NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心

Headline

NMPA Holds Meeting to Review Vaccine Regulation and Quality Management System

On May 4, the National Medical Products Administration (NMPA) held a review meeting on the vaccine regulation and quality management system in 2022, to summarize the construction and operation of the system, evaluate its appropriateness, effectiveness and adequacy, and make arrangements for the key tasks in the next stage.

NMPA Commissioner Jiao Hong attended the meeting. NMPA Deputy Commissioner Huang Guo presided over the meeting.

The establishment of a vaccine regulation and quality management system is a basic element in the World Health Organization (WHO) National Regulatory Authority (NRA)'s assessment of vaccines, and also an internal demand to comprehensively improve China's vaccine regulatory capacity and promote the healthy development of China's vaccine industry. The NMPA attaches great significance to its construction, integrates the requirements of the NRA assessment with regulatory practices, and consistently advances the construction of its vaccine regulation and quality management system, which has greatly improved science-based and standardized vaccine regulation.

At the meeting, the NMPA' s Office of Vaccine Regulation and Quality Management System reported the overall situation in the construction and operation of the system in 2022. The Department of Comprehensive Affairs, Planning, and Finance Affairs, the Department of Policies and Regulations, the Department of Drug Registration, the Department of Drug Regulation and the Department of Human Resources respectively reported the operation of the system in each department. In 2022, the NMPA advanced the quality management system based on the vaccine NRA assessment, formulated and updated procedural documents to standardize the regulatory process, improved its work through research and studies, elevated the operating efficiency and quality of the system via internal reviews, and enhanced the quality management capability of related personnel by strengthening training. Remarkable progress has been made in the construction of the vaccine regulation and quality management system.

The meeting fully affirmed the outcomes in the construction of the vaccine regulation and quality management system. The NMPA has been building the system in line with China's national conditions and improving the overall quality and effectiveness of vaccine regulatory work, which has played a positive role in enabling China to pass the latest vaccine NRA assessment. The meeting noted that in the past year, the vaccine regulation and quality management system has been operating steadily and effectively, and the regulatory work has been carried out orderly and in accordance with regulations.

The meeting stressed that the construction of the vaccine regulation and quality management system should be carried out in a profound and solid manner. First, efforts should be made to complete the vaccine NRA Institutional Development Plan (IDP) and rectify problems found during the internal review within the time limit and in line with quality requirements. Second, it is important to make further improvements by integrating quality management with regulatory work to improve the operation efficiency of the system. Third, mutual

头条

国家药监局召开疫苗监管质量管理体系管理评审会议

5月4日，国家药监局召开2022年度疫苗监管质量管理体系管理评审会议，总结体系建设运行情况，评价体系的适宜性、充分性和有效性，安排部署下一步重点工作。国家药监局局长焦红出席会议，局党组成员、副局长黄果主持会议。

疫苗监管质量管理体系建设是世界卫生组织疫苗国家监管体系（NRA）评估的基本要素，也是全面提升我国疫苗监管能力、推动我国疫苗产业健康发展的内在需求。国家药监局高度重视，将疫苗NRA评估要求与监管实际有机结合，持续推动疫苗监管质量管理体系建设，疫苗监管的科学化、规范化水平得到大幅提升。

会上，疫苗监管质量管理体系办公室汇报了2022年度疫苗监管质量管理体系建设运行整体情况，综合司、政法司、药品注册司、药品监管司、人事司汇报了本单位体系运行情况。2022年，国家药监局以疫苗NRA评估推动质量管理体系提升，以编制更新程序文件规范监管行为过程，以调查研究助力工作改进完善，以内审创新提升体系运行效率和质量，以强化培训提高人员质量管理素养，疫苗监管质量管理体系建设工作取得长足进步。

会议充分肯定疫苗监管质量管理体系建设成效。国家药监局循序渐进地建设符合我国国情的疫苗监管质量管理体系，整体提升疫苗监管工作的质量和效能，为顺利通过本轮疫苗NRA评估提供重要支撑、发挥积极作用。会议认为，过去一年，疫苗监管质量管理体系运行稳定有效，监管行为合规有序。

会议指出，要将疫苗监管质量管理体系做深做实。一是按时限、保质量完成疫苗NRA评估机构发展计划（IDP）和内审发现问题的整改。二是做好改进完善，将质量管理与监管工作紧密融合，提升体系运行效能。三是加强学习交流，指导各级质量管理体系从建设标准一致，逐步迈向运行规范一致，以质量管理协同推动监管工作有序衔接。

会议要求，要做好药品监管质量管理体系

Published by
China Center for Food and Drug International Exchange

learning and exchanges should be promoted to guide the quality management system at all levels to gradually move from standardized construction to standardized operation, so as to facilitate effective coordination between regulatory work and quality management. The meeting highlighted that the drug regulation and quality management system should be well-planned. Noting that based on the vaccine regulation and quality management system, the experience and well-received practices should be gradually promoted across all aspects of drug regulation and that the quality management concept should be implemented in every step of drug regulation.

The meeting also called for greater efforts to thoroughly implement the guiding principles of the 20th National Congress of the Communist Party of China, advance the development and operation of the regulation and quality management system, strengthen drug safety regulation, improve the efficiency of drug regulation, promote the modernization of the drug regulatory system and regulatory capacity through quality management, and to drive the high-quality development of the drug industry in a bid to contribute to the Chinese modernization of drug regulation.

(May 4, 2023)

的谋篇布局，以疫苗监管质量管理体系为基础，将取得的经验和好的工作思路、做法逐步研究推广到整个药品监管领域，将质量管理理念贯彻到药品监管的各个环节。

会议强调，要深入贯彻落实党的二十大精神，持续推进监管质量管理体系的有效运行和不断完善，强化药品安全监管，提升药品监管效能，以质量管理助推药品监管体系和监管能力现代化，促进药品产业高质量发展，奋力谱写中国式现代化的药监篇章。

国家药监局综合司、政法司、药品注册司、药品监管司、人事司主要负责同志，内审小组长、疫苗监管质量管理体系相关人员以及中国健康传媒集团主要负责同志和相关人员参加会议。

（2023-05-04）

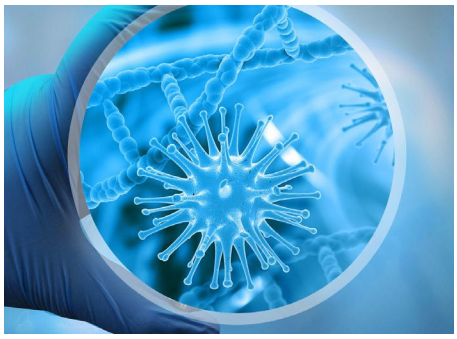
Xu Jinghe Attended GHWP TC Open Workshop

On June 14, 2023, the Technical Committee of the Global Harmonization Working Party (GHWP TC) held an open workshop in Shenzhen, Guangdong Province. Xu Jinghe, the deputy commissioner of China' s National Medical Products Administration (NMPA) and Chairman of GHWP, attended the workshop and delivered a speech.

Xu Jinghe pointed out that GHWP is an critical platform for regulatory cooperation among member countries and regions. At present, GHWP has formulated more than 40 technical guidelines, effectively facilitating the regulatory capacity improvement in member countries and regions. In the following years, GHWP will implement the GHWP Strategic Framework towards 2026 in earnest, put more efforts in regulation publicity and enforcement, continue to carry out regulatory capacity development, bolster the convergence, harmonization and reliance in regulation, and actively contribute more to global public health.

This open workshop introduced the GHWP Strategic Framework towards 2026, work achievements and future prospects of GHWP TC, review requirements for IVD and medical device software, etc.. More than 300 representatives from GHWP member countries and regions attended the workshop on-site. The live streaming of the workshop was accessible to 33 member countries and regions. The representatives highly appreciated the workshop, regarding it as a good channel for global medical device enterprises and stakeholders to better understand international regulatory rules.

（Jun. 14, 2023）



徐景和出席全球医疗器械法规协调会技术委员会法规交流开放会

2023年6月14日，全球医疗器械法规协调会技术委员会（GHWP TC）在广东省深圳市举办法规交流开放会。国家药监局党组成员、副局长、GHWP主席徐景和出席开放会并致辞。

徐景和指出，GHWP是成员国家和地区监管合作的重要平台。目前GHWP已制定40多项技术指导原则，有力促进了成员国家和地区监管能力提升。下一步，GHWP将认真落实2026年战略规划，进一步加大法规宣传和执行力度，持续开展监管能力建设，加快推进监管趋同、协调与信赖，积极为全球公众健康做出新的贡献。

本次交流开放会对GHWP 2026年战略规划、GHWP TC工作成果和未来展望、体外诊断试剂及医疗器械软件审评要求等内容进行讲解。来自GHWP成员国家和地区300余名代表现场参会，交流开放会同步向33个成员国家和地区在线直播。与会代表充分肯定GHWP TC法规交流开放会，认为这为全球医疗器械企业和利益相关方更好地了解国际监管规则提供了很好的渠道。

（2023-06-14）

Xu Jinghe Attends GHWP Technical Committee Leaders Meeting

The Technical Committee (TC) Leaders Meeting of the Global Harmonization Working Party (GHWP) was held on June 14 and 15 in Shenzhen, South China's Guangdong province. The GHWP leadership, TC working groups, consultants and relevant experts participated in the event. The meeting focused on the work plan for formulating and revising regulations and recent key work arrangements. Xu Jinghe, deputy commissioner of China's

徐景和出席GHWP TC领导人会议

2023年6月14日至15日，全球医疗器械法规协调会（GHWP）在深圳召开技术委员会（TC）领导人会议。GHWP领导团队、TC各工作组及顾问、相关专家参加会议。会议重点研究了监管法规的制修订工作计划和近期重点工

National Medical Products Administration (NMPA), attended and addressed the meeting. Xu said that health is the issue of greatest concern, the most eternal pursuit, and the most precious wealth of humanity. The GHWP TC working groups should conscientiously fulfill their mission, actively adapt to the new needs of innovative development in the global medical device industry, formulate and revise regulatory coordination plans in a timely manner, and accelerate the regulatory convergence, harmonization and reliance of member countries and regions. It is necessary to enhance the publicity, training and application of regulations and to continue to improve regulatory systems and capabilities of member countries and regions, Xu added. He also underscored the efforts to adhere to the principles of openness, cooperation, and win-win results, fully leverage the unique advantages of the GHWP and strengthen communication and cooperation with relevant international organizations, in a bid to protect and promote global public health.

(Jun. 16, 2023)

作安排。国家药监局副局长、GHWP主席徐景和出席会议并讲话。

徐景和强调，健康是人类最关切的议题、是人类最永恒的追求、是人类最宝贵的财富。GHWP TC各工作组要认真履行使命，积极适应全球医疗器械产业创新发展的新需要，及时制修订监管法规协调方案，加快推进成员国家和地区监管法规的趋同、协调与信赖。要强化监管法规的宣传、培训与应用，持续推进成员国家和地区监管体系的完善和监管能力的提升。要坚持开放、合作、共赢原则，充分发挥GHWP组织的独特优势，加强与相关国际组织的交流与合作，为保护和促进全球公众健康而努力。

（2023-06-16）

Drugs

Zuberitamab Injection Approved for Marketing

Recently, the Zuberitamab injection (Chinese trade name: 安瑞昔) of Zhejiang BioRay Biopharmaceutical Co., Ltd. is approved for marketing by China NMPA. This drug is indicated for the treatment of CD20 positive diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) for adult patients, and should be combined with standardized CHOP therapies (cyclophosphamide, doxorubicin, vincristine, prednisone).

Zuberitamab Injection is a human-mouse chimeric monoclonal antibody targeting the CD20 antigen on the surface of B cells. It can specifically bind to the CD20 antigen on the surface of B cells, thereby initiating the immune response of B cytolysis and exerting anti-tumor effects. The marketing of this drug provides more treatment options for patients.

(May 17, 2023)

药品

国家药监局批准泽贝妥单抗注射液上市

近日，国家药品监督管理局批准浙江博锐生物制药有限公司申报的泽贝妥单抗注射液（商品名：安瑞昔）上市。该药品适用于CD20阳性弥漫大B细胞淋巴瘤，非特指性（DLBCL，NOS）成人患者，应与标准CHOP化疗（环磷酰胺、阿霉素、长春新碱、泼尼松）联合治疗。

泽贝妥单抗注射液为针对B细胞表面CD20抗原的人–鼠嵌合型单克隆抗体，可特异性结合B细胞表面的CD20抗原，从而启动B细胞溶解的免疫反应，发挥抗肿瘤作用。该品种的上市为患者提供了更多的治疗选择。

（2023-05-17）

Alfosbuvir Tablets Approved for Marketing

Recently, the Class-1 innovative drug Alfosbuvir Tablets (Chinese trade name:圣诺迪) of Nanjing Sanhome Pharmaceutical Co., Ltd. is approved for marketing through the priority review and approval procedure by China NMPA. It is an innovative drug independently developed in China with independent intellectual property rights. Used in combination with daclatasvir hydrochloride, it is indicated for the treatment of chronic hepatitis C virus (HCV) of genotype 1, 2, 3 and 6 infection for adults who are initially treated or have been treated with interferon, combined with or without compensatory cirrhosis.

Alfosbuvir is an inhibitor for HCV NS5B RNA-depended polymerase (necessary for virus replication). It is a nucleotide precursor drug, metabolized into pharmacologically active metabolites (SH229M3) in the cell, which can be embedded into HCV RNA by NS5B polymerase to terminate replication. The marketing of this drug provides a new treatment option for adult patients with chronic HCV infection.

（May 17, 2023）

国家药监局批准奥磷布韦片上市

近日，国家药品监督管理局通过优先审评审批程序批准南京圣和药业股份有限公司申报的1类创新药奥磷布韦片（商品名：圣诺迪）上市。该药为我国自主研发并拥有自主知识产权的创新药，适用于与盐酸达拉他韦联用，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。

奥磷布韦是HCV NS5B RNA依赖性RNA聚合酶（为病毒复制所必需）抑制剂，是一种核苷酸前体药物，在细胞内代谢为具有药理活性的代谢产物（SH229M3），可被NS5B聚合酶嵌入HCV RNA中而终止复制。该药品的上市为成人慢性丙型肝炎病毒患者提供了新的治疗选择。

（2023-05-17）

Befotertinib Mesylate Capsules Approved for Marketing

Recently, the Class I innovative product Befotertinib Mesylate Capsules (Chinese trade name: 赛美纳) of Betta Pharmaceuticals Co., Ltd. is approved by China NMPA. It is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that had progressed after prior EGFR tyrosine kinase inhibitor therapy, and with epidermal growth factor receptor (EGFR) T790M-mutated.

Befotertinib Mesylate is the third-generation EGFR tyrosine kinase inhibitor, which can selectively inhibit EGFR sensitive mutation and EGFR T790M drug-resistant mutation kinase. The marketing of this drug provides a new treatment option for NSCLC patients.

(May 31, 2023)

国家药监局批准甲磺酸贝福替尼胶囊上市

近日，国家药品监督管理局批准贝达药业股份有限公司申报的1类创新药甲磺酸贝福替尼胶囊（商品名：赛美纳）上市。该药适用于既往经表皮生长因子受体（EGFR）酪氨酸激酶抑制剂治疗出现疾病进展，并且伴随EGFR T790M突变阳性的局部晚期或转移性非小细胞肺癌患者的治疗。

甲磺酸贝福替尼是第三代表皮生长因子受体酪氨酸激酶抑制剂，能够选择性地抑制EGFR敏感突变和EGFR T790M耐药突变激酶。该药品的上市为非小细胞肺癌患者提供了新的治疗选择。

（2023-05-31）

NMPA Holds Training on NRA for Vaccines in Beijing

The National Medical Products Administration (NMPA) held a special training session in Beijing from June 6 to 7, where experts from the World Health Organization (WHO) introduced the National Regulatory Authority (NRA) for vaccines. NMPA Deputy Commissioner Huang Guo attended and addressed the event.

Six experts, including Rogerio Gaspar, Director of Regulation and Prequalification Department of the WHO, expounded on the development of related cutting-edge technologies, international experience in the construction of the NRA, Good Regulatory Practices for regulatory authorities, the development of the quality management system, as well as drug vigilance and pre-qualification based on the assessment of the NRA for vaccines.

The event was organized by the NMPA's Institute of Executive Development. Officials from related departments of the NMPA, affiliated Institutions, the Chinese Center for Disease Control and Prevention, and provincial-level medical products administrations participated in the training.

(Jun. 8, 2023)

疫苗国家监管体系专题培训在京举办

6月6日至7日，国家药监局在京举办专题培训，邀请世界卫生组织专家就疫苗国家监管体系有关内容进行介绍和交流。国家药监局党组成员、副局长黄果出席培训并致辞。

世卫组织监管和预认证司司长罗热里奥·加斯帕尔等6位专家结合疫苗国家监管体系评估，全面介绍了前沿技术发展、监管体系建设的国际经验、国家监管体系良好监管规范、质量管理体系建设、药物警戒和预认证等内容。

培训由国家药监局高级研修学院承办。国家药监局有关司局、直属单位，中国疾控中心和省级药监部门相关人员参加培训。

（2023-06-08）

Medical Devices

Magnetic Resonance Monitoring Semiconductor Laser Treatment Equipment Approved for Marketing

Recently, the innovative product Magnetic Resonance Monitoring Semiconductor Laser Treatment Equipment of Sinovation(Beijing) Medical Technology Co., Ltd. is approved by China NMPA.

The core technology of magnetic resonance monitoring of this product has a national invention patent. During the laser treatment process, magnetic resonance temperature imaging technology is used to receive the gradient echo sequence of magnetic resonance equipment in real time, thereby calculating the temperature of the treatment area and realizing real-time monitoring during the treatment process. This product, together with disposable laser optical fiber kit, is used for laser treatment of local lesions(with a clear epileptogenic area or a clear epileptic pathway) for patients with drug non-responsive epilepsy. Due to shorter treatment time, smaller damage to healthy brain tissues and less postoperative complications, patients will recover quickly,

医疗器械

磁共振监测半导体激光治疗设备获批上市

近日，国家药品监督管理局批准了华科精准（北京）医疗科技有限公司生产的"磁共振监测半导体激光治疗设备"创新产品注册申请。

该产品磁共振监测核心技术具有国家发明专利，在激光治疗过程中，通过磁共振温度成像技术，实时接收磁共振设备的梯度回波序列，从而计算治疗区域温度，对治疗过程实时监控。

该产品与一次性使用激光光纤套件配合，用于对药物难治性癫痫患者（有明确的致痫区部位或明确的癫痫传导途径）的局部病灶进行

and the treatment difficulty of intracranial lesions in neurosurgery is reduced. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(Apr. 4, 2023)

激光治疗且治疗时间短，对健康脑组织损伤小，术后并发症少，患者恢复快，降低了神经外科颅内病灶的治疗难度。

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。

（2023-04-04）

Disposable Laser Optical Fiber Kit Approved for Marketing

Recently, the innovative product Disposable Laser Optical Fiber Kit of Sinovation (Beijing) Medical Technology Co., Ltd. is approved by China NMPA.

The core technologies such as materials, structure, and manufacturing process of this product have national invention patents. Under long-term working conditions, the optical fiber undergoes almost no deformation when heated, and therefore the intensity of laser scattering along the axis can relatively maintain consistency. This not only increases the treatment range, but also reduces the laser power density, thus effectively improving the safety of use.

This product, together with magnetic resonance monitoring semiconductor laser treatment equipment, achieves the minimally invasive treatment of intracranial lesions in neurosurgery, and is used for laser treatment of local lesions(with a clear epileptogenic area or a clear epileptic pathway) for patients with drug non-responsive epilepsy. Due to shorter treatment time, smaller damage to healthy brain tissues and less postoperative complications, patients will recover quickly, and the treatment difficulty of intracranial lesions in neurosurgery is reduced.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(Apr. 14, 2023)

一次性使用激光光纤套件获批上市

近日，国家药品监督管理局批准了华科精准（北京）医疗科技有限公司生产的“一次性使用激光光纤套件”创新产品注册申请。

该产品的材料、结构和制作工艺等核心技术具有国家发明专利。在长时间工作状态下，光纤受热几乎不发生形变，沿其轴向散射出的激光强度能够保持相对一致，不仅可以增加治疗范围，同时也可降低激光功率密度，有效提高了使用安全性。

该产品与磁共振监测半导体激光治疗设备配合使用，实现了神经外科颅内病灶的全微创治疗，用于对药物难治性癫痫患者（有明确的致痫区部位或明确的癫痫传导途径）的局部病灶进行激光治疗。治疗时间短，对健康脑组织损伤小，术后并发症少，患者恢复快，降低了神经外科颅内病灶的治疗难度。

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。

（2023-04-14）

Coronary Function Measurement System Approved for Marketing

Recently, the innovative product Coronary Function Measurement System of Suzhou RainMed Medical Technology Co., Ltd. is approved by China NMPA.

The product is composed of work station, transducer rack, IBP lead wire and IBP signal input cable(optional), and only applied with the disposable invasive pressure transducer of Suzhou RainMed Medical Technology Co., Ltd. It is intended to assess Coronary Angiography Index of Microcirculatory Resistance (caIMR) by conducting vascular segmentation and three-dimensional reconstruction on coronary angiography images, and making hemodynamic analysis combing with the aortic pressure measured by disposable invasive pressure transducer, which assists clinicians to assess the function of coronary microcirculation for patients.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(Apr. 20, 2023)

冠状动脉功能测量系统获批上市

近日，国家药品监督管理局批准了苏州润迈德医疗科技有限公司生产的“冠状动脉功能测量系统”创新产品注册申请。

该产品由工作站、传感器支架、IBP导联线、IBP信号输入电缆（选配）组成，仅限与苏州润迈德医疗科技有限公司的一次性使用有创压力传感器配合使用。该产品通过对冠状动脉造影影像进行血管分割、三维重建，获取血流速度，结合有创压力传感器测量的主动脉压进行血流动力学分析，实现对冠状动脉造影微循环阻力指数（caIMR）的评估，辅助临床医生评价患者冠状动脉微循环功能情况。

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。

（2023-04-20）

Metal Additive Manufacturing Thoracolumbar Fusion Matching Prosthesis System Approved for Marketing

Recently, the innovative product Metal Additive Manufacturing Thoracolumbar Fusion Matching Prosthesis System of Beijing AK Medical Co., Ltd. is approved by China NMPA.

This product is composed of a thoracolumbar fusion matching prosthesis, and matching components such as buckles and screws. This product innovatively adopts polyethylene buckles as a flexible connection device, combined with the posterior screw-rod system, to achieve a "truss" structure of joint fixation of the anterior and posterior approach. For patients who require multi-segment thoracolumbar resection and reconstruction, this product adopts a porous structure and can realize matching design for patients (designed and manufactured based on patient CT data) and implant fixation, which can improve the postoperative quality of life and survival rate of patients to a certain extent.

This product is intended for structural reconstruction from upper thoracic vertebrae to lower lumbar vertebrae (T1-L5) after three or more consecutive vertebral resections due to tumors or other lesions. It needs to be matched with the spinal internal fixation system and achieve permanent implantation. The marketing of this product will provide a new treatment option for patients.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(Apr. 21, 2023)

金属增材制造胸腰椎融合匹配式假体系统获批上市

近日，国家药品监督管理局经审查，批准了北京爱康宜诚医疗器材有限公司生产的创新产品“金属增材制造胸腰椎融合匹配式假体系统”注册。

该产品包括胸腰椎融合匹配式假体，以及配合组件钉扣、螺钉。该产品创新性采用聚乙烯钉扣作为柔性连接装置，联合后路钉棒系统，实现前后路联合固定的“桁架”结构。对于需进行多节段胸腰椎切除重建的患者人群，该产品采用多孔结构，同时可实现患者匹配设计（基于患者CT数据设计制造）和植入假体固定，可在一定程度提高患者术后生活质量和患者生存率。

该产品适用于上胸椎至下腰椎（T1–L5）因肿瘤或其它病变需行连续三个及以上节段椎体切除后的结构重建，需与脊柱内固定系统匹配并实现永久植入。产品的上市将为患者治疗提供新的选择。

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。

（2023-04-21）

Self-expanding Radioactive Seed-Carried Biliary Stent Approved for Marketing

On May 11, 2023, the innovative product Self-expanding Radioactive Seed-Carried Biliary Stent of Rongsheng (Nanjing) Medical Technology Co., Ltd. is approved by NMPA. By far 200 innovative medical devices have been approved by NMPA.

The product consists of an internal and an external stent, each with a disposable introducer, and the external stent with a empty seed capsule. It combines radioactive seeds therapy with stent technology for the treatment of malignant biliary obstruction. The dual stent structure of the internal and external stent reduces the diameter of the external tube of the introducer, allowing for micro-invasive therapy and providing a vehicle for 3-dimensional intra-organ radiotherapy while expanding the stent.

This product is indicated for the dilation and treatment of biliary stricture or obstruction caused by malignant tumours that are inoperable or not surgically removed due to unwillingness. After implantation, the Self-expanding Radioactive Seed-Carried Biliary Stent can dilate the biliary stricture and the radioactive seeds carried on the stent can provide brachytherapy to the tumour tissue to inhibit tumour growth, which is expected to prolong the effective bile duct patency time and improve the survival time and life quality of patients. The marketing of this product will provide a new treatment option for patient.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(May 11, 2023)

自膨式可载粒子胆道支架获批上市

2023年5月11日，国家药品监督管理局经审查，批准了南京融晟医疗科技有限公司生产的创新产品“自膨式可载粒子胆道支架”注册。截至目前，国家药监局已批准200个创新医疗器械产品。

该产品由内、外支架组成，各带有一个一次性使用置入器，外支架带有粒子囊（不含粒子）。该产品将放射性粒子与支架技术结合运用于胆道恶性梗阻治疗，采用内、外双支架结构设计，降低置入器的外管直径，实现微创介入治疗，在扩张支架的同时为三维立体空腔脏器内放射治疗提供载体。

该产品适用于因恶性肿瘤导致的无法手术或者不愿手术切除的胆道狭窄/梗阻的扩张及治疗。自膨式可载粒子胆道支架植入后，能起到扩张胆道狭窄的作用，支架上携带的放射粒子对肿瘤组织进行近距离放射治疗，抑制肿瘤生长，预期延长胆管有效通畅时间，提高患者生存时间和生活质量。产品的上市将为患者治疗提供新的选择。

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。

（2023-05-11）

Computer Aided Detection Software for Intestinal Polyps in Lower Gastrointestinal Endoscopy Approved for Marketing

Recently, the innovative product Computer Aided Detection Software for Intestinal Polyps in Lower Gastrointestinal Endoscopy of Wuhan ENDOANGEL Medical Technology Co., Ltd is approved by China NMPA.

This product is used for detecting suspected polyp areas from the independent video image output by the endoscope image processor in real-time adult colonoscopy by endoscopists in medical institutions.

This product is the first domestic software that utilizes deep learning technology to simultaneously control the quality of proctoscopy and assist in polyp detection. Compared with similar products already marketed at home and abroad, this product uses deep learning technology, perceptual hash algorithm, and other technologies to assist doctors in operation control while identifying polyps, further ensuring the quality of proctoscopy, reducing missed detections, and improving the standardization of examination operations.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(May 12, 2023)

肠息肉电子下消化道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批准了武汉楚精灵医疗科技有限公司生产的“肠息肉电子下消化道内窥镜图像辅助检测软件”创新产品注册申请。

该产品在医疗机构供执业内窥镜医师用于成人结肠内窥镜检查时，在内窥镜图像处理器输出的独立视频图像中实时显示疑似息肉的区域。

该产品为国内首个利用深度学习技术同时进行结直肠镜检查质量控制和息肉辅助检测的软件。该产品与现有国内外已上市同类产品相比，在识别息肉的同时，采用深度学习技术、感知哈希算法等技术辅助医生进行操作控制，进一步确保肠镜检查质量，减少漏检率，并提升检查操作的规范性。

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。

(2023-05-12)

Intravascular Imaging Device Approved for Marketing

Recently, the innovative product Intravascular Imaging Device (Novasight Hybrid System) of Conavi Medical Inc.is approved by China NMPA.

This product is composed of a console and a patient interface module (PIM), and is used in conjunction with a single-use IVUS OCT catheter for intravascular imaging of coronary arteries during percutaneous coronary interventional operation.

The imaging catheter of this product is equipped with IVUS and OCT probes at the far end, which can automatically obtain images and feedback them to the image processing module, achieving synchronous registration of intravascular ultrasound and optical interference tomography imaging. This product is superior to similar marketed products and can achieve both types of imaging simultaneously, which meets doctors' requirements for resolution and penetration, simplifies doctors' operations, and improves accuracy and safety of imaging.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(May 16, 2023)

血管内成像设备获批上市

近日，国家药品监督管理局批准了Conavi Medical Inc.生产的“血管内成像设备”创新产品注册申请。

该产品由控制台(ADM)和患者接口模块(PIM)组成，与一次性使用血管内成像导管连接配合使用，用于经皮冠状动脉介入手术时对冠状动脉进行血管内成像。

该产品成像导管远端安装有声学探头与光学探头，能自动获取图像并反馈至图像处理模块，实现同步配准的血管内超声和光学干涉断层成像。该产品优于同类已上市产品，能够同时实现上述两种成像，同步满足医生对分辨力和穿透力的要求，简化了医生操作，提高了成像的准确性和安全性。

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。

(2023-05-16)

Radiotherapy Planning Software Approved for Marketing

Recently, the innovative product radiotherapy planning software of Shanghai United Imaging Healthcare Co. Ltd. is approved by China NMPA.

This product is used to plan external radiotherapy treatments with photon and electron beams. Its core technology mainly includes automatic beam arrangement and automatic plan optimization algorithm. The former automatically designs the beam gantry

放射治疗计划软件获批上市

近日，国家药品监督管理局批准了上海联影医疗科技股份有限公司生产的“放射治疗计划软件”创新产品注册申请。

该产品适用于制定光子束和电子线的外照射放疗计划。其核心技术主要包括自动

angle and the collimator angle according to the information such as patient setup, target location and projection shapes etc. The latter automatically adjusts plan optimization objectives based on preset protocols, so that the quality of the final plan meets the prescription requirements. Compared to existing radiotherapy planning systems, it can minimize manual operation steps, alleviate user workload, and reduce dependence on user experience.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(May 23, 2023)

布野技术和自动计划优化技术，前者根据患者体位、靶区位置和投影形状等信息，自动设计机架射束角度和准直器角度；后者通过预设的方案自动调整相关优化目标，使得最终计划的各项要求达到处方要求。与现有放射治疗计划软件相比，可减少人工操作步骤，降低用户工作强度，减轻对用户操作经验的依赖。

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。

(2023-05-23)

Cosmetics

2023 National Popular Science Week for Cosmetic Safety Kicks Off in Beijing

On May 22, the opening ceremony of the 2023 National Popular Science Week for Cosmetic Safety was held in Beijing. The opening ceremony is guided by China NMPA and jointly organized by Beijing, Tianjin, and Hebei Medical Products Administration. Lei Ping, member of NMPA Leading Party Members' Group and Deputy Commissioner, and Chen Bei, Deputy Secretary General of the People's Government of Beijing Municipality, attended and addressed at the ceremony.

The National Popular Science Week for Cosmetic Safety is a brand activity for promoting popular science on cosmetics created by the NMPA, which has been held for 5 consecutive years. The theme of this cosmetic week is "Safe Use of Cosmetics, Co-governance and Sharing", aiming at promoting and implementing relevant regulations and provisions on the entity responsibility of cosmetics enterprises for cosmetic quality and safety, strengthening industry self-discipline, and enhancing social co-governance of cosmetic safety by taking the opportunity of implementing the rules on supervision and administration of enterprises taking entity responsibility of cosmetic quality and safety. More than 350 representatives from relevant industry associations, enterprises and news media attended the ceremony.

(May 22, 2023)

化妆品

2023年全国化妆品安全科普宣传周在京启动

5月22日，2023年全国化妆品安全科普宣传周启动仪式在北京举办。启动仪式由国家药监局指导，北京、天津、河北省（市）药监局联合承办。国家药监局党组成员、副局长雷平，北京市政府副秘书长陈蓓出席启动仪式并讲话。

全国化妆品安全科普宣传周是国家药监局打造的化妆品科普宣传品牌活动，至今已连续举办5年。本届宣传周主题为“安全用妆，共治共享”，旨在以《企业落实化妆品质量安全主体责任监督管理规定》实施为契机，进一步宣传贯彻企业落实化妆品质量安全主体责任相关法规，加强行业自律，推动化妆品安全社会共治。相关行业协会、企业、新闻媒体等各界代表350余人参加了本次启动仪式活动。

(2023-05-22)

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-paper of the Newsletter, please visit http://www.ccfdie.org

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

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, PR.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