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NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心

Headline

Xu Jinghe elected chairman of GHWP

On Feb 16, Xu Jinghe, deputy commissioner of China's National Medical Products Administration (NMPA), was elected chairman of the 27th Global Harmonization Working Party (GHWP) in Riyadh, capital of Saudi Arabia. This is of great significance in the process of China's internationalization of medical device regulation.

The GHWP is an international medical device regulatory and technological exchange platform involving the participation of regulatory authorities and industry representatives. Its predecessor was the Asian Harmonization Working Party (AHWP) and was officially renamed as the GHWP in 2022. With its growing number of members and increasing international influence, the membership of the GHWP has expanded from Asia to the Middle East, North and South Americas as well as Africa, covering 33 countries and regions. The population of the countries and regions involved accounts for more than half of the global total, with nearly 80 percent of members being located along the Belt and Road.

The 26th GHWP Annual Meeting and Technical Committee Meeting was held from Feb 13 to 16 in Riyadh. The event included open forums on regulatory reliance, digital therapy, innovative medical devices, regulatory capacity building, the GHWP Technical Committee Meeting, and the GHWP Annual Meeting.

Experts from GHWP member countries and regions, the GHWP Technical Committee and related working groups, capacity building program and representatives from the International Medical Device Regulators Forum (IMDRF), member states of the Association of Southeast Asian Nations, Asia-Pacific Economic Cooperation member economies, and other international coordinating organizations shared the latest progress in global medical device regulation.

One of the main tasks of the GHWP annual meeting is to elect a new term of the GHWP leadership. According to the Terms of Reference and House Rules of the GHWP, Xu Jinghe, deputy commissioner of the NMPA, was elected the new chairman of the GHWP by the vote of the representatives.

Xu' s election as the new chairman of the GHWP demonstrates that China's well-organized medical device regulatory system and effective regulatory work are widely and highly recognized by the international community. In his acceptance speech, Xu said that over the years, every step the GHWP's action has written its own history of rapid growth, and its work has been fruitful and influential. This annual meeting adopted the 2026 strategic framework and set out the development goals of the GHWP from 2023 to 2026. Working together with other members of the GHWP, he will devote himself to the coordination of global medical device regulatory rules and the common improvement of regulatory capacity among members.

Xu also said that during his term as chairman, he will prioritize the following six aspects of work. First, he will focus on the cutting-edge technology and promote the harmonization and unification of regulatory rules. Second, he will promote the research on regulation sciences and bring innovative products to the market at an early date. Third, he will strengthen laws and regulations training and improve

头条

国家药监局副局长徐景和成功当选全球医疗器械法规协调会主席

利雅得时间2月16日下午4时，国家药监局副局长徐景和成功当选第27届全球医疗器械法规协调会（GHWP）主席。这在我国医疗器械监管国际化进程中具有重要意义。

GHWP是由监管部门和业界代表共同参与的国际医疗器械法规、技术交流平台，其前身是亚洲医疗器械法规协调会（AHWP）。2022年正式更名为GHWP。随着成员数量不断增多，其国际影响力持续提升，成员范围已从亚洲扩展到中东、南北美洲和非洲，覆盖33个国家和地区，涉及国家和地区的人口占全球一半以上，其中近80%的国家和地区位于“一带一路”沿线。

2月13日至16日，GHWP第26届年会暨技术委员会会议在沙特首都利雅得召开。会议包括监管信赖、数字疗法、创新医疗器械、监管能力建设等开放论坛，GHWP技术委员会会议和GHWP年会。来自GHWP成员国家及地区、GHWP技术委员会及相关工作组、能力建设项目专家和IMDRF、东盟、APEC等国际协调组织代表共同分享了全球医疗器械监管工作最新进展情况。本次GHWP年会的主要任务之一是选举产生新一任期GHWP领导层。按照GHWP章程，经与会代表投票，国家药监局副局长徐景和成功当选新一届GHWP主席。

成功当选GHWP新一届主席，标志着中国系统完善的医疗器械监管体系和卓有成效的监管工作得到了国际同行的广泛、高度认可。徐景和发表当选致辞。他说，多年来，GHWP的每一步行动都在书写自己快速成长的历史，工作卓有成效，富有影响。本届年会通过了2026年战略框架，规划了GHWP2023-2026年的发展目标。我将与GHWP的各位成员一道，继续推进全球医疗器械监管法规的协调工作，促进

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the regulatory capacity and standards of member countries and regions. Fourth, he will push forward regulatory reliance and accelerate the realization of regulatory mutual recognition among member countries and regions. Fifth, he will advance the application of technical guidance and the sustainability of regulatory capacity. Sixth, he will bolster industrial cooperation and facilitate trade among member countries and regions.

(Feb 17, 2023)

成员间监管能力的共同提升。

徐景和表示，在任期内将重点做好以下六个方面工作：一是聚焦科技前沿，加快推进监管规则的协调与统一。二是加快推进监管科学研究，推动创新产品早日上市。三是加强法规培训，加快提升成员国家和地区的监管能力和水平。四是推进监管信赖，加快实现成员国家和地区监管互认。五是推进技术指南应用，促进监管能力持续。六是强化产业合作，加快推进成员国家和地区贸易增长。

(2023-02-17)

Drugs

Provisions for Supervision and Administration of Online Drug Sales

The Provisions for Supervision and Administration of Online Drug Sales is promulgated by Decree No. 58 of the State Administration for Market Regulation on August 3, 2022 and shall be effective as of December 1, 2022.

(Dec 29, 2022)

药品

NMPA英文网站发布《药品网络销售监督管理办法》英文译本

《药品网络销售监督管理办法》（国家市场监督管理总局令第58号）于2022年8月3日发布，自2022年12月1日起施行。

(2022-12-29)

Importation of MSD's Molnupiravir Capsules approved with condition

The importation registration of Molnupiravir Capsules (trade name: 利卓瑞/LAGEVRIO) for the treatment of COVID-19 of MSD Inc. is approved with condition for marketing by China NMPA on December 29, through emergency review and approval procedure in accordance with the relevant provisions of special review and approval prescribed in the Drug Administration Law.

This oral small-molecule drug for the treatment of COVID-19 is indicated for treating adult patients with mild to moderate SARS-CoV-2(COVID-19) infection with high risk factors of progressing to severe disease, such as advanced age, obesity or overweight, chronic kidney disease, diabetes, severe cardiovascular disease, chronic obstructive pulmonary disease, active cancer and so on. The patients should use the drug by strictly following the package insert under doctors' guidance. 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 in time.

(Dec 30, 2022)

国家药监局应急附条件批准默沙东公司新冠病毒治疗药物莫诺拉韦胶囊进口注册

12月29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，附条件批准默沙东公司新冠病毒治疗药物莫诺拉韦胶囊（商品名称：利卓瑞/LAGEVRIO）进口注册。

本品为口服小分子新冠病毒治疗药物，用于治疗成人伴有进展为重症高风险因素的轻至中度新型冠状病毒感染（COVID-19）患者，例如伴有高龄、肥胖或超重、慢性肾脏疾病、糖尿病、严重心血管疾病、慢性阻塞性肺疾病、活动性癌症等重症高风险因素的患者。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。

(2022-12-30)

Ainuovirine, Lamivudine and Tenofovir Disoproxil Fumarate Tablets approved for marketing

Recently, the innovative drug Ainuovirine, Lamivudine and Tenofovir Disoproxil Fumarate Tablets (trade name: 复邦德) of Jiangsu Aidea Pharmaceutical Co., Ltd. is approved by China NMPA. This product is a compound medicine composed of Ainuovirine, Lamivudine and Tenofovir Disoproxil Fumarate, which is indicated for the treatment of adult HIV-1 infected patients.

The marketing of this drug provides new treatment options for adult HIV-1 infected patients.

(Jan 4, 2023)

国家药监局批准艾诺米替片上市

近日，国家药品监督管理局批准江苏艾迪药业股份有限公司申报的1类创新药艾诺米替片（商品名：复邦德）上市。本品为艾诺韦林、拉米夫定和富马酸替诺福韦二吡呋酯组成的复方制剂，用于治疗成人HIV-1感染初治患者。

该药品的上市为成人HIV-1感染患者提供了新的治疗选择。

(2023-01-04)

Mobocertinib succinate capsules approved for marketing with conditions

Recently, the Class 1 innovative drug mobocertinib succinate capsule (trade name: 安卫力 / EXKIVITY) of Takeda Pharmaceutical, Inc. is approved for marketing with conditions through the priority review and approval procedure by China NMPA. This drug is indicated for adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy.

Mobocertinib is an irreversible tyrosine kinase inhibitor targeting the EGFR exon 20 insertion mutations. The marketing of this drug provides a new treatment option for patients with advanced NSCLC with EGFR exon 20 insertion mutations.

(Jan 11, 2023)

国家药监局附条件批准琥珀酸莫博赛替尼胶囊上市

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武田制药公司申报的1类创新药琥珀酸莫博赛替尼胶囊（商品名：安卫力/ EXKIVITY ）上市。该药适用于含铂化疗期间或之后进展且携带表皮生长因子受体（EGFR）20号外显子插入突变的局部晚期或转移性非小细胞肺癌（NSCLC）成人患者。

莫博赛替尼是一种靶向EGFR第20外显子插入突变的不可逆的酪氨酸激酶抑制剂。该药品的上市为携带EGFR外显子20插入突变阳性的晚期非小细胞肺癌患者提供了新的治疗选择。

(2023-01-11)

Biosimilar Tocilizumab Injection approved for marketing

Recently, the Tocilizumab Injection (Chinese trade name: 施瑞立) of Bio-Thera Solutions, Ltd. is approved for marketing by China NMPA. This drug is the first Tocilizumab Injection biosimilar approved in China, which is indicated for rheumatoid arthritis, systemic juvenile idiopathic arthritis, and cytokine release syndrome.

Tocilizumab is a recombinant humanized monoclonal antibody against the human interleukin-6 (IL-6) receptor that specifically binds to soluble and membrane-bound IL-6 receptors and inhibits signal transduction mediated by IL-6 receptors. At present, the Tocilizumab Injection has been included in the Diagnosis and Treatment Protocol for COVID-19 Infection (Tentative 10th Edition) and Diagnosis and Treatment Protocol for Severe Cases of Covid-19 Infection (Tentative 4th Edition), which can be used for severe cases with significantly elevated IL-6 levels detected by laboratory.

(Jan 16, 2023)

国家药监局批准托珠单抗注射液生物类似药上市

近日，国家药品监督管理局批准百奥泰生物制药股份有限公司申报的托珠单抗注射液（商品名：施瑞立）上市。该药是国内获批的首个托珠单抗注射液生物类似药，适应症为类风湿关节炎、全身型幼年特发性关节炎和细胞因子释放综合征。

托珠单抗是一种重组人源化抗人白介素6（IL-6）受体单克隆抗体，可特异性地结合可溶性和膜结合性IL-6受体，并抑制由IL-6受体介导的信号转导。目前，托珠单抗注射液被纳入《新型冠状病毒感染诊疗方案（试行第十版）》和《新型冠状病毒感染重症病例诊疗方案（试行第四版）》，对于重症病例且实验室检测 IL-6水平明显升高者可试用。

(2023-01-16)

Second Biosimilar Tocilizumab Injection approved for marketing

Recently, the Tocilizumab Injection (Chinese trade name: 安维泰) of Livzon Pharmaceutical Group Inc. is approved for marketing by China NMPA. This drug is the second Tocilizumab Injection biosimilar approved in China, which is indicated for rheumatoid arthritis.

Tocilizumab is a recombinant humanized monoclonal antibody against the human interleukin-6 (IL-6) receptor that specifically binds to soluble and membrane-bound IL-6 receptors and inhibits signal transduction mediated by IL-6 receptors. At present, the Tocilizumab Injection has been included in the Diagnosis and Treatment Protocol for COVID-19 Infection (Tentative 10th Edition) and Diagnosis and Treatment Protocol for Severe Cases of Covid-19 Infection (Tentative 4th Edition), which can be used for severe cases with significantly elevated IL-6 levels detected by laboratory.

(Jan 18, 2023)

国家药监局批准第二个国产托珠单抗注射液生物类似药上市

近日，国家药品监督管理局批准珠海市丽珠单抗生物技术有限公司申报的托珠单抗注射液（商品名：安维泰）上市。该药是国内获批的第二个国产托珠单抗注射液生物类似药，适应症为类风湿关节炎。

托珠单抗是一种重组人源化抗人白介素6（IL-6）受体单克隆抗体，可特异性地结合可溶性和膜结合性IL-6受体，并抑制由IL-6受体介导的信号转导。目前，托珠单抗注射液被纳入《新型冠状病毒感染诊疗方案（试行第十版）》和《新型冠状病毒感染重症病例诊疗方案（试行第四版）》，对于重症病例且实验室检测IL-6水平明显升高者可试用。

(2023-01-18)

Simnotrelvir Tablets/Ritonavir Tablets(co-packaged) and Deuremidevir Hydrobromide Tablets for treating COVID-19 infection approved for marketing with conditions

Recently, the class 1 innovative drug Simnotrelvir Tablets/Ritonavir Tablets (co-packaged) (Chinese trade name: 先诺欣) of Simcere Pharmaceutical Group Limited and Deuremidevir Hydrobromide Tablets (Chinese trade name: 民得维) of Shanghai Wangshi Biomedicine Technology Inc. are approved for marketing with conditions by China 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 above-mentioned two drugs are both oral small molecular drugs for COVID-19 infection treatment, indicated for adult patients with mild to moderate SARS-CoV-2 (COVID-19) infection. Patients should use drugs strictly according to the instructions under the guidance of doctors.

The MAHs are 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.

(Jan 29, 2023)

国家药监局附条件批准新冠病毒感染治疗药物先诺特韦片/利托那韦片组合包装、氢溴酸氘瑞米德韦片上市

近日，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，附条件批准海南先声药业有限公司申报的1类创新药先诺特韦片/利托那韦片组合包装（商品名称：先诺欣）、上海旺实生物医药科技有限公司申报的1类创新药氢溴酸氘瑞米德韦片（商品名称：民得维）上市。

上述两款药物均为口服小分子新冠病毒感染治疗药物，用于治疗轻中度新型冠状病毒感染（COVID-19）的成年患者。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。 (2023-01-29)

Medical Devices

Intravascular Ultrasound Diagnostic Equipment and Disposable Intravascular Ultrasound Diagnostic Catheter approved for marketing

Recently, the innovative products "Intravascular Ultrasound Diagnostic Equipment" of SonoScape Medical Corp. and "Disposable Intravascular Ultrasound Diagnostic Catheter" of Shanghai Acoustic Life Science Co., Ltd are approved for marketing by China NMPA. The two products are used together for ultrasonic imaging examination of coronary vascular diseases.

This combination product uses pulse echo

医疗器械

“血管内超声诊断设备”与“一次性使用血管内超声诊断导管”获批上市

近日，国家药品监督管理局经审查，批准了深圳开立生物医疗科技股份有限公司生产的“血管内超声诊断设备”和上海爱声生物医疗科技有限公司生产的“一次性使用血管内

technique to perform ultrasonic scanning and imaging of blood vessels. The device host and catheter controller send drive pulses to the ultrasonic transducer at the distal end of the catheter, and drive the transducer to rotate at a high speed through the driving shaft inside the sheath catheter. The transducer sends ultrasonic pulses and receives the ultrasonic echo signals reflected by the vascular tissue, which are amplified, collected and preprocessed by the catheter controller and transmitted to the device host to realize the display and processing of vascular images.

The disposable intravascular ultrasound diagnostic catheter is on the PMN-PT high frequency single crystal composite transducer, using the design and method of preparing glue free layer by evaporation with thickness ≤15μm. It realizes the localized manufacturing of high performance high frequency transducer, improves the image resolution and optimizes the image quality.

This combination product uses ultrasonic imaging with high frequency, wide bandwidth and high sensitivity, which can realize scanning, imaging and vessel diameter measurement of coronary vessels. It helps doctors to determine the severity and nature of the disease, further improve the understanding of coronary artery disease and guide interventional treatment.

The launch of this combination product is conducive to reducing the cost of clinical treatment, facilitating the clinical application and promotion of this technology, providing better diagnostic evidence for PCI precision diagnosis, and formulating better treatment strategies to benefit patients.

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

(Dec 15, 2022)

超声诊断导管”创新产品注册申请。两件产品配套使用，用于冠状动脉血管内病变的超声成像检查。

该配套产品利用脉冲回波原理对血管进行超声扫描成像。设备主机和导管控制器向位于导管远端的超声换能器发出激励脉冲，同时通过导管鞘管内部的驱动轴带动换能器高速旋转，换能器发出超声波脉冲并接受血管组织反射的超声回波信号，经导管控制器放大、采集、预处理后传输至主机，实现血管图像的显示和处理。

一次性使用血管内超声诊断导管，在PMN-PT高频单晶复合材料换能器上，采用蒸镀方式制备无胶水层且厚度≤15μm的工艺设计和方法，实现了高性能高频换能器的生产国产化，提高了图像分辨率的同时优化了图像质量。

该配套产品使用高频率、宽带宽、高灵敏度的超声波成像，能够实现冠脉血管的扫描成像和血管直径测量，帮助医生判断病变严重程度及性质，有助于提高对冠状动脉病变的认识和指导介入治疗。

该配套产品的上市有利于降低临床治疗费用和该技术的临床应用推广，为PCI精准诊疗提供更好的诊断依据，制定更佳的治疗策略使患者受益。

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。 (2022-12-15)

Medical Angiography X-ray Machine approved for marketing

Recently, the innovative product "Medical Angiography X-ray Machine" of Shanghai United Imaging Healthcare Co., Ltd. is approved for marketing by China NMPA.

The product consists of high-voltage generator, X-ray tube assembly, beam limiter, filter grid, flat panel detector, rack, patient table, display, Displayer ceiling suspension, uVision component, touch panel, control module, control box, foot switch, hand switch, image acquisition workstation, video management workstation, image advanced processing workstation, 3D image processing workstation and accessories. It is applicable to X-ray fluoroscopy, photography, vascular subtraction image and tomography image for angiography and interventional surgery.

This product adopts 9-axis robot DSA, which can realize cone beam imaging of the whole abdomen and chest, and solves the problem of small field of view upon the cone beam CT reconstruction of traditional cone beam CT. In addition, the product uses computer vision technology to realize one-click automatic cone beam CT scanning and one-click positioning, which can simplify the workflow of positioning and cone beam CT, reduce radiation exposure and intraoperative steps. Compared with the traditional medical angiography X-ray machine, this product can significantly expand field of view upon the cone beam CT reconstruction of traditional cone beam CT, reduce the operation steps, operation time and radiation dose of cone beam CT scanning, shorten the preparation time before imaging, and improve the surgical efficiency.

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

(Dec 30, 2022)

医用血管造影X射线机获批上市

近日，国家药品监督管理局经审查，批准了上海联影医疗科技股份有限公司生产的“医用血管造影X射线机”创新产品注册申请。

该产品由高压发生器、X射线管组件、限束器、滤线栅、平板探测器、机架、导管床、显示器、显示器吊架、视觉组件、触控平板、控制模块、控制盒、脚踏开关、手闸、图像采集工作站、视频管理工作站、图像高级处理工作站、3D图像处理工作站和附件组成。适用于对血管造影检查、介入手术时提供X射线透视、摄影、血管减影图像和体层图像。

该产品采用多轴机器人DSA，能实现全腹部、全胸部的锥形束成像，解决了传统锥形束CT重建视野小的问题。此外，产品采用计算机视觉技术，实现了一键自动锥形束CT扫描和一键到位，可简化定位和锥形束CT的工作流，减少辐射暴露和术中操作步骤。与传统的医用血管造影X射线机相比，该产品可显著扩大锥形束CT重建视野，减少锥形束CT扫描的操作步骤、操作时间和辐射剂量，预期缩短成像前的准备时间，提高手术效率。

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。 (2022-12-30)

China Domestic ECMO products approved for marketing

On January 4, 2023, the Extracorporeal Membrane Oxygenation System Console and its matching disposable kit of Chinabridge (Shenzhen) Medical Technology Co., Ltd. are approved through emergency review by China NMPA, to ensure the treatment needs of patients with severe cases of COVID-19 infection according to the demands of epidemic prevention and control. The system and disposable kit are used together for acute respiratory failure, acute cardiopulmonary failure or no other effective treatment methods for adult patients who have a foreseeable risk of continuous deterioration or death. As the first domestic ECMO system and disposable kit, the above products have independent intellectual property rights, and the devices' performance is on par with international level of similar products.

The Extracorporeal Membrane Oxygenation System is composed of a console, pumpdriver, an emergency pumpdriver, batteries, flow and bubble sensor, etc. The disposable kit consists of a centrifugal pumphead, a membrane oxygenator and 3x integrated pressure sensors all pre-connected with medical grade tubing along with a priming kit, oxygen tubing and other accessories.

As a rescue treatment device for patients with severe SARS-CoV-2 infection who failed to respond to conventional treatment, ECMO is the treatment measure specified in the diagnosis and treatment plan for the novel coronavirus disease (COVID-19). The launch of domestic products will play an important role in meeting clinical needs, ensuring the treatment of patients with cases of COVID-19, and ensuring the implementation of the goal of "to protect public health and prevent severe cases" for epidemic prevention and control.

During the registration and application process of this product, the NMPA establishes an emergency review task force, in accordance with the principle of "unified command, early intervention, fast and efficient, and scientific review and approval", with special person in charge, giving guidance during the whole process of guidance, releases technical review guidelines, increases the guidance of product registration and application, accelerates the review and approval process, and promotes the product to be marketed as soon as possible on the premise of ensuring safety and effectiveness, to meet the urgent needs of epidemic prevention and control.

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

(Jan 05, 2023)

我国国产体外膜肺氧合治疗（ECMO）产品获批上市

根据疫情防控工作需要，为确保新型冠状病毒肺炎重症患者治疗需要，2023年1月4日，国家药监局经审查，应急批准深圳汉诺医疗科技有限公司体外心肺支持辅助设备、一次性使用膜式氧合器套包注册申请，二者配合使用，用于急性呼吸衰竭或急性心肺功能衰竭、其他治疗方法难以控制并有可预见的病情持续恶化或死亡风险的成人患者。作为国产首个ECMO设备和耗材套包，上述产品具有自主知识产权，性能指标基本达到国际同类产品水平。

其中，体外心肺支持辅助设备由主机、泵驱动装置、紧急泵驱动装置、备用电池、流量气泡传感器等组成。一次性使用膜式氧合器套包由膜式氧合器及动静脉管路组件（含离心泵泵头），预充管路组件，配件包组件和氧气管路组成。

ECMO产品作为常规治疗无效的危重型新型冠状病毒肺炎患者的挽救性治疗设备，是《新型冠状病毒肺炎诊疗方案》中明确的治疗措施，国产产品的上市对于满足临床急需，保障新冠疫情重症患者治疗，确保疫情防控“保健康、防重症”目标落实，将发挥重要作用。

在该产品的注册申报过程中，国家药监局按照“统一指挥、早期介入、快速高效、科学审批”的原则，成立应急审评工作组，专人负责、全程指导、发布技术审查指导原则，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，满足疫情防控工作急需。

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。

(2023-01-05)

Patient monitor approved for marketing

Recently, the innovative product "patient monitor" of Shenzhen Comen Medical Instruments Co., Ltd. is approved for marketing by China NMPA.

The product consists of the main unit, plug-in module and accessories. Indicators such as ECG (including ST segment measurement and arrhythmia analysis), impedance respiration, body temperature, pulse oxygen saturation, pulse rate, non-invasive blood pressure, invasive blood pressure, respiratory and end-tidal carbon dioxide, anesthetic gas, non-invasive cardiac output (only applicable to adult patients), invasive cardiac output (only applicable to adult patients) can be monitored, and functions such as ECG, PICC, respiratory oxygenation diagram, renal function calculation, hemodynamic calculation, oxygenation calculation, ventilation calculation, drug calculation and recorder are also available. The product is expected to be used by trained and qualified

病人监护仪获批上市

近日，国家药品监督管理局经审查，批准了深圳市科曼医疗设备有限公司生产的“病人监护仪”创新产品注册申请。

该产品由主机、插件模块和附件组成。可对患者进行心电（含ST段测量及心律失常分析）、阻抗呼吸、体温、脉搏血氧饱和度、脉率、无创血压、有创血压、呼吸及呼吸末二氧化碳、麻醉气体、无创心输出量（仅适用于成人患者）、有创心输出量（仅适用于成人患者）监护，同时具有心电图、PICC、呼吸氧合图、肾功能计算、血液动力学计算、氧合计算、通气计

professional clinicians and nurses in medical institutions, and its application fields include operating rooms, ICUs and general departments. The product adopts ECG signal adaptive filtering technology and four-electrode ECG system technology, which can realize real-time positioning of catheter end during catheterization by observing the changes of P wave of intracavity ECG in real-time. Compared with the traditional central venous catheterization method, this product has the function of positioning the catheter end during central venous catheterization, which is helpful to improve the accuracy rate of PICC catheterization.

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

(Jan 06, 2023)

算、药物计算、记录仪功能。该产品预期在医疗机构由经培训合格的专业临床医生和护士使用，其应用领域包括手术室、ICU和普通科室。

该产品采用了心电信号自适应滤波技术和四电极心电系统技术，可通过实时观察腔内心电图P波的变化，反馈导管末端位置，实现置管操作过程中对导管末端的实时定位。与传统中心静脉置管术方法相比，该产品具有中心静脉置管末端定位功能，有助于提高PICC导管到位率。

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。 (2023-01-06)

Second China domestic ECMO products approved for marketing

On January 17, 2023, the Extracorporeal Membrane Oxygenation auxiliary device of RocketMedical Co., Ltd. (Rocket Medical) is approved with conditions through emergency review by China NMPA. This product is the second domestic ECMO product granted approval. The product provides power and safety monitoring during extracorporeal circulation, and is used in combination with compatible disposable consumables for pulmonary support. The product is intended for adult patients with acute respiratory failure that is difficult to control by other treatments and where there is a foreseeable risk of continued deterioration or death.

The product is composed of Revive-I ECMO, flow/bubble sensor, emergency drive, emergency drive holder, pressure connection cable, oxygenator holder, medical gas holder and cart.

The marketing of the product will further improve China's ECMO product supply capacity, meet clinical needs, improve treatment of severe cases of COVID-19, and better implement the goal of "protecting health and preventing severe diseases" of COVID-19 prevention and control.

During the registration and application process of this product, the NMPA establishes an emergency review task force, in accordance with the principle of "unified command, early intervention, fast and efficient, and scientific review and approval", with specific person in charge, giving guidance during the whole process, releases technical review guidelines, increases the guidance of product registration and application, and accelerates the review and approval process.

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

(Jan 17, 2023)

第二款国产ECMO产品获批上市

2023年1月17日，国家药监局经审查，采用附条件批准方式，应急批准了航天新长征医疗器械（北京）有限公司研发的体外肺支持辅助设备注册上市。该产品是第二款获批的国产ECMO产品。该产品在体外循环过程中提供动力及安全监测，与兼容的一次性使用耗材联合使用，实现肺功能辅助支持。该产品适用于急性呼吸衰竭、其他治疗方法难以控制并有可预见的病情持续恶化或死亡风险的成人患者。

该产品由主机、流量/气泡传感器、手摇紧急驱动装置、手摇紧急驱动装置支架、压力电缆线、氧合器支架、氧气瓶支架、推车组成。

该产品的上市将进一步提升我国ECMO产品供应能力，满足临床急需，提升新冠疫情重症患者救治水平，更好落实新冠疫情防控“保健康、防重症”目标。

该产品的注册申报过程中，国家药监局按照“统一指挥、早期介入、快速高效、科学审批”的原则，成立应急审评工作组，专人负责、全程指导、发布技术审查指导原则，加大产品注册申报指导，加快审评审批进程。

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。

(2023-01-17)

NMPA delegate elected co-chair of GHWP's Technical Committee

The 26th Annual Meeting and Technical Committee Meeting of the Global Harmonization Working Party (GHWP) were held from Feb 13 to 16, 2023, in Riyadh, capital of Saudi Arabia. Xu Jinghe, deputy commissioner of China's National Medical Products Administration (NMPA), led a delegation to the meeting.

The meetings of the GHWP Technical Committee included closed-door meetings and open meetings. The nine working groups of the GHWP respectively introduced the latest progress of their work and discussed the focuses and development directions in the next steps. The meeting elected the technical committee office and the chairs and co-chairs of all working groups for the new term. Delegates of the NMPA participated in the election of the co-chair of the Technical Committee and chairs of Working Group 7 and Working Group 9.

In accordance with the Terms of Reference and House Rules of the GHWP, Li Jun, deputy director-general of the NMPA's Department of Medical Device Regulation, was voted as the new co-chair of the GHWP Technical Committee; Chen Yan, director of the Inspection Division V of the Center for Food and Drug Inspection of the NMPA, was voted as the chair of Working Group 7; and Zhou Wenwen, second-level consultant of the Registration Research Division of the NMPA's Department of Medical Device Registration, was voted as the chair of Working Group 9. Assuming leading positions of the Technical Committee will further deepen the technological exchanges between China's medical device regulators and their international counterparts, and will promote the coordination and reliance in global medical device regulation.

(Feb 17, 2023)

国家药监局监管代表参加全球医疗器械法规协调会技术委员会会议并顺利当选副主席

2023年2月13日至16日，全球医疗器械法规协调会（GHWP）第26届技术委员会会议暨年会在沙特首都利雅得召开。国家药监局徐景和副局长率团出席会议。

GHWP技术委员会会议包括闭门会及开放会议两部分。9个GHWP工作组分别介绍了工作最新进展，并研讨了下一步工作重点和发展方向。本次会议选举产生新一任期技术委员会及各工作组主席、副主席。国家药监局代表参选技术委员会副主席，第七工作组、第九工作组主席。

按GHWP章程，经投票选举，国家药监局器械监管司副司长李军当选新一届GHWP技术委员会副主席，核查中心检查五处处长陈燕当选第七工作组主席，器械注册司注册研究处二级调研员周雯雯当选第九工作组主席。顺利担任技术委员会领导职务，将有助于进一步深化中国医疗器械监管与国际医疗器械监管的技术交流，更好促进全球医疗器械监管的协同与信赖。

(2023-02-17)

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.
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