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SERVIER
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NEWS

SFDA released the National Drug Abuse Monitoring Annual Report of the Year 2009 In the eve of the 26th June, the International Day against Drug Abuse and Illicit Trafficking, SFDA released the National Drug Abuse Monitering Annual Report of the Year 2009. The report data shows that the trend of heroin abuse in China has been further curbed, the situation regarding the prevalence of amphetamine-like substances is severe, the abuse of the medical narcotic drugs and psychotropic drugs under state control is lower, multiple drug abuse has become more complex and changeable, and reports of unlisted prescription medicine and non-prescription medicine abuse have increased.

Among new drug abusers, the abusers of narcotic drugs under state control such as heroin, opium and marijuana, the abusers of psychotropic drugs under state control such as amphetamines, and the abusers of medical narcotic drugs and psychotropic substances under state control showed three trends, namely "one decreasing, one increasing, and one relatively less".

Compared with 2005, the proportion of heroin abuse in 2009 decreased by 22.5%, but the proportion of methamphetamine ("ice") abuse increased by 31.4%. Abuse of medical narcotic drugs and psychotropic drugs did not demonstrate prominent growth, and the proportion of their abuse was low. The data shows that the more stringent was the control of drugs, the lower was the level of drug abusers being able to obtain them. However, according to the data monitored, the problem of multi-drug abuse in current drug abusers was serious; a number of unlisted prescription drugs and non-prescription drugs constituted the "multi-drug abuse".

It has been reported that China began to establish a drug abuse monitoring system in 1992, which has now become a drug abuse monitoring network covering 31 provinces, autonomous regions and municipalities directly under the central government,realized on-time and online monitoring data reporting. At the same time, food and drug regulatory departments have been continuously innovating methods of supervision, establishing a set of special control systems for specific drugs to effectively regulate the production and use of medical narcotic drugs and psychotropic substances and preventing the occurrence of drug abuse. Next, the state will expand and adjust the monitoring objectives and survey contents for drug abuse and improve the evaluation methods for the risk of medical narcotic drugs and psychotropic substances for potential dependence and abuse.

(28th June 2010)

Eleventh "W-J Awards" Selection Launched Selection for the eleventh "Wu Jieping Medical Research Award and the Paul Janssen Pharmaceutical Research Award" (abbreviated to the "W-J Awards") was officially launched in June. There are a total of 8 awards in the W-J Awards: the four for clinical medicine are gastroenterology, transplant surgery, gynecology & obstetrics and pediatrics; the two for public health are epidemiology and disease control and prevention, and hygiene and health promotion; and the two for pharmaceuticals are medicinal chemistry and pharmacology.

The W-J Awards are co-organized by the International Health Exchange and Cooperation Center of the Ministry of Health and Xi'an-Janssen Pharmaceutical Limited. They are conducted to commend and reward outstanding young Chinese health workers who are working hard in the field of health and medicine, have made outstanding contributions, and are widely recognized by the community and their peers; and are authoritative non-official awards in the field of medicine and health in China. (24th June 2010)

SFDA Warns That Switching Between Different Cyclosporine Formulations May Have Potential Risks On 8th June, Adverse Drug Reaction Information Bulletin No. 29, published by the SFDA Adverse Drug Reaction Monitoring Center, warned that switching between different cyclosporine formulations may cause

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potential risks to patients, according to drug safety information recently released by the British Medicines and Healthcare Products Regulatory Agency (MHRA). The SFDA reminded medical personnel, drug manufacturers and the public to guard against the potential risks brought about by the practice of switching between different cyclosporine formulations.

The SFDA suggested that switching between cyclosporine varieties with different trade names or formulations without monitoring should be avoided. If the treatment requires switching the cyclosporine products, the patient should use the drugs strictly in accordance with the doctor's instructions and advice, and the patient's blood drug concentration, serum creatinine level, blood pressure and other adverse reactions must be monitored. In order to avoid serious liver and kidney dysfunctions during cyclosporine administration, patients should be monitored with liver and renal functions periodically in accordance with the doctor's instructions and advices. (10th June 2010)

SFDA Issues an Announcement on Relevant Issues Concerning the Implementation of the 2010 *Chinese Pharmacopoeia*

The 2010 edition of the *Pharmacopoeia of the People's Republic of China* (hereinafter called *the Chinese Pharmacopoeia*) has been promulgated recently by [2010] No.5 Announcement of the Ministry of Health and will be enforced from 1st October 2010., the SFDA issued an announcement, on relevant issues concerning the implementation of the Chinese Pharmacopoeia, as follows:

Ⅰ The *Chinese Pharmacopoeia*, including notes, text and appendices, is the statutory basis that should be followed in pharmaceutical research and development, production, management, use and supervision. All national drug standards should conform to the relevant requirements of the notes and appendices in the Chinese Pharmacopoeia.

Ⅱ From the date, the 2010 edition of the Chinese Pharmacopoeia is enforced, all the standards of the drugs have been collected in the new edition, originally recorded in former Pharmacopoeias, including pharmaceutical standards issued by the Ministry of Health, standards issued by the SFDA and local versions of national standards shall all be repealed simultaneously.

If the drugs with registration standards not meeting the relevant requirements of the *Chinese Pharmacopoeia* the manufacturer should submit supplementary application according to the relevant provisions in the *Drug Registration Regulation*. If the test items recorded in the drug registration standards are more than in the Chinese Pharmacopoeia, or the quality indicators are higher than in the requirements of the Chinese Pharmacopoeia, the corresponding items and indicators of the original standards should be implemented, based on simultaneous implementation of the Chinese Pharmacopoeia.

For preparations and specifications which are not recorded in the Chinese Pharmacopoeia, quality standards should be implemented according to the relevant requirements for the same types as in the *Chinese Pharmacopoeia*, and the specification items should be implemented according to the original approval documents.

Ⅲ Drug manufacturers must change the instructions and labels of pharmaceuticals

国家食品药品监督管理局发布关于实施《中国药典》2010年版有关事宜的公告

《中华人民共和国药典》2010年版（以下简称中国药典）已由卫生部2010年第5号公告颁布，自2010年10月1日起执行。日前，国家食品药品监督管理局就实施中国药典的有关事宜发布公告，内容如下：

一、中国药典包括凡例、正文及附录，是药品研制、生产、经营、使用和监督管理等均应遵循的法定依据。所有国家药品标准应当符合中国药典凡例及附录的相关要求。

二、凡中国药典收载的品种，自执行之日起，原收载于历版药典、卫生部颁布药品标准、国家食品药品监督管理局颁布新药转正标准和地方标准上升国家标准的同品种药品标准同时废止。

药品注册标准不符合中国药典有关要求的，药品生产企业应按《药品注册管理办法》的有关规定提出补充申请。对于药品注册标准中收载的检验项目多于中国药典规定的或质量指标高于中国药典要求的，在执行中国药典的基础上，应同时执行原标准的相应项目和指标。

中国药典品种项下未收载的制剂规格，其质量标准按中国药典同品种相关要求执行，规格项按原批准证明文件执行。

三、药品生产企业应根据中国药典的增修订内容，按照国家食品药品监督管理局相关规定及程序变更药品说明书和标签。2010年10月1日起生产的药品必须使用变更后的说明书和标签。对于通用名称已作修订的药品，其原名称可作为曾用名过渡使用。

四、中国药典所收载的相同品种，如含有中国药典规定以外的杂质，应当增加杂质控制项目。

五、中国药典关于眼用制剂无菌要求

according to the amendments in the *Chinese Pharmacopoeia* and the relevant regulations and procedures of SFDA. Drugs produced from 1st October 2010 must use the changed instructions and labels. For drugs whose generic name has been revised, the original name can be used in the interim.

Ⅳ If the drug recorded in the *Chinese Pharmacopoeia* contained impurities outside the provisions of the Chinese Pharmacopoeia, impurity control methods should be added.

Ⅴ The specific implementation time for the requirements for sterilizing ophthalmic medication in the *Chinese Pharmacopoeia* will be issued separately in accordance with the requirements of GMP implementation.

Ⅵ Drug manufacturers should prepare actively for the implementation of the *Chinese Pharmacopoeia*. Any problems encountered during the implementation of the *Chinese Pharmacopoeia* should be reported to the provincial Food and Drug Administration in good time. Manufacturers should also continue to enhance their study of the quality standards and improve the levels of drug quality control.

Ⅶ Local food and drug supervisors and management departments at all levels should cooperate to publicize the *Chinese Pharmacopoeia*, strengthen guidance of the supervision of the implementation of the *Chinese Pharmacopoeia*, and collect and feed back related questions and comments in good time.

Ⅷ The Chinese Pharmacopoeia Commission is in charge of relevant work, such as guidance in the implementation of the China Pharmacopoeia.

Ⅸ The SFDA will open up a special column on the government website for implementing the *Chinese Pharmacopoeia*, answering relevant questions submitted from all quarters and organizing special inspections on the implementation in time.

(28th June 2010)

的具体执行时间将根据《药品生产质量管理规范》实施的要求另行规定。

六、药品生产企业应积极做好执行中国药典有关准备工作，对在中国药典执行中发现的问题应及时报所在地省级食品药品监督管理局。同时应不断加强质量标准研究，提高药品质量控制水平。

七、各级地方食品药品监督管理部门应配合做好中国药典的宣贯工作，加强中国药典执行中的监督与指导，及时收集和反馈相关问题和意见。

八、国家药典委员会负责中国药典执行中的具体指导等有关工作。

九、国家食品药品监督管理局将在政府网站开辟中国药典执行专栏，答复各地反映的有关问题，并适时组织对执行情况的专项检查。

(2010年6月28日)

"Leading the Scientific Development of the Pharmaceutical Economy by Innovation"----Wu Zhen, Deputy commissioner of SFDA, Gives Keynote Speech at China's Fifth Top 100 Pharmaceutical Enterprises Annual Meeting

On 23rd June, Wu Zhen, the deputy commissioner of SFDA, attended the China's Fifth Top 100 Pharmaceutical Enterprises Annual Meeting , and delivered a keynote speech entitled "Leading the Scientific Development of the Pharmaceutical Economy by Innovation"

Firstly, Wu Zhen reaffirmed the achievements of the pharmaceutical industry. He pointed out that since reform and opening-up 30 years ago, China's pharmaceutical industry has maintained rapid growth; the annual compound growth rate is approximately 19.9%, significantly higher than the GDP growth rate. At present, China has formed a relatively complete pharmaceutical industrial system, and completely ended the era of a lack of medical treatment; China is now able to independently produce a full range of medical products and make an important contribution to public disease prevention and treatment, and the maintenance of health. We can say that in the 30 years of reform and opening-up, the development of the pharmaceutical industry has achieved remarkable results, basically meeting the needs of medication for the masses. It is worth mentioning that despite suffering during the global financial crisis last year, China still maintained strong growth in the pharmaceutical industry, and the growth rate of the top 100 pharmaceutical enterprises improved still further in 2009.

以创新引领医药经济科学发展——国家食品药品监督管理局副局长吴浈在第五届中国制药工业百强年会上发表主题演讲

6月23日，国家食品药品监督管理局副局长吴浈出席了第五届中国制药工业百强年会，并作了题为"以创新引领医药经济科学发展"的主题演讲。

吴浈首先肯定了医药产业发展的成绩。他指出，改革开放30年以来，中国医药产业一直保持高速增长，年均复合增长率约为19.9%，明显高于同期GDP的增速。当前，我国已经形成了比较完备的医药工业体系，彻底结束了缺医少药的时代；现在我国能够自主生产品种齐全的医药产品，为公众防病治病、维护健康做出了重要贡献。可以说，改革开放30年以来制药工业的发展成效显著，基本满足了广大人民群众用药需求。值得一提的是，在去年遭受全球金融危机冲击的情况下，我国医药产业仍然保持强势增长，制药工业百强企业2009年的增速仍在进一步提高。

While affirming the achievements, Wu Zhen said that we must clearly recognize that compared with developed countries, the structural problems generated by the extensive development of China's pharmaceutical industry remain unresolved, and the problem of "numerous, small, scattered and low" still exists. For the aforementioned existing problems of the pharmaceutical industry, Wu Zhen proposed two solutions: firstly, innovation; and secondly, expanding abroad positively.

Wu Zhen said that enterprises are the main body for drug development, and we should increase investment in research and strengthen innovation. Enterprises must start original innovation, must pay attention to digestion, absorption and re-innovation of introduced technology, and must pay attention to integrated innovation. Meanwhile, the state should strengthen its guidance and support through policy guidance and funding, and actively encourage pharmaceutical innovation to change from imitation to simultaneous imitation and innovation. The State Board will give more support to innovation during reviews and approvals in future. At present, there are both opportunities and challenges. On the one hand, the strong development of the Chinese pharmaceutical economy provides strong support for pharmaceutical innovation, and by 2020, China's pharmaceutical market is expected to become the second largest pharmaceutical market in the world. On the other hand, the huge investment in China's new medical reform and the special project of major creation of new drugs has provided a broad space for the development and financial support of new drugs. Also, some domestic pharmaceutical companies have made some achievements in the independent development of new drugs and laid the foundation for independent innovation.

At the same time, however, multinational pharmaceutical giants have based their R & D centers and factories in China in an attempt to pinch some market share from China's pharmaceutical enterprises. China must therefore rely on technological innovation and product innovation to promote the independent innovation of enterprises, and then ultimately realize the structural adjustment of the industry and the scientific development of the economy.

As for how to go abroad actively, Wu Zhen proposed that domestic enterprises should strive to meet international standards to seize the international market: take the initiative to start authentication, and then access permits for the international market. Meanwhile, we should actively strengthen international exchanges and learn advanced management ideas and technology from developed countries.

Finally, Wu Zhen pointed out that the impact of the international financial crisis on the Chinese economy appears to have been an impact on economic growth, but in essence, it was an impact on the mode of economic development. In order to promote the scientific development of the pharmaceutical economy by innovation, the state will further raise standards to boost the pharmaceutical industry so it can speed up its joining with the international mainstream. (25th June 2010)

在肯定成绩的同时，吴浈指出，我们必须清醒认识到，与发达国家相比，中国医药产业粗放式发展所产生的结构性矛盾仍然没有解决，“多、小、散、低”的问题依然存在。针对医药产业存在的上述问题，吴浈提出了两个解决思路：一是加大创新力度，二是积极走出国门。

吴浈指出，企业是药品研发的主体，必须加大科研投入，加大创新力度。企业原始创新必须起步，必须重视引进技术基础上的消化、吸收、再创新，重视集成创新。同时，国家要加强政策和资金的引导扶持力度，积极推动医药创新从仿创结合、以仿为主向仿创并举转变。国家食品药品监督管理局今后在审评审批上对创新将给予更多的支持。当前机遇与挑战并存。首先，中国医药经济的强势发展为医药创新提供了强有力的支撑，到2020年，中国医药市场有望成为全球第二大医药市场。其次，中国的新医改和重大新药创制专项的巨额投入也为新药提供了广阔的发展空间和资金支持。再次，国内一些制药企业已经在新药自主研发方面取得了一些成绩，为自主创新打下了一定的基础。

但与此同时，跨国制药巨头纷纷把研发中心和工厂落户中国，欲进一步挤占中国制药企业的市场份额。因此，中国必须要靠技术创新、产品创新来促进企业的自主创新，最终实现产业的结构调整和经济的科学发展。至于如何积极走出国门，吴浈建议，国内企业要努力抢占国际市场，向国际标准看齐，主动去展开认证，进而获取国际市场的通行证。同时，要积极加强国际交流，借鉴发达国家先进的管理理念和技术。

吴浈最后指出，国际金融危机对中国经济的冲击表面上是对经济增长速度的冲击，实质上是对经济发展方式的冲击。为促进以创新引领医药经济科学发展，国家食品药品监督管理局将进一步提高标准，通过标准提高来带动医药产业加快与国际主流市场对接。 (2010年6月25日)

SFDA Requires the Implementation of E-monitoring of All Varieties of Essential Drugs

To implement the *Announcement on the Main Work of the Issuance of the Five Key Reforms of the Pharmaceutical and Health Care System in 2010* (State Council [2010] No.67) of General Office of the State Council, as required by the *Announcement on Electronic Supervision of All Varieties of Drugs* (SFDA Office [2010] No.194), the SFDA (hereinafter referred to as "the State Bureau") released an announcement

国家食品药品监管局要求做好基本药物全品种电子监管实施工作

为贯彻落实国务院办公厅《关于印发医药卫生体制五项重点改革2010年度主要工作安排的通知》（国办函〔2010〕67号）精神，根据《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〔

on 17th June on matters related to the implementation of electronic Supervision of all varieties of essential drugs.

It was announced that the State Bureau will be in charge of implementation of the electronic Supervision work of all varieties of essential drugs. The bureaus in provinces, municipalities and autonomous regions will be in charge of the implementation of electronic Supervision work of all varieties of essential drugs in their areas. Training on electronic Supervision of essential drugs will be conducted from 1st July 2010 to 15th August 2010. The State Bureau will make unified arrangements for the training, including the training of Supervision principles for the pharmaceutical electronic Supervision network, the issuance of digital certificates, relevant preparations for producing enterprises to access the network, information about pharmaceutical packaging line transformation and pharmaceutical coding printing, operating methods for pharmaceutical electronic Supervision network clients, and operating methods for Supervision code scanning terminals. And those trainings shall be undertaken by the Bureaus in provinces, municipalities and autonomous regions.

The announcement requires relevant drug producing and managing companies and drug regulatory departments at all levels to go through procedures to access the pharmaceutical electronic Supervision network. The access procedure requires:

1. Any successful enterprises winning production of essential drugs should join the pharmaceutical electronic Supervision network before 31st March 2011, and thoroughly prepare coding, registration and cancellation checks and early warnings for themselves.
2. From 1st April 2011 onwards, any varieties included in the essential drugs list which are not on the network or not using the unified identification code of electronic Supervision will not be allowed to participate in the bidding for the procurement of essential drugs.
3. Relevant pharmaceutical manufacturers should be equipped with Supervision code collecting equipment on request before 31st March 2011, and should carry out the registration and cancellation checks and early warning work for their current pharmaceutical drugs through the electronic Supervision network.
4. Drug regulatory departments at all levels should be thorough in the maintenance work of managing access to the electronic Supervision network, enterprise information, drug information and other basic data, and in real-time Supervision of the number and flow of drugs.
5. In 2010, the digital certificate annual service fee (the secret key fee of 300 yuan each per company) for the drug producing and marketing enterprises of the bureaus of provinces, autonomous regions and municipalities, those have already entered or in this time entered the network will be paid by the State Bureau. And the bureaus of provinces, autonomous regions and municipalities are responsible to conduct this matter.

If an enterprise needs additional digital certificates, it should pay the cost itself. Other costs occurred by the enterprise should also be paid by itself. (21st June 2010)

2010〕194号）要求，6月17日，国家食品药品监督管理局就基本药物全品种电子监管实施工作有关事项发布通知。

通知指出，基本药物全品种电子监管实施工作由国家食品药品监督管理局信息办牵头负责，各省（区、市）食品药品监督管理局具体负责本辖区基本药物全品种电子监管实施工作；2010年7月1日至2010年8月15日进行基本药物全品种电子监管培训，国家食品药品监督管理局统一组织包括药品电子监管网的监管原理、数字证书的发放、生产企业入网相关准备工作、药品包装线改造相关知识、药品赋码印刷相关知识、药品电子监管网客户端操作方法、监管码扫描终端操作方法等内容的培训，各省（区、市）食品药品监督管理局具体承办。

通知要求相关药品生产、经营企业和各级药品监管部门须办理药品电子监管网入网手续。入网手续要求如下：

1．凡生产基本药物品种的中标企业，应在2011年3月31日前加入药品电子监管网，按规定做好赋码、核注核销和企业自身预警处理的准备工作。

2．从2011年4月1日起，对列入基本药物目录的品种，未入网及未使用药品电子监管码统一标识的，一律不得参与基本药物招标采购。

3．相关药品经营企业应于2011年3月31日前按要求配备监管码采集设备，对所经营的相关药品通过药品电子监管网做好核注核销及预警处理工作。

4．各级药品监管部门应做好药品电子监管网的入网管理、企业信息、药品信息等基础数据的维护，并对药品数量和流向进行实时监控。

5．2010年各省（区、市）局已入网和本次入网的药品生产、经营企业数字证书年服务费（密钥费：300元/把/家企业）由国家食品药品监督管理局支付，各省（区、市）局负责统一办理。

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。 （2010年6月21日）

Production and Marketing Enterprises of Pharmaceutical Precursor Chemicals Need to Apply for New Certificates

On 4th June 2010, the SFDA released an announcement on the implementation of new licenses for designated production and marketing enterprises of pharmaceutical precursor chemicals.

The announcement said that in order to strengthen the management of pharmaceutical precursor chemicals and prevent them from being diverted to illicit channels, the Ministry of Health has

药品类易制毒化学品生产、经营企业需重新换证

2010年6月4日，国家食品药品监管局就做好药品类易制毒化学品定点生产、经营企业重新实施许可工作发出通知。

通知称，为加强药品类易制毒化学品管理，防止流入非法渠道，卫生部发布

issued *Procedures for Pharmaceutical Precursor Chemicals* (hereinafter referred to as *Procedures*), which came into operation on 1st May 2010. Production and marketing enterprises of pharmaceutical precursor chemicals which were approved by the food and drug regulatory departments before the implementation of the Procedures should apply for a new production or operation license within 3 months after the announcement was released.

The State Bureau requests the food and drug regulatory departments in the provinces, autonomous regions and municipalities to highlight the work of implementing new licenses for the production and operation of pharmaceutical precursor chemicals, to strengthen leadership, and to arrange the work meticulously. The departments should also develop work plans based on the situation of management in their areas, and complete the re-licensing work in accordance with the requirements in the *Procedures* within 3 months after the announcement was released. Departments should carefully examine the application information from enterprises according to the conditions and requirements of the *Procedures*, and organize on-site inspections, focusing on checking the security management of the production, storage and marketing links to carry out strict examination and approval. Drug manufacturers whose security managing equipment or security managing systems do not accord with the procedures will not be allowed licensed.

The announcement stresses that enterprises which have qualified as designated producers but have not carried on normal production are not allowed to be included in the scope of the re-licensing. Enterprises which were approved to produce or market pharmaceutical precursor chemicals before the implementation of the *Procedures* should not reproduce or purchase pharmaceutical precursor chemicals after 1st September 2010 if they have not applied for a new license on request, or the re-licensing was not approved. Existing pharmaceutical precursor chemicals stocked in enterprises should be documented and put on record, and then reported to the food and drug regulatory departments of their municipal districts for the records, and made available as required. (13th June 2010)

了《药品类易制毒化学品管理办法》（以下简称《办法》），于2010年5月1日起施行。《办法》施行前已经食品药品监管部门批准从事药品类易制毒化学品生产、经营的企业，应当在本通知下发之日起3个月内重新办理生产、经营许可。

国家食品药品监督管理局要求各省（区、市）食品药品监管部门要对药品类易制毒化学品生产、经营重新实施许可工作高度重视、加强领导、精心组织，并结合本地区监管工作实际，制定工作方案，在本通知发布后3个月内，按照《办法》规定的条件完成重新许可工作。要按照《办法》规定的条件和要求，认真审核企业申报资料，并组织开展现场检查，重点检查企业生产、储存、销售环节的安全管理情况，严把审批关。对未按规定配备相应安全管理设施和制定安全管理制度的药品经营企业，一律不予许可。

通知强调，原经批准取得定点生产资格，但目前未正常生产的企业，不纳入此次重新实施许可范围。《办法》施行前经批准从事药品类易制毒化学品生产、经营的企业，未按规定重新办理有关许可，或重新许可未获批准的，自2010年9月1日起不得再生产、购进药品类易制毒化学品。企业原有库存的药品类易制毒化学品，应当登记造册，报所在地设区的市级食品药品监管部门备案后，按规定售完为止。

(2010年6月13日)

Description by the SFDA Center for Drug Evaluation of Problems Relevant to Regulating Generic Names of Controlled Release Agents

On 9th June the Center for Drug Evaluation of the SFDA issued a description of problems relevant to regulating the generic names of controlled release agents, indicating that since the domestic names of various types of oral controlled release agents were not uniform in the past, and the English translations of corresponding varieties also have differences from the contents of related international technical specifications, the Center for Drug Evaluation no longer distinguishes between sustained release agents and controlled release agents by their in-vitro release characteristics since 2006. Instead, they are uniformly named sustained release formulations. Meanwhile, in order to further standardize the names of related products, if products originally licensed as controlled release formulations are applied for in supplementary applications or re-registration for importation, the Center for Drug Evaluation has standardized their names, then the names should be amended to sustained release formulations. This specification is only an amendment to the specification on the generic names, which does not involve changes in technology related to product quality such as the prescription process, the quality standards and the release behavior, which means that the quality of the product does not change even though the name has been amended.

(9th June 2010)

国家食品药品监督管理局药品审评中心关于规范缓“控”释制剂通用名有关问题的说明

国家食品药品监督管理局药品审评中心6月9日发布关于规范缓“控”释制剂通用名有关问题的说明，说明指出由于各类口服缓“控”释制剂的命名，既往国内并不统一，且相应品种的英文译名也与国际相关技术规范的内容有不一致之处，药品审评中心自2006年起已不再按体外释放特点区分命名缓释和“控释”制剂，而是统一命名为缓释制剂。

同时，为了进一步规范相关产品的名称，对于原已批准上市的命名为控释制剂的产品，若按补充申请或进口再注册等事项申报，药品审评中心对其名称进行了规范，即修订名称为缓释制剂。这种规范仅是通用名的规范修订，不涉及产品处方工艺、质量标准及释放行为等与产品质量有关的技术变更，即产品的质量不因为名称修订而发生变化。 (2010月6月9日)

Concern about the evaluation of the carcinogenicity of new medicines

The study of carcinogenicity is an important part of the safety evaluation of innovative drugs and market risk control factors. Carcinogenicity studies and new drug evaluations started relatively early in foreign countries, which have accumulated a great deal of experience at present in evaluation of carcinogenicity research and have established technological research and development platforms. We have few innovative drugs in the early stages of research and development of new drugs but with the increase in research and development projects for new drugs, however, it has become an urgent task to conduct carcinogenicity studies appropriately.

The ICH has released three technical guides (ICH S1A, S1B and S1C) for the carcinogenicity evaluation of new drugs which describe the necessity for carcinogenicity studies of drugs, drug carcinogenicity studies and the choice of dosage and dosage limits respectively. The FDA and the EMEA had also issued technical guides for carcinogenicity studies. These technical guidances provide technical support on how to conduct carcinogenicity studies and evaluations of new drugs.

China's management requirements for new drug carcinogenicity studies have been embodied in Annex 2 of *Provisions for Drug Registration* (2005), which specifies the conditions under which new drugs should be studied for carcinogenicity. For the purposes of completing these management documents, the *Technical Guiding Principles for the Necessity of Drug Carcinogenicity Studies* issued by the SFDA on 1st April 2010 indicates that the work of carcinogenicity studies of domestic new drugs has started officially.

In order to further strengthen the understanding of the importance of new drug carcinogenicity studies and effectively promote safety evaluation, the evaluators in the Center for Drug Evaluation of the SFDA expressed their views hope that in research and evaluation ,close attention should be paid to the following questions:

1. New drug research and development should pay attention to conducting the necessary carcinogenicity studies

Carcinogenicity study, an important part of safety evaluation, is mainly used for the evaluation of the potential carcinogenic risk of new drugs. New drug applications are usually required to provide complete results of animal carcinogenicity trials. If there is an obvious carcinogenic risk, it could be required to submit the test results in the early period in order to support long-term clinical trials.

At present many new drug projects in China (including major new drug projects) have been approved to enter clinic trials, among which some need to be evaluated by carcinogenicity studies; however, only a few have done so. Researchers of new drugs should recognize that carcinogenicity trials are important risk control tools in the process of research and development of new drugs. The necessary carcinogenicity studies must be conducted at an appropriate stage otherwise it will be difficult to evaluate the carcinogenicity risk while applying for marketing permission and thus affect approval of the new drug.

2. Development of new drug carcinogenicity trials can be discussed and communicated with administration and supervision authorities

The cycle of a carcinogenicity trial is relatively long and the cost is high, so

关注创新药物致癌性试验研究评价工作

致癌性试验是创新药物安全性评价和上市风险控制内容的重要组成部分。国外新药的致癌性试验和评价起步较早，目前对致癌性试验已经积累了大量评价研究经验并建立了技术研发平台。我国早期新药研发的创新药项目较少，但随着新药研发项目增加，如何合理开展致癌性试验已成为迫在眉睫的任务。

ICH已经对新药致癌性试验发布了3个技术指导原则（ICH S1A，S1B，S1C），这些指导原则对药物致癌性试验的必要性、药物致癌性试验及其剂量选择和剂量限度进行了全面阐述。FDA和EMEA也曾发布了关于致癌性试验的相关技术指导原则。这些技术指导文件对如何开展新药致癌性试验和评价提供了技术支持。

我国对新药致癌性试验的管理要求已经体现在2005年的药品注册管理办法附件2中，明确了何种情况下新药需要开展致癌性试验研究。为了配套该管理文件，国家食品药品监督管理局于2010年4月1日颁布《药物致癌试验必要性的技术指导原则》意味着国内开展新药致癌性试验的工作已正式起步。

为了进一步加强对新药致癌性试验重视性的认识，并切实推进该项安全性评价工作，国家食品药品监督管理局药品审评中心审评员从审评的角度希望研究者和评价者重点关注如下问题：

1. 新药研发需重视开展必要的致癌性试验

致癌性试验主要用于评价新药的潜在致癌性风险，是安全性评价的重要内容之一。新药上市申请时通常需提供必要的完整动物致癌性试验结果。对于明显存在可能引起致癌性风险的情况下，可要求在早期提交该项试验结果以支持长期用药的临床试验。

目前我国已有许多新药项目（包括重大创制新药项目）被批准进入临床试验阶段，其中部分项目有必要开展致癌性试验评价，但仅有极个别品种启动了致癌性试验研究。新药研究者应该认识到致癌性试验是新药研发进程中的重要风险控制工具，需要在合适阶段开展必要的致癌性试验研究，以免上市申请时难以对其致癌性风险进行评估，进而影响新药产品批准上市。

2. 开展新药致癌性试验可与管理层交流讨论

致癌性试验周期较长，花费高，研究

research units usually provide the complete results of animal carcinogenicity trials during the application for marketing. However, in the case of existing obvious risk of carcinogenicity, they could be required to submit the early test results in order to support using the drug for longer-term clinical trials. Talking about the need for carcinogenicity trials of new drugs and how to design the experimental programs, researchers could firstly refer to relevant existing guiding principles from home and abroad.

The Center for Drug Evaluation of the SFDA has also started cooperative studies with the GLP center in China on the implementation of carcinogenicity trials and technological requirements. The carcinogenicity research platform will be further improved during the carcinogenicity studies of various drugs, in order to achieve the purpose of supplying technical support for the implementation of carcinogenicity trials. Researchers can communicate with experts in the Center for Drug Evaluation, research institutes and the GLP center about relevant problems in new drug carcinogenicity trials and the Center for Drug Evaluation of the SFDA will also strengthen technical communication with applicants and researchers via seminars about technical evaluation during carcinogenicity trials.

The necessary carcinogenicity studies on new drugs have become an important part of the safety evaluation and risk control of new drugs. Although the trial cycle is long and the cost is high, we should conduct the necessary new drug carcinogenicity studies as soon as possible in order not to affect the applications for registration of new drugs.

单位通常是在上市申请时提供完整的动物致癌性试验结果。但是，对于存在明显可能引起致癌性风险的情况下，可以要求提交该项试验结果以支持长期用药的临床试验。关于新药是否需要致癌性试验、如何设计试验方案，可以首先参考国内外已有的相关技术指导原则。

此外，药品审评中心已经联合国内GLP中心就致癌性试验的实施和试验技术要求启动了合作研究，致癌性试验平台将在具体品种致癌性试验中边运行边推进，以达到致癌性试验的具体实施提供技术支持之目的。研究者可就新药致癌性试验相关问题，与药审中心、研究机构、GLP中心专家交流，药品审评中心也会通过举办致癌性试验技术评价问题学术交流讨论会，加强与申请人、研究者的技术交流。

新药开展必要的致癌性已经成为新药安全性评价和风险控制的重要内容。虽然该试验周期长，花费高，但还是应尽快开展必要的新药致癌性试验，以免影响新药注册申请。

Q&A 知识问答

Q & A about the Electronic Submission of Registration Applications (II)

关于药品注册申请电子提交的问与答（二）

(To continue)

Q: When should we electronically submit supplementary information if it is related to changes in quality standards, specifications, packaging, labeling or processes?

A: If supplementary information is related to changes in quality standards, specifications, packaging, labeling or processes, the registration applicant should first submit the supplementary information on paper to the Center for Drug Evaluation of the SFDA. Once it is displayed as being in the evaluation stage as a "progress check" item on the variety evaluation status Web site of the CDE, then the applicant can submit supplementary information electronically.

Q: Registration information has been sent, but electronic submission operation cannot be conducted on the CDE Web site.

A: There are several situations which may cause applicants to be unable to conduct electronic submission: a. The CDE has not yet received paper-based information. b. The CDE has not yet received the registration e-tasks (e-application forms). c. The evaluation has not yet started. d. The evaluation has already ended, for example, it is in the review stage or in the filing stage of the associated management department.

Q: Are there any limit to the size of the electronically-submitted documents?

A: To ensure the efficiency and smoothness

（接上期）

问：补充资料后，若涉及质量标准、说明书、包装标签和工艺的变更，应在何时进行电子提交？

答：若补充资料涉及质量标准、说明书、包装标签和工艺的变更，注册申请人在向国家食品药品监督管理局药品审计中心提交纸面补充资料后，通过CDE网站“进度查询”查询品种审评状态显示为技术审评阶段时，则可进行补充资料的电子提交。

问：注册申请资料已经寄出，但是在CDE网站无法进行电子提交操作是怎么回事？

答：可能有以下几种情况导致注册申请人无法进行电子提交，（1）CDE尚未收到纸面资料；（2）CDE尚未收到该注册申请的电子任务（即电子申请表）；（3）审评任务尚未启动；（4）审评工作已经结束（如复核阶段或管协部制件阶段）。

问：电子提交文档大小有何限制？

答：为确保注册申请人高效、顺利的进行电子提交操作，药品审评中心整合了网络资源，已将单个电子文档的提交大小

of electronic submissions by registration applicants, we have integrated our network resources and adjusted the size of single electronic document submissions from 2M to 5M.

Q: After a staff member has left the unit, the replacing staff member cannot sign into the account of the previous employee to modify information which has already been submitted.

A: a. We suggest that registration applicants manage their electronic submission accounts and passwords carefully. If they are kept by a specific staff member, please transfer the relevant work properly when a change occurs in the workplace. b. If you need to re-obtain the electronic submission account or password from us, please submit supporting documents to us, then we shall provide the relevant information about the account and password as soon as possible.

Q: What are the requirements for the "Confirmation Letter" in the electronic submission of documents? How to submit it?

A: Since the current technical review process no longer requires applicants to submit the final drafts of quality standards, instruction manuals and technological data, these documents will instead be confirmed with registration applicants during the process of drug technology evaluation, so the "Confirmation Letter" no longer needs to be submitted electronically. We have already cancelled the operation of the submission of the item "Confirmation Letter" in the electronic submission system. (12th June 2010)

由原来的2M调整放宽为5M。

问：单位某员工离职后，接替工作的员工无法登录原来员工的帐户去修改已经提交的资料怎么办？

答：（1）建议注册申请人做好电子提交帐户和密码的管理工作，如由专人保管，若工作发生变动时做好相关工作的交接等；（2）若需向药品审评中心重新获取电子提交帐户和密码，请提交单位证明文件后，药品审评中心将会为您及时办理相关帐户和密码变更业务。

问：电子提交文档资料项目中“确认书”一项有何要求？该如何进行提交？

答：鉴于现行技术审评程序已取消了提请申请人校核质量标准、说明书和提交工艺资料的工作环节，已改为在药品技术审评过程中与注册申请人沟通确认这些文件，因此“确认书”已无须电子提交，药品审评中心已在电子提交系统中取消了“确认书”一项的提交操作。

(2010年6月12日)

Meeting Brief

Seminar on Drug Elimination Mechanisms Held in Beijing

On 3rd June 2010, a seminar on drug elimination mechanisms was hosted by the Department of Drug Safety & Inspection of SFDA and undertaken by the Center for Drug Evaluation of SFDA in Beijing. This conference was the first high-level forum in the field of drug elimination mechanisms in China. Four experts in the field of drug elimination were invited to make keynote speeches on four aspects, those are drug elimination systems, drug elimination mechanisms and models, European and American pharmaceutical post-marketing monitoring legislation, and re-evaluation and elimination of Chinese patent drugs. The deputy commissioner of SFDA, Wu Zhen, and some of the Provincial Bureau leaders and related staffs attended the meeting.

Work Started to Eliminate Aerosol CFCs for Medicinal Inhalation

An initial meeting on "The program to eliminate CFC substances (CFCs) from pharmaceutical inhalation aerosols in China" was held from 8th June to 10th in Beijing, hosted by the Drug Registration Department of SFDA and the Foreign Economic Cooperation Leading Group Office of the Ministry of Environmental Protection. Relevant personnel from SFDA, the Foreign Economic Department of the Ministry of Environmental Protection, the United Nations Industrial Development Organization Representative Office in China and the China International Pharmaceutical Exchange Center exchanged views and discussed topics with domestic relevant manufacturing enterprises on the project background and policy, implementation requirements and the contracts, resources, procurement, finance and other activities related to the project, also issues such as allocation of funds, making contract templates outdated etc.

会议简讯

药品淘汰机制研讨会在京召开

2010年6月3日，由国家食品药品监督管理局药品安全监管司主办、药品评价中心承办的药品淘汰机制研讨会在京召开。本次会议为我国药品淘汰机制方面的首次高层论坛，会议邀请了4位药品淘汰研究方面的专家分别就药品淘汰制度、药品淘汰机制和模式、欧美药品上市后监管法规、中成药再评价与淘汰四个方面进行了专题演讲。国家食品药品监督管理局吴浈副局长及部分省局领导及相关人员参加了会议。

药用吸入式气雾剂CFCS淘汰工作启动

由国家食品药品监管局药品注册司、环境保护部对外经济合作领导小组办公室共同承担的“中国药用吸入式气雾剂氯氟化碳类物质（CFCS）淘汰项目实施启动会”于6月8日～10日在京举行，来自国家食品药品监管局、环保部外经办、联合国工业与发展组织驻华代表处及中国医药国际交流中心的有关人员就项目的背景及政策、实施要求和项目的合同、资金、采购、财务等相关工作要求以及资金分配方案、淘汰合同模板等内容，与国内有关生产企业进行了交流和探讨。

EU Promotes the Widespread Use of Generic Medicines

欧盟力推仿制药的普及使用

I. Enterprises producing generic medicines have obvious advantages

In the EU, generic medicines as essential medicines for patients and have the characteristics of high quality and low price. For example, generic medicines meet more than 50% of the EU's demand for drugs, but the cost only accounts for 18%. This will undoubtedly improve patients' accessibility to drugs, and also save a lot of money for the European health care systems.

表1 2009年十大药品市场销售额与增长率

Table1 Sales and Growth Rate of Ten Drug Markets in 2009

国家 Country		2009年销售额（美元） Sales in 2009 (dollars)	市场占有率（%） Market Share	增长率（%） Growth Rate
10大市场	10 Markets	560.6	77.7	3.8
美国	U.S.	288.5	40.0	2.4
日本	Japan	71.6	9.9	3.0
法国	France	41.0	5.7	2.1
德国	Germany	40.1	5.6	4.2
意大利	Italy	25.7	3.6	3.9
西班牙	Spain	22.0	3.0	7.7
英国	U.K.	20.9	2.9	4.1
中国	China	20.8	2.9	25.2
加拿大	Canada	18.0	2.5	5.8
巴西	Brazil	12.0	1.7	11.9

The EU Committee pointed out that the EU pharmaceutical industry has reported that if generic medicines are marketted more quickly, then the additional income from 219 drugs used in Europe would be increased by 20%.

The pricing systems of the EU member countries have significant differences. In some countries the prices of generic medicines are directly related to patent drugs, while in other countries the prices can be set freely according to competition in the market. However, no matter which pricing system is used, the potential of generic medicines is clear. Over the years, they have provided up to 100 billion euros of benefits to the EU medical market. And they also have a wide range of advantages:

One is to protect the supply by legitimate means of competition. Intense competition among generic medicine suppliers is the impetus to reduce prices further and improve the acceptance of drugs, which also means that allocation efficiency and drug availability are improved.

Another is continued supply of drugs after the expiration of the original patents. After a company's patent for the original drug research has expired, generic medicines will take the place of the patented drugs in the market and meet the needs of the particular patients.

The third advantage is low investment and high returns. The State invests in generic medicine companies, while the companies provide more job opportunities. It is estimated that there are more than 700 generic medicine enterprises in Europe, and about 15 million workers areemployed. The generic medicine market has enormous economic value.

II. EU promotes widespread use of generic medicines

To encourage the use of generic medicines, the EU has issued or proposed to introduce a series of incentive policies.

The first is to promote the use of generic drugs as a first choice. This prescription approach can provide cheap medicines to patients, and also help in the calculation of the expense of disease treatment. Competition between generic medicine companies will always continue, and because their

一、仿制药企业优势明显

在欧盟，仿制药作为基本药物供患者使用，它具有高质量低价格的特点。如仿制药满足了欧盟50%以上的药品需求，成本支出却只占到18%。这毫无疑问提高了患者对药物的可及性，同时也为欧盟医疗系统节省了大量资金。

欧盟委员会根据欧盟制药行业的调查报告指出，如果仿制药品可以更快上市，那么，欧洲使用的219种药物的额外收益将增加20%。

欧盟各国的定价系统差异比较显著。有的仿制药品的价格直接与专利药的价格相关，而其他的则可以根据市场竞争力来自由定价。但是无论定价系统如何，仿制药品的潜力是无可厚非的，多年来，它为欧盟市场带来的医疗福利达到1000亿欧元。同时它的优势也是多方面的：

一是以正当的竞争手段保障供应。仿制药企业间的激烈竞争是价格进一步降低和药物改进的推动器，同时意味着分配效率和药物可获得性的提高。

二是原研药期满后的持续供应。原研药企业专利过期后，仿制药品就会代替专利药占据市场，满足特殊患者的需求。

三是低投资、高回报。国家为仿制药企业投资，企业也为人们提供了大量的就业机会。据估计，欧洲约有700多家仿制药企业，而在职员工大概有15万人；仿制药市场具有巨大的经济价值。

二、欧盟力推仿制药普及使用

为了鼓励仿制药的使用，欧盟出台或拟出台一系列激励政策：

一是促进仿制药作为第一线使用。这种

图1 欧盟各国医疗费用在GDP中的百分比

Figure 1 Percentage of medical expense in GDP in countries of EU

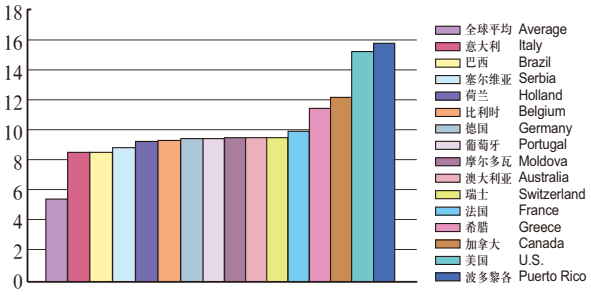
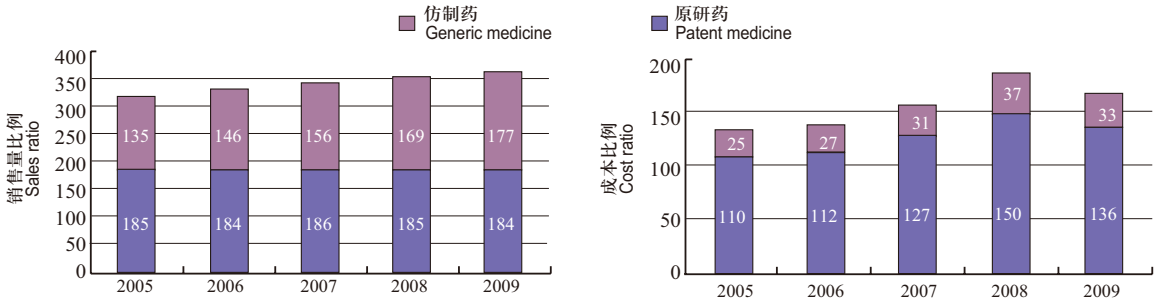


图2 仿制药使用与成本比例

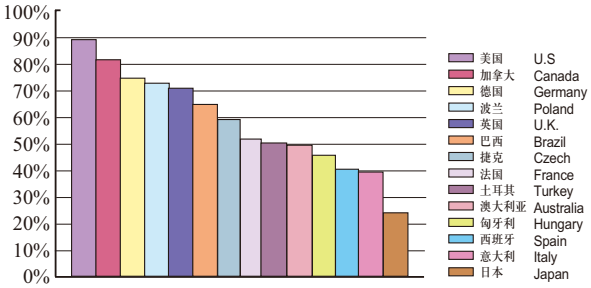
Figure 2 Usage of generic medicines and the cost ratio



drugs are the same, the continuous supply of drugs will be guaranteed. In order to maintain the motivation of pharmacists to use the essential drugs and secure their income source the EU is now planning to develop a comprehensive reimbursement and compensation scheme.

图3 仿制药品在各国药品市场中的比例

Figure 3 Percentage of generic medicines in the medical markets of countries



The second is encouraging innovation. Innovation is also a focus for generic medicine suppliers; while imitating drugs, these enterprises will continue to conduct new studies on drugs in order to improve their potency, and for this, the government would offer appropriate incentives.

The third is to encourage investment. As the regulatory procedure lacks flexibility, European generic medicine suppliers have little competitive advantage in the global market, which has caused a decline in the growth rate of European drug development and production. The European governments therefore apply certain positive measures to counter the problem, including allocating funds by the European governments to generic medicine enterprises, provide low-rate mortgages for companies to add production equipment, release tax reduction policies to stimulate exports of medicines exporting outside the EU and other policies which give generic medicine enterprises cost advantages, particularly those whose drugs are exported abroad.

Government and reimbursement departments have adopted the motivating policy for domestic generic medicine enterprises in order to create a condition of sustainable production of generic medicines which can provide the best treatment to patients at a reasonable price, in order to achieve cost savings. Because the EU governments do not want to expand only the European generic medicine market, they simultaneously provide reimbursement policies and preferential policies for generic medicines on marketing time, in-time supply to compete with patented drugs. A number of indications show that low-cost, effective generic medicines will be widely used, which also means that the health guarantee sector will have long-term economic benefits.

(21st June 2010)

处方式能够为患者提供便宜的药品，同时也可以计算出治疗疾病过程中所花的费用。仿制药企业间的竞争将会一直持续下去，因为他们的药品是相同的，这样药品的持续供应也有了保障。为了保证药剂师在使用基本药物的积极性与收益来源，拟制定完备的报销补偿计划。

二是激励创新。创新同样是仿制药企业专注的项目，企业在仿制药品时，为了提高药品的效价比会继续进行药物的新研究，政府会有相应的鼓励政策。

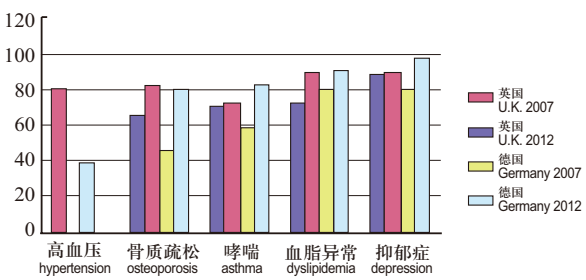
三是鼓励投资。由于监管程序缺乏灵活性，欧洲仿制药企业要在全球展开竞争基本没有优势，这使到欧洲药物的开发与生产的增长速度有所下降。因此，欧洲政府提供了一定的积极措施来应对，包括欧洲政府给予仿制药企业提供拨款、为企业增加生产设备提供了低利率的贷款、给予减税政策鼓励药品出口到欧盟以外的国家等政策，这些都给仿制药企业，尤其是所生产的药品出口到国外的企业带来成本优势。

政府与报销单位对本国仿制药企业采取激励政策，目的是为了建立一个可持续发展的仿制药生产环境，能够以合理的价格为患者提供最佳的治疗方案，从而达到节省开支的目的。因为欧盟政府不仅要扩大欧盟仿制药市场，同时在与专利药展开竞争时为其提供报销政策、上市时间和供应及时等方面的优惠政策。种种迹象表明，价格低廉，疗效显著的仿制药品将能被很好的使用，也意味医疗保障部门将有长期的经济收益。

（2010年6月21日）

图4 2007～2012年仿制药作为一线用药的比例

Figure 4 Percentage of generic medicines as first-line medicines in 2007-2012



Provided by Servier (Tianjin) Pharmaceutical Co., Ltd.
施维雅（天津）有限公司供稿

Special column

"SERVIER PEARL CLASS" Program

As an international pharmaceutical enterprise which has funded in China for over 30 years, Servier China always aims to, not only serve to a great amount of Chinese doctors and patients with our qualified products and professional services, but also to make all our efforts on undertaking social obligations we ought to.

Based on the standpoint mentioned above, from 2009, Servier China has joined a donation program with "Zhejiang Xinhua Education Fund" –"Servier Pearl Class" Program. In 2009. the first "Servier pearl Class"was successfully founded in the 1st High School of Hebei Tangshan Kailuan, totally 50 students who perform excellently in studies in spite of poverty were selected. In July 2010, servier (China) has sponsored another school – Guizhou Liupanshui No 3 Middle School. Fifty "Pearl" students and another 10 candidates who perform excellently in studies in spite of poverty were selected from Zhongshan District, Shuicheng Town, Pan Town and Liuzhi Special Region of Liupanshui City. Servier will sponsor their three-year living expenses, so that they can finish high school education without economic burden.

In order that more and more children can benefit from this program, Servier China will keep doing it. Servier is making contributions to the "Pearl Program" actively in our power, to support those children who strive against poverty and persist in study, to try our best helping them keep excellence and acquire further education in university. We are dedicated to showing our care to children in need and to lightening their path.

特约专栏

"施维雅珍珠班"项目

作为一家立足中国30年的外资制药企业，施维雅（中国）不仅在制药领域以高品质的药品与专业的服务致力于为中国广大患者的健康做贡献，还在社会公益方面，本着强烈的社会责任感，尽己所能开展着多种社会公益活动。

施维雅（中国）2009年开始与浙江新华教育基金合作开展了捐助贫困学生的活动——"施维雅珍珠班"项目。2009年在河北省唐山市开滦一中成功建立了第一个"施维雅珍珠班"，共资助该地区成绩特优、家庭特困学生50人；2010年7月又将贵州省六盘水市第三中学作为新增资助对象，在六盘水市所属的钟山区、水城县、盘县、六枝特区通过择优录取方式招收成绩特优、家庭特困学生50人，预备生10人。公司将资助这些"珍珠生们"为期三年的生活补助费，让他们安心完成高中学业。

为了使更多的孩子能够获益于此项目，施维雅（中国）将把"施维雅珍珠班"项目持续开展下去，在公司力所能及的范围内为"珍珠计划"做出积极贡献。

"施维雅珍珠班"项目是那些在最艰难的环境下依然坚持努力求学的孩子们的坚强后盾，我们将以精神和物质的力量帮助他们以优异的成绩考上大学，点亮他们的人生之路。

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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