CHINA FOOD AND DRUG NEWSLETTER

中国食品药品国际交流中心

SERVIER 施维雅（天津）制药有限公司

Issuance of *Provisions for the Allocation of Functions and Responsibilities, Internal Departments and Staffing of National Medical Products Administration*

On September 10, 2018, SCOPSR issued the Provisions for the Allocation of Functions and Responsibilities, Internal Departments and Staffing of National Medical Products Administration and the full text is as follows:

Provisions for the Allocation of Functions and Responsibilities, Internal Departments and Staffing of National Medical Products Administration

Article 1 The Provisions are developed in accordance with the Decision by the Central Committee of the Communist Party of China (CPC)on Deepening the Institutional Reform of the Party and the State and the Plan on Deepening the Reform of CPC and State Organs approved in the third plenary session of the 19th CPC Central Committee, as well as the Institutional Reform Plan of the State Council approved in the first session of the 13th National People's Congress.

Article 2 As a deputy-ministerial level National Administration, National Medical Products Administration (NMPA) is under the jurisdiction of the State Administration for Market Regulation (SAMR).

Article 3 In the course of performing its duties of executing related guidelines, policies, decisions and deployments of the CPC Central Committee, NMPA shall adhere to and strengthen the centralized and unified leadership by CPC over drug administration, and shall bear principal responsibilities for:

(I) The safety supervision and administration for drugs (including traditional Chinese medicine and ethno-medicine, and the same below), medical devices and cosmetics; NMPA shall draw up policy planning for supervision and administration, organize the drafting of laws and regulations of interest, and work out departmental rules and regulations, with their implementation supervised. Study and draft the administration and service policies that encourage new technologies and new products of drugs, medical devices and cosmetics.

(II) The management for standards of drugs, medical devices and cosmetics; NMPA shall organize the development & release of standards of drugs and medical devices, such as the Chinese Pharmacopoeia, the drafting of standards for cosmetics, and development of classification management system, with their implementation supervised. Participate in developing the National Essential Drug List to corroborate the national essential drug system.

(III) The registration management of drugs, medical devices and cosmetics; NMPA shall develop and organize the implementation of the registration management system, the strict review & approval for marketing, and the facilitative measures for review & approval services.

(IV) The quality control of drugs, medical devices and cosmetics; NMPA shall develop and supervise the implementation of the Good Development Practice. Develop and supervise, as per its powers and duties, the implementation of Good Manufacturing Practice. Develop and guide the implementation of Good Practices for Supply and Use.

(V) The risk management of post-marketed drugs, medical devices and cosmetics; NMPA shall organize the implementation

《国家药品监督管理局职能配置、内设机构和人员编制规定》发布

2018年9月10日，中国机构编制网发布《国家药品监督管理局职能配置、内设机构和人员编制规定》，全文如下：

国家药品监督管理局
职能配置、内设机构和人员编制规定

第一条 根据党的十九届三中全会审议通过的《中共中央关于深化党和国家机构改革的决定》、《深化党和国家机构改革方案》和第十三届全国人民代表大会第一次会议批准的《国务院机构改革方案》，制定本规定。

第二条 国家药品监督管理局是国家市场监督管理总局管理的国家局，为副部级。

第三条 国家药品监督管理局贯彻落实党中央关于药品监督管理工作的方针政策和决策部署，在履行职责过程中坚持和加强党对药品监督管理工作的集中统一领导。主要职责是：

（一）负责药品（含中药、民族药，下同）、医疗器械和化妆品安全监督管理。拟订监督管理政策规划，组织起草法律法规草案，拟订部门规章，并监督实施。研究拟订鼓励药品、医疗器械和化妆品新技术新产品的管理与服务政策。

（二）负责药品、医疗器械和化妆品标准管理。组织制定、公布国家药典等药品、医疗器械标准，组织拟订化妆品标准，组织制定分类管理制度，并监督实施。参与制定国家基本药物目录，配合实施国家基本药物制度。

（三）负责药品、医疗器械和化妆品注册管理。制定注册管理制度，严格上市审评审批，完善审评审批服务便利化措施，并组织实施。

（四）负责药品、医疗器械和化妆品质量管理。制定研制质量管理规范并监督实施。制定生产质量管理规范并依职责监督实施。制定经营、使用质量管理规范并指导实施。

（五）负责药品、医疗器械和化妆品上市后风险管理。组织开展药品不良反应、医疗器

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of monitoring, evaluation and disposal of adverse reactions of drugs and cosmetics, and adverse events of medical devices. Undertake law-based emergency management for safety of drugs, medical devices and cosmetics.

(VI) The qualification-based admittance management for licensed pharmacists; NMPA shall develop the qualification admittance system for licensed pharmacists, and guide and supervise the registration in this respect.

(VII) The organization of and guidance over the supervision and inspection of drugs, medical devices and cosmetics; NMPA shall develop inspection systems to perform law-based investigation and handling of illegal acts in the registration of drugs, medical devices and cosmetics, and organize and guide, pursuant to its duties, the investigation and handling of illegal acts in manufacturing.

(VIII) The international exchange and cooperation in the field of supervision and administration of drugs, medical devices and cosmetics, and the participation in the development of relevant international regulatory rules and standards.

(IX) The guidance over drug administration authorities of all provinces, autonomous regions and municipalities directly under the central government.

(X) Other tasks assigned by the CPC and the State Council.

(XI) Transformation of government functions.

1. The reform of "streamline administration and institute decentralization" shall be furthered. Specific items subject to administrative examination & approval shall be reduced. Such items as advertisements for drugs and medical devices, drug clinical trial institutions, and imported cosmetics with non-special purposes shall be gradually canceled or transferred to record filing management. Classified management shall be applied to new APIs of cosmetics: those with high risks shall be subject to licensing management, and those with low risks to record filing management.

2.The concurrent and ex post regulation shall be reinforced. NMPA shall improve the full life cycle management system for drugs and medical devices, and reinforce the whole process quality and safety risk control, with the regulatory methods innovated and credit regulation strengthened. The measures of "oversight through inspections by randomly selected inspectors from randomized entities and the public release of inspection results", and "Internet + Regulation" shall be comprehensively implemented to escalate the regulatory efficiency and meet the public need for use of drugs and medical devices in the new era.

3. The service level shall be effectively improved. NMPA shall expedite the review and approval for innovative drugs and medical devices, establish the Marketing Authorization Holder (MAH) System, and promote electronic review and approval with optimized process and improved efficiency, to create an environment encouraging innovation and protecting legitimate rights and interests. The application information for drug registration shall be released in time to guide the applicants to research, develop and apply in an orderly manner.

4. The regulatory responsibilities shall be comprehensively implemented. In accordance with the requirements of "the most stringent standards, the most rigorous regulation, the most severe punishment, the most serious accountability", the review, inspection, testing, monitoring and other systems for drugs, medical devices and cosmetics shall be optimized, and the professional level of the regulatory team shall be improved. The conformance evaluation of the quality and efficacy of generic drugs shall be expedited, the establishment of a traceability system shall be promoted, and the principal responsibilities of enterprises shall be implemented to prevent systematic and regional risks and guarantee the safety and effectiveness of drugs and medical devices.

(XII) Division of relevant responsibilities

1.Division of responsibilities in relation to the State Administration for Market Regulation; NMPA is responsible for developing the

械不良事件和化妆品不良反应的监测、评价和处置工作。依法承担药品、医疗器械和化妆品安全应急管理工作。

（六）负责执业药师资格准入管理。制定执业药师资格准入制度，指导监督执业药师注册工作。

（七）负责组织指导药品、医疗器械和化妆品监督检查。制定检查制度，依法查处药品、医疗器械和化妆品注册环节的违法行为，依职责组织指导查处生产环节的违法行为。

（八）负责药品、医疗器械和化妆品监督管理领域对外交流与合作，参与相关国际监管规则和标准的制定。

（九）负责指导省、自治区、直辖市药品监督管理部门工作。

（十）完成党中央、国务院交办的其他任务。

（十一）职能转变。

1. 深入推进简政放权。减少具体行政审批事项，逐步将药品和医疗器械广告、药物临床试验机构、进口非特殊用途化妆品等审批事项取消或者改为备案。对化妆品新原料实行分类管理，高风险的实行许可管理，低风险的实行备案管理。

2. 强化事中事后监管。完善药品、医疗器械全生命周期管理制度，强化全过程质量安全风险管理，创新监管方式，加强信用监管，全面落实“双随机、一公开”和“互联网+监管”，提高监管效能，满足新时代公众用药用械需求。

3. 有效提升服务水平。加快创新药品、医疗器械审评审批，建立上市许可持有人制度，推进电子化审评审批，优化流程、提高效率，营造激励创新、保护合法权益环境。及时发布药品注册申请信息，引导申请人有序研发和申报。

4. 全面落实监管责任。按照“最严谨的标准、最严格的监管、最严厉的处罚、最严肃的问责”要求，完善药品、医疗器械和化妆品审评、检查、检验、监测等体系，提升监管队伍职业化水平。加快仿制药质量和疗效一致性评价，推进追溯体系建设，落实企业主体责任，防范系统性、区域性风险，保障药品、医疗器械安全有效。

（十二）有关职责分工。

1. 与国家市场监督管理总局的有关职责分工。国家药品监督管理局负责制定药品、医疗器械和化妆品监管制度，并负责药品、医疗器械和化妆品研制环节的许可、检查和处罚。省级药品监督管理部门负责药品、医疗器械和化妆品生产环节的许可、检查和处

supervision and administration system for drugs, medical devices and cosmetics, as well as the licensing, inspection and administrative penalties for drugs, medical devices and cosmetics in R&D. The provincial drug administration authorities are responsible for the licensing, inspection and penalties for drugs, medical devices and cosmetics in manufacturing, as well as the permission for drug wholesale and retail chain headquarters, the record filing of third-party platforms selling on internet, as well as the inspection and penalties thereof. The market regulatory authorities at the city and county levels are responsible for the licensing, inspection and administrative penalties for drug retails and medical device distribution, as well as the inspections and penalties for cosmetics distribution, and the quality of drugs and medical devices in use.

2. Division of responsibilities in relation to National Health Commission of the People's Republic of China (NHC); NMPA, in conjunction with NHC, shall organize the Chinese Pharmacopeia Commission to develop the Chinese Pharmacopeia, and establish the mutual notification mechanism and joint disposal mechanism for serious adverse reactions of drugs and adverse events of medical devices.

3. Division of responsibilities in relation to the Ministry of Commerce; The Ministry of Commerce is responsible for drafting the development plans and policies for distribution of drugs, while NMPA shall cooperate in the execution of such plans and policies in drug administration. The Ministry of Commerce shall get the informed consent of NMPA before issuing the import licenses for pharmaceutical precursor chemicals.

4. Division of responsibilities in relation to the Ministry of Public Security; The Ministry of Public Security is responsible for organizing and guiding the investigation of criminal cases related to drugs, medical devices and cosmetics. NMPA and the Ministry of Public Security shall establish a cohesive mechanism for administrative law enforcement and criminal justice. Where a crime is suspected to have been committed, the case of illegal act shall be promptly transferred by drug administration authorities in accordance with relevant provisions to the public security organs; the latter shall investigate promptly and make the decision for filing a case or not as per the laws. Drug administration authorities shall provide such assistance as testing, identification and affirmation in case that the public security organs request them to do so in accordance with the laws.

Article 4 The following internal departments (deputy department or bureau level) have been established for NMPA:

(I) Comprehensive Planning & Finance Department; Responsibilities are: 1. The daily operations of NMPA departments, undertaking the work related to information, security, confidentiality, petition, open government affairs, information technology, and news publicity, etc.; 2. The formulation, organization and implementation of the development plans and special plans to drive the construction of administration system; 3. Work related to the budget and final accounts, finance, management of state-owned assets and internal audit for department organs and directly affiliated units; and 4. The organization and drafting of comprehensive documents and important conference papers.

(II) Department of Policies and Legal Affairs; Responsibilities are: 1. Research of significant policies for supervision and administration of drugs, medical devices and cosmetics; 2. Organizing the drafting of laws, regulations and departmental rules, and perform the legality review of normative documents; 3. Supervising law enforcement, administrative reconsideration, and responding to administrative lawsuits; 4. Seamless integration of administrative law enforcement and criminal justice; and 5. Work related to elevating legal literacy and publicity.

(III) Department of Drug Registration (Department of TCMs and Ethno-Medicines Supervision); Responsibilities are: 1. To undertake the organization, formulation, supervision and implementation of drug standards and technical guidances (such as the Chinese Pharmacopoeia), formulate and implement the drug registration management system; 2. Supervise the implementation of pharmaceutical non-clinical researches and Good Clinical Practice, the specifications for

罚，以及药品批发许可、零售连锁总部许可、互联网销售第三方平台备案及检查和处罚。市县两级市场监管部门负责药品零售、医疗器械经营的许可、检查和处罚，以及化妆品经营和药品、医疗器械使用环节质量的检查和处罚。

2. 与国家卫生健康委员会的有关职责分工。国家药品监督管理局会同国家卫生健康委员会组织国家药典委员会并制定国家药典，建立重大药品不良反应和医疗器械不良事件相互通报机制和联合处置机制。

3. 与商务部的有关职责分工。商务部负责拟订药品流通发展规划和政策，国家药品监督管理局在药品监督管理工作中，配合执行药品流通发展规划和政策。商务部发放药品类易制毒化学品进口许可前，应当征得国家药品监督管理局同意。

4. 与公安部的有关职责分工。公安部负责组织指导药品、医疗器械和化妆品犯罪案件侦查工作。国家药品监督管理局与公安部建立行政执法和刑事司法工作衔接机制。药品监督管理部门发现违法行为涉嫌犯罪的，按照有关规定及时移送公安机关，公安机关应当迅速进行审查，并依法作出立案或者不予立案的决定。公安机关依法提请药品监督管理部门作出检验、鉴定、认定等协助的，药品监督管理部门应当予以协助。

第四条 国家药品监督管理局设下列内设机构（副司局级）：

（一）综合和规划财务司。负责机关日常运转，承担信息、安全、保密、信访、政务公开、信息化、新闻宣传等工作。拟订并组织实施发展规划和专项建设规划，推动监督管理体系建设。承担机关和直属单位预决算、财务、国有资产管理及内部审计工作。组织起草综合性文稿和重要会议文件。

（二）政策法规司。研究药品、医疗器械和化妆品监督管理重大政策。组织起草法律法规及部门规章草案，承担规范性文件的合法性审查工作。承担执法监督、行政复议、行政应诉工作。承担行政执法与刑事司法衔接管理工作。承担普法宣传工作。

（三）药品注册管理司（中药民族药监督管理司）。组织拟订并监督实施国家药典等药品标准、技术指导原则，拟订并实施药品注册管理制度。监督实施药物非临床研究和临床试验质量管理规范、中药饮片炮制规范，实施中药品种保护制度。承担组织实施分类管理制度、检查研制现场、查处相关违法行为工作。参与制定国家基本药物目录，配合实施国家基本药物制度。

（四）药品监督管理司。组织拟订并依

processing TCM slices, and implement the protection system for the categorization of TCM varieties; 3. Organize and implement the classification management system, inspect the R&D Venues, and investigate and punish relevant illegal acts; and 4. Participate in the development of the National Essential Drug List and cooperate in the implementation of the national essential drug system.

(IV) Department of Drug Supervision; Responsibilities are: 1. To organize the formulation and supervise, as per its powers and duties, the implementation of drug GMPs; organize the formulation and guide the implementation of the Good Practices for Supply and Use; 2. Organize and guide the on-site inspections over production venues, investigate and punish serious illegal acts; 3. Organize random quality inspections and release Quality Announcements on a regular basis; 4. Organize the monitoring of adverse reactions and law-based disposal thereof; and 5. Undertake the supervision and administration of radioactive, narcotic, toxic, psychotropic drugs and pharmaceutical precursor chemicals.

(V) Department of Medical Device Registration; Responsibilities are: 1. To organize the formulation and supervise the implementation of standards, classification rules, nomenclature conventions and coding rules for medical devices; 2. Formulate and implement the registration management system for medical devices; 3. Formulate and supervise the implementation of the Good Clinical Practice for Medical Devices and technical guidances for medical device clinical trials; and 4. Organize the inspection of R&D Venues, investigate and punish the illegal acts.

(VI) Department of Medical Device Administration; Responsibilities are: 1. To organize the formulation and supervise, as per its powers and duties, the implementation of the GMPs for medical devices; to organize the formulation and guide the implementation of the Good Practices for Supply and Use; 2. Organize and guide the on-site inspections over production venues, investigate and punish serious illegal acts; 3. Organize random quality inspections and release Quality Announcements on a regular basis; and 4. Organize the monitoring of adverse reactions and law-based disposal thereof.

(VII) Department of Cosmetics Administration; Responsibilities are: 1. To organize and implement record filing of cosmetic registration; 2. Undertake the organization, formulation, supervision and implementation of standards, classification rules and technical guidances for cosmetics; 3. Work out the cosmetic inspection system, inspect the R&D Venues, perform duty-based organization and guidance over the on-site inspections of production venues, investigate and punish serious illegal acts; 4. Organize random quality inspections and release Quality Announcements on a regular basis; and 5. Organize the monitoring of adverse reactions and law-based disposal thereof.

(VIII) Department of Science & Technology and International Cooperation (Office of Hong Kong, Macao and Taiwan Affairs); Responsibilities are: 1. To organize the study of scientific tools and methods for implementing review, inspection and testing of drugs, medical devices and cosmetics, study and draw up the management and service policies encouraging new technologies and new products; 2. Work out and supervise the implementation of laboratory construction standards and GLPs, the qualification accreditation conditions and inspection specifications for the inspection and testing institutions; 3. Organize and implement the significant science & technology projects; 4. Organize and carry out exchange and cooperation with the world and Hong Kong, Macao and Taiwan regions; and 5. Coordinate and participate in the development of international regulatory rules and standards.

(IX) Department of Human Resources; Responsibilities are: 1. To undertake the personnel affairs of the cadres in department organs and directly affiliated units, institutional staffing, labor wages and education, and guide the construction of relevant talent teams. Undertake the qualification management for licensed pharmacists.

Party Committee; Responsibilities are: the party-masses work for NMPA organs and its directly affiliated units in Beijing.

Bureau of Retired Officials; Responsibilities

职责监督实施药品生产质量管理规范，组织拟订并指导实施经营、使用质量管理规范。承担组织指导生产现场检查、组织查处重大违法行为工作。组织质量抽查检验，定期发布质量公告。组织开展不良反应监测并依法处置。承担放射性药品、麻醉药品、毒性药品及精神药品、药品类易制毒化学品监督管理工作。

（五）医疗器械注册管理司。组织拟订并监督实施医疗器械标准、分类规则、命名规则和编码规则，拟订并实施医疗器械注册管理制度。拟订并监督实施医疗器械临床试验质量管理规范、技术指导原则。承担组织检查研制现场、查处违法行为工作。

（六）医疗器械监督管理司。组织拟订并依职责监督实施医疗器械生产质量管理规范，组织拟订并指导实施经营、使用质量管理规范。承担组织指导生产现场检查、组织查处重大违法行为工作。组织质量抽查检验，定期发布质量公告。组织开展不良事件监测并依法处置。

（七）化妆品监督管理司。组织实施化妆品注册备案工作。组织拟订并监督实施化妆品标准、分类规则、技术指导原则。承担拟订化妆品检查制度、检查研制现场、依职责组织指导生产现场检查、查处重大违法行为工作。组织质量抽查检验，定期发布质量公告。组织开展不良反应监测并依法处置。

（八）科技和国际合作司（港澳台办公室）。组织研究实施药品、医疗器械和化妆品审评、检查、检验的科学工具和方法，研究拟订鼓励新技术新产品的管理与服务政策。拟订并监督实施实验室建设标准和管理规范、检验检测机构资质认定条件和检验规范。组织实施重大科技项目。组织开展国际交流与合作，以及与港澳台地区的交流与合作。协调参与国际监管规则和标准的制定。

（九）人事司。承担机关和直属单位的干部人事、机构编制、劳动工资和教育工作，指导相关人才队伍建设工作。承担执业药师资格管理工作。

机关党委。负责机关和在京直属单位的党群工作。

离退休干部局。负责机关离退休干部工作，指导直属单位离退休干部工作。

第五条 国家药品监督管理局机关行政编制216名（含两委人员编制2名、援派机动编制2名、离退休干部工作人员编制20名）。设局长1名，副局长4名，药品安全总监1名，药品稽查专员6名，正副司长职数32名（含机关党委专职副书记1名），离退休干部局领导职数2名。

are: To undertake the affairs of retired cadres and guide the work for the retired cadres of directly affiliated units.

Article 5 The staffing of NMPA administrative personnel shall be prescribed within 216 (incl. 2 staff in two committees, 2 staff flexibly assigned for assistance and dispatch, 20 staff for the work of retired cadres), with 1 Commissioner, 4 Deputy Commissioners, 1 Inspector-general for drug safety, 6 ombudsmen for drug inspection, 32 Director-Generals and Deputy Director-Generals (incl. 1 full-time deputy secretary of the Party Committee) and 2 leaders of the Bureau of Retired Officials.

Article 6 The setting, responsibilities and staffing of the public institutions affiliated to NMPA shall be subject to separate provisions.

Article 7 The State Commission Office for Public Sectors Reform (SCOPSR) is responsible for the interpretation of the Provisions, and the adjustments for the Provisions shall be handled by the State Commission Office for Public Sector Reform in accordance with the specified procedures.

Article 8 The Provisions shall take effect from July 29, 2018. (September 10, 2018)

第六条 国家药品监督管理局所属事业单位的设置、职责和编制事项另行规定。

第七条 本规定由中央机构编制委员会办公室负责解释，其调整由中央机构编制委员会办公室按规定程序办理。

第八条 本规定自2018年7月29日起施行。 (2018-09-10)

China Pharmaceutical Association Issued Announcement Prompting the Information Release of the Fourth Batch of Over-duplicated Drug Varieties

To scientifically guide enterprises and R&D institutions to conduct R&D and optimize R&D resource allocation, and promote the benign and healthy development of the pharmaceutical industry, in accordance with the "Opinions of the State Council on the Reform of the Review & Approval System for Drugs and Medical Devices" (State Council [2015] No. 44) and the former CFDA's "Announcement on Policies Pertaining to the Review & Approval of Drug Registration"([2015] No. 230), NMPA commissioned the China Pharmaceutical Association to monitor and analyze the situation of drugs approved and marketed in 2015-2017, and selected a total of 297 varieties via Generic-Name Screening as per the criterion of over-duplicated generic varieties, involving 14 major categories and 60 sub-categories in clinical pharmacology and therapeutic classification. On September 18, 2018, the Chinese Pharmaceutical Association issued an Announcement Prompting the Information Release of the Fourth Batch of Over-duplicated Drug Varieties. (September 18, 2018)

中国药学会发布关于第四批过度重复药品提示信息的公告

为科学引导企业及研发机构有序研发、优化研发资源配置，促进医药行业良性、健康发展，按照《国务院关于改革药品医疗器械审评审批制度的意见》（国发〔2015〕44号）和原国家食品药品监督管理总局《关于药品注册审评审批若干政策的公告》（2015年第230号）要求，原国家食品药品监督管理总局委托中国药学会，对已获批上市药品在2015—2017年间的销售情况进行监测分析，按照过度重复通用名品种的筛选条件，共遴选出297个品种，涉及临床药理学和治疗学分类的14个大类、60个亚类，2018年9月18日，中国药学会发布第四批过度重复药品提示公告。 (2018-09-18)

Announcement of NMPA on Promulgating Three Guidances Covering Sterilization Filtration Technology and Application

To strengthen the supervision of drug production, further guide and standardize drug manufacturers' scientific and systematic development of sterilization filtration technology and application, and aseptic process simulation tests, NMPA has formulated, as the guiding documents for implementation of the "Good Manufacturing Practice for Drugs (2010 Revised Edition)", the "Guidance for sterilization filtration technology and application " and "Guidance for Aseptic Process Simulation Test (Aseptic APIs), and "Guidance for Aseptic Processing Simulation Tests (Aseptic Preparations)", which are hereby promulgated and shall take effect as from October 1, 2018.

(September 11, 2018)

国家药品监督管理局发布关于除菌过滤技术及应用指南等3个指南的通告

为加强药品生产监管，进一步指导和规范药品生产企业科学系统地开展除菌过滤技术及应用、无菌工艺模拟试验，国家药品监督管理局组织制定了《除菌过滤技术及应用指南》《无菌工艺模拟试验指南（无菌原料药）》《无菌工艺模拟试验指南（无菌制剂）》，作为实施《药品生产质量管理规范（2010年修订）》的指导性文件，于2018年9月11日发布，指南自2018年10月1日起施行。 (2018-09-11)

NMPA issued the "Announcement on Registration Application Situation and Self-Examination & Verification of Drug Clinical Trial Data"

On September 10, 2018, NMPA issued the "Announcement on Registration Application Situation and Self-Examination & Verification of Drug Clinical Trial Data" with a decision made to verify the clinical trial data of 24 newly received registration applications for pharmaceutical products that have completed the clinical trials and are applying for production or import; the relevant issues are hereby announced:

I. If the drug registration applicants found inauthenticity of clinical trial data before NMPA verification, they shall take the initiative to apply for withdrawal of registration application and NMPA shall announce the list of applicants and varieties withdrawn without affixing accountability.

II. Center for Food and Drug Inspection of CFDA shall publicize on its website and inform the applicants of drug registration and the competent provincial food and drug administration departments of the on-site verification plan. The Center shall, 10 working days after the public notification, inform the date for on-site verification and no longer accept the applicants' withdrawal of drug registration applications.

III. Pursuant to the laws, NMPA shall severely punish the applicants, responsible persons and managers of drug clinical trials and CROs found with frauds in on-site verification of clinical trial data.

Annex: List of 24 Registration Applications for Drugs with Self-Examination & Verification of Clinical Trial Data (Omitted)

(September 10, 2018)

国家药品监督管理局发布《关于药物临床试验数据自查核查注册申请情况的公告》

2018年9月10日，国家药品监督管理局发布《关于药物临床试验数据自查核查注册申请情况的公告》，决定对新收到的24个已完成临床试验申报生产或进口的药品注册申请进行临床试验数据核查，并将有关事宜公告如下：

一、在国家药品监督管理局组织核查前，药品注册申请人自查发现药物临床试验数据存在真实性问题的，应主动撤回注册申请，国家药品监督管理局公布其名单，不追究其责任。

二、国家食品药品监督管理总局食品药品审核查验中心将在其网站公示现场核查计划，并通知药品注册申请人及其所在地省级食品药品监管部门，公示10个工作日后该中心将通知现场核查日期，不再接受药品注册申请人的撤回申请。

三、对药物临床试验数据现场核查中发现数据造假的申请人、药物临床试验责任人和管理人、合同研究组织责任人，国家药品监督管理局将依法严肃处理。

附件：24个药物临床试验数据自查核查注册申请清单（略）　　（2018-09-10）

Conference Reports

The 9th China International Medical Device Regulatory Forum held in Fuzhou

On September 14, 2018, the 9th China International Medical Device Regulatory Forum, hosted by China Center for Food and Drug International Exchange, was opened at the Fuzhou Strait International Conference & Exhibition Center in Fuzhou, Fujian. Xu Jinghe, the NMPA Deputy Commissioner, attended the Conference and delivered a speech.

This Session closely focuses on the current medical device regulation and the theme of "strengthening the life cycle management of medical devices, bending on product quality safety and innovative development". Relevant responsible persons of NMPA Department of Policies and Legal Affairs, Department of Medical Device Registration, and Department of Medical Device Supervision, as well as experts in the field of medical device standard management, inspection and testing, have comprehensively analyzed the medical device regulatory documents in recent years, and introduce in detail the reform of China's medical device review and approval system, management of standards, adverse event monitoring, traceability system construction, industrial development, international cooperation and relevant information and the latest developments. Medical device regulatory authorities and industry experts from the United States, Japan, Singapore

会议报道

第九届中国医疗器械监督管理国际会议在福州召开

2018年9月14日，由中国食品药品国际交流中心主办的“第九届中国医疗器械监督管理国际会议”在福建省福州市海峡国际会展中心开幕。国家药品监督管理局副局长徐景和出席会议并讲话。

本届会议紧密结合当前医疗器械监管重点，围绕“加强医疗器械全生命周期管理，注重产品质量安全和创新发展”主题，国家药品监督管理局政策法规司、医疗器械注册管理司、医疗器械监管司相关负责人，以及医疗器械标准管理、检验检测等领域的专家，针对近年来我国医疗器械监管法规文件进行全面解析，并详细介绍我国医疗器械审评审批制度改革、标准管理、不良事件监测、追溯体系建设、产业发展、国际合作等方面的相关情况及最新进展。来自美国、日

and other countries and regions shared their respective new measures, new developments and new progresses in medical device regulations and supervision.

Aside from the general assembly, in view of the current hot issues in the medical device industry, this Session also set up 13 Parallel Sessions for Artificial Intelligence and Software, Medical Device Clinical Evaluation, Medical Device Network Security, Medical Device Biological Evaluation, and Medical Device Innovation Technology and Products, etc. The experts and scholars in the medical device industry at home and abroad have communicated and exchanged ideas around the current hot topics and cutting-edge technologies of medical devices. (September 14, 2018)

本、新加坡等国家和地区的医疗器械监管部门和业界专家，分享相关国家和地区医疗器械法规和监管新举措、新发展、新进步。

除全体大会外，本届会议还围绕当前医疗器械行业热点问题，设置了人工智能与软件、医疗器械临床评价、医疗器械网络安全、医疗器械生物学评价、医疗器械创新技术与产品等13个分会场。国内外医疗器械业界专家学者，围绕当前医疗器械的热点话题和前沿技术等进行沟通和交流。

(2018-09-14)

Special Focus 业界专题

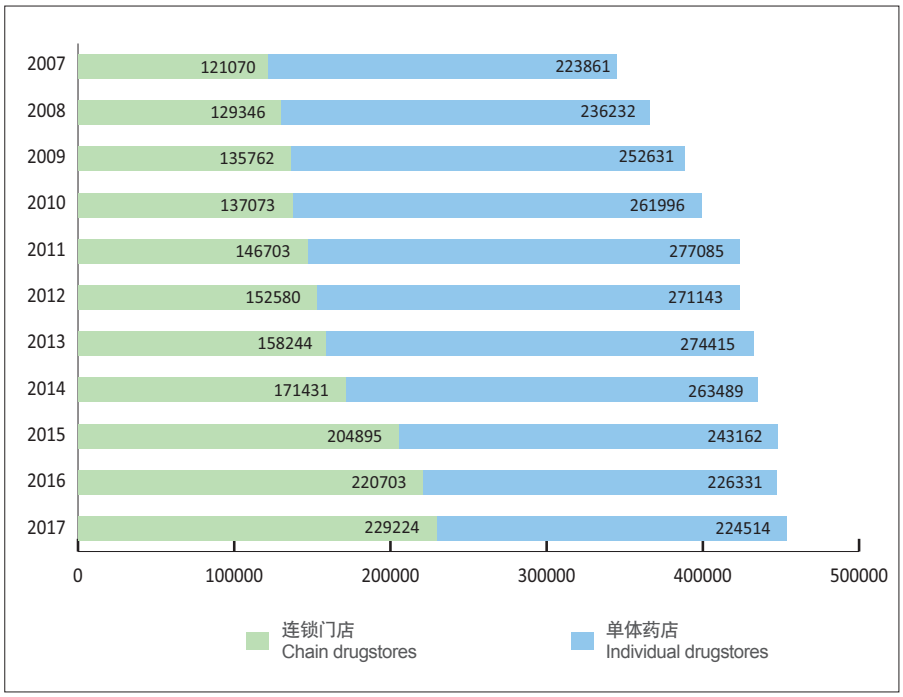
Statistics on Operation of Pharmaceutical Distribution Industry

药品流通行业运行统计

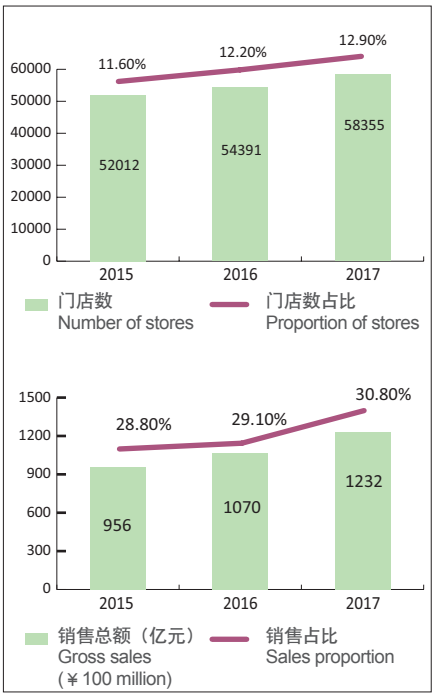
On June 21, 2018, the Ministry of Commerce issued the *Statistical Analysis Report on the Operation of Pharmaceutical Distribution Industry*, which indicates that the number of chains has continuously increased in the past 10 years, with the increase in concentration of distributors again. The sales proportion of Top 100 wholesalers has also escalated.

2018年6月21日，商务部发布了《药品流通行业运行统计分析报告》。分析报告显示，近10年连锁企业数量不断提升，流通企业的集中度再度提升。Top100批发企业销售额占比逐步增长。

近十年连锁药店和单体药店数量
Number of chain drugstores and individual drugstores in the past 10 years



Top100 连锁门店数、销售额及占比趋势
Top100 chain stores, sales and trends



(Source: Medicine Economic News, July 23, 2018)

（摘自：医药经济报 2018-07-23）

Notes:
- All Chinese information in the Newsletter is extracted from newspapers and the Internet. All English articles are translations from the Chinese version.
- For electronic version of the Newsletter please visit http://www.ccfdie.org

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