2018. Volume 1

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

CFDA Released the Announcement on the *Catalogue of China's Marketed Drugs*

On December 29, 2017, CFDA released the *Announcement on the Catalogue of China's Marketed Drugs ("Catalogue")* as follows:

As per the requirements of the General Office of the CPC Central Committee and the General Office of the State Council in the *Opinions on Deepening the Review & Approval System Reform and Encouraging the Drug and Medical Device Innovation* (SC & CPC Central Committee [2017] No. 42), to safeguard the rights and interests of the public drug use, improve the quality of medicines, reduce the medication burden, and encourage the drug R&D and innovation, CFDA organized the formulation of the Catalogue and the relevant issues are announced as follows:

I. As the carrier of CFDA for releasing information of drugs approved for marketing, the Catalogue records the specific information of such drugs approved for marketing as innovative drugs, modified new drugs, generic drugs subject to new registration classification of chemical drugs, and drugs accredited by consistency evaluation of the quality and efficacy. The reference preparations and standard preparations of generic drugs are designated, and the specific varieties of generic drugs that can replace the originators are labeled to facilitate the understanding and inquiry by the pharmaceutical industry, the medical community and the public.

II. The Catalogue publishes the drug review reports, package inserts, patent information and links to other databases via CFDA's government website.

III. The current Catalogue contains 131 varieties and 203 strengths, including 13 varieties and 17 strengths of drugs accredited by consistency evaluation of the quality and efficacy of generic drugs. CFDA will incorporate into the Catalogue with real-time updates the drugs subject to new registration classification and drugs accredited by consistency evaluation of the quality and efficacy of generic drugs, and other drugs newly approved for marketing.

(December 29, 2017)

国家食品药品监管总局发布《中国上市药品目录集》的公告

2017年12月29日，国家食品药品监督管理总局发布《中国上市药品目录集》的公告，内容如下：

根据中共中央办公厅、国务院办公厅《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》（厅字〔2017〕42号）要求，为维护公众用药权益，提高药品质量，降低用药负担，鼓励药物研发创新，国家食品药品监督管理总局组织制定了《中国上市药品目录集》，现将有关事宜公告如下：

一、《中国上市药品目录集》是国家食品药品监督管理总局发布批准上市药品信息的载体，收录批准上市的创新药、改良型新药、化学药品新注册分类的仿制药以及通过质量和疗效一致性评价药品的具体信息。指定仿制药的参比制剂和标准制剂，标示可以替代原研药品的具体仿制药品种等，供制药行业和医学界人员及社会公众了解和查询。

二、《中国上市药品目录集》在国家食品药品监督管理总局政府网站以网络版形式发布并链接药品审评报告、说明书、专利信息等数据库。

三、现发布的《中国上市药品目录集》收录了131个品种，203个品种规格，其中包括通过仿制药质量和疗效一致性评价的13个品种，17个品种规格。国家食品药品监督管理总局将对新批准上市的新注册分类药品以及通过仿制药质量和疗效一致性评价的药品直接纳入《中国上市药品目录集》，实时更新。 （2017-12-29）

CFDA Issued the *Provisions for the Disclosure of Food and Drug Safety Supervision Information*

To enhance the publicity of regulatory information on food and drug safety, protect the public's right to information, participation, expression and supervision, promote the social co-governance of food and drug safety, and enable "Government in the Sunshine", CFDA formulated the *Provisions for the Disclosure of Food and Drug Safety Supervision Information* which was issued on December 22, 2017.

(December 22, 2017)

国家食品药品监督管理总局印发《食品药品安全监管信息公开管理办法》

为加强食品药品安全监管信息公开，保障公众的知情权、参与权、表达权和监督权，推进食品药品安全社会共治，打造阳光政府部门，国家食品药品监督管理总局制定了《食品药品安全监管信息公开管理办法》，于2017年12月22日发布。 （2017-12-22）

Published by
China Center for Food and Drug International Exchange
Servier (Tianjin) Pharmaceutical Co., Ltd.

CFDA Announcement on Promulgating the *Guidelines for the Development of Drug Supplementary Testing Methods*

To regulate and guide the development of drug supplementary testing methods, and strengthen the supportive role of testing technologies in drug supervision and administration, on January 9, 2018, CFDA promulgated the *Guidelines for the Development of Drug Supplementary Testing Methods* in accordance with the regulatory needs.

(January 9, 2018)

国家食品药品监督管理总局发布《药品补充检验方法研制指南》

为规范和指导药品补充检验方法研制工作，强化检验检测技术对药品监管的支撑作用，根据监管工作需要，2018年1月9日，国家食品药品监督管理总局发布《药品补充检验方法研制指南》。（2018-01-09）

CFDA Modified the Package Inserts of 32 OTCs Encompassing DieDa WanHua Oil

According to the results of monitoring and evaluation, to further ensure the safety of public use of drugs, CFDA decided to modify the package inserts of 32 OTCs encompassing DieDa WanHua Oil, and has made a public announcement on the relevant matters on January 9, 2018.

(January 9, 2018)

国家食品药品监督管理总局修订跌打万花油等32种非处方药说明书

根据监测评价结果，为进一步保障公众用药安全，国家食品药品监督管理总局决定对跌打万花油等32种非处方药说明书进行修订。2018年1月9日，就修订有关事项发布了公告。（2018-1-09）

CFDA Issued the *Guidelines for Clinical Trials of OAB Drugs*

To guide and regulate the clinical trials of overactive bladder (OAB) drugs, CFDA organized to formulate the *Guidelines for Clinical Trials of OAB Drugs* which was issued on January 3, 2018.

(January 3, 2018)

国家食品药品监督管理总局发布《膀胱过度活动症药物临床试验指导原则》

为指导和规范膀胱过度活动症药物临床试验，国家食品药品监督管理总局组织制定了《膀胱过度活动症药物临床试验指导原则》，于2018年1月3日发布。（2018-01-03）

CFDA Issued the Announcement on Attribute Definition Results of the Fourth Batch of Drug-Device Combination Products

To guide the applicants for rational applications, on January 2, 2018, CFDA issued the Attribute Definition Results of the Fourth Batch of Drug-Device Combination Products.

Annex: Summary of Attribute Definition Results of the Fourth Batch of Drug-Device Combination Products (omitted)

(January 2, 2018)

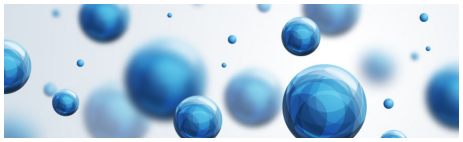
国家食品药品监督管理总局发布第四批药械组合产品属性界定结果的公告

为引导申请人合理申报，2018年1月2日，国家食品药品监督管理总局发布第四批药械组合产品属性界定结果。

附件：第四批药械组合产品属性界定结果汇总（略）。（2018-01-02）

CFDA Released the *Provisions for the Lot Release of Biological Products*

On December 29, 2017, CFDA released the revised *Provisions for the Lot Release of Biological Products* (CFDA Order No. 39) to strengthen the management in the lot release of biological products. The Provisions shall come into force as from February 1, 2018.



(December 29, 2017)

国家食品药品监督管理总局发布《生物制品批签发管理办法》

2017年12月29日，国家食品药品监督管理总局发布修订后的《生物制品批签发管理办法》（国家食品药品监督管理总局令第39号），强化生物制品批签发管理工作。《办法》自2018年2月1日起施行。 (2017-12-29)

CFDA Issued the List of Reference Preparations of Generic Drugs (Eleventh Batch)

On December 29, 2017, CFDA issued the List of Reference Preparations of Generic Drugs (Eleventh Batch), which has been reviewed and determined by the Committee of Experts on Consistency Evaluation of the Quality and Efficacy of Generic Drugs.

(December 29, 2017)

国家食品药品监督管理总局发布仿制药参比制剂目录（第十一批）

经国家食品药品监督管理总局仿制药质量和疗效一致性评价专家委员会审核确定，2017年12月29日，仿制药参比制剂目录（第十一批）发布。 (2017-12-29)

NHFPC & CFDA Issued the Management Practice for the Storage and Transportation of Vaccines (2017 Edition)

To strengthen the management of vaccine storage and transportation, according to the revised *Regulations for Vaccine Distribution and Vaccination and the Opinions on Further Strengthening the Management of Vaccine Distribution and Vaccination (SC [2017] No. 5)*, NHFPC and CFDA have amended the *Management Practice for the Storage and Transportation of Vaccines* (Bureau of Disease Prevention and Control, NHFPC [2006] No. 104), and formed the 2017 Edition thereof which was issued on December 28, 2017.

(December 28, 2017)

国家卫生计生委 食品药品监管总局印发疫苗储存和运输管理规范（2017年版）

为加强疫苗储存和运输管理工作，根据修订后的《疫苗流通和预防接种管理条例》和《关于进一步加强疫苗流通和预防接种管理工作的意见》（国办发〔2017〕5号），国家卫生计生委、食品药品监管总局对《疫苗储存和运输管理规范》（卫疾控发〔2006〕104号）进行了修订，形成了《疫苗储存和运输管理规范（2017年版）》，于2017年12月28日印发。 (2017-12-28)

CFDA Released the *Opinions on Encouraging Pharmaceutical Innovation via Priority Review & Approval*

On December 28, 2017, CFDA released the *Opinions on Encouraging Pharmaceutical Innovation via Priority Review & Approval*, which clarified the scope, procedures of and requirements for the priority review & approval and shall be effective since the date of promulgation.

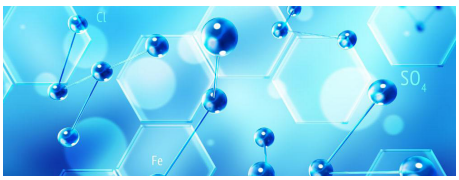
(December 28, 2017)

国家食品药品监督管理总局发布《关于鼓励药品创新实行优先审评审批的意见》

2017年12月28日，国家食品药品监督管理总局发布《关于鼓励药品创新实行优先审评审批的意见》，明确了优先审评审批的范围、优先审评审批的程序以及优先审评审批工作要求。《意见》自发布之日起实施。 (2017-12-28)

CFDA Released Five Technical Guidelines for Clinical Study Incl. the Technical Guidelines for Clinical Study of New TCMs for Irritable Bowel Syndrome

To encourage and guide the R&D and innovation of new TCMs and accelerate the improvement of technical standards system for review in line with the TCM characteristics, CFDA organized to formulate the Technical Guidelines for Clinical Study of New TCMs for Irritable Bowel Syndromes, the *Technical Guidelines for Clinical Study of New TCMs for Functional Dyspepsia*, the *Technical Guidelines for Clinical Study of New TCMs for Cough Variant Asthma*, the *Technical Guidelines for Clinical Study of New TCMs for Rheumatoid Arthritis*, and the *Technical Guidelines for Clinical Study of New TCMs for Chronic Heart Failure*, which were issued on December 27, 2017.



(December 27, 2017)

国家食品药品监督管理总局发布中药新药用于肠易激综合征临床研究技术指导原则等5个临床研究技术指导原则

为鼓励和引导中药新药的研发创新，加快完善符合中医药特点的审评技术标准体系，国家食品药品监督管理总局组织制定了《中药新药用于肠易激综合征临床研究技术指导原则》《中药新药用于功能性消化不良临床研究技术指导原则》《中药新药用于咳嗽变异性哮喘临床研究技术指导原则》《中药新药用于类风湿关节炎临床研究技术指导原则》《中药新药用于慢性心力衰竭临床研究技术指导原则》，于2017年12月27日发布。 (2017-12-27)

CFDA Released the *Technical Guidelines for Assessment of TCM Resources*

To protect, realize the sustainable use of, and guarantee the stable supply of, TCM resources, and ensure the quality controllability of TCMs, CFDA organized to formulate the *Technical Guidelines for Assessment of TCM Resources* which was issued on December 25, 2017.

(December 25, 2017)

国家食品药品监督管理总局发布《中药资源评估技术指导原则》

为保护中药资源，实现中药资源可持续利用，保障中药资源的稳定供给和中药产品的质量可控，国家食品药品监督管理总局组织制定了《中药资源评估技术指导原则》，于2017年12月25日发布。 (2017-12-25)

CFDA Released the *Technical Guidelines for Expression of Chinese Patent Medicine Strengths*

To strengthen the registration management and standardize the expression of strengths of Chinese patent medicines (CPMs), CFDA organized to formulate the *Technical Guidelines for Expression of Chinese Patent Medicine Strengths* which was issued on December 25, 2017.

The expression of CPM strengths shall invariably follow the above Guidelines for new TCMs whose registration applications have been accepted prior to or after the issuance of the said Guidelines, and for post-marketing applications for changes and supplementary applications that are subject to CFDA approval. The standardization of strengths of the marketed CPMs will be gradually implemented via the development and revision work of national standards and post-marketing applications for changes and supplementary applications.

(December 25, 2017)

国家食品药品监督管理总局发布《中成药规格表述技术指导原则》

为加强注册管理，规范中成药规格表述，食品药品监管总局组织制定了《中成药规格表述技术指导原则》，于2017年12月25日发布。

上述技术指导原则发布前已经受理的及发布后新受理的中药新药、属于国家食品药品监督管理总局审批的上市后变更补充申请，均应根据此技术指导原则的要求规范表述中成药规格。对已上市中成药规格的规范，将通过国家标准的制修订工作及上市后变更补充申请等逐步进行。 (2017-12-25)

Medical Devices

CFDA Released the *Technical Guidelines for Accepting Overseas Clinical Trial Data of Medical Devices*

As per the *Opinions on Deepening the Review & Approval System Reform and Encouraging the Drug and Medical Device Innovation* (SC & CPC Central Committee [2017] No. 42) issued by the General Office of the CPC Central Committee and the General Office of the State Council, to strengthen the registration management for medical devices, further improve the quality of registration review, and encourage the R&D and innovation of medical devices, CFDA organized to formulate the Technical Guidelines for Accepting Overseas Clinical Trial Data of Medical Devices which was issued on January 11, 2018. The Guidelines put forward the ethical principles, legal principles and scientific principles for accepting data from overseas clinical trials and clarified the dossiers requirements and technical requirements for such data. The Guidelines expounded the considerations and technical requirements for accepting overseas clinical trial data in relation to the technical review requirements, the subject population and the differences in clinical trial conditions, and give specific examples for diversified factors' clinical implications on the data.

(January 11, 2018)

CFDA Released the *Guidelines for Design of Medical Device Clinical Trials*

As per the *Opinions on Deepening the Review & Approval System Reform and Encouraging the Drug and Medical Device Innovation* (SC & CPC Central Committee [2017] No. 42) issued by the General Office of the CPC Central Committee and the General Office of the State Council, to strengthen the registration management for medical devices, further improve the quality of registration review, and encourage the R&D and innovation of medical devices, CFDA organized to formulate the *Guidelines for Design of Medical Device Clinical Trials* which was issued on January 8, 2018.

(January 8, 2018)

CFDA General Office *Released the Notice on Conducting Medical Device Testing*

As per the *Opinions on Deepening the Review & Approval System Reform and Encouraging the Drug and Medical Device Innovation* (SC & CPC Central Committee [2017] No. 42) issued by the General Office of the CPC Central Committee and the General Office of the State Council, and the *Opinions of the State Council on the Reform of the Review & Approval System for Drugs and Medical Devices* (SC [2015] No. 44), to effectively give play to the technical support of medical device testing agencies and ensure orderly registration of medical devices, on January 3, 2018, the General Office of CFDA released the *Notice on Conducting Medical Device Testing*, requiring the food and drug administrations of all provinces, autonomous regions and municipalities directly under the central government to further strengthen the supervision

医疗器械

国家食品药品监督管理总局发布《接受医疗器械境外临床试验数据技术指导原则》

为贯彻落实中共中央办公厅、国务院办公厅《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》（厅字〔2017〕42号），加强医疗器械产品注册工作的管理，进一步提高注册审查质量，鼓励医疗器械研发创新，国家食品药品监督管理总局组织制定了《接受医疗器械境外临床试验数据技术指导原则》，于2018年1月11日发布。指导原则提出了接受境外临床试验数据的伦理原则、依法原则和科学原则，明确了境外临床试验数据的资料要求和技术要求。指导原则从技术审评要求、受试人群、临床试验条件的差异等方面，阐述了接受境外临床试验资料时的考虑因素及技术要求，并给出了不同因素对临床数据产生有临床意义影响的具体实例。（2018-01-11）

国家食品药品监督管理总局发布《医疗器械临床试验设计指导原则》

为贯彻落实中共中央办公厅、国务院办公厅《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》（厅字〔2017〕42号），加强医疗器械产品注册工作的管理，进一步提高注册审查质量，鼓励医疗器械研发创新，国家食品药品监督管理总局组织制定了《医疗器械临床试验设计指导原则》，于2018年1月8日发布。（2018-01-08）

国家食品药品监督管理总局办公厅发布《关于做好医疗器械检验有关工作的通知》

为贯彻落实中共中央办公厅、国务院办公厅《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》（厅字〔2017〕42号）和《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），切实发挥好医疗器械检验机构技术支撑力量，保证医疗器械注册工作秩序，2018年1月3日，国家食品药品监督管理总局办公厅发布《关于做好医疗器械检验有关工作的通知》，要求各省、自治区、直辖市食品药品监督管理局要进一步加强对所属医疗器械检验机构的

and management and perform effective guidance and coordination of their affiliated medical device testing agencies, which shall perform testing over the to-be-registered products commissioned by medical device applicants based on product technical specifications, and issue the testing reports for product registration.

(January 3, 2018)

监督管理，做好指导协调，各医疗器械检验机构要对医疗器械注册申请人委托检验的注册产品依据产品技术要求进行检验，并出具检验报告用于产品注册。 (2018-01-03)

CFDA Issued the *Announcement on Adjusting the Attributes and Classification of Allergen IVD Reagents, Supportive IVD Reagents for Flow Cytometer, and Immunohistochemistry and In Situ Hybridization IVD Reagents*

As per the *Opinions of the State Council on the Reform of the Review & Approval System for Drugs and Medical Devices* (SC [2015] No. 44) and the *Opinions on Deepening the Review & Approval System Reform and Encouraging the Drug and Medical Device Innovation* (SC & CPC Central Committee [2017] No. 42) issued by the General Office of the CPC Central Committee and the General Office of the State Council,, to further improve the classification management of IVD reagents, determine and divide the attributes and categories of some IVD reagents in an scientific and reasonable manner, CFDA organized the study and adjusted the attribute definition and classification principles of allergen IVD reagents, supportive IVD reagents for flow cytometer, and immunohistochemistry and in situ hybridization IVD reagents, formulated the product classification list, and clarified the implementation requirements according to the *Regulations for the Supervision and Administration of Medical Devices*, the *Provisions for In-vitro Diagnostic Reagent Registration* and other relevant provisions, as well as the status of medical device production, distribution, use and risk analysis, the comprehensive opinions of medical device manufacturers, distributors, user units and trade organizations, and the practice of international classification of medical devices. The Announcement shall come into force as from March 1, 2018.

(December 29, 2017)

国家食品药品监督管理总局发布《关于过敏原类、流式细胞仪配套用、免疫组化和原位杂交类体外诊断试剂产品属性及类别调整的通告》

为贯彻落实《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）和中共中央办公厅、国务院办公厅印发的《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》（厅字〔2017〕42号），进一步做好体外诊断试剂分类管理工作，科学、合理确定和划分部分体外诊断试剂属性和类别，根据《医疗器械监督管理条例》《体外诊断试剂注册管理办法》等有关规定，国家食品药品监督管理总局根据医疗器械生产、经营、使用情况和风险分析，充分听取医疗器械生产经营企业以及使用单位、行业组织的意见，参考国际医疗器械分类实践，组织研究调整了过敏原类、流式细胞仪配套用、免疫组化和原位杂交类体外诊断试剂的属性界定和分类原则，制定了产品分类列表并明确了有关实施要求。通告自2018年3月1日起实施。 (2017-12-29)

CFDA Released the *Guidelines for Technical Review of Mobile Medical Device Registration*

On December 29, 2017, CFDA released the first *Guidelines for Technical Review of Mobile Medical Device Registration* (hereinafter referred to as the *Guidelines*) for mobile medical devices.

The *Guidelines* apply to devices and/or software that use noninvasive "mobile computing terminals" for one or more medical purposes. The definitions, types, judgment principle and general requirements for registration application dossiers of mobile medical devices are further clarified.

According to the *Guidelines*, mobile medical devices, as a combination of mobile computing technology and traditional medical devices, shall take into account the characteristics, risks and control measures of mobile computing technologies in addition to the requirements of traditional medical devices, including cybersecurity capability, display screen limit, ambient light image, battery capacity limit, cloud computing service and so forth. (December 29, 2017)

国家食品药品监督管理总局发布《移动医疗器械注册技术审查指导原则》

2017年12月29日，国家食品药品监管总局发布了首个关于移动医疗器械的《移动医疗器械注册技术审查指导原则》（以下简称《指导原则》）。《指导原则》适用于采用无创“移动计算终端”实现一项或多项医疗用途的设备和/或软件。明确了移动医疗器械的定义、类型、判定原则和注册申报资料总体要求。

根据《指导原则》要求，移动医疗器械作为移动计算技术与传统医疗器械的结合，除考虑传统医疗器械的要求之外还需综合考虑移动计算技术的特点、风险及其控制措施，包括网络安全能力、显示屏限制、环境光影像、电池容量限制、云计算服务等。

(2017-12-29)

CFDA Released the *Management Practice for the Development and Revision of Medical Device Standards*

As per the *Opinions on Deepening the Review & Approval System Reform and Encouraging the Drug and Medical Device Innovation* (SC & CPC Central Committee [2017] No. 42) issued by the General Office of the CPC Central Committee and the General Office of the State Council, and the Provisions for Medical Device Standards (CFDA Order No. 33), CFDA organized to revise the *Management Practice for the Development and Revision of Medical Device Standards* which was issued on December 25, 2017. (December 25, 2017)

国家食品药品监督管理总局发布《医疗器械标准制修订工作管理规范》

为贯彻落实中共中央办公厅、国务院办公厅《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》（厅字〔2017〕42号），根据《医疗器械标准管理办法》（国家食品药品监督管理总局令第33号）有关规定，国家食品药品监督管理总局组织修订了《医疗器械标准制修订工作管理规范》，于2017年12月25日发布。 (2017-12-25)

CFDA Released the *Provisions for the Supervision and Administration of Online Sales of Medical Devices*

On December 22, 2017, CFDA promulgated the *Provisions for the Supervision and Administration of Online Sales of Medical Devices* (CFDA Order No. 38), which shall come into force on March 1, 2018. (December 22, 2017)

国家食品药品监督管理总局发布《医疗器械网络销售监督管理办法》

2017年12月22日，国家食品药品监督管理总局发布《医疗器械网络销售监督管理办法》（国家食品药品监督管理总局令第38号），办法自2018年3月1日起施行。 (2017-12-22)

Special Column

Comprehensively Improve the Quality and Efficacy of Generic Drugs: the First Batch of 17 Strengths Passed the Consistency Evaluation

The high-profile consistency evaluation of the quality and efficacy of generic drugs reaped phased achievements in the pharmaceutical industry - CFDA recently released the list of the first batch of 17 strengths that passed the consistency evaluation of the quality and efficacy of generic drugs. This marks another step forward in the process of comprehensively improving the quality and efficacy of generic drugs in China.

In recent years, CFDA has stepped up the pace of the drug review & approval system reform and gradually solved the resource constraints of clinical trial institutions for bioequivalence (BE) trials and difficult access to reference preparations. The selection of reference preparations was conducted smoothly and the human BE study of some drug varieties was exempted. The review, verification, testing and other work have been consolidated to accelerate the consistency evaluation. As of January 2, 2018, a total of 309 records of BE test for consistency evaluation were filed, covering 182 records for 73 varieties (in the Essential Drug List) from 124 enterprises, and 127 records for 77 varieties (not covered by the Essential Drug List) from 84 enterprises. A total of 6,028 records for reference preparations were filed, covering 3,141 varieties in the Essential Drug List and 695 record-filing enterprises.

Of the 13 varieties (17 strengths) that have passed the consistency evaluation, there are 4 varieties (4 strengths) out of 289-Essential Drug List and 9 varieties (13 strengths) not covered by the 289-Essential Drug List. (January 4, 2018)

专栏

全面提升仿制药质量和疗效首批17个品规通过一致性评价

备受医药行业瞩目的仿制药质量和疗效一致性评价工作取得阶段性成果——国家食品药品监管总局日前发布首批17个通过仿制药质量和疗效一致性评价品种规格的目录。这标志着我国全面提升仿制药质量和疗效的进程又迈出坚实步伐。

近年来，总局加大药品审评审批制度改革步伐，逐步解决生物等效性试验（BE）临床试验机构资源紧张，参比制剂难获得等难题，扎实做好参比制剂遴选，豁免体内BE品种研究，强化审评、核查、检验等各项工作，加快推进一致性评价工作。截至2018年1月2日，一致性评价BE备案共计309条，属于基药目录内的182条，共计124家企业73个品种，目录外的127条，共计84家企业77个品种；参比制剂备案共计6028条，其中基药目录中品种为3141条；备案的企业695家。

目前已通过一致性评价的13个品种（17个品规）中，289个基药目录中有4个品种（4个品规），非289个基药目录中有9个品种（13个品规）。 (2018-01-04)

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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- 电子版Newsletter阅览请登录网站http://www.ccfdie.org

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