summary Report can refer to relevant technical guidelines, and reflect the characteristics of Phase I trial.

Chapter XIV Miscellaneous

Article 53 The State Food and Drug Administration is responsible for the interpretation of this Guideline.

Article 54 This Guideline shall enter into force as of the date of publication.

(December 5, 2011)

第十二章　数据管理和统计分析

第四十六条　Ⅰ期试验的原始数据（包括电子数据）是试验过程中采集的第一手资料，应保证其真实性、准确性和完整性。产生数据的仪器设备与方法需经过验证。

第四十七条　计算机系统指直接或间接用于数据接收、采集、处理、报告和存储的信息系统，或是整合在自动化设备中的系统，包括一个或多个硬件单元和相关软件。用于临床试验数据管理和统计分析的计算机系统应经过验证，并具有系统自动生成的稽查踪迹，对数据的所有修改都自动保留更改痕迹；计算机系统升级时应及时保存原有数据，防止数据丢失或更改。计算机系统的使用应有严格的登陆权限和密码管理制度。

第四十八条　数据录入应有核查措施（比如双份录入、系统自动的逻辑检查等）以避免数据录入错误。核查与锁定数据的过程应有详细记录，数据改动应有相应的文档支持。

第四十九条　统计分析人员在试验方案确定后制订统计分析计划，在数据锁定前加以细化和确认；统计分析必须采用公认的统计学软件和合适的统计学方法；统计分析过程必须程序化，程序源代码应具有可读性，以便核查；统计分析的结果表达应专业、客观、规范。

第五十条　Ⅰ期试验的统计分析应重点关注剂量对安全性指标、药代动力学参数、药效学指标的影响及其变化规律。

第十三章　总结报告

第五十一条　Ⅰ期试验结束后，综合临床试验的所有数据，撰写Ⅰ期试验总结报告（以下简称总结报告）。总结报告须经申办者和主要研究者签署确认，并由申办者和药物临床试验机构盖章。生物样本分析报告应由实验室负责人签署，并由其机构盖章。

第五十二条　总结报告的结构和内容可参考有关技术指导原则，并体现Ⅰ期试验的特点。

第十四章　附　则

第五十三条　本指导原则由国家食品药品监督管理局负责解释。

第五十四条　本指导原则自发布之日起施行。　（2011年12月5日）

SFDA Center for Drug Evaluation's 2012 Open Day Work Arrangements

SFDA Center for Drug Evaluation(CDE)'s Open Day Activities have provided an open window for government transparency, the 2012 Open Day Activities shall witness major adjustments: the former single pattern of activity shall be adjusted to diversified activities that integrate online registration with CDE invitation and give equal importance to popularity (Universal type) & professionalism (In-depth type). The online registration shall be enabled in the meantime.

国家食品药品监督管理局药品审评中心2012年开放日工作安排

国家食品药品监督管理局药品审评中心开放日活动是审评中心对外公开的窗口，2012年的开放日工作将由单一活动模式调整为多元化的活动方式，网上报名与审评中心邀请相结合，普及与深入相结合。网上报名同时开通。

2012年药品审评中心开放日活动安排
2012 Open Day Work Arrangements

Time 活动时间	Types of activities 活动类型	Target attendees 活动对象	Organization models 组织方式	Overview of Activities 活动内容概述
March 6 3 月 6 日	In-depth type 深入型	Veterans in registration and drug R&D, know the ropes of CDE´s previous works, and familiar with relevant laws and regulations on Drug Administration (hereinafter inclusive). 长期从事注册和药品研发工作，了解审评中心既往工作，且熟悉药品管理相关法规的有关人员（下同）。	Online registration, sequential arrangement, 20~25 one time. Timing: the afternoon of the second Tuesday of the month for the activities. 网上报名，按序安排，每期20～25 名。时间安排为活动当月的第二周周二下午。	Introduce CDE´s recent important regulations, key work ideas and implementation status, site visits, reviewers´ site briefing, panel discussions. Duration: 3 hours. (hereinafter inclusive) 介绍审评中心近期实施的重要规范和重点工作的思路和执行情况，实地参观，审评工位审评人员实地讲解，组织座谈。时间 3 小时。（下同）
April 11 4 月 11 日	Universal type 普及型	Green hands in registration, or those who are unfamiliar with the basic information and works contents of CDE (hereinafter inclusive). 初涉注册事务或对药品审评中心基本情况和工作内容不甚了解的相关人员（下同）。	Online registration, sequential arrangement, 20 - 25 people one time. Timing: the afternoon of the second Wednesday of the month for the activities. 网上报名，按序安排，每期20 - 25 名。时间安排为活动当月的第二周周三下午。	Introduce the basic situation of CDE, including the organization, the review process, tips (for dossier submission, documents submission, and consultation etc.). Organize onsite visits (mainly including the workplaces of Dossier Management and Review Departments). Duration: 1.5 hours. (hereinafter inclusive) 介绍审评中心基本情况，主要包括组织机构设置，审评流程，办事须知（资料提交、公文提交、咨询等），组织现场参观（主要包括资料管理部门和审评工作场所）。时间 1.5 小时。（下同）
May 8 5 月 8 日	In-depth type 深入型	Ditto 同上	Ditto 同上	Ditto 同上
June 6 6 月 6 日	Universal type 普及型	Ditto 同上	Ditto 同上	Ditto 同上
July 10 7 月 10 日	In-depth type 深入型	Ditto 同上	Ditto 同上	Ditto 同上
August 8 8 月 8 日	Universal type 普及型	Ditto 同上	Ditto 同上	Ditto 同上
September 11 9 月 11 日	In-depth type 深入型	Ditto 同上	Ditto 同上	Ditto 同上

October 17 10 月 17 日	Universal type 普及型	Ditto 同上	Ditto 同上	Ditto 同上
To be determined 待定	Thematic type 专题型	In light of CDE´s key tasks of 2012, carry out communication and discussions with registration applicants experts and other professionals around the deepgoing problems of drug R&D, evaluation, etc. in a more specific field. 根据年内审评中心的重点工作，在更专业的领域与注册申请人、专家等专业人士围绕药品研发、评价等深层次问题 开展沟通交流 CDE shall invite the participation of representatives. 审评中心特邀代表参加。 Appropriate schedule. 适时安排。		

(February 9, 2012) （2012年2月9日）

Special Focus 业界专题

Scrip Releases 2011 List of Global Top 100 Pharmaceutical Companies

Scrip, the global authority of pharmaceutical news agencies recently announced the 2011 List of Global Top 100 Pharmaceutical Companies, Pfizer remains at the top, Sanofi-Aventis ranked second, Merck Sharp and Dohme rose from last year's 7th to the 3rd place.

Judging from the List, European and American enterprises dominated the forefront of the ranking List. Of the Top 25 enterprises with sales exceeding five billion U.S. dollars, 10 enterprises are from the United States, 9 from Europe, 5 from Japan, and 1 from Israel.

Scrip公布2011全球百强制药企业名单

全球权威的全球制药新闻机构Scrip在近期公布了2011年最新的全球100强制药企业排行榜，辉瑞继续位居榜首，赛诺菲排名第二，默沙东制药公司从去年的第7位跃居第3位。

从排名上看，百强药企排行榜中位居前列的以欧洲和美国的企业为主。前25名销售额超过50亿美元的企业，10家来自于美国，9家来自于欧洲，5家来自于日本，1家来自于以色列。

排名	公司	排名	公司	排名	公司
1	辉瑞 Pfizer	2	赛诺菲 Sanofi-Aventis	3	默沙东 Merck Sharp and Dohme
4	诺华 Novartis	5	葛兰素史克 GlaxoSmith-Kline	6	罗氏 Roche Group
7	阿斯利康 AstraZeneca	8	强生 Johnson&Johnson	9	礼来 Eli Lilly
10	雅培 Abbott Laboratories	11	百时美施贵宝 Bristol Myers Squibb	12	梯瓦 Teva
13	安进 Amgen	14	拜耳 Bayer	15	武田制药 Takeda
16	勃林格殷格翰 Boehringer Ingelheim	17	安斯泰来 Astellas	18	诺和诺德 Novo Nordisk
19	第一三共株式会社 Daiichi-Sankyo	20	卫才 Eisai	21	大冢控股 Otsuka
22	百特国际 Baxter International	23	默克 Merck	24	吉利德科技 Gilead
25	迈兰 Mylan	26	施维雅 Servier	27	三菱田边 Mitsubishi Tanabe
28	福雷斯特 Forest	29	奈科明 Nycomed	30	美国CSL制药公司 CSL

(February 10, 2012) （2012年2月10日）

The Status of China's Pharmaceutical Exports Remains Stable in 2011

China Chamber of Commerce for Import & Export of Medicines & Health Products recently released the 2011 statistics of China's pharmaceutical foreign trade, the data has shown that China's "tripartite confrontation (Asia, Europe and North America) of Major Pharmaceutical Foreign Trade Markets remains stable, accounting for more than 80% share of exports.

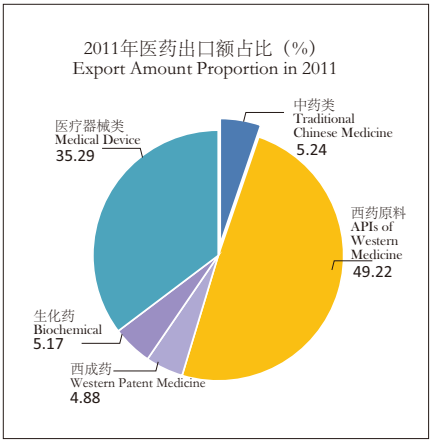
2011年中国医药保健品进出口统计
China's Import and Export of Medicines & Health Products in 2011

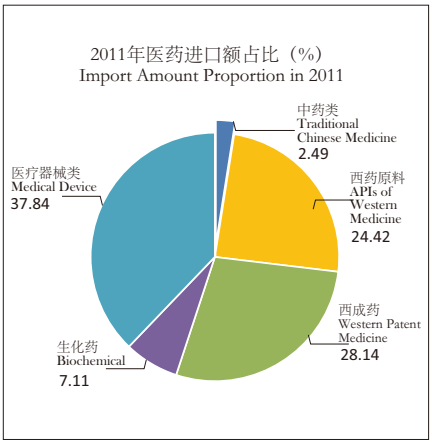
单位：亿美元（100 million）

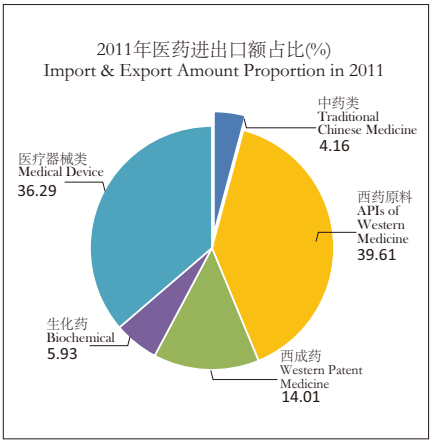
商品分类 Category	出口额 Export Amount	出口额同比(%) Growth Rate in Equal Terms	出口额占比(%) Export Amount Proportion	进口额 Import Amount	进口额同比(%) Growth Rate in Equal Terms	进口额占比(%) Import Amount Proportion
中药类 Traditional Chinese Medicine	23.32	36.48	5.24	7.15	29.07	2.49
西药类 Western Medicine	264.74	25.68	59.47	171.65	41.43	59.67
西药原料 APIs of Western Medicine	220	26.58	49.42	70.24	23.92	24.42
西成药 Western Patent Medicine	21.74	40.17	4.88	80.96	60.48	28.14
生化药 Biochemical	23	7.82	5.17	20.45	43.59	7.11
医疗器械类 Medical Device	157.11	53.62	35.29	108.87	55.62	37.84

2011年我国医药出口格局稳定

中国医药保健品进出口商会日前公布了2011年我国医药外贸行业统计情况，数据显示，我医药外贸主要市场格局稳定，亚洲、欧洲和北美洲合计占总出口额的80%以上。



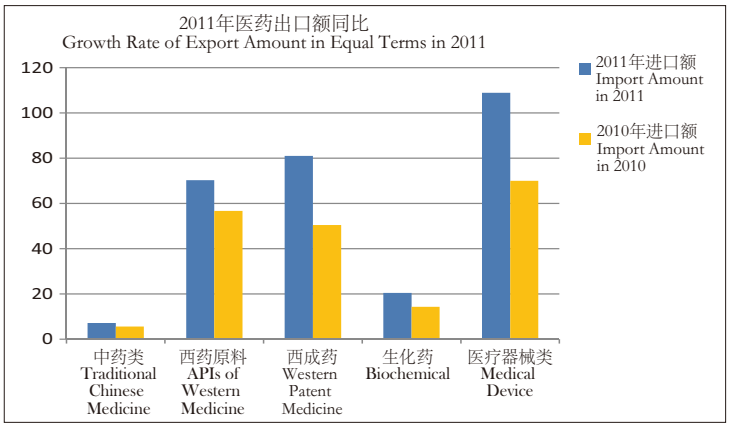


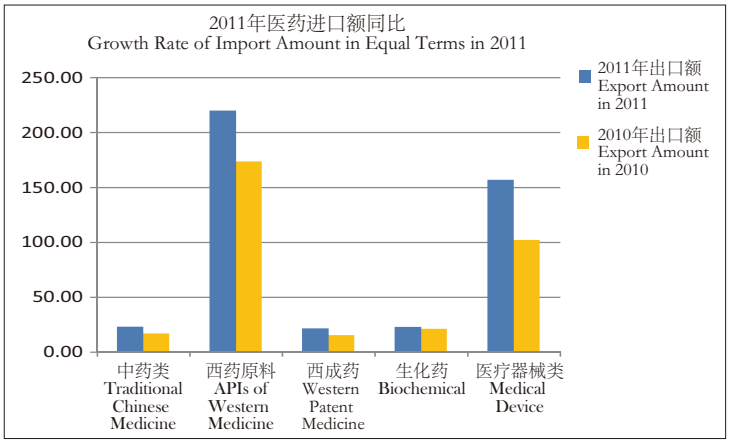


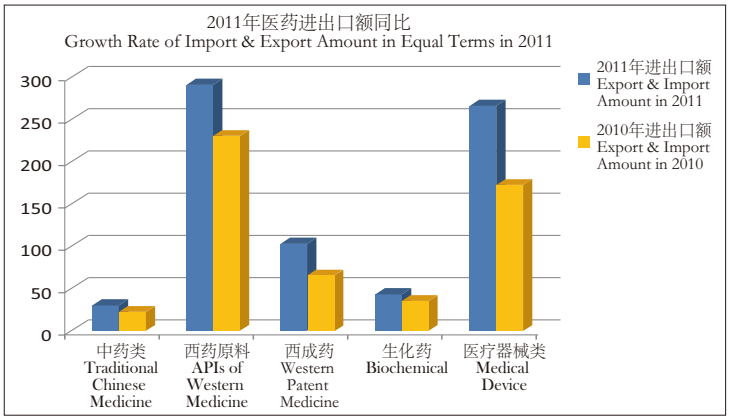
2011年中国医药保健品进出口统计
China's Import and Export of Medicines & Health Products in 2011

单位：亿美元（100 million）

商品分类 Category	进出口额 Export & Import Amount	进出口同比(%) Growth rate in equal terms	进出口占比(%) Export & Import Proportion
中药类 Traditional Chinese medicine	30.47	34.67	4.16
西药类 Western Medicine	436.39	31.44	59.55
西药原料 APIs of Western Medicine	290.25	25.93	39.61
西成药 Western patent medicine	102.7	55.7	14.01
生化药 Biochemical	43.44	22.14	5.93
医疗器械类 Medical Device	265.98	54.43	36.29







(February 9, 2012)　（2012年2月9日）

France-Gidy
(法国−Gidy)

Spain-Madrid
(西班牙−马德里)

Russia-Moscow
(俄国−莫斯科)

Brazil-Rio de Janeiro
(巴西−里约热内卢)

施维雅全球部分机构掠影
Photos of Servier in the world

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

• Read the electronic version of the newsletter please visit http://www.ccpie.org

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• 电子版Newsletter阅览请登录网站http://www.ccpie.org

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