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NEWS

The General Office of the State Council issued the "Notice on the 2012 Major Work Tasks for Deepening the Healthcare System Reform" On April 18, 2012, the General Office of the State Council issued the "Notice on the 2012 Major Work Tasks for Deepening the Healthcare System Reform" (hereinafter referred to as the "Notice"), which assigned the 2011 healthcare reform tasks respectively to the Ministry of Health, the National Development and Reform Commission, the Ministry of Human Resources and Social Security, the Ministry of Finance, the State Administration of Traditional Chinese Medicine, the Ministry of Supervision, the State Commission Office for Public Sector Reform, the China Insurance Regulatory Commission and other departments.

The "Notice" pointed out that the healthcare reform will focus on achieving breakthroughs in three key areas of accelerating the establishment of a universal health insurance system, consolidating and improving the essential drug system and new operation mechanism for primary health care institutions, and actively promoting the reform of public hospitals.

The Work Tasks consist of 4 aspects and 21 specific contents.

A. Accelerate the establishment of a universal health insurance system

(1) Consolidate and expand basic health insurance coverage; (2) Continue to raise the level of basic health insurance; (3) Reform the health insurance payment system; (4) Further increase the efforts of medical assistance; (5) Explore the establishment of a security system for major diseases; (6) Improve the management level of the basic health insurance agencies; (7) Vigorously develop commercial health insurance.

B. Consolidate and improve the essential drug system and new operation mechanism for primary health care institutions

(8) Consolidate and improve the essential drug system; (9) Deepen the comprehensive reform of primary health care institutions; (10) Improve the service capacity of primary health care institutions; (11) Build a strong rural health service network.

C. Actively promote the reform of public hospitals

(12) Accelerate the reform of county-level public hospitals; (13) Broaden and deepen the reform of urban public hospitals; (14) Vigorously develop non-public medical institutions; (15) Fully deliver services for the benefit and convenience of the people.

D. Coordinate and push forward the reforms of relevant fields

(17) Improve the level of the equalization of basic public health services; (18) Promote the structure optimization and layout adjustment for healthcare resources; (19) Innovate the training and employment system for health workers; (20) Promote the reform in the area of drug production and distribution; (21) Improve medical and health regulatory system.

Among which, the major tasks for food and drug administration departments are: to consolidate and improve the system of essential drugs, promote drug production & distribution sector reforms, and build a sound medical and health regulatory system. (April 19, 2012)

国务院办公厅发布《深化医药卫生体制改革2012年主要工作安排的通知》

2012年4月18日，国务院办公厅发布《深化医药卫生体制改革2012年主要工作安排的通知》（以下简称《通知》），将2011年医改任务分解到卫生部、国家发改委、人力资源和社会保障部、财政部、国家中医药管理局、监察部、中央编办、保监会等部门。

《通知》指出，医改将着力在加快健全全民医保体系、巩固完善基本药物制度和基层医疗卫生机构运行新机制、积极推进公立医院改革三个方面取得重点突破。

工作任务有4个方面21项具体内容

一、加快健全全民医保体系

（1）巩固扩大基本医保覆盖面；（2）继续提高基本医疗保障水平；（3）改革医保支付制度；（4）进一步加大医疗救助力度；（5）探索建立大病保障机制；（6）提高基本医保经办管理水平；（7）大力发展商业健康保险。

二、巩固完善基本药物制度和基层医疗卫生机构运行新机制

（8）巩固完善基本药物制度；（9）深化基层医疗卫生机构综合改革；（10）提高基层医疗卫生机构服务能力；（11）筑牢农村医疗卫生服务网底。

三、积极推进公立医院改革

（12）加快推进县级公立医院改革试点；（13）拓展深化城市公立医院改革试点；（14）大力发展非公立医疗机构；（15）全面开展便民惠民服务。

四、统筹推进相关领域改革

（17）提高基本公共卫生服务均等化水平；（18）推进医疗资源结构优化和布局调整；（19）创新卫生人才培养使用制度；（20）推进药品生产流通领域改革；（21）健全医药卫生监管体制。

其中食品药品监管部门承担的主要任务是，巩固完善基本药物制度、推进药品生产流通领域改革、健全医药卫生监管体制。

（2012年4月19日）

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Activity Brief

NIFDC Strategic Advisory Expert Committee and the Eighth Academic Committee Established

On April 16, 2012, the Inaugurating Meeting of Strategic Advisory Expert Committee and the Eighth Academic Committee of the National Institutes for Food and Drug Control (NIFDC) was held in Beijing. Academician Sang Guowei, Vice Chairman of the Standing Committee of the National People's Congress (NPC) and Yin Li, Commissioner of the Sate Food and Drug Administration (SFDA) were present at the meeting and made speeches. Li Yunlong, Director-General of NIFDC issued the Committee Member Certificates respectively to Strategic Advisory Experts, Chairman and Vice Chairman of the Academic Committee, foreign Committee Members and representatives of Committee Members.

The Strategic Advisory Expert Committee of NIFDC has engaged 17 academicians of the relevant fields from the Chinese Academy of Engineering, with Academician Sang Guowei, Vice Chairman of the NPC Standing Committee served as Chairman of the Academic Committee, Academician Zhao Kai and Ding Jian as Vice Chairmen, and 14 academicians as Members. The Eighth Academic Committee of NIFDC has made timely adjustments to engage five foreign Committee Members from the European Union, Japan, the United Kingdom, the United States and other countries, this will help to broaden the visions and horizons of NIFDC, and improve the international level of food and drug control and inspection.

The main responsibilities of the NIFDC Strategic Advisory Expert Committee are: to provide constructive ideas and policy recommendations for long-term, global and strategic issues on the construction and development of a world-class NIFDC; to provide guidance on the academic development and research orientation of NIFDC, and the control and inspection capacity building with respect to food and drug safety; and to provide advices on major NIFDC research projects and evaluations.

(April 18, 2012)

活动报道

中检院战略咨询专家委员会暨第八届学术委员会成立

2012年4月16日，中国食品药品检定研究院战略咨询专家委员会暨中检院第八届学术委员会成立大会在京举行。全国人大常委会副委员长桑国卫院士、国家食品药品监督管理局局长尹力出席会议并讲话，中国食品药品检定研究院院长李云龙分别为战略咨询专家、学委会主任委员、副主任委员和外籍委员及委员代表颁发证书。

中检院战略咨询专家委员会聘请了中国工程院相关领域17位院士，全国人大常委会副委员长桑国卫院士担任主任委员，赵铠院士、丁健院士担任副主任委员，14位院士担任委员。中检院第八届学术委员会还进行了适时调整，特别聘请了来自欧盟、日本、英国、美国等国家的5名外籍委员，这将有助于中检院拓宽视野、开阔眼界，提高检验检定工作的国际化水平。

中检院战略咨询专家委员会的主要职责是对建设国际一流中检院发展的长远性、全局性和战略性问题，提出建设性意见和决策建议；对中检院学科发展、研究方向，以及围绕食品药品安全的检验检测能力建设提供指导性意见；对中检院重大研究项目立项、评估提供咨询意见等。

（2012年4月18日）

The Symposium on Implementing the Policies Set Forth in the National Work Conference on Deepening the Healthcare System Reform Held in Beijing

On April 17, 2012, SFDA held in Beijing the Symposium on Implementing the Policies Set Forth in the National Work Conference on Deepening the Healthcare System Reform, to clarify the major tasks of SFDA on deepening the healthcare system reform. SFDA Commissioner Yin Li pointed out that the year of 2012 is a nexus year on deepening healthcare reform, the concrete implementation of this year's work tasks is of vital importance to the consolidation and expansion of the achievements of healthcare reform in the previous three years, and the deepening of healthcare reform in the "12th Five-Year Plan Period." The positioning of food and drug administration system in the overall healthcare reform is to guarantee drug safety, promote the reform in the area of drug production and distribution, and serve for the overall healthcare reform. We should seize the opportunities of the healthcare reform, accelerate the improvement of standards, the implementation of GMP and GSP, as well as the full implementation of electronic supervision, the staffing of practicing pharmacists and other regulatory works.

国家食品药品监督管理局召开贯彻全国深化医药卫生体制改革工作会议精神座谈会

2012年4月17日,国家食品药品监督管理局在京召开贯彻全国深化医药卫生体制改革工作会议精神座谈会，明确食品药品监管系统深化医药卫生体制改革主要工作任务。

国家食品药品监督管理局尹力局长指出，今年是深化医改工作承上启下之年，做好今年的工作，关系到前三年医改成果的巩固扩大，关系到“十二五”期间医改工作的深入推进。食品药品监管系统在医改大局中的定位是，保障药品质量安全，促进药品生产流通领域改革，服务医改

Commissioner Yin Li stressed that strict administration is to be implemented to ensure safety, standards are to be improved to promote the reform, and firm implementation is called for to achieve practical results. We should intensify the whole process supervision to further improve the level of quality and safety of essential drugs; continue to keep a watchful eye on the source standards, and the enterprises' production, circulation, distribution and end-use links; lay emphasis on the improvement of standards to realize full coverage testing of all varieties, implement electronic supervision, and improve the monitoring of adverse reactions ; achieve "Two Ups and One down", namely, to lift up the quality controllability levels of essential drugs, lift up the safety level of ex-factory essential drugs, and cut down the safety risks of essential drugs in distribution and application to safeguard their quality and safety. Meanwhile the quality consistency evaluation of generic drugs should be carried out to strengthen the supervision of drug production and distribution, the communication and coordination of SFDA with provincial drug administrations, administrative supervision with technical supervision should be promoted, and a drug administration system featuring resource sharing, rapid response, risk anticipation, and powerful fight against illegal acts shall be constructed. The role of the Inter-Ministerial Coordination Joint-Meeting on combating counterfeit drugs shall be promoted to crack down on illegal behaviors.

At the meeting, SFDA signed Letters of Responsibility for Healthcare Reform with Food and Drug Administration of all provinces (autonomous regions, municipalities) and Xinjiang Production and Construction Corps. (April 18, 2012)

大局。要抓住医改之机，加快推进标准提高，GMP、GSP 实施，电子监管和配备执业药师等各项监管工作全面开展。

尹力局长强调要严格监管保安全，提高标准促改革，狠抓落实求实效。要加大全过程监管力度，进一步提高基本药物质量安全水平；要继续盯紧源头标准、企业生产、流通配送和终端使用环节；强化标准提高，落实全品种覆盖抽验，推行电子监管，完善不良反应监测；实现"两提高一降低"，即提高基本药物的质量可控水平、提高生产企业出厂的基本药物安全水平、降低配送和使用环节基本药物的安全风险，保障基本药物质量安全。同时要开展仿制药质量一致性评价工作，加强药品生产流通领域监管，加强国家食品药品监督管理局与省局的衔接、行政监管与技术监督的沟通协调，建设资源共享、快速反应、风险预判、打击有力的药品监管体系。要发挥打击假药部际协调联席会议的作用，严厉打击违法违规行为。

会上，国家食品药品监督管理局与各省（区、市）食品药品监督管理局及新疆兵团局签订了医改工作责任书。

（2012年4月18日）

National Food and Drug Administration Policies & Regulations Work Meeting Held in Shijiazhuang

On April 12, 2012, the National Food and Drug Administration Policies & Regulations Work Meeting was held in Shijiazhuang, Li Jiping, SFDA Deputy Commissioner, and Yu Xiancheng, CCDI-accredited SFDA Discipline Inspection Team Leader attended the meeting and delivered speeches.

At the meeting, Li Jiping affirmed the work achievements with respect to food and drug policies & regulations in the past year, and indicated that the tasks for food and drug policies and regulations in the future shall be heavier and more demanding, and should adhere to the overall situation and scientific methods, conduct good investigation and coordination, and focus on effective implementation.

Liu Pei, Director General of SFDA Department of Policy & Regulations, said that in recent years, the fundamental and forward-looking role of policies and regulations in food and drug administration have become increasingly obvious. This year's major tasks for policies and regulations shall aim to: speed up the progress of legislation, serve for law enforcement practices; strengthen supervision over and improve the level of law enforcement; seize the opportunity of healthcare reform to strengthen the supervision of the essential drugs; carry out policy research around hot and difficult issues; lay emphasis on the coordination of all forces, and form a synergy with news media publicity. (April 13, 2012)

全国食品药品监督管理政策法规工作会议在石家庄召开

2012年4月12日，全国食品药品监督管理政策法规工作会议在石家庄召开，国家食品药品监督管理局副局长李继平、中央纪委驻局纪检组组长于贤成到会并讲话。

会上，李继平副局长对过去一年来食品药品政策法规工作予以了肯定，并指出，今后食品药品政策法规工作任务更重、要求更高，政策法规工作要坚持讲大局讲方法、善调查善协调、抓重点抓落实。

国家食品药品监督管理局政策法规司司长刘沛表示，近年来，政策法规工作在食品药品监管全局中的基础性、前瞻性的重要作用日渐显现。今年政策法规工作将包括：加快立法进度，服务执法实践；强化执法监督，提高执法水平；抓住医改契机，加强基本药物监管；围绕热点难点，开展政策研究；强调上下联动，形成新闻宣传整体合力。（2012年4月13日）

National Drug Registration Work Conference Held in Fuzhou

From 29 to 30 March 2012, the National Drug Registration Work Conference was held in Fuzhou. SFDA Deputy Commissioner Wu Zhen attended the meeting and delivered a speech.

Wu stated that since the implementation of the newly revised “Drug Registration Regulation", drug registration management has made remarkable achievements, an innovation-conducive environment has been initially formed, there has been a good momentum of stable improvement: 1. A new registration management concept that is innovation-oriented and taking “innovation, excellence, simultaneousness and authenticity” has been established; 2. The management methods continuously improved, focusing on the production site inspection, and a new “3-in-1” new review mechanism has been established; 3. The order of Registration management is gradually improved, drug registration application regained a rational order, innovation is encouraged, and the effect of strict review and approval has been obvious; 4. The implementation of work programs is regulated and orderly. We implemented the "Three Systems: Collective Responsibility System for the review personnel, the Accountability System for review and approval, the Public Notification System for personnel in review, approval and inspection, as well as the Information Network Construction", increased the information disclosure efforts to enhance the work standardization; 5. New progress has been made in the enforcement of standards.

Wu pointed out that currently the drug registration management still has "four incompatibles”: service capabilities incompatible with these innovation needs, review and approval strategy incompatible with innovation encouraging policies, work mechanism incompatible with the improvement of quality and efficiency, the level of drug quality standards incompatible with public expectations. To face the problems and challenges, Wu requires to focus the following three work aspects: first, to reform and improve the drug registration work to build a more scientific drug registration management system; second, comprehensively improve the quality of generic drugs to ensure the public's safe use of drugs; third, to strengthen infrastructure construction, and enhance the service capabilities.

At the meeting, major leaders in charge of the SFDA Drug Registration Department deployed the 2012 drug registration management work plan. The 2012 work priorities are: continue to improve the drug review and approval mechanisms; fully deploy the consistency evaluation of generic drugs; continue to promote the improvement of pharmaceutical standards; comprehensively strengthen the supervision of drug research; put more efforts into research of the macro-policy of registration management and the regulatory system; promote the orderly development of Chinese traditional medicine and ethnic medicine.

During the meeting, the participants listened to 3 expert reports on "Drug Safety Situation Analysis", "Analysis and introduction of the FDA commissioner order on Revocation of the Indications of Bevacizumab monoclonal antibody for Breast Cancer", and "Solid Dosage Forms Dissolution/Release Curves and Biological Equivalence".

(April 9, 2012)

全国药品注册管理工作会议在福州召开

2012年3月29至30日，全国药品注册管理工作会议在福州召开，国家食品药品监督管理局副局长吴浈出席会议并讲话。

吴浈副局长表示，新修订的《药品注册管理办法》实施以来，药品注册管理工作取得了显著的成绩，鼓励创新的氛围已经初步形成，药品注册态势趋稳，稳中向好的走势已经显现：一是确立了以鼓励创新为导向，“新、优、同、实”为目标的注册管理新理念；二是管理方式不断完善，注重了生产现场检查，建立了“三合一”审评新机制；三是注册秩序明显好转，药品注册申报逐步回归理性，鼓励创新、严格审批成效明显；四是程序运行规范有序，实行了“三制一化”（主审集体负责制，审评公示制，审评审批责任追究制以及整个行政许可过程的信息化管理），加大了信息公开力度，增强了工作的规范性；五是标准提高取得新进展。

吴浈副局长指出，当前药品注册管理工作还存在“四个不相适应”，即服务能力与创新需求不相适应，审评审批策略与鼓励创新政策不相适应，工作机制与提高质量和效率不相适应，药品质量标准水平与公众期望不相适应。面对问题和挑战，吴浈副局长要求，应着重抓好以下三方面工作：一是要改革和完善药品注册工作，构建更加科学的药品注册管理体系；二是全面提高仿制药质量，确保公众用药安全；三是加强基础建设，提升服务能力。

会上，药品注册司主要负责人会部署了2012年药品注册管理工作。2012年的重点工作是：继续完善药品审评审批机制；全面部署仿制药的一致性评价工作；不断推进药品标准提高工作；全面加强药物研究监管；加大注册管理宏观政策和监管制度研究；促进中药、民族药有序发展。

会议期间，与会人员听取了《药品安全形势分析》、《FDA关于撤销贝伐珠单抗乳腺癌适应症局长裁定的分析介绍》、《固体制剂溶出度/释放度曲线与生物等效性》等3个专家报告。

（2012年4月9日）

SFDA Go All Out to Supervise and Control the Medicinal Hollow Capsules That Contain Excessive Chromium

On April 15, 2012, once informed of the media coverage of some pharmaceutical manufacturers using Chromium-excessive capsules in drug production, SFDA deployed relevant supervision, inspection and product testing, immediately issued the "Notice on Suspending the Sales and Consumption of 13 Chromium-Excessive Products Confirmed by Media Exposure" and the "Notice on Conducting Inspections on Manufacturers Using Chromium-Excessive Hollow Gelatin Capsules in Drug Production As Confirmed by Media Exposure", and held a national teleconference for related deployment.

SFDA will stand for public interest to punish pharmaceutical enterprises with illegal activities, and strengthen supervision to prevent industrial gelatin from entering into the pharmaceutical production processes. China has explicit standards and regulations for the production and sales of pharmaceutical capsules, but unscrupulous enterprises put profit above conscience and deliberately produce counterfeit capsules, resulting in serious negative social impact. SFDA shall crack down on such activities, eliminate potential risks, and effectively protect the public safety and interests.

On April 19, 2012, SFDA announced the sampling test results of the first batch of capsules, based on the Inspection Reports of the National Institutes for Food and Drug Control and some of the provincial food and drug control and inspection institutions. SFDA instructed relevant Provincial Food and Drug Administrations to mete out severe punishment measures on enterprises with illegal behaviors.

On April 20, 2012, SFDA held a Videophone Conference to further deploy a comprehensive Special Supervision & Inspection Campaign for the quality and safety of medicinal capsules, to take strict precautions against the utilization of industrial gelatin for the production of medicinal capsules, prevent the inflow of Chromium-excessive medicinal capsules (CEMCs) into drug manufacturers, and strictly guard against the market entrance of drugs made of CEMCs, sparing no efforts to protect drug quality and protect public interests. The Conference pointed out that the CEMC event currently under media exposure is manifested in the production of medicinal capsules with illegal use of industrial gelatin, and the production of substandard drugs with CEMCs. Relevant provincial Food and Drug Administrations are required to further the in-depth investigation on enterprises with illegal behaviors and their products, strictly investigate and prosecute the involved manufacturers and suspects, and resolutely control and destroy substandard products.

On April 23, 2012, SFDA issued a Notice requiring the Food and Drug Administration Departments of all provinces (autonomous regions and municipalities) to strictly supervise the destruction of the sequestrated Chromium-excessive medicinal capsules and capsula drugs, resolutely prevent the re-inflow of substandard products into the market, and take strict precautions against the enterprises' inappropriate disposal of substandard products, such as the willful in-situ abandonment etc., to ensure that the destruction is in place and fully implemented. (April 23, 2012)

国家食品药品监督管理局全力以赴查控铬超标药用胶囊和胶囊剂药品

2012年4月15日，媒体报道部分药品生产企业使用铬超标胶囊生产药品的问题后，国家食品药品监督管理局立即部署开展有关的监督检查和产品抽验工作，紧急下发了《关于暂停销售使用媒体曝光的13个铬超标产品的通知》和《关于对媒体报道明胶空心胶囊铬超标生产企业进行检查的通知》，召开全国电视电话会议，部署有关工作。

国家食品药品监督管理局表示，将站在公众立场严惩药品生产经营企业违法违规行为，加强监管，严防工业明胶进入药品生产环节。对于药用胶囊的生产销售使用，国家有明确的标准和规定，不法企业利益熏心，故意造假，造成了严重的社会影响，国家食品药品监督管理局将严厉打击，消除隐患，切实维护公众利益。

2012年4月19日，国家食品药品监督管理局公布第一批抽检结果，根据中国食品药品检定研究院和部分省食品药品检验机构检验报告，责成相关省食品药品监管局对违法违规企业予以严肃处理。

2012年4月20日，国家食品药品监督管理局召开电视电话会议，进一步全面部署药用胶囊质量安全专项监督检查行动，严防工业明胶用于药用胶囊生产，严防铬超标药用胶囊进入药品生产企业，严防用铬超标药用胶囊生产的药品流入市场，全力保障药品质量，维护公众利益。会议指出，本次媒体曝光的铬超标药用胶囊事件，是非法使用工业明胶生产药用胶囊及使用铬超标胶囊生产劣药案。要求相关省食品药品监管局对违法违规企业及其产品继续深入开展调查，严肃查办涉案企业，坚决控制销毁不合格产品。

2012年4月23日，国家食品药品监督管理局发出通知，要求各省（自治区、直辖市）食品药品监管部门严格监督销毁被查封的铬超标药用胶囊和胶囊剂药品，坚决防止不合格产品重新流入市场，严防企业以就地抛弃等不恰当的方式处理不合格产品，确保销毁工作到位。（2012年4月23日）

National Development and Reform Commission Will Adjust Some Drugs' Price Ceiling in May

Recently, the National Development and Reform Commission (NDRC) issued a Notice to adjust the maximum retail price of some digestive drugs from May 1. This drug price adjustment involves a total of 53 varieties, more than 300 formulations specifications, with an average price decline of 17%, among which the high-priced drugs shall have an average reduction of 22%. It is expected to relieve the public's burden by more than 3 billion per year.

Relevant NDRC leaders stated that, to accommodate with the new situation of healthcare reform, NDRC will intensify reform measures and improve the price formation mechanism from six aspects.

1. Strengthen the investigation and monitoring of costs and ex-factory prices, and lay a sound foundation for reasonably determining the level of price ceiling. 2. Improve drug pricing methods, explore parmacoeconomics assessment and international price comparisons for some drugs, and explore uniform pricing on some others. 3. Further increase the price reduction of high-priced drugs, especially reduce the prices of foreign original developed drugs. 4. Coordinate with drug production and distribution sector reform, put efforts to regulate the pricing behaviors in drug circulation, promote the integration and optimization of drug circulation enterprises and encourage the development of modern logistics industry. 5. Establish a dynamic drug price adjustment mechanism to timely adjust drug prices according to the cost of drug production, market price changes and other factors. 6. Research and introduce pricing policies that encourage pharmaceutical R & D and innovation. Provide preferential price policies to generic drugs that have reached the international levels.

Relevant NDRC leaders also pointed out that currently China is in the full implementation of the new GMP and the National Drug Standards Improvement Plan, while adjusting drug prices, the cost variation in the wake of pharmaceutical manufacturers' implementation of the new GMP and drug standards improvement shall be taken into account, to appropriately make price adjustments. In addition, for generic drugs produced by a number of manufacturers, the price ceiling shall be adjusted in reference to the cost and market price of manufacturers with advanced enterprise quality standards.

(March 30, 2012)

国家发展和改革委员会5月将调整部分药品最高限价

近日，国家发改委发出通知，决定从5月1日起调整部分消化系统类药品最高零售限价。此次药品价格调整共涉及53个品种，300多个剂型规格，平均降幅17%，其中高价药品平均降幅22%，预计每年可减轻群众负担30多亿元。

国家发改革有关负责人表示，为适应医改新形势，今后发改委将加大改革力度，从六个方面完善价格形成机制。

一是加强成本和出厂价格调查与监测工作，为合理确定最高限价水平奠定基础。二是改进药品定价方法，对部分药品探索采用药物经济性评价和国际价格比较方式定价，对部分药品探索试行统一定价。三是进一步加大对高价药品降价力度，特别是降低外资原研制药品价格。四是配合药品生产流通领域改革，着力规范药品流通环节价格行为，促进药品流通企业的整合和优化，鼓励发展现代物流产业。五是建立药品价格动态调整机制，根据药品生产成本和市场价格变化等因素，适时调整药品价格。六是研究实施鼓励药品研发创新的价格政策。对已达到国际水平的仿制药，在价格政策上给予支持。

国家发改委有关负责人还表示，目前我国正在全面实施新版GMP和国家药品标准提高行动计划，在调整药品价格时，将考虑药品生产企业实施新版GMP和提升药品标准的成本变化情况，适当把握价格调整力度。另外对多家生产的仿制药品将参考质量标准先进企业的成本和市场价格调整最高限价。（2012年3月30日）

The Newly Established Column on CDE Websit–"Information of Repeatedly Applied Varieties of Chemicals" "Database of Commonly Used Pharmaceutical Excipients"

Recently, SFDA Center for Drug Evaluation (CDE) set upon its website the Column of "Registered Approval Numbers and Varieties under Review and Approval", to collect and publicize the updates of Registered Approval Numbers of chemicals and the Varieties under Review and Approval, according to the major indications and generic names, and two categories (including raw materials) of "injection" and "non-injection" by route of administration. The Registered varieties shall be recorded in approval numbers (Import Drug Certificate No.), the Varieties under Review and Approval shall be recorded in acceptance notification numbers. On March 6, 2012, CDE website established the column of "Database of Commonly Used Pharmaceutical Excipients".

药品审评中心网站开设"化药重复申报品种信息"栏目"常用药用辅料数据库"栏目

日前，国家食品药品监督管理局药品审评中心网站开设了"已有批准文号与在审品种信息"栏目，按主要适应症和通用名将目前化学药品已有批准文号与在审评品种数的动态情况进行汇集公布。按给药途径划分为"注射"和"非注射"两类（含原辅料）。已批品种按批准文号（进口注册证号）进行统计，在审品种按受理号进行统计。

The database integrates the information of pharmaceutical excipients that can be partly publicized, and records relevant information such as the pharmaceutical excipients' names, functions and applications, safety, the common dosage and the maximum dosage. At present, the database collects the first batch information of 299 commonly used pharmaceutical excipients varieties, and other varieties are subjected to ongoing information research work, and shall be recorded into the database in next batches.
(March 6, 2012)

2012年3月6日，国家食品药品监督管理局药品审评中心网站开通了“常用药用辅料数据库”栏目。

该数据库是部分公开药用辅料信息的整合，收载了药用辅料名称、功能与应用、安全性、常用量及最大用量等相关信息，目前，数据库首批收录了299个常用药用辅料品种信息，其他品种正在进行信息研究工作，此后将分批次录入数据库。

（2012年3月6日）

Special Focus

业界专题

2011 APIs Exports Maintained Stable Growth

In 2011, China's drug imports and exports maintained stable growth. From 2010 to 2011, exports of APIs recovered rapidly with year-on-year growth rate of 25% to 27%; the varieties and involved species have covered most of the chemicals, pro-drugs and intermediates of biochemical drugs. According to date tracking of the Health Net for the past ten years on import and export value of APIs, the import of pharmaceutical API commodities (biochemical drugs, raw materials of Western medicine, herb extracts) maintained a stable growth higher than that of the exports.

The structure of the import and export of APIs was stable, and after the segmentation of potential product categories, it can be seen that the main components of the imports are immunological products, amino acids and antibiotics APIs. This structure witnessed no obvious changes in recent years.

In export commodities, antibiotics, vitamins, amino acids, organic acids and biochemical APIs extracted from animal organ were still the main components of exports. In addition to the above-mentioned API exports compositions, sweeteners, losartan class antihypertensive drugs, minor vitamin APIs gradually showed an upward trend.

2011原料药出口保持稳定增长

2011年，药品进出口情况保持稳定增长态势。2010—2011年，出口原料药类迅速回升，同比增长率达到25%～27%，品种和涉及种类覆盖了大部分的化学类和生化类药物的前体和中间体。健康网连续十年对原料药进出口额的跟踪显示，原料药类商品（生化药、西药原料、植物提取物）的进口保持稳定增长，进口额的增长幅度高于出口额增长。

进出口原料药的结构稳定，在细分可能的产品类别后可以看出，免疫制品、氨基酸类和抗生素类原料药是构成进口商品的主要成分，这个构成近些年没有发生明显的改变。

在出口商品中，抗生素、维生素、氨基酸类、有机酸类和动物脏器提取的生化类原料药仍是出口的主要构成。除了上述大类原料药出口构成之外，甜味剂、沙坦类降压药、小品种类维生素原料药等逐渐显示出强势。

图1：1999—2011年原料类商品进口额变化 （单位：亿美元）
Figure 1: Trends of imports of API commodity 1999-2011
(Unit: 100 million U.S. dollars)

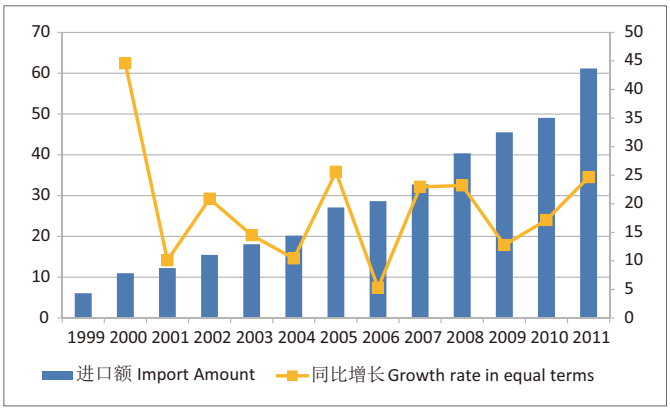

图2：1999—2011年原料类商品出口额变化 （单位：亿美元）
Figure 2: Trends of 1999-2011 exports of API commodity
(Unit: 100 million U.S. dollars)

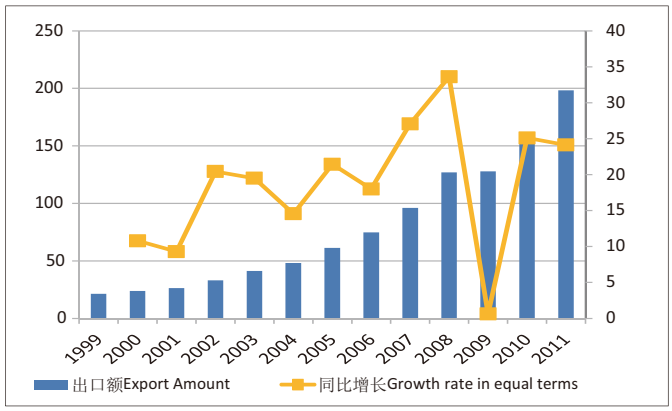

表1：2011年出口典型医药原料药或相关商品分类分布
Table 1: Distribution of 2011 Exports of Typical APIs or Related Pharmaceutical Goods

Categories 分类	Exports ($ Millions) 出口额（百万美元）	Proportion 比例（%）
Antibiotics抗生素	2,790.21	21.16
Vitamins维生素	2,391.51	18.14
Additives添加剂	1,383.34	10.49
Amino Acids氨基酸类	1,021.73	7.75
Blood system血液系统	921.53	6.99
Sweeteners甜味剂	847.78	6.43
Antipyretic and analgesic drugs 解热镇痛	576.52	4.37
Fodder Antibiotics饲用抗生素	523.96	3.97
Hormones激素类	518.37	3.93
Nutritional supplements 营养补充剂	278.95	2.12
Antihypertensive drugs降压药	275.20	2.09
Anti- virus抗病毒	207.24	1.57
Quinolones喹诺酮类	180.35	1.37
Medicine intermediates 医药用中间体	175.68	1.33
Bone drugs骨病用药	173.94	1.32
Lipid-lowering agents降脂药	169.80	1.29
Spices 香料	140.74	1.07
Sulfanilamide products磺胺类	108.09	0.82
Antimalarial抗疟药	72.87	0.55
Weight loss drugs减肥	71.52	0.54
Cardiovascular drugs心血管	55.12	0.42
Antiepileptic抗癫痫	54.42	0.41
Anti-tumor drugs抗肿瘤	50.16	0.38
Glucose lowering drugs降糖	45.82	0.35
Insect repellent驱虫剂	43.84	0.33
Diuretics利尿药	30.07	0.23
Contrast agents造影剂	28.82	0.22
Immunosuppressant免疫抑制剂	23.75	0.18
Respiratory drugs呼吸系统	23.10	0.18
Digestion medicine消化用药	1.74	0.01
Nervous system drugs神经系统	0.13	0.00
Total合计	13,186.31	100.00

表2：2011年进口原料药或医药相关商品分布
Table 2: Distribution of 2011 Imports of APIs or Related Pharmaceutical Goods

Categories 分类	Imports ($ Millions) 进口额（百万美元）	Proportion 比例（%）
Immunological products 免疫制品	1,622.64	26.41
Amino Acids 氨基酸类	688.86	11.21
Pharmaceutical chemical intermediates 医药用化工中间体	523.54	8.52
Antibiotics 抗生素	484.62	7.89
Organic acids 有机酸类	431.39	7.02
Other biochemical drugs 其他生化药	379.49	6.18
Vitamins维生素	341.57	5.56
Enzyme products酶制品	165.04	2.69
Sulfanilamide products 磺胺类	111.56	1.82
Anti-virus抗病毒	100.84	1.64
Serum products血清制品	88.52	1.44
Herb extracts植物提取物	29.37	0.48
Food additives食品添加剂	28.97	0.47
Alkaloids生物碱	19.44	0.32
Hormones激素	16.09	0.26
Antipyretic and analgesic drugs 解热镇痛药	5.79	0.09
Barbital巴比妥	0.30	0.00
Organ extracts脏器提取	0.23	0.00
Antimalarial抗疟药	0.00	0.00
Not classified未分类	1,105.32	17.99
Total总计	6,143.58	100.00

(April 2, 2012) （2012年4月2日）

Notes: • All Chinese information in Newsletter extracted from Newspapers and Internet. All English articles are the translations from the Chinese version.
• Read the electronic version of the newsletter please visit http://www.ccpie.org

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