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CHINA PHARMACEUTICAL NEWSLETTER

中国医药国际交流中心
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NEWS

SFDA Commissioner Shao Mingli Signs Cooperation Agreement with Tsinghua University In the morning of December 2, Shao Mingli, Commissioner of SFDA signed a cooperation agreement with Gu Binglin, President of Tsinghua University. The two parties will focus on scientific supervision and expand cooperation in science & technology, talent and management. This is the first time that SFDA carries out comprehensive strategic cooperation with a renowned university.

On December 1~5, the two parties jointly organized an advanced training course on food and drug regulatory strategy.

(Dec. 7, 2010)

SFDA Deputy Commissioner Wu Zhen meets Associate Assistant Deputy Minister of Health Canada Health Products and Food Branch On November 25, 2010, Catherine MacLeod, Associate Assistant Deputy Minister of Health Canada Health Products and Food Branch together with her entourage came to the SFDA to take part in the 2010 China-Canada High-level Meeting.

SFDA Deputy Commissioner Wu Zhen attended and chaired the meeting. Both parties made in-depth discussions on the 2010—2013 China-Canada Regulatory Cooperation Action Plan, this being the supervision on drugs, medical devices and natural health products reaching agreements on the relevant cooperation programs.

(Nov. 26, 2010)

SFDA Commissioner Shao Mingli Stresses Crackdown on Manufacturing and Selling Counterfeit and Substandard Drugs On November 23, SFDA held a videophone conference in Beijing to implement the program of combating infringement of intellectual property rights and manufacturing and selling counterfeit and shoddy goods.

SFDA Commissioner Shao Mingli stressed at the meeting that food and drug supervision departments at all levels should work in close coordination with relevant departments in the next five months, carry out and implement the requirements of the special action.

Shao Mingli stressed that we should focus on combating publicizing and selling counterfeit medicines with the help of the Internet, carry out a special action on cracking down violations of intellectual property rights and making and selling counterfeit and shoddy goods, strengthen publicity, create an atmosphere, make the public understand laws and regulations related to drug administration and basic medication knowledge, and guide them to obtain drugs from legitimate channels to maintain their own health benefits.

Shao Mingli required that food and drug supervision departments at all levels should take advantage of the ongoing drug safety campaign, crack down the illegal acts of manufacturing and selling counterfeit and substandard drugs and disruption of drug production and operation order.

(Nov. 24, 2010)

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SFDA Commissioner Shao Mingli Requires Promoting the Electronic Supervison of Essential Drugs Firmly and Unswervingly

Exchange of Electronic Supervison of Essential Drugs Conference was held in Beijing on November 25~26, 2010. SFDA Commissioner Shao Mingli announced at the meeting that the push should to towards electronic supervison of all varieties of essential drugs forcefully, firmly and unswervingly to achieve the target stage laying a solid foundation for promoting the national essential drug system and ensure quality safety for essential medicines.

Shao stressed the implementation of electronic supervison is the basis for smooth implementation of essential drug systems. A unified platform must be set up that covers the whole system and all the pharmaceutical production and operation enterprises all over China, provide important support for the future realization of the whole process of supervison essential drugs. It is particularly urgent that starting from 2011 being included into the electronic supervison will become a prerequisite for enterprises' participation in the procurement of essential drugs thus having a direct influence on the production and supply of essential drugs, the interests of drug production and operation enterprises and the implementation of essential drug system. All departments must put the electronic supervison of essential drugs as the top priority of their current work status.

Participants at the conference included leaders of the food and drug administration of all provinces (autonomous regions and municipalities) and officials in charge of electronic supervison of drugs. (Nov. 27, 2010)

CHINA-PHARM 展览会展品　Exhibits of CHINA-PHARM 2010

国家食品药品监管局局长邵明立要求坚定不移 毫不动摇地推进基本药物电子监管

2010年11月25–26日，基本药物电子监管工作交流会在北京召开。国家食品药品监管局局长邵明立在会上要求，要统一思想，坚定信心，毫不动摇地推进基本药物全品种电子监管工作，实现阶段性目标，为推进国家基本药物制度、确保基本药物质量安全奠定坚实基础。

邵明立强调，实行电子监管是确保基本药物制度顺利实施的重要基础。我们要建成覆盖全系统、全国生产经营企业的统一平台，为今后实现基本药物全过程监控提供重要支撑。尤为迫切的是，从2011年起纳入电子监管将成为企业参与基本药物采购的先决条件之一，直接影响基本药物的生产供应、药品生产经营企业的利益和整个基本药物制度的施行。各部门必须坚定不移、全力以赴，把基本药物电子监管作为当前工作的重中之重，切实抓紧抓好。

各省（区、市）食品药品监管局领导和负责药品电子监管工作的负责人参加了会议。（2010年11月27日）

Supplementary Notice on Further Strengthening Electronic Supervision of Essential Drugs

Comprehensive planning for electronic supervision of all varieties of essential drugs has been made according to the Notice on Electronic Supervision of all Varieties of Essential Drugs (SFDA [2010] 194) and Notice on Implementation of Electronic Supervision of all Varieties of Essential Drugs (SFDA [2010] 237)

SFDA issued another Supplementary Notice:

Strengthening Electronic Supervision of Essential Drugs on December 22, for further promoting the electronic supervision of all variety of essential drugs:

Notice on Electronic Supervision of all Varieties of Essential Drugs (SFDA [2010] 194) and Notice on Implementation of Electronic Supervision of all Varieties of Essential Drugs (SFDA [2010] 237) making comprehensive deployment on the electronic supervision of all varieties of essential drugs. In order to promote its in-depth implementation, solve problems existing through the implementation, a supplementary circular on the relevant matters is hereby given as follows:

I. Enhancing electronic supervision of imported bid-winning essential drugs

All imported varieties of bid-winning essential drugs should be entered into the network and coded according to the requirements of documents of SFDA [2010] 194 and 237. For varieties that are

关于进一步加强基本药物电子监管工作的补充通知

为推动基本药物全品种电子监管工作的开展，在《关于基本药物进行全品种电子监管工作的通知》（国食药监办〔2010〕194号）和《关于做好基本药物全品种电子监管实施工作的通知》（国食药监办〔2010〕237号）已对基本药物实施全品种电子监管工作进行全面部署的基础上，12月22日，国家食品药品监督管理局发布《关于进一步加强基本药物电子监管工作的补充通知》，内容如下：

《关于基本药物进行全品种电子监管工作的通知》（国食药监办〔2010〕194号）和《关于做好基本药物全品种电子监管实施工作的通知》（国食药监办〔2010〕237号）已对基本药物实施全品种电子监管工作进行了全面部署。为推动该项工作的深入开展，解决当前实施过程中存在的有关

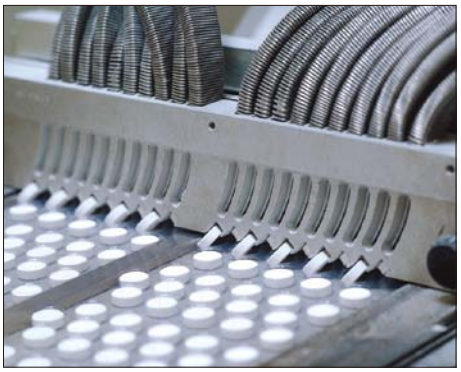
sub-packaged in China the sub-packaging manufacturers must print/paste the drug electronic supervision code with a unified logo in the smallest sales package before March 31, 2011.

Those drugs that are sub-packaged in the original producing areas, relevant enterprises shall print/paste the drug electronic supervision code with a unified logo in the larger package before March 31, 2011 and print/paste the same on the smallest one before December 31, 2011. These companies affected by these new regulations should complete the task of network entry, coding, registration and write-off after verification.

Training of the imported manufacturers will be organized by SFDA. The annual service fee for 2010 digital certificate (Key fee: 300 RMB/key/manufacturer) of manufacturers will be paid by the administration of the province (autonomous region or municipality) where the enterprise is located. If any digital certificates are needed expenses shall be the onus and be borne by the manufacturer. Other related expenses incurred shall also be borne by the enterprises concerned.

II. Standardizing management of printing/pasting electronic supervision codes on some Minimum packages

According to the requirements of the annex--"Printing Standard of Drug Supervision Code" the-- "Supplementary Notice on Related Problems Arising from Implementation of Electronic Supervision of Drugs (SFDA [2008]153)" states:-- If the size of the minimum package is too small or the bottles are specially shaped and under other special circumstances--where drug electronic supervision codes with unified logo cannot be printed/pasted the code may be printed on the larger package of the minimum one. If there are any such variances the manufacturers should apply to the provincial food and drug administration for its examination and approval. Thereafter they should be confirmed in the system applicable.



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If the imported varieties of bid-winning essential drugs that are packaged in the original producing areas belong to circumstances prescribed in the preceding paragraph, their offices or authorized agents in China shall apply to the provincial food and drug administration for its examination and approval. Thereafter they should be confirmed in the system applicable.

III. Guiding drug electronic supervision and manufacturers on system integration transformation

System integration of manufacturers plays an important role in the smooth completion of varieties of electronic supervision. The provincial administrations should guide the enterprises in their jurisdiction to design their technical transformation programs according to their actual situations, scales, financial capacity and enterprise resource planning (ERP) system status, choose suitable and reliable system integrators, urge drug manufacturers to transform production lines and jointly debug and test with SFDA system platform so that electronic supervision of all varieties of essential drugs will be completed on schedule.

IV. Strengthening electronic supervision of the varieties of essential drugs added by the provinces

The network entry of the varieties of essential drugs added by the provinces shall be managed by the corresponding provincial administrations. The enterprises

问题，现就有关事宜补充通知如下：

一、加强中标的基本药物进口品种的电子监管

凡中标的基本药物进口品种，应按照国食药监办〔2010〕194号、国食药监办〔2010〕237号文件要求，积极做好相关品种的入网、赋码工作。在国内分包装的中标的基本药物进口品种，分包装生产企业应于2011年3月31日前在最小销售包装上加印（贴）统一标识的药品电子监管码；在原产地包装的中标的基本药物进口品种，相关企业应于2011年3月31日前在大包装上加印（贴）统一标识的药品电子监管码，2011年12月31日前在最小销售包装上加印（贴）统一标识的药品电子监管码。上述企业应按照国家食品药品监督管理局要求做好入网、赋码和核注核销工作。

进口生产企业培训由国家食品药品监督管理局统一组织。进口生产企业2010年数字证书年服务费（密钥费：300元/把/家企业）由所在省（区、市）局负责统一支付。企业如需增加数字证书，由企业自行承担费用。企业所发生的其他相关费用，由企业自行承担。

二、规范部分最小包装印（贴）药品电子监管码的管理

按照《关于实施药品电子监管工作有关问题的补充通知》（食药监办〔2008〕153号）附件中“药品电子监管码印刷规范”要求，对于产品最小包装体积过于狭小或属于异型瓶等特殊情况，无法在产品最小包装上加印（贴）统一标识药品电子监管码的品种，可在最小包装的上一级包装上加印（贴）统一标识的电子监管码。具体品种由药品生产企业向企业所在地的省局提出申请，由省局负责审查，并在系统中确认。

在原产地包装的中标的基本药物进口品种，如属于前款所规定的情形，由其驻中国境内的办事机构或者由其委托的中国境内代理机构向所在地的省局提出申请，由省局负责审查，并在系统中确认。

三、做好药品电子监管生产企业系统集成改造的指导工作

药品电子监管中，生产企业系统集成对保障基本药物全品种电子监管工作的顺利完成具有重要作用，请各省局引导辖区内企业，根据实际情况，综合考虑企业自身的规模、财力和企业资源计划（ERP）系统现状，设计好技术改造方案，因地制

should apply to the China Pharmaceutical Electronic Supervision Network for drug electronic supervision codes.

Unsuccessful tenders of essential drug manufacturers are encouraged to join China Pharmaceutical Electronic Supervision Network voluntarily.

The unsuccessful tenders of essential drug manufacturers that join China Pharmaceutical Electronic Supervision Network voluntarily will be managed by their corresponding provincial administrations. These enterprises should apply to China Pharmaceutical Electronic Supervision Network for drug electronic supervision codes.

Varieties that have joined in China Pharmaceutical Electronic Supervision Network should be registered and written-off after verification by operation and wholesale enterprises to ensure the normal operation of the network and the integrity and reliability of the data.

V. Further increasing the intensity of training and technical guidance

Information management departments of provincial administration should effectively conduct training of drug electronic supervision on the production and wholesale companies and staff of drug regulatory agencies in their jurisdiction, make good use of technical advantages, coordinate and conduct technical services of electronic supervision in their jurisdiction. (December 28, 2010)

宜、实事求是地自由选择合适并可信赖的系统集成商；敦促药品生产企业做好生产线改造和与国家食品药品监督管理局系统平台的联调测试工作，确保基本药物全品种电子监管工作的按期完成。

四、加强各省增补的基本药物品种等的药品电子监管

各省增补基本药物品种入网由各省局自行管理，企业向中国药品电子监管网申请电子监管码。

鼓励未中标基本药物生产企业自愿加入中国药品电子监管网。凡自愿加入中国药品电子监管网的未中标基本药物生产企业，由各省局自行管理，企业向中国药品电子监管网申请电子监管码。

对加入药品电子监管网的品种，经营批发企业均应对该产品进行核注核销，以确保网络的正常运行和数据的完整、可靠。

五、进一步加大培训和技术指导工作力度

各省局信息管理部门要切实承担起对辖区内的生产、经营批发企业以及药品监督管理部门工作人员的药品电子监管培训工作，充分发挥信息管理部门的技术优势，协调并做好所在地的电子监管技术服务工作。（2010年12月28日）

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SFDA Carries out Pilot Work of Drug Safety Responsibility System Evaluation

To further establish and improve the drug safety responsibility system, SFDA recently issued "Guidance on Carrying out the Pilot Work of Drug Safety Responsibility System Evaluation ". It decided to carry out pilot work of drug safety responsibility evaluation in certain places and to encourage qualified provinces (autonomous regions and municipalities) to conduct the pilot work.

The assessment will focus on recourses guarantees, strengthening long-term supervison to set up coordination mechanisms, improving emergency management, strengthening publicity and education, etc. Pilot work was conducted based on the experience of other pilot work ended in October 2011, to implement the work in a larger scale in 2012 and explore a long-term mechanism of strengthening drug safety. So far, the reference index and assessment criteria for the pilot work of drug safety responsibility system have been developed, which will soon be issued to provinces (autonomous regions and municipalities) for their reference.

(Dec. 21, 2010)

国家食品药品监督管理局组织开展药品安全责任体系评价试点

为进一步建立健全“地方政府负总责，监管部门各负其责，企业是第一责任人”的药品安全责任体系，近日，国家食品药品监督管理局下发了《关于开展药品安全责任体系评价试点工作的指导意见》，决定在部分地方组织开展药品安全责任体系评价试点工作，并鼓励有条件的省（区、市）自行开展试点，主要从资源保障、加强长效监管、建立协调机制、完善应急管理、强化宣传教育等方面对试点地区进行评价。试点工作将在2011年10月底前实施试点工作经验的基础上，争取2012年在更大范围内组织实施，以探索强化药品安全的长效机制。目前，药品安全责任体系试点工作评价参考指标和评分标准已经拟定，将下发供各省（区、市）在开展试点时参考使用。

（2010年12月21日）

SFDA Requires Further Enhancement of Supervision and Inspection to TCM Production

In order to strengthen the supervision to the production and distribution of traditional Chinese medicine (TCM) and guarantee the product quality the SFDA issued a notice specifying relevant requirements on further enhancement of the supervision and inspection to the TCM production on November 28, 2010.

The notice states that the food and drug administrations at provincial levels should pay special attention to new problems aroused in the production and operation of TCM as well as production quality and safety risks. They should strengthen leadership, clarify regulatory responsibility and carry out supervison and inspection on TCM production quality--to eliminate safety risks, strengthen supervision and inspection on the purchase of crude drugs and herbal slices of TCM production enterprises within their jurisdiction. The inspection should be focused on procurement channels, relevant qualification certificates, supplier audit, quality test and quality archive in accordance with “Chinese Pharmacopoeia" (2010 Edition). They should strengthen supervision and inspection of GMP in TCM production to prevent adulteration. On-site inspection should be focused on administering conditions, medicines pre-treatment or extraction conditions, intermediate product quality control, batch production records, the extract yield, material balance of herbal slices and Chinese medicine extract in accordance with the "Chinese Pharmacopoeia" (2010 version) and requirements of preparation product registration.

The notice requests that food and drug administration departments at all levels make consolidated supervision, combine the supervision of TCM with drug sampling and evaluation testing, strengthen on-site supervision and inspection of Chinese medicine production and include inspection work into the annual work plan of 2011 drug safety supervision. SFDA will supervise and inspect traditional Chinese medicine production in due course of time.(Dec. 3, 2010)

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国家食品药品监督管理局要求进一步加强中药生产监督检查工作

为加强中药生产经营环节监督管理，切实保证产品质量，2010年11月28日，国家食品药品监督管理局发出通知，就进一步加强中药生产监督检查工作提出要求。

通知强调，各省级食品药品监督管理部门必须高度关注当前中药生产经营环节出现的新情况，高度警惕中药生产质量及安全隐患，切实加强领导，落实监管责任，组织开展中药生产质量的监督检查，切实消除中药生产质量安全风险。要加强对辖区内中药生产企业药材和饮片购入情况的监督检查，特别是对生产企业药材、饮片购入渠道及相关资质证明、供应商审计、按照《中国药典》（2010年版）对购进药材和饮片的质量检验、质量档案等情况进行重点检查。加强对中药生产过程执行GMP情况的监督检查，防止生产过程中的掺杂使假。现场检查应特别关注企业按照《中国药典》（2010年版）和符合制剂产品注册要求的中药饮片和中药提取物的投料情况、中药材前处理或提取情况、中间产品质量控制、批生产记录、浸膏收率、物料平衡等情况。

通知要求，各级食品药品监督管理部门应注重发挥综合监管效力，将中药生产监管工作与药品抽验和评价性检验工作相结合，充分利用检验结果，加强对中药生产的现场监督检查，将监督检查工作纳入2011年药品安全监管年度工作计划。国家食品药品监督管理局将适时组织对中药生产监督检查工作进行督导检查。

（2010年12月3日）

SFDA Revises Model Instructions of Levonorgestrel Tablets Non-prescription Drugs

According to the results of the adverse reactions assessment, SFDA decided to revise model instructions of levonorgestrel tablets non-prescription drugs to control risks. At the same time, it required that the food and drug regulatory authorities of provinces (autonomous regions and municipalities) notify drug manufacturers within their jurisdiction to amend the instructions and labels as soon as possible and timely notify the amendment to related medical institutions, pharmaceutical operation

国家食品药品监督管理局修订左炔诺孕酮片非处方药说明书范本

根据不良反应评估结果，为控制药品使用风险，国家食品药品监督管理局决定对左炔诺孕酮片的非处方药说明书范本进行修订。同时，要求各省（区、市）食品药品监管部门通知辖区内药品生产企业尽快修订说明书和标签，并将修订的内容及时通知相关医疗机构、药品经营企业等单

enterprises and other units. Related drug manufacturers should also take the initiative to track the clinical application safety of such drugs, collect adverse reactions and report them timely, as required. (Dec. 2, 2010)

位。相关药品生产企业还应主动跟踪该类药品临床应用的安全性情况，按规定收集不良反应并及时报告。（2010年12月02日）

SFDA Reminds People of Increased Risk of Rhabdomyolysis Caused by Combination Use of Simvastatin and Amiodarone or High Dose of Simvastatin

On November 16, " the 34th Adverse Drug Reaction Information Bulletin" issued by the National Adverse Drug Reaction Supervison Center said that foreign drug administrations found that combination use of simvastatin and amiodarone or high dose use of simvastatin may increase the risk of rhabdomyolysis. Considering that this risk also exists in China's clinical applications, and other serious adverse drug reactions of simvastatin can not be ignored the SFDA reminded the majority of medical staff, pharmaceutical manufacturers and the public that combination of simvastatin and amiodarone or high doses of simvastatin may increase the risk of rhabdomyolysis. (Nov. 16, 2010)

国家食品药品监督管理局提醒警惕辛伐他汀与胺碘酮联合使用或高剂量使用增加横纹肌溶解发生风险

11月16日，国家药品不良反应监测中心发布第34期《药品不良反应通报》并表示，近期国外药品管理部门发现辛伐他汀与胺碘酮联合使用或高剂量使用增加横纹肌溶解发生风险。考虑到此风险在我国临床应用中也同样存在，且辛伐他汀的其他严重药品不良反应也不容忽视，国家食品药品监督管理局提醒广大医务人员、药品生产企业和公众警惕辛伐他汀与胺碘酮联合使用或高剂量使用可能增加横纹肌溶解发生风险。（2010年11月16日）

General Office of the State Council Issues "Guidance on Establishing and Regulating Essential Drug Procurement Mechanism of the Government-run Grass-root Health Institutions"

On December 9, the General Office of the State Council issued "Guidance on Establishing and Regulating Essential Drug Procurement Mechanism of the Government-run Grass-root Health Institutions". Provincial-level platforms will be responsible for the centralized procurement and delivery. The prices will be linked with the quantity. The principle of good quality and reasonable price will be followed. Grass-root health facilities managers and medical representatives will participate in the development of procurement plans, bid evaluation, negotiations and other important aspects.

"The Guidance" clarifies the fifteen measures of establishing and regulating the procurement mechanism of essential drugs and five measures to guarantee its implementation. It also defines the time to implement it in various places. The implementation of the "Guidance" will bring about ten changes in the procurement mechanism of essential drugs.

1 The government will be the procuring entity.

2. Manufacturing enterprises are the suppliers responsible for the product supply process.

CHINA-PHARM 展览会展品　Exhibits of CHINA-PHARM 2010

国务院办公厅发布《建立和规范政府办基层医疗卫生机构基本药物采购机制的指导意见》

12月9日，国务院办公厅发布了《建立和规范政府办基层医疗卫生机构基本药物采购机制的指导意见》。基本药物采购将实行以省（区、市）为单位集中采购、统一配送，采购工作将实行量价挂钩，坚持质量优先、价格合理的原则。在采购计划制定、评标、谈判等重要环节，今后都将有基层医疗卫生机构管理者和医务人员代表参与。

《指导意见》明确了建立和规范基本药物采购机制的十五项措施和保障落实的五项举措，并规定了各地的实施时间，《指导意见》的实施将会给基本药物采购机制带来十大变化。

1．政府将成为采购主体；

2．生产企业是供货主体，对产品供应的全过程负责；

3．针对不同的基本药物，采用不同的招标方式，可以采用单独议价、邀请招标、询价采购、定点生产的方式；鼓励各地探索省际联合采购的方式；

3. Different tender ways will be adopted depending on essential drugs. Separate pricing, selected bidding, shopping and designated production may be employed. Inter-provincial joint procurement is encouraged.
4. Two-envelope system is encouraged in tendering. That is a bidding format in which technological tenders will be assessed first and then the business tender.
5. Prices will be linked with quantities. Enterprises may make quotations according to the quantity getting exclusive rights to supply.
6. The species, dosage form and specification for tendering of essential drugs should be determined according to the standard ones. Before the standard dosage forms and specifications of essential medicines of the province are publicized, there should not be more than three dosage forms for a species and over two specifications for a dosage form, in principle.
7. The price should be based on the actual market purchase price and the price of retail pharmacies over the past three years. It should not exceed them, in principle.
8. The payment of essential drugs to procurement agencies designated by the government will be made in a unified manner. In principle, it will not take over 30 days from the delivery and acceptance to payment.
9. Electronic supervison should be made on the whole variety of basic drugs, the establishment of information management including production, circulation, inventory and use is encouraged. Procurement information will be publicized and the rational use of grass-root health agencies will be supervised with the help of the information system;
10. "The Guidance" specifies that there should be a unified national market to address the problem of local protectionism during tenders.

(Dec. 20, 2010)

4．鼓励各地采用双信封制招标，即先评技术标，再评商务标的招标方式；

5．采用量价挂钩，单一货源承诺的机制，让生产企业可以按照数量进行报价，并获取独家供应的权利；

6．按照标准品种、剂型、规格确定招标基本药物的品种、规格和剂型，各省在国家尚未出台规范的基本药物剂型和规格之前，原则上一品三剂型两规格，即每种基本药物原则上不超过三种剂型，每种剂型对应的规格原则上不超过两种；

7．以各地近三年的基本药物市场实际采购价和零售药店的价格作为依据，原则上不得高出；

8．政府指定的基本药物采购机构进行货款的统一支付，原则上从交货验收到付款时间不超过30天；

9．对基本药物实行全品种电子监管，鼓励建立从生产、流通、库存、使用全过程的信息管理；采购信息公开；利用信息系统对基层医疗机构的合理用药进行监督；

10．针对招标中出现的各种形式的地方保护主义，"指导意见"明确了坚持全国统一市场，反对各种形式的地方保护主义的要求。（2010年12月20日）

Private Hospitals will Enjoy Equal Treatment with Public Ones in Access.etc

On November 26, to encourage and guide social capital to develop medical health services, National Development and Reform Commission, Ministry of Health, Ministry of Finance, Ministry of Commerce and Ministry of Human Resources and Social Security jointly issued "Opinions on Further Encouraging and Guiding the Social Capitals to Investing in Foundation of the Medical Organizations " "The Opinions" puts forward that private hospitals will enjoy equal treatment with public medical institutions in access, practice, development and so on.

(Dec. 6, 2010)

民营医院将在准入等方面与公立医院享受同等待遇

为鼓励和引导社会资本发展医疗卫生事业，发展改革委、卫生部、财政部、商务部和人力资源社会保障部等五部委11月26日发布了《关于进一步鼓励和引导社会资本举办医疗机构意见》。

意见提出民营医院在准入、执业、发展等方面享受与公立医疗机构同等待遇。（2010年12月6日）

NDRC Reduced the Prices of Some Drugs on November 29

On November 29, the National Development and Reform Commission (NDRC) issued a notice saying that the highest retail prices of some separate pricing drugs such as ceftriaxone will be reduced starting from December 12. The drugs involve seventeen

国家发展改革委降低部分药品价格

11月29日，国家发展改革委员会发出通知，决定从12月12日起，降低头孢曲松等部分单独定价药品的最高零售价格，涉及抗生素、心脑血管等十七大类药品。调整后的价格比现行规定价格平均降

categories like antibiotics and cardiovascular drugs. The adjusted prices are lower than the current prices by 19% on average. It is expected to reduce the burden on people by nearly 2 billion yuan every year. The retail prices of some commonly used drugs will be significantly reduced. Therefore, people will truly benefit from this decision. (Nov. 30, 2010)

低19%，预计每年可减轻群众负担近20亿元。一些常用药品零售价格水平明显下调，群众将切实感受到实际价格的降低。（2010年11月30日）

Mainland and Taiwan Sign Health Agreement

Chen Yunlin, President of Association of Relations Across the Taiwan Strait (ARATS) and Chiang Pin-kung, Chairman of the Taiwan-based Strait Exchange Foundation (SEF), signed Health Cooperation Agreement across the Taiwan Strait in Taipei on Dec. 21, 2010.

According to the agreement, the two parties will conduct extensive exchanges and cooperation in pharmaceuticals, including non-clinical detection, clinical testing, premarket review, production management, post marketing management, technical standards and inspection techniques.

In the aspect of quality and safety management, the two parties will set up cooperation mechanisms in Good Laboratory Practice (GLP), Good Clinical Practices (GCP), inspection of Good Manufacturing Practices (GMP) notification, disposal and tracking of pharmaceutical adverse reactions and adverse events, inspection, exchange of information and sources tracking of false, inferior, forbidden and illegal pharmaceuticals.

The two parties will establish a coordination mechanism in major pharmaceutical security incidents across the strait. The specific measures include emergency consultations, exchange of relevant information; take control measures to prevent the spread of events; provide facilities for on-site inspection; verify the release of information and inform each other; provide analysis of the causes and timely inform the results of the investigation and treatment; urge the responsible manufacturers and persons in charge to handle the disputes properly.

In the aspect of coordination of standards, the two parties will strengthen cooperation in the principle of recognized standards of pharmaceutical safety management actively promoting coordination of bilateral technical standards and specifications so as to enhance the safety and effectiveness of pharmaceuticals. Based on the above the two sides will carry out cooperation in pharmaceutical testing, examination and approval (inspection and registration) as well as the production management standards inspection.

In the cooperation of clinical trials, the two parties will conduct exchanges and cooperation in rules and regulations of clinical trials, management of executive agencies and teams, interests guarantee of subjects, review mechanism of clinical trials plans and test results. Under the premise of complying with GCP standards, they will minimize duplication of trials thereby actively promote cross-strait clinical trials and pharmaceutical research and development cooperation.

For the purpose of this agreement, "pharmaceuticals" refer to drugs, medical equipment, health food and cosmetics. It does not include Chinese herbal medicines. (Dec. 23, 2010)

海峡两岸签署医药卫生合作协议

12月21日，海峡两岸关系协会会长陈云林与台湾海峡交流基金会董事长江丙坤在台北签署了《海峡两岸医药卫生合作协议》。

根据《海峡两岸医药卫生合作协议》，两岸将在医药品的非临床检测、临床试验、上市前审查、生产管理、上市后管理，以及技术标准、检验技术等领域开展广泛的交流与合作。

在品质与安全管理方面，双方将在药品非临床试验管理规范（GLP）、药品临床试验管理规范（GCP）、药品生产质量管理规范（GMP）的检查，医药品不良反应及不良事件的通报、处置与追踪，伪、劣、禁及违规医药品的稽查、信息交换，以及源头追溯等方面建立合作机制。

在协处机制方面，双方将建立两岸重大医药品安全事件协处机制，具体措施包括：紧急磋商，交换相关信息；采取控制措施，防止事态蔓延；提供实地了解的便利；核实发布信息，并相互通报；提供事件原因分析，及时通报调查及处理结果；督促应负责的厂商及其负责人妥善处理纠纷。

在标准规范协调方面，双方将在医药品安全管理公认标准的原则下加强合作，积极推动双方技术标准及规范的协调性，以提升医药品的安全性和有效性。在上述基础上，进行医药品检验、审批（查验登记）以及生产管理规范检查合作。

在临床试验合作方面，双方将围绕临床试验的相关制度规范、执行机构及执行团队的管理、受试者权益保障和临床试验计划及试验结果审核机制等问题进行交流与合作。在符合药品临床试验管理规范（GCP）标准的前提下，尽量减少重复试验，积极推动两岸临床试验及医药品的研发合作。

协议所称的“医药品”，指药品、医疗器材、保健食品（健康食品）及化妆品，不包括中药材。（2010年12月23日）

Special Events

The Inaugural Conference of the Tenth Chinese Pharmacopoeia Commission and the 60th Anniversary Ceremony of Chinese Pharmacopoeia was held in Beijing

The Inaugural Conference of the Tenth Chinese Pharmacopoeia Commission and the 60th Anniversary Ceremony of Chinese Pharmacopoeia was held in Beijing on December 23.

The Tenth Chinese Pharmacopoeia Commission has an executive board and 23 professional committees consisting of 348 experts and scholars including 28 academicians. The Committee invited NPC Vice Chairman Sang Guowei as honorary chairman, MOH Minister Chen Zhu as chairman of the committee, MOH Deputy Minister, SFDA Commissioner Shao Mingli as deputy chairman.

Chen Zhu mentioned at the meeting that raising pharmaceutical standards is a long-term strategic goal. Everything must be done to connect "Chinese Pharmacopoeia" properly. Chinese Pharmacopoeia 2015 version should focus on the distinct theme of "scientific development" striving to achieve the target of enhancing both the level and number of entries, pay more attention to people's need of health, coordinating the inheritance and innovation, combination of science, use and standards, implementing the strategy of "going out". The 2015 version of "Chinese Pharmacopoeia" must cover national essential drugs, the medicine list of national basic medical insurance, industrial injury insurance and maternity insurance.

Shao Mingli said at the meeting that the main tasks of Pharmacopoeia in the coming period includes: advancing the national drug standards, accelerating the process of implementation of action plans and criteria management standardization, promulgating "Drug Standards Regulations" as soon as possible, speeding up the reform on the formation mechanism of the national drug standards, guiding and encouraging scientific research institutes and drug manufacturers to participate in and undertake research work of standards, make use of the national drug standard evaluation to add good drugs and eliminate bad ones, accelerating the informatization of national drug standards management, establishing a national drug standard information platform, unifying and regulating national drug standard information, setting up a standard database and application network that will cover all the statutory drug criteria.

At the meeting Sang Guowei presented awards to former members and experts who have made outstanding contributions in various historical periods of the development of Chinese Pharmacopoeia. Chen Zhu granted letters of appointment to members of the Tenth Pharmacopoeia Commission.

It is very important for the meeting to be held during the crucial period when China is deepening its health care system reform comprehensively and implementing “Health China 2020.” It marks China's drug standards is entering a new stage of development significant for strengthening supervision and management of drugs, improving the work of drug standards, completing the compilation of Chinese Pharmacopoeia 2015 edition, protecting people's medication safety, and promoting the healthy development of China's pharmaceutical industry. (Dec. 25, 2010)

第十届药典委员会成立大会暨中国药典60年庆典在京召开

12月23日，第十届药典委员会成立大会暨中国药典60年庆典在京召开。第十届药典委员会下设执行委员会及23个专业委员会，包括348名委员，其中两院院士28名。第十届药典委员会特别邀请全国人大常委会副委员长桑国卫担任名誉主任委员。卫生部部长陈竺任主任委员。卫生部副部长、国家食品药品监管局局长邵明立任常务副主任委员。

陈竺部长在会上指出，必须坚持不懈地把提高药品标准作为一项长期的战略目标，扎扎实实做好《中国药典》的各项工作。2015年版《中国药典》要紧紧围绕“科学发展”的鲜明主题，努力实现“收载标准水平和数量同步提高”的目标，更加注重人民群众的健康需要，更加注重统筹继承和创新，更加注重科学、使用与规范相结合，更加注重实施“走出去”战略。2015年版《中国药典》必须全面覆盖国家基本药物、国家基本医疗保险、工伤保险和生育保险用药目录。

邵明立局长在会上介绍说，今后一段时期药典工作的主要任务包括：加快推进国家药品标准提高行动计划实施和标准管理规范化进程，尽快出台《药品标准管理办法》；加快改革国家药品标准形成机制，引导和鼓励科研院所，特别是药品生产企业参加、承担标准研究和提高工作，做好国家药品标准评价，形成“有进有出、有增有减”的新格局；加快推进国家药品标准管理的信息化进程，要建立国家药品标准信息化平台，统一规范国家药品标准信息，建立能够覆盖所有法定药品标准的标准数据库和标准应用网络。

会上，桑国卫副委员长向受表彰的在《中国药典》发展的各个历史时期做出卓越贡献的老一辈药典委员会委员和专家颁奖。陈竺部长为第十届药典委员会委员颁发聘书。

此次大会是在我国全面深化医药卫生体制改革，深入实施“健康中国2020”战略规划的关键时期召开的一次十分重要的会议，标志着我国药品标准工作进入了一个崭新的发展阶段，对于加强药品监督管理，强化药品标准工作，高水平完成2015年版《中国药典》编制任务，保障人民用药安全，促进我国医药事业健康发展具有十分重要的意义。（2010年12月25日）

Special Brief

The Clinical Analysis Division of National Center for Safety Evaluation of Drugs obtains CAP Accreditation

Recently, the Clinical Analysis Division of National Center for Safety Evaluation of Drugs which is attached to the National Institute for the Control of Pharmaceutical and Biological Products received the CAP Accreditation after passing the onsite inspection by the experts from College of American Pathologists (CAP).

CAP accreditation is an international certification created by College of American Pathologists. It is now the internationally accepted standard of international laboratories an important basis for reference in the United States FDA drug review. Obtaining CAP accreditation means that the laboratory has achieved world-class standard recognized by relevant international agencies.

Most laboratories that have received CAP Accreditation are in the U.S.A. As of November 2010, the number of Asian laboratories having obtained CAP accreditation is as follows: 33 in Japan, 17 in Singapore, 15 in China Mainland, two in Hong Kong and 17 in Taiwan. The Clinical Analysis Division of National Center for Safety Evaluation of Drugs is the only certified laboratory in China Mainland that is engaged in drug preclinical safety evaluation and research.

The fact that the Clinical Analysis Division of National Center for Safety Evaluation of Drugs has received CAP certification provides an internationally recognized testing platform for Research and development of China's independent innovative drugs and pharmaceutical Research and development outsourcing services and helps enterprises obtain a “pass" into the international market. (Dec. 7, 2010)

国家药物安全评价监测中心临床检验实验室通过美国CAP认证

近日，中国食品药品检定研究院国家药物安全评价监测中心临床检验实验室在通过了美国病理学家学会（CAP）专家的现场检查后，通过了CAP认证。

CAP认证是美国病理学家学会创建的一种国际认证，目前是世界各国公认的国际级实验室标准，是美国FDA药品审评时参考的重要依据。通过CAP认证则意味实验室达到世界顶尖水准，并获得国际间各相关机构认可。

通过CAP认证的实验室大部分在美国。截至到2010年11月份，亚洲通过CAP认证的实验室在日本有33家、新加坡有17家、中国内地有15家、香港地区有2家，台湾地区有17家。国家药物安全评价监测中心是内地通过CAP认证中唯一从事药物临床前安全性评价研究的实验室。

此次安评中心通过CAP认证将为我国自主创新药物研发和医药研发外包服务提供了国际认可的检验平台，帮助企业获得去往国际市场的“通行证”。

（2010年12月7日）

Special Focus

业界专题

Medical Industry Keeps Growing at a High Rate in 2010

2010年医药工业保持高速增长

Outline of the Conditions of World Self-Medication Industry in Asia-Pacific Region

I. Asia-Pacific Region

In 2009, the OTC market in the Asia-Pacific region reached $27.5 billion, second only to the $ 30 billion European market. North America, whose OTC market was over $24 billion, ranked the third.

China's OTC market in 2009 was approximately $10 billion surpassing Japan and ranked first in Asia-Pacific region. Countries came third to fifth place were Australia, India and South Korea.

The Asian-Pacific countries whose market growth rate increased most rapidly from 2007 to 2009 was India (10.3%) China (9.2%) and Indonesia (7.7%) while Malaysia, the Philippines and Hong Kong came fourth to sixth place.

The growth rate of Japan, South Korea and Taiwan did not exceed 2.2% and came last.

II. China

With the constant improvement of the medical insurance system, self-medication

世界自我药疗产业亚太地区情况概要

一、亚太地区情况

2009年，亚太地区OTC市场规模达275亿美元，仅次于欧洲市场的300亿美元，北美地区以240多亿美元位列第三位。在亚太地区，2009年中国OTC市场规模约为100亿美元，超过日本成为亚洲第一，排在第三至第五位的分别是澳大利亚、印度和韩国。

从亚洲国家和地区的OTC市场增长率来看，2007年至2009年的平均增长率排在前三位的是印度、中国和印度尼西亚，分别为10.3%、9.2%和7.7%，马来西亚、菲律宾和中国香港排在第四至第六位，日本、

makes up a growing percentage of the drug consumption. China's OTC market grew from 1.9 billion RMB in 1990 to 129.5 billion RMB in 2008. In 2009, it overtook Japan and became the world's second largest OTC market, second only to the US market.

China adopted a system of classified management for prescription and non-prescription drugs starting from January 1, 2000.

The OTC market increasing by 11.5% in 2007, 6.8% in 2008 and 7.7% in 2009.

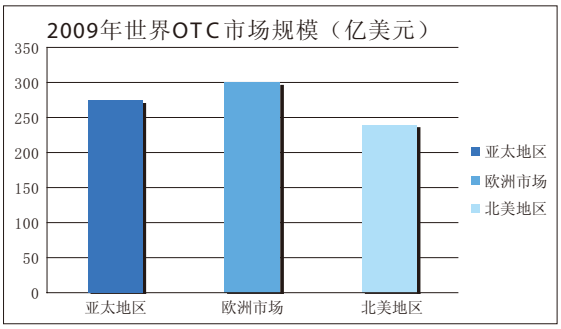
III. Japan

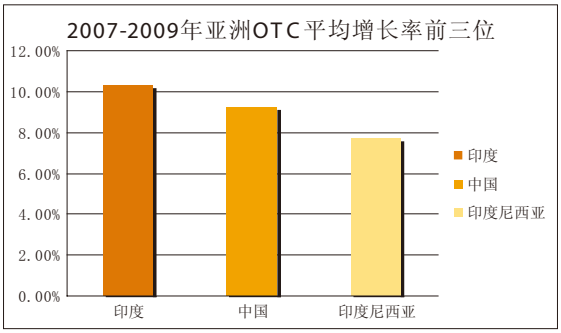
The proportion of Japanese medical costs in national income began to rise in 1990. This accounted for 5.9% in 1990, 7.2% in 1995, 8.1% in 2000, 9.1% in 2005 and remained 9.1% in 2007. Japanese national medical expenses in 2007 amounted to 34.163 billion Yen.

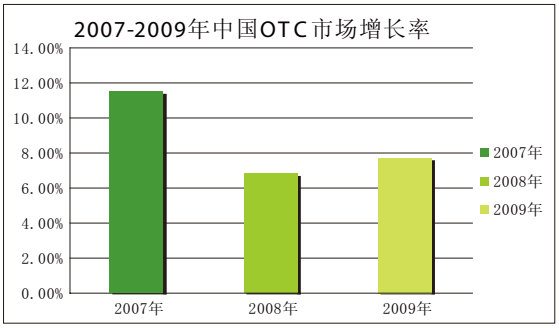
In recent years Japan adopted five measures: 1,to promote the use of generic medicines; 2, to reduce prices of health insurance drugs; 3, to increase the proportion of patients' payment; 4, to encourage responsible self-medication; 5, to strengthen the development of non-prescription drug market in order to enhance the development of the pharmaceutical industry.

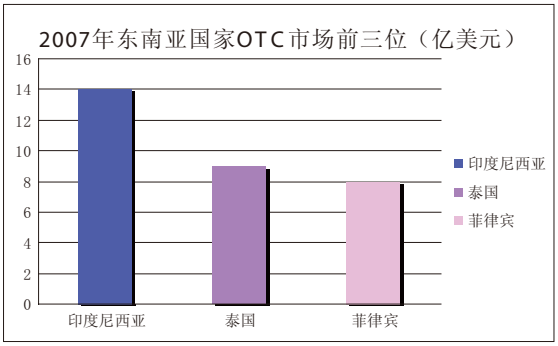
Japan began its reform on retail drugs in June, 2009. The retail scale reached 121.1 billion U.S. Dollars in 2009. Non-prescription drugs sold in Japanese pharmacies fall into three categories. Consumers can only buy the second and third categories. The retail sales of the second and third categories amounted to 78.7 billion and 36.3 billion U.S. dollars and accounted for 65% and 30% respectively. While the retail sales of the first class OTC drugs was only 6.1 billion U.S. Dollars making up 5% of the total retail sales.

The Japanese Ministry of Health, Labor and Welfare approved the change of seven pharmaceutical components into non-prescription drugs in 2008, 8 in 2009 and 2 in 2010.









IV. Australia

Australia's Therapeutic Goods Administration (TGA) believes that non-prescription drugs will continue to play

韩国和中国台湾的增长率均未超过2.2%，排在最后。

二、中国情况

随着医疗保险制度的不断完善，自我药疗在药品消费中所占的比重越来越大，中国OTC市场规模已经从1990年的19亿元上升到2008年的1295亿元，在2009年超过日本，成为仅次于美国的全球第二大OTC市场。

中国从2000年1月1日开始实施处方药与非处方药分类管理制度，2007年OTC市场增长11.5%，2008年OTC市场增长6.8%；2009年OTC市场增长7.7%。

三、日本情况

日本国民医药费用占国民收入的比例从1990年开始上升，1990年为5.9%，1995年为7.2%，2000年为8.1%，2005年为9.1%，2007年维持在9.1%，2007年国民医药费用总额为341.63亿日元。

近年来，日本采取五项措施，即一是促进普通药品的使用，二是降低医疗保险药品价格，三是增加患者支付比例，四是促进负责任的自我药疗，五是加大非处方药市场发展，以促进医药产业的发展。

2009年6月，日本开始改革药品零售业，2009年零售业规模达1211亿美元。日本药店销售的非处方药分为三类，消费者只能自主购买第二类和第三类药品，故第二、第三类药品的零售额分别以787亿美元和363亿美元占总零售额的65%和30%；而第一类药品的零售额仅为61亿美元，只占总零售额的5%。

2008年，日本厚生劳动省批准7个药品成份转换为非处方药，2009年批准了8个，2010年已批准了2个。

四、澳大利亚情况

澳大利亚治疗商品管理局（TGA）认为非处方药将在健康体系中继续扮演重要角色，指定了从2009年8月至2012年7月为

an important role in the health system thus specified a three-year restructuring plan from August 2009 to July 2012 and developed detailed tasks and goals at different stages to adapt to new developments.

From 2000 to 2004, the Australian Government approved the conversion of 14 prescription drugs into non-prescription ones but rejected 4 applications. From 2005 to 2009, however, 10 applications were approved while 10 were rejected.

Australian non-policy focus will shift to disease prevention. It will make better use of its limited medical resources to provide consumers with more choices: support the public for responsible self-medication by drugs and improve the health self-management skills of the public, etc.

V. Southeast Asian Countries

The sale of OTC in Southeast Asian countries in 2007 was $4.3 billion. The top three were Indonesia ($1.4 billion), Thailand ($900 million) and the Philippines ($ 800 million) followed by Malaysia, Singapore and Vietnam.

In all Southeast Asian countries the first three products in market scale are Vitamin and nutritional supplement category, cough, flu and allergy category including pain medication.

Vitamins and nutritional supplements category in Singapore, Malaysia and Thailand accounted for the largest proportion of their non-prescription drugs markets—73.4%, 60.2% and 57.9% respectively.

(Extracts from WSMI 8th Asia-Pacific Regional Conference, China Nonprescription Medicines Association)

期三年的机构改革计划，并制定详细的阶段性任务和目标，以适应新的发展形势。

在审批处方药转换非处方药申请方面，2000年至2004年，澳大利亚政府批准了14个申请，拒绝了4个申请；2005年至2009年，批准了10个申请，同时拒绝了10个申请。

澳大利亚非政策关注的重点将转向于疾病的预防，更好地利用有限的医疗资源，为消费者提供更多选择，支持公众进行负责任的自我药疗，提高公众的健康自我管理能力等等。

五、东南亚国家情况

2007年，东南亚国家非处方药市场规模为43亿美元，印度尼西亚、泰国和菲律宾分别以14亿美元、9亿美元和8亿美元排在前三位，马来西来、新加坡和越南排在第四至六位。在所有东南亚国家中，维生素和营养补充类，咳嗽、感冒和过敏类和止痛药类排在市场规模前三位。新加坡、马来西亚和泰国的维生素和营养补充类市场占各自国家非处方药市场的比例最大，分别为73.4%、60.2%和57.9%。

（摘自：世界自我药疗产业第8次亚太地区会议报告，中国非处方药协会）

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