2025 Volume 1

NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心

Headline

NMPA Announcement on Issuing the Pharmaceutical Excipients Annex and Pharmaceutical Packaging Materials Annex of the Good Manufacturing Practice for Drugs (2010 Revision) (No. 1, 2025)

To implement relevant regulations such as the Drug Administration Law of the People's Republic of China, the Regulations for the Implementation of the Drug Administration Law of the People's Republic of China, the Provisions for Drug Registration, and the Provisions for Drug Manufacturing Supervision and Administration, and to supervise and guide the standardized production of pharmaceutical excipients and pharmaceutical packaging materials manufacturers, the National Medical Products Administration has organized the formulation of the Pharmaceutical Excipients Annex and Pharmaceutical Packaging Materials Annex. These serve as supplementary provisions for the Good Manufacturing Practice for Drugs (2010 Revision) in accordance with Article 310 of the Good Manufacturing Practice for Drugs (2010 Revision). They are hereby issued (see Annexes 1 and 2), and the relevant matters concerning the strengthening of the quality supervision of pharmaceutical excipients and pharmaceutical packaging materials are announced as follows:

I. Pharmaceutical Excipients and Pharmaceutical Packaging Materials Manufacturers to Establish a Comprehensive Quality Management System

(1) Implement the primary responsibility for product quality. Pharmaceutical excipient and pharmaceutical packaging material manufacturers shall establish and maintain a comprehensive quality management system in accordance with the requirements of the Pharmaceutical Excipients Annex and Pharmaceutical Packaging Materials Annex. They shall allocate appropriate organizations and personnel according to the scale of production, develop detailed management documents and operating procedures, and maintain accurate records. Manufacturers are also required to conduct regular quality assessments on the raw material suppliers used in the production of pharmaceutical excipients and packaging materials. Production shall be organized according to the information registered on the Center for Drug Evaluation of National Medical Products Administration (NMPA) (hereinafter referred to as the CDE) platform for APIs, excipients, and packaging materials, including company names, production addresses, and formulation processes. Each batch of products must undergo inspection based on specifications and can only be released after approval by the quality management department.

(2) Strict change management. Pharmaceutical excipient and pharmaceutical packaging material manufacturers shall establish a change management system in accordance with the requirements of the Pharmaceutical Excipients Annex and Pharmaceutical Packaging Materials Annex. Based on risk assessments, they shall classify the types of changes that occur during the production of pharmaceutical excipients and pharmaceutical packaging materials, conduct the necessary studies, and implement changes only after approval from the quality management department. The information on the CDE platform for APIs, excipients, and packaging materials shall be updated, and the drug marketing authorization holder (MAH) must be promptly notified.

For changes that may affect the quality of pharmaceutical excipients and pharmaceutical packaging materials (such as changes in the production process, raw material sources, or production sites), manufacturers shall ensure

头条

国家药监局关于发布《药品生产质量管理规范（2010年修订）》药用辅料附录、药包材附录的公告（2025年第1号）

为贯彻落实《中华人民共和国药品管理法》《中华人民共和国药品管理法实施条例》《药品注册管理办法》《药品生产监督管理办法》等有关规定，监督指导药用辅料、药包材生产企业规范生产，国家药监局根据《药品生产质量管理规范（2010年修订）》第三百一十条规定，组织制定了药用辅料附录、药包材附录，作为《药品生产质量管理规范（2010年修订）》的配套文件，现予以发布（见附件1、2），并就加强药用辅料、药包材质量监管有关事项公告如下：

一、药用辅料、药包材生产企业建立健全质量管理体系

（一）落实产品质量主体责任。药用辅料、药包材生产企业应当对照药用辅料附录、药包材附录的要求，建立健全质量管理体系，配备与生产规模相适应的机构与人员，建立详细的管理文件、操作规程，并做好相关记录，定期对生产药用辅料、药包材所用原材料的生产企业进行质量评估，按照在国家药监局药品审评中心（以下简称药审中心）原辅包登记平台登记的企业名称、生产地址、配方工艺等信息组织生产，按照质量标准对每批产品进行检验，由质量管理部门审核批准后方可放行。

（二）严格变更管理。药用辅料、药包材生产企业应当按照药用辅料附录、药包材附录等要求，建立变更管理体系，根据风险确定药用辅料、药包材生产过程中变更的类别，开展相应研究，由质量管理部门批准后方可实施，并更新药审中心原辅包登记平台信息，及时告知药品上市许可持有人。

对于可能影响药用辅料、药包材质量的变更（如生产工艺、原材料来源、生产场地等变更），应当在研究过程中与药品上市许可持有人充分沟通。

（三）强化外部沟通协作。药用辅料、药包材生产企业应当配合药品上市许可持有人开

full communication with the drug MAH during the research process.

(3) Strengthen external communication and cooperation. Pharmaceutical excipient and pharmaceutical packaging material manufacturers shall cooperate with the drug MAH during audits, provide access to relevant areas or facilities, and supply accurate, valid, and complete documents, records, and other relevant materials. They shall also cooperate with the MAH in quality management activities, including complaints, returns, and recalls.

In cases involving entrusted testing, pharmaceutical excipients and packaging material manufacturers shall strictly adhere to the requirements for entrusted testing. They shall sign appropriate quality agreements with the contracted testing institutions to ensure the reliability of the test results.

II. Strengthening the Management of Pharmaceutical Excipients and Pharmaceutical Packaging Materials Usage by MAH

(4) Implement the primary responsibility for drug quality and safety. The MAH shall establish and maintain a comprehensive quality management system, strictly managing the use of pharmaceutical excipients and pharmaceutical packaging materials. The MAH shall sign quality agreements with key pharmaceutical excipient and packaging material manufacturers to ensure that the pharmaceutical excipients and pharmaceutical packaging materials used in drug production meet the required pharmaceutical standards and intended purposes.

(5) Strengthen the audit of suppliers. The MAH shall evaluate and approve all suppliers of pharmaceutical excipients and pharmaceutical packaging materials (including manufacturers and distributors) in accordance with the requirements of the Pharmaceutical Excipients Annex and Pharmaceutical Packaging Materials Annex. A supplier quality file shall be established, and regular quality evaluations shall be conducted. In accordance with the principle of risk management, the MAH shall conduct regular on-site audits of the quality management systems of the main suppliers (especially manufacturers) of pharmaceutical excipients and pharmaceutical packaging materials.

(6) Strengthen the quality audit of pharmaceutical excipients and pharmaceutical packaging materials. The MAH shall conduct audits of the quality control and product release capabilities of pharmaceutical excipients and pharmaceutical packaging material manufacturers and conduct incoming inspections in strict accordance with the requirements. If necessary, based on risk assessments and intended use, the MAH shall add incoming inspection items for the pharmaceutical excipients and pharmaceutical packaging materials required for the production of drugs.

(7) Strengthen the management of changes in pharmaceutical excipients and pharmaceutical packaging materials. The MAH shall promptly monitor any changes in the pharmaceutical excipients and pharmaceutical packaging materials being used, assess the impact of these changes on the quality of the drug, and conduct the required studies according to drug change management procedures. Changes shall be implemented only after approval or filing, or reported according to the annual reporting requirements. If a change or addition of pharmaceutical excipients and pharmaceutical packaging materials suppliers is proposed for the drug preparations, the MAH must follow post-approval change management procedures.

III. Strengthening Supervision and Management by Drug Regulatory Authorities

(8) Strengthen supervision and inspection. Provincial drug regulatory authorities shall strengthen policy promotion and urge pharmaceutical excipient and packaging material manufacturers to conduct self-inspections and ensure continuous improvement of their quality management systems according to the requirements of the appendices. Provincial drug regulatory authorities shall use the information on the registration platform for APIs, excipients, and packaging materials of the CDE to carry out supervision and inspections of manufacturers in their jurisdiction whose excipient and packaging material registration status is marked as "A" and urge the manufacturers to organize production in strict accordance with the registered information. They may, according to the actual needs of supervision and the principle of risk management, conduct

展审核，开放相关场所或者区域，提供真实、有效、完整的文件、记录等相关材料；配合药品上市许可持有人开展质量管理活动，包括投诉、退货和召回等。

涉及委托检验的，药用辅料、药包材生产企业应当严格按照委托检验的相关要求，与受托检验机构签订相应检验质量协议，确保检验结果的可靠性。

二、药品上市许可持有人加强药用辅料和药包材使用管理

（四）落实药品质量安全主体责任。药品上市许可持有人应当建立健全质量管理体系，严格药用辅料、药包材使用管理，与主要药用辅料、药包材生产企业签订质量协议，确保生产药品所需要的药用辅料、药包材符合药用要求和预定用途。

（五）加强供应商审核。药品上市许可持有人应当对照药用辅料附录、药包材附录的要求，对生产药品所需要的所有药用辅料、药包材供应商（包括生产企业、经销商）进行评估批准，建立供应商质量档案，对供应商定期开展质量评估。依据风险管理原则，对主要药用辅料、药包材供应商（尤其是生产企业）的质量管理体系定期进行现场审核。

（六）加强药用辅料和药包材质量审核。药品上市许可持有人应当对药用辅料、药包材生产企业的质量控制和产品放行能力开展审核，并严格按要求进行入厂检验。必要时，药品上市许可持有人应当基于风险评估和预定用途对生产药品所需要的药用辅料、药包材增加入厂检验项目。

（七）加强药用辅料和药包材变更管理。药品上市许可持有人应当及时掌握所使用药用辅料、药包材的变更情况，评估变更对药品质量的影响，并按照药品变更管理要求开展相应研究，经批准、备案后实施，或者按照年度报告要求进行报告。药品制剂拟变更或者增加药用辅料、药包材供应商的，药品上市许可持有人应当按照药品上市后变更管理要求办理。

三、药品监管部门加强监督管理

（八）强化监督检查。省级药品监督管理部门应当加强政策宣贯，督促药用辅料、药包材生产企业自查，对照附录要求持续提高质量管理水平。省级药品监督管理部门应当利用药审中心原辅包登记平台信息，对行政区域内药用辅料、药包材登记状态为“A”的生产企业组织开展监督检查，督促企业严格按照登记信息组织生产；可根据监管实际需要和风险管理原则，对药用辅料、药包材开展质量抽检。药品上市许可持有人所在地省级药品监督管理部门必要时开展延伸检查。

quality sampling inspections of pharmaceutical excipients and pharmaceutical packaging materials. Provincial drug regulatory authorities where the MAH of drugs are located shall conduct extended inspections when necessary.

(9) Strengthen risk management and enforcement against violations. If a pharmaceutical excipient and pharmaceutical packaging material manufacturer is found to have violated the requirements of the Pharmaceutical Excipients Annex and Pharmaceutical Packaging Materials Annex during the inspection, provincial drug regulatory authorities shall investigate and handle the matter in accordance with Article 126 of the Drug Administration Law and other relevant regulations, and urge the manufacturer to report the situation to the MAH. The MAH shall assess the quality risk of the drug preparation and, if necessary, proactively implement risk control measures. For serious violations or if the manufacturer fails to rectify within the specified time after being ordered to do so, the provincial regulatory authority shall report the inspection results to the CDE. Based on the inspection findings, the CDE will consider adjusting the registration status of the relevant product.

(10) Other matters. This Announcement shall come into force on January 1, 2026. Before the formal implementation, pharmaceutical excipients and pharmaceutical packaging materials manufacturing enterprises shall promptly improve their facilities and equipment and perfect their quality management systems to ensure compliance with the requirements of the Pharmaceutical Excipients Annex and Pharmaceutical Packaging Materials Annex. As of the date of implementation of this Announcement, the Notice on Printing and Issuing the GMP for Pharmaceutical Excipients (GSYJA [2006] No.120) shall be repealed.

It is hereby announced.

National Medical Products Administration

December 27, 2024

(January 02, 2025)

（九）强化风险处置、查处违法行为。对检查发现药用辅料、药包材生产企业未遵守药用辅料附录、药包材附录的，省级药品监督管理部门按照《药品管理法》第一百二十六条等规定调查处置，并督促企业将有关情况通报药品上市许可持有人。药品上市许可持有人应当评估药品制剂的质量风险，必要时主动采取风险控制措施。对于情节严重的或者责令其限期改正而逾期未改正的，省级药品监督管理部门还应当将检查情况通报药审中心；药审中心依据检查情况，研究调整相应产品的登记状态。

（十）其他事项。本公告自2026年1月1日起施行。在正式实施前，药用辅料、药包材生产企业应当及时改进设施设备并完善质量管理体系，确保符合药用辅料附录、药包材附录的各项要求。自本公告施行之日起，原国家食品药品监督管理局《关于印发〈药用辅料生产质量管理规范〉的通知》（国食药监安〔2006〕120号）废止。

特此公告。

国家药监局

2024年12月27日

（2025-01-02）

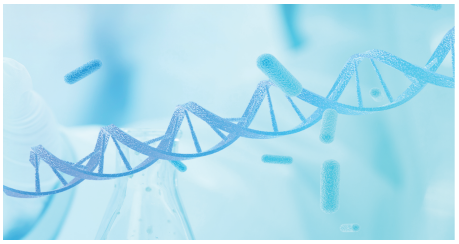
Drugs

Zolbetuximab for Injection Approved for Marketing by China NMPA

Recently, the Zolbetuximab for Injection (trade name: 威络益/VYLOY) of Astellas Pharma Europe B.V. is approved for marketing by China NMPA. Indications: This product is indicated for use in combination with fluorouracil and platinum-based chemotherapy regimens as first-line treatment for patients with CLDN18.2-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced unresectable or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma.

Zolbetuximab is a human-mouse chimeric IgG1 monoclonal antibody targeting claudin 18 splice variant 2 (CLDN18.2), which specifically binds to CLDN18.2 and induces antibody-dependent cell-mediated cytotoxicity (ADCC) and complement-dependent cytotoxicity (CDC). The marketing of this drug provides a new treatment option for relevant patients.

(December 31, 2024)



药品

国家药监局批准注射用佐妥昔单抗上市

近日，国家药品监督管理局批准Astellas Pharma Europe B.V.申报的注射用佐妥昔单抗（商品名：威络益）上市。适应症为：本品联合含氟尿嘧啶类和铂类药物化疗用于CLDN18.2阳性、人表皮生长因子受体2（HER2）阴性的局部晚期不可切除或转移性胃或胃食管交界处（GEJ）腺癌患者的一线治疗。

佐妥昔单抗是一种抗claudin 18剪接变体2（CLDN18.2）人鼠嵌合IgG1单克隆抗体，可特异性与CLDN18.2结合，诱导产生抗体依赖性细胞毒作用（ADCC）和补体依赖性细胞毒作用（CDC）。该品种的上市为相关患者提供了新的治疗选择。

（2024-12-31）

Tagitanlimab Injection Approved for Marketing by China NMPA

Recently, the Tagoliticimab Injection (trade name: 科泰莱) of Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. is approved for marketing by China NMPA. Indications: This product is indicated as monotherapy for the treatment of patients with recurrent or metastatic nasopharyngeal carcinoma who have failed to respond to second-line and later chemotherapy.

国家药监局批准塔戈利单抗注射液上市

近日，国家药品监督管理局批准四川科伦博泰生物医药股份有限公司申报的塔戈利单抗注射液（商品名：科泰莱）上市。适应症为：

Tagitanlimab Injection is a humanized IgG1κ subtype monoclonal antibody that specifically binds to programmed cell death ligand-1 (PD-L1), blocking its interaction with programmed cell death receptor-1 (PD-1). As a result, it can relieve the inhibitory effect of tumor cells on T cells through the PD-1/PD-L1 pathway, enabling immune cells to resume their anti-tumor cellular immune function. The marketing of this drug provides a new treatment option for patients with nasopharyngeal carcinoma.

(December 31, 2024)

本品单药用于既往接受过二线及以上化疗失败的复发或转移性鼻咽癌患者的治疗。

塔戈利单抗注射液是一种人源化IgG1κ亚型单克隆抗体，可特异性结合细胞程序性死亡配体-1（PD-L1），阻断其与程序性死亡受体-1（PD-1）之间的相互作用，从而解除肿瘤细胞通过PD-1/PD-L1通路对T细胞的抑制作用，使免疫细胞重新发挥抗肿瘤细胞免疫作用。该品种的上市为鼻咽癌患者提供了新的治疗选择。

（2024-12-31）

Amimestrocel Injection Approved with Conditions for Marketing by China NMPA

Recently, the Amimestrocel Injection (trade name: 睿铂生) of Platinumlife Biotechnology (Beijing) Co., Ltd. is approved with conditions through the priority review and approval procedure by China NMPA. Indication: This product is indicated for the treatment of steroid-refractory acute graft-versus-host disease with predominant gastrointestinal involvement in patients aged 14 years and older.

Graft-versus-host disease is a multi-organ syndrome that occurs after allogeneic hematopoietic stem cell transplantation, in which lymphocytes from the donor attack the tissues of the recipient, manifesting as tissue inflammation, fibrosis, etc., mainly involving the skin, gastrointestinal tract, liver, lungs, and mucosal surfaces. Amimestrocel Injection is an injection of human umbilical cord-derived mesenchymal stem cells. The marketing of this drug provides a new treatment option for relevant patients.

(January 02, 2025)

国家药监局附条件批准艾米迈托赛注射液上市

近日，国家药品监督管理局通过优先审评审批程序附条件批准铂生卓越生物科技（北京）有限公司申报的艾米迈托赛注射液（商品名：睿铂生）上市。适应症为：用于治疗14岁以上消化道受累为主的激素治疗失败的急性移植物抗宿主病。

移植物抗宿主病是异基因造血干细胞移植后，来源于供者的淋巴细胞攻击受者组织发生的一类多器官综合征，表现为主要累及皮肤、胃肠道、肝、肺和黏膜表面的组织炎症、纤维化等。艾米迈托赛注射液系人脐带间充质干细胞注射剂。该品种的上市为相关患者提供了新的治疗选择。

（2025-01-02）

Innovative TCM Xiao'er Huangjin Zhike Granules Approved for Marketing by China NMPA

Recently, the Class 1.1 innovative traditional Chinese medicine (TCM) Xiao'er Huangjin Zhike Granules of Beijing Dongfang Yunjia Pharmaceutical Co., Ltd. is approved for marketing through the priority review and approval procedure by China NMPA.

This product has the functions of clearing the lung, resolving phlegm, and suppressing cough by purifying lung qi, and is indicated for the treatment of cough caused by mild acute bronchitis with phlegm-heat obstructing the lung syndrome in children, characterized by clinical manifestations including red tongue with thin yellow or yellow greasy coating. The marketing of this TCM provides new treatment options for children with mild acute bronchitis.

(January 03, 2025)

国家药监局批准中药创新药小儿黄金止咳颗粒上市

近日，国家药品监督管理局通过优先审评审批程序批准北京东方运嘉药业有限公司申报的中药1.1类创新药小儿黄金止咳颗粒上市。

该药品具有清肺化痰，肃肺止咳功效。用于儿童轻度急性支气管炎痰热阻肺证引起的咳嗽,舌红苔薄黄或黄腻。该药品的上市为轻度急性支气管炎儿童患者提供了新的治疗选择。

（2025-01-03）

Recaticimab for Injection Approved for Marketing by China NMPA

Recently, the Recaticimab for Injection (trade name: 艾心安) of Guangdong Hengrui Pharmaceutical Co., Ltd. is approved for marketing by China NMPA. Indications: On the basis of dietary control, it can be used in combination with statins, or in combination with statins and other lipid-lowering therapies for adult patients with primary hypercholesterolemia

国家药监局批准注射用瑞卡西单抗上市

近日，国家药品监督管理局批准广东恒瑞医药有限公司申报的注射用瑞卡西单抗（商品名：艾心安）上市。适应症为：在控制饮食的

(including heterozygous familial and non-familial hypercholesterolemia) and mixed dyslipidemia who, despite treatment with moderate or higher doses of statins, still fail to reach the target level of low-density lipoprotein cholesterol (LDL-C). Alternatively, it can be used as monotherapy for adult patients with non-familial hypercholesterolemia and mixed dyslipidemia to reduce the levels of low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), and apolipoprotein B (ApoB).

Recaticimab is a fully human monoclonal IgG1 antibody targeting the preprotein convertase subtilisin/kexin type 9 (PCSK9). It blocks the binding of PCSK9 to the low-density lipoprotein receptor (LDLR) by specifically binding to PCSK9, preventing PCSK9-mediated degradation of the LDLR, and increasing the number of LDLRs on the surface of the cells, thereby reducing serum LDL-C levels. The marketing of this drug provides a new treatment option for relevant patients.

(January 10, 2025)

基础上，与他汀类药物、或者与他汀类药物及其它降脂疗法联合用药，用于接受中等或以上剂量他汀类药物治疗仍无法达到低密度脂蛋白胆固醇(LDL-C)目标的原发性高胆固醇血症（包括杂合子型家族性和非家族性高胆固醇血症)和混合型血脂异常的成人患者；或单药用于非家族性高胆固醇血症和混合型血脂异常的成人患者，以降低低密度脂蛋白胆固醇(LDL-C)、总胆固醇(TC)、载脂蛋白B（ApoB)水平。

瑞卡西单抗是一种作用靶点为前蛋白转化酶枯草溶菌素9（PCSK9）的全人源单克隆IgG1抗体，通过特异性结合PCSK9，阻断PCSK9与低密度脂蛋白受体（LDLR）结合，阻止PCSK9介导的LDLR降解，提高细胞表面LDLR数目，进而降低血清中LDL-C水平。该品种的上市为相关患者提供了新的治疗选择。

（2025-01-10）

Prusogliptin Tablets Approved for Marketing by China NMPA

Recently, the Class 1 innovative drug Prusogliptin Tablets (trade name: 善泽平) of CSPC OUYI PHARMACEUTICAL CO., LTD. is approved for marketing by China NMPA. This product is indicated for improving the blood glucose control of adult patients with type 2 diabetes, providing new treatment options for patients.

(January 10, 2025)

国家药监局批准普卢格列汀片上市

近日，国家药品监督管理局批准石药集团欧意药业有限公司申报的1类创新药普卢格列汀片（商品名：善泽平）上市，该药适用于改善成人2型糖尿病患者的血糖控制，为患者提供新的治疗选择。

（2025-01-10）

Innovative TCM Qifang Bitong Tablets Approved for Marketing by China NMPA

Recently, the Class 1.1 innovative traditional Chinese medicine (TCM) Qifang Bitong Tablets of Beijing Yiling Pharmaceutical Co., Ltd. is approved for marketing by China NMPA.

This product is designed to strengthen Qi and unblock the orifices. It is indicated for the treatment of persistent allergic rhinitis with lung and spleen deficiency in patients not complicated by seasonal allergens, and is effective in alleviating symptoms such as sneezing, runny nose, itching, and nasal congestion. The typical clinical presentation includes a pale tongue, white coating, and a floating or weak pulse. This approval provides a new treatment option for patients with non-seasonal persistent allergic rhinitis.

(January 16, 2025)

国家药监局批准中药创新药芪防鼻通片上市

近日，国家药品监督管理局批准了北京以岭药业有限公司申报的中药1.1类创新药芪防鼻通片上市。

该药品具有益气通窍功效。用于改善肺脾两虚型持续性变应性鼻炎未合并季节性过敏原患者的喷嚏、流涕、鼻痒、鼻塞，舌淡，苔白，脉浮或脉细弱。该药品为持续性变应性鼻炎未合并季节性过敏原患者提供新的用药选择。

（2025-01-16）

Limertinib Tablets Approved for Marketing by China NMPA

Recently, the Class 1 innovative drug Limertinib Tablets (trade name: 奥壹新) of Jiangsu Osaikang Pharmaceutical Co., Ltd. is approved for marketing by China NMPA. This drug is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) who have experienced disease progression during or after

国家药监局批准利厄替尼片上市

近日，国家药品监督管理局批准江苏奥赛康药业有限公司申报的1类创新药利厄替尼片（商品名：奥壹新）上市，该药适用于既往经表皮生长因子受体(EGFR)酪氨酸激酶抑制剂

previous treatment with epidermal growth factor receptor (EGFR) tyrosine kinase inhibitors (TKI) and have been confirmed by testing to carry the EGFR T790M mutation. The approval of this drug provides a new treatment option for this patient population.

(January 16, 2025)

(TKI)治疗时或治疗后出现疾病进展,并且经检测确认存在 EGFR T790M 突变阳性的局部晚期或转移性非小细胞肺癌(NSCLC)成人患者的治疗，为患者提供新的治疗选择。

(2025-01-16)

Senaparib Capsules Approved for Marketing by China NMPA

Recently, the Class 1 innovative drug Senaparib Capsules (trade name: 派舒宁/Paishuning) of Shanghai Inpai Pharmaceutical Co., Ltd. is approved for marketing by China NMPA. This product is indicated for the maintenance treatment of adult patients with advanced epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer, who have achieved complete or partial response following first-line platinum-based chemotherapy. The approval of this drug provides a new treatment option for relevant patients.

(January 16, 2025)

国家药监局批准塞纳帕利胶囊上市

近日，国家药品监督管理局批准上海英派药业有限公司申报的1类创新药塞纳帕利胶囊（商品名：派舒宁）上市，该药适用于晚期上皮性卵巢癌、输卵管癌或原发性腹膜癌成人患者在一线含铂化疗达到完全缓解或部分缓解后的维持治疗，为患者提供新的治疗选择。

(2025-01-16)

Efsubaglutide Alfa Injection Approved for Marketing by China NMPA

Recently, the Efsubaglutide Alfa Injection (trade name: 怡诺轻) of Shanghai Yinnuo Pharmaceutical Technology Co., Ltd. is approved for marketing by China NMPA. This product is indicated for blood glucose control in adult patients with type 2 diabetes.

Efsubaglutide Alfa Injection is a long-acting glucagon-like peptide-1 receptor agonist (GLP-1RA). It is a recombinant protein formed by the fusion of human glucagon-like peptide-1 (GLP-1) with the Fc fragment of human immunoglobulin G2 (IgG2). This product increases insulin secretion in a glucose-dependent manner and suppresses glucagon release, making it a treatment option for type 2 diabetes. The marketing of this drug provides a new treatment option for relevant patients.

(January 26, 2025)

国家药监局批准依苏帕格鲁肽α注射液上市

近日，国家药品监督管理局批准上海银诺医药技术有限公司申报的依苏帕格鲁肽α注射液（商品名：怡诺轻）上市。适用于成人2型糖尿病患者的血糖控制。

依苏帕格鲁肽α注射液是一种长效胰高血糖素样肽-1受体激动剂（GLP-1RA），是人胰高血糖素样肽-1（GLP-1）与人免疫球蛋白G2（IgG2）的Fc片段融合形成的重组蛋白，可以血糖依赖性地增加胰岛素分泌，抑制胰高血糖素释放，用于2型糖尿病的治疗。该品种的上市为相关患者提供了新的治疗选择。

(2025-01-26)

Medical device

Phakic Intraocular Lens Approved for Marketing

Recently, the innovative product "Phakic Intraocular Lens" of Eyebright Medical Technology (Beijing) Co., Ltd. is approved by China NMPA.

This product is designed for the treatment of adults with a crystalline lens in the eye, specifically to correct or reduce myopia in adults ranging from -3.25D to -18.00D. It features a zero spherical aberration large optical zone and a double-concave design with stable arc height, which enhances visual quality and provides a wider peripheral arc height.

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

(January 07, 2025)

医疗器械

有晶体眼人工晶状体获批上市

近日，国家药品监督管理局批准了爱博诺德（北京）医疗科技股份有限公司“有晶体眼人工晶状体”创新产品注册申请。

该产品用于成年人有晶状体眼的治疗，矫正/降低成年人-3.25D~-18.00D的近视度数。产品采用零球差大光学区及双凹面型的稳定拱高设计，可提升视觉质量，带来更开阔的周边拱高。

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。

(2025-01-07)

Innovative Product Cryoablation Apparatus Approved for Marketing

Recently, the innovative product Cryoablation Apparatus of Synaptic Medical Technology (Beijing) Co., Ltd. is approved by China NMPA.

This product consists of the main unit, coaxial fluid connecting tubes, and connection cables. It is designed for use in combination with the company's balloon-type cryoablation catheter. Utilizing pressure-flow dual control technology, the system monitors and controls the flow of refrigerant and balloon pressure in real time, ensuring stable pressure during both inflation and ablation processes. This technology effectively reduces the risk of balloon displacement caused by pressure fluctuations during pulmonary vein occlusion and ablation, making it suitable for the treatment of adult patients with drug-resistant, recurrent, symptomatic paroxysmal atrial fibrillation.

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

(January 20, 2025)

冷冻消融仪创新产品获批上市

近日，国家药品监督管理局批准了心诺普医疗技术（北京）有限公司的冷冻消融仪创新产品注册申请。

该产品由主机、同轴流体连接管和连接电缆组成，与该公司生产的球囊型冷冻消融导管配合使用，采用压力流量双控制技术，通过实时监测和控制制冷剂流量与球囊压力，实现球囊在充气和消融过程中的压力稳定。该技术可有效降低球囊在封堵肺静脉和消融过程中因压力波动而产生的弹跳移位风险，用于成人患者药物难治性、复发性、症状性的阵发性房颤治疗。

药品监督管理部门将加强上述产品上市后监管，保护患者用械安全。

（2025-01-20）

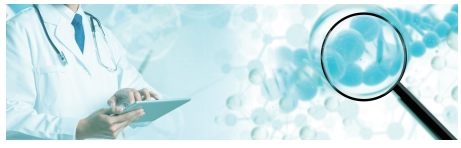
Innovative Product Human CDO1/AJAP1/GALR1 Gene Methylation Detection Kit (Fluorescent PCR Method) Approved for Marketing

Recently, the Human CDO1/AJAP1/GALR1 Gene Methylation Detection Kit (Fluorescent PCR Method) of Wuhan KadWise Biotechnology Co., Ltd. is approved by China NMPA.

This product, consisting of primers, probes, and polymerase, is used for the qualitative detection of gene methylation status in human endometrial exfoliated cell samples. It aids in the diagnosis of suspected endometrial cancer, providing valuable assistance in the prevention and treatment of the disease and improving patient survival rates.

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

(January 20, 2025)



人CDO1/AJAP1/GALR1基因甲基化检测试剂盒（荧光PCR法）创新产品获批上市

近日，国家药品监督管理局批准了武汉凯德维斯生物技术有限公司的人CDO1/AJAP1/GALR1基因甲基化检测试剂盒（荧光PCR法）创新产品注册申请。

该产品由引物、探针、聚合酶等材料组成，对人宫腔脱落细胞样本中基因甲基化状态进行定性检测，用于疑似子宫内膜癌患者的辅助诊断，对子宫内膜癌的防治、提升患者生存率具有重要意义。

药品监督管理部门将加强上述产品上市后监管，保护患者用械安全。

（2025-01-20）

Paclitaxel Coated PTA Balloon Catheter Approved for Marketing

Recently, the innovative product Paclitaxel Coated PTA Balloon Catheter of TriReme Medical,LLC is approved by China NMPA.

This over-the-wire (OTW) balloon dilation catheter consists of a distal tip, balloon, nitinol constraining structure (CS), catheter shaft, stress diffusion tube, catheter hub, and radiopaque marker. The nitinol constraining structure is a ring-shaped external structure surrounding the balloon, with constraint wires distributed both axially and radially. The balloon surface is coated with paclitaxel, and propyl gallate serves as the coating excipient. This product is sterilized by ethylene oxide and is intended for single use, with a shelf life of 6 months. It is indicated for percutaneous transluminal angioplasty of primary stenotic lesions in the superficial femoral artery and popliteal artery, with lesion lengths not exceeding 180 mm and applicable vessel diameters of 4-7 mm. Pre-dilation of the lesions is required prior to use.

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

(January 24, 2025)

紫杉醇药物涂层外周球囊导管获批上市

近日，国家药品监督管理局批准了特里雷米医疗有限责任公司紫杉醇药物涂层外周球囊导管创新产品注册申请。

该产品为OTW型球囊扩张导管，由远端尖端、球囊、镍钛合金约束结构(CS)、导管轴、应力扩散管、导管座、射线显影环等组件组成。镍钛合金约束结构为球囊外的环状结构，在轴向和径向均分布有约束丝。球囊表面涂覆有紫杉醇，涂层辅料为没食子酸丙酯。产品经环氧乙烷灭菌，一次性使用，货架有效期6个月。该产品用于在股浅动脉、腘动脉原发狭窄病变的经皮腔内血管成形术治疗，病变长度不超过180mm，适用血管直径范围为4-7mm，使用该产品前需经充分预扩张。

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。

（2025-01-24）

Innovative Product Microsatellite Instability (MSI) Detection Kit (Fluorescent PCR-Capillary Electrophoresis Method) Approved for Marketing

Recently, the innovative product Microsatellite Instability (MSI) Detection Kit (Fluorescent PCR-Capillary Electrophoresis Method) of Shanghai Promega Biological. Products Ltd. is approved by China NMPA.

This product uses fluorescent PCR-capillary electrophoresis to qualitatively detect eight microsatellite loci in the genome of colorectal cancer tumor tissues, providing precise determination of the status of cancer tissue samples. It is mainly used to assist in the detection of Lynch syndrome in colorectal cancer patients, aiding in the prevention and treatment of rectal cancer and improving patient survival rates.

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

(January 25, 2025)

微卫星不稳定性（MSI）检测试剂盒（荧光PCR-毛细管电泳法）创新产品获批上市

近日，国家药品监督管理局批准了上海普洛麦格生物产品有限公司的微卫星不稳定性（MSI）检测试剂盒（荧光PCR-毛细管电泳法）创新产品注册申请。

该产品采用了荧光PCR-毛细管电泳法，通过对结直肠癌患者肿瘤组织基因组中的8个微卫星位点定性检测，可实现癌组织样本位点状态的精准判定。该产品主要用于辅助结直肠癌中可能的林奇综合征检测，有利于直肠癌防治、提升患者生存率。

药品监督管理部门将加强上述产品上市后监管，保护患者用械安全。

（2025-01-25）

Cosmetics

NMPA Announcement on Issuing Several Provisions for Supporting the Innovation on Cosmetic Raw Materials (No. 12, 2025)

In line with the spirit of the Third Plenary Session of the 20th Central Committee of the Communist Party of China, and to further encourage innovation in cosmetic raw materials and promote the high-quality development of the cosmetic industry, the NMPA has issued the Several Provisions for Supporting the Innovation on Cosmetic Raw Materials in accordance with the Regulations on Supervision and Administration of Cosmetics and related laws. These regulations are hereby issued and shall be implemented as of the date of publication.

It is hereby announced.

National Medical Products Administration

January 26, 2025

(February 06, 2025)

化妆品

国家药监局关于发布支持化妆品原料创新若干规定的公告（2025年第12号）

为贯彻落实党的二十届三中全会精神，进一步鼓励化妆品原料创新，促进化妆品产业高质量发展，根据《化妆品监督管理条例》等相关法规要求，国家药监局组织制定了《支持化妆品原料创新若干规定》，现予以发布，自发布之日起施行。

特此公告。

国家药监局

2025年1月26日

（2025-01-26）

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.

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