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- Novartis' innovative medicine Tabrecta® approved in China

- 拜耳肺癌新型靶向治疗药物获CDE突破性治疗品种认定
- Bayer receives CDE Breakthrough Therapy designation for new targeted therapeutic drug for lung cancer
- 云南白药INR101注射液获药物临床试验批准
- Yunnan Baiyao's INR101 injection approved for clinical trial
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案例
Cases

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- SPC case: Six-year patent dispute in the Sino-US medical field, awarding damages of RMB 20 million
- 最高院案例：依据专利审查历史，应对生物序列专利侵权主张
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监管动向
Supervision Dynamics

《药品经营和使用质量监督管理办法》施行

市场监管总局公布《药品经营和使用质量监督管理办法》（国家市场监督管理总局令第84号），自2024年1月1日起施行。《办法》共7章79条，强化药品上市许可持有人的质量管理责任，细化其对药品销售人员、销售行为等的管理要求，强调药品上市许可持有人委托储存、运输活动的质量管理要求。主要包括以下内容：药品追溯、委托销售签订协议、委托销售两地报备、委托储运，评估并签订协议、委托储存两地报备、药企销售人员培训、记录保存至少5年且不少于效期后一年等。

阅读原文

The implementation of *Measures for the Quality Supervision and Administration of the Distribution and Use of Medicinal Products*

The State Administration for Market Regulation has promulgated *Measures for the Quality Supervision and Administration of the Distribution and Use of Medicinal Products (Order No. 84 of the State Administration for Market Regulation)*, which came into effect on January 1, 2024. The Measures consists of 7 chapters and 79 articles, which strengthen the quality management responsibilities of pharmaceutical marketing authorization holders, detail their management requirements for pharmaceutical sales personnel and sales activities, etc., and emphasize the quality management requirements for the entrusted storage and transportation activities of pharmaceutical marketing authorization holders. The main contents include: pharmaceutical traceability, signing of agreements for entrusted sales, filing at both sites for entrusted sales, entrusted storage and transportation, assessment and signing of agreements, filing at both sites for entrusted storage, training of pharmaceutical company sales personnel, the retention of records for at least 5 years and no less than one year after the expiration date, etc.

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《放射性化学仿制药药学研究技术指导原则》发布

2024年1月31日，为落实和推进国家药监局《关于改革完善放射性药品审评审批管理体系的意见》相关工作，促进放射性药品研发和科学监管，在国家药品监督管理局的部署下，药审中心组织制定了《放射性化学仿制药药学研究技术指导原则》，经国家药品监督管理局审查同意，现予发布，自发布之日起施行。

该文件旨在明确放射性化学仿制药与普通化学药物相比，在药学研究方面的特殊技术要求，为放射性核

素、化学前体和放射性药物配套药盒配体、自动装置合成的放射性药物（含PET放射性药物）、放射性核素发生器制备放射性药物、放射性药物配套药盒等的研发提供技术指导。

阅读原文

The promulgation of *Technical Guidelines for the Pharmaceutical Research on Radiopharmaceutical Generics*

On January 31, 2024, in order to implement and advance the work related to the National Medical Products Administration (NMPA)'s *Opinions on Reforming and Improving the Review and Approval Management System for Radiopharmaceuticals*, and to promote the research and development of radiopharmaceuticals and scientific supervision, under the deployment by the National Medical Products Administration, the Center for Drug Evaluation has organized the formulation of *Technical Guidelines for the Pharmaceutical Research on Radiopharmaceutical Generics*. After being reviewed and approved by the NMPA, the *Guidelines* is hereby promulgated and shall come into effect upon promulgation.

This document aims to clarify the special technical requirements of radiopharmaceutical generics for the pharmaceutical research compared to conventional chemical drugs, providing technical guidance for the research and development of radionuclides, chemical precursors, ligands for radiopharmaceutical kits, automated synthesis of radiopharmaceuticals (including PET radiopharmaceuticals), radiopharmaceuticals prepared by radionuclide generators, radiopharmaceutical kits, etc.

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国家药监局关于实施药品注册行政许可文书电子化的公告

为进一步优化营商环境，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，国家药品监督管理局自2024年5月1日起，对国家药品标准颁布件、药品注册申请终止通知书、对照药品一次性进口审批意见通知件等药品注册行政许可文书实行电子化，药品注册行政许可电子文书与纸质文书具有同等法律效力。

阅读原文

The NMPA announces the implementation of electronic administrative license documents for drug registration

In order to further optimize the business environment, stimulate the vitality of market entities, and provide more efficient and convenient government affairs services for enterprises, the National Medical Products Administration (NMPA) has made a decision through research that started from May 1, 2024, NMPA will implement the electronic issuance of administrative license documents for drug registration, which include the promulgation document of national drug standards, notices of termination of drug registration applications, one-time import approval opinion notices for reference drugs, etc. Electronic administrative license documents for drug registration shall have the same legal force as their paper counterparts.

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《〈已上市化学药品药学变更研究技术指导原则（试行）〉原料药变更的问答》发布

6月7日，国家药监局药审中心发布《〈已上市化学药品药学变更研究技术指导原则（试行）〉原料药变更的问答》，自发布之日起实施。该规范旨在规范和指导当化学原料药的生产工艺、生产场地、生产批量、质量标准等发生变更时，相关制剂持有人应进行哪些研究工作，并进一步明确当制剂所用原料药的供应商发生变更时，相关制剂的技术要求。

阅读原文

The promulgation of *Q&A on Active Pharmaceutical Ingredient (API) Changes in "Technical Guidelines for Pharmaceutical Changes in Marketed Chemical Drugs (For Trial Implementation)"*

On June 7, the Center for Drug Evaluation of the NMPA promulgated *Q&A on Active Pharmaceutical Ingredient (API) Changes in "Technical Guidelines for Pharmaceutical Changes in Marketed Chemical Drugs (For Trial Implementation)"*, which shall come into effect upon promulgation. This specification aims to regulate and guide the research activities that pharmaceutical preparation holders should undertake when there is a change in the production process, production site, batch size, quality standards, etc., of the chemical APIs. It further delineates the technical requirements for related preparations when there is a change in the supplier of the APIs used for the preparations.

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《化学药品仿制药混悬型鼻用喷雾剂药学研究技术指导原则》发布

为了规范和指导化学仿制药混悬型鼻用喷雾剂的药学研发，在国家药品监督管理局的部署下，药审中心组织制定了《化学药品仿制药混悬型鼻用喷雾剂药学研究技术指导原则》。根据《国家药监局综合司关于印发药品技术指导原则发布程序的通知》（药监综药管〔2020〕9号）要求，经国家药品监督管理局审查同意，现予发布，自发布之日（6月7日）起施行。

阅读原文

The promulgation of *Technical Guidelines for the Pharmaceutical Research on Chemical Generic Suspension Nasal Sprays*

In order to regulate and guide the pharmaceutical research and development of chemical generic suspension nasal sprays, under the deployment by the National Medical Products Administration (NMPA), the Center for Drug Evaluation has organized the formulation of *Technical Guidelines for the Pharmaceutical Research on Chemical Generic Suspension Nasal Sprays*. In accordance with the requirements of the Notice on the Procedures for Release of Technical Guidelines for Drugs (No. 9 [2020] of the Department of Comprehensive Affairs, Planning, and Finance Affairs of the National Medical Products Administration), after being reviewed and approved by the NMPA, the Guidelines is hereby promulgated and shall come into effect upon promulgation (June 07).

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《化学药品注射剂配伍稳定性药学研究技术指导原则（试行）》发布

为进一步明确化学药品注射剂配伍稳定性研究技术要求，完善化学药品注射剂评价标准体系，在国家药品监督管理局的部署下，药审中心组织起草了《化学药品注射剂配伍稳定性药学研究技术指导原则（试行）》。根据《国家药监局综合司关于印发药品技术指导原则发布程序的通知》（药监综药管〔2020〕9号）要求，经国家药品监督管理局审查同意，现予发布，自发布之日（6月7日）起施行。

阅读原文

The promulgation of *Technical Guidelines for the Pharmaceutical Research on Compatibility and Stability of Chemical Injection (For Trial Implementation)*

To further clarify the technical requirements for the pharmaceutical research on the compatibility and stability of chemical injection and to improve the evaluation standard system for chemical injection, under the deployment by the NMPA, the Center for Drug Evaluation has organized the formulation of *Technical Guidelines for the Pharmaceutical Research on Compatibility and Stability of Chemical Injection (For Trial Implementation)*. In accordance with the requirements of *Notice of the Department of Comprehensive Affairs, Planning, and Finance Affairs of the NMPA on the Procedures for Release of Technical Guidelines for Drugs (No. 9 [2020] of the Department of Comprehensive Affairs, Planning, and Finance Affairs of the National Medical Products Administration)*, after being reviewed and approved by the NMPA, the Guidelines is hereby promulgated and shall come into effect upon promulgation (June 07).

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国家药监局发布药品生产质量管理规范（2010年修订）血液制品附录修订稿

《中华人民共和国药品管理法》实施后，国家药品监督管理局根据《药品生产质量管理规范（2010年修订）》第三百一十条规定，对《血液制品》附录进行了修订，现作为《药品生产质量管理规范（2010年修订）》的配套文件予以发布，自发布之日（6月4日）起实施。其中，对于附录第25条和35条，企业信息化建设工作需要一定周期，应在2027年1月1日前符合相关要求；新建车间或者新建生产线应符合上述要求。

阅读原文

The National Medical Products Administration promulgates revised draft of the blood products appendix to *Good Manufacturing Practice for Drugs (2010 Revision)*

Following the implementation of *Drug Administration Law of the People's Republic of China*, the National Medical Products Administration, in accordance with Article 310 of *Good Manufacturing Practice for Drugs (2010 Revision)*, has revised the Blood Products Appendix. It is now promulgated as a supporting document of *Good Manufacturing Practice for Drugs (2010 Revision)* and shall come into effect upon promulgation (June 04). Specifically, for Articles 25 and 35 of the Appendix, the informatization construction of enterprise requires a certain period, and should comply with the relevant requirements by January 1, 2027; newly built workshops or production lines should meet the aforementioned requirements.

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国务院办公厅印发《深化医药卫生体制改革2024年重点工作任务》

6月3日，国务院办公厅印发了《深化医药卫生体制改革2024年重点工作任务》，从深入推广三明医改经验、深化药品领域改革创新等7个方面，提出了深化医保支付方式改革、深化药品审评审批制度改革等22条具体措施。

阅读原文

The General Office of the State Council promulgates *Key Tasks for Deepening Medical System Reform in 2024*

On June 3, the General Office of the State Council promulgated *Key Tasks for Deepening Medical System Reform in 2024*, in which 22 specific measures, including the deepening of the reform of the medical insurance payment method, the deepening of the reform of the drug review and approval system, etc. are proposed across 7 areas, including the in-depth promotion of experience of medical reform in Sanming city, the deepening of reform and innovation in the pharmaceutical sector, etc.

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《在罕见疾病药物临床研发中应用去中心化临床试验的技术指导原则》发布

5月28日，国家药监局药审中心发布了《在罕见疾病药物临床研发中应用去中心化临床试验的技术指导原则》。该指导原则结合罕见疾病特征，对罕见疾病药物临床研发过程中如何应用去中心化临床试验（DCT）提出建议，为罕见疾病药物研发中科学、规范地开展DCT提供参考。该指导原则指出，无论是否采用DCT元素，均应遵循GCP的基本原则，即保护受试者的安全与权益，以及确保数据真实、可靠、可溯源。其中，保护受试者的安全与权益高于对其他因素的考量。在罕见疾病药物临床研发过程中应用DCT元素不应增加受试者的安全性风险。

阅读原文

The promulgation of *Technical Guidelines for the Application of Decentralized Clinical Trials (DCT) in the Clinical Research and Development of Rare Disease Drugs*

On May 28, the Center for Drug Evaluation of the National Medical Products Administration promulgated *Technical Guidelines for the Application of Decentralized Clinical Trials (DCT) in the Clinical Research and Development of Rare Disease Drugs*. The Guidelines offers recommendations on how to apply DCT in the clinical research and development process of rare disease drugs, tailored to the unique characteristics of rare diseases, providing a reference for scientific and standardized DCT in the research and development of rare disease drugs. The guidelines stipulates that regardless of the adoption of DCT elements, the fundamental principles of Good Clinical Practice (GCP) must be adhered to, i.e., protecting the safety and rights of trial subjects, as well as ensuring the authenticity, reliability, and traceability of data. Among these, the safety and rights of the trial sub-

jects take precedence over other considerations. The application of DCT elements in the clinical research and development of rare disease drugs should not increase the safety risks for the trial subjects.

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国家药监局综合司公开征求《关于发布境内生产药品再注册申报程序和申报资料要求的通告》意见

为贯彻实施新修订《药品管理法》《疫苗管理法》《药品管理法实施条例》《药品注册管理办法》等法律法规规章文件，落实药品审评审批制度改革要求，完善药品注册体系，加强药品再注册管理，服务、推动医药产业高质量发展，国家药监局组织拟定《关于发布境内生产药品再注册申报程序和申报资料要求的通告（征求意见稿）》。现向社会公开征求意见。本次公开征求意见的时间为2024年5月13日至6月12日。

阅读原文

Public comments sought by the Department of Comprehensive Affairs, Planning and Finance Affairs of the National Medical Products Administration on *Announcement on the Promulgation of Requirements for Application Procedure and Application Materials of Domestically Manufactured Drug Re-registration*

The National Medical Products Administration has organized the formulation of *Announcement on the Promulgation of Requirements for Application Procedure and Application Materials of Domestically Manufactured Drug Re-registration (Draft for Comment)* to earnestly implement legal documents such as the newly revised Drug Administration Law, Vaccine Administration Law, Regulations for the Implementation of the Drug Administration Law, and Measures for the Administration of Drug Registration, fulfill the requirements for reform of the drug review and approval system, improve the drug registration system, strengthen the management of drug re-registration, and serve and promote the high-quality development of the pharmaceutical industry. Public comments are hereby solicited. The term of public comments is from May 13, 2024 to June 12, 2024.

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《抗肿瘤药物临床试验中SUSAR分析与处理技术指导原则（征求意见稿）》公开征求意见

5月31日，国家药品监督管理局药品审评中心就《抗肿瘤药物临床试验中SUSAR分析与处理技术指导原则（征求意见稿）》公开征求意见。指导原则旨在对抗肿瘤药物临床试验进行试验药物安全性分析监测过程中，如何合理收集SUSAR，并进行科学分析，以协助发现、识别药物安全性信号，从而助力于后续开展试验药物的安全风险评估，以及后续临床研发和风险管理提供思路和建议。征求意见时限为自发布之日起一个月。

阅读原文

Public comments sought on *Technical Guidelines for Analysis and Handling of Suspected and Unexpected Serious Adverse Reactions (SUSAR) in Clinical Trials of Anticancer Drugs (Draft for Comment)*

On May 31, the Center for Drug Evaluation of the National Medical Products Administration sought public comments on *Technical Guidelines for Analysis and Handling of Suspected and Unexpected Serious Adverse Reactions (SUSAR) in Clinical Trials of Anticancer Drugs (Draft for Comment)*. The guidelines aims to provide ideas and suggestions for the rational collection and scientific analysis of SUSAR during the trial drug safety analysis and monitoring process of clinical trials for anticancer drugs, so as to assist in the discovery and identification of drug safety signals, thereby facilitating subsequent safety risk assessment of the trial drugs, as well as subsequent clinical research and development and risk management. The term of public comments is one month from the date of promulgation.

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《中药改良型新药研究技术指导原则（试行）》发布

为进一步落实《中共中央 国务院关于促进中医药传承创新发展的意见》《国家药品监督管理局关于促进中药传承创新发展的实施意见》等对于鼓励中药二次开发、促进中药产业高质量发展的要求，指导申请人开展中药改良型新药的研究，促进中医药传承精华、守正创新，药审中心组织制定了《中药改良型新药研究技术指导原则（试行）》。现予发布，自发布之日（5月13日）起施行。

阅读原文

The promulgation of *Technical Guidelines for Research on Improved New Traditional Chinese Medicine (For Trial Implementation)*

The Center for Drug Evaluation has organized the formulation of *Technical Guidelines for Research on Improved New Traditional Chinese Medicine (For Trial Implementation)* to further implement the encouragement of secondary development of traditional Chinese medicine, the promotion of high-quality development of the traditional Chinese medicine industry, etc. as required in *Opinions of Central Committee of CPC and State Council on Promotion of the Inheritance and Innovative Development of TCM*, *Implementation Opinions of the National Medical Products Administration on Promotion of the Inheritance and Innovative Development of TCM*, etc., and guide applicants in conducting research on improved new traditional Chinese medicine, thereby facilitating the inheritance of the essence of traditional Chinese medicine and to adhere to correct and innovative approaches. The guidelines is hereby promulgated and shall come into effect upon promulgation (May 13).

Read More

国家药监局、国家卫生健康委发布《关于加强右美沙芬等药品管理的通知》

根据《国家药监局、公安部、国家卫生健康委关于调整精神药品目录的公告》（2024年第54号），自2024年7月1日起，右美沙芬（包括盐、单方制剂）、纳呋拉啡（包括盐、异构体和单方制剂）、氯卡色林（包括盐、异构体和单方制剂）、含地芬诺酯复方制剂列入第二类精神药品目录；咪达唑仑原料药

（包括盐、异构体）和注射剂由第二类精神药品调整为第一类精神药品。

阅读原文

The National Medical Products Administration and National Health Commission promulgated *Notice on Strengthening the Management of Dextromethorphan and Other Drugs*

Pursuant to *Announcement of the National Medical Products Administration, the Ministry of Public Security and the National Health Commission on Adjusting the Catalogue of Psychotropic Substances (no. 54, 2024)*, started from July 1, 2024, dextromethorphan (including salts, single-component preparations), nalfurafine (including salts, isomers, and single-component preparations), lorcaserin (including salts, isomers, and single-component preparations), and compound preparations containing diphenoxylate shall be included in the catalogue of Schedule II psychotropic substances; midazolam API (including salts, isomers) and injections are adjusted from Schedule II to Schedule I psychotropic substances.

Read More

《中国新药注册临床试验进展年度报告（2023年）》发布

5月20日，国家药监局药审中心发布《中国新药注册临床试验进展年度报告 （2023年）》。《报告》显示，2023年，药物临床试验登记与信息公示平台登记临床试验总量首次突破4000项，临床试验实施效率进一步改善，启动效率进一步提高。从《报告》来看，1类创新药试验占新药临床试验登记总量的69.1%。1类创新药总体仍处于研发早期阶段，但与2022年度相比，II、III期临床试验占比均出现小幅增加。通过《报告》，也能感受到鼓励研发政策所带来的积极影响：儿童人群、罕见疾病患者等特定人群用药的临床试验数量呈现显著增长趋势，医学影像学和放射性药物临床试验保持小幅增加。研发企业在细胞治疗、基因治疗等新技术领域加强布局，2023年登记细胞和基因治疗产品类临床试验81项，较2022年增长近1倍。

阅读原文

The promulgation of *Annual Report of Clinical Trial Progress for New Drug Registration in China (2023)*

On May 20, the Center for Drug Evaluation of the National Medical Products Administration promulgated *Annual Report of Clinical Trial Progress for New Drug Registration in China (2023)*. The *Report* indicates that, in 2023, the total number of clinical trials registered on the drug clinical trial registration and information disclosure platform exceeded 4,000 for the first time. The efficiency of clinical trial implementation is further improved, with the initiation efficiency also seeing an enhancement. According to the *Report*, trials for Schedule 1 innovative drugs accounted for 69.1% of the total volume of new drug clinical trial registrations. Although Schedule 1 innovative drugs are generally still in the early stage of research and development, there has been a slight increase in the proportion of Phase II and III clinical trials compared to the previous year. The *Report* also reflects the positive impact of policies that encourage research and development: there is a significant upward trend in the number of clinical trials of drugs for specific populations, such as pediatric and rare disease patients; and the number of clinical trials of medical imaging and radiopharmaceuticals has maintained a slight increase.

Research and development enterprises have strengthened their layout in new technical fields such as cell therapy and gene therapy. In 2023, a total of 81 clinical trials for cell and gene therapy products were registered, nearly doubling compared to 2022.

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国家药监局发布《体外诊断试剂分类目录》

为贯彻落实《医疗器械监督管理条例》（国务院令第739号）有关要求，进一步指导体外诊断试剂分类，根据《体外诊断试剂注册与备案管理办法》（国家市场监督管理总局令第48号）、《国家药监局关于发布〈体外诊断试剂分类规则〉的公告》（国家药品监督管理局公告2021第129号）等有关规定，国家药监局组织修订了《6840体外诊断试剂分类子目录（2013版）》，形成《体外诊断试剂分类目录》，现予发布。

阅读原文

National Medical Products Administration promulgated *Classification Catalogue of In Vitro Diagnostic Reagents*

In accordance with the provisions of *Administrative Measures on the Registration and Record-filing of In Vitro Diagnostic Reagents (Decree No.48 of the State Administration for Market Regulation)*, *Announcement of the NMPA on the Promulgation of Classification Catalogue of In Vitro Diagnostic Reagents (No. 29 Announcement of NMPA, 2021)*, etc., the National Medical Products Administration has organized the revision of *6840 In Vitro Diagnostics Reagents Classification Sub-catalog (2013)* to form *Classification Catalogue of In Vitro Diagnostic Reagents*, in order to implement the relevant requirements of *Regulation on the Supervision and Administration of Medical Devices (Decree No.739 of the State Council)* and further guide the classification of in vitro diagnostic reagents. The *Classification Catalogue of In Vitro Diagnostic Reagents* is hereby promulgated.

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国家药监局开展疫苗监管质量管理体系管理评审

5月11日，国家药监局开展2023年度疫苗监管质量管理体系（疫苗QMS）管理评审，国家药监局党组书记、局长李利主持会议并对国家药监局机关疫苗监管质量管理体系的适宜性、充分性和有效性做出评价。管理评审中，政法司作为国家药监局机关疫苗QMS建设的牵头部门，汇报了2023年度局机关疫苗QMS的建设运行整体情况，并报告了发现问题及整改情况和对体系的改进建议。会议审议了综合司、政法司、药品注册司、药品监管司、人事司等体系组成部门的年度体系运行情况。

阅读原文

National Medical Products Administration conducts management review of the vaccine quality management system

On May 11, the National Medical Products Administration conducted the 2023 annual management review of the Vaccine Quality Management System (Vaccine QMS). Li Li, Secretary of the Leading Party Group and Director of the NMPA, chaired the meeting and evaluated the suitability, adequacy, and effectiveness of the NMPA organ's vaccine quality management system. During the management review, the Policy and Law Department, as the leading department for the construction of the NMPA organ's Vaccine QMS, reported on the overall situation of the construction and operation of the Vaccine QMS in 2023, and reported on identified issues, rectification and reform, and suggestions for system improvement. In the meeting, the annual system operation of various system constituent departments, such as Department of Comprehensive Affairs, Planning, and Finance Affairs, Department of Policies and Regulations, Department of Drug Registration, Department of Drug Regulation, Department of Human Resources, etc., are deliberated.

Read More

国家卫健委等八部门印发《关于加强重症医学医疗服务能力建设的意见》

5月6日，国家卫健委等八部门印发《关于加强重症医学医疗服务能力建设的意见》。意见提出，到2025年末，全国重症医学床位（包括综合ICU床位和专科ICU床位，下同）达到15张/10万人，可转换重症医学床位达到10张/10万人，相关医疗机构综合ICU床医比达到1:0.8，床护比达到1:3。到2027年末，全国重症医学床位达到18张/10万人，可转换重症医学床位达到12张/10万人，重症医学医疗服务资源有效扩容，区域布局更加均衡，专科服务能力显著提升。

阅读原文

National Health Commission and Seven Other Departments issue *Guiding Opinions on Strengthening the Construction of Critical Medical Service Capacity*

On May 6, the National Health Commission, along with seven other departments, issued *Guiding Opinions on Strengthening the Construction of Critical Medical Service Capacity*. The opinions propose that, by the end of 2025, the national capacity for critical care medical beds (including comprehensive ICU beds and specialty ICU beds, the same below) will reach 15 per 100,000 people, with convertible critical care medical beds reaching 10 per 100,000 people, and the ratio of comprehensive ICU beds to physicians in relevant medical institutions will reach 1:0.8, with a bed-to-nurse ratio of 1:3. By the end of 2027, the national capacity for critical care medical beds is expected to reach 18 per 100,000 people, with convertible critical care medical beds reaching 12 per 100,000 people, effectively expanding the resources for critical medical service and achieving a more balanced regional layout with significantly enhanced specialty service capabilities.

Read More

国家药监局关于优化已在境内上市的境外生产药品转移至境内生产的药品上市注册申请相关事项的公告

为进一步优化外商投资环境，促进医药行业高质量发展，提高药品可及性，满足人民群众的用药需求，根据国务院《关于进一步优化外商投资环境加大吸引外商投资力度的意见》（国发〔2023〕11号）、

《国家药监局关于发布〈药品上市后变更管理办法（试行）〉的公告》（2021年 第8号）要求，优化已在境内上市的境外生产药品转移至境内生产的药品上市注册申请的申报程序。现将有关事项公告如下：

一、 已在境内上市的境外生产药品转移至境内生产的，应当由境内申请人按照药品上市注册申请的要求和程序提出申请。

二、已在境内上市的境外生产药品转移至境内生产的,可提交境外生产药品的原注册申报资料，并提交转移至境内生产的相关研究资料，以支持其药品上市注册申请。具体申报资料要求由国家药监局药品审评中心另行制定发布。

三、对原研的化学药品和生物制品转移至境内生产的药品上市注册申请，国家药监局纳入优先审评审批适用范围。

阅读原文

Notice of National Medical Products Administration on relevant matters concerning optimizing the application for the marketing registration of overseas-manufactured drugs that have been marketed in China and are transferred to be manufactured in China

For the purposes of further optimizing the foreign investment environment, promoting the high-quality development of the pharmaceutical industry, improving the accessibility of drugs, and satisfying the people's needs for drugs, the application procedure for the marketing registration of the overseas-manufactured drugs that have been marketed in China and are transferred to be manufactured in China is hereby optimized in accordance with *Opinions of the State Council on Further Optimizing the Foreign Investment Environment and Increasing Efforts to Attract Foreign Investment (No. 11 [2023], State Council)* and *Announcement of the NMPA on Promulgation of the Administrative Measures for Drug Post-marketing Changes (for Trial Implementation) (No. 8 [2021], State Council)*. The relevant matters are hereby announced as follows:

I. Where any overseas-manufactured drug that has been marketed in China is transferred to be manufactured in China, a domestic applicant shall file an application in accordance with the requirements and procedures of application for registration of drug marketing.

II. Where any overseas-manufactured drug that has been marketed in China is transferred to be manufactured in China, the domestic applicant may submit the original registration application materials of the overseas-manufactured drug, and submit the relevant research materials on the transfer of the drug to domestic manufacturing in support of its application for registration of drug marketing. The specific requirements for application materials shall be separately formulated and promulgated by the Center for Drug Evaluation of the National Medical Products Administration.

III. For the application for marketing registration of RLD chemical drug and biological product that are transferred to be manufactured in China, the National Medical Products Administration shall incorporate it into the scope of application of priority review and approval.

Read More

《国家药品抽检年报（2023）》发布

3月26日，中国食品药品检定研究院发布《国家药品抽检年报（2023）》。《年报》显示，2023年国家药品抽检共完成132个品种18762批次制剂产品与中药饮片的抽检任务，样品来源涉及1114家药品生产、2528家经营企业和511家使用单位，由中检院等47个承检机构负责检验样品，检出136批次不符合规定产品。抽检结果显示，当前我国药品安全形势总体平稳可控，药品质量持续保持在较高水平。

阅读原文

The promulgation of *National Drug Sampling Inspection Annual Report (2023)*

On March 26, the National Institutes for Food and Drug Control promulgated *National Drug Sampling Inspection Annual Report (2023)*. The Annual Report indicates that, in 2023, the national drug sampling inspection tasks involving a total of 18,762 batches of preparation products and traditional Chinese medicine slices across 132 varieties are completed, with samples sourced from 1,114 drug manufacturers, 2,528 operating enterprises, and 511 usage institutions. The inspection of samples was conducted by 47 testing organizations, including the National Institutes for Food and Drug Control, and 136 batches of non-compliant products were identified. The sampling inspection results demonstrate that the current drug safety situation in China is generally stable and controllable, with drug quality consistently maintained at a high level.

Read More

2023年度国家药品不良反应监测报告发布

3月26日，国家药品不良反应监测中心发布《国家药品不良反应监测年度报告（2023年）》。《报告》显示，2023年全国药品不良反应监测网络收到《药品不良反应/事件报告表》241.9万份，每百万人口平均报告数为1716份，全国98.5%的县级地区报告了药品不良反应/事件。

《报告》全面反映了2023年我国药品不良反应监测的总体情况和作用发挥。《报告》显示，2023年，国家药品不良反应监测中心扎实有效开展各项监测工作，如配合推进《药品不良反应报告和监测管理办法》修订，推进创新药和附条件批准药品不良反应术语提取信息化建设等，为药品监管提供科学有力支撑，切实保护和促进公众健康。

阅读原文

The promulgation of *National Adverse Drug Reaction Monitoring Annual Report (2023)*

On March 26, the National Center for Adverse Drug Reaction Monitoring promulgated *National Adverse Drug* Reaction *Monitoring Annual Report (2023)*. The *Report* indicates that, in 2023, the national adverse drug reaction monitoring network received 2.419 million *Adverse Drug Reaction/Event Report Forms*, with an average of 1,716 reports per million population, and 98.5% of the county-level areas across the country reported adverse drug reactions/events.

The *Report* comprehensively reflects the overall situation and role of adverse drug reaction monitoring in China in 2023. It demonstrates that the National Center for Adverse Drug Reaction Monitoring effectively carried out various monitoring works throughout the year of 2023, e.g., collaborating on the revision of *Measures for the Reporting and Monitoring of Adverse Drug Reactions*, and advancing the informatization construction for the extraction of adverse drug reaction terminology of innovative drugs and drugs conditionally approved, which provides scientific and robust support for drug regulation and effectively protects and promotes public health.

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行业动态（中国）
Industry Dynamics (China)

中国将首次举办世界知识产权大会

由中国贸促会和国际保护知识产权协会（AIPPI）主办、杭州市人民政府和AIPPI中国分会承办的2024年AIPPI世界知识产权大会将于10月19日至22日在浙江省杭州市举办。这是AIPPI成立127年来首次在中国举办世界知识产权大会。

据中国贸促会新闻发言人赵萍介绍，本次大会主题为“知识产权的平衡保护与创新发展”，预计将有来自80多个国家和地区的1500名中外嘉宾参会。“中国首次举办AIPPI世界知识产权大会反映了国际社会对中国高度重视知识产权保护、加强知识产权法治保障、完善知识产权管理体制的充分认可，对于促进中外知识产权界交流与合作，推动我国深入参与知识产权国际规则制定，向世界宣传中国知识产权保护成就意义重大，将成为中国知识产权保护工作历史上一次里程碑事件。”

阅读原文

China to host AIPPI for the first time

China is set to host the AIPPI Congress for the first time, marking a significant milestone in the organization's 127-year history. The 2024 AIPPI Congress, hosted by the China Council for the Promotion of International Trade (CCPIT) and the International Association for the Protection of Intellectual Property (AIPPI), and organized by the People's Government of Hangzhou and the China Branch of AIPPI, will take place in Hangzhou, Zhejiang Province, from October 19th to 22nd.

Zhao Ping, spokeswoman for the CCPIT, said that the theme of the conference is "Balanced Protection and Innovative Development of Intellectual Property Rights", and it is expected that 1,500 guests from over 80 countries and regions will attend. "The first-time hosting of the AIPPI Congress in China reflects the international community's high regard for China's great focus on intellectual property protection, strengthening of the legal safeguard of intellectual property, and improvement of the intellectual property management system. It is of great significance for promoting exchanges and cooperation between Chinese and foreign intellectual property worlds, deepening China's participation in the formulation of international intellectual property rules, and promoting China's achievements in intellectual property protection to the world. This will become a milestone event in the history of China's work on intellectual property protection,” she said.

Source: CCPIT

诺华创新药妥瑞达®中国获批

6月12日，诺华宣布其治疗非小细胞肺癌药物妥瑞达®（盐酸卡马替尼片）获得中国国家药品监督管理局批准，用于未经系统治疗的携带间质上皮转化因子（MET）外显子14跳跃突变的局部晚期或转移性非小细胞肺癌（NSCLC）成人患者。

阅读原文

Novartis' innovative medicine Tabrecta® approved in China

On June 12, Novartis announced that its non-small cell lung cancer (NSCLC) treatment, Tabrecta ® (capmatinib hydrochloride tablets), has been approved by the National Medical Products Administration of China, and is indicated for adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) who have not received systematic treatment and carry a mesenchymal-epithelial transition factor (MET) exon 14 skipping (METex14).

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拜耳肺癌新型靶向治疗药物获CDE突破性治疗品种认定

近日，中国国家药品监督管理局（NMPA）药品审评中心（CDE）授予拜耳肺癌新型靶向治疗药物BAY2927088突破性治疗品种认定，适应症为适用于治疗携带HER2激活突变且既往接受过一种全身性治疗的不可切除或转移性非小细胞肺癌（NSCLC）成人患者。BAY 2927088是拜耳在研的一款酪氨酸激酶抑制剂，正在作为一种潜在的新型靶向药物被开发用于治疗携带HER2激活突变的非小细胞肺癌（NSCLC）患者。今年2月，BAY 2927088获得美国FDA突破性疗法认定。

阅读原文

Bayer receives CDE Breakthrough Therapy designation for new targeted therapeutic drug for lung cancer

Recently, the Center for Drug Evaluation of the National Medical Products Administration (NMPA) of China has granted Breakthrough Therapy designation for BAY 2927088, a new targeted therapy for adult patients with unresectable or metastatic non-small cell lung cancer (NSCLC), whose tumors have activating HER2 mutations, and who have received a prior systemic therapy. BAY 2927088 is a tyrosine kinase inhibitor in development by Bayer. It is currently being evaluated as a potential new targeted treatment option for patients with NSCLC harboring HER2 activating mutations. In February 2024, the U.S. Food and Drug Administration (FDA) also granted BAY 2927088 Breakthrough Therapy designation.

Read More

云南白药INR101注射液获药物临床试验批准

5月9日，云南白药全资子公司云核医药INR101注射液获国家药品监督管理局药品审评中心临床试验默示许可。INR101注射液是云核医药研发的化学1类放射性诊断类创新药，适用于前列腺癌患者PSMA阳性

病灶的PET成像。

阅读原文

Yunnan Baiyao's INR101 injection approved for clinical trial

On May 9, Yunnan Baiyao's wholly-owned subsidiary, Yunhe Pharmaceutical, received tacit approval from the Center for Drug Evaluation of the National Medical Products Administration for its INR101 injection. The INR101 injection is a Schedule 1 innovative drug in the field of radiodiagnosis developed by Yunhe Pharmaceutical, and is indicated for PET imaging of PSMA-positive lesions in patients with prostate cancer.

Read More

罗氏制药美罗华®皮下制剂在华获批

4月8日，罗氏制药中国宣布，旗下美罗华®（通用名：利妥昔单抗注射液（皮下注射））获得中国国家药品监督管理局（NMPA）正式批准，用于治疗：

- 先前未经治疗的CD20阳性III-IV期滤泡性非霍奇金淋巴瘤患者，应与化疗联合使用。
- 初治滤泡性淋巴瘤患者经本品联合化疗后达完全或部分缓解后的单药维持治疗。
- 复发或化疗耐药的滤泡性淋巴瘤。
- CD20阳性弥漫大B细胞性非霍奇金淋巴瘤（DLBCL）应与标准CHOP化疗（环磷酰胺、多柔比星、长春新碱、泼尼松）8个周期联合治疗.

阅读原文

Roche's MabThera® subcutaneous formulation approved in China

On April 8, Roche Pharma China announced that its product MabThera® (generic name: rituximab injection for subcutaneous use) has been officially approved by the National Medical Products Administration of China for:

- patients with CD20-positive Stage III-IV follicular non-Hodgkin's lymphoma, who have not received treatment, in combination with chemotherapy;
- patients with previously-treated follicular lymphoma, who are to receive alone-maintenance treatment after the disease is completely or partially alleviated by MabThera plus chemotherapy;
- relapsed or chemotherapy resistance follicular lymphoma;
- CD20-positive diffuse large B-cell lymphoma (DLBCL), in combination with the standard CHOP chemotherapy regimen (cyclophosphamide, doxorubicin, vincristine, prednisone) for 8 cycles.

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案例
Cases

最高院案例：中美医药领域6年专利纠纷案，判赔2000万

2024年2月，最高人民法院就美国某公司（原审原告，下称原告）与岳阳某生物科技公司等（原审被告，下称被告）侵害发明专利权纠纷一案作出二审判决，判决被告赔偿原告经济损失1850万元及合理开支150万元。

2017年10月25日，原告在上海知识产权法院（下称"一审法院"）发起专利侵权诉讼，指控被告侵犯其第200480036105.7号名称为"内切葡聚糖酶STCE和含有内切葡聚糖酶的纤维素酶配制品"的发明专利，2021年5月31日，一审法院就该案件做出一审判决，判决金额合计1100万元，原被告双方均不服一审判决向最高院提起上诉。最高院认为依据在案证据，不能将原告主张的所有型号的纤维素酶或被告生产的所有纤维素酶都认定为侵权产品，但可以认定涉案侵权产品的范围包括但不限于GC-66/99/863、LS-68/98/868型号的产品；此外，最高院根据被告提供的部分产品型号的财务账册，认定被告在2016年5月至2021年3月期间，对GC-66、GC-99、LS-68、LS-98四种型号产品的最低销售收入应为197910204元（约2亿），侵权获利至少23749224元（约2375万），超出了原告在本案中主张的经济损失数额，故对原告关于经济损失的诉讼请求予以全额支持。

来源：最高人民法院

SPC case: Six-year patent dispute in the Sino-US medical field, awarding damages of RMB 20 million

In February 2024, SPC issued a second instance judgment in a patent infringement dispute between a US company (the plaintiff) and a Yueyang biotechnology company, among others (the defendants). The court held the defendants to pay economic damages of RMB 18.5 million and reasonable expenses of RMB 1.5 million.

On October 25, 2017, the plaintiff filed a patent infringement lawsuit in the Shanghai Intellectual Property Court (the first instance court), accusing the defendants of infringing its invention patent. On May 31, 2021, the court issued a first instance judgment, awarding damages of RMB 11 million. Both the plaintiff and the defendants appealed to SPC. SPC held that based on the evidence presented, not all the products claimed by the plaintiff shall be identified as infringing products. In addition, SPC, relying on the financial ledgers provided by the defendants for some product models, held that the defendants' minimum sales revenue during the period from May 2016 to March 2021 shall be RMB 197,910,204 (approximately RMB 200 million). The profit from infringement was at least RMB 23,749,224 (approximately RMB 23.75 million), which exceeded the amount of damages claimed by the plaintiff in this case. Therefore, SPC fully supported the plaintiff's claim for damages.

Source: SPC

最高院案例：依据专利审查历史，应对生物序列专利侵权主张

近日，最高院审结爱美科生物株式公司与河北凯恩利生物技术有限公司、上海喜好贸易有限公司侵害发明专利权纠纷案，该案是涉生物序列专利侵权案件，法院审理认为，涉案专利涉及具有特定突变序列的蛋白酶。在专利授权程序中，第一次第二次审查意见通知书均明确指出涉案专利申请文本的权利要求得不到说明书的支持，原告采纳了上述修改意见，将“包括”改为“存在”，并根据第三次审查意见通知书进行修改，最终被授予专利权。由此可知，原告在涉案专利授权程序中通过对权利要求的修改，放弃了已验证活性的7种突变方式以外的其他突变可能，而其在本案侵权诉讼中又主张涉案专利权利要求3保护范围包括7种突变方式外其他位点的氨基酸序列突变可能，缺乏法律依据，不予支持。在案证据不能证明被诉侵权产品与涉案专利权利要求4中的氨基酸序列相同，无法认定被诉侵权产品落入涉案专利权的保护范围。爱美科公司主张凯恩利公司被诉侵权产品落入涉案专利权利要求3、4的保护范围，缺乏事实和法律依据，法院对此不予支持。

来源：上海知识产权法院

SPC Case: Responding to biosequence patent infringement claims based on patent examination history

Recently, SPC concluded the case of patent infringement involving Amyris Biotechnologies (Plaintiff) and Hebei Kainali Biotechnology Co., Ltd. and Shanghai Xihao Trading Co., Ltd. (Defendants). This case relates to biosequence patent infringement. The court found that the patent involved a protease with a specific mutation sequence. During patent prosecution, both the first and second office actions clearly stated that the claims in the patent application documents were not supported by the specification. Plaintiff adopted these amendment suggestions, changing "including" to "existing" and making further amendments based on the third office action, ultimately being granted a patent. It can be inferred that during patent prosecution, Plaintiff gave up the possibility of other mutations beyond the seven validated mutation methods by amending the claims. However, in this infringement lawsuit, the plaintiff argued again that the scope of protection of claim 3 of the patent included the possibility of amino acid sequence mutations at other sites beyond the seven mutation methods, which lacks legal basis and is not supported. The evidence in the case does not prove that the infringing product has the same amino acid sequence as claim 4 of the patent, so it cannot be determined that the infringing product falls within the scope of protection of the patent. Plantiff's claim that Kainali's infringing product falls within the scope of protection of claims 3 and 4 of the patent lacks factual and legal basis, and the court does not support this.

Source: Shanghai Intellectual Property Court

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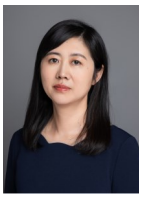

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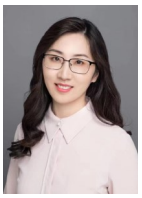

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