NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心

Headline

NMPA Announcement on Further Improvement and Optimization of Matters Concerning the Production of Imported Medical Devices in Domestic Enterprises in China (No. 30, 2025)

In September 2020, the NMPA Announcement on Matters Concerning the Production of Imported Medical Devices in Domestic Enterprises in China (No. 104, 2020, hereinafter referred to as the Announcement) was issued and implemented. To thoroughly implement the decisions of the CPC Central Committee and the State Council on advancing high-level opening-up, fully carry out the requirements of the Opinions of the General Office of the State Council on Comprehensively Deepening the Regulatory Reform of Drugs and Medical Devices to Promote the High-Quality Development of the Pharmaceutical Industry (GBF [2024] No. 53), continuously deepen the reform of medical device regulation, and promote the high-quality development of the medical device industry, the following adjustments and optimizations are hereby made to certain provisions of the Announcement:

I. Scope of Application

The foreign-invested enterprises referred to in the Announcement can either be an enterprise established by the imported medical device registrant or an enterprise that shares the same actual controller as the registrant of the imported medical device. In other words, this Announcement is applicable to matters concerning the production of Class II and Class III medical devices with imported medical device registration certificates in the People's Republic of China by the imported medical device registrants through their foreign-invested enterprises established in China or the foreign-invested enterprises that share the same actual controller as the registrants of the imported medical device. The actual controller shall comply with the relevant definitions and provisions of the Company Law of the People's Republic of China, which stipulates that an actual controller refers to a person who can actually control the company's actions through investment relationships, agreements, or other arrangements.

II. Requirements for Registration and Application

(1) The registration applicant shall submit the application dossiers in accordance with the formats, contents, etc. specified in the NMPA Announcement on the Issuance of the Requirements for Registration Application Dossiers of Medical Device and the Format of Approval Documents (No. 121, 2021) and the NMPA Announcement on the Issuance of the Requirements for Registration Application Dossiers of In Vitro Diagnostic Reagents and the Format of Approval Documents (No. 122, 2021).

For the summary data, non-clinical data (except for the list of basic principles of safety and performance, product technical requirements, and test reports), and clinical evaluation data of the product, the original registration application dossiers for the imported medical devices can be submitted. However, the product technical requirements and test reports shall reflect that the product complies with the applicable mandatory standard requirements.

(2) Where the registration applicant and the imported medical device registrant share the same actual controller, a statement and supporting documents proving such a relationship shall be provided. The statement

头条

国家药监局关于进一步调整和优化进口医疗器械产品在中国境内企业生产有关事项的公告（2025年第30号）

2020年9月，《国家药监局关于进口医疗器械产品在中国境内企业生产有关事项的公告》（2020年第104号，以下简称《公告》）发布实施。为深入贯彻党中央、国务院关于推进高水平对外开放等部署，全面落实《国务院办公厅关于全面深化药品医疗器械监管改革促进医药产业高质量发展的意见》（国办发〔2024〕53号）要求，持续深化医疗器械监管改革，促进医疗器械产业高质量发展，现就《公告》部分要求进一步调整和优化如下：

一、适用范围

《公告》中所述的外商投资企业，可以是进口医疗器械注册人设立的企业，或者与进口医疗器械注册人具有同一实际控制人的企业。即进口医疗器械注册人设立的，或者与其具有同一实际控制人的外商投资企业在中华人民共和国境内自行生产第二类、第三类已获进口医疗器械注册证产品的有关事项，适用《公告》。

实际控制人应当符合《中华人民共和国公司法》相关定义和规定，即实际控制人是指，通过投资关系、协议或者其他安排，能够实际支配公司行为的人。

二、注册申报要求

（一）注册申请人按照《国家药品监督管理局关于公布医疗器械注册申报资料要求和批准证明文件格式的公告》（2021年第121号）、《国家药品监督管理局关于公布体外诊断试剂注册申报资料要求和批准证明文件格式的公告》（2021年第122号）中要求的格式、目录等提交注册申报资料。

其中，产品的综述资料、非临床资料（安全和性能基本原则清单、产品技术要求及检验报告除外）、临床评价资料，可使用进口医疗器械的原注册申报资料。产品技术要求及检验报告应当体现产品符合适用的强制性标准要求。

（二）注册申请人与进口医疗器械注册人具有同一实际控制人的，应当提供双方具有同一实际控制人的说明及佐证文件。说明文件可包含双方的股权关系说明等，佐证文件应当包括距注册申请日期最近的注册申请人《企业年

document may include a description of the equity relationship between the two parties. The supporting documents shall include the most recent Enterprise Annual Report of the registration applicant closest to the registration application date and other reports containing information about the actual controller, as been uploaded or disclosed per requirements by the competent department. These corresponding statements and supporting documents shall be archived and retained by the medical product regulatory authority for future reference.

(3) The registration applicant shall submit a letter of authorization issued by the registrants of the imported medical devices, explicitly consenting to the registration applicant's use of the original registration application dossiers of the imported medical device for domestic registration application and product production purposes. The letter of authorization shall be notarized by a notary institution located in the place where the registrant of the imported medical device is located.

III. Registration System Verification Requirements

The registration applicant shall commit that there will be no changes in the main raw materials and main production processes and provide a self-inspection report that the domestic production quality management system of the product complies with the Good Manufacturing Practice for Medical Devices and a comparison report of overseas and domestic quality management systems.

According to the working procedure for the verification of quality management system for medical device registration, drug regulatory authorities shall conduct verifications for domestic registration applicants, focusing on the substantial equivalence of the domestic and overseas quality management systems in the product design and development process.

Where differences exist between the quality management systems of the proposed domestically registered products and imported medical devices, the registration applicant shall provide a detailed explanation, commit that such differences will not result in any changes to the registered items, conduct a risk analysis to identify major risk points and corresponding control measures, and ensure the safety, effectiveness, and controllable quality of the product.

IV. Other Aspects

(1) For imported innovative medical devices produced within China in accordance with the requirements of the Announcement, the relevant registration, production licensing, and other matters shall be given priority in processing.

(2) For the production of Class II and Class III medical devices with imported medical device registration certificates in China by overseas registrants invested by Chinese domestic enterprises, the domestic investor enterprise or another domestic enterprise that shares the same actual controller may serve as the registration applicant to apply for product registration and undertake production.

(3) For products already approved for registration, subsequent matters such as registration changes and renewals shall be handled in accordance with the Provisions for Medical Device Registration and Filing and the Provisions for In-vitro Diagnostic Reagent Registration and Filing.

It is hereby announced.

National Medical Products Administration

March 17, 2025

(March 18, 2025)

度报告书》等含实际控制人信息的报告并已按主管部门要求上传或披露。相应说明和佐证文件由药品监管部门存档备查。

（三）注册申请人应当提交由进口医疗器械注册人出具的明确同意注册申请人使用进口医疗器械原注册申报资料开展境内注册申报和生产产品的授权书。授权书应当经进口医疗器械注册人所在地公证机构公证。

三、注册体系核查要求

注册申请人应当承诺主要原材料和主要生产工艺不发生改变，提供产品在境内生产质量管理体系符合我国《医疗器械生产质量管理规范》的自查报告和境内外质量管理体系对比报告。

药品监管部门按照医疗器械注册质量管理体系核查工作程序，对境内注册申请人开展核查，同时重点关注产品设计开发环节境内外质量管理体系的实质等同性。

对于境内拟申报注册产品和进口医疗器械产品质量管理体系存在差异的，注册申请人应当详细说明，承诺相关差异不会引起注册事项的变更，同时做好风险分析，明确主要风险点和控制措施，确保产品安全、有效、质量可控。

四、其他方面

（一）对于进口创新医疗器械产品按照《公告》要求在中国境内生产的，相应注册、生产许可等事项优先办理。

（二）中国境内企业投资的境外注册人在境内生产已获进口医疗器械注册证的第二类、第三类医疗器械产品的，由投资境外注册人的中国境内企业或者与该境内企业具有同一实际控制人的其他境内企业作为注册申请人，申请该产品注册并自行生产。

（三）获准注册的产品后续办理变更注册、延续注册等事项，按照《医疗器械注册与备案管理办法》《体外诊断试剂注册与备案管理办法》规定办理。

特此公告。

国家药监局

2025年3月17日

（2025-03-18）

Drugs

NMPA Announcement on Further Improvement and Optimization of Matters Concerning the Production of Imported Medical Devices in Domestic Enterprises in China (No. 30, 2025)

To accelerate the implementation process of the Electronic Common Technical Document (eCTD) in China and enhance the service capabilities of "Internet + Drug Regulation" applications, the following matters concerning the expansion of the eCTD implementation scope are hereby announced:

I. Based on the eCTD implementation scope

药品

国家药监局关于扩大药品电子通用技术文档实施范围的公告（2025年第10号）

为加快推进药品电子通用技术文档（以下简称eCTD）在我国的实施进程，提升“互联网+药品监管”应用服务水平，现将扩大eCTD实施范围有关事项公告如下：

outlined in the NPMA Announcement on Implementing the Application with Electronic Common Technical Documents (No.119, 2021), the implementation scope will be further expanded, allowing the following applications to be submitted in eCTD format starting from January 27, 2025: drug clinical trial applications for Class 1 to 5 chemical drugs; marketing authorization applications for Class 2, 3, 4, and 5.2 chemical drugs; drug clinical trial applications for Class 1 to 3 preventive biological products and therapeutic biological products; and marketing authorization applications for Class 2 and 3.

II. For submissions made in eCTD format, applicants shall prepare and submit eCTD electronic submission dossiers in accordance with the current eCTD technical document requirements. Applicants are encouraged to submit eCTD electronic dossiers via online transmission. For detailed operational guidelines, please refer to the Notice on Pilot Implementation of Online Transmission for Drug Registration Electronic Application Dossier Submission published on the official website of the Center for Drug Evaluation of the National Medical Products Administration.

It is hereby announced.

National Medical Products Administration

January 22, 2025

(January 23, 2025)

一、在《国家药监局关于实施药品电子通用技术文档申报的公告》（2021年第119号）中eCTD实施范围基础上，进一步扩大实施范围，自2025年1月27日起，化学药品1类至5类的药物临床试验申请，化学药品2类、3类、4类、5.2类的上市许可申请，以及预防用生物制品和治疗用生物制品1类至3类的药物临床试验申请、2类和3类的上市许可申请，可按照eCTD进行申报。

二、采用eCTD进行申报的，申请人按照现行的eCTD技术文件要求准备和提交eCTD电子申报资料。鼓励采用网络传输方式提交eCTD电子申报资料，具体操作请参考国家药品监督管理局药品审评中心网站《关于试行以网络传输方式提交药品注册电子申报资料的通知》。

特此公告。

国家药监局

2025年1月22日

（2025-01-23）

Netanasvir Phosphate Capsules Approved for Marketing by China NMPA

Recently, the Class 1 innovative drug Netanasvir Phosphate Capsules (trade name: 东卫卓/Dongweizhuo) of Sunshine Lake Pharma Co., Ltd. is approved for marketing by China NMPA. This product is indicated for use in combination with Encofosbuvir Tablets for the treatment of adult patients with chronic hepatitis C virus (HCV) genotype 1, 2, 3, or 6, who are either treatment-naïve or have been previously treated with interferon, with or without compensated liver cirrhosis. The marketing of this drug provides a new treatment option for relevant patients.

(February 08, 2025)

国家药监局批准磷酸萘坦司韦胶囊上市

近日，国家药品监督管理局批准广东东阳光药业股份有限公司申报的1类创新药磷酸萘坦司韦胶囊（商品名：东卫卓），该药适用于与艾考磷布韦片联用，治疗初治或干扰素经治的基因1、2、3、6型成人慢性丙型肝炎病毒（HCV）感染，可合并或不合并代偿性肝硬化。该药品上市为患者提供了新的治疗选择。

（2025-02-08）

Finotonlimab Injection Approved for Marketing by China NMPA

Recently, the Finotonlimab Injection (trade name: 安佑平/Anyouping) of Sino Cell Technologies Inc. is approved for marketing by China NMPA. Indications: This product is indicated for first-line treatment of recurrent and/or metastatic squamous cell carcinoma of the head and neck in combination with platinum-containing chemotherapy.

Finotonlimab Injection is a recombinant humanized anti-programmed death receptor-1 (PD-1) monoclonal antibody that blocks the interaction between PD-1 and its ligands, thereby inhibiting tumor growth. The marketing of this drug provides a new treatment option for relevant patients.

(February 08, 2025)

国家药监局批准菲诺利单抗注射液上市

近日，国家药品监督管理局批准神州细胞工程有限公司申报的菲诺利单抗注射液（商品名：安佑平）上市。适应症为：本品与含铂化疗联合用于复发性和/或转移性头颈部鳞状细胞癌的一线治疗。

菲诺利单抗注射液是一种重组人源化抗程序性死亡受体-1（PD-1）单克隆抗体，可通过阻断PD-1与其配体的结合，从而抑制肿瘤的生长。该品种的上市为患者提供了新的治疗选择。

（2025-02-08）

Siltartoxatug Injection Approved for Marketing by China NMPA

Recently, the Siltartoxatug Injection (trade name: 新替妥/Xintituo) of Zhuhai Trinomab Pharmaceutical Co., Ltd. is approved for marketing through the priority review and

国家药监局批准斯泰度塔单抗注射液上市

近日，国家药品监督管理局通过优先审评

approval procedure by China NMPA. This product is indicated for emergency prophylaxis of tetanus in adults.

It is a recombinant anti-tetanus toxin monoclonal antibody, which provides passive immunity primarily by binding to the AB fragment of tetanus toxin. The marketing of this drug provides a new option for clinical medication.

(February 14, 2025)

审批程序批准珠海泰诺麦博制药股份有限公司申报的斯泰度塔单抗注射液（商品名：新替妥）上市，用于成人破伤风紧急预防。

本品为重组抗破伤风毒素单克隆抗体，主要通过结合破伤风毒素的AB片段，起到被动免疫作用。该品种的上市为临床用药提供了新的选择。

（2025-02-14）

Innovative TCM Compound Binafuxi Granules Approved for Marketing by China NMPA

Recently, the Class 1.1 innovative traditional Chinese medicine (TCM) Compound Binafuxi Granules of Xinjiang Yinduolan Uighur Medicine Co., Ltd. is approved for marketing by China NMPA.

This product is a compound preparation formulated based on Uyghur medicine theory. It has undergone a randomized, double-blind, placebo-controlled, multicenter clinical trial and has demonstrated efficacy in clearing abnormal bodily fluids. It is indicated for the treatment of febrile common cold, with symptoms such as fever, nasal congestion, runny nose, sore throat, headache, dry mouth, etc. This drug provides a new treatment option for patients with febrile common colds, as diagnosed by TCM and Uyghur medicine differentiation in the case of common colds.

(January 03, 2025)

国家药监局批准中药创新药复方比那甫西颗粒上市

近日，国家药品监督管理局批准了新疆银朵兰药业股份有限公司申报的中药1.1类创新药复方比那甫西颗粒上市。

该药品为按照维吾尔医药理论组方的复方制剂，开展了随机、双盲、安慰剂平行对照的多中心临床试验，具有清除体内异常体液质的功效，用于热性感冒，症见发热、鼻塞、流涕、咽痛、头痛、口干等。该药品为普通感冒中维医辨证属于热性感冒的人群提供新的用药选择。

（2025-02-27）

Announcement of the National Medical Products Administration and National Health Commission on Issuing the 2025 Edition of the Pharmacopoeia of the People's Republic of China (No. 29, 2025)

According to the Drug Administration Law of the People's Republic of China, the Pharmacopoeia of the People's Republic of China (2025 Edition) (hereinafter referred to as Chinese Pharmacopoeia) has been reviewed and approved by the Plenary Meeting of the Executive Committee of the 12th Chinese Pharmacopoeia Commission. It is hereby issued and shall come into force as of October 01, 2025. For the contents of the Chinese Pharmacopoeia (2025 Edition), see the attachment.

It is hereby announced.

National Medical Products Administration

National Health Commission

March 20, 2025

(March 25, 2025)

国家药监局 国家卫生健康委关于颁布2025年版《中华人民共和国药典》的公告（2025年第29号）

根据《中华人民共和国药品管理法》，2025年版《中华人民共和国药典》（以下简称《中国药典》）经第十二届药典委员会执行委员会全体会议审议通过，现予颁布，自2025年10月1日起施行。2025年版《中国药典》目录见附件。

特此公告。

国家药监局　国家卫生健康委

2025年3月20日

（2025-03-25）

NMPA Announcement on Matters Related to the Implementation of the 2025 Edition of the Pharmacopoeia of the People's Republic of China (No. 32, 2025)

The 2025 Edition of the Pharmacopoeia of the People's Republic of China (hereinafter referred to as the Chinese Pharmacopoeia) has been issued by Announcement No. 29, 2025 of the National Medical Products Administration and the National Health Commission and shall come into force as of October 01, 2025. The relevant matters concerning the implementation of this edition of the Chinese Pharmacopoeia are hereby announced as follows:

II. Chinese Pharmacopoeia is primarily composed of General Notices, Monographs, General Technical Requirements and Guidelines. As of the date of implementation, all Marketing Authorization Holders (MAHs) and marketed drugs shall comply with the

国家药监局关于实施2025年版《中华人民共和国药典》有关事宜的公告（2025年第32号）

2025年版《中华人民共和国药典》（以下简称《中国药典》）已由国家药监局、国家卫生健康委2025年第29号公告颁布，自2025年10月1日起实施。现就实施本版《中国药典》有关事宜公告如下：

一、根据《药品管理法》规定，药品应当符合国家药品标准。《中国药典》是国家药品标准的重要组成部分，是药品研制、生产（进

requirements of this announcement and the current edition of the Chinese Pharmacopoeia. Among these, the requirements outlined in the Guidelines are recommended technical requirements.

III. As of the date of implementation, for drug varieties that have been recorded in former editions of pharmacopoeias or in standards promulgated by CFDA or Ministry of Health (MOH), but now are included in this edition of the Chinese Pharmacopoeia, the corresponding former editions of pharmacopoeias and the standards promulgated by CFDA or MOH shall be abolished simultaneously; where those varieties are not recorded in this edition of the Chinese Pharmacopoeia, the corresponding former editions of pharmacopoeias and the standards promulgated by CFDA or MOH shall still prevail, but shall comply with the relevant general technical requirements of this edition of the Chinese Pharmacopoeia; for drug varieties revoked or cancelled after post-marketing evaluation, the corresponding former editions of pharmacopoeias and the standards promulgated by CFDA or MOH shall be abolished.

For preparation specifications and TCM preparation methods that are not recorded in the Monographs of this edition of the Chinese Pharmacopoeia, their quality standards shall comply with the requirements for the same kind of varieties specified in this edition of the Chinese Pharmacopoeia, while specifications and preparation methods shall comply with the original approval documents.

IV. After the issuance of this edition of the Chinese Pharmacopoeia, MAHs implementing drug registration standards shall promptly conduct relevant comparative studies to assess whether the drug registration standards meet the requirements of the new edition pharmacopoeia standards.

For any necessary change to drug registration standards, MAHs shall, prior to the implementation date of this edition of the Chinese Pharmacopoeia, submit supplementary applications, filings or reports in accordance with the relevant regulations on post-marketing management regulations and ensure compliance.

Where the test items recorded in drug registration standards outnumber or differ from those specified in the pharmacopoeia, or where the quality indicators are stricter than the pharmacopoeia requirements, the corresponding items and indicators of the registration standard shall be implemented simultaneously while requirements of the pharmacopoeia must also be met. Conversely, where the test items recorded in drug registration standards are fewer than those specified in the pharmacopoeia, or the quality indicators are lower than the pharmacopoeia requirements, the pharmacopoeia provisions shall prevail.

V. To comply with the requirements of this edition of the Chinese Pharmacopoeia, where changes in drug formulation, production processes, raw materials and excipients, or packaging materials/containers in direct contact with drugs are involved, MAHs and manufacturers shall conduct adequate research and validation in accordance with the requirements of the Provisions for Drug Registration, Provisions for Post-approval Changes of Drugs (Interim), relevant technical guidelines for change research, and the Good Manufacturing Practice for Drugs. Changes should be implemented following approval, filing, or reporting according to their classification.

VI. Due to the specificity of dissolution, release rate, and other items in quality control, if generic drug registration standards approved in accordance with the requirements of the consistency evaluation of the quality and efficacy of generic drugs differ from the Chinese Pharmacopoeia, the approved drug registration standards shall prevail.

VII. For drugs whose generic names have been revised in this edition of the Chinese Pharmacopoeia, the names specified in this edition of the Chinese Pharmacopoeia shall prevail, and their original names can be transitionally used as former names. Prior to the implementation date of the next edition of the Chinese Pharmacopoeia, the former names can be used simultaneously with the names specified in this edition of the Chinese Pharmacopoeia.

VIII. As of the date of implementation of this edition of Chinese Pharmacopoeia, the corresponding application dossiers for drug registration application shall comply with the relevant requirements of this edition of Chinese Pharmacopoeia.

For registration applications that have been accepted with pending technical review before the date of implementation of this edition of the

口）、经营、使用和监督管理等相关单位均应当遵循的法定技术标准。

二、《中国药典》主要包括凡例、品种正文、通用技术要求和指导原则。自实施之日起，所有药品上市许可持有人及生产上市的药品应当执行本公告和本版《中国药典》相关要求。其中，指导原则相关要求为推荐技术要求。

三、自实施之日起，凡原收载于历版药典、局（部）颁标准的品种，本版《中国药典》收载的，相应历版药典、局（部）颁标准同时废止；本版《中国药典》未收载的，仍执行相应历版药典、局（部）颁标准，但应当符合本版《中国药典》的相关通用技术要求。经上市后评价撤销或者注销的品种，相应历版药典、局（部）颁标准废止。

本版《中国药典》品种正文未收载的制剂规格、中药的制法，其质量标准按本版《中国药典》同品种相关要求执行，规格项、制法项分别按原批准证明文件执行。

四、本版《中国药典》颁布后，执行药品注册标准的，药品上市许可持有人应当及时开展相关对比研究工作，评估药品注册标准是否符合新颁布的药典标准有关要求。

对于需要变更药品注册标准的，药品上市许可持有人应当在本版《中国药典》实施之日前，按照药品上市后变更管理相关规定提出补充申请、备案或者报告，并按要求执行。

药品注册标准中收载检验项目多于或者异于药典规定的，或者质量指标严于药典要求的，应当在执行药典要求的基础上，同时执行注册标准的相应项目和指标。药品注册标准收载检验项目少于药典规定或者质量指标低于药典要求的，应当执行药典规定。

五、为符合本版《中国药典》要求，如涉及药品处方、生产工艺和原料、辅料、直接接触药品的包装材料和容器等变更的，药品上市许可持有人、生产企业应当按照《药品注册管理办法》《药品上市后变更管理办法（试行）》以及有关变更研究技术指导原则和药品生产质量管理规范等要求进行充分研究和验证，按相应变更类别批准、备案后实施或者报告。

六、由于溶出度、释放度等项目在质量控制中的特殊性，按照仿制药质量和疗效一致性评价要求核准的仿制药注册标准中有别于《中国药典》的，按经核准的药品注册标准执行。

七、本版《中国药典》已进行通用名称修订的药品，应当使用本版《中国药典》中载明的名称，其原名称可作为曾用名过渡使用。在下一版药典实施之日前，曾用名可与本版《中国药典》中载明的名称同时使用。

八、自本版《中国药典》实施之日起，提出的药品注册申请，相应申报资料应当符合本版《中国药典》相关要求。

在本版《中国药典》实施之日前已受理，并且尚未完成技术审评的注册申请，自本版《中

Chinese Pharmacopoeia, the drug regulatory authority shall carry out corresponding review and approval according to the relevant requirements of this edition of the Chinese Pharmacopoeia, effective from the date of implementation of this edition of the Chinese Pharmacopoeia. Applicants who need to supplement technical information shall complete the supplement in a single submission.Drugs approved for marketing according to the relevant requirements of previous pharmacopoeias after the date of issuance and before the date of implementation of this edition of the Chinese Pharmacopoeia shall comply with the relevant requirements of this edition of the Chinese Pharmacopoeia within 6 months after approval.

IX. Drug marketing authorization holders, manufacturers, and applicants for drug registration shall actively prepare for the implementation of this edition of the Chinese Pharmacopoeia, and promptly report any problems encountered in practice to the Chinese Pharmacopoeia Commission, while continuously studying and improving drug quality standards to persistently improve the level of drug quality control.

X. All provincial drug regulatory authorities shall cooperate in the publicity and implementation of this edition of Chinese Pharmacopoeia, reinforce the supervision and guidance during its implementation, and promptly collect and provide feedback on related issues and opinions.

XI. The Chinese Pharmacopeia Commission is responsible for organizing and coordinating the publicity, implementation, training and technical guidance of this edition of Chinese Pharmacopoeia, opening up the Chinese Pharmacopoeia Implementation Column on its official website, and in a timely manner, answering questions reflected during implementation.

It is hereby announced.

National Medical Products Administration

March 25, 2025

(March 25, 2025)

国药典》实施之日起药品监督管理部门应当按照本版《中国药典》相关要求开展相应审评审批，申请人需要补充技术资料的，应当一次性完成提交。

在本版《中国药典》颁布之日后、实施之日前按原药典标准相关要求批准上市的药品，批准后6个月内应当符合本版《中国药典》相关要求。

九、药品上市许可持有人、生产企业和药品注册申请人应当积极做好执行本版《中国药典》的准备工作，对在《中国药典》执行过程中发现的问题及时向国家药典委员会报告，同时应当持续研究完善药品质量标准，不断提升药品质量控制水平。

十、各省级药品监督管理部门应当配合做好本版《中国药典》的宣传贯彻，加强本版药典执行中的监督与指导，及时收集和反馈相关问题和意见。

十一、国家药典委员会负责组织和协调本版《中国药典》的宣贯培训和技术指导工作，在官方网站开设“《中国药典》执行专栏”，及时答复执行中反映的问题。

特此公告。

国家药监局

2025年3月25日

（2025-03-25）

Medical device

Transcatheter Mitral Valve Clip System Approved for Marketing

Recently, the innovative product Transcatheter Mitral Valve Clip System of Hangzhou Dawneo Medical Technology Co., Ltd. is approved by China NMPA.

This product is indicated for patients with degenerative mitral regurgitation (MR ≥ 3+) who are assessed by a heart team to be at high surgical risk and have suitable mitral valve anatomy for the procedure. The product features a wrapped and supportive closed configuration designed to ensure stable anchoring post-implantation. Its four-channel control system for anchoring components allows for either simultaneous or independent leaflet grasping, which is expected to enhance procedural success rates and reduce surgical risks.

The NMPA will strengthen the post-marketing surveillance of the product to ensure the safe use of this medical device.

(February 08, 2025)

医疗器械

经导管二尖瓣夹系统获批上市

近日，国家药品监督管理局批准了杭州端佑医疗科技有限公司“经导管二尖瓣夹系统”创新产品注册申请。

该产品适用于经心脏团队评估后认为存在外科手术高风险，且二尖瓣瓣膜解剖结构适合的退行性二尖瓣反流（MR≥3+）患者。产品采用包裹托举状的闭合形态设计，预期可以实现植入后稳固的锚定；采用锚固件四通道控制通路设计，能够实现瓣叶同时或者分别捕获，预期提高手术成功率，减少手术风险。

药品监督管理部门将加强该产品上市后监管，保护患者用械安全。

（2025-02-08）

Aortic Covered Stent System Approved for Marketing

Recently, the innovative product "Aortic Covered Stent System" of Lifetech Scientific (Shenzhen) Co., Ltd. is approved by China NMPA.

This product is indicated for patients with Stanford Type B aortic dissection requiring revascularization of the left subclavian artery, with a proximal landing zone length ≥15mm. This product is the first active stent-graft system explicitly designed for chimney

主动脉覆膜支架系统获批上市

近日，国家药品监督管理局批准了先健科技（深圳）有限公司“主动脉覆膜支架系统”创新产品注册申请。

该产品适用于需要重建左锁骨下动脉血运的Stanford B型夹层患者，其近端锚定区长度应≥15mm。该产品为首款明确适用于烟囱技术的

techniques Its aortic branch stent employs a dual-layer stent design with an outer skirt, which fills the gap between the stent and the vessel after deployment. This design is expected to prevent and reduce endoleaks, thereby lowering the risk of complications.

The NMPA will strengthen the post-marketing surveillance of the product to ensure the safe use of this medical device.

(February 08, 2025)

主动覆膜支架系统，其主动脉分支支架采用带外层裙边的双层支架结构设计，外层裙边可在支架释放后填补支架与血管形成的间隙，预期可以防止和减少内漏发生，降低并发症风险。

药品监督管理部门将加强该产品上市后监管，保护患者用械安全。

（2025-02-08）

Interpretation of the NMPA Announcement on Further Adjustment and Optimization of Matters Concerning the Production of Imported Medical Devices in Domestic Enterprises in China

The NMPA Announcement on Further Adjustment and Optimization of Matters Concerning the Production of Imported Medical Devices in Domestic Enterprises in China (No. 30, 2025) was issued on March 18, 2025. This Announcement shall come into force as of the date of issuance (hereinafter referred to as the Announcement). The background, main principles, and key issues of the adjustments and optimizations in this Announcement are explained as follows:

I. Background

In 2020, the National Medical Products Administration (NMPA) issued the Announcement on Matters Concerning the Production of Imported Medical Devices in Domestic Enterprises in China (No. 104, 2020) (hereinafter referred to as Announcement No. 104), which optimized the requirements for registration application dossiers, accelerated the marketing process of corresponding products, and further enriched the supply of domestic medical devices. On December 30, 2024, the Opinions of the General Office of the State Council on Comprehensively Deepening the Regulatory Reform of Drugs and Medical Devices to Promote the High-Quality Development of the Pharmaceutical Industry (GBF [2024] No. 53) was issued, which explicitly called for "optimizing the review and approval process for the transfer of already-marketed overseas drugs and medical devices to domestic production, and for supporting foreign-invested enterprises in localizing the production of original drugs and high-end medical equipment". To implement these relevant requirements, the NMPA drafted this Announcement based on in-depth research and by widely soliciting opinions from all parties.

II. Main Principles

Taking into account industry feedback on the need to further optimize relevant measures during the implementation of Announcement No. 104, this Announcement adopts a problem-oriented approach. It combines the current regulatory requirements for medical device registration management, and based on the principle of scientific regulation, further makes adjustment to the scope of application, adjusts and optimizes the registration application requirements, optimizes the requirements for registration system verification, and increases support for the domestic production of innovative products on the basis of Announcement No. 104. The contents of Announcement No. 104 not addressed in this Announcement shall remain valid.

III. Explanation of Key Issues

(1) Adjustment of the scope of application. The definition of "foreign-invested enterprise" in Announcement No. 104, which was originally an enterprise established by the registrant of the imported medical device, is adjusted to "It can be an enterprise established by the registrant of the imported medical device, or an enterprise that shares the same actual controller as the registrant of the imported medical device." At the same time, it is clarified that the actual controller shall comply with the relevant definitions and regulations in the Company Law of the People's Republic of China. An actual controller refers to a person who can actually control the company's actions through investment relationships, agreements, or other arrangements.

(2) Adjustment and optimization of registration application dossier requirements.

First, the registration applicant shall submit the application dossiers in accordance with the formats, contents, etc., required by the current application dossier requirements. That is, the registration applicant shall submit the application dossiers in accordance with the formats, contents, etc. specified in the NMPA Announcement on the Issuance of the Requirements for Registration Application

《关于进一步调整和优化进口医疗器械产品在中国境内企业生产有关事项的公告》的解读

《关于进一步调整和优化进口医疗器械产品在中国境内企业生产有关事项的公告》（2025年第30号）已于2025年3月18日印发。自发布之日起实施（以下简称《公告》）。现将《公告》调整和优化的背景、主要原则和重点问题说明如下：

一、背景

2020年，国家药监局印发《关于进口医疗器械产品在中国境内企业生产有关事项的公告》（2020年104号）（以下简称104号公告），优化了有关注册申报资料要求，加快了相应产品上市进程，进一步丰富了国内医疗器械产品供应。2024年12月30日，《国务院办公厅关于全面深化药品医疗器械监管改革促进医药产业高质量发展的意见》（国办发〔2024〕53号）印发，明确提出“优化已在境内上市的境外生产药品医疗器械转移至境内生产的审评审批流程，支持外商投资企业将原研药品和高端医疗装备等引进境内生产”。为落实有关要求，国家药监局在深入调研、广泛听取各方面意见基础上，起草本《公告》。

二、主要原则

结合104号公告实施过程中业界提出进一步优化有关举措的诉求，《公告》坚持问题导向，结合当前医疗器械注册管理法规要求，基于科学监管的原则，在104号公告基础上进一步调整适用范围、调整和优化注册申报要求、优化注册体系核查要求、加大对创新产品在境内生产的支持力度。《公告》中未提及的104号公告内容继续有效。

三、重点问题说明

（一）调整适用范围。将104号公告中“外商投资企业”由进口医疗器械注册人设立，调整至“可以是进口医疗器械注册人设立的企业，或者与进口医疗器械注册人具有同一实际控制人的企业”，同时明确实际控制人应当符合《中华人民共和国公司法》相关定义和规定。即实际控制人是指，通过投资关系、协议或者其他安排，能够实际支配公司行为的人。

（二）调整和优化注册资料申报要求。

一是明确注册申请人根据现行申报资料要求的格式和目录提交注册申报资料，即按照《国家药品监督管理局关于公布医疗器械注册申报资料要求和批准证明文件格式的公告》（2021

Dossiers of Medical Device and the Format of Approval Documents (No. 121, 2021) and the NMPA Announcement on the Issuance of the Requirements for Registration Application Dossiers of In Vitro Diagnostic Reagents and the Format of Approval Documents (No. 122, 2021). For the summary data, non-clinical data (except for the list of basic principles of safety and performance, product technical requirements, and test reports), and clinical evaluation data of the product, the original registration application dossiers for the imported medical devices can be submitted. However, the product technical requirements and test reports shall reflect that the product complies with the applicable mandatory standard requirements.

Second, where the registration applicant and the imported medical device registrant share the same actual controller, a statement and supporting documents proving such a relationship shall be provided by the registration applicant. The statement document may include a description of the equity relationship between the two parties. The supporting documents shall include the most recent Enterprise Annual Report of the registration applicant closest to the registration application date and other reports containing information about the actual controller, as uploaded or disclosed per requirements by the competent department. These corresponding statements and supporting documents shall be archived and retained by the medical product regulatory authority for future reference.

Third, the registration applicant shall submit a letter of authorization issued by the registrants of the imported medical devices, explicitly consenting to the registration applicant's use of the original registration application dossiers of the imported medical device for domestic registration application and product production purposes. The letter of authorization shall be notarized by a notary institution located in the place where the registrant of the imported medical device is located.

(3) Optimization of registration system verification requirements. According to the working procedure for the verification of quality management system for medical device registration, drug regulatory authorities shall conduct verifications for domestic registration applicants, focusing on the substantial equivalence of the domestic and overseas quality management systems in the product design and development process.

Where differences exist between the quality management systems of the proposed domestically registered products and imported medical devices, the registration applicant shall provide a detailed explanation, commit that such differences will not result in any change to the registered items, conduct a risk analysis to identify major risk points and corresponding control measures and ensure the safety, effectiveness, and controllable quality of the product.

(4) Support for the transfer of production of innovative products. The Announcement specifies that priority will be given to the registration and production licensing procedures for innovative imported medical devices being transferred to domestic production.

Additionally, for products approved for registration in accordance with this Announcement, subsequent change registrations and renewals shall be handled in accordance with relevant laws and regulations and will not be bound to the handling of corresponding matters for already registered imported products.

(March 18, 2025)

年第121号）、《国家药品监督管理局关于公布体外诊断试剂注册申报资料要求和批准证明文件格式的公告》（2021年第122号）中要求的格式、目录等提交注册申报资料。

产品的综述资料、非临床资料（安全和性能基本原则清单、产品技术要求及检验报告除外）、临床评价资料，可使用进口医疗器械的原注册申报资料。产品技术要求及检验报告应当体现产品符合适用的强制性标准要求。

二是明确对于注册申请人与进口医疗器械注册人具有同一实际控制人的，注册申请人应当提供双方具有同一实际控制人的说明及佐证文件。说明文件可包含双方的股权关系说明等，佐证文件应当包括距注册申请日期最近的注册申请人《企业年度报告书》等含实际控制人信息的报告并已按主管部门要求上传或披露。相应说明和佐证文件由药品监管部门存档备查。

三是明确注册申请人应当提交由进口医疗器械注册人出具的明确同意注册申请人使用进口医疗器械原注册申报资料开展境内注册申报和生产产品的授权书。授权书应当经进口医疗器械注册人所在地公证机构公证。

（三）注册体系核查要求优化。明确药品监管部门按照医疗器械注册质量管理体系核查工作程序，对境内注册申请人开展核查，同时重点关注产品设计开发环节境内外质量管理体系的实质等同性。

对于境内拟申报注册产品和进口医疗器械产品质量管理体系存在差异的，注册申请人应当详细说明，承诺相关差异不会引起注册事项的变更，同时做好风险分析，明确主要风险点和控制措施，确保产品安全、有效、质量可控。

（四）支持创新产品转产。《公告》明确对于进口创新医疗器械产品转产的，相应注册、生产许可等事项优先办理。

此外，对于按照本《公告》要求获准注册的产品，后续办理变更注册、延续注册等事项依法依规开展，不与进口已注册产品办理相应事项绑定。

（2025-03-18）

Notes:
- All the Chinese information in the Newsletter is from newspapers and the Internet. All English articles are translated from the Chinese version. In case of any discrepancy, the Chinese version shall prevail.
- For e-copy of the Newsletter, please visit http://www.ccfdie.org
- The translation is credited for the support of RDPAC and ISPE.

备 注：
- Newsletter中所有中文信息均摘自报刊及网络。英文均系中文翻译。如有出入，请以中文为准。
- 电子版Newsletter阅览请登录网站http://www.ccfdie.org
- 本刊翻译感谢中国外商投资企业协会药品研制和开发工作委员会（RDPAC）和国际制药工程协会（ISPE）支持。

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