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中国食品药品国际交流中心

Headline

NMPA Announcement on Further Strengthening the Supervision and Administration of Entrusted Manufacturing by Registrants of Medical Devices (No.38, 2024)

Pursuant to the implementation of the Regulations for the Supervision and Administration of Medical Devices, and with the objective of fully enforcing the primary responsibility for quality and safety on the part of the registrant of medical devices (hereinafter referred to as "Registrant"), this announcement aims to further strengthen the supervision and administration of entrusted manufacturing by registrants of medical devices, and enable effective prevention and control of quality and safety risks associated with medical devices. Relevant matters are hereby announced as follows:

I. Strictly Enforcing the Primary Responsibility for Registrant of Medical Devices

(I) The registrant shall fully assume the primary responsibility for the quality and safety of medical devices and establish an effective quality management system covering the entire life cycle of medical devices. If the registrant entrusts manufacturing to others, they shall establish and improve a management organization that is compatible with the characteristics of the products entrusted for manufacturing and the scale of the manufacturer, fully perform the responsibilities such as product risk management, change control, product release, after-sales service, product complaint handling, adverse event monitoring and product recall. Registrant shall regularly audit the operation of the contract manufacturer's quality management system in accordance with the Good Manufacturing Practice for medical devices.

Even when a registrant solely relies on entrusted manufacturing, the registrant shall also maintain the quality management competency for the entire life cycle of the product, and maintain the integrity and effectiveness of the quality management system; establish a management organization that is compatible with the entrusted manufacturing, and at least clearly define the responsibilities of relevant departments such as technology, production, quality management, adverse event monitoring and after-sales service. The quality management department shall be independently established, staffed with a sufficient number of full-time qualified quality management personnel, as well as technicians who are familiar with the products and have relevant professional knowledge. They shall be able to carry out effective monitoring and control of the entrusted manufacturing activities.

The registrant shall be able to assume responsibility for the quality and safety of medical devices in accordance with the law. It is recommended to procure commercial insurance and adopt additional mechanisms to establish a liability compensation capacity that is commensurate with factors such as the product risk level, market scale and personal injury compensation standards.

(II) The registrant shall give preference to manufacturers with a higher level of quality management, a larger scale of production, a good credit record, and a higher level of production automation and informatization management as the entrusted party. Before carrying out the entrusted manufacturing, the registrant shall require the entrusted party to submit a statement of credit status and consult the public information of the regulatory authority to fully understand the credit status of the entrusted party.

(III) For implantable medical devices, self-manufacturing is encouraged. However, if entrusted manufacturing is necessary, the registrant shall, in principle, select and dispatch personnel with experience in manufacturing quality management in relevant fields and familiar with product manufacturing process and quality control requirements to be stationed

头条

国家药监局关于进一步加强医疗器械注册人委托生产监督管理的公告（2024年第38号）

为贯彻实施《医疗器械监督管理条例》，全面落实医疗器械注册人（以下简称注册人）质量安全主体责任，进一步加强注册人委托生产监督管理，有效防控医疗器械质量安全风险。现就有关事宜公告如下：

一、严格落实医疗器械注册人主体责任

（一）注册人应当全面落实医疗器械质量安全主体责任，建立覆盖医疗器械全生命周期的质量管理体系并保持有效运行。注册人委托生产的，应当建立健全与所委托生产的产品特点、企业规模相适应的管理机构，充分履行产品风险管理、变更控制、产品放行、售后服务、产品投诉处理、不良事件监测和产品召回等职责，定期按照医疗器械生产质量管理规范对受托生产企业质量管理体系运行情况进行审核。

注册人仅委托生产时，也应当保持产品全生命周期质量管理能力，维持质量管理体系完整性和有效性；设置与委托生产相适应的管理机构，并至少明确技术、生产、质量管理、不良事件监测、售后服务等相关部门职责，质量管理部门应当独立设置，配备足够数量和能力的专职质量管理人员，以及熟悉产品、具有相应专业知识的技术人员，能够对委托生产活动进行有效的监测和控制。

注册人应当能够依法承担医疗器械质量安全责任，鼓励通过购买商业保险等形式，建立与产品风险程度、市场规模和人身损害赔偿标准等因素相匹配的责任赔偿能力。

（二）注册人应当优先选择质量管理水平较高、生产规模较大、信用记录良好、生产自动化程度和信息化管理水平较高的企业作为受托方。进行委托生产前，注册人应当要求受托方提交信用情况说明，并查阅监管部门公开信息，全面了解受托方信用情况。

（三）对于植入性医疗器械，鼓励注册人自行生产，确需进行委托生产的，在委托生产活动期间，注册人原则上应当选派具有相关领域生产质量管理工作经验、熟悉产品生产过程和质量控制要求的人员入驻受托生产企业，对生产管理、质量管理关键环节进行现场指导和监督，确保按照法规、规章、规范性文件、强制性标准和经注册的产品技术要求组织生产。派驻人员工作职责应当在质量协议中予以明确。《禁止委托生产医疗器械目录》中的产品不得委托生产。

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at the contract manufacturer during the entrusted manufacturing activities, so as to provide on-site guidance and supervision for critical steps of manufacturing and quality management. These personnel shall ensure that manufacturing activities are conducted in accordance with laws, regulations, normative documents, mandatory standards, and registered product technical requirements. The job responsibilities of the assigned personnel shall be specified in the quality agreement. The product included in the Catalogue of Medical Device Prohibited from Entrusted Manufacturing shall not be entrusted for manufacturing.

(IV) If the registrants entrust manufacturing to others, they shall in accordance with the requirements of the Guidance for Preparation of Contract Manufacturing Quality Agreement of Medical Devices, sign a quality agreement with the contract manufacturer, taking into account their specific circumstances. In principle, the valid term of the quality agreement shall not exceed the valid term of the product registration certificate and the manufacturing license of the contract manufacturer. Subject to compliance with relevant regulatory requirements, the registrant may, in the quality agreement, negotiate with the contract manufacturer the specific implementation methods for document control, procurement control, process control, inspection control, product release, and change control, among others. However, the registrant must clearly define the communication and coordination requirements.

(V) The registrant shall, in collaboration with the contract manufacturer, convert the quality agreement requirements into executable management documents associated with entrusted manufacturing and supervise the contract manufacturer to ensure their effective implementation. The registrants are encouraged to adopt controlled information systems to optimize their management processes related to entrusted manufacturing and enhance the efficiency of quality management.

The registrant and the contract manufacturer shall review the appropriateness, adequacy and effectiveness of the quality agreement annually to confirm that the relevant requirements of the quality agreement are consistent with the entrusted manufacturing management documents and the actual manufacturing. If any inconsistency is found, rectification measures shall be taken promptly.

(VI) The registrant shall, in collaboration with the contract manufacturer, establish a management approach for purchased items and suppliers based on the level of risk posed by these items to the product. For key purchased items or major raw materials, such as raw materials of animal origin, outsourced sterilization process, key components/parts/assemblies of active products as well as antigens and antibodies of in vitro diagnostic reagents, which are purchased by the contract manufacturer, the registrant shall determine the procurement acceptance criteria and audit the relevant suppliers on its own or in collaboration with the contract manufacturer.

(VII) If the products entrusted for manufacturing and other products (including different varieties, specifications, models and etc.) share the same manufacturing premises or manufacturing equipment, the contract manufacturer shall establish a management system to prevent risks such as possible mixups of products or materials, cross-contamination and misuse of process parameters based on principles of product quality risk management, risk control measures, and overall risk-benefit balance. The registrant shall strengthen the supervision and guidance of the contract manufacturer to ensure that relevant risk control measures are in place.

(VIII) If the registrants entrust manufacturing to others, they shall establish the procedures for marketing release of products, specifying the release criteria and conditions, and reviewing the manufacturing process records, quality testing reports of the medical devices and manufacturing release document from the contract manufacturer, and if conforming to criteria and conditions, the medical products can enter the market only upon signature of the authorized release personnel. The marketing release of products shall be completed by the registrant by themselves, and shall not be entrusted to other manufacturers.

The contract manufacturer shall establish procedures for manufacturing release, specify the criteria and conditions for manufacturing release, review the manufacturing process of medical devices and inspect the products to ensure that only those conforming to the criteria and conditions could be released for manufacturing.

The retention period of records for marketing release of products and manufacturing release

（四）注册人进行委托生产，应当按照《医疗器械委托生产质量协议编制指南》要求，结合企业实际情况，与受托生产企业签订质量协议，原则上质量协议有效期限不超过产品注册证和受托生产企业生产许可证有效期限。在符合相关法规要求的前提下，注册人可以与受托生产企业在质量协议中自行约定文件控制、采购控制、过程控制、检验控制、产品放行、变更控制等的具体实施方式，但必须明确沟通和衔接要求。

（五）注册人应当会同受托生产企业，将质量协议相关要求转化为可执行的委托生产相关管理文件，并监督受托生产企业落实到位。鼓励企业采用受控的信息化系统优化委托生产相关管理流程，提升质量管理效能。

注册人和受托生产企业应当每年对质量协议的适宜性、充分性、有效性开展评审，确认质量协议相关要求与委托生产管理文件和实际生产情况相一致。发现不一致的，应当及时采取整改措施。

（六）注册人应当会同受托生产企业，根据采购物品对产品的影响程度，确定采购物品和供应商的管理方式。对于关键采购物品或者主要原材料，如动物源性原材料、外包的灭菌过程、有源产品的关键元器件/部件/组件、体外诊断试剂的抗原和抗体等，由受托生产企业进行采购的，注册人应当自行或者会同受托生产企业确定采购验收标准、对相关供应商进行审核。

（七）受托生产的产品与其他产品（含不同品种、规格、型号等）共用生产场地或者生产设备的，受托生产企业应当基于产品质量风险管理、风险控制措施和收益整体平衡等原则，建立相应管理制度，防止可能发生的产品或者物料混淆、交叉污染、工艺参数误用等风险。注册人应当加强对受托生产企业的监督和指导，确保相关风险控制措施落实到位。

（八）注册人委托生产时，应当建立产品上市放行规程，明确放行标准、条件，对医疗器械生产过程记录、质量检验结果和受托生产企业生产放行文件进行审核，符合标准和条件的，经授权的放行人员签字后方可上市。产品上市放行应当由注册人自行完成，不得委托其他企业上市放行。

受托生产企业应当建立生产放行规程，明确生产放行的标准、条件，对医疗器械生产过程进行审核，对产品进行检验，确认符合标准、条件的，方可生产放行。

产品上市放行、生产放行的记录保存期限，应当符合医疗器械生产质量管理规范相关要求。

shall comply with the relevant requirements of the Good Manufacturing Practice for medical devices.

(IX) The registrant shall, in collaboration with the contract manufacturer, specify the corrective and preventive action communication mechanism, the responsibilities of both parties and disposal requirements in the quality agreement, and develop corrective and preventive control procedures appropriate to the risk of the product. In the event of trend-related, systemic, or sudden issues such as a significant decline in product quality conformance, consecutive batches of intermediate or finished products being non-conforming, or post-market risk management events exceeding the acceptance criteria, the registrant shall, in collaboration with the contract manufacturer, conduct a joint investigation and analysis of the issues, develop and review corrective and preventive action plans, implement the necessary measures, and evaluate the effectiveness of these measures.

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(IX) The registrant shall, in collaboration with the contract manufacturer, specify the corrective and preventive action communication mechanism, the responsibilities of both parties and disposal requirements in the quality agreement, and develop corrective and preventive control procedures appropriate to the risk of the product. In the event of trend-related, systemic, or sudden issues such as a significant decline in product quality conformance, consecutive batches of intermediate or finished products being non-conforming, or post-market risk management events exceeding the acceptance criteria, the registrant shall, in collaboration with the contract manufacturer, conduct a joint investigation and analysis of the issues, develop and review corrective and preventive action plans, implement the necessary measures, and evaluate the effectiveness of these measures.

(XII) If the registrants (applicants) entrust manufacturing to others, they shall clearly include the entrusted manufacturing processes of the contract manufacturer within the scope of their quality management system in the documents on quality management system. Additionally, the registrant shall include the procedures and relevant documentation for measuring, analyzing, and improving performed by the entrusting party to the entrusted party in the "Documents on Quality Management System - Measurement, Analysis and Improvement Procedure of Quality Management System" submitted as part of the registration application.

When conducting the verification of quality management system for registration, the focus shall be on the establishment of the manufacturer's quality management organization, the staffing and job performance of key personnel in the quality system, the signing of quality agreements, and the management of entrusted research and development and entrusted manufacturing. If cross-region entrusted manufacturing within China is involved, the verification of quality management system for registration shall, in principle, be performed by the drug regulatory authority at the registrant's (applicant's) location, either independently or in conjunction with the drug regulatory authority at the contract manufacturer's location, to conduct a comprehensive inspection of the quality management system of both the registrant (applicant) and the contract manufacturer. In exceptional circumstances where the drug regulatory authority at the registrant's (applicant's) location is genuinely unable to dispatch inspection personnel, they may delegate the drug regulatory authority at the contract manufacturer's location to conduct the verification of the contract manufacturer. In such cases, the drug regulatory authority at the registrant's (applicant's) location shall review and confirm the verification report of the contract manufacturer in conjunction with the system inspection of the registrant (applicant).

(XIII) For registration application or registration renewal application involving domestic entrusted manufacturing, the registration department shall record the address of the contract manufacturer in the Manufacturing Address column of the medical device registration certificate, with the notation "(Contracted Manufacturing)". Additionally, the department shall note the name and unified social credit identifier of the contract manufacturer in the Remarks column, in the format "Contract manufacturer: XXXX Company; Unified social credit identifier: XXXX". If the change registration involves a change in the entrusted manufacturing, the

（九）注册人应当会同受托生产企业，在质量协议中明确纠正预防措施沟通机制、双方职责和处置要求，并制定与产品风险相适宜的纠正预防控制程序。出现产品质量符合性有显著降低趋势，连续多批次中间品或者成品不合格，上市后风险管理中的风险事件超出可接受准则等趋势性、系统性、突发性问题时，注册人应当与受托生产企业共同对发现的问题进行调查和分析，制定并评审纠正预防措施计划，实施相关措施并对措施的有效性进行评价。

（十）注册人应当强化变更控制能力，会同受托生产企业，建立完善的变更控制程序，做好变更评估、验证或者确认。对于委托研发、生产过程外包和服务外包等外包供方的引入或者变更，应当通过风险评估判定相关变化是否影响质量管理体系有效运行，做好变更控制。

（十一）委托生产的注册人应当按照《医疗器械不良事件监测和再评价管理办法》等规定，结合产品风险特点，在制度体系建设、机构人员配备、信息收集上报、事件调查处置、风险研究评价等方面，配足资源、完善机制、强化能力，切实承担医疗器械不良事件监测责任，并在质量协议中约定在不良事件调查处置中委托双方的责任义务。对于《医疗器械监督管理条例》等法规规定的注册人应当履行的不良事件监测责任，不得通过质量协议向受托生产企业转移。

二、切实强化医疗器械委托生产注册管理

（十二）注册（申请）人委托生产的，应当在质量管理体系文件中明确将受托生产企业的委托生产相关过程纳入注册人质量管理体系覆盖范围，并在注册申报提交的"质量管理体系文件—质量管理体系的测量、分析和改进程序"中涵盖委托方对受托方进行测量、分析和改进的程序及相关资料。

开展注册质量管理体系核查时，应当重点关注企业质量管理机构建立情况，质量体系关键人员配备和在职履职情况，质量协议签订情况，委托研发和委托生产管理情况等内容。涉及境内跨区域委托生产的，注册质量管理体系核查原则上应当由注册（申请）人所在地药品监督管理部门自行或者联合受托生产企业所在地药品监督管理部门，对注册（申请）人及受托生产企业质量管理体系运行情况进行全面检查。特殊情况下注册（申请）人所在地药品监督管理部门确实无法派出检查人员的，可以委托受托生产企业所在地药品监督管理部门对受托生产企业进行核查，注册（申请）人所在地药品监督管理部门应当结合注册（申请）人体系核查情况对受托生产企业核查报告进行审核确认。

registrant shall also indicate the relevant information about the entrusted manufacturing in the change registration documents in the manner described above, and update the changed information in the corresponding fields of the registration certificate, including the manufacturing address and remarks. The registrant shall also submit the changed information in accordance with the data collection requirements of the National Drug Regulatory Data Sharing Platform. The registrant and the provincial drug regulatory department at the contract manufacturer's location shall promptly record the information about the entrusted manufacturing in the credit files of contract manufacturer.

If only the name of the contract manufacturer has changed in a textual manner, no application for change filing is required. In such cases, the modified registration certificate shall be issued at the time of registration renewal.

Each provincial drug regulatory department shall organize a review of the entrusted manufacturing registration certificates that have been issued within their administrative areas. If any certificate is found to not have the required information marked, the department shall instruct the registrant to apply for the marking to be added to the former registration department, and complete the marking within 3 months from the date of implementation of this announcement.

(XIV) When a domestic medical device manufacturer changes its manufacturing address and the contract manufacturer's manufacturing scope can cover the variety of the manufactured products, without involving a change in the manufacturing license, the registrant shall submit a statement issued by the drug regulatory authority at the contract manufacturer's location when applying for change filing of registration certificate.

If the registrants cease to entrust manufacturing to others, they shall promptly notify the former registration department to cancel the address of contract manufacturer; the contract manufacturer shall also promptly report the relevant situation to the provincial drug regulatory authority at its location.

III. Continuously Strengthening Supervision and Administration of Entrusted Manufacturing

(XV) The provincial drug regulatory departments shall fulfill their territorial supervision responsibilities, and through various means and channels, such as collecting entrusted manufacturing registration certificate information, urging enterprises to report on their products, and receiving cross-regional product reports, comprehensively sorting out and grasping the number of registrants and contract manufacturers of all types within their administrative areas. Based on the principle of risk management, they shall strengthen supervision in a targeted manner.

The provincial drug regulatory department where the registrant is located shall pay continuous attention to the registrant's ability to quality management over the whole life cycle of medical devices, the ability to assess and control the contract manufacturer, the ability to manage changes, and verify the information provided by the registrant in conjunction with the inspection of the contract manufacturer. The provincial drug regulatory department where the contract manufacturer is located shall pay continuous attention to the production and quality management of products entrusted for manufacturing, supervise the contract manufacturer to carry out manufacturing activities in accordance with the laws, regulations, normative documents, mandatory standards, registered product technical requirements and entrusted manufacturing quality agreement.

(XVI) If the registrants change from self-manufacturing to entrusted manufacturing, or change the contract manufacturer, they shall promptly report to the provincial drug regulatory authority at their location. The provincial drug regulatory authority where the registrant is located shall carry out a comprehensive inspection of the quality management system of the registrant and the contract manufacturer, and the inspection of the contract manufacturer can be carried out in conjunction with the provincial drug regulatory department where the contract manufacturer is located.

(XVII) Drug regulatory departments at all levels shall be deeply aware of the complexity and uniqueness of the supervision of entrusted manufacturing by the registrant, scientifically allocate regulatory resources, and enrich regulatory measures.

In regions where the registrants of entrusted manufacturing are concentrated, the provincial drug regulatory authority shall, in light of the supervision and inspection work, hold regular

（十三）涉及境内委托生产的注册申请或者延续注册申请，注册审批部门应当在医疗器械注册证生产地址栏中登载受托生产地址并注明“（委托生产）”，同时在备注栏备注受托生产企业名称和统一社会信用代码，备注形式为“受托生产企业：XXXX公司；统一社会信用代码：XXXX”。变更注册涉及注册人委托生产的，也应当在变更注册文件中按照上述方式注明委托生产相关信息，并将变更信息在注册证书生产地址和备注相应字段中更新，按照国家药品监管数据共享平台数据采集要求报送。注册人、受托生产企业所在地省级药品监督管理部门应当及时将委托生产相关信息记录在企业信用档案中。

仅受托生产企业名称文字性变化的，无需申请变更备案，在延续注册时，核发修改后的注册证。

各省级药品监督管理部门应当组织对本行政区域内已核发的委托生产的注册证进行梳理，发现未按照上述要求标注相关信息的，应当督促注册人及时向原注册部门申请标注，并在本公告施行之日起3个月内完成标注。

（十四）境内医疗器械生产地址变更且受托生产企业生产范围可以涵盖受托生产品种，不涉及生产许可证变更的，办理注册证变更备案时应当提交受托生产企业所在地药品监督管理部门出具的说明。

注册人不再进行委托生产的，应当及时向原注册部门核减受托生产地址；受托生产企业应当及时向所在地省级药品监督管理部门报告有关情况。

三、持续加强委托生产监督管理

（十五）省级药品监督管理部门应当切实落实属地监管责任，通过收集委托生产注册证信息、督促企业上报生产品种、接收跨区域生产品种通报等多种方式和途径，全面梳理和掌握本行政区域内各类型注册人和受托生产企业底数，按照风险管理原则，有针对性加强监管。

注册人所在地省级药品监督管理部门应当持续关注注册人医疗器械全生命周期质量管理能力、对受托生产企业的评估和管控能力、变更管理能力，并结合对受托生产企业检查情况核实注册人提供的信息。受托生产企业所在地省级药品监督管理部门应当持续关注受托生产产品的生产和质量管理情况，督促受托生产企业按照法规、规章、规范性文件、强制性标准、经注册的产品技术要求和委托生产质量协议等开展生产活动。

（十六）注册人由自行生产转为委托生产，或者变更受托生产企业的，应当及时向注册人所在地省级药品监督管理部门报告。注册人所

special meetings to discuss the supervision of entrusted manufacturing by registrant, analyze the results of supervision and inspection as well as product sampling, comprehensively identify potential safety concerns in the quality management system and product quality, and take targeted preventive measures to eliminate systemic and regional risks.

The drug regulatory authorities are encouraged to explore the use of simultaneous on-site inspections at both the registrant's and contract manufacturer's premises, utilizing information technology such as remote connections to facilitate real-time communication of inspection information and standardize the inspection criteria.

(XVIII) The National Medical Products Administration (NMPA) will continue to promote the construction of medical device variety files and credit files, and through the standardization of entrusted manufacturing information notation in the registration certificate, promote the interconnection of relevant information on entrusted manufacturing by registrant. The provincial drug regulatory authorities shall achieve the information interconnection of the whole chain of medical device supervision within their administrative areas, collecting and integrating information on review and approval, verification of quality management system for registration, manufacturing licensing, supervision and inspection, manufacturer reporting, supervisory sampling inspection, and investigation and handling of illegal acts, and continuously updating and improving the credit files of registrants and contract manufacturers. They shall also push this information to the National Drug Regulatory Data Sharing Platform as required by the NMPA, gradually achieving cross-provincial information interconnection.

If the cross-region entrusted manufacturing is involved, the provincial drug regulatory departments where the registrant and contract manufacturer are located shall, in accordance with the requirements of the Provisions for Supervision and Administration of Medical Device Manufacturing and the Opinions on Strengthening Collaborative Supervision of Cross-region Entrusted Manufacturing of Medical Devices, promptly share regulatory information on the variety of the manufactured products, inspection results, and responsibility interviews.

(XIX) If, during supervision and inspection, it is found that the quality management system of the registrant or contract manufacturer is not operating effectively, the provincial drug regulatory department shall order a rectification within a stipulated period. If the registrant or contract manufacturer fails to take effective measures to eliminate existing quality and safety risks, the provincial drug regulatory department shall take prompt action, including warnings and responsibility interviews. If necessary, the provincial drug regulatory departments where the registrant and contract manufacturer are located may conduct joint responsibility interviews.

If the registrant or contract manufacturer seriously violates the Good Manufacturing Practice for medical devices, and after comprehensive evaluation, it is determined that the violation may affect product safety and efficacy, and might cause potential harm to human health, the provincial drug regulatory department may take emergency control measures to suspend their manufacturing, distribution and use, and shall strictly impose penalties in accordance with Article 86 of the Regulations for the Supervision and Administration of Medical Devices.

(XX) This announcement shall come into force on June 1, 2024.

National Medical Products Administration

April 02, 2024

(April 03, 2024)

在地省级药品监督管理部门应当对注册人和受托生产企业质量管理体系进行全面检查，对受托生产企业的检查可以会同受托生产企业所在地省级药品监督管理部门进行。

（十七）各级药品监督管理部门应当深刻认识到注册人委托生产监管的复杂性和特殊性，科学配备监管资源，丰富监管手段。

委托生产注册人相对集中的地区，省级药品监督管理部门应当结合监管工作开展情况，定期对注册人委托生产监管情况进行专题会商，分析监督检查和产品抽检结果，全面排查企业质量管理体系、产品质量方面存在的安全隐患，采取针对性防控措施，杜绝系统性、区域性风险。

鼓励药品监督管理部门探索在注册人和受托生产企业两个场地同步开展监督检查，通过网络远程方式连接检查现场等信息化手段，及时沟通检查信息、统一检查尺度。

（十八）国家药监局持续推进医疗器械品种档案和信用档案建设，通过规范注册证委托生产信息标注，推动注册人委托生产相关信息互联互通；省级药品监督管理部门应当实现本行政区域内医疗器械监管全链条信息贯通，汇集审评审批、注册质量管理体系核查、生产许可、监督检查、企业报告、监督抽检、违法行为查处等信息，持续更新完善注册人、受托生产企业信用档案，并按国家药监局要求推送至国家药品监管数据共享平台，逐步实现跨省监管信息互通。

涉及跨区域委托生产的，注册人、受托生产企业所在地省级药品监督管理部门应当按照《医疗器械生产监督管理办法》《关于加强医疗器械跨区域委托生产协同监管工作的意见》要求，及时将企业生产品种、检查结果和责任约谈等监管信息进行通报。

（十九）监督检查中发现注册人、受托生产企业质量管理体系未有效运行的，省级药品监督管理部门应当责令其限期整改；注册人、受托生产企业对存在的质量安全风险未采取有效措施消除的，省级药品监督管理部门应当及时采取告诫、责任约谈等措施，必要时，注册人和受托生产企业所在地省级药品监督管理部门可以开展联合责任约谈。

注册人、受托生产企业严重违反医疗器械生产质量管理规范，综合研判后认为影响产品安全、有效，可能危害人体健康的，省级药品监督管理部门可以采取暂停生产、经营和使用的紧急控制措施，并严格按照《医疗器械监督管理条例》第八十六条进行处罚。

（二十）本公告自2024年6月1日起施行。

国家药监局

2024年4月2日

（2024-04-03）

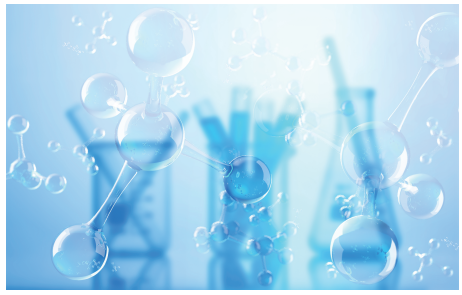
Drugs

Repotrectinib capsules approved with conditions for marketing by China NMPA

Recently, the Class 1 innovative drug Repotrectinib Capsules (trade name: 奥凯乐/AUGTYRO) of Bristol-Myers Squibb Company is approved for marketing with conditions through the priority review and approval procedure by China NMPA. The product is indicated for adult patients with ROS1-positive locally advanced or metastatic non-small cell lung cancer (NSCLC).

Repotrectinib is a tyrosine kinase inhibitor that targets the ROS1 oncogene and the tropomyosin receptor kinases (TRKs), including TRKA, TRKB and TRKC. The marketing of this drug provides new treatment options for adult patients with ROS1-positive locally advanced or metastatic non-small cell lung cancer.

(May 11, 2024)



Crisugabalin Besilate Capsules approved for marketing by China NMPA

Recently, the Class 1 innovative drug Crisugabalin Besilate Capsules (trade name: 思美宁) of Haisco Pharmaceutical Group Co., Ltd. is approved for marketing by China NMPA. This drug is indicated for adult patients with diabetic peripheral neuropathic pain.

Crisugabalin Besilate is a structural derivative of the inhibitory neurotransmitter γ-aminobutyric acid (GABA). The marketing of this drug provides new treatment options for adult patients with diabetic peripheral neuropathic pain.

(May 20, 2024)

Rezivertinib Mesylate Capsules approved for marketing by China NMPA

Recently, the Class 1 innovative drug Rezivertinib Mesylate Capsules (trade name: 瑞必达) of Beta Pharma (Shanghai) Co., Ltd. is approved for marketing by China NMPA. This drug is indicated for adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) who have experienced disease progression on or after prior epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) therapy and have been confirmed to have an EGFR T790M mutation.

Rezivertinib Mesylate is an epidermal growth factor receptor (EGFR) kinase inhibitor that irreversibly inhibits EGFR mutants (e.g., EGFR T790M, L858R). The marketing of this drug provides new treatment options for adult patients with non-small cell lung cancer.

(May 20, 2024)

药品

国家药监局附条件批准瑞普替尼胶囊上市

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Bristol-Myers Squibb Company申报的1类创新药瑞普替尼胶囊（商品名：奥凯乐/AUGTYRO）上市，适用于ROS1阳性的局部晚期或转移性非小细胞肺癌（NSCLC）成人患者。

瑞普替尼是一种酪氨酸蛋白激酶原癌基因ROS1和原肌球蛋白受体酪氨酸激酶（TRKs）TRKA、TRKB及TRKC的抑制剂。该药品的上市为ROS1阳性的局部晚期或转移性非小细胞肺癌成人患者提供了新的治疗选择。

（2024-05-11）

国家药监局批准苯磺酸克利加巴林胶囊上市

近日，国家药品监督管理局批准海思科医药集团股份有限公司申报的1类创新药苯磺酸克利加巴林胶囊（商品名称：思美宁）上市。该药品用于治疗成人糖尿病性周围神经病理性疼痛。

苯磺酸克利加巴林为抑制性神经递质γ-氨基丁酸（GABA）的结构衍生物。该药品上市为糖尿病性周围神经病理性疼痛成人患者提供了新的治疗手段。

（2024-01-09）

国家药监局批准甲磺酸瑞齐替尼胶囊上市

近日，国家药品监督管理局批准上海倍而达药业有限公司申报的1类创新药甲磺酸瑞齐替尼胶囊（商品名：瑞必达）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（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。

甲磺酸瑞齐替尼是表皮生长因子受体(EGFR)激酶抑制剂，对EGFR突变体（如EGFR T790M、L858R）具有不可逆抑制作用。该药品上市为非小细胞肺癌成人患者提供了新的治疗选择。

（2024-05-20）

Medical device

4 innovative products including implantable deep brain stimulation electrode lead kit approved for marketing

Recently, the China NMPA approved the registration applications for 4 innovative products developed by Beijing PINS Medical Co., Ltd., including implantable deep brain stimulation electrode lead kit, dual channel rechargeable implantable deep brain stimulation pulse generator kit, dual channel implantable deep brain stimulation pulse generator kit and implantable deep brain stimulation extension lead kit.

These products are the first domestically developed directional deep brain stimulation products in China. When used in combination, they can stimulate the subthalamic nucleus or globus pallidus interna, providing a treatment option for patients with advanced Parkinson's disease who experience levodopa-induced dyskinesia and whose symptoms are not adequately managed by medication. Compared to traditional electrodes, these products can provide directional stimulation to specific functional sub-regions of the target nucleus, while minimizing the risk of deep brain stimulation side effects and reducing the need for secondary surgical implantation of electrodes.

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

(May 28, 2024)

医疗器械

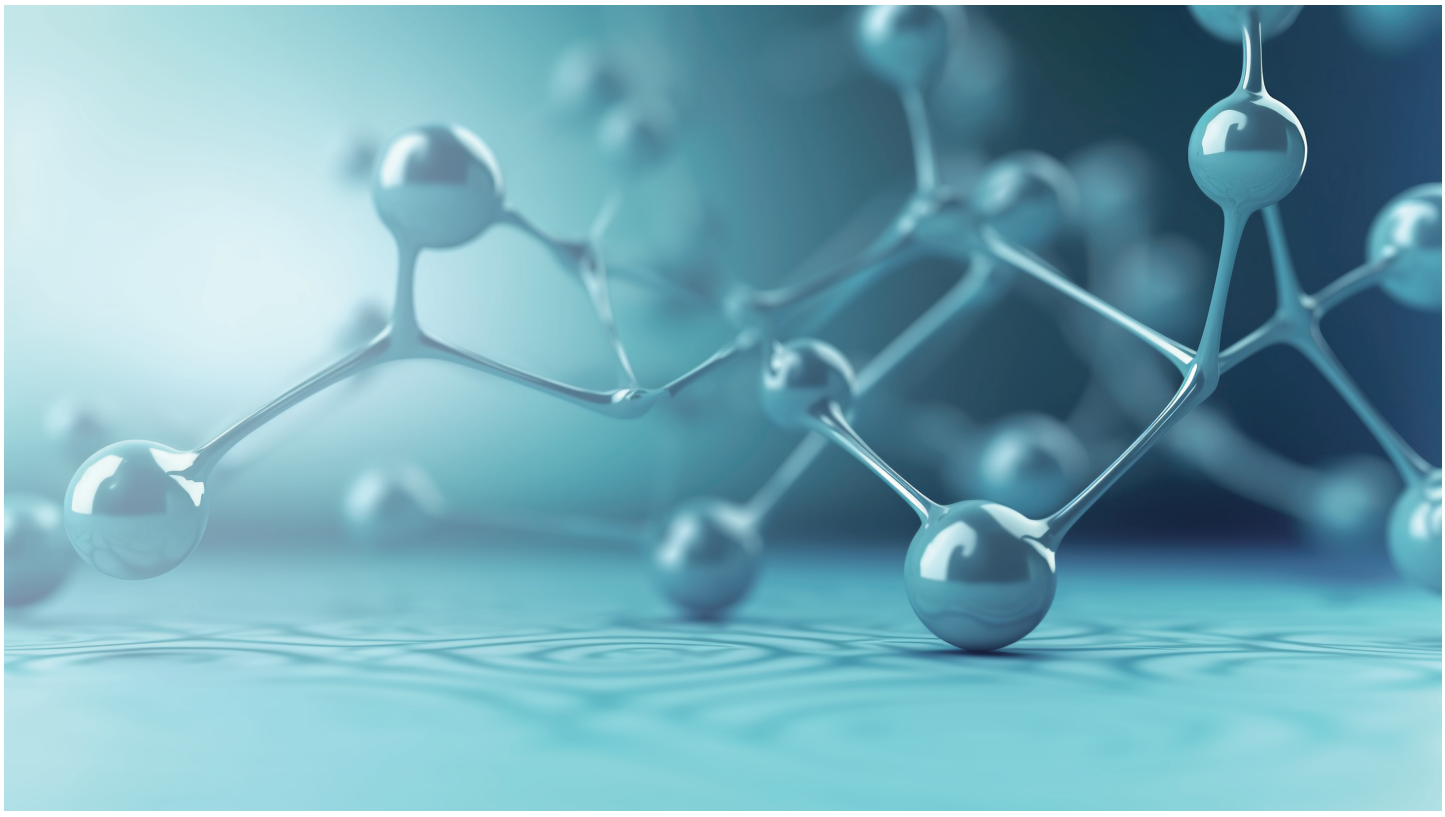
植入式脑深部电刺激电极导线套件等4个创新产品获批上市

近日，国家药品监督管理局批准了北京品驰医疗设备有限公司的植入式脑深部电刺激电极导线套件、双通道可充电植入式脑深部电刺激脉冲发生器套件、双通道植入式脑深部电刺激脉冲发生器套件和植入式脑深部电刺激延伸导线套件等4个创新产品注册申请。

上述产品是国产首个方向性脑深部电刺激产品，通过配套使用，可对丘脑底核或内侧苍白球进行刺激，用于对药物不能有效控制某些症状的晚期左旋多巴反应性帕金森病患者进行联合治疗。与传统电极相比，上述产品可为目标核团的特定功能亚区提供方向性刺激，同时在电极轻微植偏的情况下可避免脑深部刺激的副作用，减少再次手术植入电极的风险。

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。

（2024-05-28）



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

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- 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。
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