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NEWS

- From January 28-29 of 2010, the National Drug Safety Supervision Conference was held in Ningbo, Zhejiang Province. The Conference made arrangements for the work in 2010: centering the whole-process supervision on essential medicines, to strengthen daily management so as to ensure drug safety and quality to take the opportunity of promulgation and implementation of newly revised drug GMP to further elevate drug manufacturing administration; and to take drug GSP revision as the engine to comprehensively push forward drug distribution administration. As for the drug safety supervision in 2010, Wu Zhen made emphases on the following aspects: firstly, focusing on quality administration to guarantee drug safety; secondly, working on institutional reform to further renovate supervision ideas; thirdly, making efforts on information construction to bring about the elevation of supervision methods; fourthly, take the opportunity of medical reform for the overall elevation of drug safety guarantee level.

  (Jan. 30, 2010)

- **Newly Revised Drug GMP be Issued in the First Half of Year** News from the National Food and Drug Administration Conference goes that the revision of most concerned Good Manufacturing Practice for Drugs (revised in 2010) is generally completed, waiting to be finally approved by the legislative department and to be issued in the first half of this year. Newly-established enterprises, essential medicine manufacturers and injection manufacturers shall be among the first group to implement newly-revised drug GMP.

  Sun Xianze, the Director-General of the Department of Drug safety and Inspection of SFDA commented that the newly revised drug GMP had set advanced requirements for hardware and further enhanced requirements for software, focusing on quality administration in the course of drug manufacturing, which are helpful to ensure drug quality and safety. SFDA shall focus on publicity and implementation of newly revised drug GMP following its promulgation, with a first implementation in newly-established enterprises, essential medicine manufacturers and injection manufacturers. In the meanwhile, SFDA shall take time to organize the drafting and revision of relevant addenda and technical guidelines; to study the development of work mechanism

- 2010年1月28～29日，全国药品安全监管工作会议在浙江省宁波市召开。会议对2010年的工作进行了安排：以基本药物全程监管为中心，强化日常监督管理，确保药品质量安全；以新版药品GMP颁布实施为契机，大力提升药品生产监督管理水平；以药品GSP修订工作为龙头，全面带动药品经营监管工作等。对于2010年药品安全监管工作，吴浈指出重点抓好以下几方面的工作：一是抓质量管理，全力保障药品安全。二是抓机制改革，进一步创新监管思路。三是抓信息化建设，实现监管手段的提升。四是抓医改机遇，推动药品安全保障水平的整体提升。 （2010-01-30）

- **新修订的药品GMP上半年颁布** 从全国食品药品监督管理工作会议上获悉，备受业界关注的《药品生产质量管理规范》（2010年修订）修订技术工作已基本完成，正待法规部门进行最后审核，将于今年上半年发布。新开办企业、基本药物生产企业和注射剂品种生产企业将率先实施新修订的药品GMP。

  国家食品药品监管局药品安全监管司司长孙咸泽介绍，新修订的药品GMP硬件要求有所提高，软件要求进一步加强，突出强调了药品生产过程的质量管理，有助于保证药品质量安全。新修订的药品GMP发布后，国家局将重点做好新修订的药品GMP的宣传贯彻工作，新开办企业、基本药物生产企业和注射剂品种生产企业应率先实施。同时，国家局还要抓紧组织起草修订相关附录，撰写技术指南，研究制定

combining the coordination of drug GMP certification with daily inspection on one hand, and on-site inspection for drug registration on the other hand; to summarize experiences and practice of "Qualified Person" system and drug non-on-site regulation. In addition, drug GMP certification mechanism shall be perfected. In coordination with implementation of newly revised drug GMP, SFDA shall strengthen training for regulators, especially for GMP inspectors.

The newly-revised drug GMP is in line with internationally acknowledged drug GMP level, accommodating supervision requirements of our country and reflecting the level of drug manufacturing administration on pharmaceuticals, biological products, blood products, TCM preparations, drug substances, etc. in China. It not only represents the characteristics of drug manufacturing and its regulation, but also catches up with the international level. (Jan. 21, 2010)

Essential Drugs Quality Administration Enhanced Comprehensively: Anti-microbial Drugs and All Injections shall be listed into Electronic Supervision this Year News from the National Food and Drug Administration Conference goes that in 2010 the SFDA shall strengthen its efforts on essential medicines quality administration to ensure safety and quality of essential medicines.

SFDA shall improve the specifications of 307 essential medicines, complete evaluative sample testing for 150 essential medicines, implement supervisory sample testing on full coverage, establish nationwide an efficient, stable and reliable information sharing platform for quality of essential medicines, and initiate nationwide the electronic supervision on all category of drugs on the national essential medicines list, putting antimicrobial drugs and all injections into the network of electronic supervision within this year. Meanwhile, SFDA will organize verification on the manufacturing processes and formulations, implementing the Qualified Person system in an all-round way and promoting the implementation of newly-revised drug GMP; establish a database of essential medicine manufacturers and distributors open to the public; conduct pilot quality monitoring on manufacturing, distribution and using of essential medicines; and push forward the construction of ADR monitoring, reporting and assessment in cities.

The National Pharmacopoeia Commission has already put essential medicines into drug standard improvement plan, aiming at revising and improving the standards of essential medicines that are not listed into the *Chinese Pharmacopoeia (2010 version)* in this year, and publishing an extended version of pharmacopeia.

The National Institute for the Control of Pharmaceutical and Biological Products shall go all out on the work concerning the administration on the national essential medicines to ensure the quality of essential medicines. It shall transform the methods of evaluative sample testing step by step, from regular testing to investigative testing, to strengthen the deepening analysis and research on the samples and to put forward possible solutions on identified quality-related issues. In the meantime, it shall take the leadership in

药品GMP认证与日常检查相结合、与药品注册现场核查相结合的工作机制；总结提炼各地实施质量受权人制度和药品非现场监管工作的经验和做法。此外，还要完善药品GMP认证管理机制。结合新修订的药品GMP的实施，国家局将加大对监管人员，尤其是GMP检查员的培训力度。

新修订的药品GMP在高度上与国际通行的药品GMP水准相当，广度上满足了当前我国监管需要，能够反映我国对化学药品、生物制品、血液制品、中药制剂、原料药等药品的生产质量管理水平。它既体现了我国药品生产特色与监管特色，也达到了目前国际水准。（2010-01-21）

基本药物质量监管全面加强——抗微生物药和所有注射剂品种今年纳入电子监管 从全国食品药品监督管理工作会议上获悉，2010年，国家食品药品监管局将大力加强基本药物质量监管，确保基本药物质量安全。

国家局将开展307种基本药物质量标准提高工作；完成150种基本药物评价性抽验，实施监督性抽验全品种覆盖；建设覆盖全国的高效、稳定、可靠的基本药物质量信息共享平台；在全国范围内启动国家基本药物目录全品种电子监管，今年把抗微生物药和所有注射剂品种纳入电子监管网。同时，还将组织开展生产工艺和处方核查，全面实施质量受权人制度，推动新修订的药品GMP实施；建立向社会公开的基本药物生产经营企业数据库；开展基本药物生产、配送和使用环节质量监测试点；推动地市级药品不良反应监测、报告和评价体系建设。

国家药典委员会已将基本药物优先列入药品标准提高计划。今年，力争对未收入2010年版中国药典的基本药物品种进行修订提高，推出药典增补本。

中国药品生物制品检定所将全力做好国家基本药物质量监督管理的相关工作，确保基本药物质量可控；转变评价抽验方式，逐步由常规检验向研究型检验转变，加大对样品的深入分析研究，发现质量问题并提出可行解决方案。同时，牵头组织实施好"中央补助地方基本药物质量信息平台"建设项目，实现全国基本药物检验任务、检验数据的交流共享，构建技术监督管理信息化网络。

国家食品药品监管局药品评价中心和

organizing and implementing the establishment of "Local Platforms of Quality Information of Essential Medicines with Central Subsidy" to realize the sharing and exchange of national essential medicines testing missions and testing data, establishing an information network of technical supervision and administration.

The Center for Drug Reevaluation of SFDA and 34 provincial ADR Monitoring Centers all over the country shall take essential medicine as the key content during monitoring. (Jan. 20, 2010)

- SFDA organized to hold the Seminar on Legal Issues in Drug Review and Registration, inviting legal experts from the Supreme People's Court, the Higher People's Court of Beijing, the People's Procuratorate of Beijing, the 1st Intermediate People's Court of Beijing, etc. to deeply discuss about legal issues involved in drug review and registration. Mr. Wu Zhen, the Deputy Commissioner of SFDA, attended the seminar and delivered a speech.(Jan 14, 2010)

- According to the *Drug Administration Law, Customs Law* and other relevant laws and regulations, SFDA and the General Administration of Customs co-published the custom commodity codes for narcotic drugs and psychotropic substances to be implemented starting from Jan 1, 2010. The narcotic drugs and psychotropic substances catalogue shall comply with the *Narcotics Drugs Category List (2007 version)* and the *Psychotropic Substances Category List (2007 version)* published on October 11, 2007 by SFDA, the Ministry of Public Security and the Ministry of Health. (Jan 11, 2010)

全国34个省级药品不良反应监测中心将把基本药物监测作为重点监测品种。（2010-01-20）

- 国家食品药品监督管理局在京组织召开药品审评注册疑难法律研讨会，邀请了来自最高人民法院、北京市高级人民法院、北京市人民检察院、北京市第一中级人民法院等单位的法律专家，就药品审评注册工作中涉及的疑难法律问题进行了深入研讨。国家食品药品监督管理局副局长吴浈出席并讲话。（2010-1-14）

- 根据《药品管理法》、《海关法》等有关法律法规规定，日前，国家食品药品监督管理局、海关总署联合公布了麻醉药品和精神药品的海关商品编号，自2010年1月1日起施行。麻醉药品和精神药品目录仍按照国家食品药品监督管理局、公安部、卫生部2007年10月11日公布的《麻醉药品品种目录（2007年版）》和《精神药品品种目录（2007年版）》执行。（2010-01-11）

Requirements for the National Drug Registration Regulation in 2010---Innovation Mechanism, Enhanced Management and Raised Efficiency

On 4 February, the National Meeting on Drug Registration Regulation was held in Wuhan. Wu Zhen, the Deputy Commissioner of SFDA was present and making an important speech. Zhang Wei, the Director-General of the Department of Drug Registration, SFDA gave a working report on the meeting.

The main objective of the meeting is to deeply study the scientific view of development, to set up and implement the scientific concept of regulation, to fully carry out the spirits of 17th National Congress of Communist Party of China (CPC), the Fourth Plenary Meeting of 17th Central Committee of CPC, the Central Economic Working Conference, the Fifth Plenary Meeting of 17th Commission for Discipline Inspection of the Central Committee of CPC, and the National Conference on Food and Drug Administration,

2010年全国药品注册管理工作会议要求——创新机制 提高管理质量和效率

2月4日，2010年全国药品注册管理工作会议在武汉召开。国家食品药品监督管理局副局长吴浈出席会议并作重要讲话，药品注册司司长张伟在会上作了工作报告。

此次会议的主要任务是：深入学习实践科学发展观，牢固树立和践行科学监管理念，全面贯彻落实党的十七大、十七届四中全会、中央经济工作会议、中纪委十七届五次全会和2010年全国食品药品监督管理工作暨党风廉政建设工作会议精神，总结回顾2009年药品注册管理工作，深入分析和研究当前药品注册管理面临的形势和存在的主要问题，部署2010年工作。

取得阶段性成绩　2010年任务艰巨

吴浈在会上肯定了2009年药品注册管理工作取得的成绩，并深入分析了当前药品

Construction of CPC Conduct and Incorrupt Government, to retrospect the drug registration regulation in 2009, to deeply analyze and study the present situation and problems in drug registration, and to deploy the 2010 tasks.

Interim Progress Achieved Hard Work in 2010

Wu Zhen firmly appraised the achievement of drug registration regulation in 2009, and deeply analyzed the present situation and profound problems in the drug registration.

He pointed out there was a good trend for the drug registration regulation in 2009: a large drop in the number of drug registration applications, an improved structure of submitted applications, and an obviously shortened reviewing time. In addition, in the examination and approval of drugs for the prevention and treatment of A-H1N1 influenza, the target of early involvement, timely introduction and innovation encouraging is fulfilled. Though an interim progress has been achieved in present drug registration regulation, the quality and efficiency of the review and approval of drug registration need be further improved.

Wu Zhen required that four aspects of drug registration needed be emphasized in 2010:

First to encourage innovation. The drug registration regulation in this year should fully reflect the regulatory concept of "new, advantageous and identical" settled in the *Provisions for Drug Registration*. For new drugs, innovativeness and new therapeutic effects shall be emphasized; for drugs with changed dosage forms, advantages of the changed dosage forms shall be reflected; for generic drugs, the generic drugs shall be identical to the originated drugs. SFDA will further improve the legislative system and technical guidelines in this year, exploring to establish the drug master file (DMF) for extended regulation on pharmaceutical excipients, which could proceed to control the drug quality from the source. Furthermore, SFDA will strengthen the whole-process regulation on the drug research and manufacturing, which focused this year on the GCP certification of and daily monitoring on institutions, to intensify the regulation on drug research, improve the quality and efficiency of review and approval.

Second to improve the standards. Drug standards reflect the level of the drug development in the State, and its progress is directly associated to the quality control, safety and efficacy of marketed drugs. Therefore, we shall soberly recognize the emergency of drug standard improvement in drug registration regulation. In 2010, we shall speed up the planning of drug standard improvement, make well of the drafting of the *Chinese Pharmacopeia*, rationalize the drug standard management, and establish a long-term encouraging mechanism for the formulation, improvement and elimination. The *Provisions for Drug Standards* shall be drafted in this year for future implementation.

Third to set up innovation system. For deepening the drug registration regulation, we shall actively explore in this year to establish the accountability system, that is, "responsibility taken mainly by local government, shared by regulatory departments and manufacturer is first accountable person." Two-level review and approval system of SFDA and provincial food and drug administrations (FDAs) should be set up,

注册工作面临的形势和存在的深层次问题。

他指出，2009年我国药品注册管理显示出良好态势：药品注册申报数量大幅下降，申报结构明显改善，审评时限明显缩短。另外，在防治甲型H1N1流感药物的审批工作中，实现了早期介入、及时引导、鼓励创新的目标。尽管当前药品注册管理工作取得了阶段性的成绩，但药品注册审评审批运行的质量和效率仍需进一步提高。

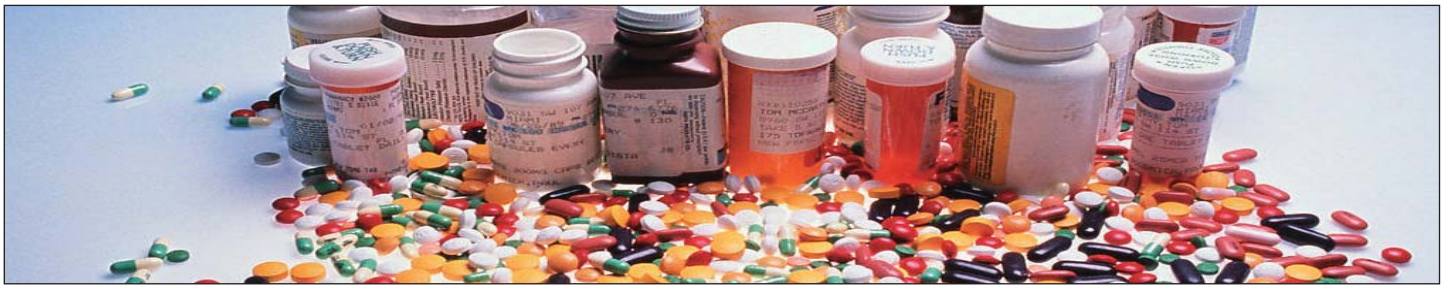
吴浈要求2010年药品注册管理工作重点要抓好四个方面的工作：

一是要鼓励创新。今年的药品注册管理工作要全面体现《药品注册管理办法》"新、优、同"的管理理念，新药要有创新性和注重新疗效；改剂型药物要体现新剂型的优越性；仿制药要与被仿制药相同。国家局今年将进一步完善法规体系和技术指导原则，研究建立药用原辅料登记备案管理制度（DMF）延伸监管环节，从源头把好药品质量关。要加强对药品研究和生产的全过程监管，今年要重点抓好GCP机构的认定工作及日常监管，强化药品研究环节的监管，提高审评审批的质量和效率。

二是要提高标准。药品标准是国家药品发展水平的体现，其完善与否直接影响到上市药品的质量控制和安全有效。因此，药品注册管理工作要清醒地认识到提高药品标准的紧迫性。2010年要抓紧制定药品标准提高的规划，进一步做好《中国药典》的编制工作，理顺药品标准管理的机制，建立药品标准形成、提高与淘汰的长效机制和激励机制。今年要完成《药品标准管理办法》的制定，并颁布实施。

三是要创新机制。为了不断深化药品注册管理工作，今年在"地方政府负总责、监管部门各负其责、企业是第一责任人"的责任体系建设上要开展积极探索。建立国家局和省局两级审评审批体制，把药品注册审批的初审权和部分事项的审批权、申报产品的检验权、生物制品的批签发权逐步交给省局，而国家局今后将重点开展监管政策的研究，督促指导地方的监管工作，集中精力抓标准提高、创新产品的审批、风险产品的检验评估等。

四是要提升效率。2010年要进一步强化信息化对提高药品注册管理工作效率的重要作用，要加大建设力度，改造硬件设施，提升软



transferring the responsibility of preliminary review, review and approval for some items, items of applied products, and lot release of biological products to provincial FDAs, while keeping SFDA focused on research of regulation policies, supervision and instruction of local regulation, standards improvement, review and approval for innovative products, testing and assessment of risk products, etc.

Fourth to elevate efficiency. In 2010, we shall further emphasize the importance of information on the efficiency elevation of drug registration regulation, intensifying the construction, upgrading hardware and software, and cultivate information intellectuals. We shall actively promote the publicity of government affairs information, explore to establish electronic regulation on drug clinical trials, play a maximum role of information technology to elevate the level of drug registration.

Wu Zhen pointed out that we were facing a tough work in 2010, so that departments on each level should deeply study and carry out the scientific view of development and concept of regulation, based on the general requirements of drug quality improvement and drug safety guarantee, make innovations in regulation models, ensure the drug safety from the source and bring the drug registration into a new era.

Fulfilling "Three Conversions", Emphasis on "Four Tasks"

Zhang Wei retrospected the drug registration in 2009. He pointed out that in 2009, we further improved the system of drug registration. SFDA accepted 3,357 drug applications for registration, slightly decreasing about 1.6% compared to the 2008 number. Among them, there were 1,184 new drug applications, occupying 35.3%, increasing 2% than 2008; and there were 870 generic applications, occupying 26.0%, decreasing 8% than 2008. The above-mentioned data shows that the drug registration applications were more rational and orderly. In addition, we further strengthened the on-site inspection for drug registration, developed GCP verification inspection and third party validation, initiated the drug re-evaluation, regulated the protection on TCM products, facilitated the implementation of drug standard improvement, and intensified the investigations and team construction.

Despite of the pleasing achievement, the system, mechanism and procedures for drug registration were not perfected, with a less developed legislative system and inconsistent personal abilities, etc. which should be improved as emphasis.

Zhang Wei pointed out that drug registration in 2010 should be under the guidance of scientific view of development, with establishment of scientific concept of regulation, centered in "quality and efficiency". We should grasp the two main tasks, which were "enhancing the drug registration regulation and elevating the drug standards", fulfilling "three conversions", i.e. converted emphasis from on product review to on policy research, regulations and guidance formulation, converted emphasis from micro-management to on macro-control, and converted emphasis from single linkage to whole process organization and quality supervision. "Four tasks" should be paid attention to, i.e. further speeding up the reform on system and mechanism, as well as the

件水平，培养信息化人才。积极推进药品注册政务信息公开，探索建立药品临床试验电子监管系统，最大限度地发挥信息化技术手段的作用，提升注册管理水平。

吴浈强调指出，2010年药品注册管理任务艰巨，各级部门要深入学习实践科学发展观，大力实践科学监管理念，围绕提高药品质量、保障用药安全的总体要求，创新监管模式，从源头确保药品安全，推动药品注册管理工作迈入新阶段。

实现"三个转变" 重点做好"四项工作"

张伟回顾了2009年的药品注册管理工作。他指出，2009年进一步完善了药品注册管理体系。国家局共受理药品注册申请3357件，与2008年相比略有下降，约为1.6%。其中，新药申请1184件，所占比例为35.3%，与2008年相比上升2%；仿制药申请870件，所占比例为26.0%，与2008年相比下降8%。上述数据表明，我国2009年药品注册申报更趋于理性，秩序趋于正常。另外，进一步加强了药品注册现场核查、开展GCP复核检查和第三方验证，并启动了药品再评价工作，规范了中药品种保护工作；进一步加快实施药品标准提高工作；同时还紧抓调查研究和队伍建设。

尽管成绩喜人，但药品注册的体制、机制和制度不完善，法规建设仍显滞后，人员能力参差不齐等方面仍有待重点加强。

张伟指出，2010年药品注册工作要坚持以科学发展观为指导，牢固树立科学监管理念，围绕"质量和效率"这个中心；紧紧抓住"提升药品注册管理水平和药品标准提高"两条主线；实现"三个转变"，即由注重品种的审批转变为注重政策研究、法规和指导原则的制定，实现由注重微观管理转变为注重宏观调控，实现由注重注册的一个环节转变为注重注册全过程的组织协调和质量监督；重点做好"四项工作"，即进一步加快体制、机制改革和法制建设，提高药品审评审批能力，强化药物研究全过程监管，推进药品标准提高工作。

legislative construction, improving the ability to drug review and approval, strengthening the whole-process administration of drug research and promoting the drug standard improvement.

Zhang Wei put forward that four aspects of drug registration in 2010 should be focused: 1) Reform on innovation. We should further speed up the reform on system and mechanism, as well as the legislative construction, among which the rational division of review and approval rights by law would become an emphasis of this year. Firstly, to consider the transferring partial rights for supplementary applications to provincial FDAs; secondly, to strengthen the study and implementation of review and approval system for drug registration on the basis of present working mode of "three separates and three in one", esp. the drafting work of GRP (Good Review Practice); thirdly, to continue the improvement of legislative system related to drug registration; and fourthly, to use information method in the advancing the drug registration regulation. 2) Team construction. Both methods of going out and introducing in should be adopted to strengthen the exchange and cooperation with advanced countries, to continuously promote the ability of review and approval on drugs, esp. innovative drugs, to gradually realize the integration of drug registration regulation with the international level, and to facilitate the training and anti-corrupt construction of personnel in the whole system of registration management. 3) Whole-process regulation of drug research. With stick to the principle of "strict" and "excellent", we should strengthen the supervision on drug research, in association of power decentralization, cooperation between central and local, play effective role of the lot release for biological products. We could start in this year to assess the drug control laboratories in provinces where vaccine manufacturers located, with pilot implementation in provinces meeting requirements so as to fulfill the goal of transferring all the lot release on vaccines to provincial FDAs within two-year time. 4) Standard improvement. One of the important tasks in this year is to publicize and implement the *2010 Chinese Pharmacopeia*. Meanwhile we should promulgate and implement the *Provisions for Drug Standards*, make well of the formulation of planning of drug standards improvement in 2010 to 2015, organize relevant work in drafting the *2015 Chinese Pharmacopeia*, and promote the trial standards into formal ones. In general, we should work steadily with active exploration, based on the requirements deployed in the 2010 National Conference on Food and Drug Administration, Construction of CPC Conduct and Incorrupt Government, to elevate the drug registration regulation into a higher level. (20 Feb. 2010)

张伟强调指出，2010年药品注册管理工作要突出四个方面的重点：一是锐意创新改革，进一步加快药品注册管理体制、机制和法制建设。其中，依法合理划分审评审批事权，将成为今年的工作重点。首先要重点考虑补充申请的部分事项交由省局进行审批。同时，在实施现行“三分离、三合一”工作模式的基础上，加强药品注册审批机制和制度的研究和落实，特别是GRP研究起草工作；继续完善药品注册相关的法规体系；运用信息化手段改善药品注册监管方式。二是要加强队伍建设，采取走出去和请进来的方式，加强和药品管理先进国家的交流与合作，不断提高药品审评审批能力，尤其是在创新药物的审评能力，逐渐实现药品注册管理工作与国际接轨。加强全系统注册管理人员的培训工作以及廉政建设。三是要强调药物研究的全程监管。坚持“严”字当头，“好”字为先，加强药物研制环节的监督，同时要重心下移、上下配合、有效发挥生物制品批签制度的作用，今年开始要对疫苗生产企业所在地的药检所进行评估，具备条件的可以先行先试，争取在两年内所有疫苗的批签发任务全部交由省局承担。四是要提高标准。今年的一个重点工作是2010年版《中国药典》的宣贯工作。同时还包括颁布和实施《药品标准管理办法》，认真做好2010_2015年药品标准提高工作规划的制定，组织做好2015年版《中国药典》编制的相关工作，继续推进试行标准转正工作。总之，要根据2010年全国食品药品监督管理工作会议暨党风廉政建设工作会议的部署要求，扎实工作，开拓进取，努力把药品注册管理工作提高到一个新的水平。（2010-02-20）

The 2010 National Conference on Food and Drug Administration was held in Beijing

On 18 January 2010, the 2010 National Conference on Food and Drug Administration was held in Beijing. Li Keqiang, the member of the Standing Committee of the Political Bureau of CPC Central Committee, and the Vice Premier of the State Council, made important instructions to the meeting. Shao Mingli, the Secretary of the Party Leadership Group and the Commissioner of SFDA, concluded the work

2010年全国食品药品监督管理工作会议在京召开

2010年1月18日，2010年全国食品药品监督管理工作会议在京召开。中共中央政治局常委、国务院副总理李克强对会议召开作出重要批示。国家食品药品监督管理局党组书记、局长邵明立总结了食品药品监管系统2009年工作，并就2010年工作做出总体部署。

国家局党组书记、局长邵明立作了题为《振奋精神 坚定信心 努力开创食品药品监管工作新局面》的工作报告。邵明立指出，

of food and drug regulation in 2009 and made a general disposition on the work in 2010.

Shao Mingli delivered a speech titled Be Vigorous and Confident to Initiate a New Phase for Food and Drug Administration. He pointed out that the reform and development of food and drug administration was still facing an important strategic opportunity. At present, the food and drug industry had become one of the pillar industries of the national economy. Its gross output value increased from less than 1 trillion in 2000 to more than 5 trillion in 2008, with an annual increase rate of nearly 20%. Along with that, the deepening of the reform of medical and health system, and the implementation of the national essential medicine system had provided a rare opportunity for the elevation of the food and drug administration level. Meanwhile, we had to keep a sober mind from time to time, for there was no fundamental change in the high occurrence of risk problems and outstanding conflicts of food and drug safety. We needed to assault fortified positions in the reform of food and drug regulation system. The whole system should properly recognize the situation we were now facing, manipulate the working principles and rules of administration, steady the confidence and resolution to make well of food and drug regulation.

Shao Mingli emphasized that 2010 was a critical year for promoting the reform of medical and health system, and an important year for entitling new function of provincial FDAs and adjusting the regulatory agencies on city and county level. An excellent achievement of this year will pose great importance for the consolidation of food and drug administration, for the guarantee of the public food and drug safety, and for a harmonized development of economy and society. Firstly we should emphasize the building of regulatory agencies on city and county level to deeply enhance the reform of food and drug regulation system. Secondly we should ensure the quality and safety of essential medicines to fulfill relevant work associate with the reform of medical and health system, by means of breaking down assignments, strengthening supervision and inspection, and strictly determine the responsibility. Thirdly, we should improve the long-term mechanism to launch a special rectification on drug safety with enhanced intensity, fastened steps and more practical measures, so as to get breakthroughs in the set up of long-term mechanism. Fourthly we should elevate the level of standardization to strengthen the daily supervision on medical devices, with a continued effort to improve the foundation and standards. Fifthly, we should strengthen the infrastructure to implement new regulatory functions in catering, health food, cosmetics, etc., by means of steadying foundation, strengthening supervision, deepening rectification and enhancing abilities. Sixthly we should promote the capacity building to fulfill the formulation of the Twelfth Five Year Plan.

Wu Zhen, the Deputy Commissioner of SFDA deployed the drug regulation in 2010. He required an innovation of regulatory mechanism and an improvement of regulatory system with an aim at outstanding problems and weakness in the regulation to fully enhance the level of guarantee on the quality and safety of drugs. The following aspects are the emphases:

Full elevation of drug review. We will improve the technical guidelines and standardize the review process. We are

食品药品监管改革与发展仍处于重要战略机遇期。当前，食品药品产业已经成为国民经济的重要支柱产业之一，工业总产值从2000年的不到1万亿元增长到2008年的5万多亿元，年增长速度将近20%。而深化医药卫生体制改革，实施国家基本药物制度，也为提升食品药品监管水平提供了难得的历史机遇。同时，食品药品安全风险高发和矛盾凸显的特征还没有发生根本改变，务必时刻保持清醒的头脑。食品药品监管体制改革仍处在攻坚破难阶段。全系统要正确认识面临的食品药品监管形势，努力把握监管工作规律，坚定做好食品药品监管工作的信心和决心。

邵明立强调，2010年是推进医药卫生体制改革的攻坚之年，是省级食品药品监管机构全面履行新职能、市县级机构改革全面推开的重要一年。做好今年的工作，对夯实食品药品监管基础，确保公众饮食用药安全，促进经济社会协调发展，具有十分重要的意义。一是以加强市县监管机构建设为重点，深入推进食品药品监管体制改革。二是以确保基本药物质量安全为重点，认真做好医药卫生体制改革相关工作。要分解细化任务，强化监督检查，严格落实责任。三是以完善长效机制为重点，深入开展药品安全专项整治，整治力度要更大、步子要更快、措施要更实，要在长效机制建设上取得新突破。四是以提高规范化水平为重点，切实加强医疗器械日常监管。今年要继续打基础、抓规范。五是以加强基础建设为重点，积极履行餐饮服务、保健食品、化妆品监管等新职责。要夯实基础、强化监管、深化整治、提升能力。六是以提升监管能力为重点，认真抓好“十二五”规划编制工作。

国家食品药品监督管理局副局长吴浈部

facilitating the establishment of technical guidelines system for drug research, making the technical guidelines related to drug research in China systemized and connecting the international level within three years time. Meanwhile, we should set up systems of norms for innovative drugs R&D and evaluation, of support for national new drug review data, of dynamic management on the national drug review information, of web labs for drug technical review, and of transferring and application service for significant new drug research, establishing a new technical platform for and realizing the standardization of drug review.

Strict evaluation to lead to the innovative drug R&D. We will further improve relevant regulations for the drug safety study (GLP) and clinical trials (GCP) in this year, combining the review of applied products, intensifying the on-site inspection and supervision, playing full function of modern information technology, enhancing the quality and efficiency of inspections, and ensuring the authenticity of application dossiers. We will also formulate measures to encourage and provide service for innovation.

Stepped improvement of drug quality standards. We will promote steadily the work plan of drug standard improvement, formulating relevant plans in 2010 and the Twelfth Five Year Plan. We should prepare for the drafting of *2015 Chinese Pharmacopeia*, organizing a new pharmacopeia committee and drafting the mission for scientific research. We are also developing the *Provisions for Drug Standards*. In 2010, we should be focused on reevaluation on two marketed products: on the TCM injections safety and on the quality of vaccines.

Comprehensive supervision on drug quality. Firstly, a newly revised GMP for drugs will be issued on the first half of this year, focusing on the publicity and implementation of the revised GMP. Newly set-up enterprises, manufacturers for essential medicines and injection manufacturers shall be the first to implement revised GMP. Secondly, the drug distribution order will be regulated. Combined with the implementation of essential medicine system, we shall promote the resource allocation, mergers and acquisitions, selection of the superior and elimination of the inferior in drug distribution, accelerating the modern drug logistics and ensuring the timely delivery of essential medicines. We should revise the GSP, raising the threshold for market access of newly set-up enterprises and indicating trend of development for present enterprises. We should improve the regulatory methods for distributors, pushing forward the electronic regulatory code, which will be firstly used in the newly set-up wholesalers and essential medicines distributors. We should also facilitate the establishment of demonstrative counties of drug safety, continuously utilizing the functions of the "Two Networks" in rural areas to ensure the quality and safety of drugs used in the rural. Thirdly, the drug testing and ADR monitoring will be strengthened. We shall form and implement the sampling plan for drug testing, intensifying the sampling on products in the essential medicines category, and timely identifying the hidden problems in drug safety or quality problems. SFDA will also promulgate the newly revised *Provisions for Adverse Drug Reaction Report and Monitoring*, comprehensively strengthen the ADR monitoring.

署了2010年药品监管工作。吴浈要求针对监管中的突出问题和薄弱环节，创新监管机制，完善监管制度，全面提升药品质量安全保障水平，着重做好以下几个方面的重点工作：

全面提升药品审评水平。完善技术指导原则，实现审评行为标准化。加快我国药品研制技术指导原则体系建设，争取用3年左右的时间，使我国药品研制相关技术指导原则系统化并基本与国际接轨。同时，要构建"创新药物研发和评价规范体系"、"国家新药审评数据支持体系"、"国家药品审评信息化动态管理体系"、"药品技术审评网络实验室体系"、"重大新药创制成果转化与应用服务体系"，以此构筑药品审评新的技术平台，实现药品审评的规范化、标准化。

严格审评，把药品研发引导到创新上来。今年将进一步完善药物安全性研究（GLP）和药物临床试验(GCP)的有关管理规定，结合申报品种的审评，加大现场核查和监督检查力度，充分利用现代信息化手段，提高检查质量和效率，保证申报资料的真实性。制定鼓励创新、服务创新的措施。

稳步提高药品质量标准。扎实推进药品标准提高行动计划，编制2010年及"十二五"药品标准提高计划；着手2015版《中国药典》的编制准备工作，组建新一届药典委员会，拟定科研任务；研究制定《药品标准管理办法》。2010年要重点开展两类上市药品的再评价工作，即中药注射剂安全性再评价和疫苗质量再评价。

全面加强药品质量监管。一是今年上半年将颁布新修订的药品GMP，要重点做好新版药品GMP的宣传贯彻工作，新开办企业、基本药物生产企业和注射剂品种生产企业应率先实施新版药品GMP。二是整顿药品流通秩序。结合基本药物制度的实施，推动药品经营的资源整合、兼并重组、优胜劣汰，促进药品现代物流发展，保证基本药物的及时配送。修订GSP，提高新开办企业准入门槛，对现有企业指明发展方向；提升对流通企业的监管手段，大力推行电子监管码，在新开办批发企业和基本药物配送企业率先使用；推动药品安全示范县创建活动，继续发挥农村药品"两网"作用，保障农村药品质量安全。三是加强药品检验和ADR监测。制定并落实好药品抽验计划，加大对基本药物目录品种的抽验力度，及时发现药品安全隐患或质量问题的苗头。国家局还将发布新修订的《药品不良反应报告和监测管理办法》，全面加强ADR监测工作。

探索改革药品监管机制。一是改革药品审评的机制。合理划分国家局和省局的审评

Exploration on reform of drug regulation mechanism. First, the reform of drug review mechanism. We would rationally divide the review and approval rights of SFDA and provincial FDAs, and transfer the review items that could be taken by provincial centers for drug evaluation to provincial FDAs. We would also try to set up regional evaluation institutions to carry out the missions given by SFDA. Second, the perfection of GMP certification management. SFDA would combine the implementation of revised GMP with the training on regulatory personnel esp. GMP inspectors. On this basis, SFDA would put its emphasis on the supervision inspections and flight inspections, gradually developing the international GMP inspections and, with decentralizing step by step the certification inspections for injections, etc. to provincial FDAs depending from category to category. Third, a new mechanism for the regulation on vaccine manufacturing. We would improve the lot release system, playing full function of provincial FDAs with a goal of taking the lot release of vaccines since the year of 2012. (20 Jan. 2010)

审批事权，把可以由省级审评中心承担的审评事项交给省局。尝试建立区域审评机构，承担国家局交给的技术审评任务。二是完善药品GMP认证管理机制。结合新版药品GMP的实施，国家局加大对监管人员，尤其是GMP检查员的培训力度。在此基础上，可以分类别、有步骤地将注射剂类等药品的认证检查任务交给省局承担，国家局重点做好督促检查和飞行检查工作，并逐步开展国际GMP检查。三是研究疫苗生产监管的新机制。进一步完善批签发制度，充分发挥省局作用，争取从2012年开始全部由省局承担起疫苗批签发任务。（2010-01-20）

The 2010 National Health Working Conference Held in Beijing---Medical Reform Witnessing a Good Start with this Year a Key Year of Connection

On January 5th, 2010, the National Health Working Conference was held in Beijing. Health Minister Chen Zhu pointed out that 2010 was a key year of connection to push forward the medical and health system reform. The health work this year is significant both to realize near-term goal for medical and health system reform, and to complete the Eleventh Five-Year Program.

Overall requirements for health work in 2010 are to serve the overall situation centering around pivot mission, comprehensively implementing the Medical Reform Opinions and spirit of the Economic Work Conference of the Central Committee of CPC, putting deepening of medical and health system reform as the central work of health system, to actively push forward scientific development of health undertaking. Centering overall requirements, Chen Zhu pointed out that the following work should be done well in 2010.

Firstly, to consolidate and improve new rural cooperative medical system from 8 aspects including ensuring number of

2010年全国卫生工作会议在京召开——医改开局良好，今年是承上启下关键年

1月5日，2010年全国卫生工作会议在北京召开。卫生部部长陈竺在会上指出，2010年是全面推进医药卫生体制改革承上启下的关键一年，做好今年的卫生工作，对于实现医药卫生体制改革近期目标、圆满完成“十一五”规划目标至关重要。

会上提出2010年卫生工作的总体要求是：紧紧围绕中心，服务大局，全面贯彻落实《医改意见》和中央经济工作会议精神，将深化医药卫生体制改革作为卫生系统的中心工作，积极推进卫生事业科学发展。围绕总体要求，陈竺提出2010年要全力做好以下重点工作：

一是从确保参合人数、提高筹资标准、提高补偿比例等8个方面，巩固完善新型农村合作医疗制度。2010年，各级政府的补助水平达到每人每年120元，并适当提高个人缴费水平，同时力争使政策性住院费用报销比例达到60%左右，较2009年再提高5个百

participants, raising fundraising standards, improving compensation proportion, etc. In 2010, subsidy for every individual obtained from various levels of governments reached 120 RMB per year and individual payments for the system have been moderately raised. Meanwhile efforts shall be made to raise reimbursement proportion for policy-based hospitalization expenses up to about 60%, 5 percentage points higher than that in 2009.

Secondly, through consolidating and expanding coverage of essential medicines system, intensify the procurement and distribution management for essential medicines, strengthen the allocation and usage management for essential medicines, and encourage locals to implement compensation policy to actively explore preparation and usage of essential medicines in village health facilities, steadily pushing forward essential medicines system construction.

Thirdly, to streamline urban and rural primary medical and health service system. While implementing service system construction task for this year, managing well grassroots personnel training and improvement, and improving the mechanism of one-to-one urban assistance to rural areas, we should come up with performance assessment guideline for urban community health facilities and rural health institutes, conduct performance assessment to implement rural doctor subsidy policy, aiming at solution of the qualification for medical practitioners in villages within 3 to 5 years time.

Fourthly, to gradually promote equalization of basic public health service. In 2010, basic public health service program provided by primary health facilities shall be comprehensively implemented in urban and rural areas, and a guarantee mechanism for public health funding shall be established and perfected in an all-around way. Meanwhile, we shall enhance supervision and guidance on gradual equalization of basic public health service in various local areas to identify loopholes, summarize experience and improve performance assessment mechanism.

Fifthly, to steadily push forward pilots reforms for public hospitals with efforts to strengthen medical quality management and medical service supervision. Chen Zhu expressed that in 2010 the pilot public hospital reform shall give prominence to key contents to conduct explorations centering around some key links and issues in management mechanism and performance mechanism, such as implementing governmental responsibility of programme initiation and supervision, strengthening programme administration, adjusting special distribution and structure, perfecting input policy, supporting to improve service quality of basic medical institutes, transforming the system of obtaining medical funding from medication, reforming personnel and income distribution system, strengthening position performance assessment, etc.

In addition to that, we shall emphasize all other important work in health system in 2010, such as handling well of A-H1N1 influenza and other major incidents; actively executing comprehensive coordination responsibility of food safety to do well in food safety rectification; actively managing health supervision work; going all out to push forward scientific development of TCM undertaking; and accelerating health information system.

Chen Zhu pointed out that several aspects shall be emphasized to steadily push forward essential medicine system:

Firstly, to consolidate and expend coverage of essential medicine system. Essential

分点。

二是通过巩固和扩大基本药物制度实施范围；严格基本药物采购配送管理；加强基本药物配备使用管理；鼓励各地落实补偿政策，积极探索村级卫生室配备使用基本药物工作等措施，稳步推进基本药物制度建设。

三是健全城乡基层医疗卫生服务体系。在落实好本年度服务体系建设任务，抓好基层人员培训和提高工作，完善对口支援协作机制的同时，研究提出城市社区卫生服务机构和乡镇卫生院绩效考核指导意见，开展绩效考核工作，落实乡村医生补助政策，争取用3～5年时间解决乡村医生执业资格问题。

四是促进基本公共卫生服务逐步均等化。2010年将全面落实城乡基层医疗卫生机构提供的基本公共卫生服务项目，全面建立和完善公共卫生经费保障机制。同时，加强督导，对各地促进基本公共卫生服务逐步均等化工作进展情况进行检查督导，发现问题，总结经验，改善提高。完善绩效考核制度。

五是稳妥推进公立医院改革试点，着力加强医疗质量管理和医疗服务监管。陈竺表示，2010年公立医院改革试点工作要突出关键内容，重点围绕管理体制和运行机制的某些环节和内容，如落实政府举办和监管责任、加强规划管理、调整布局结构、完善投入政策、支持基层医疗卫生机构提高服务水平、转变以药补医机制、改革人事和收入分配制度、加强岗位绩效考核等开展探索。

另外，努力做好甲型H1N1流感和其他重大事件处置工作；积极落实食品安全综合协调职责，做好食品安全整顿工作；积极做好卫生监督工作；全力推进中医药事业科学发展；加快医药卫生信息系统建设等也是2010年卫生系统的重要工作。

陈竺指出，在稳步推进基本药物制度方面今年要着力做好几个方面：

一是巩固和扩大基本药物制度实施范

medicine system shall be implemented in not less than 60% government-funded primary health facilities, selling essential medicines with no addition on bidding price. In secondary and tertiary hospitals in areas of public hospital reform pilots shall initiate the implementation of essential medicines.

Secondly, to manage strictly the procurement and distribution of essential medicines. We should actively promoting centralized procurement and united distribution at provincial level to raise efficiency and decrease mid-links, gaining no profits from the people.

Thirdly, to strengthen essential medicines allocation and usage management. All primary health facilities established by local governments in counties (cities and districts) where essential medicine system is under implementation shall be equipped with and use essential medicines, and the percentage of secondary and tertiary hospitals using essential medicines shall achieve corresponding requirements.

Fourthly, to encourage local government to implement subsidy policies and to actively explore for equipment with and usage of essential drugs in village health facilities.

Fifthly, to coordinate with relevant departments to improve reimbursement policy of essential medicines to promote reasonable use of essential medicines and decrease people's burden.

Sixthly, to conduct examination and assessment on the implementation of essential medicine system, timely summarizing and exchanging experience to prevent the occurrence of major problems.

Seventhly, to strengthen publicity to guide people on use of essential medicines.

(Jan. 8, 2010)

围。在不少于60%的政府举办的基层医疗卫生机构实施基本药物制度，零差率销售基本药物，公立医院改革试点地区的二、三级医院也要启动基本药物实施工作。

二是严格基本药物的采购配送管理。积极推行以省为单位的集中采购和统一配送工作，提高流通效率，减少中间环节，让利于民。

三是加强基本药物配备使用管理。推行基本药物制度的县（市、区）政府举办的城乡基层医疗卫生机构要全部配备使用基本药物，二、三级医院使用比例要达到相应的要求。

四是鼓励各地落实补偿政策，积极探索村级卫生室配备使用基本药物工作。

五是会同有关部门，完善基本药物报销政策，促进基本药物合理使用，减轻群众负担。

六是对基本药物制度实施情况进行检测和评估，及时总结和交流经验，防范重大问题发生。

七是加强舆论宣传，引导群众使用基本药物。

(2010-01-08)

Special Focus

业界专题

Successful Launch of CLARIFY (ProspeCtive observational LongitudinAl RegIstry oF patients with stable coronary) Study in China

稳定性冠心病前瞻性、观察性、纵向注册研究——CLARIFY研究在中国成功启动

CLARIFY (ProspeCtive observational LongitudinAl RegIstry oF patients with stable coronary arterY disease) study was successfully launched at Beijing, Shanghai, Guangzhou, and Wuhan recently. It is an international, multicenter study in patients with coronary artery disease (CAD). This project is sponsored by Servier, a French famous pharmaceutical company, and strongly supported by the experts of the European Society of Cardiology and Chinese Medical Association.

It is well known that CAD is the leading cause of death worldwide and a major threat for human health. With progress in prevention and treatment of CAD in the last two decades, epidemiological data and demographic data have changed greatly. Data from previous studies do not adequately represent global status due to

日前，全球38个国家参与的"稳定性冠心病前瞻性、观察性、纵向注册研究"（ProspeCtive observational LongitudinAl RegIstry oF patients with stable coronary arterY disease，CLARIFY研究）在北京、上海、广州、武汉四地成功启动，这是我国近年参与的规模最大的国际多中心冠心病注册研究之一，该项目得到欧洲心脏病学会和中华医学会的大力支持，法国制药企业施维雅公司独家赞助了本次研究。

众所周知，冠心病目前高居全球死因的首位，严重威胁公众健康。WHO预计到2020年，冠心病仍将是人类健康的头号杀手。随着近20年来冠心病的预防与治疗水平地提高，冠心病患者的流行病学资料、人口学资料以及其治疗、预后有了很大变化和改善，但是目前仍缺乏这方面的数据。许多研究由于研究对象的高度选择性和区域限制，并不能准确地反映全球现状。因此，急需一项大规模的、基于门诊患者的注册研究，来了解

stringent enrollment and regional limits, therefore, there is an emergent need for a large registry study based on outpatients to understand baseline characteristics, management and outcomes of outpatients with stable CAD and to explore new prognostic factors (such as heart rate).

CLARIFY is exactly a prospective, observational, longitudinal registry focusing on outpatients with stable CAD, in which a minimum of 30,000 patients with stable CAD from 38 countries/regions will be enrolled and followed up for 5 years. In China, there will be 2,500 patients at 65 hospitals planned to be enrolled. One of aims in this study is to characterize contemporary CAD patients in terms of their demographic characteristics, clinical profiles, management practices. On the other hand, CLARIFY will explore if resting heart rate can be used as a prognostic factor for CAD.

Recently, much evidence has shown that heart rate is closely related to prognosis of patients with CAD and elevated heart rate (>70 beats/min) is a risk factor for the prognosis of CAD. It is showed that an innovative drug Ivabradine, the first selective sinus node If channel inhibitor with a pure heart rate-lowering effect and without negative inotropic or lusitropic effects, not only alleviated myocardial ischemia/angina symptom effectively, but also significantly improved prognosis of patients with CAD. It is believed that results from CLARIFY will provide further evidence of the relationship between heart rate and prognosis in patients.

"As the first large study focusing on heart rate-lowing and its long-term effect on prognosis in patients with stable CAD, CLARIFY study will provide further evidence of the relationship between resting heart rate and cardiovascular events, and reinforce the concept of control of heart rate in management of patients with CAD," concludes Professor Hu Dayi, the Principal Investigator of CLARIFY in China, Chairman of Chinese Society of Cardiology of Chinese Medical Association, "and it will also provide updated data on global and Chinese population of patients with CAD."

目前稳定性冠心病门诊患者的基线特点、治疗和预后、以及探讨新的危险预测因子（如心率）。

CLARIFY 正是针对门诊稳定性冠心病患者的前瞻性、观察性、纵向注册研究，全球共有38个国家和地区开展本研究，计划入组30,000例患者，接受为期5年的随访，其中中国计划在全国65家医院入组2,500例患者。其目的一是了解稳定性冠心病患者的人口统计学特点、临床特点、治疗策略和现状。另一方面是探讨静息心率是否能作为冠心病预后的风险预测因子。最近已有大量证据表明心率与冠心病患者预后密切相关，增加的心率（>70次/分）是冠心病预后的危险因素。近年关于创新性新药伊伐布雷定（全球首个选择性特异性窦房结阻滞剂，具有单纯减慢心率作用，无负性肌力和负性传导作用）的研究显示，冠心病患者将心率控制在50～70次/分不仅可以有效缓解心肌缺血/心绞痛症状，而且可以显著改善冠心病患者预后，相信CLARIFY的结果能够为此提供进一步的证据。

"CLARIFY 研究作为全球首个针对稳定性冠心病患者心率控制状况及其长期预后影响的大规模研究，能使我们更好地了解稳定性冠心病患者的静息心率与心血管事件的关联性，强化冠心病患者心率控制的治疗理念。" CLARIFY 中国地区主要研究者，中华医学会心血管病分会主任委员胡大一教授总结说，"同时也将提供全球和我国冠心病人群的最新资料，为医疗和卫生决策提供依据。"

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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