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NATIONAL MEDICAL PRODUCTS 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

National Work Conference on Drug Administration Convened in Beijing

From January 10 to 11, 2019, the National Work Conference on Drug Administration was held in Beijing. Guided by Xi Jinping's *Thought on Socialism with Chinese Characteristics for a New Era*, the Conference conscientiously studied the policies of the 19th CPC National Congress and the Second and Third Plenary Session of the 19th CPC Central Committee, implemented the deployment of the Central Economic Working Conference, summarized the work in 2018, and deployed the missions in 2019. The Conference conveyed important instructions from State Councilor Wang Yong on drug administration. Zhang Mao, Secretary of the Party Committee and Minister of State Administration for Market Regulation (SAMR), attended the Conference and put forward requirements for furthering drug administration. Liu Shi, member of the Party Committee of SAMR and the head of CCDI and National Supervisory Commission-Dispatched Discipline Inspection and Supervision Group, attended the Conference. Li Li, Member of the Party Committee of SAMR, Party Secretary and Deputy Director of National Medicinal Products Administration (NMPA), and Jiao Hong, Director of NMPA, attended the Conference and delivered speeches. Xu Jinghe, Chen Shifei and Yan Jiangying, Members of the Party Committee and Deputy Directors of NMPA, also attended the Conference.

The participants unanimously agreed that the important instruction of the State Councilor Wang Yong has fully affirmed the achievement of drug administration, which constitutes a great encouragement to the cadres and workers of the national drug administration system, and is thus of important significance for guiding the effective drug administration in the new era. The whole system shall conscientiously study, profoundly understand and put in place Wang's instruction, effectively guarantee the safety and efficacy of the people's medication, and strive to make fresh progress in the drug administration in the new era.

The Conference pointed out that the year 2019 marks the 70th anniversary of the founding of New China. It is therefore a crucial year for building a well-off society in an all-round way. It is also the first year for full swing of the drug administration system after the institutional reform. Under the guidance of Xi's Thought, the national drug administration system shall thoroughly implement the policies set forth in the 19th CPC National Congress and the Second and Third Plenary Session of the 19th CPC Central Committee. Following the deployments of the Central Economic Working Conference, conscientiously implement the *Four Strictest (Strictest Standards, Regulation, Punishment, and Accountability)* requirements; adhere to the overall principle of *seeking improvement in stability* and the new development concept of innovation, coordination, greenness, openness and sharing; focus on strengthening the life cycle management of drugs; start from promoting the scientific development of administration to advance reform, ensure safety, improve quality, consolidate foundation, and constantly optimize the institutional mechanisms for administration; innovate administration methods, reinforce risk control, deepen the implementation of responsibilities; improve the scientific, legalized, international, and modern levels of drug administration, to effectively protect the people's medication safety and efficacy, and strive to write a new *chapter* of drug administration in the new era.(January 11, 2019)

全国药品监督管理工作会议在京召开

2019年1月10至11日，全国药品监督管理工作会议在京召开。会议以习近平新时代中国特色社会主义思想为指导，认真贯彻党的十九大和十九届二中、三中全会精神，落实中央经济工作会议部署，总结2018年工作，部署2019年任务。会上传达了国务委员王勇对药品监管工作的重要批示。国家市场监督管理总局党组书记、局长张茅出席会议并就进一步加强药品监管工作提出要求，国家市场监督管理总局党组成员、中央纪委国家监委驻总局纪检监察组组长刘实出席会议。国家市场监督管理总局党组成员、国家药品监督管理局党组书记、副局长李利，国家药品监督管理局局长焦红出席会议并讲话。国家药品监督管理局党组成员、副局长徐景和、陈时飞、颜江瑛出席会议。

与会代表一致认为，王勇国务委员的重要批示充分肯定了药品监管工作取得的成绩，是对全国药品监管系统广大干部职工的极大鼓励，对做好新时代药品监管工作具有重要指导意义。全系统要认真学习深刻领会，把王勇国务委员的指示落实到位，切实保障人民群众用药安全有效，奋力开创新时代药品监管工作新局面。

会议指出，2019年是新中国成立70周年，是全面建成小康社会的关键之年，也是机构改革后药监系统全面开展工作的起步之年。全国药品监管系统要以习近平新时代中国特色社会主义思想为指导，深入贯彻党的十九大和十九届二中、三中全会精神，按照中央经济工作会议部署，认真落实“四个最严”要求，坚持稳中求进工作总基调，坚持新发展理念，以强化药品全生命周期管理为重点，以推进监管科学发展为抓手，抓改革、保安全、提质量、强基础，不断完善监管体制机制，创新监管方式方法，强化风险治理，深化责任落实，提高药品监管的科学化、法治化、国际化、现代化水平，切实保障人民群众用药安全有效，奋力谱写新时代药品监管事业新篇章。(2019-01-11)

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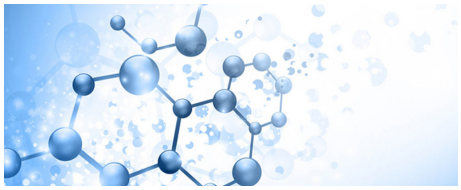
Servier (Tianjin) Pharmaceutical Co., Ltd.

NMPA Issued the Announcement on Revising the Package Inserts of Human Immunoglobulin for Intravenous Injection and Lyophilized Human Immunoglobulin for Intravenous Injection

To further protect the safety of medication for the people, on January 11, 2019, NMPA issued the *Announcement on Revising the Package Inserts of Human Immunoglobulin for Intravenous Injection and Lyophilized Human Immunoglobulin for Intravenous Injection* (Announcement [2019] No. 1), with decisions made to add warnings to the corresponding package inserts and revise the sections such as [Adverse reactions], [Precautions], and [Geriatric use].

(January 11, 2019)



国家药品监督管理局发布《关于修订静注人免疫球蛋白和冻干静注人免疫球蛋白说明书的公告》

为进一步保障公众用药安全，2019年1月11日，国家药品监督管理局发布《关于修订静注人免疫球蛋白和冻干静注人免疫球蛋白说明书的公告》（2019年第1号），决定对静注人免疫球蛋白（pH4）和冻干静注人免疫球蛋白（pH4）说明书增加警示语，并对【不良反应】【注意事项】【老年用药】等项进行修订。 (2018-11-08)

NMPA Issued the Announcement on Drug Varieties Subject to Exempted or Simplified Human Bioequivalence (BE) Test (Second Batch)

To fulfill the requirements of the *Announcement on Matters Concerning the Consistency evaluation of the Quality and Efficacy of Generic Drugs* (CFDA Announcement [2017] No. 100), after research, investigation, demonstration and solicitation for comments, the Office for Quality & Efficacy Consistency evaluation of Generic Drugs has determined and issued on December 29, 2018 the *Drug Varieties Subject to Exempted or Simplified Human Bioequivalence (BE) Test (Second Batch)*.

(December 29, 2018)

国家药品监督管理局发布可豁免或简化人体生物等效性（BE）试验品种（第二批）

为落实《关于仿制药质量和疗效一致性评价工作有关事项的公告》（国家食品药品监督管总局公告2017年第100号）的要求，仿制药质量与疗效一致性评价办公室经调研论证和征求意见，确定了可豁免或简化人体生物等效性（BE）试验品种（第二批），于2018年12月29日发布。 (2018-12-29)

NMPA Issued the Announcement on Cessation of Production, Sales and Use of Pyrithioxine Injections

On December 29, 2018, NMPA issued the *Announcement on Cessation of Production, Sales and Use of Pyrithioxine Injections* (Announcement [2018] No. 99), which reads as follows:

As per Article 42 of the *Drug Administration Law of the People's Republic of China*, *Article 40 of the Regulations for Implementation of the Drug Administration Law of the People's Republic of China*, and NMPA re-evaluation, Pyrithioxine injections are deemed as prone to serious adverse reactions, the risk of use outweighs it's benefit in China. NMPA hereby decide to stop with immediate effect the production, sales and use of Pyrithioxine injections in China, and revoke the corresponding drug approval proof documents. The marketed Pyrithioxine injections shall be recalled by the manufacturers responsible, the recall shall be completed before January 15, 2019, and the recalled products shall be destructed under the supervision of the local food and drug regulatory authorities.(December 29, 2018)

国家药品监督管理局发布《关于停止生产销售使用吡硫醇注射剂的公告》

2018年12月29日，国家药品监督管理局发布《关于停止生产销售使用吡硫醇注射剂的公告》（2018年第99号），内容如下：

根据《中华人民共和国药品管理法》第四十二条和《中华人民共和国药品管理法实施条例》第四十条规定，经国家药品监督管理局组织再评价，认为吡硫醇注射剂存在严重不良反应，在我国使用风险大于获益，决定自即日起停止吡硫醇注射剂在我国的生产、销售和使用，撤销药品批准证明文件。已上市销售的吡硫醇注射剂由生产企业负责召回，召回工作应于2019年1月15日前完成，召回产品由企业所在地药品监督管理部门监督销毁。 (2018-12-29)

NMPA Issued the *Announcement on Matters Concerning the Consistency evaluation of the Quality and Efficacy of Generic Drugs*

On December 28, 2018, NMPA issued the *Announcement on Matters Concerning the Consistency evaluation of the Quality and Efficacy of Generic Drugs*, which reads as follows:

In recent years, all relevant departments have conscientiously implemented the *Opinions of the State Council on Reforming the Review & Approval System for Drugs and Medical Devices* (State Council [2015] No. 44) and the *Opinions of the State Council General Office on Carrying out Consistency evaluation of the Quality and Efficacy of Generic Drugs* (State Council General Office [2016] No. 8) and other regulations, take effective measures to promote consistency evaluation; enterprises continue to beef up investment in R&D, and actively carry out evaluation. In order to further improve the consistency evaluation, with the consent of the State Council, the relevant matters are hereby announced as follows:

1. Strictly implement evaluation standards and strengthen post-marketing supervision

Strictly implement the review & approval of consistency evaluation, adhere to the review principle of the consistency of quality and efficacy of original drugs with that of generic drugs, stick to the principle of not lowering the standards, and carry out technical review in accordance with the published Technical Guidelines for the R&D technology of related drugs. Strengthen post-marketing supervision and inspection of drugs, drugs that passed the consistency evaluation shall be incorporated into the next-year national drug sampling inspection plan, and the supervision and inspection of relevant enterprises shall be intensified.

2. Quality First, Timeliness Second. Reasonably adjust the time limits and requirements for relevant tasks

(1) The *National Essential Drugs List* (2018 Edition) has been implemented since November 1, 2018 with an established dynamic adjustment mechanism, to achieve linkage with the consistency evaluation. Varieties that have passed the consistency evaluation are prioritized to be included in the Drugs List, while varieties that have not passed the consistency evaluation will be phased out from the List. For the varieties included in the List, the evaluation time limit requirements are no longer uniformly set.

(2) For generic drugs containing the essential drug varieties approved for marketing before the implementation of the new registration classification of chemicals, after the first variety has passed the consistency evaluation, in principle, the consistency evaluation shall be completed for the same varieties of other pharmaceutical manufacturers within three years. For overdue evaluation of a variety, if the enterprise considers it to be clinically-necessary or under-supplied upon evaluation, an application for deferred evaluation may be submitted to the local provincial drug regulatory authority, the evaluation can be appropriately postponed upon the joint approval made by the provincial drug regulatory authority and the health administrative authority after organized research. Where the evaluation failed again to be completed within the time limit, the variety shall be prohibited from re-registration.

3. Consolidate service guidance, and fully promote the consistency evaluation

Thoroughly implement the *State Council's reform requirements of Streamlining*

国家药品监督管理局发布《关于仿制药质量和疗效一致性评价有关事项的公告》

2018年12月28日，国家药品监督管理局发布《关于仿制药质量和疗效一致性评价有关事项的公告》，内容如下：

近年来，各有关部门认真贯彻落实《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）、《国务院办公厅关于开展仿制药质量和疗效一致性评价的意见》（国办发〔2016〕8号）等规定，采取切实有效措施推进一致性评价工作；企业持续加大研发投入，积极开展评价。为进一步做好一致性评价工作，经国务院同意，现就有关事项公告如下：

一、严格评价标准，强化上市后监管

严格一致性评价审评审批工作，坚持仿制药与原研药质量和疗效一致的审评原则，坚持标准不降低，按照现已发布的相关药物研发技术指导原则开展技术审评。强化药品上市后监督检查，通过一致性评价的药品，纳入下一年度国家药品抽验计划，加大对相关企业的监督检查力度。

二、时间服从质量，合理调整相关工作时限和要求

（一）《国家基本药物目录（2018年版）》已于2018年11月1日起施行并建立了动态调整机制，与一致性评价实现联动。通过一致性评价的品种优先纳入目录，未通过一致性评价的品种将逐步被调出目录。对纳入国家基本药物目录的品种，不再统一设置评价时限要求。

（二）化学药品新注册分类实施前批准上市的含基本药物品种在内的仿制药，自首家品种通过一致性评价后，其他药品生产企业的相同品种原则上应在3年内完成一致性评价。逾期未完成的，企业经评估认为属于临床必需、市场短缺品种的，可向所在地省级药品监管部门提出延期评价申请，经省级药品监管部门会同卫生行政部门组织研究认定后，可予适当延期。逾期再未完成的，不予再注册。

三、强化服务指导，全力推进一致性评价工作

深入贯彻落实国务院“放管服”改革要求，坚持引导、督导与服务并重，根据评价

Administration, Delegating More Powers to Lower-level Governments and Society, Improving Regulation and Optimizing Services, attaching equal importance to guidance, supervision and service. According to the specific conditions of the varieties to be evaluated, handle the cases with classified treatment, separate measures, and further beef up service guidance. Establish a green channel to realize prompt review upon application for consistency evaluation, thus speeding up the review process. Where a company encounters major technical problems in the course of research, it may communicate with the drug evaluation institutions in accordance with the relevant provisions of the Administrative Measures for Communication of Drug R&D and Technical Review. Further strengthen the guidance over key varieties and key enterprises, organize on-site research and communication, and help enterprises solve difficult problems.

4. Reinforce supporting policies and mobilize the enthusiasm of enterprise to engage in consistency evaluation

Give full play to the role of the market mechanism and stimulate the enthusiasm of enterprises to carry out consistency evaluation. Drug regulatory authorities can allow the varieties that have passed the consistency evaluation to be marked with the pass on the package inserts and labels, and included in the *Catalogue of China's Marketed Drugs*. For the same variety of drugs, where more than three manufacturers have passed the consistency evaluation, in terms of centralized procurement of drugs, varieties that fail the consistency evaluation shall be, in principle, no longer selected. All localities shall improve the centralized procurement policy on the basis of ensuring the quality and supply of drugs. The National Health Commission of the People's Republic of China shall support via matching policies the cost-effective, clinically-necessary essential drugs in the National Essential Drug List (2018 Edition) to guarantee the demand for clinical medication. (December 28, 2018)

品种具体情况，分类处理、分别施策，进一步加大服务指导力度。建立绿色通道，对一致性评价申请随到随审，加快审评进度。企业在研究过程中遇到重大技术问题的，可以按照《药物研发与技术审评沟通交流管理办法》的有关规定，与药品审评机构进行沟通交流。进一步加强对重点品种、重点企业的指导，组织现场调研和沟通，帮助企业解决难点问题。

四、加强配套政策支持，调动企业评价积极性

充分发挥市场机制作用，激发企业开展一致性评价的积极性。通过一致性评价的品种，药品监管部门允许其在说明书和标签上予以标注，并将其纳入《中国上市药品目录集》；对同品种药品通过一致性评价的药品生产企业达到3家以上的，在药品集中采购等方面，原则上不再选用未通过一致性评价的品种。各地要在保证药品质量和供应的基础上，从实际出发完善集中采购政策；国家卫生健康委对《国家基本药物目录（2018年版）》中价格低廉、临床必需的药品在配套政策中给予支持，保障临床用药需求。

(2018-12-28)

NMPA Issued the *Regulations on the Administration of Overseas Inspection of Drugs and Medical Devices*

In order to further standardize the overseas inspection of drugs & medical devices and ensure the quality of imported drugs & medical devices, NMPA issued on December 28, 2018 the *Regulations on the Administration of Overseas Inspection of Drugs and Medical Devices* (hereinafter referred to as the *Regulations*).

The *Regulations* clarifies that overseas inspections are for drugs and medical devices that have been marketed or are intended to be marketed in the territory of the People's Republic of China; they are not limited to production site inspections, but are extended to overseas R&D and production site inspections. The formulation of the inspection task is to consider the multi-channel risk factors as in the registration review and approval, supervision and inspection, testing, complaints & reports, and adverse reaction monitoring of drugs & medical devices, etc., and reflect the management requirements for risk prevention and control.

The comprehensive evaluation of the inspection results adopts the principle of risk assessment to comprehensively consider the nature and severity of the defects, the types of the products under evaluation to judge the inspection results, and the evaluation results are classified as: meeting the requirements, meeting the requirements after rectification, or

国家药品监督管理局发布《药品医疗器械境外检查管理规定》

为进一步规范药品医疗器械境外检查工作，保证进口药品医疗器械质量，国家药监局2018年12月28日发布《药品医疗器械境外检查管理规定》（以下简称《规定》）。

《规定》明确，境外检查是针对已在中华人民共和国境内上市或者拟在境内上市的药品和医疗器械；境外检查不限于生产现场检查，而延展为境外研发及生产场地检查。检查任务的形成，是考虑药品医疗器械的注册审评审批、监督检查、检验、投诉举报、不良反应监测等多渠道风险因素，体现风险防控管理要求。

检查结果综合评定采取风险评估的原则，综合考虑缺陷的性质、严重程度以及所评估产品的类别判定检查结果，评定为符合要求、整改后符合要求或不符合要求。《规定》将拖延、阻碍、限制或拒绝检查等情形

not meeting the requirements. The *Regulations* directly determine the results as not meeting the requirements in case of delay, obstruction, restriction or refusal of inspection.

The inspection result handling distinguishes between the risk control measures and the case investigation and handling. Risk control measures will be taken immediately for the serious quality risks identified by the inspection. Where risk control measures are taken, after the risk is removed, the inspected entity may apply to NMPA for the termination of risk control measures. Where any suspected violations of laws and regulations are spotted during the inspection, an investigation shall be initiated and the case handled pursuant to the law.

(December 28, 2018)

直接判定为“不符合要求”。

检查结果处理区分了风险控制手段和立案调查处理两种情形。对于检查发现的严重质量风险的，将立即采取风险控制措施。对于采取风险控制措施的，风险排除后，被检查单位可以向国家药监局申请解除风险控制措施。在检查中发现涉嫌违法违规的，组织依法立案调查处理。 (2018-12-28)

NMPA Issued the *Notice on Strengthening Drug Administration during the Centralized Procurement and Pilot Use of Drugs*

In order to fully implement their important decisions and arrangements and the requirements in *Pilot Program for Nationally Organized Centralized Procurements for Drugs* to truly guarantee the quality and medication safety of the winning drugs during the centralized procurement and pilot use of drugs, On December 27, 2018, NMPA issued the *Notice on Strengthening Drug Administration during the Centralized Procurement and Pilot Use of Drugs* and put forward specific work requirements, requiring the drug regulatory authorities of all provinces, autonomous regions, municipalities directly under the central government, and the Administration for Market Supervision of Xinjiang Production and Construction Corps to profoundly understand the significance of the pilot; reinforce the supervision over drug production, distribution and use; strengthen drug sampling and adverse reaction monitoring; accelerate the consistency evaluation; implement the innovation-driven development strategy to promote the high quality development of drugs, etc.

(December 27, 2018)

国家药品监督管理局印发《关于加强药品集中采购和使用试点期间药品监管工作的通知》

为全面落实党中央、国务院重要决策部署和《国家组织药品集中采购试点方案》各项工作要求，切实保证药品集中采购和使用试点期间中标药品的质量，保障人民群众用药安全，2018年12月27日，国家药品监督管理局印发《关于加强药品集中采购和使用试点期间药品监管工作的通知》，要求各省、自治区、直辖市药品监督管理局，新疆生产建设兵团市场监督管理局，要深刻认识试点工作重要意义、加强药品生产监管、加强药品流通使用监管、加强药品抽检和不良反应监测、加快推进一致性评价工作、实施创新驱动发展战略，助推药品高质量发展，并提出了具体工作要求。 (2018-12-27)

NMPA Issued the *Guidelines for the Collection and Reporting of Adverse Drug Reactions in Individual Cases*

To standardize the monitoring and reporting of post-marketing adverse drug reactions, and fulfill the drug Marketing Authorization Holders' principal responsibility for directly reporting ADRs, following the relevant provisions and guidelines of the *International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)*, NMPA formulated and released on December 21, 2018 the *Guidelines for the Collection and Reporting of Adverse Drug Reactions in Individual Cases*.

(December 21, 2018)

国家药品监督管理局发布《个例药品不良反应收集和报告指导原则》

为规范持有人药品上市后不良反应监测与报告工作，落实持有人直接报告药品不良反应主体责任，遵循国际人用药品注册技术协调会（ICH）指导原则相关规定，国家药品监督管理局组织制定了《个例药品不良反应收集和报告指导原则》，于2018年12月21日发布。 (2018-12-21)

Medical Devices

NMPA Approved the Promulgation of 27 Medical Device Industry Standards Including YY 0042- 2018 *High Frequency Jet Ventilator*

On December 25, 2018, NMPA approved the promulgation of 27 medical device industry standards (4 compulsory + 23 voluntary standards) such as YY 0042-2018 *High Frequency Jet Ventilator*.

(December 21, 2018)

NMPA Issued the *Guidelines for Technical Review of the Registration of Medical Laser Fiber Optic Products*

To strengthen the supervision and guidance over the registration of medical device products and further improve the quality of registration review, NMPA has organized the formulation of the *Guidelines for Technical Review of the Registration of Medical Laser Fiber Optic Products*, which has been promulgated on December 24, 2018.

(December 24, 2018)

NMPA Issued Two Guidelines for *Technical Review of the Registration of Single-Use Bilirubin Plasma Hemoperfutors* and Others

To strengthen the supervision and guidance over the registration of medical device products and further improve the quality of registration review, NMPA has organized the formulation of the *Guidelines for the Technical Review of Registration of Single-Use Bilirubin Plasma Hemoperfutors, and the Guidelines for Technical Review of the Registration of Single-use Biopsy Needles*, which have been promulgated on December 18, 2018.

(December 18, 2018)

NMPA issued the *Guidelines for Compiling the Application Dossiers for Special Review of Innovative Medical Devices*

To implement the policies set forth in the *Opinions of the General Office of the CPC Central Committee and the General Office of the State Council on Deepening the Reform of Review and Approval System to Encourage Innovation in Drugs and Medical Devices*, and further elaborate the technical review and compiling of application dossiers for innovative medical device as stipulated in the *Special Review Procedures for Innovative Medical Devices*, NMPA organized the formulation of the *Guidelines for Compiling the Application Dossiers for Special Review of Innovative Medical Devices*, which has been released on December 18, 2018. The *Guidelines for Compiling the Application Dossiers for Special Review and Approval of Innovative Medical Devices*, issued by the former China Food and Drug Administration (CFDA Announcement [2016] No. 166), shall be repealed simultaneously.

(December 18, 2018)

医疗器械

国家药品监督管理局批准发布YY 0042—2018《高频喷射呼吸机》等27项医疗器械行业标准

2018年12月25日，国家药品监督管理局批准发布YY 0042—2018《高频喷射呼吸机》等27项医疗器械行业标准，其中，强制性标准4项，推荐性标准23项。 (2018-12-25)

国家药品监督管理局发布《医用激光光纤产品注册技术审查指导原则》

为加强医疗器械产品注册工作的监督和指导，进一步提高注册审查质量，国家药品监督管理局组织制定了《医用激光光纤产品注册技术审查指导原则》，于2018年12月24发布。 (2018-12-24)

国家药品监督管理局发布一次性使用胆红素血浆吸附器等2项注册技术审查指导原则

为加强医疗器械产品注册工作的监督和指导，进一步提高注册审查质量，国家药品监督管理局组织制定了《一次性使用胆红素血浆吸附器注册技术审查指导原则》《一次性使用活检针注册技术审查指导原则》，2018年12月18日发布。 (2018-12-18)

国家药品监督管理局发布《创新医疗器械特别审查申报资料编写指南》

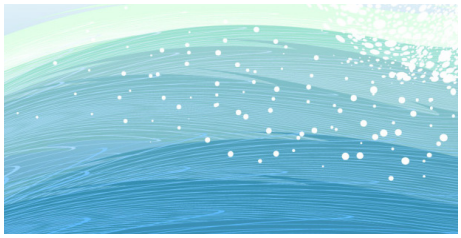
为贯彻落实中共中央办公厅、国务院办公厅《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》，进一步做好《创新医疗器械特别审查程序》规定的创新医疗器械申报资料编写和技术审查工作，国家药品监督管理局组织制定了《创新医疗器械特别审查申报资料编写指南》，于2018年12月18日发布。原国家食品药品监督管理总局印发的《创新医疗器械特别审批申报资料编写指南》（国家食品药品监督管理总局通告2016年第166号）同时废止。 (2018-12-18)

General Information

NMPA has cumulatively approved the marketing of 54 innovative medical device products

In recent years, as per the *Opinions of the State Council on the Reform of the Review and Approval System for Drugs and Medical Devices* (State Council [2015] No. 44) and the *Opinions of the General Office of the CPC Central Committee and the General Office of the State Council on Deepening the Reform of Review and Approval System to Encourage Innovation in Drugs and Medical Devices (General Office [2017] No. 42),* NMPA has advanced the in-depth reform of the medical device review and approval system, and accelerated the development of medical device innovation. Since the promulgation of the Special Review Procedures for Innovative Medical Devices, as of December 31, 2018, there have been 197 products that entered the special review channel for innovative medical devices, 54 products have been approved for registration, encompassing neurosurgical navigation and positioning systems, positron emission tomography and magnetic resonance imaging system, etc. The marketing of an array of highly innovative, high-tech, and clinically imperative products has filled the gaps in related fields and better met the health needs of the people.

For products entering the review and approval channel for innovative medical devices, NMPA carries out scientific review and approval through early intervention, designated responsibility, multiple communication, expert consultation, etc., under the premise that standards are not lowered, procedures are not reduced, giving priority to innovative medical devices. According to statistics, the average review and approval time for innovative medical devices is reduced by 83 days compared with the other three types of initial-registration products, and the time from R&D to marketing is further shortened.



To better implement the special review and approval system for innovative medical devices, in November 2018, NMPA issued the newly revised *Special Review Procedures for Innovative Medical Devices*. The revised Procedures are more scientific and reasonable in setting, which is conducive to further concentrating on escalating efficiency, so as to facilitate the innovation-driven development of the medical device industry. (January 11, 2019)

综合信息

国家药品监督管理局已累计批准54个创新医疗器械产品上市

近年来，国家药品监督管理局贯彻落实《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），深入推进医疗器械审评审批制度改革，加速医疗器械创新发展。自《创新医疗器械特别审批程序》发布以来，截止2018年12月31日，已有197个产品进入创新医疗器械特别审查通道，批准神经外科手术导航定位系统、正电子发射断层扫描及磁共振成像系统等54个产品注册，一批创新性强、技术含量高、临床需求迫切的创新产品上市，填补了相关领域的空白，更好的满足了人民群众的健康需求。

对于进入创新医疗器械审评审批通道的产品，国家药品监督管理局通过早期介入、专人负责、多次沟通、专家咨询等方式开展科学审评审批，在“标准不降低、程序不减少”的前提下，对创新医疗器械予以优先办理。据统计，对创新优先平均审评审批时间较其他普通三类首次注册产品平均压缩83天，创新产品从研发到上市的时间进一步缩短。

为更好地实施创新医疗器械特别审批制度，2018年11月，国家药品监督管理局发布了新修订的《创新医疗器械特别审查程序》。修订后的程序设置更科学合理，有利于进一步集中力量，提高效率，促进医疗器械产业创新发展。

(2018-12-18)

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

备 注： • Newsletter中所有中文信息摘自报刊及网络。英文均系中文翻译。

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