NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心

Drugs

China's vaccine regulatory system passes WHO assessment

The World Health Organization (WHO) announced on Aug 23 that China had passed the assessment of the National Regulatory Authority (NRA) for vaccines.

The WHO's assessment of the NRA for vaccines is an important measure and effective means to evaluate the national vaccine regulatory capacity. It is a world-recognized international assessment that can scientifically and comprehensively evaluate the level of vaccine regulation in a country. China's vaccine regulatory system has passed the assessment twice, in 2011 and 2014, and received a new round of comprehensive assessment in July 2022 after the WHO upgraded its evaluation standards. The assessment indicators have been greatly increased, the contents more comprehensive and the standards stricter.

The fact that China's vaccine regulatory system has passed the WHO's latest assessment means the country has a stable, well-functioning and integrated regulatory system, which can ensure that vaccines manufactured, imported and distributed in China are of a controllable quality, are safe and effective. It is also an important foundation for the export of Chinese vaccines.

The WHO takes passing the NRA assessment for vaccines as the premise for purchasing vaccine products in a country, which means that, only when a national regulatory system passes the assessment can enterprises in that country apply for the WHO's vaccine product prequalification and be listed in the procurement list of the United Nations and other international organizations. In addition, the assessment is also an important reference for other countries to register and purchase vaccine products.

Since China first passed the assessment, several vaccines, including the domestic live attenuated encephalitis B vaccine, live attenuated poliomyelitis type I and III vaccine, and inactivated hepatitis A vaccine, have passed the WHO's vaccine prequalification and entered the international procurement list. They have been purchased by the United Nations International Children's Emergency Fund, the Global Alliance for Vaccines and Immunization, and other international institutions. Relevant products have been exported to dozens of countries and regions. Since the outbreak of COVID-19, three Chinese COVID-19 vaccines have been included in the WHO emergency use listing to help in the global fight against the virus.

China's latest successful WHO assessment shows that the country has seen improvements in its vaccine regulatory capacity and level, with international standards as a benchmark. It also shows that China can ensure that its vaccine products are safe, effective and controllable in quality, so as to better protect people's health. At the same time, it creates favorable conditions for the export of Chinese vaccines and China's contribution to the development of global public health undertakings. China can play a more active role in global vaccine supply, and make more contributions to promoting future vaccine accessibility and affordability around the world, especially in developing countries.

(August 23, 2022)

药品

我国疫苗监管体系通过世界卫生组织评估

2022年8月23日，世界卫生组织（WHO）宣布中国通过疫苗国家监管体系（NRA）评估。

WHO对疫苗国家监管体系的评估，是对国家疫苗监管能力评估的一项重要举措和有效手段，是一项世界范围内公认的、可以科学全面评估一个国家疫苗监管水平的国际考核。我国疫苗监管体系已于2011年、2014年先后两次通过评估，在2022年7月迎来了WHO升级评估标准后的新一轮全面评估。此次评估指标大幅增加、内容更加全面、标准更加严格。

通过评估，不仅意味着中国拥有稳定、运行良好且完整统一的监管体系，能确保在中国生产、进口或流通的疫苗质量可控、安全、有效，也是我国疫苗出口全球的重要基础。WHO将通过疫苗监管体系评估作为采购该国疫苗产品的前提，即只有国家监管体系通过评估，该国企业才能申请WHO疫苗产品预认证，并列入联合国等国际组织采购清单。此外，通过评估也是其他国家注册和采购他国疫苗产品的重要参考。

我国自首次通过疫苗国家监管体系评估以来，有国产乙型脑炎减毒活疫苗、I型III型脊髓灰质炎减毒活疫苗、甲型肝炎灭活疫苗等多个疫苗通过WHO的疫苗预认证，进入国际采购清单，被联合国儿童基金会、全球疫苗免疫联盟等国际机构采购，相关产品已经出口至数十个国家和地区。新冠肺炎疫情发生以来，我国有3个新冠病毒疫苗被列入WHO紧急使用清单，助力全球抗疫。

此次我国疫苗监管体系通过WHO评估，彰显了我国疫苗监管体系对标国际标准、监管能力和水平提升，能够保障疫苗产品安全、有效、质量可控，从而更好地守护人民健康，同时也为我国疫苗产品走出国门、助力世界公共卫生事业发展创造了良好条件。中国可在全球疫苗供应中扮演更积极角色，为促进全球、特别是发展中国家的疫苗可及性和可负担性作出贡献。

（2022-08-23）

Published by
China Center for Food and Drug International Exchange

Announcement on Issuing the Technical Guideline for Electronic Records of Vaccine Manufacturing and Testing (Interim) (2022 No.1)

In order to implement the relevant requirements of the *Vaccine Administration Law of the People's Republic of China* and the *NMPA Announcement on Issuing the Revised Draft of the Appendix of Biological Products of the Good Manufacturing Practice for Drugs* (2010 Revision) (2020 No. 58), the *Technical Guideline for Electronic Records of Vaccine Manufacturing and Testing (Interim)* (see the Attachment), which was jointly drafted by the Center for Information and the Center for Food and Drug Inspection of NMPA, is issued upon the review and approval of NMPA on June 22, 2022 and shall come into force on the date of issuance.

(June 27,2022)

Candonilimab Injection Approved with Condition for Marketing

Recently, the Candonilimab Injection (Chinese trade name: 开坦尼) of Akeso Inc. is approved with condition for marketing through the priority review and approval procedure by NMPA in China. This biological product is a bispecific antibody of which the research and development is taken independently in China. The Candonilimab Injection is applied for the treatment of relapsed or metastatic cervical cancer patients who progressed on or after platinum-based chemotherapy

The Candonilimab Injection is a PD-1/CTLA-4 bispecific antibody, which blocks the interaction between PD-1 and CTLA-4 with their ligands PD-L1/PD-L2 and B7.1/B7.2, thereby blocking the immunosuppressive response of PD-1 and CTLA-4 signaling pathways, promoting tumor-specific T cell immune activation, and then conducting anti-tumor effect. This product provides a new treatment option available for patients.

(June 29, 2022)

Finerenone Tablets Approved for Marketing

Recently, the Finerenone Tablets (English trade name: Kerendia, Chinese trade name: 可申达) is approved for marketing by NMPA in China, which is an innovative drug of Bayer. The drug is indicated for the treatment of adults with chronic kidney disease associated with type 2 diabetes (estimated glomerular filtration rate [eGFR] of ≥ 25 to <75 mL/min/1.73 m2 with albuminuria) to reduce the risk of sustained eGFR decline and end-stage kidney disease.

Finerenone is a non-steroidal, selective mineralocorticoid receptor (MR) antagonist. MR is expressed in the kidney, heart, and

国家药品监督管理局信息中心 食品药品审核查验中心关于发布《疫苗生产检验电子化记录技术指南（试行）》的通告（2022年第1号）

为贯彻落实《中华人民共和国疫苗管理法》《国家药监局关于发布〈药品生产质量管理规范（2010年修订）〉生物制品附录修订稿的公告》（2020年第58号）等有关要求，国家药品监督管理局信息中心、食品药品审核查验中心共同组织起草了《疫苗生产检验电子化记录技术指南（试行）》，经国家药品监督管理局审查同意，于2022年6月22日发布并实施。

（2022-06-27）

国家药监局附条件批准卡度尼利单抗注射液上市

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康方药业有限公司卡度尼利单抗注射液（商品名：开坦尼）上市。该药品为我国自主研发的创新双特异性抗体，适用于既往接受含铂化疗治疗失败的复发或转移性宫颈癌患者的治疗。

卡度尼利单抗注射液是一种靶向人PD-1和CTLA-4的双特异性抗体，可阻断PD-1和CTLA-4与其配体PD-L1/PD-L2和B7.1/B7.2的相互作用，从而阻断PD-1和CTLA-4信号通路的免疫抑制反应，促进肿瘤特异性的T细胞免疫活化，进而发挥抗肿瘤作用。该品种的上市为患者提供了新的治疗选择。

（2022-06-29）

国家药监局批准非奈利酮片上市

近日，国家药品监督管理局批准拜耳公司申报的1类创新药非奈利酮片（商品名：可申达/Kerendia）上市。该药适用于与2型糖尿病相关的慢性肾脏病成人患者（肾小球滤过率估计值[eGFR] 25 至<75 mL/min/1.73 m2，伴白蛋白尿），可降低eGFR持续下降、终末期肾病的风险。

非奈利酮是一种非甾体类、选择性盐皮

blood vessels, and Finerenone attenuates inflammation and fibrosis mediated by MR overactivation. This product provides a new treatment option available for adult patients with chronic kidney disease associated with type 2 diabetes. (June 29, 2022)

质激素受体（MR）拮抗剂。MR在肾脏、心脏和血管中均有表达，非奈利酮可减轻MR过度激活介导的炎症和纤维化。该药品的上市为2型糖尿病相关的慢性肾脏病成人患者提供了新的治疗选择。

（2022-06-29）

Rezvilutamide Tablets Approved with Condition for Marketing

Recently, the Rezvilutamide Tablet (Chinese trade name: 艾瑞恩) of Jiangsu Hengrui Pharmaceuticals Co., Ltd is approved with condition for marketing through the priority review and approval procedure by NMPA in China. This drug is indicated for the treatment of metastatic hormone-sensitive prostate cancer (mHSPC) patients with high tumor burden.

Rezvilutamide is an androgen receptor (AR) inhibitor that competitively inhibits androgen binding to AR, thereby inhibiting AR nuclear translocation and DNA binding, and reducing AR-mediated gene transcription. This product provides a new treatment option available for patients with prostate cancer.

(June 29, 2022)

国家药监局附条件批准瑞维鲁胺片上市

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江苏恒瑞医药股份有限公司申报的1类创新药瑞维鲁胺片（商品名：艾瑞恩）上市。该药适用于治疗高瘤负荷的转移性激素敏感性前列腺癌（mHSPC）患者。

瑞维鲁胺是一种雄激素受体（AR）抑制剂，可竞争性抑制雄激素与AR结合，从而抑制AR核移位及DNA结合，降低AR介导的基因转录。该品种上市为前列腺癌患者提供了新的治疗选择。

（2022-06-29）

NMPA Announcement on Issuing the Provisions for Vaccine Manufacturing and Distribution (2022 No. 55)

In order to implement the requirements of the *Drug Administration Law of the People's Republic of China* and the *Vaccine Administration Law of the People's Republic of China* and other laws and regulations, build a scientific and effective supervision and administration system for the manufacturing and distribution of vaccines, and standardize the manufacturing and distribution management activities of vaccines in accordance with the characteristics of vaccine products and vaccine regulatory requirements, NMPA organized to formulate the *Provisions for the Manufacturing and Distribution of Vaccines*, which are issued and implemented on July 8, 2022.

(July 8,2022)

国家药监局关于发布《疫苗生产流通管理规定》的公告（2022年 第55号）

为贯彻落实《中华人民共和国药品管理法》和《中华人民共和国疫苗管理法》等法律法规要求，构建科学、有效的疫苗生产流通监督管理体系，根据疫苗产品特性和疫苗监管要求，依法对疫苗的生产、流通管理活动进行规范，国家药监局组织制订了《疫苗生产流通管理规定》，于2022年7月8日发布并施行。

（2022-07-08）

Azvudine Tablets New Indication for anti COVID-19 Approved with Condition

On July 25, Azvudine Tablets of Genuine Biotech is approved with condition for adding the indications for treatment of COVID-19 by NMPA through emergency review and approval procedure in accordance with the relevant provisions of special review and approval prescribed in the *Drug Administration Law*.

The drug is an oral small molecule for the treatment of COVID-19 independently developed in China. On July 20, 2021, NMPA has conditionally approved the

阿兹夫定抗新冠病毒新适应症获批准

7月25日，国家药监局根据《药品管理法》相关规定，按照药品特别审批程序，进行应急审评审批，附条件批准河南真实生物科技有限公司阿兹夫定片增加治疗新冠病毒肺炎适应症注册申请。

本品是我国自主研发的口服小分子新

combination of this product with other reverse transcriptase inhibitors for the treatment of HIV-1 infected adult patients with high viral load. This conditional approval is for adding the new indication for treatment of COVID-19 adult patients with medium symptoms. Patients should use the drug in strict accordance with instructions under the guidance of physicians.

The MAH is asked by NMPA to complete relevant research works of the conditional requirements within a time limit, and submit the follow-up research results as soon as possible.

(July 25, 2022)

冠病毒肺炎治疗药物。2021年7月20日，国家药监局已附条件批准本品与其他逆转录酶抑制剂联用治疗高病毒载量的成年HIV-1感染患者。此次为附条件批准新增适应症，用于治疗普通型新型冠状病毒肺炎（COVID-19）成年患者。患者应在医师指导下严格按说明书用药。

国家药监局要求上市许可持有人继续开展相关研究工作，限期完成附条件的要求，及时提交后续研究结果。

（2022-07-25）

NMPA Announcement on Adopting ICH Guidelines E8(R1) and E14

To align the technical standards for drug registration with international standards, the NMPA has decided to adopt the ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) Guidelines *E8 (R1): General Considerations for Clinical Studies* and *E14: Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-antiarrhythmic Drugs* (hereinafter referred to as E8 (R1) and E14). The relevant items are hereby announced as follows:

1. The Guidelines E8 (R1) and E14 shall be adopted to the drug clinical trials initiated from July 31, 2023. From the date of implementation of Guideline E8 (R1), the Guideline E8 shall be revoked.
2. The relevant technical guidelines may be accessed on the website of the Center for Drug Evaluation of NMPA. CDE of NMPA shall carry out technical guidance in relation to the implementation of this Announcement.

(August 12, 2022)

国家药监局关于适用《E8（R1）：临床研究的一般考虑》和《E14：非抗心律失常药物致QT/QTc间期延长及潜在致心律失常作用的临床评价》国际人用药品注册技术协调会指导原则的公告（2022年第61号）

为推动药品注册技术标准与国际接轨，经研究，国家药品监督管理局决定适用《E8（R1）：临床研究的一般考虑》和《E14：非抗心律失常药物致QT/QTc间期延长及潜在致心律失常作用的临床评价》国际人用药品注册技术协调会（ICH）指导原则。现就有关事项公告如下：

一、 自2023年7月31日起，启动的药物临床研究的相关要求适用《E8（R1）：临床研究的一般考虑》和《E14：非抗心律失常药物致QT/QTc间期延长及潜在致心律失常作用的临床评价》。E8（R1）实施之日起，E8停止实施。

二、相关技术指导原则可在国家药品监督管理局药品审评中心网站查询。国家药品监督管理局药品审评中心负责做好本公告实施过程中的相关技术指导工作。

（2022-08-12）

Innovative TCM Desmodium Styracifolium Flavonoids Capsule Approved for Marketing

The National Medical Products Administration (NMPA) recently approved Desmodium Styracifolium Flavonoids Capsule (Chinese name by Pinyin: Guangjinqiancao Zonghuangtong Jiaonang) for marketing, an innovative traditional Chinese medicine (TCM). The main ingredient of the drug is the flavonoids

国家药监局批准中药创新药广金钱草总黄酮胶囊上市

近日，国家药品监督管理局批准了1.2类中药创新药广金钱草总黄酮胶囊的上市注册申请。该药的主要成份是从广金钱草中提取得到的总黄酮类成份，药品上市许可持有人为武汉光谷人福生物医药有限公司。

composition extracted from Desmodium Styracifolium. The Marketing Authorization Holder of this medical product is Wuhan Guanggu Humanwell Biomedical Co., LTD.

Randomized, double-blinded and placebo-controlled multicenter clinical trials were conducted to evaluate the safety and efficacy of the drug. The results showed statistical differences between the placebo-controlled group and treatment group, which indicates that the drug can be used for the treatment of ureteral calculi with syndrome of accumulated damp-heat.

The marketing of the drug will provide a new treatment option for the patients. The NMPA will strengthen post-marketing surveillance to ensure the safety of public medication. (September 15, 2022)

该药开展了随机、双盲、安慰剂平行对照、多中心临床试验，临床试验研究结果显示与安慰剂对照组间比较有统计学差异，可用于输尿管结石中医辨证属湿热蕴结证患者的治疗。

该品种上市将为临床相关疾病的患者提供新的治疗选择。药品监督管理部门将加强该药品上市后监管，保护患者用药安全。

（2022-09-15）

NMPA Announcement on Issuing Electronic Drug Registration Certificates

In order to implement the decision and deployment of the CPC Central Committee and the State Council's important decision to deepen the reform to delegate power, improve regulation, and upgrade services, improve the business environment, further stimulate the development vitality of market entities, and provide more efficient and convenient government services for enterprises, it is decided to issue the electronic drug registration certificates for pharmaceutical products from November 1, 2022. The relevant matters are hereby announced as follows:

I. The scope of the issuance of the electronic drug registration certificates are those from November 1, 2022, approved by the NMPA for the certificates for clinical trials, marketing authorization, renewal of drug registration, supplementary applications, traditional Chinese medicine variety protection, imported medicinal materials, chemical active drug ingredients etc. as well as the GLP document.

II. The electronic drug registration certificate has the same legal effect as the paper certificate. The electronic certificate has the functions of instant delivery, SMS reminder, certificate authorization, code scanning verification, online verification, whole network sharing, etc.

III. The drug marketing authorization holders or applicants must first register and authenticate with their real-names at the Online Service Hall of the NMPA website, enter the "My Certificates" section of the Online Service Hall, and view and download the corresponding electronic drug registration certificate. They can also log on to the NMPA APP to view and download the electronic registration certificates.

IV. The electronic drug registration certificate does not contain attachments such as the pharmaceutical manufacturing process, quality standards, package inserts, labels etc. The above-mentioned attachments will be pushed to the "My Certificates" section of the legal representative space at the Online Office Hall of the NMPA website in the form of electronic documents simultaneously with the electronic drug registration certificate, which will be delivered upon successful push. The drug marketing authorization holders or applicants can download the documents.

V. The drug marketing authorization holder or applicant should properly keep the account number of the Online Office Hall of the NMPA website, the electronic registration certificate and relevant attached electronic documents, etc.

VI. Questions related to the use of the electronic drug registration certificates can be found in the "Frequently Asked Questions about Electronic Certificates" section at the Online Service Hall of the NMPA website.

(October 9, 2022)

国家药监局关于发放药品电子注册证的公告（2022年第83号）

为贯彻落实党中央、国务院关于深化“放管服”改革的重要决策部署，优化营商环境，进一步激发市场主体发展活力，为企业提供更加高效便捷的政务服务，经研究决定，自2022年11月1日起，发放药品电子注册证。现将有关事项公告如下：

一、药品电子注册证发放范围为自2022年11月1日起，由国家药监局批准的药物临床试验、药品上市许可、药品再注册、药品补充申请、中药品种保护、进口药材、化学原料药等证书以及药物非临床研究质量管理规范认证证书。

二、药品电子注册证与纸质注册证具有同等法律效力。电子证照具有即时送达、短信提醒、证照授权、扫码查询、在线验证、全网共享等功能。

三、药品上市许可持有人或申请人须先行在国家药监局网上办事大厅注册并实名认证，进入网上办事大厅“我的证照”栏目，查看下载相应的药品电子注册证。也可登录“中国药监APP”，查看使用电子注册证。

四、药品电子注册证不包含药品生产工艺、质量标准、说明书和标签等附件。上述附件以电子文件形式和药品电子注册证同步推送至国家药监局网上办事大厅法人空间“我的证照”栏目，推送成功即送达，药品上市许可持有人或申请人可自行登录下载获取。

五、药品上市许可持有人或申请人应妥善保管国家药监局网上办事大厅账号、电子注册证及相关附件电子文件等。

六、药品电子注册证使用相关问题可查看国家药监局网上办事大厅“电子证照常见问题解答”栏目。

（2022-10-09）

Medical devices

Computer aided detection software for colorectal polyps approved for marketing

Recently, the "computer aided detection software for colorectal polyps" is approved for marketing by NMPA in China, which is an innovative product of Chengdu Wision Medical Device Co., LTD.

This product is provided in CD form and installed and used in stand-alone mode. It has 9 functional modules: acquisition card management, authorization management, drawing detection area, sound prompt, display option, displaying software information, monitoring running time, processing algorithm management and main program. The product is intended to be used in conjunction with designated models of video colonoscopes only in medical facilities to enable physicians to review the identified areas of suspect polyps presented in real time on the output stand-alone video images during colonoscopy in adults. The information is for reference only and physicians should make their own clinical judgment in combination with the patient's conditions.

The working principle of this product is to import video images at the video signal output port of endoscopic image processor, identify the areas of suspect polyps after software processing and algorithm analysis, and present it in a separate display. The product is the first medical device software in China that uses deep learning model to assist in the detection of polyps in endoscopic images. Small sample deep learning technology and local labeling technology are used to select and develop the algorithm model framework. The overall performance of the algorithm is not completely subject to the increase of training data and can achieve high performance, strong generalization and robustness in small samples.

This product is applied with electronic colonoscopes to help physicians identify the areas of suspect polyp during colonoscopy examination, which is conducive to earlier detection of precancerous lesions of rectal cancer, thereby reducing the incidence and mortality of rectal cancer.

NMPA will protects the public health by strengthening the post-marketing supervision to assure the quality, safety and effectiveness of this product.

(August 3, 2022)

Anastomotic Reinforcement Patch Approved for Marketing

Recently, the National Medical Products Administration has approved the registration of Anastomotic Reinforcement Patch, the innovative product manufactured by Beijing Biosis Healing Biological Technology Co., Ltd.

The anastomotic reinforcement patch includes tubular, flat and circular model. The tubular and the circular are composed of three parts, namely the patch, the backing and the traction stitch; the flat has only the patch. The patch is made of decellularized porcine intestinal submucosa, and is sutured and fixed to the backing with traction stitch. The flat patch has neither backing nor traction stitch.

This product is a degradable anastomotic reinforcement product. Its manufacturing process can remove the immunogenicity of animal tissue, while retaining the structure and bioactivity of the natural extracellular matrix; its structural design enables the product to be matched and connected to various models of staplers

医疗器械

肠息肉电子结肠内窥镜图像辅助检测软件获批上市

近日，国家药品监督管理局经审查，批准了成都微识医疗设备有限公司生产的“肠息肉电子结肠内窥镜图像辅助检测软件”创新产品注册申请。

该产品以光盘形式提供，以单机方式安装使用。具有采集卡管理、授权管理、绘制检测区域、声音提示、显示选项、显示软件信息、监测运行时间、处理算法管理、主程序9大功能模块。产品仅在医疗机构内与指定型号的电子结肠内窥镜配合使用，供执业医生在成人结肠内窥镜检查时，对输出的独立视频图像进行实时显示疑似息肉区域。该信息仅供参考，医生应当结合患者病情进行临床决策。

该产品工作原理为在内窥镜图像处理器的视频信号输出端口导入视频图像，经过软件处理和算法分析后找出其中疑似息肉的位置，并在单独的显示器中显示。该产品为国内首个利用深度学习技术对内窥镜图像中息肉进行辅助检测的医疗器械软件，采用了小样本深度学习技术和局部标记技术进行算法模型框架的选择和开发，算法的整体性能不完全依赖训练数据的增加，能够在较小样本下实现高性能、强泛化性和鲁棒性。

该产品与电子结肠内窥镜配合使用，可帮助医生在进行结肠镜检查时找出疑似息肉位置，有利于更早发现直肠癌的癌前病变，从而降低直肠癌发生率和死亡率。

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。

（2022-08-03）

吻合口加固修补片获批上市

近日，国家药品监督管理局经审查，批准了北京博辉瑞进生物科技有限公司生产的创新产品“吻合口加固修补片”注册。

吻合口加固修补片共包含管状型、平片型、圆型。管状型和圆型由修补片、背衬、牵引线三部分构成，平片型只有修补片。修补片由脱细胞猪小肠粘膜下层材料制备而成，与背衬用牵引线进行缝合固定。平片型无背衬和牵引线。

该产品是可降解吻合口加固产品，其采用的生产工艺实现了去除动物组织免疫原性的同时，保留天然细胞外基质的结构和生物活性；其结构设计使产品能配套连接各种型号吻合器并提高手术安全性。该产品配合吻

and improve operation safety. This product is, in combination with staplers, applied for reinforcement of anastomosis in distal gastrectomy, proximal gastrectomy, sleeve gastrectomy, gastrointestinal anastomosis. It is able to reduce anastomotic leakage, bleeding and other related complications after gastroenterectomy and bring the benefits to the patients.

The drug regulatory department will strengthen the post-marketing supervision of the product to protect the safety of medical device for the patients.

(August 15, 2022)

合器用于吻合部位的加固，适用于远端胃切除术、近端胃切除术、袖状胃切除术、胃肠吻合术，能够降低胃肠切除手术术后发生吻合口漏、出血等相关并发症，为患者带来受益。

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。

（2022-08-15）

The first China's domestically developed Proton Therapy System approved for marketing

In recent years, the National Medical Products Administration has fully implemented the requirements of the CPC Central Committee and the State Council on deepening the reform of the medical device review and approval system, and actively promoted the marketing of innovative medical devices, including those in the national key research, the development program and the major project of science and technology, therefore to reinforce the innovation and high-quality development of the industry and to better meet the health needs of patients.

On September 26, 2022, the innovative product "Proton Therapy System" by Shanghai APACTRON Particle Equipment Co., Ltd. is approved by NMPA in China. The product is a major supporting project of the key research and development program "Digital Diagnostic and Therapeutic Equipment Program" of the Ministry of Science and Technology during the "13th Five Year Plan", and also the first domestically developed proton therapy system approved for marketing in China. The marketing of this product marks another step forward in the progress of the advanced medical devices made in China, and demonstrates great significance to improve the means and level of medical diagnosis and treatment of cancers in China.

The product consists of the accelerator system and the treatment system. The proton accelerator system includes a linac injector, a low-energy beam transfer line, a synchrotron, a high energy beam transfer line and an auxiliary electrical system. The treatment system includes a fixed-beam treatment system, 180-degree rotational beam treatment system and treatment planning system. The product provides proton beam for radiotherapy. It can deliver high dose in tumor volume, while significantly reducing the dose in surrounding normal tissues, especially in tissues behind the target volume. It is applicable to the treatment of solid malignant tumors and some benign diseases in the whole body. The specific indications should be determined by the clinicians according to the actual situation.

The product shall be used in strict accordance with the approved scope of indication, and at the same time the diagnosis and treatment guidelines formulated by the health authority shall be strictly followed.

During the registration of the product, NMPA, in accordance with the principle of "early intervention, assignment to specific person, whole process guidance, and scientific review and approval", under the premise of no compromising in standards and procedures, actively communicates and coordinates with multiple parties, and enhances guidance to accelerate the review and approval process. NMPA works to promote the marketing process as soon as possible on the basis that the safety and effectiveness of the product is ensured, so as to meet the patients' need of using advanced medical devices.

(September 26, 2022)

我国国产首台质子治疗系统获批上市

近年来，国家药品监督管理局全面贯彻落实党中央国务院有关深化医疗器械审评审批制度改革要求，积极推动创新医疗器械、国家重点研发计划和重大科技专项医疗器械上市，促进产业创新高质量发展，更好满足患者健康需要。

2022年9月26日，国家药品监督管理局批准了上海艾普强粒子设备有限公司生产的“质子治疗系统”创新产品注册申请。该产品是“十三五”期间科技部重点研发计划“数字诊疗装备专项”的重点支持项目，也是我国首台获准上市的国产质子治疗系统。该产品的获批上市，标志着我国高端医疗器械装备国产化又迈出一步，对于提升我国医学肿瘤诊疗手段和水平，具有重大意义。

该产品由加速器系统和治疗系统两部分组成。其中加速器系统包括注入器系统、低能传输系统、主加速器系统、高能束流传输系统和辅助电气系统，治疗系统包括固定束治疗系统、180°旋转束治疗系统和治疗计划系统。产品提供质子束进行放射治疗，在实现肿瘤部位高剂量的同时，可降低周围正常组织剂量，特别是靶区后组织的剂量，适用于治疗全身实体恶性肿瘤和某些良性疾病，具体适应症应由临床医师根据实际情况确定。

使用者应当严格按照产品批准的适用范围使用产品，同时应当严格遵守卫生健康部门的诊疗规范。

在该产品的注册申报过程中，国家药监局按照“提前介入、专人负责、全程指导，科学审批”的原则，在标准不降低、程序不减少的前提下，积极沟通，多方协调，加大产品注册申报指导，加快审评审批进程，在保证安全、有效的基础上推动产品尽快上市，满足患者使用高水平医疗器械的需要。

（2022-09-26）

NMPA Announcement on Issuing the Guidelines for the Inspection of the Quality Management System for Medical Device Registration (2022 No. 50)

In order to effectively carry out the inspection of the quality management system for registration under the medical device registrant system and improve the inspection quality of the quality management system for medical device registration, in accordance with the *Regulations on Supervision and Administration of Medical Devices* (State Council Decree No. 739), *Provisions for Medical Device Registration and Filing* (SAMR Decree No. 47), *Provisions for In-vitro Diagnostic Reagent Registration and Filing* (SAMR Decree No. 48), *Provisions for Supervision and Administration of Medical Device Manufacturing* (SAMR Decree No. 53) and other requirements, NMPA has organized to revise the Guidelines for the Inspection of the Quality Management System for Medical Device Registration (see the Attachment), which is hereby issued on September 29, 2022 and shall take effect as of the date of issuance. The NMPA Announcement on Issuing the Guidelines for the Inspection of the Quality Management System for Medical Device Registration (2020 No. 19) shall be abolished simultaneously.

(October 10,2022)

国家药监局关于发布医疗器械注册质量管理体系核查指南的通告（2022年第50号）

为做好医疗器械注册人制度下注册质量管理体系核查工作，提高医疗器械注册质量管理体系核查工作质量，根据《医疗器械监督管理条例》（国务院令第739号）及《医疗器械注册与备案管理办法》（市场监管总局令第47号）、《体外诊断试剂注册与备案管理办法》（市场监管总局令第48号）、《医疗器械生产监督管理办法》（市场监管总局令第53号）等要求，国家药品监督管理局组织修订了《医疗器械注册质量管理体系核查指南》（见附件），于2022年9月29日发布，自发布之日起实施。国家药品监督管理局《关于发布医疗器械注册质量管理体系核查指南的通告》（2020年第19号）同时废止。

（2022-10-10）

Notes: • All Chinese information in the Newsletter is extracted from newspapers and the Internet. All English articles are translations from the Chinese version. In case of any discrepancy, the Chinese version shall prevail.

• 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。如有出入，以中文为准。

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China Center for Food and Drug International Exchange (CCFDIE)
中国食品药品国际交流中心

Address: Room 1106, 11th Floor, Office Building B, Maples International Center, No. 32, Xizhimen North Street, Haidian District, Beijing, 100082, P.R.C.
中国北京市海淀区西直门北大街32号枫蓝国际中心B座写字楼11层1106室
邮编：100082

Tel: 010-8221 2866
Email: ccfdie@ccfdie.org

Fax: 010-8221 2857
Website: www.ccfdie.org